RE: Addendum to White Paper/Leon Margolin, MD, PhD/CPMI

Index to Materials
Volume 1 of 1

I. BACKGROUND
- A. CV of Dr. Margolin
- B. Awards
  1. 2nd Place NY State competition award
  2. 2023 Three best rating in Columbus
  3. Compassionate care & patient choice awards
  4. Top Doctor by OH Top Docs
  5. 2025 Ohio Top Doctor Award
- C. Research
  1. Certificates of recognition for research & prescriptions
  2. Publication on importance of research
- D. Continuing Medical Education
  1. CME transcript for ethics courses
  2. CME transcript on recognizing fraud & abuse
  3. CME transcripts on substance use disorders
  4. CME transcripts on opioid use disorders & opioid prescribing
  5. CME transcripts on pain management
  6. CME transcripts on medical legal issues
  7. CME Office based treatment
  8. Maintenance of Certification Progress Report
  9. Comprehensive Pain Management – Ohio State Med Bd. License
  10. CME transcript on Pain Review, Opioid Safety & Efficacy

II. DOJ INVESTIGATION
- A. PowerPoint presentation to DOJ RE: Medical necessity for nerve conduction studies
- B. PowerPoint presentation to DOJ RE: Medical necessity for SBIRT – "G Code Presentation"
- C. DOJ Settlement Agreement
- D. Letter to DOJ RE: Reasons for Settlement

III. SUPPORT FOR DR. MARGOLIN'S DEFENSE

A. Endorsement from Dr. Lynn Webster – Former president of the American Academy of Pain Medicine and Current Senior Fellow at the Center of U.S. Policy
B. Endorsement from Dr. William Vasilakis – Clinical Psychologist
C. Endorsement from Dr. David J. Norris – Cardiac Anesthesiologist
D. Publications by Dr. Margolin & others supporting medical necessity of NCS & SBIRT
    1. Misguided Medical Insurance & Government Policies in the Opioid Epidemic: A Chart Review & NARX Score Analysis
    2. Journal of Diabetes & Treatment – Impact of Screening & Brief Intervention (SBIRT), Urinary Drug Testing, Minimally Invasive Procedures, & Electromyography on Pain Reduction, Functional Improvement, & Continuity of Care in Chronic Pain Patients
    3. American Board of Physical Medicine & Rehabilitation Approval of Practice Improvement Programs
    4. NARX Research Poster
E. Governmental Support of Dr. Margolin's Practices
    1. DEA Training Requirement of SBIRT
    2. DEA MATE Course Relating Controlled Substance Prescribing & Substance use Disorder
    3. Substance Abuse & Mental Health Services Administration Support for SBIRT
    4. 15 U.S. Senators' Letter to CareSource RE: CareSource's Contribution to Exacerbating the Opioid Epidemic
    5. Ohio Board of Pharmacy Inspects Dr. Margolin's Practice & finds "No Issues"
    6. Pain Management Best Practices Inter-Agency Task Force Report
    7. Substance use outcomes of patients served by a large US implementation of Screening, Brief Intervention and Referral to Treatment (SBIRT)
    8. How to Improve SBIRT to Address Substance Use Disorder
F. Non-Governmental Support
    1. NIH Supports Integrating SBIRT into Clinical Practice

2. Literature Supporting SBIRT
    i. Screening, Brief Intervention & Referral to Treatment (SBIRT) in Behavioral Healthcare
    ii. Strategies to promote the implementation of Screening, Brief Intervention, & Referral to Treatment (SBIRT) in healthcare settings: a scoping review
    iii. NY State Screening, Brief Intervention, and Referral to Treatment - Why is SBIRT important

3. PEW Substance Use Prevention & Treatment Initiative Supports SBIRT
4. National Expert Panel Recommends SBIRT
5. Epidemiological & geospatial profile of the prescription opioid crisis in Ohio, United States
6. Affirmation Letter of Richard Harrow

IV. PATIENT COMMUNICATIONS
- A. Pictures of Challenges with high-risk patients
- B. Criminal Complaint against Patient who assaulted Dr. Margolin
- C. Patient Communication Training Documents
    1. MD Anderson Communication Presentation
    2. Employee Signature Pages Reflecting Participation in Patient Communication Training
- D. CME Certificates Relating to Patient Communication Training

A

CURRICULUM VITA

Leon Margolin M.D., Ph.D.

tel.: 718-530-5953
e mail: md@cpmiohio.com
www.cpmiohio.com

Board certified and fellowship trained in pain management

I am a board certified (Pain Medicine and PM&R) and fellowship trained interventional pain physician. I am competent in interventional and medical management of acute and chronic pain, peripheral joint injections, EMG, and PM&R management of pain.

EMPLOYMENT:

03/11-Current	Medical Director, Comprehensive Pain Management Insitute, LLC Columbus, OH
07/09 – 03/11	Interventional Pain Management , Assistant Professor (Clinical) OSUMC
09/07 – 06/30/09	Interventional Pain Management Practice, NY Including Basset Health Care System *(affiliated with Columbia School of Medicine).*

EDUCATION AND TRAINING

POSTGRADUATE:

9/06 to 8/07	University of Pittsburgh Pittsburgh, PA	Fellowship Pain Medicine (ACGME accredited program)
	Award of the Medical Society	

	Of Pennsylvania	
7/03 to 6/06	Albert Einstein College of Medicine Bronx, NY *ASRA resident/fellow award* *Pfizer Award in Pain Management*	Residency Physical Medicine and Rehabilitation
7/02 to 6/03	Staten Island University Hospital Staten Island, NY *ACP Certificate of Merit,* *2nd place NY State resident/fellow Competition award*	Internship in Internal Medicine

GRADUATE:

1994 to 2002	Hebrew University Hadassah Medical School Jerusalem, Israel	M.D./Ph.D.

UNDERGRADUATE:

1991 to 1994	Bar-Ilan University Ramat-Gan, Israel	B.Sc., Magna Cum Laude Human Biology

---

SPECIALTY CERTIFICATION:

July 2007 Board Certified by the American Board of Physical Medicine and Rehabilitation
October 2008 Board Certified in Pain Medicine by ACGME

MEDICAL OR OTHER ACTIVE PROFESSIONAL LICENSURE:

Ohio LIC # 0900064

MEMBERSHIPS IN PROFESSIONAL AND SCIENTIFIC SOCIETIES

2002 to present ,American Medical Association
2003 to present, Association of Academic Physiatrists
2003 to present, American Academy of Physical Medicine and Rehabilitation
2003 to present, American Society of Regional Anesthesia and Pain Medicine
2005 to present, Medical Society of the State of New York
2006 to present, Pennsylvania State Medical Society

HONORS

2007 and 2014	Physician Recognition Award, American Medical Association
2014	"Top Ten Physicians" Award in Pain Medicine (Online patient satisfaction survey)
2011	Most Compassionate Physician Award (Online patient satisfaction survey)

2008, 2009, 2010 Patients' Choice Award (Online patient satisfaction survey)
2008 CRH Doctor Targets Pain – Article, Times Journal
2005, Best of Meeting Presentation, American Society of Regional Anesthesia and Pain Medicine 2005 Fall Pain Meeting and Workshops
2005, Award of the Annual Young Investigator Symposium Albert Einstein College of Medicine
2004, Resident Award of the American Society of Regional Anesthesia and Pain Medicine
2004, Pfizer Scholars in Pain Management Award, Albert Einstein College of Medicine
2003, Second Place in the New York State (Downstate) Residents and Fellows Research Competition
2003, Certificate of Merit in the National Residents and Fellows research competition, American College of Physicians
2003, Certificate of Merit, Poster Finalist at the National Research, Competition of American College of Physicians, San Diego, California.
2003, Honorable Mention Award, Annual Research competition of Academy of Medicine of Richmond.
2003, Certificate of Achievement, Department of Medicine, Staten Island University Hospital
2000, Pratt Foundation Award, Hebrew University Hadassah Medical School
1999-2000, Scholarship for Excellence in M.D./Ph.D. program, Hadassah Medical School, Hebrew University
1999, Scientific Innovation Award of the Hebrew University
1994-1999, Scholarship for M.D./Ph.D. program, Hadassah Medical School-Hebrew University (annually)
1991-1994, Scholarship of Dean of Students, Bar-Ilan University (annually)
1991, Prize of Ministry of Education of Russian Federation

PUBLICATIONS

Please review www.cpmiohio.com for additional publications, presentation (instate and international)

Manuscripts:

Leon Margolin MD, PhD; Role of Matrix Metalloproteinases in Tissue Remodeling (relevance to pathogenesis of restenosis, aortic aneurism, joint and disc degeneration); 2009; IBSN# 9783639207897

Leon Margolin MD, PhD et al.; Assessment of Antibiotic Properties of Maggosts; 2019; Lambert Publishing; IBSN # 6200327890

Refereed Articles

1. ***Margolin L***. Gialanella P. Assessment of the antimicrobial properties of maggots. Int Wound J. 2010 Jun;7(3):202-4. .

2. ***Margolin L***, Tuluca L, Kaylakov R. Transforaminal Epidural Injection Induces Hypertensive Crisis in Patient whose Nifedipine was Withdrawn. *Clin Drug Invest* 2005;25(5):353-354.

3. ***Margolin L***, Bakst-Sisser R, Segal M, Nissinoff J, Thomas M. High Fever Induced by Dexamethasone Withdrawal. *Clin Drug Invest* 2004;24(11):689-691.

4. ***Margolin L***. Acute Pulmonary Oedema Induced by COX-2 Inhibitors in a Patient with Chronic Pain. *Clin Drug Invest* 2004;24(8):491-492.

5. ***Margolin L***, Haliulin Y. Recalcitrant psoriasis vulgaris associated with Laurence-Moon-Biedl syndrome. *J Eur Acad Dermatol Venereol* 2003;17(5):554-5.

6. ***Margolin L***. Non-L-Tryptophan Related Eosinophilia-Myalgia Syndrome with Hypoproteinemia and Hypoalbuminemia. *J Rheumatol* 2003;30(3):628-9.

7. ***Margolin L***, Fishbein I, Banai S, Golomb G, Reich R., Perez L, Gertz SD. Metalloproteinase inhibitor attenuates neointima formation and constrictive remodeling after angioplasty in rats: augmentative effect of $\alpha_v\beta_3$ receptor blockade. *Atherosclerosis* 2002;163(2):269-77.

8. **Margolin L**, et al. 20-Week Study of Clinical Outcomes of Over-the-Counter COVID-19 Prophylaxis and Treatment. J Evid Based Integr Med. 2021 Jan-Dec;26:25

9. **Margolin L**, et al. Benefit of OTC Formula Against COVID-19-Statistical Analysis Explained. J Evid Based Integr Med. 2021 Jan-Dec;26:25

Reviews, invited published papers, proceedings of conference and symposia, monographs, books and book chapters

1. ***Margolin L***. Severe Rosacea associated with colon cancer recurrence. *Int J Dermatol* 2004 Mar;43(3):213-4.

2. ***Margolin L***. Impaired Rehabilitation Secondary to Muscle Weakness Induced by Meropenem. *Clin Drug Invest* 2004;24(1):61-62.

3. ***Margolin L***, Engelgard D. Bilateral pneumonia associated with *Shigella sonnei* dysentery. *Am J Infect Control* 2003;31(7):445-6.

4. ***Margolin L***, Hershko K, Garcia-Rojas M, Ingber A. Andogsky Syndrome Variant: Atopic Dermatitis Associated with Bilateral Cataracts and Retinal Degeneration with Left Retinal Detachment. *Pediatr Dermatol* 2003;20(5):419-420.

5. ***Margolin L***. Severe Psoriasis *Palmaris et Plantaris* Associated with Topical Use of Dorzolamide. *Clin Drug Invest* 2003;23(7):487-489.

6. ***Margolin L***. Fatal Cardiogenic Shock and Liver Failure Induced by Verapamil in a Thyrotoxic Patient. *Clin Drug Invest* 2003;23(4):285-286.

7. ***Margolin L***, Feinmesser M, Hodak E. Leukocytoclastic vasculitis associated with bullous erysipelas. *Int J Dermatol* 2003;42(4):300-1.

8. ***Margolin L***. Increased Warfarin Sensitivity Complicated by Retroperitoneal Haemorrhage in a Patient with Merkel Cell Carcinoma. *Clin Drug Invest* 2003;23(3):217-218.

9. ***Margolin L***. Severe Leucocytoclastic Vasculitis Induced by Repaglinide in a Patient with Chronic Hepatitis C. *Clin Drug Invest* 2002;22(11):795-796.

Published Abstracts

1. Margolin L. Metalloproteinase Inhibition in Axial Low Back Pain from Animal Model to Clinical Study. *Reg Anesth Pain Med* 2006;31(3):A79.

2. ***Margolin L***. C-ABEX: Gelatinase A Inhibition Attentuates Extracellular Matrix Remodeling and Cell Proliferation and Migration in Rats: Relevance ot the Pathogenesis and Management of Chronic Pain. *Am J Phys Med Rehab* 2005 March;84(3):223-224.

3. **Margolin L**, Gialanella P, Thomas M, Oh-Park, M. B-ABEX: Assessment of the Antimicrobial Properties of Maggots. *Am J Phys Med Rehab* 2005 March;84(3):223.

4. ***Margolin L***. A-ABEX: Association between Complex Regional Pain Syndrome Type 1 and Solar Injury. *Am J Phys Med Rehabil* 2005 March;84(3):223.

5. ***Margolin L***. Fishbein I, Gertz S. Gelatinase A Inhibition Attentuates Extracellular Matrix Remodeling and Cell Proliferation and Migration in Rats. Relevance to the Pathogenesis and Management of Chronic Pain. Poster Accepted for the American Society of Regional Anesthesiology 2004 Fall Pain Meeting, Phoenix, AZ, November 11-14, 2004.

6. ***Margolin L***, Segal M, Fast A. Poster 100 Low Back Pain and Bilateral Pure Motor Paraparesis Induced by Retroperitoneal Hematoma. *Archives of Physical Medicine and Rehabilitation* 2004 Sept.;85(9):e27.

7. ***Margolin L***, Fishbein I, Banai, S, Reich R, Perez L, Gertz SD. Metalloproteinase Inhibition and $\alpha_v\beta_3$ Receptor Blockade Attenuates Extracellular Matrix Remodeling and Cell Proliferation and Migration in Rats. Possible Relevance to Wound Healing and Arthritis Research. *Am J PM&R* 2004;3(S):4.

8. ***Margolin L***, et al. Metalloproteinase Inhibitor and $\alpha_v\beta_3$ Receptor Inhibitor Synergistically Inhibits Luminal Narrowing, Remodeling Cell Proliferation and Migration after Balloon Angioplasty. American College of Physicians Annual Session, National Clinical Vignette and Research Paper Competition, San Diego, CA, April 2003, p.71.

9. ***Margolin L***, et al. Metalloproteinase Inhibitor and $\alpha_v\beta_3$ Receptor Inhibitor Synergistically Inhibits Cell Proliferation and Migration After Balloon Angioplasty. American College of Physicians Annual Session, Clinical Vignette and Research Paper Competition, New York State (Downstate), NY, March 2003, p.15.

10. ***Margolin L***, et al. Metalloproteinase Inhibitor and Receptor Inhibitor Synergistically Inhibits Neointimal Formation and Constrictive Wall Remodeling After Balloon Angioplasty. *Journal of American College of Cardiology* 2000;35(A):48.

11. ***Margolin L***, et al. Effect of Metalloproteinase Inhibition and $\alpha_v\beta$ Receptor Blockade Inhibits Neointima Formation and Constrictive Remodeling. *Journal of Israeli College of Cardiology* 2000;8(A):16.

12. ***Margolin L***. Mask for the treatment of headache. Hebrew University Award for Scientific Innovation Year Book, p.8-10.

PROFESSIONAL ACTIVITIES

TEACHING:

Hadassah Medical College, Hebrew University, Jerusalem, Israel

Clinical Instructor, anatomy course for medical students.

OSU: Teaching residents and fellow

Multiple grand round presentations and seminars for the community on medical topics

RESEARCH:

Seminars and invited lectureships

Association of Academic Physiatrists Annual Meeting, Daytona Beach, FL, March 1-4, 2006.

Medical Society of the State of New York 2006 Annual Meeting, Buffalo, NY.

Association of Academic Physiatrists Annual Meeting, Tucson, AZ, February 22-26, 2005.

2005 Annual Young Investigator Symposium AECOM, NY.

2004 Annual Meeting of American Academy of PM&R, Phoenix, AZ.

2004 Annual Meeting of NY Academy of PM&R, New York, NY.

Association of Academic Physiatrists Annual Meeting, Albuquerque, NM, March 25-28, 2004.

2003 Basic Research part of the Annual Meeting of American College of Physicians, NY Chapter (Downstate), March 22, NYC.

2003 Basic Research part of the Annual Meeting of American College of Physicians, April 4, San Diego, CA.

2001 Basic Research part of the Annual Meeting of Annual Meeting of Israeli Medical Association, Jerusalem, Israel (project selected for special presentation for excellence and scientific innovation).

2000 Basic Research part of the Annual Meeting of Annual Meeting of Israeli Medical Association, Jerusalem, Israel.

1999 Senate of Hebrew University of Jerusalem, Jerusalem, Israel.

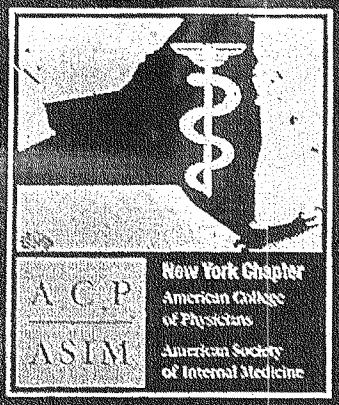
Community Activities

Medical education (wellness, pain medicine, opioid epidemic prevention) – YouTube channel

Volunteer, Montefiore Medical Center, New York, NY

Volunteer, Jerusalem Center for Senior Immigrants, Jerusalem, Israel

B



Downstate
Poster Competition

March 2003

Leon Margolin, M.D., Ph.D.

Second Place
Research

Certificate

OF EXCELLENCE

2023

COLUMBUS, OH

TOP 3 PAIN MANAGEMENT DOCTORS

Comprehensive Pain Mgt Inst, LLC

On behalf of **ThreeBestRated®** this Certificate of Excellence is proudly presented after duly checking extensive customer reviews, ratings, history, complaints, satisfaction, trust, cost and general excellence. Your consistent commitment to these values and high quality in your area of business is hereby acknowledged and certified.

ThreeBest Rated EXCELLENCE

ThreeBest Rated®

B. [illegible]

PRESIDENT

ThreeBest [illegible]®

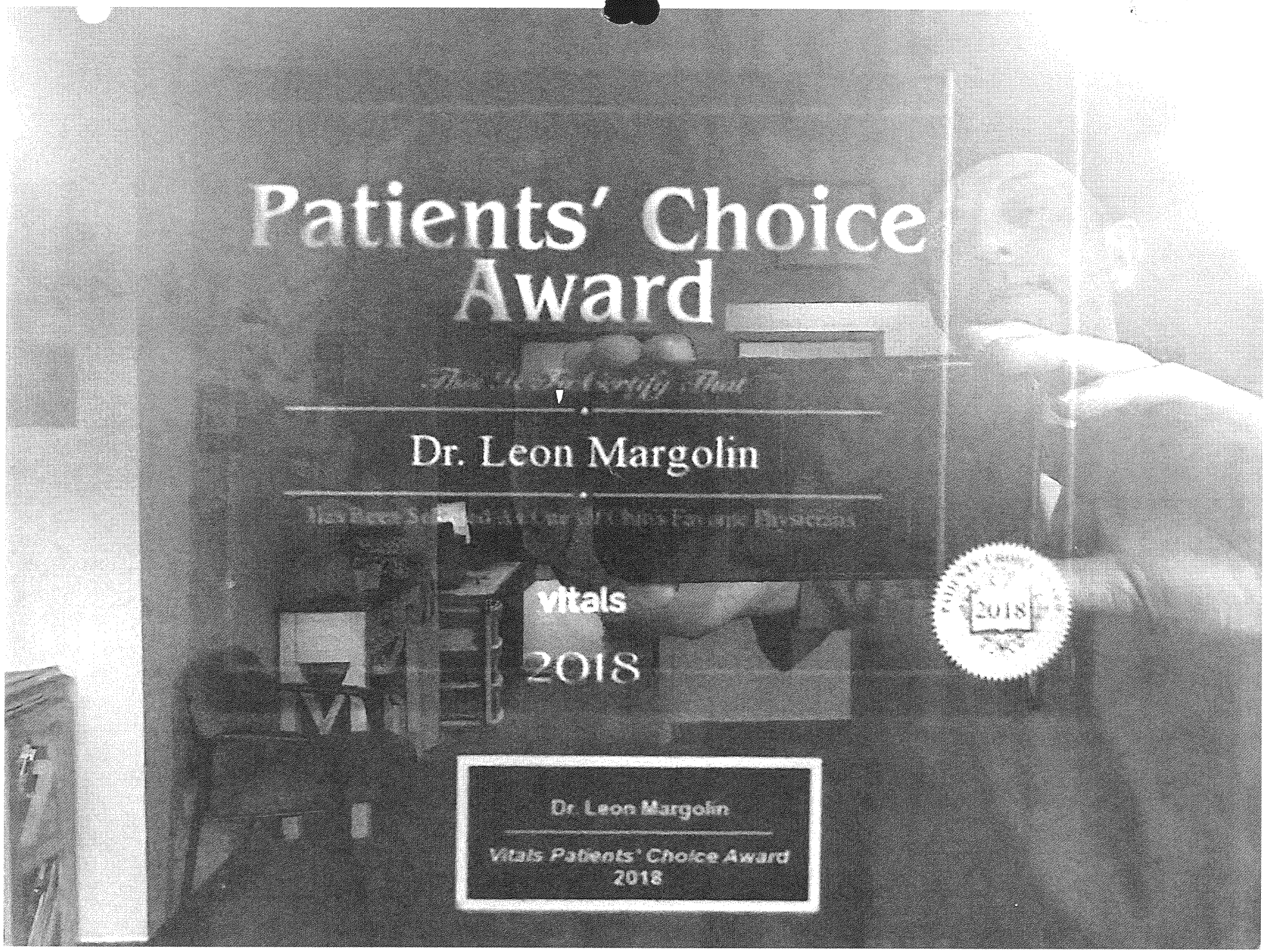
Compassionate Doctor Award

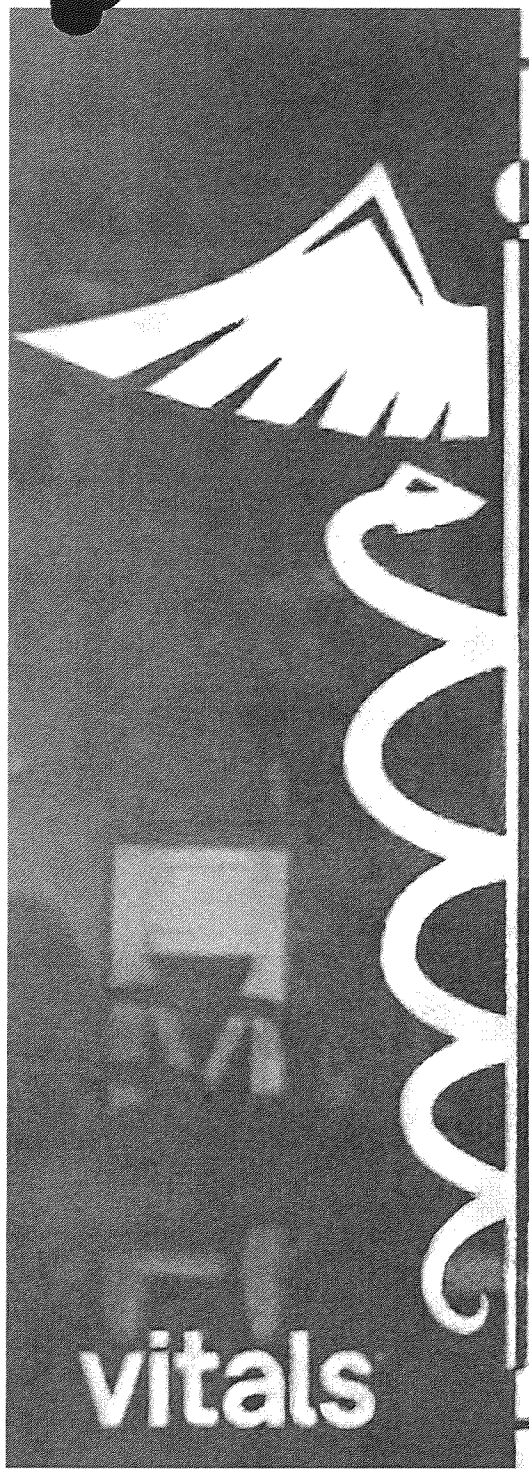
Dr. Leon Margolin

In gratitude for faithful service, you have been recognized by your patients as one of America's Most Compassionate Doctors.

2016

vitals


Patients' Choice
Award
Dr. Leon Margolin
vitals
2018
2018
Dr. Leon Margolin
Vitals Patients' Choice Award
2018



2019

On-Time Doctor Award 2019

This Is To Certify That

Dr. Leon Margolin

Recognized by patients for
having the shortest wait-time

Certificate of Appreciation

is awarded to

Dr. Leon Margolin

Voted a 2010 Most Compassionate Doctor

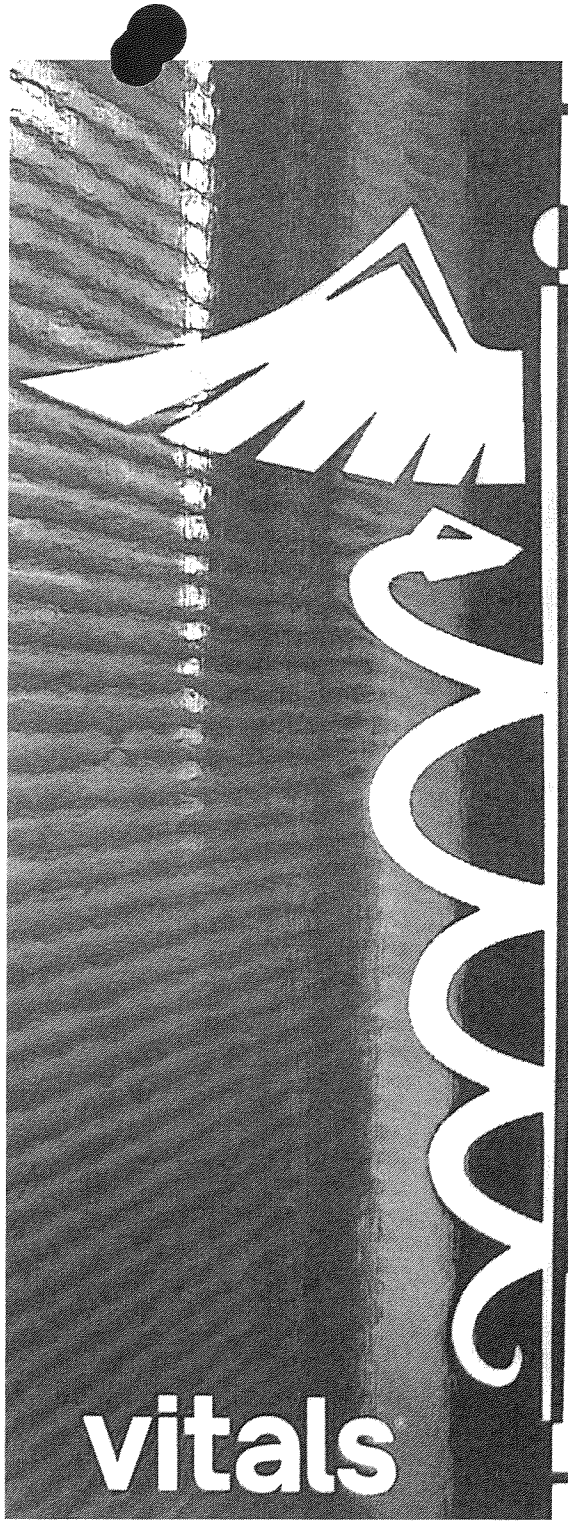
In gratitude for faithful service to patients and has been recognized by patients as being one of America's Most Compassionate Doctors.

Awarded on this 15th day of March in the year 2011

PATIENTS' CHOICE
2010
COMPASSIONATE DOCTOR

Erika Beyer

Erika Beyer
Vice President
Consumer Research

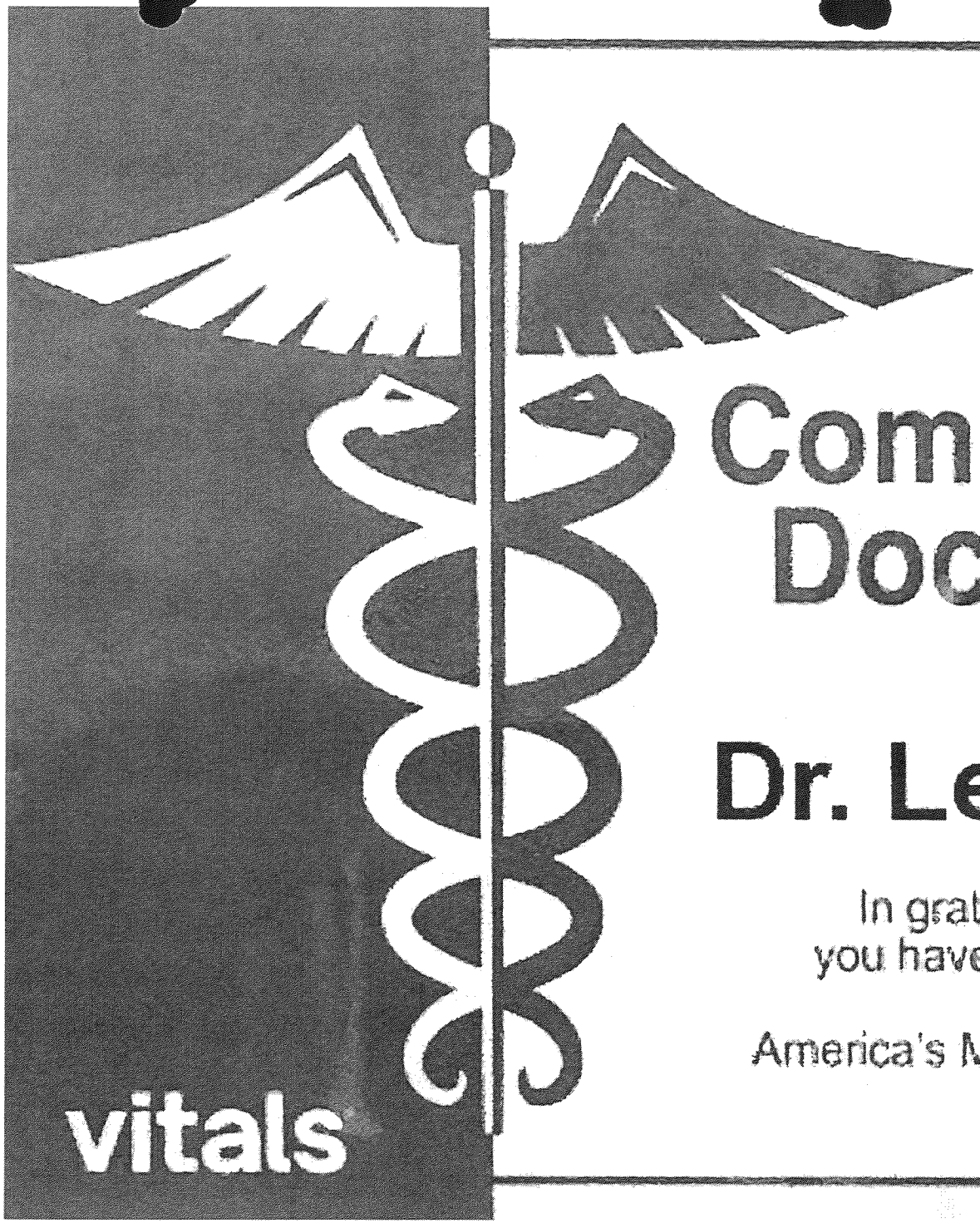


PATIENTS' CHOICE AWARD 2019

Patients' Choice Award 2019

Dr. Leon Margolin

Has Been Selected As One Of Ohio's Favorite Physicians



2019

Compassionate Doctor Award 2019

Dr. Leon Margolin

In gratitude for faithful service,
you have been recognized by your
patients as one of
America's Most Compassionate Doctors.

Compassionate Doctor Award

Dr. Leon Margolin

In gratitude for faithful service, you have been recognized by your patients as one of America's Most Compassionate Doctors.



2015

vitals

OHTopDocs

A DIVISION OF USA TOP DOCS

October 1, 2021

Leon Margolin, MD
Comprehensive Pain Management Institute
5245 East Main Street
Columbus, OH 43213

Dear Dr. Leon Margolin,

Congratulations! You have been approved as a Top Doctor by OH Top Docs.

Our selection committee received the application you submitted and additional background information we compiled and verified. Based on your education, training, malpractice & license background check, accolades /awards along with patient reviews you have been approved as a OH Top Doctor for 2021. Congratulations!

You will be listed in the October 2021 Approved Provider Press Release we will distribute online next month and you will also receive the 2021 approved provider logo for your use.

Additionally, as an approved provider, you are eligible to take part in a variety of options available. Please find information and imagery in the subsequent pages and also on our website at www.OHTopDocs.com/Order. If you have any questions or would like to discuss anything further pleas reach out to me directly at Harper@OHTopDocs.com or via phone at 908-288-7240 x 105.

If you would like to stop receiving all communication from OH Top Docs, please either email info@USATopDocs.com, fax this form back with "Remove" written across the top to 908-288-7241 o you can leave a message 24/7/365 at 908-288-7240. Your information will be removed within 7 business days.

I look forward to working with you.

Respectfully,

Sue Pane
Administrative Coordinator

TOP DOCTOR 2021
OHTopDocs

For his Dedication, Accomplishments and
Devotion to Patient Care

Leon Margolin, MD, PhD

Has Been Awarded the Honor of



For his excellence in the field of

Pain Medicine (SBIRT Program)

C

PULSUS

WWW.PULSUSCONFERENCE.COM

Certificate of Recognition

PULSUS and the Editors of Current Research: Integrative Medicine, American Journal of Phytomedicine and Clinical Therapeutics & Journal of Pharmacology Research wish to thank

Dr. Leon Margolin

Comprehensive Pain Management Institute, LLC, USA

for his E-Poster Participation

"Correlation between NARX score and food addictive behavioral patterns in chronic pain patients"

at the "3rd World Congress on Complementary and Alternative Medicine" held during November 24, 2021 | Webinar

Francislete Melo
UNICEUB, Brazil

Fai Chan
Deli Aroma LLC, USA

Certificate of Appreciation

Awarded to

Prof. / Dr. **Leon Margolin,** Comprehensive Pain Management Institute, LLC, USA

for speaking on *20-Week Study of Clinical Outcomes of Over-the-counter COVID-19 Prophylaxis and Treatment*

at

4th International Conference on Traditional Medicine, Phytochemistry and Medicinal Plants (Online Meeting)

February 07-08, 2022

Dr Abdullatof Azab

Dr. Abdullatif Azab
Carobway, Israel
Conference Chair
TMedPM-2022

ESMED

European Society of Medicine

Certificate of Participation

Presented to

Leon Margolin

For speaking at

ESMED General Assembly 2022

Organized by *the European Society of Medicine*

on *August 4-6, 2022*

ESMED 2022

Certificate of Recognition

Pulsus
35 Ruddlesway, Windsor, Berkshire, SL4 5SF
WWW.PULSUSCONFERENCE.COM Ph: +44-203-769-1778

PULSUS and the Editors of Current Research: Integrative Medicine, American Journal of Phytomedicine and Clinical Therapeutics & Journal of Pharmacology Research wish to thank

Dr. *Leon Margolin*

Comprehensive Pain Management Institute, LLC, USA

for his phenomenal and worthy keynote presentation on

"20-week study of clinical outcomes of over-the-counter COVID-19 prophylaxis and treatment"

at the "3rd World Congress on Complementary and Alternative Medicine" held during November 24, 2021 | Webinar

Francislete Melo
UNICEUB, Brazil

Fai Chan
Deli Aroma LLC, USA

CAM Therapies 2021 Organizing Committee Members

Francislete Melo
UNICEUB, Brazil

Fai Chan
Deli Aroma LLC, USA

STATEN ISLAND UNIVERSITY HOSPITAL

"METALLOPROTEINASE INHIBITOR ATTENUATES CELL PROLIFERATION 1/2 MONTHS AFTER AGIOPLASTY IN RATS: AUGMENTATIVE EFFECT OF ALPHA-V, BETA-3 RECEPTOR BLOCKADE"

CERTIFICATE OF ACHIEVEMENT

This Certificate is presented to

LEON MARGOLIN, M.D.

by the Department of Medicine

for Participation and Distinguished Achievement

in Medical Research and Scholarly Activity

FIRST PLACE RESEARCH - $450.00

IN WITNESS WHEREOF, we have caused this certificate to be signed

this 12th *day of* June *in the year* 2003

President

Director of Medicine

SI 0686 (5/97)

© GOES 746

STATEN ISLAND UNIVERSITY HOSPITAL

CERTIFICATE OF ACHIEVEMENT

This Certificate is presented to

Leon Margolin, M.D., Ph.D.

by the Department of Medicine

for Participation and Distinguished Achievement

in Medical Research and Scholarly Activity

IN WITNESS WHEREOF, we have caused this certificate to be signed

this 30th *day of* June *in the year* 2003

President

Director of Medicine

SI 0686 (5/97)

© 001 5 746

LITHO IN U.S.A.

Certificate of Achievement

In Recognition Of

Leon Margolin, MD

First Place, Basic Science Category

for the poster presentation of, **"Assessment of the Antimicrobial Properties of Maggots"**

Pennsylvania Medical Society

Third Annual Poster Contest - October 21, 2006

www.pamedsoc.org

Pennsylvania
MEDICAL SOCIETY
Doctors and Patients Preserve the Relationship

2006

PULSUS

WWW.PULSUSCONFERENCE.COM

Certificate of Recognition

PULSUS and the Editors of Current Research: Integrative Medicine, American Journal of Phytomedicine and Clinical Therapeutics & Journal of Pharmacology Research wish to thank

Dr. Leon Margolin

Comprehensive Pain Management Institute, LLC, USA

for his E-Poster Participation

"Correlation between NARX score and food addictive behavioral patterns in chronic pain patients"

at the "3rd World Congress on Complementary and Alternative Medicine"

held during November 24, 2021 | Webinar

Francislete Melo
UNICEUB, Brazil

Fai Chan
Deli Aroma LLC, USA

Research During Residency and Fellowship: Why Bother?

LEON MARGOLIN, MD, PhD

Residency and fellowship can be challenging, combining an intensive work schedule with reading, preparation for boards and trying to maintain your personal life.

Doing research requires a lot of dedication, time and abilities. There is no guarantee that your project will succeed and that your article will be accepted for publication, and usually there are no financial rewards for the resident as well. So why would somebody spend the extra time and effort in research?

There are two especially good reasons I believe you should consider a research project. First, it's intellectually stimulating. I usually see it as a *gym time* for my brain. Like any exercise, you may not see the results immediately but you will see a difference over time. Second, it's a team sport. You can meet good people and make friends through research. You learn to appreciate different opinions and personalities.

I am sure almost all of us were asked in our medical school admission interview why we decided to become medical doctors. Many of us probably replied that we want to help people, save lives and improve health care. I believe that successful clinical research can be an excellent way to achieve this ideal. While you feel a lot of satisfaction with your clinical work, the magnitude of that satisfaction is increased substantially with research.

In my field, physical medicine/rehabilitation and pain management, we deal with chronic problems that, while almost impossible to cure, need to be alleviated and controlled. I believe that many of the patients we treated during the fellowship year improved; some reported a significant difference in their lives and a few wrote appreciation letters.

I would estimate that, at best, I might have impacted the lives of a few hundred patients over the fellowship year through my clinical work. Over the same period of time, I received numerous inquires from many different places around the world about the research article I published. That could well have impacted the care of tens of thousands of patients.

The National Institute of Cancer (Havana), Belgium Poison Center (Brussels) and the Central Library of Medicine Foundation (Buenos Aires) all contacted me recently regarding my research. But the most rewarding letter for me was sent in March by a grandmother of an eight-year-old girl with a diagnosis of mesenchymal chondrosarcoma. She stated that my article was used in the treatment of children and adults battling sarcoma and by the national online support group for mesenchymal chondrosarcoma, as well as several adult and pediatric sarcoma groups. That particular article required a very significant investment of time. At some point, I felt guilty for taking so much from my own family; but, after receiving her message, I felt that I would do it again.

We all believe that our mission as physicians is to alleviate suffering, save lives and improve health care. Occasionally this high ideal is blurred with the concerns of "making the bottom line," "getting the job done," and the pressure to pass the boards or be promoted. I believe that clinical research is an excellent altruistic opportunity to achieve a higher ideal and make your personal microscopic contribution to making the world around you a better place to live.

Dr. Margolin is a Fellow at the University of Pittsburgh Medical Center and winner of several research awards, including the Pennsylvania Medical Society's 2006 resident/fellow competition. He can be reached at leon3087@gmail.com.

The opinion expressed in this column is that of the writer and does not necessarily reflect the opinion of the Editorial Board, the *Bulletin*, or the Allegheny County Medical Society.

D

Certificate of Continuing Medical Education

ccreditation Statement: The ippincott Continuing Medical Education Institute is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

Designation Statement: The Lippincott Continuing Medical Education Institute designates most Audio Digest Enduring Materials for a maximum of 2.00 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity. *Note: Each ACCEL program is designated for a maximum of 4.00 *AMA PRA Category 1 Credits™*.

Lippincott Professional Development is accredited as a provider of nursing continuing professional development by the American Nurses Credentialing Center's Commission on Accreditation. Lippincott Professional Development awards up to 2.00 CE contact hours (or up to 4.00 CE contact hours for an ACCEL activity) for each clinical activity.

Dr. Leon Margolin

DATE 9/26/2024
CUSTOMER ID# 25348086

THIS PARTICIPANT HAS SUCCESSFULLY COMPLETED THE FOLLOWING CME ACTIVITIES
(APPLIES TO TESTS GRADED Jan 01 2024 THRU Dec 30 2024)

DATE	VOLUME ISSUE LECTURE	TITLE	PRE/POST-TEST		CREDITS
ANESTHESIOLOGY					
09/26/2024	65-12-01	Palliative Care Sedation	0%	100%	0.75
09/24/2024	64-25-02	Responding to Patient Questions About Physician Aid-in-dying	0%	100%	0.50
24/2024	64-25-01	New Thinking About Advance Care Planning	0%	100%	0.75
TAL AMA PRA CATEGORY 1 CREDITS™ IN ANESTHESIOLOGY: 2.00					
EMERGENCY MEDICINE					
09/26/2024	40-08-03	Applying Clinical Ethics in the Emergency Department	0%	100%	0.50
TOTAL AMA PRA CATEGORY 1 CREDITS™ IN EMERGENCY MEDICINE: 0.50					

*The AAFP has reviewed **Audio Digest Emergency Medicine Volume 41**, and deemed it acceptable for AAFP credit. Term of approval is from 01/01/2021 to 12/31/2021. Physicians should claim only the credit commensurate with the extent of their participation in the activity.*

See individual activities for session-specific credit approval information.

*This enduring material activity, **Audio Digest Emergency Medicine, 41**, Issues 1-24, has been reviewed and is acceptable for up to 48 Prescribed credits by the **American Academy of Family Physicians**. AAFP certification begins January 1, 2020. Term of approval is for one year from this date. Each issue is approved for 2 Prescribed credits. Credit may be claimed for 1 year from the date of each issue. Physicians should claim only the credit commensurate with the extent of their participation in the activity.*

AAFP members may claim Elective Credit for Audio Digest Emergency Medicine Volume 40 (specifically, issues with publication dates that are older than 1 year), Volume 39 (all issues), and Volume 38 (only issues with publication dates that are less than 3 years old).

GENERAL SURGERY					
09/26/2024	70-03-02	Ethical Considerations in Mechanical Circulatory Support Decision-Making	0%	100%	0.75

AudioDigest
1800 Dual Hwy Ste 201,
Hagerstown, MD 21740
(818) 240-7500
audiodigest.org

Diane M Ezard
Director of Accreditation & Communication

Accreditation Statement: The Lippincott Continuing Medical Education Institute is accredited by he Accreditation Council for ontinuing Medical Education to provide continuing medical education for physicians.

Designation Statement: The Lippincott Continuing Medical Education Institute designates most Audio Digest Enduring Materials for a maximum of 2.00 *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity. *Note: Each ACCEL program is designated for a maximum of 4.00 *AMA PRA Category 1 Credits*™.

Lippincott Professional Development is accredited as a provider of nursing continuing professional development by the American Nurses Credentialing Center's Commission on Accreditation. Lippincott Professional Development awards up to 2.00 CE contact hours (or up to 4.00 CE contact hours for an ACCEL activity) for each clinical activity.

Dr. Leon Margolin

DATE 9/26/2024
CUSTOMER ID# 25348086

THIS PARTICIPANT HAS SUCCESSFULLY COMPLETED THE FOLLOWING CME ACTIVITIES
(APPLIES TO TESTS GRADED Jan 01 2024 THRU Dec 30 2024)

DATE	VOLUME ISSUE LECTURE	TITLE	PRE/POST-TEST		CREDITS
TOTAL AMA PRA CATEGORY 1 CREDITS™ IN GENERAL SURGERY: 0.75					
INTERNAL MEDICINE					
09/24/2024	69-23-02	Healer Until the End: Physician-assisted Death	0%	100%	1.00
TOTAL AMA PRA CATEGORY 1 CREDITS™ IN INTERNAL MEDICINE: 1.00					
OTOLARYNGOLOGY					
26/2024	56-02-01	Ethics: Decision-Making for Children and Adolescents When Parents and Medical	0%	80%	1.00
/26/2024	55-19-01	Ethics: The Physician's Role in the Opioid Crisis	0%	80%	1.25
TOTAL AMA PRA CATEGORY 1 CREDITS™ IN OTOLARYNGOLOGY: 2.25					
PSYCHIATRY					
09/26/2024	52-14-01	Ethics for the Mental Health Provider	0%	90%	2.00
TOTAL AMA PRA CATEGORY 1 CREDITS™ IN PSYCHIATRY: 2.00					

TOTAL AMA PRA CATEGORY 1 CREDITS™: 8.50

PLEASE NOTE : CREDIT LISTED BELOW IS INCLUDED IN (AND NOT IN ADDITION TO) THE TOTAL HOURS OF AMA PRA CATEGORY 1 CREDITS™ LISTED ABOVE

A COURSE MAY QUALIFY FOR ONE OR MORE OF THE CATEGORIES LISTED BELOW.

Accreditation Statement: The Lippincott Continuing Medical Education Institute is accredited by he Accreditation Council for ontinuing Medical Education to provide continuing medical education for physicians.

Designation Statement: The Lippincott Continuing Medical Education Institute designates most Audio Digest Enduring Materials for a maximum of 2.00 *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity. *Note: Each ACCEL program is designated for a maximum of 4.00 *AMA PRA Category 1 Credits*™.

Lippincott Professional Development is accredited as a provider of nursing continuing professional development by the American Nurses Credentialing Center's Commission on Accreditation. Lippincott Professional Development awards up to 2.00 CE contact hours (or up to 4.00 CE contact hours for an ACCEL activity) for each clinical activity.

Dr. Leon Margolin

DATE 9/26/2024
CUSTOMER ID# 25348086

THIS PARTICIPANT HAS SUCCESSFULLY COMPLETED THE FOLLOWING CME ACTIVITIES
(APPLIES TO TESTS GRADED Jan 01 2024 THRU Dec 30 2024)

DATE	VOLUME ISSUE LECTURE	TITLE	PRE/POST-TEST QUALIFYING CREDITS	CREDITS
ABA MOCA				
AN	65-12-01	Palliative Care Sedation		0.75
AN	64-25-02	Responding to Patient Questions About Physician Aid-in-dying		0.50
AN	64-25-01	New Thinking About Advance Care Planning		0.75
BOHNS Continuing Certification				
T	55-19-01	Ethics: The Physician's Role in the Opioid Crisis		1.25
ABS Continuous Certification				
GS	70-03-02	Ethical Considerations in Mechanical Circulatory Support Decision-Making		0.75
CLINICAL PHARMACOLOGY				
AN	65-12-01	Palliative Care Sedation		0.75
OT	55-19-01	Ethics: The Physician's Role in the Opioid Crisis		1.25
CONTROLLED SUBSTANCES				
OT	55-19-01	Ethics: The Physician's Role in the Opioid Crisis		1.25
END OF LIFE/PALLIATIVE CARE				
AN	65-12-01	Palliative Care Sedation		0.75
AN	64-25-02	Responding to Patient Questions About Physician Aid-in-dying		0.50
AN	64-25-01	New Thinking About Advance Care Planning		0.75

Diane M Ezard
Director of Accreditation & Communication

Accreditation Statement: The Lippincott Continuing Medical Education Institute is accredited by ıe Accreditation Council for ontinuing Medical Education to provide continuing medical education for physicians.

Designation Statement: The Lippincott Continuing Medical Education Institute designates most Audio Digest Enduring Materials for a maximum of 2.00 *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity. *Note: Each ACCEL program is designated for a maximum of 4.00 *AMA PRA Category 1 Credits*™.

Lippincott Professional Development is accredited as a provider of nursing continuing professional development by the American Nurses Credentialing Center's Commission on Accreditation. Lippincott Professional Development awards up to 2.00 CE contact hours (or up to 4.00 CE contact hours for an ACCEL activity) for each clinical activity.

Dr. Leon Margolin

DATE 9/26/2024
CUSTOMER ID# 25348086

THIS PARTICIPANT HAS SUCCESSFULLY COMPLETED THE FOLLOWING CME ACTIVITIES
(APPLIES TO TESTS GRADED Jan 01 2024 THRU Dec 30 2024)

DATE	VOLUME ISSUE LECTURE	TITLE	PRE/POST-TEST	CREDITS
ETHICS				
EM	40-08-03	Applying Clinical Ethics in the Emergency Department		0.50
GS	70-03-02	Ethical Considerations in Mechanical Circulatory Support Decision-Making		0.75
AN	65-12-01	Palliative Care Sedation		0.75
OT	55-19-01	Ethics: The Physician's Role in the Opioid Crisis		1.25
S	52-14-01	Ethics for the Mental Health Provider		2.00
T	56-02-01	Ethics: Decision-Making for Children and Adolescents When Parents and Medical Teams Disagree		1.00
IM	69-23-02	Healer Until the End: Physician-assisted Death		1.00
AN	64-25-02	Responding to Patient Questions About Physician Aid-in-dying		0.50
AN	64-25-01	New Thinking About Advance Care Planning		0.75
PAIN MANAGEMENT				
AN	65-12-01	Palliative Care Sedation		0.75
OT	55-19-01	Ethics: The Physician's Role in the Opioid Crisis		1.25
SUBSTANCE ABUSE/DEA-MATE ELIGIBLE				
OT	55-19-01	Ethics: The Physician's Role in the Opioid Crisis		1.25

AudioDigest Anesthesiology activities contribute to the CME component of the American Board of Anesthesiology's redesigned Maintenance of Certification in Anesthesiology™ (MOCA®) program, known as MOCA 2.0®.

NOTE: Audio Digest submits accredited-CME credits directly to the ABA (via PARS) within 30 days of participation (assuming your valid ABA ID is on file).

AudioDigest
1800 Dual Hwy Ste 201,
Hagerstown, MD 21740
(818) 240-7500
audiodigest.org

Diane M Ezard
Director of Accreditation & Communication

Accreditation Statement: The Lippincott Continuing Medical Education Institute is accredited by he Accreditation Council for ontinuing Medical Education to provide continuing medical education for physicians.

Designation Statement: The Lippincott Continuing Medical Education Institute designates most Audio Digest Enduring Materials for a maximum of 2.00 *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity. *Note: Each ACCEL program is designated for a maximum of 4.00 *AMA PRA Category 1 Credits*™.

Lippincott Professional Development is accredited as a provider of nursing continuing professional development by the American Nurses Credentialing Center's Commission on Accreditation. Lippincott Professional Development awards up to 2.00 CE contact hours (or up to 4.00 CE contact hours for an ACCEL activity) for each clinical activity.

Dr. Leon Margolin

DATE 9/26/2024
CUSTOMER ID# 25348086

THIS PARTICIPANT HAS SUCCESSFULLY COMPLETED THE FOLLOWING CME ACTIVITIES
(APPLIES TO TESTS GRADED Jan 01 2024 THRU Dec 30 2024)

DATE	VOLUME ISSUE LECTURE	TITLE	PRE/POST-TEST	CREDITS

*Any AC, GS, IM, OT, and PD activities displayed on this certificate as Qualifying for MOC/CC are eligible for MOC/CC only if the test was taken Online (and therefore provided feedback to the learner). Tests submitted via Paper provide CME credit only. MOC/CC participant reports submitted by Audio Digest for AC, GS, IM, OT, and PD activities include only credits earned via Online Testing.

AudioDigest
1800 Dual Hwy Ste 201,
Hagerstown, MD 21740
(818) 240-7500
audiodigest.org

Diane M Ezard
Director of Accreditation & Communication

SPPM
SOCIETY FOR PAIN PRACTICE MANAGEMENT

Fraud and Abuse -What Auditors are looking For
Presented by
Amy Turner, RN, BSN, CPC, MHHC, CHIAP
Vicki Myckowiak, Esq.
July 30, 2024

CONTINUING MEDICAL EDUCATION CERTIFICATE

Awards 1.5 credits to

Leon Margolin

These credits are for participation in a Webinar Activity and Interactive Q&A Session focusing on the topic of Fraud and Abuse Prevention and Compliance for Pain Management Practices.

The Society For Pain Practice Management is accredited by ACCME to provide continuing medical education to physicians. This activity has been planned and implemented in accordance with the Essentials and Standards of the Accreditation Council for Continuing Medical Education (ACCME) by the Society For Pain Practice Management. The Society For Pain Practice Management takes responsibility for the content, quality, and scientific integrity of this CME activity.

The Society For Pain Practice Management designates this educational activity for a maximum of 1.50 Category 1 AMA *PRA Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Katherine Waldman

Katherine Waldman
Executive Director
The Society For Pain Practice Management

powered by cea

CERTIFICATE

Clinical Care Options, LLC certifies that

Leon Margolin, MD

has participated in the enduring material titled

Module 5: Introduction to Substance Use Disorders

on **10/14/2024** and is awarded **1.00** *AMA PRA Category 1 Credit.*

This activity provides 1.00 hours of mandatory controlled substances CME credit for physicians and other prescribers.

JOINTLY ACCREDITED PROVIDER™
INTERPROFESSIONAL CONTINUING EDUCATION

In support of improving patient care, Clinical Care Options, LLC is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

IPCE CREDIT™

This activity was planned by and for the healthcare team, and learners will receive 1.00 Interprofessional Continuing Education (IPCE) credit for learning and change.

The AAFP has reviewed DEA Course: Controlled Substance Prescribing: Comprehensive Education To Improve Quality of Care - Enduring, and deemed it acceptable for AAFP credit. Term of Approval is from 05/31/2023 to 05/30/2024. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

AAFP Prescribed credit is accepted by the American Medical Association as equivalent to *AMA PRA Category 1 credit(s)*™ toward the AMA Physician's Recognition Award. When applying for the AMA PRA, Prescribed credit earned must be reported as Prescribed, not as Category 1.

12001 Sunrise Valley Drive
Suite 300
Reston, VA 20191
Contact Us - Clinical Care Options (clinicaloptions.com)
Jointly Accreditated Provider Number: 4008176

Sophia Kelley

Sophia Kelley, MBA
Manager, Accreditation
Clinical Care Options, LLC

powered by cea

CERTIFICATE

Clinical Care Options, LLC certifies that

Leon Margolin, MD

has participated in the enduring material titled

Module 8: Tobacco and Cannabis Use Disorders

on **10/14/2024** and is awarded **1.00** *AMA PRA Category 1 Credit.*

This activity provides 1.00 hours of mandatory controlled substances CME credit for physicians and other prescribers.

JOINTLY ACCREDITED PROVIDER™
INTERPROFESSIONAL CONTINUING EDUCATION

In support of improving patient care, Clinical Care Options, LLC is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

IPCE CREDIT™

This activity was planned by and for the healthcare team, and learners will receive 1.00 Interprofessional Continuing Education (IPCE) credit for learning and change.

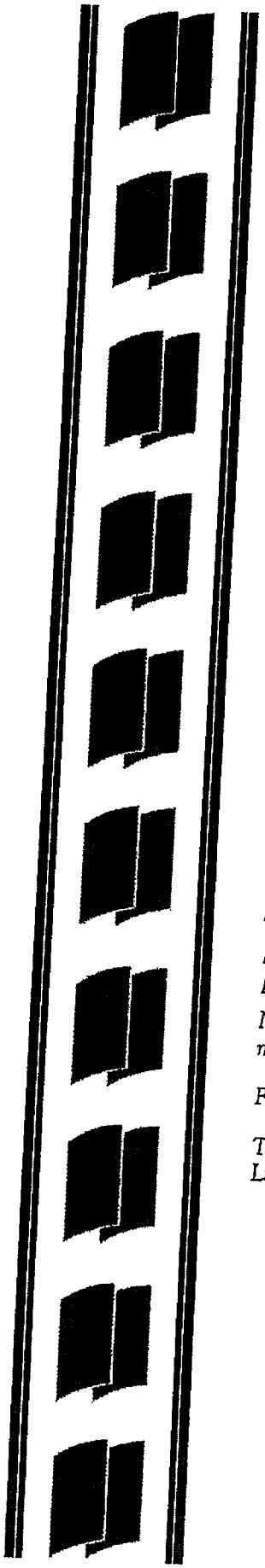
The AAFP has reviewed DEA Course: Controlled Substance Prescribing: Comprehensive Education To Improve Quality of Care - Enduring, and deemed it acceptable for AAFP credit. Term of Approval is from 05/31/2023 to 05/30/2024. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

AAFP Prescribed credit is accepted by the American Medical Association as equivalent to *AMA PRA Category 1 credit(s)*™ toward the AMA Physician's Recognition Award. When applying for the AMA PRA, Prescribed credit earned must be reported as Prescribed, not as Category 1.

12001 Sunrise Valley Drive
Suite 300
Reston, VA 20191
Contact Us - Clinical Care Options (clinicaloptions.com)
Jointly Accreditated Provider Number: 4008176

Sophia Kelley

Sophia Kelley, MBA
Manager, Accreditation
Clinical Care Options, LLC



Certificate of Completion

NetCE certifies that
Leon Margolin 35.090064
has participated in the enduring material titled
#95170 Medical Marijuana
and Other Cannabinoids
on February 16, 2016
and is awarded 5
AMA PRA Category 1 Credit(s) ™.

Freda S. O'Brien
Freda S. O'Brien
Director of Academic Affairs

Erin K. Meinyer
Erin K. Meinyer
Executive Director

NetCE is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

Florida CE Broker Provider #50-2405, Board of Medicine.

This activity is designed to comply with the requirements of California Assembly Bill 1195, Cultural and Linguistic Competency.

NetCE
Continuing Education

PO BOX 997571 • SACRAMENTO, CALIFORNIA 95899-7571 • (800) 232-4CEU

Statement of Participation

The University of Pittsburgh Center for Continuing Education in the Health Sciences certifies that

Leon Margolin, MD

is awarded 2.0 AMA PRA Category 1 Credits™ for participation in

Medical Use of Marijuana Continuing Medical Education Course Certification ESA102

on **August 9, 2018.**

Accreditation and Credit Designation

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of the University of Pittsburgh School of Medicine and Extra Step Assurance.

The University of Pittsburgh School of Medicine is accredited by the ACCME to provide continuing medical education for physicians. The University of Pittsburgh School of Medicine designates this live activity for a maximum of 2 AMA PRA Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation in the activity

UPM Center for Continuing Education in the Health Sciences
3600 Forbes Avenue Iroquois Building, Suite 300
Pittsburgh, PA 15213
Phone: 412-647-8232
Website: http://ccehs.upmc.com

powered by cea

CERTIFICATE

Clinical Care Options, LLC certifies that

Leon Margolin, MD

has participated in the enduring material titled

Module 7: Alcohol Use Disorder

on **10/14/2024** and is awarded **1.00** *AMA PRA Category 1 Credit.*

This activity provides 1.00 hours of mandatory controlled substances CME credit for physicians and other prescribers.

JOINTLY ACCREDITED PROVIDER™
INTERPROFESSIONAL CONTINUING EDUCATION

In support of improving patient care, Clinical Care Options, LLC is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

IPCE CREDIT™

This activity was planned by and for the healthcare team, and learners will receive 1.00 Interprofessional Continuing Education (IPCE) credit for learning and change.

The AAFP has reviewed DEA Course: Controlled Substance Prescribing: Comprehensive Education To Improve Quality of Care - Enduring, and deemed it acceptable for AAFP credit. Term of Approval is from 05/31/2023 to 05/30/2024. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

AAFP Prescribed credit is accepted by the American Medical Association as equivalent to *AMA PRA Category 1 credit(s)*™ toward the AMA Physician's Recognition Award. When applying for the AMA PRA, Prescribed credit earned must be reported as Prescribed, not as Category 1.

12001 Sunrise Valley Drive
Suite 300
Reston, VA 20191
Contact Us - Clinical Care Options (clinicaloptions.com)
Jointly Accreditated Provider Number: 4008176

Sophia Kelley

Sophia Kelley, MBA
Manager, Accreditation
Clinical Care Options, LLC

Certificate of Completion

NetCE certifies that
Leon Margolin 35.090064
has participated in the enduring material titled
#95150 Responsible and
Effective Opioid Prescribing
on January 2, 2021
and is awarded 3
AMA PRA Category 1 Credit(s) ™.

Freda S. O'Brien
Freda S. O'Brien
Director of Academic Affairs

Erin K. Meinyer
Erin K. Meinyer
Executive Director

JOINTLY ACCREDITED PROVIDER™
INTERPROFESSIONAL CONTINUING EDUCATION

In support of improving patient care, NetCE is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

Florida CE Broker Provider #50-2405, Board of Medicine.

This activity is designed to comply with the requirements of California Assembly Bill 1195, Cultural and Linguistic Competency.

NetCE
Continuing Education

PO BOX 997571 • SACRAMENTO, CALIFORNIA 95899-7571 • (800) 232-4CEU

powered by cea

CERTIFICATE

Clinical Care Options, LLC certifies that

Leon Margolin, MD

has participated in the enduring material titled

Module 6: Opioid Use Disorder

on **10/14/2024** and is awarded **1.00** *AMA PRA Category 1 Credit.*

This activity provides 1.00 hours of mandatory controlled substances CME credit for physicians and other prescribers.

JOINTLY ACCREDITED PROVIDER™
INTERPROFESSIONAL CONTINUING EDUCATION

In support of improving patient care, Clinical Care Options, LLC is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

IPCE CREDIT™

This activity was planned by and for the healthcare team, and learners will receive 1.00 Interprofessional Continuing Education (IPCE) credit for learning and change.

The AAFP has reviewed DEA Course: Controlled Substance Prescribing: Comprehensive Education To Improve Quality of Care - Enduring, and deemed it acceptable for AAFP credit. Term of Approval is from 05/31/2023 to 05/30/2024. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

AAFP Prescribed credit is accepted by the American Medical Association as equivalent to *AMA PRA Category 1 credit(s)*™ toward the AMA Physician's Recognition Award. When applying for the AMA PRA, Prescribed credit earned must be reported as Prescribed, not as Category 1.

12001 Sunrise Valley Drive
Suite 300
Reston, VA 20191
Contact Us - Clinical Care Options (clinicaloptions.com)
Jointly Accreditated Provider Number: 4008176

Sophia Kelley

Sophia Kelley, MBA
Manager, Accreditation
Clinical Care Options, LLC

SCHOOL OF MEDICINE
CASE WESTERN RESERVE UNIVERSITY

Leon Margolin
5245 EAST MAIN ST
COLUMBUS, OH 43213

Certificate of Attendance

Leon Margolin

has attended the

Pain Management During the Opioid Crisis: Balancing Quality of Care & Patient Safety

on
May 10, 2018 - May 11, 2018

The Case Western Reserve University School of Medicine certifies that
Leon Margolin has participated in the live activity
titled Pain Management During the Opioid Crisis: Balancing Quality of Care & Patient Safety
on May 10, 2018 - May 11, 2018
and is awarded 10.00 *AMA PRA Category 1 Credit(s).*™
toward the AMA Physicians Recognition Award

Case Western Reserve University School of Medicine is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The Case Western Reserve University School of Medicine designates this live activity for a maximum of 10.00 *AMA PRA Category 1™ Credit(s).* Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Continuing Medical Education Program
10524 Euclid Avenue, Cleveland, OH 44106-6026
Tel: 216-983-1239 Fax: 216-844-8133 http://casemed.case.edu/cme/

Copyright Harvard Medical School, 2013. All Rights Reserved.

Risk Stratification with Chronic Opioid Therapy

Ronald J. Kulich, Ph.D.
Professor
Tufts School of Dental Medicine
Craniofacial Pain and Headache Center
Lecturer, Department of Anesthesia, Critical Care and Pain Medicine
Massachusetts General Hospital
Harvard Medical School

Disclosures

Dr. Kulich has nothing to disclose

Copyright Harvard Medical School, 2013. All Rights Reserved.

OPIOIDS:
Basic Science and Clinical Practice

Jianren Mao, MD, PhD

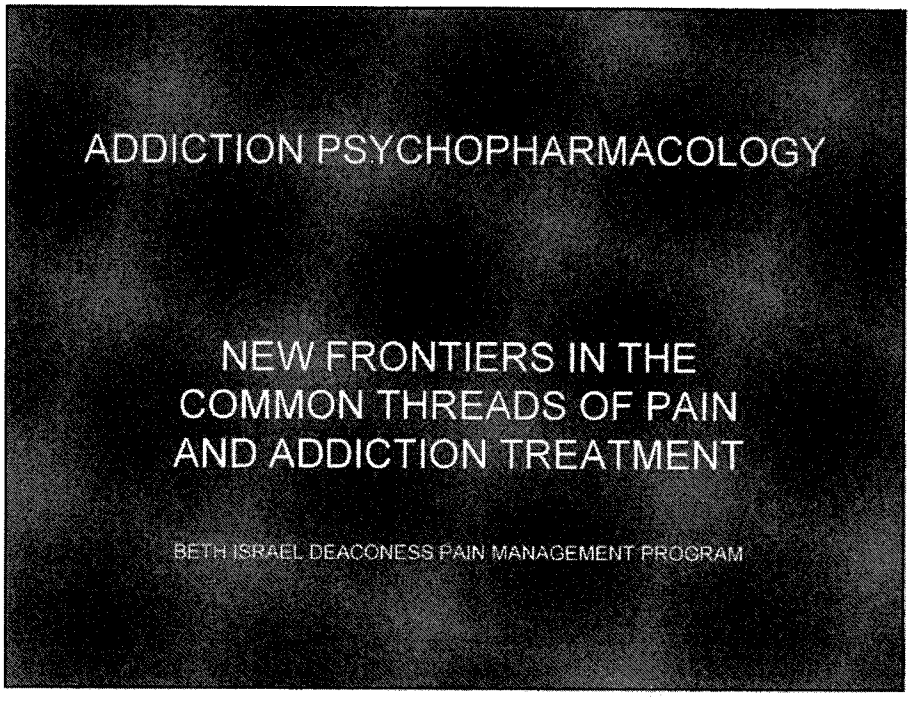
Richard J. Kitz Professor of Anaesthesia Research
Harvard Medical School

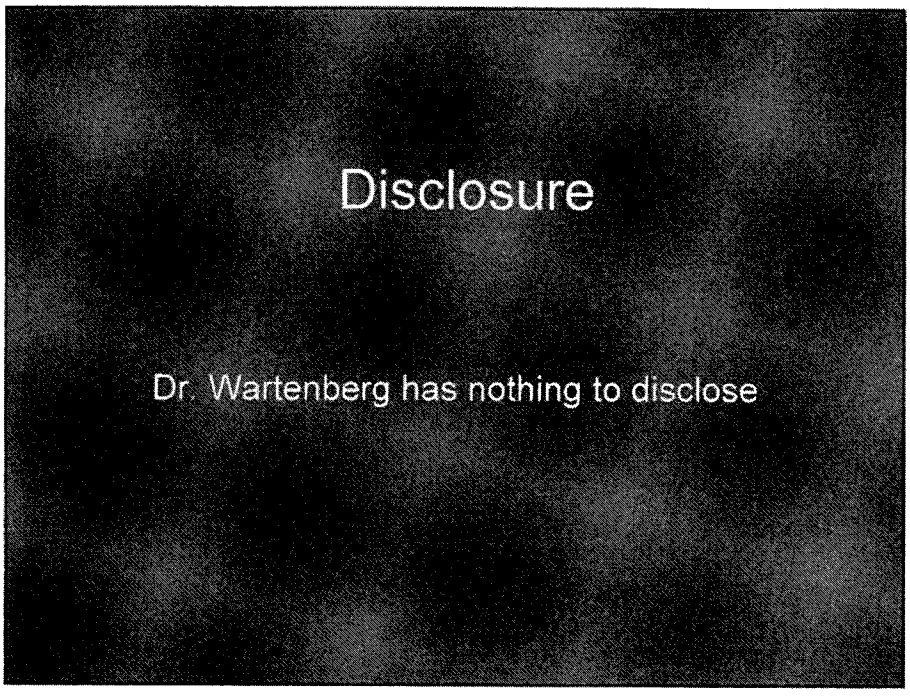
Vice Chair for Research
Department of Anesthesia, Critical Care and Pain Medicine
Director, MGH Center for Translational Pain Research
Massachusetts General Hospital

Disclosure

Dr. Mao has nothing to disclose

Copyright Harvard Medical School, 2013. All Rights Reserved.





powered by cea

CERTIFICATE

Clinical Care Options, LLC certifies that

Leon Margolin, MD

has participated in the enduring material titled

Module 1: General Principles of Controlled Substance Prescribing

on **10/10/2024** and is awarded **0.50** *AMA PRA Category 1 Credit.*

This activity provides 0.50 hours of mandatory controlled substances CME credit for physicians and other prescribers.

JOINTLY ACCREDITED PROVIDER™

In support of improving patient care, Clinical Care Options, LLC is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

IPCE CREDIT™

This activity was planned by and for the healthcare team, and learners will receive 0.50 Interprofessional Continuing Education (IPCE) credit for learning and change.

The AAFP has reviewed DEA Course: Controlled Substance Prescribing: Comprehensive Education To Improve Quality of Care - Enduring, and deemed it acceptable for AAFP credit. Term of Approval is from 05/31/2023 to 05/30/2024. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

AAFP Prescribed credit is accepted by the American Medical Association as equivalent to *AMA PRA Category 1 credit(s)*™ toward the AMA Physician's Recognition Award. When applying for the AMA PRA, Prescribed credit earned must be reported as Prescribed, not as Category 1.

Sophia Kelley

12001 Sunrise Valley Drive
Suite 300
Reston, VA 20191
Contact Us - Clinical Care Options (clinicaloptions.com)
Jointly Accreditated Provider Number: 4008176

Sophia Kelley, MBA
Manager, Accreditation
Clinical Care Options, LLC

powered by cea

CERTIFICATE

Clinical Care Options, LLC certifies that

Leon Margolin, MD

has participated in the enduring material titled

Module 2: Universal Risk Mitigation Strategies for Controlled Substances

on **10/10/2024** and is awarded **0.50** *AMA PRA Category 1 Credit.*

This activity provides 0.50 hours of mandatory controlled substances CME credit for physicians and other prescribers.

JOINTLY ACCREDITED PROVIDER™

In support of improving patient care, Clinical Care Options, LLC is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

IPCE CREDIT™

This activity was planned by and for the healthcare team, and learners will receive 0.50 Interprofessional Continuing Education (IPCE) credit for learning and change.

The AAFP has reviewed DEA Course: Controlled Substance Prescribing: Comprehensive Education To Improve Quality of Care - Enduring, and deemed it acceptable for AAFP credit. Term of Approval is from 05/31/2023 to 05/30/2024. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

AAFP Prescribed credit is accepted by the American Medical Association as equivalent to *AMA PRA Category 1 credit(s)*™ toward the AMA Physician's Recognition Award. When applying for the AMA PRA, Prescribed credit earned must be reported as Prescribed, not as Category 1.

Sophia Kelley

Sophia Kelley, MBA
Manager, Accreditation
Clinical Care Options, LLC

12001 Sunrise Valley Drive
Suite 300
Reston, VA 20191
Contact Us - Clinical Care Options (clinicaloptions.com)
Jointly Accreditated Provider
Number: 4008176

powered by cea

CERTIFICATE

Clinical Care Options, LLC certifies that

Leon Margolin, MD

has participated in the enduring material titled

Module 4: Managing Opioid Therapy

on **10/10/2024** and is awarded **1.00** *AMA PRA Category 1 Credit.*

This activity provides 1.00 hours of mandatory controlled substances CME credit for physicians and other prescribers.

JOINTLY ACCREDITED PROVIDER™

In support of improving patient care, Clinical Care Options, LLC is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

IPCE CREDIT™

This activity was planned by and for the healthcare team, and learners will receive 1.00 Interprofessional Continuing Education (IPCE) credit for learning and change.

The AAFP has reviewed DEA Course: Controlled Substance Prescribing: Comprehensive Education To Improve Quality of Care - Enduring, and deemed it acceptable for AAFP credit. Term of Approval is from 05/31/2023 to 05/30/2024. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

AAFP Prescribed credit is accepted by the American Medical Association as equivalent to *AMA PRA Category 1 credit(s)*™ toward the AMA Physician's Recognition Award. When applying for the AMA PRA, Prescribed credit earned must be reported as Prescribed, not as Category 1.

Sophia Kelley

12001 Sunrise Valley Drive
Suite 300
Reston, VA 20191
Contact Us - Clinical Care Options (clinicaloptions.com)
Jointly Accreditated Provider Number: 4008176

Sophia Kelley, MBA
Manager, Accreditation
Clinical Care Options, LLC

powered by cea

CERTIFICATE

Clinical Care Options, LLC certifies that

Leon Margolin, MD

has participated in the enduring material titled

Module 3: The Basics of Pain Management

on **10/14/2024** and is awarded **1.00** *AMA PRA Category 1 Credit.*

This activity provides 1.00 hours of mandatory controlled substances CME credit for physicians and other prescribers.

JOINTLY ACCREDITED PROVIDER™
INTERPROFESSIONAL CONTINUING EDUCATION

In support of improving patient care, Clinical Care Options, LLC is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

IPCE CREDIT™

This activity was planned by and for the healthcare team, and learners will receive 1.00 Interprofessional Continuing Education (IPCE) credit for learning and change.

The AAFP has reviewed DEA Course: Controlled Substance Prescribing: Comprehensive Education To Improve Quality of Care - Enduring, and deemed it acceptable for AAFP credit. Term of Approval is from 05/31/2023 to 05/30/2024. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

AAFP Prescribed credit is accepted by the American Medical Association as equivalent to *AMA PRA Category 1 credit(s)*™ toward the AMA Physician's Recognition Award. When applying for the AMA PRA, Prescribed credit earned must be reported as Prescribed, not as Category 1.

12001 Sunrise Valley Drive
Suite 300
Reston, VA 20191
Contact Us - Clinical Care Options (clinicaloptions.com)
Jointly Accreditated Provider Number: 4008176

Sophia Kelley

Sophia Kelley, MBA
Manager, Accreditation
Clinical Care Options, LLC

HARVARD MEDICAL SCHOOL
DEPARTMENT OF CONTINUING EDUCATION

Beth Israel Deaconess Medical Center

certify that

Leon Marglin

has participated in the enduring material titled

Principles and Practice of Pain Medicine

on 01-05-2014

This activity was designated 30.50 AMA PRA Category 1 Credits™

The Harvard Medical School is accredited by the Accreditation Council for Continuing Medical Education to provide continuing education for physicians. The Harvard Medical School designates this enduring material activity for a maximum of 30.5 AMA PRA Category 1 Credits™ Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Sanjiv Chopra, M.B.B.S., M.A.C.P.
Faculty Dean for Continuing Education
Professor of Medicine

Copyright Harvard Medical School, 2013. All Rights Reserved.

The Practice of Pain Medicine

Carol A Warfield, MD
Lowenstein Distinguished Professor of Anesthesia
Harvard Medical School
Department of Anesthesia, Critical Care and Pain Medicine
Beth Israel Deaconess Medical Center
Boston

Disclosure Statement

Dr. Carol A Warfield has nothing to disclose.

Copyright Harvard Medical School, 2013. All Rights Reserved.

Managing the Difficulty with *Difficult Patients*

Joshua Wootton, MDiv, PhD
Director of Pain Psychology
Arnold Pain Management Center
Beth Israel Deaconess Medical Center
Harvard Medical School

Principles and Practice of Pain Medicine
Harvard Medical School CME
June 18th, 2012
Boston, Massachusetts

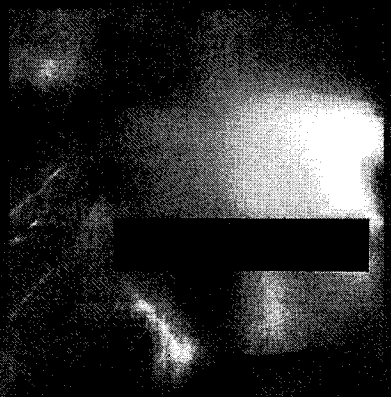
Beth Israel Deaconess Medical Center

Disclosure Statement

- Dr. Joshua Wootton has nothing to disclose.

Copyright Harvard Medical School, 2013. All Rights Reserved.

Psychological Assessment and Psychotherapeutic Management of Chronic Pain



Joshua Wootton, MDiv, PhD
Director of Pain Psychology
Arnold Pain Management Center
Beth Israel Deaconess Medical Center
Harvard Medical School

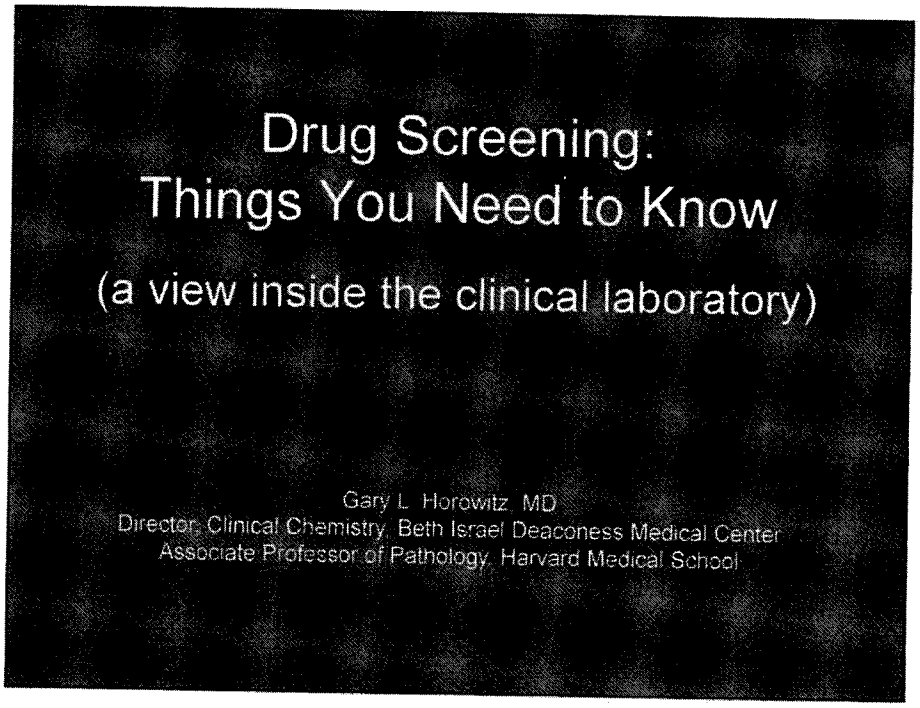
Principles and Practice of Pain Medicine
Harvard Medical School CME
Boston, Massachusetts

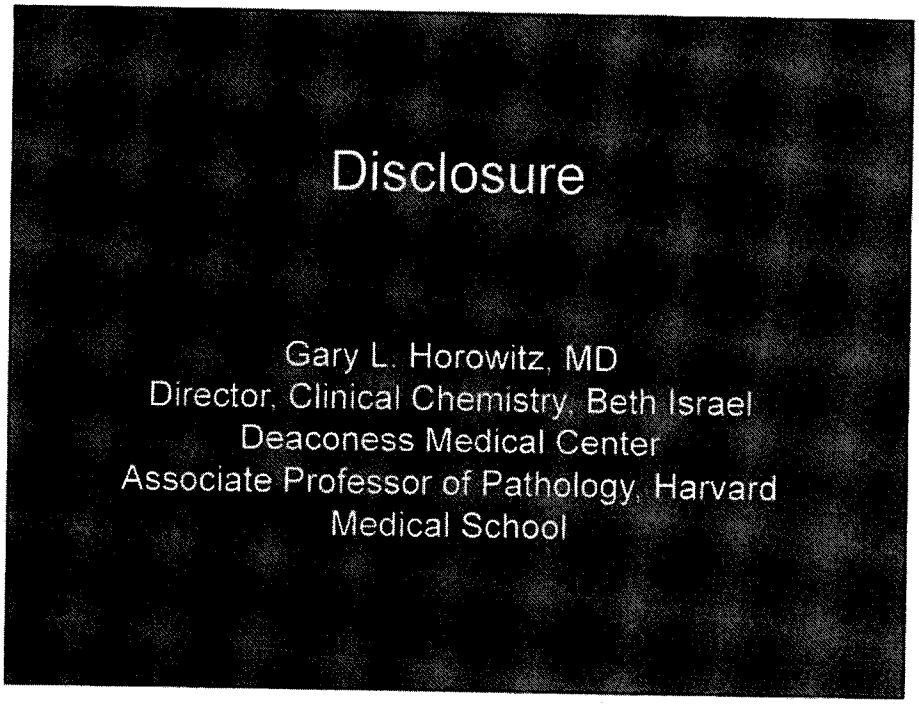
Beth Israel Deaconess Medical Center

Disclosure

- Dr. Wootton has nothing to disclose

Copyright Harvard Medical School, 2013. All Rights Reserved.





AMERICAN EDUCATIONAL INSTITUTE, INC.

CE2024-37367

certifies that

LEON MARGOLIN, MD

has participated in the enduring material titled,

The 2017-18 Medical-Dental-Legal Update

during the period of

10/30/2017-11/3/2017 Naples/Bonita Beach

via Streaming

and is hereby awarded 20 *AMA PRA Category 1 Credit(s)*™.

AMERICAN EDUCATIONAL INSTITUTE, INC. is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians.

David R. Victor, J.D.
President

THE 2020-21 MEDICAL-DENTAL-LEGAL UPDATE
CERTIFICATE OF PARTICIPATION

CE2021-12880

IT IS HEREBY CERTIFIED THAT

LEON MARGOLIN, MD

Participated in

The 2020-21 Medical-Dental-Legal Update

A 20 Hour Seminar

at Park City (near Deer Valley & Canyons) during the week(s) of 7/5/2021-7/9/2021

David R. Victor, J.D.
President

THE 2020-21 MEDICAL-DENTAL-LEGAL UPDATE
CERTIFICATE OF PARTICIPATION

CE2021-12880

IT IS HEREBY CERTIFIED THAT

LEON MARGOLIN, MD

Participated in

The 2020-21 Medical-Dental-Legal Update

A 20 Hour Seminar

at Park City (near Deer Valley & Canyons) during the week(s) of 7/5/2021-7/9/2021

David R. Victor, J.D.
President

AMERICAN EDUCATIONAL INSTITUTE, INC.

CE2024-37410

certifies that

LEON MARGOLIN, MD

has participated in the enduring material titled,

The 2021-22 Medical-Dental-Legal Update

during the period of

8/15/2022-8/19/2022 Myrtle Beach

and is hereby awarded 20 *AMA PRA Category 1 Credit(s)*™.

AMERICAN EDUCATIONAL INSTITUTE, INC. is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians.

David R. Victor, J.D.
President

AMERICAN EDUCATIONAL INSTITUTE, INC.

CE2024-37410

certifies that

LEON MARGOLIN, MD

has participated in the enduring material titled,

The 2021-22 Medical-Dental-Legal Update

during the period of

8/15/2022-8/19/2022 Myrtle Beach

and is hereby awarded 20 *AMA PRA Category 1 Credit(s)™*.

AMERICAN EDUCATIONAL INSTITUTE, INC. is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians.

David R. Victor, J.D.
President

AMERICAN EDUCATIONAL INSTITUTE, INC.

CE2024-37416

certifies that

LEON MARGOLIN, MD

has participated in the enduring material titled,

The 2022-23 Medical-Dental-Legal Update

during the period of

3/20/2023-3/24/2023 St. Petersburg

and is hereby awarded 20 *AMA PRA Category 1 Credit(s)*™.

AMERICAN EDUCATIONAL INSTITUTE, INC. is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians.

David R. Victor, J.D.
President

AMERICAN EDUCATIONAL INSTITUTE, INC.

CE2024-36960

certifies that

LEON MARGOLIN, MD

has participated in the enduring material titled,

The 2023-24 Medical-Dental-Legal Update

during the period of

8/19/2024-8/22/2024 Aruba

and is hereby awarded 16 *AMA PRA Category 1 Credit(s)*™.

AMERICAN EDUCATIONAL INSTITUTE, INC. is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians.

David R. Victor, J.D.
President

CLINICAL TOOLS
ONLINE HEALTH EDUCATION
www.clinicaltools.com

Certificate of Completion

Clinical Tools, Inc. certifies that

Leon Margolin, MD PhD

has participated in the enduring material titled

Buprenorphine Training Program v3.0 (2013-04-23 Update)

on **Wednesday, July 2, 2014**
and is awarded **9** *AMA PRA Category 1 Credit(s)*™

This activity was designated for up to 9 *AMA PRA Category 1 Credit(s)*™.

Clinical Tools, Inc. is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

Authorized Signature

THE
OAKSTONE
INSTITUTE

Oakstone Publishing, LLC certifies that

Leon Margolin

has participated in the enduring material titled

W03 - Pain Management

Date of Original Release: August 15, 2014
Date Credits Expire: August 15, 2017

On 12-27-2015 and is awarded 12.00 *AMA PRA Category 1 Credits*™

Oakstone Publishing, LLC is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians.

Oakstone Publishing, LLC designates this enduring material for a maximum of 12.00 *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

D Deye MD. FACP

Donald L Deye, MD, FACP
Medical Director
Oakstone Publishing, LLC

Oakstone Publishing, LLC | 2700 Corporate Drive, Suite 100 | Birmingham, AL 35252
phone: 800.633.4743 | fax: 800.284.5964 | email: service@oakstone.com

American Association of Neuromuscular & Electrodiagnostic Medicine
2621 Superior Drive NW, Rochester, MN 55901 T: 507.288.0100 F: 507.288.1225 www.aanem.org

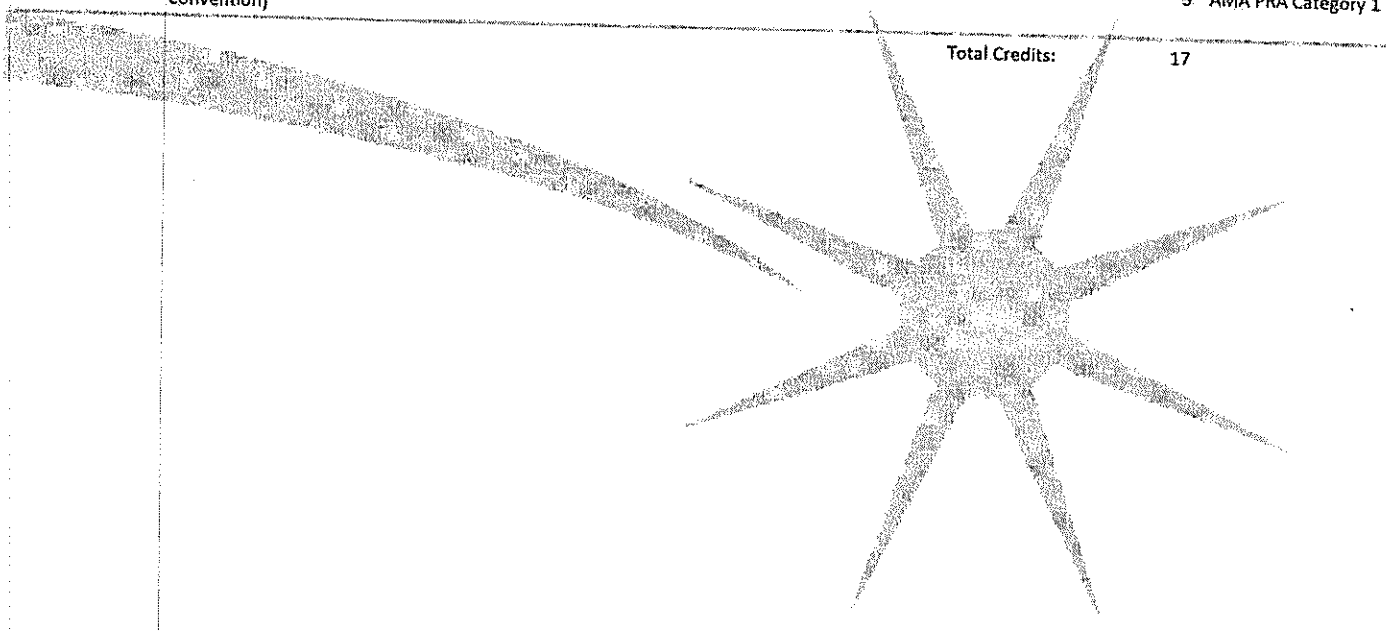
Education Transcript

The American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The AANEM also provides continuing education units (CEU) for non physician health professionals.

Below is a listing of credits obtained between **01/01/2018** and **10/28/2018** for **Leon Margolin, MD, PhD.**

Date	Activity Type	Title	Code	Score	Credits	Credit Type
10/12/2018	Live (Gaylord National Resort & Convention)	18ATE21F Basic Nerve	18ATE21F		1.5	AMA PRA Category 1
10/11/2018	Live (Gaylord National Resort & Convention)	18ATE07T Evidence-Based Medicine	18ATE07T		1.5	AMA PRA Category 1
10/11/2018	Live (Gaylord National Resort & Convention)	18C05 Use of Electrodiagnosis and Ultrasound for Evaluation of Focal Neuropathies of the Upper Limb	18C05		3	AMA PRA Category 1
10/10/2018	Live (Gaylord National Resort & Convention)	18W50C Advanced Autonomic Testing	18W50C		1.5	AMA PRA Category 1
10/10/2018	Live (Gaylord National Resort & Convention)	18W82C NCS Basics	18W82C		1.5	AMA PRA Category 1
10/10/2018	Live (Gaylord National Resort & Convention)	18W62W1 NCS Workshop/NCS Case Studies	18W62W1		3.5	AMA PRA Category 1
10/10/2018	Live (Gaylord National Resort & Convention)	18SYM03 Cutting Edge Ultrasound	18SYM03		1.5	AMA PRA Category 1
10/10/2018	Live (Gaylord National Resort & Convention)	18SYM19 EDX NM Challenging Cases	18SYM19		3	AMA PRA Category 1
				Total Credits:	17	



Advancing Neuromuscular, Musculoskeletal & Electrodiagnostic Medicine

Center for Continuing
Medical Education
Tower Suite 1603
1492 E. Broad Street
Columbus, OH 43205
614-257-3638
614-257-3636 Fax

March 3, 2010

Leon Margolin, MD
OSU Comprehensive Spine Center
2050 Kenny Road, 7th Floor
Columbus, Ohio 43221

This document certifies your participation in the continuing medical education activity, **Super EMG *Plus***, February 25-28, 2010, held at the Columbus Hilton at Easton, Columbus, Ohio and sponsored by The Ohio State University Medical Center in cooperation with The Ohio State University Department of Physical Medicine and Rehabilitation.

The Ohio State University Center for Continuing Medical Education is accredited by the Accreditation Council for Continuing Medical education (ACCME) to sponsor continuing medical education for physicians. This office certifies your participation in this continuing medical education activity and awards up to **13.25 Category 1** credits toward the Physician's Recognition Award of the American Medical Association based on registration and sign-in procedures.

Jon Hollett
Director, Continuing Medical Education

THIS DOCUMENT SHOULD BE RETAINED AS A RECORD OF YOUR ATTENDANCE AND CREDIT HOURS EARNED. HOURS STATED HEREIN MAY DIFFER FROM PUBLISHED HOURS TO REFLECT ACTUAL ARRIVAL AND DEPARTURE TIMES OF THE PARTICIPANT, OR OTHER SIGN-IN REQUIREMENTS.

State of Ohio Board of Pharmacy

77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836 | http://www.pharmacy.ohio.gov

License 022141400

Comprehensive Pain Management Institute, Llc

5245 E. Main Street
Columbus, OH 43213
Franklin County

Terminal - Pain Management Clinic - Category 3

TDDD Inspection (Updated 11/7/2024)

December 18, 2024

License 022141400 - Comprehensive Pain Management Institute, Llc

Full

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836
http://www.pharmacy.ohio.gov

Completed by Keenan Reese
Start 12/18/2024 8:00 AM
End 12/18/2024 8:35 AM

Organization

Name	License Type	Category
Comprehensive Pain Management Institute, Llc	Terminal - Pain Management Clinic - Category 3	

License Number	Business Type	DEA Number
022141400	PMC - Pain Management Clinic	FM0315780

Responsible Person
Leon Margolin

Hours of Operation
Mon-Tues: 8a-5p Wed: Closed (Administrative)Thurs:

Contact

Address	Primary Number	Fax Number	Website
5245 E. Main Street Columbus, OH 43213 Franklin County	(330) 488-4989	(216) 795-1105	

Personnel

Name	Initials	Position	I.D. No.	Phone	Email
Leon Margolin		Responsible Person	35.090064		leon3087@gmail.com

1) *Initial Inspection Information

1) Personnel conducting inspection

Observation
Agent Keenan Reese

2) Were multiple inspection guides used during this inspection?

No

3) Facility Description

Observation
Pain Management Clinic

4) *Does the TDDD have a valid registration issued by the Drug Enforcement Administration?

No: Utilizes prescriber's DEA registration

5) Is the Responsible Person present during the inspection?

Yes

6) Does the TDDD distribute dangerous drugs outside of Ohio?

No

16.1) Responsible Person - Terminal Distributor (OAC 4729:5-2-01)

3) PMC: Is a physician the responsible person on a category III TDDD licensed with a pain management classification?

Yes

4) PMC: Did the responsible person submit a criminal records check?

Yes

5) PMC: Does the responsible person meet one of the specialty or certification requirements required in rule?

Yes: Holds current board certification in anesthesiology, psychiatry, neurology, physical medicine and rehabilitation, occupational medicine, or rheumatology by the American board of medical specialties or hold current primary certification in anesthesiology, psychiatry, neurology, physical medicine and rehabilitation, occupational medicine, or rheumatology by the American osteopathic association bureau of osteopathic specialists

Observation
Dr. Leon Margolin holds certifications in Physical Medicine and Rehabilitation and Anesthesiology by the American Board of Medical Specialties.

17.2) *Report theft/significant loss: dangerous drug, controlled substance, drug document(OAC 4729:5-3-02)

1) *REMINDER: Theft or significant loss of dangerous drugs and drug documents

Observation
A terminal distributor of dangerous drugs shall notify the following upon discovery of the theft or significant loss of any dangerous drug or controlled substance, including drugs in transit that were either shipped from or to the licensed location: (1) The state board of pharmacy, by telephone or other method determined by the board, immediately upon discovery of the theft or significant loss; (2) If a controlled substance, the drug enforcement administration (DEA) pursuant to 21 C.F.R. 1301.76 (9/9/2014); (3) Law enforcement authorities pursuant to section 2921.22 of the Revised Code.

A terminal distributor of dangerous drugs shall, immediately upon discovery, notify the state board of pharmacy, in a manner determined by the board, and law enforcement authorities of any theft or loss of uncompleted prescription blank(s) used for writing a prescription, written prescription order(s) not yet dispensed and original prescription order(s) that have been dispensed.

A terminal distributor of dangerous drugs shall, immediately upon discovery, notify the state board of pharmacy, in a manner determined by the board, law enforcement authorities and the drug enforcement administration (DEA) pursuant to 21 C.F.R. 1305.16 (9/9/2014) of the theft or loss of any DEA form 222.

For more information on reporting, visit: www.pharmacy.ohio.gov/theft

2) *Has the TDDD experienced any theft or significant loss of any dangerous drugs in the past 24 months?

No

17.4) Verification of licensure prior to sale or purchase (OAC 4729:5-3-04)

2) PURCHASE: Has the TDDD completed an annual query of the board's online roster prior to purchase of dangerous drugs at wholesale?

No

Observation
If no documented query is conducted before a purchase is made, it shall be presumed that the purchase of dangerous drugs by the terminal distributor is in violation of section 4729.51 of the Revised Code.
Wholesaler Documented Query 11/23/2023
No documented query observed at beginning of inspection, however was the query was produced and observed by the end of the inspection.

17.7) Controlled substances inventory requirements (OAC 4729:5-3-07)

1) Are controlled substance inventory records maintained as required by rule?

Yes: Annual inventory is completed

2) Does the controlled substance inventory record(s) meet the requirements of 21 CFR 1304.11?

Other: See Observation Below

Observation
No controls on-site.

26.1) Pain Management Clinics - Definitions (OAC 4729:5-11-01)

1) ****Is the Clinic Physician Owned?

Yes

2) ****Does each physician owner of a pain management clinic meet the requirements for ownership?

Yes

3) ****Does the owner (or owners) of the clinic own or practice at any other facility?

Yes

Observation
Dr. Leon Margolin owns Comprehensive Pain Management Institute, LLC (022775650) in Cleveland, Ohio

4) ****How many hours per week does the owner work at the clinic?

Observation
40 Hours

26.2) Criminal records checks for pain management clinics (OAC 4729:5-11-02)

1) Are employee FBI/BCI criminal record checks for all employees available for inspection?

Yes

Observation
Observed.

26.3) Security, control and storage of dangerous drugs (4729:5-11-03)

4) Are all records relating to the receipt, administration, distribution, personal furnishing and sale of dangerous drugs shall be maintained under appropriate supervision and control to restrict unauthorized access.

Yes

5) Do only prescribers have access to uncompleted prescription blanks?

Yes

Observation
Some prescription blank are kept on hand.

6) Are all areas where dangerous drugs are stored shall be dry, well-lit, well-ventilated, and maintained in a clean and orderly condition.

Yes

7) Does the licensee comply with the security requirements for storing thiafentanil, carfentanil, etorphine hydrochloride, and diprenorphine?

Not Applicable

9) Are non-controlled drugs stored in a secure area during non-business hours?

Yes

Observation
Kept in lockable mini refrigerator(not plugged in).

10) Do refrigerators and freezers used for the storage of drugs comply with 4729:5-11-03(K)?

Not Applicable

11) Are non-controlled drugs disposed of in accordance with 4729:5-3-06?

Yes

Observation
Uses service Stericycle

12) Are hypodermics maintained under appropriate supervision and control?

Yes

16) Are expired and adulterated drugs stored in accordance with 4729:5-3-06?

Yes

Observation
Discussed.

26.4) Record keeping (OAC 4729:5-11-04)

1) ****Does this clinic use a manual, computerized or combination of both to maintain drug records?

Combination of both

Observation
Practice Fusion and electronic records, site also uses manual patient records.

2) If using a computerized record keeping system, does the system have effective security controls to prevent unauthorized access?

Yes

Observation
Staff members have individualized username/passwords to access the electronic system.

3) If using a computerized system, are records backed up daily to prevent against record loss?

Yes

4) Are all records maintained for a period of three years?

Yes

50) Substance Abuse and Mental Health Resources for Healthcare Professionals

1) Substance Abuse and Mental Health Resources for Healthcare Professionals

Observation
The healthcare profession is not immune to substance use disorder and mental health conditions. Such medical conditions impair a healthcare professional's competency, ability, and judgment. Substance use disorder and/or mental health conditions that are left untreated may not only cause a healthcare professional to risk their career, but may also endanger the life of a patient. These medical conditions can be effectively treated, and it is possible for healthcare professionals that are in treatment or recovery to return to practice.

The State of Ohio Board of Pharmacy encourages all healthcare professionals who may be struggling with substance use disorder or mental health condition to seek help. The following are resources that can assist healthcare professionals in getting help: (The resources listed here are for informational purposes only and do not constitute an endorsement by the State of Ohio Board of Pharmacy. They do not represent a complete list of the resources available)

Ohio Careline 1-800-720-9616, emotional support, with referral to other resources if needed.
Crisis text line, text "4hope" to 741 741 to speak with a crisis counselor.
Treatment Bridge 1-877-275-6364, for addiction and mental health services.
National Suicide prevention dial 988, or call 1-800-273-8255.
Ohio Domestic Violence Network 1-800-934-9840
Pharmacist Rehabilitation Organization (www.ohiopro.org) for pharmacists and pharmacy interns.
Ohio Physicians Health Program (www.ophp.org)

51) Inspection Affirmation

1) Inspection Affirmation

Observation
As the person in charge at the time of this inspection, I affirm that I have reviewed this inspection report with the Specialist/Agent/Inspector, and understand its content.

If this inspection report requires a written response, I understand, per OAC 4729:5-3-03, that either of the following must be submitted to the State of Ohio Board of Pharmacy within 30 days of this inspection:
(1) The action(s) the licensee or applicant has taken to correct the violation(s) and the date of implementation of the corrective action(s); or
(2) An explanation disputing the observed violations.

I understand that if I am not the responsible person documented on this site's Ohio terminal distributor of dangerous drugs license, I will ensure the responsible person is provided a complete copy of this inspection report in a timely manner.

I further acknowledge that a written response does not release the licensee listed in this inspection report from potential disciplinary action.

Responses must be either emailed (with a copy of the inspection report) to WRITTENRESPONSE@PHARMACY.OHIO.GOV or mailed to 77 South High Street, 17th Floor, Columbus, Ohio 43215.

Summary

No Issue Found

Reviewed by Leon Margolin

(signature)

NEJM Knowledge+

NEJM Knowledge+ Internal Medicine Board Review

CME Transcript

LEON MARGOLIN

Activity:

NEJM Knowledge+ Self-Assessment: NEJM Knowledge+ Internal Medicine

Date Range:

Start Date: 01/01/2022 **End Date: 12/31/2022**

AMA PRA Category 1 Credit™ Awarded (CME Credits):

Pain Management/Opioids	10
Cumulative Total	10

Credits are rounded down to the nearest whole number in each specialty. The cumulative total earned might be higher across all specialties due to partial credits earned in those specialties.

The Pain Management and Opioids module will provide efficient, effective learning on pain management and the safer prescribing of opioids. You will first be prompted to answer all the case-based questions in the module and view the detailed feedback. The adaptive-learning system will then begin, allowing you to efficiently obtain mastery of the material and earn all the associated CME.

Want to Save This?

Many browsers allow you to create a PDF. To do this, go to File, choose Print, and see if PDF is included in the options. If so, select this option, and it will prompt you to indicate where you want to have the PDF. On both an iPad and any standard computer, you can also take a screen shot (also known as "print screen").

PRINT PAGE

CME Learning Format: Enduring Material
Accredited Provider: Massachusetts Medical Society

NEJM Knowledge+ is a product of NEJM Group, a division of the Massachusetts Medical Society.

Learning technology by area9

Greetings Dr Margolin,

Because our records show that your ABPMR certificate expires this year, we're reaching out today to provide a snapshot of your Maintenance of Certification (MOC) Program progress.

In order to maintain your certification and get a new 10-year certificate at the beginning of next year, all Maintenance of Certification (MOC) requirements must be completed by December 31, 2017.

Where You Stand: Completed and Outstanding Requirements

Annual Fees	*Professional Standing*	**CME**	*Self-Assessments*	*Cognitive Expertise*	*Practice Performance*
10/10 years	*10/10 years*	***504/300 credits***	*3/4 items*	*1/1 exams*	*1/1 projects*

Successfully completed
Not yet complete; needs to be completed by December 31, 2017

For additional details on your progress and outstanding requirements, please login to your "My MOC Status" page on the ABPMR website.

How Can We Help? Support for Completing your MOC Requirements

Diplomates like you have told us that choosing MOC activities that fit your practice helps to maximize the value and relevance of maintaining your certification.

Please visit our website for an ever-expanding menu of options for CME, Self-Assessments, and Practice Performance, including listings of products, links to external sites with ABPMR-approved activities, practice exam questions, instructional videos, example projects, and checklists.

What's next?

Once you've completed all your requirements, simply wait until your current cycle has ended on December 31. Your new certificate will arrive at the beginning of next year, specifically:

- If all requirements are marked complete by October 31, your new certificate will arrive around January 1.
- If all requirements are marked complete in November or December, your new certificate will be ordered and shipped within approximately 10-12 weeks.

If you do not complete all requirements by the end of this year, your certification will lapse and you will be marked "Not Certified" on our website and other certification and credentialing sites and products.

Questions?

If you have specific questions about your requirements or need further assistance, please don't hesitate to contact the MOC team by phone or email. We're here to help!

ABPMR MOC Team
507-282-1776, option #3
moc@abpmr.org

Leon Margolin
3082 Eldern Avenue
Columbus, Ohio 43209

DANNEMILLER

Certificate

Dannemiller certifies that the above individual has participated in the enduring material titled **Pain Review Course with CME (8th Edition)** on Sunday May 8th, 2016 and is awarded 24.00 *AMA PRA Category 1 Credit(s)™*.

Gordon W. Ringler
Director, Medical Education

5711 Northwest Parkway – San Antonio, TX 78249 – Tel: (800) 328-2308 – Fax: (210) 641-8329

Certificate of Completion

NetCE certifies that
Leon Margolin 35.090064
has participated in the enduring material titled
#95140 Optimizing Opioid Safety and Efficacy
on July 16, 2018
and is awarded 15

AMA PRA Category 1 Credit(s)™.

Freda S. O'Brien
Director of Academic Affairs

Erin K. Meinyer
Executive Director

NetCE is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

Florida CE Broker Provider #50-2405, Board of Medicine.

This activity is designed to comply with the requirements of California Assembly Bill 1195, Cultural and Linguistic Competency.

NetCE
Continuing Education
PO BOX 997571 SACRAMENTO, CALIFORNIA 95899-7571 1-800-232-4CEU

ASIPP®

American Society *of* Interventional Pain Physicians

The Voice of Interventional Pain Since 1998

This is to certify that

LEON MARGOLIN, MD

has completed 20 hours of category
1 CME credit through participation in

Comprehensive Review Course and Cadaver Workshop
Intermediate
conducted on November 19-21, 2010 in Memphis, TN.

This CME activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) thru the Joint Sponsorship of the Institute for Medical Studies (IMS) and the American Society of Interventional Pain Physicians. The Institute for Medical Studies is accredited by the ACCME to provide continuing medical education for physicians. IMS designates this educational activity for a maximum 20.0 AMA PRA Category 1 Credits™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

THE INSTITUTE FOR MEDICAL STUDIES
14 MONARCH BAY PLAZA, SUITE 202
MONARCH BEACH, CA 92629

University of Wisconsin
SCHOOL OF MEDICINE
AND PUBLIC HEALTH

The University of Wisconsin School of Medicine and Public Health

certifies that

Leon Margolin MD, PhD

has participated in the educational activity titled

Responsible Opioid Prescribing: A Physician's Guide

On October 28, 2011 and is awarded 7.25 *AMA PRA Category 1 Credit(s)*™.

George C. Mejicano, MD, MS
Associate Dean for OCPD

=

A

Medical Necessity for NCV and EMG testing

Leon Margolin M.D., Ph.D.

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

Background

- LCD guidelines
- Understanding AANEM guidelines
- Framework of PM&R (ABPMR position)
- Documentation of organic pathology
- Extension of physical exam
- Reviw of billing patterns
- Expert opinion (AANEM, ABPMR, billing and coding)

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

Federal Register:
Federal Register Vol. 62, 59047, Supervision of Diagnostic Tests, describes the degree of physician supervision required for diagnostic tests.

CMS Publications:
CMS Publication 100-03, Medicare National Coverage Determinations (NCD) Manual, Chapter 1, Part 2:
160.23 Sensory Nerve Conduction Threshold Tests (sNCTs)
Program Memorandum Carriers Transmittal B-01-28 Change Request 850, describes tests that may be performed by PTs with ABPTS certification
CMS IOM 100-2. Medicare Benefit Policy Manual Chapter 15 Section 80 Requirements for Diagnostic Tests p. 88-91. 2009.
Transmittal 2663 Change Request 8169 April Update to the CY 2013 Medicare Physician Fee Schedule Database (MPFSDB)

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

CGS Administrators expects healthcare professionals who perform electrodiagnostic (ED) testing will be appropriately trained

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

CGS Administrators expects healthcare professionals who perform electrodiagnostic (ED) testing will be appropriately trained and/or credentialed, either by a formal residency/fellowship program, certification by a nationally recognized organization, or by an accredited post-graduate training course covering anatomy, neurophysiology and forms of electrodiagnostics (including both NCS and EMG) acceptable to this Contractor, in order to provide the proper testing and assessment of the patient's condition, and appropriate safety measures. It would be highly unlikely that this training and/or credentialing is possessed by providers other than Neurologists, or Physical Medicine & Rehabilitation physicians.

The electrodiagnostic evaluation is an extension of the neurologic portion of the physical examination. Both require a detailed knowledge of a patient and his/her disease. Training in the performance of electrodiagnostic procedures in isolation of knowledge about clinical diagnostic and management aspects of neuromuscular diseases, may not be adequate for proper performance of an electrodiagnostic evaluation and correct interpretation of electrodiagnostic test results. Without awareness of the patterns of abnormality expected in different diseases and knowledge that the results of nerve conduction studies (NCS) and electromyography (EMG) may be similar in different diseases, diagnosis solely by EMG-NCS findings may be both inadequate and ultimately be detrimental to the patient.

Guidelines about proper qualifications for qualified health care professionals performing electrodiagnostic evaluations have been developed and published by AANEM (American Association of Neuromuscular and Electrodiagnostic Medicine) and other medical organizations, including the AMA, the American Academy of Neurology, the American Academy of Physical Medicine and Rehabilitation, American Neurological Association, the American Board of Physical Therapy Specialties (ABPTS) in Clinical Electrophysiology, and the Department of Veterans Affairs.

Both EMGs and NCSs are usually required for a clinical diagnosis of peripheral nervous system disorders. Performance of one type of testing does not eliminate the need for the other. The intensity and extent of testing with EMG and NCS are matters of clinical judgment developed after the initial pre-test evaluation, and later modified during the testing procedure.

Decisions to continue, modify or conclude a testing rely on knowledge of anatomy, physiology and neuromuscular diseases. Ongoing real-time assessment of data is required during the clinical diagnostic evaluation and especially during EMG examination.

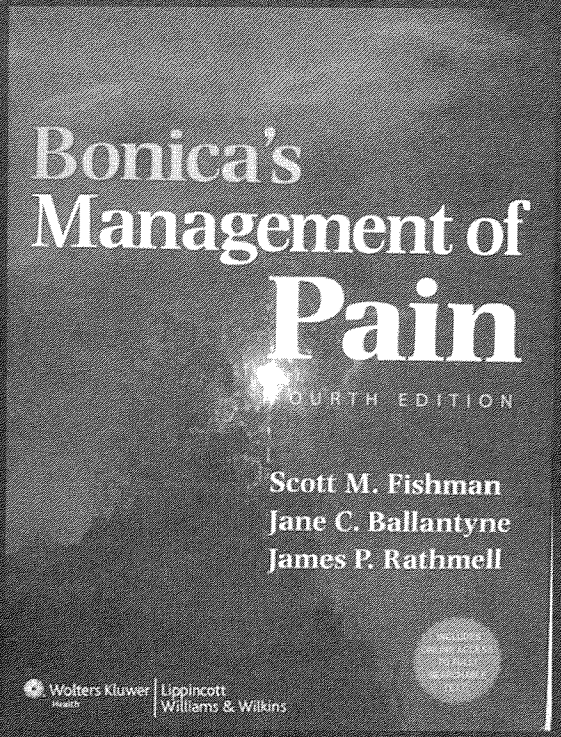
Nerve conduction studies (NCS) are used to measure action potentials resulting from peripheral nerve stimulation which are recordable over the nerve or from an innervated muscle. With this technique, responses are measured between two sites of stimulation, or between a stimulus and a recording site.

Nerve conduction studies are of two general types: sensory and motor. Either surface or needle electrodes can be used to stimulate the nerve or record the response. Axonal damage or dysfunction

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

49 (1).pd

Textbook recommended by ABPMR, FSMB, ABPM



Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

CHAPTER 18 ELECTRODIAGNOSTIC EVALUATION OF ACUTE AND CHRONIC PAIN SYNDROMES

DOUGLAS G. CHANG AND ELAINE S. DATE

INTRODUCTION

Before a clinician can treat pain effectively, the utmost must be done to identify what condition is being treated, and identify what may be causing pain. For this purpose, electrodiagnostic studies are important in the evaluation of acute and chronic pain syndromes. They give valuable, quantitative information on the physiologic health and functioning of nerve and muscle. They help localize injuries, quantify the extent of injury, suggest age of injury, and give valuable prognostic information that can change treatment protocols. They can monitor interval progression. All of this complements the static, anatomic structural information provided by radiological imaging studies. In other words, radiological imaging can identify anatomy that may or may not be the cause of symptoms. Electrodiagnostic studies can quantify symptoms (e.g., show evidence of spinal nerve root compression) but cannot identify the anatomic cause (e.g., infection, tumor, or disk herniation). Together, electrodiagnostic and radiologic studies are extensions of the physical exam and serve to refine the differential diagnosis suggested by a clinical presentation.

Common reasons for ordering electrodiagnostic studies include symptomatic complaints (weakness, pain, numbness and/or tingling in an extremity) and physical examination findings (focal [illegible] sensory losses). Typical clinical scenarios involve radiculopathies, entrapment syndromes, trauma, and metabolic pathology seen in diabetes and alcoholism. Other important scenarios include rheumatologic disease, neuromuscular disease, and various infectious and neoplastic neuropathies. Further details about these conditions can be found in several electrodiagnostic textbooks.[1,2,3,4,5,6]

Practically, electrodiagnostic studies should be thought of when the diagnosis is in doubt, either during the initial patient presentation or as the result of nonresponse to treatment. The studies can evaluate the possibility of additional lesions (e.g., concomitant nerve entrapment syndromes, peripheral neuropathies, and so-called "double crush syndromes"), be used to follow the interval progression of both operative and nonoperative treatments, and provide pre-operative baselines. The objectives of this chapter are to introduce basic principles of electrodiagnosis. Hopefully, this will provide information on when to order electrodiagnostic tests, and help interpret and utilize the resulting electrodiagnostic reports.

TERMINOLOGY

Electrodiagnostic studies involve two components: nerve conduction studies (NCS) and needle electromyography (EMG). Al

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

...ential and part of settlement discussions governed by Fed. R. ...408. Nothing in this presentation shall be construed as intent... waive or waiving otherwise applicable ...ney-client or work product privileges.

Indications	Limbs Studies by Needle EMG 95860-95864, 95867-95870, 95885-95887	Nerve Conduction Studies Total nerves Studied 95907-95913	Neuromuscular junction testing (Repetitive simulation 95937)
Carpal Tunnel unilateral	1	7	N/A
Carpal Tunnal bilateral	2	10	N/A
Radiculopathy	2	7	N/A
Mononeuropathy	2	8	N/A
Polyneuropathy/Mononeuropathy Multiplex	3	10	N/A
Myopathy	2	4	2
Motor Neuropathy (e.g., ALS)	4	6	2
Plexopathy	2	12	N/A
Neuromuscular Junction	2	4	3
Tarsal Tunnel Syndrome (unilateral)	1	8	N/A
Tarsal Tunnel Syndrome (bilateral)	2	11	N/A
Weakness, fatigue, cramps, or twitching (local)	2	7	2

Indications	Limbs Studied by Needle EMD 95860-95864, 95867 -95870, 95885-95887	Nerve Conduction Studies Total nerves studied 95907-95913	Neuromuscualr Junction Testing (Repetitive simulation 95937)
Weakness, fatigue, cramps, or twitching(general)	4	8	2
Pain, numbness, or tingling (unilateral)	1	9	N/A
Pain numbness, or tingling (bilateral)	2	12	N/A

C. Electromyography

- Use EMG codes 95860-95864 and 95867-95870 when no nerve conduction studies (95907-95913) are performed on that day.
- Use 95885, 95886, and 95887 for EMG services when nerve conduction studies (95907-95913) are performed on the same day.
- To bill these codes, extremity muscles innervated by three nerves (for example, radial, ulnar, median, tibial, peroneal, femoral, not sub branches) or four spinal levels must be evaluated; a minimum of five muscles must have been studied.

cicle Guidance

Article Text:

Coding Guidelines

A. Evaluation and Management (E&M)

- Usually an E&M service is included in the exam performed just prior to and during nerve conduction studies and/or electromyography. If the E&M service is a separate and identifiable service, the medical record must document medical necessity and the CPT code must be bill with a modifier 25.
- A clinical history from the referral source must indicate the need for testing. Such data containing pertinent clinical information must be attainable for review in instances where the need for a test may come under scrutiny. Absolute inclusive or exclusive criteria for performance of a diagnostic test are difficult to enumerate.

B. Nerve Conduction Studies

- The table below provides a reasonable maximum number of studies per diagnostic category necessary for a physician to arrive at a diagnosis in 90% of patients with that final diagnosis.
- The appropriate number of studies to be performed is left to the judgment of the physician performing the evaluation; however, in the small number of cases, which require testing in excess of the numbers listed in the table, the physician should be able to provide supplementary documentation to justify the additional testing.
- In some situations it may be necessary to test an asymptomatic contralateral limb to establish normative values for an individual patient. Documentation must support the medical necessity of the additional test.
- Codes 95907-95913 describe one or more nerve conduction studies. A single conduction test is defined as a sensory conduction test, a motor conduction test with or without an F wave test, or an H-reflex test. Each type of study (sensory, motor with or without F wave, H reflex) for each nerve is counted as a distinct study when determining the number of studies billed.
  Each type of study is counted only once when multiple sites on the same nerve are stimulated and recorded. The number of tests (sensory, motor with or without F wave, H reflex) per nerve should be added to determine the code to be billed.

Nerve conduction codes 95907-95913 had their Physician Supervision of Diagnostic Procedures Indicators adjusted to 7A effective 01/01/2013 (CR 8169). Therefore if authorized by state law Physical Therapists are

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

Verification of the Chronic Pain Diagnosis

- 1. Detailed records compliant with OH state TDDD/HB 93 standard
- 2. Referral provider records (enclosed in the chart)
- 3. Imaging enclosed on the charts
- 4. Prescription Monitoring Program reports (OARRS) obtained on each visit proves narcotic prescriptions (indicated *only* for moderate to severe pain) for most patients by several independent providers prior to coming to our practice

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

providers and clearly documented on the cha[redacted]st studies are performed for the pain in two or more extremities and most studies have a goal of documenting possible diagnosis of peripheral neuropathy since this is the most common referring diagnosis and evaluation request by the referring doctors in our practice.

According to the enclosed OH Local Coverage Article: Nerve Conduction Studies and Electromyography Coding and Billing (A54158) policy, page 3, Appendix J from 2013 CPT codebook such the diagnoses that our patient have require 12 nerve conduction studies, which is the most common test performed at our office.

COMPREHENSIVE PAIN MANAGEMENT INSTITUTE, LLC
5245 E. Main Street, Columbus, OH: 43213
Ph. 614-557-6075, F. 614-453-8222

The rationale for such testing includes the complexity of our patients as reflected by the diagnoses made by referring and CPMI providers, our individualized treatment programs (including the use of medications for neuropathic pain), and the resultant significant time spent directly one-on-one with patients which allow them to achieve an extraordinary level of function relative to managing their pain, all based on documented medical necessity (medical necessity form is used for each test).

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

Compliance with AANEM

- 1. Informed consent based on the AANEM guidelines
- 2. Medical necessity form for each test
- 3. Proper history documentation (initial, follow up evaluation, PADT, OARRS, etc.)
- 4. Referral provider information / impact of referral patterns
- 5. Full compliance confirmed by the experts (including the past president of AANEM)

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

GUIDELINES FOR ETHICAL BEHAVIOR RELATING TO CLINICAL PRACTICE ISSUES IN NEUROMUSCULAR AND ELECTRODIAGNOSTIC MEDICINE

NAOMI A. ABEL MD,[1] EDUARDO A. DE SOUSA MD, FAAN,[2] RAGHAV GOVINDARAJAN MD,[3] MATTHEW P. MAYER MD,[4] and DAVID A. SIMPSON DO, MS[5]

[1] Physical Medicine and Rehabilitation, Department of Neurosurgery & Brain Repair, University of South Florida, Tampa, Florida, USA
[2] Department of Neurology, University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma, USA
[3] Department of Neurology, University of Missouri, Columbia, Missouri, USA
[4] Department of Pediatric Rehabilitation Medicine, University of Missouri–Kansas City, Children's Mercy Kansas City, Kansas City, Missouri, USA
[5] MDA Clinic and ALS Center, Michigan Institute for Neurological Disorders, Farmington Hills, Michigan, USA

Revised 10 June 2015; Revised 9 September 2015; Accepted 14 September 2015

ABSTRACT. The American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) developed guidelines to formalize the ethical standards that neuromuscular and electrodiagnostic (EDx) physicians should observe in their clinical and scientific activities. Neuromuscular and EDx medicine is a subspecialty of medicine that focuses on evaluation, diagnosis, and comprehensive medical management, including rehabilitation of individuals with neuromuscular disorders. Physicians working in this subspecialty focus on disorders of the motor unit, including muscle, neuromuscular junction, axon, plexus, nerve root, anterior horn cell, and the peripheral nerves (motor and sensory). The neuromuscular and EDx physician's goal is to diagnose and treat these conditions to mitigate their impact and improve the patient's quality of life. The guidelines are consistent with the Principles of Medical Ethics adopted by the American Medical Association and represent a revision of previous AANEM guidelines.

Muscle Nerve **52**: 1122–1129, 2015

THE PATIENT–PHYSICIAN RELATIONSHIP IN NEUROMUSCULAR AND ELECTRODIAGNOSTIC MEDICINE

The Patient–Physician Relationship. The relationship between the patient and the physician is a key component to assure that excellent care is provided. The quality of this relationship can impact not only the success of the outcome of the interaction between patient and physician, but also the outcome of the patient's treatment. The physician has a fiduciary duty to first safeguard the interests of the patient. The physician must practice competently, respect patient autonomy and confidentiality, maintain patient safety, and protect the patient's best interests.

Beginning and Ending the Relationship. The physician is free to decide whether to perform an EDx or neuromuscular evaluation on a particular patient. The physician should not decline the evaluation on the basis of the patient's race, color, religion, national origin, gender, disability, age, or other personal characteristics. The physician also should not decline an evaluation on the basis of the patient's known or suspected medical diagnosis. The physician should decline performance of the EDx or neuromuscular evaluation if he or she believes it to be unnecessary or not beneficial to the patient.

If possible, it is best for the EDx physician and the referring physician to concur on who should inform the patient (or designated surrogate) of the results of the EDx or neuromuscular evaluation. The physician should discuss with the patient the reason for the evaluation and the methods to be employed. The physician should advise the patient as to who will be [illegible]

Abbreviations: AANEM, American Association of Neuromuscular and Electrodiagnostic Medicine; EDx, electrodiagnostic; EMG, electromyogr[illegible]

waive or waiving otherwise applicab[illegible]ney-client or work product privileges.

responsibility for urgent care of the patient until an appropriate referral can be made.

Informed Consent in Clinical Evaluation. The physician must obtain valid verbal or written consent from the patient. When the patient cannot give consent or lacks decisional capacity, a verbal or written consent must be obtained from the patient's appropriate legally authorized representative (LAR), who acts as a surrogate decision-maker. If the LAR is unavailable and the situation is urgent, the physician may proceed without consent. The physician must disclose information that the average person would need to know to make an appropriate medical decision. This information must include the benefits and risks of the proposed tests and should include the costs of the proposed tests if the patient desires this information. If the patient is referred for evaluation of a painful symptom, the physician should explain that the EDx studies are directed toward evaluation of certain measurable peripheral nerve abnormalities, not whether pain is present or absent. The patient must give consent voluntarily. If reasonable explanation fails to elicit a patient's consent to carry out the EDx examination, the physician should not undertake the evaluation. The patient may withdraw a prior consent; if this occurs at any point during testing, the physician should not continue with the examination. Physicians must comply with applicable state and federal laws governing informed consent requirements.

Federal Food and Drug Administration (FDA) and institutional review board (IRB) rules should be followed when conducting experimental or investigational studies of procedures, pharmaceuticals, or medical devices that involve human subjects (see section "Clinical Research").

Patient Communication, Comfort, and Preparation. The physician has a duty to communicate with the patient. The physician should convey relevant information in terms the patient can understand and allow adequate opportunity for the patient to [illegible]

Relationship"). Moreover, suggestions for changes in clinical management should generally be made to the referring physician rather than the patient, unless the referring physician has requested that the physician participate in the direct clinical management of the patient.

Medical Risk to the Physician. Physicians have needs and concerns that are relevant for ethical decision-making in the context of evaluation. At the same time, a physician should provide appropriate, compassionate care to all patients, including patients with infectious and other communicable diseases (e.g., human immunodeficiency virus (HIV) or antibiotic-resistant infections). A physician should not deny care to a patient solely because of real or perceived medical risk to the physician. Physicians must utilize appropriate universal precautions during the examination of any patient to minimize their own medical risk.

Ethical Considerations and the Management of Neuromuscular Disease. Some neuromuscular disorders are progressive or debilitating and may impact a patient's autonomy or competence. Many neuromuscular disorders have limited treatments, which may lead patients to seek unproven interventions. Others may have effective but costly treatments that their insurance may not cover or which patients may not be able to afford. Still others are known to shorten a patient's life expectancy with the prospect of a challenging final few months of life, leading the patient to seek alternatives for end-of-life care. In addition, genetically diagnosed diseases may include issues that affect relatives and future decision-making and have social implications.

Discussion of Disease Implications. First and foremost, physicians must provide patients with their best diagnostic and management skills. They also have a duty to discuss openly with their patients the implications of their EDx diagnosis and related illnesses. This discussion may require a great deal of sensitivity [illegible]

Comprehensive Pain Management Institute, LLC

Informed Consent for Nerve Conduction Study and/ or EMG testing

Patient's Name _____ Date _____

I hereby authorize Dr. Leon Margolin or Associates or Assistants of his choice at Comprehensive Pain Management Institute, LLC to perform upon me/the patient named above the following EMG/NCV(s)

Nerve Conduction Study and/ or EMG testing

PLEASE INFORM THE DOCTOR

- IF YOUR HAVE PACEMAKER OR DEEP BRAIN STIMULATOR
- IF YOU ARE OR COULD BE PREGNANT
- IF YOU HAVE TAKEN PLAVIX, COUMADIN, ANY OTHER BLOOD THINNER

Dr. Margolin has fully explained the nature and the purpose of this test and has also informed me of expected benefits and complications (from known and unknown causes), attendant discomforts and risks that may arise.

I have been given the opportunity to ask questions or request testing by an alternative provider, and all my questions have been answered fully and satisfactorily. All my questions about the charges for this test were answered. Dr. Margolin has fully explained to me that medical management including initiation or continuation of narcotic medications does not depend on my consent to this or any other procedure or test.

I was informed that scheduling EMG/NCV on the same day as the office visit may result in a substantial increase in the waiting time and was offered an alternative appointment for EMG/NCV only.

Needle EMG testing was offered and discussed with the patient. I explained that the needle EMG report testing is recommended for diagnosis of radiculopathy and better diagnosis of peripheral neuropathy.

I also explained that only diagnosis of "possible" / "cannot exclude" of the S1 level radiculopathy only, can be done without the needle study.

❑patient agreed ❑ patient refused ❑patient wants to reschedule the needle testing.

Patient's signature Date

Physician's signature Date

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

Patient Name: INS: DOB: Date:

NCV/EMG Clinical Necessity/Indication form

Right / Left / Bilateral Symptoms or Signs of:

1) Lumbar Radiculopathy

2) Carpal Tunnel Syndrome

3) Cubital Tunnel Syndrome (Ulnar Neuropathy)

4) Cervical Radiculopathy

5) Peripheral Neuropathy

6) Polyneyropathies

7) Myopathies

8) Diabetics with persistent or progressive symptoms

9) Dialysis patients or those considering dialysis.

10) Pain, numbness, paresthesia with or without weakness in the spine and upper or lower extremities

11) Other ❑Hepatitis (HBV, HCV), ❑Rheumatic disease (SLE, RA, Other _____) ❑ on statins
❑ History of Cancer (chemo / radiation therapy) ❑ Wrist numbness or pain

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

Bern. .. Abrams, MD
10701 Nall Ste 120
Overland Park, KS 66211
816-322-4834
Fax: 816-322-2005
Email: babrams@kc.rr.com

February 17, 2018

To whom it may concern:

Re: review of Electrodiagnostic procedures concerning Leon Margolin, M.D., PhD.

Task: I was asked to review Dr. Margolin's policy and procedures including informed consent, training of personnel in an entity doing business as CPMI.

Qualifications: I am Clinical Professor Emeritus, University of Missouri-Kansas City School of Medicine, Past President of the AANEM (then the AAEE), a six year member of the Board of Directors of the AANEM, Board Certified in EMG by the AANEM, author of numerous textbook chapters on Electrodiagnosis in major pain textbooks and have lectured dozens of times on Clinical Neurophysiology and its use in Pain Medicine.

Disclaimer: I have not requested nor have I been paid for rendering my opinion. I am not a colleague or social friend of Dr. Margolin.

Materials reviewed: Updated CPMI NCV EMG policy, NCV 2012 policy informed consent, Pain Medicine CME, CPMI informed consent and EMG paperwork, Staff education in service sessions, NCV technician certificates, AANEM informed consent policy, 5 outside billing and coding reviews, Ohio LCD Medicare policy and EMG CME and the CMPI NCV/EMG medical indications form.

Conclusions:
1. CPMI's informed consent is appropriate and based on the AANEM informed consent policy.
2. CPMI NCV EMG policy appropriately addresses documenting medical necessity.
3. The CMPI NCV/EMG medical indications form appropriately addresses documenting medical necessity.
4. The policy description of our scope of practice according to Ohio LCD is appropriate.
5. In pain medicine practice it is reasonable to use NCV/EMG to document organic pathology as required for proper narcotic medication/ pain program management.
6. The attached CMEs, outside reviews and staff education are appropriate.

Very truly yours,

Bernard M. Abrams, M.D.

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

THE UNIVERSITY HOSPITAL FOR
ALBERT EINSTEIN COLLEGE OF MEDICINE

March 27, 2018

To whom it May Concern,

Dr Leon margolin has asked me to review and comment upon the policies and procedures in his practice regarding neuromuscular electrodiagnostic (more commonly referred to as EMG) studies, their role in evaluating patients with chronic pain, and their appropriateness as part of patient care. I have reviewed these policies in detail.

I am a Board-certified physiatrist with more than 40 years of clinical experience, which has included performance of and interpretation of electrodiagnostic testing. I have several publications in this area as part of my Curriculum Vitae. As a clinician who sees many patients with chronic pain associated with motor and/or sensory symptoms in arms and legs, nerve conduction and needle electromyography are invaluable to objectively document the presence or absence of pathology involving the peripheral nervous system, including nerve root compression, plexus lesions, or peripheral neuropathies. In the case of patients with suspected cervical or lumbar disc herniations, these studies are complementary with MRI scans: the latter documents the anatomical location of the problem, while EMG clarifies its severity in terms of muscle denervation. It is entirely appropriate to utilize both of these diagnostic tests when evaluating patients with chronic pain, since they provide objective confirmation of the subjective symptoms of pain. A physician with thorough training in the performance and interpretation of nerve conduction/EMG studies, such as Dr margolin, provides valuable clinical data for such patients. I can attest to his competence in these areas since he did his residency training at Montefiore MedicalCenter, where I have been working for the past 21 years.

Yours truly,

Stanley F. Wainapel MD, MPH, Clinical Director, Department of Physical Medicine and Rehabilitation

Montefiore Medical Center

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

Unique features of our practice

- MD/PhD (implementations of additional methods, research / guidelines analysis)
- Double board certification (PM&R, Anesthesia Pain) – Most practices have a separate pain (medication /procedures) physician and a separate (PM&R or Neurology) NCV / EMG physician
- Additional certification the American Academy of Addiction Medicine, training / courses by AANEM and Radiology (MRI and X rays reading)
- Lab Director training and certification by CLIA / COLA

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

Unique features of our practice 2

- More than 30 publications (including a research manuscript), recent original study performed at the practice accepted for presentation at the national meeting, request for 2nd manuscript being processed
- Physician's Recognition Award from the American Medical Association (2008, 2014), Resident / Fellow Award from the American Society of Regional Anesthesia and Pain Medicine
- Two Certificates of Merit of the American College of Physicians, the Medical Society of Pennsylvania Award, the Pfizer Scholars in Pain Management Award , Patient's Choice Award (several years including 2019)
- Most Compassionate Physician Award (several years) and "Top Ten Physicians" Award in Pain Medicine (2014)
- America's Most Honored Professionals Award (2017, 2018, 2019) 1% percent ranking

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

Letter of Acceptance: AAFP Poster Presentation for FMX

Входящие ×

Lisa Leader

ср, 1 мая, 11:43 (1 день на

кому: LEON3087@GMAIL.COM

Hello Leon,

Congratulations! Your poster entitled "Correlation between NARX Score and food addictive behavioral patterns in chronic pain patients." has been accepted for presentation at the Philadelphia. Attached you will find two important documents:

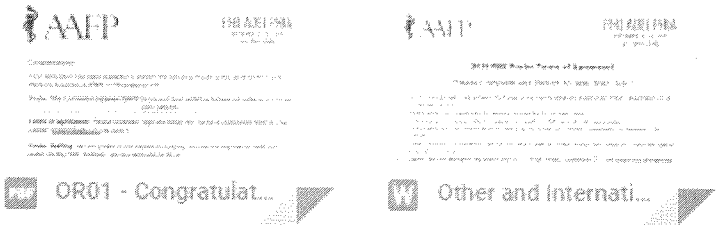
1. Congratulations Letter including information on registration, housing, size of poster display area, and poster set up/dismantling.
2. Terms of Agreement which must be completed and returned to me by July 31.

If you have additional questions, please feel free to reach out to me at 800 274-2237 x 6098.

Best Regards,
Lisa Leader

Lisa Leader | CME Program Specialist
Continuing Medical Education Division
American Academy of Family Physicians
11400 Tomahawk Creek Parkway, Leawood, KS 66211
Office: (913) 906-6000, ext 6098
lleader@aafp.org

2 прикрепленных файла



OR01 - Congratulat...

Other and Internati...

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.



Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

Unique features of our practice 3

- CPMI a solo practice all procedures performed and billed by the same physician
- Tertiary referral based practice with a high percent of high risk patients (based on the OARRS, PADT, SOAPP-R, COMM, ORT and other tools (i.e. NARX score)
- In compliance with the CDC and SMBO regulations, since inception in 2011, more than 2000 patients were discharged from CPMI (non-adherence with the patient contract / aberrant behavior)

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

Unique features of our practice 4

- High discharge rate and high demand for evaluation of the high risk patients creates a high turnover and high new evaluations rate
- Many new evaluations require NCV / EMG testing as per guidelines
- As an independent practice (not affiliated with a physician group or hospital or provider network) we get higher rate of referrals for difficult patients (risk assessed with the criteria mentioned above) that other physician groups unable or unwilling to handle

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

FEDERATION OF STATE MEDICAL BOARDS

Guidelines for the Chronic Use of Opioid Analgesics

Adopted as policy by the Federation of State Medical Boards
April 2017

INTRODUCTION

In April 2015, the Federation of State Medical Boards (FSMB) Chair, J. Daniel Gifford, MD, FACP, appointed the Workgroup on FSMB's *Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain* to review the current science for treating chronic pain with opioid analgesics and to revise the Model Policy as appropriate.

To accomplish this charge, the workgroup conducted a thorough review and analysis of FSMB's existing policy document and other state and federal policies on the prescribing of opioids in the treatment of pain, including the March 2016 *CDC Guideline for Prescribing Opioids for Chronic Pain* (https://www.cdc.gov/drugoverdose/prescribing/guideline.html)

In updating its existing policy, the FSMB sought input from a diverse group of medical and policy stakeholders that ranged from experts in pain medicine and addiction to government officials and other thought leaders. Over the course of the last 12 months, the workgroup met on several occasions to examine and explore the key elements required to ensure FSMB's policy document remains relevant and is sufficiently comprehensive to

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

FSMB opioid policy requirements

- Documentation of the medical indications for opioid prescriptions / organic pathology
- Increased requirements for the patients on opioids referred by other clinicians / started on high doses of opioids by referring provider (the majority of patients in our practice)

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

The patient evaluation may include information from family members and/or significant others[10-11,31-32]. It is strongly recommended that the state prescription drug monitoring program (PDMP) be consulted prior to initiating opioid therapy and at appropriate intervals thereafter to determine whether the patient is receiving prescriptions from any other clinicians, and the results obtained from the PDMP should be reviewed.

In working with a patient who is taking opioids prescribed by another clinician—particularly a patient on high doses—the evaluation and risk stratification assume even greater importance[9-11]. Therefore, to ensure a smooth transition of care, clinicians are encouraged to collaborate with the primary prescriber.

Caution should be used with the administration of chronic opioids in women of childbearing age, as chronic opioid therapy during pregnancy increases risk of harm to the newborn. Opioids should be administered with caution in breastfeeding women, as some opioids may be transferred to the baby in breast milk. When chronic opioid therapy is used for an elderly patient, clinicians should carefully consider the initial dose, titrating slowly upwards if necessary, using a longer dosing interval, and monitoring more frequently. Patients at risk for sleep disordered breathing are at increased risk for harm with the use of chronic opioid therapy. Clinicians should consider the use of a screening tool for obstructive sleep apnea and refer patients for proper evaluation and treatment when indicated.

The patient evaluation should include most of the following elements:

- Post-traumatic stress disorder (PTSD)
- Medical indication(s) for use of opioids
- Review of the PDMP results
- Obtain consultation with other clinicians when applicable
- Urine, blood or other types of biological samples and diagnostic markers

Development of a Treatment Plan and Goals

The goals of pain treatment include reasonably attainable improvement in pain to decrease suffering and to increase function; improvement in pain-associated symptoms such as sleep disturbance, depression, and anxiety; screening for side effects of treatment; and avoidance of unnecessary or excessive use of medications[2,4]. There should be a balance between monitoring for efficacy and side effects with the use of medications for the shortest duration appropriate.

The treatment plan and goals should be established as early as possible in the treatment process and revisited regularly, so as to provide clear-cut, individualized objectives to guide the choice of therapies[22] for both the clinician and the patient.

The treatment plan may contain information supporting the selection of therapies, both pharmacologic (medications other than opioids to include [illegible]

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

NCV required for the State of OH compliance

- TDDD license (in addition to regular license) based on the HB 93 law
- SMBO/BoPh requirement for organic pathology documentation
- Requires onsite audits
- OH is in the epicenter of the opioid epidemic / high risk patients

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

Initial E[illegible]uation
4731-21-02, O.A.C.

- Patient history, including alcohol & substance abuse
- Assessment of pain impact on function
- Review of previous studies & therapies
- Assessment of coexisting illnesses
- Physical exam

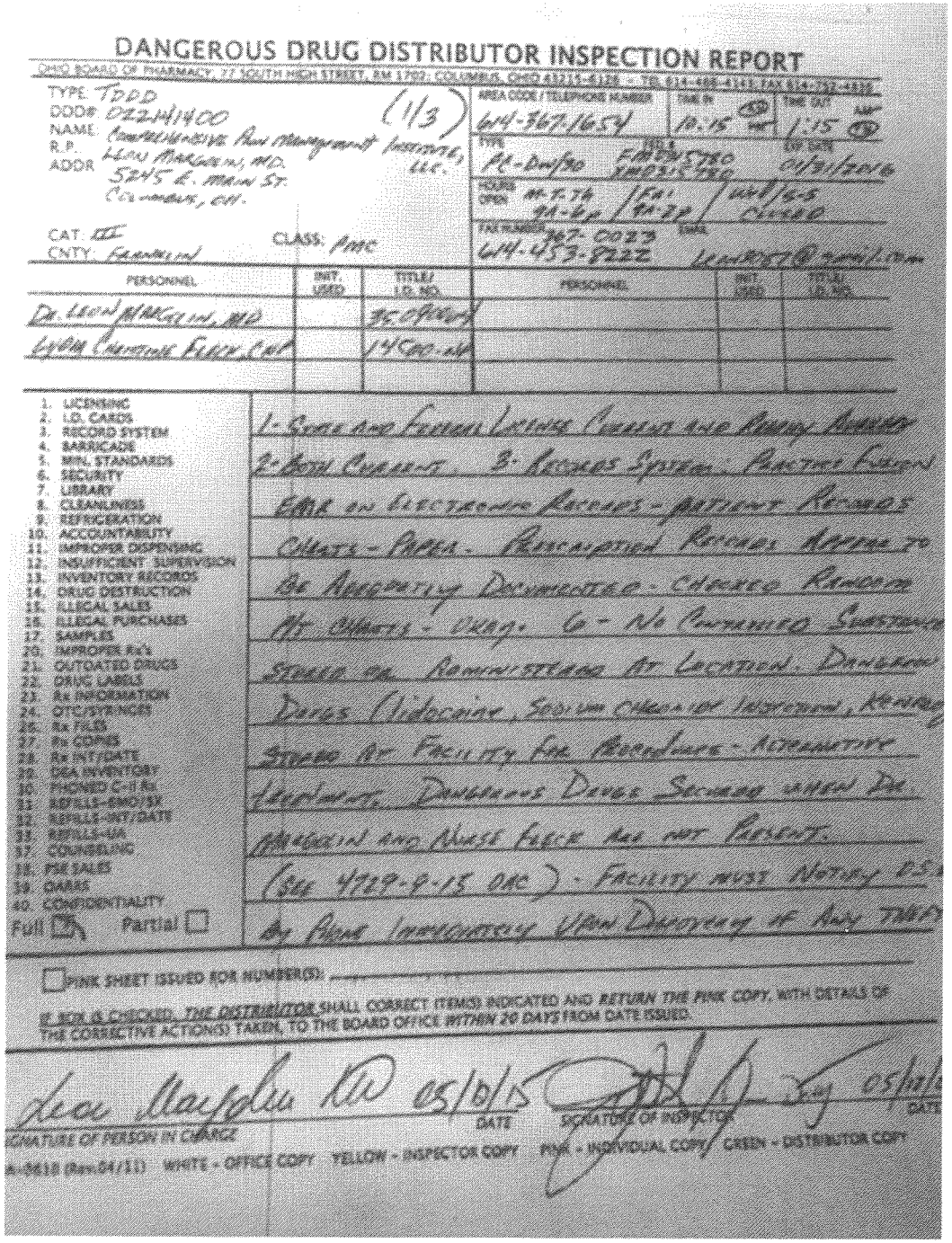
Medical Diagnosis

Document presence of chronic pain

Identify signs, symptoms & causes

- Nature of underlying disease
- Pain mechanism

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.



DANGEROUS DRUG DISTRIBUTOR INSPECTION REPORT

OHIO BOARD OF PHARMACY, 77 SOUTH HIGH STREET, RM 1702, COLUMBUS, OHIO 43215-6126 – TEL 614-466-4143, FAX 614-752-4836

TYPE: TDDD
DDD#: 02244400 (1/3)
NAME: Comprehensive Pain Management Institute, LLC.
R.P.:
ADDR: Leon Margolin, MD
5245 E. Main St.
Columbus, OH.

AREA CODE / TELEPHONE NUMBER: 614-367-1654
TIME IN: 10:15 AM PM
TIME OUT: 1:15 AM PM
TYPE: RA-Dmf30
LICENSE: FA1234780 / MD23.5780
LIC. DATE: 04/21/2014
HOURS OPEN: M-F 7A-6P / SA 9A-12P / Wed 1-5 Closed
FAX NUMBER: 367-0023
EMAIL: 614-453-8222 LeonMD78@gmail.com

CAT.: III
CNTY: Franklin
CLASS: PMC

PERSONNEL	INIT. USED	TITLE/ I.D. NO.	PERSONNEL	INIT. USED	TITLE/ I.D. NO.
Dr. Leon Margolin, MD		35 Owner			
Lyon Christine Flack, CMA		14500 - MA			

1. LICENSING	1- Some Are Expired License Copies and Renew Asap
2. I.D. CARDS	2- Both Current. 3- Records Spoken - Practice Explain
3. RECORD SYSTEM	EMR on Electronic Records - Patient Records
4. BARRICADE	Charts - Paper - Prescription Records Access To
5. MIN. STANDARDS	Be Accessed by Computer - Charges Random
6. SECURITY	At Charts - Okay. 6 - No Controlled Substances
7. LIBRARY	Stored on Room Stored At Location - Dangerous
8. CLEANLINESS	Drugs (Lidocaine, Sodium Chloride for Injection, Normal
9. REFRIGERATION	Stored At Facility for Procedures - Retrospective
10. ACCOUNTABILITY	Treatment. Dangerous Drugs Secured when Dr.
11. IMPROPER DISPENSING	Margolin and Nurse Flack are not Present.
12. INSUFFICIENT SUPERVISION	(See 4729-9-15 OAC) - Facility must Notify B.O.P
13. INVENTORY RECORDS	by Phone Immediately Upon Discovery of Any Theft
14. DRUG DISTRUCTION	
15. ILLEGAL SALES	
16. ILLEGAL PURCHASES	
17. SAMPLES	
18. IMPROPER Rx's	
19. OUTDATED DRUGS	
20. DRUG LABELS	
21. Rx INFORMATION	
22. OTC/SYRINGES	
23. Rx FILES	
24. Rx COPIES	
25. Rx INIT/DATE	
26. DEA INVENTORY	
27. PHONED C-II Rx	
28. REFILLS-EMO/SX	
29. REFILLS-INT/DATE	
30. REFILLS-UA	
31. COUNSELING	
32. FSE SALES	
33. DARRS	
34. CONFIDENTIALITY	

Full ☒ Partial ☐

☐ PINK SHEET ISSUED FOR NUMBER(S):

IF BOX IS CHECKED, THE DISTRIBUTOR SHALL CORRECT ITEM(S) INDICATED AND RETURN THE PINK COPY, WITH DETAILS OF THE CORRECTIVE ACTION(S) TAKEN, TO THE BOARD OFFICE WITHIN 20 DAYS FROM DATE ISSUED.

Leon Margolin MD 05/01/15
SIGNATURE OF PERSON IN CHARGE — DATE

SIGNATURE OF INSPECTOR — DATE 05/01/15

4729-9-18 (Rev. 04/11) WHITE - OFFICE COPY YELLOW - INSPECTOR COPY PINK - INDIVIDUAL COPY GREEN - DISTRIBUTOR COPY

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

COMMUNICATION LOG

PATIENT NAME: STATE of OH TOOO compliance audit memo

DATE/TIME	NOTES
05/12/15	Inspectors reviewed prescription storage area & safes. OARRS policy discussed.
	Inspectors spent about an hour reviewing patient charts. We discussed guidelines for treatment, role of injection for alternative treatments.
	Reviewed imaging prior records, NCV exams & informed consent & medical necessity forms, initial & f/u notes, PAOT & flow chart forms.
	Need to document organic pathology discussed. On site NCV, EMG lab & POC testing lab inspected.
	The charts & the policies found compliant and adequately documented.
	Leon Margolin MD

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

COMMUNICATION LOG

PATIENT NAME: [redacted]

DATE/TIME	NOTES
05/12/15	This chart has been reviewed by Inspector during State of OH DEA compliance audit Leon Margolin MD

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

COMMUNICATION LOG

PATIENT NAME: [redacted]

DATE/TIME	NOTES
05/12/15	This chart was viewed during the state of the board of pharmacy 100% compliance audit Leon Margolin MD

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges

DANGEROUS DRUG DISTRIBUTOR INSPECTION REPORT

OHIO BOARD OF PHARMACY: 77 SOUTH HIGH STREET, RM 1702; COLUMBUS, OHIO 43215-6126 – TEL 614-466-4143; FAX 614-752-4836

TYPE: PMC Pg 1 of 3
DDD#: 02-2141400
NAME: Comprehensive Pain
R.P.: Management Institute, LLC
ADDR: Leon Margolin, M.D.
1120 Polaris Parkway, Suite 200
Columbus, Ohio 43240
CAT: III
CNTY: Delaware
CLASS: PMC

AREA CODE / TELEPHONE NUMBER: 614-557-6075
TIME IN: 1:35 A.M. P.M.
TIME OUT: A.M. P.M.
TYPE: Practitioner
FED. #: FM0513780
EXP. DATE: 1/31/13
HOURS OPEN: M, T, T, F 9a-5:30p
Closed Wed
FAX NUMBER: 614-545-0474
EMAIL:

PERSONNEL	INIT. USED	TITLE/ I.D. NO.	PERSONNEL	INIT. USED	TITLE/ I.D. NO.
Leon Margolin, MD		35 090064			

1. LICENSING
2. I.D. CARDS
3. RECORD SYSTEM
4. BARRICADE
5. MIN. STANDARDS
6. SECURITY
7. LIBRARY
8. CLEANLINESS
9. REFRIGERATION
10. ACCOUNTABILITY
11. IMPROPER DISPENSING
12. INSUFFICIENT SUPERVISION
13. INVENTORY RECORDS
14. DRUG DESTRUCTION
15. ILLEGAL SALES
16. ILLEGAL PURCHASES
17. SAMPLES
20. IMPROPER Rx's
21. OUTDATED DRUGS
22. DRUG LABELS
23. Rx INFORMATION
24. OTC/SYRINGES
26. Rx FILES
27. Rx COPIES
28. Rx INT/DATE
29. DEA INVENTORY
30. PHONED C-II Rx
31. REFILLS-RMO/SX
32. REFILLS-INT/DATE
33. REFILLS-UA
37. COUNSELING
38. PSE SALES
39. OARRS
40. CONFIDENTIALITY

Full ☒ Partial ☐

1) New PMC license delivered to Dr. Leon Margolin on todays date. Dr Margolin provided state of Ohio certificate # 1950626 as articles of organization LLC. Dr. Leon Margolin signed ownership form attached.

2) I.D. Card - valid and on person

3) Dr. Margolin uses paper patient charts, prescriptions records are adequately documented

6) No controlled substances or dangerous drugs are stored or administered to patients. Dr. Margolin does not give or store drug samples at location.

☐ PINK SHEET ISSUED FOR NUMBER(S):

IF BOX IS CHECKED, *THE DISTRIBUTOR* SHALL CORRECT ITEM(S) INDICATED AND *RETURN THE PINK COPY*, WITH DETAILS OF THE CORRECTIVE ACTION(S) TAKEN, TO THE BOARD OFFICE *WITHIN 20 DAYS* FROM DATE ISSUED.

Leon Margolin 08/31/11
SIGNATURE OF PERSON IN CHARGE DATE

[signature] 8/31/11
SIGNATURE OF INSPECTOR DATE

PHA-0010 (Rev.04/11) WHITE - OFFICE COPY YELLOW - INSPECTOR COPY PINK - INDIVIDUAL COPY GREEN - DISTRIBUTOR COPY

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

COMMUNICATION LOG

PATIENT NAME: HB-93 T000 license Audit memo

DATE/TIME	NOTES
08/31/11	Inspector requested to review random charts to document compliance.
	We reviewed & discussed: Patient contract, consent for treatment, Initial & Follow up evaluation form, PADT form, Flowchart forms, Injection reports & consent forms, NCV/reports with or without EMG needle exams, NCV/EMG report addendum forms.
	I explained the increase in the high risk patient population, the inspector complimented on the correct documentation necessary for proper narcotic prescription & organic pathology documentation as required by the national and state guidelines to comply with the HB93 T000 license requirements.
	I explained that all the pts seen by referral only. Previous records & referral forms reviewed.
	Records found compliant and adequately documented (report enclosed)
	Leon Margolin MD

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

[redacted]

Ref Dr Shabsigh 08/31/11
Medicare

COMMUNICATION LOG

DATE/TIME	NOTES
	This chart was reviewed and discussed with the inspector during the mandatory 4000 MC license audit by the state OIT (based on the HB 93 law).
	The chart was found fully compliant.
	Leon Margolin MD

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

[redacted]

Medicare 03/31/11

COMMUNICATION LOG

DATE/TIME	NOTES
	This chart was reviewed and discussed with the Inspector during the mandatory state of OH terminal distributor DMC license audit (based on the recent HB 93 law). The chart found to be in full compliance.
	Leon Margolin MD

Catch 22

- NCV tests required for the TDDD / HB 93 State of OH compliance
- Noncompliance with HB 93 may result in license revocation, $5000 a day fine and even criminal charges
- Despite state mandates, federal agencies raise concerns regarding medical necessity of tests

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

Ohio – Epicenter of Opioid Epidemic

- 172,000 people died in 2017 in US;
- **Every Day**: 5,800 individuals misuse opioid prescription for the fist time
- **Every Day**: 1,000 individuals treated in the emergency for prescription opioid misuse
- Our practice is in the forefront of the opioid epidemic
- High incidence of high risk patient/ risk of overdose, withdrawal, diversion, aggression
- Proper testing/organic pathology documentation is crucial

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

The most-read pain publication in the United States

PAIN MEDICINE NEWS

THE INDEPENDENT MONTHLY NEWSPAPER FOR MANAGING PAIN

PainMedicineNews.com • APRIL 2019 • Volume 17 Number 4

PRIMARY CARE

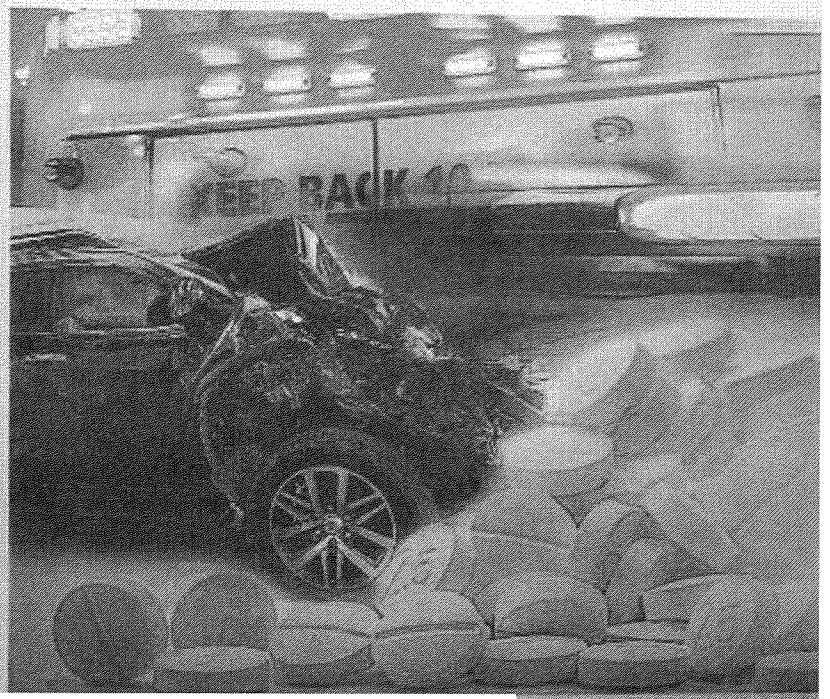
Rural NPs Drive Growth In Primary Care

The number of nurse practitioners (NPs) in primary care practices grew substantially from 2008 to 2016, from 17.6% and 15.9% in rural and nonrural practices to 25.2% and 23.0%, respectively.

States with full scope of practice laws have the highest percentages of practicing NPs, but growth was fastest in states with reduced and restricted scopes of practice. The research was published in *Health Affairs* (2018;37[6]:908-914).

"NPs now constitute about 25% of primary care providers overall, and as much as 45% of primary care providers in rural areas in full scope of practice states," said Linda H. Aiken, PhD, RN, a professor and the director of the Center for Health Outcomes and Policy Research at the University of Pe
Philadelphia.

Opioid Overdose Now Leads to More Deaths Than Motor Vehicle Accidents



Americans are now more likely to die from an accidental opioid overdose than from a motor vehicle accident, according to the annual Odds of Dying report by the National Safety Council (NSC), released in January.

The Odds of Dying report is a reanalysis of the mortality data collected by the National Center for Health Statistics. The NSC, a nonprofit organization focused on lowering the number of preventable deaths, publishes the report "to provide people the information they need to know to make better, safer, more logical decisions," said Ken Kolosh,

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

Very High Cost of the Epidemic

- More than 500 billion cost nationwide
- Denial of proper testing necessary for organic pathology documentation puts patient at risk
- It is also "save a penny – loose a dollar" approach because of extremely high costs of noncompliance

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

U.S. DEPARTMENT OF HEAL[illegible]ND HUMAN SERVICES

Strategy to Combat Opioid Abuse, Misuse, and Overdose

A Framework Based on the Five Point Strategy

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

"The five-point HHS strategy to end the opioid crisis, unveiled under President Trump in 2017, uses the best science and evidence to directly address this public health emergency. Now, HHS is expanding the scope and improving the effectiveness of the strategy. The dedicated men and women of HHS will continue to support communities and families across America until, together, we have brought an end to this crisis."

Programs (PDMP) that are accessible b[illegible]ders (prescribers and pharmacies) across state lines and integrated into the electro[illegible]ealth record.

BETTER PAIN MANAGEMENT

Advance the practice of pain management to enable access to high-quality, evidence-based pain care that reduces the burden of pain for individuals, families, and society while also reducing the inappropriate use of opioids and opioid-related harms.

- Provide prescribers with actionable information on the appropriate use of opioids and other pain treatment modalities, such as the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain, which also ensure patients pain management needs are met.
- Develop evidence-based guidance on appropriate management of acute pain including non-opioid approaches and, when appropriate, short-term opioid management.
- Develop further evidence-based guidance on the management of chronic pain, including non-opioid approaches, pre/peri-operative treatment, and when appropriate, opioid management.
- Develop payment policies and other incentives to encourage best practices for the appropriate prescribing of opioids and the use of a full range of non-opioid pain treatments.
- Develop regulatory strategies, guidance, and policies to promote the appropriate use of opioids, including professional and patient labeling, and packaging at the time of marketing approval and in the post-marketing period.
- Assist states to monitor and support best practices by providers, including through the use of comprehensive prescription drug monitoring programs, other data integration mechanisms across states, and clinical decision support in electronic health records.
- Encourage the use of multidisciplinary team models for the management of pain.

Mike C presentatio.

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

Comprehensive Management

Show all data where the Procedure Code is between 95885,95913
and the Date From is between 1/1/2015, 12/31/2015

Total *

Procedure Code		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total Units
95885	EMG - 1-4 MUSCLES	5	5	0	1	4	0	2	2	7	14	11	6	57
95886	EMG - 5+ MUSCLES V	9	6	11	8	2	4	1	4	4	52	70	102	273
95907	NCS 1-2	0	0	1	0	0	0	0	0	0	0	0	0	1
95909	NCS 5-6	0	0	3	1	0	9	27	33	17	3	5	0	98
95910	NCS 7-8	0	0	1	0	0	0	0	0	0	0	0	0	1
95911	NCS 9-10	0	1	1	0	1	1	0	0	1	0	0	0	5
95912	NCS 11-12	120	114	107	77	96	76	83	92	59	129	132	164	1,249
95913	NCS 13+	70	84	101	72	84	44	30	26	28	54	9	1	603
Report Totals:		**204**	**210**	**225**	**159**	**187**	**134**	**143**	**157**	**116**	**252**	**227**	**273**	**2,287**

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

Printed on: 3/8/2019 1:36:20 PM

Billing patterns 2015

- 57+275=330 needle examinations
- 1+98+1+5+1249+603=1957 NCV
- 330/1957=16.9% of tests with the needle
- The percent of needle examination related to the higher per cent of high risk (including Medicaid HMO patients with poor cooperation)
- NCV even without EMG is valuable and necessary to document organic pathology within the framework of Pain Medicine
- Contemporary documentation / expert opinion support (AANEM, ABPMR, Billing and coding)

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

2015 Billing continued

- As per CPMI policy and consent (based on AANEM) needle examination provides additional information
- Practice actually gets additional reimbursement for the separate needle code (there is no financial incentive to avoid needle EMG test)
- Dr. Margolin is always on premises during examination

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

form is used for each test).

Comprehensive Evaluation: A detailed medical necessity form based on the AANEM and OH Local Coverage Article: Nerve Conduction Studies and Electromyography Coding and Billing (A54158) policy definitions of Medical necessity will be filled out prior to each test.

CPMI performs a comprehensive evaluation including detailed history, physical examination and past medical history and prior medical records review.

Frequency of testing: Frequency of testing is defined based on the results of a detailed clinical evaluation. Such evaluation is repeated and documented prior to the decision to repeat the NCV or EMG study. Most common indication in our practice to repetition of the test is chronic moderate to severe pain and or numbness in neck, back and extremities (this documented by the patient in the intake history and by the staff using the SOAP note, VAS, PADT and other tools).

Written Consent: All patients will be offered a written consent for the test (enclosed) based on the ethical guidance of the AANEM (enclosed). Risk and benefits of the test are explained to the patient and documented in the consent form. Based on the level of patient tolerance to the test and the clinical evaluation, patient may undergo separate studies of the upper and lower extremities or a combined study.

Needle Examination: CPMI offered an option of needle examination to every patient but respects patient right to refuse this invasive test (that may include 6-12 needle sticks) as per the ethical guidance of the AANEM. The benefits of the needle examination explained to each patient.

NCV/EMG results incorporated in the treatment plan: All NCV/EMG reports are read by Dr. Margolin. The results are used for the use of medications for neuropathic pain (most common are Gabapentin, Lyrica, compounding medications) and other pain treatment modalities.

In order to avoid prescribing pain medications based on the subjective report of pain alone, the accepted guidelines encourage a thorough evaluation (such as NCV/EMG) and documentation of the underlying pathology (such as peripheral neuropathy or radiculopathy) before prescribing pain medications.

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

Procedure Code Units by Month

Comprehensive Pain Management

Show all data where the Procedure Code is between 95885,95913
and the Date From is between 1/1/2016, 12/31/2016

Total *

Procedure Code	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total Units
95885 EMG - 1-4 MUSCLES	10	7	15	18	13	9	4	1	2	2	4	17	102
95886 EMG - 5+ MUSCLES V	85	109	54	57	58	50	55	25	74	20	43	53	683
95908 NCS 3-4	0	0	0	0	0	0	0	0	0	0	1	0	1
95909 NCS 5-6	0	0	2	0	2	1	0	0	0	0	0	0	5
95910 NCS 7-8	0	0	0	0	0	0	1	0	0	0	0	0	1
95911 NCS 9-10	0	0	1	0	0	0	0	0	0	0	0	0	1
95912 NCS 11-12	125	154	94	105	96	105	81	43	106	45	92	105	1,151
Report Totals:	**220**	**270**	**166**	**180**	**169**	**165**	**141**	**69**	**182**	**67**	**140**	**175**	**1,944**

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

Billing patterns 2016

- 102+683=783 needle examinations
- 1+5+1+1+1,151=1,160 NCV
- 785/1,160=**67.2**% of tests with the needle
- The percent of needle EMG testing has increased almost 4 times in 2016 comparison to 2015
- This proves implementation the practice NCV / EMG policy we reviewed in compliance with the AANEM and ABPMR guidelines

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

Procedure Code Units by Month

Comprehensive Pain Management

Show all data where the Procedure Code is between 95885,95913
and the Date From is between 3/1/2017, 2/28/2018

Procedure Code	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total Units
95885 EMG - 1-4 MUSCLES	18	0	35	15	15	22	22	21	17	18	26	9	218
95886 EMG - 5+ MUSCLES \	22	0	30	10	17	17	14	11	13	6	17	4	161
95909 NCS 5-6	0	0	0	0	0	1	0	0	0	0	2	2	5
95910 NCS 7-8	0	0	1	1	0	0	1	0	0	0	1	0	4
95912 NCS 11-12	44	1	69	21	33	41	38	31	33	25	46	14	396
Report Totals:	**84**	**1**	**135**	**47**	**65**	**81**	**75**	**63**	**63**	**49**	**92**	**29**	**784**

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

Billing patterns 2017 - Feb 2018

- 161+218=379 needle examinations
- 5+4+396=405
- 379/ 405 = **95.7**% of tests with the needle
- Almost all electro-diagnostic tests were performed with the needle examination for over 14 months prior to the CID
- Clear indication that practice has no intention to avoid performance of needle examinations

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

ABPMR analysis

- ABPMR is references in the LCD / National certifying body
- Maintenance of Certification / Research (PIP) project
- All the charts in the CID analyzed by the ABPMR expert panel
- Rigorous statistical analysis applied
- Two full professors (one from the AANEM, one from ABPMR) recommended the project

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

ABPMR analysis conclusions

- Strong evidence for the medical necessity for NCV / EMG (with or without the needle) for the charts in the sample
- Clear NCV / EMG (with or without the needle) testing impact on the pain reduction and functional improvement
- Full compliance with the LCD / AANEM / ABPMR guidelines
- Study recommended for the third party payers

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

idential and part of settlement discussions governed by Fed. R. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

from the ABPMR

AMERICAN BOARD OF PHYSICAL MEDICINE AND REHABILITATION

Thursday, December 13, 2018

Dr Margolin:

Congratulations! Your Practice Improvement Project (PIP) has been accepted for MOC Part IV credit. Your MOC Homepage will be updated to reflect this acceptance within 2 business days.
Final comments from your reviewer may be available by logging in to your account.

Questions? Please contact our MOC team at moc@abpmr.org or (507) 282-1776, menu option 3.

American Board of Physical Medicine and Rehabilitation
3015 Allegro Park Lane SW
Rochester MN 55902-4139
507-282-1776 / Fax 507-282-9242

---------- Forwarded message ---------
От: **Shelly Walker** <swalker@abpmr.org>
Date: ср, 3 апр. 2019 г. в 15:55
Subject: RE: ABPMR MOC PIP addendum files attached
To: leon3087@gmail.com <leon3087@gmail.com>

Dr Margolin,

Thank you for the submission of your Practice Improvement Project and additional materials you've attached. Well done!

Kind Regards,

Shelly Walker | Maintenance of Certification Manager
American Board of Physical Medicine and Rehabilitation
Ph: 507.282.1776 Ext 1742
swalker@abpmr.org | www.abpmr.org

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

After review of the NCV studies and the protocols of our practice, ABPMR reported high level of compliance with the LCD and AANEM guidelines

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

oads/Dr.%
ifidential and part of settlement discussions governed by Fed. R. 408. Nothing in this presentation shall be construed as intent to waive or waiving otherwise applicable attorney-client or work product privileges.

The number of NCV/EMG tests based on the enclosed CPMI NCV/EMG policy and OH local coverage determination (A54158). All patient had a comprehensive evaluation including initial, follow up evaluation forms, PADT forms enclosed and extensive review of OARRS repots, offered a written consent based on the AANEM guidelines with a detailed explanations of the risk and benefits of the tests. NCV are reviewed and incorporated in the treatment plan.

The most commonly tested nerves in the upper extremities were sensory ulnar, median and radial studies, motor median, ulnar, radial and in selected cased Axillary studies with Median and Ulnar F waves. For the low extremities the studies included sensory Sural, Superior Peroneal, Motor studies included Common Peroneal, Tibial nerves and Common Peroneal and Tibial nerve; F waves and H reflex studies selected based on the comprehensive assessment results. The needle examination typically included (UE) Cervical Paraspinals, Deltoid, Biceps, Extensor Carpi Radialis, Triceps, Flexor Carpi Radialis, APB muscle, (LE) Lumbar Paraspinals, Vastus medialis, Extensor Hallucis Longus, Biceps Femoris, Peroneus Longus, Medial Gastrocnemius, the studies selected based on the comprehensive assessment result.

Between 2011-2015 as a result of regulatory changes in the state of Ohio (including HB 93 law), CPMI received a high number of referral/evaluation requests for high risk challenging patient population. Many of these chronic pain patients seen by the CPMI suffer from anxiety and depression, and/or drug seeking behavior and had a poor tolerance of the NCV/EMG testing and poor cooperation with the test, especially with the needle part of the test (EMG), (this part performed with inserting EMG needle in 6-12 sites) and frequently refused by the challenging patient population. All the patients were offered the enclosed written consent based on the enclosed AANEM guidelines.

Dr. Margolin maintains certification by the ABPM&R (that includes NCV and EMG training) in addition to the Pain Medicine certification and has completed a large number of the relevant CMEs (examples attached). CPMI demonstrated a high level of compliance with the AANEM guidelines, OH Local Coverage Determination and state and national guidelines as reflected by the attached CPMI policies and paperwork (i.e. NCV EMG forms, initial follow up evaluation forms and PADT forms).

ABPMR took a position that not performing the NCV tests with or without the needle could put our practice in noncompliance with the state requirements and professional guidelines

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

What do you want to improve? Look for inefficiencies, annoyances, or safety issues. Consider complex issues, but focus on simple solutions.

Is there a problem that has led you to test the impact of the NCV with or without EMG. Those without testing do worse for example--

Re(Comment): Can you clarify the problem--is it incomplete evaluations that do not include EMG/NCS and poor outcomes prior to your implementation ?
Answer: NCV and EMG testing is an extension of PMR examination (please review medical necessity below), it's important to show the impact of the test on the program outcomes.frequently pain management patients are not fully cooperative with the full test (please see below) and the goal is to test the impart of the NCV with or without EMG.

"Many of these chronic pain patients seen by the CPMI suffer from anxiety and depression, and/or drug seeking behavior and had a poor tolerance of the NCV/EMG testing and poor cooperation with the test, especially with the needle part of the test (EMG), (this part performed with inserting EMG needle in 6-12 sites) and frequently refused by the challenging patient population. All the patients were offered the enclosed (e mailed to Kendell) written consent based on the enclosed AANEM guidelines."

All the patients in the study were referred to us after the opioid medications have been started by the previous provider (typically PCP), under the circumstances we could not wave a necessary test for research purposes to maintain proper Ohio state (TDDD HB 93) compliance. That's why there no controls without NCV/EMG. We did internal controls patients with only NCV, patients who got different degrees of functional improvement and pain reduction. That's the best ethical set up for the study we can create.

ABPMR reported high cost efficiency and cost savings for the third party payers with our protocol

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

attac[illegible]d). CPMI demonstrated a high level of comp[illegible]e with the AANEM guidelines, OH Local Co[illegible]ge Determination and state and national guidelines as reflected by the attached CPMI policies and paperwork (i.e. NCV EMG forms, initial follow up evaluation forms and PADT forms).

Cost Efficiency of the Testing: The cost of opioid epidemic is more than 55 billion dollars a year and keeps rising annually. Pain Management programs like our practice that carefully screen and test patient to properly document organic pathology and utilize alternative treatments, careful monitoring and SBIRT approach not only prevent significant morbidity and mortality, but save very significant costs to the healthcare system.

Insufficient testing, can potentially result in either prescribing opioid medications to not appropriate candidates that can potentially overdose or divert medications to other people, or not prescribing

appropriate pain medications to patients who may look for alternatives "on the street" with significant risks or morbidity and mortality. The host of hospitalization including ER, inpatient care, ICU, detoxification and maintenance programs is astronomic and can be reduced by patient screening and testing including NCV/EMG testing and other testing.

Our practice performs the NCV/EMG testing and other testing for a fraction of the cost charged by main hospitals in the area including the Ohio State University clinic.

B) What data (objective measurements) do you have that supports this as a problem?

Review your records or begin tracking how often the issue is occurring and under what conditions.

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

Montefiore
THE UNIVERSITY HOSPITAL FOR
ALBERT EINSTEIN COLLEGE OF MEDICINE

November 14, 2018

Dear Dr Margolin,

I have reviewed your study on the role of neuromuscular electrodiagnostic testing (including nerve conduction studies and needle electromyography) in the context of your chronic pain practice, found its methodology to be well considered, and its positive impact on clinical outcome provocative and quite compelling. I commend you for making a significant contribution to the specialty area of chronic pain management. These findings would likely be of considerable interest to physiatrists, other specialists treating chronic pain patients, and to the third party payors responsible for authorizing payment for electrodiagnostic testing.

Yours truly,

Stanley F.Wainapel MD, MPH, Clinical Director, Department of Rehabilitation Medicine

Montefiore Medical Center

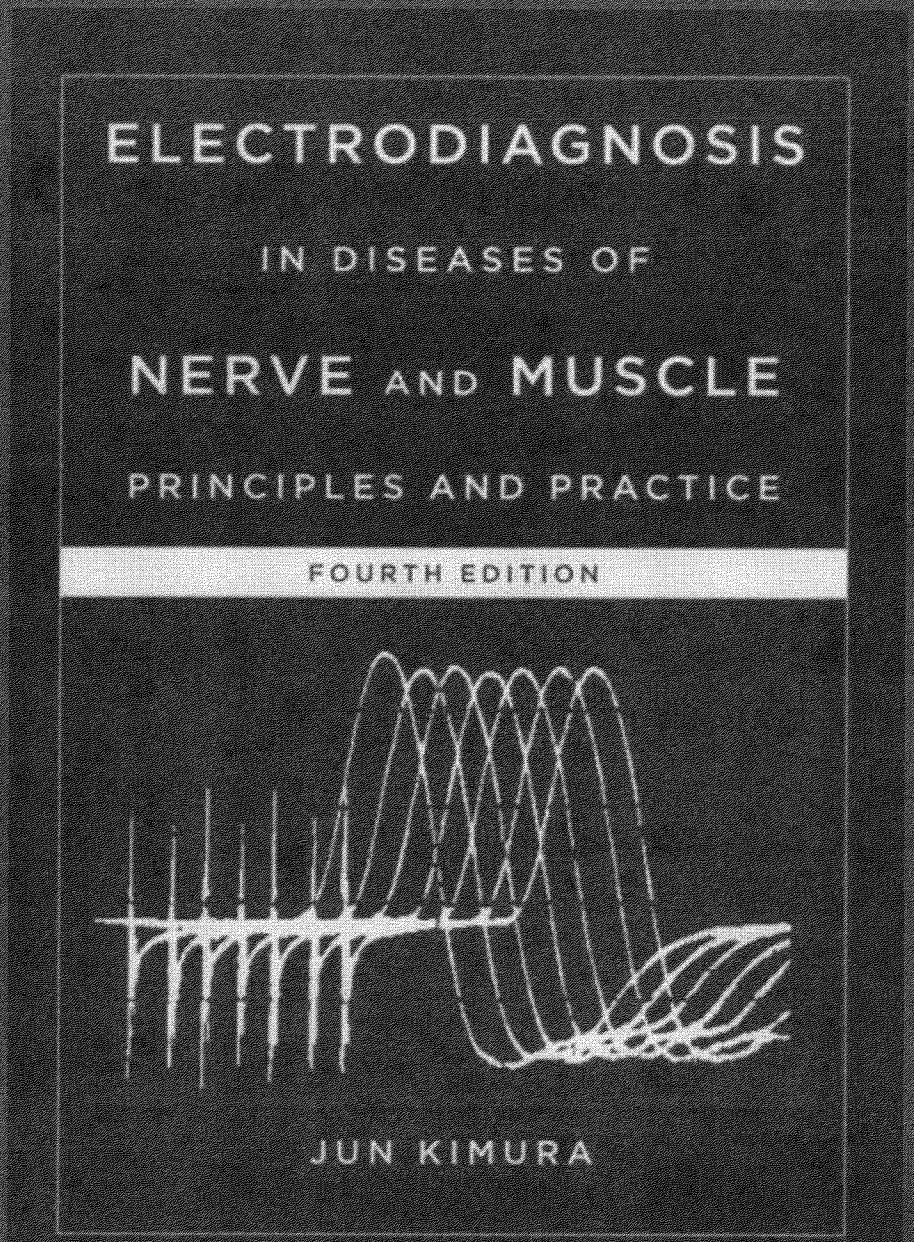
Professor of clinical Rehabilitation Medicine, Albert Einstein college of Medicine

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

Dr. Jun Kemura

- Jon Kimura got the Distinguished Researcher Award
- by the AANEM (which is the academy mentioned in the LCD) https://old.aanem.org/Membership/Member-Achievement-Awards/Award-Recipients.aspx#FAQLink389
- Author of a major textbook recommended by the AANEM and ABPMR
- Lecturer in the AANEM NCV and EMG courses
- More than 500 publications in the field / 25 professional honorary society membership all around the world

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.



Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

Basics With The Experts

Table of Contents

Course Committees & Course Objectives	4
Faculty	5
The Evaluation of Polyneuropathy *John D. England, MD*	7
Long and Short of Nerve Conduction Studies for Neuropathy *Jun Kimura, MD*	13
Repetitive Nerve Stimulation Testing *Vern C. Juel, MD*	19
Muscle Cramps and Hyperactivity Syndromes *Bassam A. Bassam, MD*	25
CME Questions	31

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges

Jun Kimura, MD

Department of Neurology
University of Iowa Health Care
Iowa City, Iowa

Dr. Kimura received his medical degree from Kyoto University in Japan. He moved to the United States as a Fulbright scholar for residency training in neurology and a fellowship in electrophysiology at the University of Iowa, where he now serves as Professor of Neurology. He also has taught at the University of Manitoba in Canada, Kyoto University in Japan, and Tiantan Hospital in China. Dr. Kimura has more than 500 original publications, including four editions of his book, Electrodiagnosis in Diseases of Nerve and Muscle. Dr. Kimura has received honorary membership from 25 national societies of neurology, neurophysiology, and rehabilitation medicine.

academic erest inc
chemodenervation for f

Bassam A. Bass

Neuromuscular Progr
University of South A
Mobile, Alabama

Dr. Bassam completec
fellowship in neuromu
with additional fellows
certified by the Americ
the American Board of
is a diplomate in the n
Bassam has served on
chair of the Workshop C
Examination Committe
focus on neuromuscula

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges

UNIVERSITY OF IOWA HOSPITALS & CLINICS

University of Iowa Health Care

George B Richerson, MD, PhD
Professor & Head
The Roy J Carver Chair in Neuroscience

Department of Neurology
University of Iowa Health Care
200 Hawkins Drive
Iowa City, IA 52242
319-356-4296 Tel
319-384-7199 Fax
www.uihealthcare.org

December 28, 2018

Leon Margolin MD, PhD
5245 E Main St
Columbus, OH 43213

Dear Dr. Margolin,

Thank you for asking me to review your project on chronic pain management, which is of considerable interest not only to physiatrists but also to other related specialties in general and neurology in particular. I am pleased to evaluate your proposal as a neurologist with special interest in clinical electrophysiology, which I practiced over 50 years.

The project you are undertaking relates to the role of nerve conduction studies (NCS) and needle electromyography (EMG) on clinical assessments of chronic pain patients. I find the study well designed using appropriate methodology to gain a positive impact on clinical practice. I am pleased to learn that the American Board of PM&R has approved this project that was highly evaluated by Dr. Wainapel, an expert in this field. As a neurologist, I too consider the project of considerable value and interest to other specialists and the third party payers.

From my personal experience, I consider NCS as one of the most important tests for evaluation of neuropathy and EMG as an essential tool for clinical study of radiculopathy, two very common conditions where chronic pain management plays an important role. As such these electrodiagnostic methods have demonstrated strong medical necessity on patient care dealing with chronic pain. I wish you continued success in this important endeavor.

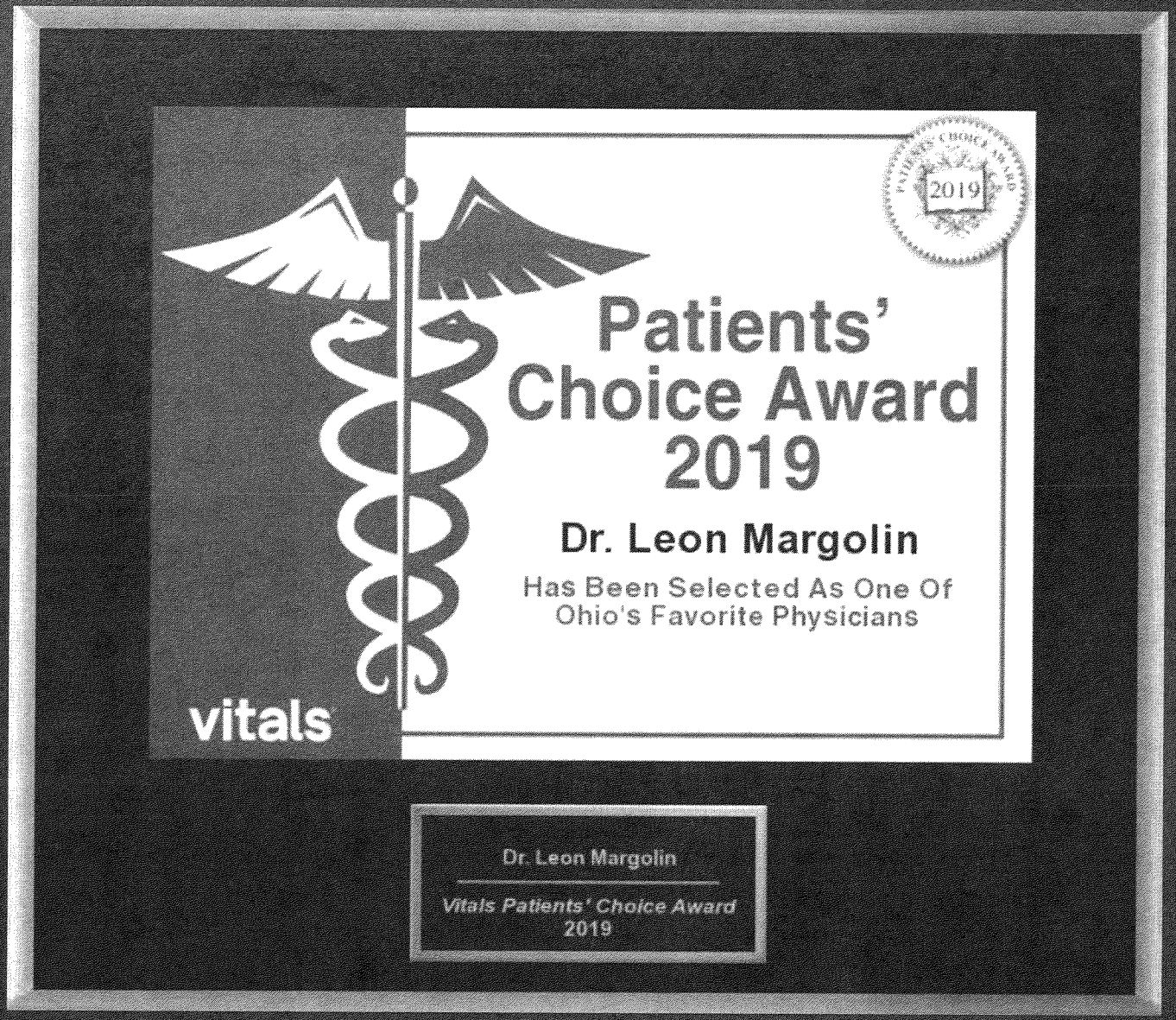
Regards,

Jun Kimura, MD
Professor Emeritus
Department of Neurology
University of Iowa
Professor Emeritus

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.



Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.



Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

B

G CODE BILLING

Leon Margolin M.D., Ph.D.

От: **David Deppen** <ddeppen@practice-pro.net>
Date: ср, 12 мар. 2014 г. в 08:17
Subject: RE: screening G codes
To: Leon Margolin <leon3087@gmail.com>,
David Guido <dguido@practice-pro.net>

Here are the codes from the HCPCS book:

G0396 Alcohol and/or substance (other than tobacco) abuse

structured assessment (e.g., audit, dast), and brief

intervention 15 to 30 minutes

G0397 Alcohol and/or substance (other than tobacco) abuse

structured assessment (e.g., audit, dast), and intervention,

greater than 30 minutes

Nothing speaks to only time for MD so time spent by other associates on this service could be included. Only item that we suggest is that somewhere in the chart note it is documented that more than 30 minutes was spent covering this issue separately from other services.

Fit to page view | Read

Patient Name: Edwards, Harry **INS: Medicare/TriCare** **DOB: 01/28/1984** **Date: 05/18/2015**

COMPREHENSIVE PAIN MANAGEMENT INSTITUTE, LLC (CPMI)
5245 E. Main Street, Columbus, OH; 43213
Ph. 614-557-6075, F. 614-453-8222

Screening And Brief Intervention Review Sheet

In compliance with the SMBO guidelines the CPMI provider reviewed:

- SOAPP R
- Review of PADT tool that includes 4As of chronic pain treatment (Analgesia, Activities of Daily Living, Aberrant Drug Related Behavior, Adverse Events) , patient progress towards objective for the duration of treatments.
- Review of Assessment Of Patient Receiving Protracted Prescription Medication For The Treatment Of Intractable Pain Form (Pursuant to State Medical Board of Ohio Administrative Rule 4731-21-02)
- Review Withdrawal Assessment form
- Review OARRS report
- ORT / COMM assessment tools on selected charts
- Results of the screening, history, physical examination, responses to and assessment of the particular items required for chronic prescription of controlled medications (including PADT tool enclosed), and alternatives to treatment reviewed and discussed with the patient

Total time spent - greater than 30 minutes

❑ at least 15-30 / other _____ minutes

Comments:

620main.pdf

Fit to page

Multiple medical problems requiring a high level of decision-making addressed. Overall patient status appears stable. Patient presenting with chronic pain syndrome. Refer to the SOAP note (pages 1-4), medications review, SBIRT assessments (urine screen results, OARRS review, PADT, SOAPP-R/COMM, ORT, SMBO Administrative Rule 4731-21-02 form) and to recent orders.

Medical and ancillary therapy services remain available to patient as needed. Continue to monitor medical conditions, risk or injury, psycho-social factors, activity level, exposure to infection, medication, treatments, care plans and interventions.

Counseling and coordination of care discussed with caregivers. Refer to physician / nurse practitioner order and care plan. Extensive and complex physician interaction representing patient related contacts with the patient, patient representatives, caregivers and ancillary staff, including but not limited to face-to-face examination of the patient, review of diagnostic tests, therapy, chart review conversations and coordination of care with the patient, caregivers, patient representatives, generating orders and coordination of care with caregivers and consulting other providers when indicated.

Level 3/4 visit

- CPT 99213 or 99214 performed but not billed

- 20-25 min according to Medicare

Patient Name: [redacted] INS: Medicare/TriCare DOB: [redacted] Date: 05/18/2015

Follow Up Evaluation Note

DATE OF FIRST VISIT:_____ Age: _____ Referring Physician: _____

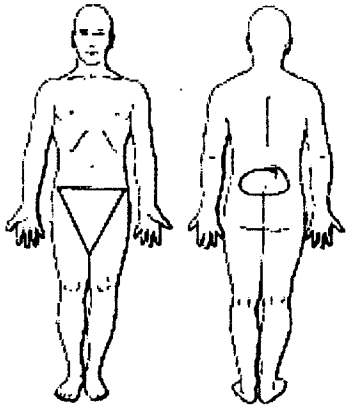
CC: The patient's main complaint is Low Back

Present Illness: Our patient is here for follow up visit evaluation VAS /10
Our patient presents for management of pain arising at _____ Pain radiates to _____

New issues and problems (For Office Use Only):

Signs of Addiction/Tolerance/Drug Seeking Behavior/Secondary Gain: If Yes, specify

Pain Location: Put an "X" over the area that hurts the most and mark the quality of the pain:



- ☒ Sharp
- ☐ Gnawing
- ☐ Tender
- ☒ Stabbing
- ☐ Dull
- ☒ Shooting
- ☐ Tingling
- ☐ Throbbing
- ☐ Aching
- ☐ Other

The pain is made worse with:

- ☐ Activity
- ☐ Walking
- ☐ Sitting
- ☐ Lying
- ☐ Medication
- ☐ Bending/twisting
- ☐ Stress
- ☐ Standing
- ☐ Sleep
- ☐ Other

The pain is made better with:

- ☐ Medications
- ☐ Rest
- ☐ Activity
- ☐ Relaxation
- ☐ Distraction
- ☐ Other

(8) **Vital Signs:**
HT: 6ft 1in
WT: 285 lbs
P: 96
SpO2: 94
R-(14)

Medical management: with/without/with partial benefit.
☐ Side effects If Yes, specify_____ ☐ tried a high dose of NSAIDs and still suffering from severe intractable pain

Previously employed procedures include: none/epidural steroid injection (caudal/caudal with catheter/interlaminar/transforaminal) /facet joint injections/ medial branch block/radiofrequency treatment/ major joint injection _____/ other peripheral nerve injection _____/trigger pint injections
Spine/Neck Surgery Specify Area_____Soft/Hard Collar Corset Brace TENS Unit
Other_____
with/without/with partial benefit.

Physical Therapy Home Exercise Program Past/Present/Current (circle): Walking Program Chiropractic Swimming
Other_____ with/without/with partial benefit.

Please Sign _____ **Date:** 5/18/15

PLEASE STOP HERE THE REST OF NEXT PAGE WITH BE REVIEWED WITH YOU AND YOUR PHYSICIAN

Functional Improvement: Yes/No/Partial
The patient denies any fever, chills, night sweats, numbness in the buttock area (saddle anesthesia) and any acute changes in bowel or bladder habits.
Other_____

History/Controlled Prescribing Evaluation
Additional history reviewed by me appear in the chart as a separate form to record an evaluation of the specific points of focus required by SMBO Administrative Rule 4731.21.02 pertaining to protracted prescription of controlled medications.

❑**Urine Toxicology** Periodic urine toxicology was ordered /reviewed today. _____

Social History

Family/Social – unchanged updated – _____
Surgical – unchanged updated – _____
Medication – unchanged updated – _____
Allergies – unchanged updated- _____
Other - _____

Please find Review of Systems form enclosed

Data Reviewed: (e.g. x-ray, CT scan, MRI,myelogram/outside records or reports/referral documents:
Comments:_____

Physical Exam:

Constitutional: Patient is alert and oriented x3, no acute distress, answers questions appropriately, maintains good eye contact----

Other: _____

Head and neck: Coordination and cranial nerves II – XII are ☑ Grossly intact ❑ Other

HEENT: ☑ Normocephalic/Atraumatic. Sclera Anecteric. ❑Other _____

Eyes: ☑ PERLAA, Sclera anicteric ❑Other _____

Neck: ☑ no masses, no gross adenopathy, no gross thyromegaly ❑Other _____

Lymphatic: ☑ no adenopathy in the neck and in the axillae ❑Other _____

Skin: ☑ Inspection and palpation are normal (no discoloration or induration) ❑ Other _____

Patient Name: [redacted] **INS: Medicare/TriCare** **DOB** [redacted] **Date: 05/18/2015**

Cardiovascular: ☑ RRR S1 S2 no murmurs; extremities no signs of CVT or significant edema

❑ Other _____

Respiratory: ☑ breaths easily, clear to auscultation, no wheezes ❑ Other _____

Abdomen: ☑ soft non-tender, positive bowel sounds ❑ Other _____

❑ Ileohypogastric/ Ilioinguinal / genitofemoral nerve area tenderness (R/L/ BL)

Focused Neurologic exam is ❑ Non focal ❑ Other _____

General musculskeletal exam: ❑ Motor 5/5, sensory 2/2, reflexes 2/4 full range of motion, tone grossly intact

❑ Decreased ROM ❑ joint line tenderness of ❑ Shoulder (R/L/ BL); ❑ Knee (R/L/ BL); ❑ Hip/ Greater Trochanter (R/L/ BL)

Joint ❑ other _____ ;

❑ Other _____

Lumbar Spine: **ROM** – decreased / normal
Midline tenderness – L4L5 / L5S1 Other: _____
Straight leg rise test B/L negative / positive
Tenderness over SI joints R / L / BL negative / positive
Facet loading R / L / BL negative / positive
Other: _____

Cervical Spine: **ROM** – decreased / normal
Midline tenderness – negative / positive
Spurling – negative / positive
Facet loading R / L / BL negative / positive
Tenderness in the area of the occipital nerve R / L / BL negative / positive
Trigger points in the trapezius and cervical paraspinals R L BL negative / positive
Other: _____

Gait is antalgic / normal ❑ Other _____

COMMENT: _____

ASSESSMENT AND PLAN

Diagnosis:

337.20 CRPS type 1	**729.1 Myofascial pain/Fibromyalgia**	**339.89 Headache**
722.52 DDD of the L/S	**721.3 Lumbar Facet Spondylosis**	**719.41 Shoulder Pain (R/L)**
724.2 Low back pain	**721.0 Cervical Spondylosis**	**719.45 Hip Pain (R/L)**
724.4 Lumbar Radiculitis	**721.2 Thorasic Spondylosis**	**719.46 Knee Pain (R/L)**
724.4 Thorasic Radiculitis	**724.02 Lumbar Spinal Stenosis**	**724.6 SI Pain (R/L)**
723.4 Cervical Radiculitis	**723.0 Cervical Spinal Stenosis**	**338.4 Chronic Pain Syndrome**
625.9 Pelvic Pain (female)	**356.9 Peripheral neuropathy**	**724.79 Coccydynia**
789.09 Pelvic Pain (male)		

❑ This patient had a NCV study today of the LE / UE, needle er _____

Interventional Management: ❑ Patient had at least 50% reduction o. ..is pain score (locally) and a significant improvement in the limitations in functional activities (as documented with PADT and Rule 4731-21-02 form enclosed). ❑ Reduction in medication use after the previous procedure. ❑ The effect had a limited duration ❑ Patient was reevaluated and a different pain generator was addressed ❑ We will repeat the same procedure ❑ No intervention(s) indicated at this time. ❑ I elect to proceed with the following interventions:

Right/ Left / Bilateral Sacroiliac / Knee/ Shoulder/ **Joint** / Greator Trochanter injection/ Greater / Occipital/ Cluneal / Suprascapular / Iliohypogastric / Intercostal x 3 (x) **nerve block**/ Trigger point injections / Lumbar / Thorasic facet joint injections x 3levels / SCS / peripheral nerve stimulator trial / radiofrequency treatment / Epidural steroid injection (caudal/ transforaminal other_____

❑ SOAPP-R score 10 ❑ Neuropathic medications and interventions reassessed based on the NCV report results.

❑ start / continue /adjust dose of Gabapentin / Lyrica/ Cymbalta / other _____. ❑ Pt refused / reports intolerance / other _____ ❑ Trial of NSAIDs offered , patient agreed / refused / will await clearance from PCP ❑ pt has contraindications for NSAIDs ❑ other_____

Medical Management: ❑ Immediate results / ❑ conformation of the urine screen is/are ❑ consistent ❑ positive for ❑ THC / ❑ Cocaine metabolite ❑ Other _____ ❑ negative for prescribed medications.

❑ An OARRS report was obtained on-line by accessing the Ohio Automated Prescription Reporting System, and I reviewed the report. ❑ All of the patient's dispensed controlled substances displayed in the report are explained. ❑ OARRS history reviewed and discussed with the patient, office policies and patient contract reviewed and explained in details. ❑ The presence of an unexpected prescribing event identified in the report:

Comments: c/o ↑ R buttock & pain x 1 yr
Repeat NCV studies - c/o high copay
for Oxycodone

❑ After thorough review of condition, history, responses to and assessment of the particular items required for chronic prescription of controlled medications (including PADT tool enclosed), and alternatives to treatment, ❑ I found the patient not to be a reasonable candidate for schedule 2 or 3 medications at this time ❑ Addiction Medicine referral, Detox. programs information package and non narcotic treatment plan option offered / pt refused / pt accepted referral

❑ I will await conformation of the urine screen ❑ I will wait for the additional records/imaging reports

❑ Secondary to ongoing pain that interferers with function will proceed with dose increase

❑ I will initiate/continue the following medications:

Oxycontin 10mg ter Bid Dis 5/27
Oxycodone-apap 325/5mg QID Dis 5/24

The patient has signed a medication agreement with the understanding that periodic urine toxicology will be performed and that if there is no effect of medications, that the patient will be weaned off of them. ❑ I spent at least 25 / 35 / 45 / 50 minutes with this case, and at least 50% of this time in face-to-face interaction, discussion of pathology, testing.

Return Visit: _____ days / weeks / mo Signature:_____ Leon Margolin, MD, PhD 4

Patient Name: [redacted] **INS: Medicare/TriCare** **DOB** [redacted] **Date: 05/18/2015**

REVIEW OF SYSTEMS

Please indicate if you are experiencing any of the following health symptoms or issues by circling the "Y", or "N" if you are not having an issue:

Constitutional

Y	N	Fever/Sweats
Y	N	Headache
Y	N	Loss of appetite
Y	N	Weight gain/loss
Y	N	Fatigue

Eyes/Ears

Y	N	Eye pain, redness/drying
Y	N	Blurred or double vision
Y	N	Loss of hearing
Y	N	Ear pain
Y	N	Ringing in ears

Nose/Mouth

Y	N	Nosebleeds (frequent)
Y	N	Persistent congestion
Y	N	Sinus issues
Y	N	Mouth sours
Y	N	Pain with chewing
Y	N	Dry mouth

Head/Neck

Y	N	Balance problems
Y	N	Swollen gland(s)
Y	N	Vertigo

Cardiovascular

Y	N	Palpitations
Y	N	Chest Pain
Y	N	Swelling (edema)
Y	N	Persistent cough
Y	N	Pain when breathing
Y	N	Shortness of breath
Y	N	Heart murmur

Gastrointestinal

Y	N	Nausea/loss of appetite
Y	N	Vomiting
Y	N	Difficult swallowing
Y	N	Stomach ulcer
Y	N	Loose stool/diarrhea
Y	N	Constipation
Y	N	Rectal Bleeding

Kidney and Bladder

Y	N	Frequency
Y	N	Urgency
Y	N	Hesitancy
Y	N	Bloody or rusty urine

Musculoskeletal

Y	N	Bone pain
Y	N	Joint pain
Y	N	Muscle pain
Y	N	arthralgia(s)
Y	N	osteoporosis

Skin

Y	N	Rash
Y	N	Redness
Y	N	Eczema

Neurologic

Y	N	Seizures
Y	N	Numbness/Tingling
Y	N	Memory loss
Y	N	Weakness/Paralysis

Psychologic

Y	N	Depression
Y	N	Panic attacks
Y	N	Mood swings
Y	N	Anxiety
Y	N	Suicidal thoughts

Endocrine

Y	N	Diabetes
Y	N	Thyroid disease

Blood and Immune

Y	N	Anemia
Y	N	Bruising
Y	N	Clots

Allergy and Immunology

Y	N	Seasonal allergies
Y	N	Environmental allergies
Y	N	Immune deficiency

Patient Signature: _____

Physician Signature: _____

PADT Assessment

- Performed for every G code billed
- 15-20 minutes as per ASAM

PADT (Based on Janssen Pharmaceutical Products, L.P. ©2003 All rights reserved)

Continued on the second page

Current Analgesic Regimen (Please refer to the chart)

The PADT is a clinician- directed interview; that is, the clinician asks the question, and the clinician records the responses. The Analgesia, Activities of Daily Living, and Adverse Events sections may be completed by the physician, nurse practitioner, physician assistant, or nurse. The Potential Aberrant Drug-Related Behavior and Assessment sections must be completed by the physician. Ask the patient the questions below, except as noted.

Analgesia

If zero indicates "no pain" and ten indicates "pain as bad as it can be," on a scale of 0 to 10, what is your level of pain for the following questions?

1. **What was your pain level on average during the past week? (Please circle the appropriate number)**

No Pain 0 1 2 3 4 (5) 6 7 8 9 10 Pain as bad as it can be

2. **What was your pain level at its worse during the past week?**

No Pain 0 1 2 3 4 5 6 (7 8) 9 10 Pain as bad as it can be

What percentage of your pain has been relieved during the past week? (Write in a percentage between 0% and 100 %.)

_____

3. **Is the amount of pain relief you are now obtaining from your current pain reliever(s) enough to make a real difference in your life?**

☐ **Yes** ☐ **No** ☐ **Not applicable**

4. **Query to clinician: is the patient's pain relief clinically significant?**

☐ **Yes** ☐ **No** ☐ **Unsure**

Activities of Daily Living

Please indicate whether the patient's functioning with the current pain reliever(s) is Better, the Same, or Worse since the patient's last assessment with PADT.* (Please check the box for better, Same, or Worse for each item below)

☐ **No prior assessment available**

	Better	Same	Worse
1. **Physical functioning**	☒	☐	☐
2. **Family relationships**	☒	☐	☐
3. **Social relationships**	☒	☐	☐
4. **Mood**	☒	☐	☐
5. **Sleep patterns**	☒	☐	☐
6. **Overall functioning**	☒	☐	☐

***If the patient is receiving his or her first PADT assessment, the clinician should compare the patient's functional status with other reports from the last office visit.**

Fit to page Page view

Patient Name: [redacted] INS: Medicare/TriCare DOB: [redacted] Date: 05/18/2015

Adverse Events

1. Is patient experiencing any side effects from current pain reliever? ☐ Yes ☒ No

Ask patient about potential side effects :

	None	Mild	Moderate	Severe
a. Nausea	☒	☐	☐	☐
b. Vomiting	☒	☐	☐	☐
c. Constipation	☒	☐	☐	☐
d. Itching	☒	☐	☐	☐
e. Mental Cloudiness	☒	☐	☐	☐
f. Sweating	☒	☐	☐	☐
g. Fatigue	☒	☐	☐	☐
h. Drowsiness	☒	☐	☐	☐
i. Other_____		☐	☐	☐
j.Other_____		☐	☐	☐

Potential Aberrant Drug-Related Behavior

This section must be completed by *THE PHYSICIAN*

Please check any of the following items that you discovered during your interactions with the patient. Please note that some of these are directly observable (eg. appears intoxicated), while others may require more active listening and/ or probing. Use the "Assessment" section below to note additional details.

☐ NONE

- ☐ Purposeful over sedation
- ☐ Negative mood change
- ☐ Appears intoxicated
- ☐ Increasingly unkempt or impaired
- ☐ Involvement in car or other accidents
- ☐ Requests frequent early renewals
- ☐ Increased does without authorization
- ☐ Reports lost or stolen prescriptions
- ☐ Attempts to obtain prescriptions from other doctors
- ☐ Changes route of administration
- ☐ Uses pain medication in response to situational stressor
- ☐ Insists on certain medications by name
- ☐ Contact with street drug culture
- ☐ Abusing alcohol or illicit drugs
- ☐ Hoarding (i.e., stockpiling) of medication
- ☐ Arrested by police
- ☐ Victim of abuse
- ☐ Other _ ☐ Urine screen / CAPPS

SMBO compliance flowchart

Required by SMBO; 10-15 min (assessment performed for every G code)

Comprehensive Pain Management Institute, LLC

Assessment of patient receiving protracted prescription medication for the treatment of intractable pain

Pursuant to State Medical Board of Ohio Administrative Rule 4731-21-02

Utilizing prescription drugs for the treatment of intractable pain, effective 11/11/98

eatment objectives:

- ❑ Employment; return to or maintain
- ❑ Physical therapy or rehab; participate in
- ☑ Ambulation and mobility; improve
- ☑ ADL, self-care; increase ability to perform
- ☑ Pain relief; reduce pain and suffering

Other:_____ ❑ **Not a candidate for narcotic medications at this time**

ogress towards treatment objectives: ❑ **New Patient**

' *None* ❑ *Slight* ❑ *Moderate* ☑ *Substantial* ❑ *Complete*

fectiveness of treatment:

' *None* ❑ *Slight* ❑ *Moderate* ☑ *Substantial* ❑ *Complete*

terference with ADL (activities of daily living e.g. bathing, dressing, cooking, cleaning) due to pain:

' *None* ❑ *Slight* ❑ *Moderate* ☑ *Substantial* ❑ *Complete*

ıality of life and
ility to function;
anges due to
scription drug usage:

- ☑ Daily Chores
- ☑ Walking ▭ Exercising
- ▭ Perform Job Duties
- ▭ Taking Care Of Family

- ❑ Improved greatly
- ☑ Improved somewhat
- ❑ Unchanged
- ❑ Lessened somewhat
- ❑ Lessened greatly

Other: _____

ysical activity:

- ❑ Active, unrestricted
- ☑ Limited standing or walking
- ❑ Cane or walker, limited mobility
- ❑ Wheelchair much of the time
- ❑ Bedridden most of the time

Other:_____

mily relationship:

- ☑ Improved greatly
- ❑ Improved somewhat
- ❑ Unchanged
- ❑ Strained/Stressed
- ❑ Normal

Other: _____

ork status:

- ❑ Employed/employable, working with pain
- ❑ Light duty, temporary
- ❑ Partial disability, limited work capacity
- ❑ Temporary total disability, off work
- ❑ Retired or permanently total disability

Other: _____

COMM

- Required by SMBO and natinal guidelines

- 10-15 min (signed by patients)

Patient Name: [redacted] **INS: Medicare/TriCare** **DOB:** [redacted] **Date: 05/18/2015**

COMM

Please answer each question as honestly as possible. Keep in mind that we are only asking about the **past 30 days**. There are no right or wrong answers. If you are unsure about how to answer the question, please give the best answer you can.

Please answer the questions using the following Scale:	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
1. In the past 30 days, how often have you had trouble with thinking clearly or had memory problems?	●	○	○	○	○
2. In the past 30 days, how often do people complain that you are not completing necessary tasks? (i.e., doing things that need to be done, such as going to class, work or appointments)	●	○	○	○	○
3. In the past 30 days, how often have you had to go to someone other than your prescribing physician to get sufficient pain relief from medications? (i.e., another doctor, the Emergency Room, friends, street sources)	●	○	○	○	○
4. In the past 30 days, how often have you taken your medications differently from how they are prescribed?	●	○	○	○	○
5. In the past 30 days, how often have you seriously thought about hurting yourself?	●	○	○	○	○
6. In the past 30 days, how much of your time was spent thinking about opioid medications (having enough, taking them, dosing schedule, etc.)?	●	○	○	○	○
7. In the past 30 days, how often have you been in an argument?	●	○	○	○	○
8. In the past 30 days, how often have you had trouble controlling your anger (e.g., road rage, screaming, etc.)?	●	○	○	○	○

Please Sign: [signature] 5/18/15

©2004 Inflexxion, Inc. Permitted

Patient Name: [redacted] INS: Medicare/TriCare DOB: [redacted] Date: 05/18/2015

	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
9. In the past 30 days, how often have you needed to take pain medications belonging to someone else?	●	○	○	○	○
10. In the past 30 days, how often have you been worried about how you're handling your medications?	●	○	○	○	○
11. In the past 30 days, how often have others been worried about how you're handling your medications?	●	○	○	○	○
12. In the past 30 days, how often have you had to make an emergency phone call or show up at the clinic without an appointment?	●	○	○	○	○
13. In the past 30 days, how often have you gotten angry with people?	●	○	○	○	○
14. In the past 30 days, how often have you had to take more of your medication than prescribed?	●	○	○	○	○
15. In the past 30 days, how often have you borrowed pain medication from someone else?	●	○	○	○	○
16. In the past 30 days, how often have you used your pain medicine for symptoms other than for pain (e.g., to help you sleep, improve your mood, or relieve stress)?	●	○	○	○	○
17. In the past 30 days, how often have you had to visit the Emergency Room?	●	○	○	○	○

Please Sign: [signature] 5/18/15

Please include any additional information you wish about the above answers.
Thank you.

Withdrawal Assessment Form

- Assessment performed for every G code
- 10-15 min (18 point history and exam plus the form)

Patient Name: [redacted] INS: Medicare/TriCare DOB: [redacted] Date: 05/18/2015

WITHDRAWAL ASSESSMENT FORM:

(By Physician or NP only)

Patient was instructed to go to the nearest emergency room in case of withdrawal

☑ **No signs or symptoms listed below:**

1. AGITATION:	Mild / Moderate / Severe
2. TACTILE DISTUBANCE:	Mild / Moderate / Severe
3. AUDITORY DISTURBANCES:	Mild / Moderate / Severe
4. VISUAL DISTURBANCES:	Mild / Moderate / Severe
5. HEADACHE (not explained by other factors)::	Mild / Moderate / Severe
6. NAUSEA AND VOMITING:	Mild / Moderate / Severe
7. TREMOR:	Mild / Moderate / Severe
8. PAROXYSMAL SWEATS:	Mild / Moderate / Severe
9. ANXIETY (not explained by other factors):	Mild / Moderate / Severe
10. GOOSE FLESH:	Mild / Moderate / Severe
11. RESTLESSNESS:	Mild / Moderate / Severe
12. LARCRIMATION:	Mild / Moderate / Severe
13. NASAL CONGESTION:	Mild / Moderate / Severe
14. YAWNING:	Mild / Moderate / Severe
15. ABDOMINAL CHANGES: PAIN & DIARRHEA:	Mild / Moderate / Severe
16. FEELING OF CHANGE IN TEMPERATURE SENSATION (HOT TO COLD/ COLD TO HOT):	Mild / Moderate / Severe
17. MUSCLE ACHES:	Mild / Moderate / Severe
18. PUPIL DILATION (for opioid withdrawal assessment):	Mild / Moderate / Severe

Other:

OARRS

- Required by SMBO and national guidelines
- Usually 2-3 pages (2 year history) Sometimes requires additional verifications of records, pharmacy or providers (between 10-30 min)

Ohio Automated Rx Reporting System

77 South High Street, Room 1702; Columbus, OH 43215-6126
-Equal Opportunity Employer and Service Provider-
TEL: 614/466-4143 E-MAIL: info@ohiopmp.gov Fax: 614/644-8556
TTY/TDD: Use the Ohio Relay Service: 1-800/750-0750 URL: http://www.ohiopmp.gov

Patient Rx History Report

[redacted]
32731021

Date: 5/18/2015 1:56:35 PM

Search Criteria: (Last Name = [redacted] And First Name = [redacted] And D.O.B. = [redacted] And Gender = 'M' And Street = '' And Zip = '43219' And Phone = '' And Request Period = '5/1/2014 to 5/18/2015' And States = OH

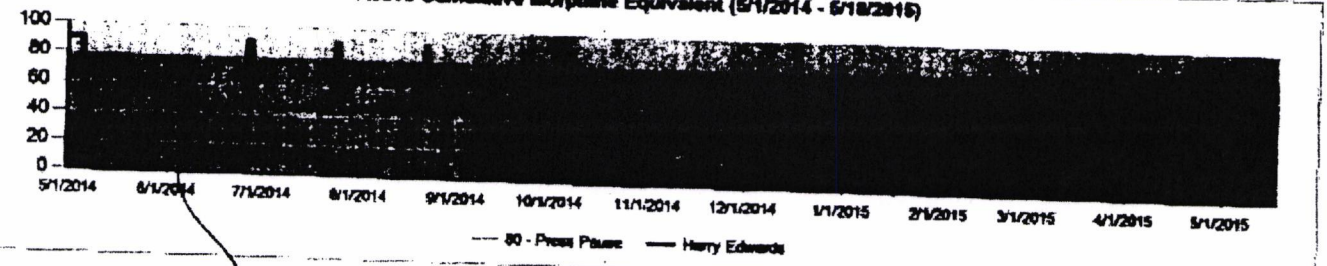
Patients included in report that appear to match search criteria

0944 [redacted] DOB [redacted] [redacted]
1163 [redacted] DOB [redacted] [redacted]

Active Cumulative Morphine Equivalent
See explanation provided at the end of the report

60

Active Cumulative Morphine Equivalent (5/1/2014 - 5/18/2015)



Prescriptions

[illegible]	Product, Str, Form	Qty	Days	Patient	Prescriber	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
5/12/2015	OXYCONTIN 10 MG TER	30	15	1163	LY FLE 7	5/4/2015	01168400-02	30	Y	CVS5717	M2
[redacted]											
4/14/2015	OXYCODONE AND APAP 325 MG-7.5 MG TAB	90	23	1163	LY FLE 7	4/6/2015	01162167-02	44	N	CVS5717	M2
[redacted]											

Disclaimer: The State of Ohio does not warrant the above information to be accurate or complete. The Report reflects the search criteria entered by the requestor, the data entered by the dispensing pharmacy, and the frequency at which the data is reported. For more information about any prescription, please contact the dispensing pharmacy or the prescriber.

[redacted]

PATIENT RX HISTORY REPORT

DATE:5/19/2015 1:58:36

3/15/2015	OXYCODONE AND APAP 325 MG-7.5 MG TAB	120	30	1163	LY FLE 7	3/9/2015	01155046-02	45	N	CVS5717	M2
[redacted]											
2/19/2015	OXYCODONE AND APAP 325 MG-7.5 MG TAB	100	25	1163	LY FLE 7	2/16/2015	01149930-02	45	N	CVS5717	M2
[redacted]											
1/19/2015	OXYCODONE AND APAP 325 MG-7.5 MG TAB	90	30	1163	LY FLE 7	1/19/2015	01142984-02	33.8	N	CVS5717	M2
[redacted]											
12/18/2014	OXYCODONE AND APAP 325 MG-7.5 MG TAB	90	30	1163	LY FLE 7	12/15/2014	01136268-02	33.8	N	CVS5717	M2
[redacted]											
12/4/2014	OXYCODONE AND APAP 325 MG-7.5 MG TAB	45	15	1163	LE MAR 7	12/4/2014	01133145-02	33.8	N	CVS5717	M2
[redacted]											
11/20/2014	LYRICA 75 MG CAP	60	30	1163	LE MAR 7	11/20/2014	01130298-02	-	N	CVS5717	M2
[redacted]											
10/15/2014	ALPRAZOLAM 2 MG TAB	90	30	1163	DO SCH 2	8/19/2014	01121132-02	-	N	CVS5717	M2
[redacted]											
8/22/2014	OXYCODONE 10 MG TAB	90	30	1163	DO SCH 2	8/19/2014	01109804-02	45	N	CVS5717	M2
[redacted]											
7/24/2014	AMPHETAMINE SALTS 5 MG TAB	60	30	1163	DO SCH 2	7/24/2014	01103587-02	-	N	CVS5717	M2
[redacted]											
6/26/2014	AMPHETAMINE SALTS 5 MG TAB	60	30	1163	DO SCH 2	6/24/2014	01097321	-	N	CVS5717	M2
6/7/2014	ALPRAZOLAM 2 MG TAB	270	90	0944	DO SCH 2	5/21/2014	59014154-26863	-	N	ESI 68263	CI
[redacted]											
5/29/2014	OXYCODONE 10 MG TAB	90	30	1163	DO SCH 2	5/21/2014	01091205	45	N	CVS5717	M2
[redacted]											

Disclaimer: The State of Ohio does not warrant the above information to be accurate or complete. The Report reflects the search criteria entered by the requestor, the data entered by the dispensing pharmacy, and the frequency at which the data is reported. For more information about any prescription, please contact the dispensing pharmacy or the prescriber.

[redacted]

PATIENT RX HISTORY REPORT

DATE:9/18/2015 1:56:36 PM

[redacted] 28

[1]Daily MED - The morphine equivalent per day for the individual prescription based on CDC conversion chart, the days supply and quantity dispensed provided by the pharmacy.

* - Indicates that a licensing board has adopted a position statement regarding this issue. For more information regarding this position statement, click the link for licensing board: State Medical Board of Ohio, Ohio Board of Nursing, Ohio State Dental Board

[2]Active - Indicates whether a prescription is active (Y/N) based on the date filled and the days supply provided by the pharmacy.

[3]Pay - C=Cash M1=Medicare M2=Medicaid WC=Workers Comp CI=Commercial Insurance U=Unknown

Prescribers for prescriptions listed: 4

DO SCH 2	DONALD MERLE SCHREIBER, MD; 1329 CHERRY WAY DRIVE, SUITE 500, GAHANNA, OH 43230
JE MEI 1	JEFFREY ALEXANDER MEIRING, DO; 3341 EAST LIVINGSTON AVE., SUITE D, COLUMBUS, OH 43227
LE MAR 7	LEON MD, MARGOLIN, PHD; COMPREHENSIVE PAIN MANAGEMENT INSITTUTE, 5245 E. MAIN STREET, COLUMBUS, OH 43213
LY FLE 7	LYDIA C FLECK, ; COMPREHENSIVE PAIN MANAGEMENT INSTITUTE, 5245 E MAIN ST, COLUMBUS, OH 43213

Pharmacies that dispensed prescriptions listed: 2

CVS5717	OHIO CVS STORES, L.L.C.; DBA: CVS/PHARMACY # 05717, 3506 GENDER RD., , CANAL WINCHESTER, OH, 43110, PHONE (614) 837-5588
ESI 68263	ESI MAIL PHARMACY SERVICE, INC; DBA EXPRESS SCRIPTS, 7909 SOUTH HARDY, , TEMPE, AZ, 85284, PHONE (314) 702-7555

Disclaimer: The State of Ohio does not warrant the above information to be accurate or complete. The Report reflects the search criteria entered by the requestor, the data entered by the dispensing pharmacy, and the frequency at which the data is reported. For more information about any prescription, please contact the dispensing pharmacy or the prescriber.

POC UDS

- Required by SMBO and national guidelines
- 5-10 min to review and correlate with OARRS, H&P and other assessments

5 из множес

Letter of Acceptance: AAFP Poster Presentation for FMX

Входящие ×

Lisa Leader ср, 1 мая, 11:43 (1 день на:

кому: LEON3087@GMAIL.COM

Hello Leon,

Congratulations! Your poster entitled "Correlation between NARX Score and food addictive behavioral patterns in chronic pain patients." has been accepted for presentation at the Philadelphia. Attached you will find two important documents:

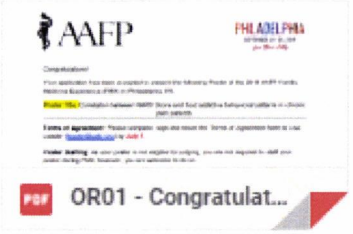
1. Congratulations Letter including information on registration, housing, size of poster display area, and poster set up/dismantling.
2. Terms of Agreement which must be completed and returned to me by July 31.

If you have additional questions, please feel free to reach out to me at 800 274-2237 x 6098.

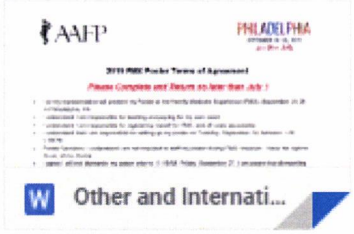
Best Regards,
Lisa Leader

Lisa Leader I CME Program Specialist
Continuing Medical Education Division
American Academy of Family Physicians
11400 Tomahawk Creek Parkway, Leawood, KS 66211
Office: (913) 906-6000, ext 6098
lleader@aafp.org

2 прикрепленных файла



PDF OR01 - Congratulat...



W Other and Internati...

For Office use only:

Patient Name: [redacted] Requisition Form ID: 333827782

Collectors Initials: ENB. Date: 5.18.15

Urine Temperature 96.0

• Methamphetamine (MAMP)	____POS	____NEG
• Ecstasy (MAMP)	____POS	____NEG
• Marijuana (THC)	____POS	X NEG
• Benzodiazephine (BZO)	____POS	____NEG
• Methadone (MTD)	____POS	____NEG
• Barbiturates (BAR)	____POS	____NEG
• Amphetamines (AMP)	____POS	____NEG
• Opiate (MOP)	____POS	____NEG
• Oxycodone (OXY)	____POS	____NEG
• Phencyclidine (PCP)	____POS	____NEG
• Cocaine (COC)	____POS	____NEG
• Buprenorphine (BUP)	____POS	____NEG
• *Pregnancy (PT)*	____POS	____NEG
• *ETOH*	____POS	X NEG

Results:

THC ⊖ 010
ETOH ⊖

Conformation of UDS

- Required by SMBO and national guidelines
- 10-15 min to review discuss with Pharm. D. consultant and correlate with OARRS, H&P and other assessments

AEGIS PAINCOMP
Pain Medication Compliance Testing

Laboratory Report

Laboratory Director, Sheila Dowling, PhD CChem FRSC
CLIA Number 44D1083416
515 Great Circle Road Nashville, TN 37228
(615) 255-2400 - Fax (615) 255-3030

Clinic Information
Client: Leon Margolin, MO
5245 E. Main St.
Columbus, OH 43213
Requesting Provider:
Leon Margolin

Patient Information
Patient Name: [redacted]
Patient ID: [redacted]
Date of Birth: [redacted]
Male/Female: Male

Sample Information
Lab Sample ID: 33282983
Specimen Type: Urine
Collected: 4/6/2015
Received: 4/7/2015
Reported: 4/9/2015

Medication(s) Prescribed
Oxycodone

Test(s) Requested
00197IU - OMP Plus D/L 04440r - Marijuana Confirmation

Result(s)/Interpretation(s)/Comment(s)

Drug and/or Metabolites	Result Interpretation	Normalized Result	Comment
Oxycodone	COMPLIANT	302 ng/mL	Test result is consistent and expected with prescribed drug

Tested For	Result	Normalized Result
Buprenorphine	NONE DETECTED	
Amphetamines	NONE DETECTED	
Barbiturates	NONE DETECTED	
Benzodiazepines	NONE DETECTED	
Cannabinoids (Marijuana)	NONE DETECTED	
Gabapentin/Pregabalin	NONE DETECTED	
Cocaine Metabolite	NONE DETECTED	
Opiates		
Noroxycodone	POSITIVE	
6-Monoacetylmorphine	NONE DETECTED	302 ng/mL
Methadone	NONE DETECTED	
Meperidine	NONE DETECTED	
Fentanyl Analogues	NONE DETECTED	
Carbamazepin/Metabolite	NONE DETECTED	
Tramadol	NONE DETECTED	

Specimen Validity Testing	Normal Range	Result	Comment
Specific Gravity	≥1.0020	1.0057	NORMAL
Creatinine	≥2 mg/dL	43 mg/dL	NORMAL
pH	3.5 - 9.0	6.1	NORMAL
Chromates	< 50 mcg/mL	<50 mcg/mL	NORMAL
Nitrites	< 200 mcg/mL	<200 mcg/mL	NORMAL

Additional Comments

Previous test date for [redacted] was 02/16/2015

Note: Urine drug and metabolite concentrations do not correlate with blood drug concentrations or medication dosage. Aegis Sciences Corporation does not compare urine drug and metabolite concentrations to the dose of drug prescribed or administered to the patient. Normalized results have been calculated using a factor that adjusts the original results up to those of an ideal urine with a specific gravity equal to 1.0200. Alcohol and alcohol metabolites are not normalized.

Aegis PainComp® Reporting Thresholds can be found at www.aegislabs.com/PainCompThresholds

Please call 1 800 533 7052 if you require additional information.
Aegis® is certified by the US Department of Health & Human Services/Substance Abuse & Mental Health Services Administration
Copyright © 2015 Aegis Sciences Corporation All Rights Reserved

Activate Win
Go to Settings to

Educational Materials

- Review the SMBO and national guidelines requirements, educate and enhance compliance
- 5-10 minutes each (at least 2-3 educational materials per visit)

Opioid(Narcotic) Medicatio[illegible]ty Policy

Please refer to the patient agreement, consent for treatment and patient [illegible]es for detailed instructions. This policy is a brief reminder.

The **DOS** and **DONTS** of Opioid (Narcotic) Medications

DO:

- Read the Medication Guide.
- Take your medicine exactly as prescribed.
- Store your medicine away from children and in a safe place.
- Bring the unused medication to the office.
- Call your healthcare provider for medical advice about side effects.
- Please let us know about any changes in your medical history or medications
- Referrals for imaging studies (X ray, CT scan, MRI etc.) and other specialist evaluations may be required. Please schedule appointments and follow up on these referrals in a timely fashion.

DONT:

- Do not give your medicine to others
- Do not cut, break, chew, crush dissolve, snort or inject your medicine. If you can not swallow your medicine whole, please let us know
- Do not drink alcohol or use while taking this medicine
- Do not use any recreational substances
- Do not store/hoard unused narcotic medications at home

Call 911 or your local emergency service right away if:

- You take too much medicine.
- You have trouble breathing, or shortness of breath.
- A child has taken this medicine.

Talk to your healthcare provider:

- If the dose you are taking does not control your pain.
- About any side effects you may be having.
- About all the medicines you take, including over-the-counter medicines, vitamins, and dietary supplements.

I have read the conditions and terms stated above and have had all of my questions regarding these conditions and terms explained to my satisfaction. I have met the conditions, and I agree to honor all of the terms unconditionally. I agree that if I am unable to read or write that this policy has been verbally explained to me to my satisfaction. I also understand that if I violate any term of this policy, it is cause for the staff at Comprehensive Pain Management Institute to refuse prescriptions and/or treatment or discharge me from practice. I agree that if I am unable to read or write that this has been verbally explained to me to my satisfaction.

Patient Signature [signature] **Date:** 5/18/15

[redacted]

OPIOIDS, BENZODIAZEPINES, AND ALCOHOL

Opioid: Opioid analgesics, also known as narcotic analgesics, are pain relievers that act on the central nervous system. Like all narcotics they may become habit-forming if used long periods.

Benzodiazepines: Benzodiazepines are medicines that help relieve nervousness, tension, and other symptoms by slowing down the central nervous system.

Alcohol: Ethanol especially when considered as the intoxicating agent in fermented and distilled liquors, drink (as whiskey or beer) containing ethanol.

It is important that you understand that it is **NOT** acceptable for you to take narcotic medication and/or benzodiazepines and drink alcoholic beverages. Narcotic medications and benzodiazepines can be safely prescribed together in appropriate dosages. Use of alcohol along with a narcotic medications and/or benzodiazepines contributes to the increasing numbers of overdoses and death even when the narcotics/benzodiazepines is associated have risk factors of increasing respiratory depression, pre-existing COPD and sleep-disordered breathing problems. There is also a risk of increase in renal or hepatic (liver) impairment (please see the consent for treatment, patient contract and the guidelines for treatment).

IF YOU TEST POSITIVE FOR ALCOHOL ON A URINE DRUG SCREEN, YOU MAY BE DISMISSED FROM THE PRACTICE AND OR REQUIRE ADDITIONAL EVALUATION AS PER PATIENT CONTRACT AND THE GUIDELINES FOR TREATMENT.

IF YOU HAVE A DRINKING PROBLEM AND YOU NEED HELP OR HAVE OTHER QUESTIONS, YOU MAY SPEAK TO EITHER LYDIA FLECK OR DR. MARGOLIN IN TOTAL CONFIDENCE.

5/18/15

Patient Name: Edwards, Harry INS: Medicare/TriCare DOB: 01/28/1984 Date: 05/18/2015

Please Note

Drug Testing Policy.

If you are being evaluated for controlled medications to manage the pain you are asking us to treat, we will continue doing **compliance checks** (drug, oral fluid or blood screens) randomly or as indicated. Every person who is evaluated for controlled medications from our office will need to undergo this testing on a random basis. No exceptions are allowed per the guidelines.

The testing is done in the office and confirmed by an outside laboratory using an extremely reliable method. If the test results show any unusual results (examples: prescribed medications not present as expected, or other non-reported controlled medications or chemicals are present), we will not be able to prescribe any controlled medications to you and might remove ourselves from your care.

If you cannot or will not give us a sample for testing within a reasonable period of time on the day we request the sample, we will not be able to prescribe any medications and will not be able to participate in your care any longer.

Patient Signature: _____ Date: 5/18/2015

32 Comliance Video

Screened in the office frequently.

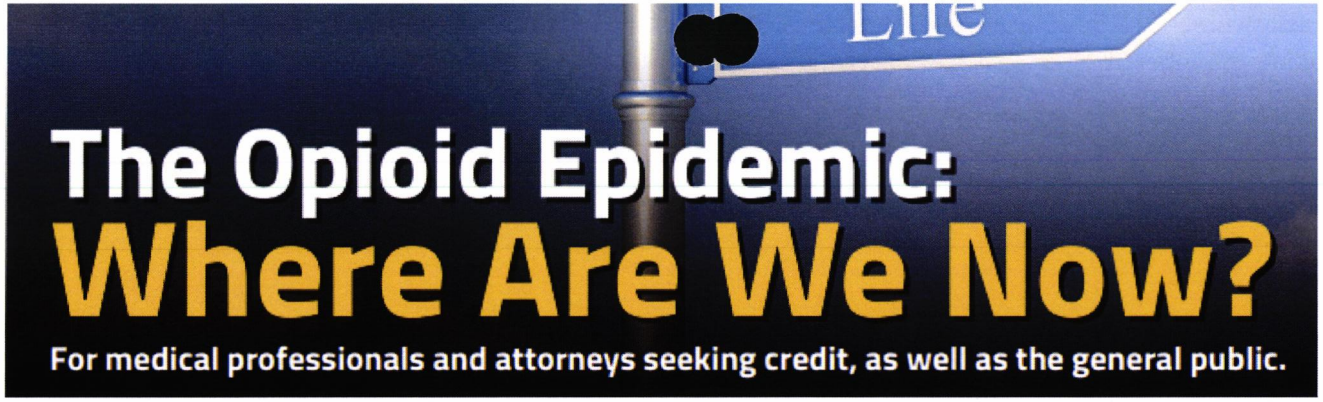

GUIDELINES FOR OPIOD USE
Comprehensive Pain Management
0:02 / 32:36
Scroll for details
Activate Windows
Go to Settings to activate Windows.

G CODE SUMMARY

- All G codes billed appropriately according to the CPT definition of the code
- Medicare has no limitation on the frequency
- High frequency of G codes in our practice explained by low frequency of E/M level 3 or 4 codes (assessment performed but not billed)
- We did not bill additional time codes (spending 1h or more frequently for assessing high risk patients)
- In summary, we chose appropriate medically necessary codes that saved a lot money for Medicare and helped to provide of high quality care to patients.
- The time spent is clearly documented based on the accepted national standards.

CWSM CME presentation

- We invited to share our experience with SBIRT G code protocol at the event sponsored by the Case Western University, Academy of Medicine, University Hospitals and ADAMHS board of Cuyahoga county



The Opioid Epidemic: Where Are We Now?

For medical professionals and attorneys seeking credit, as well as the general public.

Sunday, December 8, 2019
9:30 a.m.–4:30 p.m.

Siegal Lifelong Learning
Landmark Centre Office Building
25700 Science Park Dr., Suite 100
Beachwood, OH 44122

Keynote Speaker:
Nicole Labor, DO
Medical Director
OneEighty

$75/professional credit
$25 General Public

This CME activity has been approved for 5 AMA PRA Category 1 Credit™

CLE pending for 5 credit hours

Thank you to the many organizations that have helped make this program possible: Cleveland Clinic, MetroHealth System, University Hospitals and the ADAMHS Board of Cuyahoga County.

In the immortal words of Bob Dylan: "how many deaths will it take till he knows, that too many people have died?"

I can assure you, the answers are not blowing in the wind. Some of the answers, however, will be identified at this one-day seminar.

Declared the worst epidemic of our time in 2014, the opioid epidemic, addiction and mental health have become a central part of our conversation in hospitals, doctors' offices, courtrooms, and at our own kitchen tables. What has changed in the last five years, and what still needs to change? Join us to hear from the doctors, nurses, psychologists, judges, and lawyers who are on the front lines analyzing and assessing what works to help those suffering from the disease of addiction and updating our systems so this problem is not perpetuated. It is imperative for all of us to continue to work collaboratively to make a change in the battle against addiction.

"how many deaths will it take till he knows, that too many people have died?"

Join us and discover how you can become part of the solution!

REGISTRATION REQUIRED:
216.368.2091 or **https://case.edu/lifelonglearning/addiction**

Questions? Contact Sheryl Hirsh at 216.368.4623

This conference is co-sponsored by the Academy of Medicine Education Foundation and made possible by the generous support of Karen and Richard Spector, and the Melissa Rae Fund in Support of Addiction Education, Understanding and Change.

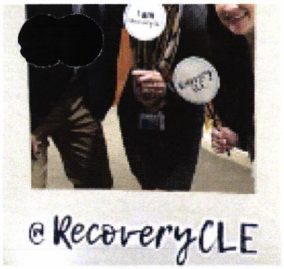
AMEF
Academy of Medicine Education Foundation

SCHOOL OF MEDICINE
CASE WESTERN RESERVE UNIVERSITY

CASE WESTERN RESERVE UNIVERSITY
THE LAURA & ALVIN SIEGAL LIFELONG LEARNING PROGRAM







Agenda

9:30–10 a.m.
Registration

Speakers/Panels
10–11 a.m.
Keynote Speaker:
Nicole Labor, DO
Medical Director for OneEighty
The Science of Addiction

The Individual Legally
11 a.m.–12 p.m.
Justin Herdman
United States Attorney for the Northern District of Ohio

Patti London
Attorney, Cuyahoga County Public Defender's Office

Brian Hoffman
Attorney, Cuyahoga County Public Defender's Office

Judge Joan Synenberg
Cuyahoga County Court of Common Pleas and Cuyahoga County Recovery Court

12–1 p.m.
Lunch
Buffet lunch included

The Individual Medically
1–2 p.m.
Jennifer Bailit, MD, MPH
Maternal-Fetal Medicine, MetroHealth System

Andy Getz
LISW-S-Grief Counselor

(1–2 p.m. panel continued)
Ted Parran, MD
Internal Medicine, Addiction Medicine, Isabel and Carter Wang Professor and Chair in Medical Education, CWRU School of Medicine St. Vincent Charity Medical Center

Leon Margolin, MD, PhD, FAPM
Comprehensive Pain Management Institute

Jessica McCullough, APRN
APRN Addiction Fellow; PhD Student, Case Western Reserve University

The Systems
2:15–3:15 p.m.
Christine Antenucci, MD
MetroHealth System

David Brager
Psychiatric Nurse Practitioner, Center for Families and Children

Joan Papp, MD, FACEP
MetroHealth System

David Streem, MD
Psychiatric Medicine, Cleveland Clinic; Incoming Chair, Northeast Ohio Hospital Opioid Consortium

Where Are We Going?
Final Questions
3:30–4:30 p.m.
Scott S. Osiecki
CEO, ADAMHS Board of Cuyahoga County

Christine Delos-Reyes, MD,
Chair
Associate Professor of Psychiatry, Case Western Reserve University School of Medicine; Addiction Psychiatry Fellowship and Addiction Services, University Hospitals Cleveland Medical Center

Sheryl Hirsh,
Program Coordinator Community Advocate; Assistant Director of Jewish Learning, Siegal Lifelong Learning Program at Case Western Reserve University

Joan Papp, MD, FACEP,
MetroHealth System

Jessica McCullough, APRN,
APRN Addiction Fellow; PhD Student, Case Western Reserve University

David Brager
Psychiatric Nurse Practitioner, Center for Families and Children

Case Western Reserve University School of Medicine is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

Case Western Reserve University School of Medicine designates this live activity for a maximum of *5 AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Case Western Presentation

- “Comprehensive Pain Management Institute (CPMI) developed Screening and Brief Intervention (SBRIT) protocol that helps to screen and stratify risk for complex patients and address aberrant drug seeking behavior. The SBIRT protocol includes several assessments: H&P (level 3 or 4 E/M visit), PADT, SOAPP-R, COMM, Rule 4731 Flowchart, POC and conformation UDS, OARRS review and input from other specialties (i.e. pain psychology and clinical pharmacology). CPMI was able to reduce the cost for the third party payers by utilizing the low cost G0397 codes instead of more expensive office visit and time codes. In addition, CPMI made significant progress in utilizing imaging and electrodiagnostic studies in documenting organic pathology and per CDC and SMBO guidelines. As a result of these developments, CPMI enjoys referrals from major hospitals including OSU, Riverside, Grant, Mt Caramel, Adina Health System and University Hospitals.”

C

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS) (collectively, the "United States"), and Leon Margolin, M.D. and Comprehensive Pain Management Institute, LLC (CPMI) (together, Defendants) (hereafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

A. Leon Margolin is an interventional pain physician in Columbus, Ohio. He owns and operates CPMI. Margolin performs a variety of pain management and diagnostic procedures, including nerve conduction studies (NCS) and alcohol/substance abuse structured assessments and brief interventions of 30 minutes of longer, under code G0397 (referred to below as, "SBIRT").

B. The United States contends that Margolin submitted or caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll ("Medicare").

C. The United States contends that it has certain civil claims against Defendants arising from their knowingly submitting, or causing to be submitted, false claims to Medicare during the period from January 1, 2013 through September 19, 2019 for: (1) NCS that were medically unnecessary because the patients did not need them and/or the studies were performed without electromyography, and (2) SBIRTs that were medically unnecessary and/or not provided as billed. That conduct is referred to below as the "Covered Conduct."

D. This Settlement Agreement is neither an admission of liability by Defendants nor a concession by the United States that its claims are not well founded.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Defendants shall pay to the United States $650,000 ("Settlement Amount") plus interest at a rate of 1.75 percent *per annum* from January 1, 2020, of which $325,849.00 is restitution. Defendants shall pay $450,000 of the total Settlement Amount no later than ten days after the Effective Date of this Agreement and shall pay the remaining $200,000 plus interest within four months of the Effective Date of this Agreement. Defendants shall make these payments by check pursuant to written instructions to be provided by the Civil Division of the United States Department of Justice.

2. Subject to the exceptions in Paragraph 3 (concerning excluded claims) below, and conditioned upon Defendants' full payment of the Settlement Amount, the United States releases Defendants, together with CPMI's current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; current or former corporate owners; and the corporate successors and assigns of any of them, from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

3. Notwithstanding the release given in Paragraph 2 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any criminal liability;

c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory or permissive exclusion from Federal health care programs;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Any liability based upon obligations created by this Agreement;

f. Except as explicitly stated in this Agreement, any liability of individuals; and

g. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

4. Defendants waive and shall not assert any defenses Defendants may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

5. Defendants fully and finally release the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Defendants have asserted, could have asserted, or may assert in the future against the United States, and its agencies, officers, agents, employees, and servants related to the Covered Conduct and the United States' investigation and prosecution thereof.

6. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier) or any state payer, related to the Covered Conduct; and Defendants agree not to resubmit to any Medicare contractor or any state payer any previously denied claims related to the Covered Conduct, agree not to appeal any such denials of claims, and agree to withdraw any such pending appeals.

7. Defendants agree to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Defendants, including CPMI's present or former officers, directors, employees, shareholders, and agents in connection with:

(1) the matters covered by this Agreement;

(2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;

(3) Defendants' investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);

(4) the negotiation and performance of this Agreement; and

(5) the payments Defendants make to the United States pursuant to this Agreement

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Defendants, and Defendants shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Defendants or any of CPMI's subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Defendants further agree that within 90 days of the Effective Date of this Agreement they shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Defendants or any of CPMI's subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. Defendants agree that the United States, at a minimum, shall be entitled to recoup from Defendants any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The

United States reserves its rights to disagree with any calculations submitted by Defendants or any of CPMI's subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Defendants' or any of CPMI's subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Defendants' books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

8. Defendants agree to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Defendants shall encourage, and agree not to impair, the cooperation of CPMI's directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Defendants further agree to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that they have undertaken, or that has been performed by another on their behalf.

9. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 10 (waiver for beneficiaries paragraph), below.

10. Defendants agree that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

11. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

12. Each Party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

13. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Southern District of Ohio. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

14. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

15. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

16. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

17. This Agreement is binding on Defendants' successors, transferees, heirs, and assigns.

18. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

19. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 1/22/2020 BY: _____

CHRISTOPHER G. WILSON
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 1/22/2020 BY: _____

MARK T. D'ALESSANDRO
Civil Chief

ANDREW M. MALEK
Assistant United States Attorney
United States Attorney's Office
for the Southern District of Ohio

DATED: 01/21/20 BY: _____

LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

MARGOLIN AND CMPI - DEFENDANTS

DATED: 01/15/2020 BY: _____
LEON MARGOLIN, M.D.

Individually and on behalf of Comprehensive Pain Management Institute, LLC

DATED: 1.15.20 BY: _____
NICK OBERHEIDEN

Counsel for Margolin and Comprehensive Pain Management Institute, LLC

D

->

Comprehensive Pain Management Institute, LLC

Medical and Interventional Pain Management
5245 East Main Street, Columbus, Ohio 43213
Phone: 614.367.1654; Fax: 614.453.8222

10/18/19

Attn: Christopher G. Wilson Esq.

By e mail: Christopher.G.Wilson@usdoj.gov

ear Mr. Wilson,

lease find two additional expert letters attached. As we discussed during my PowerPoint presentation we have been fully compliant with the CID procedures, we have produced more than 35,000 documents and prepared a detailed PowerPoint presentation and we want to confirm our commitment of compliance in the future.

Our practice representative contacted AANEM and received a written clarification from Millie Sulk, JD, MPP, AANEM Health Policy Director stating that "AANEM does not have any "best practices" established for pain management" and that AANEM endorses AAPMR policies.

We provided a detailed study ABPMR (certifying body of AAPMR) that analyzed all the CID charts, provided a clear scientific proof of medical necessity and showed our full compliance with the state and national guidelines. This study was validated by the top experts in the field (Professor Kimura and Professor Wainepal).

We also provided independent certified billing and coding expert reviews (2012-2015) that confirm compliance of our billing practices.

In addition, I attached to this letter the expert report from Dr. William Vasilakis PhD who is a clinical pain psychologist, the former director of the department of Addiction Medicine at Lancaster Hospital) who treated most of the patients in the CID list and is closely familiar with our NCV/EMG consent policy and SBIRT/G code protocol.

I also attached expert letter of Michael Staples (former SMBO investigator and police detective) provides a detailed eport based on onsite voluntarily self-audit that explains how our policies and practices (including EMG/NCV protocol

and SBIRT protocol) are necessary to comply with the state law and SMBO regulations (of note MLN (ICN 904084) requires a physician to create the SBIRT protocol in compliance with the state law).

At the same time we are not aware of any expert opinions that lead the CID team investigation. This a very complex area of medicine that involves high risk vulnerable patients that cannot be evaluated based on the statistical extrapolations and financial objectives without proper clinical expert guidance.

For example, we find it concerning that we are challenged on the necessity of our SBIRT protocol(G codes) procedures that are required by the state law (please review Michael Staples attached) . At the same time, our practice is invited by the leading experts to present our SBIRT protocol procedures at the state and national meetings to other physicians in the field. These procedures include face to face time spent by physician and the nurse practitioners, more that 30 min of telecommunication video material, structured review of several assessments including patient's history and physical examination, PADT, COMM, Flowchart form based on SMBO Administrative Rule 4731-21-02, withdrawal assessment form, point of care and conformation urine and saliva drug screen reviews, OARRS reviews, and several educational materials. The initial evaluations include additional assessments such as SOAPP-R and ORT and additional educational materials.

Denial payments for the appropriate testing and screening procedures for drugs and alcohol required by the state and national guidelines would not only significantly impact CPMI's ability to function as a business, but would also put an extremely vulnerable patient population at risk. Our patient population is unique as compared to many of my peers. Our patients are extremely complex; we take pride in creating individualized treatment plans which do require a significant amount of testing and time for screening for substance and alcohol use. However, this allows our patients to achieve an extraordinary level of function relative to managing their pain and prevent morbidity and mortality. The quality of care we provide resulted in several clinical awards (i.e. Patient Choice Award, Most Compassionate Doctor awards for several years, 2019 "Top 10" Ohio physician award in Pain Medicine) and referrals we get from major hospitals such as OSU Medical Center, Riverside, Grant, Mt Carmel, Adina Health and University Hospitals in Cleveland and even other pain management practices.

Our practice has already run into a 6 figure cost for this protracted investigation, productivity loss and significant time investment in the review and production of more than 35,000 documents that have already taken a toll on our ability to operate, manage records and treat our patients (as you know, we are a small independent practice).

Many of our patients are opioid-dependent, if their medications are not timely reviewed, this can cause patient morbidity incident to abruptly stopping treatment.

As you know, it is difficult for many patients to find alternative providers. If left untreated, patients may turn to illicit means of obtaining substitute medications which drastically increases the risk of overdose and death (overdose death rate in Ohio is the highest in the nation and is up more than 800% since 2013). The cost of the opioid epidemic is estimated as more the 600 billion nationwide, we run a low cost program that saved hundreds of thousands of dollars to Medicare by identifying and referring for addiction treatments hundreds of patients using our SBIRT protocol. We billed much lower rates than comparable hospital based programs and chose lower cost codes (i.e. G codes vs. office visit and time codes).

In summary, denial payments for the appropriate testing and screening procedures for drugs and alcohol puts in danger about several hundred high-risk patients. As we discussed during my PowerPoint presentation, as a physician and medical director that is committed to the ethical treatment and care of my patients, I have a duty and obligation to xpress these concerns without fear of retaliation.

I will enclose this letter to my compliance policy and will have to generate appropriate notes in the charts of the patients at risk and may need to take additional appropriate steps (as per state and federal guidelines) to ensure safety of this vulnerable patient population.

Our practice is in the forefront of the "opioid epidemic" fight. We hope to see Medicare and DOJ as an ally in this fight acting in compliance with the HHS 5 point strategy, rather than an adversary who tries to avoid payments for the appropriate services, so we can benefit the care and safety of our patients.

Sincerely,

Leon Margolin, M.D., Ph.D.

A

LW

LYNN R. WEBSTER, M.D.
SALT LAKE CITY, UT

RE: Leon Margolin M.D. PhD
5245 E Main ST. Columbus
Ohio 43213

To Whom It May Concern:

I am writing to offer my strong support for Dr. Leon Margolin's advocacy for universal Screening, Brief Intervention, and Referral to Treatment (SBIRT) for all patients prescribed opioids, especially those at high risk, as well as his use of electrodiagnostic studies (NCS/EMG) to document organic pathology, such as neuropathic pain, in complex pain patients. As a board-certified anesthesiologist, pain medicine physician, and addiction specialist with over 30 years of experience, I have seen firsthand the value of these tools in enhancing patient safety, ensuring proper opioid prescribing, and improving outcomes. I am an authority on screening tools for substance use disorders for patients being considered opioid therapy.

SBIRT is a critical component of responsible opioid prescribing. By screening patients for risk factors such as substance misuse, intervening early, and referring them for additional support, when necessary, SBIRT helps mitigate the risks associated with opioid therapy. SBIRT reduces healthcare costs, decreases substance misuse, and lessens the likelihood of overdose. This tool is particularly vital in high-risk populations, who are often at a greater risk of addiction and adverse outcomes from opioid treatment. By integrating SBIRT as a universal precaution, we can enhance our ability to identify patients needing additional support, ultimately improving patient safety and care continuity.

The U.S. government, specifically the Substance Abuse and Mental Health Services Administration (SAMHSA), actively supports the use of SBIRT by providing funding for states, territories, and tribal organizations to implement SBIRT programs in various healthcare and community settings. SAMHSA funds training and technical assistance to support SBIRT implementation across healthcare practices, underscoring the recognized value of SBIRT as a proactive approach to substance misuse prevention.

Adopting these methods as standard practice offers a powerful approach to managing the complexities of opioid prescribing and chronic pain treatment. SBIRT and electrodiagnostic studies collectively provide a framework for comprehensive risk management, allowing providers to make well-informed decisions about pain management. These tools not only help ensure medical necessity for opioid use but also support providers in adhering to best practices and legal standards, safeguarding patient care and reducing liability.

I offer this letter of support freely and without compensation, drawing upon my background as a co-founder of the Utah Academy of Pain Medicine, past president of the American Academy of Pain Medicine, and current Senior Fellow at the Center for U.S. Policy, where I work on issues related to pain management and opioid safety. With over 300 peer-reviewed publications, multiple NIH and FDA engagements, and three decades of clinical research and education in pain and addiction medicine, I am confident that Dr. Margolin's approach will enhance patient care and set a high standard for safe, responsible opioid prescribing practices.

Thank you for considering this endorsement of Dr. Margolin's proposals to strengthen patient safety and opioid prescribing standards.

Warm regards,

L.R. Webster MD

Lynn Webster M.D.

801.560.1707
LRWEBSTERMD@GMAIL.COM

B

WV
William Vasilakis, PsyD
Clinical Psychologist #5481

01/14/2025

RE : Comprehensive Pain Management Institute, LLC (CPMI)

Leon Margolin M.D. PhD,
5245 E Main ST. Columbus, Ohio 43213

To Whom It May Concern:

I am writing to offer my strong support for Dr. Leon Margolin's practice, publications and advocacy for public safety via universal Screening, Brief Intervention, and Referral to Treatment (SBIRT) for all patients prescribed opioids especially those at high risk, as well as his use of electrodiagnostic studies (NCS/EMG), autonomic studies to document organic pathology, such as neuropathic pain, in complex pain patients, procedures and other services of his program.

I am a licensed psychologist, who has certification in Addiction Medicine and has taken training in pain management counseling and evaluation. I had been a clinical director of a recovery program for Fairfield County, Ohio (please find my resume enclosed).

I have evaluated and followed up hundreds of Dr. Leon Margolin's patients (including the patient charts reviewed by the government regulators and the insurance companies), however, I am not (and never was) an employee, colleague, or social friend of Dr. Margolin; I have never received any payment or remuneration for my expert reviews or Dr. Margolin and his practice .

Dr. Margolin and his program enhance our ability to safely manage high risk patients needing opioids medications, ultimately improving patient safety and reducing opioids mortality .This are supported by my clinical experience, independent studies and studies and publication by Dr. Margolin and his team. I fully endorse Dr. Margolin's presentations and publications (see www.cpmiohio.com) based on my own clinical experience in the field of addiction and pain medicine in Ohio.

As a board-certified clinical psychologist, who has certification in addiction medicine with over 30 years of practice in OH, I have seen firsthand the value of Dr. Margorin's practice and the CPMI services in enhancing patient safety, documenting organic pathology, ensuring proper opioid prescribing, and improving outcomes (please find my resume enclosed).

Denial of such services or falsely labeling them as "unnecessary" puts the public at a significant risk. Since SBIRT helps to diagnose alcohol and drug use and aberrant drug seeking behavior, false labeling of the SBIR and other services, provided by Dr. Margolin,

740.503.8193
w.vasilakis@gmail.com

as "unnecessary" or "allowed only for patients with documented history of drug and alcohol abuse" is absurd. It is dangerous and can be responsible for hundreds of opioid deaths in Ohio. These services are supported by the evidence-based data published by NIH, SAMSHA, NIDA, Pew Institute and other agencies. In addition, these services and programs are cost effective and save limited Medicare and Medicaid resources.

Based on the review of the national academy (ABPMR) and the peer reviewed Dr. Margolin's publication with Dr. Streem (Director of Drug and alcohol services, Cleveland Clinic Foundation), Dr. Margolin's program has diagnosed and referred to addiction medicine evaluation more than 3000 patients since 2011 saving several hundred lives and a very significant health care costs. In fact, Dr. Margolin was awarded the Ohio Top Doctor award for 2025 specifically for his excellence in the pain management program and the use of the SBIRT .

I think Dr. Margolin has created one of the best SBIRT programs in the state of Ohio which is medically necessary and fully compliant.

SBIRT is a critical component of responsible opioid prescribing. By screening patients for risk factors such as substance misuse, intervening early, and referring the patients for additional evaluation support, when necessary, SBIRT helps diagnose aberrant drug seeking behavior and save lives. SBIRT reduces healthcare costs, decreases substance misuse, and lessens the likelihood of overdose. This tool is particularly vital in high-risk populations regardless of documented prior history of addiction, alcohol or drug use, who are often at a greater risk of adverse outcomes from opioid treatment (like the patients in Dr. Margolin's practice). We have to integrate the SBIRT as a universal precaution, and a standard of care required by the DOJ MATE act, SAMSHA, HHS, and other state and federal regulations.

The U.S. government, specifically the Substance Abuse and Mental Health Services Administration (SAMHSA), actively supports the use of SBIRT by providing funding for states as a mandatory, standard of care proactive approach to substance misuse prevention that saves lives.

I personally evaluated most of the patients that has NCS/EMG eletrodiagnostic testing at the CPMI/ DR. Margolin between 2012 and 2020, and I can attest to the complexity of this patients. Many of these patients who were on anticoagulation medications had significant psychopathology such as anxiety, depression, bipolar disorder, PTSD that made the invasive test like needle EMG not possible and I recommended against the invasive needle testing. I also supported Dr. Margolin's practice of written consent for these procedures. To the best of my knowledge CPMI/Dr. Margolin is the only practice in Ohio that implemented I*CARE MD Anderson excellence in patient communication protocol. I requested and received CPMI medical records on hundreds of patients. The records were provided efficiently, timely and in full compliance with HIPAA and 42 CFR part 2.

Services and methods provided by CPMI/Dr. Margolin are mandatory evidence based standard practice that offers a powerful approach to managing the challenges and the complexities of opoid pain and chronic pain treatment while effectively screening for aberrant drug seeking behavior.

740.503.8193
w.vasilakis@gmail.com

In summary, the CPMI/ Dr.Margolin program that include SBIRT, office visits, electrodiagnostic and autonomic studies, procedures, patient education, psychological assessments and interventions collectively provide a framework for comprehensive risk management of patients on opioids medications that saves patient lives.

I offer this letter of support freely and without compensation, drawing upon my background and 30 years of experience of addiction and pain medicine in the state of Ohio. I laud Dr. Margolin commitment to research and public advocacy. Dr. Margolin used his own personal funds for research and free patient and public educational videos.

I am confident that Dr. Margolin's approach and research will enhance patient care and set a high standard for effectives patient screening safe, responsible opioid prescribing, reducing opioids mortality and saving limited healthcare resources.

Warm regards,

William Vasilakis, Psy.D.

William Vasilakis, PsyD

740.503.8193
w.vasilakis@gmail.com

William H. Vasilakis, Psy.D.

130 Tarkiln Road
Lancaster, OH 43130
1-740-503-5455

PROFESSIONAL EXPERIENCE

Hocking Valley Community Hospital
Logan Ohio
Work with geriatric population, counsel veterans and perform Gastric Bypass evaluation, pain management evaluations. Current

Apex Counseling
Ph: 614-751-1090
General counseling, psychological testing, forensic evaluations and custody evaluations, Pain management (Spinal Stimulator Evaluations), Work with LHI (Logistics Health Institution) evaluating candidates for military service. Current

Integrity Psychological Counseling, Inc 2005-2012
42 Hill Road South Pickerington, Oh 43137
Private Practice specializing in forensic evaluation, dual diagnosis, addictions, counseling, competency evaluations, psychological evaluations, Impaneled with Tricare for referrals with current service personal and veterans PTSD diagnosis and counseling with veterans of WWII, Vietnam, Desert Storm
Legal work for Fairfield County Court System.
Bariatric & Gastric Bypass Evaluation, Spinal Stimulator Exams

Senior Life Consultants 2006-2011
6465 Reflections Drive, Suite 110
Dublin, OH 43017
Nursing Home evaluations, counseling geriatric population, consultation with physicians competency evaluations

Circleville Juvenile Correctional Facility 2006 - 2007
640 Island Road Circleville OH 43113
Clinical Experience: Psychology Supervisor.
Responsible for program development, scheduling, supervision of staff and caseloads, overall clinical management of institution, responsible for QI implementation and testing, and supervision of units.

River Valley Counseling 2001 - 2005
131 N. Ewing Street, Lancaster, OH 43130
Clinical Experience: Adult and adolescent individual and family psychotherapy, specialize in dual diagnoses; bariatric evaluations, spinal stimulator evaluations and evaluations for rehab, assessments for work injuries. BWC evaluations

Fairfield Medical Center 2001 -2012

401 North Ewing Street, Lancaster, OH 43130
Affiliate Staff Psychologist: Consultations, evaluations, therapy and triage of patients admitted to the Behavioral Health Unit.

Drug & Alcohol Recovery Center of Fairfield County 2000 -2001
1856 Cedar Hill Road, Lancaster, 01143130
Clinical Experience: Clinical Director: Responsible for program development, supervision of staff caseloads, crisis work, responsible for Q.I. implementation, and overall clinical management of agency.

Maryville Academy City of Youth 1996 - 1999
1150 North River Road, Des Plaines, Illinois 60016

Clinical Experience: Caseload involved assignment to two diagnostic group homes with youth and adolescents ages 7 years to 18 years. Tasks included psychological testing, individual therapy, develop group therapy for both group homes, court appearances on behalf of the youth, and staff training, and recommended alternate and additional placement and crisis intervention.
Doctoral Internship Jan. 1995 to Jan. 1996

Alexian Brothers Medical Center-Niehoff Mental Health Unit
995 Beisner Road, Elk Grove, Illinois 60007
Supervisor John Noto, PH.D.
Clinical Experience: Psychological testing, psychological reports, individual assessments, diagnosis, in-patient admissions, case management, supervision of practicum students, led groups for substance abuse and dual-diagnosis.

Samaritan House-Outpatient Adolescent Addictions 1994 - 1994
999A Leichester Road, Elk Grove, Illinois 60007
Supervisor: John Noto, Ph.D.
Clinical experience: Led adolescent addiction therapy groups, parent education groups, psychological testing, led multi-family educational groups, drug screens.

Alexian Brothers Medical Center-Addictions Treatment Center. 1993 - 1993
800 Beisterfield Road, Elk Grove, Illinois 60007
Supervisor Joan Stiech, RN CSADC
Clinical Experience: Coed psychotherapy groups, individual therapy, drug screens, intake und admissions, lecturer in addiction lectures series.

EDUCATIONAL BACKGROUND:

CHICAGO SCHOOL OF PROFESSIONAL PSYCHOLOGY 2009- 2009
Degree Conferred: Certificate of Forensic Psychology

ADLER SCHOOL OF PROFESSIONAL PSYCHOLOGY

65 East Wacker, Chicago, Illinois 60601
Degree Conferred: Doctor of Psychology, (Psy.D.) Clinical Psychology 1991 - 1996
Certification : Substance Abuse Counseling

NORTHEASTERN ILLINOIS UNIVERSITY
5500 North Louis, Chicago, Illinois 60625
Degree Conferred: M.A. Community & Family Counseling Sep. 1984 to Oct. 1986
Degree Conferred: M.A. History Jan. 1981 to Dec. 1983

NORTHEASTERN ILLINOIS UNIVERSITY
5500 North Louis, Chicago, Illinois 60625
Degree Conferred: B.A. Psychology. Sep. 1977 to Jun. 1980

HARPER COLLEGE
1200 W. Algonquin Rd., Palatine, Illinois, 60067
Degree Conferred: A.A. Liberal Arts Jan. 1975 to Aug. 1977

LICENSURE AND CERTIFICATIONS
State of Ohio #5481
Certificate: Forensic Psychology
Certificate Substance Abuse Counseling
(Alder School of Professional Psychology) Apr. 1994 to Dec. 1994

PRESENTATIONS
-Psychological Needs of the Substance Dependent Patient
-Pain Management Team, Fairfield Medical Center, Lancaster, OH
-Identifying Drug Abusers and Pain Management Technique in Patients
-With a History of Drug Abuse, Pain Management Physicians, Fairfield Medical Center, Lancaster, OH
-Peer Pressure and Anger Management; Thomas Ewing Junior High School, Lancaster, Ohio
-"Catch Me If You Can—Obsessive Compulsive Disorder", and
-"Stress and Anxiety Disorder in the Adult Population" 12th Annual
-Early Childhood Conference, Ohio University, Lancaster Campus,
Sponsored By the Children's Committee,
a subcommittee of Fairfield County Family,
Adult and Children First Counsel
-"Competency Evaluation: presented to the Ohio State Bar Association, Lancaster, OH
-"Childhood Depression", interview for Medical Minute presented by WLOH Radio, Lancaster, OH
-"Signs and Symptoms of Childhood Depression: written for Lancaster Eagle Gazette through Fairfield Medical Center.
-Interview, Fairfield Focus, WLOH Radio, Lancaster, OH
-"Out of the Box" Workshop, presented with Dr. Miller and Dr. Wing

Ohio University Inn, Athens. OH
-"Emotional and Psychological Health: How to Support Employees",
Women's Division, Lancaster Chamber of Commerce, Presented at
Fairfield Medical Center, Lancaster, OH.

Book Written under Pseudonym T.L. Shull: Do They Have a Pill for That?
Publisher I Universe Press, March 2019.

C

As a fellow physician and consultant, I am deeply impressed by the approach Dr. Leon Margolin employs to train his staff using the principles and protocols outlined in the I CARE Communication Manual. His dedication to cultivating a patient-centered environment is evident in how he integrates evidence-based communication frameworks like C-L-A-S-S, S-P-I-K-E-S, and B-U-S-T-E-R to enhance staff proficiency in navigating complex patient interactions. These tools empower his team to approach every conversation—whether it involves breaking bad news, managing strong emotions, or discussing cultural competence—with empathy, clarity, and professionalism.

Dr. Margolin's commitment to excellence in communication is not only reflected in the theoretical underpinnings he adopts but also in the practical, hands-on training he offers. His focus on contextualizing conversations, actively listening, and providing clear summaries ensures that patients and families feel understood and supported. By teaching his staff how to engage in meaningful dialogue and validate patients' emotions, Dr. Margolin fosters a therapeutic alliance that extends beyond clinical care to genuinely holistic healing.

In a field where communication can significantly impact outcomes and patient satisfaction, Dr. Margolin's leadership sets a gold standard. His use of structured protocols not only builds staff confidence but also enhances the overall patient experience. I wholeheartedly endorse his methods as a model for other practices aiming to prioritize compassionate, effective communication in healthcare delivery. His work exemplifies how thoughtful leadership and rigorous training can elevate the standard of care in any clinical setting.

David J Norris, MD, MBA

THE
2022-23

Medical-Dental-Legal UPDATE

Medical Malpractice • Risk Management • Practice Management
Healthcare Law • Selected Clinical Topics

AMERICAN EDUCATIONAL INSTITUTE, INC.

401 South Old Woodward Ave. • Suite 333
Birmingham, Michigan 48009

1 800 354-3507
AEIseminars.com

David J. Norris, MD, MBA, CPE

David J. Norris, MD, MBA, CPE, of Wichita, Kansas, is a practicing cardiac anesthesiologist and maintains deep expertise in the communication, financial and organizational skills, as well as business processes, needed for effective, economical, and efficient delivery of high-quality patient care. He is currently medical director for the HCA Woodlawn Campus and is president of Wichita Anesthesiology. Dr. Norris is a frequent speaker on medical practice business, leadership and financial issues and is author of *The Financially Intelligent Physician*, with a short, weekly podcast of the same name, and *Great Care, Every Patient.*

You may learn more about Dr. Norris at www.davidnorrismdmba.com, and contact him with your questions and comments at david@davidnorrismdmba.com, or by phone at 316-200-2785.

THE FINANCIALLY INTELLIGENT PHYSICIAN
WHAT THEY DIDN'T TEACH YOU IN MEDICAL SCHOOL

David J. Norris, MD, MBA, CPE
316-200-2785 david@davidnorrismdmba.com

Emotional Intelligence - Improving Relationships with Staff and Patients

Better Relationships

Staff

Better Relationships

Staff

Co-workers

Better Relationships

Staff Patients

Co-workers

Better Relationships

Staff Patients

Co-workers

Family

Self awareness

Self awareness

Self control

Self awareness

Social awareness

Self control

Self awareness

Social awareness

Emotional Intelligence

Self control

Understand Yourself

Of all knowledge, the wise and good seek most to know themselves

- William Shakespeare

From there you can understand people

Understand Others

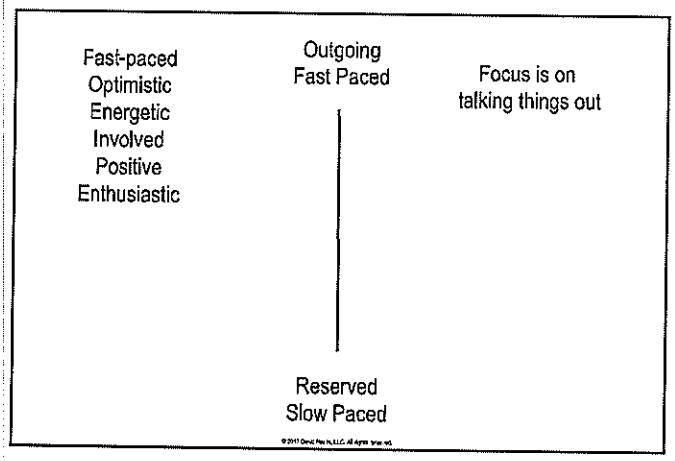
The biggest mistake you can make in trying to talk convincingly is to put your highest priority on expressing your ideas and feelings. What most people really want is to be listened to, respected, and understood. The moment people see that they are being understood, they become more motivated to understand your point of view.

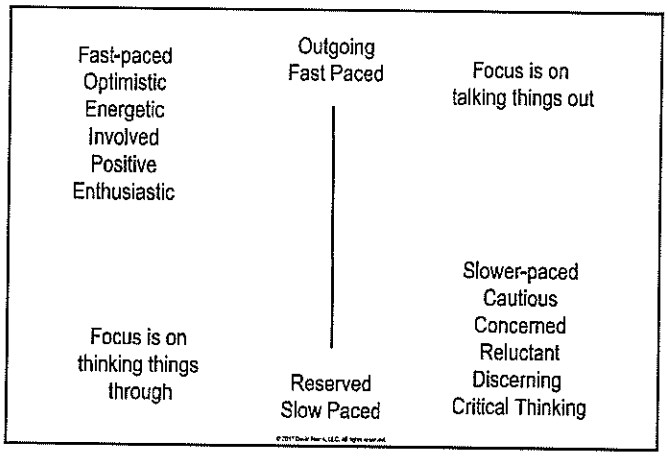
- Dr. David Burns, UPenn

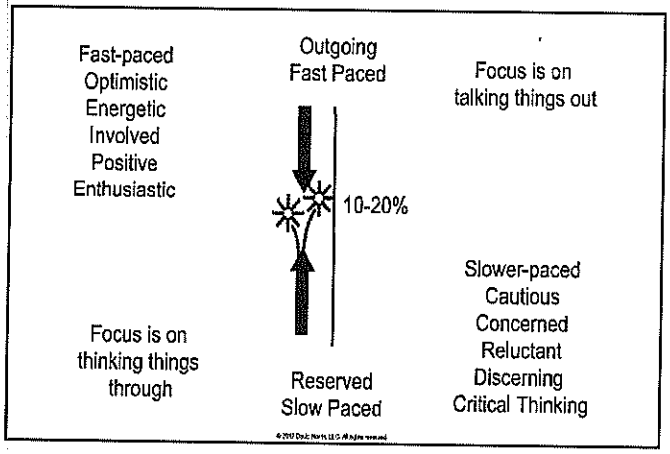
Understanding Yourself

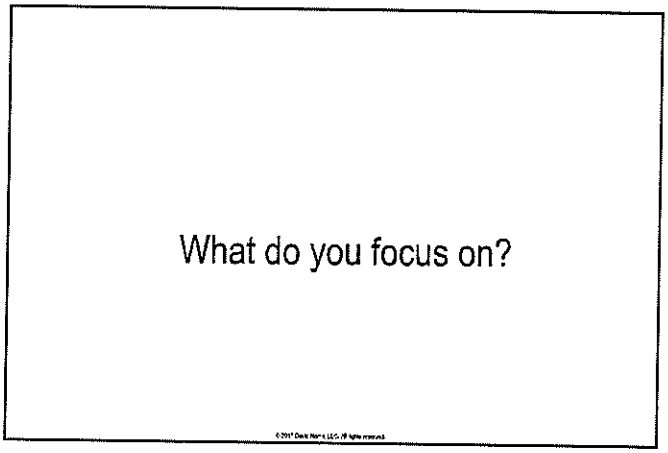
THE FINANCIALLY INTELLIGENT $PHYSICIAN

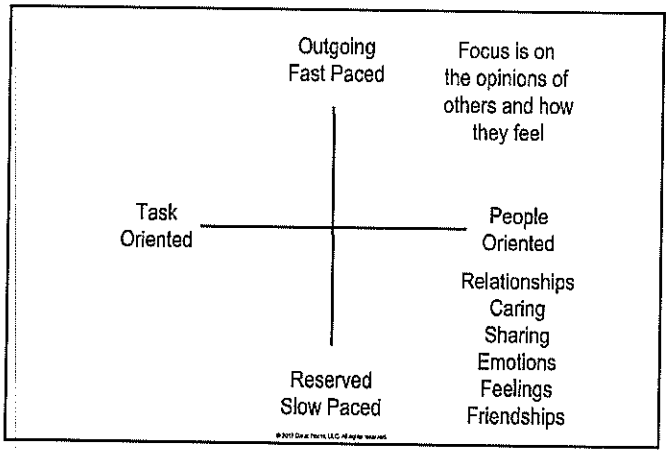
What's your pace?

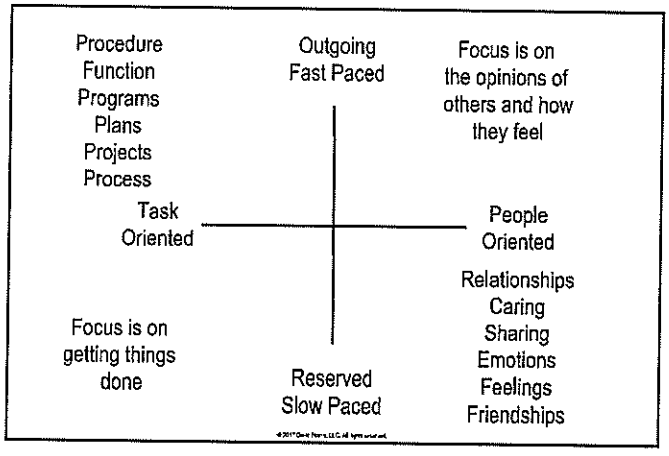

Fast-paced
Optimistic
Energetic
Involved
Positive
Enthusiastic
Outgoing
Fast Paced
Focus is on
talking things out
Reserved
Slow Paced

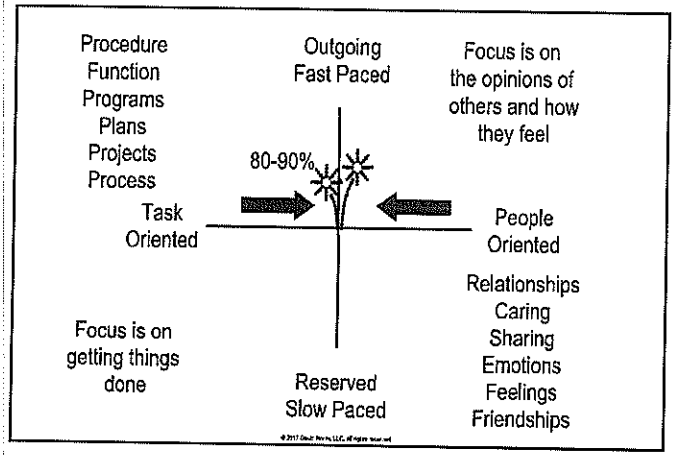

Fast-paced
Optimistic
Energetic
Involved
Positive
Enthusiastic
Outgoing
Fast Paced
Focus is on
talking things out
Slower-paced
Cautious
Concerned
Reluctant
Discerning
Critical Thinking
Focus is on
thinking things
through
Reserved
Slow Paced

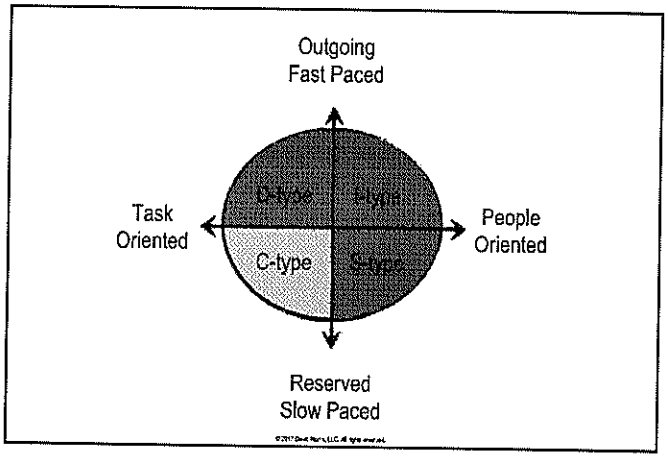

Fast-paced
Optimistic
Energetic
Involved
Positive
Enthusiastic
Outgoing
Fast Paced
Focus is on
talking things out
10-20%
Slower-paced
Cautious
Concerned
Reluctant
Discerning
Critical Thinking
Focus is on
thinking things
through
Reserved
Slow Paced

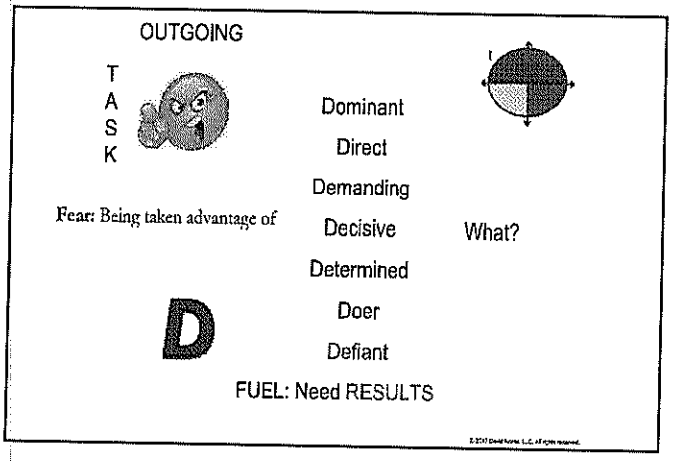

What do you focus on?

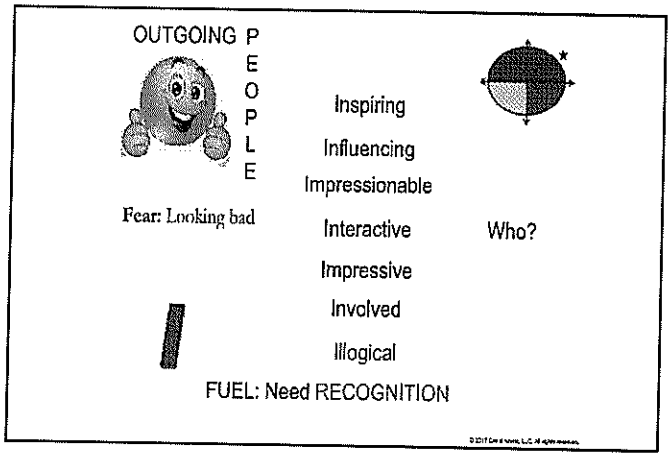

Outgoing
Fast Paced
Focus is on
the opinions of
others and how
they feel
Task
Oriented
People
Oriented
Relationships
Caring
Sharing
Emotions
Feelings
Friendships
Reserved
Slow Paced

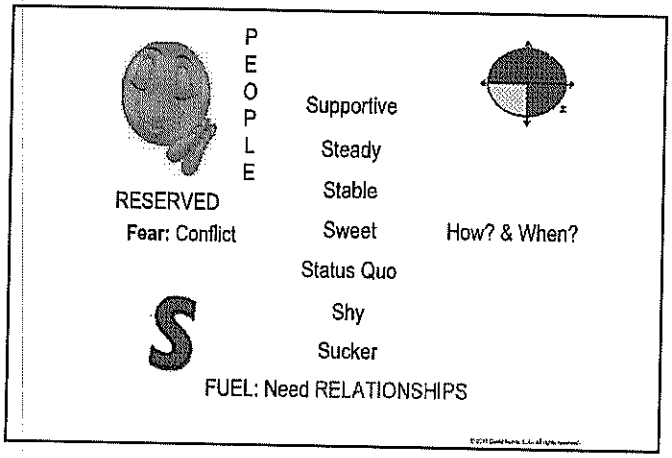

Procedure
Function
Programs
Plans
Projects
Process
Outgoing
Fast Paced
Focus is on
the opinions of
others and how
they feel
Task
Oriented
People
Oriented
Relationships
Caring
Sharing
Emotions
Feelings
Friendships
Focus is on
getting things
done
Reserved
Slow Paced

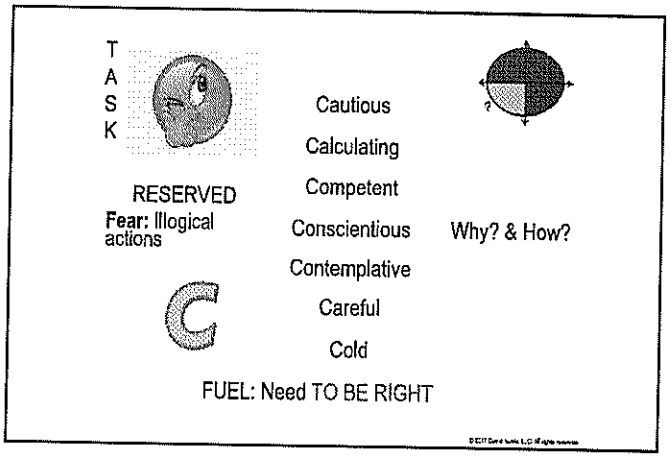

Procedure
Function
Programs
Plans
Projects
Process
Task
Oriented
Outgoing
Fast Paced
80-90%
Focus is on
the opinions of
others and how
they feel
People
Oriented
Relationships
Caring
Sharing
Emotions
Feelings
Friendships
Focus is on
getting things
done
Reserved
Slow Paced

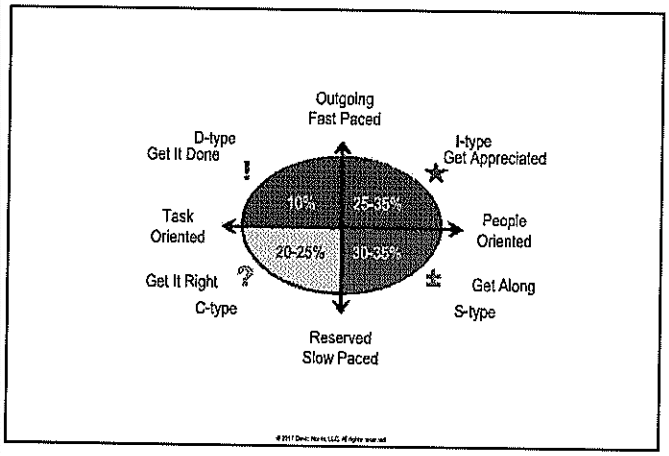

Outgoing
Fast Paced
Task
Oriented
D-type
I-type
C-type
S-type
People
Oriented
Reserved
Slow Paced

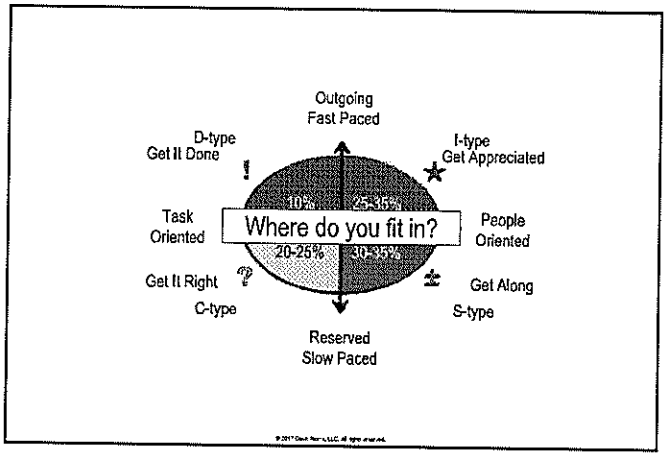

OUTGOING
TASK
Fear: Being taken advantage of
Dominant
Direct
Demanding
Decisive
Determined
Doer
Defiant
What?
D
FUEL: Need RESULTS


OUTGOING
PEOPLE
Fear: Looking bad
Inspiring
Influencing
Impressionable
Interactive
Impressive
Involved
Illogical
Who?
I
FUEL: Need RECOGNITION


PEOPLE
RESERVED
Fear: Conflict
Supportive
Steady
Stable
Sweet
Status Quo
Shy
Sucker
How? & When?
S
FUEL: Need RELATIONSHIPS


TASK
RESERVED
Fear: Illogical actions
Cautious
Calculating
Competent
Conscientious
Contemplative
Careful
Cold
Why? & How?
C
FUEL: Need TO BE RIGHT





Keys to Self - Management

THE FINANCIALLY INTELLIGENT PHYSICIAN

D-Type Self-Management Keys

People are important

Relaxation is not a crime

Some controls are necessary

Everyone has a boss

Verbalizing conclusions helps others understand them better

I-Type Self-Management Keys

Time must be managed

Too much optimism can be harmful

Listening is important

Tasks must be completed

Accountability is imperative

S-Type Self-Management Keys

Change provides opportunity

Friendship isn't everything

Discipline is good

It is OK to say "No!"

Being a "servant" doesn't mean being a "sucker"

C-Type Self-Management Keys

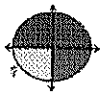
Total agreement is not always necessary

Thorough explanations are not always possible

Deadlines must be met

Taking a calculated risk can be profitable

There are varying degrees of excellence

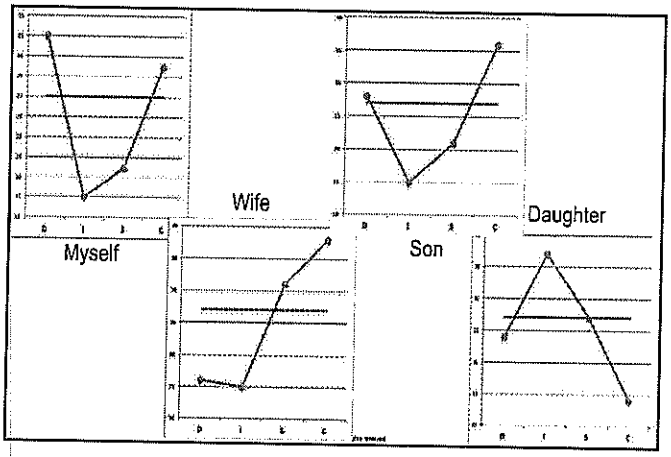


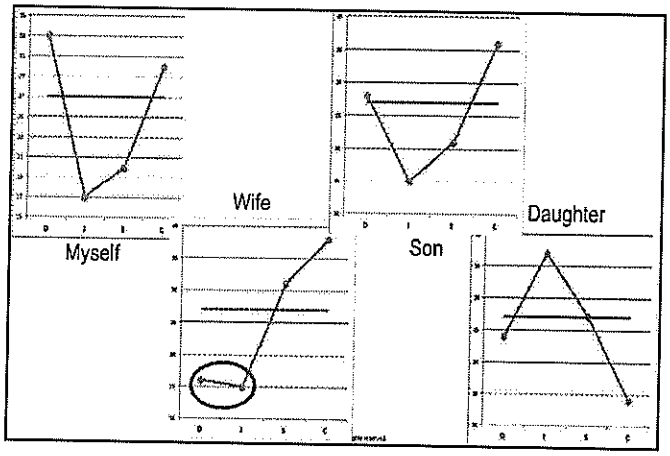
© 2017 Direct Peers, LLC, all rights reserved.

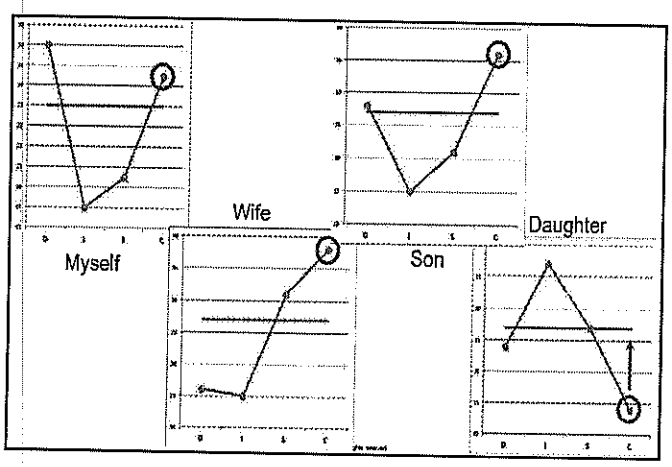
Relationships

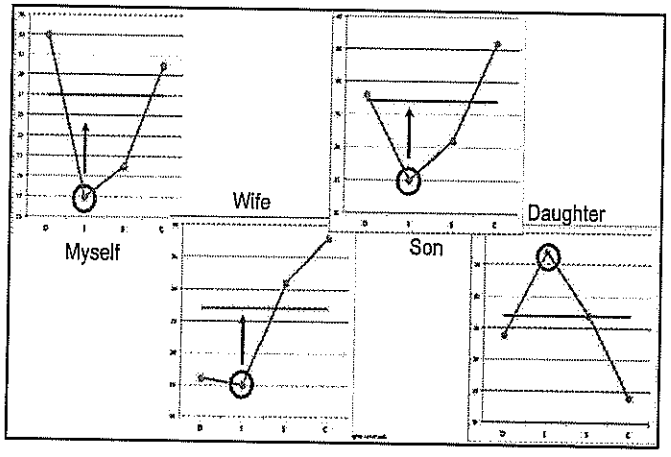
THE FINANCIALLY INTELLIGENT $PHYSICIAN

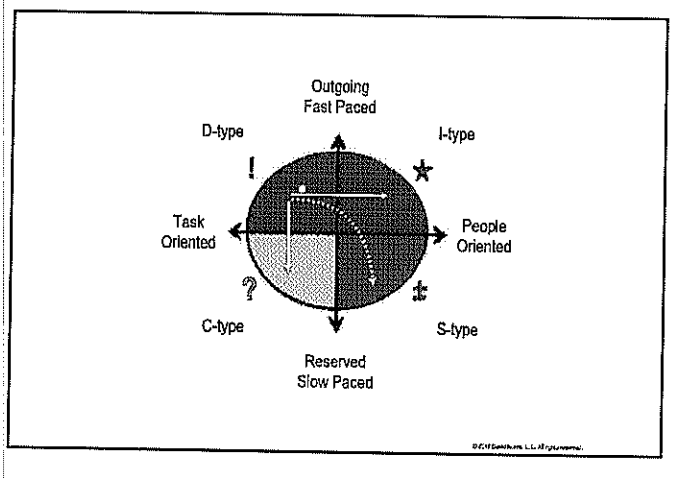
© 2017 Direct Peers, LLC, all rights reserved.











Building Rapport

THE FINANCIALLY INTELLIGENT PHYSICIAN

Why?

Connection

↓

Communication

↓

Compliance

Everyone Is Different

What is natural for you, may take EFFORT for others

What energizes you, may DE-MOTIVATE others

Some multi-task easily, while other excel at mono-tasking

Some work best ALONE and prefer to ISOLATE or RETREAT

Others need discussion and dialogue to stimulate them. They want to ENGAGE and INTERACT

Some are FAST-PACED and other are SLOW-PACED

Task-oriented people Building Rapport

To do business or be in a relationship with you
They must first TRUST you

Rapport

For most Task people "I will trust you when you prove I can"

- Highest state of relatability
- Relationships - Based on task
  - I see value in you
  - I believe in your accomplishments
  - I believe you get things done
- Trust - Based on performance
  - Earned
  - Proven
  - Results

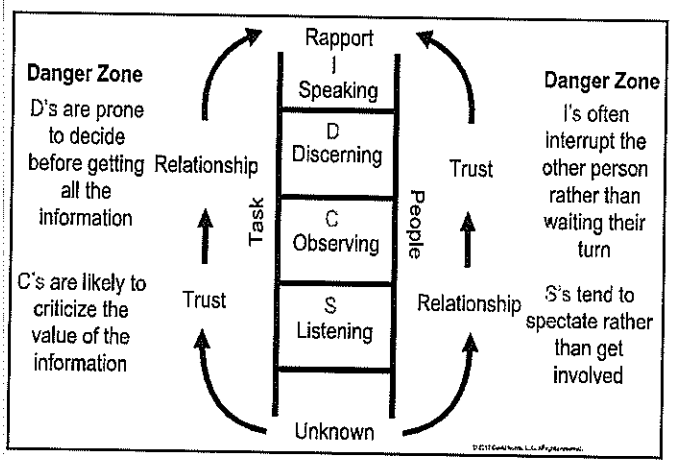
People-oriented people Building Rapport

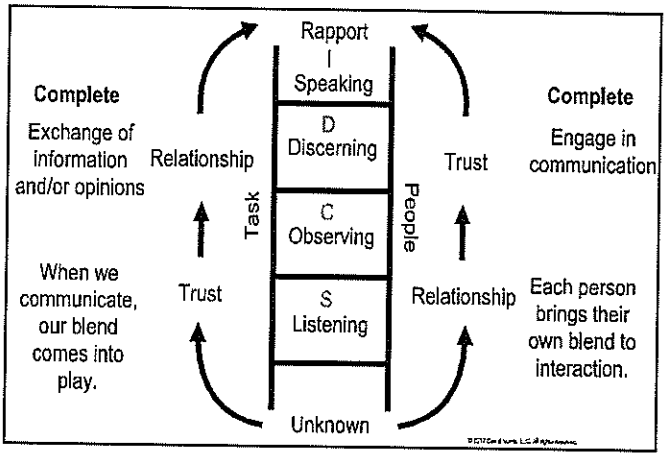
To do business or be in a relationship with you
They must first LIKE you

Rapport

For most People people "I will trust you until you prove I can't"

- Highest state of relatability
- Relationships - Based on emotions
  - Kind
  - Pleasant
  - Caring
- Trust - Based on feelings
  - I like you
  - Do you care about me?
  - I feel safe with you





A Recent Personal Example

56 y/o female

Admitted with abdominal pain

Liked to tell stories

- I asked about allergies

- Well, it all started when I was seven. I was visiting my cousins in ... and that's how I discovered I was allergic.

- Let's see, it was three years ago when I began to experience some chest pain and I went to the ER... but it turned out to be GERD.

What Happened Next

I let her talk. I quickly recognized she might be a high I and allowed her to talk while gently redirecting her to stay on topic

The endoscopist is a high C - doesn't "have time to listen to the stupid stories"

He barges in "What questions? That's not a question. What's your question"

Who got good marks and who got bad marks?

D Type Patients

Direct

Want to get in and out

Concerned about one, maybe two issues

Expect you to be on time

Expect you to have answers and a plan

D-Type Patients

Outline tasks for them and they will follow

Tie your instructions/tasks to other tasks or the ability to do other tasks

If you appear confident, they'll trust you

The minute you demonstrate a lack of confidence, you're in trouble

Will push back if they don't agree with plan

I Type Patients

Talkative

Their answers might take a few minutes

They might not know the medicine they're on or why they are taking it

They might get distracted or go off on a tangents easily

Wanders from point to point

Expects you to be friendly, talkative

I-Type Patients

Expects you to listen

Don't interrupt them immediately, let them talk a bit

Judges you based upon your friendliness

Provide written instructions and repeat all instructions

They might not focus on the task, particularly if it isn't fun

To motivate them, tie the task to the people in their life and how un-fun things can get

S Type Patients

Very quiet

Patient

Will typically say "Ok Doc, whatever you say."

Won't push back if they think the diagnosis or treatment is wrong

Won't question you

S Type Patients

Forgiving if you're late

If you seem rushed or uninterested, they will shut down and not ask questions they need/want to

Judges you on compassion

Tie the tasks to the people. It'll motivate them comply and follow through

They may be your best referral source

C Type Patients

Will have their own copy of their medical record

Lists, lists, lists (meds, surgeries, every doctor's appointment they've ever had)

Will have questions written down

Will push you for answers

Won't tolerate / accept "I don't know"

C Type Patients

Will challenge you if they think you're wrong

Wants you to be right, confident

Answer all their questions

Have reasons for each task you want them to complete

If things make sense, they'll follow orders

Communication

THE FINANCIALLY INTELLIGENT $PHYSICIAN

Attitudes that Hinder Listening

D	I
You've already decided, made up your mind	You are too dreaming
You're "zoning out" before completely understanding or listening to all the necessary information	You have distractions or are focusing on other activities
You jump to conclusions too quickly	You assume you know what is going on when you really don't
You're hearing specific things that were said in a general manner	You've developed "selective hearing"
You're trying remember too much detail	You shut down when you're processing or don't understand information
You tend to find one word or concept that might be incorrect rather than seeing the big picture	You try to change the subject or procrastinate because you don't like the topic
C	S

Obstacles that Keep Others From Listening to You

D	I
Thinking of their own agenda	Thinking how they can get attention and recognition
Quit listening once they've determined the information is useless	They tune out "boring" conversations and are easily distracted by the environment
What you need to do: GET TO THE POINT	What you need to do: BE MORE EXCITING
They will stop listening to judge the speaker	They can lose the speaker's train of thought
They try to run ahead and form their own conclusion but if the information doesn't mesh with their conclusion, they'll shut down	They might shut down in response to a tone of voice, information they find fearful, or you're speaking too fast
What you need to do: I KNOW I'M RIGHT!	What you need to do: SLOW DOWN A LITTLE
C	S

To be an effective communicator with

D	I
• Be concise and realistic. • Prepare your "case" in advance. • Stick to business.	
C	S

Leadership

There's more to it than meets the eye...

It's really a blend of all the styles - it's emotional intelligence

- Self-awareness - knowing yourself
- Self-control - having disciplined actions
- Social awareness - knowing other
- Social skill - connecting with others

Building Trust

Trust is a cornerstone for relating and communicating more effectively with others.

Without trust:

- Barriers and guards go up
- Lower performance
- Limited communication takes place
- Ideas and creativity stops
- Lower morale
- Increase in conflicts and misunderstanding
- People become indifferent
- Time and energy is wasted in conflicts

Building Trust

Trust is a cornerstone for relating and communicating more effectively with others.

Attitudes that Create or Reflect a Poor Environment

Criticism	Uncommitted
Disengaged Involvement	Negative Assumptions
Indifference / Apathy	Unproductive
Resentment	Defiant Mindset
"Not My Responsibility"	Tension
Mindset	Fear
Blame	Hurt Feelings
No Accountability	Anger
Low Morale	

Building Trust

Trust is a cornerstone for relating and communicating more effectively with others.

With trust:

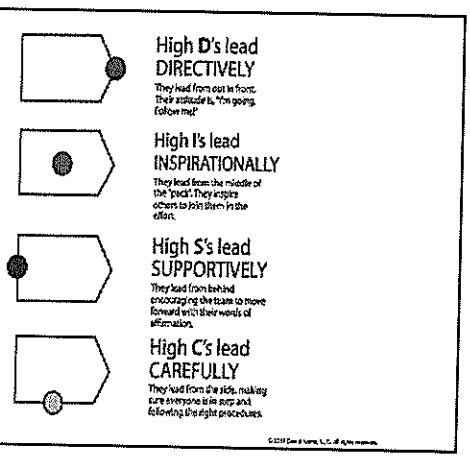
- Open and honest dialogue for effectiveness and improvement
- Increased performance
- Ideas and creativity flow freely
- Higher levels of mutual respect
- Higher morale
- People become engaged
- Productive with time
- People take personal responsibility

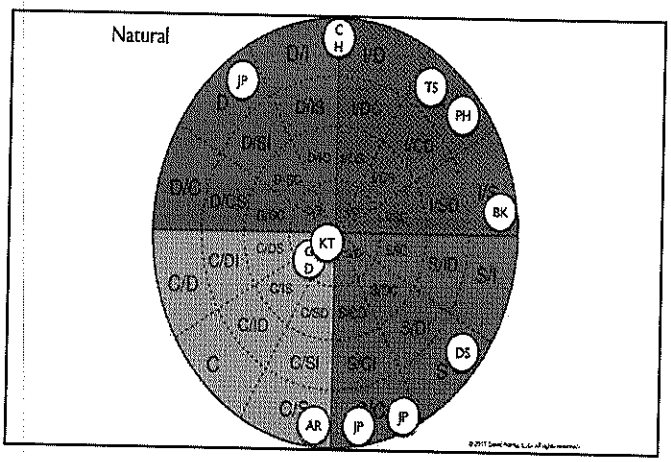
Building Trust

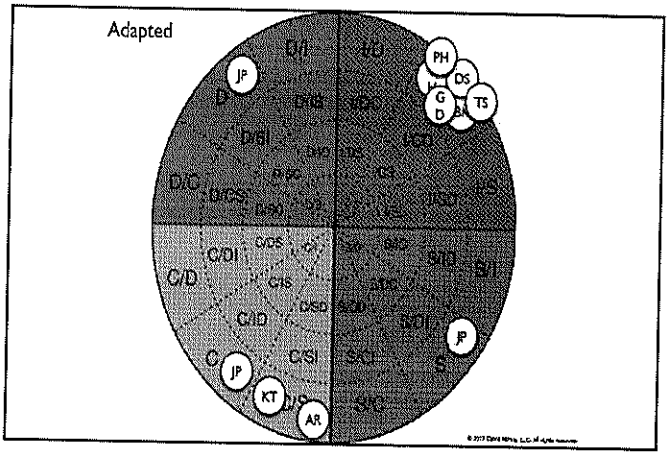
Trust is a cornerstone for relating and communicating more effectively with others.

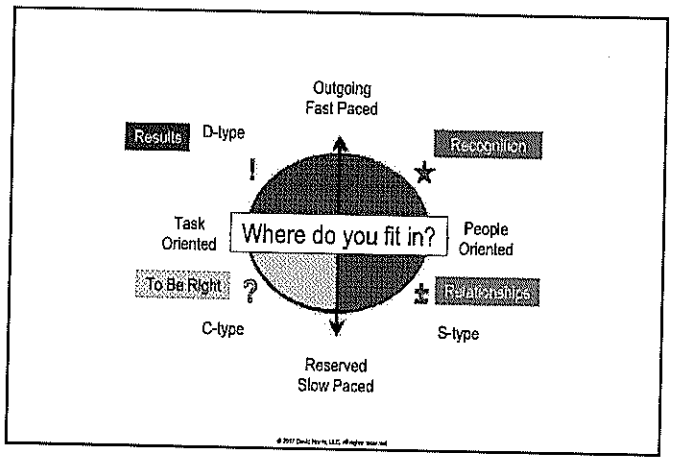
Attitudes that Create or Reflect a Great Environment

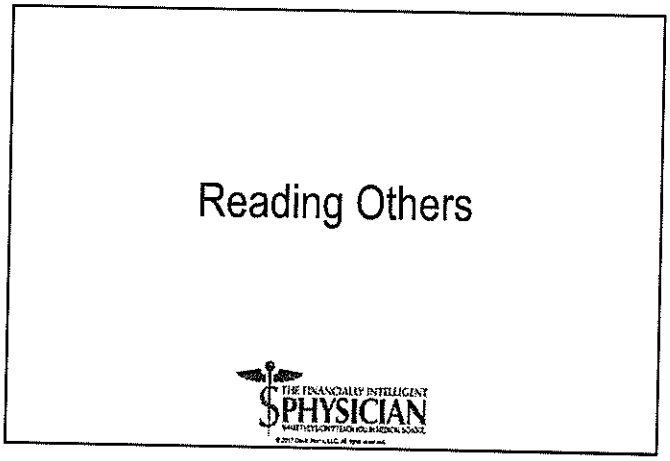
Excitement	Influence
Energy	Commitment
Can-Do Attitude	Confidence
Peak Performance	Positive Energy
Team Effort	High Morale
"I'm Responsible"	Co-operative mindset
Mindset	Productivity
Ownership	Peaceful Environment
Personal Accountability	

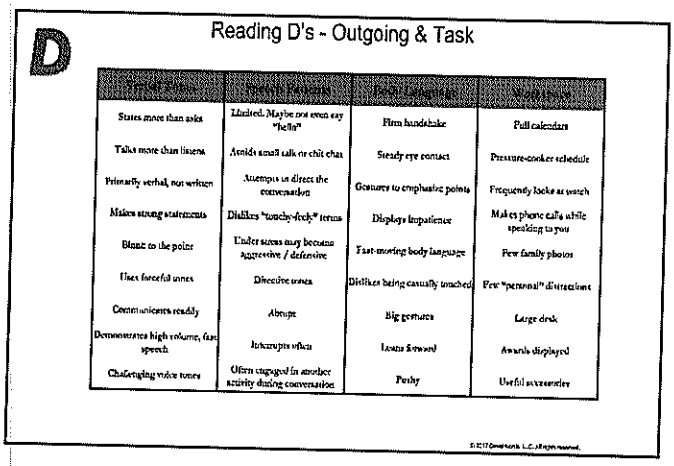


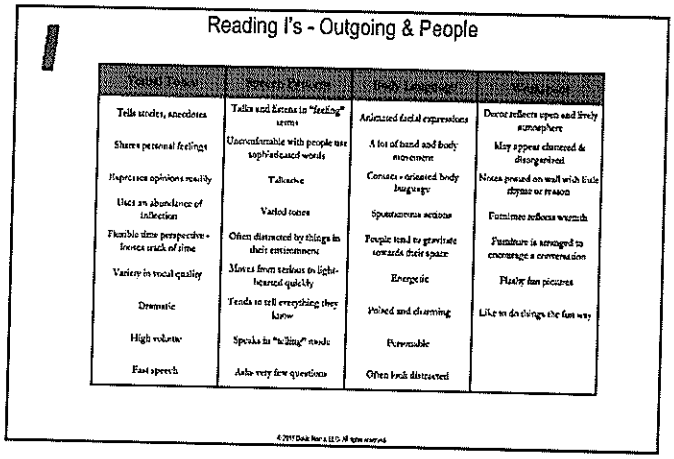


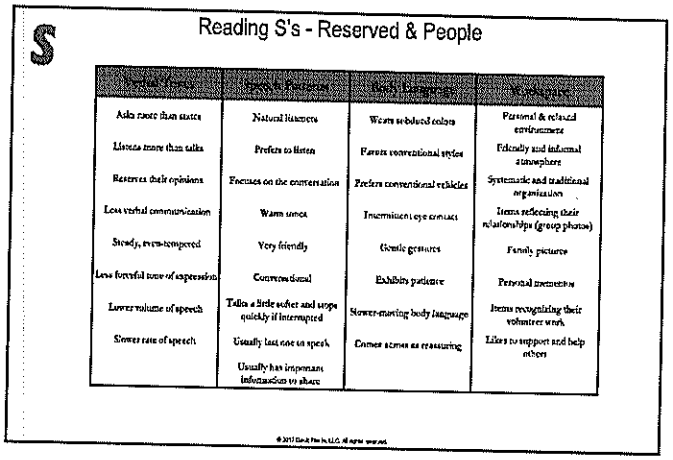


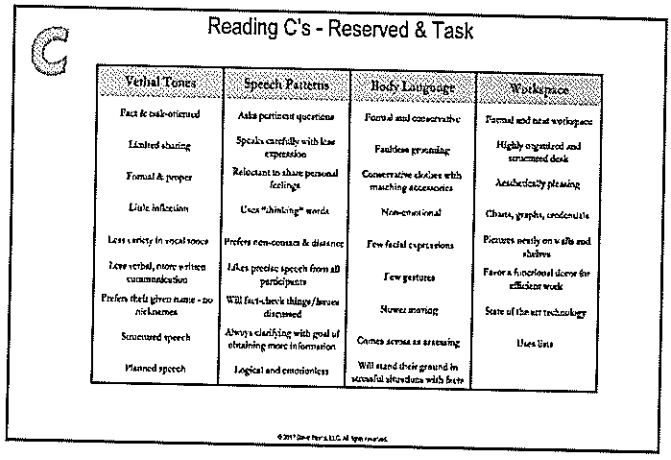

Outgoing
Fast Paced
Results
D-type
Recognition
Task
Oriented
Where do you fit in?
People
Oriented
To Be Right
Relationships
C-type
S-type
Reserved
Slow Paced

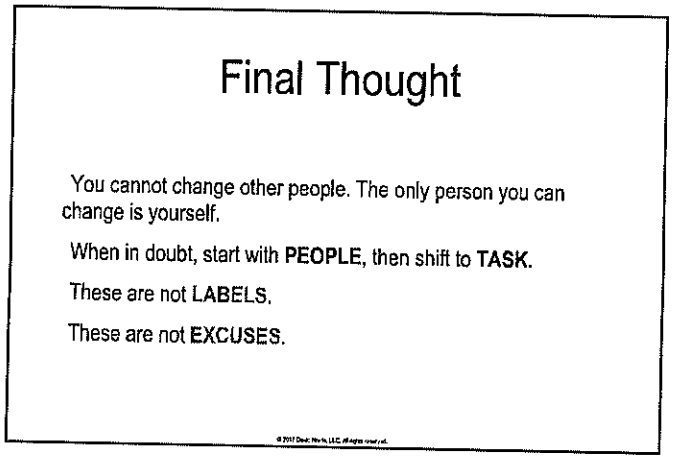

Reading Others
THE FINANCIALLY INTELLIGENT
PHYSICIAN

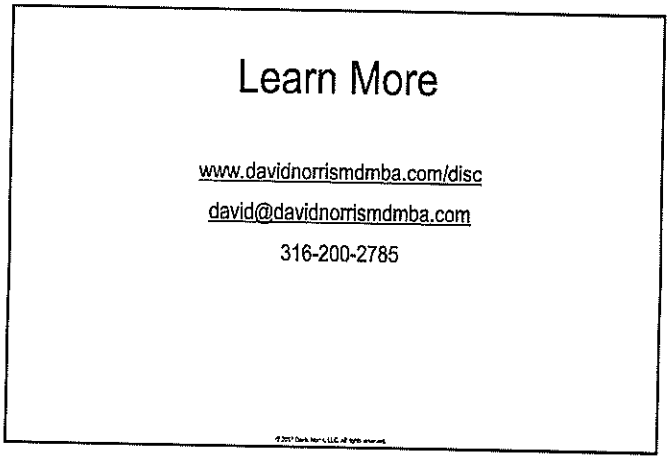

D
Reading D's - Outgoing & Task
Verbal Tones
Speech Patterns
Body Language
Workspace
States more than asks
Talks more than listens
Primarily verbal, not written
Makes strong statements
Blunt to the point
Uses forceful tones
Controls interviews readily
Demonstrates high volume, fast speech
Challenging voice tones
Limited. Maybe not even say "hello"
Avoids small talk or chit chat
Attempts to direct the conversation
Dislikes "touchy-feely" terms
Under stress may become aggressive / defensive
Directive tones
Abrupt
Interrupts often
Often engaged in another activity during conversation
Firm handshake
Steady eye contact
Gestures to emphasize points
Displays impatience
Fast-moving body language
Dislikes being casually touched
Big gestures
Leans forward
Perky
Full calendars
Pressure-cooker schedule
Frequently looks at watch
Makes phone calls while speaking to you
Few family photos
Few "personal" distractions
Large desk
Awards displayed
Useful accessories


I
Reading I's - Outgoing & People
Verbal Tones
Speech Patterns
Body Language
Workspace
Tells stories, anecdotes
Shares personal feelings
Expresses opinions readily
Uses an abundance of inflection
Flexible time perspective - knows much of time
Variety in vocal quality
Dramatic
High volume
Fast speech
Talks and listens to "feeling" terms
Uncomfortable with people use sophisticated words
Talkative
Varied tones
Often distracted by things in their environment
Moves from serious to light-hearted quickly
Tends to tell everything they know
Speaks in "selling" mode
Asks very few questions
Animated facial expressions
A lot of hand and body movement
Contact - oriented body language
Spontaneous actions
People tend to gravitate towards their space
Energetic
Poised and charming
Persuasive
Often look distracted
Decor reflects open and lively atmosphere
May appear cluttered & disorganized
Notes pinned on wall with little rhyme or reason
Furniture reflects warmth
Furniture is arranged to encourage a conversation
Flashy fun pictures
Likes to do things the fun way


S
Reading S's - Reserved & People
Verbal Tones
Speech Patterns
Body Language
Workspace
Asks more than states
Listens more than talks
Reserves their opinions
Less verbal communication
Steady, even-tempered
Less forceful tone of expression
Lower volume of speech
Slower rate of speech
Natural listeners
Prefers to listen
Focuses on the conversation
Warm tones
Very friendly
Conversational
Talks a little softer and stops quickly if interrupted
Usually last one to speak
Usually has important information to share
Wears subdued colors
Favors conventional styles
Prefers conventional vehicles
Intermittent eye contact
Gentle gestures
Exhibits patience
Slower-moving body language
Comes across as reassuring
Personal & relaxed environment
Friendly and informal atmosphere
Systematic and traditional organization
Items reflecting their relationships (group photos)
Family pictures
Personal mementos
Items recognizing their volunteer work
Likes to support and help others


C
Reading C's - Reserved & Task
Verbal Tones
Speech Patterns
Body Language
Workspace
Fact & task-oriented
Limited sharing
Formal & proper
Little inflection
Less variety in vocal tones
Less verbal, more written communication
Prefers their given name - no nicknames
Structured speech
Planned speech
Asks pertinent questions
Speaks carefully with less expression
Reluctant to share personal feelings
Uses "thinking" words
Prefers non-contact & distance
Likes precise speech from all participants
Will fact-check things/issues discussed
Always clarifying with goal of obtaining more information
Logical and emotionless
Formal and conservative
Faultless grooming
Conservative clothes with matching accessories
Non-emotional
Few facial expressions
Few gestures
Slower moving
Comes across as reserving
Will stand their ground in stressful situations with facts
Formal and neat workspace
Highly organized and structured desk
Aesthetically pleasing
Charts, graphs, credentials
Pictures neatly on walls and shelves
Favor a functional decor for efficient work
State of the art technology
Uses lists





SELF EVALUATION

Emotional Intelligence: Improving Relationships with Staff and Patients

1. Which of the following is NOT a general characteristic of a D-Type personality?
   a. Direct
   b. Strong-willed
   c. Focuses on one or two issues
   d. Enjoys people who take their time doing just about anything
2. Which of the following is NOT a general characteristic of a I-Type personality?
   a. Inspiring
   b. Focusing on details
   c. Full of enthusiasm
   d. Loves big gatherings
3. Which of the following is NOT a general characteristic of a S-Type personality?
   a. Are forceful in getting what they want
   b. Supportive
   c. Wants stability
   d. Very resistant to change
4. Which of the following is NOT a general characteristic of a C-Type personality?
   a. Loves working with data
   b. Expects precision and excellence
   c. Cautious
   d. Dislikes checklists, procedures, and prefers to wing it
5. T/F - Everyone is motivated by the same things and you should craft a plan that is generic and applies to everyone equally.
6. T/F - The best way to lead others is by focusing on your strengths and lead according to your style
7. T/F - The personality style you might have the most difficult time establishing or maintaining a relationship is with someone who is opposite of you. If you're fast-paced and task-focused, you might have a difficult time with someone who is slow-paced and people-focused.

Answer Key: 1. D, 2. B, 3. A, 4. D, 5. F, 6. F, 7. T

D

The International Journal of Risk & Safety in Medicine

MISGUIDED MEDICAL INSURANCE AND GOVERNMENT POLICIES IN THE OPIOID EPIDEMIC: A CHART REVIEW AND NARX SCORE ANALYSIS.

--Manuscript Draft--

Manuscript Number:	
Full Title:	MISGUIDED MEDICAL INSURANCE AND GOVERNMENT POLICIES IN THE OPIOID EPIDEMIC: A CHART REVIEW AND NARX SCORE ANALYSIS.
Short Title:	POLICIES IN THE OPIOID EPIDEMIC\
Article Type:	Research Article
Corresponding Author:	Leon Margolin CPMI Columbus, OH UNITED STATES
Corresponding Author Secondary Information:	
Corresponding Author's Institution:	CPMI
Corresponding Author's Secondary Institution:	
First Author:	Leon Margolin
First Author Secondary Information:	
Order of Authors:	Leon Margolin
	Faina Linkov
	Juscelino F. Colares
	Sanford Lefkowitz
	Richard B. Ancowitz
	Sanford Rosenblum
Order of Authors Secondary Information:	
Abstract:	OBJECTIVES: Despite the investment of significant effort and resources, our country remains exposed to an alarming risk of opioid overdoses due to opioid addiction. This study demonstrates the impact of misguided medical insurance and government policies on the opioid epidemic. METHODS: This is a retrospective chart review study of 142 patients who were denied access to care by insurance companies (CareSource, Molina, Aetna, government regulators, and contractors). The study provides a systematic analysis of the risk stratification of these patients based on the NARX score, prescribed medications, and OARRS report analysis. FINDINGS: Patient who were denied access to care by the major insurance carriers in Ohio, CareSource, Aetna, and Molina had an average high NARX score of 309.8-310.5 range. The review of the prescribing provider lists on Ohio Automated RX Reporting System reports showed that, in most occasions, patients had significant difficulty in finding a qualified pain provider for three months or more. CONCLUSIONS: Review of denied-care patient NARX scores shows, conclusively, that very high-risk patients were affected the most. These misguided medical insurance and government policies have exposed the most vulnerable and high risk patients to significant risk of mortality and morbidity. KEYWORDS: opioids, SBIRT, Nerve Conductive Studies, drug screening, prescription drugs, health care law and regulation, pharmaceutical industry, insurance, medically necessary
Suggested Reviewers:	Jacqueline Cleary Jacqueline.Cleary@acphs.edu

Powered by Editorial Manager® and ProduXion Manager® from Aries Systems Corporation

	Clinical and research experience, ASAM activism
Additional Information:	
Question	**Response**
By submitting this article I agree with the IOS Press author copyright agreement, privacy policy and ethics policy.	Yes
Authors publishing a paper with IOS Press should certify that: (i) all those mentioned in the list of authors have contributed significantly to the paper according to the IOS Press Authorship Policy; (ii) no person who has made a significant contribution has been omitted from the list of authors or acknowledged persons; <p> In accordance with the above excerpt from the IOS Press ethics policy, authors cannot be added to or omitted from the author list of the submission after it has been accepted. <p> Please select 'I confirm and consent.' to acknowledge that you have submitted your manuscript in accordance with these guidelines, and that all subsequent changes to the author list require a signed approval from all authors and from the Editor(s) in Chief.	I confirm and consent.

anuscript

Click here to access/download;Manuscript;the manuscript file no absract.docx

BACKGROUND

The explosion of overdose risk in the opioid epidemic since 1999, and the concomitant Opiate Use Disorder (OUD) have cost in excess of $600 billion, killing tens of thousands nationally, devastating families, and harming communities and the country. Another opioid epidemic cost estimate from 2011 by the Institute of Medicine put the cost in the vicinity of 560-635 billion dollars annually (74). Since 1999, more than 600,000 people in the USA and Canada have died from an opioid overdose. Indeed, the rate of mortality in each country exceeds that of the worst of the HIV/AIDS epidemic (75). In 2007-2014 opioid dependence rose 3,203% (per cent), and, between 2011-2015, privately insured opioid abuse charges rose from 72$ million to 722$ million. A sizable portion of the public has opioids in their blood, with opioid-impaired driving implicated in multiple accidents, from 2011 to 2014 pregnancy drug dependence diagnoses rising 511%, and neonatal abstinence syndrome diagnosis rising more than fourfold (76).

According to the Centers for Disease Control and Prevention (CDC), between 2015-2020, Ohio had consistently been one of the top-5 states for drug overdose mortality rates. (CDC 2022). In 2015, Ohio tied with Kentucky for the third highest drug overdose mortality rate in the United States, with 29.9 deaths per 100,000 people (3,310 total deaths). (CDC 2022). In 2016, Ohio had the second highest drug overdose mortality rate with 39.1 deaths per 100,000 people (4,329 total deaths). (CDC 2022). In 2017, Ohio had the second highest drug overdose mortality rate in the nation with 46.3 deaths per 100,000 people (5,111 total deaths). (CDC 2022). Additional research conducted in 2017, focusing on opioid mortality, found Ohio to have the second-highest opioid mortality rate in the US, representing more than 2.6 times the death rate compared to the US average (39.2 per 100,000 people in OH vs. 14.6 per 100,000 people in US, see **Figure 1a** below).

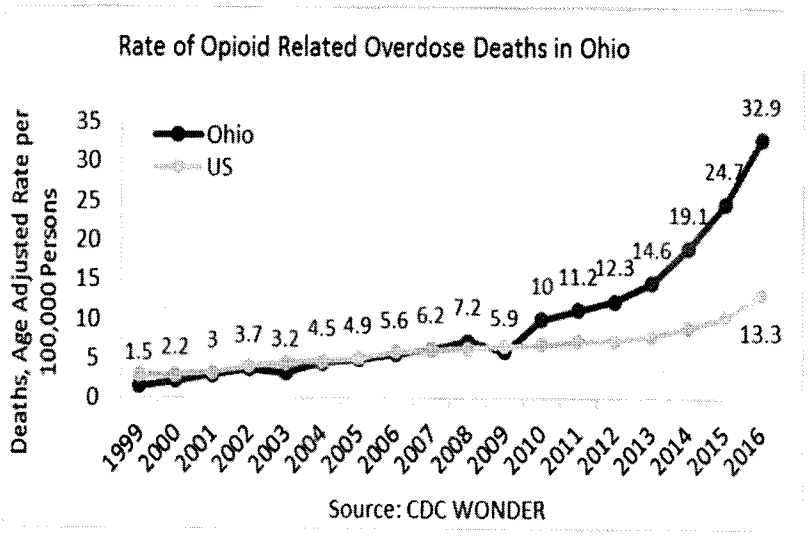


Figure 1.a

Note: Based on 2017 CDC data, Ohio has the second highest opioid mortality rate in the U.S. with more than 2.6 times the U.S. national average mortality rate (OH = 39.2 deaths per 100,000 people; National Average = 14.6 deaths per 100,000).

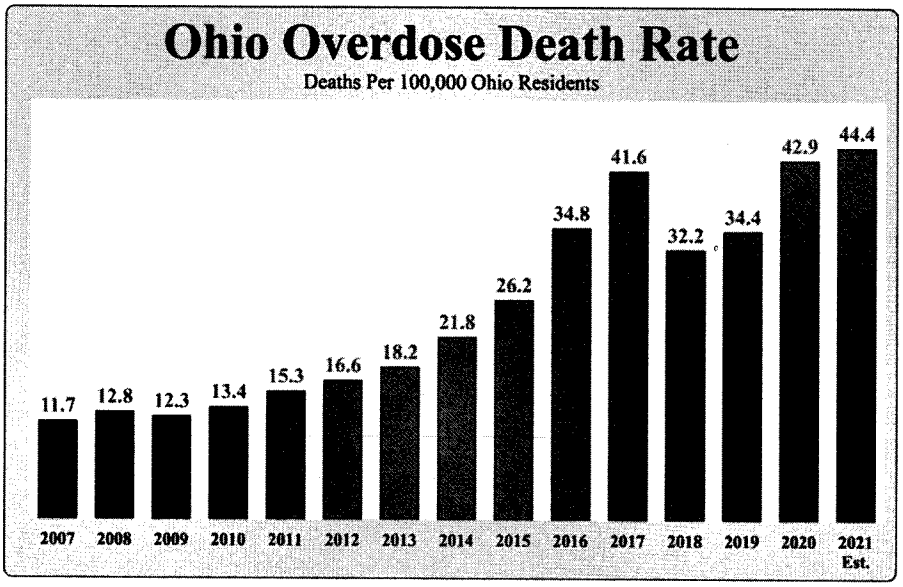


Figure 1.b

Note: Unintentional overdose death rate (based on harm Reduction Ohio).

Source:

The above data clearly demonstrates the devastating effect the opioid epidemic has had on the state of Ohio. DEA data shows that, on average, at least 12-15 people die in Ohio. Franklin county alone reported than 11,300 overdoses since 2018. (DEA 2020). According to the CDC, in 2020, Ohio saw 47.2 unintentional drug overdose deaths per 100,000 residents.(CDC 2022) This was the fourth highest drug overdose rate death in the United States and resulted in 5,204 total deaths.(CDC 2022) That same year, 86% of overdose deaths involved opioids, with 81% included fentanyl or fentanyl analogs, according to the Ohio Department of Health, which appropriately noted that "every community has been impacted by the disease of addiction." (Ohio Attorney General 2021). As evidenced above, opioid-related deaths have increased annually since 2010 (except for one-year interval between 2017-18), and fatalities exceeded 5,200 in 2020, with a 26 percent increase following the previous year. (CDC 2022).

In Ohio, a serial cross-sectional analysis for all fatal opioid poisonings between January 1, 2010 and December 31, 2016 (N = 12,782). Calculated the burden of fatal opioid overdoses in Years of Life Lost (YLL). YLL were mapped with respect to geographic and cultural regions. Opioid overdoses resulted in 508,451 total YLL. In the year 2016 alone, there were 136,679 YLL attributable to fatal opioid poisonings. Fentanyl-related YLL rose from 7.5% of all YLL related to opioid overdose in 2010 to 69.0% in 2016, while overall opioid overdose mortality continued to rise annually. (O.T. Hall, *et al.* 2020).

Notably, both addiction professionals (O.T. Hall, *et al.* 2020) and the Substance Abuse and Mental Health Services Administration (SAMHSA 2017) have identified Screening, Brief Intervention, and Referral to Treatment (SBIRT) services as being effective in preventing opioid mortality, improving function, and decreasing pain. SBIRT services are evidence-based, early interventions that physicians use to address the risk of substance abuse, overdose, and death with patients receiving treatment with opioids or other dangerous drugs. SBIRT consists of three primary components:

(1) Screenings to assess a patient's risk for substance abuse and to determine the appropriate level of treatment;

(2) Brief interventions by engaging the patient in short conversations to increase their awareness of risky substance use behaviors and to provide feedback, motivation, and advice; and

(3) Referral for additional treatment or services when necessary. (CMS 2022).

Notably, a large study of SBIRT outcomes found that SBIRT, at the six-month follow-up point, lowered illicit drug use by 68% and lowered heavy alcohol use by 39%. (Agerwala, SM, *et al.* 2012). Moreover, SBIRT protocols are often mandatory for the compliant operation of a pain management clinic, especially clinics providing medical management to populations with a significant portion of high-risk patients in high-risk areas, like Ohio. By way of example, Ohio law sets stringent requirements for pain management clinics and physicians that prescribe controlled substances as part of their pain management services. (OAC § 4731-29-01).

Despite the clear benefit (and potential necessity for compliance purposes), SBIRT services are frequently denied coverage by insurance carriers. Defining them as "unallowable costs," cCoverage denials for these services by third-party payers have placed both patients and pain medicine staff at considerable risk. This article aims discusses how specific policies and methods implemented by certain insurers have impacted Ohio families, communities, and the state.

Pain Medicine Practice Protocols Based on the American Society of Addiction Medicine Guidance:

The American Society of Addiction Medicine (ASAM) recommends pain medicine practitioners provide SBIRT screening and other services to monitor and assess pain patients and/or patients with substance use disorders (SUDs). Over the past several decades, there has been an increased call for "universal precautions" in the evaluation and management of patients with SUDs and serious pain issues, particularly chronic pain. Similar to the management of patients with infectious diseases (wherein clinicians generally assume that all patients are potential carriers of serious transmissible agents (*e.g.*, HIV, hepatitis B/C, etc.) and must take appropriate precautions), clinicians specializing in pain management must consider each patient presenting with pain issues to potentially suffer from (or be at risk for) substance use disorders, including the potential for aberrant behaviors and adverse outcomes.(ASAM 2017; Douglas Gourlay, *et al.* 2006; Laxmaiah Machikanti, *et al.* 2010; Ohio Dept. MHAS 2023).

Somatic pain comes from damage to musculoskeletal structures and certain soft tissues (*e.g.*, bones, muscles, skin, and mucus membranes). Somatic pain is the type of pain you experience from cuts to your skin or overused muscles. (Cleveland Clinic 2024). Analgesics such as opioids block the experience of somatic pain. For this reason, they sometimes are referred to as anti-nociceptive agents because they block the perception of noxious (painful) information. In the case of inflammatory pain (in contrast to visceral pain or musculoskeletal pain), where inflammation is the cause of the pain, an analgesic such as a non-steroidal, anti-inflammatory drug (NSAID) actually blocks the generation of the pain. However, neuropathic pain does not signal injury to a bone, muscle, or organ in the body, but rather an injury to a nerve cell. This distinction is important in clinical practice because traditional anti-nociceptive agents are typically ineffective at relieving neuropathic pain. (R. Dworkin, *et al.* 2010). Therefore, distinguishing between somatic (nociceptive) and neuropathic pain is an important component of clinical care. (ASAM 2017; M. Bennett 2001). The general lack of efficacy of anti-nociceptive agents to treat neuropathic pain provides the basis for the medical necessity of alternative treatments, such as electro diagnostic and autonomic studies in chronic pain management. Moreover, the availability of an opioid-alternative treatment for chronic pain patients should be viewed as a positive considering the current state of the opioid epidemic.

InsurersOften Deny SBIRT and Opioid-Alternative Treatments

Many insurance companies operate as for-profit corporations that are invested in the stock market, with a strong financial incentive to maximize their bottom line. Even federal healthcare programs are under significant pressure to cut healthcare costs with strong financial incentive programs. Unfortunately, this focus appears to provide insurers a strong financial incentive to adopt policies that inappropriately deny life-saving services, such as SBIRT and other pain management services and procedures.

Notably, fifteen U.S. Senators recognized this problem and sent a letter to the largest Ohio Medicaid insurer, CareSource, in 2018 to voice their concerns over the insurer's pain management and substance use disorder policies. In brief, the U.S. senators expressed their concerns to CareSource that it had adopted certain policies which were exacerbating the nation's opioid epidemic. (Sherrod Brown 2018). The Senators urged CareSource to reexamine its policies and to adopt new policies to promote non-addictive pain management options. In addition to CareSource, Molina has adopted similar policies restricting non-addictive pain management options, which could also exacerbate the nation's opioid epidemic. We are concerned based on the documents enclosed that Molina demonstrated similar concerns to the issues described in the letter (please find Molina patient complaints enclosed).

Inappropriate denials of beneficial SBIRT services can result in insufficient testing, monitoring, screening and lack of alternatives to opioid medications which could very likely lead to: (i) providers prescribing opioids in inappropriate situations to patients with heightened risks of substance abuse or diversion to other people; or (ii) providers not prescribing appropriate pain medications to patients who may look for alternatives "on the street." Both situations pose significant risks of morbidity and mortality. Moreover, the inappropriate denials could lead to increased costs for patients. The cost of SBIRT is minimal: about 50-60 dollars per 30 minutes of physician time of level 3 or 4 office visit charge. The cost of hospitalization, including ER, inpatient care, ICU, detoxification, and maintenance programs is astronomic. These risks and costs can be reduced by appropriate patient screening and treatment in outpatient programs like our practice (Comprehensive Pain Management Institute).

Until insurers adopt policies insurers that promote (and cover the costs of) services focused on better monitoring (*e.g.*, SBIRT services) and provide opioid-alternative treatment options (*e.g.*, EMGs) to high-risk patients, opioid-related mortality and crime rates will continue to rise. Families, communities, the state, and the country will face growing negative implications from the opioid epidemic. For instance, in 2022, every branch of the U.S. military announced record low recruitment due, in part, to the opioid epidemic.(NBC News 2022).

METHOD

Inclusion criteria for the records included:

This is a retrospective review of the overdose risk as reflected by the NARX score of the individuals who were referred SBIRT and urine drug screens, evaluation, and treatment by our program but were denied coverage by insurance. We have obtained a Prescription Monitoring Data (PMD) report for each **of the 142 patients.** The charts were selected randomly from the database of the denied referrals available.

Exclusion criteria for the records included:

The patients who got the insurance denial overturn and were able to obtain access to the services.

Ethical considerations:

All data was collected and processed in compliance with the Comprehensive Pain Management Institute (CPMI) HIPAA and CFR 42 part2 policy, state, and federal regulations.

Statistical analysis:

To determine if there is a significant difference in NARX score based on MME, a t two sample t-test was used. For each insurer, the t-test compared the average NARX score for low MME patients (<=15) and high MME (>15) patients.

To measure the efficacy of participation in the treatment program, patients were measured in terms of Functional Improvement and Pain reduction. Patients were compared based on their length of participation in the program (less than 2 years, versus 2 years or more) versus their degree of improvement. A chi square test was used to measure efficacy versus treatment length.

The actual p-values are shown (not just whether the value exceeds a threshold value, such as .05).

Medical Legal Literature Review:

The authors utilized state news and press release archives, state, and federal government websites (including those pertaining to opioid statistics and the opioid epidemic), medical journals, medical insurer websites, professional organization websites, state and federal regulations, and medical records to investigate the impact of medical insurance and governmental regulators policies on public safety and the opioid epidemic (see "Discussion") .

Point-of-care (POC) urine drug screen studies (UDS) testing was performed in compliance with state and federal guidelines as part of the patient monitoring program, using the risk stratification scale discussed above. Data shows a significant impact of the testing on the patient treatment plan and compliance.

Ultrasound-guided procedures (peripheral nerve blocks, trigger-point injections, and others) are minimally invasive procedures that are *cost-effective alternatives* to opioid medications required by the guidelines. All patients received the informed consent and the medical necessity forms. Statistical analysis shows these procedures had a strong impact on patient treatment plans and compliance.

RESULTS

Table 1:

Insurer	AVERAGE NARX SCORE	Number Patients
Aetna	310.5	43
Caresource	309.8	59

Molina	310.0	34

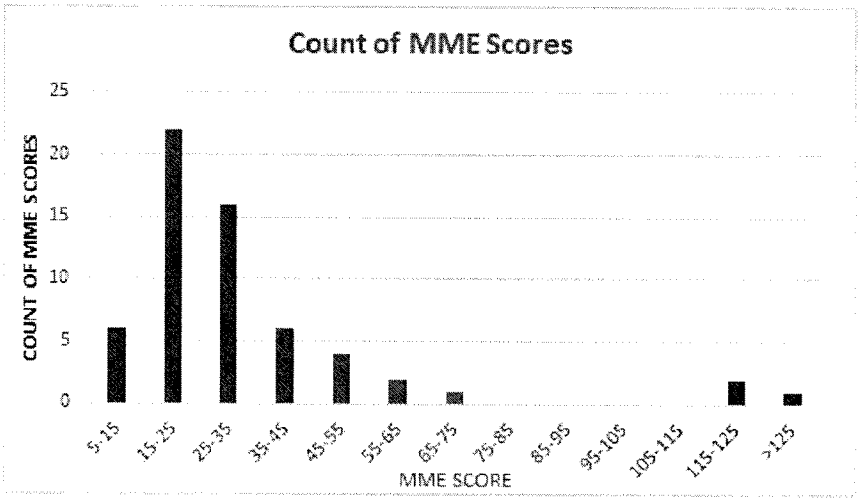
Review of the prescribing provider lists on Ohio Automated RX Reporting System (OARRS) reports show that, on most occasions, the patients had significant difficulties in finding a qualified pain provider for three months or more.

Analysis of NARX/MME Data by Insurer (DATA SUMMARY).

There are one-hundred forty-two (142) data points. Of these, eighty-two (82) had a morphine milligram equivalent (MME) value of zero (0) and the medication was "None." These points were excluded from the analysis. One (1) patient had a medication of "None" but had a non-zero MME score. This patient was included in the analysis. Three (3) patients had MME values that were outliers (illustrated below). Since the MME values were more than six (6) standard deviations above the mean, it was assumed these values were incorrect and were excluded from the analysis. After these adjustments, we had fifty-six (56) data points remaining for analysis.

Based on the review of NARX score of patients denied care, it is abundantly evident that the very high-risk patients (*i.e.*, NARX score above 300, which indicates they are more than 25 times above average risk of overdose) were affected the most (see Fig. 2 below). The systematic denial of SBIRT services resulted in a higher risk for overdose and death which was about 10 times higher than average.[1]

The patients' high MME values reflect the fact that the vast majority of patients in the study who were denied access to care were already on significant doses of opioids, initiated by their primary care or other providers.This fact greatly increases the risks of denial of access to care.



[1] Please refer to the NARX score review material enclosed.

Figure 2: MME scores analysis

SUMMARY OF RESULTS

For Aetna, the average NARX score was significantly higher for high MME patients than for low MME patients.

For CareSource, the average NARX score was NOT significantly higher for high MME patients than for low MME patients.

For Molina, the average NARX score was higher for high MME patients than for low MME, but the result was not strong enough to be considered statistically significant.

DETAILS

AETNA

	NARX AVERAGE	NUMBER PATIENTS
MME<=15	232.9	7
MME>15	366.7	18
Difference	133.8	

Difference in means is tested with a t-test

t= -2.93 p=.008

The probability of seeing a difference this large by chance is .008 (i.e., negligible). This large difference is statistically significant and corroborates our hypothesis that denial of these tests has a clear detrimental effect for high MME patients.

CARESOURCE

	NARX AVERAGE	NUMBER PATIENTS
MME<=15	310.0	5
MME>15	322.7	11

Difference	12.7	

Difference in means is tested with a t-test

t= -.18 p=.85

The probability of seeing a difference this large by chance is .85. As such, we conclude that this difference is not statistically significant.

MOLINA

	NARX AVERAGE	NUMBER PATIENTS
MME<=15	233.2	3
MME>15	260.9	12
Difference	127.6	

Difference in means is tested with a t-test.

t= -1.27 p=.23

The probability of seeing a difference this large by chance is .23. Again, we conclude that this difference is not statistically significant. .

AETNA DATA

Patient	**NARX**	**MME**	**Medication**
R *	260	15	Percocet 5/325mg
D*	50	15	Percocet 5/325mg
S *	180	15	Norco 5/325mg
L *	260	15	Norco 5/325mg
P *	200	15	Norco 5/325mg
S *	450	10	Norco 5/325mg

M*	230	15	Percocet 5/325mg
L *	160	30	Norco 7.5/325mg
L *	520	37.5	Oxycodone 5mg
A *	500	22.5	Percocet 5/325mg
B *	300	60	Oxycodone 10mg
A *	270	22.5	Percocet 5/325mg
B *	470	30	Oxycodone Sol 5mg/5ml
J *	280	30	Percocet 5/325mg
F *	320	30	Norco 7.5/325mg
J *	320	30	Percocet 10/325mg
M *	480	45	Oxycodone 10mg
C *	380	40	Norco 10/325mg
E *	380	33.75	Percocet 7.5/325mg
B *	300	45	Percocet 7.5/325mg
P *	450	40	Norco 10/325mg
M *	300	20	Norco 5/325mg
W *	450	40	Tramadol ER 100mg
K *	360	18.75	Percocet 5/325mg
M *	360	67.5	Oxycodone 15mg

CARESOURCE DATA

Patient	**NARX**	**MME**	**Medication**
S *	190	15	Same (Norco 5/325mg)
T *	340	15	Same (Norco 5/325mg)
L *	340	10	Same (Norco 5/325mg)

P*	250	15	Same (Percocet 5/325mg)
C *	430	10	Same (Tramadol 50mg)
D *	470	22.5	Same (Oxycodone 5mg)
L *	160	30	Same (Percocet 5/325mg)
B *	440	37.5	Same (Oxycodone 5mg)
R *	540	45	Same(Percocet7.5/325mg)
C *	310	20	Same (Tramadol 50mg)
J *	320	40	Same (Tramadol 50mg)
H *	320	33.75	Same(Percocet7.5/325mg)
B *	340	22.5	Same (Percocet 5/325mg)
K *	420	30	Same (Norco 10/325mg)
T *	120	60	Same(OxycontinER 20mg)
L *	110	30	None
D *	270	15	Same Norco 5/325mg
C *	220	7.5	Same Butrans Patch 20mcg
V *	390	30	Same Oxycodone 5mg
G *	50	11.63	Same Percocet 7.5/325mg

MOLINA DATA

Patient	**NARX**	**MME**	**Medication**
D *	270	15	Same Norco 5/325mg
C *	220	7.5	Same Butrans Patch 20mcg
V *	390	30	Same Oxycodone 5mg
G *	50	11.63	Same Percocet 7.5/325mg

T *	430	10	Same Norco 5/325mg
B *	270	30	Same Tramadol 50mg
T *	430	22.5	Percocet 5/325mg
R *	150	30	Same Norco 7.5/325mg
T *	630	45	Same Oxycodone 10mg
J *	280	30	Same Tramadol 50mg
C *	540	22.5	Same Percocet 5/325mg
S *	160	30	Same Norco 7.5/325mg
L *	370	20	Different Tramadol 50mg
E *	340	30	Same Tamadol 50mg
J *	410	22.5	Same Oxycodone 5mg

As demonstrated in a previous publication, the SBIRT services, which were unjustly denied by the insurers, often results in a very significant functional improvement and pain reduction over 1-2 years of treatment. (L. Margolin, D. Streem, *et al.* 2020). Moreover, SBIRT services can help prevent aberrant drug-seeking behavior and opioid use disorder.(L. Margolin, D. Streem, *et al.* 2020).

Functional Improvement Analysis

Based on the previously data (31,32), the table below compares Months in Program vs Functional Improvement (based on the PADT and other tools). Given the low number of patients in the 'less than a 2-year group, these 3 groups are combined.

Table 2:

	Moderate	Significant	Very	Total
Less than 2 years	16	7	6	29
2 years	5	1	20	26
	21	8	26	55

Table 3:

	Moderate	Significant	Very

Less than 2 years	55.2%	24.1%	20.7%
2 years	19.2%	3.8%	76.9%

Note: % of Row Totals for the table above.

For example, of the 26 patients with two years of treatments (for whom we also had data on Functional Improvement), 20 of them (76.9%) showed Very Significant Improvement. Performing a chi-square test in Table 3 (combining the first 2 columns to enhance the test) shows there is a significant difference in months of Treatment ($p<.01$).

Functional Improvement Analysis Results

Based on the previously data (31,32), there is a significant relation (at .05 level) between Months in Program and Functional Improvement. The SBIRT protocol and other treatments in our program showed a strong statistically significant impact on the patient's functional improvement – which is the main outcome measure of the pain management program.

Pain Reduction analysis

Table 4:

	Moderate	Significant	Very	Total
Less than 2 years	22	4	2	28
2 years	17	5	4	26
Total	39	9	6	54

Table 5:

	Moderate	Significant	Very
Less than 2 years	78.6%	14.3%	7.1%
2 years	65.4%	19.2%	15.4%

Note: % of Row Totals for the table above.

Most patients had only moderate pain reduction (72.2%). Of the patients in the program for two years, 15% (4 out of 26) had Very Significant pain reduction while 65% of the two-year patients had Moderate Pain Reduction. Performing a chi-square test on Table 5 (combining the last 2 columns to enhance the test) shows there is a statistically significant difference in "months of Treatment" ($p=.02$).

Pain Reduction analysis results

Based on the previously data (31,32), we could demonstrate a very significant pain (p=.02) reduction over time in our program. As time and participation in the program increases (more than 2 years), the pain reduction becomes more significant.

DISCUSSION

CPMI is a specialty pain management practice with offices in Columbus and Cleveland, Ohio. CPMI provides comprehensive care for hundreds of Medicaid patients and many others. CPMI primarily receives patients through referrals from hospitals and other physician practices (including primary care physicians). CPMI also takes patient referrals from other pain medicine practices for patients that have proven to be very difficult and/or very high risk. Generally, CPMI's patient population are complex, medium-to-high risk chronic pain patients with multiple medical and/or psychological co-morbidities. CPMI is licensed as a terminal distributor of dangerous drugs with a "pain management" classification through the Ohio Board of Pharmacy as required by Ohio law. (ORC § 4729.552).

CPMI employs one pain-medicine physician, Dr. Leon Margolin, M.D., as well as several certified nurse practitioners. Dr. Margolin is responsible for coordinating narcotic prescriptions for CPMI patients following appropriate screening and providing interventional pain management. Due to CPMI's unique patient population and the increased risk for drug abuse or overdose, CPMI relies on SBIRT services to screen and track patient compliance with their opioid treatment regimen. Moreover, CPMI seeks to identify and provide non-opioid treatment alternatives and **provide free evidence based patient education (see www.cpmiohio.com)** to further minimize the risk of opioid abuse and overdose.

I. CONCERNS WITH INSURER POLICES THAT DO NOT COMPLY WITH EXPERT ADVICE AND REGULATORY REQUIREMENTS

It appears that insurers with policies that frequently deny SBIRT services and Nerve Conductive Study ("NCS") treatments, autonomic studies and other services to treat chronic pain patients are bereft of any consideration for accepted medical practices in pain medicine, legal requirements, or social demands (*i.e.*, to shift away from opioid-dependent treatments).

Academic and Expert Evidence Support SBIRT and NCS for Treatment of Chronic Pain Patients

By implementing policies that denied coverage for opioid-alternative treatments (*e.g.*, NCS without EMG, autonomic studies and other testing) and SBIRT services, insurers fail to acknowledge the plethora of evidence from academic and pain medicine expert sources that supports the use of SBIRT and NCS, autonomic studies and other services to treat chronic pain patients. The American Board of Physical Medicine and Rehabilitation (ABPMR) and numerous pain medicine experts have published academically reviewed articles and research in support of the medical necessity of such services for the treatment of chronic pain patients.

By way of example, CPMI and the Chief of Psychiatry and Medical Director of the Alcohol and Drug Recovery Center at Cleveland Clinic Foundation published a peer-reviewed article demonstrating the benefits of SBIRT and NCS with or without EMG, autonomic studies and other services in treating chronic pain patients. (L. Margolin, D. Streem, *et al.* 2020). The publication reviewed fifty (50) high-risk CPMI chronic pain patients, seventy-four (74%) percent of whom had high-to-extremely high NARX scores ranging from 100-350. Patients with these ranges of high-risk NARX scores are 10-12 times more likely to overdose on opioids than the average patient. Accordingly, SBIRT services and NCS without

EMG autonomic studies and other services to treat chronic pain patients.were deemed essential to combat the heightened risks of over-prescription, overdose, and/or diversion. (L. Margolin 2020).

Additionally, CPMI has engaged with the American Board of Physical Medicine and Rehabilitation (ABPMR) and several pain medicine experts, to assess CPMI's protocols and patient outcomes pertaining to NCS, autonomic studies and other services to treat chronic pain patients. Upon review of CPMI's NCS protocols and outcomes, the pain medicine experts confirmed the medical necessity of such services in the interventional pain medicine setting. (Jim Kimura 2018; Stanley Wainapel 2018; William Vasilakis 2019).

II. INSURER POLICIES DO NOT COMPLY WITH STATE AND FEDERAL REGULATION AND CMS REQUIREMENTS

Insurer policies that frequently deny coverage for SBIRT and NCS, autonomic studies and other services also fail to appropriately consider state laws, which may require such services. By way of example, Ohio law requires pain specialists prescribing controlled substances to continuously monitor their high-risk patients. (OAC § 47311-11-14). In fact, pain specialists are prohibited from allowing more than three (3) months to pass between assessments. (OAC § 47311-11-14). The purpose of the law is to ensure opioid-using patients are properly monitored for signs of misuse, diversion, and risk of overdose. Aside from the 3-month rule, the frequency of SBIRT services is a clinical determination made by the treating physician, with high-risk patients requiring more frequent SBIRT services.

Ohio Law Supports SBIRT and NCS for Treatment of Chronic Pain Patients

In May 2011, Ohio passed H.B. 93, which established new rules and requirements for dispensing controlled substances and new requirements for pain management clinics (*e.g.*, CPMI) and pain medicine physicians (*e.g.*, Dr. Margolin). (Ohio 129th General Assembly 2011). Notably, the new law required for the first time:

- For pain management clinics seeking to possess, sell, deliver, or distribute dangerous drugs and/or controlled substances to obtain a license as a terminal distributor of dangerous drugs (86) with a pain management clinic classification from the Ohio State Board of Pharmacy (ORC §§ 4729.51, 4729.54, and 4729.552);
- The Ohio State Medical Board to adopt rules establishing standards for physician operation of pain management clinics and physicians who treat patients with chronic pain (ORC § 4729.54); and
- The Ohio State Medical Board to adopt rules and standards for physicians who provide care at pain management clinics. (ORC §§ 4729.54 and 4729.552)

In accordance with Ohio H.B. 93, the Ohio State Medical Board issued certain rules setting forth minimal standards, with which pain management clinics must comply. By way of example, those standards include:

- Prior to treating or continuing to treat subacute or chronic pain with an opioid analgesic, the physician shall first consider and document non-medication and non-opioid treatment options. (OAC 4731-11-14(A));
- When prescribing or personally furnishing a reported drug (including Schedule II-V controlled substances), a physician shall take into account all the following: (i) potential for abuse; (ii) the possibility that use of the drug may lead to dependence; (iii) the possibility the

patient will obtain the drug for a nontherapeutic use or distributed it to others; and (iv)the potential existence of an illicit market for the reported drug. (OAC 4731-11-11(B)(1));

- Physicians seeking to prescribe or personally furnish a reported drug shall obtain and review a report from The Ohio Automated Rx Reporting System ("OARRS") (*i.e.*, Ohio Board of Pharmacy's database, accessible by physicians, and certain others, used to track controlled substance prescriptions) prior to prescribing or personally furnishing any opiate analgesic or benzodiazepine to a patient, unless an exception applies. (OAC §§ 4731-11-11(B)(2) and 4731-11-11(C);
- Physicians shall obtain and review an OARRS report when a patient's course of treatment with a reported drug (other than an opioid analgesic or benzodiazepine) lasts more than 90 days. OAC § 4731-11-11(C);
- Physicians ***shall obtain and review an OARRS report when certain delineated "red flags" pertain to the patient, including inconsistent drug screenings***, a history of chemical abuse and/or dependency, and increasing dosages beyond the prescribed amount. (OAC 4731-11-11(C)(3);
- Physicians must perform a history and physical examination of the patient, including a review of prior treatments, patient's adherence to the medication or non-medication treatment, and ***screening for substance misuse or substance use disorder***. (OAC § 4731-11-14(B)(1));
- ***Physicians must perform laboratory or diagnostic testing or documented review of any available relevant laboratory or diagnostic test results***. If evidence of substance misuse or substance use disorder exists, ***diagnostic testing shall include urine drug screening***. (OAC § 4731-11-14(B)(2));
- Physicians must perform a functional pain assessment, which includes the patient's ability to engage in work and other purposeful activities, the pain intensity and its interference with activities of daily living, quality of family life and social activities and the physical activity of the patient. (OAC § 4731-11-14(B)(4));
- Physicians must develop a treatment plan based on clinical information obtained, which must include a diagnosis, objective goals for treatment, rationale for the medication, planned duration of treatment, and steps for follow up. (OAC § 4731-11-14(B)(5));
- Physicians must have a discussion with the patient regarding the risks and benefits of the medication, including risks for addiction and overdose. (OAC § 4731-11-14 (B)(6));
- For patients being treated with opioid analgesics at doses below fifty (50) morphine equivalent dosage (MED) per day, ***physicians must provide periodic follow-up assessment and documentation of the patient's functional status***, the patient's progress towards treatment objectives, ***indicators of possible addiction, drug abuse or drug diversion***, and the notation of any adverse drug effects. (OAC § 4731-11-14(F));
- For patients being treated with opioid analgesics at doses at or above fifty (50) MED per day, the physician must complete and document certain information no less than every 3 months, which includes: (i) a review of any complications or exacerbation of the underlying condition causing pain through appropriate interval history, patient examination, appropriate diagnostic tests, and specific treatments to address the findings; (ii) assessment of patient's adherence to treatment including any prescribed non-pharmacological and non-opioid treatment modalities; (iii) *screening for medication misuse or substance use disorder via urine drug screenings based on the clinical assessment of the physician with frequency based upon*

presence or absence of aberrant behaviors or other indications of addiction or drug abuse; and (iv) *evaluation of other forms of treatment and tapering of opioid medication if continued benefit cannot be established.* (OAC § 4731-11-14(G)); and

- Pain clinics must establish and ensure compliance with an on-going quality assurance program that objectively and systematically monitors and *evaluates the quality and appropriateness of patient care*, evaluates methods to improve patient care, identifies and corrects deficiencies within the clinic, *and provides the opportunities to improve the clinic's performance and quality of care.* (*See* O.A.C. § 4731-29-01(E)(3)).

As clearly evidenced above, Ohio law requires frequent contact and interventions between a pain specialist and patient. Urine drug screenings and frequent assessments are required to not only track a patient's progress with their treatment regiment, but also to monitor the patient for potential addiction and overdose risks. In short, Ohio law effectively requires pain specialists and physicians treating patients with opioids to perform SBIRT services (*i.e.*, screenings, interventions, and referrals for additional treatments). Further, as demonstrated above, Ohio law requires physicians to consider and implement (if necessary) non-opioid alternative treatments for patients. Accordingly, insurer policies should neither seek to limit the provision of SBIRT services nor promote opioid-based treatments over non-opioid-based treatments, as such policies would directly conflict with Ohio law.

HB 93 law sets requirements for proper pain clinic licensing and mandatory audits of pain clinics. Our program has passed several licensing inspections (86) that required most of our services as part of the licensing requirement. Ironically, the same services are being denied by the insurance providers and government regulators discussed below.

As demonstrated above, SBIRT protocol is mandatory for the compliant operation of a pain management clinic providing medical management to the population with a significant percent of high-risk patients in the high-risk area like Ohio. (L. Margolin, D. Streem, *et al.* 2020). Deference should be given to experts in the medical field (*e.g.*, ABPMR and other licensed medical providers specializing in pain medicine) in determining the medical necessity of services (*e.g.*, NCS and SBIRT services autonomic studies and other CPMI services) for treating chronic pain patients. This multitude of failures by the insurers to promote SBIRT services (and other services aimed at reducing opioid dependence and associated risks) appear far from accidental to the point they could be deemed motivated purely by unjustified financial objectives, which put vulnerable members at risk.

Federal Guidelines and Guidance Supports SBIRT and NCS for Treatment of Chronic Pain Patients

Utilization of SBIRT services and NCS, autonomic studies and other services. for treatment of chronic pain patients is also supported by federal and state guidance, which insurer policies often fail to appropriately consider. CMS issued guidance regarding both SBIRT (CMS 2022) and NCS services (CMS 2019). Further, the Ohio Automated Rx Reporting System (OARRS) Manual, which sets forth certain requirements for Ohio-based prescribers, requires consultations and assessments with patients that are being treated with opioids based on their NARX scores. (State Medical Board of Ohio 2019). The higher the NARX score, the more frequent the need for consultations and assessments. Accordingly, pain clinics and pain specialists treating vulnerable, high-risk chronic pain patients would need to perform frequent consultations and assessments to meet this requirement.

In addition to the above requirements, national and state guidelines require documentation of the organic pathology as part of a comprehensive evaluation in a pain management clinic. By way of example, Mayo Clinic Proceedings that were adopted by the state of Ohio and referenced on each printed copy of the OARRS report, reported that in the area of pain management "[t]he predominant reason for inappropriate care was a failure of the prescribing physician to adequately verify patient's prior medical history."

(Chantal Berna 2015).Autonomic (SSR, RSW, NCV/EMG) testing is a part of the effort to document organic pathology. Both initial tests and follow up tests are medically necessary tests and cost-effective tests that have a strong statistically significant impact on the proper choice of medications, proper procedures for chronic pain patients, and strongly associated with functional improvement and pain reduction.(DEA 2020).Using Pain Assessment and Documentation Tool (*see* **Figure 3** – PADT) and other validated assessment tools, these services demonstrate a statistically significant impact on pain reduction and functional improvement of moderate-to-high risk (as defined by NARX score and other factors) chronic pain patients over a 2-year period. Using these services and testing since 2011,our practice – Comprehensive Pain Management Institute, LLC (CPMI) – has been able to identify patients in need and refer more than 2,000 high-risk patients to addiction medicine evaluation and treatment who would otherwise be at significant risk of opioid mortality, morbidity, diversion, and incarceration.

Evidence-based literature supports the use of autonomic studies (SSR/ PSW) for Treatment of Chronic Pain Patients

Scientific studies have consistently shown that autonomic nervous system function is disturbed in chronic pain patients (Bruehl and Chung, 2004). Acute pain also impacts the autonomic nervous system in predictable and measureable ways (Koenig, 2014). In chronic pain, the balance between the two branches of the autonomic nervous system is disturbed, such that the sympathetic branch excessively dominates over the parasympathetic, resulting in all the negative long-term effects of low HRV (Tracy, LM, Ioannou L, et al., 2016). The relationship between the autonomic nervous system and both chronic and acute pain has important implications for the complete medical treatment of chronic pain.

As Koenig outlined in his 2013 review paper on the topic, "The systems controlling cardiovascular function are closely coupled to systems modulating the perception of pain (Randich and Maixner, 1984) and extensive interactions between the neural structures involved in pain sensation and autonomic control can be observed (Benarroch, 2001; Benarroch, 2006)." Koenig further stated in his 2016 review that, "The functional interaction of these systems is an important component involved in the endogenous modulation of pain, and there is strong evidence that the functionality of these networks is altered in patients with chronic pain" (Koenig J et al, 2016). Indeed, a recent study using simultaneous HRV and fMRI showed that bodily pain does in fact induce pain- processing brainstem nuclei to function in concert with autonomic nuclei in the production of the observed cardio-vagal pain response (Sclocco R, 2016).

Koenig's 2016 systematic review and meta-analysis, the most extensive review of the current evidence, concluded that chronic pain patients had significantly lower heart rate variability than healthy controls (Koenig J et al, 2016) and a separate experimental study the same year again confirmed this conclusion (Koenig J, Loerbroks A, 2016). Another study of 6,783 individuals published in 2018 likewise found that "beyond effects of age, sex and body mass index, the CP [chronic pain] group displayed significantly lower HRV" than the control group (Bruehl S, Olsen RB, et al., 2018).

Numerous studies have shown the relationship between HRV, as a measure the balance between the parasympathetic and sympathetic branches of the ANS, and the body's experience of, and response to, pain. Both the sympathetic and parasympathetic nervous systems are intimately involved in the body's pain regulation system. The balance between the two branches is disturbed in chronic pain such that the sympathetic branch excessively dominates over the parasympathetic, resulting in negative long term effects (Tracy, LM, et al., 2015).

Chronic pain, via its correlation to sympathetic dominance, is therefore associated with reduced heart rate variability. Study results suggest that patients with chronic pain also have decreased parasympathetic activity when compared to controls and that these alterations in the ANS's effects on the CV system "influence the central processing and subjective experience of pain" (Tracy, LM, et al., 2015). Notably,

regions of the brain that control the autonomic nervous system and those that control pain regulation lie in close physical proximity (Bruehl and Chung, 2004).

Reduced HRV has also been reported in numerous studies on chronic pain itself, as well as in studies looking at ANS responses to acute pain. Following up on this correlation, an investigational study found that reducing pain improves heart rate variability, indicating improved ANS balance with improved pain control (Koenig, et al., 2015).

The applications of HRV measurement in pain management are many. HRV is a sensitive quantitative measure of the body's experience of pain. When used as a monitoring tool, i.e. before and after changes in medications or other treatments, HRV can act as a quantitative indicator of pain level change with treatment. HRV also has tremendous potential to help evaluate pain in patients who cannot communicate well, such as very young children and those who have suffered stroke, trauma or degenerative CNS disease.

Federal and Ohio State Guidelines and Guidance Support Regular Office Visits (E/M codes and modifier 25) and Pain Management Procedures Use for Treatment of Chronic Pain Patients

1. Ohio law sets stringent requirements for pain management clinics and physicians who prescribe controlled substances as part of their pain management services. CPMI has met each of these requirements, including the rigorous licensure process to obtain a Category III Terminal Distributor of Dangerous Drugs ("TDDD") license, which is required for any practice seeking to possess and/or distribute Schedule I-V controlled substances or other dangerous drugs.[2]
2. Significantly, many of CPMI's patients are on long-term opiate therapy due to injury or illness. These patients present a significant risk of addiction, overdose, and death. Ohio had one of the highest death rates in the U.S. due to drug overdose in 2017 – 5,111 deaths (46.3% death rate).[3] A patient's risk level is determined by their NARX score (*i.e.*, an analytic score based on the patient's prescriptions, MED, and other data). The higher the NARX score, the higher the patient's risk of substance abuse. The majority of CPMI's patients has a high to extremely high-risk NARX score, meaning they are at extreme risk and must be closely monitored during treatment.[4]
3. Ohio law also mandates that physicians continuously monitor their patients utilizing high levels of opioids due to the heightened risk of addiction, substance abuse, and overdose with opioids.[5] A physician who prescribes an opioid analgesic for subacute or chronic pain is required to complete and document an assessment with the patient to determine the appropriateness and safety of the medication prior to its prescription.[6] Appropriate and required monitoring includes assessments and discussions with the patient regarding the benefits and risks of their medication

---

[2]*See* Ohio Rev. Code § 4729.552.

[3]*See* CDC, *Drug Overdose Mortality by State*, National Center for Health Statistics (available at https://www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm).

[4]*See* Margolin L., *et al.*, *Impact of Screening and Brief Intervention (SBIRT), Urinary Drug Testing, Minimally Invasive Procedures, and Electromyography on Pain Reduction, Functional Improvement, and Continuity of Care in Chronic Pain Patients*, Journal of Diabetes and Treatment, Vol. 5, Issue 1, p. 2 (July 14, 2020).

[5]*See* OAC § 4731-11-14.

[6]*See* OAC § 4731-11-14(B).

treatment plan.[7] The physician is also required to discuss the patient's responsibility to appropriately store and dispose of the prescribed opioids.[8]

Reassessments are also required whenever a patient is on a continuous course of treatment with opioids at or above 50 morphine equivalent daily dose ("MED").[9] In such circumstances, the physician must continuously review the patient's response/adherence to the treatment and screen the patient for opioid misuse.[10] Such screenings must occur noless than once every three months.[11]

4. For all of the evaluation and management ("E&M") services reviewed, that provider has billed a medically necessary E&M visit was performed and appropriately documented. In cases where a procedure (e.g., injection for pain management) was performed, the E&M visit note documents work performed above and beyond the usual pre- and post-procedure evaluations. The patients required and received an evaluation of their multi-body systems, screening for non-compliance, required risk/benefit assessment for opioid prescriptions, and Ohio Automated RX Reporting System ("OARRS") review.
5. Pain management procedures (including the ultrasound guided and X ray guided procedures) are required as opioid alternative treatments. Implementation of such alternatives is one of the requirements of the Ohio pain management clinic license and HB 93 law (39, 65, 83).

Potential Risks from Insurer Policies that Deny SBIRT and/or NCS, Autonomic Studies, office visits, pain management procedures and other Chronic Pain Patients Services

Denying coverage for SBIRT or defining the services as "Unallowable costs" can pose serious compliance issues for pain practices pertaining to governmental requirements and the professional guidelines described above. Ultimately, insurer denials of SBIRT services make the ethical operation of pain practices impossible and places both patients and staff at considerable risk. These procedures include: (i) face-to-face time spent by physicians and nurse practitioners for more than 30 min of telecommunication video to conduct a structured review of several assessments (including patient's history and physical examination); (ii) PADT; (iii) COMM; (iv)completion of withdrawal assessment forms; (v) point of care and conformation urine and saliva drug screen reviews; (vi) OARRS reviews; and (vii) provision of certain educational materials pertaining to opioid treatment. Moreover, initial evaluations of a chronic pain patient often require additional assessments (*e.g.*, SOAPP-R and ORT) and provision of additional educational materials pertaining to opioid-based treatments.

Denying appropriate testing and screening procedures for drugs and alcohol (which are required by the state and national guidelines) not only significantly impacts a pain program's ability to function as a business, but also puts an extremely vulnerable patient population at risk. Insufficient testing, monitoring, SBIRT screening and lack of alternatives to opioid medications can potentially result in either: (i) prescribing opioid medications to inappropriate candidates, which can increase risk of overdose or

---

[7] *See* OAC § 4731-11-14(B)(6)(a)).

[8] *See* OAC § 4731-11-14(B)(6)(b)).

[9] *See*OAC § 4731-11-14(G)).

[10] *See* OAC § 47311-11-14(G)(6)).

[11] *See* OAC § 47311-11-14(G)).

diversion; or (ii) failing to prescribe appropriate dosages/quantities of pain medications to patients, which could lead the patients to searching for alternative "street" drugs with morbidity/mortality significant risks. Moreover, the cost of hospitalization (including ER, inpatient care, ICU, detoxification, and maintenance programs) is astronomic, but can be reduced by patient screenings and non-opioid treatments (such as provided by CPMI) in outpatient programs like CPMI. Importantly, this approach of frequent screenings and preference of non-opioid treatments complies with the 5-Point Opioid Strategy to reduce opioid-related deaths launched by the U.S. Dept. of Health and Human Services in 2017. (HHS 2017).

III. EXAMPLES OF OTHER INAPPROPRIATE INSURER POLICIES

Failure to credential qualified providers and blocking beneficial services/treatments.

In addition to the issues with CareSource (the largest Ohio Medicaid HMO) described above, CPMI has faced credentialing issues with Molina (the second largest Medicaid HMO in Ohio). Since 2019, Molina has continuously denied credentialing for CPMI providers, which provide pain management services to high-risk patients in one of the epicenters of the Ohio opioid epidemic. Franklin County, which CPMI serves, has one of the highest opioid overdose death rates in the state with a rate of 19.43 per 100,000 people. (ONDCP 2015).

Insurer failure to credential qualified pain providers in an epicenter of the opioid epidemic places an unjustified risk to patients' safety, health, and lives. Such failure could cause increases in preventable opioid-related deaths, crime, family violence, drug-related human trafficking, increased medical expenses related to hospital stays/ICU/ER/detox programs, and drug-related motor vehicle accidents. Additionally, there is additional cost to treat other medical problems related to opioid use (*e.g.*, Hepatitis C cases are spiking with more than 15,000 people dying annually).

As discussed throughout this article, SBIRT services and non-opioid treatments (*e.g.*, NCS) are vital to combating the opioid epidemic. However, Molina's policies have blocked access to SBIRT services and NCS treatment, which place high-risk (predominantly minority) patients at increased risk of opioid overdose. Ultimately, the current, unjustified focus on meeting financial objectives as means to save limited Medicare and Medicaid resources has led to exacerbating results for the opioid epidemic, including potential increased risk to overdose, opioid misuse, and conversion which would ultimately result in greater losses of resources to the Medicare and Medicaid programs.

Focus on unjustified financial objectives over policies that combat the opioid epidemic.

Insurer policies that typically deny payment for NCS and SBIRT services fail to properly take into consideration the potential cost-savings (and life-savings) effect such services could have on patients. By way of example, CPMI's SBIRT and NCS policy and outcomes demonstrate that such services can result in overwhelming cost savings to both the patient and the overall treatment costs billed to insurers.

CPMI's patient population is unique as compared to many of our peers. Most CPMI patients are referred to our practice for the evaluation of chronic pain in two or more extremities or have been diagnosed with peripheral neuropathy, lumbar, or cervical radiculopathy by the referring provider. Our patients are extremely complex and we take pride in creating individualized treatment plans, which require a significant amount of testing and screening for substance and alcohol use. However, this allows our patients to achieve an extraordinary level of function relative to managing their pain with opioids alone, without any SBIRT services and/or non-opioid treatment options. After 2011, as a result of regulatory changes in the state of Ohio (including HB 93 law), CPMI received a high number of referral/evaluation requests for high-risk and challenging patient populations (86). Many of these chronic pain patients seen by CPMI suffer from anxiety, depression, substance use disorders, and/or drug-seeking behavior.

The numbers of NCV/EMG, autonomic and other tests performed at our practice are based on the OH local coverage determination. (CMS 2019).All patients undergo a comprehensive evaluation including initial, follow up evaluation forms, PADT forms enclosed, and extensive review of OARRS reports. The patients are also offered, and each signed, a written consent based on the AANEM guidelines with a detailed explanation of the risk and benefits of the tests. (AANEM 2022; AANEM 2023). NCV is reviewed and incorporated into the treatment plan.

In addition to lowering costs to our patients by cutting down on hospitalization costs, our practice performs the Autonomic (SSR, PSW, NCV/EMG testing) and another testing for a fraction of the cost charged by main hospitals in the area, including the Ohio State University clinic. This is another cost-reducing benefit of having these services available through outpatient facilities, such as CPMI. It is difficult for many patients to find alternative providers. If left untreated, patients may turn to illicit means of obtaining substitute medications which drastically increases the risk of overdose and death. As noted above, the drug overdose death rate in Ohio is one of the highest in the nation (rising more than 800% since 2013). The cost of the opioid epidemic is estimated as more than 500 billion nationwide. (Jeri D. Ropero-Miller 2019). CPMI runs a low-cost program that saves hundreds of thousands of dollars to Medicare by identifying and referring patients for addiction treatments using our SBIRT protocol, which ultimately cuts down on inevitable hospitalization costs and other opioid-related costs. All the insurance providers and government regulators discussed below ignored expert opinions, national academy review and independent billing and coding review available to them (83) because of the unjustified financial objectives.

Major providers in Ohio (Aetna, CareSource, Molina) inappropriately denied services because of unjustified financial objectives and bias:

Molina

Molina Medicaid HMO is the second largest Medicaid HMO insurer in the state of Ohio, and one of the biggest Medicare advantage plans in the Franklin County.

Molina HealthCare put unjustified financial objectives above vulnerable member's safety bydenying coverage for SBIRT and other life-saving services (Figure 2 – Molina denial letter). This has led to a severe limitation of patient access to certain lifesaving addiction screening and pain management care throughout Ohio (our findings show a NARX score of about 310 and a lack of access to care based on the OARSS report, including traditionally underserved mostly minority communities, like the one served by CPMI, and an increase in opioid-related mortality and death rates) please review the original patient complaints below, (68). These complaints were ignored by Molina who justified their denial of coverage as a "pure business decision". Molina leadership enjoyed exuberant salary compensation and stock bonuses with their CEO's annual salary reaching 22.1 million in 2022 (67).

In February 2022 Molina abruptly, and without warning, recouped close to 34 thousand dollars from the CPMI program. Molina's recoupment was corrected after a formal complaint and concern for legal intervention. In fact, on June 2nd, 22, Paul N St. Germain RN, the quality-of-care supervisor for Ohio, wrote the following email to Comprehensive Pain Management Institute, LLC (see attached):"Thank You Dr. Margolin, many Thanks for the GREAT (capitalized by Mr. Garmin) care that you take care of our Molina members and all of your patients!!" (68)

Four days later, Molina again abruptly and without any warning or explanation terminated coverage for this life-saving program, blocking access to SBIRT care and putting hundreds of vulnerable, mostly minority members at risk of opioid overdose death (Figure 2).

In addition, Molina refused to process the program credentialing application (Figure 3- application denial).

CareSource

In May 2015, our practice, CPMI, has voluntary invited a CareSource investigator to review CPMI's practice, policies, and patient interactions, as part of CPMI self audit policy. Notably, the CareSource investigator stated that she was impressed with CPMI's practice and everything that Dr. Margolin did to care for his patients. (65, Exhibit OO). In fact, the CareSource investigator was so impressed with Dr. Margolin/CPMI quality of care, that she directed referrals for pain management services from other CareSource-enrolled providers to CPMI (Id.)

Despite this positive review, driven by unjustified financial objectives, CareSource kept denying services and inappropriately withholding payments.

CPMI, has submitted several business integrity complaints (71) to CareSource between 2016 and 2022 related to abrupt denial of services and unannounced recoupment attempts (70) of tens of thousands of dollars in 2016 and 2017.

We did not receive a formal response from CareSource. Rather, CareSource inappropriately denied credentialing for the CPMI program that provides life-saving services to high-risk CareSource patients in the epicenter of the opioid epidemic over more than six years (85), while hundreds of the CareSource members died in the opioid epidemic due to lack of access to these services. Many CareSource patients submitted complaints that were ignored by CareSource (69).

Aetna

Unfortunately, our experience with Aetna (as detailed below) indicates that the insurer has focused its efforts on pursuing unjustified financial objectives over implementing policies that are focused on effectively combating the opioid epidemic and prioritizing member safety.

Unpaid Aetna services:

Insurance Name	CPT Code	Line Items	Sum of Charge Amount
AETNA	76942	226	$4,507.36
AETNA	64450	184	65,548.08
AETNA	99213	213	26,221.46
AETNA	03922	16	8,188.78
AETNA	95923	19	6,684.3
AETNA	95924	19	6,329.36
AETNA	64418	17	5,670.16
AETNA	33301	171	5,142.79
AETNA	99204	9	2,925
AETNA	80305	109	2,668.55
AETNA	80307	33	2,310
AETNA	20553	10	1,375
AETNA	99214	10	1,045.3
AETNA	93040	24	639.55
AETNA	27096	5	547.54
AETNA	99215	1	400
AETNA	99490	5	315.85
AETNA	80320	1	20
AETNA BETTER HEALTH OF OHIO	76942	114	23,064.52
AETNA BETTER HEALTH OF OHIO	99213	52	5,197.89
AETNA BETTER HEALTH OF OHIO	64450	27	2,488.51
AETNA BETTER HEALTH OF OHIO	03922	3	1,800
AETNA BETTER HEALTH OF OHIO	99214	7	935.98
AETNA BETTER HEALTH OF OHIO	95923	2	740
AETNA BETTER HEALTH OF OHIO	95924	2	700
AETNA BETTER HEALTH OF OHIO	99204	2	561.93
AETNA BETTER HEALTH OF OHIO	64405	1	460
AETNA BETTER HEALTH OF OHIO	80305	20	430.31
AETNA BETTER HEALTH OF OHIO	64418	1	400
AETNA BETTER HEALTH OF OHIO	80307	7	381.41
AETNA BETTER HEALTH OF OHIO	20553	3	375
AETNA BETTER HEALTH OF OHIO	33301	25	280.38
AETNA BETTER HEALTH OF OHIO	27096	1	250
AETNA BETTER HEALTH OF OHIO	93040	5	133.5
AETNA BETTER HEALTH OF OHIO	99490	2	107.94
AETNA BETTER HEALTH OF OHIO	80320	2	40
Grand Total		1346	258,891.28

No Of Claims	Charge Am
478	258,891.2

On December 25, 2022, CPMI submitted a formal complaint to Aetna. It had been brought to CPMI's attention that Aetna had been denying pain management procedures (even after giving authorization confirmation), requesting unreasonable amounts of records, holding reviews of standard services for 90 days or more, and inappropriately labeling standard procedures (*e.g.*, SIJ injection - first approved more than 30 years ago) as "experimental." These insurer policies focused on cost-savings inappropriately denied coverage of services, blocked patients from receiving legitimate life-saving services, and resulted in heightened risk to patient health (which were often vulnerable, high-risk chronic pain patients). The services (*i.e.*, UDT, office visits, pain procedures, and other tests) appear to have been denied across the board without a proper review or justification, as required per the Medicare Medicaid manual and applicable state and federal regulations. Aetna failed to respond to the complaint.

Even when Aetna approved services for coverage, CPMI often underwent timely record reviews (*i.e.*, often 90+ days) before payment would be remitted. These denials and delays have resulted in a severe limitation on patient access to certain addiction screenings and pain management care throughout Ohio. Such delays/denials can have a tremendously negative impact on opioid-related drug abuse and overdose in traditionally underserved, minority communities, such as Franklin County, Ohio (served by CPMI). Such communities are often impacted the hardest by the opioid epidemic. By way of example, the Franklin County Forensic Science Center issued a report in August 2022 demonstrating that the 2021 drug overdose fatality rate in Franklin County (825 deaths) had increased by 48% since 2019 (556 deaths). (FCFSC 2022).

Government regulatory agencies

In 2020, the government regulatory agencies labeled SBIRT and other chronic pain patient services as not "allowed" and issued a public press release (73). To our knowledge, no medical experts were involved in this decision. In fact, the data indicates that the government regulatory agencies were avoiding expert opinions (for example the government regulatory agencies refused to wait for the results of the review of

our program by the national academy, ABPMR), independent experts, which was published a month after the press release by the government regulatory agencies (see the white paper and exhibits) (65).

The government regulatory agencies failed to acknowledge the plethora of evidence that the national and government agencies (CDC, SAMSHA, NIDA), independent experts, and our office provided in support of the medical necessity of the lifesaving services they denied (65). The government regulatory agencies ignored a written warning about these issues sent to them in October 2020.
In a sense, the government inadvertently (and inappropriately) engaged in the practice of medicine without a license when it failed to consider all of the evidence from expert and governmental sources and disallowed SBIRT and other similar opioid alternative services.

The government regulatory agencies/insurers position has had devastating effects on pain specialists in Ohio, essentially handcuffing them from appropriately practicing pain management. Ohio law explicitly requires frequent monitoring of opioid patients (*See e.g.*, OAC 4731-11-14(F)-(G)), which creates a catch-22 with the government regulatory agencies/insurers position. We have evidence of over 100 complaints submitted by Ohio patients to Medicaid insurers regarding the lack of access to vital pain management services. *(67, 69)*

The government regulatory agencies/insurers policy has far-reaching implications, including a negative impact on opioid-related death and crime rates. While these are nationwide issues, Ohio is a key focal point of the opioid epidemic, with one of the highest death rates in the U.S. due to drug overdose for years (65). The year the government regulatory agencies /insurers published the above-cited press release regarding its settlement with CPMI, Ohio experienced a 22% increase in drug-related overdoses (77).

Ohio-based pain medicine practices have also experienced increased criminal activity from drug-seeking patients, including property destruction, attempted break-ins, and assaults on staff (80, 81). Many drug-seeking patients are lashing out due to a lack of access to appropriate pain management services.

So long as the government regulatory agencies/insurers continue to target pain specialists by limiting their ability to provide medically necessary services to pain patients, the opioid-related death and crime rate will continue to rise, and our society will continue to face negative implications from the opioid epidemic.

Covent Bridge

Covent Bridge is a contractor for Medicare, which is supposed to educate providers and enforce compliance. They have a clear financial incentive to deny services or label them as "not allowable" or "not necessary" since this increases the Covent Bridge reimbursement and bonus structure.

In 2021 Covent Bridge sent us an "educational letter" labeling most of the program services including urine drug screens, office visits, and screening for drug and alcohol (which are required by the state and federal guidelines) as "not medically necessary" or "not covered". When we contacted Coven Bridge it turned out that the review was performed by a former insurance agent with no medical background and subsequently by a RN with no background in pain management or addiction services. No appropriately educated/trained/experienced medical expert was involved. The reviewers had no basic understanding of the life-saving services they denied and the "catch 22" the denial created in regard to state and federal regulations/guidelines. (77)

We submitted a detailed complaint to the Covent Bridge legal advisor but to no avail. In 2024 Covent Bridge expanded their "not medically necessary" or "not covered" services to 92% of the services provided in our practice (78).

IV. CONCERNING INSURER POLICIES HAVE THE POTENTIAL TO SINGLE OUT MINORITIES

There are multiple concerns raised about racial disparity and social injustice in context of the opioid crisis. (PBS 2023). Specifically, there are significant concerns related to minority populations being subject to policies and practices which unjustly deny SBIRT and other essential services. On many occasions, these denials may be made in disregard to the proper review process specified in the Medicare integrity manual. Denials may be made without adequate expert review by a medical specialist (or with no expert review at all). Consequently, the opioid mortality rate for minorities is growing significantly larger than the national average (*i.e.*, 2.6 times higher in Ohio. *see* Figure 1).

Notably, Case Western Reserve University, Board of Health of Cuyahoga County scheduled a conference on the Racial Disparity, Social Justice and the Opioid Crisis Conference at Case Western Reserve University in April 2020. (Case Western Reserve University 2020). The conference focused on addressing the issue of structural racism, which prevents communities of color from receiving the necessary treatment, recovery, and wrap around social services to combat opioid use disorders. Similar concerns pertaining to racial disparity were acknowledged and reviewed in our presentations at Case Western Reserve University (Leon Margolin 2019) and the Ohio Opioid Task Force. (Leon Margolin 2020).

Further, as discussed during the Case Western Reserve University meeting, audits and supervision are necessary to combat the opioid crisis. Case Western Reserve University 2020. However, simultaneously, there are excessive regulations that interfere with the efficient function of the pain clinics (*i.e.*, the "first responders" in the opioid crisis).

V. CONCERNING INSURER POLICIES REPRIORITIZE RESOURCES AWAY FROM PRACTICE OPERATIONS, POTENTIALLY RESULTING IN PROVIDER SAFETY RISKS

A recent survey by the American Academy of Pain Medicine found high rates of violent threats toward pain practitioners. (AAPM 2020). Per the survey, more than two-thirds of responding pain providers reported that a patient had threatened them physically at least once a year, and roughly half reported that they had been threatened regarding their management of opioids. Moreover, the survey found that 8.9% or responding pain providers reported that they had actually been physically attacked.

By way of example, our practice has suffered from property damage, threats to the staff, and most recently an unprovoked assault of a physician and two female medical assistants by a violent patient with aberrant drug seeking behavior. Unfortunately, many pain practices lack the funding to appropriately address these rising security concerns. In fact, during the investigation related to assault of our staff members, the Columbus city prosecutor (Case 2020 CR B 001416)mentioned that "Because of the lack of funding secondary to insurance denials of essential services (such as screening and brief intervention for drug and alcohol) [pain practices like ours] do not have appropriate funding for additional security measures." These rising security risks to pain providers and their staff is yet another example of why a different approach to combating the opioid epidemic is necessary.

Each insurance plan creates several-hundred-page regulations that are ambiguous, convoluted, and different from the regulation of another insurance plan. Moreover, the insurer rules and regulations are not fully applicable to the reality facing pain management clinics. This is doomed to increase denial of services that can potentially save the lives of vulnerable patients without involving an expert, medical director or applying clinical judgment. Our practice is credentialed with 11 different plans which makes

adhering to the ongoing changes of requirements for each plan a stagnant daunting task and causes denial of essential services by the insurance plans.

Management of high-risk patients is frequently performed in a private practice setting. In contrast to more typical compensation arrangements for hospitals, private practices get neither government assistance nor grants, and receive much lower reimbursements for the same services (CPT codes). For example, CPT 62311, an interlaminar or caudal epidural steroid injection, when performed in a hospital surgical care center, can be reimbursed by government insurance at between $1,200-1,400 . The same injection given at a private practice setting is reimbursed at $80 only. Remarkably, despite receiving much lower reimbursements, private practices must still compete with hospitals in hiring, offering competitive salary and benefit packages, and retaining quality staff.

In 2017, the U.S. Dept. of Health and Human Services announced its "Strategy to Combat Opioid Abuse, Misuse, and Overdose: A Framework Based on the Five Point Strategy." (25) One of its five focal points is the development and enhancement of pain management programs. One wonders how such commendable goal can be accomplished by retaining patently flawed insurance company policies and government regulations that achieve the opposite result.

Some insurance plans use sophisticated software based on the frequency of services and sometimes compares codes to a specialty average and other criteria. Pain Management and opioid medication programs are highly specialized tertiary facilities that cannot be compared to other practices in the same specialty that do not prescribe opioids or do not manage high-risk patients (testing and assessment frequency are defined by the patient risk for opioid misuse, such NARX score, ORT, SOAPP-R, COMM, and clinical judgment). It is unreasonable to use these programs without proper clinical judgment by an independent expert.

Further, manipulation of the regulatory framework by insurers and government regulators, results in a significant negative impacts on of the opioid crisis. (*See* Figure 1.) The current regulatory and legal system creates legal loopholes and practically exempts the insurance policy makers and government regulatory agents from any personal or financial liability towards the physicians or victims of opioids.

We have documented evidence of abusive behavior by the insurance managers toward the staff and patients, such as ignoring and dismissing valid patient complaints (67,69) abrupt unannounced fund recoupment and defunding life-saving services (70), or denial of one week extension to pull the paper charts from storage while maintaining COVID precautions for a high-risk manager which resulted in the manager's hospitalization.(84)

Small to mid-size private practices (like CPMI) that carry limited legal resources and budgets are frequently "soft targets" for denials, flawed overpayment demands, false labeling of life-saving services as unnecessary, and other abusive actions motivated by bias and unjustified financial objectives.

CONCLUSION

Insurer policies have had far-reaching implications in the ongoing opioid crisis. Ohio is a key focal point of the opioid epidemic, having one of the highest annual death rates in the United States over the past decade due to drug overdose. Unfortunately, current insurer and government regulatory agencies policies in Ohio appear to be contributing to opioid-related death toll and crime rates. While there are viable screening and treatment options (e.g. SBIRT, urine drug screening, and other screening and treatment options at the CPMI program) that could greatly benefit high-risk chronic pain patients, insurers often

deny such services and treatment options as not medically necessary. This article focuses on potential policy updates (*i.e.*, covering SBIRT and services and testing for screening and treatment of chronic pain patients on opioid medications) that could not only decrease treatment costs to patients and healthcare programs, but significantly mitigate the impact of the ongoing opioid epidemic. Academic/expert evidence and CPMI's own experience indicates that SBIRT and NCS services could potentially lower opioid dependence and abuse, which could potentially result in decreased opioid reliance, overdose, crime rates, motor vehicle accidents, domestic violence, divorce, child abuse, and human trafficking.

Until action is taken, current insurer policies in Ohio (and out of state) that deny SBIRT and viable opioid-screening and treatment options will continue to subject the most vulnerable, high-risk chronic pain patients (*i.e.*, patients with NARX scores equal or greater than300) to increased risks of opioid abuse, overdose, and conversion. Failure to adequately address these issues will impact high-risk minority groups at a much higher rate than the national average, leaving impoverished areas battling increased rates of opioid-related mortality and crime. It is patently clear that insurers must shift their focus from unjustified financial goals to solutions that are supported by academic findings, pain specialist clinical judgments, and the plethora of governmental (state and federal) guidance that promote screening (*i.e.*, SBIRT, UDS, SOAPP-R, COMM, etc.), testing (NCS, imaging), and opioid alternative treatment options. The importance of this shift is only further supported by the significant increase of the illicit Fentanyl use in the United States. The number of individual pills containing fentanyl seized by law enforcement was 2,300 times greater in 2023 compared to 2017, with 115,562,603 pills seized in 2023 vs. 49,657 in 2017. (79).

In 2022 alone, over 107,000 people died of a drug overdose (82), with 75% of those deaths involving an opioid.

We call for urgent legislative or executive action that will prescribe reasonable "checks and balances", legal and regulatory accountability, and require the establishment of an independent pain medicine or addiction medicine expert review before denial of these services. Such action will save tens of thousands of lives and billions of healthcare dollars annually.

References

1. 42 U.S.C.A. § 1395ddd(f)(3). 2019. "Medicare Integrity Program." https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title42-section1395ddd&num=0&edition=prelim#:~:text=(1)%20Review%20of%20activities%20of,fraud%20review%20(employing%20similar%20standards%2C

2. AAPC (American Academy of Professional Coders). 2021. "E/M Utilization Benchmarking Tool." *AAPCResource*. https://www.aapc.com/tools/em_utilization.aspx.

3. AAPM (American Academy of Pain Medicine). 2020. "Pain Management Best Practices from Multispecialty Organizations During COVID-19 Pandemic and Public Health Crisis." *Pain Med.* 21(7):1331-1346.

4. AANEM (American Association of Neuromuscular & Electrodiagnostic Medicine Ethics Committee). 2022. "Guidelines for Ethical Behavior Related to Clinical Practice Issues in Neuromuscular and Electrodiagnostic Medicine." *Muscle Nerve*. 65(4):391-399.

5. AANEM (American Association of Neuromuscular & Electrodiagnostic Medicine Ethics Committee). 2023. "Model Policy for Nerve Conduction Studies and Needle Electromyography." *Position Statement*. https://www.aanem.org/docs/default-source/documents/aanem/advocacy/model-policy-for-nerve-conduction-studies-and-needle-electromyography.pdf?sfvrsn=fba901ae_3.

6. Agerwala SM, McCance-Katz EF. 2012. "Integrating Screening, Brief Intervention, and Referral to Treatment (SBIRT) into Clinical Practice Settings: A Brief Review." *J. Psychoactive Drugs*. 44(4):307-17.

7. AMA (American Medical Association). 2020. "Issue Brief: Reports of Increases in Opioid Related Overdose and Other Concerns During COVID Pandemic." *Advocacy Resource Center*. https://www.asapnys.org/wp-content/uploads/2020/07/Issue-brief_-Reports-of-increases-in-opioid-related-overdose-and-other-concerns-during-COVID-pandemic.pdf.

8. ASAM (American Society of Addiction Medicine). 2017. "Appropriate Use of Drug Testing in Clinical Addiction Medicine. *ASAM Consensus Statement*. https://downloads.asam.org/sitefinity-production-blobs/docs/default-source/guidelines/the-asam-appropriate-use-of-drug-testing-in-clinical-addiction-medicine-full-document.pdf?sfvrsn=700a7bc2_0.

9. ASAM (American Society of Addiction Medicine). 2018. "Handbook on Pain and Addiction."

10. In re Bailey, 581 N.E.2d 577, 580 (Ohio App. 10th Dist. 1989).

11. Case Western Reserve University, Board of Health of Cuyahoga County. 2020. "Racial Disparity, Social Justice and the Opioid Crisis." *Conference at Case Western Reserve University*. https://www.csuohio.edu/sites/default/files/Racial%20Disparity%20and%20Opioid%20Crisis%20Flyer.pdf.

12. Case Western Reserve University. 2019. "The Opioid Epidemic: Where are we now?" *YouTube*. https://www.youtube.com/watch?v=Tqlp_N_z-Xw&t=2945s.

13. CDC (Centers for Disease, Control and Prevention). 2022. "Drug Overdose Mortality by State." National Center for Health Statistics. https://www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm.

14. Chantal Berna, Ronald J. Kulich, James P. Rathmell. 2015. "Tapering Long-Term Opioid Therapy in Chronic Noncancer Pain: Evidence and Recommendations for Everyday Practice." *Mayo Clin. Proc.* 90(6):828-42.

15. Cleveland Clinic. 2024. "Overview: What is Somatic Pain?" *My.ClevelandClinic.org*https://my.clevelandclinic.org/health/symptoms/somatic-pain.

16. CMS (Centers for Medicare & Medicaid Services). 2019. "Nerve Conduction Studies and Electromyography." *Local Coverage Determination, L35897.* https://localcoverage.cms.gov/mcd_archive/view/lcd.aspx?lcdInfo=35897:24.

17. CMS (Centers for Medicare & Medicaid Services). 2022. "SBIRT Services." *Medicare Learning Network MLN 904084.* https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/SBIRT_Factsheet_ICN904084.pdf.

18. CMS (Centers for Medicare & Medicaid Services). 2023. "Urine Drug Testing." *Local Coverage Determination, L36707.* https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=36707&ver=36.

19. CMS (Centers for Medicare & Medicaid Services). 2023. "Urine Drug Testing." *Local Coverage Determination, L36029.* https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=36029&ver=41.

20. CMS (Centers for Medicare & Medicaid Services). 2024. "Chapter 8 – Administrative Actions and Sanctions and Statistical Sampling for Overpayment Estimation." *Medicare Program Integrity Manual.* https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/pim83c08.pdf.

21. DEA (Drug Enforcement Agency). 2020. "DEA 360 Central Ohio." *DEA Public Service Announcement.* https://www.youtube.com/watch?v=RvNQwQrqRBQ.

22. Debora Dowell, MD, Tamara Haegerich, PhD, Roger Chou, MD. 2016. "CDC Guideline for Prescribing Opioids for Chronic Pain – United States." *CDC Recommendations and Reports.* https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

23. Douglas Gourlay, Howard Heit. 2006. "Universal Precautions: A Matter of Mutual Trust and Responsibility. *Pain Medicine.* 7(2):210-1.

24. FCFSC (Franklin County Forensic Science Center). 2022. "Franklin County Ohio 2021 Drug Overdose Fatalities Data Brief." https://coroner.franklincountyohio.gov/getattachment/81c81378-bd61-49aa-bd88-22355ddf9907/Overdose_2017-2021_Report.pdf.aspx?lang=en-US.

25. HHS (U.S. Dept. of Health and Human Services). 2017. "Strategy to Combat Opioid Abuse, Misuse, and Overdose: A Framework Based on the Five Point Strategy." https://www.hhs.gov/overdose-prevention/.

26. Jeri D. Ropero-Miller, Paul J. Speaker. 2019. "The Hidden Costs of the Opioid Crisis and the Implications for Financial Management in the Public Sector." *Forensic Sci. Int. Synerg.* 1:227-238.

27. Jim Kimura, MD. 2018. "Letter Validating ABPMR Study re CPMI Protocols." *Attached asExhibit BB to Whitepaper: Overview of CPMI's Provision of Pain Management Services to Chronic Pain Patients and the DOJ's Wrongful Investigation and Settlement.* https://cpmiohio.com/wp-content/uploads/2024/03/White-Paper-SBIRT.x46178.pdf.

28. LaxmaiahManchikanti, Bert Fellows, HaryAilinani, Vidyasagar Pampati, 2010. "Therapeutic Use, Abuse, and Nonmedical Use of Opioids: A Ten-Year Perspective." *Pain Physician.* 13(5):401-35

29. Leon Margolin. 2019. "Opioid Epidemic: How many deaths are too many." *Case Western Reserve University Life Learning Program Conference.* https://www.youtube.com/watch?v=ujAS9UnHbgU.

30. Leon Margolin. 2020. "How to make a change in the opioid crisis." *Ohio Opioid Task Force Meeting.* https://www.youtube.com/watch?v=hA8VOQArqyQ&t=1s.

31. Leon Margolin. 2020. "Impact of the Frequency of the SBIRT protocol (G Codes such as G0397), of the POC UDS (80307, 80304) and minimally invasive procedures (76942, 64450, 20533, and other similar codes) on the pain reduction, functional improvement, and continuity of care of chronic pain patients. *American Board of Physical Medicine and Rehabilitation.* MOC Project.

32. L. Margolin, D. Streem, *et al.* 2020. "Impact of Screening and Brief Intervention (SBIRT), Urinary Drug Testing, Minimally Invasive Procedures, and Electromyography on Pain Reduction, Functional Improvement, and Continuity of Care in Chronic Pain Patients." *J. Diabetes Treat.* 5: 1080.

33. L. Margolin, S. Wainapel, *et al.* 2018. "Impact of Nerve Conduction Studies with or without needle EMG testing on the medical management, pain reduction and the functional outcomes of chronic pain patients." *American Board of Physical Medicine and Rehabilitation.* MOC Project.

34. LivinRite, Inc. v. Azar, 386 F.Supp.3d 644, 653-654 (E.D. Va. 2019).

35. Margaret Jarvis, Jessica Williams, *et al.* 2017. "Appropriate Use of Drug Testing in Clinical Addiction Medicine. *J Addict Med.* 11(3):163-173.

36. Martijn Boon, Eveline Van Dorp, Suzanne Broens, Frank Overdyk. 2020. "Combining opioids and benzodiazepines: Effects on mortality and severe adverse respiratory events." *Ann Palliat Med.* 9(2):542-557.

37. M. Bennett. 2001. "The LANSS Pain Scale: The Leeds Assessment of Neuropathic Symptoms and Signs. *Pain.* 92(1-2).

38. Michael E. Schatman, Kelly Kooharian, Patricia Guerrero. 2022. "Violence Against Pain Care Providers: The Frightening Future of American Pain Medicine." *J. Pain Res.* 15:2025-2027.

39. Michael Staples. 2019. "AuditofCPMI." https://cpmiohio.com/wp-content/uploads/2020/12/Self-Audit-report-Mike-Staples.x19540.pdf.

40. NBC News. 2022. "Every Branch of the Military is Struggling to Make its 2022 Recruiting Goals, Officials Say." *Military.* https://www.nbcnews.com/news/military/every-branch-us-military-struggling-meet-2022-recruiting-goals-officia-rcna35078.

41. O. T. Hall, Orman E. Hall, Ryan P. McGrath, Zelalem T. Haile. 2020. "Years of Life Lost due to Opioid Overdose in Ohio: Temporal and Geographic Patterns of Excess Mortality." *Journal of Addiction Medicine.* 14(2):156-162.

42. OAC (Ohio Administrative Code) § 4731-11-11. 2021. "Standards and Procedures for Review of "Ohio Automated Rx Reporting." https://codes.ohio.gov/ohio-administrative-code/rule-4731-11-11.

43. OAC (Ohio Administrative Code) § 4731-11-13. 2017. "Prescribing of Opioid Analgesics for Acute Pain." https://codes.ohio.gov/ohio-administrative-code/rule-4731-11-13.

44. OAC (Ohio Administrative Code) § 4731-11-14. 2023. "Prescribing for Subacute and Chronic Pain." https://codes.ohio.gov/ohio-administrative-code/rule-4731-11-14.

45. OAC (Ohio Administrative Code) § 4731-29-01. 2017. "Standards and Procedures for the Operation of a Pain Management Clinic." https://codes.ohio.gov/ohio-administrative-code/rule-4731-29-01.

46. OAC (Ohio Administrative Code) § 5160-1-27. 2015. "Review of Provider Records." https://codes.ohio.gov/ohio-administrative-code/rule-5160-1-27.

47. Ohio Board of Pharmacy. 2017. "Ohio Automated RX Reporting System: Ohio PDMP AWARE User Support Manual." https://www.ohiopmp.gov/Documents/OARRS%20User%20Manual.pdf.

48. Ohio 129th General Assembly. 2011. "Ohio H.B. 93." https://legiscan.com/OH/text/HB93/2011.

49. ONDCP (Office of National Drug Control Policy). 2015. "Epidemic: Responding to the Prescription Drug Abuse Crisis." *Executive Office of the President.*

50. Ohio Attorney General. 2021. "Record Surges in Opioid Overdoses Prompts AG Yost to Urge Vigilance." *News Releases.* https://www.ohioattorneygeneral.gov/Media/News-Releases/January-2021/Record-Surges-in-Opioid-Overdoses-Prompts-AG-Yost.

51. Ohio Dept. of Mental Health and Addiction Services. 2023. "Ohio Awards $6 Million to Case Western Reserve to Help Stem State's Increasing Opioid Epidemic." *PressRelease.* https://mha.ohio.gov/about-us/media-center/news/pr-05-07-2023#:~:text=In%202020%2C%20Ohio%20had%2045.6,by%20the%20disease%20of%20addiction.

52. ORC (Ohio Revised Code) § 4729.51. 2023. "Persons who may sell, deliver, distribute and possess dangerous drugs or investigational drugs or products."

53. ORC (Ohio Revised Code) § 4729.54. 2023. "Licensure as a terminal distributor of dangerous drugs; duties of licensees."

54. ORC (Ohio Revised Code) § 4729.552. 2017. "Eligibility Requirements for category III terminal distributor of dangerous drug license with a pain management clinic classification.

55. PBS (Public Broadcasting Service). 2023. "Racial Disparity in Addiction Treatment Access Highlights Inequities of Opioid Epidemic." *PBS News Hour.* https://www.pbs.org/newshour/show/racial-disparity-in-addiction-treatment-access-highlights-inequities-of-opioid-epidemic.

56. R. Dworkin, PhD, A. O'Connor, M.D., *et al.* 2010. "Recommendations for the Pharmacological Management of Neuropathic Pain: An Overview and Literature Update." *Mayo Clinic Proc.* 85(3 Suppl).

57. SAMHSA (Substances Abuse and Mental Health Services Administration). 2017. "Quick Facts: Screening, Brief Intervention, and Referral for Treatment." *Fact Sheet.* https://prevention.nd.gov/files/pdf/parentsleadforprof/SBIRT%20Quick%20Facts.pdf.

58. Sherrod Brown, Edward J. Markey, *et al.* 2018. "Letter to CareSource President & CEO." 18-23. https://cpmiohio.com/wp-content/uploads/2021/02/the-final-opioid-screening-article.x19540.pdf.

59. Stanley F. Wainapel. MD, MPH. 2018. "Letter Validating ABPMR Study re CPMI Protocols." *Attached asExhibit CC to Whitepaper: Overview of CPMI's Provision of Pain Management Services to Chronic Pain Patients and the DOJ's Wrongful Investigation and Settlement.* https://cpmiohio.com/wp-content/uploads/2024/03/White-Paper-SBIRT.x46178.pdf.

60. State Medical Board of Ohio. 2019. "Cat. 1: Improper Prescribing, Dispending, or Administering of Drugs." *Disciplinary Guidelines.* https://www.med.ohio.gov/Portals/0/Regulation/Disciplinary%20Guidelines%20rev.%2007-Final.pdf?ver=0A5Y-4G4x8uUJliB7IRoyA%3d%3d.

61. Stephen F. Butler, Simon H. Budman, *et al.* 2007. "Development and validation of the Current Opioid Misuse Measure." *Pain.* 130(1-2):144-56.

62. Steven P. Cohen, Zafeer B. Baber, *et al.* 2020. "Pain Management Best Practices from Multispecialty Organizations During the COVID-19 Pandemic and Public Health Crises." *Pain Med.* 21(7):1331-1346.

63. Steven D. Passik, Kenneth L. Kirsh, *et al.* 2004. "A new tool to assess and document pain outcomes in chronic pain patients receiving opioid therapy." *Clin. Ther.* 26(4):552-61.

64. William Vasilakis, Psy.D. 2019. "Letter Validating ABPMR Study re CPMI Protocols." *Attached asExhibit DD to Whitepaper: Overview of CPMI's Provision of Pain Management Services to Chronic Pain Patients and the DOJ's Wrongful Investigation and Settlement.* https://cpmiohio.com/wp-content/uploads/2024/03/White-Paper-SBIRT.x46178.pdf.

65. Adrienne Dresevic Esq, The Health Law Partner, *Whitepaper: Overview of CPMI's Provision of Pain Management Services to Chronic Pain Patients and the DOJ's Wrongful Investigation and Settlement.* https://cpmiohio.com/wp-content/uploads/2024/03/White-Paper-SBIRT.x46178.pdf.

66. NGO petition to Molina 07/09/23

https://cpmiohio.com/wp-content/uploads/2024/05/Ohio-Value-Voters-Letter-Molina.x26591.pdf

67. Examples of Molina patients complaints (names blotted for HIPAA compliance):

https://cpmiohio.com/wp-content/uploads/2024/05/Molina-complaint-2_Redacted.x26591.pdf
https://cpmiohio.com/wp-content/uploads/2024/05/Molina-complaints-3_Redacted.x26591.pdf

https://cpmiohio.com/wp-content/uploads/2024/05/Molina-complaints-4_Redacted.x26591.pdf

68. Molina quality of care evaluation June2nd, 2022:

https://cpmiohio.com/wp-content/uploads/2024/05/Molina-quality-of-care-evaluation.x14555.pdf

69. CareSource patient complaints example (names blotted for HIPAA compliance):

https://cpmiohio.com/wp-content/uploads/2024/05/Patient-complaints-examples.x21518.pdf

70. CareSource EOB/ unannounced service denial example:
https://cpmiohio.com/wp-content/uploads/2024/05/Apruptly-denied-EOB-examples.x21518.pdf

71. CareSource business integrity complaint example:
https://cpmiohio.com/wp-content/uploads/2024/05/Caresource-HEDIS-non-compliance.x21518.pdf

72. Ohio Capital Journal, Fatal overdoses update, July 15, 2021:
https://ohiocapitaljournal.com/2021/07/15/new-data-fatal-overdoses-leapt-22-in-ohio-last-year/

73. DOJ press release publicly admonishing CPMI for its provision of NCS and SBIRT:
(https://www.justice.gov/opa/pr/columbus-pain-clinic-and-owner-agree-pay-650000-resolve-allegations-unnecessary-procedures).

74. Institute of Medicine (US) Committee on Advancing Pain Research, Care, and Education. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research.* Washington (DC): National Academies Press (US); 2011

75. Humphreys K, Shover CL, Andrews CM, et al. Responding to the opioid crisis in North America and beyond: recommendations of the Stanford-Lancet Commission. *Lancet.* 2022;399(10324):555-604. doi:10.1016/S0140-6736(21)02252-2
76. The Consortium Pain Task Force White Paper: https://dpbh.nv.gov/uploadedFiles/dpbhnvgov/content/Resources/opioids/Evidence_Based_Non pharmacologic_Strategies_for_Comprehensive_Pain_Care_White_Paper.pdf

77. CPMI letter to CoventBridge 2021: https://cpmiohio.com/wp-content/uploads/2024/05/Letter-to-CoventBridge-2021.x68908.pdf
78. CPMI letter to CoventBridge 2024: https://cpmiohio.com/wp-content/uploads/2024/05/Letter-to-CoventBridge-Feb-24.x68908.pdf

79. NIH press release May 13, 2024: https://www.nih.gov/news-events/news-releases/over-115-million-pills-containing-illicit-fentanyl-seized-law-enforcement-2023

80. Evidence of high risk patients aggressive behavior: https://cpmiohio.com/wp-content/uploads/2024/06/High-risk-patients.x92936.pdf

81. Survey Finds High Rate of Violent Threats Toward Pain Practitioners:

https://www.painmedicinenews.com/Multimedia/Article/05-20/Survey-Finds-High-Rate-of-Violent-Threats-Toward-Pain-Practitioners/58619?utm_source=Social&utm_medium=facebook&utm_campaign=0615violentvid

82. 2022 Opioid mortality (CDC press release): https://www.cdc.gov/nchs/products/databriefs/db491.htm

83. CPMI Independent Billing and Coding review (mdbillingky.com): https://cpmiohio.com/wp-content/uploads/2020/12/Billing-and-coding-review.x92936.pdf
84. CPMI Manager Amanda Rutherford letter to CovenBridge: CPMI-manager-Amanda-letter-to-CoventBridge.x88572.pdf (cpmiohio.com)
85. Evidence of CareSource application denial: Margolin-Letter-to-CareSource-re-Credentialing-Status-4874-4318-7492v1.x79175.pdf (cpmiohio.com)
86. CPMI Pain Management Clinic category 3 license based on Ohio law: https://cpmiohio.com/wp-content/uploads/2024/06/CamScanner-06-14-2024-12.51.x28381.pdf

MOLINA HEALTHCARE

June 7, 2022

Comprehensive Pain Management Institute, LLC
5340 E. Main Street, Ste. 100
Columbus, OH 43213

Re: Termination of Provider Services Agreement Without Cause

Dear Comprehensive Pain Management Institute, LLC:

Pursuant to Section 4.2, Termination Without Cause, of your Provider Services Agreement between Molina Healthcare of Ohio, Inc. and Comprehensive Pain Management Institute, LLC ("Agreement"), Molina Healthcare of Ohio, Inc. is terminating your Agreement without cause.

The Agreement will be terminated ninety (90) days after receipt of this letter, and shall be effective September 6, 2022.

If you have any other questions, please contact Brad Bryant at brad.bryant@molinahealthcare.com.

Sincerely,

Brad Bryant
Director, Provider Contracting

MOLINA HEALTHCARE

December 1, 2023

Leon Margolin, MD
Comprehensive Pain Management Institute LLC
1120 Polaris Parkway, Ste 202
Columbus, OH 43240

Dear Leon Margolin:

Molina Healthcare of Ohio has received your application for participation in our provider network. We regret to inform you that we will not be processing your application at this time.

Should you have any questions or concerns, please contact me at 614-540-3223 or by email at Toni.Hopewell@molinahealthcare.com

Sincerely,

Toni Hopewell
Molina Healthcare of Ohio, Inc

GAVIN PUBLISHERS

OPEN ACCESS

Journal of Diabetes and Treatment

Review Article

Margolin L, et al. J Diabetes Treat 5: 1080.

DOI: 10.29011/2574-7568.001080

Impact of Screening and Brief Intervention (SBIRT), Urinary Drug Testing, Minimally Invasive Procedures, and Electromyography on Pain Reduction, Functional Improvement, and Continuity of Care in Chronic Pain Patients

Leon Margolin[1*], David Sreem[2], Daniel Margolin[1], Sandford Lefkowitz[1]

[1]Comprehensive Pain Management Institute, LLC (www.cpmiohio.com), Columbus, Ohio, USA

[2]Chief of Psychiatry and Medical Director of the Alcohol and Drug Recovery Center (Lutheran Hospital Division), Cleveland Clinic Foundation

Associate Professor of Medicine at the Cleveland Clinic Lerner College of Medicine of Case Western Reserve University

***Corresponding author:** Leon Margolin, Comprehensive Pain Management Institute, LLC, Columbus, Ohio 43213, USA

Citation: Margolin L, Sreem D, Margolin D, Lefkowitz S (2020) Impact of Screening and Brief Intervention (SBIRT), Urinary Drug Testing, Minimally Invasive Procedures, and Electromyography on Pain Reduction, Functional Improvement, and Continuity of Care in Chronic Pain Patients. J Diabetes Treat 5: 1080. DOI: 10.29011/2574-7568.001080

Received Date: 26 June, 2020; **Accepted Date:** 10 July, 2020; **Published Date:** 14 July, 2020

Abstract

With the alarming explosion of overdose risk in the opioid epidemic since 1999, Opiate Use Disorder (OUD) has cost in excess of $600 billion, harming the economy and killing tens of thousands nationally. According to research conducted in 2017 on opioid mortality, data showed Ohio to be the second-highest opioid mortality state in the US, representing more than 2.6 times the death rate per 100,000 population compared to the US average (39.2 in OH vs. 14.6 in US, see Figure 1 below).

Although socioeconomic factors play a role, authors suggest that lack of availability or the consistent denial of these services by insurance carriers play a role in this situation. A recent Ohio Department of Health report showed that the population of patients susceptible to the opioid epidemic was in fact at least twice the non-minority risk level for COVID 19 pandemic (Figure 2). The recent AMA brief [26] alarms about great concern over increased opioid mortality during COVID 19 pandemic.

This retrospective chart review study provides a systematic analysis of the Screening and Brief Intervention (SBIRT), urinary drug testing, minimally invasive procedures and electromyography on the pain reduction and functional improvement of moderate to high risk chronic pain patients, with risk level determined by NARX scores.

Key Points

SBIRT protocol is mandatory for the compliant operation of a pain management clinic providing medical management to the population with a significant percent of high-risk patients in the high-risk area like Ohio.

Nerve Conduction Studies (NCS)/ Nerve Conduction Velocity (NCV) with or without needle EMG tests as part of the effort to document organic pathology (both initial tests and follow up tests) are medically necessary tests and cost-effective tests that have a strong statistically significant contribution to the proper choice of medications and procedure for chronic pain patients and strongly associated with functional improvement and pain reduction [18].

Using Pain Assessment and Documentation Tool (Figure 3 – PADT) and other validated assessment tools, we demonstrated a statistically significant impact of these services on pain reduction and functional improvement of moderate to high risk (as defined by NARX score and other factors) chronic pain patients over a 2 year period. Using these services and testing since 2011, our practice has been able to identify patients in need and refers to Addiction medicine evaluation and treatment for more than 2000 high-risk patients (who would otherwise be at significant risk of opioid mortality, morbidity, diversion, and incarceration).

Denial coverage for these services by third-party payers or defining them as "Unallowable costs" puts the practice in noncompliance with the guidelines described above, making the ethical operation of the practice impossible and putting patients and staff at considerable risk.

Objective data (Figure 1) shows that a new approach described in this review by the medico-legal system and third

party payors required to address the opioid crisis and protect the population at the high risk for COVID 19 epidemic (Figure 2).

Background

Opioid epidemic crisis affects the lives of thousands of Americans on a daily basis. Since 1999 hundreds of thousands of Americans have died from overdoses. On an average day in the US close to 5,800 people misuse opioids for the first time, and over 1,000 Americans on an average day are treated in the emergency departments for issues related to opioid misuse. The societal and healthcare cost of the opioid epidemic is at least 600 billion dollars and it continues to rise. Proper screening of pain management program patients (including SBIRT protocol G codes, POC UDS, and NCV/EMG) for narcotic medications is extremely important in the prevention of street drug use. The 2018 National Drug Threat Assessment conducted by the Drug Enforcement Administration, showed that prescription drugs such as "Opioids were responsible for the most overdose deaths of any illicit drugs since 2001" and "heroin-related deaths nearly doubled from 2013 to 2016". Ohio is one of the states most affected by the opioid crisis. Ohio has one of the highest death rates related to the Opioid crisis. Efficient and Ethical pain management program that uses appropriate testing to document organic pathology and screen appropriate candidates for pain medications and refer other patients to Addiction medicine evaluation is extremely important in this challenging environment of the opioid epidemic crisis.

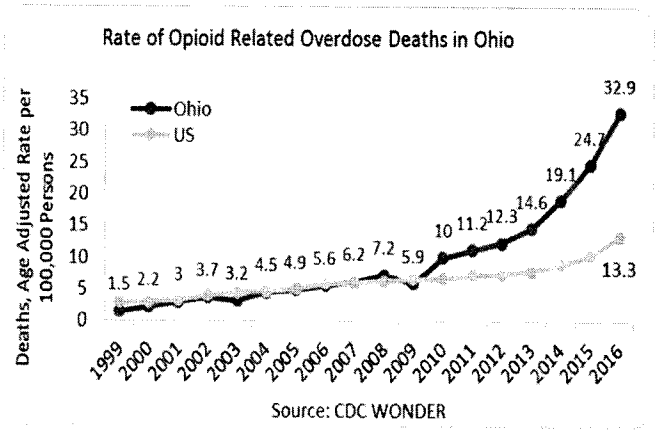


Figure 1: Based on 2017 government Opioid mortality data, Ohio is rated number two in the US with more than 2.6 times death rate per 100,000 population compared to US average rate (39.2 in OH vs. 14.6 average).

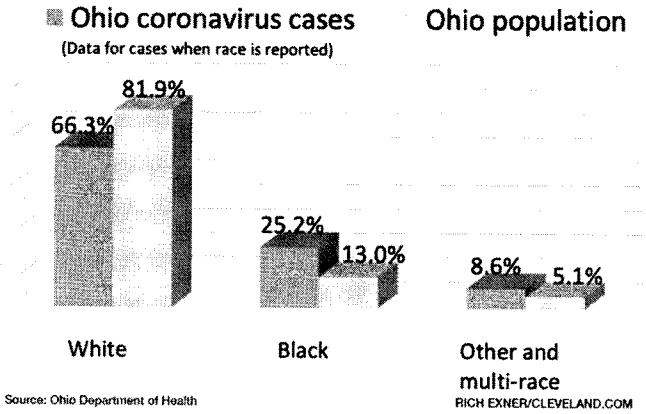


Figure 2: Based on the age, medical comorbidities, socio-economic challenges and possible immunosuppressive effect of Opioids, our patient is at increased risk for the COVID-19 pandemic.

The national and state guidelines require risk stratification and close monitoring of patients on chronic Opioid medication [1]. This study tests the impact of the frequency of the SBIRT protocol (G codes such as G0397), of the POC UDS (80307, 80304) and minimally invasive procedures on the pain reduction (76942, 64450, 64418, 20533 and other similar codes) functional improvement and continuity of care of chronic pain patients. This is frequency of the SBIRT protocol (G codes such as G0397), POC UDS (80307, 80304) and minimally invasive procedures (76942, 64450, 64418, 20533 and other similar codes are based on the "Pain Management Best Practices Inter-Agency Task Force Report", Medicare MLN and LCD OH L36029, Medicare guidelines for the presumptive and definitive testing [1,10,15].

Our practice is a tertiary referral practice that gets referrals for high-risk patients. This is the reason for conducting this study that tests the impact of the frequency of the SBIRT protocol (G codes such as G0397), of the POC UDS (80307, 80304) and minimally invasive procedures on the pain reduction (76942, 64450, 64418, 20533 and other similar codes) functional improvement and continuity of care of chronic pain patients for the quality of care documentation and information for the third-party payers.

Consequences of denial labeling as unallowed service for SBIRT and other services.

Unfortunately, on many occasions' providers face denial of the SBIRT and other services by the private and the government insurance plans. When the insurance carriers challenge the

necessity of SBIRT protocol (G codes), it denies coverage for procedures that are required by the Ohio state law (please review Michael Staples attached) and creates a "catch 22 scenario" that puts the patients and the staff at risk. These procedures include face to face time spent by physician and the nurse practitioners, more than 30 min of telecommunication video material, structured review of several assessments including patient's history and physical examination, PADT [2], COMM [3], Flowchart form based on SMBO Administrative Rule 4731-21-02 [4], withdrawal assessment form, point of care and conformation urine and saliva drug screen reviews, OARRS reviews, and several educational materials. The initial evaluations include additional assessments such as SOAPP-R and ORT and additional educational materials.

Denial payments for the appropriate testing and screening procedures for drugs and alcohol required by the state and national guidelines not only significantly impact pain program ability to function as a business, but also puts an extremely vulnerable patient population at risk. Our patient population is unique as compared to many of our peers. Our patients are extremely complex; we take pride in creating individualized treatment plans which do require a significant amount of testing and time for screening for substance and alcohol use. However, this allows our patients to achieve an extraordinary level of function relative to managing their pain and prevent morbidity and mortality.

At the time of the COVID-19 pandemic additional requirements for SBIRT, withdrawal screening and mental screening suggested by the American Academy of Pain Medicine [17]. Denial of these services exposes staff and patients for additional risks during the pandemic and depletes necessary practice funds required for the personal protection equipment suggested by the American Academy of Pain Medicine [17] during the COVID-19 pandemic.

National and state guidelines require documentation of the organic pathology as part of a comprehensive evaluation in a pain management clinic. NCV, EMG, and Autonomic testing is part of such evaluation.

For example, Mayo Clinic Proceedings [5] that were adopted by the state of Ohio and referenced on each printed copy of the OARRS report, reported that in the area of pain management "The predominant reason for inappropriate care was a failure of the prescribing physician to adequately verify patient's prior medical history". Appropriate testing including NCV and EMG is a step in such verification.

Most of the patients referred to Comprehensive Pain Management Institute, LLC (CPMI) for the evaluation of chronic pain in two or more extremities, or have the diagnosis of peripheral neuropathy, lumbar, or cervical radiculopathy suggested by the referring provider.

The numbers of NCV/EMG tests are based on the OH local coverage determination [6]. All patients had a comprehensive evaluation including initial, follow up evaluation forms, PADT forms enclosed, and extensive review of OARRS reports offered a written consent based on the AANEM guidelines [7] with a detailed explanation of the risk and benefits of the tests. NCV is reviewed and incorporated into the treatment plan.

The most commonly tested nerves in the upper extremities were sensory ulnar, median and radial studies, motor median, ulnar, radial, and in selected cased Axillary studies with Median and Ulnar F waves. For the low extremities the studies included sensory Sural, Superior Peroneal, Motor studies included Common Peroneal, Tibial nerves, and Common Peroneal, and Tibial nerve; F waves and H reflex studies selected based on the comprehensive assessment results. The needle examination typically included (UE) Cervical Paraspinals, Deltoid, Biceps, Extensor Carpi Radialis, Triceps, Flexor Carpi Radialis, APB muscle, (LE) Lumbar Paraspinals, Vastus medialis, Extensor Hallucis Longus, Biceps Femoris, Peroneus Longus, Medial Gastrocnemius, the studies selected based on the comprehensive assessment result.

Between 2011-2015 as a result of regulatory changes in the state of Ohio (including HB 93 law), CPMI received a high number of referral/evaluation requests for high risk challenging patient populations.

Many of these chronic pain patients seen by the CPMI suffer from anxiety and depression, and/or substance use disorders, drug-seeking behavior and had a poor tolerance of the NCV/EMG testing and poor cooperation with the test, especially with the needle part of the test (EMG), (this part performed with inserting EMG needle in 6-12 sites) and frequently refused by the challenging patient population. All the patients signed a written consent based on the AANEM guidelines [6,7].

Cost Efficiency

The cost of the opioid epidemic is more than 600 billion dollars and keeps rising annually. Pain Management programs like our practice that carefully screen and test patients to properly document organic pathology and utilize alternative treatments, careful monitoring, and SBIRT approach not only prevent significant morbidity and mortality but save very significant costs to the healthcare system.

Insufficient testing, monitoring, SBIRT screening and lack of alternatives to opioid medications can potentially result in either prescribing opioid medications to not appropriate candidates that can potentially overdose or divert medications to other people, or not prescribing 5/9 appropriate pain medications to patients who may look for alternatives "On the street" with significant risks or morbidity and mortality.

The host of hospitalization including ER, inpatient care, ICU, detoxification, and maintenance programs is astronomic and can be reduced by patient screening treatment in outpatient programs like our practice (Comprehensive Pain Management Institute). This approach is also supported by the 2017 five-point strategy by the HHS.

When the insurance carriers challenge the necessity of SBIRT protocol (G codes), it denies coverage for procedures that are required by the Ohio state law and creates a "catch 22 scenario" that puts the patients and the staff at risk. These procedures include face to face time spent by physician and the nurse practitioners, more than 30 min of telecommunication video material, structured review of several assessments including patient's history and physical examination, PADT, COMM, Flowchart form based on SMBO Administrative Rule 4731-21-02, withdrawal assessment form, point of care and conformation urine and saliva drug screen reviews, OARRS reviews, and several educational materials. The initial evaluations include additional assessments such as SOAPP-R and ORT and additional educational materials.

Insufficient testing, monitoring, SBIRT screening, can potentially result in either prescribing opioid medications to not appropriate candidates that can potentially overdose or divert medications to other people, or not prescribing appropriate pain medications to patients who may look for alternatives "on the street" with significant risks or morbidity and mortality. The host of hospitalization including ER, inpatient care, ICU, detoxification, and maintenance programs are astronomic and can be reduced by patient screening and testing including NCV/EMG testing and other testing.

Our practice performs the NCV/EMG testing and another testing for a fraction of the cost charged by main hospitals in the area including the Ohio State University clinic.

It is difficult for many patients to find alternative providers. If left untreated, patients may turn to illicit means of obtaining substitute medications which drastically increases the risk of overdose and death (overdose death rate in Ohio is the highest in the nation and is up more than 800% since 2013). The cost of the opioid epidemic is estimated as more than 600 billion nationwide, we run a low-cost program that saves hundreds of thousands of dollars to Medicare by identifying and referring for addiction treatments for hundreds of patients using our SBIRT protocol. We billed much lower rates than comparable hospital-based programs and chose lower-cost codes (i.e. G codes vs. office visit and time codes).

In summary, denial payments for the appropriate testing and screening procedures for drugs and alcohol put in danger about several hundred high-risk patients (just in December of 2019 we had a case of assault by a discharged drug-seeking patient and an attempted assault by another patient at our office).

Denial payments for the appropriate testing and screening procedures for drugs and alcohol required by the state and national guidelines would not only significantly impact pain program (such as CPMI) ability to function as a business, but would also put an extremely vulnerable patient population at risk. Our patient population is unique as compared to many of our peers. Our patients are extremely complex; we take pride in creating individualized treatment plans which do require a significant amount of testing and time for screening for substance and alcohol use. However, this allows our patients to achieve an extraordinary level of function relative to managing their pain and prevent morbidity and mortality.

Methodology

Risk Stratification for the patient in sample 1 (please see NARX table below):

NARX Score analysis of the patients in the sample.

Our treatment protocol, including the SBIRT protocol (G codes such as G0397), of the POC UDS (80307, 80304) and minimally invasive procedures on the pain reduction (76942, 64450, 64418, 20533 and other similar codes) is based on patient risk stratification, NARX risk stratification (validated by the CMS) LCD OH L36029 [27] and state and national guidelines.

NARX score is a nationally validated risk score accepted in the state of Ohio and many other states [9]. There are no frequency guidelines for the G code, however, the NARX score (that shows the risk of overdose and death) seems to be the golden standard accepted by the CMS and Medicare. The clinical recommendations by the CMS and SMBO attached (attachment NARX Manual, NARX clinical application).

Only 6% of the sample 1 patients (3/50 pts) are low risk (NARX below 100)

Only 16% are high risk (NARX 100-189) Odd ratio for overdose increased 10 times (chapter 12 Overdose Risk Score page 63 attached).

The rest are at a very high risk of 34% (NARX above 200) and an extremely high risk of 24% (NARX above 350). The odds ratio for death from overdose is 10-12 times average (see the clinical application of the NARX score attached page 67). The odd ratio for overdose increased 10-12 times or more (chapter 12 Overdose Risk Score page 63 attached).

Undoubtedly the patient with this type of risk would require frequent G code screening and another testing such as EMG.

The vast majority of the "sample 1" patients were on increased risk dose of the opioids (more than 20 MME- increased risk of death as per CDC 2016 guidelines increased adjusted Hazard Ratio (HR) for an overdose and death) [10], many patients obtained opioids

from more than one prescriber, used multiple pharmacies and multiple classes of opioid medications, some also used sedatives or stimulates that greatly increased the risk according to the CDC guidelines and NARX score database (please find original NRAX score reports for each patient attached).

These types of risky patients require a high frequency of SBIRT (G code use) based on the criteria discussed above.

Risk stratification of sample 2 (sent by a separate email) demonstrated similar results.

Use of SBIRT G code vs. use of the E/M office visit codes.

Many of the CPMI patients have multiple medical comorbidities and dependent on transportation (can schedule only a limited number of visits). Therefore on many occasions, we have to schedule the minimally invasive procedure and the office visit for medical management on the same date.

This study shows the advantages of using SBIRT/G codes rather instead of E/M level 3 or 4 codes in these encounters. This approach provides cost-saving to third party insurance payers and emphasizes the screening and brief intervention approach which is crucial in managing high-risk patients on opioid medications.

Cost-saving secondary to use of G code use vs more expensive office visit (E/M) codes:

According to the national standards for Pain Medicine [11] office visit codes, 99213 and 99214 combined constitute almost 100% of the total visit billings (48.8% for 99213 + 44.9% 99214). These codes are more expensive than G codes and can also be combined with time codes.

Our billing data analysis below shows that in our practice these more expensive office visit codes (99213 and 99214) constitute only 16-30 percent of the total annual visits.

Our practice started the appropriate use of G codes since its inception in 2014 (which explains the 91% percent increase in comparison to 2013).

The use of these codes was based on the certified biller and coder review below and saved Medicare tens of thousands of dollars (as proven by the billing and coding data below).

Between 16-30 % of our follow up visits were billed as the more expensive E/M codes 99213, 99214, the rest were billed as G codes instead of more expensive office visit codes.

In other words, analysis of G code and office visit codes E/M codes billed shows significant cost savings in using G codes vs. the use of more expensive E/M codes for the office visits. That is clearly demonstrated in the patient example 1: the 79 times the G code was billed - it was billed for 79 follow up visits instead of more expensive office visit code.

Coding and billing statistics for our office

	Office Visits	G Codes	Total Visits
2014	2330	5104	8239
2015	2056	5622	8157
2016	1146	6621	7885
2017	1373	7294	8491
2018	1160	7907	8111
2019	2317	8838	9494

Implementation of the LCD OH L36029 [27]

Our study also provides a clear proof that frequency of the SBIRT/G code monitoring should depend on the compliance with the prescribed opioid medications and NARX score risk stratification, rather than reliance on the self-reported risk factors like alcohol or drug use in the initial evaluation by the staff or by a pain psychologist.

LCD OH L36029 [27] sets the frequency of monitoring that depends on prescribed opioid medications and other elements and not only on the initial psychological evaluation that used. These are the factors that set the frequency of testing and screening (including the SBIRT/ G codes use).

- Patient history, physical examination, and previous laboratory findings
- Current treatment plan
- Prescribed medication(s)
- Risk assessment plan

The rationale for such screening LCD OH L36029 defines as:

- Identifies the absence of prescribed medication and potential for abuse, misuse, and diversion;
- Identifies undisclosed substances, such as alcohol, unsanctioned prescription medication, or illicit substances;
- Identifies substances that contribute to adverse events or drug-drug interactions;
- Provides objectivity to the treatment plan; e. Reinforces therapeutic compliance with the patient;
- Provides additional documentation demonstrating compliance with patient evaluation and monitoring; g. Provide diagnostic information to help assess individual patient response to medications (e.g., metabolism, side effects, drug-drug interaction, etc.) over time for ongoing management of prescribed medications.

All these elements and factors are documented in our records and evaluated in our study. We would like to illustrate the importance of this approach using the examples below:

Patient examples that show an efficient SBIRT implementation that enables successful patient participation in the program and timely detection of aberrant drug-seeking behavior.

(Patient examples reviewed by the ABPMR without protective health care information disclosure and provide examples of the common cases mistakenly denied overlooked by providers and denied by third party payers).

Example #1: DS. This patient-reported the last drink 26 years ago, however, this patients meet criteria for a high-risk patient with a chronic pain syndrome failed back syndrome after (s/p)4 back surgeries). This is an example of SBIRT screening directed towards compliance with the prescribed opioid substances and confirmation of the lack of the non prescribed narcotic substances as per SMBO, Ohio Board of Pharmacy and NARX (25), CDC, and LCD OH L36029 We will analyze the necessity and the frequency of the SBIRT and G code screening (SBIRT /G code) code at least 79 SBIRT (G code) performed since 2015) and the impact on patient compliance and participation in the program.

Case Review: This is a patient s/p 4 back surgeries that require chronic pain management.

NARX score analysis/ example 1

Narcotic Score 470 Sedative Score 170 Overdose Risk Score 190 (Odds ratio for overdose and death is about 10 times higher than average please refer to the NARX score review material enclosed (25 In addition, he is currently on 60 MME daily (Three times the dangerous dose threshold per CDC guidelines), he has received more than 150 prescriptions from 5 different prescribers using 2 different pharmacies including high-risk substances like Oxycodone, Morphine Sulphate and Fentanyl (that is responsible for a large number of overdoses and death).

Since this is a high-risk patient on chronic opioid medications, he requires frequent follow-ups and compliance monitoring. Our practice monitored the patient compliance with at least 79 screenings and brief interventions performed over the span of the last 3-4 years. This number is conservative for this type of patient and required by the SMBO, Ohio Board of Pharmacy and NARX, CDC, and LCD OH L36029.

The screenings are related to continuous exposure to different narcotic substances and not to his prior drinking history as described above. Of note, this chart was reviewed by the Board of Pharmacy in 2015 and found fully compliant.

Use of different codes for this patients would have resulted in increased cost for the third party payers.

This example shows how efficient and cost-effective use of the SBIRT screening (G0397 code) use saves significant costs funds for the third party payers and enforces compliance for the high-risk patients.

Also, this patient has been coming to our practice for close to 5 years (despite multiple competing providers just a few miles away) and even volunteered a video testimonial (together with close to 70 other patients).

Example #2: LH, on the initial interview with the pain psychologist – the patient did not report any history of alcohol or drug abuse. The Board of Pharmacy NARX score defines this patient as a very high-risk patient:.

NARX score analysis/example 2

Narcotic Score 451 Sedative Score 290 Overdose Risk Score 370 Stimulant Score 20 (Odds ratio for overdose and death is about at least 12 times higher than average or more please refer to the NARX score review material enclosed [25] Additional risk factor more than 100MME with an average 40 MME daily (please find the original NARX report enclosed). Recently patients are getting 60 MME daily. These are very dangerous doses according to the NARX and CDC guidelines attached that require frequent SBIRT (G code screenings).

The patient received more than 82 prescriptions for several types of medications including Percocet, Oxycodone, Morphine, Hydrocodone, Phentermine, Lyrica, and Gabapentin from 7 prescribers and 5 pharmacies.

44 screenings and brief interventions (SABIRT/G code) performed over the span of the last 3-4 years for such risk patients is a reasonable required number as per SMBO, Ohio Board of Pharmacy, and NARX, CDC, and LCD OH L36029. The screenings are related to continuous exposure to different narcotic substances.

Use of different codes for this patients would have resulted in increased cost for the third party payers.

This example shows how efficient and cost-effective use of the SBIRT screening (G0397 code) saves enforcement for the very high-risk patients on multiple controlled substances and saves funds for third-party payers.

Example #3: LH

Case Review: This is a chronic pain patient with a symptomatic spinal stenosis who requires chronic pain management. Besides, the patient reported being a victim of physical domestic abuse (additional risk factor) and required chronic benzodiazepine therapy (alprazolam).

The patient had multiple prescriptions of alprazolam (potent benzodiazepine) combined with opioids (12) which is an additional high-risk factor for overmedication and death that requires SBIRT interventions each time the combination is prescribed according to the CDC guidelines. Please find the list of the prescriptions enclosed.

The patient had an abnormal urine drug screen which positive for non prescribed benzodiazepine (which a very high-risk factor combination of medications as per accepted guidelines) and the follow up pain psychology report that conditioned patient clearance for opioids with closed monitoring (SBIRT protocol/G codes). 26 screenings and brief interventions (SBIRT/ G codes) performed over for such a very high-risk patient is a reasonably required r as per SMBO, Ohio Board of Pharmacy and NARX, CDC, and LCD OH L36029.

The screenings are related to continuous exposure to a combination of benzodiazepines narcotic substances and not to the patient's prior drinking history. Use of different codes for this patients would have resulted in increased cost for the third party payers. This example shows how efficient and cost-effective use of the SBIRT screening (G0397 code) saves enforcement for the high-risk patients on opioids and benzodiazepines and saves funds for the third-party payers.

Cases 1-3 show that despite the initial denial of prior risk factors (i.e drinking history) on the initial psychological interview, NARX score and structured assessment analysis can help to implement proper SBIRT/ G code screening for safety and compliance.

Example #4: JM

Patient chart review shows that the patient was prescribed on October 20, 2016, 30 tablets of OxyCodone 5 /APAP 325 for 15 days as per state prescription monitoring system (OARRS). On 11/2/16 our practice performed a random urine screen that was NEGATIVE for prescribed OxyCodone. The urine screen was reviewed by a Doctor of Pharmacology consultant and discussed with a pain psychologist, both of them requested tight monitoring because of concern for medication diversion (which is considered a felony by the state of Ohio and federal law).

Also, the follow-up note dated 11/02/16 states that the patient did not bring medication bottles for a pill count. The patient claimed she "has a lot of Percocet at home" raising additional concerns about hoarding and medication misuse. Unfortunately, the patient was not compliant with the reasonable monitoring and self-discharged herself.

NARX score analysis/example 4

This patient has a high NARX score (Narcotic score 371, Sedative score 150, Overdose risk score 170), she received opioid medications from 7 prescribers, using 4 pharmacies based on the Board of Pharmacy database.

In summary, our management of the case was appropriate and mandated by the federal and state law, SMBO, Ohio Board of Pharmacy, DEA, and CDC regulations. Patient examples of proper use of informed consent and respect for patient autonomy based on the AANEM policies and guidelines [6,7].

In the previous part of the study dedicated to the EMG/ NCV protocol, we introduced the use of informed consent in our practice. The following examples analyze the use of the informed consent by the patients.

Example # 5

ST This is a high-risk patient (NARX score analysis defines her as a high-risk patient: Narcotic Score 441 Sedative Score 200 Overdose Risk Score 340 (Odds ratio for overdose and death is about 10 times higher than average as per Ohio PMDS (OARRS) manual [25]. The Board of pharmacy summary also mentioned more than 5 opioids or sedative providers from 4 pharmacies. Proper testing such as NCV/EMG testing is necessary for such a patient for documentation of organic pathology.

This patient "First refused the needle EMG, then left the box unchecked and then agreed to the needle EMG test". The patient refused the needle EMG in 2014, later when the patient required prolonged care in 2016, and in 2017 she agreed to the needle testing. In 2016 she gave verbal consent (not marking the checkbox is irrelevant based on the AANEM ethical guidelines enclosed) and 2017 she gave both verbal and written consent which is also consistent with the guidelines. Patient informed consent for and against the testing was respected each time as per AANEM and Medicare consent policy. The 2014 and 2016 tests were both carpal tunnel evaluation exempt by the AANEM policy and provided credible information even without the needle testing.

Example # 6 MS

MS is a high-risk patient. (NARX score analysis defines her as a high-risk patient: Narcotic Score 381 Sedative Score 160 Overdose Risk Score 210 (Odds ratio for overdose and death is about 10 times higher than average please refer to the NARX score review material enclosed [25]. Mark recently had a urine screen positive for use of illicit marijuana (as per consultation with the Doctor of Pharmacology consultant). The Board of pharmacy also mentioned more than 4 opioids or sedative providers from 2 pharmacies (total more than 50 prescriptions). Proper monitoring testing such as NCV/EMG testing and alternative procedures are necessary for this patient.

This patient also has been seen at our practice for several years (despite multiple competing providers just a few miles away) that testifies for the quality of care she has received. Close follow up that included an interview by pain psychologist and psychological assessments helped to address patient anxiety. This patient initially refused the needle EMG testing. Even though the test is called "Needle" EMG, the test is performed using a recording probe (and not a needle) in a conventional sense (nothing is injected through the EMG "needle"). Therefore it's quite natural for a patient to refuse the needle EMG testing that does not directly relieve the pain (and also involves 6-12 probe sticks).

At the same time, the patient agreed to the nerve block injection that involved one small needle stick that provides immediate pain relief through medications injected through the needle. Patient informed consent for and against the testing was respected each time as per AANEM and Medicare consent policy. The 2014 and 2016 tests were both carpal tunnel evaluation exempt by the AANEM policy and provided credible information even without the needle testing.

POC UDS testing

Use of the POC UDS testing performed in compliance with the state and federal guidelines as part of the patient monitoring program using the risk stratification scale discussed above. Data shows a significant impact of the testing on the patient treatment plan and compliance [13-15].

Ultrasound-guided procedures

Ultrasound-guided procedures (peripheral nerve blocks, trigger point injections, and others). The minimally invasive procedures are cost-effective alternatives to the opioid medications required by the guidelines. All the patients received the informed consent and the medical necessity forms. Statistical analysis shows a strong impact of these procedures on the patient treatment plan and compliance.

Analysis of sample 2 – discharged patients

We have reviewed the charts of patients positively screened for non-compliance with the patient contract (illicit substance abuse, failed pill counts, doctor shopping, urine screens negative for prescribed medications, and other issues) using the SBIRT protocol (G codes) that we discussed.

Methods

- A retrospective review of charts of regular and incomplete studies to assess the impact of the test on the treatment decision making (such as choosing non-opioid adjuvant medications and opioid medications, pain reduction and functional improvement as documented by PADT forms and performance of proper clinical assessment that justify study repletion in the selected group of patients.
- The retrospective review studies the impact of the frequency of the SBIRT protocol (G codes such as G0397), of the POC UDS (80307, 80304) and minimally invasive procedures on the pain reduction (76942, 64450, 64418, 20533 and other similar codes) on the treatment decision making (such as choosing non-opioid adjuvant medications and opioid medications), pain reduction and functional improvement as documented by PADT forms and performance of proper clinical assessment as all the compliance and participation in the program (lengths of participation in months).

When pain reduction was 30%-50% we defined it as a "Moderate", above 50% a "Significant" and more than 70% a very significant pain reduction. When functional improvement as documented by PADT included 2 parameters or more, we called it significant, if only one parameter we called it a "moderate" functional improvement. If three or more functional parameters improved we called a very significant improvement. The effect is illustrated with several patient example analyses.

Results

SBIRT and UDS and procedure impact analysis

Sample 1

NARX Score (risk stratification) and SBIRT protocol screening effectiveness analysis.

The table below how the average NARX scores change with Months in Program:

Table 1:

Months	Average	Max	Number Patients
Short (1 month)	308	450	6
Medium (>1 month, < 2 years)	271	390	13
Long (2 years)	309	770	23

NARX Score (risk stratification) and SBIRT protocol screening effectiveness analysis results

Enforcing and monitoring patient compliance is a major challenge for pain management programs. The average and the maximum NARX scores reflect the high risk and the very high-risk profile of our patient population. Our SBIRT protocol and other tests and treatment described in the study is effective in monitoring and enforcing the high-risk patient compliance for prolonged periods (more than 23 months).

Functional Improvement Analysis

The table below compares Months in Program vs Functional Improvement (based on the PADT and other tools). Given the low number of patients in the 'less than a 2-year group, these 3 groups are combined.

Table 2:

	Moderate	Significant	Very	Total
Less than 2 years	16	7	6	29
2 years	5	1	20	26
	21	8	26	55

Table 3:

% of Row Totals for the table above.

	Moderate	Significant	Very
Less than 2 years	55.2%	24.1%	20.7%
2 years	19.2%	3.8%	76.9%

For example, of the 26 patients with 2 years of treatments (for whom we also had data on Functional Improvement), 20 of them or 76.9% showed Very Significant Improvement.

Performing a chi-square test in Table 3 (combining the first 2 columns to enhance the test) shows there is a significant difference in 'months of Treatment ($p<.01$).

Functional Improvement Analysis Results

There is a significant relation (at .05 level) between Months in Program and Functional Improvement. The SBIRT protocol and other treatments in our program showed a strong statistically significant impact on the patient functional improvement – which is the main outcome measure of the pain management program.

Pain Reduction analysis

Table 5:

	Moderate	Significant	Very	Total
Less than 2 years	22	4	2	28
2 years	17	5	4	26
Total	39	9	6	54

Table 6:

% of Row Totals for Table above

	Moderate	Significant	Very
Less than 2 years	78.6%	14.3%	7.1%
2 years	65.4%	19.2%	15.4%

Most patients had only moderate pain reduction (72.2%). Of the patients in the program for 2 years, 15% (4 out of 26) had Very Significant pain reduction while 65% of the 2-year patients had Moderate Pain Reduction.

Performing a chi-square test on Table 5 (combining the last 2 columns to enhance the test) shows there is a significant difference in 'months of Treatment ($p=.02$).

Pain Reduction analysis results

We demonstrated a very significant pain ($p=.02$) reduction over time in our program. As time participation in the program increases (more than 2 years), the pain reduction becomes more significant.

Statistical analysis

Sample 2

NARX Score (risk stratification) and SBIRT protocol screening effectiveness analysis

The table below how the average NARX scores change with Months in Program

Table 7:

NARX Score vs Months in Program

	Average	Max	Number Patients
< 2 years	317	480	9

NARX Score (risk stratification) and SBIRT protocol screening effectiveness analysis results (sample 2):

Enforcing and monitoring patient compliance is a major challenge for pain management programs. As we have observed in sample 1, in sample 2 the average and the maximum NARX scores reflect the high risk and the very high-risk profile of our patient population. Our SBIRT protocol and other tests and treatment described in the study is effective in monitoring and enforcing the high-risk patient compliance for prolonged periods (more than 23 months).

Functional Improvement Analysis

The table below compares Months in Program vs Functional Improvement (based on the PADT and other tools). Given the low number of patients in the 'less than a 2-year group, these 3 groups are combined.

Table 8:

Months in Program vs Functional Improvement

	Significant	Very	Total
< 2 years	5	6	11
2 years	8	25	33

Table 9:

% of Row Totals for the table above

	Significant	Very
< 2 years	45.5%	54.5%
2 years	24.2%	75.8%

The table below compares Months in Program vs Functional Improvement (based on the PADT and other tools). Given the low number of patients in the 'less than a 2-year group, these 3 groups are combined.

Functional Improvement Analysis Results

All the patients in the sample stayed in the program for 6 months or longer, most of the patients for 2 years or longer. All the patients achieved functional improvement at 6 months and continue with significant or very significant improvement after that.

Pain Reduction analysis

Table 10:

Months in Program vs Pain Reduction

	Moderate	Significant	Very	Total
< 2 years	4	5	0	9
2 years	0	21	11	32

The difference between the "< 2 years" group and the "2 years" group is statistically significant (binomial test, P<.01)

Table 11:

% of Row Totals for Above Table

	Moderate	Significant	Very
<2 years	44.4%	55.6%	0.0%
2 years	0.0%	65.6%	34.4%

Pain Reduction analysis results

We demonstrated a very significant pain (p=.01) reduction over time in our program. As time participation in the program increases (more than 2 years), the pain reduction becomes more significant.

Sample 3 (discharged patients)

Discharge Reason	Number Patients	% Total Patients	3 months	6 Months	12 Months	2 years	Average NARX Score	Number with NARX Score
COC	14	35.9%	7	2	4	1	367	14
THC	2	5.1%	2	0	0	0	160	1
METH	2	5.1%	2	0	0	0	80	1
ETOH	12	30.8%	2	2	5	3	442	11
FENT	1	2.6%	1	0	0	0	50	1
ADLTERATION OF URINE	3	7.7%	3	0	0	0	236	3
BUP	5	12.8%	4	0	0	1	486	5

Two-thirds of all Discharge reasons were for COC or FPC.

Dividing the patients into 3 groups, COC, FPC, ALL Others, there is no significant difference in Average NARX Score amongst the 3 groups (t-test at .05 level).

Discharged patient analysis results

Data shows the high complexity and the high-risk status of our patients. The most discharged patient tested positive for cocaine (COC) and ETOH (35.9 and 30.8 percent), the highest NARX score was associated with buprenorphine (486).

NCV/EMG study analysis results

All initial and repeated tests were performed after a comprehensive evaluation and proper documentation of medical necessity as required by the AANEM guidelines and Ohio LCD.

All NCV tests with or without EMG testing had a documented impact on the narcotic and non-narcotic medication prescriptions, pain reduction, and functional improvement.

There was a significant association between pain reduction and functional improvement.

	Pain Reduction	Functional Improvement
Moderate	58.3%	20.8%
Significant	16.7%	25.0%
Very Significant	25.0%	54.2%

Applying a chi-square statistic to patient outcomes of functional improvement, we observe: that NCV and NCV+EMG are statistically significant at the .05 level.

Association between the repetition of the test and functional improvement (number of studies and percent of patients):

	Moderate	Significant
No Repeat	5	5
Repeat	0	14

	Moderate	Significant
No Repeat	20.8%	20.8%
Repeat	0.0%	58.3%

Conclusion

SBIRT analysis

The use of the SBIRT protocol (G codes such as G0397), of the POC UDS (80307, 80304) and minimally invasive procedures on the pain reduction (76942, 64450, 64418, 20533 and other similar codes) show a significant documented positive effect on increasing overall patient safety, encouragement of safe controlled substance prescribing for practitioners, maintaining compliance with State and Federal laws and regulations, reduction of patient overdose deaths, early detection and intervention of substance use disorder, and improving overall standards of care.

The vast majority of patients in the sample fit the high-risk profile which requires frequent SBIRT monitoring. CPMI SBIRT protocol is associated with effective long-term monitoring of compliance of the chronic pain patients on opioid medications and effective diagnostics of aberrant drug-seeking behavior and referral to Addiction Medicine evaluation. Our protocol is based on the "Pain Management Best Practices Inter-Agency Task Force Report", Medicare MLN and LCD OH L36029, Medicare guidelines for the presumptive and definitive testing, Medicare CPT code definitions.

This study has important conclusions for third-party payers and clinicians. SBIRT protocol (G codes such as G0397) is mandatory for a compliant pain management practice. Without proper implementation of the SBIRT protocol (G codes such as G0397), a safe and compliant pain management program is hardly possible, and patients and staff are exposed to significant risks.

Alcohol/substance abuse structured assessments and brief interventions of 30 minutes or longer, under code G0397 (SBIRT protocol) performed at Comprehensive Pain Management Institute, LLC are based on the accepted guidelines and "HHS Pain management best practices inter-agency task report" and required for the state and federal guidelines compliance. The SBIRT protocol is documented on all the charts in the study and compliant with the Medicare MLN # and LCD OH L36029.

This study shows a significant positive impact of the SBIRT protocol on pain reduction and function improvement is well documented in this study. SBIRT protocol is mandatory for the compliant operation of a pain management clinic providing medical management to the population with a significant percent of high-risk patients in the high-risk area like Ohio. Denial coverage for these services by third-party payers or defining them as "unallowable costs" puts the practice in noncompliance with the guidelines described above making the ethical operation of the practice impossible and putting patients and staff at considerable risk.

Denial payments for the appropriate testing and screening procedures for drugs and alcohol (such as of the SBIRT protocol (G codes such as G0397) required by the state and national guidelines) would not only significantly impact of a pain program ability to function as a business, but would also put an extremely vulnerable patient population at risk. The chronic pain patient population is unique as compared to many other specialties. Our patients are extremely complex; we take pride in creating individualized treatment plans which do require a significant amount of testing and time for screening for substance and alcohol use and other tests and procedures described in this study. However, this allows our patients to avoid the risk of morbidity and mortality (Ohio has one of the highest rates of opioid mortality per 1000 population in the country) and achieve significant pain relief and improvement in the level of function relative to managing their pain.

NCV/EMG analysis

Using a chi-square test, we can and conclude (with $P<.01$) that repeating the test has a positive association with functional improvement.

The association can be explained by the fact that an additional comprehensive evaluation was performed prior to the test and additional NCV and EMG test results were incorporated in the treatment plan that helped to achieve additional functional improvement.

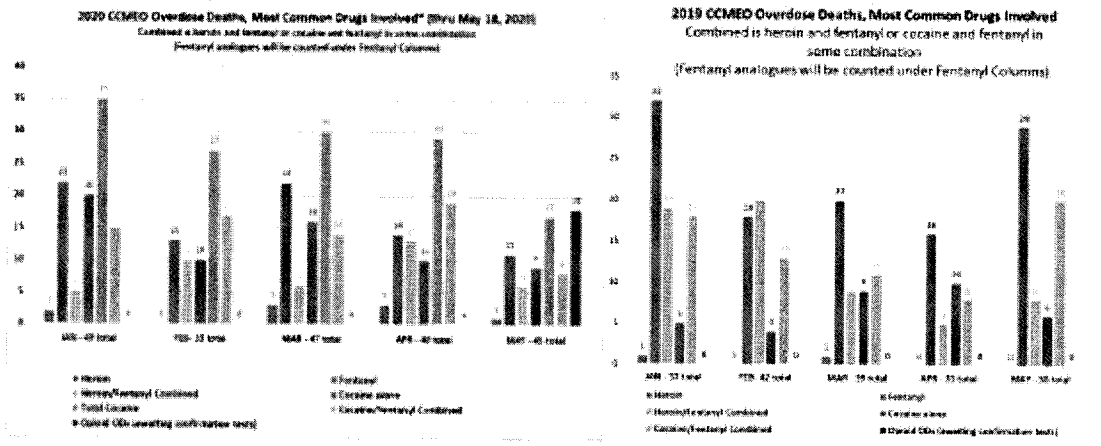
A functional improvement which is the main goal of pain management program (which is more important that pain reduction) has most strong statistically significant improvement with the use

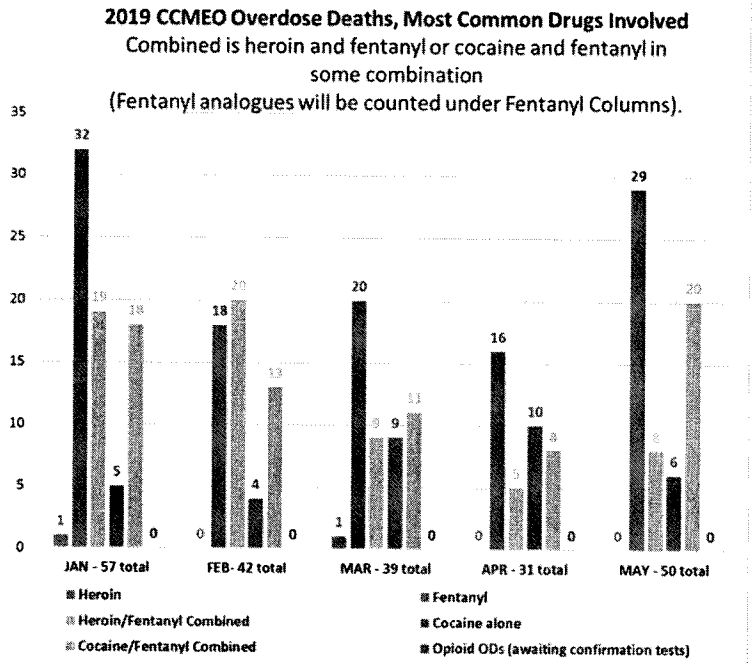
of the NCV and EMG testing (with or without the needle testing). These findings underscore the medical necessity and cost-effectiveness of the NCV and EMG tests based on the sample examined.

NCV with or without needle EMG tests as part of the effort to document organic pathology (both initial tests and follow up tests) are medically necessary tests and cost-effective tests that have a strong statistically significant contribution to the proper choice of medications and procedure for chronic pain patients and strongly associated with functional improvement and pain reduction.

Despite a possible improvement in 2018-2019 data, objective data (figure 1) shows that a new approach described in this review by the medico-legal system and third party payers required to address the opioid crisis and protect the population at the high risk for COVID 19 epidemic (figure 2). These trends are confirmed by the Cuyahoga County Medical Examiner's Office (figure 4 and 5) for 2019 and the beginning of the 2020. Of note, Cuyahoga County is one the most affected counties by COVID-19 as well.

Figure 4,5 and 6 (Cuyahoga County Medical Examiner's Office)





As a small independent office, without a special research budget me have done our best to provide SBIRT care with is compliant with the best standards in the specialty based on the American Board of Physical medicine and Rehabilitation and HHS guidelines discussed above.

We advocate for large prospective studies and provider and third party payor education on these subjects.

Additional risks of SBIRT denials during the COVID-19 pandemic American Academy of Pain Medicine (AAPM)

American Academy of Pain Medicine (AAPM) recently made recommendations for COVID-19 pandemic 20) additional requirements for SBIRT including additional withdrawal screening and mental screening suggested. Denial of the SBIRT and other services exposes staff and patients for additional risks during the pandemic. In addition the AAPM guidelines required using expensive personal protective equipment (such as N-95 masks). Denials of the SBIRT and other services deplete necessary practice funds required for the personal protection equipment and creates additional risks for staff and patients. The recent AMA brief [26] alarms about great concern over increased opioid mortality during COVID 19 pandemic.

Concerns for singling out minority patient populations and practices

There are multiple concerns raised about racial disparity, social injustice in context of the opioid crisis. Specifically concerns related to the fact that minority populations and practices targeted with unjust denials of the SBIRT and other essential services. On many occasions, these denials are done without a proper review process specified in the Medicare integrity manual, without adequate expert review and with no expert review at al. That is one the reasons for the increased gap between opioid mortality in Ohio and average nation levels (2,6 time higher in Ohio, see Figure 1).

Huge Medicare Medic Aid HMOs silence criticism of these policies and denials by ignoring business integrity and patients safety retaliatory recoupment and forcing providers to resign from the plan. Several concerns were raised about Caresource the billion dollar HMO that controls more then 50% of the Ohio market by more than ten senators (Figure 7, 4) in 2018. In April 2020 Case Western Reserve University, Board of Health of Cuyahoga County organized a conference on the Racial Disparity, Social Justice and the Opioid Crisis Conference at Case Western Reserve University [21] (the conference had to be postponed because of the pandemic). In June 2020, both Columbus and Cleveland proclaimed racism a public health emergency [22,23]. It is important to see these declaration and concerns translated into practical changes to avoid additional risk to the medical personnel and patients.

Concerns of the overregulated environment

As discussed during the Case Western Reserve University meeting [16], regulations, audits and supervision are necessary in middle of the opioid crisis. At the same time excessive regulations that interfere with efficient function of the pain clinics (the first responders in the opioid crisis), manipulation of the regulatory agencies by the retaliatory complaints from patients discharged for non compliance result in a significant worsening of the opioid crisis. (Figure 1).

SBIRT and other services denials and security risks to the staff and patients

The recent survey by the American Academy of Pain Medicine found high rate of finds high rate of violent threats toward pain practitioners [24]. Our practice has suffered from property damage, threats to the staff and recently from an unprovoked assault of the physician and two female medical assistants by a violent patient with aberrant drug seeking behavior.

The Columbus city prosecutor (Case 2020 CR B 001416) mentioned that "Because of the lack of funding secondary to insurance denials of essential services (such as screening and brief intervention for drug and alcohol) (pain practices like ours) do not have appropriate funding for additional security measures".

This is a real public safe and health crisis that requires urgent attention.

Acknowledgements

An expression of gratitude for reviewing data and supporting this study conclusions is given towards:

Professor Stanley Wainepal MD, Professor and Clinical Director, Department of Rehabilitation Medicine, Montefiore Medical Center, Albert Einstein College of Medicine, NY.

Professor Jun Kimura MD, Professor of Neurology, University of Iowa; Kyoto University; Distinguished Researcher Award by the American Association of Neuromuscular & Electro diagnostic Medicine; Author of a major textbook recommended by the AANEM and ABPMR; Lecturer in the AANEM NCV and EMG courses; Author of more than 500 publications in the field / 25 professional honorary society membership all around the world.

Expert panel of the American Board of Physical Medicine and Rehabilitation (ABPMR)

Roneet Lev MD, Chief Medical Office, White House Office of National Drug Control Policy Executive Office of The President.

Sabaitu I. Mansarai a Senior Executive Service (SES) with the Office of National Drug Control Policy where she is the Assistant Director for Public Health, Education and Treatment Task Force in support of combating the opioid crisis.

Ohio Opioid Task Force, Cuyahoga County Board of Health

Case Western Reserve University continuous education program expert panel

This data was reviewed and approved by the American Board of Physical Medicine and Rehabilitation [19].

References

1. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS). Strategy to Combat Opioid Abuse, Misuse, and Overdose A Framework Based on the Five Point Strategy. 2017
2. Passik SD, Kirsh KL, Whitcomb L, Portenoy RK, Katz NP, et al. (2004) A New Tool to Assess and Document Pain Outcomes in Chronic Pain Patients Receiving Opioid Therapy. CLINICAL THERAPEUTICS 26: 552-561.
3. Butler SF, Budman SH, Fernandez KC, Houle B, Benoit C, et al. (2007) Development and Validation of the Current Opioid Misuse Measure. Pain 130: 144-156.
4. State Medical Board of Ohio Administrative Rule 4731-21-02 The State Medical Board of Ohio Administrative Rule 4731-21-02 pertains to "utilizing prescription drugs for the treatment of intractable pain".
5. Berna C, Kulich RJ, Rathmell JP (2015) Tapering Long-term Opioid Therapy in Chronic Noncancer Pain: Evidence and Recommendations for Everyday Practice. Mayo Clin Proc 90: 828-842.
6. AANEM Model Policy for Needle Electromyography and Nerve Conduction Studies. And AANEM Recommended Policy for Electro diagnostic Medicine.
7. AANEM Guidelines For Ethical Behavior Relating To Clinical Practice Issues In Neuromuscular And Electrodiagnostic Medicine
8. LCD OH A54158 (local coverage determination).
9. State of Ohio Board of Pharmacy, Ohio Automated Rx Reporting System (OARRS), Ohio PDMP AWARE User Support Manual p.45-67
10. Dowell D, Haegerich TM, Chou R (2016) CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016. MMWR Recomm Rep 65: 1-49.
11. AAPC. E/M Utilization Benchmarking Tool
12. Boon M, van Dorp E, Broens S, Overdyk F (2020) Combining opioids and benzodiazepines: effects on mortality and severe adverse respiratory events. Ann Palliat Med 9: 542-557.
13. Jarvis M, Williams J, Hurford M, Lindsay D, Lincoln P, et al. (2017) Appropriate Use of Drug Testing in Clinical Addiction Medicine. J Addict Med 11: 163-173.
14. ASAM. Consensus Statement. Appropriate Use of Drug Testing in Clinical Addiction Medicine
15. Local Coverage Determination (LCD): Lab:Controlled Substance Monitoring and Drugs of Abuse Testing (L36707)
16. Case Western Reserve University. The Opioid Epidemic: Where are we now? December 8th, 2019; page 9-10. Posted online: https://www.youtube.com/watch?v=Tqlp_N_z-Xw&t=2945s
17. American Academy of Pain medicine. Pain Med. 2020 Apr 7. Pain Management Best Practices from Multispecialty Organizations during the COVID-19 Pandemic and Public Health Crises. Cohen SP, Baber ZB, Buvanendran A, McLean LTCBC, Chen Y, Hooten WM, Laker SR,Wasan WAD, Kennedy DJ, Sandbrink F, King LTCSA, Fowler CDRIM, Stojanovic MP, Hayek SM, Phillips CDRCR
18. Leon Margolin MD, PhD, Stanley Wainapel MD, Jun Kimura MD. American Board of Physical Medicine and Rehabilitation. Impact of Nerve Conduction Studies with or without needle EMG testing on the medical management, pain reduction and the functional outcomes of chronic pain patients.MOC project. December 2018.
19. Leon Margolin MD, PhD. American Board of Physical Medicine and Rehabilitation. Impact of the frequency of the SBIRT protocol (G codes such as G0397), of the POC UDS (80307, 80304) and minimally invasive procedures on the pain reduction (76942, 64450, 64418, 20533 and other similar codes) on the pain reduction, functional improvement and continuity of care of chronic pain patients. MOC project. February 2020
20. Cohen SP, Baber ZB, Buvanendran A, McLean LTCBC, Chen Y, Hooten WM, Laker SR, Wasan WAD, Kennedy DJ, Sandbrink F, King LTCSA, Fowler CDRIM, Stojanovic MP,Hayek SM, Phillips CDRCR. Pain Management Best Practices from Multispecialty Organizations during the COVID-19 Pandemic and Public Health Crises. Pain Med.2020 Apr 7
21. Case Western Reserve University, Board of Health of Cuyahoga County. Racial Disparity, Social Justice and the Opioid Crisis Conference at Case Western Reserve University. April 17-18, 2020
22. https://abc6onyourside.com/news/local/racism-declared-a-public-health-threat-as-large-crowds-gather-to-protest-in-columbus.
23. https://www.cleveland.com/cityhall/2020/06/cleveland-city-council-declares-racism-a-public-health-crisis-launching-community-wide-effort-to-tackle-inequities.html
24. Pain Medicine News, June 8, 2020 . Survey Finds High Rate of Violent Threats Toward Pain Practitioners.
25. Ohio Prescription Drug Monitoring Program user manual p. 54-67.
26. American Medical Association (AMA) July 8, 2020 Issue brief: Reports of increases in opioid related overdose and other concerns during COVID pandemic.
27. Local Coverage Determination (LCD): Controlled Substance Monitoring and Drugs of Abuse Testing (L36029)
28. file:///C:/Users/Lina/Downloads/Local_Coverage_Determination_for_Controlled_Substance_Monitoring%20(1).pdf

ABPMR PIP Form

Created: 11/18/2018 • Last updated: 12/06/2018

e: If you begin one of the Guided PIP projects and later wish to switch to another topic, your work will not automatically transfer over. In that case, we recommend copying all your work to a separate file (Word or similar) before you "Withdraw application" and start over.

Please make an initial selection below.

Which ABPMR PIP are you completing? Create my own project

Create my own PIP

1.) General Data

A) Describe, in detail, your role in the project.

untary Practice Improvement Project (PIP): Impact of Nerve Conduction Studies with or without needle EMG testing on the medical management, pain reduction and the functional outcomes of chronic pain patients.

Leon Margolin MD, PhD/Comprehensive Pain Management Institute, LLC
Submitted as a required for maintenance of certification of American Board of Physical Medicine and Rehabilitation

Adviser: Professor Stanley F. Wainepal MD, MPH, Clinical Director Deaprtment of PM&R, Momtefiore Medical Center.

Background: Opioid epidemic crisis affects the lives of thousands of Americans on a daily basis. From 1999 more than 183,000 Americans died from overdoses (more than 3 times the number of victims of Vietnam War). On an average day in the US close to 5,800 people misuse opioids for the first time, over 1,000 Americans on an average day treated in the emergency departments for issues related to opioid misuse. The societal and healthcare cost of opioid epidemic is 55 billion dollars each year and it inues to rise.

per screening of pain management program patients (including NCV/EMG) for narcotic medications is extremely important in prevention of street drug use. 2018 National Drug Threat Assessment conducted by the Drug Enforcement Administration, showed that prescription drugs such as "opioids were responsible for the most overdose deaths of any illicit drugs since 2001" and "heroin-related deaths nearly doubled from 2013 to 2016".

Ohio one of the state mostly affected by the opioid crisis. Efficient and ethical pain management program that uses appropriate testing to document organic pathology and screen appropriate candidates for pain medications and referred other patients to Addiction medicine evaluation is extremely important in this challenging environment of the opioid epidemic crisis.

National and state guidelines require documentation of the organic pathology as part of a comprehensive evaluation in a pain management clinic. NCV, EMG and Autonomic testing is part of such evaluation. For example, Mayo Clinic Proceedings (June 2015; 90(6):828-842) that were adopted by the state of Ohio and referenced on each printed copy of the OARRS report, reported that in the area of pain management "the predominate reason for inappropriate care was a failure of the prescribing physician to adequately verify patient's prior medical history". Appropriate testing including NCV and EMG is a step in such erification.

3) Dates of your project:

rt date: 10/01/2018

End date: 11/17/2018

2.) Plan: Identify an area in your practice that needs improvement.

A) What is the problem you are trying to solve?

What do you want to improve? Look for inefficiencies, annoyances, or safety issues. Consider complex issues, but focus on simple solutions.

Is there a problem that has led you to test the impact of the NCV with or without EMG. Those without testing do worse for example--

Re(Comment): Can you clarify the problem--is it incomplete evaluations that do not include EMG/NCS and poor outcomes prior to your implementation ?

wer: NCV and EMG testing is an extension of PMR examination (please review medical necessity w), it's important to show the impact of the test on the program outcomes.frequently pain nagement patients are not fully cooperative with the full test (please see below) and the goal is to test the impart of the NCV with or without EMG.

"Many of these chronic pain patients seen by the CPMI suffer from anxiety and depression, and/or drug seeking behavior and had a poor tolerance of the NCV/EMG testing and poor cooperation with the test, especially with the needle part of the test (EMG), (this part performed with inserting EMG needle in 6-12 sites) and frequently refused by the challenging patient population. All the patients were offered the enclosed (e mailed to Kendell) written consent based on the enclosed AANEM guidelines."

All the patients in the study were referred to us after the opioid medications have been started by the previous provider (typically PCP), under the circumstances we could not wave a necessary test for research purposes to maintain proper Ohio state (TDDD HB 93) compliance. That's why there no controls without NCV/EMG. We did internal controls patients with only NCV, patients who got different degrees of functional improvement and pain reduction. That's the best ethical set up for the study we can create.

edical Necessity: Most of the Comprehensive Pain Management Institute, LLC (CPMI) patients are plex high/medium risk chronic pain patients. Neuropathic pain, peripheral neuropathy, chronic radiculopathy and other neurodiagnostic pathology is prevalent among this patient population and

require appropriate neurodiagnostic studies.

The practice of the CPMI is to see patient by referral from primary care providers or specialists.

Most of the patients referred to CPMI for the evaluation of chronic pain in two or more extremities, or e the diagnosis of peripheral neuropathy, lumbar or cervical radiculopathy suggested by the referring vider.

The number of NCV/EMG tests based on the enclosed CPMI NCV/EMG policy and OH local coverage determination (A54158). All patient had a comprehensive evaluation including initial, follow up evaluation forms, PADT forms enclosed and extensive review of OARRS repots, offered a written consent based on the AANEM guidelines with a detailed explanations of the risk and benefits of the tests. NCV are reviewed and incorporated in the treatment plan.

The most commonly tested nerves in the upper extremities were sensory ulnar, median and radial studies, motor median, ulnar, radial and in selected cased Axillary studies with Median and Ulnar F waves. For the low extremities the studies included sensory Sural, Superior Peroneal, Motor studies included Common Peroneal, Tibial nerves and Common Peroneal and Tibial nerve; F waves and H reflex studies selected based on the comprehensive assessment results. The needle examination typically included (UE) Cervical Paraspinals, Deltoid, Biceps, Extensor Carpi Radialis, Triceps, Flexor Carpi Radialis, APB muscle, (LE) Lumbar Paraspinals, Vastus medialis, Extensor Hallucis Longus, Biceps Femoris, Peroneus Longus, Medial Gastrocnemius, the studies selected based on the comprehensive assessment result.

/een 2011-2015 as a result of regulatory changes in the state of Ohio (including HB 93 law), CPMI ived a high number of referral/evaluation requests for high risk challenging patient population. Many of these chronic pain patients seen by the CPMI suffer from anxiety and depression, and/or drug seeking behavior and had a poor tolerance of the NCV/EMG testing and poor cooperation with the test, especially with the needle part of the test (EMG), (this part performed with inserting EMG needle in 6-12 sites) and frequently refused by the challenging patient population. All the patients were offered the enclosed written consent based on the enclosed AANEM guidelines.

Dr. Margolin maintains certification by the ABPM&R (that includes NCV and EMG training) in addition to the Pain Medicine certification and has completed a large number of the relevant CMEs (examples attached). CPMI demonstrated a high level of compliance with the AANEM guidelines, OH Local Coverage Determination and state and national guidelines as reflected by the attached CPMI policies and paperwork (i.e. NCV EMG forms, initial follow up evaluation forms and PADT forms).

Cost Efficiency of the Testing: The cost of opioid epidemic is more than 55 billion dollars a year and keeps rising annually. Pain Management programs like our practice that carefully screen and test patient to properly document organic pathology and utilize alternative treatments, careful monitoring and SBIRT approach not only prevent significant morbidity and mortality, but save very significant costs to the lthcare system.

fficient testing, can potentially result in either prescribing opioid medications to not appropriate candidates that can potentially overdose or divert medications to other people, or not prescribing

appropriate pain medications to patients who may look for alternatives "on the street" with significant risks or morbidity and mortality. The host of hospitalization including ER, inpatient care, ICU, detoxification and maintenance programs is astronomic and can be reduced by patient screening and ing including NCV/EMG testing and other testing.

r practice performs the NCV/EMG testing and other testing for a fraction of the cost charged by main hospitals in the area including the Ohio State University clinic.

3) What data (objective measurements) do you have that supports this as a problem?

Review your records or begin tracking how often the issue is occurring and under what conditions.

Can you provide data that serves as a baseline that can be compared to the results after implementation

Re: Comment: Rigorous categorical data based on PADT, Functional Flowchart forms, initial and follow up evaluation forms, informed consent and medical necessity forms (examples e mailed to Kendall), OARRS (Ohio PMR) etc.

Data reviewed by Professor Wainapel (his letter fo support e mailed to Kendall) he wrote that: "These findings would likely be of considerable interest to physiatrist, other specialties... and to the third party payors..."

y design: Retrospective review of charts (please see the list of the selected charts enclosed) both of regular and incomplete studies to assess the impact of the test on the treatment decision making (such as choosing non opioid adjuvant medications and opioid medications, pain reduction and functional improvement as documented by PADT forms and performance of proper clinical assessment that justify study repletion in the selected group of patients.

When pain reduction was 30%-50% we defined it as a "moderate", above 50% a "significant" and more than 70% a very significant pain reduction. When functional improvement as documented by PADT included 2 parameters or more, we called it significant, if only one parameter we called it "moderate" functional improvement. If 3 or functional parameters improved we called a very significant improvement.

Results Analysis and Conclusions:

All initial and repeated tests were performed after a comprehensive evaluation and proper documentation of medical necessity as required by the AANEM guidelines and Ohio LCD.

All NCV tests with or without EMG testing had a documented impact on the narcotic and non narcotic dication prescriptions, pain reduction and functional improvement.

There was a significant association with the pain reduction and functional improvement.

Pain Reduction Functional
Improvement
Moderate 58.3% 20.8%
Significant 16.7% 25.0%
Very Significant 25.0% 54.2%

Applying a chi-square statistic to patient outcomes of functional improvement, we observe: that NCV and NCV+EMG are statistically significant at the .05 level.

Association between the repetition of the test and functional improvement (number of studies and per t of patients):

Moderate Significant
No Repeat 5 5
Repeat 0 14

Moderate Significant
No Repeat 20.8% 20.8%
Repeat 0.0% 58.3%

Using a chi-square test, we can and conclude (with $P<.01$) that repeating the test has a positive association with functional improvement.

The association can be explained by the fact that an additional comprehensive evaluation was performed prior to the test and additional NCV and EMG test results were incorporated in the treatment plan that ed to achieve additional functional improvement.

C) What is your opportunity statement? State the goal you hope to achieve.

Based on record review or measurement of current performance, determine what kind of improvement hope to make and set a timeframe to achieve it.

Re Comment: Yes, I can - "Show correlation between NCV with or without EMG on the at least one functional parameter of PADT assessment or more, at least 30 per cent reduction in pain or more".

Functional improvement which is the main goal of pain management program (which is more important that pain reduction) has most strong statistically significant improvement with the use of the NCV and EMG testing (with or without the needle testing). These findings underscore the medical necessity and cost effectiveness of the NCV and EMG test based on the sample examined.

NCV with or without needle EMG tests (both initial tests and follow up tests) are medically necessary and cost effective tests that have a strong statistically significant contribution to the proper choice of medications and procedure for chronic pain patients and strongly associated with functional improve and pain reduction

What is the underlying cause of the performance/quality problem?

her and brainstorm with other physicians and staff on your unit/team. What's causing this issue? How did you determine the cause?

What was preventing you from doing EMG/NCV studies prior to now? Was it lack of appreciation of their value, no standardized ay to identify appropriate candidates etc..

Re Comment: We are a tertiary highly subspecialized referral private clinic, the vast majority (practically all) of our patients including all the patients in the study were referred to us after the opioid medications have been started by the previous provider (typically PCP), PCP are typically not trained in NCV/EMG and defer this testing to us (we operate as "one stop" evaluation and multidisciplinary treatment model). Some time tests were done a long time in the past but records were not available.

There is no performance problem, however there is a challenge related to performance of the test for a challenging patient population as described below.

Most of the patients referred to CPMI for the evaluation of chronic pain in two or more extremities, or ve the diagnosis of peripheral neuropathy, lumbar or cervical radiculopathy suggested by the referring ider.

The number of NCV/EMG tests based on the enclosed CPMI NCV/EMG policy and OH local coverage

determination (A54158). All patient had a comprehensive evaluation including initial, follow up evaluation forms, PADT forms enclosed and extensive review of OARRS repots, offered a written consent based on the AANEM guidelines with a detailed explanations of the risk and benefits of the tests. NCV are reviewed incorporated in the treatment plan.

most commonly tested nerves in the upper extremities were sensory ulnar, median and radial studies, motor median, ulnar, radial and in selected cased Axillary studies with Median and Ulnar F waves. For the low extremities the studies included sensory Sural, Superior Peroneal, Motor studies included Common Peroneal, Tibial nerves and Common Peroneal and Tibial nerve; F waves and H reflex studies selected based on the comprehensive assessment results. The needle examination typically included (UE) Cervical Paraspinals, Deltoid, Biceps, Extensor Carpi Radialis, Triceps, Flexor Carpi Radialis, APB muscle, (LE) Lumbar Paraspinals, Vastus medialis, Extensor Hallucis Longus, Biceps Femoris, Peroneus Longus, Medial Gastrocnemius, the studies selected based on the comprehensive assessment result.

Between 2011-2015 as a result of regulatory changes in the state of Ohio (including HB 93 law), CPMI received a high number of referral/evaluation requests for high risk challenging patient population.

Many of these chronic pain patients seen by the CPMI suffer from anxiety and depression, and/or drug seeking behavior and had a poor tolerance of the NCV/EMG testing and poor cooperation with the test, especially with the needle part of the test (EMG), (this part performed with inserting EMG needle in 6-12 s) and frequently refused by the challenging patient population. All the patients were offered the losed written consent based on the enclosed AANEM guidelines.

R

E) What Institute of Medicine (IOM) Quality Dimensions will be addressed by your project?	Care Delivery Efficiency Timeliness in Care Care Delivery Effectiveness

3.) Do: Describe the desired outcomes and the requirements needed to achieve them.

A) What change(s) did you implement?

You can implement one change, or you can choose to do several at a time. Be specific about the changes you made.

implemented appropriate medically necessary electrodiagnostic studies with or without the needle for our patient population.

4.) Study/Check: Describe the measurement used to assess the success of the plan.

A) Did you achieve your goal or target reported in your opportunity statement? What a do you have to support your conclusion?

...is is a simple yes or no, and cite the evidence. After the timeframe indicated in your opportunity statement, review your performance. (It's good practice to check-in at least midway through your project, too, to see whether adjustments need to be made.) Did you meet the goal you set?

Yes

5.) Act: Change(s) to your practice as a result of this project.

A) Will you continue with the changes you have implemented?

If you achieved your goal, describe how you will sustain your success, or how it led to new ideas. If you did not achieve your goal, how could you try again with new tactics? What will be your next process change to keep the improvement evolution going?

. cessful implementation of the electrodiagnostic studies supported by the appropriate comprehensive assessment (initial and follow up evaluation forms, PADT forms, flowchart forms, informed consent, medical necessity and other paperwork).

Successful documentation of the medical necessity, impact on the medication prescription, pain reduction and functional improvement.

UNIVERSITY OF IOWA
HOSPITALS & CLINICS

University of Iowa Health Care

George B Richerson, MD, PhD
Professor & Head
The Roy J Carver Chair in Neuroscience

Department of Neurology
University of Iowa Health Care
200 Hawkins Drive
Iowa City, IA 52242
319-356-4296 Tel
319-384-7199 Fax
www.uihealthcare.org

December 28, 2018

Leon Margolin MD, PhD
5245 E Main St
Columbus, OH 43213

Dear Dr. Margolin,

Thank you for asking me to review your project on chronic pain management, which is of considerable interest not only to physiatrists but also to other related specialties in general and neurology in particular. I am pleased to evaluate your proposal as a neurologist with special interest in clinical electrophysiology, which I practiced over 50 years.

The project you are undertaking relates to the role of nerve conduction studies (NCS) and needle electromyography (EMG) on clinical assessments of chronic pain patients. I find the study well designed using appropriate methodology to gain a positive impact on clinical practice. I am pleased to learn that the American Board of PM&R has approved this project that was highly evaluated by Dr. Wainapel, an expert in this field. As a neurologist, I too consider the project of considerable value and interest to other specialists and the third party payers.

From my personal experience, I consider NCS as one of the most important tests for evaluation of neuropathy and EMG as an essential tool for clinical study of radiculopathy, two very common conditions where chronic pain management plays an important role. As such these electrodiagnostic methods have demonstrated strong medical necessity on patient care dealing with chronic pain. I wish you continued success in this important endeavor.

Regards,

Jun Kimura, MD
Professor Emeritus
Department of Neurology
University of Iowa
Professor Emeritus
Kyoto University

Montefiore
THE UNIVERSITY HOSPITAL FOR
ALBERT EINSTEIN COLLEGE OF MEDICINE

November 14, 2018

Dear Dr Margolin,

I have reviewed your study on the role of neuromuscular electrodiagnostic testing (including nerve conduction studies and needle electromyography) in the context of your chronic pain practice, found its methodology to be well considered, and its positive impact on clinical outcome provocative and quite compelling. I commend you for making a significant contribution to the specialty area of chronic pain management. These findings would likely be of considerable interest to physiatrists, other specialists treating chronic pain patients, and to the third party payors responsible for authorizing payment for electrodiagnostic testing.

Yours truly,

Stanley F.Wainapel MD, MPH, Clinical Director, Department of Rehabilitation Medicine

Montefiore Medical Center

Professor of clinical Rehabilitation Medicine, Albert Einstein college of Medicine

Department of Rehabilitation Medicine
111 East 210 Street
Bronx, New York 10467
718-920-4133 Office
718-920-4083 Office
718-654-9831 Fax

Physiatric Consultation
Physical Therpy
Occupational Therapy
Speech Language Pathology

Pt. Initials/Type of test	Impact on Med use	Pain Reduction	Functional improvement	Repeated test
PE ☑ NCV ☑ EMG	☑ Documented	☑ Moderate ☐ significant	☑ moderate ☐ significant	☐ Comprehensive evaluation ☐ pain reduction/functional improvement N/A
HS ☐ NCV ☐ EMG	☐ Documented	☐ Moderate ☐ significant	☐ moderate ☐ significant	☐ Comprehensive evaluation ☐ pain reduction/functional improvement N/A
BBK ☑ NCV ☑ EMG	☑ Documented	☑ Moderate ☐ significant	☑ moderate ☐ significant	☐ Comprehensive evaluation ☐ pain reduction/functional improvement
HL ☑ NCV ☑ EMG	☑ Documented	☐ Moderate ☑ significant very	☐ moderate ☑ significant very	☐ Comprehensive evaluation ☐ pain reduction/functional improvement N/A
CC ☑ NCV ☐ EMG	☑ Documented	☐ Moderate ☑ significant	☐ moderate ☑ significant very	☑ Comprehensive evaluation ☑ pain reduction/functional improvement
MR ☑ NCV ☐ EMG	☑ Documented	☐ Moderate ☑ significant	☐ moderate ☑ significant	☑ Comprehensive evaluation ☑ pain reduction/functional improvement
LB ☑ NCV ☐ EMG	☑ Documented	☐ Moderate ☐ significant	☐ moderate ☐ significant	☐ Comprehensive evaluation ☐ pain reduction/functional improvement N/A
ST ☑ NCV ☑ EMG	☑ Documented	☑ Moderate ☐ significant	☐ moderate ☑ significant very	☑ Comprehensive evaluation ☑ pain reduction/functional improvement
AE ☑ NCV ☑ EMG	☑ Documented	☐ Moderate ☑ significant	☐ moderate ☑ significant	☐ Comprehensive evaluation ☐ pain reduction/functional improvement N/A
PV ☑ NCV ☐ EMG	☑ Documented	☐ Moderate ☐ significant	☐ moderate ☐ significant	☐ Comprehensive evaluation ☐ pain reduction/functional improvement
SM ☑ NCV ☐ EMG	☑ Documented	☑ Moderate ☐ significant	☐ moderate ☑ significant very	☑ Comprehensive evaluation ☑ pain reduction/functional improvement
CJ ☑ NCV ☐ EMG	☑ Documented	☐ Moderate ☐ significant	☐ moderate ☐ significant	☑ Comprehensive evaluation ☑ pain reduction/functional improvement
TD ☑ NCV ☑ EMG	☑ Documented	☐ Moderate ☑ significant very	☐ moderate ☑ significant very	☑ Comprehensive evaluation ☑ pain reduction/functional improvement

II ☑ NCV ☐ EMG	☑ Documented	☐ Moderate ☐ significant	☐ moderate ☐ significant	☑ Comprehensive evaluation ☐ pain reduction/functional improvement
HR ☑ NCV ☐ EMG	☑ Documented	☐ Moderate ☑ significant very	☐ moderate ☑ significant very	☐ Comprehensive evaluation ☐ pain reduction/functional improvement
PT ☑ NCV ☑ EMG	☑ Documented	☑ Moderate ☐ significant	☐ moderate ☑ significant very	☑ Comprehensive evaluation ☐ pain reduction/functional improvement
MG ☑ NCV ☐ EMG	☑ Documented	☐ Moderate ☑ significant	☐ moderate ☑ significant very	☐ Comprehensive evaluation ☐ pain reduction/functional improvement
SD ☑ NCV ☑ EMG	☑ Documented	☐ Moderate ☐ significant	☐ moderate ☑ significant	☑ Comprehensive evaluation ☐ pain reduction/functional improvement
RL ☑ NCV ☐ EMG	☑ Documented	☑ Moderate ☐ significant	☒ moderate ☐ significant	☐ Comprehensive evaluation ☐ pain reduction/functional improvement N/A
MT ☑ NCV ☐ EMG	☑ Documented	☐ Moderate ☐ significant	☐ moderate ☐ significant	☑ Comprehensive evaluation ☐ pain reduction/functional improvement
MM ☑ NCV ☐ EMG	☑ Documented	☐ Moderate ☑ significant	☐ moderate ☑ significant very	☑ Comprehensive evaluation ☐ pain reduction/functional improvement
LA ☑ NCV ☐ EMG	☑ Documented	☐ Moderate ☑ significant very	☐ moderate ☑ significant	☐ Comprehensive evaluation ☐ pain reduction/functional improvement
FG ☐ NCV ☐ EMG	☑ Documented	☐ Moderate ☑ significant	☐ moderate ☑ significant very	☐ Comprehensive evaluation ☐ pain reduction/functional improvement
SR ☑ NCV ☐ EMG	☑ Documented	☑ Moderate ☐ significant	☐ moderate ☑ significant	☑ Comprehensive evaluation ☐ pain reduction/functional improvement
EA ☑ NCV ☑ EMG	☑ Documented	☐ Moderate ☐ significant	☐ moderate ☑ significant	☐ Comprehensive evaluation ☐ pain reduction/functional improvement NA
WG ☑ NCV ☑ EMG	☑ Documented	☑ Moderate ☐ significant	☐ moderate ☑ significant	☑ Comprehensive evaluation ☐ pain reduction/functional improvement
KT ☑ NCV ☐ EMG	☑ Documented	☑ Moderate ☐ significant	☐ moderate ☑ significant very	☐ Comprehensive evaluation ☐ pain reduction/functional N/A

DT ☑ NCV ☑ EMG	☑ Documented	☐ Moderate ☐ significant very	☐ moderate ☐ significant	improvement ☐ Comprehensive evaluation ☐ pain reduction/functional improvement N/A
KI ☐ NCV ☐ EMG	☑ Documented	☑ Moderate ☐ significant	☐ moderate ☑ significant very	☑ Comprehensive evaluation ☑ pain reduction/functional improvement
BD ☑ NCV ☐ EMG	☑ Documented	☑ Moderate ☐ significant	☐ moderate ☑ significant very	☑ Comprehensive evaluation ☑ pain reduction/functional improvement
MJ ☐ NCV ☑ EMG	☑ Documented	☑ Moderate ☐ significant	☑ moderate ☐ significant	☐ Comprehensive evaluation ☐ pain reduction/functional improvement N/A
EH ☑ NCV ☑ EMG	☑ Documented	☑ Moderate ☐ significant	☐ moderate ☑ significant very	☑ Comprehensive evaluation ☑ pain reduction/functional improvement
MC ☑ NCV ☑ EMG	☑ Documented	☐ Moderate ☑ significant very	☐ moderate ☑ significant very	☑ Comprehensive evaluation ☑ pain reduction/functional improvement
CA ☐ NCV ☐ EMG N/A	☐ Documented	☐ Moderate ☐ significant	☐ moderate ☐ significant	☐ Comprehensive evaluation ☐ pain reduction/functional improvement
HW ☐ NCV ☑ EMG	☑ Documented	☑ Moderate ☐ significant	☐ moderate ☑ significant very	☐ Comprehensive evaluation ☐ pain reduction/functional improvement NA
KW ☐ NCV ☐ EMG	☐ Documented	☐ Moderate ☐ significant	☐ moderate ☐ significant	☐ Comprehensive evaluation ☐ pain reduction/functional improvement
LJ ☐ NCV ☐ EMG	☐ Documented	☐ Moderate ☐ significant	☐ moderate ☐ significant	☐ Comprehensive evaluation ☐ pain reduction/functional improvement
PB ☐ NCV ☐ EMG	☐ Documented	☐ Moderate ☐ significant	☐ moderate ☐ significant	☐ Comprehensive evaluation ☐ pain reduction/functional improvement
CJ ☐ NCV ☐ EMG	☐ Documented	☐ Moderate ☐ significant	☐ moderate ☐ significant	☐ Comprehensive evaluation ☐ pain reduction/functional improvement
FA ☑ NCV ☐ EMG	☑ Documented	☑ Moderate ☐ significant N/A	☐ moderate ☑ significant very	☑ Comprehensive evaluation ☐ pain reduction/functional improvement [redacted]
TC ☐ NCV ☐ EMG	☐ Documented	☐ Moderate ☐ significant	☐ moderate ☐ significant	☐ Comprehensive evaluation ☐ pain

MFF ☑ NCV ☐ EMG	☑ Documented	☐ Moderate ☐ significant	☐ moderate ☐ significant	reduction/functional improvement ☑ Comprehensive evaluation ☑ pain reduction ☑ functional

N/A

COMPREHENSIVE PAIN MANAGEMENT INSTITUTE, LLC

Correlation Between NARX Score And Food Addictive Behavioral Patterns in Chronic Pain Patients

INTRODUCTION

Studies have shown the effect of drug addiction on brain activity of humans and animals. One study highlights the relation between amphetamine and cocaine use on the dopamine activity of the brain (Volkow et al., 2014). As higher doses of drug were consumed via injection or other routes, the higher the Dopamine release activity in the nucleus accumbens (NAc) part of the brain (Volkow et al., 2014). NAc is also activated by eating and plays an important role in food addiction (Baik, 2013). If the same part of the brain is activated by drug addiction as with food addiction to provide similar pain relieving effect, recognizing signs of food addiction in correlation to chronic pain could play an important role in providing insight on high risk addictive behaviors in chronic pain patients (Baik, 2013; Choi et al.,2014). The purpose of this research study is to show a relationship between food addiction related behavior in chronic pain patients and the effectiveness of NARX score in predicting high risk factors in such patients.

DISCUSSION:

NARX Score

- The NARX score, a tool calculating the amount of narcotics (opioids), sedatives, and stimulants (State of Ohio Board of Pharmacy, n.d.),
- The NARX score uses a particular calculation system, which is based on 3 digits, and it can range from 000 to 999,
- The scores correspond to the number of literature based risk factors that exist within the PDMP data
  - a. The number of prescribers
  - b. The number of pharmacies
  - c. The amount of medication dispensed (often measured in milligram equivalencies)
  - d. The number of times prescriptions of a similar type overlap from different prescribers. (State of Ohio Board of Pharmacy, n.d.),
- The distribution of NARX Scores for patients found in a PDMP is approximated as follows: a. 75% score less than 200 b. 5% score more than 500 c. 1% score more than 650 (State of Ohio Board of Pharmacy, n.d.).
- The NAXR Scores were designed such that: Patients who use small amounts of medication with limited provider and pharmacy usage will have low scores and vice versa.
- The NARX score serves as an effective reference to patients in pain management area (Breneman et al., 2016).

Relationship between Dopamine and Food Addiction

- Dopamine (DA) is a chemical messenger that regulates emotional and motivational behavior and is widely recognized as being associated with reward-related behaviors.
- Recent research suggest eating behaviors, which are related to the reward circuitry of the brain, is comparable to drug addiction that also involves reward circuitry of the brain.
- Research indicates that obese people and drug addicts appear to show dysfunction of Dopamin (DA) D2 receptors and that similar areas of the brain are activated by food-related and drug-related cues.
- One study identified the relationship between the level of DA receptors and drug addiction, which shows that low D2 receptors may contribute to drug addiction given that the drugs are used as a means of compensation for decrease activation of the reward circuitry system (Volkow et al., 1999).
- A study has shown that amphetamine and cocaine injection increases the DA levels in the NAc, which is normally activated by eating. As a result, it suggests that the release of DA by eating could be a factor in food addiction (Baik, 2013).

The Effect of Food Addiction on Pain

- Research has shown that there is a correlation between food and chronic pain.
- The research found that foods that were high in sugar, calories and fat had pain relieving effects on these patients by possibly interfering with endogenous opioid pathways and reducing activity of the region of the brain that reacts to pain (Choi et al., 2014).
- The researchers found that patients reporting a higher level of pain were more inclined to eat foods that were less healthy with higher levels of fat, calories and sugar (Choi et al., 2014).
- When a person consumes foods that are high in fat and sugar content, dopamine receptor pathways are activated in the brain, which are the same dopamine pathways that are activated in cocaine and amphetamine use. Food addiction activates the same regions of the brain as control drug addiction (Baik, 2013).
- According to the Arthritis Foundation, foods that are high in sugar, gluten, casein, refined carbohydrates, and saturated fats trigger an inflammatory response in the body by releasing inflammatory cytokines and when inflammation continues over periods of time it can lead to damage in different parts of the body such as the joints leading to osteoarthritis(Arthritis Foundation, n.d.).

RESEARCH STUDY

Objective

The purpose of this research study is to show a relationship between food addiction patterns to different types of food in chronic pain patients and the effectiveness of NARX score in predicting high risk factors in such patients.

Method

We used an eight-question survey, that addressed the following elements of addictive behavior:

Q1 Consumption to feel better or to change mood
Q2 Tolerance
Q3 Withdrawal
Q4 Consumption more than initially thought
Q5 Tried reduce/stop but fail
Q6 Spending substantial time (> 2 hours) in trying to get them
Q7 Reduce Activities
Q8 Health/Mental Problems

- With each question the patient had four possible answers. We analyzed 832 responses from 106 patients.

1. Which of the following foods have you ever had persistent desire for or take more than once to feel better or to change your mood?
   a. Chocolate b. Cheese c. Meat d. Other
2. Which of the following foods have you needed to increase the amount of to get the same effect that you did when first started taking it?
   a. Chocolate b. Cheese c. Meat d. Other
3. Reduction or discontinuation of which of the following foods caused you withdrawal symptoms (aches, shaking, fever, weakness, diarrhea, nausea, sweating, heart pounding, difficulty sleeping, or feeling agitated, anxious, irritable, or depressed)?
   a. Chocolate b. Cheese c. Meat d. Other
4. Which of the following you ended up taking more than you thought you would?
   a. Chocolate b. Cheese c. Meat d. Other
5. Which of the following have you tried to reduce or stop eating, but failed?
   a. Chocolate b. Cheese c. Meat d. Other
6. On the days you have the following eaten foods, did you spend substantial time (> 2 hours) in trying to get them, eat them, recover from their effects, or thinking about them?
   a. Chocolate b. Cheese c. Meat d. Other
7. Which of the following have you ever reduced your activities (e.g., hobbies, work, daily activities) for or caused you to spend less time with your family or friends?
   a. Chocolate b. Cheese c. Meat d. Other
8. Which of the following foods you continue to consume even though they cause health or mental problems?
   a. Chocolate b. Cheese c. Meat d. Other

Results

- Out of a 106 patients that completed the form, 848 answers (8 questions times 106 respondents) would be the total number of responses. However the survey generated 802 answers, as some patients did not respond to all eight of the questions. When a question was not answered, the survey was still counted, but the unanswered question was counted as 'missing'.
- Of the possible answers, 'Other' was the most often selected with 510 responses and 'Chocolate' was the second most often selected response with a total of 137 responses. Of the 510 'Other' responses, 423 of the answers were 'None' or 'NA'. There were 33 respondents that gave the same answer to all eight questions and in most of those cases the answer was 'other'. When foods were mentioned under 'other', 39 occurrences were 'Coffee', 23 occurrences were 'Pepsi, Soda, or Mountain Dew', and there were 12 occurrences for both 'Breads' and 'Sweats'.
- Of the 106 respondents, the average NARX score was 383.5 and the median was 380. The high was 740 and the low was 80.

RESPONSE FREQUENCY BY QUESTION AND ANSWER

	Chocolate	Cheese	Meat	Other
Q1 Mood	33	16	15	46
Q2 Same Effect	12	9	20	61
Q3 Withdrawal	10	7	10	74
Q4 More than Thought	22	9	18	56
Q5 Reduce/Stop but Fail	18	10	16	57
Q6 Recover from Effect	9	6	10	75
Q7 Reduce Activities	11	2	11	74
Q8 Health/Mental Problems	22	3	9	67
Totals	137	62	109	510

AVERAGE NARX SCORE BY QUESTION AND ANSWER

	Chocolate	Cheese	Meat	Other
Q1 Mood	376.7	293.8	391.3	401.5
Q2 Same Effect	340.8	358.9	438.0	377.0
Q3 Withdrawal	376.0	412.9	373.0	385.9
Q4 More than Thought	379.5	312.2	423.9	383.9
Q5 Reduce/Stop but Fail	401.1	395.0	422.5	371.8
Q6 Recover from Effect	341.1	375.0	424.0	385.2
Q7 Reduce Activities	335.5	405.0	358.2	390.8
Q8 Health/Mental Problems	403.6	390.0	388.9	377.3

Inferences of Data

The tables shows the average NARX score broken down by question and answer. For example, the 378.8 in the upper left corner of the table means that amongst all respondents who answered 'Chocolate' on Question 1, the average NARX score was 378.8 The four cells highlighted in orange are the highest average NARX scores and the cells highlighted in blue are the lowest average NARX scores. Of possible interest is the fact that all of the highest average NARX scores are associated with eating meat. The two lowest NARX scores are associated with eating cheese.

The highest correlations with NARX scores came from question 5 (reduce or stop eating food, but failed) and 7 (reduce activities). That means that in terms of trying to predict NARX scores based on the answers to these questions, questions 5 and 7 are the most useful. However, the R-squared value of these questions on a linear regression of NARX score against these questions is 16%. The R-squared value of a linear regression of NARX core against all questions is 35%. This suggests that this list of cravings explain a moderately small part of the variability in the NARX score.

Conclusion and Discussion

There is a strong correlation between the food addictive behavioral patterns in chronic pain patients and high risk factors in chronic pain patients as manifested and measured by the NARX score. The three foods that were reported most frequently were chocolate, cheese and meat (this finding correlates with the previous research findings). Interestingly, meat was associated with the highest NARX score (the highest risk) chronic pain patients. Other foods reported most frequently were coffee, sodas and sweets that emphasizes the role of sugar in the chronic pain syndromes. We advocate further research on the topic of the food addictive behavioral patterns in chronic pain patients and life style modifications.

Refer References

1. Arthritis Foundation. Arthritis Diet. Available at: https://www.arthritis.org/living-with-arthritis/arthritis-diet/. Accessed January 8, 2019.
2. Baik, J. Dopamine signaling in food addiction: role of dopamine D2 receptors. *BMB Reports*. 2013;46(11):519-526. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4133846/pdf/BMB-46-519.pdf. Accessed January 7, 2019.
3. Breneman, B., Huizenga, J., Patel, V., Raz, A. and Speights, D. NARxCHECK® Score as a Predictor of Unintentional Overdose Death. Appriss, Inc. https://apprisshealth.com/wp-content/uploads/sites/2/2017/02/NARxCHECK-Score-as-a-Predictor.pdf. Published 2016. Accessed January 26, 2019.
4. Choi, K., Somers, T., Babyak, M., Sikkema, k., Blumenthal, J. and Keefe, F. The relationship between pain and eating among overweight and obese individuals with osteoarthritis: An ecological momentary study. *Pain Research & Management*. 2014; 19(6): e159–e163. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4273714/#b17-prm-19-e159. Accessed January 19, 2019.
5. Janke, E. A. and Kozak, A. (2012). "The More Pain I Have, the More I Want to Eat": Obesity in the Context of Chronic Pain. *Obesity A Research Journal*. 2012:20(10): 2027-2034. https://doi.org/10.1038/oby.2012.39. Published 2012. Accessed January 9, 2019.
6. State of Ohio Board of Pharmacy. Ohio Automated RX Reporting System. Available at: https://www.ohiopmp.gov/Documents/OARRS%20User%20Manual.pdf. Accessed January 20, 2019.
7. Volkow, N., Tomasi, D., Wang, G., Logan, J., Alexoff, D., Jayne, M., Fowler, J., Wong, C., Yin, P. and Du, C. Stimulant-induced dopamine increases are markedly blunted in active cocaine abusers. *Molecular Psychiatry*. 2014;19(9): 1037–1043. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4827430/pdf/nihms762997.pdf. Accessed January 17, 2019.
8. Volkow, N., Wang, G., Fowler, J., Logan, J., Gatley, S., Gifford, A., Hitzmann, R., Ding, Y. and Pappas, N. Prediction of reinforcing responses to psychostimulants in humans by brain dopamine D2 receptor levels. *The American Journal of Psychiatry*. 1999: 156(9):1440-3. https://www.ncbi.nlm.nih.gov/pubmed/10484959. Accessed January 21, 2019.

E

U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

DEA Registered-Practitioners

Dear Registrants:

On December 29, 2022, the Consolidated Appropriations Act of 2023 enacted a new **one-time**, eight-hour training requirement for all Drug Enforcement Administration (DEA)-registered practitioners on the treatment and management of patients with opioid or other substance use disorders. Below is information on this new requirement.

Who is responsible for satisfying this new training requirement?

- All DEA-registered practitioners, with the exception of practitioners that are solely veterinarians.

How will practitioners be asked to report satisfying this new training requirement?

- Beginning on June 27, 2023, practitioners will be required to check a box on their online DEA registration form—regardless of whether a registrant is completing their initial registration application or renewing their registration—affirming that they have completed the new training requirement.

What is the deadline for satisfying this new training requirement?

- The deadline for satisfying this new training requirement is the date of a practitioner's next scheduled DEA registration submission—regardless of whether it is an initial registration or a renewal registration—on or after June 27, 2023.
- This one-time training requirement affirmation will not be a part of future registration renewals.

How can practitioners satisfy this new training requirement?

There are multiple ways that practitioners can satisfy this new training requirement.

- First, the following groups of practitioners are deemed to have satisfied this training:
    1. **Group 1:** All practitioners that are board certified in addiction medicine or addiction psychiatry from the American Board of Medical Specialties, the American Board of Addiction Medicine, or the American Osteopathic Association.
    2. **Group 2:** All practitioners that graduated in good standing from a medical (allopathic or osteopathic), dental, physician assistant, or advanced practice nursing school in the United States within five years of June 27, 2023, and successfully completed a comprehensive curriculum that included at least eight hours of training on:

  - Treating and managing patients with opioid or other substance use disorders, including the appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of a substance use disorder; or
  - Safe pharmacological management of dental pain and screening, brief intervention, and referral for appropriate treatment of patients with or at risk of developing opioid and other substance use disorders.

- Second, practitioners can satisfy this training by engaging in a total of eight hours of training on treatment and management of patients with opioid or other substance use disorders from the groups listed below. A few key points related to this training:
  1. The training does not have to occur in one session. It can be cumulative across multiple sessions that equal eight hours of training.
  2. Past trainings on the treatment and management of patients with opioid or other substance use disorders can count towards a practitioner meeting this requirement. In other words, if you received a relevant training from one of the groups listed below—prior to the enactment of this new training obligation on December 29, 2022—that training counts towards the eight-hour requirement.
  3. Past DATA-Waived trainings count towards a DEA registrant's 8-hour training requirement.
  4. Trainings can occur in a variety of formats, including classroom settings, seminars at professional society meetings, or virtual offerings.

What accredited groups may provide trainings that meet this new requirement?

- The American Society of Addiction Medicine (ASAM)
- The American Academy of Addiction Psychiatry (AAAP)
- American Medical Association (AMA)
- The American Osteopathic Association (AOA), or any organizations accredited by the AOA to provide continuing medical education
- The American Dental Association (ADA)
- The American Association of Oral and Maxillofacial Surgeons (AAOMS)
- The American Psychiatric Association (APA)
- The American Association of Nurse Practitioners (AANP)
- The American Academy of Physician Associates (AAPA)
- The American Nurses Credentialing Center (ANCC)
- Any other organization accredited by the Accreditation Council for Continuing Medical Education (AACCME) or the Commission for Continuing Education Provider Recognition (CCEPR), whether directly or through an organization accredited by a State medical society that is recognized by the ACCME or CCEPR
- Any other organization approved or accredited by the Assistant Secretary for Mental Health and Substance Use, the ACCME, or the CCEPR

We hope this information is helpful. For information regarding the DEA Diversion Control Division, please visit www.DEAdiversion.usdoj.gov. If you have any additional questions on this issue, please contact the Diversion Control Division Policy Section at (571) 362-3260.

Sincerely,

THOMAS PREVOZNIK
Digitally signed by THOMAS PREVOZNIK
Date: 2023.03.27 16:37:23 -04'00'

Thomas W. Prevoznik
Acting Assistant Administrator
Diversion Control Division



DEA Course: Controlled Substance Prescribing and Substance Use Disorders - Comprehensive Education to Improve Quality of Care

Join us for a series of 9 interactive modules in which experts discuss controlled

This site uses cookies and related technologies for purposes that may include site operation, analytics, enhanced user experience, or advertising. You may choose to consent to our use of these technologies, or manage your own preferences. For more information, see our **Privacy policy**

Accept

Manage Settings

Course Fee **$299.00**

Add to Cart I have an institution Enrollment ID

Program Content

Module 1: Principles of Controlled Substance Prescribing

Activities



Module 1: General Principles of Controlled Substance Prescribing

Video

Released: May 31, 2023 Expires: May 30, 2026

View Activity



Module 1: General Principles of Controlled Substance Prescribing

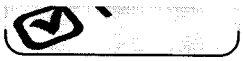
Text Module

Released: May 31, 2023 Expires: May 30, 2026

View Activity

Module 2: Universal Risk Mitigation Strategies for Controlled Substances

This site uses cookies and related technologies for purposes that may include site operation, analytics, enhanced user experience, or advertising. You may choose to consent to our use of these technologies, or manage your own preferences. For more information, see our **Privacy policy**



Video

Released: May 31, 2023 Expires: May 30, 2026

View Activity



Module 2: Universal Risk Mitigation Strategies for Controlled Substances

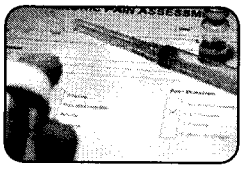
Text Module

Released: May 31, 2023 Expires: May 30, 2026

View Activity

Module 3: Basics of Pain Management

Activities

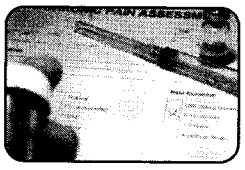


Module 3: Basics of Pain Management

Video

Released: May 31, 2023 Expires: May 30, 2026

View Activity



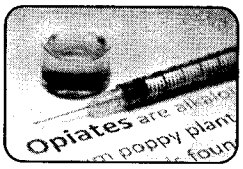
Module 3: The Basics of Pain Management

Text Module

Released: May 31, 2023 Expires: May 30, 2026

View Activity

This site uses cookies and related technologies for purposes that may include site operation, analytics, enhanced user experience, or advertising. You may choose to consent to our use of these technologies, or manage your own preferences. For more information, see our **Privacy policy**

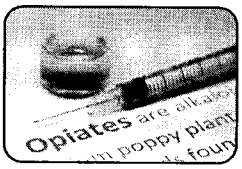


Module 4: Managing Opioid Therapy

Video

Released: May 31, 2023 Expires: May 30, 2026

View Activity



Module 4: Managing Opioid Therapy

Text Module

Released: May 31, 2023 Expires: May 30, 2026

View Activity

Module 5: Introduction to Substance Use Disorders

Activities



Module 5: Introduction to Substance Use Disorders

Video

Released: May 31, 2023 Expires: May 30, 2026

View Activity



Module 5: Introduction to Substance Use Disorders

Text Module

Released: May 31, 2023 Expires: May 30, 2026

This site uses cookies and related technologies for purposes that may include site operation, analytics, enhanced user experience, or advertising. You may choose to consent to our use of these technologies, or manage your own preferences. For more information, see our **Privacy policy**

Activities



Module 6: Opioid Use Disorder

Text Module

Released: May 31, 2023 Expires: May 30, 2026

View Activity



Module 6: Opioid Use Disorder

Video

Released: May 31, 2023 Expires: May 30, 2026

View Activity

Module 7: Alcohol Use Disorder

Activities



Module 7: Alcohol Use Disorder

Video

Released: May 31, 2023 Expires: May 30, 2026

View Activity

This site uses cookies and related technologies for purposes that may include site operation, analytics, enhanced user experience, or advertising. You may choose to consent to our use of these technologies, or manage your own preferences. For more information, see our **Privacy policy**

[redacted] Released: May 31, 2023 Expires: May 30, 2026

View Activity

Module 8: Tobacco and Cannabis Use Disorder

Activities



Module 8: Tobacco and Cannabis Use Disorders

Video

Released: May 31, 2023 Expires: May 30, 2026

View Activity



Module 8: Tobacco and Cannabis Use Disorders

Text Module

Released: May 31, 2023 Expires: May 30, 2026

View Activity

Module 9: Stimulant and Sedative Use Disorder

Activities

This site uses cookies and related technologies for purposes that may include site operation, analytics, enhanced user experience, or advertising. You may choose to consent to our use of these technologies, or manage your own preferences. For more information, see our **Privacy policy**



Released: May 31, 2023 Expires: May 30, 2026

View Activity



Module 9: Stimulant and Sedative Use Disorders

Text Module

Released: May 31, 2023 Expires: May 30, 2026

View Activity

Additional State Specific Modules (applicable only for licensed healthcare professionals in those states listed)

Activities



Tennessee Specific Prescribing Laws and Guidelines

Video

Released: May 31, 2023 Expires: May 30, 2026

View Activity

DEA Course Webinar

No activities added yet

This site uses cookies and related technologies for purposes that may include site operation, analytics, enhanced user experience, or advertising. You may choose to consent to our use of these technologies, or manage your own preferences. For more information, see our **Privacy policy**

Management
Vanguard Pain Management
Consulting LLC
Nashville, Tennessee

Tennessee Medical Association



Michael Weaver, MD, DFASAM
Medical Director, Center for
Neurobehavioral Research on
Addiction
Professor, Department of Psychiatry
and Behavioral Sciences
McGovern Medical School
The University of Texas Health Science
Center at Houston
Houston, Texas

Provided by

Provided by Clinical Care Options, LLC

Users may be eligible for a refund in the event that we fail to provide (without reasonably rescheduling) any contractually required training webinar. With regard to our on-demand courses, to the extent permitted by law, all transactions are final and no refunds are available.

This site uses cookies and related technologies for purposes that may include site operation, analytics, enhanced user experience, or advertising. You may choose to consent to our use of these technologies, or manage your own preferences. For more information, see our **Privacy policy**



Company

Additional Information

CE Requirements

Publications

Contact Us

Legal

Ad Policy

Privacy Policy

Terms and Conditions

Cookie Policy

Our Clinical Education Alliance (CEA) Sites:

Practicing Clinicians Exchange (PCE)

ProCE

MDOutlook

Clinical Care Solutions (CCS)

Copyright© 2024 - CCO, LLC - All Rights Reserved

This site uses cookies and related technologies for purposes that may include site operation, analytics, enhanced user experience, or advertising. You may choose to consent to our use of these technologies, or manage your own preferences. For more information, see our **Privacy policy**

SBIRT: Screening, Brief Intervention, Referral to Treatment (Pain Management or Addiction Specialist)



samhsa.gov/sites/default/files/sbirtwhitepaper_0.pdf.

Slide credit: clinicaloptions.com

United States Senate

WASHINGTON, DC 20510

March 1, 2018

Pamela B. Morris
President & Chief Executive Officer
CareSource
230 North Main Street
Dayton, Ohio 45402

Dear Ms. Morris:

We write to share our concern over the reported utilization of several industry practices that, when used in the context of pain management and substance use disorder treatment and recovery, may be counterproductive to efforts to address our nation's opioid epidemic. We urge you to reexamine CareSource's current policies and procedures to identify and, more importantly, rectify, any practices that could be contributing to or exacerbating our country's drug addiction crisis.

Our country continues to fight back against the worst drug overdose epidemic in its history. According to the Centers for Disease Control and Prevention (CDC), drug overdoses accounted for more than 63,600 deaths in 2016 – an average of 174 drug overdose deaths per day. These tragedies are not limited to one group of individuals; rather, deaths resulting from drug overdose continue to increase across all populations – men and women, young and old, urban and rural, and across all races. And the cost of this epidemic extends beyond the loss of human lives – according to a recent economic analysis conducted by the Council of Economic Advisors, the economic impact of this addiction crisis represents a loss of nearly $504 billion annually, a number roughly equivalent to three percent of the entire country's gross domestic product (GDP). Without additional investments and changes to the status quo, these numbers will only continue to increase at an exponential rate.

Despite these devastating statistics, the pain that drives many individuals to these addictive drugs in the first place remains a problem. A 2015 analysis by the National Institutes of Health (NIH) estimated that more than 25 million adults experience chronic pain and nearly 40 million adults experience severe levels of pain. These numbers will only continue to increase as our nation grows older. In order to make progress in our nation's fight against the addiction epidemic, we must do more to ensure all Americans – whether they are suffering from chronic or acute pain – have access to non-addictive pain management options.

Unfortunately, it is often much harder for an individual to seek non-addictive pain medications or non-pharmacologic treatment options at the outset of treatment than it is to get a prescription opioid. We understand that there are many reasons for this, including restrictions on benefit design, the high cost of alternative pain treatments, the limited availability and effectiveness of clinically proven alternatives, a lack of clinician awareness regarding alternatives, and ingrained prescribing practices. However, it is important to note that opioid prescribing decisions are not governed solely by clinicians. Health insurance coverage policies play a significant role when it comes to accessing non-addictive pain treatment options, which is why we are urging CareSource to look into its benefit design and internal practices and take a more active role as it relates to preventing and treating addiction. If a clinician chooses to prescribe a non-addictive therapy to treat chronic pain, which is simply overridden by an insurance algorithm that defaults to the cheapest opioid alternative, an opportunity to turn the tide against addiction may be missed.

Recent news reports have raised serious concerns over a lack of insurer accountability when it comes to this epidemic. Take Ms. Lauren Kafka, for example. Ms. Kafka recently wrote about her experience recovering from surgery to correct a torn rotator cuff.[1] Her surgeon and two separate physical therapists recommended renting a cool-therapy device to help manage her pain throughout her recovery. Coverage for this device was denied by her insurance plan, leaving Ms. Kafka with two options: (1) pay out-of-pocket for the device rental; or (2) resort to the opioid painkillers covered by her insurance. Ms. Kafka made the decision to try to take the minimum number of pills necessary to aid in her recovery, and while she was able to pay out-of-pocket for the device rental fees to help decrease her dependence on opioids throughout her recovery, others in her situation may opt to elect only the covered drugs and find themselves at a higher risk for dependence.

Ms. Alisa Erkes, a patient with chronic abdominal pain, was forced to switch from using Butrans, a pre-dosed buprenorphine painkiller patch, to morphine when her insurance provider stopped covering the patch.[2] Though both buprenorphine and morphine are opioids, morphine is categorized as having a higher risk of abuse, dependence, and overdose. Similarly, Ms. Amanda Jantzi, a patient with a painful bladder condition, weaned herself off opioids using the non-opioid painkiller drug Lyrica, only to find that it was not covered by her new insurance policy when she switched employers.[3] While we recognize that Lyrica remains an expensive option with its own set of risks, this example highlights how substituting a traditional opioid may not always be appropriate in circumstances where another option may exist – whether it be pharmacologic or non-pharmacologic. In each of these examples, despite the efforts by both patients and providers to seek out non-addictive pain management options, it was the default policies of the insurers that dictated the available therapy – pushing each individual toward the cheapest and easiest fix: a potentially addictive opioid. Whenever possible, non-addictive options and drugs with a lower risk of addiction and/or abuse should be utilized.

An insurance policy's benefit design may also hinder access to non-pharmacological, or nondrug, pain management alternatives, which can provide valuable support and relief for patients in lieu of narcotics. Mr. Douglas Scott is one such patient who experienced opioid dependence following back and spine injuries from two car accidents.[4] Luckily, Mr. Scott's insurance covered treatment at a local clinic specializing in alternative pain management techniques, and he was able to be successfully weaned off of opioids. Evidence has shown that patients participating in such comprehensive pain rehabilitation programs can experience significant and sustained improvement in pain severity and functioning.[5] Unlike Mr. Scott, however, not all patients have coverage for such programs, which can cost upwards of $20,000; and we encourage CareSource to explore such options and offer them to beneficiaries where clinically appropriate.

---

[1] https://www.npr.org/sections/health-shots/2017/11/25/566032620/the-insurance-company-paid-for-opioids-but-not-cold-therapy

[2] https://www.nytimes.com/2017/09/17/health/opioid-painkillers-insurance-companies.html?_r=0

[3] https://www.nytimes.com/2017/09/17/health/opioid-painkillers-insurance-companies.html?_r=0

[4] https://www.nytimes.com/2016/06/23/business/new-ways-to-treat-pain-without-opioids-meet-resistance.html

[5] https://insights.ovid.com/pubmed?pmid=18804915

Lastly, we note reports that some insurance coverage plans appear to act as a barrier to accessing medication-assisted treatment (MAT) for individuals who are working to overcome addiction. Medical necessity requirements, high deductibles and copayments, prior authorization rules, and low reimbursement rates can delay and deter treatment, despite the wealth of evidence demonstrating the effectiveness of MAT. Furthermore, insurers that do cover MAT seldom cover all three Food and Drug Administration (FDA)-approved medications - methadone, buprenorphine and naltrexone – which are not interchangeable in their indications and uses. Similar hurdles exist for access to residential rehabilitation centers and detox facilities, for which insurers will often require "medical necessity" before covering care.

For example, Mr. Sean Mattos, a patient struggling with addiction, unsuccessfully went through two outpatient addiction programs before entering a residential facility, only to find that his insurer would not cover the full duration of treatment he required.[6] Despite agreement by his overseeing clinicians that he was not ready to leave the facility, Mr. Mattos was forced to call his insurer while in treatment to request coverage to remain under the facility's care, before ultimately paying $8000 of the $23,000 bill out of pocket. In response to such unfortunate situations and a desire to remedy them, we appreciate that multiple major insurers have recently lifted their prior authorization requirements for MAT – a step forward in reducing barriers to care. However, such efforts must be replicated and expanded across the industry in order for them to make a meaningful difference.

While we appreciate the work CareSource is already doing to help address this epidemic, and we are encouraged by recent industry led efforts to reevaluate some policies in light of the addiction epidemic, we remain concerned by the rules and authorization requirements that may be employed by insurance companies that could potentially limit beneficiary access to non-addictive and alternative pain management options as well as addiction treatment options. In order to effectively address this ongoing epidemic, we believe insurance companies must take additional steps to ensure they are playing a more active role in addiction prevention and treatment and providing beneficiaries full access to the range of clinically appropriate services available. Eliminating cost-sharing requirements for overdose reversal drugs is not enough. Insurer policies such as prior authorization, drug tiering, abrupt formulary changes, preferred pricing lists, restrictions or additional cost-sharing requirements for non-pharmaceutical interventions, lengthy and burdensome appeals process, and other clinician incentives can be insurance tools that, when used improperly, may harm efforts to combat addiction and should be reviewed to avoid furthering the current epidemic.

It is time for insurance industry leaders like CareSource to reexamine these policies in light of the substance/opioid use disorder and update your coverage policies in a way that maximizes the accessibility and affordability of a wide range of safe alternatives to narcotics. The insurance industry is on the front line of this epidemic, and we need your help identifying what policies are working and what barriers to less-addictive pain treatment options and substance use disorder treatments exist.

[6] http://www.modernhealthcare.com/special/opioid-addiction

Recognizing there is a difference in the way insurers are able to design their benefits across commercial, Medicare, and Medicaid books of business, we respectfully request that you respond to the following questions by March 30, 2018:

1. What internal policies and procedures does CareSource have in place that may create a barrier to accessing affordable non-addictive or less addictive pain treatments, including those that are non-pharmacological?

2. What flexibilities does CareSource offer to ensure that individuals struggling with acute or chronic pain receive the least addictive pain treatment option, in a timely manner?

3. What internal policies and procedures does CareSource have in place that may create a barrier to accessing affordable options for medication-assisted treatment and other behavioral therapy options for addicted individuals?

4. What flexibilities does CareSource offer to ensure that individuals struggling with substance use disorder receive the proper treatment, in a timely manner?

5. What non-pharmacological alternative pain therapies, such as acupuncture, does CareSource offer to beneficiaries? Do alternative pain therapy options vary by benefit design? If so, are there any barriers or restrictions preventing the use of alternative or innovative pain therapy options in federal programs, such as Medicare or Medicaid?

6. How often does CareSource review and update its list of approved pain management options and services, both pharmacological and non-pharmacological? As less addictive treatment options become available, how quickly are you able to cover them?

7. How often does CareSource review and update its list of approved addiction treatment options and services, both pharmacological and non-pharmacological? As additional substance use disorder treatments become available, how quickly are you able to cover them?

8. Does CareSource have a fail-first, stepped, or medical necessity standard for non-addictive, including non-pharmacological, or abuse-deterrent options for pain management?

9. Does CareSource have a fail-first or medical necessity standard for medication-assisted treatment or other behavioral therapy options for individuals who have a substance use disorder?

10. When reviewing coverage appeals from beneficiaries, members, or providers, at what level of appeal does CareSource implement a clinician review? How quickly are appeals escalated for individuals struggling with severe pain needs? How quickly are appeals escalated for individuals struggling with access to addiction services?

11. When it comes to opioids and other controlled substances, does CareSource implement a unique set of internal policies or controls?

12. What is the typical difference, if any, in cost-sharing for members/beneficiaries using non-addictive, including non-pharmacological pain management approaches vs. potentially addictive therapies?

13. What are the typical cost-sharing amounts for members/beneficiaries using medication-assisted treatment options or other behavioral therapy options offered by CareSource? Are any addiction treatment options offered to beneficiaries without cost-sharing requirements?

14. Does CareSource cover all three medication-assisted treatment drug options (methadone, buprenorphine and naltrexone) and if not, what is the rationale for exclusion?

15. How does CareSource identify individual members/beneficiaries who may already be struggling with substance use disorder? Are any policies or procedures waived for these individuals when it comes to accessing alternative options for pain management?

16. Is it your belief that all of CareSource's internal policies and procedures live up to both the letter and the spirit of the *Mental Health Parity Act*, as intended by Congress?

17. Recognizing there are always ways to improve these processes, are there other plan designs or benefit flexibilities you could implement to improve access to less addictive pain management options or the full range of treatment options?

18. Are there any additional factors that Congress should be aware of as it considers the nation's substance abuse/opioid crisis?

It is critical that we ensure access to clinically appropriate, non-addictive pain management options for all Americans across all payers as well as comprehensive coverage for the full range of addiction treatment services, from medication-assisted treatment options to inpatient and outpatient therapy.

Thank you for your attention to this matter. We look forward to working with you on policies that will make it as easy for an individual to access addiction treatment and non-addictive remedies for pain as it is for them to access opioids in the first place.

Sincerely,

Sherrod Brown
United States Senator

Edward J. Markey
United States Senator

Jeanne Shaheen
United States Senator

Tammy Baldwin
United States Senator

Margaret Wood Hassan
United States Senator

Sheldon Whitehouse
United States Senator

Chris Van Hollen
United States Senator

Richard Blumenthal
United States Senator

Cory A. Booker
United States Senator

Christopher Murphy
United States Senator

Tim Kaine
United States Senator

Patrick J. Leahy
United States Senator

Angus S. King, Jr.
United States Senator

Dianne Feinstein
United States Senator

Elizabeth Warren
United States Senator

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836 | http://www.pharmacy.ohio.gov

License 022141400

Comprehensive Pain Management Institute, Llc

5245 E. Main Street
Columbus, OH 43213
Franklin County

Terminal - Pain Management Clinic - Category 3

Pain Management Clinic Inspection

December 8, 2023

License 022141400 - Comprehensive Pain Management Institute, Llc

Full

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836
http://www.pharmacy.ohio.gov

Completed by Keenan Reese
Start 12/8/2023 10:00 AM
End 12/8/2023 11:10 AM

Organization

Name	License Type	Category
Comprehensive Pain Management Institute, Llc	Terminal - Pain Management Clinic - Category 3	

License Number	Business Type	DEA Number
022141400	PMC - Pain Management Clinic	FM0315780

Responsible Person
Dr. Leon Margolin

Hours of Operation
Mon-Tues: 8a-5p Wed: Closed (Administrative)Thurs: 8a-5p Fri: 8a-1:00p Sat-Sun: Closed

Contact

Address	Primary Number	Fax Number	Website
5245 E. Main Street Columbus, OH 43213 Franklin County	(330) 488-4989	(216) 795-1105	

Personnel

ame	Initials	Position	I.D. No.	Phone	Email
r. Leon Margolin		Responsible Person	35.090064		leon3087@gmail.com

1) Initial Inspection Information

1) Were multiple inspection guides used during this inspection?

No

2) Licensing, Ownership, and Responsible Person

1) Is the terminal distributor of dangerous drugs license current?

Yes

Observation
The current TDDD license expires on 03/31/2025.

2) Is the clinic physician-owned?

Yes

Observation
The PMC is owned by Dr. Leon Margolin.

3) Have there been any changes in the facility's ownership, business name or trade name, category, or address without submitting a new application to the Board?

No

4) Does each physician owner of a pain management clinic meet the requirements for ownership?

Yes

Observation
Dr. Leon Margolin holds certifications in Physical Medicine and Rehabilitation and Anesthesiology by the American Board of Medical Specialties.

5) Does the owner (or owners) of the clinic own or practice at any other facility?

Yes

Observation
Dr. Leon Margolin owns Comprehensive Pain Management Institute, LLC (022775650) in Cleveland, Ohio and Advanced Treatment Center, LLC (022839650)(Inactive) in Columbus, Ohio.

6) Does the responsible person match what is indicated in eLicense?

Yes

7) If owner is not the responsible person, does the responsible person meet the requirements to be the responsible person on the license?

Yes

Observation
Dr. Margolin works approximately 40 hours per week at the clinic.

8) How many hours per week does the owner work at the clinic?

Observation
Dr. Margolin works approximately 40 hours per week at the clinic.

10) If the responsible person is not at the clinic while it is open, who supervises the clinic?

Observation
Dr. Margolin is typically at the office during normal business hours. If he is running late, a CNP will supervise.

11) Is the responsible person providing adequate supervision of the licensed site?

Yes

3) Personnel

1) Are employee FBI/BCI criminal record checks for all employees available for inspection?

Yes

Observation

Agents reviewed BCI/FBI checks for the following employees:

- Leon Margolin, MD
- Jing Liu, CNP
- Jing Yu, CNP
- Manisha Bhattarai, MA
- Asmita Bhattarai, MA
- Lachhi Bhattarai, MA
- Elsa Abebe, MA
- Tracy Brown, MA
- Amanda Rutherford
- Emily Gonzalez
- Felekech Asrat

2) Does the clinic employ any other prescribers (physicians, advanced practice nurses, or physician assistants)?

Observation

Jing Liu, CNP prescriber APRN.CNP.17169 – No Action

Jing Yu, CNP non prescriber APRN.CNP.0034493 – No Action (Newer CNP, will start prescribing once proper clinical sufficient experience is gained.)

3) If employing an advanced practice nurse or physician assistant, does the licensee have a valid standard of care arrangement or supervision agreement?

Yes

Observation

Observed.

Jing Yu - Signed 8/4/2023

Jing Jiu - Signed 9/11/2023

4) Have any licensed/registered employees at the facility with access to drug stock ever been disciplined by an Ohio licensing agency?

No

4) Patient Records and Drug Administration

1) Does this site use a manual, computerized or combination of both to maintain drug records?

The clinic uses an electronic (computer) system.

Observation
Practice Fusion and electronic records, site also uses manual patient records.

2) If using a computerized record keeping system, does the system have effective security controls to prevent unauthorized access?

Yes

Observation
Staff members have individualized username/passwords to access the electronic system.

3) If using a computerized system, are records backed up daily to prevent against record loss?

Yes

4) If using computerized record keeping system, is it stand-alone or able to be shared or accessed by another location?

Stand-alone system

5) Does the licensee maintain records of drug administration containing the required information?

Yes

6) Are orders for the administration of dangerous drugs properly documented?

Not Applicable

7) Does the clinic keep a patient log that meets the requirements set by the State Medical Board?

Yes

Observation
Observed Patient Log:
(1) Each log sheet shall contain the month, day, and year;

(2) Each log entry shall include the legible first and last name of each patient;

(3) Each patient shall be required to sign the log at each visit; and

(4) Patient logs shall be maintained for seven years.

8) How many active patients does the clinic currently treat?

Greater than 200 patients

9) How many patients does the licensee see per day?

25 to 50 patients

10) Are medical assistants being used to administer drugs?

No

5) Drug and Hypodermic Security

1) Are controlled substances stored in a securely locked, substantially constructed cabinet or safe?

Not Applicable - No controlled substances on-site

2) Do the methods utilized for accessing the cabinet or safe containing controlled substances prevent unauthorized access?

Not Applicable - No controlled substances on-site

3) Are patient-specific controlled substances maintained under appropriate security and control?

Not Applicable - No controlled substances on-site

4) Does the licensee comply with the security requirements for storing thiafentanil, carfentanil, etorphine hydrochloride, and diprenorphine?

Not Applicable - No thiafentanil, carfentanil, etorphine hydrochloride, or diprenorphine on-site

5) Are non-controlled dangerous drugs maintained under appropriate supervision and control?

Yes

6) Are hypodermics maintained under appropriate supervision and control?

Yes

Observation
Needles are kept in procedure room. A staff member is always present in the procedure room with the patient.

6) Drug Storage and Temperature Control

1) Are areas where dangerous drugs are stored dry, well-lit, well-ventilated, and maintained in a clean and orderly condition?

Yes

2) Are storage areas maintained at temperatures and conditions which will ensure the integrity of the drug stock?

Yes

3) Are refrigerators and freezers used for the storage of drugs maintained at the proper temperature?

Not Applicable

4) Does the licensee have a policy to respond to any out of range individual temperature readings or excursions to ensure the integrity of stored drugs?

Not Applicable

5) Are refrigerators and freezers used for the storage of drugs free of food or beverage products?

Not Applicable

7) Theft or Significant Loss of Drugs and Drug Documents

1) Has the licensee experienced any theft or significant loss of any dangerous drugs in the past twenty-four months?

No

2) Has the licensee experienced any theft or loss of uncompleted prescription blank(s), written prescription order(s) not yet dispensed, or D.E.A. controlled substance order forms in the past twenty-four months?

No

3) REMINDER: Theft or significant loss of dangerous drugs and drug documents.

Observation
REMINDER

A licensee is required to report to the the Board and law enforcement authorities of any theft or significant loss of dangerous drugs (controlled and non-controlled prescription drugs) immediately upon discovery of the theft or significant loss. This includes dangerous drugs in transit that were either shipped from or to a prescriber, terminal distributor, or drug distributor.

A licensee is required to report, immediately upon discovery, to the Board and law enforcement authorities any theft or loss of uncompleted prescription blank(s) used for writing a prescription, D.E.A. controlled substance order forms (Form 222), written prescription order(s) not yet dispensed, and original prescription order(s) that have been dispensed.

For more information on reporting, visit: www.pharmacy.ohio.gov/theft

8) Orders for Schedule II Controlled Substances

1) Are all executed DEA Forms 222 retained for at least three years?

Not Applicable

2) Are DEA Forms 222 secured when not in use?

Not Applicable

9) Controlled Substance Inventory

1) Does the licensee conduct an annual inventory of controlled substances?

Yes

Observation
An Annual Medication Review Log was completed on 11/28/2023. Also observed 2020, 2021 and 2022. The clinic does not dispense or store controlled substances on the premises.

2) How does the licensee monitor its inventory of controlled substances?

Observation
The clinic does not dispense or store controlled substances on the premises.

10) Drug Purchases and Online Sales

1) Does the licensee maintain complete and accurate records of drugs purchased?

Yes

2) Has the licensee performed and documented an annual query of eLicense prior to purchasing drugs at wholesale?

Yes

Observation
Observed 11/28/2023 Medline Medtox

3) Does the licensee sell or offer to sell dangerous drugs on its website?

No

11) Drug Disposal

1) Does the licensee dispose of controlled substances on-site using a method that renders the drug non-retrievable?

Not Applicable - Does not dispose of controlled substances on-site

2) Does the licensee use a reverse distributor for the disposal of controlled substances?

Not Applicable

3) Does the licensee maintain complete and accurate records of the disposal of controlled substances?

Not Applicable

4) Does the licensee maintain complete and accurate records of the disposal of unused portions of controlled substances resulting from patient administration?

Not Applicable

Observation
Discussed:
Records must include the name of the drug, the quantity disposed, the date and manner of disposal, and the positive identification of two licensed healthcare professionals (nurses, physicians, etc.) conducting and witnessing the disposal.

Documentation may be maintained in the patient record (i.e. with administration record).

The disposal method does not have to render the unused portion of the drug non-retrievable.

All records must be maintained for a period of three years.

OAC 4729:5-3-01 & 4729:5-11-04 (G)

6) Does the licensee maintain complete and accurate records of the disposal of non-controlled dangerous drugs?

Not Applicable

Observation
Has not disposed of any dangerous drugs on-site.

12) Personally Furnishing

1) Does the licensee personally furnish any dangerous drugs to patients?

No

13) Drug Samples

1) Does the licensee distribute samples to patients?

No

14) OARRS

1) Are any of the prescribers using delegates to request OARRS reports?

No

2) REMINDER: Ohio law requires prescribers to obtain and review OARRS reports before initially prescribing or personally furnishing an opiate analgesic or benzodiazepine to a patient.

Observation
REMINDER: Ohio law requires prescribers to obtain and review OARRS reports before initially prescribing or personally furnishing an opiate analgesic or benzodiazepine to a patient.

The prescriber must also make periodic requests for patient information from OARRS if treatment with an opioid or benzodiazepine continues for more than 90 days. The requests must be made at intervals not exceeding ninety days, determined according to the date the initial request was made.

Prescribers must document they have reviewed OARRS. This can be a chart note or the OARRS report can become part of the chart record.

For more information about these requirements, visit: www.pharmacy.ohio.gov/check

3) REMINDER: OARRS reports cannot be provided directly to a patients or other health care professionals.

Observation
REMINDER: OARRS reports may be reviewed with the patient or another health care provider, however a copy may not be provided to the patient.

Patients requesting a copy of their OARRS report must submit a notarized request to the Board of Pharmacy in person or by mail, and the report must be received in person at the Board office during normal business hours. Proof of identity is required to obtain an OARRS report.

16) Prescriptions

5) REMINDER: All prescriptions must be issued in accordance with applicable Ohio laws and rules.

Observation
REMINDER: All prescriptions must be issued in accordance with applicable Ohio laws and rules.

For more information on the issuance of valid prescriptions, visit: www.pharmacy.ohio.gov/rx.

17) Expired/Adulterated Drugs

1) Are multi-dose vials properly labeled?

No

Observation
Upon the initial puncture of a multiple-dose vial containing a drug, the vial shall be labeled with a beyond-use date or date opened. The beyond-use date for an opened or entered (e.g., needle punctured) multiple-dose container with antimicrobial preservatives is twenty-eight days, unless otherwise specified by the manufacturer. A multiple-dose vial that exceeds its beyond-use date shall be deemed adulterated.

OAC 4729:5-11-03 (K)

2) Are there expired/adulterated drugs present in the licensee's active drug stock?

No

3) Are expired/adulterated drugs appropriately segregated from the licensee's active drug stock?

No

Observation
No observed expired drugs at time of inspection.
Policy and rule discussed.

4) Are expired/adulterated drugs stored no longer than one year from the date of expiration/adulteration?

No

Observation
No observed expired drugs at time of inspection.

18) General Record Keeping

1) Does the licensee maintain all required records on-site for a period of three years in a readily retrievable manner?

Yes

2) Are records maintained under appropriate supervision and control to restrict unauthorized access?

Yes

3) Does the clinic use electronic or paper records for patient charting?

Electronic

Paper

4) If the records are electronic, what software system is being used?

Observation
Practice Fusion

21) Standards of Care

1) Does the clinic document a patient's history and physical examination, including a screening for substance misuse or substance use disorder?

Yes

2) Does the clinic develop treatment plans for patients receiving opioids for the treatment of subacute and chronic pain?

Yes

3) Does the clinic document the review of OARRS reports for patients receiving opioids for chronic or subacute pain?

Yes

4) Are drug screens performed on patients?

Observation
New Patient Screens
Urine (Non-observed) or saliva in specials circumstances.
Random screen after established.
Review lab and discussed with patient. Make sure taken at proper time. Pill count. Pain Psychology consult. Reassessment.
Review lab, Pain Psychology consult, consider referral.

22) Temporary Removal of Drugs

1) Does the licensee engage in the temporary off-site storage of dangerous drugs?

No

24) Naloxone for Emergency Use

1) Does the licensee provide naloxone for emergency use?

No

26) Substance Abuse and Mental Health Resources for Healthcare Professionals

1) Substance Abuse and Mental Health Resources for Healthcare Professionals

Observation
The healthcare profession is not immune to substance use disorder and mental health conditions. Such medical conditions impair a healthcare professional's competency, ability, and judgment. Substance use disorder and/or mental health conditions that are left untreated may not only cause a healthcare professional to risk their career but may also endanger the life of a patient.
These medical conditions can be effectively treated, and it is possible for healthcare professionals that are in treatment or recovery to return to practice.

The State of Ohio Board of Pharmacy encourages all healthcare professionals who may be struggling with substance use disorder or mental health condition to seek help. The following are resources that can assist healthcare professionals in getting help: (the resources listed here are for informational purposes only and do not constitute an endorsement by the State of Ohio Board of Pharmacy. They do not represent a complete list of the resources available)

Ohio Careline 1-800-720-9616, emotional support, with referral to other resources if needed.
Crisis text line, text "4hope" to 741 741 to speak with a crisis counselor.
Treatment Bridge 1-877-275-6364, for addiction and mental health services.
National Suicide prevention dial 988, or call 1-800-273-8255.
Ohio Domestic Violence Network 1-800-934-9840
Pharmacist Rehabilitation Organization (www.ohiopro.org) for pharmacists and pharmacy interns.
Ohio Physicians Health Program (www.ophp.org)

30) Inspection Affirmation

1) Inspection Affirmation

Observation
As the person in charge at the time of this inspection, I affirm that I have reviewed this inspection report with the Specialist/Agent/Inspector, and understand its content.

If this inspection report requires a written response, I understand, per OAC 4729:5-3-03, that either of the following must be submitted to the State of Ohio Board of Pharmacy within 30 days of this inspection:

(1) The action(s) the licensee or applicant has taken to correct the violation(s) and the date of implementation of the corrective action(s); or

(2) An explanation disputing the observed violations.

I understand that if I am not the responsible person documented on this site's Ohio terminal distributor of dangerous drugs license, I will ensure the responsible person is provided a complete copy of this inspection report in a timely manner.

I further acknowledge that a written response does not release the licensee listed in this inspection report from potential disciplinary action.

This inspection report is not intended as an exhaustive listing of all observed conditions. There may be deficiencies, non-compliance, or violation(s) of Ohio laws and rules not detected or noted in this report.

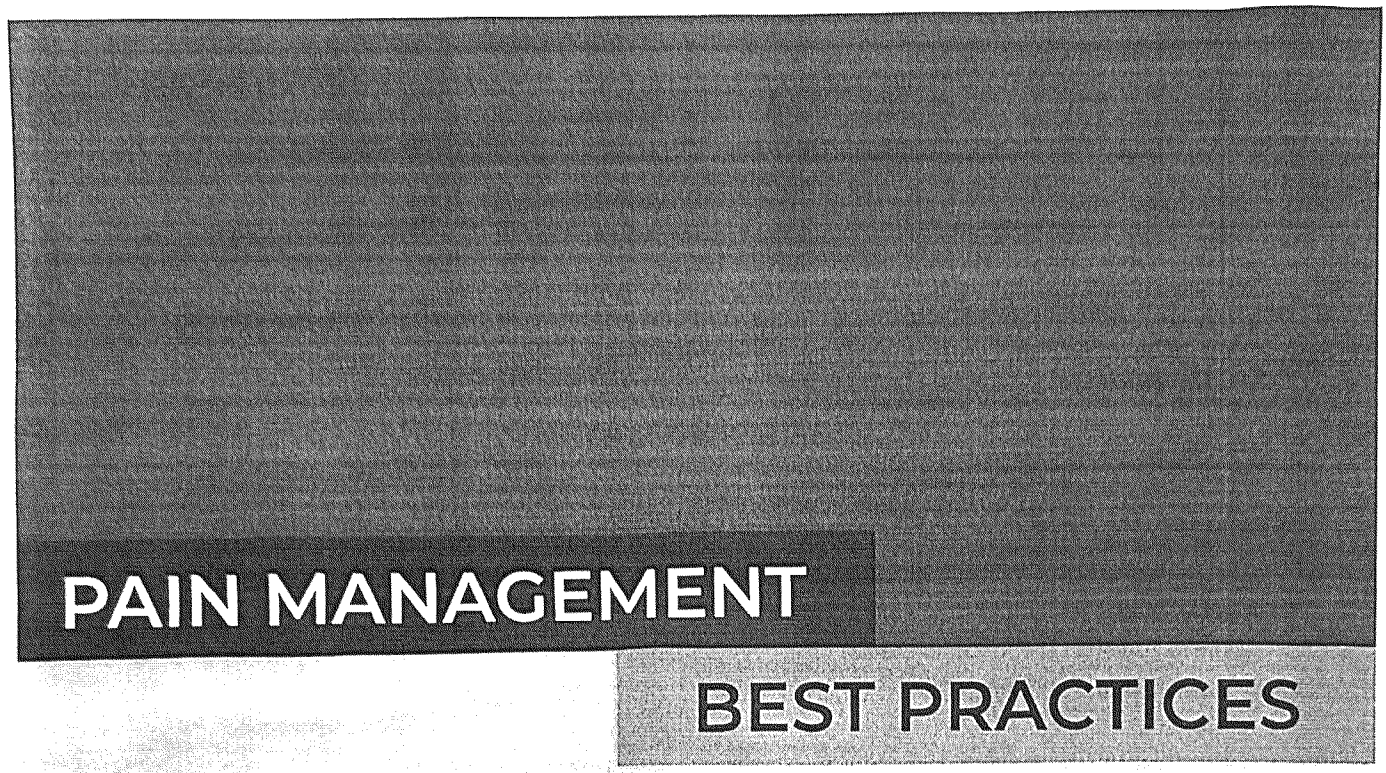
Responses must be either emailed (with a copy of the inspection report) to writtenresponse@pharmacy.ohio.gov or mailed to 77 South High Street, 17th Floor, Columbus, Ohio 43215.

Summary

No Issue Found

Reviewed by Dr. Leon Margolin

(signature)



PAIN MANAGEMENT BEST PRACTICES INTER-AGENCY TASK FORCE REPORT

Updates, Gaps, Inconsistencies, and Recommendations

DRAFT FINAL REPORT

- **Restorative Therapies** including those implemented by physical therapists and occupational therapists (e.g., physiotherapy, therapeutic exercise, and other movement modalities) are valuable components of multidisciplinary, multimodal acute and chronic pain care.
- **Interventional Approaches** including image-guided and minimally invasive procedures are available as diagnostic and therapeutic treatment modalities for acute, acute on chronic, and chronic pain when clinically indicated. A list of various types of procedures including trigger point injections, radiofrequency ablation, cryoneuroablation, neuro-modulation and other procedures are reviewed.
- **Behavioral Health Approaches** for psychological, cognitive, emotional, behavioral, and social aspects of pain can have a significant impact on treatment outcomes. Patients with pain and **behavioral health comorbidities** face challenges that can exacerbate painful conditions as well as function, QOL, and ADLs.
- **Complementary and Integrative Health,** including treatment modalities such as acupuncture, massage, movement therapies (e.g., yoga, tai chi), spirituality, among others, should be considered when clinically indicated.

- Effective multidisciplinary management of the potentially complex aspects of acute and chronic pain should be based **on a biopsychosocial model** of care.
- Health systems and clinicians must consider the pain management needs of the **special populations** that are confronted with unique challenges associated with acute and chronic pain, including the following: children/youth, older adults, women, pregnant women, individuals with chronic relapsing pain conditions such as sickle cell disease, racial and ethnic populations, military active duty and reserve service members and Veterans, and cancer and palliative care.
- **Risk assessment** is one of the four cross-cutting policy approaches that is necessary for best practices in providing individualized, patient-centered care. A thorough patient assessment and evaluation for treatment that includes risk benefit analysis are important considerations when developing patient-centered treatment. Risk assessment involves identifying risk factors from patient history, family history, current biopsychosocial factors, as well as screening and diagnostic tools, including PDMP, laboratory data, and other measures. Risk stratification for a particular patient can aid in determining appropriate treatments for the best clinical outcomes for that patient. The final report and this section in particular emphasizes safe opioid stewardship with regular re-evaluation of the patient.
- **Stigma** can be a barrier to treatment of painful conditions. Compassionate, empathetic care centered on a patient-clinician relationship is necessary to legitimize the suffering of patients with painful conditions and to address the various challenges associated with the stigma of living with pain. Stigma often presents a barrier to care, and is often cited as a challenge for both patient, families, caregivers, and providers.
- Improving **education** about pain conditions and their treatment for patients, families, caregivers, clinicians and policymakers is vital to enhancing pain care. Patient education can be emphasized through various means including clinician discussion, informational materials and web resources. More effective education and training about acute and chronic pain should occur at all levels of clinician training, including undergraduate educational curricula, graduate professional training, and continuing professional education, including the use of proven innovations such as the Extension for Community Healthcare Outcomes (Project ECHO) model. Education for the public as well as for policymakers and legislators is emphasized to ensure expert and cutting-edge understanding is part of policy that can affect clinical care and outcomes.
- Addressing **access to care** barriers is essential to optimizing pain care. Recommendations include addressing the gap in our **workforce** for all disciplines involved in pain management. Additionally, improved **insurance coverage and payment** for different pain management modalities is a critical component in improving access to effective clinical care, and should include coverage and payment for care coordination, complex opioid management and

- **Recommendation 1d:** If already preformed upon admission in the inpatient hospital setting, the health care provider team should not be mandated to repeatedly check PDMP if already performed upon admission and pending discharge.
- **Recommendation 1e:** Conduct studies to better identify where PDMP data are best used (e.g., inpatient versus outpatient settings). Adjust PDMP data use based on the findings of the recommended studies to minimize undue burdens and overuse of resources (i.e., streamline PDMP data use).
- **Recommendation 1f:** States are encouraged to have interoperability between PDMP and EHR platforms (Code of Federal Regulations 170.315). EHR vendors should work to integrate PDMPs into their system design at minimal to no additional cost or burden to providers (to eliminate barriers to accessing PDMP data), especially when these data points are mandated.
- **Recommendation 1g:** Enhance the interoperability of PDMPs across state lines to allow for more effective use, along with reporting to PDMP by the VA and military health system on a consistent basis.
- **Recommendation 1h:** Clinicians within and outside federal health care entities should have access to each other's data to ensure safe continuity of care.
- **Recommendation 1i:** Allow access to PDMPs by all opioid prescribers.
- **Recommendation 1j:** Encourage funding programs, such as the Harold Rogers Prescription Drug Monitoring Program and the National All Schedules Prescription Electronic Reporting Act of 2005, to link interstate PDMP programs to each other.

3.1.2 SCREENING AND MONITORING

Screening and monitoring in pain management seeks to identify and reduce the risk of substance misuse, abuse, and overdose as well as improve overall patient care. Evaluations of patient physical and psychological history can screen for risk factors and characterize pain to inform treatment decisions. Screening approaches include efforts to assess for concurrent substance use and mental health disorders that may place patients at higher risk for OUD and overdose. This includes screening for drug and alcohol use and the use of urine drug testing, when clinically indicated.[84,409] These approaches allow providers to identify high-risk patients so that they can consider substance misuse and mental health interventions, ADFs, and education materials to mitigate opioid misuse.[410]

Screening tools can help clinicians identify risks and help determine which medication classes may be appropriate for the patient, including for long-term opioid therapy. Effective screening can include single questions, such as, "How many times in the past year have you used an illegal drug or used a prescription medication for nonmedical reasons?"[411] Other validated screening tools include the Drug Abuse Screening Test[412] and the Alcohol Use Disorders Identification Test.[413] Clinicians must recognize the limits of screening tools in detecting prior or developing SUD or OUD.

Urine drug tests (UDTs) can provide information about drug use that the patient does not report, including not using prescribed medications as intended and unreported drug use. UDTs can also potentially inform treatment decisions by assessing an individual's drug metabolism rate. However, according to a systematic review by the Agency for Healthcare Research and Quality (AHRQ), evidence demonstrating the effectiveness of UDTs for risk mitigation during opioid prescribing for pain is lacking.[414,415] UDT results can be subject to misinterpretation and may sometimes be associated with practices that can harm patients (e.g., stigmatization, inappropriate termination from care). Clinicians do not consistently use practices intended to decrease the risk for misuse, such as UDTs[409] and opioid treatment agreements,[416] likely in part because of competing clinical demands, perceived inadequate time to discuss the rationale for UDTs and order confirmatory testing, and feeling unprepared to interpret and address results.[417]

To mitigate the risks of prescription opioid misuse, medical societies, in conjunction with state and federal regulatory agencies, have recommended specific risk-reduction strategies, including written treatment agreements for patients with

chronic pain who are prescribed opioids.[416] Pain agreements or treatment agreements can be useful in defining the responsibilities of the patient and the provider, and they create a structure to guide and evaluate opioid use. The agreement should be viewed as an opportunity for ongoing dialogue about the risks of opioids and what the patient and clinician can expect from each other.[361] The agreement should not be about simply getting a form signed or a means to "fire" a patient for breaking the terms of the agreement; rather, it is a tool for facilitating a conversation between the clinician and the patient.[416]

Monitoring approaches should be applied transparently and consistently in a manner that emphasizes safety so that miscommunication and accidental stigmatization are minimized.[418] At follow-up, doctors should assess benefits in function, pain control, and QOL using tools such as the three-item "Pain average, interference with Enjoyment of life, and interference with General activity" Assessment Scale[419] or asking patients about progress toward functional goals that have meaning for them. Clinicians should also screen for factors that predict risk for poor outcomes and substance abuse, such as sleep disturbance, mood disorder, and stress, either by using a pain rating scale such as the Defense and Veterans Pain Rating Scale, which includes brief questions, or by routinely asking about these factors on clinical examination.[420] Clinicians should ask patients about their preferences for continuing opioids, given their effects on pain and function relative to any adverse effects they experience.[397] These factors illustrate the importance of health care providers having sufficient time with the patient for a thorough evaluation.

GAPS AND RECOMMENDATIONS

Gap 1: Comprehensive screening and risk assessment of patients is time-consuming but vital for proper evaluation of their chronic pain conditions. Lack of sufficient compensation for time and payment for services have contributed to barriers in best practices for opioid therapy.

- **Recommendation 1a:** Encourage CMS and private payers to provide sufficient compensation for time and payment for services to implement the various screening measures (e.g., extensive history taking, review of medical records, PDMP query, urine toxicology screenings, when clinically indicated). These are vital aspects of risk assessment and stratification for patients on opioids and other medications.
- **Recommendation 1b:** Consider referral to pain, mental health and other specialists, including addiction medicine trained physicians when high-risk patients are identified.

Gap 2: UDTs are not consistently used as part of the routine risk assessment for patients on opioids.

- **Recommendation 2a:** Use UDTs as part of the risk assessment tools prior to the initiation of opioid therapy and as a tool for reevaluating risk, using the clinical judgment of the treatment team.
- **Recommendation 2b:** Clinicians should educate patients on the use of UDTs and their role in identifying both appropriate and potentially inappropriate use.

Gap 3: Variability exists in what is included in opioid treatment agreements and should be based on common principles and reflect provider, practice, and patient demographics.

- **Recommendation 3a:** Conduct studies to evaluate the effectiveness of the different components of opioid treatment agreements. Treatment agreements should include the responsibilities of both the patient and the provider.
- **Recommendation 3b:** Use opioid treatment discussions as an educational tool between providers and patients to inform the patient about the risks and benefits of and alternatives to chronic opioid therapy.

3.2 STIGMA

Stigma associated with having chronic pain, especially when opioid therapy is used as a treatment modality, is a major concern and has far-reaching effects on patients and all those involved in their care.[421] The different facets of stigma — at the patient, provider, and social levels — collectively serve as a significant barrier to effective treatment of chronic pain.[422] There is a growing body of empirical research into stigmatization and the resulting barriers to care. Studies suggest that patients

ADDICTION
SSA SOCIETY FOR THE STUDY OF ADDICTION
RESEARCH REPORT
doi:10.1111/add.13651

Substance use outcomes of patients served by a large US implementation of Screening, Brief Intervention and Referral to Treatment (SBIRT)

Arnie Aldridge[1], Robyn Linford[1] & Jeremy Bray[2]

RTI International, Research Triangle Park, NC, USA[1] and The University of North Carolina at Greensboro, Bryan School of Business and Economics, NC, USA[2]

ABSTRACT

Aims To estimate changes in the substance use behaviors of patients who received services as part of the US Substance Abuse and Mental Health Services Administration's (SAMHSA) Screening, Brief Intervention and Referral to Treatment (SBIRT) grant program. **Methods** We use a pre–post design and performance monitoring data collected by SBIRT organizations. For a sample of 17 575 patients, we compare pre-SBIRT substance use with substance use 6 months after receipt of SBIRT services. SBIRT's correlation with changes in substance use was estimated using generalized linear mixed models to account for the clustering of patients within health-care facility and US state. **Results** From pre- to post-SBIRT we found large and statistically significant decreases for almost every measure of substance use. Model-adjusted means indicate that the prevalence of alcohol use was lower 6 months later by 35.6%, heavy drinking by 43.4% and illicit drug use by 75.8%. Greater intervention intensity was associated with larger decreases in substance use. The study design does not support causal conclusions and estimated decreases in reported substance use are due, at least in part, to a well-known set of confounders and natural substance use patterns that may be unrelated to any particular SBIRT intervention. **Conclusions** Compared with previously published findings on the Screening, Brief Intervention and Referral to Treatment grant program, our estimates of substance use reduction were smaller, but still consistently large in absolute magnitude and within ranges of estimates from past trials of Screening, Brief Intervention and Referral to Treatment.

Keywords Brief intervention, brief therapy, brief treatment, illicit drugs, moderator, SBI, SBIRT.

Correspondence to: Arnie Aldridge, RTI International, 3040 East Cornwallis Rd. Hobbs 239, Research Triangle Park, NC 27709, USA. E-mail: aaldridge@rti.org
Submitted 14 June 2014; initial review completed 8 September 2014; final version accepted 7 July 2015

INTRODUCTION

In 2003, the Substance Abuse and Mental Health Services Administration (SAMHSA) established the Screening, Brief Intervention and Referral to Treatment (SBIRT) grant program to screen patients systematically in medical settings and, based on screening results, provide brief intervention (BI), brief treatment (BT) or referral to treatment (RT) as appropriate. SAMHSA's SBIRT program is the largest SBIRT dissemination effort ever undertaken in the United States. In the initial cohort of projects, six states and one tribal organization were awarded 5-year grants to promote the adoption and sustained implementation of SBIRT in a variety of medical settings. The goals of these grants were to expand the continuum of care for substance use disorders, including hazardous, harmful and dependent use, and to promote the integration of substance use disorder care into the traditional medical care community.

In the only published study of patient outcomes for SAMHSA's SBIRT initiative, Madras *et al.* [1] reported preliminary outcomes for six of the first seven SAMHSA SBIRT projects. In analyses performed separately for each project, Madras *et al.* found that past-month substance use outcomes were dramatically lower 6 months after exposure to SBIRT services than they were at the time of SBIRT screening. In addition to being the first published, multi-site assessment of SAMHSA's SBIRT program, Madras *et al.* received attention because it has provided novel evidence for areas in which SBIRT has been less well studied; namely, patients screened in emergency departments and in-patient settings as opposed to primary care settings, as well as patients screened for illicit substance use.

Despite having the largest sample of patients ever examined in an SBIRT study (459 599), the Madras *et al.* findings have several limitations noted by other SBIRT

© 2017 Society for the Study of Addiction

researchers [2–4]. The primary criticism is the study's lack of a rigorous design to eliminate alternative explanations of patient improvements. Such alternative mechanisms of change following SBIRT are an important and unresolved area of research. Screening and assessment alone may produce changes [5,6]. Study elements can be a factor and were in place to some extent in all the SBIRT projects. Informed consent procedures, the need to provide contact information for follow-up contacts and the desire to meet outcome expectations or please a researcher might influence treatment and control patients [7–9]. Regression to the mean [10,11] probably explains a large portion of 'improvement' seen in all patients who qualified for the study based on a relatively high screening score. In addition to these potential problems, Saitz [3] notes that the magnitude of improvement in outcomes reported by Madras *et al.* are unrealistic and are five times the best absolute outcomes reported for randomized controlled trials (RCTs) (e.g. 50 versus 12% for alcohol in a primary care setting). Other criticisms include possible selection bias due to inconsistent follow-up rates across projects and the lack of evidence of receipt of SBIRT services, which undermines the validity of an intent-to-treat framework.

In addition, we note several criticisms of the Madras *et al.* study that have not been described in the literature. First, the average substance use of the full program population at baseline was compared to the average substance use of a follow-up sample representing fewer than 10% of the baseline population, substantially increasing the potential for selection bias. Secondly, the statistics reported were unconditional means that did not control for potential confounding factors available in the data. Thirdly, the estimates and their statistical significance did not take into account the variation and clustering across projects, which could lead to bias and Type I errors.

This paper re-visits the Madras *et al.* analysis for two reasons. First, an analysis of the SAMHSA SBIRT grant program using all seven cohort I projects and covering the entire period of program implementation is needed to provide a full account of the initiative's outcomes. Secondly, while Madras *et al.* cannot be used as positive evidence for SBIRT's effectiveness [12,13], we attempt to address some of the criticisms of the Madras *et al.* analyses and to extend them in several key areas. Specifically, we use multi-level models on matched pre–post patients to account properly for the clustering of observations and to explore possible bias from sample selection and attrition. We reiterate that because of the pre–post design, no causal inference can be made about SBIRT from these analyses. We do, however, provide context for the pre–post changes in the 'SBIRT-treated' groups by comparing them to the pre–post results for treated groups in previous RCTs.

METHODS

Data

Data were obtained from the Services and Accountability Improvement System (SAIS), which collects data required under the Government Performance and Results Act (GPRA) for all Center for Substance Abuse Treatment (CSAT) discretionary grantees. SBIRT cohort I projects were required to collect select GPRA data from all patients receiving SBIRT services at each of their sites. Patients entering a site were eligible for screening if they were awake, medically stable, not in severe distress and not intoxicated. All patients screened by the cohort I projects between January 2004 and March 2010 were considered for our analyses. The projects submitted data on 754 525 adult patients, 171 921 of whom screened positive for hazardous or harmful use and were recommended to BI (n = 118 323), BT (n = 24 071) or RT (n = 29 527). Recommendations to these service levels were based on patients' screening scores and on the clinical discretion of the providers administering the screens.

Each individual SBIRT program developed its own SBIRT model. Models varied due to time and space constraints of the medical settings and due to providers' willingness to provide and patients' acceptance of specific SBIRT services. Evidence-based screening instruments were primarily the Alcohol Use Disorders Identification Test (AUDIT) for alcohol and Drug Abuse Screening Test (DAST) for illicit drug use, which offered tested and validated service recommendations based on patient risk. Five of the programs adopted pre-screening questions. Although the majority of SBIRT services were provided by specialists (e.g. social workers, substance abuse counselors, health educators) who were associated with the SBIRT project, pre-screening and screenings were also conducted at some sites by a combination of medical generalists (e.g. nurses) and self-administration.

For BIs, all projects used a motivational interviewing (MI) [14,15] style and all used elements of the FRAMES model [16] (Feedback regarding personal risk or impairment, emphasis on personal Responsibility for change, clear Advice to change, providing a Menu of change options, Empathy as a counseling style and enhancement of Self-efficacy or optimism). All projects incorporated MI techniques and the transtheoretical model of change [17] in their BT service. Two projects used cognitive–behavioral therapy (CBT) [18,19] and two projects used a community reinforcement approach (CRA) [20]. Projects offered both on-site and telephonic BT sessions. All projects enhanced their process of referral to specialty treatment with MI techniques, and explicit BI sessions were often provided at the time of the referral.

Within the BI, BT and RT service categories, at least a 10% sample was selected randomly for follow-up by the

© 2017 Society for the Study of Addiction

13600443, 2017, S2, Downloaded from https://onlinelibrary.wiley.com/doi/10.1111/add.13651, Wiley Online Library on [25/12/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

projects, with some projects choosing higher percentages throughout the course of their program. Randomization was based on the patient's Social Security Number (SSN) or birthdate. Follow-up interviews were conducted between 150 and 240 days after baseline screening and were administered either in person or by telephone. As noted in Madras *et al.* [1] most were by telephone because projects found it difficult to have patients return to the original site after 6 months.

Measures

The GPRA data collection tool (http://www.samhsa.gov/grants/CSAT-GPRA/services.aspx) recorded SBIRT screening results, demographic information, substance use, family and living conditions, education, employment and income, crime and criminal justice involvement, mental and physical health problems and discharge status, including SBIRT services planned. Assessment items in the instrument were based in part on the Addiction Severity Index-Lite Version [21]. Substance use questions were the days used during the past 30 days for alcohol, alcohol to intoxication ('heavy drinking days' or HDD), illicit substances and both alcohol and illicit substances on the same day. For dependent variables in our statistical analyses, we use indicator variables for at least 1 day of use of a substance in the past 30 days ('any use') and counts of days of use for each substance conditional on any use (i.e. from 1 to 30 days).

The complete GPRA data collection instrument was not administered to all patients. For patients screening negative, only the demographic section (gender, age, race/ethnicity) was completed and no follow-up interview was conducted. For those recommended to BI, only the demographic, substance use and planned services sections were completed at baseline and at follow-up (for those patients in the follow-up sample). Patients recommended to either BT or RT were administered all GPRA sections at baseline and at follow-up (for those patients in the follow-up sample). A patient and grantee identifier was also included in the GPRA data.

Design

The study design is a pre–post comparison of outcomes within an individual patient who was screened and recommended to one of the screen-positive (SP) categories. Assignment to service recommendation categories is based on screener scores and provider discretion rather than on actual service received. Therefore, the analysis is of the intent-to-treat influence of SBIRT rather than the exact services received by each patient. The number of services that they would ultimately receive is a function of patients' substance use, possible initial response to the screen or first intervention and other unobserved characteristics that might be correlated with their acceptance of services and retention. Thus, estimates of the dose–response of SBIRT services would be biased without some model or control for these confounding factors, which is beyond the scope of this study.

Data analysis

Analyses began with a comparison of the full SP sample at baseline to the sample selected for follow-up and to the sample actually completing a follow-up interview using simple descriptive statistics. Madras *et al.* [1] noted that response rates were particularly low in two projects, one due to program interruption and the other to a significant shift in the program's follow-up model. We therefore calculated alternative response rates that were adjusted based on the timing of these events. Analyses were conducted for all SP patients and by SBIRT service recommendation (BI, BT or RT).

Next, we estimated the change in substance use outcomes over time associated with SBIRT using two specifications of generalized linear mixed models (GLMM). Measures of whether or not a substance (e.g. alcohol, heavy alcohol, illicit drug) was used are discrete outcomes, and so were modeled assuming a binomial distribution and a probit link function. Measures of the number of days each type of substance was used were analysed using negative binomial models. Reflecting the repeated-measures design, we included individual random-effects in both types of models to estimate properly the sampling variance in clustered data. Clustering within each project was modeled using nested random-effects. Hausman tests were used to determine whether random-effects failed to meet the assumption of independence with respect to other covariates. When this occurred, we used fixed-effects instead and noted such in the results.

The main independent variable of interest is an indicator of whether an observation is from the 6-month follow-up interview. We controlled for gender, race and ethnicity, age, baseline educational attainment and household income. Because the data for BI patients were limited, models that included the sample of patients recommended for BI only controlled for gender, race and ethnicity and age. Analyses were conducted for all SP patients and separately by SBIRT service recommendation (BI, BT or RT).

Comparison with results from other studies

SAMSHA's SBIRT project did not include a control group, and hence effectiveness cannot be tested using project data; in our re-analysis of the data, we compare the project data to data from other studies. We used a review of 32 controlled trials of BIs targeting alcohol problems [16].

© 2017 Society for the Study of Addiction

13600443, 2017, S2, Downloaded from https://onlinelibrary.wiley.com/doi/10.1111/add.13651, Wiley Online Library on [25/12/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

We selected the studies because they involved a BI group and a control group, and each had a calculated within- and between-group effect. Although there are larger and more recent reviews of SBIRT trials, Bien *et al.* [16] was the only one that reported the within-patient changes for 'treated' patients, which are design-equivalent measures to our sample outcomes. In total, these trials examined more than 6000 problem drinkers from 14 different nations. The average time between baseline and follow-up observations was 22 months, and follow-ups occurred between 2 and 120 months after baseline, depending on the study. The between-group effects compared changes in alcohol use among patients who received BI with changes among a control group of patients. All but one of the between-group effects reported in Bien *et al.* were positive and 10 were significant.

Because many different alcohol use measures were employed in these studies, Bien *et al.* calculated standardized effect sizes (Cohen's *d*) of the changes in alcohol use measures after patients received BI. While our alcohol use measures differed from most reported in Bien *et al.*, we constructed analogous standardized effect sizes using our alcohol use measures and compared these effects with those reported by Bien *et al.*

RESULTS

Response rate analysis

This paper uses the 17 575 individuals with valid baseline and follow-up information. The overall response rate among the randomly selected SBIRT screens was 47.5%. Follow-up rates, however, varied considerably across the projects—87.6, 76.1, 73.3, 69.4, 62.2, 41.7 and 28.5%. Table 1 shows how these follow-up rates change when they are calculated only for SBIRT participants seen during periods when programs were fully functional; Madras *et al.* [1] suggest that interruptions in full functionality are a primary cause of low response rates. The response rate of the project with the second lowest response rate (41.7%) increases dramatically to 74.9% when service interruption periods are removed from the data. The lowest response rate, however, increases only marginally from 28.5 to 38% when we remove these periods from the data. Moreover, this project had almost half the total eligible patients and thus has a large influence on the overall follow-up rate. When removed from the calculation, the overall response rate is 75.1%.

Sample descriptions

Table 2 presents patient demographic and substance use information for patients used in the analyses. For each service category (all SP, BI, BT and RT), the first column presents descriptive information for all patients in that category and subsequent columns present information for the subsample of patients who have both a baseline and a follow-up observation (i.e. the matched sample). Patients screening positive for SBIRT were, on average, middle-aged (mean age = 37.5) and more likely to be male than female. SP patients were primarily white (53.4%), black (24.6%) or Hispanic (17.4%). Among those for whom educational attainment and income were recorded (BT and RT patients), approximately 60% were high school graduates. As a whole, BT patients reported $1648 in total monthly household income, and RT patients reported $1514. Males reported higher monthly income than females ($324, $P < 0.01$). Patients with both a baseline and a follow-up observation (hereafter the matched sample) reported lower income than the full baseline samples.

Substance use measures are presented for all SP patients and separately for the three intervention categories in Table 2. The most common type of substance reported at baseline was alcohol (71.1%). Illicit drug use was reported less commonly than alcohol, but was still highly prevalent (40.0% of all positive screens). Fewer than one-third of all screens were dual substance users (alcohol and illicit drugs). Heavy drinking was moderately higher among RT patients (66.2%) than among BT (50.0%) or BI patients (47.5%). Illicit drug use was more common among BT (57.6%) than BI (33.8%) or RT patients (51.1%). Conditional days of use also varied by substance and SBIRT intervention. RT patients reported the most days of use for all outcomes. RT patients also used alcohol, had a heavy drinking day or used illicit drugs on more than half of the past 30 days (17.4, 17.6 and 15.7 days, respectively). BI patients reported the fewest conditional days of use for all substance categories.

Table 2 also indicates where baseline differences between the matched sample (i.e. those with both a baseline and a follow-up observation) and the remainder of patients (i.e. those who were either not selected for a follow-up interview or those that were selected but did not complete a follow-up interview) are statistically significant based on simple *t*- and χ^2 tests. This comparison demonstrates how representative is the analysis sample of matched patients is of the project as a whole. Many of the demographic characteristics of the matched sample are significantly different from those patients not in the matched sample, suggesting an obvious need to control for these characteristics in any analyses of outcomes. Of greater interest, however, are statistically significant baseline differences for more than half of the substance use behaviors, which could indicate selection bias. We see that in most cases the matched sample variables had similar values to the remainder sample (e.g. 71.1 versus 71.5 for the percentage with any alcohol use). This suggests that the *t*- and χ^2 tests may be overly sensitive due to the large sample sizes and their failure to correct for clustering of observations within clinical sites and projects.

© 2017 Society for the Study of Addiction

13600443, 2017, S2, Downloaded from https://onlinelibrary.wiley.com/doi/10.1111/add.13651, Wiley Online Library on [25/12/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

Table 1 Baseline eligibility and response rates by project.

	Screen positive					*Brief intervention*					*Brief treatment*					*Referral to treatment*				
	Eligible at BL		*Completed FU*			*Eligible at BL*		*Completed FU*			*Eligible at BL*		*Completed FU*			*Eligible at BL*		*Completed FU*		
Project	*Raw*	*adj.*	#	%		*Raw*	*adj.*	#	%		*Raw*	*adj.*	#	%		*Raw*	*adj.*	#	%	
5	2507		1907	76.1		1124		878	78.1		363		270	74.4		1020		759	74.4	
6	17 546	13 179	5007	28.5	38.0	12 035	8866	3630	30.2	40.9	2803	2084	596	21.3	28.6	2708	2229	781	28.8	35.0
7	2133		1868	87.6		1192		1044	87.6		343		293	85.4		598		531	88.8	
8	2465		1710	69.4		1744		1293	74.1		564		318	56.4		157		99	63.1	
9	238		148	62.2		136		91	66.9		40		27	67.5		62		30	48.4	
10	6091	3393	2542	41.7	74.9	3926	2116	1728	44.0	81.7	754	571	362	48.0	63.4	1411	706	452	32.0	64.0
11	5990		4393	73.3		3551		2651	74.7		979		730	74.6		1460		1012	69.3	
All Projects	36 970	29 905	17 575	47.5	58.8	23 708	18 729	11 315	47.7	60.4	5846	4944	2596	44.4	52.5	7416	6232	3664	49.4	58.8

BL = baseline; FU = follow-up.

© 2017 Society for the Study of Addiction

13600443, 2017, S2, Downloaded from https://onlinelibrary.wiley.com/doi/10.1111/add.13651, Wiley Online Library on [25/12/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

Table 2 Characteristics and substance use of screen positive patients: full and matched samples.

		Screen positive			*Brief intervention*			*Brief treatment*			*Referral to treatment*		
		Matched sample			*Matched sample*			*Matched sample*			*Matched sample*		
		All	*BL*	*FU*	*All*	*BL*	*FU*	*All*	*BL*	*FU*	*All*	*BL*	*FU*
n		171 921	17 575		118 323	11 315		24 071	2596		29 527	3664	
Age (years)		38.1	37.5***		37.7	36.9		37.7	37.3		40.1	39.6**	
		(0.03)	(0.10)		(0.04)	(0.14)		(0.08)	(0.25)		(0.07)	(0.19)	
Female		0.360	0.383***		0.377	0.396***		0.332	0.376***		0.313	0.349*	
		(0.00)	(0.00)		(0.00)	(0.00)		(0.00)	(0.01)		(0.00)	(0.01)	
Black		0.246	0.200***		0.238	0.187**		0.267	0.205		0.261	0.237***	
		(0.00)	(0.00)		(0.00)	(0.00)		(0.00)	(0.01)		(0.00)	(0.01)	
Hispanic		0.174	0.209***		0.188	0.231***		0.171	0.200***		0.116	0.144***	
		(0.00)	(0.00)		(0.00)	(0.00)		(0.00)	(0.01)		(0.00)	(0.01)	
Other		0.029	0.028**		0.033	0.029		0.023	0.028**		0.018	0.023***	
		(0.00)	(0.00)		(0.00)	(0.00)		(0.00)	(0.00)		(0.00)	(0.00)	
High school degree		0.604	0.605					0.602	0.612		0.606	0.600	
		(0.00)	(0.01)					(0.00)	(0.01)		(0.00)	(0.01)	
Income		214.6	237.9					738.9	782.5		664.8	586.5	
		(8.3)	(9.8)					(47.8)	(48.9)		(28.5)	(29.8)	
Alcohol	Any	0.711	0.715***	0.516	0.708	0.714***	0.543	0.662	0.688	0.478	0.762	0.739*	0.462
		(0.00)	(0.00)	(0.00)	(0.00)	(0.00)	(0.00)	(0.00)	(0.01)	(0.01)	(0.00)	(0.01)	(0.01)
	Days	11.6	10.9	8.3	9.7	9.0	7.6	12.5	11.4	8.5	18.5	16.3***	10.7
		(0.03)	(0.09)	(0.09)	(0.03)	(0.10)	(0.10)	(0.08)	(0.24)	(0.24)	(0.07)	(0.21)	(0.24)
Heavy drinking	Any	0.510	0.536***	0.352	0.475	0.502***	0.347	0.500	0.540	0.354	0.662	0.637	0.369
		(0.00)	(0.00)	(0.00)	(0.00)	(0.00)	(0.00)	(0.00)	(0.01)	(0.01)	(0.00)	(0.01)	(0.01)
	Days	10.4	9.6***	7.0	7.4	6.7***	5.9	11.5	10.3	7.7	18.5	16.3	9.9
		(0.04)	(0.10)	(0.10)	(0.04)	(0.11)	(0.11)	(0.10)	(0.26)	(0.26)	(0.08)	(0.24)	(0.27)
Illicit drugs	Any	0.400	0.389*	0.191	0.338	0.327***	0.168	0.576	0.518***	0.239	0.511	0.487	0.227
		(0.00)	(0.00)	(0.00)	(0.00)	(0.00)	(0.00)	(0.00)	(0.01)	(0.01)	(0.00)	(0.01)	(0.01)
	Days	12.9	12.8	11.9	10.8	10.9	11.3	14.7	13.9	12.2	16.8	16.0***	13.0
		(0.04)	(0.14)	(0.19)	(0.05)	(0.18)	(0.25)	(0.10)	(0.31)	(0.45)	(0.10)	(0.27)	(0.39)
Both on same day	Any	0.280	0.284***	0.140	0.233	0.231***	0.122	0.381	0.374	0.174	0.390	0.383***	0.170
		(0.00)	(0.00)**	(0.00)	(0.00)	(0.00)	(0.00)	(0.00)	(0.01)	(0.01)	(0.00)	(0.01)	(0.01)
	Days	7.5	7.4	6.4	5.5	5.0	5.9	7.4	6.9	5.9	10.9	10.4***	7.5
		(0.05)	(0.15)	(0.18)	(0.05)	(0.17)	(0.23)	(0.10)	(0.32)	(0.40)	(0.11)	(0.30)	(0.38)

BL = baseline; FU = follow-up. Standard errors in parentheses. Income is monthly household income. 'Both' refers to the use of alcohol and drugs on the same day. *t*-Tests and χ^2 tests of baseline values were used to compare matched subsample to the remainder of the sample (***$P < 0.01$; **$P < 0.05$; *$P < 0.1$).

© 2017 Society for the Study of Addiction

13600443, 2017, S2, Downloaded from https://onlinelibrary.wiley.com/doi/10.1111/add.13651, Wiley Online Library on [25/12/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

Analysis of changes in substance use is reserved for the Main outcomes section (below). We note here that prevalence of use is lower at follow-up. Conditional days of use also decrease, with two exceptions: among the BI group, days of illicit drug use and days of combined illicit drug/alcohol use increase, conditional on use.

Main outcomes

Table 3 shows changes in the model-adjusted means for substance use measures. The difference between these is the estimated change in each outcome. Changes for most substance use measures were statistically significant at the $P < 0.01$ level, so we specify significance only when this is not the case. The probability of using any alcoholin the past 30 days decreased by 0.296 (35.6 %) for all SP patients, from 0.827 to 0.532. Among those patients who did drink alcohol, they drank 1.8 fewer days at follow-up. The proportion of BI patients who drank alcohol decreased the least (0.263) of the three SBIRT groups, despite starting at a similar prevalence. Similarly, BIs only decreased conditional days of drinking by 1.0, compared with 2.2 for BT patients and 4.7 for RT patients. The proportion of patients reporting heavy drinking dropped by 0.245 (43.4%) for all SP patients, with RT patients reporting the largest decrease (0.371). RT patients also had the largest decrease in conditional days of heavy drinking, dropping from 14.9 to 9.8 days on average.

The prevalence of illicit drug use dropped by half or more for each service modality and 75.8% for SP patients as a group. Days of illicit drug use dropped by 2.1 for BT and 2.9 for RT patients. However, BI patients who continued to use illicit drugs used them for the same number of days as those who used at baseline. The proportion of patients with at least 1 day of consuming both alcohol and drugs also fell by approximately half. However, the conditional number of days of consuming both increased slightly for BI patients and decreased 0.6 days for BT patients ($P < 0.1$).

Moderator analyses

Two sets of moderator analyses were examined. First, we estimated all outcome models separately for males and females. Secondly, for a subsample of the data for which we had information on clinical setting (e.g. ED versus in-patient), we interacted indicators for clinical setting with the post-SBIRT indicator to assess differential effects by setting.

When estimated for males and females separately, changes in substance use outcomes were similar in magnitude and statistical significance to most pooled estimates. Female patients recommended to BI exhibited the most substance use outcomes that were statistically significantly different from males. Decreases in conditional days of

Table 3 Model adjusted changes in substance use outcomes by SBIRT category.

		Screen positive			*Brief intervention*			*Brief treatment*			*Referral to treatment*		
		BL	*FU*	*Δ*	*BL*	*FU*	*Δ*	*BL*	*FU*	*Δ*	*BL*	*FU*	*Δ*
Alcohol	Any	0.827	0.532	0.296	0.839	0.576	0.263	0.782	0.469	0.313	0.825	0.454	0.371
	Days	10.7	8.0	2.7	8.8	7.1	1.7	11.2	8.1	3.1	16.0	10.4	5.6
Heavy drinking	Any	0.560	0.315	0.245	0.519	0.312	0.207	0.567	0.301	0.266	0.686	0.336	0.350
	Days	9.7	7.1	2.6	6.9	5.9	1.0	10.4	7.7	2.7	16.0	9.9	6.1
Illicit drugs	Any	0.343	0.079	0.264	0.244	0.051	0.193	0.539	0.146	0.393	0.495	0.141	0.354
	Days	12.3	10.6	1.7	10.3	9.6	0.7	13.4	11.0	2.4	14.9	11.4	3.5
Alcohol and illicit drugs	Any	0.207	0.050	0.157	0.134	0.031	0.103	0.332	0.086	0.246	0.354	0.101	0.254
	Days	7.3	6.3	1.0	4.7	5.5	−0.8	6.7	5.6	1.2	10.1	7.1	3.0

BL = baseline; FU = follow-up. All estimates for measures of any recent use are from probit models with individual random-effects and site fixed-effects. Estimates for measures of days of use are from general linear mixed models with individual random-effects and site fixed-effects. Recent use includes any use within the past 30 days. Number of days of using a given substance is conditional on using that substance on at least 1 day. Heavy drinking is defined as becoming intoxicated from five or more alcoholic drinks. Conditional measures only include observations where outcome occurred at least once. All differences were significant at 0.01 level unless specified. $^{**}P < 0.05$; $^{*}P < 0.1$; NS = not significant; SBIRT = Screening, Brief Intervention and Referral to Treatment.

© 2017 Society for the Study of Addiction

13600443, 2017, S2, Downloaded from https://onlinelibrary.wiley.com/doi/10.1111/add.13651, Wiley Online Library on [25/12/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

drinking and heavy drinking were smaller among females, with males seeing almost a half day more reduction ($P < 0.05$). Females who continued to use drugs increased their conditional days of use. Although not statistically significant, female BT and RT patients reported a greater decrease in any heavy drinking and any illicit drug use than men.

To analyse the role of health-care setting, we requested data from each project that contained setting identifiers. These data represent a subsample of the data described previously with the addition of a set of setting indicators. Six of the projects provided data on patients screened between October 2005 and February 2008 that included identifiers for clinical setting. The remaining project provided data covering October to December 2005 and June 2007 to February 2008. Altogether, the total number of patients screened during these periods was 336 832. Of those, 81 538 screened positive for hazardous or harmful use and were recommended to BI (n = 52 531), BT (n = 13 149) or RT (n = 15 858).

Because models examining the role of clinical setting were estimated using a subset of the overall data, we first note that the magnitude and statistical significance of changes on substance use behaviors are, for the most part, similar to the results presented earlier. Overall, changes in prevalence of substance use differed little by the setting in which patients were screened, particularly between outpatient (OP) and emergency departments (ED) patients. For example, the largest statistically significant difference between OP and ED patient outcomes was the proportion of any heavy drinking among BI patients: ED patients decreased by 0.114 versus 0.159 for OP patients. The most striking differences across settings were for any heavy drinking and illicit drug use among IP patients. The decreases in any heavy drinking among OP and ED patients were not realized by IP patients, for whom there was either no decrease (BI) or a much smaller magnitude of decrease (BT and RT). In contrast, IP patients saw a greater decrease in any illicit drug use than OP or ED patients (−0.367 versus −0.221 and −0.241, respectively).

Comparisons with results from other SBI studies

To place our estimates in context, we compared standardized effect sizes from our analysis to those presented in the literature. Standardized effect sizes from 14 of the studies reviewed by Bien *et al.* [16] are given in Table 4 [22–35]. The within-group effects are described by the baseline to follow-up changes in alcohol use among patients receiving BI, and are thus similar in design to the standardized effect sizes from our analysis also given in Table 4. The standardized effect sizes for all of our alcohol measures, across all SBIRT service groups, fall within the range of statistically significant effect sizes calculated by Bien *et al.* [16]. In particular, BI patients are the group that is most comparable with the studies in Bien *et al.*'s review. Our effect size of 0.72 for any drinking is larger than those of five studies that found statistical significance when BI was compared to a control group: Babor & Grant [22], Heather *et al.* [23,27,29] and Daniels *et al.* [26]. Finally, effect sizes for the studies for which pre–post changes in control-group outcomes were available, were consistently lower than SAMHSA's effect sizes.

DISCUSSION

SAMHSA's SBIRT grant program is the largest SBIRT dissemination effort ever undertaken in the United States, yet the only published multi-site study of patient outcomes for this initiative is Madras *et al.* [1], which has been cited widely as evidence of SBIRT's effectiveness, despite critical evaluations by several commentators [2–4] who have noted several limitations of the Madras *et al.* [1] findings that limit their utility. In this paper, we re-visit the Madras *et al.* in an attempt to address these limitations. Using data from all seven projects in the first cohort of SAMHSA SBIRT grants, we examined response rates and sample selection concerns carefully, used more appropriate statistical methodology and explored potential moderators of the correlation between SBIRT services and substance use outcomes.

The findings from our study provide evidence, albeit imperfect, in support of SAMHSA's SBIRT being associated with changes in patient outcomes consistent with earlier, rigorous SBIRT trials. Significant improvements in substance use outcomes were demonstrated by changes in simple means and model-adjusted means. We conclude that SBIRT was associated with improvement in patient outcomes, but with several caveats. First, no data on comparison groups were available for our analyses. In an effort to address this issue, we calculated standardized effect sizes for different alcohol use measures in our data and compared them to those from the controlled trials summarized by Bien *et al.* [16]. We found that our estimated changes were similar to the within-group effects of several clinical trials, suggesting that the changes observed among SBIRT services recipients are consistent with the clinical trial literature.

Next, we did not observe the delivery of SBIRT services to the patients in our sample. This is a concern, because some patients might not have actually received services so that the changes we observed might have been due to factors other than SBIRT. A related concern is that because we did not observe the screening score or other screening factors, we do not know the true severity of substance use risk among our sample of patients. More importantly, we note that we were unable to validate the accuracy of self-reported substance use. At baseline, the use of screening instruments with strong psychometric properties

© 2017 Society for the Study of Addiction

13600443, 2017, S2, Downloaded from https://onlinelibrary.wiley.com/doi/10.1111/add.13651, Wiley Online Library on [25/12/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

Table 4 Standardized effects sizes of brief intervention on changes in alcohol measures (Bien *et al.* [16]).

		Effect sizes		
Study	*Measure*	*Within intervention*	*Withincontrol*	*Between*
Babor & Grant [15]	Typical daily alcohol consumption	0.17	0.06	0.32[a]
Heather *et al.* [16]	Last month alcohol consumption	0.29	0.16	0.35[a]
Miller *et al.* [17]	Weekly alcohol consumption	0.33	0.25	-0.03[a]
Kristenson *et al.* [18]	Decreases in GGT levels	0.44[a]	–	0.1
Daniels *et al.* [19]	Alcohol consumption/problem score	0.47	–	0.25[a]
Heather *et al.* [20]	Last week alcohol consumption	0.53	–	0.27[a]
Wallace *et al.* [21]	Weekly alcohol consumption	0.63[a]	0.31	0.35
Heather *et al.* [22]	Avg. alcohol consumption	0.65	–	0.34[a]
Miller *et al.* [23]	Weekly alcohol consumption	0.7	–	0.64
Chick *et al.* [24]	Last week alcohol consumption	0.87	0.75	0.07[a]
Maheswaran *et al.* [25]	Alcohol consumption	1.11	0.21	1.04[a]
Scott & Anderson [27]	Weekly alcohol consumption	1.16	–	0.03[a]
Harris & Miller [28]	Weekly alcohol consumption	1.18[a]	0.82	0.64
Anderson & Scott [26]	Weekly alcohol consumption	1.35	0.50	0.42[a]
SAMHSA's SBIRT	Past 30 days alcohol measure			
Brief intervention	Any alcohol use	0.72[a]		–
	No. of days of alcohol use	0.38[a]		–
	Any heavy drinking days	0.52[a]		–
	No. of heavy drinking days	0.25[a]		–
Brief treatment	Any alcohol use	0.68[a]		–
	No. of days of alcohol use	0.77[a]		–
	Any heavy drinking days	0.53[a]		–
	No. of heavy drinking days	0.61[a]		–
Referral to treatment	Any alcohol use	0.85[a]		–
	No. of days of alcohol use	0.97[a]		–
	Any heavy drinking days	0.73[a]		–
	No. of heavy drinking days	0.87[a]		–

All within-group effect sizes are computed as (intake mean – follow-up mean)/weighted pooled standard deviation. All between-group effect sizes are computed as (control follow-up mean – brief intervention follow-up mean)/weighted pooled standard deviation. [a]Effect sizes represent significant differences at the 0.05 level. GGT = gamma glutamyl transpeptidase; BIRT = Screening, Brief Intervention and Referral to Treatment; SAMHSA = Substance Abuse and Mental Health Services Administration.

provides some confidence that baseline substance use was reported accurately. However, at follow-up, the interview only collected the raw substance use quantities, via a different mode of data collection. Social acceptability bias, a lack of rapport with the interviewer, differential recall bias under the different modes and a desire to complete the interview more quickly, among other factors, could all influence (probably suppressing) the reported use. These challenges again highlight the vital need for comparison groups.

Finally, our samples are not perfectly representative of the entire SAMHSA initiative. Because of disruptions in several projects, there is a group of patients who received services but who are excluded from our analysis because their outcome data were not collected. More problematic is the follow-up response rate that varies by project. Patients who do not respond at follow-up may be systematically different from responders. Such differences may, in turn, be associated with a poor response to SBIRT services and with worse outcomes. However, we note that, after adjusting for project disruptions, one project in particular, number 6, is responsible for the low overall response rate. In analyses not reported here, we re-estimated our outcome models by project and compared the results of project 6 with those of the other six. We found that the estimated pre–post change for project 6 was never an outlier with respect to those of the other six projects. Specifically, for each outcome, the project 6 estimate was always lower than the project with the highest estimate and higher than the project with the lowest estimate.

Despite these important caveats, our findings provide value to ongoing assessment of SAMHSA's SBIRT initiative and to the broader SBIRT research community. Large public health programs such as SBIRT are constrained in their ability to conduct rigorous research by the practicalities of implementation, human subjects protections and resources. Evaluating the effectiveness of evidence-based SBIRT services is a complex and ongoing project that requires further randomized controlled trials. A variety of research must be completed and be maintained over time to conclude that SBIRT is having its potential impact. Two recent RCTs highlight the complexity of the science

© 2017 Society for the Study of Addiction

13600443, 2017, S2, Downloaded from https://onlinelibrary.wiley.com/doi/10.1111/add.13651, Wiley Online Library on [25/12/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

around SBIRT. Saitz *et al.* [36] tested the efficacy of a brief negotiated intervention for any illicit drug use or prescription drug misuse versus no BI, and found no effect. Roy-Byrne *et al.* [37] found no effect of a BI plus telephone booster for drug use. These two studies emphasize the need for deliberate, targeted use of SBIRT public health rather than as a panacea. Other research needs range from fidelity and quality studies of SBIRT to subgroup studies with a comparison group design to time–series assessment of population level outcomes. For such research to accrue, SBIRT would need to continue as a provided service. While we cannot claim that SBIRT caused improvements in patient outcomes, our results support proceeding with its service provision and further more rigorous study.

Declaration of interests

None.

References

1. Madras B. K., Compton W. M., Avula D., Stegbauer T., Stein J. B., Clark H. W. Screening, brief interventions, referral to treatment (SBIRT) for illicit drug and alcohol use at multiple healthcare sites: comparison at intake and 6 months later. *Drug Alcohol Depend* 2009; **99**: 280–95.
2. Bernstein E., Bernstein J. A., Stein J. B., Saitz R. SBIRT in emergency care settings: are we ready to take it to scale? *Acad Emerg Med* 2009; **16**: 1072–7.
3. Saitz R. Candidate performance measures for screening for, assessing, and treating unhealthy substance use in hospitals: advocacy or evidence-based practice? *Ann Intern Med* 2010; **153**: 40–3.
4. Saitz R., Alford D. P., Bernstein J., Cheng D. M., Samet J., Palfai T. Screening and brief intervention for unhealthy drug use in primary care settings: randomized clinical trials are needed. *J Addict Med* 2010; **4**: 123–30.
5. Kypri K., Langley J. D., Saunders J. B., Cashell-Smith M. L. Assessment may conceal therapeutic benefit: findings from a randomized controlled trial for hazardous drinking. *Addiction* 2007; **102**: 62–70.
6. Walters S. T., Vader A. M., Harris T. R., Field C. A., Jouriles E. N. Dismantling motivational interviewing and feedback for college drinkers: a randomized clinical trial. *J Consult Clin Psychol* 2009; **77**: 64–73.
7. Rosenthal R., Rosnow R. L. *Essentials of Behavioral Research: Methods and Data Analysis*. New York, NY: McGraw-Hill Book Company; 1984.
8. Makäla K. Ethical control of social research. *Nordic Stud Alcohol Drugs* 2006; **25**: 5–19.
9. Babor T. F. Research ethics: when the tail wags the dog. *Nord Stud Alcohol Drugs [English Suppl]* 2006; **23**: 23–4.
10. Cook T. D., Campbell D. T. *Quasi-Experimentation. Design and Analysis Issues for Field Settings*. Boston: Houghton Mifflin Company; 1979.
11. Bertholet N., Daeppen J.-B., Wietlisbach V., Fleming M., Burnand B. Reduction of alcohol consumption by brief alcohol intervention in primary care: systematic review and meta-analysis. *Arch Intern Med* 2005; **165**: 986–95.
12. McLellan A. T., Turner B. J. Chronic noncancer pain management and opioid overdose: time to change prescribing practices. *Ann Intern Med* 2010; **152**: 123–4.
13. Marlatt G. A., Witkiewitz K. Update on harm-reduction policy and intervention research. *Annu Rev Clin Psychol* 2010; **6**: 591–606.
14. Miller W. R. Motivational interviewing with problem drinkers. *Behav Psychother* 1983; **11**: 147–72.
15. Miller W. R., Rollnick S. *Motivational Interviewing: Preparing People to Change Addictive Behavior*. New York, NY: Guilford Press; 1991.
16. Bien T. H., Miller W. R., Tonigan J. S. Brief interventions for alcohol problems: a review. *Addiction* 1993; **88**: 315–35.
17. Prochaska J. O., DiClemente C. C. Toward a comprehensive model of change. In: Miller W. R., Heather N., editors. *Treating Addictive Behaviors: Processes of Change*. New York: Plenum Press; 1986, pp. 3–27.
18. Carroll K. M. A Cognitive Behavioral Approach: Treating Cocaine Addiction. In: *National Institute on Drug Abuse Therapy Manuals for Drug Addiction, Manual 1*. Rockville, MD: National Institutes of Health; 1998. Publication No. 98-4308
19. Sampl S., Kadden R. *Motivational Enhancement Therapy and Cognitive Behavioral Therapy for Adolescent Cannabis Users: 5 Sessions, Cannabis Youth Treatment (CYT) Series*, Vol. **1**. Rockville, MD: Center for Substance Abuse Treatment (CSAT), Substance Abuse and Mental Health Services Administration (SAMHSA); 2001.
20. Smith J. E., Meyers R. J. The treatment. In: Meyers R., Miller W., editors. *A Community Reinforcement Approach to the Treatment of Addiction*. Cambridge, UK: University Press; 2001, pp. 28–62.
21. McLellan A. T., Cacciola J. S., Zanis D. *The Addiction Severity Index-'Lite'(ASI-'Lite'): Center for the Studies of Addiction*. Philadelphia, PA: University of Pennsylvania/Philadelphia VA Medical Center; 1997.
22. Babor T. F., Grant M., editors. *Project on Identification and Management of Alcohol-Related Problems. Report on Phase II: A Randomized Clinical Trial of Brief Interventions in Primary Health Care*. Geneva, Switzerland: World Health Organization; 1992.
23. Heather N., Campion P. D., Neville R. G., Maccabe D. Evaluation of a controlled drinking minimal intervention for problem drinkers in general practice (the DRAMS scheme). *J R Coll Gen Pract* 1987; **37**: 358–63.
24. Miller W. R., Sovereign R. G., Krege B. Motivational interviewing with problem drinkers: II. The Drinker's Checkup as a preventive intervention. *Behav Psychother* 1988; **16**: 251–68.
25. Kristenson H., Ohlin H., Hulten-Nosslin M. B., Trell E., Hood B. Identification and intervention of heavy drinking in middle-aged men: results and follow-up of 24–60 months of long-term study with randomized controls. *Alcohol Clin Exp Res* 1983; **7**: 203–9.
26. Daniels V., Somers M., Orford J., Kirby B. How can risk drinking amongst medical patients be modified? The effects of computer screening and advice and a self-help manual. *Behav Psychother* 1992; **20**: 47–60.
27. Heather N., Whitton B., Robertson I. Evaluation of a self-help manual for media-recruited problem drinkers: six-month follow-up results. *Br J Clin Psychol* 1986; **25**: 19–34.
28. Wallace P., Cutler S., Haines A. Randomised controlled trial of general practitioner intervention in patients with excessive alcohol consumption. *BMJ* 1988; **297**: 663–8.

© 2017 Society for the Study of Addiction

13600443, 2017, S2, Downloaded from https://onlinelibrary.wiley.com/doi/10.1111/add.13651, Wiley Online Library on [25/12/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

29. Heather N., Kissoon-Singh J., Fenton G. W. Assisted natural recovery from alcohol problems: effects of a self-help manual with and without supplementary telephone contact. *Br J Addict* 1990; **85**: 1177–85.
30. Miller W. R., Benefield R. G., Tonigan J. S. Enhancing motivation for change in problem drinking: a controlled comparison of two therapist styles. *J Consult Clin Psychol* 1993; **61**: 455–61.
31. Chick J., Lloyd G., Crombie E. Counselling problem drinkers in medical wards: a controlled study. *BMJ (Clin Res Ed)* 1985; **290**: 965–7.
32. Maheswaran R., Beevers M., Beevers D. G. Effectiveness of advice to reduce alcohol consumption in hypertensive patients. *Hypertension* 1992; **19**: 79–84.
33. Anderson P., Scott E. The effect of general practitioners' advice to heavy drinking men. *Br J Addict* 1992; **87**: 891–900.
34. Scott E., Anderson P. Randomized controlled trial of general practitioner intervention in women with excessive alcohol consumption. *Drug Alcohol Rev* 1990; **10**: 313–21.
35. Harris K. B., Miller W. R. Behavioral self-control training for problem drinkers: components of efficacy. *Psychol Addict Behav* 1990; **4**: 82–90.
36. Saitz R., Palfai T. P., Cheng D. M., Alford D. P., Bernstein J. A., Lloyd-Travaglini C. A. *et al.* Screening and brief intervention for drug use in primary care: the ASPIRE randomized clinical trial. *JAMA* 2014; **312**: 502–13.
37. Roy-Byrne P., Bumgardner K., Krupski A., Dunn C., Ries R., Donovan D. *et al.* Brief intervention for problem drug use in safety-net primary care settings: a randomized clinical trial. *JAMA* 2014; **312**: 492–501.

© 2017 Society for the Study of Addiction

13600443, 2017, S2, Downloaded from https://onlinelibrary.wiley.com/doi/10.1111/add.13651, Wiley Online Library on [25/12/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

https://www.chess.health/blog/how-to-improve-sbirt-to-address-substance-use-disorder/

How to Improve SBIRT to Address Substance Use Disorder

January 30, 2023

SBIRT (screening, brief intervention, and referral to treatment) is an evidence-based tool to help address the crisis of substance use disorder (SUD).

SBIRT programs have helped medical professionals, social workers, counselors, and community leaders:

- Identify individuals at risk of developing SUD or those with problematic use of substances
- Intervene early in cases of problematic substance use
- Refer them to proper treatment

Given recent study findings from SAMHSA (the U.S. Substance Abuse and Mental Health Services Administration) that 94% of people with a diagnosable SUD did not receive treatment in 2021, identifying and referring people to treatment is more important than ever.

SBIRT is effective against SUD

A five-year study of one million people screened for drug and alcohol found SBIRT effective in reducing alcohol misuse among the participants. The study, conducted by SAMHSA, is one of the most successful examples of how research in the field of addiction science translated to on-ground reality.

Additionally, there is a growing body of evidence that SBIRT can be helpful for risky drug use. Because of this, public health agencies and medical professionals are looking to expand programs across the country.

Leading challenges with SBIRT

SBIRT is an evidence-based way to help tackle the high rates of SUD in the country. However, there are roadblocks to expanding access to more people.

Reasons include:

- **Reluctance to get screened; no option to stay anonymous**.
- In many instances, physicians do not believe that patients are honest about their substance use. There is a stigma associated with substance abuse. As a result, some individuals may resist getting screened.
- Many people with SUD may be uncomfortable during in-person visits because there is no option to stay anonymous. Others may be intimidated in clinical settings when speaking with a physician or another medical professional.

- Additionally, people may be more reluctant to tell the truth if there are legal or criminal consequences. For example, if they indulge in unauthorized opioid use, drive when drunk, potentially endanger a child or other such instances.
- Marginalized communities like the LGBTQ+, recent immigrants, tribal communities, or people who are suspicious of the medical community may also be reluctant to disclose their use of substances.
- **Limited resources to train more people approved to administer SBIRT.** SBIRT is a staged, multi-faceted process that needs trained individuals to screen their communities. Plus, truly effective training involves repetition, constructive feedback loops, and continuous monitoring. Unfortunately, many communities have few resources to train others. Qualified individuals may be too busy with their own practice to teach others.
- **Inconsistent data collection and reporting.** In this digital age, having valuable grassroots-level data for communities can help healthcare providers improve their local SBIRT initiatives. This type of analytics can help guide research, funding, on-ground effectiveness, and reporting. But if data collection is inconsistent and inefficient, it is hard to improve overall effectiveness.
- **Financial challenges.** As a good start, Medicare covers SBIRT. However, SBIRT is not covered under all insurance and Medicaid programs. Expanded insurance and Medicaid coverage can help as states continue to work on tackling the rising SUD rates in their regions. More funding will go a long way toward easing the financial burden, raising awareness, and expanding the reach of SBIRT.

How can we improve SBIRT programs in the United States?

- **Expand SBIRT screening tools at a grassroots level.** Until now, SBIRT has been more focused on medical settings. However, better community outreach is needed. Let's look at an example. The state of New York was recently awarded a five-year SBIRT grant from SAMHSA to implement community outreach models for marginalized populations.
- **Improve access to best practices.** More than 16 states have implemented formalized programs. SBIRT is research-based and has proven effectiveness against SUD. It helps the healthcare system save $3.81 to $5.60 for each $1 spent. It is also strongly supported by the Federal Government (SAMHSA) and Medicare.
- **Select evidence-based screening tools**. The National Institute on Drug Abuse offers a wide range of approved and validated evidence-based screening tools for SBIRT.
- **Introduce digital options for self-reporting.** The mode of administration for screening can make a difference. Instruments that allow people to self-report can perform well. This way, they get the option to stay anonymous and seek help. Additionally, approved assessment tools like the AUDIT-C can be more effective when administered electronically versus through a paper-based form.
- **Enhance the 'brief intervention' stage.** With more funding and awareness, the brief intervention stage can be more than telling people with SUD, "drink less" or "don't do drugs." Ideally, SBIRT needs more than one consultation and involves client-centric discussions without judgment or bias. Improving this part of SBIRT requires more skilled

professionals, but there is a huge resource gap. Only 15 of the 180 American medical programs teach addiction.

- **Remove barriers to finding appropriate treatment and refer patients accordingly.** Unfortunately, it can be highly complicated for individuals to find the right treatment for their SUD. The reasons why are multifaceted, but many issues rest on a lack of substantial quantitative information about treatment capacity, resources, and effective methods. Providers and states can benefit the most when they can consistently monitor how many screenings and brief interventions lead to inpatient and outpatient treatment.

A comprehensive, integrated approach to addiction and substance use disorder screening, intervention, and treatment is the best way forward. CHESS Health can help.

CHESS Health offers an evidence-based digital platform to support better SBIRT. Learn more about how CHESS Health can help improve your SBIRT program.

F

NIH Public Access
Author Manuscript
J Psychoactive Drugs. Author manuscript; available in PMC 2013 October 21.

Published in final edited form as:
J Psychoactive Drugs. 2012 ; 44(4): 307–317.

Integrating Screening, Brief Intervention, and Referral to Treatment (SBIRT) into Clinical Practice Settings: A Brief Review

Suneel M. Agerwala, B.A.[a] and **Elinore F. McCance-Katz, M.D., Ph.D.**[b]

[a]Research Analyst, University of California, San Francisco, Addiction Medicine Research, Department of Psychiatry, San Francisco, CA.

[b]Professor in Residence, University of California, San Francisco, Addiction Medicine Research, Department of Psychiatry, San Francisco, CA.

Abstract

Screening, brief intervention, and referral to treatment (SBIRT) is a public health approach to the delivery of early intervention and treatment services for individuals at risk of developing substance use disorders (SUDs) and those who have already developed these disorders. SBIRT can be flexibly applied; therefore, it can be delivered in many clinical care settings. SBIRT has been adapted for use in hospital emergency settings, primary care centers, office- and clinic-based practices, and other community settings, providing opportunities for early intervention with at-risk substance users before more severe consequences occur. In addition, SBIRT interventions can include the provision of brief treatment for those with less severe SUDs and referrals to specialized substance abuse treatment programs for those with more severe SUDs. Screening large numbers of individuals presents an opportunity to engage those who are in need of treatment. However, additional research is needed to determine how best to implement SBIRT.

Keywords

brief intervention; referral to treatment; SBIRT; screening; substance use disorders

Screening, brief intervention, and referral to treatment (SBIRT) is a public health approach to the delivery of early intervention and treatment services for individuals at risk of developing substance use disorders (SUDs) as well as those who have already developed these disorders. SBIRT is an intervention that can be flexibly applied, so it can be delivered in many clinical care settings. SBIRT has been adapted for use in hospital emergency settings, primary care centers, office- and clinic-based practices, and other community settings, providing opportunities for early intervention with at-risk substance users before more severe consequences occur. In addition, SBIRT interventions can include the provision of brief treatment for those with less severe SUDs or referrals to specialized substance abuse treatment programs for those with higher severity disorders.

The current model of SBIRT is based on the Institute of Medicine (IOM 1990) report, *Broadening the Base of Treatment for Alcohol Problems*. The IOM recommended the development of integrated service systems that link community-based screening and brief intervention to assessment and referral activities. This type of intervention fills the gap between primary prevention and more intensive treatment for those with SUDs. The main goal for SBIRT is to improve community health by reducing the prevalence of adverse

Please address correspondence to Suneel M. Agerwala, San Francisco General Hospital, 1001 Potrero Ave, Suite 7M, Ward 95, San Francisco, CA 94110; phone: 845-893-9171, fax: 415-206-5569, suneel@gmail.com.

NIH-PA Author Manuscript
NIH-PA Author Manuscript
NIH-PA Author Manuscript

NIH-PA Author Manuscript NIH-PA Auth script NIH-PA Author Manuscript

consequences of substance misuse, including SUDs, through early intervention and, when needed, referral to treatment (IOM 1990).

In practice, SBIRT comprises three stages: screening, brief intervention, and referral to treatment. Screening involves a rapid assessment of substance use. SBIRT was developed for tobacco and alcohol use disorders, but its use is being expanded to include illicit drug and prescription drug use, although for these latter categories there is no strong research evidence for its effectiveness as yet. If it is determined that a patient's substance use patterns are hazardous, a brief intervention follows. When practitioners first began using SBIRT, the brief intervention utilized brief advice approaches, whereas current U.S. SBIRT efforts focus on motivational interviewing approaches of various lengths (Pringle et al. 2012). Depending on severity, patients may be offered brief treatment (a variable number of sessions, depending on the program and client, focusing on motivating clients to change substance use patterns) or be referred to a substance abuse treatment program. Referral to treatment may be more useful for excessive drinkers, as brief intervention has been shown to have little effect on this population (Beich et al. 2007; Beich, Thorsen & Rollnick 2003; Beich, Gannic & Malterud 2002).

The importance of integrating SBIRT into the clinical setting is becoming increasingly apparent. Problem substance use is highly prevalent in the United States. According to the 2008 National Survey on Drug Use and Health, conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA 2009), 23% of Americans engage in risky drinking, 8% engage in illicit drug use, and 10% meet the criteria for either alcohol or other substance abuse or dependence. The same survey revealed that 90% of people with SUDs do not receive treatment. Of those who do not receive treatment, 95% do not know that they have a problem. The integration of SBIRT into clinical settings attempts to raise awareness of substance use issues among patients and help them to find relevant treatment solutions, where appropriate.

SBIRT HISTORY

The current model of SBIRT was not feasible until the 1980s. It was during this time period that reliable screening tools for alcohol and drug abuse, such as the Michigan Alcohol Screening Test, the CAGE, and the Drug Abuse Screening Test, were developed (Babor & Kadden 2005). These tools permitted the development of rapid methods of screening to be devised.

One early successful demonstration that SBIRT could be a helpful intervention found that brief physician advice helped some to stop smoking tobacco cigarettes, when undertaken in concert with support from a local smokers' clinic (Russell, Stapleton & Hajek 1988). In another study, conducted in Malmo, Sweden, 585 males who engaged in heavy drinking received screening and brief intervention (SBI) and were followed over a two- to six-year period during the late 1970s and early 1980s. The study showed that SBI, in the form of repeated encouragement from a health care provider, was helpful in decreasing overall alcohol consumption, lowered the incidence of negative medico-social consequences, and decreased mortality associated with heavy drinking (Kristenson et al. 1983).

Evidence supporting the effectiveness of alcohol SBI in primary care settings continued to grow. A randomized, controlled clinical trial conducted in 1997 found that for problem drinkers (men consuming more than 14 drinks per week and women consuming more than 11 drinks per week), two 10- to 15-minute counseling visits led to reductions in seven-day alcohol use, episodes of binge drinking, and frequency of excessive drinking at a 12-month follow-up (Fleming et al. 1997).

NIH-PA Author Manuscript NIH-PA Author Manuscript

Upon recognizing the importance of the Malmo study and others, the World Health Organization (WHO) began to focus resources on research to develop an international screening test as well as to evaluate the effectiveness of various brief interventions for at-risk alcohol drinkers (Babor et al. 2007). The screening tool that they developed was the Alcohol Use Disorders Identification Test (AUDIT; Saunders et al. 1993). The organization also conducted a cross-national clinical trial comparing brief interventions among patients who were deemed at risk of alcohol-related problems (WHO Brief Intervention Study Group 1996). This program also began to integrate SBIRT into primary care settings in Europe as well as in developing nations (Babor et al. 1989).

Recognizing the potential of SBIRT, the WHO's focus turned to research investigating how to best implement screening and brief intervention for alcohol problems in primary care settings, and, on a broader scale, how to integrate SBIRT into the health care systems of countries around the world (Babor et al. 2007). In 1997, a program, similar to the above for alcohol, was started to develop a quick and accurate screening test as well as evaluate the effectiveness of brief interventions for illicit drugs and tobacco (WHO ASSIST Working Group 2002). In the United States, the dissemination of SBIRT technologies has been strongly supported by SAMHSA's SBIRT initiative. This program has demonstration sites operating in 11 states (Babor et al. 2007). Other large programs of note are located in Brazil, South Africa, and the European Union (Babor et al. 2007). Currently, most SAMHSA-funded projects use dedicated personnel or "specialists" to deliver SBIRT services. Clinics using specialists have been shown to implement a higher percentage of completed interventions, although clear differences between sites have emerged. Whether the physician or specialist delivery model works best depends on a variety of provider and organizational characteristics (Babor et al. 2005).

SBI in primary care settings has shown significant promise. A summary of evidence taken from 12 controlled trials found that six to 12 months after good quality, brief, multicontact behavioral counseling interventions, participants reduced the average number of drinks they consumed per week by 13% to 34% when compared to controls not receiving the intervention, and the proportion of participants drinking at moderate or safe levels was 10% to 19% greater compared to controls (Whitlock et al. 2004). A systematic review and meta-analysis found that brief alcohol intervention in primary care settings reduced alcohol consumption for both men and women at six- and 12-month follow-ups (Bertholet et al. 2005).

INTRODUCTION TO SBIRT IN MEDICAL SETTINGS

Self-report screening tests are simple and can be given in a variety of settings. They are often administered as part of a clinician interview, via a questionnaire, or they may be completed by patients given access to a computer. Automated telephone screening, where clients respond via touchtone keypads to telecomputer-administered versions of the CAGE and AUDIT screening assessments, has been shown to be comparable to clinician-administered screening (Dyches et al. 1999). Internet websites have also been found to be effective as screening tools when they are well publicized and easily accessible. Many users screened in this way who drink excessively have sought referral information (Saitz et al. 2004). Some single-question screens for risky drinking and alcohol use disorders have been developed and validated (Dawson, Compton & Grant 2010; Dawson, Pulay & Grant 2010; Seale et al. 2006; Williams & Vinson 2001) as has a single-question screening test used in primary care settings for illicit drug use and abuse of prescription drugs (Smith et al. 2010). See Table 1 <TQ>first mention of table 1</TQ> for a summary of SBIRT screening tools.

IH-PA Author Manuscript NIH-PA Auth script NIH-PA Author Manuscript

SBIRT IN EMERGENCY DEPARTMENTS

Emergency departments (ED) across the United States are part of the health care safety net and, by default, become the point of primary care for millions of Americans. Forty percent of ED visits are due to trauma, and of these, between 40% and 50% are alcohol related (Nilsen et al. 2008). As of 2006, the Committee on Trauma of the American College of Surgeons has recommended that all Level I and II trauma centers be equipped to use SBIRT screening tools and that Level I centers offer a brief intervention when necessary (Soderstrom et al. 2007). Recent studies have shown mixed results regarding the effectiveness of SBI delivered in EDs (Academic ED SBIRT Research Collaborative 2010). A systematic review and meta-analysis did, however, find that SBI reduced ED utilization (Bray, Cowell & Hinde 2011).

In the ED, a physician, nurse, or specially trained health education paraprofessional may administer SBIRT. The process involves administration of screening questions to ED patients. When at-risk drinkers are identified, brief advice, motivational interviewing (MI), or a brief negotiated interview (BNI) is administered. BNI attempts to integrate the early approach of offering brief advice with the more current approach of using MI (D'Onofrio, Bernstein & Rollnick 1996). If the patient expresses interest in reducing consumption, the provider helps to establish alcohol use reduction goals and follow-up plans. In a recent study, those patients receiving a brief intervention (BI) were more likely to enter into substance abuse treatment in the year following BI. This was particularly true of patients who had no substance abuse treatment in the past two years (Krupski et al. 2010).

Using computers as a means of screening has been in evolution for two decades (Davis & Morse 1991; Barry & Fleming 1990), and recent studies have shown promise for this method (Heron & Smyth 2010; Kypri et al. 2008; Linke et al. 2008; Riper et al. 2008). One such study evaluates the administration of SBIRT in the ED via a Computerized Alcohol Screening and Intervention (CASI). The CASI takes less than five minutes to administer, can be conducted in many languages, and includes the AUDIT. It undertakes a BNI, prints a personalized alcohol reduction plan, and provides treatment referral information. A six-month follow-up found that 47% of at-risk patients who received the CASI-administered BNI were no longer drinking over the National Institutes of Alcohol Abuse and Alcoholism (NIAAA) low-risk limits, defined as no more than four drinks in a day or no more than 14 drinks in a week for men aged 64 years and younger and no more than three drinks in a day or no more than seven drinks in a week for women and for men age 65 years and older (Vaca et al. 2011).

The Academic Emergency Department SBIRT Research Collaborative has studied the implementation of SBIRT in EDs. As part of this multisite study, 14 sites participated in training ED staff in SBIRT. This included a total of 402 doctors, nurse practitioners, physician assistants, nurses, social workers, and emergency medical technicians. Of these health practitioners, 74% reported less than ten hours of alcohol education during graduate or post-graduate education, and 78% reported less than two hours of alcohol education in the previous year. Training in SBIRT involved either a two-hour interactive workshop with case simulations or a web-based program. At three months post-training, practitioners reported a small but significant increase in the belief that SBIRT would make a difference for patients receiving the intervention. Seventy-two percent reported delivering at least one SBIRT intervention in their clinical practice, and trainees were more likely to use SBIRT. At 12 months after the training, health practitioners had increased confidence in their ability to perform SBIRT and a greater sense of responsibility to screen. Identified barriers included a lack of belief in the effectiveness of SBIRT, a lack of role models among faculty, a concern for angry responses from patients, lack of reimbursement, and lack of referral sources. These

NIH-PA Author Manuscript NIH-PA Auth script NIH-PA Author Manuscript

barriers underscore the need for institutional support, the continued supervised clinical practice of SBIRT, and system-wide change that supports the intervention (Academic ED SBIRT Research Collaborative 2007a).

A companion study conducted by the same collaborative evaluated the effectiveness of SBIRT on ED patients. In this study, 7,751 patients were screened. Of those, 2,051 exceeded the NIAAA low-risk drinking limits. Over 1,100 patients consented to participate in the study, in which patients were randomly assigned to receive either SBIRT/BNI or a control intervention that consisted of written advice and a referral list from providers. At three months, those who received a brief intervention reported significantly fewer drinks per week and were more likely than controls to report alcohol use that was below the NIAAA low-risk limit. This study shows the potential for an ED intervention to directly benefit patients, as evidenced by reduction in alcohol consumption, alcohol-associated morbidity, mortality, and healthcare costs (Academic ED SBIRT Research Collaborative 2007b). However, a follow-up study showed that the effects associated with SBIRT/BNI observed at three months were no longer significant at six and 12 months (Academic ED SBIRT Research Collaborative 2010).

Other models of SBIRT in the ED have also shown promise. In a study of nurses delivering SBI in an ED, decreases in alcohol consumption determined by quantity as well as frequency were reported. SBI was also associated with a decrease in recurring ED visits when compared to the usual care group (Desy et al. 2010). Another approach, which addresses the time constraints and the lack of referral experience among ED providers, involves the use of health promotion advocates (HPA) who have experience in the recognition and treatment of SUDs and function as physician extenders. These advocates see all patients to assess general health, safety, and substance abuse issues. If a patient has substance abuse issues, the HPA will assist in making a referral to treatment. Important contributions of ED HPAs have included improving patient flow and community relations, as well as reducing the need for security involvement and success in finding detoxification placements (Bernstein et al. 2009c).

Not all SBIRT research outcomes have been positive. Some ED SBIRT studies show little difference in drinking results between people who have received SBIRT and controls (D'Onofrio et al. 2008; Daeppen et al. 2007). The traumatic event that led to admission to the emergency department may act as a motivating factor for patients, regardless of whether they receive SBIRT. A follow-up SBIRT session with a trained interviewer at a date six to 12 months after the initial emergency room visit may help individuals to reassess their motivation to change (Korcha et al. 2012). In addition to multicontact interventions, active referral to primary care providers offers another opportunity to increase the effectiveness of ED interventions (Academic ED SBIRT Research Collaborative 2010).

There are challenges that may hinder the integration of SBIRT into EDs. Up to 75% of patients screened will not be at risk for SUDs, and the time spent to screen all patients in the ED when the yield is expected to be 25% or less (Madras et al. 2009) may discourage the use of SBIRT among ED staff. Screening plus BNI lasts approximately ten minutes, which in ED settings is a lengthy period that some clinicians may not find to be the best use of ED time. The comfort level of the ED staff is important as well. Effective training is needed before SBIRT becomes routine and staff can administer it efficiently (Bernstein et al. 2009c). There is also a general lack of referral sources, which points to a larger systemic problem.

There also are reimbursement issues surrounding SBIRT. Although SBIRT is being reimbursed by Medicare and at least three major U.S. insurance carriers, a study found that

IH-PA Author Manuscript NIH-PA Auth script NIH-PA Author Manuscript

implementation of billing codes was insufficient to promote utilization of SBI (Fussel, Rieckmann & Quick 2011). Ongoing challenges include a low reimbursement rate, a minimum 15-minute length of service requirement for billing, and the availability of reimbursement only for licensed healthcare providers delivering the intervention.

However, several studies indicate that SBIRT may decrease health care costs. In a Washington State Medicaid cost analysis study, SBIRT was delivered by substance abuse counselors to working-age disabled Medicaid patients in nine hospital ED units. Patients receiving SBIRT were found to have significant reductions in need for health care services in the year following the SBIRT intervention, with a reduction in Medicaid costs per month per member of $366 (Estee et al. 2010). Similarly, Gentilello and colleagues (2005) reported a $3.81 reduction in health expenditures for every $1.00 spent on screening and intervention in trauma patients. If applied nationwide, this was estimated to potentially produce a net savings of $1.82 billion annually. Another study has suggested that a $43,000 reduction in future health care costs would be realized for every $10,000 invested in early intervention (Fleming et al. 2002).

SBIRT use in trauma centers also shows some promise. At a 12-month follow-up, those receiving a brief intervention decreased alcohol consumption by 21.8 drinks per week. The most significant drop in consumption was seen in mild to moderate drinkers. In addition, trauma recidivism, measured using a statewide database of all ED and hospital discharges over the subsequent three years, was reduced by 47% in those receiving SBIRT (Gentilello et al. 1999). This study contributed to the recommendation by the Committee on Trauma of the American College of Surgeons that all patients seeking treatment for trauma in Level I EDs receive SBIRT. Another study showed that two brief interventions, personalized motivational intervention and brief information and advice results in decreases in alcohol consumption and fewer negative consequences from drinking in trauma center patients receiving SBIRT at six- and 12-month follow-ups (Sorderstrom et al. 2007).

SBIRT IN PRIMARY CARE

Evidence supporting the use of SBIRT in primary care is quite strong (Kaner et al. 2007). Numerous studies show that alcohol screening and brief counseling interventions reduce unhealthy alcohol use in primary care patients (Williams et al. 2011; Babor et al. 2007; Kaner et al. 2007). Gryczynski and colleagues (2011) evaluated SBIRT implementation in rural New Mexican primary health care settings including Federally Qualified Health Centers, public health offices, and Indian Health Service clinics. This study is one of a limited number of studies to describe use of a full SBIRT model in primary care, with services provided by dedicated SBIRT providers. The AUDIT was used to screen for at-risk alcohol consumption, and those identified with hazardous drinking (AUDIT score > 8) were referred to behavioral health counselors (BHC). To screen for illicit and nonmedical prescription drug use, a yes/no questionnaire about past-year use was also administered. Any patient who answered in the affirmative to a screening question was referred to a BHC. The counselors were licensed psychologists, clinical social workers, or substance abuse counselors. These staff received 80 hours of initial training as well as additional booster trainings by supervisors. At the six-month follow-up, brief intervention and brief therapy were associated with a decreased frequency of illicit drug use, alcohol use, and alcohol intoxication in patients who received the intervention. Brief therapy and referral to treatment was associated with the greatest reductions in alcohol and illicit drug use. It is important to note that this study included no control group (Gryczynski et al. 2011).

SAMHSA has developed and funded the creation of SBIRT Medical Residency Programs (MRP). In these programs, medical residents are taught SBIRT skills and how to incorporate

NIH-PA Author Manuscript NIH-PA Author Manuscript

SBIRT into their practices (Seale, Shellenberger & Clark 2010). Some have suggested that a team-based learning approach would help residents to learn and implement SBI better than education through a traditional lecture format (Shellenberger et al. 2009). However, barriers to implementation of SBIRT in primary care settings mirror those in the ED: lack of substance use disorder knowledge, lack of time, reimbursement issues, and lack of faculty mentors (Pringle et al. 2012; Chossis et al. 2007). SBIRT training may also be useful as a platform to teach medical residents about pharmacotherapy treatments for substance use disorders, which can be provided by primary care providers. Two recently completed studies show the effectiveness of the use of a SBIRT curriculum and the reinforcement of skills taught in SBIRT curriculum through the use of standardized patients (Satre et al. In press; Satterfield et al. In press).

The importance of the availability of mentors who can provide faculty and residents with ongoing advice and encouragement is underscored by the current lack of a structured system of identification and treatment of substance abuse issues in medical settings. Single trainings of medical providers will not be sufficient to adequately establish this intervention (Chossis et al. 2007). Ongoing support, training, and the addressing of questions regarding the appropriate identification and treatment of patients with need for substance abuse treatment interventions is necessary (Pringle et al. 2012).

SBIRT FOR CHILDREN AND ADOLESCENTS

Alcohol and drug use is a leading cause of injury and death in children and adolescents. The National Survey on Drug Use and Health reported that 16% of 12- to 17-year-olds reported drinking in the past 30 days (US DHHS 2008). Binge drinking, defined as consuming more than five drinks on one occasion, is also a growing concern among adolescents, with 8% of eighth graders and 19% of twelfth graders reporting an episode in the past 30 days (Office of the Surgeon General 2007). Approximately 47% of adolescents try an illicit drug by the time that they graduate from high school (Johnston et al. 2009). This information is important because the use of drugs and alcohol before the age of 15 has been shown to be a predictor of SUDs in adulthood (Grant & Dawson 1997).

A survey was conducted to assess implementation of SBIRT in the 12- to 17-year-old population seeking treatment in EDs (Schweer 2009). Of 242 hospitals that responded to the survey, 18% reported screening all adolescents in the ED, and 26% screened adolescents admitted to trauma service. Blood alcohol concentration (BAC) was used by 52% of ED units as an indicator of whether to screen or not. The problem with this, however, is that it is the clinician who decides which patients are tested for BAC. This means that health care professionals decide who is at risk, and they may miss many adolescents who are likely to be engaged in at-risk behaviors (Schweer 2009).

Another study conducted at the Children's Hospital of Philadelphia evaluated SBIRT implementation by trauma advanced-practice nurses for patients aged 12 to 18 years old. Nurses used the CRAFFT screener, a six-question instrument that queries about problem alcohol and drug use, with all adolescent trauma patients to determine if substance misuse was a problem for them (Knight et al. 2002). This screening tool was chosen for ease of use, age appropriateness, and its ability to address both risky alcohol and drug use. A positive response to any of the six screening questions led to a referral to a social worker or trauma advanced-practice nurse for further assessment. A specialty treatment referral was made if necessary. Nurses expressed concern about confidentiality issues and therefore created a "Specially Protected Information" section of the medical record for information about participants' substance use. Of 115 adolescent trauma patients, 25% screened positive

NIH-PA Author Manuscript NIH-PA Auth script NIH-PA Author Manuscript

(Robinson 2010). Although preliminary studies show some promise, currently there is insufficient evidence to indicate the efficacy of SBIRT for adolescents.

Brief motivational interviewing has been associated with reduced young adult (18- to 24-year-olds) alcohol consumption at six- and 12-month follow-up (Monti et al. 2007). This intervention has also shown a reduction in the incidence of alcohol-related injury, traffic violations, and driving after drinking among 18- and 19-year-olds, although this particular study showed no significant differences in reduction of alcohol consumption between brief intervention and standard care (Monti et al. 1999).

SBIRT IN EMPLOYEE ASSISTANCE PROGRAMS

In one of the only studies of SBIRT outside of medical settings, a telephone-based intervention was tested with employees who either self-referred or were manager-referred to the company's employee assistance program (EAP). The telephone interview offered an AUDIT screening. If the interviewee screened positive for hazardous alcohol use, they were given feedback including alcohol education, simple advice, a discussion of the pros and cons of alcohol use, the importance of cutting back, and a referral to outside care, when appropriate. Over a five-month period, 295 people were offered screening, of which 93% participated. Common reasons for contacting the EAP were stress/anxiety/panic (38%), depression (19%), alcohol use (6%), and other drug issues (1%). Forty percent of those who consented were found to have a positive screen by the AUDIT, and of those, 52% scored at moderate to high risk. An overall rate of approximately 8% for alcohol disorders approached that of the general population in the United States. Of those who had a positive screen by the AUDIT, 72% contacted the EAP clinician for the recommended appointment to begin to address problem alcohol use (McPherson et al. 2010). This study shows the potential usefulness of screening and brief intervention in settings outside of health care systems and the wide applicability of this intervention. Limitations of this approach include limited participation rates by employees and patient concerns about confidentiality.

ONGOING QUESTIONS REGARDING SBIRT

SBIRT research has focused mainly on alcohol use. There is little data on effective screening tools and usefulness of SBIRT interventions in illicit drug users. Recently, however, the Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) has been developed, validated, and used as the screen for a randomized controlled trial of a brief intervention for illicit drugs. The study found that those receiving BI had significantly reduced scores for all ASSIST measures (Humeniuk et al. 2012). Also, a study attempting to reduce marijuana use among teens and young adults in a pediatric ED setting using SBI found that intervention participants were more likely to be abstinent for the past 30 days and showed a reduction in days of substance use at 12-month follow-up (Bernstein et al. 2009b). More research is needed to explore the effectiveness of SBIRT for those who engage in at-risk drug use behaviors. Further, most SBIRT studies have focused on short-term effects (up to one year after the initial intervention). One study did, however, find that brief physician advice was associated with sustained reductions in alcohol use four years after the intervention (Fleming et al. 2002). Moving forward, it will be important to conduct more long-term studies to examine the durability of the effects of SBIRT and to explore the most useful forms of SBIRT intervention. Such studies could evaluate the impact of SBIRT in the larger community and society as a whole.

The United States Preventive Services Task Force (2004) has given SBIRT in the primary care setting a "B" recommendation. This means that there is fair evidence that the benefits outweigh the harms. They reached this conclusion after considering research that suggested participants reduced their average number of drinks per week by 13% to 34% more than did

IH-PA Author Manuscript NIH-PA Auth script NIH-PA Author Manuscript

controls who did not receive a SBIRT intervention, and the proportion of participants drinking at moderate or safe levels was 10% to 19% greater as compared to controls (Bernstein et al. 2009a; Whitlock et al. 2004). More research will be needed to determine whether SBIRT should be required in all health care settings.

Some experts believe that the scope of SBIRT should be expanded to include tobacco misuse and possibly depression screening due to the high prevalence rates of these disorders. Benefits of routine screening for these issues include improved health outcomes as well as cost savings. Further cost savings could be realized by training individuals with bachelor's degrees to dispense SBIRT services (Brown 2011). It should also be noted that SBIRT in its current form is still not entirely an evidence-based practice. While studies do indicate that alcohol and drug use decrease at six months after service delivery, some of these studies lack control groups. Future studies should focus on a randomized clinical trial approach to demonstrate efficacy.

SUMMARY

SBIRT is increasingly used in medical settings in the United States and internationally. In a large study of SBIRT outcomes, at six-month follow-up, illicit drug use was 68% lower and heavy alcohol consumption was 39% lower among individuals who had screened positive for hazardous drug and alcohol use. Those same individuals reported improvements in general health, mental health, employment, and housing, as well as decreased criminal activity (Madras et al. 2009). Although this cohort study is promising, follow-up occurred at six months after baseline, making its findings less conclusive than aforementioned studies with longer follow-up times.

SBIRT shows promise in many medical settings in facilitating early identification of risky substance use. Screening large numbers presents a greater opportunity to engage those individuals who are in need of treatment. SBIRT can also be used as an opportunity to teach medical staff about substance use disorders and their treatment, including pharmacotherapies that can be implemented in primary care. However, additional research is needed to determine how best to implement SBIRT and to assure its routine use in primary care settings. Recent studies have begun to explore new approaches to understanding SBIRT and how best to implement the intervention to achieve the greatest positive results. For example, how the sequence of "change talk" within a brief motivational intervention relates to alcohol consumption is being explored (Bertholet et al. 2010), the use of motivational enhancement therapy to increase resident physician engagement in substance abuse education is being studied (Hettema et al. 2009), text-message-based drinking assessments and brief interventions are being explored (Suffoletto et al. 2011), and identification of behavior change techniques that will reduce excessive alcohol consumption that might be implemented in the SBIRT model are being researched (Michie et al. 2012). Further, studies of curriculum development and innovative approaches to teaching SBIRT using interventions such as medical resident interactions with standardized patients have been developed (Satre et al. In press; Satterfield et al. In press). While these studies show some promise, future studies are needed to fully evaluate their effectiveness.

Further evaluation of what training is most effective in improving the SBIRT skills of medical staff and to increase the receptivity of health care providers to use SBIRT with their patients is needed (Whitlock et al. 2004). One meta-analysis did find, however, that promising programs are those that have a specific focus on alcohol and those that are multi-component (Anderson et al. 2004). Equally important is continued exploration to determine what types of supports are needed for patients to maintain gains in reductions in hazardous substance use that result from SBIRT interventions. Finally, although there is some evidence

NIH-PA Author Manuscript NIH-PA Auth script NIH-PA Author Manuscript

to support the efficacy of SBIRT for illicit drug use (Bernstein et al. 2005), cautionary notes have been raised about extrapolating what works in SBIRT for alcohol problems to SBIRT for illicit drug use (Saitz et al. 2010). Future studies focusing on the effect of SBIRT interventions in identifying and altering drug misuse and abuse will help to clarify these issues.

REFERENCES

Academic ED SBIRT Research Collaborative. The impact of screening, brief intervention and referral to treatment of emergency department patients' alcohol use: A 3-, 6-, and 12-month follow-up. Alcohol and Alcoholism. 2010; 45(6):514–519. [PubMed: 20876217]

Academic ED SBIRT Research Collaborative. An evidence-based alcohol screening, brief intervention and referral to treatment (SBIRT) curriculum for emergency department providers improves skills and utilization. Substance Abuse. 2007a; 28(4):79–92. [PubMed: 18077305]

Academic ED SBIRT Research Collaborative. The impact of screening, brief intervention and referral to treatment of emergency department patients' alcohol use. Annals of Emergency Medicine. 2007b; 50:699–710. [PubMed: 17870206]

Anderson P, Laurant M, Kaner E, Wensing M, Grol R. Engaging general practitioners in the management of hazardous and harmful alcohol consumption: Results of a meta-analysis. Journal of Studies on Alcohol. 2004; 65(2):191–199. [PubMed: 15151349]

Babor TF, Kadden RK. Screening and interventions for alcohol and drug problems in medical settings: What works? Journal of Trauma. 2005; 59(Suppl 3):S80–S87. [PubMed: 16355071]

Babor TF, McRee BG, Kassebaum PA, Grimaldi PL, Ahmed K, Bray J. Screening, Brief Intervention, and Referral to Treatment (SBIRT). Substance Abuse. 2007; 28(3):7–30. [PubMed: 18077300]

Babor TF, Higgins-Biddle J, Dauser D, Higgins P, Burleson JA. Alcohol screening and brief intervention in primary care settings: Implementation models and predictors. Journal of Studies on Alcohol. 2005; 66(3):361–368. [PubMed: 16047525]

Babor, TF.; de la Fuente, JR.; Saunders, J.; Grant, M. AUDIT: The Alcohol Use Disorders Identification Test: Guidelines for Use in Primary Health Care. Geneva: World Health Organization; 1989. WHO/MNH/DAT 89.4

Barry KL, Fleming MF. Computerized administration of alcoholism screening tests in a primary care setting. Journal of the American Board of Family Practice. 1990; 3(2):93–98. [PubMed: 2185611]

Beich A, Thorsen T, Rollnick S. Screening in brief intervention trials targeting excessive drinkers in general practice: Systematic review and meta-analysis. British Medical Journal. 2003; 327(7414): 536–542. [PubMed: 12958114]

Beich A, Gannik D, Malterud K. Screening and brief intervention for excessive alcohol use: Qualitative interview study of the experiences of general practitioners. British Medical Journal. 2002; 325(7369):870. [PubMed: 12386040]

Beich A, Gannik D, Saelan H, Thorsen T. Screening and brief intervention targeting risky drinkers in Danish general practice—a pragmatic controlled trial. Alcohol and Alcoholism. 2007; 42(6):593–603. [PubMed: 17855332]

Bernstein E, Bernstein JA, Stein JB, Saitz R. SBIRT in emergency care settings: Are we ready to take it to scale? Academic Emergency Medicine. 2009a; 16:1072–1077. [PubMed: 20053225]

Bernstein E, Edwards E, Dorfman D, Heeren T, Bliss C, Bernstein J. Screening and brief intervention to reduce marijuana use among youth and young adults in a pediatric emergency department. Academic Emergency Medicine. 2009b; 16(11):1174–1185. [PubMed: 20053238]

Bernstein E, Topp D, Shaw E, Girard C, Pressman K, Woolcock E, Bernstein J. A preliminary report of knowledge translation: Lessons from taking screening and brief intervention techniques from the research setting into regional systems of care. Academic Emergency Medicine. 2009c; 16:1225–1233. [PubMed: 20053242]

Bernstein J, Bernstein E, Tassiopoulos K, Heeren T, Levenson S, Hingson R. Brief motivational intervention at a clinic visit reduces cocaine and heroin use. Drug and Alcohol Dependence. 2005; 77(1):49–59. [PubMed: 15607841]

NIH-PA Author Manuscript NIH-PA Auth script NIH-PA Author Manuscript

Bertholet N, Faouzi M, Gmel G, Gaume J, Daeppen JB. Change talk sequence during brief motivational intervention, towards or away from drinking. Addiction. 2010; 105(12):2106–2112. [PubMed: 20840175]

Bertholet N, Daeppen JB, Wietlisbach V, Fleming M, Burnand B. Reduction of alcohol consumption by brief alcohol intervention in primary care: Systematic review and meta-analysis. Archives of Internal Medicine. 2005; 165(9):986–995. [PubMed: 15883236]

Bray JW, Cowell AJ, Hinde JM. A systematic review and meta-analysis of health care utilization outcomes in alcohol screening and brief intervention trials. Medical Care. 2011; 49(3):287–294. [PubMed: 21263359]

Brown RL. Configuring health care for systematic behavioral screening and intervention. Population Health Management. 2011; 14(6):299–305. [PubMed: 22074564]

Chossis I, Lane c, Gache P, Michaud PA, Pécoud A, Rollnick S, Daeppen JB. Effect of training on primary care residents' performance in brief alcohol intervention: A randomized controlled trial. Journal of General Internal Medicine. 2007; 22(8):1144–1149. [PubMed: 17541671]

Daeppen JB, Gaume J, Bady P, Yersin B, Calmes JM, Givel JC, Gmel G. Brief alcohol intervention and alcohol assessment do not influence alcohol use in injured patients treated in the emergency department: A randomized controlled clinical trial. Addiction. 2007; 102(8):1224–1233. [PubMed: 17565563]

Davis L, Morse R. Self-administered alcoholism screening test: A comparison of conventional versus computer administered formats. Alcoholism, Clinical and Experimental Research. 1991; 15(2): 155–157.

Dawson DA, Pulay AJ, Grant BF. A comparison of two single-item screeners for hazardous drinking and alcohol use disorder. Alcoholism, Clinical and Experimental Research. 2010; 34(2):364–374.

Dawson DA, Compton WM, Grant BF. Frequency of 5+/4+ drinks as a screener for drug use and drug-use disorders. Journal of Studies on Alcohol and Drugs. 2010; 1(5):751–760. [PubMed: 20731982]

Desy PM, Howard PK, Perhats C, Li S. Alcohol screening, brief intervention, and referral to treatment conducted by emergency nurses: An impact evaluation. Journal of Emergency Nursing. 2010; 36(6):538–545. [PubMed: 21078465]

D'Onofrio G, Bernstein E, Rollnick S. Motivating patients for change: A brief strategy for negotiation. Emergency Medicine and the Health of the Public. 1996:51–62.

D'Onofrio G, Pantalon MV, Degutis LC, Fiellin DA, Busch SH, Chawarski MC, Owens PH, O'Connor PG. Brief intervention for hazardous and harmful drinkers in the emergency department. Annals of Emergency Medicine. 2008; 51(6):742–750. [PubMed: 18436340]

Dyches H, Alemagno S, Llorens SA, Butts JM. Automated telephone administered substance abuse screening for adults in primary care. Health Care Management Science. 1999; 2:199–294. [PubMed: 10994485]

Estee S, Wickizer T, He L, Shah MF, Mancuso D. Evaluation of the Washington State Screening, Brief Intervention, and Referral to Treatment Project. Medical Care. 2010; 48(1):18–24. [PubMed: 19927016]

Fleming MF, Mundt MP, French MT, Manwell LB, Stauffacher EA, Barry KL. Brief physician advice for problem drinkers: Long-term efficacy and benefit-cost analysis. Alcoholism, Clinical and Experimental Research. 2002; 26(1):36–43.

Fleming MF, Barry KL, Manwell LB, Johnson K, London R. Brief physician advice for problem alcohol drinkers. A randomized controlled trial in community-based primary care practices. Journal of the American Medical Association. 1997; 277(13):1039–1045. [PubMed: 9091691]

Fussell HE, Rieckmann TR, Quick MB. Medicaid reimbursement for screening and brief intervention for substance misuse. Psychiatric Services. 2011; 62(3):306–309. [PubMed: 21363904]

Gentilello LM, Ebel BE, Wickizer TM, Salkever DS, Rivara FP. Alcohol interventions for trauma patients treated in emergency departments and hospitals: A cost benefit analysis. Annals of Surgery. 2005; 241(4):541–550. [PubMed: 15798453]

Gentilello LM, Rivara FP, Donovan DM, Jurkovich GJ, Daranciang E, Dunn CW, Villaveces A, Copass M, Ries RR. Alcohol interventions in a trauma center as a means of reducing the risk of injury recurrence. Annals of Surgery. 1999; 230(4):473–480. [PubMed: 10522717]

NIH-PA Author Manuscript NIH-PA Author Manuscript

Grant BF, Dawson DA. Age at onset of alcohol use and its association with DSM-IV alcohol abuse and dependence: Results from the National Longitudinal Alcohol Epidemiologic Survey. Journal of Substance Abuse. 1997; 9:103–110. [PubMed: 9494942]

Gryczynski J, Mitchell SG, Peterson TR, Gonzales A, Moseley A, Schwartz RP. The relationship between services delivered and substance use outcomes in New Mexico's Screening, Brief Intervention, Referral and Treatment (SBIRT) Initiative. Drug and Alcohol Dependence. 2011; 118(2–3):152–157. [PubMed: 21482039]

Heron KE, Smyth JM. Ecological momentary interventions: Incorporating mobile technology into psychosocial and health behaviour treatments. British Journal of Health Psychology. 2010; 15(1): 1–39. [PubMed: 19646331]

Hettema JE, Sorensen JL, Uy M, Jain S. Motivational enhancement therapy to increase resident physician engagement in substance abuse education. Substance Abuse. 2009; 30(3):244–247. [PubMed: 19591061]

Humeniuk R, Ali R, Babor T, Souza-Formigoni ML, de Lacerda RB, Ling W, McRee B, Newcombe D, Pal H, Poznyak V, Simon S, Vendetti J. A randomized controlled trial of a brief intervention for illicit drugs linked to the Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) in clients recruited from primary health-care settings in four countries. Addiction. 2012; 107(5): 957–966. [PubMed: 22126102]

Institute of Medicine (IOM). Broadening the Base of Treatment for Alcohol Problems. Washington DC: National Academies Press; 1990.

Johnston, LD.; O'Malley, PM.; Bachman, JG.; Schulenberg, JE. Monitoring the Future National Results on Adolescent Drug Use: Overview of Key Findings, 2008. Bethesda, MD: National Institute on Drug Abuse; 2009. NIH Publication No. 09-7401

Kaner EF, Beyer F, Dickinson HO, Pienaar E, Campbell F, Schlesinger C, Heather N, Saunders J, Burnand B. Effectiveness of brief alcohol interventions in primary care populations. Cochrane Database of Systematic Reviews. 2007; (2) CD004148.

Knight JR, Sherrit L, Shrier LS, Harris SK, Chang G. Validity of the CRAFFT substance abuse screening test among adolescent clinic patients. Archives of Pediatric Adolescent Medicine. 2002; 156:607–614.

Korcha RA, Cherpitel CJ, Moskalewicz J, Swiatkiewicz G, Bond J, Ye Y. Readiness to change, drinking, and negative consequences among Polish SBIRT patients. Addictive Behaviors. 2012; 37(3):287–292. [PubMed: 22119521]

Kristenson H, Ohlin H, Hultén-Nosslin MB, Trell E, Hood B. Identification and intervention of heavy drinking in middle-aged men: Results and follow-up of 24–60months of long-term study with randomized controls. Alcoholism, Clinical and Experimental Research. 1983; 7:203–209.

Krupski A, Sears JM, Joesch JM, Estee S, He L, Dunn C, Huber A, Roy-Byrne P, Ries R. Impact of brief interventions and brief treatment on admissions to chemical dependency treatment. Drug and Alcohol Dependence. 2010; 110:126–136. [PubMed: 20347234]

Kypri K, Langley JD, Saunders JB, Cashell-Smith ML, Herbison P. Randomized controlled trial of web-based alcohol screening and brief intervention in primary care. Archives of Internal Medicine. 2008; 168(5):530–536. [PubMed: 18332300]

Linke S, McCambridge J, Khadjesari Z, Wallace P, Murray E. Development of a psychologically enhanced interactive online intervention for hazardous drinking. Alcohol and Alcoholism. 2008; 43(6):669–674. [PubMed: 18693217]

Madras BK, Compton WM, Avula D, Stegbauer T, Stein JB, Clark HW. Screening, brief interventions, referral to treatment for illicit drug and alcohol use at multiple healthcare sites: Comparison at intake and 6 months. Drug and Alcohol Dependence. 2009; 99(1–3):280–295. [PubMed: 18929451]

McPherson TL, Goplerud E, Derr D, Mickenberg J, Courtemanche S. Telephonic screening and brief intervention for alcohol misuse among workers contacting the employee assistance program: A feasibility study. Drug and Alcohol Review. 2010; 29:641–646. [PubMed: 20973849]

Michie S, Whittington C, Hamoudi Z, Zarnani F, Tober G, West R. Identification of behaviour change techniques to reduce excessive alcohol consumption. Addiction. 2012 [Epub ahead of print].

NIH-PA Author Manuscript NIH-PA Auth script NIH-PA Author Manuscript

Monti PM, Barnett NP, Colby SM, Gwaltney CJ, Spirito A, Rohsenow DJ, Woolard R. Motivational interviewing versus feedback only in emergency care for young adult and problem drinking. Addiction. 2007; 102:1234–1243. [PubMed: 17565560]

Monti PM, Colby SM, Barnett NP, Spirito A, Rohsenow DJ, Myers M, Woolard R, Lewander W. Brief intervention for harm reduction with alcohol positive older adolescents in a hospital emergency department. Journal of Consulting and Clinical Psychology. 1999; 67:989–994. [PubMed: 10596521]

Nilsen P, Baird J, Mello MJ, Nirenberg T, Woolard R, Bendtsen P, Longabaugh R. A systematic review of emergency care brief alcohol interventions for injury patients. Journal of Substance Abuse Treatment. 2008; 35:184–201. [PubMed: 18083321]

Office of the Surgeon General. The Surgeon General's Call to Action to Prevent and Reduce Underage Drinking. Rockville MD: Office of the Surgeon General, US Department of Health and Human Services; 2007.

Pringle JL, Kowalchuk A, Meyers JA, Seale JP. Equipping residents to address alcohol and drug abuse: The national SBIRT residency training project. Journal of Graduate Medical Education. 2012; 4(1):58–63. [PubMed: 23451308]

Riper H, Kramer J, Smit F, Conijn B, Schippers G, Cuijpers P. Web-based self-help for problem drinkers: A pragmatic randomized trial. Addiction. 2008; 103(2):218–227. [PubMed: 18199300]

Robinson RL. The advanced practice nurse role in instituting screening, brief intervention, and referral to treatment programs at the Children's Hospital of Philadelphia. Journal of Trauma Nursing. 2010; 17(2):74–79. [PubMed: 20559054]

Russell MA, Stapleton JA, Hajek P. District programme to reduce smoking: Can sustained intervention by general practitioners affect prevalence? Journal of Epidemiology and Community Health. 1988; 42:111–115. [PubMed: 3265427]

Saitz R, Alford DP, Bernstein J, Cheng DM, Samet J, Palfai T. Screening and brief intervention for unhealthy drug use in primary care settings: Randomized clinical trials are needed. Journal of Addiction Medicine. 2010; 4(3):123–130. [PubMed: 20936079]

Saitz R, Helmuth ED, Aromaa SE, Guard A, Belanger M, Rosenbloom DL. Web-based screening and brief intervention for the spectrum of alcohol problems. Preventive Medicine. 2004; 39(5):969–975. [PubMed: 15475031]

Satre D, McCance-Katz EF, Moreno-John G, Julian K, O'Sullivan P, Satterfield J. Using needs assessment to develop curricula for screening, brief intervention, and referral to treatment (SBIRT) in academic and community health settings. Substance Abuse. In press.

Satterfield J, O'Sullivan P, Satre D, McCance-Katz EF, Batki S, Tsoh J, Wamsley M. Using standardized patients to evaluate SBIRT knowledge and skill acquisition for internal medicine residents. Substance Abuse. In press.

Saunders JB, Aasland OG, Babor TF, de la Fuente JR, Grant M. Development of the Alcohol Use Disorders Identification Test (AUDIT): WHO collaborative project on early detection of persons with harmful alcohol consumption-II. Addiction. 1993; 88:791–804. [PubMed: 8329970]

Schweer LH. Pediatric SBIRT: Understanding the magnitude of the problem. Journal of Trauma Nursing. 2009; 16(3):142–147. [PubMed: 19888019]

Seale JP, Boltri JM, Shellenberger S, Velasquez MM, Cornelius M, Guyinn M, Okosun I, Sumner H. Primary care validation of a single screening question for drinkers. Journal of Studies on Alcohol. 2006; 67(5):778–784. [PubMed: 16847548]

Seale JP, Shellenberger S, Clark DC. Providing competency-based family medicine residency training in substance abuse in the new millennium: A model curriculum. BMC Medical Education. 2010; 10(33):1–12. [PubMed: 20074350]

Shellenberger S, Seale JP, Harris DL, Johnson JA, Dodrill CL, Velasquez MM. Applying team-based learning in primary care residency programs to increase patient alcohol screenings and brief interventions. Academic Medicine. 2009; 84(3):340–346. [PubMed: 19240441]

Smith PC, Schmidt SM, Allensworth-Davies D, Saitz R. A single-question screening test for drug use in primary care. Archives of Internal Medicine. 2010; 170(13):1155–1160. [PubMed: 20625025]

NIH-PA Author Manuscript NIH-PA Author Manuscript

Soderstrom CA, DiClemente CC, Dischinger PC, Hebel JR, McDuff DR, Auman KM, Kufera JA. A controlled trial of brief intervention versus brief advice for at-risk drinking trauma center patients. Journal of Trauma-Injury Infection & Critical Care. 2007; 62(5):1102–1112.

Substance Abuse and Mental Health Services Administration (SAMHSA). Results from the 2008 National Survey on Drug Use and Health: National Findings. Rockville MD: SAMHSA; 2009. Office of Applied Studies, NSDUH Series H-36, HHS Publication No. SMA 09-4434

Suffoletto B, Callaway C, Kristan J, Kraemer K, Clark DB. Text-message-based drinking assessments and brief interventions for young adults discharged from the emergency department. Alcoholism, Clinical and Experimental Research. 2011; 36(3):552–560.

United States Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Office of Applied Studies (US DHHS). National Survey on Drug Use and Health. 2007. Ann Arbor, MI: Inter-university Consortium for Political and Social Research; 2008.

United States Preventive Services Task Force. Screening and behavioral counseling interventions in primary care to reduce alcohol misuse: Recommendation statement. Annals of Internal Medicine. 2004; 140(7):554–556. [PubMed: 15068984]

Vaca FE, Winn D, Anderson CL, Kim D, Arcila M. Six-month follow-up of computerized alcohol screening, brief intervention, and referral to treatment in the emergency department. Substance Abuse. 2011; 32(3):144–152. [PubMed: 21660874]

Whitlock, EP.; Green, CA.; Polen, MR.; Berg, A.; Klein, J.; Siu, A.; Orleans, C. Behavioral Counseling Interventions in Primary Care to Reduce Risky/Harmful Alcohol Use [Internet]. Rockville, MD: Agency for Healthcare Research and Quality (US); 2004.

WHO ASSIST Working Group. The Alcohol, Smoking and Substance Involvement Screening Test (ASSIST): Development, reliability and feasibility. Addiction. 2002; 97:1183–1194. [PubMed: 12199834]

WHO Brief Intervention Study Group. A cross national trial of brief intervention with heavy drinkers. American Journal of Public Health. 1996; 86:948–955. [PubMed: 8669518]

Williams EC, Johnson ML, Lapham GT, Caldeiro RM, Chew L, Fletcher GS, McCormick KA, Weppner WG, Bradley KA. Strategies to implement alcohol screening and brief intervention in primary care settings: A structured literature review. Psychology of Addictive Behaviors. 2011; 28(2):206–214. [PubMed: 21517141]

Williams RH, Vinson DC. Validation of a single question screen for problem drinking. Journal of Family Practice. 2001; 50(4):307–312. [PubMed: 11300981]

NIH-PA Author Manuscript NIH-PA Au nuscript NIH-PA Author Manuscript

TABLE 1

Screening Tools

Tool (Positive)	Questions
CAGE (two or more "yes" answers)	Have you ever felt you should *cut* down on your drinking? Have people *annoyed* you by criticising your drinking? Have you ever felt bad or *guilty* about your drinking?[c] Have you ever had a drink first thing in the morning to steady your nerves or get rid of a hangover (*eye-opener*)?
CRAFFT (two or more "yes" answers)	Have you ever ridden in a *car* driven by someone (including yourself) who was "high" or had been using alcohol or drugs? Do you ever use alcohol or drugs to *relax*, feel better about yourself or fit in? Do you ever use alcohol or drugs while you are by yourself, or *alone*? Do you ever *forget* things you did while using alcohol or drugs? Do your *family* or *friends* ever tell you that you should cut down on your drinking or drug use? Have you ever gotten into *trouble* while you were using alcohol or drugs?
AUDIT (all questions ranked on a severity scale from 0 to 4 —total score of ≥ 8 indicates a positive screen)	How often do you have a drink containing alcohol? How many standard drinks do you have on a typical day when you are drinking? How often do you have six or more standard drinks on one occasion ? How often during the last year have you found that you were not able to stop drinking once you had started? How often during the last year have you failed to do what was normally expected of you because of drinking? How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session? How often during the last year have you had a feeling of guilt or remorse after drinking? How often during the last year have you been unable to remember what happened the night before because you had been drinking? Have you or someone else been injured because of your drinking? Has a relative, friend, doctor, or other health care worker been concerned about your drinking or suggested you cut down?
ASSIST (administration and scoring is more complicated)	Which substances have ever been used in the patient's lifetime? What is the frequency of substance use in the past three months? What is the frequency of experiencing strong desire or urge to use each substance in the last three months? What is the frequency of health, social, legal or financial problems related to substance use in the last three months? What is the frequency with which use of each substance has interfered with role responsibilities in the past three months? Has anyone ever expressed concern about the patient's use of each substance? How recently has that occurred? Has the patient ever tried and failed to cut down or give up their use of each substance? How recently has that occurred? Has the patient ever injected any drug?
Maximum Drinks Screener (≥ 4 drinks)	During the last 12 months, what was the LARGEST number of drinks that you drank in a single day?

NIH-PA Author Manuscript

NIH-PA Au

nuscript

NIH-PA Author Manuscript

Tool (Positive)	Questions
Frequency of 5+/4+ Drinking Screener (≥ once per year)	During the last 12 months, about how often did you drink FIVE OR MORE drinks in a single day? (for men) During the last 12 months, about how often did you drink FOUR OR MORE drinks in a single day? (for women)
Single-Question Screening Test for Drug Use in Primary Care (any use)	How many times in the past year have you used an illegal drug or used a prescription medication for nonmedical reasons?

Screening, Brief Intervention and Referral to Treatment (SBIRT) in Behavioral Healthcare

I. INTRODUCTION

This report discusses the evidence supporting the effectiveness of screening, brief intervention, and referral to treatment (SBIRT) as a comprehensive approach, as well as for the implementation and effectiveness of the individual components of SBIRT for different behavioral health conditions.[1] The report describes briefly the underlying research that has been conducted in the prevention and early intervention of risky alcohol, substance abuse and tobacco consumption, as well as commonly reported mental health problems, and describes existing studies/models for specific populations and settings. Further, the report addresses the question of what a model SBIRT program is, compared to programs which include or adapt components of the comprehensive SBIRT approach. Literature reviews are included in Attachment I. This paper is intended for use by policy makers, research organizations and governmental agencies seeking to understand the complexities of the SBIRT model and/or considering the adoption and implementation of SBIRT systems change or behavioral health integration within primary care settings.

Screening, brief intervention, and referral to treatment (SBIRT) was originally developed as a public health model designed to provide universal screening, secondary prevention[2] (detecting risky or hazardous substance use before the onset of abuse or dependence), early intervention, and treatment for people who have problematic or hazardous alcohol problems within primary care and other health care settings (Babor et al., 2007; Babor & Higgins-Biddle, 2001). Based on the SAMHSA model, SBIRT is unique in its universal screening of all patients regardless of an identified disorder, allowing health care professionals to address the spectrum of such behavioral health problems even when the patient is not actively seeking an intervention or treatment for his or her problems.

Following are the key points of this paper:

- SBIRT has been defined by SAMHSA as a comprehensive, integrated, public health approach to the delivery of early intervention for individuals with risky alcohol and drug use, and the timely referral to more intensive substance abuse treatment for those who have substance abuse disorders. There is consensus that a comprehensive SBIRT model includes screening, brief intervention/brief treatment and referral to treatment. In addition to these

[1] Excludes medical conditions.

[2] There is some discussion about whether SBIRT is selective prevention (Kumpfer & Baxley, (1997) or early intervention given the overlap in SBIRT's approach and objectives.

integral components, SAMHSA defines a comprehensive SBIRT model to include the following characteristics:

- It is brief (e.g., typically about 5-10 minutes for brief interventions; about 5 to 12 sessions for brief treatments).
- The screening is universal.
- One or more specific behaviors related to risky alcohol and drug use are targeted.
- The services occur in a public health non-substance abuse treatment setting.
- It is comprehensive (comprised of screening, brief intervention/treatment, and referral to treatment).
- Strong research or experiential evidence supports the model's effectiveness.

- No standard SBIRT definition has been articulated by the U.S. Preventive Services Task Force or other authoritative/coordinating bodies. The SAMHSA definition of SBIRT is based on methodology that was developed during the implementation of a comprehensive SBIRT grant program comprised of all the integral components, and supported by research by the National Institute on Drug Abuse and the National Institute on Alcohol Abuse and Alcoholism.

- There is substantial research on the effectiveness of SBIRT in reducing risky alcohol consumption. However, the evidence for the effectiveness of SBIRT in reducing risky drug use, although promising, is still accumulating. The results for the SAMHSA model of SBIRT for drug misuse are inconsistent depending on the characteristics of the provider, the specific setting, and the patient population that is targeted for SBIRT implementation. While there is robust evidence for screening and referral for depression in primary care, to date, little empirical evidence for the use of comprehensive SBIRT-like models for mental health problems commonly reported by health care patients. There is also no research that has demonstrated the implementation or effectiveness of SBIRT-like models in addressing trauma or anxiety disorders in clinical health settings.

II. THE SAMHSA SBIRT MODEL

SBIRT is a comprehensive, integrated, public health approach to the delivery of early intervention for individuals with risky alcohol and drug use, as well as the timely referral to more intensive substance abuse treatment for those who have substance use disorders. Primary care centers, hospital emergency rooms, trauma centers, and community health settings provide opportunities for early intervention with at-risk substance users before more severe consequences occur.

SAMHSA supports a research based comprehensive behavioral health SBIRT model which reflects the six following characteristics:

1. It is brief. The initial screening is accomplished quickly (modal time about 5-10 minutes) and the intervention and treatment components indicated by the screening results are completed in significantly less time than traditional substance abuse specialty care.

2. The screening is universal. The patients, clients, students, or other target populations are all screened as part of the standard intake process.

3. One or more specific behaviors are targeted. The screening tool addresses a specific behavioral characteristic deemed to be problematic, or pre-conditional to substance dependence or other diagnoses.

4. The services occur in a public health, or other non-substance abuse treatment setting. This may be an emergency department, primary care physician's office, school, etc.

5. It is comprehensive. The program includes a seamless transition between brief universal screening, a brief intervention and/or brief treatment, and referral to specialty substance abuse care.

6. Strong research or substantial experiential evidence supports the model. At a minimum, programmatic outcomes demonstrate a successful approach.

As a comprehensive or model approach, SBIRT has only been demonstrated to be effective for risky alcohol use. There is substantial evidence for the effectiveness of brief interventions for harmful drinking when delivered by a physician or other qualified health professional (Bien et al, 1993; Kahan et al, 1995; Wilk et al, 1993). There is a growing body of literature showing the effectiveness of SBIRT for risky drug use (Madras et al, 2008; Saitz et al, 2010; Bernstein et al., 2005) but the results vary by the characteristics of the provider, the specific setting, and the patient population that is targeted for SBIRT implementation.

To determine the effectiveness of SBIRT beyond alcohol, a comprehensive literature review was conducted. SBIRT-like models including not only a simple screening tool, but also an appropriate and brief intervention that addressed the level of problem indicated by the screening results. Table 1 (p. 4) identifies the substance abuse and mental health conditions where SBIRT or components of SBIRT have been employed. The literature review did not include studies that employed SBIRT or approaches that are similar to SBIRT for general medical conditions such as blood pressure, HIV/AIDS, or other behavioral issues such as domestic violence.

As shown in Table 1, the comprehensive SBIRT model has not been consistently demonstrated as effective in addressing harmful or risky drug misuse, depression, trauma, or anxiety problems. Findings showing the effectiveness of SBIRT for drug misuse are accumulating, and there is some programmatic data from the SAMHSA State SBIRT programs showing promising findings for depression among primary care patients. Public health approaches that are consistent with the SBIRT model have also been demonstrated for tobacco use. They are described in the latter sections of this paper. Table 1 presents a brief analysis of the evidence for the effectiveness of SBIRT for various behavioral health conditions.

Table 1. EFFECTIVENESS OF SBIRT AND ITS COMPONENTS FOR BEHAVIORAL HEALTH CONDITIONS

	Screening	Brief Intervention[1]	Brief Treatment[2]	Referral to Treatment	Evidence for Effectiveness of SBIRT
Alcohol Misuse/Abuse	✓	✓	✓	✓	Comprehensive SBIRT effective (Category B classification, USPSTF)
Illicit Drug Misuse/Abuse	✓	*	*	✓	Growing but inconsistent evidence
Tobacco Use	✓	✓	✓	✓	Effective brief approach consistent with SBIRT (USPSTF; 2008 U.S. Public Health Service (PHS) Clinical Practice Guideline
Depression	✓	—	✓	✓	No evidence to date for depression
Trauma/Anxiety Disorders	✓	*	—	✓	No evidence to date for trauma/anxiety disorders

Key: ✓ Evidence for effectiveness/utility of component

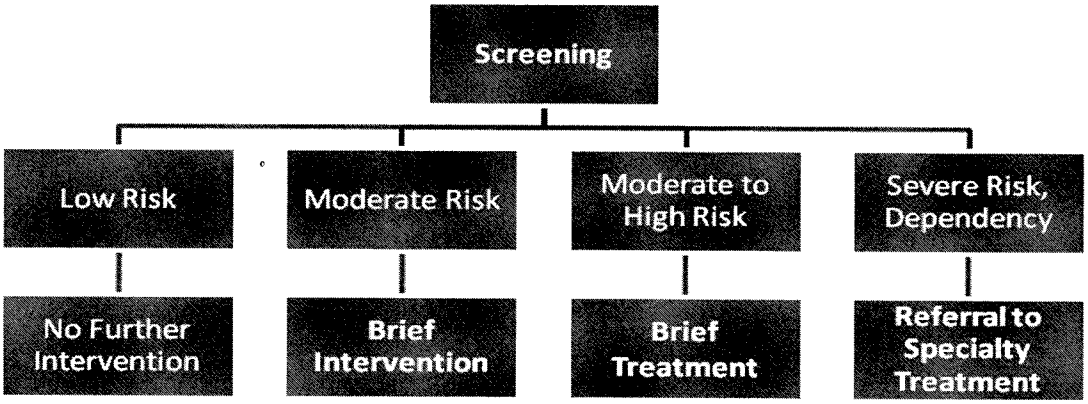
* Component Demonstrated to show Promising Results

— Not Demonstrated and/or Not Utilized

[1]Brief intervention as defined by the SAMHSA SBIRT program involves 1-5 sessions lasting 5 minutes to an hour. Among SBIRT grantees funded by SAMHSA, about 15% of patients receive scores that indicate a brief intervention.

[2]Brief treatment as part of SBIRT involves 5-12 sessions, lasting up to an hour. Among State SBIRT grantees funded by SAMHSA, about 3% of patients receive a score that dictates a brief treatment.

Chart 1. FLOW CHART FOR SBIRT PROCESS



Screening

Universal screening helps identify the appropriate level of services needed based on the patient's risk level. Patients who indicate little or no risky behavior and have a low screening score may not need an intervention. Those who have moderate risky behaviors and/or reach a moderate threshold on the screening instrument may be referred to brief intervention. Patients who score high may need either a brief treatment or further diagnostic assessment and more intensive, long term specialty treatment. Screening typically takes 5-10 minutes and can be repeated at various intervals as needed to determine changes in patients' progress over time. Some commonly used screens for the implementation of SBIRT for alcohol and drug use are the Alcohol Use Disorders Identification Test (AUDIT), Drug Abuse Screening Test (DAST), Alcohol, Smoking, Substance Involvement, Screening Test (ASSIST), and the Cut Down, Annoyed, Guilty, Eye-Opener (CAGE). In addition, a recent study found a single question related to drug use to be effective in detecting drug use among primary care patients (Smith et al., 2010).

Prescreening, which is not a core component of SBIRT but is frequently used, reduces the time needed by busy clinic staff to identify patients with risky behavior. Examples of validated pre-screens are the Alcohol Use Disorders Identification Test-Consumption (AUDIT-C), which consists of the first three alcohol consumption questions from the full 10-item AUDIT questionnaire, and the NIAAA prescreening question ("On any single occasion during the past 3 months, have you had more than 5 drinks containing alcohol?", Taj et al., 1998). If a patient scores high on any domain in the pre-screen, a full screen is conducted.

Brief Intervention (BI) and/or Brief Treatment

Patients are provided with BI, brief treatment, or referral to intensive specialty treatment depending on their level of risk using a validated pre-screen and/or screening tool (Babor & Higgins-Biddle, 2001). With respect to substance abuse, in general only a small proportion of patients in primary care settings screened positive for some level of substance misuse, abuse or dependency. This is usually 5%-20%, but may be as high as 40% in some clinical settings. The majority of patients report minimal or no problems with alcohol or drugs and as such may be an ideal group for primary or universal prevention activities for maintenance of non-risky use or abstinence. The goal of a BI (which usually involves 1-5 sessions lasting about 5 minutes to one hour) is to educate patients and increase their motivation to reduce risky behavior.

The goal of brief treatment (which usually involves 5-12 sessions) is to change not only the immediate behavior or thoughts about a risky behavior but also to address long-standing problems with harmful drinking and drug misuse and help patients with higher levels of disorder obtain more long term care. Based on performance data from state SBIRT grantees funded by SAMHSA, only about 3% receive a score that indicates a brief treatment. Patients referred to a brief treatment often have higher risk factors than those referred to a BI. Brief treatment may also require a manualized course of (advanced) motivational enhancement and cognitive behavioral approaches to help patients address unhealthy cognitions and behaviors associated with current use patterns and adopt change strategies. If patients report greater risk factors than what brief treatment can address, they are referred to specialty substance abuse care. In some cases, a patient may receive a BI first and then move on to a brief treatment or longer term care. Although the time required to execute BI/BT is generally considered brief, it is far too lengthy for physicians to do. Also, physicians cite concerns about angering or insulting patients by bringing up sensitive issues such as alcohol and/or drug use. While these concerns are understandable, when SBIRT is implemented properly, the time commitment is reasonable and acceptably low given the demonstrated success in identifying persons requiring referral to treatment (RT). Similarly, concerns about patient reactions can be neutralized by proper training for the providers and ensuring that access to referral services is available. In addition, SBIRT is frequently implemented by allied health professionals such as nurses, social workers, or health educators, with results and actions noted in the patient chart for physician notification and oversight.

Referral to Treatment (RT)

Referral to treatment can be a complex process involving coordination across different types of services. As such, the absence of linkages to treatment referrals can be a significant barrier to the adoption of SBIRT. Referral is recommended when patients meet the diagnostic criteria for substance dependence or other mental illnesses as defined by the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV).[3] In these cases, a referral to a specialized treatment provider is often made. Referral requires the primary care system to establish new and complex linkages with the traditional specialty care system to connect clients who score in the problematic range to recognized, evidence based treatment in a timely manner. Although only 3% to 4% of screened patients in primary care settings typically need to be referred, the absence of a proper treatment referral will prevent the patient from accessing appropriate and timely care that can impact other psychosocial and medical issues. Research findings suggest that motivational-based BIs can increase patient participation and retention in substance abuse treatment (Hillman et al., 2001; Dunn and Ries, 1997). Strong referral linkages are critical, as well as tracking patient referrals. SAMHSA requires SBIRT grantees to have a comprehensive referral to treatment and follow-up system in place for the duration of the program. In the case where RT is incorporated into an integrated care model, this may require shifts in provider allocation and hiring.

[3] The diagnostic criteria are likely to change when DSM V is released in 2012 or 2013.

The following characteristics of SBIRT identified in the research literature (see Reference section) have been shown to be important in effectively addressing behavioral health problems. They have therefore formed the foundation for the SAMHSA SBIRT programs.

1) Use of brief, validated, universal pre-screening/screening tools. These tools allow health care professionals to address the problem behavior even when the patient is not actively seeking treatment for his or her problem. Prescreening/screening tools accurately and quickly identify individuals with problematic conditions in as little time as 2-4 minutes. Because of its briefness and its universal application (that is, can be used with all patients), SBIRT may be more generally accepted by health care professionals working in busy practices.

2) Relatively easy to learn by diverse providers. The SBIRT approach is easy to learn relative to other behavioral treatment techniques that may require lengthy specialized training. As such, it can be implemented by diverse health professionals who work in busy medical settings such as physicians, nurses, social workers, health educators and paraprofessionals.

3) Incorporation of strong referral linkages to specialty treatment. Approaches that are effective integrate comprehensive strategies that include referral to specialty treatments (Gentillelo, Donavan, Dunn & Rivara, 1999). While RT may be difficult in underserved areas, this should not deter programs from engaging in developing SBI activities as they have beneficial effects separate from the referral. However, the goal is to provide a quick handoff for dependent patients to specialty treatment if the primary care site cannot provide more intensive services for substance abuse. Establishing linkages with specialty care through identification of local treatment service contracts, an MOU agreement between sites, or dedicated central referral services has been a major barrier for many providers in their decision to adopt SBIRT. The availability of well established referral linkages to specialty care is essential to the uptake and maintenance of SBIRT, and closely tracking to confirm patient compliance with treatment is critical to good health care provision. Primary care locations engaged in referral to specialty care make efforts to determine the patient's engagement and participation in treatment, as this may also affect the course of treatment in the general medical practice.

III. ALCOHOL MISUSE, ABUSE, AND PREVENTION

There is substantial evidence from review studies (Babor, 2007; Bein et al, 1993; Kaner, et al., 2009) and meta-analyses of randomized clinical trials (Beich et al., 2003; Bertholet et al, 2005) that show the effectiveness of SBIRT in reducing hazardous drinking in patients presenting in primary care and other health care settings. The U.S. Preventative Services Task Force (USPSTF) has recommended that "behavioral counseling interventions for risky/harmful alcohol use among adult primary care patients can provide an effective public health approach to reducing problematic drinking" (USPSTF, 2004). The USPSTF also concluded that counseling for risky drinkers should include advice to reduce current drinking; feedback about current drinking patterns; and explicit goal-setting, usually for moderation and assistance in achieving the goals.

Research also indicates that despite the robustness of the evidence for SBIRT's effectiveness for unhealthy alcohol drinking, other factors can impact its effects. For example, studies have shown that multiple contacts or sessions (in contrast to a single contact) with a provider can increase the impact of SBIRT in reducing risky alcohol consumption (Brown et al., 2007; Longabaugh et al., 2001). Moreover, demographic factors and psychosocial conditions also have been shown to influence SBIRT's effects on alcohol misuse (Saitz et al., 2006). For example, homelessness makes SBIRT less effective due to the challenges involved in working with this population, and brief interventions have improved linkages with those who can provide assistance to younger men and hospitalized women.

The conduct of universal screening, brief intervention and treatment, and referral to treatment for alcohol disorders has been found to be effective in various healthcare settings for diverse patient populations including primary care (Babor et al., 2007), emergency departments (Gentilello et al., 1999), as well as schools and colleges (O'Brian et al., 2006). Data are currently being collected that suggest that SBIRT may also be effective in addressing alcohol problems in employee assistance programs (McPherson and Goplerud, 2008). Recent research also has demonstrated the efficacy of conducting screenings and BIs using innovative strategies such as the use of personalized feedback via the internet (Cunningham, 2010), as well as web-based outcomes monitoring to assist with treatment decisions and cognitive behavioral techniques (Roy-Bryne, 2010).

Also promising is the utilization of computerized interventions which has been shown to be effective in augmenting and complementing the gains made through the initial face to face brief interventions. The Veterans Administration, for example, examined the use of electronic clinical reminders with patients following screening with the AUDIT-C and showed such approaches reinforced moderate drinking reductions at follow up (Williams, 2010). Other research reviews indicate that electronic methods can enhance brief interventions with substance users by offering assessment and feedback in brief motivational interviewing; monitoring individual treatment patient's progress; tracking patients in aftercare; and providing educational opportunities for clinicians (Cucciare, 2009). Electronic intervention can also help bridge the treatment capacity gap by providing another source of assistance for women who do not complete traditional substance abuse treatment (Van DeMark, et al., 2010). In addition, the cost savings offered by the implementation of SBIRT in primary care are significant. One study (Gentilello, 2005) showed that for every one dollar spent on providing SBIRT approximately $3.81 is saved. The Washington State SBIRT program cost study also reflects similar savings.

The concept of SBIRT can be applied across the continuum of care for alcohol problems. Based on the severity of the problem indicated by the screening results, interventions ranging from universal prevention to brief interventions to traditional specialty treatment can be provided to health care patients. For individuals who are abstinent, universal prevention practices can be implemented to sustain alcohol abstinence. For moderate risky drinking, the first two components of SBIRT – screening and brief interventions (SBI)– may be implemented which can address inappropriate expectancies (beliefs about substance use effects and social norms of acceptable behavior) and lack of motivation to change risk factors that contribute to substance abuse (Dimeff et al., 1999).

Extensive research supports screening and brief intervention as effective universal and selective prevention strategies for alcohol problems. Universal screening with educational content has measurable prevention effects with accompanying feedback (Kunz et al., 2004). The prevention approach may also be successful for abstainers and non-risky drinkers by providing behavioral support and normative information to maintain healthy behaviors. For at-risk individuals, early identification and brief intervention around false expectancies, normative use misperceptions and skills acquisition can prevent progression to severe drinking problems. For example, the BASICS program, which is consistent with the SBIRT approach, has been shown to be effective in addressing problematic or risky drinking in college age groups (Dimeff et al., 1999). SBIs also incorporate motivational interviewing components (Miller and Rollnick, 2002) that are also integrated in brief treatment for higher risk patients. SBIs have proven effective in decreasing overall consumption and binge drinking (Casset et al., 2008; Hanewinkel & Wiborg 2005; Kunz Jr. et al., 2004; Martens et al., 2007; Heather et al., 2004; Toumbourou et al. 2007; Murphy et al., 2001), as well as increasing productivity (Osilla et al., 2010). Evidence further demonstrates that strengthening resiliency, competencies, and social connectedness supports recovery for those individuals who show early symptoms of alcohol misuse.

Extensive reviews of the effectiveness of SBI (Babor et al., 2007, 2008) have found that there are "irrefutable" improvements in short-term health benefits as well as indications of "substantial" long-term benefits. Follow up at three, six or nine month intervals can help document the effectiveness of SBI and reinforces normative ideation and skills enhancement for individuals with minimal risk behaviors. To achieve long term effects, SBI must be implemented with fidelity through targeted training for providers (Cameron et al., 2010; Seale et al., 2005; Christensen et al., 2004; Bray et al., 2009; Ronzani et al., 2008; Furtado et al., 2008; Heather et al., 2004; Tollison et al., 2008; Babor et al., 2004; Brown & Fleming, 1998). In many instances providers implementing SBI may not necessarily be physicians but allied health professionals such as nurses, counselors, health educators, and peers (Mastroleo, 2009; Blume & Marlatt, 2004), who may experience fewer barriers in service provision than physicians (Babor et al., 2004). Also, SBI can be conducted individually or with groups (Shellenberger et al., 2009; Henslee, 2009), with web-based instruments (i.e. college oriented E-Chug and E-Toke or Alcohol Skills Training Programs), or online feedback (Blume & Marlatt, 2004), and applied through strategic planning by communities or providers.

IV. DRUG MISUSE, ABUSE, AND PREVENTION

In 1995, based on the scant availability of published research on SBIRT for drugs, the USPSTF (1995) determined that there was "insufficient evidence to recommend for or against" the effectiveness of using an SBIRT approach for drugs. Some researchers have cited the relative scarcity of validated brief drug screening tools (Smith PC, et. al., 2010) and the low prevalence rates of drug use (Saitz, 2010) in primary care settings, as two reasons for the comparatively small number of studies showing SBIRT's effects with drugs (De Micheli D, et. al., 2004). Nevertheless, since 1995, there has been a growing body of investigator-initiated research as well as findings from SAMHSA-funded SBIRT projects that have shown promising results for the use of the comprehensive SBIRT approach, as well as selected use of individual components, in reducing risky drug use (Copeland et al., 2001). For instance, a randomized controlled trial indicated that BIs can reduce cocaine and heroin use (Bernstein et al., 2005). Motivational

interviewing coupled with a self-help booklet given to regular amphetamine users also resulted in reduced levels of drug use (Baker, Lee, Claire, Lewin, Grant, & Pohlman, 2005). BIs for patients screening positive for cocaine, heroin, and amphetamine are also showing promising results in various settings beyond emergency departments (Cunningham et al., 2009). In small sample sizes, screening and BIs have been linked with reductions in the use of marijuana, amphetamine-type stimulants, cocaine, and heroin (Madras et al., 2008). The World Health Organization (2008) sponsored a multi-national study demonstrating that screening and brief interventions resulted in short-term reductions of a wide variety of illicit drugs, including marijuana, cocaine, amphetamine-type stimulants, and opioids.

As with alcohol consumption, universal and selective prevention efforts may also be targeted to those with minimal or mild drug misuse. Like with alcohol, identified abstainers can benefit from supportive and normative information to maintain healthy lifestyles. For individuals at risk for drug problems, early identification and brief intervention around false expectancies and skill acquisition can prevent progression to more severe drug problems. In addition, tools that can be used for universal screening of drug use in health settings such as the DAST and the ASSIST as well as on-line tools such as E-TOKE (Electronic – THC Online Knowledge Experience) are prevention-ready applications designed to detect the presence of drug use.

V. SBIRT AND TOBACCO USE

The utility of SBIRT approaches for all forms of tobacco use, especially smoking, has been endorsed by the USPSTF and has elicited interest in primary care and hospital personnel. Cigarette smoking continues to be the leading cause of preventable disease and death in the United States (USDHHS, 2004) and is attributed to approximately 443,000 deaths per year (CDCP, 2010) from lung cancer: ischemic heart disease, chronic obstructive pulmonary disease, strokes, and other diagnoses. Smoking also affects health outcomes of people other than the smokers, with smoking during pregnancy resulting in premature births, spontaneous abortions, stillbirths, and intrauterine growth retardation. In addition, research has shown that psychiatric disorders and cigarette smoking are frequently co-morbid conditions (Dome et al, 2010; Brown et al, 2008; Brown et al, 2002; Degenhardt & Hall, 2001; Grant et al, 2004). A recent study using data from the 2005-2006 National Survey on Drug Use and Health reported that adults with lifetime depression, anxiety, anxiety with depression, or major depressive episodes were more likely to be "current smokers, smoke with higher intensity and frequency, have more dependence, and have lower success at quitting" when compared to individuals without these psychiatric conditions (Trosclair & Dube, 2010).

However, despite smoking's established risks and the health benefits of quitting, 23 percent of adults in the United States continue to smoke and more than 2,000 adolescents become regular tobacco users daily (NSDUH, SAMHSA). Nearly 90 percent of smokers start by age 18, and 25 percent of teen smokers remain addicted as adults. Because 70 percent of smokers see a physician each year (Fiore, Bailey, Cohen, et al., 2000) clinicians have a unique opportunity to intervene and implement tobacco SBIRT in primary care settings and emergency departments.

As such, the USPSTF strongly recommends that clinicians screen all adults for tobacco use and provide brief interventions, including screening, brief behavioral counseling (less than 3 minutes), and pharmacotherapy delivered in primary care settings. The USPSTF also strongly

recommends that clinicians screen all pregnant women for tobacco use and provide augmented pregnancy-tailored counseling to those who use tobacco products. These interventions have been shown to be effective in increasing the proportion of smokers who successfully quit smoking and remain abstinent after 1 year.

The USPSTF advises that the clinical interventions for tobacco cessation that are cited in the 2008 U.S. Public Health Service (PHS) Clinical Practice Guideline, *Treating Tobacco Use and Dependence* (Fiore et al, 2008), become integrated in standard clinical practice. The PHS Guideline also recommends that clinicians use the screening instrument known as the 5A's of tobacco use intervention, which provides a useful strategy for engaging all medical patients in smoking cessation discussions. The 5A's are consistent with the SBIRT approach and parallel the screening and brief intervention or counseling components of the SBIRT model.

1. ***Ask*** about tobacco use.
2. ***Advise*** to quit through clear personalized messages.
3. ***Assess*** willingness to quit.
4. ***Assist*** to quit.
5. ***Arrange*** follow-up and support.

The Guideline's behavioral treatments include counseling, social support, problem solving, and cessation skills training offered in face-to-face individual or group formats or via telephone quit lines. Medication assisted treatments for tobacco use/dependence have also been suggested and include seven FDA-approved, first-line medications (i.e., bupropion SR, nicotine gum, inhaler, lozenge, nasal spray, and patch), and two second-line medications (clonidine and nortriptyline).

The Agency for Healthcare Research and Quality (AHRQ) also reviewed tobacco guidelines developed in England in 2006 and supports recommendations for brief interventions for patients who use tobacco products, including: simple advice to stop, assessment of the patients' commitment to quit, an offer of pharmacological or behavioral support, and provision of self help materials or referral to supportive resources such as Quit lines.

VI. DEPRESSION

The USPSTF supports screening for adult depression where accurate diagnosis, effective treatment, and follow-up are available. The USPSTF also recommends screening adolescents (12-18 years of age) for major depressive disorder (MDD), again with accurate diagnosis, psychotherapy (cognitive behavioral or interpersonal), and follow-up. There are many commonly used screening tools for depressive symptoms, such as the Patient Health Questionnaire 2 (PHQ-2) (Kroenke, et al., 2003) and the Patient Health Questionnaire 9 (PHQ-9) (Kroenke, et al., 2001) which both have established validity and reliability.

Primary care physicians are the providers most likely to see patients when they first become depressed and are most capable of initiating and monitoring treatments with pharmacologic agents (McNaughton, 2009). Previous studies, however, have shown that at least half of patients with active depression seen by primary care physicians remain undiagnosed (Spitzer et al, 1994; Schulberg et al., 1988; Ormell et al, (1991). Depression is particularly prevalent among "high

utilizers" of medical care resources, of whom as many as 40% have been found to have a current depressive illness (Katon et.al., 1990). Due to time constraints and training issues, physicians in primary care are often unable to provide effective behavioral interventions and treatments for the patients with mental disorders (McNaughton, 2009).

Promising but preliminary data are available from SBIRT grantees funded by SAMHSA that indicate that the SBIRT approach may be adapted for depression treatment. For example, the State of Wisconsin incorporated depression screening into a Wisconsin Initiative to Promote Healthy Lifestyles (WIPHL) pilot program. Patients with mild or moderate depression were provided behavioral activation by health educators using specific protocols developed by the program.

Behavioral activation also offers promise as a strategy for brief intervention and there is some evidence that it would fit an SBIRT-like approach. Behavioral activation assists individuals to identify and engage in daily activities and situations they find positively reinforcing and consistent with their long-term goals (Dimidjain et al., 2006). Behavioral activation as a brief intervention has been demonstrated in three meta-analyses, one randomized control trial, and one follow-up study of a previous randomized control trial, to be an effective intervention for the treatment of depression (Sturmey, 2009).

VII. ANXIETY DISORDERS AND TRAUMA

Anxiety disorders are among the most common mental health problems seen in primary care settings and as many as one-third of primary care patients have been found to have significant anxiety symptoms (Fifer, 1994). Approximately 15% of primary care patients have a current anxiety disorder, and 24% have had a lifetime anxiety disorder, as assessed by diagnostic interviews (Nisenson et al., 1998). Primary care patients with anxiety disorders typically have considerable disability and impairment in functioning (Roy-Byrne et al., 1999; Sherbourne et al., 1996) and high utilization rates of general medical services which ultimately result in higher health care costs (Simon et al., 1995). Screening tools are also available for anxiety such as the Brief Symptom Checklist-18 (Derogatis, 2001) which provides a measure of both anxiety and depression. The My Mood Monitor (M-3) (Gaynes et al., 2010) screening is a valid and efficient one page tool for screening multiple common psychiatric illnesses in primary care and other settings. The M-3 can function both as a screen for specific anxiety and mood disorder diagnoses, as well as a general screen for the presence of any mood or anxiety disorder in addition to bipolar disorder and PTSD.

Interventions such as passive psychoeducation, including bibliotherapy, have been shown to reduce symptoms of anxiety, psychological distress, and depression (Donker et al., 2009). These approaches may be offered as a brief intervention to patients who screen positive for mild or moderate levels of anxiety. Passive psychoeducational interventions are cost-effective and can be easily put into practice by non medical professionals and may have a less-stigmatizing impact on consumers, especially when delivered through a Web site, e-mail or a brochure (Donker et al., 2009) .

Evidence of emotional trauma is also common in primary care. Walker et al.(1993) report that rates as high as 37% for childhood sexual abuse and 29% for adult sexual assault are evident in primary care settings. Walker et al. found that 61% of women reported that they believed that it was appropriate for their primary care physician to ask about previous victimization, but only 4 percent had been actually asked. In the Adverse Childhood Experiences (ACE) Study (Dube et al., 2004), patients received an assessment using the Family Health History and Health Appraisal questionnaires as measures. The authors found the reliability statistics of the ACE study support the use of these questionnaires for retrospective reports of adverse childhood experiences such as childhood maltreatment, household dysfunction, and other socio-behavioral factors. Other tools for screening trauma and anxiety include: the Trauma Symptom Inventory (Briere, 1995), the PTSD-8 (Hansen, et al., 2010), and the Primary Care PTSD Screen (PC-PTSD) (Prins, et al., 2003).

The National Child Traumatic Stress Network has developed an evidence-based practice which may be suitable for use in a BH SBIRT program. The Trauma Adaptive Recovery Group Education and Therapy for Adolescents and Pre-Adolescents (TARGET-A) has been evaluated in 248 clinical trials with control groups and can be completed in as little as 4 sessions. This intervention is designed for groups and/or individual children, adolescents and their parents that is easily adapted to settings where youth or families enter and leave services rapidly (NCTSN, 2008).

The prevalence of issues such as depression, anxiety, and trauma among primary care patients call for further exploration to determine if certain SBIRT components may be applied to symptoms of these disorders among medical patients. These findings also highlight the value of universal screening, a principal component of SBIRT, in addressing mental health issues in primary care and other health care settings.

VIII. IMPLICATIONS FOR FUTURE PROGRAMS

While there is substantial research for the effectiveness of SBIRT in reducing unhealthy alcohol use and tobacco use/misuse, the evidence for similar models in addressing drug abuse and mental health conditions such as depression, anxiety and trauma is still being developed. As such, SAMHSA would recommend investment in developing SBIRT-like models for most common behavioral health conditions, for use in public health settings. This would involve services research, demonstrations, and conducting rigorous comparative effectiveness evaluations of behavioral health SBIRT programs beyond those already proven effective for alcohol or tobacco, in possible collaboration with NIMH, NIAAA and/or NIDA.

Numerous screening and intervention programs in a variety of settings and populations have recently defined themselves as "SBIRT programs." Most often these programs do not meet the criteria established in this paper to be designated as a comprehensive SBIRT model. Both a strong research base and more consistent terminology and definitions for what constitutes a true SBIRT model are lacking. Although SBIRT and its components have been utilized across programs, the effectiveness of SBIRT programs can vary in their fidelity, application, and comprehensiveness.

In considering the future of SBIRT program implementation, some or all of the following could be pursued:

- Partnership with one or more external, authoritative bodies. This may involve approaching the US Preventative Services Task Force to develop an SBIRT definition and/or taxonomy which reflects the latest science-base approach and is vetted with the field.

- Collaboration with NIH (NIDA, NIMH) and/or AHRQ to conduct more research on SBIRT approaches for drug abuse, depression, anxiety, trauma, etc., to help establish parameters that are critical to effective implementation.

- Diversifying the SAMHSA SBIRT program portfolio and dedicating increased evaluation resources to examine the value of complementing SBIRT for alcohol and drugs with screening and intervention for other behavioral health conditions.

References

Amaral, M.B., Ronzani, T.M., Souza-Formigoni, Maria, L.O. (2010). Process evaluation of the implementation of a screening and brief intervention program for alcohol risk in primary health care: An experience in Brazil. *Drug and Alcohol Review,* 29 (2), 162-168.

Amaro, H., Reed, E., Rowe, E., Picci, J., Mantella, P., et al. (2010). Brief screening and intervention for alcohol and drug use in a college student health clinic: Feasibility, implementation, and outcomes. *Journal of American College Health, 58*(4), 357–364.

American Psychiatric Association. (2000). *Diagnostic and statistical manual of mental disorders* (4th ed., text revision). Washington, DC: Author.

APA Achievement Awards (2010). A new direction in depression treatment in Minnesota, DIAMOND program, Institute for Clinical Systems Improvement, Bloomington, Minnesota. *Psychiatric Services*, 61(10), 1042-1044.

Arndt, S., Schultz, S. K., Turvey, C., & Petersen, A. (2002). Screening for alcoholism in the primary care setting: Are we talking to the right people? *Journal of Family Practice, 51*(1), 41–46.

Babor, T. F., McRee, B. G., Kassebaum, P. A., Grimaldi, P. L., Ahmed, K., & Bray, J. (2007). Screening, Brief Intervention, and Referral to Treatment (SBIRT): Toward a public health approach to the management of substance abuse. *Substance Abuse*, *28*(3), 7–30.

Babor, T.F. (2008). Taking stock: Twenty-five years of translational research on alcohol screening and brief intervention. *NAT: Nordisk Alkohol & Narkotikatidskrift,* 25(6), 578-580.

Babor, T. F., & Higgins-Biddle, J. C. (2000). Alcohol screening and brief intervention: Dissemination strategies for medical practice and public health. *Addiction, 95*, 677–686.

Babor, T. F., Higgins-Biddle J., Dauser, D., Higgins P, & Burleson, J. (2005). Alcohol screening and brief intervention in primary care settings: Implementation models and predictors. *Journal on Studies of Alcohol and Drugs, 66*(3), 361–369.

Babor, T., Higgins-Biddle, J., Higgins, P., Gassman, R., Gould, B. Training Medical Providers to Conduct Alcohol Screening and Brief Interventions. *Substance Abuse,* 25 (1), 17-26.

Babor, T., McRee, B., Kassebaum, P., Grimaldi, P., Ahmed, K., Bray, J. (2007). Screening, Brief Intervention, and Referral to Treatment (SBIRT). *Substance Abuse,* 28 (3), 7-30.

Baer, J.S., Kivlahan, D.R., Blume, A.W., McKnight, P., & Marlatt, A. (2001). Brief intervention for heavy-drinking college students: 4 Year follow-up and natural history. *American Journal of Public Health,* 91(8), 1310-1316.

Baker, A., Lee, N. K., Claire, M., Lewin, T. J., Grant, T., & Pohlman, S. (2005). Brief cognitive behavioural interventions for regular amphetamine users: A step in the right direction. *Addiction, 100*, 367–378.

Barry, D. (2002). Brief Alcohol Screening and Intervention for College Students (BASICS): A Harm Reduction Approach. *Journal of Psychiatry & Law*, 30 (2), 275-9.

Begun,A. L., Rose, S.J., LeBel, T. P., & Teske-Young, B. A. (2009). Implementing Substance Abuse Screening and Brief Motivational Intervention With Women in Jail. *Journal of Social Work Practices in the Addictions, 9*(1), 113–131.

Beich, A., Gannik, D., Malterud, K. (2002). Screening and brief intervention for excessive alcohol use: Qualitative interview study of the experiences of general practitioners. *British Medical Journal,* 325 (7369), 870-870.

Beich, A., Thorsen, T., & Rollnick, S. (2003). Screening in brief intervention trials targeting excessive drinkers in general practice: Systematic review and meta-analysis. *BMJ, 327*, 536–542.

Bernstein, E., Bernstein, J., & Levenson, S. (1997). Project ASSERT: An ED-based intervention to increase access to primary care, preventive services, and the substance abuse treatment system. *Annals of Emergency Medicine, 30*, 181–189.

Bernstein, J., Bernstein, E., Tassiopoulos, K., Heeren, T., Levenson, S., & Hingson, R. (2005). Brief motivational intervention at a clinic visit reduces cocaine and heroin use. *Drug Alcohol Dependence, 77*(1), 49–59.

Bernstein E., Topp D., Shaw E., Girard C., Pressman K., Woolcock E., Bernstein J., (2009). A preliminary report of knowledge translation: Lessons from taking screening and brief intervention techniques from the research setting into regional systems of care. *Academic Emergency Medicine,* 16 (11), 1225-33.

Bertholet, N., Daeppen, J.-B., Wietlisbach, V., Fleming, M., & Burnand, B. (2005). Reduction of alcohol consumption by brief alcohol intervention in primary care: systematic review and meta-analysis. *Archives of Internal Medicine* 165, 986–995.

Bien, T., Miller, W. R., & Tonigan, J. S. (1993). Brief interventions for alcohol problems: A review. *Addiction, 88,* 315–336.

Blume, A.W.; Marlatt, G. A. (2004). Motivational Enhancement as a Brief Intervention for College Student Drinkers. *In: Handbook of Motivational Counseling: Concepts, Approaches, and Assessment,* 409-420. New York, NY: John Wiley & Sons Ltd.

Bondy, S. J., Rehm, J., Ashley, M. J., Walsh, G., Single, E., & Room, R. (1990). Low-risk drinking guidelines: the scientific evidence. *Canadian Journal of Public Health, 90*(4), 264–70. [PMID: 10489725]

Borsari, B.; Carey, K. B. (2000). Effects of a brief motivational intervention with college students. *Journal of Consulting and Clinical Psychology*, 68(4),728-733.

Bradley, K. A., DeBenedetti, A. F., Volk, R. J., Williams, E. C., Frank, D., & Kivlahan, D. R. (2007). AUDIT-C as a brief screen for alcohol misuse in primary care. *Alcoholism, Clinical and Experimental Research, 31,* 1208–1217.

Bray, J., Mills, M., Bray, Lessell M., Lennox, R., McRee, B., Goehner, D., Higgins-Biddle, J. (2009). Evaluating web-based training for employee assistance program counselors on the use of screening and brief intervention for at-risk alcohol use. *Journal of Workplace Behavioral Health,* 24 (3). 307-319.

Bray, J.W., Zarkin, G.A., Davis, K.L., Mitra ,D., Higgins-Biddle, J.C., Babor, T.F. (2007). The effect of screening and brief intervention for risky drinking on health care utilization in managed care organizations. (eng), *Medical Care,* 45 (2), 177-82.

Brewin, C. (2005). Systematic review of screening instruments for adults at risk of PTSD. *Journal of Traumatic Stress*. Feb; 18(1): 53-62

Briere, J. (1995). Trauma Symptom Inventory professional manual. Odessa, FL: Psychological Assessment Resources

Brown, R.L., Fleming, M.F., (1998). Training the trainers: substance abuse screening and intervention. (eng), *International Journal of Psychiatry in Medicine,* 28 (1), 137-46.

Brown, R. L., Saunders, L. A., Bobula, J. A., Mundt, M. P., & Koch, P. E. (2007). Randomized-controlled trial of a telephone and mail intervention for alcohol use disorders: Three-month drinking outcomes. *Alcoholism, Clinical and Experimental Research, 31*(8), 1372–1379.

Bruce, M. L., Ten Have, T. R., Reynolds III C.F., et al. (2004). Reducing suicidal ideation and depressive symptoms in depressed older primary care patients: a randomized controlled trial. *JAMA,* 294, 1081-1091.

Cameron, Jacqui; Lee, Nicole; Harney, Angela. (2010). Changes in attitude to, and confidence in, working with comorbidity after training in screening and brief intervention. *Mental Health and Substance Use: Dual Diagnosis*, 3(2), 24-130.

Casset J.C., Bérenger P., Bosson J.L., Lacroix A., (2008). Evaluation à 1 an de l'intervention brève pratiquée par des médecins généralistes chez des patients ayant un mésusage d'alcool. *La Revue Du Praticien,* 58 (12), 25-31.

Center for Substance Abuse Treatment. (1999). *Brief interventions and brief therapies for substance abuse.* Treatment Improvement Protocol 34. HHS Publication No. (SMA) 99-3353. Rockville, MD: Substance Abuse and Mental Health Services Administration.

Charbonney, Emmanuel (2009). Alcohol, drugs and trauma: Consequences, screening and intervention in 2009. *Trauma,* 12 (1) 5-12.

Chisholm, D. J., Young, R. R., & McAlearney, A. S. (2005). Implementation of a touch-screen new patient registration system: A case study. *Journal of Medical Practice & Management, 21*(3), 159–162.

Christensen, M.H., Boisse, N., Sanchez, W., Friedmann, P.D. (2004). Enhancing vocational rehabilitation counselors' substance abuse screening and brief intervention practices. *Journal of Vocational Rehabilitation,* 21 (3), 157-163.

Cole, M. G., Dendukuri, N. (2004). The feasibility and effectiveness of brief interventions to prevent depression in older subjects: a systematic review. *International Journal of Geriatric Psychiatry, 19,* 1019-1025.

Copeland, J., Swift, W., Roffman, R., & Stephens, R. (2001.) A randomized controlled trial of brief cognitive-behavioral interventions for cannabis use disorder. *Journal of Substance Abuse Treatment. 21*(2), 55–64.

Corrao, G., Bagnardi, V., Zambon, A., & Arico, S. (1999). Exploring the dose-response relationship between alcohol consumption and the risk of several alcohol-related conditions: a meta-analysis. *Addiction, 94,* 1551–1573.

Covell, N., Essock, S., Felton, C., and Donahue, S. (2006). Characteristics of Project Liberty clients that predicted referrals to intensive mental health services. Psychiatric Services, 57(9), 1313-1315.

Crawford et al. (2010). The effect of referral for brief intervention for alcohol misuse on repetition of deliberate self-harm: an exploratory randomized controlled trial. Psychological Medicine, 40, 1-8.

Cucciare MA, Weingardt KR, Humphreys K. (2009). How Internet technology can improve the quality of care for substance use disorders. *Curr Drug Abuse Rev,* Sep;2(3):256-2.

Cuijpers, P., van Straten, A., van Schaik, A., Andersson, G., (2009). Psychological treatment of depression in primary care: a meta-analysis. British Journal of General Practice, 59(559), 51-60.

Cunningham, R., Bernstein, S., Walton, M., Broderick, K., Vaca, F., & Woolard, R., et al. (2009). Alcohol, Tobacco, and Other Drugs: Future Directions for Screening and Intervention in the Emergency Department. *Academic Emergency Medicine, 16*:1078–1088

Daeppen, J. B., Gaume, J., Bady, P., Yersin, B., Calmes, J. M., & Givel, J. C., et al. (2007). Brief alcohol intervention and alcohol assessment do not influence alcohol use in injured patients treated in the emergency department: A randomized controlled clinical trial. *Addiction, 102,* 1224 –1233.

Donker, T., Griffiths, K.M., Cuijpers, P., & Christensen, H. (2009) Psychoeducation for depression, anxiety and psychological distress: a meta-analysis. *BMC Medicine*, 7(79).

De Micheli, D, Fisberg M, Formigoni ML. (2004). Study on the effectiveness of brief intervention for alcohol and other drug use directed to adolescents in a primary health care unit. *Rev Assoc Med Bras,* 50:305-13.

Derogatis, L. R. (2001). Brief Symptom Inventory (BSI)-18: Administration, scoring and procedures manual. Minneapolis, MN: NCS Pearson.D'Onofrio, G., & Degutis, L. C. (2002). Preventive care in the emergency department: Screening and brief intervention for alcohol problems in the emergency department: A systematic review. *Academic Emergency Medicine, 9,* 627–638.

D'Onofrio, G., Bernstein, E., Bernstein, J., Woolard, R. H., Brewer, P. A., & Craig, S. A., et al. (1998). Patients with alcohol problems in the emergency department, part 2: Intervention and referral. SAEM Substance Abuse Task Force. *Academic Emergency Medicine*, *5*, 1210–1217.

Diehl, A., Nakovics, H., Bernhard, C., Reinhard, I., Kiefer, F., & Mann, K. (2007). Consultation-liaison psychiatry in general hospitals: improvement in physicians' detection rates of alcohol use disorders. *Journal of Psychosomatics*, 50, 599-604.

Donker, T., Griffiths, K., Cuijpers, P., Christensen, H. (2009). Psychoeducation for depression, anxiety and psychological distress: A meta-analysis. *BMC Medicine*7(79).

Dube, SR, Williamson, DF, Thompson, T, Felitti, VJ, Anda, RF (2004). Assessing the reliability of retrospective reports of adverse childhood experiences among adult HMO members attending a primary care clinic. *Child Abuse and Neglect*, 28, 729-737.

Dimidjian, S., et al. (2006). "Randomized Trial of Behavioral Activation, Cognitive Therapy, and Antidepressant Medication in the Acute Treatment of Adults With Major Depression". *Journal of Consulting and Clinical Psychology* 74 (4): 658–670.

Dunn, C. W., & Ries, R. (1997). Linking substance abuse services with general medical care: Integrated, brief interventions with hospitalized patients. *American Journal of Drug and Alcohol Abuse*, *23*, 1–13.

Dyches, H., Alemagno, S., Llorens, S. A., & Butts, J. M. (1999). Automated telephone-administered substance abuse screening for adults in primary care. *Health Care Management Science, 2*(4), 199–204.

Elvy, G. A., Wells, J. E., & Baird, K. A. (1988). Attempted referral as intervention for problem drinking in the general hospital. *British Journal of Addiction, 83*, 83–89.

Emmen, M. J., Schippers, G. M., Bleijenberg, G., & Wollersheim, H. (2004). Effectiveness of opportunistic brief interventions for problem drinking in a general hospital setting: Systematic review. *BMJ. 328*(7435), 318.

Falk, D. E., Yi, H. Y., & Hiller-Sturmhöfel, S. (2006). An epidemiologic analysis of co-occurring alcohol and tobacco use and disorders: Findings from the National Epidemiologic Survey on Alcohol and Related Conditions. *Alcohol Research & Health, 29*, 162–171.

Ford, JD, and Russo, E. (2006). Trauma-focused, present-centered, emotional self-regulation approach to integrated treatment for posttraumatic stress and addiction: Trauma adaptive recover group education and therapy (TARGET). American Journal of Psychotherapy, 60(4), 335-355.

Fleming, M. F., Barry, K. L., Manwell, L. B., Johnson, K., & London, R. (1997). Brief physician advice for problem alcohol drinkers: A randomized controlled trial in community-based primary care practices. *JAMA, 277*, 1039–1045.

Fleming M.F., Graham A.W. (2001). Screening and brief interventions for alcohol use disorders in managed care settings. (eng), *Recent Developments in Alcoholism: An Official Publication of The American Medical Society on Alcoholism, The Research Society on Alcoholism, and The National Council on Alcoholism,* 15, 393-416.

Fleming, M.F.; Mundt, M.P.; French, M.T., Manwell, L. B., Stauffacher, E. A., Barry, K. L. (2002). Brief physician advice for problem drinkers: Long-term efficacy and benefit-cost analysis. *Alcoholism: Clinical and Experimental Research, 26*(1), 36–43.

Fornili, K., Alemi, F. (2007). Medicaid Reimbursement for Screening and Brief Intervention: Amending the Medicaid State Plan and Approving State Appropriations for the Medicaid State Match. *Journal of Addictions Nursing,* 18 (4), 225-232.

Foy, J., ed. (2010). Enhancing pediatric mental health care: Report from the American Academy of Pediatrics task force on mental health. *Pediatrics*, June, 125, supplement 3, S69-S160.

Funderburk, J. S., Maisto, S. A., & Sugarman, D. (2008). Brief alcohol intervention and multiple risk factors in primary care. *Substance Abuse, 28*(4), 93–105.

Furtado, E. F.; Corradi-Webster, C. M.; Laprega, M. R. (2008). Implementing brief interventions for alcohol problems in the public health system in the region of Ribeirao Preto, Brazil: Evaluation of the PAI-PAD training model. *NAT: Nordisk Alkohol & Narkotikatidskrift,* 25(6), 539-551.

Gallo, J., Zubritsky, C., Maxwell, J., et al. (2004). Primary care clinicians evaluate integrated and referral models of behavioral health care for older adults: results from a multisite effectiveness trial (PRISM-E). Annals of Family Medicine, 2(4).

Gaynes et al. (2010). Feasibility and diagnostic validity of the M-3 checklist: a brief, self-rated screen for depressive, bipolar, anxiety, and post-traumatic stress disorders in primary care. Annals of Famiy Medicine, Mar-Apr, 8(2): 160-9.

Gentilello, L. M., Donovan, D. M., Dunn, C. W., Rivara, F. P. (1999). Alcohol interventions in a trauma center as a means of reducing the risk of injury recurrence. *Annals of Surgery, 230,* 1–18.

Gilbody, S., House, A., Sheldon, T., (2009). Screening and case finding instruments for depression (review). *The Cochrane Library, 3,* 1-30.

Grupp-Phelan, J., et al. (2009). Referral and resource use patterns for psychiatric-related visits to pediatric emergency departments. Pediatric Emergency Care, 25(4), 217-220.

Guevara, J., Greenbaum, P., Shera, D., Bauer, L., and Scharz D. (2009). Survey of mental health consultation and referral among primary care physicians. (2009). *Academic Pediatrics, 9*(2), 123-127.

Hanewinkel, Reiner; Wiborg, Gudrun (2005). Brief alcohol screening and intervention for college students (BASICS): A German pilot study. *Sucht: Zeitschrift für Wissenchaft und Praxis,* 51(5), 285-290.

Hansen, M., Andersen, T. Armour, C Elklit, A., Palic, S., and Mackrill, T. (2010). PTSD-8: A short PTSD inventory. *Clinical Practice & Epidemiology in Mental Health, 6,* 101-108

Heather, Nick; Dallolio, Emma; Hutchings, Deborah; Kaner, Eileen; White, Martin (2004). Implementing routine screening and brief alcohol intervention in primary health care: A Delphi survey of expert opinion. *Journal of Substance Abuse,* 9(2), 68-85.

Henslee, A.M. (2009 Providing personalized feedback regarding alcohol use in a group format to college freshmen. *Dissertation Abstracts International: Section B: The Sciences and Engineering,* 69(10-B), 6414.

Hillman, A., McCann, B., & Walker, N. P. (2001). Specialist alcohol liaison services in general hospitals improve engagement in alcohol rehabilitation and treatment outcome. *Health Bulletin, 59,* 420-423.

Hungerford, D.W., Williams, J.M., Furbee, P.M., Manley, W.G. 3rd, Helmkamp, J.C., Horn, K., Pollock, D.A. (2003). Feasibility of screening and intervention for alcohol problems among young adults in the ED. *The American Journal of Emergency Medicine,* 21 (1) 14-22.

Hungerford, D. W., & Pollock, D. A. (2003). Emergency department services for patients with alcohol problems: Research directions. *Academy of Emergency Medicine, 10*(1), 79–84.

Kahan, M., Wilson, L., & Becker, L. (1995). Effectiveness of physician-based interventions with problem drinkers: A review. *Canadian Medical Association Journal, 152,* 851–859.

Kaner, E. F. S., Beyer, F., Dickinson, H. O., Pienaar, E., Campbell, F., Schlesinger, C., et al. (2009). Effectiveness of brief alcohol interventions in primary care populations. *Cochrane Database of Systematic Review, 18*(2), CD004148.

Kaner, E. F., Dickinson, H. O., Beyer, F., Pienaar, E., Schlesinger, C., & Campbell, F., et al. (2009). The effectiveness of brief alcohol interventions in primary care settings: A systematic review. *Drug and Alcohol Review, 28*(3), 301–323.

Kroenke K, Spitzer R L, Williams J B. The PHQ-9: validity of a brief depression severity measure. Journal of General Internal Medicine 2001; 16(9): 606-613

Kroenke K, Spitzer RL, Williams JB. The Patient Health Questionnaire-2: Validity of a two-item depression screener. *Med Care*. 2003; 41(11):1284-1292.

Kraemer, K. (2007). The Cost-Effectiveness and Cost-Benefit of Screening and Brief Intervention for Unhealthy Alcohol Use in Medical Settings. *Substance Abuse,*28 (3), 67-77.

Kunz F.M. Jr, French M.T., Bazargan-Hejazi S. (2004). Cost-effectiveness analysis of a brief intervention delivered to problem drinkers presenting at an inner-city hospital emergency department. *Journal of Studies on Alcohol,* 65 (3), 363-70.

Larimer, Mary E.; Cronce, Jessica M.; Lee, Christine M.; Kilmer, Jason R. (2004). Brief Intervention in College Settings. *Alcohol Research & Health*, 28 (2), 94-104.

Levkoff, S. E., Chen, H., Coakley E., et al. (2002). Design and sample characteristics of the PRISM-E multisite randomized trail to improve behavioral health care for the elderly. *Journal of Aging Health*, 16, 3-27.

Levy, S., & Knight, J. R. (2008). Screening, brief intervention, and referral to treatment for adolescents. *Journal of Addiction Medicine, 2*(4), 215–221

Longabaugh, R., Woolard, R. F., Nirenberg, T. D., Minugh, A. P., Becker, B., & Clifford, P. R., et al. (2001). Evaluating the effects of a brief motivational intervention for injured drinkers in the emergency department. *Journal on Studies of Alcohol and Drugs*, *62*, 806–16.

Ludman, E., Katon, W., Bush T., Rutter, C., Lin, E., & Simon, G., et al. (2003). Behavioral factors associated with symptom outcomes in a primary care-based depression prevention intervention trial. *Psychological Medicine, 33,* 1061-1070.

Luoma, J, Martin, C., Pearson, J. (2002) Contact with mental health and primary care providers before suicide: a review of the evidence. *American Journal of Psychiatry*. Jun,159(6) :909-16.

Madras, B. K., Compton, W. M., Avula, D., Stegbauer, T., Stein, J. B., & Clark, H. W. (2008). Screening, brief interventions, referral to treatment (SBIRT) for illicit drug and alcohol use at multiple healthcare sites: Comparison at intake and 6 months later. *Drug Alcohol Dependence,* doi:10.1016/j.drugalcdep.2008.08.003

Magill M, Barnett NP, Apodaca TR, Rohsenow DJ, Monti PM. (2009). The role of marijuana use in brief motivational intervention with young adult drinkers treated in an emergency department. *J Stud Alcohol Drugs.70* (3):409-13.

Mallett, K., Bachrach, R., Turrisi, R. (2009). Examining the Unique Influence of Interpersonal and Intrapersonal Drinking Perceptions on Alcohol Consumption Among College Students. *Journal of Studies on Alcohol and Drugs,* 70 (2), 178-185.

Marlatt, G. A., Baer, J. S., Dimeff, L. A., Larimer, M. E., Quigley, L. A., & Somers, J. M., et al. (1998). Screening and brief intervention for high-risk college student drinkers: Results from a 2-year follow-up assessment. *Journal of Consulting and Clinical Psychology*, 66, 604-615.

Marsden, J., Stillwell, G., Barlow, H., Boys, A., Taylor, C., & Hunt, N., et al. (2006). An evaluation of a brief motivational intervention among young ecstasy and cocaine users: no effect on substance and alcohol use outcomes. *Addiction. 101*(7), 1014–1026.

Martens, M. P.; Cimini, M. D.; Barr, A. R.; Rivero, E. M.; Vellis, P.A.; Desemone, G. A.; Horner, K. J. (2007). Implementing a screening and brief intervention for high-risk drinking in university-based health and mental health care settings: Reductions in alcohol use and correlates of success. *Addictive Behaviors* 32(11), 2563-2572.

Mastroleo, Nadine R. (2009). Comparison of supervision training techniques in a motivational enhancement intervention on college student drinking. *Dissertation Abstracts International Section A: Humanities and Social Sciences*, 69(11-A), 4254.

McNaughton, J. (2009). Brief interventions for depression in primary care: a systematic review. *Canadian Family Physician*, Aug , 55(8) 789-96.

McPherson, T. L, Goplerud, E., Olufokunbi-Sam, D., Jacobus-Kantor, L., Lusby-Treber, K. A., et al. (2009). Workplace Alcohol Screening, Brief Intervention, and Referral to Treatment (SBIRT): A Survey of Employer and Vendor Practices. *Journal of Workplace Behavioral Health, 4*(3), 285–306.

McQueen, J., Howe, T. E., Allan, L., & Mains, D. (2009). Brief interventions for heavy alcohol users admitted to general hospital wards (review). Cochrane Database Syst Rev, 3:CD005191.

McRee, B., Babor, T.F.. Maranjian Church, O. (2002). Instructor's Manual for Alcohol Screening & Brief Intervention. *Instructor's Manual for Alcohol Screening & Brief Intervention,* 61.

McRee, B., Granger, J., Babor T. F., Feder, I., Folino, M., et al. (2005). Reducing tobacco use and risky drinking in underserved populations: The need for better implementation models. *Annals of Family Medicine, 3*(2), 558–560

Mertens, J. R., Weisner, C., Ray, G. T., Fireman, B., & Walsh, K. (2005). Hazardous drinkers and drug users in HMO primary care: prevalence, medical conditions, and costs. *Alcoholism, Clinical and Experimental Research, 29*, 989–998.

Meyer, F., Peteet, J., Joseph R. (2009). Models for co-occurring mental and medical disorders. *Harvard Reveiew of Psychiatry*, Nov/Dec, 353-360.

Miller, W. R., & Rollnick, S. (2002). Motivational interviewing: Preparing people for change. (2nd ed.) New York, NY: The Guilford Press.

Modesto-Lowe, V., & Boornazian, A. (2000). Screening and brief intervention in the management of early problem drinkers: Integration into healthcare settings. *Disease Management & Health Outcomes, 8*(3), 129–137.

Moos, R. H., & Moos, B. S. (2003). Long-term influence of duration and intensity of treatment on previously untreated individuals with alcohol use disorders. *Addiction, 98*(3), 325–337.

Morrissey, J., Jackson, E., Ellis, A., Amaro, H., Brown, V., & Najavits L. (2005). Twelve-month outcomes of trauma-informed interventions for women with co-occurring disorders. *Psychiatric Services*, 56(10), 1213-1221.

Moyer, A., Finney, J., Swearingen, C., & Vergun, P. (2002). Brief interventions for alcohol problems: A meta-analytic review of controlled investigations in treatment-seeking and non-treatment-seeking populations. *Addiction, 97*, 279–292.

Murphy, J. G., Duchnick, J. J., Vuchinich, R. E., Davison, J. W., Karg, R. S. et al. (2001). Relative efficacy of a brief motivational intervention for college student drinkers. *Psychology of Addictive Behaviors, 15*(4), 373–379.

National Institute on Alcohol Abuse and Alcoholism (NIAAA). (2005a). *Alcohol alert number 66: Brief interventions*. Rockville, MD: U.S. Department of Health and Human Services, National Institute on Alcohol Abuse and Alcoholism. Retrieved June 4, 2010 from http://pubs.niaaa.nih.gov/publications/AA66/AA66.pdf.

Nisenson, LG, Pepper, CM, Schwenk, TL & Coyne, JC (1998). The nature and prevalence of anxiety disorders in primary care. General Hospital Psychiatry, 20, 21-28.

O'Brien, M. C., McCoy, T. P., Champion, H., Mitra, A., Robbins, A., & Teuschlser, et al. (2006). Single question about drunkenness to detect college students at risk for injury. *Academic Emergency Medicine, 13*(6), 629–636

Olfson, M., Shea, S., Feder, A., Fuentes, M., Nomura, Y., & Gameroff, M., et al. (2000). Prevalence of anxiety, depression, and substance use disorders in an urban general medicine practice. *Archives of Family Medicine, 9*(9), 876–883.

Osilla, K.C.; Cruz, E. dela; Miles, J. N.V.; Zellmer, S.; Watkins, K.; Larimer, M. E.; Marlatt, G. A.. (2010). Exploring productivity outcomes from a brief intervention for at-risk drinking in an employee assistance program. *Addictive Behaviors,* 35 (3) 194-200.

Oslin, D. W., Sayers, S., Ross, J., et al. (2003). Disease management for depression and at-risk drinking via telephone in an older population of veterans. *Psychosomatic Medicine*, 65, 931-937.

Palmer, et al. *(2003).* Screening for depression in medical care: Pitfalls, alternatives, and revised priorities. *Journal of Psychosomatic Research, 54, 279-287.*

Paperny, D. M. N. (1997). Computerized health assessment and education for adolescent HIV and STD prevention in health care settings and schools. *Health Education & Behavior*, *24*(1), 54–70.

Paperny, D. M. N., Aono, J., Lehman, R., Hammar, S., & Risser, J. (1990). Computer-assisted detection and intervention in adolescent high-risk health behaviors. *Journal of Pediatrics, 116*(3), 453–462.

Peltzer K., Seoka, P., Babor, T., Obot, I. (2006). Training primary care nurses to conduct alcohol screening and brief interventions in South Africa. (eng), *Curationis,* 29 (2), 16-21. Prevention of "Risky" Drinking among Students at a Brazilian University Alcohol and Alcoholism: International Journal of the Medical Council on Alcoholism. *International Journal of the Medical Council on Alcoholism,* (2008). 43 (4), 470-476.

Prins A, Ouimette P, Kimerling R et al. (2003). The primary care PTSD screen (PC-PTSD): Development and operating characteristics. *Primary Care Psychiatry, 9*: 9–14.

Regar, M. A., Gahm, G. A., Swanson, R. D., Duma, S. J. (2009). Association between number of deployments to Iraq and mental health screening outcomes in US Army soldiers. *Journal of Clinical Psychiatry, 70*(9), 1266-1272.

Reid, M. C., Fiellin, D. A., & O'Connor, P. G. (1999). Hazardous and harmful alcohol consumption in primary care. *Archives of Internal Medicine, 159*(15), 1681–1689. [PMID: 10448769]

Resick, PA (2001). Cognative therapy for posttraumatic stress disorder. Journal of Cognitive Psychotherapy: An International Quarterly, 15(4), 321-329.

Richmond, R., Heather, N., Wodak, A., Kehoe, L., & Webster, I. (1995). Controlled evaluation of a general practice-based brief intervention for excessive drinking. *Addiction, 90*(1), 119–132.

Rinfrette, E. S. (2009). Treatment of anxiety, depression, and alcohol disorders in the elderly: social work collaboration in primary care. *Journal of Evidence-Based Social Work, 6,* 79-91.

Rivara, F. P., Tollefson, S., Tesh, E., & Gentilello, L. M. (2000). Screening trauma patients for alcohol problems: Are insurance companies barriers? *Journal of Trauma, 48*(1), 115–118.

Roberts, N. P., Kitchiner, N. J., Kenardy, J., & Bisson, J. I. (2009). Systematic review and meta-analysis of multiple-session early interventions following traumatic events. *American Journal of Psychiatry, 166* (3), 293-301

Roche, A. M., & Freeman, T. (2004). Brief interventions: Good in theory but weak in practice. *Drug and Alcohol Review, 23*(1), 11–18.

Ronzani, T. M., do Amaral, M., Bitarello; Souza-Formigoni, M. L. O., Babon, T. F. (2008). Evaluation of a training program to implement alcohol screening, brief intervention and referral to treatment in primary health care in Minas Gerais, Brazil. *NAT: Nordisk Alcohol & Narkotikatidskrift,* 25(6), 529-538.

Ronzani T.M., Mota D.C., Souza I.C., (2009). Alcohol prevention within primary care in municipalities in the state of Minas Gerais, Southeastern Brazil. *Revista De Saúde Pública,* (43), 51-61.

Roy-Byrne, P., Craske, M. G., Sullivan, G., Rose, R. D., Edlund, M. J., & Lang, A. J. et al. (2010). Delivery of evidence-based treatment for multiple anxiety disorders in primary care a randomized controlled trial. *JAMA, 303*(19), 1921–1928.

Rueda S, Park-Wyllie LY, Bayoumi AM, Tynan AM, Antoniou TA, & Rourke SB, et al. (2006). Patient support and education for promoting adherence to highly active antiretroviral therapy for HIV/AIDS. *Cochrane Database Syst Rev. 19* (3):CD001442.

Saitz, R. (2010). Candidate Performance Measures for Screening for, Assessing, and Treating Unhealthy Substance Use in Hospitals: Advocacy or Evidence-Based Practice? Commentary from the Ann Intern Med. 2010;153:40-43.

Saitz, R., Helmuth, E. D., Aromaa, S. E., Guard, A., Belanger, M., et al. (2004). Web-based screening and brief intervention for the spectrum of alcohol problems. *Preventive Medicine, 39,* 969–975.

Saitz, R., Horton, N. J., Sullivan, L. M., Moskowitz, M. A., & Samet, J. H. (2003). Addressing alcohol problems in primary care: A cluster randomized, controlled trial of a systems intervention. *Annals of Internal Medicine, 138*(5), 372–382.

Saitz R, Svikis D, D'Onofrio G, et al. Challenges applying alcohol brief intervention in diverse practice settings: Populations, outcomes, and costs. *Alcohol Clin Exp Res.* 2006; 30:332–338.

Saitz, R., Palfa, T. P., Cheng, D. M., Horton, N. J., Freedner, N., & Dukes, K. et al. (2007). Brief intervention for medical inpatients with unhealthy alcohol use: a randomized, controlled trial. *Annals of Internal Medicine, 146*, 167–176.

SAMHSA's National Registry for Evidence-Based Programs and Practices. (2008). Brief alcohol screening and intervention for college students (basics). Retrieved on June 4, 2010 from http://nrepp.samhsa.gov/programfulldetails.asp?PROGRAM_ID=156

Schermer C.R. (2005). Feasibility of alcohol screening and brief intervention. (eng). *The Journal of Trauma*, 59, S119-23.

Schermer, C. R., Gentilello, L. M., & Hoyt, D. B. (2003). National survey of trauma surgeons' use of alcohol screening and brief intervention. *Journal of Trauma, 55*, 849–855.

Schonfeld L, King-Kallimanis B.L., Duchene D.M., Etheridge R.L., Herrera J.R., Barry K.L., Lynn N. (2010). Screening and brief intervention for substance misuse among older adults: The Florida BRITE project. (eng), *American Journal of Public Health,* 100 (1), 108-14.

Schwartz. Allan J. (2006). College student suicide in the United States: 1990-1991 through 2003-2004. *Journal of American College Health, 54 (6),* 341-352.

Seale, J.P. Monteiro, M.G. (2008). The dissemination of screening and brief intervention for alcohol problems in developing countries: Lessons from Brazil and South Africa. NAT: Nordisk Alkohol & Narkotikatidskrift, 25(6),. 565-577.

Seale J.P., Shellenberger S., Boltri J.M., Okosun I.S., Barton B. (2005). Effects of screening and brief intervention training on resident and faculty alcohol intervention behaviours: A pre-post-intervention assessment. *BCM Family Practice*, 6, 46.

Shelbourne, CD, Jackson, CA, Meredith, LS, Camp P, &Wells KB (1996). Prevalence of comorbid anxiety disorders in primary care outpatients. *Archives of Family Medicine,* 5(1), 27-34.

Shellenberger S., Seale J.P., Harris D.L., Johnson J.A., Dodrill C.L., Velasquez M.M., (2009) Applying team-based learning in primary care residency programs to increase patient alcohol screenings and brief interventions. *Journal of the Association of American Medical Colleges,* 84 (3), 340-6.

Simon, G. E., Von Korff, M., Ludeman, E. J., et al. (2002). Cost-effectiveness of a program to prevent depression relapse in primary care. *Med Care*, 40, 941-950.

Simon, G. E., Katon, W. J., VonKorff, et al. (2001). Cost-effectiveness of a collaborative care program for primary care patients with persistent depression. *American Journal of Psychiatry*, 158, 1638-1644.

Smith, P.C., Schmidt, S.M., Allensworth-Davies, D., & Saitz, R. (2010) A single-question screening test for drug use in primary care. *Archives of Internal Medicine*, 170(13):1155-1160.

Souza-Formigoni, M. L. O.; Boemgen-Lacerda, R.; Vianna, V. P. T. (2008). Implementation of alcohol Screening and brief intervention in primary care units in two Brazilian states: A case study. *NAT: Nordisk Alkohol & Narkotikatidskrift,* 25(6), 533-564.

Spandorfer, J. M., Israel, Y., & Turner, B. J. (1999). Primary care physicians' views on screening and management of alcohol abuse: Inconsistencies with national guidelines. *Journal of Family Practice, 48*(11), 899–902.

Stephens R. S., Roffman R. A., & Curtin L. (2000). Comparison of extended versus brief treatments for marijuana use. *Journal of Consulting and Clinical Psychology, 68,* 898–908.

Tait, R. J., Hulse, G. K., & Robertson, S. I. (2004). Effectiveness of a brief intervention and continuity of care in enhancing attendance for treatment by adolescent substance users. *Drug Alcohol Dependence, 74*(3), 289–296.

Tait, R. J., Hulse, G. K., Robertson, S. I., & Sprivulis, P. C. (2005). Emergency department-based intervention with adolescent substance users: 12-month outcomes. *Drug Alcohol Dependence, 79,* 359-363.

Taj, N., Devera-Sales, A., & Vinson, D. C. (1998). Screening for problem drinking: Does a single question work? *Journal of Family Practice, 46*(4), 328-335.

Tenth Special Report to the U.S. Congress on Alcohol and Health. (2000). Rockville, MD: National Institute on Alcohol Abuse and Alcoholism (NIAAA); NIH publication no. 00-1583.

Terrell F., Zatzick D.F., Jurkovich G.J., Rivara F.P., Donovan D.M., Dunn C.W. et al. (2008). Nationwide survey of alcohol screening and brief intervention practices at US Level I trauma centers. (eng), *Journal of The American College of Surgeons,* 207 (5), 630-8.

Timko, C., Moos, R. H., Finney, J. W., Moos, B. S., & Kaplowitz, M. S. (1999). Long-term treatment careers and outcomes of previously untreated alcoholics. *Journal of Studies on Alcohol, 60,* 437–447.

Thomas B. (2004). Training Medical Providers to Conduct Alcohol Screening and Brief Interventions. *Substance Abuse,* 25 (1), 17-26.

Tollison S.J., Lee C.M., Neighbors C., Neil T.A., Olson N.D., Larimer M.E. (2008). Questions and reflections: The use of motivational interviewing microskills in a peer-led brief alcohol intervention for college students. (eng), *Behavior Therapy,* 39 (2), 183-94.

Toumbourou, J.W.; Stockwell, T.; Neighbors, C.; Marlatt, G.A.; Sturge, J.; Rehm, J. (2007). Interventions to reduce harm associated with adolescent substance use. *The Lancet (ScienceDirect),* 69 (9570), 1391-1401.

Turrisi, R., Larimer, M., Mallett, K., Kilmer, J., Ray, A., Mastroleo, N. et al. (2009), A Randomized Clinical Trial Evaluating a Combined Alcohol Intervention for High-Risk College Students. *Journal of Studies on Alcohol and Drugs,* 70 (4), 555-567.

Unutzer, J., Katon, W., Callahan, C. M., et al. (2002). Collaborative care management of late-life depression in the primary care setting: a randomized controlled trial. *JAMA,* 2836-45.

U.S. Preventive Services Task Force. *Screening for Depression.* (2002, May) Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/clinic/ 3rduspstf/depression/

U.S. Preventive Services Task Force (USPSTF). (2004). Screening and behavioral counseling interventions in primary care to reduce alcohol misuse: Recommendation statement. *Annals of Internal Medicine, 140*(7), 554-556.

U.S. Preventive Services Task Force. (2009). Screening and treatment for major depressive disorder in children and adolescents: US preventative task force recommendation statement. *Pediatrics, 123*(4), 1223-1228

VanDeMark NR, Burrell NR, Lamendola WF, Hoich CA, Berg NP, Medina E. (2010). An exploratory study of engagement in a technology-supported substance abuse intervention. *Subst Abuse Treat Prev Policy,* Jun 8;5:10.

Walker, EA, Torkelson N, Katon, WJ, & Koss, MP (1993). The prevalence rate of sexual trauma in a primary care clinic. *Journal of the American Board of Family Practice,* Sep-Oct; 6(5): 465-71

Whiteside, U., Cronce, J. M., Pedersen, E. R., & Larimer, M. E. (2010). Brief motivational feedback for college students and adolescents: a harm reduction approach. *Journal of Clinical Psychology, 66*(2), 150–163.

WHO ASSIST Working Group. (2002). The Alcohol, Smoking and Substance Involvement Screening Test (ASSIST): Development, reliability and feasibility. *Addiction, 97,* 1183–1194.

Wilk, A.I., Jensen, N.M., and Havighurst, T.C. (1997). Meta-analysis of randomized control trails addressing brief interventions in heavy alcohol drinkers. *Journal of General Medicine,* 12 (5), 274-283.

Williams EC, Lapham G, Achtmeyer CE, Volpp B, Kivlahan DR, Bradley KA. (2010). Use of an electronic clinical reminder for brief alcohol counseling for unhealthy alcohol use. *J Gen Intern Med.* Jan; 25 Suppl 1:11-7.

World Health Organization. (2008.) The effectiveness of a brief intervention for illicit drugs linked to the alcohol, smoking, and substance involvement screening test (ASSIST) in

primary health care settings: a technical report of phase III findings of the WHO ASSIST Randomized control trial. Retrieved June 16, 2010, from http://www.who.int/substance_abuse/activities/assist_technicalreport_phase3_final.pdf.

Zarkin, G.A., Bray, J.W., Davis, K.L., Babor, T.F., Higgins-Biddle, J.C. (2003). The costs of screening and brief intervention for risky alcohol use. (eng), *Journal of Studies on Alcohol,* 64 (6), 849-57.

Thoele et al. Substance Abuse Treatment, Prevention, and Policy (2021) 16:42
https://doi.org/10.1186/s13011-021-00380-z

Substance Abuse Treatment, Prevention, and Policy

REVIEW Open Access

Strategies to promote the implementation of Screening, Brief Intervention, and Referral to Treatment (SBIRT) in healthcare settings: a scoping review

Kelli Thoele[1*], Laura Moffat[2], Stephanie Konicek[3], Monika Lam-Chi[4], Erica Newkirk[5], Janet Fulton[6] and Robin Newhouse[7]

Abstract

Background: Screening, brief intervention, and referral to treatment (SBIRT), is an approach for the prevention and treatment of substance use disorders, but is often underutilized in healthcare settings. Although the implementation of SBIRT is challenging, the use of multi-faceted and higher intensity strategies are more likely to result in the successful incorporation of SBIRT into practice in primary care settings. SBIRT may be used in different healthcare settings, and the context for implementation and types of strategies used to support implementation may vary by setting. The purpose of this scoping review is to provide an overview regarding the use of strategies to support implementation of SBIRT in all healthcare settings and describe the associated outcomes.

Methods: A scoping review was conducted using CINAHL Complete, HealthBusiness FullTEXT, PsycINFO, PubMed, and Embase to search for articles published in English prior to September 2019. The search returned 462 citations, with 18 articles included in the review. Two independent reviewers extracted data from each article regarding the theory, design, timeline, location, setting, patient population, substance type, provider, sample size and type, implementation strategies, and implementation outcomes. The reviewers entered all extracted data entered into a table and then summarized the results.

Results: Most of the studies were conducted in the United States in primary care or emergency department settings, and the majority of studies focused on SBIRT to address alcohol use in adults. The most commonly used strategies to support implementation included training and educating stakeholders or developing stakeholder interrelationships. In contrast, only a few studies engaged patients or consumers in the implementation process. Efforts to support implementation often resulted in an increase in screening, but the evidence regarding the brief intervention is less clear, and most studies did not assess the reach or adoption of the referral to treatment.

(Continued on next page)

* Correspondence: kellithoele@gmail.com
[1]Robert Wood Johnson Future of Nursing Scholar, Indiana University School of Nursing, 600 Barnhill Drive, Indianapolis, IN 46202, USA
Full list of author information is available at the end of the article

© The Author(s). 2021 **Open Access** This article is licensed under a Creative Commons Attribution 4.0 International License, which permits use, sharing, adaptation, distribution and reproduction in any medium or format, as long as you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons licence, and indicate if changes were made. The images or other third party material in this article are included in the article's Creative Commons licence, unless indicated otherwise in a credit line to the material. If material is not included in the article's Creative Commons licence and your intended use is not permitted by statutory regulation or exceeds the permitted use, you will need to obtain permission directly from the copyright holder. To view a copy of this licence, visit http://creativecommons.org/licenses/by/4.0/. The Creative Commons Public Domain Dedication waiver (http://creativecommons.org/publicdomain/zero/1.0/) applies to the data made available in this article, unless otherwise stated in a credit line to the data.

(Continued from previous page)
Discussion: In addition to summarizing the strategies used to increase reach and adoption of SBIRT in healthcare settings, this scoping review identified multiple gaps in the literature. Two major gaps include implementation of SBIRT in acute care settings and the application of implementation theories to inform healthcare efforts to enable use of SBIRT.

Keywords: Implementation, Implementation strategies, Screening, brief intervention, referral to treatment (SBIRT), Substance-related disorders, Scoping review

Background

More than 20 million people aged 12 and older in the United States have a substance use disorder [1]. Substance use disorders (SUD), defined as health problems, disability, and failure to meet responsibilities caused by alcohol or drug use [1], have a significant impact on individuals, families, and communities. In addition to healthcare costs associated with the treatment of comorbidities, a projected $42 billion will be spent on SUD treatment in 2020 [2]. When including direct and indirect costs related to crime and lost worker productivity, the national cost of substance abuse increases to $740 billion annually [3]. Despite the known consequences of SUD, healthcare providers rarely use validated tools to screen patients for SUD, and only 11% of people who need substance use treatment receive treatment at a specialty facility [1, 4].

Screening, Brief Intervention, and Referral to Treatment (SBIRT) is a comprehensive public health approach to delivering care for individuals who have or are at risk of developing SUD [5]. SBIRT is a three-step process that involves 1) using a validated tool to screen patients to assess the severity of substance use, 2) providing a brief intervention when indicated by screening and clinical judgment, and 3) providing a referral to treatment when appropriate [5]. The receipt of SBIRT is associated with reductions in alcohol and illicit drug use [6] and diminished societal costs related to automobile accidents, arrests, incarcerations, work absences, and other factors [7, 8]. Compared to usual care, a brief intervention is effective in the reduction of alcohol consumption [9], although the evidence for other substances is unclear [9, 10]. Several organizations recognize the potential of SBIRT in addressing substance use [11–14]. Despite the potential benefits of using SBIRT in clinical practice, this intervention is underutilized in healthcare settings representing a substantial gap in implementation. Clinicians report that they infrequently use screening tools to screen for substance use, and clinical students may not have preceptors with SBIRT experience [4, 15]. Additionally, less than 2% of pediatric emergency physicians report consistent use of SBIRT for adolescents with alcohol-related emergency department visits [16].

When an intervention is underutilized in clinical practice, the next step is to study the implementation of that intervention [17, 18]. Greenhalgh et al. define implementation as "active and planned efforts to mainstream an innovation within an organization."[19,p. 582] This process includes the decision to use an intervention (described using the terms adoption, assimilation, acceptance, and uptake) [19–22], and continued use of the intervention (described using the terms sustainment and maintenance) [20, 21, 23]. The methods used to enhance adoption, implementation, and sustainment of a new practice are referred to as implementation strategies [24]. Implementation strategies may include activities such as training and educating stakeholders, adapting the intervention to fit the context, or providing interactive assistance during the implementation process [25, 26]. While there are several different measures to determine the outcomes associated with implementation [27], the outcomes in this review include *reach* (i.e., the proportion of patients who received the intervention) and *adoption* (i.e., the proportion of individual providers, groups, or organizations that decided to use the intervention) [28, 29].

Previous reviews on the use of strategies to support the implementation of SBIRT have focused on unhealthy alcohol use within primary care settings and were published in 2005 and 2016. These analyses indicated that the use of multi-faceted strategies that addressed a combination of patients, professionals, and organizations, was more effective than the use of strategies that only addressed the healthcare professionals [30]. These studies additionally found that a higher intensity of an implementation strategy (e.g., amount of training) was associated with greater efficacy of implementation of a brief alcohol intervention in primary care [31].

Prior reviews are limited to the primary care setting, but SBIRT can be used in other settings such as acute care and emergency departments which may have different contexts for implementation than primary care. Investigators have studied the implementation of SBIRT in various healthcare settings, and an understanding of the strategies used to increase the number of patients who receive SBIRT and providers who use SBIRT in various contexts may inform future research and clinical practice. Therefore, the research question guiding this research is, "What implementation strategies are used to increase the reach and adoption of SBIRT when implementing SBIRT in healthcare settings, and what are the associated outcomes related to reach and adoption?"

Scoping reviews are used to map the current field of study and identify gaps in the existing literature [32, 33]. Scoping reviews include a systematic search and summary of the existing literature; however, unlike a systematic review, the scoping review method does not include an assessment of the risk of bias within each study or synthesis of the evidence [33]. A scoping review was therefore determined most appropriate, as this method will provide an overview of the evidence. The purpose of this scoping review is to provide an overview of existing evidence regarding the use of implementation strategies to promote the implementation of SBIRT in healthcare settings.

Methods

Investigators used a scoping review method as described by Arksey and O'Malley [32]. This method includes identifying a research question, identifying and selecting studies, extracting data, and then collating and summarizing results [32].

Identifying a research question

The investigators noted a gap in the literature and established the research question. The investigators developed but did not publish a protocol to conduct the review and answer this research question.

Identifying and selecting studies

To be included in this review, articles had to be published in English, contain empirical evidence, address the implementation of SBIRT in healthcare settings, describe strategies to promote implementation, and measure an outcome of interest (i.e., reach or adoption of SBIRT). Additionally, there had to be a comparison of the outcome, such as pre-intervention and post-intervention data, longitudinal data, or comparison to a control group. Exclusion criteria included abstracts, posters, dissertations, or articles that used SBIRT for something other than unhealthy substance use. These inclusion and exclusion criteria were selected to obtain evidence to address the purpose of the review and to summarize evidence regarding the changes in reach and adoption related to the use of implementation strategies.

The articles for this review were identified through a literature search, using the key terms "SBIRT" OR "screening brief intervention referral to treatment" AND multiple terms related to implementation (adopt*, assimilation, acceptance, uptake, implement*, sustain*, maintenance). Because not all authors use the term 'strategy' when describing methods to enhance implementation, this term was not included in the search. Databases for the search included CINAHL Complete, HealthBusiness FullTEXT, PsycINFO, PubMed, and Embase. These databases were selected to capture nursing, healthcare administration, behavioral science literature, and international literature. Publication dates were not limited, and the literature search was conducted on August 31, 2019. A health science librarian provided feedback on the search strategy prior to the completion of the literature search.

The initial screening process included a review of all titles and abstracts and then removal of the citations that clearly did not meet the criteria for inclusion in the review. After obtaining the full text for all of the remaining citations, the investigator then removed all non-English articles, abstracts, posters, and dissertations. The remaining full-text articles were then screened for inclusion in the review using a screening tool that listed the inclusion and exclusion criteria.

Extracting data

Variables of interest for this review included the study theory or framework, design and timeline, location and setting, patient population, substance type, the type of providers using SBIRT, sample size and type, implementation strategies used, and implementation outcomes. Most of the variables (theory/framework, design and timeline, location, setting, population, substance type, and providers using SBIRT) were extracted directly from the articles. When the study authors did not clearly state the study design, the reviewers selected a design to describe the study. The sample size and type were extracted directly from the article, with a focus on the sample size included in the final data analysis. When the study authors did not provide the exact sample size, the reviewers described the sample size based on information in the article.

To identify implementations strategies, the reviewers looked for descriptions of methods to facilitate adoption, implementation, or sustainment of SBIRT, such as training, adapting the intervention, providing ongoing support, or providing financial incentives. The implementation strategies described in each article were extracted and then categorized by the reviewers into categories, as defined and described by Powell et al. [25] and Waltz et al. [26] When reviewing the articles, research activities, such as data collection for research purposes and data analysis, were not considered to be implementation strategies. Funding and academic/practice partnerships were included as implementation strategies when they were explicitly mentioned in the article but were not included based on the acknowledgments section or authors' credentials or places of employment.

The outcomes of reach and adoption were extracted from each article. Although adoption is generally defined as a cognitive decision [22], researchers often measure self-reported behavior or actual behavior as a proxy for the adoption decision. For this review, reviewers

extracted adoption data on providers' intention to use SBIRT or behavior regarding SBIRT. Study outcomes other than reach or adoption (e.g., provider attitude, knowledge, patient use of substances after receiving SBIRT) were not extracted from the articles. When extracting outcomes related to the brief intervention, reviewers also included different terms used to describe a brief intervention, such as 'brief advice,' 'motivational interviewing,' and 'counseling.'

A data collection instrument was developed and built into Qualtrics XM®, a cloud-based survey software tool, with pilot testing completed prior to use. This tool was used to guide data extraction, collect and organize data from each article, and compare reviewer responses. Once reviewers determined that an article met criteria for inclusion in the review, each article was independently reviewed by the primary investigator and a second reviewer. Both reviewers entered data into the Qualtrics tool. The study timeline was not included in the original data collection tool, and this variable was extracted later in the scoping review process. At the completion of the independent reviews, all discrepancies were discussed by the two independent reviewers. All unresolved discrepancies were then brought to one of two additional investigators, who then made a final determination. One study author was contacted to clarify the substance type addressed in an article. In alignment with the scoping review methods described by Arksey & O'Malley [32], reviewers did not appraise the quality of each article.

Collating and summarizing results

Once consensus was reached, the results were entered into a table in Microsoft Word to collate the results and summarize the data. The reviewers met in person to summarize the information, and all investigators provided additional input via email or in-person discussions.

Results

The literature search identified 462 unique records after the removal of duplicates. Two hundred sixty-eight articles were excluded based on a review of the titles and abstracts, and then a review of full-text citations led to the exclusion of abstracts, dissertations, and non-English articles. Two reviewers assessed the remaining 102 full-text articles for eligibility based on previously noted inclusion and exclusion criteria. The search concluded with 18 articles identified for in-depth review (see Fig. 1).

Study characteristics

The majority of studies ($n = 15$) did not state a specific theory or framework; however, investigators of the remaining three studies noted the use of the following frameworks: Framework for Design and Evaluation of Complex Interventions to Improve Health, the Consolidated Framework of Implementation Research, and Knowledge Translation. The most common study designs were pre-post studies, randomized controlled trials, longitudinal studies, and quality improvement, with the timeframe of the studies ranging from 30 days to 5.5 years. Thirteen studies were conducted in the United States, followed by Europe ($n = 3$), Canada ($n = 1$), and Australia (n = 1). The most common settings were primary care and emergency departments/trauma centers. The majority of the included patient populations were adults and/or trauma patients ($n = 10$), although three of the studies addressed the implementation of SBIRT in the adolescents and pediatric populations. More than half of the studies were implementing SBIRT to address alcohol use, while the remaining studies focused on SBIRT to address alcohol and other drugs, tobacco, or all substance types. SBIRT was generally provided by multiple professions within each study, although the studies in which only one profession provided SBIRT generally focused on physicians (see Table 1).

Implementation strategies

The authors of each study described the use of multiple strategies to support the implementation of SBIRT. Nearly every study used strategies to train and educate stakeholders ($n = 17$). Training and education included the development and distribution of educational materials, as well as the provision of in-person training ranging from 5 min to 1 full day. While training and education were used most often, the next most common approach was the development of stakeholder interrelationships ($n = 12$). Studies described developing these relationships through the identification of champions, development of interdisciplinary teams, and collaboration with researchers and other stakeholders (see Table 2).

Half of the studies described strategies to support clinicians ($n = 9$), such as embedding reminders into the electronic health record and shifting tasks from one role (e.g., physician) to a different role (e.g., research assistant, health education specialist, or behavioral health care practitioner). Other strategies used included the use of evaluative and iterative strategies to support implementation (n = 9), such as the use of monthly or quarterly reports to summarize data, and the completion of a baseline needs assessment to assess for readiness for the implementation of SBIRT (see Table 2).

The remaining categories of implementation strategies were used in fewer than half of the studies. These included the use of interactive assistance to support implementation ($n = 8$) by providing technical assistance, conducting one-time or monthly conference calls, or by providing ongoing support, facilitation, and supervision. Several studies also described adapting and tailoring the

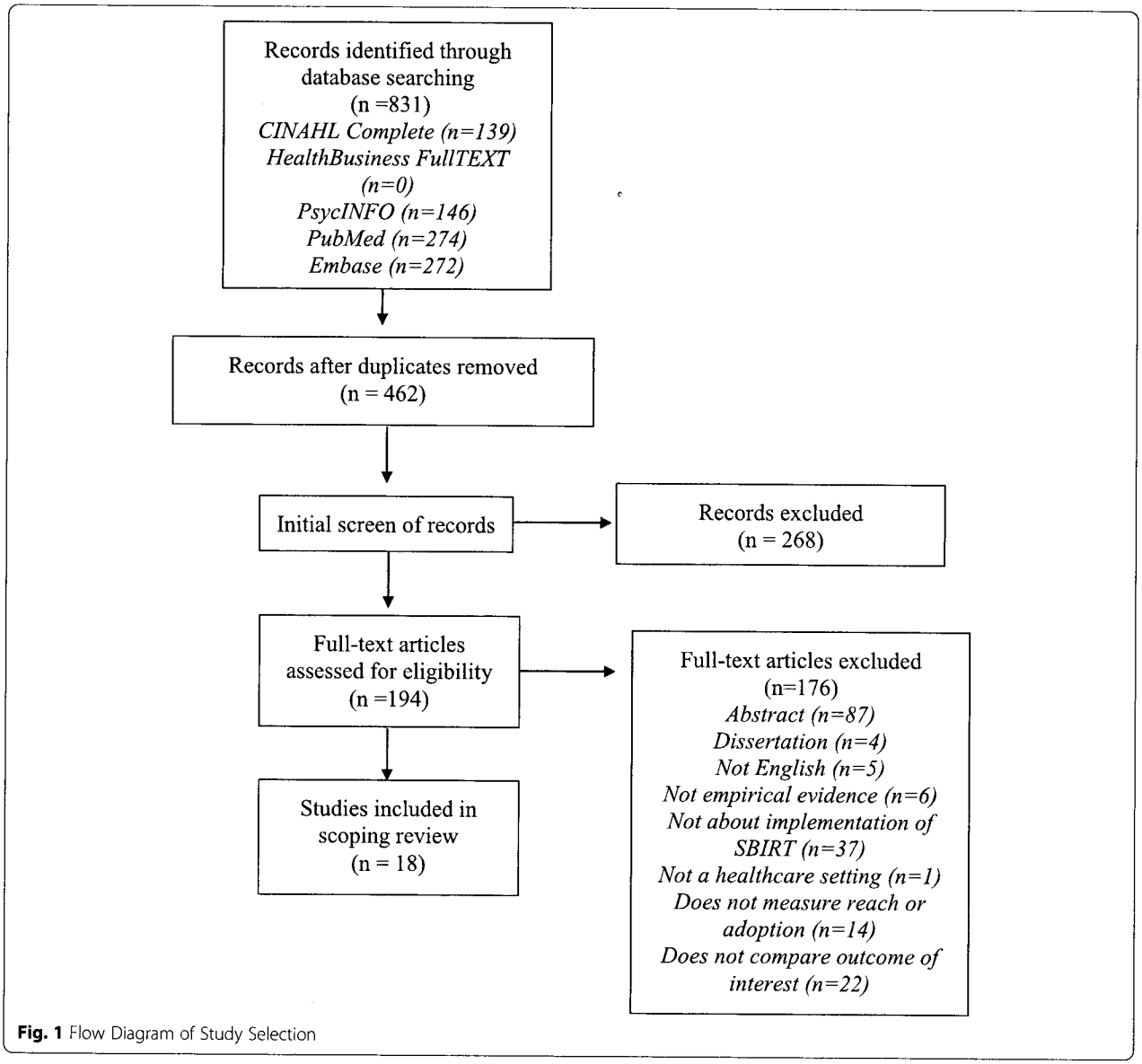


Fig. 1 Flow Diagram of Study Selection

intervention or implementation plan to the local context (n = 8). Implementation leaders most commonly tailored the resources, intervention, process, and training materials to meet the local needs or to fit into a specific setting (e.g., community emergency department) or specific population (e.g., Indigenous people). Another approach included the use of strategies to change infrastructure (n = 8). The most common infrastructure change was the modification of the electronic health record to incorporate SBIRT into the documentation. Several studies described the use of financial strategies ($n = 7$) to increase the use of SBIRT. Financial strategies included receiving funding to support the implementation of SBIRT or providing incentives or reimbursement for the use of SBIRT. Finally, a few studies described the engagement of consumers to support implementation ($n = 3$) by partnering with people with unhealthy substance use or people from a specific population (i.e., Indigenous people) to develop resources and train providers (see Table 2).

Implementation outcomes

The majority of the studies in this review measured the percentage of patients who received the intervention ($n = 15$), while one of these studies additionally measured differences in adoption among providers. The remaining three studies measured the self-reported use of SBIRT by providers. Most of the studies in this scoping review evaluated outcomes related to screening (n = 15), followed by brief intervention ($n = 10$), referral to treatment ($n = 4$), brief intervention/referral to treatment (n = 1), and SBIRT overall ($n = 2$) (see Table 1).

Table 1 Key Features of Included Studies

Article	Framework	Design and Timeline	Location	Setting	Population	Substance Type	Who is providing SBIRT	Sample	Outcomes
Anderson et al., 2016 [43]	None	Cluster randomized 2x2x2 factorial trial *4 weeks (baseline)* *12 weeks (implementation)*	Catalonia, England, the Netherlands, Poland, Sweden	120 primary healthcare centers	Adults	Alcohol	Providers (general practitioners, nurses, or other professionals)	Approximately 5000–20,000 registered patients at the healthcare centers Average of 1500 consultations at each center per month	Screening significantly increased in groups that received training/support (Groups 2, 5, 6, 8) compared to groups that did not. Screening significantly increased in groups who received financial reimbursement (Groups 3, 5,7, 8) compared to groups that did not. Not a significant increase in screening for the groups that received the electronic brief intervention (Groups 4, 6, 7, 8) compared to groups that did not.
Bendsten et al., 2016 [45]	None	Subanalysis of a randomized controlled trial (Anderson et al., 2016) *4 weeks (baseline)* *12 weeks (implementation)*	Catalonia, England, the Netherlands, Poland, Sweden	120 primary healthcare centers	Adults	Alcohol	Providers (general practitioners, nurses, or other professionals)	Approximately 5000–20,000 registered patients at the healthcare centers Average of 1500 consultations at each center per month	Not a significant increase in screening for the groups that received the electronic brief intervention (Groups 4, 6, 7, 8) compared to groups that did not. Significant increase in proportion of patients who received brief advice in the sample as a whole (70 to 80%, $p < 0.05$).
Bernstein et al., 2007 [51]	None	Pre-post-repeated measures design *12 months*	United States	14 academic emergency departments	Emergency department patients	Alcohol	Providers (physicians, registered nurses, advanced practice providers, social workers, and other staff)	288 providers	Significantly higher utilization of SBIRT skills 3 months ($p < 0.001$) and 12 months ($p < 0.001$) after receiving education, when compared to baseline. Providers reported higher utilization of SBIRT skills at 3 months than 12 months.
Egizio et al., 2019 [50]	None	Pre-post[a] *30 days*	United States	Field placement of supervisors (e.g., family service agencies, hospitals, community	All patients coming in contact with field supervisors	Alcohol and other drugs	Social workers who provided field supervision to social work students delivering SBIRT	74 field supervisors	Increase in the percentage of supervisors who used motivational interviewing (73.9 to 86.5%) and SBIRT (17.4 to 43.2%) when comparing baseline to 30 days after training.

Table 1 Key Features of Included Studies *(Continued)*

Article	Framework	Design and Timeline	Location	Setting	Population	Substance Type	Who is providing SBIRT	Sample	Outcomes
				clinics, housing programs)					
Henihan et al., 2016 [44]	Framework for Design and Evaluation of Complex Interventions to Improve Health	Randomized controlled pre-and-post design *3 months*	Ireland	15 primary care facilities	Adults receiving addiction treatment with an opioid agonist	Alcohol	General practitioners	81 patients (34 in the intervention group and 47 in the control group)	A higher percentage of patients in the intervention group were screened (53% versus 26%), received a brief intervention (47% versus 19%) and received a referral to treatment (3% versus 0%) when compared to the control group.
Lapham et al., 2012 [49]	None	Retrospective, natural history study *12 months (baseline) 3 months (transition) 3 months (implementation) 9 months (dissemination)*	United States	Outpatient Veteran Affairs facilities	Veterans	Alcohol	Providers	6788 patients who screened positive for alcohol misuse	The percentage of patients receiving a brief intervention increased significantly over time from 5.5 to 29% ($p < 0.001$).
Lindholm et al., 2010 [34]	None	Pre-post[a] *12 months (pre-intervention) 12 months (post-intervention)*	United States	18 primary care clinics	Adults	Tobacco	Medical assistant completed screening, clinicians provided brief intervention	502,359 patients (255,138 pre-intervention and 247, 221 post-intervention)	Statistically significant increase in documentation of smoking status from 71.6 to 78.4% ($p < 0.001$). Pre-intervention data not available for brief intervention or referral to treatmen.t
Mello et al., 2009 [42]	None	Quality improvement[a] *1 month (baseline) 6 months (Phase 1) 6 months (Phase 2)*	United States	1 community hospital emergency department	Not a specific population	Alcohol	Physicians, physician assistants, and nurse practitioners provided the screening and referral. Research assistants provided the brief intervention	1509 patients (254 baseline, 922 when research assistant was in the emergency department during the study, 333 patients one month after the research assistant was no longer present)	Screening by emergency department staff increased from 50% (baseline) to 71% (when research assistant was present), then back to 50% after research assistant was no longer present.
Mello et al., 2013 [35]	None	Longitudinal[a] *12 months (adoption) 12 months (implementation)*	United States	7 pediatric trauma centers	Admitted adolescent trauma patients	Alcohol	Differed at each site, but in general, nurses completed screening and social workers provided brief intervention and	400 patients (160 baseline, 116 in implementation phase, 124 in maintenance phase)	The percentage of patients screened increased from 11% (baseline) to 73% (implementation and maintenance phases).

Table 1 Key Features of Included Studies *(Continued)*

Article	Framework	Design and Timeline	Location	Setting	Population	Substance Type	Who is providing SBIRT	Sample	Outcomes
		12 months (maintenance)					decided on referral to treatment		
Mertens et al., 2015 [46]	None	Cluster randomized implementation trial *12 months*	United States	54 primary care clinics	Adults	Alcohol	Arm 1: Physicians Arm 2: Non-physician providers (i.e., clinical health educators, behavioral medicine specialists, nurses) and medical assistants Arm 3: Usual care	Average number of visits per month= 35,519 patients in Arm 1, 34,167 patients in Arm 2, 31,935 patients in Arm 3	Screening was highest in Arm 2 (51%) compared to Arm 1 (9%) and Arm 3 (3.5%). For patients screening positive, the brief intervention and referral was highest in Arm 1 (44%) compared to Arm 2 (3.4%) and Arm 3 (2.7%).
Muench et al., 2015 [36]	None	Longitudinal[a] *2 years*	United States	6 primary care clinics	Adults	Alcohol and other drugs	Receptionists gave annual screen to patients at check-in Medical assistants scored the screen, and if indicated, completed a more detailed brief assessment Clinicians (physician, physician's assistant, nurse practitioner) performed the brief intervention	Approximately 11,000 patients each quarter	Screening rates significantly increased over time, with a median increase of 6.4% between quarters ($p < 0.05$). Brief assessment rates (AUDIT and/or DAST) increased over time, with a median increase of 7.0% between quarters ($p < 0.05$). Brief intervention rates decreased over time, with a decrease of 3.7% between quarters. A non-significant trend ($p > 0.05$).
Rieckmann et al., 2018 [37]	Consolidated Framework of Implementation Research	Longitudinal mixed- methods design *30 months (pre-implementation)* *6 months (transition period)* *30 months (post-implementation)*	United States	Primary care	18–64 year old Medicaid recipients enrolled in a coordinated care organization	Alcohol and other drugs	Unknown	516,708 members in the study population	Quantitative analysis revealed a significant increase in SBI rates from 0.1% of patients (baseline) to 4.6% of patients (last six months of study). Qualitative analysis revealed the importance of aligning incentives, workflow redesign, and leadership facilitation.
Salvalaggio et al., 2015 [47]	Knowledge Translation	Non-randomized, pre-post, quasi-experimental intervention design *6 months (patient-level*	Canada	3 primary care networks, 3 emergency departments, 3 residency programs	Patients who received care in socio-economically disadvantaged neighborhoods	Alcohol and other drugs	Physicians/residents	64 physicians/residents (39 in the intervention group and 25 in the control group)	Overall, physicians reported that they were more likely to screen ($p = 0.008$) and refer for treatment ($p = 0.017$) after 12 months. Exposure to the intervention predicted

Table 1 Key Features of Included Studies *(Continued)*

Article	Framework	Design and Timeline	Location	Setting	Population	Substance Type	Who is providing SBIRT	Sample	Outcomes
		implementation) 6 months (provider access to knowledge translation resources)							brief intervention behavior ($p < 0.05$) but not screening or referral behavior.
Sharifi et al., 2014 [41]	None	Pre-post study *3 months (pre-intervention) 1 month (intervention) 3 months (post-intervention)*	United States	1 pediatric primary care clinic	Parents (of pediatric patients ≤12 years old) who smoke	Tobacco	Physicians/residents	3919 patients (2024 pre-intervention and 1895 post-intervention)	Not a significant change in screening. There was a significant increase in counseling for parents who screened positive.
Sterling et al., 2015 [48]	None	Cluster randomized controlled trial *2 years*	United States	1 pediatric primary care system	Adolescents 12–18 years old	Alcohol, tobacco, other drugs	Arm 1: Pediatricians Arm 2: Pediatricians and embedded behavioral health care practitioners Arm 3: Usual care	1871 patients (584 in Arm 1, 671 in Arm 2, 616 in Arm 3)	In Arm 1, pediatricians who attended 2+ trainings assessed more patients than pediatricians who attended fewer trainings($p < 0.001$) and provided more brief interventions ($p < 0.001$) than pediatricians who attended fewer trainings. The total number of assessments in Arm 1 and Arm 2 were not significantly different. Arm 1 and Arm 2 provided significantly more brief interventions than Arm 3 ($p < .001$) Arm 1 provided more brief interventions related to substance use than Arm 2 ($p < 0.001$). Arm 2 had significantly lower referral to treatment when compared to usual care ($p = 0.006$), but Arm 1 was not significantly different from usual care
Thomas et al., 2016 [38]	None	Quality improvement (using Plan-Do-Study-Act) *12 months*	United States	1 emergency department and hospital	Adult trauma patients	Alcohol and other drugs	Multiple roles provided SBIRT (including nurses and health education specialists), and the process changed throughout the project	1664 patients	The percentage of patients who were screened significantly increased over time from 47% (Quarter 1) to 86.1% (Quarter 2) ($p < 0.001$) Specialist-delivered SBIRT

Table 1 Key Features of Included Studies *(Continued)*

Article	Framework	Design and Timeline	Location	Setting	Population	Substance Type	Who is providing SBIRT	Sample	Outcomes
									(assessment and brief intervention when applicable) did not significantly change over time.
Whitty et al., 2015 [39]	None	Mixed-method, uncontrolled, pre-post trial *6 months (pre-intervention) 13 months (implementation) 6 months (post-intervention)*	Australia	1 hospital	Patients treated for alcohol-related injury and maxillo-facial trauma; the majority of patients who met criteria at this hospital were Indigenous	Alcohol	Not specified (the best practice pathway was designed for medical, surgical and nursing departments)	144 patients (76 pre and 68 post)	Screening significantly increased from 9 to 81% of patients ($p \leq 0.001$). No significant change in brief intervention, internal referral, or external referral.
Zimmermann et al., 2018 [40]	None	Quality improvement[a] *8 months*	United States	1 trauma center	Trauma patients 15+ years old	Alcohol	Blood alcohol levels used as a screening tool; if a patient screened positive (blood alcohol level > 0.02%) the social worker provided a brief intervention and evaluated for treatment services	693 patients	Screening increased from 30% (month 1) to 100% (months 4–8).

[a] = Authors did not state the design

Table 2 Implementation Strategies and Categories

		Use evaluative and iterative strategies	Provide interactive assistance	Adapt and tailor to context	Develop stakeholder interrelationships	Train and educate stakeholders	Support clinicians	Engage consumers	Utilize Financial Strategies	Change infrastructure
Article	**Implementation Strategies**	**Implementation Strategy Categories**								
Anderson et al., 2016 [43]	Conducted one (10–30 min) telephone support call (Groups 2, 5, 6, 8)		x							
	Offered an option to refer patients to an online brief intervention as an alternative to face-to-face intervention (Groups 4, 6, 7, 8)			x						
	Distributed educational materials (Groups 1, 2, 4, 5, 6, 7, 8) Asked providers to screen patients (Groups 1, 2, 4, 5, 6, 7, 8) Provided two (1–2 h) in-person trainings (Groups 2, 5, 6, 8)					x				
	Provided financial reimbursement for screening and advice activities (Groups 3, 5, 7, 8)								x	
	Provided a record sheet to document SBIRT (Groups 1, 2, 4, 5, 6, 7, 8)									x
Bendsten et al., 2016 [45]	Conducted one (10–30 min) telephone support call (Groups 2, 5, 6, 8)		x							
	Offered an option to refer patients to an online brief intervention as an alternative to face-to-face intervention (Groups 4, 6, 7, 8)			x						
	Distributed educational materials (Groups 1, 2, 4, 5, 6, 7, 8) Asked providers to screen patients (Groups 1, 2, 4, 5, 6, 7, 8) Provided two (1–2 h) in-person trainings (Groups 2, 5, 6, 8)					x				
	Provided financial reimbursement for screening and advice activities (Groups 3, 5, 7, 8)								x	
	Provided a record sheet to document SBIRT (Groups 1, 2, 4, 5, 6, 7, 8)									x
Bernstein et al., 2007 [51]	Provided technical assistance Facilitated learning of individual clinicians		x							
	Tailored brief intervention and referral resources to meet local needs			x						
	Partnered with research team and other stakeholders at each site				x					
	Provided one (2-h) interactive workshop or a web-based learning module Developed and distributed educational materials					x				
	Collaborated with volunteers from Alcoholics Anonymous							x		
Egizio et al., 2019 [50]	Provided monthly implementation support Facilitated clinical supervision		x							
	Tailored plan to address limited training and clinical supervision for SBIRT			x						
	Identified champions (i.e., field supervisors) and partnered				x					

Table 2 Implementation Strategies and Categories *(Continued)*

		Use evaluative and iterative strategies	Provide interactive assistance	Adapt and tailor to context	Develop stakeholder interrelationships	Train and educate stakeholders	Support clinicians	Engage consumers	Utilize Financial Strategies	Change infrastructure
	with instructors									
	Provided one (1-day) training for field supervisors					x				
	Received grant to develop SBIRT certificate program								x	
Henihan et al., 2016 [44]	Partnered with the research assistant who conducted practice visits				x					
	Distributed training and educational materials Demonstrated intervention implementation Provided educational support after the workshop					x				
Lapham et al., 2012 [49]	Monitored quarterly facility-level reports	x								
	Disseminated clinical reminders via the electronic medical records						x			
	Linked performance measure to financial incentives for clinical leaders								x	
	Created a national performance measure for a brief intervention for patients with alcohol misuse									x
Lindholm et al., 2010 [34]	Completed pilot tests before wide-scale implementation	x								
	Developed a team of representatives from healthcare system (including a physician champion) and a university-based tobacco dependence research center				x					
	Provided one (20-min) onsite training and an additional visit if needed					x				
	Listed interventions in the electronic medical record if patient indicated an interest in quitting						x			
	Modified the electronic medical record to improve identification and treatment of tobacco use									x
Mello et al., 2009 [42]	Adapted plan to community emergency department environment (Phase 1) Continued ongoing exploration and adaptation (Phases 1, 2)			x						
	Met with stakeholders to obtain feedback on intervention and implementation plan (Phase 1)				x					
	Provided one (5-min) initial training of staff (Phase 2) Provided small laminated reference cards (Phase 2)					x				
	Partnered with the research assistant, who provided the brief intervention (Phase 2)						x			
Mello et al., 2013 [35]	Assessed for readiness and created an SBIRT policy (Adoption phase)	x								
	Facilitated monthly conference calls (Adoption and implementation phases)		x							

Table 2 Implementation Strategies and Categories *(Continued)*

		Use evaluative and iterative strategies	Provide interactive assistance	Adapt and tailor to context	Develop stakeholder interrelationships	Train and educate stakeholders	Support clinicians	Engage consumers	Utilize Financial Strategies	Change infrastructure
	Hosted a web site for technical assistance (Adoption and implementation phases)									
	Identified and prepared site leaders (Adoption phase)				x					
	Provided online curriculum and in-person workshop (Adoption phase) Provided another in-person workshop and webinar on the brief intervention (Implementation phase)					x				
Mertens et al., 2015 [46]	Reviewed quality feedback reports and addressed challenges (Arms 1 and 2) Emailed quarterly reports of SBIRT rates to each clinic (Arms 1 and 2)	x								
	Provided in-person technical assistance and facilitation (Arms 1 and 2)		x							
	Provided one (2-h) initial training and one (30-min) booster training (Arms 1 and 2) Posted educational videos on intranet site (Arms 1 and 2) Provided one (1-h) training for medical assistants (Arm 2) Provided an on-demand 30-min webinar session (Arm 3)					x				
	Obtained public support from leaders (Arms 1 and 2) Directed the medical assistants to use the tool (Arm 2) Added screening questions to the electronic health record to facilitate SBIRT (Arms 1, 2, 3)									x
Muench et al., 2015 [36]	Adapted the process to the workflow at each site			x						
	Designated champions at each site				x					
	Provided one (3.5-h) training for residents and shorter training for faculty physicians and clinic staff					x				
	Created reminders in the electronic health record to alert clinicians						x			
	Received funding from the Substance Abuse and Mental Health Services Administration								x	
	Created documentation flow sheets in the electronic health record									x
Rieckmann et al., 2018 [37]	Identified champions				x					
	Developed the workforce					x				
	Selected screening and brief intervention as incentive metrics Aligned incentives								x	
	Redesigned workflow									x
Salvalaggio et al., 2015	Completed a baseline needs assessment	x								
	Used a web platform to centralize materials		x							

Table 2 Implementation Strategies and Categories *(Continued)*

		Use evaluative and iterative strategies	Provide interactive assistance	Adapt and tailor to context	Develop stakeholder interrelationships	Train and educate stakeholders	Support clinicians	Engage consumers	Utilize Financial Strategies	Change infrastructure
[47]	Provided implementation support									
	Toured other sites Identified champions				x					
	Provided one (2–3 h) workshop Distributed educational materials Provided online modules and links to resources					x				
	Provided point-of-care tools to remind clinicians of SBIRT and available resources						x			
	Partnered with community members with lived experiences, who discussed scenarios and answered questions during workshops							x		
Sharifi et al., 2014 [41]	Completed a baseline needs assessment	x								
	Provided one (15-min) training session					x				
	Embedded a reminder and decision support tool in the electronic medical record Simplified the education and referral process						x			
Sterling et al., 2015 [48]	Provided feedback on rates of screening and referral each quarter and reviewed protocol and skills to promote use of SBIRT (Arms 1, 2)	x								
	Provided technical assistance and clinical consultation (Arms 1, 2)		x							
	Provided three (60-min) training sessions (Arm 1) Provided one (60-min) training session (Arm 2)					x				
	Shifted tasks of brief intervention and referral to treatment to the behavioral health care practitioner when indicated (Arm 2) Informed pediatricians of tools in the electronic medical records (Arms 1, 2, 3) Reminded pediatricians to document clinical activities (Arms 1, 2, 3)						x			
Thomas et al., 2016 [38]	Presented data monthly	x								
	Tailored implementation strategies based on identified barriers			x						
	Assembled an interdisciplinary SBIRT committee that met monthly Identified an SBIRT champion				x					
	Provided brief in-service training meetings					x				
	Designated SBIRT health education specialist to screen all patients and contact trauma resident daily						x			
	Received funding from the Substance Abuse and Mental								x	

Table 2 Implementation Strategies and Categories *(Continued)*

		Use evaluative and iterative strategies	Provide interactive assistance	Adapt and tailor to context	Develop stakeholder interrelationships	Train and educate stakeholders	Support clinicians	Engage consumers	Utilize Financial Strategies	Change infrastructure
	Health Services Administration									
	Integrated an order for an SBIRT consult into the trauma order set									x
Whitty et al., 2015 [39]	Adapted the implementation approach and training materials to the local setting and Indigenous population			x						
	Developed resources in collaboration with consultants and other experts				x					
	Developed best practice pathway and other resources Provided six (1-h) workshops					x				
	Collaborated with an Indigenous reference group to develop the resources							x		
Zimmermann et al., 2018 [40]	Reported status updates at monthly meetings	x								
	Assembled a multidisciplinary team and developed a process for SBIRT				x					
	Provided one (4-h) training for social workers Provided an in-service to all key staff					x				
	Disseminated a list of eligible patients daily and kept this list in a project binder						x			

Screening

Reach Of the 15 studies measuring outcomes related to screening patients with a valid and reliable tool, most of the studies measured *reach*, or the percentage of patients who received screening ($n = 13$). Most of these studies ($n = 9$) utilized the same implementation strategies for all study participants via a quality improvement, pre-post, or longitudinal study design. In these studies, screening generally increased over time [34–40], but three studies did not report if this increase was significant [35, 37, 40]. Only one study, which focused on parents of patients rather than patients, reported no change in screening [41]. Another study reported an increase in screening when a research assistant was present, then a return to baseline when the research assistant was no longer present [42].

The remaining studies ($n = 4$) divided participants into groups and evaluated outcomes using randomized controlled, randomized controlled pre-post, or non-randomized pre-post quasi-experimental designs. The use of training [43, 44] and financial reimbursements [43] resulted in significant increases in screening, but the opportunity to adapt the brief intervention did not result in changes in the percentage of patients who were screened [43, 45]. When non-physician providers and physicians were exposed to the same implementation strategies, a higher percentage of patients were screened by non-physician providers than physicians [46].

Adoption Two studies examined the adoption of screening by providers. One study found that physicians at the completion of the study were more likely to screen than at the beginning of the study. However, the adoption of screening was not significantly different between the intervention group and the control group in this study [47]. In contrast, another study found that providers who attended more training sessions were significantly more likely to screen patients for substance use than providers who attended fewer training sessions [48].

Brief intervention

Reach Seven out of the 10 studies reporting outcomes related to the brief intervention measured the percentage of patients who received the brief intervention. Most of these studies ($n = 5$) used the same implementation strategies for all study participants using a quality improvement, pre-post, longitudinal study design, or retrospective design. The results of these studies differed; while the percentage of patients receiving the brief intervention significantly increased in one study [41], other studies demonstrated no change in reach [36, 38, 39], A retrospective study evaluating a new nationwide performance measure (supported by electronic decision support and financial incentives) demonstrated a significant increase in reach of the brief intervention. However, this study does not assess or describe implementation strategies used within each facility to promote the use of SBIRT [49].

The remaining studies on the reach of the brief intervention ($n = 2$) compared different implementation strategies between and among groups. In a randomized controlled trial, reach was higher in the intervention group than the control group, but it is not clear if this difference was statistically significant [44]. Adapting the intervention to allow for an electronic brief intervention did result in a significant increase in the percentage of patients who received a brief intervention overall [45].

Adoption Three studies measured the adoption of brief intervention by providers. More providers reported using the brief intervention after exposure to the implementation strategies [47, 50], and providers who attended more training sessions were more likely to use the brief intervention than their peers who attended fewer training sessions [48].

Referral to treatment

Reach Of the four studies reporting outcomes related to the percentage of patients who received a referral to treatment, most measured reach ($n = 3$). There was not a notable change in referral to treatment for two studies [39, 44], but Sterling et al. [48] found that embedding a behavioral health care practitioner into primary care resulted in a significantly lower percentage of patients receiving a referral to treatment than patients receiving usual care.

Adoption In one study of provider adoption of referral to treatment, Salvalaggio et al. [47] noted a significant increase over time in the overall percentage of physicians reporting that they refer patients to treatment. This outcome, however, was not significantly different between the intervention and control groups.

Brief intervention/referral to treatment

Adoption Mertens et al. [46] measured the outcome, brief intervention/referral to treatment, based on documentation of either a brief intervention or a referral to treatment. Evidence suggests that physicians may be more likely to provide a brief intervention/referral to treatment than non-physician providers, but the physicians in this study were also less likely to screen patients than non-physician providers [46].

SBIRT

Adoption Two studies did not differentiate screening, brief intervention, and referral to treatment as three separate interventions, but instead asked providers about their use of SBIRT overall before and after exposure to implementation strategies. In both studies, providers reported an increase in the use of SBIRT [50, 51], although the reported use of SBIRT 12 months after the intervention was not as high as the reported use of SBIRT 3 months after the intervention [51].

Discussion

SUD are common and detrimental to individuals and society as a whole. SBIRT, an approach to the prevention and treatment of unhealthy substance use, is not consistently implemented in healthcare settings. Different implementation strategies may be used to increase the delivery of SBIRT to patients or the use of SBIRT by providers, but there had not been a recent review of the evidence from multiple healthcare settings. This scoping review included 18 articles and was guided by the research question, "What implementation strategies are used to increase the reach and adoption of SBIRT when implementing SBIRT in healthcare settings, and what are the associated outcomes related to reach and adoption?"

The majority of the studies were conducted in the United States and focused on screening and providing a brief intervention for alcohol use in the emergency department and primary care settings. These study characteristics align with the recommendations for practice from the American College of Surgeons Committee on Trauma [52] and the U.S. Preventive Services Task Force [53]. There is a gap, however, in the existing literature about the implementation of SBIRT in acute care settings. When compared to the general population, patients admitted to the hospital have higher rates of SUD [1, 54]. McQueen and colleagues [55] contend that when a brief intervention for heavy alcohol is used in hospitalized patients, this intervention is associated with a reduction in alcohol consumption and death rates. Additionally, The Joint Commission quality measures for hospitalized adult patients support and recommend screening and providing a brief intervention for unhealthy alcohol use [56].

While most of the studies did not state a theory used to guide the study, each study described a multi-modal approach with the use of various strategies to support implementation. Numerous studies included strategies to train stakeholders and develop stakeholder interrelationships, but less attention has been given to adapting and tailoring SBIRT. There are core components of SBIRT that must remain the same to maintain fidelity to the intervention, but the peripheral components of SBIRT (e.g., who completes the screening, how the brief intervention is provided) can be adapted to fit the organizational context. Bendsten et al. [45] found that allowing providers to select between an electronic brief intervention or a face-to-face brief intervention was associated with an increase in the percentage of patients who received a brief intervention. SBIRT is a multi-step intervention that involves multiple professions and teamwork. More research about adapting the intervention or implementation process may be beneficial to increase the reach and adoption of SBIRT. Of note, only a few studies engaged patients or other consumers in the implementation process. Providers and patients report discomfort discussing substance use as a barrier to the implementation of SBIRT [57], but 95% of hospitalized patients reported that they would feel comfortable if a nurse discussed alcohol use with them [58]. There is a potential to enhance implementation by further researching adaptation of SBIRT and patient and consumer engagement.

When evaluating outcomes associated with the implementation of SBIRT, most of the studies evaluated organizational or group-level outcomes and did not evaluate provider-level outcomes. Nevertheless, the factors influencing individual providers' decisions about the adoption of an intervention differ from the factors influencing organizational decisions [59]. Additionally, the use of SBIRT may increase initially and then decrease over time [42, 51], but there is a paucity of research on the sustainment of SBIRT. This review also revealed that the use of implementation strategies is generally associated with increases in the reach and adoption of screening, but evidence about the brief intervention is inconclusive, and evidence regarding the referral to treatment is scarce.

Limitations

There are several limitations of this scoping review. Only one reviewer screened all of the titles and abstracts, and therefore some studies may have been inaccurately excluded from the study. The reviewers also extracted implementation strategies from each article and then selected categories for each strategy, but the categories selected by the reviewers may not reflect the actual intention of investigators in the original study. Furthermore, the authors of each article may not have described every implementation strategy used to support the implementation of SBIRT, and those strategies that were described may not have included all pertinent details. As the method did not include an appraisal of the quality of evidence, the results of this scoping review indicate gaps in the evidence but does not draw conclusions regarding the effectiveness of different implementation strategies.

Conclusion

In summary, this scoping review provides a summary of the strategies used in healthcare settings to support the reach and adoption of SBIRT. Most of the empirical evidence about the implementation of SBIRT in healthcare settings is from studies conducted in the United States in primary care and emergency department settings. Additional research in other healthcare settings (such as acute care) may identify strategies to support the implementation of SBIRT in other contexts. Healthcare leaders and researchers often train and educate stakeholders and use strategies to develop stakeholder interrelationships, but there is a lack of empirical evidence about adapting the intervention or engaging consumers. Because implementation is more effective when strategies address patient, professional, and organizational factors, leaders should consider using a comprehensive approach that does not limit the focus to providers. Finally, researchers often measure the reach of screening and the brief intervention, with less focus on adoption of SBIRT by providers or reach and adoption of referral to treatment. Referral to treatment is a complex process, and strategies to implement screening and brief intervention within one healthcare interaction may differ from the strategies required to effectively refer a patient to treatment.

Abbreviations

SBIRT: Screening, Brief Intervention, Referral to Treatment; SUD: Substance use disorder

Acknowledgements

The authors would like to thank Caitlin Pike, MLS, AHIP for providing feedback on the literature search strategy.

Authors' contributions

KT, RN, and JF contributed to the design of the review. KT, LM, SK, ML, & EN completed the reviews of each article, and RN & JF provided input if consensus was not reached by the two independent reviewers. All authors contributed to the manuscript and reviewed and approved the final manuscript.

Funding

n/a

Availability of data and materials

Data sharing is not applicable to this article as no datasets were generated or analyzed during the current study.

Declarations

Ethics approval and consent to participate

n/a

Consent for publication

n/a

Competing interests

The authors declare that they have no competing interests.

Author details

[1]Robert Wood Johnson Future of Nursing Scholar, Indiana University School of Nursing, 600 Barnhill Drive, Indianapolis, IN 46202, USA. [2]Sigma Theta Tau International Rising Star of Research and Scholarship, Indiana University Health Arnett Hospital, Purdue University, 5165 McCarty Lane, Lafayette, IN 47905, USA. [3]Indiana University Health, South Central Region, 601 West 2nd Street, Bloomington, IN 47403, USA. [4]Indiana University Health, Fairbanks Hall, 340 West 10th Street, Suite 3200, Indianapolis, IN 46202, USA. [5]Indiana University Health West, 1111 Ronald Reagan Parkway, Avon, IN 46123, USA. [6]Indiana University School of Nursing, 600 Barnhill Drive, NU 132, Indianapolis, IN 46202, USA. [7]Indiana University School of Nursing, Distinguished Professor, Indiana University, 600 Barnhill Drive, NU 132, Indianapolis, IN 46202, USA.

Accepted: 29 April 2021
Published online: 11 May 2021

References

1. Substance Abuse and Mental Health Services Administration. Key substance use and mental health indicators in the United States: Results from the 2018 National Survey on drug use and health (HHS publication no. PEP19–5068, NSDUH Series H-54). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. 2019. https://www.samhsa.gov/data/Accessed 30 Aug 2019.
2. Substance Abuse and Mental Health Services Administration. (2014). Projections of national expenditures for treatment of mental and substance use disorders, 2010–2020 HHS Publication No SMA-14-4883 Rockville, MD: Substance Abuse and Mental Health Services Administration 2014 https://storesamhsagov/system/files/sma14-4883pdf Accessed 30 Aug 2019.
3. National Institute on Drug Abuse. Trends & Statistics. 2019. https://www.drugabuse.gov/related-topics/trends-statistics#supplemental-references-for-economic-costs Accessed 30 Aug 2019.
4. Agley J, Carlson JM, McNeilis AM, Gassman RA, Schwindt R, Crabb D, Vannerson J. 'Asking' but not 'screening: assessing physicians' and nurses' substance-related clinical behaviors. Subst Use Misuse, 2018;53(11):1834–1839. https://doi.org/https://doi.org/10.1080/10826084.2018.1438806.
5. Substance Abuse and Mental Health Services Administration. About screening, brief intervention, and referral to treatment (SBIRT). 2017. https://www.samhsa.gov/sbirt/about Accessed 30 Aug 2019.
6. Aldridge A, Linford R, Bray J. Substance use outcomes of patients served by a large US implementation of screening, brief intervention and referral to treatment (SBIRT). Addiction, 2017;112(Suppl. 2):43–53.https://doi.org/https://doi.org/10.1111/add.13651.
7. Barbosa C, Cowell A, Bray J, Aldridge A. The cost-effectiveness of alcohol of screening, brief intervention and referral to treatment (SBIRT) in emergency and outpatient medical settings. J Subst Abus Treat 2015;53:1–8.https://doi.org/ https://doi.org/10.1016/j.jsat.2015.01.003.
8. Quanbeck A, Lang K, Anami K, Brown RL. A cost-benefit analysis of Wisconsin's screening, brief intervention, and referral to treatment program: adding the Employer's perspective. Wis Med J. 2010;109(1):9–14.
9. Kaner EFS, Beyer FR, Muirhead C, Campbell F, Pienaar ED, Bertholet N, et al. Effectiveness of brief alcohol interventions in primary care populations. Cochrane Database Syst Rev. 2018;(Issue 2) Art. No.: CD004148. https://doi.org/10.1002/14651858.CD004148.pub4.
10. Young MM, Stevens A, Galipeau J, Pirie T, Garritty C, Sign K, … Moher D. Effectiveness of brief interventions as part of the screening, brief intervention and referral to treatment (SBIRT) model for reducing the nonmedical use of psychoactive substances: A systematic review. Syst Rev. 2014;24:3:50. https://doi.org/https://doi.org/10.1186/2046-4053-3-50.
11. Centers for Disease Control and Prevention. Planning and implementing screening and brief intervention for alcohol use: A step-by-step guide for primary care practices. Atlanta, Georgia: Centers for Disease Control and Prevention, National Center on Birth Defects and Developmental Disabilities. 2014 https://www.cdc.gov/ncbddd/fasd/documents/alcoholsbiimplementationguide.pdf Accessed 30 Aug 2019.
12. Centers for Medicare and Medicaid Services. (2019). Screening, brief intervention, and referral to treatment (SBIRT) services 2019 https://wwwcmsgov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ SBIRT-Factsheet-ICN904084TextOnlypdf Accessed 30 Aug 2019.
13. National Institute on Drug Abuse. Principles of drug addiction treatment: A research-based guide (3rd edition). 2018. https://www.drugabuse.gov/node/pdf/675/ principles-of-drug-addiction-treatment-a-research-based-guide-third-edition. Accessed 30 Aug 2019.

14. National Institute on Alcohol Abuse and Alcoholism. Alcohol screening and brief intervention for youth: A practitioner's guide. NIH Publication No. 11-7805. 2019. https://www.niaaa.nih.gov/sites/default/files/publications/YouthGuide.pdf. Accessed 30 Aug 2019.
15. Covington K, Johnson JA, Henry D, Chalmers S, Payne F, Tuck L, Seale JP. Alcohol and drug screening and brief intervention behaviors among advanced practice registered nurse (APRN) students in clinical settings. Appl Nurs Res 2018;39:125-129. https://doi.org/https://doi.org/10.1016/j.apnr.2017.11.015.
16. Jun S, Plint AC, Curtis S, Newton AS. Screening, brief intervention, and referral to treatment (SBIRT) for adolescent alcohol use in emergency departments: a national survey of pediatric emergency physicians. Can J Emerg Med 2019;21(1):97-102. https://doi.org/https://doi.org/10.1017/cem.2018.390.
17. Bauer MS, Damschroder L, Hagedorn H, Smith J, Kilbourne AM. BMC Psychol, 2015;3:32. https://doi.org/https://doi.org/10.1186/s40359-015-0089-9, An introduction to implementation science for the non-specialist, 1.
18. Lane-Fall MB, Curran GM, Beidas RS. Scoping implementation science for the beginner: locating yourself on the "subway line" of translational research. BMC Med Res Methodol. 2019;19:133. https://doi.org/https://doi.org/10.1186/s12874-019-0783-z, 1.
19. Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of innovations in service organizations: systematic review and recommendations. Milbank Q 2004;82(4):581-629. https://doi.org/https://doi.org/10.1111/j.0887-378X.2004.00325.x.
20. Aarons GA. Measuring provider attitudes towards evidence-based practice: consideration of organizational context and individual differences. Child Adolesc Psychiatr Clin N Am 2005;14(2):255-271 https://doi.org/https://doi.org/10.1016/j.chc.2004.04.008
21. Rabin BA, Brownson RC, Haire-Joshu D, Kreuter MW, Weaver NL. A glossary for dissemination and implementation research in health. J Public Health Manag Pract 2008;14(2):117-123. https://doi.org/https://doi.org/10.1097/01.PHH.0000311888.06252.bb.
22. Wisdom JP, Chor KHB, Hoagwood KE, Horwitz SM. Innovation adoption: a review of theories and constructs. Admin Pol Ment Health 2014;41(4):480-502. https://doi.org/https://doi.org/10.1007/s10488-013-0486-4.
23. Chambers DA, Glasgow RE, Stange KC. The dynamic sustainability framework: addressing the paradox of sustainment amid ongoing change. Implement Sci 2013;8:117. https://doi.org/https://doi.org/10.1186/1748-5908-8-117, 1.
24. Proctor EK, Powell BJ, McMillen JC. Implementation strategies: recommendations for specifying and reporting. Implement Sci 2013;8:129. https://doi.org/https://doi.org/10.1186/1748-5908-8-139, 1.
25. Powell BJ, Waltz TJ, Chinman MJ, Damschroder LJ, Smith JL, Matthieu MM, Proctor EK, Kirchner JE. A refined compilation of implementation strategies: results from the expert recommendations for implementing change (ERIC) project. Implement Sci 2015;10:21. https://doi.org/https://doi.org/10.1186/s13012-015-0209-1, 1.
26. Waltz TJ, Powell BJ, Matthieu MM, Damschroder LJ, Chinman MJ, Smith JL, Proctor EK, Kirchner JE. Use of concept mapping to characterize relationships among implementation strategies and assess their feasibility and importance: results from the expert recommendations for implementing change (ERIC) study. Implement Sci 2015; 10:109. https://doi.org/https://doi.org/10.1186/s13012-015-0295-0, 1.
27. Proctor E, Silmere H, Raghavan R, Hovmand P, Aarons G, Bunger A, Griffey R, Hensley M. Outcomes for implementation research: conceptual definitions, measurement challenges, and research agenda. Admin Pol Ment Health, 2011;38: 65-76. https://doi.org/https://doi.org/10.1007/x10488-010-0319-, 2.
28. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. Am J Public Health, 1999;89(9), 1322-1327. https://doi.org/https://doi.org/10.2105/AJPH.89.9.1322.
29. Stoutenberg M, Galaviz KI, Lobelo F, Joy E, Heath GW, Hutber A, Estabrooks P. A pragmatic application of the RE-AIM framework for evaluating the implementation of physical activity as a standard of care in health systems. Prev Chronic Dis. 2018;15(E54). https://doi.org/https://doi.org/10.5888/pcd15.170344.
30. Keurhorst M, van de Glind I, Amaral-Sabadini MBD, Anderson P, Kaner E, Newbury-Birch D, ... Laurant M. Implementation strategies to enhance management of heavy alcohol consumption in primary health care: a meta-analysis. Addiction, 2015;110, 1877-1900. https://doi.org/https://doi.org/10.1111/add.13088, 12.
31. Nilsen P, Aalto M, Bendtsen P, Seppä K. Effectiveness of strategies to implement brief alcohol intervention in primary healthcare: a systematic review. Scand J Prim Health Care, 2006;24, 5-15. https://doi.org/https://doi.org/10.1080/02813430500475282, 1.
32. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. Int J Soc Res Methodol 2005; 8(1), 19-32. https://doi.org/https://doi.org/10.1080/1364557032000119616.
33. Munn Z, Peters MDJ, Stern C, Tufanaru C, McArthur A, Aromataris E. Systematic review of scoping review? Guidance for authors when choosing between a systematic or scoping review approach BMC Med Res Methodol 2018;18:143. https://doi.org/https://doi.org/10.1186/s12874-018-0611-x, 1.
34. Lindholm C, Adsit R, Bain P, Reber PM, Brein T, Redmond L, et al. (2010). A demonstration project for using the electronic health record to identify and treat tobacco users. Wis Med J. 2010;109(6):335-40.
35. Mello MJ, Bromberg J, Baird J, Nirenberg T, Chun T, Lee C, Linakis JG. Translation of alcohol screening and brief intervention guidelines to pediatric trauma centers. J Trauma Acute Care Surg. 2013;75(4 SUPPL. 3), S301-S307. https://doi.org/https://doi.org/10.1097/TA.0b013e318292423a.
36. Muench J, Jarvis K, Gray M, Hayes M, Vandersloot D, Hardman J, Grover P Winkle J. Implementing a team-based SBIRT model in primary care clinics. J Subst Use, 2015;20(2):106-112. https://doi.org/https://doi.org/10.3109/14659891.2013.866176.
37. Rieckmann T, Renfro S, McCarty D, Baker R, McConnell KJ. Quality metrics and systems transformation: are we advancing alcohol and drug screening in primary care? Health Serv Res 2018;53(3):1702-1726. https://doi.org/https://doi.org/10.1111/1475-6773.12716.
38. Thomas P, Seale P, Johnson A, Dhabilwala J, Kitchens D, Okosum IS, et al. Impact of a quality improvement intervention to increase brief alcohol and drug interventions on a level I trauma service. Am Surgeon. 2016;82(5):468-73. https://doi.org/10.1177/000313481608200524.
39. Whitty M, Nagel T, Ward L, Jayaraj R, Kavanagh D. Evaluation of an intervention for patients with alcohol-related injuries: results of a mixed methods study. Aust NZ J Publ Health, 2015;39(3), 216-221. https://doi.org/https://doi.org/10.1111/1753-6405.12375.
40. Zimmermann E, Sample JM, Zimmermann ME, Sullivan F, Stankiewicz S, Saldinger P. Successful implementation of an alcohol screening, brief intervention, and referral to treatment program. J Trauma Nurs 2018;25(3), 196-200. https://doi.org/https://doi.org/10.1097/JTN.0000000000000368.
41. Sharifi M, Adams WG, Winickoff JP, Guo J, Reid M, Boynton-Jarrett R. Enhancing the electronic health record to increase counseling and quit-line referral for parents who smoke. Acad Pediatr 2014;14(5), 478-484. https://doi.org/https://doi.org/10.1016/j.acap.2014.03.017.
42. Mello MJ, Baird J, Nirenberg TD, Smith JC, Woolard RH, Dinwoodie, R. G. project integrate: translating screening and brief interventions for alcohol problems to a community hospital emergency department. Subst Abuse, 2009; 30(3), 223-229. https://doi.org/https://doi.org/10.1080/08897070903040956.
43. Anderson P, Bendtsen P, Spak F, Reynolds J, Drummond C, Segura L, Keurhorst M.N., Palacio-Vieira J., Wojnar M., Parkinson K., Colom J., Kloda K., Deluca P., Baena B., Newbury-Birch D., Wallace P., Heinen M., Wolstenholme A., van Steenkiste B., Mierzecki A., Okulicz-Kozaryn K., Ronda G., Kaner E., Laurant M.G.H., Coulton S. Gual T. Improving the delivery of brief interventions for heavy drinking in primary health care: outcome results of the optimizing delivery of health care intervention (ODHIN) five-country cluster randomized factorial trial. Addiction. 2016;111(11), 1935-1945. https://doi.org/https://doi.org/10.1111/add.13476.
44. Henihan AM, McCombe G, Klimas J, Swan D, Leahy D, Anderson R, Bury G, Dunne CP, Keenan E, Lambert JS, Meagher D, O'Gorman C, O'Toole TP, Saunders J, Shorter GW, Smyth BP, Kaner E Cullen W. Feasibility of alcohol screening among patients receiving opioid treatment in primary care. BMC Fam Pract 2016; 17:153. https://doi.org/https://doi.org/10.1186/s12875-016-0548-2, 1.
45. Bendtsen P, Mussener U, Karlsson N, Lopez-Pelayo H, Palacio-Vieira J, Colom J, ... Anderson P. Implementing referral to an electronic alcohol brief advice website in primary healthcare: results from the ODHIN implementation trial. BMJ Open, 2016;6(6), e010271. https://doi.org/https://doi.org/10.1136/bmjopen-2015-010271asdf.
46. Mertens JR, Chi FW, Weisner CM, Satre DD, Ross TB, Allen S, Pating D, Campbell CI, Lu YW Sterling SA. Physician versus non-physician delivery of alcohol screening, brief intervention and referral to treatment in adult primary care: the ADVISe cluster randomized controlled implementation trial. Addict Sci Clin Pract. 2015;10: 26. https://doi.org/https://doi.org/10.1186/s13722-015-0047-0, 1.

47. Salvalaggio G, Dong K, Vandenberghe C, Kirkland S, Cummings GG, McKim R, et al. Effect of a knowledge translation intervention on physician screening, brief intervention, and referral to treatment behaviour in a socioeconomically disadvantaged setting. Can J Addict. 2015;6(1):7–14.
48. Sterling S, Kline-Simon AH, Satre DD, Jones A, Mertens J, Wong A, Weisner C. Implementation of screening, brief intervention, and teferral to treatment for adolescents in pediatric primary care: a cluster randomized trial. JAMA Pediatr, 2015;169(11), e153145. https://doi.org/https://doi.org/10.1001/jamapediatrics.2015.3145.
49. Lapham GT, Achtmeyer CE, Williams EC, Hawkins EJ, Kivlahan DR, Bradley KA. Increased documented brief alcohol interventions with a performance measure and electronic decision support. Med Care 2012;50(2), 179–187. https://doi.org/https://doi.org/10.1097/MLR.0b013e3181e35743.
50. Egizio LL, Smith DC, Bennett K, Campbell C, Windsor L. Field supervision training for a screening brief intervention and referral to treatment (SBIRT) implementation project. Clin Soc Work J 2019;47, 53–60. https://doi.org/https://doi.org/10.1007/s10615-018-0686-1, 1.
51. Bernstein E, Bernstein J, Feldman J, Fernandez W, Hagan M, Mitchell P, Safi C, Woolard R, Mello M, Baird J, Lee C, Bazargan-Hejazi S, Broderick K, Laperrier KA, Kellermann A, Wald MM, Taylor RE, Walton K, Grant-Ervin M, Rollinson D, Edwards D, Chan T, Davis D, Buchanan Marshall J, Aseltine R, James A, Schilling E, Abu-Hasaballah K, Baumann BM, Boudreaux ED, Maio RF, Cunningham RM, Murrell T, Doezema D, Anglin D, Eliassen A, Martin M, Pines J, Buchanan L, Turner J, D'Onofrio G, Degutis LC Owens P. An evidence-based alcohol screening, brief intervention and referral to treatment (SBIRT) curriculum for emergency department (ED) providers improves skills and utilization. Subst Abuse, 2007;28(4), 79–92. https://doi.org/https://doi.org/10.1300/J465v28n04_01.
52. American College of Surgeons Committee on trauma. Alcohol screening and brief intervention (SBI) for trauma patients: COT quick guide. 2007. https://www.facs.org/~/media/files/quality%20programs/trauma/publications/sbirtguide.ashx Accessed 15 Feb 2020. February 15, 2020.
53. U.S. Preventive Services Task Force. Screening and behavioral counseling interventions to reduce unhealthy alcohol use in adolescents and adults: US preventative services task force recommendation statement. JAMA, 2018; 320(18), 1899–1909. https://doi.org/https://doi.org/10.1001/jama.2018.16789.
54. Center for Health Information and Analysis. Behavioral health & readmissions in Massachusetts acute care hospitals. 2019. http://www.chiamass.gov/assets/docs/r/pubs/19/Behavioral-Health-Readmissions-2019.pdf. Accessed 7 Feb 2020.
55. McQueen J, Howe TE, Allan L, Mains D, Hardy V. Brief interventions for heavy alcohol users admitted to general hospital wards. Cochrane Database Syst Rev, 2011, Issue 8. Art. No.: CD005191. https://doi.org/ https://doi.org/10.1002/14651858.CD005191.pub3
56. The Joint Commission. Specifications manual for Joint Commission national quality measures (v2020A2). 2019. https://manual.jointcommission.org/releases/TJC2020A2/. Accessed 15 Feb 2020.
57. McNeely J, Kumar PC, Rieckmann R, Sedlander E, Farkas S, ... Rotrosen J. Barriers and facilitators affecting the implementation of substance use screening in primary care clinics: a qualitative study of patients, providers, and staff. Addict Sci Clin Pract 2018;13:8. https://doi.org/https://doi.org/10.1186/s13722-018-0110-8asdf, 1.
58. Broyles LM, Rosenberger E, Hanusa BH, Kraemer KL, Gordon AJ. Hospitalized patients' acceptability of nurse-delivered screening, brief intervention, and referral to treatment. Alcohol Clin Exp Res 2012;36(4), 725–731. https://doi.org/https://doi.org/10.1111/j.1530-0277.2011.01651.x.
59. Aarons GA, Hurlburt M, Horwitz SM. Advancing a conceptual model of evidence-based practice implementation in public service sectors. Admin Pol Ment Health 2011;38(1), 4–23. https://doi.org/https://doi.org/10.1007/s10488-010-0327-7.

Publisher's Note

Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

Ready to submit your research? Choose BMC and benefit from:

- fast, convenient online submission
- thorough peer review by experienced researchers in your field
- rapid publication on acceptance
- support for research data, including large and complex data types
- gold Open Access which fosters wider collaboration and increased citations
- maximum visibility for your research: over 100M website views per year

At BMC, research is always in progress.

Learn more biomedcentral.com/submissions



Addressing Substance Use for Better Patient Care

Screening, Brief Intervention and Referral to Treatment (SBIRT) is an evidence-based approach to identifying patients who use alcohol and other drugs at risky levels with the goal of reducing and preventing related health consequences, disease, accidents and injuries. Risky substance use is a health issue and often goes undetected.

1-877-8-HOPENY
1-877-846-7369

Find help for alcoholism, drug abuse and problem gambling

New York State HOPEline
Toll-Free, Anonymous and Confidential 24 hours a day, 365 days a year

---

New York State Office of Alcoholism and Substance Abuse Services
1450 Western Avenue
Albany, NY 12203-3526

518.473.3460 | www.oasas.ny.gov

Governor
Andrew M. Cuomo

Commissioner
Arlene González-Sánchez, MS, LMSW

New York State
Screening, Brief Intervention, and Referral to Treatment

A Standard of Practice
Resulting in Better Health Care

Why is SBIRT important?

22.6 million people suffer from a substance use disorder and six times as many people are using alcohol and/or drugs at risky levels.[1]

Hundreds of thousands of ED visits each year involve substance misuse: 20,000 people enter EDs each day for alcohol related injuries;[2] 40% of ED trauma cases are alcohol related;[3] and 20% of patients being tested in STD clinics screen positive for substance use disorders.[4]

Individuals with chronic medical conditions who have a comorbid SUD incur health care costs **2-3 times higher** compared with individuals who don't have a comorbid SUD.[5]

SBIRT is Cost-Saving and Cost-Effective

People who received SBI from their physician experienced **20% fewer ED visits**, 33% fewer nonfatal injuries, **37% fewer hospitalizations**, 46% fewer arrests and 50% fewer motor vehicle crashes.

Additionally, economic analyses showed that screening and brief counseling of nondependent, risky alcohol users allowed for a cost savings of $4.30 in future healthcare costs for every dollar invested in intervention.[6]

Of the 21 preventative services recommended by the USPSTF, screening and brief intervention ranks among the top five based on benefit and cost-effectiveness—higher than screening for high blood pressure, high cholesterol, breast, colon or cervical cancer and osteoporosis[7]—providing a net savings of $254 per person screened.[8]

See Sources on reverse side.

For more information about SBIRT, including how it can work in your healthcare setting, visit: http://www.oasas.ny.gov/AdMed/sbirt/index.cfm or contact OASAS at SBIRTNY@oasas.ny.gov

NYSBIRT is funded by a grant from the Substance Abuse and Mental Health Services Administration (SAMHSA, TI023470).

NEW YORK STATE | Office of Alcoholism and Substance Abuse Services

Sources

[1] Substance Abuse and Mental Health Services Administration. (2013). Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings. NSDUH Series H-46, HHS Publication No. (SMA) 13-4795. Rockville, MD.

[2] Emergency Nurses Association. Emergency Nurses Position Statement (2009): Available at: http://www.ena.org/SiteCollection Documents/Position%20Statements/Alcohol_Screening_and_Brief_Intervention_-_ENA_PS.pdf.

[3] Higgins-Biddle J, Hungerford D, Cates-Wessel K. (2009) Screening and Brief Interventions (SBI) for Unhealthy Alcohol Use: A Step-By-Step Implementation Guide for Trauma Centers. Atlanta (GA): Centers for Disease Control and Prevention, National Center for Injury Prevention and Control.

[4] Appel, P.W. Piculell, R., Jansky, H.K., & Griffy, K. (2006). Assessing alcohol and other drug problems (AOD) among sexually transmitted disease (STD) clinic patients with a modified CAGE-A: Implications for AOD intervention services and STD prevention. *American Journal of Drug and Alcohol Abuse*, 32, 129–153.

[5] National Council for Behavioral Health. (2014). The business case for effective substance use disorder treatment. Retrieved from http://www.thenationalcouncil.org/wp-content/ uploads/2015/01/14_Business-Case_Substance-Use.pdf. Accessed on June 27, 2016.

[6] Fleming, M. F., Mundt, M. P., French, M.T., Manwell, L. B., Stauffacher, E. A., & Barry, K. L. (2000). Benefit-cost analysis of brief physician advice with problem drinkers in primary care settings. *Medical Care*, 38(1), 7–18.

[7] Maciosek, M.V., Coffield, A.B., Edwards, N.M., Flottemesch, T.J, & Solberg, L.I. (2009). Prioritizing Clinical Preventive Services: A Review and Framework with Implications for Community Preventive Services. *Annu. Rev. Public Health*, 30, 341–55.

[8] Solberg, L., Maciosek, M., & Edwards, N. (2008). Primary care intervention to reduce alcohol misuse: Ranking its health impact and cost effectiveness. *American Journal of Preventive Medicine*, 34(2), 143-152.

Primary Care Providers Can Help Steer People to Opioid Addiction Treatment

Evidence indicates that tool could help more patients get prompt care and prevent overdoses

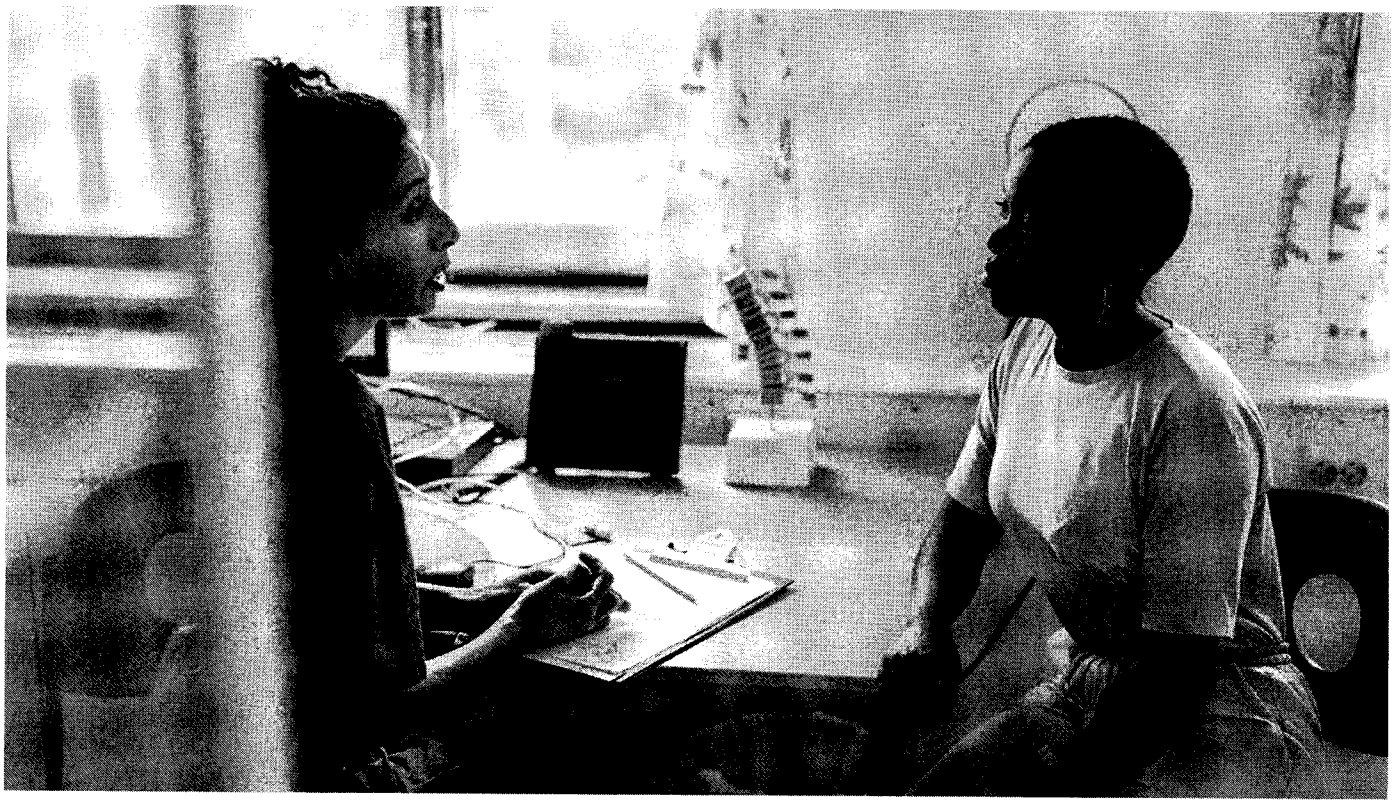
ARTICLE

January 25, 2021

By: Beth Connolly & Vanessa Baaklini

Read time: 3 min

Projects: Substance Use Prevention and Treatment



Cookie Settings

Privacy Notification

We use cookies and other technologies to help improve your browsing experience; some are necessary for the site to work, and some are optional. Learn more in our Cookie Notice.

More than ever, it is key to connect patients with opioid use disorder (OUD) to treatment as early as possible. Primary care offices can be among the most promising places to make this connection because they typically see patients over long periods of time. And a model for confronting substance use disorder, including OUD, that was pioneered by the National Academy of Medicine can help. This approach, which has been around for decades, has a long name—screening, brief intervention, and referral to treatment—that is usually shortened to SBIRT.

SBIRT is used in health care settings to screen patients for substance misuse. Based on an initial assessment, providers can start an intervention, provide treatment, or refer patients to specialty care. Although most research on the use of SBIRT is for alcohol misuse, a growing number of studies indicate that the approach may be effective in reducing misuse of other substances as well.

One reason for that is so many Americans routinely visit their doctors. Just more than three-quarters of U.S. adults surveyed in 2018 reported visiting or consulting a primary care physician at least once a year. And a three-year study that concluded in 2016 found the prevalence of OUD among primary care patients as high as 1.4%, higher than the prevalence of OUD among U.S. adults generally (0.8%) during the last year of the analysis. Still, these rates may not fully capture the amount of OUD because many physicians do not generally assess or document the illness. Broader use of SBIRT assessments could ensure that they do.

Primary Care Providers Can Routinely Screen for Opioid Use Disorder

To follow the SBIRT approach, clinicians can take the following steps and ask these sample questions during standard checkups and office visits.

Step 1: Screening

Clinician uses an evidence-based questionnaire to assess possible severity of patient substance use and identifies the appropriate level of intervention.

"How many times in the past year have you used an illegal drug or prescription medication for nonmedical reasons?"

Step 2: Brief Intervention

Privacy Notification

We use cookies and other technologies to help improve your browsing experience; some are necessary for the site to work, and some are optional. Learn more in our Cookie Notice.

Source: The U.S. Department of Health and Human Services' Substance Abuse and Mental Health Services Administration

Evidence of SBIRT's effectiveness

Peer-reviewed research indicates that SBIRT may be effective in reducing drug misuse in a variety of medical and community settings. A 2017 study of 11 programs serving over 1 million in total people found an 80% reduction in self-reported illicit substance use, including opioid use, following intervention. For example, Washington state's SBIRT program found that 84% of those who had been assessed using the process reported a reduction in days of drug use six months later. The program also saw an increase—from 55% to 71%—in the number of people reporting abstinence from illicit drugs in the past month. And in a randomized controlled trial in 2005 at an urban teaching hospital, researchers found that use of heroin and cocaine each declined by 29% following SBIRT interventions by peer educators.

But some of these outcomes are based on self-reported data, and other studies suggest no difference in outcomes for some who received SBIRT. That means additional research is needed to fully assess how effective the intervention is in identifying, intervening, and facilitating treatment for people with OUD.

Next steps

Federal policymakers can support SBIRT implementation and evaluation through grant awards to states. These efforts should focus on evaluating outcomes broken down by setting and substance being misused. States interested in implementing SBIRT programs for OUD should monitor federal funding availability and the evolving research.

Further, state Medicaid program administrators should opt to cover SBIRT so providers can get reimbursed for these services, which can be done by activating Medicaid SBIRT billing codes already authorized by the federal government and assigning reimbursement amounts. This process varies by state, but would encourage a more sustainable funding mechanism for

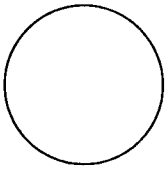
Privacy Notification

We use cookies and other technologies to help improve your browsing experience; some are necessary for the site to work, and some are optional. Learn more in our Cookie Notice.

approach to help their patients. In this time of great need, such approaches can offer clinicians more opportunities to link people with OUD to lifesaving treatment.

Beth Connolly is a director and Vanessa Baaklini is an associate for Pew's substance use prevention and treatment initiative.

AUTHORS



Vanessa Baaklini
Senior Associate
Substance Use Prevention and Treatment Initiative

MEDIA CONTACT

Erin Davis

Manager, Communications

202.540.6677

RELATED

Topics	Health Care, U.S. Policy, Behavioral Health
Projects	Substance Use Prevention and Treatment
Places	United States

Privacy Notification

We use cookies and other technologies to help improve your browsing experience; some are necessary for the site to work, and some are optional. Learn more in our Cookie Notice.

PLOS ONE

RESEARCH ARTICLE

Confronting challenges to opioid risk mitigation in the U.S. health system: Recommendations from a panel of national experts

Erin P. Finley[1,2]*, Suyen Schneegans[1], Megan E. Curtis[1], Vikhyat S. Bebarta[3], Joseph K. Maddry[4,5,6], Lauren Penney[1,2], Don McGeary[1], Jennifer Sharpe Potter[1]

1 UT Health San Antonio, San Antonio, Texas, United States of America, 2 South Texas Veterans Health Care System, San Antonio, Texas, United States of America, 3 University of Colorado School of Medicine, Aurora, CO, United States of America, 4 Emergency Department, Brooke Army Medical Center, San Antonio, Texas, United States of America, 5 59th Medical Wing Science and Technology Cell, San Antonio, Texas, United States of America, 6 San Antonio Uniformed Services Health Education Consortium, San Antonio, Texas, United States of America

* finleye@uthscsa.edu

Check for updates

OPEN ACCESS

Citation: Finley EP, Schneegans S, Curtis ME, Bebarta VS, Maddry JK, Penney L, et al. (2020) Confronting challenges to opioid risk mitigation in the U.S. health system: Recommendations from a panel of national experts. PLoS ONE 15(6): e0234425. https://doi.org/10.1371/journal.pone.0234425

Editor: Igor Linkov, US Army Engineer Research and Development Center, UNITED STATES

Received: August 27, 2019

Accepted: May 26, 2020

Published: June 15, 2020

Copyright: This is an open access article, free of all copyright, and may be freely reproduced, distributed, transmitted, modified, built upon, or otherwise used by anyone for any lawful purpose. The work is made available under the Creative Commons CC0 public domain dedication.

Data Availability Statement: Data cannot be shared publicly because comments cannot be fully anonymized, resulting in confidentiality concerns for participants. De-identified data are available from Dr. Kimberly Summers (summers@uthscsa.edu), who is Director of our Institutional Review Board, the University of Texas Health Science Center at San Antonio Institutional Review Board.

Funding: We gratefully acknowledge support awarded to UT Health San Antonio, PI Jennifer

Abstract

Background

Amid the ongoing U.S. opioid crisis, achieving safe and effective chronic pain management while reducing opioid-related morbidity and mortality is likely to require multi-level efforts across health systems, including the Military Health System (MHS), Department of Veterans Affairs (VA), and civilian sectors.

Objective

We conducted a series of qualitative panel discussions with national experts to identify core challenges and elicit recommendations toward improving the safety of opioid prescribing in the U.S.

Design

We invited national experts to participate in qualitative panel discussions regarding challenges in opioid risk mitigation and how best to support providers in delivery of safe and effective opioid prescribing across MHS, VA, and civilian health systems.

Participants

Eighteen experts representing primary care, emergency medicine, psychology, pharmacy, and public health/policy participated.

training. Panelists pointed to need for provider training in application of clinical practice guidelines, use of existing information resources (e.g., PDMPs, CDS) and risk management practices (e.g., urine drug screens, opioid tapering), and effective communication with patients (e.g., realistic goal-setting, shared decision-making).

> [G]ive the providers that are [asking for help] some education and tools in how to address this type of patients in the future. [Civilian Clinician]

Implement new measures with appropriate training and support to achieve uptake and sustainment. Panelists also noted the importance of ensuring new tools (e.g., CDS), guidelines, and other resources (e.g., screening or referral technologies) are introduced alongside appropriate training and other implementation strategies, such as backing from leadership, clinical champions, and/or continuing education and feedback, in order to ensure uptake and sustainment.

> [S]ome healthcare leader in that institution needs to be involved in this. This will need consistent reinforcement, otherwise you're going to get folks who do this great for about a month or two, and then they're like, "Ahh it's too much work, I'm done," and then they never see it again. So you have to have that sustainment. . .that continued implementation tail. [Military Clinician]

Educate and engage patients in safe and effective chronic pain management. Panelists offered a vision for supporting patients to achieve reduced pain intensity and improved functioning and quality of life. They cited the need for resources to help patients set and achieve realistic goals for pain management.

> I think we need to really set those expectations up and help [patients] understand their options. And then figure out, work with them to help them understand what is acceptable for them kinda going forward. [VA Researcher and Policymaker]

Discussion

We conducted qualitative discussions with a panel of national experts to identify key challenges and recommendations in reducing risks associated with prescribed opioids. Panelists provided insight into challenges across multiple levels of the U.S. health system, including: the technical complexity of treating chronic pain; the fraught national climate around opioids; the need to integrate surveillance data across a fragmented health system; a lack of access to non-pharmacological options for chronic pain care; and the difficulties inherent in asking providers and patients to negotiate treatment for a complex condition in brief clinical encounters, often without adequate knowledge on either side of the risks, benefits and/or availability of chronic pain care options. Panelists' discussion of core challenges for providers underscore findings of other recent studies, in which providers described navigating a "tightrope" between the push to avoid opioid prescriptions for chronic pain and pressure from patients to prescribe [10,24–26]. A study of patient satisfaction scores by Sites et al. [27] found that, among patients with musculoskeletal pain, those receiving opioid medications were more likely to report being highly satisfied with their care. Patients with chronic pain, meanwhile, may report feeling reliant on opioids even when expressing ambivalence regarding their benefit [28,29]. Given this, prescribers' sense of walking a tightrope becomes understandable, particularly given the tense national climate described by participating experts.

In the course of these expert discussions, panelists collaboratively imagined a healthcare delivery system that would ensure access to behavioral health and other non-pharmacological therapies for chronic pain, achieve interconnectivity and care coordination within and across health systems, utilize thoughtful CDS and tools to support providers in real-time assessment of likely treatment risks and benefits, and provide education and training for both providers and patients. They recommended that clinical teams would also facilitate patients' access to consultation and treatment for substance use disorders [30], while permitting opioid use as part of safe and appropriate pain management for those most likely to benefit. Establishment of the new Defense Health Agency may enhance opportunities to improve collaboration across the MHS, civilian sector, and VA.

These findings point to challenges and opportunities at multiple levels, beginning with providers and patients themselves. Repeated studies have shown deficits in patient-provider communication around opioid prescribing for acute and chronic pain [31–33], consistent with those described by panel members. These deficits persist despite availability of a variety of resources to educate providers to engage in "healthy dialogue" with patients around appropriate use of opioids [34]. Participating experts also highlighted continued need to identify and disseminate evidence-based practices for comprehensive pain management, to include best practices for opioid prescribing and screening and referral for substance use disorders, as needed. Although there is growing consensus regarding recommendations for chronic pain care [6], opioid risk mitigation strategies remain complex. Providers require ongoing training and support to implement recommendations. Practical tools for decision support in busy clinical settings[10,35] are required, but must be feasible for health care providers to use routinely amid juggling a continuum of other health issues.

At the broader system level, panelists acknowledged that access to both nonpharmacologic pain care and substance use disorder treatment remains constrained in many–and particularly rural–areas. There are well-recognized disparities in the availability of specialty providers and evidence-based treatment options across the country [36–40]. In addition, many healthcare insurance plans limit coverage for nonpharmacologic chronic pain treatment options, despite efforts to increase parity in coverage of mental health and substance use care under the Affordable Care Act [41–43]. Healthcare coverage plans may also be inconsistent with CDC and other guidelines for pain care, which explicitly recommend multimodal pain care and integration of CBT. Although one survey of state Medicaid agencies found that most reported providing at least some coverage for non-opioid pain treatment [44], a cross-sectional study of 45 plans representing Medicaid, commercial, and Medicare Advantage insurers found that few covered acupuncture or psychological interventions like CBT for chronic non-cancer pain [45]. Evidence from the VA suggests, however, that patients are receptive to nonpharmacologic pain management when those options are made available [44]. Thus efforts to ensure healthcare coverage aligns with guidelines for effective pain care are likely to remain an important area for future work. Creative solutions must also be identified to address geographic impediments to comprehensive pain management.

The method of qualitative panel discussions used here has a number of strengths, which include reflecting expert knowledge and incorporating diverse national, cross-system, and multidisciplinary perspectives [46]. Given constraints on expert panelists' time, we did not adopt a formalized process of developing consensus (e.g., Delphi method); as a result, weighting recommendations in terms of their perceived importance or feasibility awaits further investigation. Our semi-structured discussion approach, however, allowed for more in-depth exploration of topics than is often possible with consensus-focused methods [47]. Additional limitations included modest sample size and incomplete representation across diverse medical specialties and health systems.

SCIENTIFIC REPORTS
natureresearch

OPEN

Epidemiological and geospatial profile of the prescription opioid crisis in Ohio, United States

Andres Hernandez[1,2], Adam J. Branscum[3], Jingjing Li[4], Neil J. MacKinnon[5], Ana L. Hincapie[5] & Diego F. Cuadros[1,2*]

The underlying reasons behind the unprecedented increase of the mortality rates due to the opioid epidemics in the United States are still not fully uncovered. Most efforts have been focused on targeting opioids, but there is little information about vulnerable populations at high risk of opioid abuse and death. In this study, we used data from the Ohio Department of Health for deaths caused by prescription opioids from 2010–2017 to analyze the spatiotemporal dynamics of the opioid overdose epidemic. Our results showed a rapid increase in prescription opioid death rates among the white male population aged 30–39 but also a considerable increase among the black male population with an exponential growth trend. Our geospatial analysis suggests that the increasing rates of the opioid overdose epidemic in Ohio were driven by the epidemic hotspot areas. Our findings highlight the relevance of prioritizing public health measures targeting specific locations and vulnerable populations to mitigate the current opioids crisis.

The United States (US) is currently experiencing an opioid overdose crisis with an unprecedented magnitude. Adjusted for age, the opioid-related death rate of 21.7 deaths per 100,000 people in 2017, and 20.7 in 2018 were the highest worldwide[1]. According to the Centers for Disease Control and Prevention (CDC), 67,367 deaths by drug overdose occurred in the US during 2018, and 351,564 deaths were related to opioids resulting in 0.36 years of life expectancy lost in 2016[1,2]. The major cause of death among people under 50 years old in the US in 2017 was drug overdose, exceeding the rates of death caused by motor vehicle and firearms[3]. Opioids have become a widespread cause of accidental fatal overdose, which historically were attributed to heroin and prescription opioid pain relievers. Recent reports show that overdoses caused by synthetic opioids (e.g., fentanyl and analogues) are emerging as a national public health emergency, as declared by the US Department of Health and Human Services in 2018[4].

National data on opioid overdose mortality rates show that the epidemic is not homogenously distributed within the US. Twenty states and the District of Columbia have reported age-adjusted drug mortality rates that are statistically higher than the national rate. Among these, West Virginia (51.5 deaths per 100,000 inhabitants), Delaware (43.8), Maryland (37.2), Pennsylvania (36.1.3), Ohio (35.9), and New Hampshire (35.8) had the highest age-adjusted drug overdose rates in 2018[1]. Moreover, Ohio is one of eight states with a doubling of the opioid mortality rate every three years from 1999 to 2016, and recently has experienced an unprecedented number of deaths caused by unintentional drug overdose, especially deaths caused by synthetic opioids[2,5]. Specifically, there was a 169% increase from 1,544 deaths in 2010 to 4,157 deaths in 2017, and approximately 13,000 overdose events reversed by the use of naloxone.

Several reasons are attributed to the geographical disparity of the opioid overdose mortality[6–8]. Among the potential factors of the uneven distribution, special attention has been devoted to the association between the opioid overdose mortality and drug prescription rates, and the availability of medications to reverse overdose events (naloxone)[8]. This approach can be linked to the intervention measures implemented in these high opioid overdose burden areas to tackle the epidemic, which are focused on controlling prescription while increasing the availability of resources to treat the adverse effects of the overdose events[9]. Additionally, other studies also

[1]Department of Geography and Geographic Information Science, University of Cincinnati, Cincinnati, USA. [2]Health Geography and Disease Modeling Laboratory, University of Cincinnati, Cincinnati, USA. [3]Department of Biostatistics, College of Public Health and Human Sciences, Oregon State University, Corvallis, USA. [4]Urban Health Collaborative, Dornsife School of Public Health, Drexel University, Philadelphia, Pennsylvania, USA. [5]James L. Winkle College of Pharmacy, University of Cincinnati, Cincinnati, Ohio, USA. *email: diego.cuadros@uc.edu

propose socioeconomic characteristics associated with the high-risk opioid overdose areas[10]. Health accessibility (primary care and mental health accessibility), unemployment rate, urbanicity, and availability of prescription vs. non-prescription opioids seem to be associated with high rates of opioid overdose mortality[7,8]. However, the reasons behind the uneven spatial distribution of the opioid epidemic in the US are still not well understood. Although the link between the number of opioid prescriptions and opioid overdose deaths has been observed, explanations about the rapid rise in the epidemic in specific areas remain incomplete, especially in areas where the number of opioid prescriptions is low and the determinants (i.e., drivers) of the epidemic have not been completely established[11]. Moreover, the epidemiological characteristics of the opioid public health crisis remain understudied and there is a lack of substantial spatial analysis for allowing health authorities to make decisions for resource allocation at small scales.

While most efforts have been focused on targeting opioids, there is little information about vulnerable populations at high risk of opioid abuse and death, where and what demographical groups are at higher risk, and what are the drivers boosting the epidemic of opioid overdose deaths in the recent years[12].

In this context, geospatial statistical and epidemiological models are important tools for identifying the spatial and temporal dynamics of the epidemic[13]. Understanding the critical spatiotemporal characteristics of the opioid overdose crisis will provide valuable information to identify the potential socio-economic drivers of the epidemic as well as geographic areas where vulnerable populations are located, and where interventions should be implemented.

In this study, we used data from the Ohio Department of Health for deaths caused by prescription opioids from 2010–2017 to analyze the spatiotemporal dynamics of the opioid overdose epidemic in Ohio. The objective of the present paper is threefold, namely, to identify (i) the demographic groups in Ohio at higher risk of prescription opioid overdose death, (ii) the geographic areas in Ohio where the burden of overdose mortality is concentrated, and (iii) the temporal trend of the opioid epidemic in Ohio. The results from this study will inform public health authorities and clinical practitioners about which locations and groups should be prioritized for surveillance to improve public health response addressed to mitigate the current opioids crisis, not only in Ohio but also inform other parts of the country experiencing emerging epidemics, and even other countries of the world where opioid epidemics seems to be emerging.

Results

General profile of the opioid overdose epidemic. Deaths by unintentional prescription opioids overdose in Ohio for 2010–2017 resulted in 11,790 cases (white population: 10,712 – black population: 1,078). Deaths have increased continuously from 653 in 2010 to 3,674 in 2017, with an exponential growth trend. Prescription opioid overdose mortality rates increased from 9.98 to 57.31 per 100,000 inhabitants from 2010 to 2017 (Table 1). The highest prescription opioid overdose mortality rates were found in the white male population aged 30–34, with 131.45 cases per 100,000 inhabitants, followed by males aged 35–39 with 120.48 cases per 100,000 inhabitants, compared to the 57.31 cases per 100,000 inhabitants for the total population in 2017 (Table 1). Figure 1 illustrates the temporal growth trends for race and gender categories and shows that black males were experiencing the fastest estimated annual increase (46.73%) of the opioid overdose mortality rate, compared to the total population rate (31.65%) during the period of study. For this specific race group, the highest rate was found in black males aged 35–39, with 109.55 cases per 100,000 inhabitants in 2017.

Spatial clustering analysis of the opioid overdose epidemic. We identified 12 geographical clusters (hotspots) of prescription opioid overdose mortality cases where most of the burden of the epidemic in Ohio was concentrated during 2010–2017 (Table 2). These 12 hotspots encompassed 21% of the population at risk (1,363,811) and contained 4,769 (40%) total deaths by prescription opioids overdose from 2010 to 2017. In 2017, mortality rates by prescription opioid overdose were almost three times higher within the hotspots compared with the outside areas, with 116.00 cases per 100,000 inhabitants within the hotspot areas and 40.49 cases per 100,000 inhabitants outside of the hotspots. The geographical locations of the identified hotspots are presented in Fig. 2. Most hotspots (Clusters 1, 2, 4, 6, 7, 9, 11, and 12) were located around the three major southwestern cities of Ohio (Dayton, Cincinnati, and Columbus). Three additional hotspots (Clusters 3, 5, and 8) were identified in the cities of Cleveland, Akron, and Youngstown, and one small hotspot (Cluster 10) was identified in the city of Toledo on the northern border with Michigan.

Space and space-time relative risk estimation. The spatial distribution of the relative risk (RR) of death by prescription opioid overdose is presented in Fig. 2A. RR ranged from 0 to 8.16, and was classified as lowest risk areas (RR < 0.50), low risk (RR: 0.50–0.80), intermediate risk (RR: 0.80–1.20), high risk (RR: 1.20–2.00), and highest risk (RR > 2.00). In 2017, the RR within the hotspot areas was significantly higher (average RR = 2.42, 95% confidence interval [CI] 2.15–2.68) compared to the non-hotspot areas (RR = 0.80, 95% CI: 0.77–0.84). Additionally, the RR was significantly higher than 1 in most of the hotspots except for Cluster 6 (RR = 2.45, 95% CI: 0.63–4.26), Cluster 11 (RR = 2.20, 95% CI: 0.77–5.28), and Cluster 12 (RR = 1.28, 95% CI: 0.76–1.81). The highest RR values were in Cluster 1 (RR = 3.61, 95% CI: 2.33–4.89) around the city of Dayton, followed by Cluster 3 (RR = 2.94, 95% CI: 1.83–4.05) in Cleveland, and Cluster 4 located in the Cincinnati area (RR 2.61, 95% CI: 1.90–3.31).

Temporal analysis of the RR of death caused by prescription opioid overdose identified a significant increase over time within the hotspot areas (RR change from 2010 to 2017: +10.17%, 95% CI: +4.82–+15.51%) (Fig. 2B). Conversely, RR in the non-hotspots areas was significantly decreasing (RR Change: −3.20%, 95% CI: −4.10–−2.31%). The highest RR increase was observed in Cluster 1, with an RR increase of 48.94% (95% CI: 25.72–72.16%). The only hotspot for which RR had a significant reduction was Cluster 6 located within the area of Columbus, Ohio (RR Change: −16.99%, 95% CI: −33.85–−0.12%).

RACE	GENDER	AGE GROUP	2010	2011	2012	2013	2014	2015	2016	2017
Black	Female	20–24	1.67	0.00	1.52	0.00	1.46	4.45	7.62	20.36
Black	Female	25–29	0.00	1.90	3.76	5.49	1.74	3.29	12.48	10.37
Black	Female	30–34	6.07	3.97	0.00	1.92	5.76	7.67	17.00	37.05
Black	Female	35–39	2.05	6.37	2.17	0.00	12.78	8.27	18.16	39.21
Black	Female	40–44	8.37	4.12	2.03	2.02	4.08	10.45	15.14	19.78
Black	Female	45–49	1.92	1.98	6.17	6.36	10.81	12.94	19.00	22.87
Black	Female	50–54	14.83	5.56	14.98	13.33	9.69	9.94	12.31	29.62
Black	Female	55–59	8.85	10.75	8.34	6.06	7.93	17.58	25.36	29.47
Black	Female	60–64	5.63	5.26	7.70	5.04	12.22	7.12	27.62	17.78
Black	**Female**	**All**	**5.39**	**4.22**	**5.06**	**4.36**	**6.91**	**8.79**	**16.62**	**24.73**
Black	Male	20–24	0.00	3.32	4.68	1.48	4.36	10.19	14.74	22.55
Black	Male	25–29	2.14	4.24	4.16	7.95	7.48	19.33	47.73	52.61
Black	Male	30–34	4.53	4.46	6.61	4.33	17.35	34.48	57.13	70.00
Black	Male	35–39	6.83	2.36	4.82	0.00	16.48	29.80	40.25	109.55
Black	Male	40–44	2.30	4.53	2.25	4.49	13.62	18.68	31.28	100.25
Black	Male	45–49	4.32	4.45	9.14	11.69	2.39	18.86	34.79	48.04
Black	Male	50–54	8.41	14.67	10.57	8.58	17.45	11.17	25.13	93.78
Black	Male	55–59	5.12	17.45	9.64	18.71	22.90	31.54	51.59	74.59
Black	Male	60–64	0.00	0.00	12.59	21.44	17.77	39.91	55.29	106.70
Black	**Male**	**All**	**3.78**	**6.21**	**6.87**	**7.96**	**12.62**	**22.58**	**38.62**	**70.91**
Black	**All**	**All**	**4.63**	**5.16**	**5.92**	**6.07**	**9.63**	**15.37**	**27.14**	**46.83**
White	Female	20–24	4.31	2.62	2.60	2.60	9.18	14.36	21.78	25.91
White	Female	25–29	6.65	7.38	7.79	7.76	13.19	23.30	36.12	43.88
White	Female	30–34	7.21	8.17	12.35	11.57	12.99	22.20	44.24	71.31
White	Female	35–39	9.33	8.32	8.14	9.27	16.59	27.33	44.46	51.41
White	Female	40–44	11.02	10.72	10.25	10.14	16.88	25.91	27.11	50.52
White	Female	45–49	13.20	15.98	16.55	12.25	15.79	23.43	32.14	42.38
White	Female	50–54	8.59	11.72	10.06	14.32	15.42	23.18	27.91	33.73
White	Female	55–59	6.01	6.48	8.01	10.06	9.45	15.14	21.93	29.15
White	Female	60–64	2.63	1.87	2.52	2.81	11.08	6.33	10.09	11.34
White	**Female**	**All**	**7.79**	**8.32**	**8.77**	**9.10**	**13.30**	**19.81**	**28.90**	**38.84**
White	Male	20–24	10.12	9.02	6.69	7.63	15.07	24.71	47.15	49.84
White	Male	25–29	13.61	15.04	11.89	14.47	26.29	45.18	80.33	95.13
White	Male	30–34	21.61	16.67	17.61	17.16	35.44	64.09	97.89	131.45
White	Male	35–39	16.01	14.58	20.10	14.16	38.42	54.72	97.81	120.48
White	Male	40–44	16.47	11.42	17.73	17.49	26.92	49.14	77.72	107.20
White	Male	45–49	16.31	18.94	14.14	15.82	19.47	34.63	54.79	77.64
White	Male	50–54	15.27	16.66	12.84	17.57	22.41	26.19	47.70	70.33
White	Male	55–59	9.22	8.18	6.89	8.48	18.83	24.80	42.14	54.04
White	Male	60–64	5.57	1.66	4.01	3.97	6.84	8.62	16.00	25.57
White	**Male**	**All**	**13.80**	**12.52**	**12.25**	**12.94**	**22.86**	**35.91**	**60.87**	**79.43**
White	**All**	**All**	**10.77**	**10.40**	**10.49**	**11.00**	**18.05**	**27.81**	**44.80**	**59.04**
All	**All**	**All**	**9.98**	**9.72**	**9.89**	**10.34**	**16.90**	**26.10**	**42.33**	**57.31**

Table 1. Descriptive demography of proportion (%) for deaths by prescription opioid overdose deaths in Ohio (2010–2017).

Temporal trend analysis. Temporal trend analysis identified three significant changing trends of the opioids overdose epidemic in Ohio. Figure 3 shows the cumulative percentage difference between the observed growth rate of death rates by prescription opioid overdose and the expected counterfactual in the significant trimesters (dashed, black lines). The first trend was identified in January 2011 with a decreasing effect in the trajectory of the epidemic ($p < 0.005$). Conversely, two trends with an increasing effect in the mortality rate were identified in July 2013 and October 2015 ($p < 0.005$). The increasing trend identified in July 2013 had the highest impact in the temporal dynamics of the epidemic, with an estimated difference between the observed and expected changes in the mortality rate of +21.00% (95% CI: +6.10–+37.00%). This result indicates that in absence of any disturbance, we would have an expected decrease of the mortality rate of −3.00% (95% CI: −19.00–+12.00%) for each month, but in contrast we observed a monthly average increase of +18.00% starting in this time point (July 2013). Similarly, effects for the second trending increase in 2015 corresponded to a difference between observed and expected mortality rate change of +13.00% (95% CI: −3.00–+30.00%). Detailed

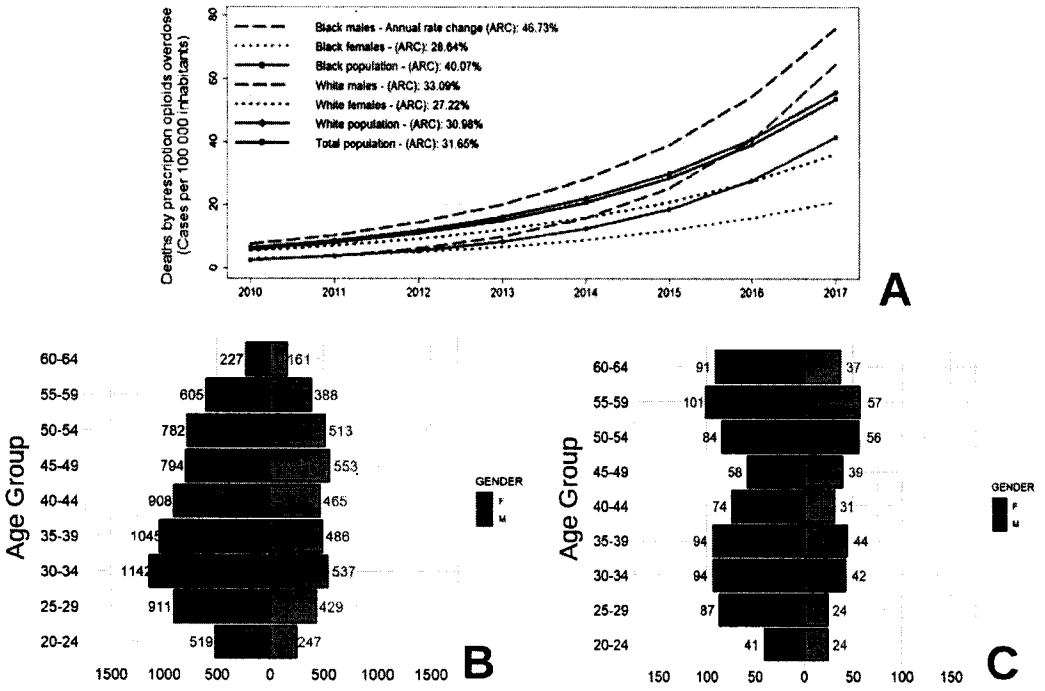


Figure 1. (**A**) Descriptive demographics and annual rate change (ARC) of prescription opioids overdose mortality rates by major demographic groups in Ohio (2010–2017). (**B**) Case counts by age groups for white population. (**C**) Case counts by age groups for black population.

results of temporal trending causal effect estimation can be found in Supplementary Table 1, and spatio-temporal dynamics of the opioid overdose cases are illustrated in Supplementary Video 1 in Supplementary Materials.

Discussion

We combined a novel spatial epidemiology approach with data for prescription opioid overdose deaths from 2010–2017 from Ohio and determined that the opioid overdose epidemic is concentrated in specific locations and severely affecting specific demographic groups. We found that the burden of deaths related to prescription opioid abuse was concentrated mostly in the white male population aged 30–39, followed by black males aged 35–44, especially in Southwestern Ohio, with a remarkable exponential increasing trend. Sociodemographic risk factors have been related to substance abuse disorders by several studies conducted previously[14]. These studies found that age, gender, race, and economic factors have a significant impact in the risk of substance abuse disorders[15]. Moreover, the opioid use disorder (OUD) epidemic currently experienced in Ohio can be the result of a long complex series of epidemics related to substance abuse that have been reported in the U.S. since the early 20th century. These epidemics have several interconnected elements at individual and interpersonal level, as well as with the relationship between individuals, families and their communities[14].

Opioid overdose deaths are often the result of a previous history of substance abuse, which often starts between the ages of 18 to 25 years[16]. Adolescents with a family history of substance abuse are 10-fold more likely to suffer drug abuse disorders in the future than other individuals[14]. Individuals aged 25–44 years may start using opioids for medical or recreational purposes, and then shift to more cost-effective substances like fentanyl[17]. Such early onset of substance addiction is consistent with our results, which show that the young adult population (25–39 years) was experiencing the highest burden of opioid overdose deaths, possibly in the last stage of an OUD history. Also, consumption of synthetic opioids such as fentanyl and analogs, which are the current leading substances associated with overdose deaths, is more frequent in white non-Hispanic males.

Our results suggest notable disparity among gender and racial groups. This could be due to the opioid overdose epidemic following a temporal trend that is comprised of three waves[14,16]. Briefly, the first wave of the opioid overdose epidemic, from 1970 to 1999, was driven by heroin overdoses, which showed a larger burden centered in the black population. The second wave, from 1999 to 2010, was mainly caused by prescription opioids often used for pain management therapy, which produced a steeper increase in death rates among the white population. This increase was driven in part by broader access to healthcare, marketing campaigns, and socio-economic determinants, as well as the marketing of opioid products to medical doctors, which was found to be associated with increased opioid prescribing and, subsequently, with elevated mortality from overdoses[18,19]. Finally, the third wave, which includes the current study time period (2010 to 2017), is mainly attributed to the combination of prescription opioids and the introduction of synthetic opioids[16,18]. Nationwide, this last wave has shown a similar increase in both racial groups (white and black)[18].

Our results showed a rapid increase in prescription opioid death rates among the white male population but also a larger increase among the black male population. However, the underlying causes of these

Cluster	Radius (Km)	Estimated population in 2017	Total death cases (All years)	Total death cases (2010–2017)	Mortality rate (2010–2017) per 100,000 hab.	RR (95% CI) Mean [95% CI]	RR temporal change 2010–2017 [95% CI]
1	12.64	188,097	771	353	187.66	3.61 [2.33–4.89]	+48.94 [+25.72–+72.16]
2	17.09	152,828	647	211	138.06	2.20 [1.76–2.64]	+9.63 [−10.69–+30.22]
3	9.20	165,470	607	216	130.54	2.94 [1.83–4.05]	+20.58 [−0.98–+42.16]
4	8.92	181,154	598	194	107.09	2.61 [1.90–3.31]	+7.87 [−2.55–+18.30]
5	8.87	127,772	437	105	82.18	2.58 [1.90–3.26]	+17.88 [+4.55–+31.20]
6	7.14	112,734	386	121	107.33	2.45 [0.63–4.26]	-16.99 [−33.85–−0.12]
7	15.66	69,965	254	82	117.20	1.78 [1.20–2.36]	+1.77 [−9.77–+13.31]
8	13.93	125,693	381	128	101.84	1.78 [1.37–2.18]	+1.18 [−7.76–+10.12]
9	24.34	49,170	173	46	93.55	2.41 [1.51–3.31]	−2.10 [−12.66–+8.47]
10	6.44	120,373	315	78	64.80	1.71 [1.26–2.17]	−9.07 [-19.49–+1.36]
11	10.96	8,672	37	7	80.72	3.04 [0.77–5.28]	−1.65 [−15.58–+12.28]
12	25.83	61,884	163	41	66.25	1.28 [0.76–1.81]	−2.84 [−25.20–19.53]
TOTAL HS	161.01	1,363,811	4,769	1,582	116.00	2.42 [2.15–2.68]	+10.17 [+4.82–+15.51]
TOTAL NHS		5,166,333	7,021	2,092	40.49	0.80 [0.77–0.84]	−3.20 [−4.10–−2.31]
TOTAL		6,530,144	11,790	3,674	56.26	1.01 [0.95–1.06]	−1.51 [−2.57–−0.45]

Table 2. Identified clusters of deaths by prescription opioid overdose for Ohio 2010–2017, and aggregations by hotspots (HS) and Non-Hotspots (NHS) areas. Confidence Intervals (CI) at 95% are included for averaged relative risks (RR) and RR temporal change of mortality rate of prescription opioid overdose. [a]RR temporal change 2010–2017 was defined as: $\frac{\left(\overline{RR}_{\text{last semester 2017}} - \overline{RR}_{\text{first semester 2010}}\right)}{\overline{RR}_{\text{first semester 2010}}}$*.

epidemiological trends differ among these demographic groups[14,18]. Misuse of synthetic opioids differs by gender and race. Moreover, previous analysis of healthcare accessibility among major racial groups suggests that black males are less likely to get appropriate treatment and effective medication for OUD. Black males were also reported to have a higher rate of overdose deaths caused by cocaine compared to other demographic groups[14,18]. However, this trend is rapidly changing, due in part by the current state of the opioid epidemic in which the price of synthetic opioids is decreasing while demand is increasing[16]. The access to addiction treatment and medications to reverse the effects of opioids addiction (naloxone) could also contribute to the racial disparity in the temporal trends of the opioid epidemic[20].

We found a rapid and large increase in the rate of prescription opioids overdose death in the male population. Although, gender disparities for the OUD epidemics have shown that females are more likely to get prescription opioids than men[14], the high amount of overdose deaths caused by synthetic drug overdoses since 2013 tends to obscure death rates caused by other types of opioids. The countermeasures to limit the effects of the opioid epidemic focusing on limiting prescriptions have resulted in declining overdose deaths by prescription opioids mainly in the female population[16]. Finally, females were found to be more likely to obtain a naloxone prescription than males[21].

Our geospatial analysis suggests that the increasing rates of the opioid overdose epidemic in Ohio were driven by the epidemic hotspot areas. The results highlight the need for identifying areas with high and low risks when analyzing the overall epidemiological trends of the opioid crisis[22]. In fact, intrinsic spatial dynamics of epidemics identified in previous studies suggest that an overall decreasing trend in the epidemic at large geographical scales could mask local disparities with sustained or increasing burden of the epidemic in hotspot areas[22,23]. For example, whereas the RR slightly declined in the areas outside of the clusters identified, the highest RR was found in Cluster 1 (RR = 3.61), which was also the cluster with the highest temporal increase between 2010 and 2017 (RR increase: 48.94%). This area includes the city of Dayton, the city with the highest death rate due to drug overdose in the U.S. for 2017[24,25]. Moreover, reasons for the spatial concentration of opioid overdoses in the southwestern counties could be partially explained by the high amount of opioids seizures recorded in Ohio, Kentucky and Indiana, which suggest that state borders may be areas where opioid consumption for non-medical purposes (especially illegally manufactured fentanyl) is common[26]. Geographic differences in the opioid demand are also linked to the historic substance abuse burden, exacerbated by areas where job and educational opportunities have been traditionally more difficult to access[10].

The opioid overdose epidemic may continue to increase over time. Therefore, identifying social determinants is critical to mitigate the current growing phase of the epidemic[27]. Our temporal analysis identified two periods with significant increasing trends in death rates by prescription opioid overdose. Among these periods, the steepest increase in death rates was found in July 2013. An additional discrimination analysis by drug involved in the overdose showed that death rates due to opioids excluding fentanyl had a decreasing trend until mid-2013[28]. From this time point, fentanyl-related overdoses started increasing mortality rates until 2017. Moreover, we identified an increasing trend in mortality rate over time, growing from 10.34 cases per 100,000 inhabitants in 2013 to 16.90 in 2014. The second significant increase trend in opioid related mortality rate was found during July 2015, potentially associated with the introduction of carfentanyl, which is an ultra-potent fentanyl analog known to be approved only for veterinary use[29,30]. The highest increase in mortality rates took place during this period, from 26.10 cases per 100,000 inhabitants in 2015 to 42.33 in 2016. These temporal dynamics of the opioid overdose epidemic are consistent with the time frame when the federal government classified opioid painkillers

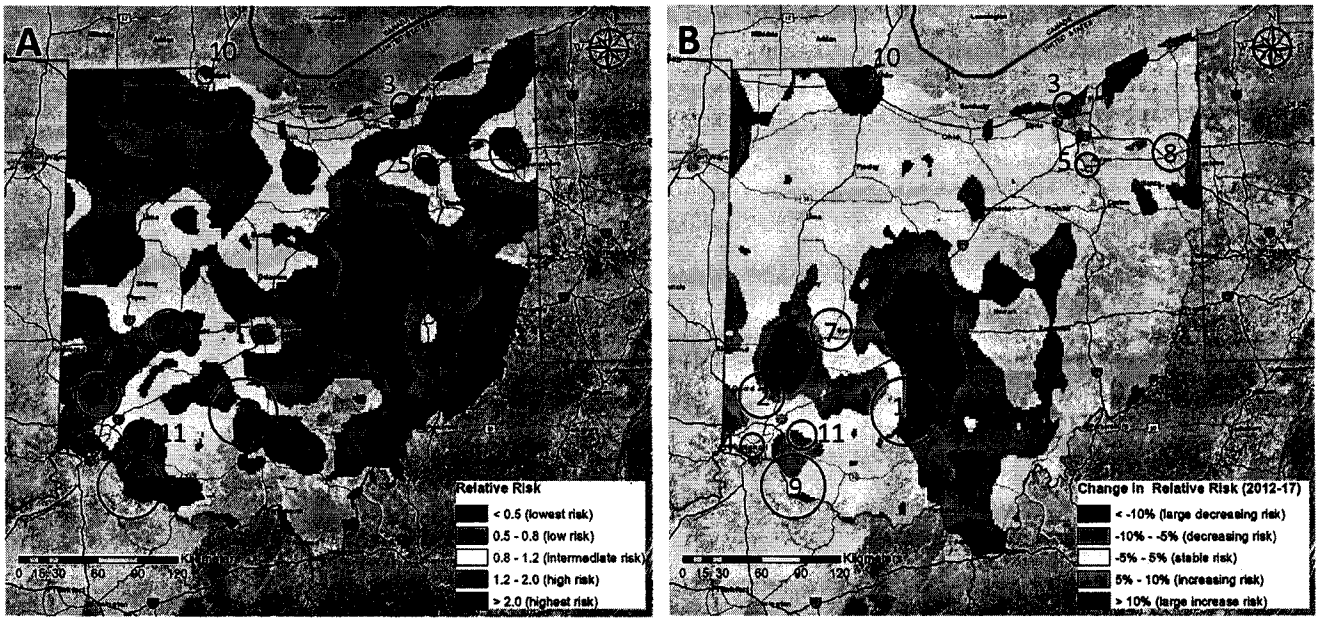


Figure 2. (**A**) Spatial distribution of relative risk for death by prescription opioids overdose in Ohio (2010–2017) with identified clusters of opioids overdoses. (**B**) Change of the relative risk (First semester 2010 compared to Last semester 2017) with identified clusters of opioids overdoses. Maps were created using ArcGIS by Esri version 10.5 (http://www.esri.com)[38], and basemaps were obtained from ESRI and National Geographic available at ArcGIS Online basemaps[39].

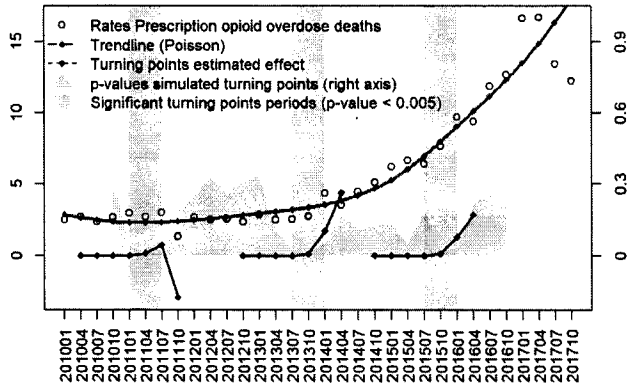


Figure 3. Ohio prescription opioid overdose death rates (cases per 100,000 inhabitants) aggregated by trimester (from January 2010 to October 2017). Percentual causal effect estimation for trimesters with significant changes (p-value < 0.005) over a period of 24 months are included in the black trends. P-values for the simulated turning points from October 2010 to October 2016 are described in the blue area (scaled to the right axis).

from Schedule 3 to Schedule 2 in 2014, limiting its access to both prescribers and patients. The abuse of opioids painkillers plateaued after this period, but this change also might have boosted heroin and fentanyl overdoses that increased significantly due to a rebound effect[31]. These results suggest that the opioid crisis is a complex epidemic, potentially caused by excessive prescription of pain reliever medications, but also driven by the recent inclusion of synthetic opioids for recreational use, especially involving fentanyl and analogs.

This research study has some limitations. Data from the Ohio Department of Health do not distinguish between prescription opioids for medical use and abuse by illicit manufactured synthetic opioids. Several reports suggest that many drug abusers are not aware that cocaine and heroin are being contaminated with fentanyl[16], and deaths by overdose after consuming multiple drugs at the same time may be classified as opioid overdose. Additionally, we limited our causal trend analysis to data from January 2011 to December 2016. Some reports have indicated a decrease in deaths by opioid overdose in Ohio during the last semester of 2017 and early 2018, thought to be caused by decreased availability of carfentanyl in the illegal market and the wider availability of naloxone in Ohio and nationwide[21,24]. However, data for opioid overdose mortality data for 2018 are still not available, and there are no official reports for deaths in Ohio by drug overdose for 2018 currently available.

Despite these limitations, our study explored the epidemiological and spatiotemporal dynamics of the opioid overdose epidemic in Ohio from 2010 to 2017. We identified specific geographic areas in Ohio where the epidemic was concentrated during this time period. The methodology used and the findings derived from them are of fundamental importance, particularly for identifying and preventing the emergence of similar drug abuse epidemics in the country and worldwide[10]. For example, oxycodone, known to be one of the first prescription opioid used for pain management, is suspected to be the main driver of emerging substance addiction epidemics not only in Canada, UK, and Australia, but also in China, Brazil, Colombia, Egypt, Mexico, Philippines, Singapore, South Korea, South Africa, and Spain[10].

Methods to eradicate the opioid epidemic include targeting the socio-economic and demographic drivers of the epidemic, together with projects to increase access to naloxone and the creation of safe places for controlled drug use to help avoid death and prevent the spread of other diseases[10,27]. Additionally, tighter controls on prescriptions and the flow of illicitly manufactured fentanyl to the black market are starting to force a declining trend in overdose death rates[9,16]. Strategies to monitor the amount of fentanyl diluted in other drugs and disseminating information among drug users may reduce consumption[10]. However, there is an undeniable need for more comprehensive strategies to fully understand the epidemic, including a strategy that focuses on potential differences among demographic groups, standardization of the guidelines for the formulation of prescription opioids, and appropriate training of medical personnel[10], especially since an opioid epidemic could be a key driver of infectious disease outbreaks such as HIV, hepatitis C virus, and endocarditis[32].

Methods

Data sources and demographic analysis. Data were provided by the Ohio Department of Health and included 20,938 unintentional deaths by drug overdose from January 1st2010, to December 31st, 2017 in Ohio. This dataset was filtered to include only deaths caused by prescription opioid overdose (International Classification of Diseases, 10th Revision (ICD-10) cause of death codes: T40.2, T40.4, T40.6) among the majority racial groups (white and black population) aged 20–64 years (more than 95% of cases were aged 20–64) to focus analysis on adults of working age. As a result, 11,790 deaths by unintentional prescription opioid overdose were included in the analysis. The dataset also included information about gender, race, and age of the deceased individuals. Cases were geolocated by zip code of residency using the American Community Survey conducted by the United States Census Bureau[33].

Estimated population sizes were retrieved from the United States Census Bureau American FactFinder portal[33] by race, gender, and age group for each year from 2010 to 2017 and aggregated by zip code. Specifically, population size for each year by zip code was determined using projections made from 2010 Census Bureau data to estimate the number of males and females for white and black populations across five-year age groups from age 20 to 64 years. Since population density is reported yearly, population by month and trimester were estimated using a non-parametric regression spline interpolation. Aggregated deaths by race, gender, and five-year period were merged with data on population density to compute opioid overdose death rates per 100,000 inhabitants in each demographic category. Population sizes, number of deaths, and death rates were also computed for each zip code and year for use in the spatial and spatiotemporal analyses.

Identification of high-risk groups was conducted using opioid overdose mortality rates by race and gender. Prescription opioid death rates were estimated using Poisson regression analysis to quantify the annual percentage change for each race-gender group, and to identify the group with the highest increase in death rate during the period of analysis. Demographic profiles of death rates and number of deaths by race, gender, and age group were used to determine which groups were most impacted by prescription opioid overdose.

Spatial clustering analysis of the opioid overdose epidemic. The spatial distribution of prescription opioid overdose deaths was analyzed using a spatial scan statistical analysis of data from 2010 to 2017, implemented in the SaTScan software[34]. We used scan statistics to identify geographical locations where the number of prescription opioid overdose deaths was higher than expected under the null hypothesis of a random spatial distribution of the deaths across the state. We refer to clusters of prescription opioid overdose deaths as hotspots. We analyzed death counts (from 2010 to 2017) using the SaTScan Poisson model with the size of the population at risk by location included as an offset. Briefly, identification of hotspots using the Poisson model implemented in SaTScan is achieved by testing each potential cluster against the null hypothesis that the distribution of cases was proportional to the population size (no clustering) using likelihood ratio and t-tests[34]. A hotspot was identified if the p-value was less than 0.05 and the grouping contained more than three zip code locations.

Space and space-time relative risk estimation. Spatial and spatiotemporal RR estimation of deaths caused by prescription opioid overdose at the zip code level were conducted using Bayesian models that were fit using an integrated nested Laplace approximation (INLA) implemented in the R-INLA software package[35]. INLA is a computational algorithm designed to approximate complex integrals involved in posterior distributions by using a latent Gaussian model approximation[13]. The number of deaths by prescription opioid overdose was modeled using a zero-inflated Poisson regression to accommodate excess zero counts in sparse area-specific data[36] in the context of a Besag-York-Mollie (BYM) model[37]. The BYM model used incorporated spatially correlated random effects that were modeled using a conditionally autoregressive structure (i.e., neighboring zip codes have correlated random effects). A second unstructured random effect was included in the model, and its variance component was modeled with a diffuse gamma prior distribution. Spatial analysis was conducted by zip code on the total number of deaths from 2010 to 2017, while spatiotemporal analysis was conducted by zip code on monthly data from 2010 to 2017.

To identify areas with high risk of opioid overdose mortality rates, we computed the prevalence and average RR in 2017, and temporal changes in RR by zip code within hotspots and non-hotspots. The temporal change

in RR was defined as the percent difference between the average RR for the last semester of 2017 and the first semester of 2010. Finally, smoothed surfaces of the estimated RR and temporal change in RR were mapped along with the identified hotspots. Maps were created using ArcGIS by Esri version 10.5 (http://www.esri.com)[38], and basemaps were obtained from ESRI and National Geographic available at ArcGIS Online basemaps[39].

Temporal trend analysis. Temporal trends of overdose death rates were identified using Bayesian interrupted time series analysis implemented in the CausalImpact package in R[40]. In short, the analysis quantifies significant changing trends of the opioid overdose death rate (over a 12-month period) from the death rate expected in the absence of any disturbance of the opioid epidemic. Disturbances are assumed to be caused by external events that could positively (or negatively) influence death rates of prescription opioid overdoses over time (e.g., new government policies for reducing opioids prescriptions, new drugs available in the market).

Using this analysis, we modeled death rates for Ohio as a time series of monthly periods to estimate the monthly percent difference between the observed period and the (unobservable) change of death rates that would have occurred under the absence of any disturbance (called a counterfactual)[40]. The algorithm uses three sources of information to construct the counterfactual. The first source was a control time series given by the Ohio population at risk (aged 20–64) for each month, and the analysis assumes that in the absence of a positive or negative disturbance, overdoses are proportional to the population at risk. Second, the algorithm uses the death rates before a given time to estimate the alternative outcome without the effect of the disturbance. Finally, prior distributions of the outcome are used to include prior knowledge about the model using Bayesian regression. The three sources of information are combined using a state-space time series model. Death rates under the counterfactual model are computed from their posterior distributions, and the difference between the monthly percent change in the observed and counterfactual death rates are used to identify significant trends of the opioid epidemic.

Using this method, we simulated changes in the trajectory of the epidemic each month from January 2011 to December 2016 to identify the periods when the most significant changes occurred. Data from a period of 12 months before and 12 months after were used to estimate the observed and counterfactual percent differences in death rates of the epidemic. Then, estimated p-values for each month were grouped by trimesters to avoid short term variations, and non-contiguous periods, with p-values less than 0.005 selected to represent significant temporal trends in the epidemic[41].

A video was generated to illustrate the spatio-temporal dynamics of the opioid overdose cases (Supplementary Video 1). Maps in the video were created using the open source framework Mapbox GL JS v 1.3.1 (https://www.mapbox.com/)[42], and basemaps were obtained from OpenStreetMap (https://www.openstreetmap.org/#map=5/38.007/−95.844). Plot charts in the video were created using d3.js. JavaScript library (https://d3js.org/). To learn more, visit https://www.mapbox.com/about/maps/ and http://www.openstreetmap.org/copyright. Data extracted from OpenStreetMap after September 2012 is licensed on terms of the Open Database License, "ODbL" 1.0, previously it was licensed CC-BY-SA 2.0.

Ethic statement. All data used in this study were in accordance with the ethical standards, following protocols for secondary data analysis, and with the approval of the Institutional Review Board (IRB) University of Cincinnati number CR01_2017-7637, and the Ohio Department of Health.

Data availability

The datasets generated and analyzed during the current study are not publicly available due to privacy restrictions of sensitive data. However, unidentified datasets are available from the corresponding author on reasonable request and with permission of the Ohio Department of Public Health.

Code availability

Code for all analyses are available within the article and its Supplementary Information.

Received: 20 November 2019; Accepted: 24 February 2020;
Published online: 09 March 2020

References

1. Hedegaard, H., Miniño, A. M. & Warner, M. Drug overdose deaths in the United States, 1999–2018. (National Center for Health Statistics, 2020).
2. Kiang, M. V., Basu, S., Chen, J. & Alexander, M. J. Assessment of Changes in the Geographical Distribution of Opioid-Related Mortality Across the United States by Opioid Type, 1999–2016. *JAMA network open* **2**, e190040–e190040, https://doi.org/10.1001/jamanetworkopen.2019.0040 (2019).
3. Kochanek, K. D., Murphy, S. L., Xu, J. & Arias, E. Deaths: Final Data for 2017. (National Center for Health Statistics, 2019).
4. The White House. Ending Americas Opioid Crisis, https://www.whitehouse.gov/opioids/ (2018).
5. Ohio Opioid Summary (March 2019). (National Institute on Drug Abuse (NIDA), 2019).
6. Schoenfeld, E. R. *et al.* Geographic, Temporal, and Sociodemographic Differences in Opioid Poisoning. *American Journal of Preventive Medicine* **57**, 153–164, https://doi.org/10.1016/j.amepre.2019.03.020 (2019).
7. Dean, A. & Kimmel, S. Free trade and opioid overdose death in the United States. *SSM - Population Health* **8**, 100409, https://doi.org/10.1016/j.ssmph.2019.100409 (2019).
8. Haffajee, R. L., Lin, L. A., Bohnert, A. S. B. & Goldstick, J. E. Characteristics of US Counties With High Opioid Overdose Mortality and Low Capacity to Deliver Medications for Opioid Use Disorder. *JAMA Network Open* **2**, e196373–e196373, https://doi.org/10.1001/jamanetworkopen.2019.6373 (2019).
9. Penm, J. *et al.* Strategies and policies to address the opioid epidemic: a case study of Ohio. *Journal of the American Pharmacists Association: JAPhA* **57**, S148–S153, https://doi.org/10.1016/j.japh.2017.01.001 (2017).
10. Humphreys, K. Avoiding globalisation of the prescription opioid epidemic. *The Lancet* **390**, 437–439, https://doi.org/10.1016/S0140-6736(17)31918-9 (2017).

11. Stopka, T. J. *et al.* Opioid overdose deaths and potentially inappropriate opioid prescribing practices (PIP): A spatial epidemiological study. *International Journal of Drug Policy* **68**, 37–45, https://doi.org/10.1016/j.drugpo.2019.03.024 (2019).
12. James, K. & Jordan, A. The Opioid Crisis in Black Communities. *J Law Med Ethics* **46**, 404–421, https://doi.org/10.1177/1073110518782949 (2018).
13. Blangiardoa, M., Camelettib, M., Baiocd, G. & Rue, H. Spatial and spatio-temporal models with R-INLA. Spatial and Spatio-temporal. *Epidemiology* **4**, 33–49, https://doi.org/10.1016/j.sste.2012.12.001 (2013).
14. Mohammad, J. S., Botticelli, M., Hwang, R., Koh, H. K. & McHugh, R. K. The Opioid Crisis: A Contextual Framework and Call for Systems Science Research. (working paper).
15. Jalal, H. *et al.* Changing dynamics of the drug overdose epidemic in the United States from 1979 through 2016. *Science* **361**, eaau1184, https://doi.org/10.1126/science.aau1184 (2018).
16. Ciccarone, D. The triple wave epidemic: Supply and demand drivers of the US opioid overdose crisis. (2019).
17. Spencer, M. R., Warner, M., Bastian, B. A., Trinidad, J. P. & Hedegaard, H. Drug Overdose Deaths Involving Fentanyl 2011–2016. (National Center for Health Statistics, 2019).
18. Alexander, M. J., Kiang, M. V. & Barbieri, M. Trends in Black and White Opioid Mortality in the United States, 1979-2015. *Epidemiology* **29**, 707–715, https://doi.org/10.1097/EDE.0000000000000858 (2018).
19. Hadland, S. E., Rivera-Aguirre, A., Marshall, B. D. L. & Cerdá, M. Association of Pharmaceutical Industry Marketing of Opioid Products With Mortality From Opioid-Related Overdoses. *JAMA Network Open* **2**, e186007–e186007, https://doi.org/10.1001/jamanetworkopen.2018.6007 (2019).
20. Wu, L.-T., Zhu, H. & Swartz, M. S. Treatment utilization among persons with opioid use disorder in the United States. *Drug and alcohol dependence* **169**, 117–127, https://doi.org/10.1016/j.drugalcdep.2016.10.015 (2016).
21. Guy, G. J. *et al.* Vital Signs: Pharmacy-Based Naloxone Dispensing — United States, 2012–2018., (2019).
22. Cuadros, D. F. & Abu-Raddad, L. J. Spatial variability in HIV prevalence declines in several countries in sub-Saharan Africa. *Health & Place* **28**, 45–49, https://doi.org/10.1016/j.healthplace.2014.03.007 (2014).
23. Cuadros, D. F., Branscum, A. J. & Mukandavire, Z. Temporal stability of HIV prevalence in high-burden areas regardless of declines in national HIV prevalence in Malawi and Zimbabwe. *Aids* **32**, 1381–1383 (2018).
24. Goodnough, A. This City's Overdose Deaths Have Plunged. Can Others Learn From It? New York Times (2018).
25. Harm Reduction Ohio. Deadly mystery: Ohio's carfentanil death rate 2000% higher than other states. (2018).
26. Center for Disease Control and Prevention. Increases in Fentanyl Drug Confiscations and Fentanyl-related Overdose Fatalities. (Center for Disease Control and Prevention, 2015).
27. Feinberg, J. in World View Vol. 573 (Nature, 2019).
28. Ohio Department of Health. 2017 Ohio Drug Overdose Data: General Findings (Ohio Department of Health, Columbus, Ohio, 2018).
29. O'Donnell, J., Gladden, M. R., Mattson, C. L. & Kariisa, M. Notes from the Field: Overdose Deaths with Carfentanil and Other Fentanyl Analogs Detected — 10 States, July 2016–June 2017 | MMWR. (Center for Disease Control and Prevention, 2019).
30. Fomin, D. *et al.* Human deaths from drug overdoses with carfentanyl involvement-new rising problem in forensic medicine: A STROBE-compliant retrospective study. *Medicine (Baltimore)* **97**, e13449–e13449, https://doi.org/10.1097/MD.0000000000013449 (2018).
31. Lopez, G. The opioid painkiller and heroin epidemic, explained., https://www.vox.com/2015/10/1/9433099/opioid-painkiller-heroin-epidemic (2017).
32. Reardon, S. The US opioid epidemic is driving a spike in infectious diseases. *Nature* **571**, 15–16, https://doi.org/10.1038/d41586-019-02019-3 (2019).
33. US Census Bureau.
34. Kulldorff, M. & Nagarwalla, N. Spatial Disease Clusters: Detection and Inference. *Statistics in medicine* **14**, 799–810 (1995).
35. Rue, H., Martino, S. & Chopin, N. Approximate Bayesian Inference for Latent Gaussian Models by Using Integrated Nested Laplace Approximations. Journal of the Royal Statistical Society. *Series B (Statistical Methodology)* **71**, 319–392 (2009).
36. Inferring lung cancer risk factor patterns through joint Bayesian spatio-temporal analysis. *Cancer Epidemiology* **39**, 430–439, 10.1016/j.canep.2015.03.001 (2015).
37. Besag, J., York, J. & Mollié, A. Bayesian image restoration, with two applications in spatial statistics. *Annals of the Institute of Statistical Mathematics* **43**, 1–20, https://doi.org/10.1007/BF00116466 (1991).
38. ESRI. ArcGIS 10.x. Redlands, CA, USA: ESRI. (2004).
39. ESRI. "Topographic" [basemap]. "World Topographic Map", http://www.arcgis.com/home/item.html?id=30e5fe3149c34df1ba922e6f5bbf808f (2012).
40. Brodersen, K. H., Gallusser, F., Koehler, J., Remy, N. & Scott, S. L. Inferring causal impact using Bayesian structural time-series models. *Annals of Applied Statistics* **9**, 247–274 (2015).
41. Benjamin, D. J. & Berger, J. O. Three Recommendations for Improving the Use of p-Values. *The American Statistician* **73**, 186–191, https://doi.org/10.1080/00031305.2018.1543135 (2019).
42. Mapbox. Mapbox GL JS 1.3.x. Washington, D.C., San Francisco, CA. (2010)

Acknowledgements

This project was supported by grant number 5NU17CE002738, funded by the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention or the Department of Health and Human Services.

Author contributions

A.M.H., A.J.B., J.L. and D.F.C. conceived the study and its design, conducted the statistical and spatial modeling analyses, and wrote the first draft of the paper. A.L.H. and N.M. contributed to study conception, design and writing of the manuscript. A.M.H., A.J.B. and D.F.C. conduct of the statistical modeling analyses, interpretation of the results, and writing of the manuscript.

Competing interests

The authors declare no competing interests.

Additional information

Supplementary information is available for this paper at https://doi.org/10.1038/s41598-020-61281-y.

Correspondence and requests for materials should be addressed to D.F.C.

Reprints and permissions information is available at www.nature.com/reprints.

Publisher's note Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

Open Access This article is licensed under a Creative Commons Attribution 4.0 International License, which permits use, sharing, adaptation, distribution and reproduction in any medium or format, as long as you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons license, and indicate if changes were made. The images or other third party material in this article are included in the article's Creative Commons license, unless indicated otherwise in a credit line to the material. If material is not included in the article's Creative Commons license and your intended use is not permitted by statutory regulation or exceeds the permitted use, you will need to obtain permission directly from the copyright holder. To view a copy of this license, visit http://creativecommons.org/licenses/by/4.0/.

© The Author(s) 2020

O'CONNELL ARONOWITZ

ATTORNEYS AT LAW

November 12, 2024

Re: Leon Margolin, M.D.

To whom it may concern:

I am of counsel to the law firm of O'Connell and Aronowitz since 2011 and am a member of the Health and Criminal Law Practice Groups in the Albany, New York office. I defend Medicaid and other health care providers in the state and federal courts in every stage of criminal and regulatory investigations and prosecutions.

Prior to entering private practice, I was a prosecutor for the New York State Attorney General's Medicaid Fraud Unit ("MFCU") for 27 years and was the regional director for the last 10 years of state service, ending in 2011. During my tenure with the New York MFCU, I investigated and prosecuted hundreds of Medicaid fraud cases.

In 1989, I received the MFCU's special achievement award for prosecuting the largest theft by a single Medicaid provider in United States history. In 2001, I received the Louis J. Lefkowitz Award for the successful prosecution of an adult daycare center for larceny that was the largest theft by a single Medicaid provider in United States history. In 2008, I received the Attorney General's special achievement award for a comprehensive investigation of the home care industry, which resulted in over 100 criminal convictions, millions of dollars in restitution, and systematic changes in the home care industry.

Between August 1992 and September 1993, I was appointed as a special assistant to the United States Attorney for the Southern District of New York to assist on Medicaid fraud prosecutions. I have lectured at health care fraud training seminars conducted by the United States Department of Justice, the FBI, and the National Association of Medicaid Fraud Control Units.

Between 1999 and 2004, I was an adjunct professor at John J. College of Criminal Justice and St. John's University, teaching criminal law and evidence.

I have been retained by Dr. Leon Margolin to review the January 2020 settlement agreement between Dr. Margolin and the United States Department of Justice ("DOJ"), and materials related to Dr. Margolin and Comprehensive Pain Management Institute's

EDWARD J. O'CONNELL
1925-1939
SAMUEL E. ARONOWITZ
1925-1973
LEON ARONOWITZ
1941-1969
LEWIS A. ARONOWITZ
1951-1979

STEPHEN R. COFFEY
THOMAS J. DiNOVO
PAMELA A. NICHOLS
DAVID R. ROSS
KURT E. BRATTEN
MICHAEL P. McDERMOTT
PETER A. PASTORE
KEVIN LAURILLIARD
KELLY J. MIKULLITZ
WILLIAM F. BERGLUND
ROBERT J. KOSHGARIAN
MATTHEW J. DORSEY
FRANCIS J. SMITH, JR.
GRAIG F. ZAPPIA
DANIEL J. TUCZINSKI
STEVEN G. THOMAS

OF COUNSEL
CORNELIUS D. MURRAY
JEFFREY J. SHERRIN
JEFFREY A. SIEGEL
RICHARD S. HARROW
FLORENCE M. RICHARDSON
KAREN MARTINO VALLE
BRIAN M. CULNAN
CRISTINA D. COMMISSO
MICHAEL Y. HAWRYLCHAK

ALLEN F. LIGHT
JAMES D. WIGHAUS
SAMANTHA L. FEMIA
REBECCA M. DUNNING
NICHOLAS M. CERVINI
MICHAEL J. LAWSON
JENNA M. DiBENEDETTO
ANNA R. MYERS
LILLIAN C. HAHN
CHARLES E. SERINO
RYAN A. FORBES

HOLLY E. VEGAS*
(DIRECTOR, HEALTHCARE CONSULTING GROUP)

***NOT A MEMBER OF THE LEGAL PRACTICE**

("CPMI") provision of medically necessary pain management services to chronic pain patients.

The DOJ and the Inspector General for Health and Human Services ("IG") civil settlement agreement signed by Dr. Margolin on 1/15/20 ("Agreement") was in the amount of $650,000.00, which was timely paid in full. The Medicare claims described in the covered conduct were submitted between January 1, 2013 and September 19, 2019. The agreement alleged that these claims were false because, "NCS were medically unnecessary because the patients did not need them …. and (2) SBIRT's that were medically unnecessary and/or not provided as billed (Agreement, Page 1C). The Agreement further states:

> "This settlement agreement is neither an admission of liability by defendants nor a concession by the United States that its claims are not well founded." (Agreement, Page 1D).

It is abundantly clear that Dr. Margolin, by entering into this Agreement, made no admissions with respect to the government description of the covered conduct. Dr. Margolin entered into this Agreement, "to avoid the delay, uncertainty, inconvenience, and expense of protracted litigation." (Agreement, Page 2D). Dr. Margolin primarily entered into the Agreement to avoid the possibility that his Medicare billings would be put on hold pending the outcome of a protracted litigation. This scenario, hinted to by DOJ prosecutors, would have effectively shut down his practice and resulted in potential fatalities among his patient population.

The Agreement did not release Dr. Margolin from "any criminal liability" or "any administrative liability, including mandatory or permissive exclusion from federal health care programs," (Agreement, Page 3, 3B, 3C). Despite not being released from criminal liability, no criminal charges were pursued. Also, despite being subject to potential exclusion from federal health care programs, no person or entity ever pursued such an exclusion.

Finally, Dr. Margolin agreed, " … to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement." (Agreement, Page 6, 8). To date, there is no indication that the investigation continued beyond the civil settlement agreement. Dr. Margolin no longer bills Medicare for the SBIRT services (screening, brief intervention and referral to treatment services), even though not prohibited by the Agreement. He continues to utilize SBIRT tests. These services are evidence based, early interventions that physicians use to address the risk of substance abuse, overdose and death with patients receiving treatment with opioids. Given the modern-day tragedy of the opioid epidemic, SBIRT testing has become a mandatory protocol in the pain management field.

During the course of my career, I have seen numerous instances when insurance reimbursement is at odds with accepted medical protocols. This results in a danger to individual patients and a threat to public safety. The financial tension between insurance company coverage and accepted medical protocols results in deficiencies in patient care due to a failure of insurance coverage. In time, as medical advances become mainstream, insurance coverage will follow. In the interim, lives are lost, and more expenses are incurred by the health care system because of the failure to utilize all available treatments.

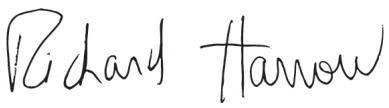
In 2008, the MFCU in New York prosecuted individuals for felonies for billing Medicaid for the care of immediate family members. Subsequently, New York established the Consumer-Directed Personal Assistance Program (CDPAP, Social Service Law 365-f), which allowed people to care for immediate family members and get reimbursed by Medicaid. Regardless of the new avenues for fraud opened by the CDPAP program, what was once illegal is now legal.

In 2015, I represented an owner of a drug treatment center who had been charged with paying kickbacks to patients by providing apartments or "sober homes" for them to live in during their drug treatment (People v. Alan Brand, Indictment # 0783, Bronx County). These "sober homes" proved to be beneficial for the patients because they now had a place to live away from the environment on the streets that encouraged their drug use. Over time, the use of "sober homes" made sense in the battle against drug addiction, and their use was encouraged and made reimbursable by Medicaid. Once again, what was once considered illegal conduct has become an accepted practice in drug treatment.

In conclusion, the civil settlement Dr. Margolin entered into with DOJ has been paid in full. There were no admissions made by Dr. Margolin in the covered conduct, and DOJ did not refer the case for either criminal prosecution or for HHS to exclude Dr. Margolin from health care programs. This matter should be put to rest.

Respectfully submitted,

O'CONNELL AND ARONOWITZ, P.C.

By: 

Richard S. Harrow

RSH/rd

A

Difficult Pt – Car Damage

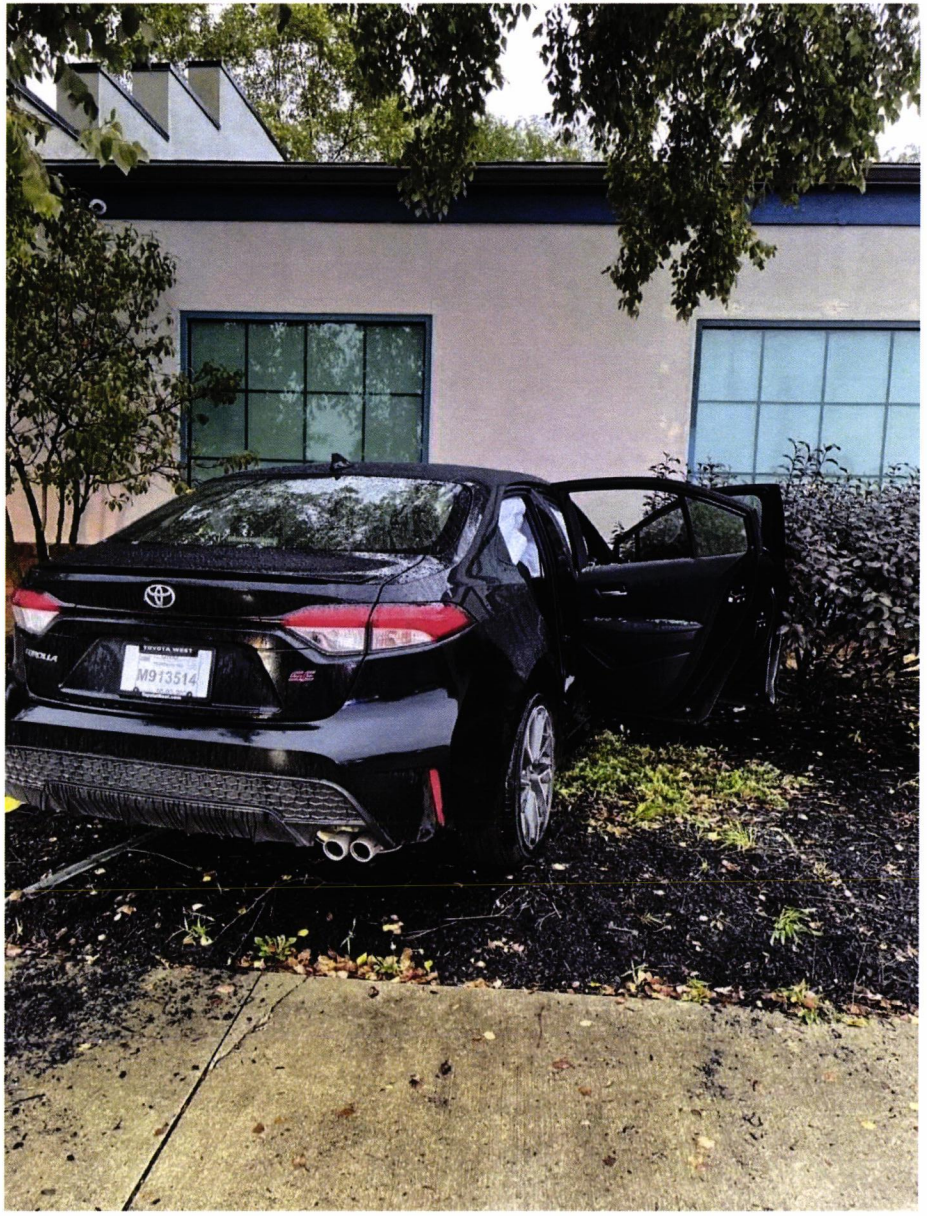


Difficult Pts– Broken door hinges, thermos thrown at the staff





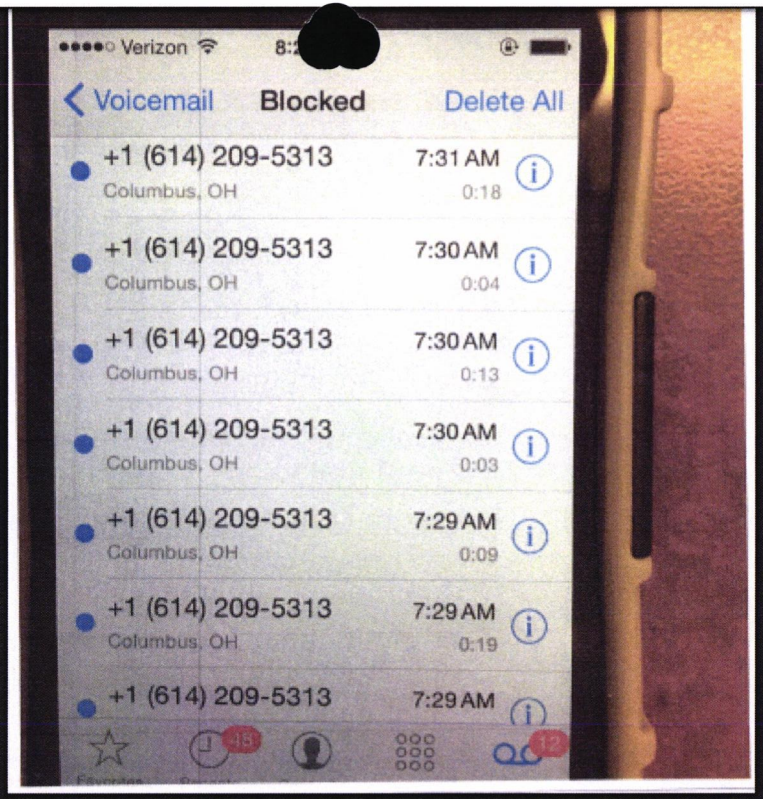
Car driven into the office wall

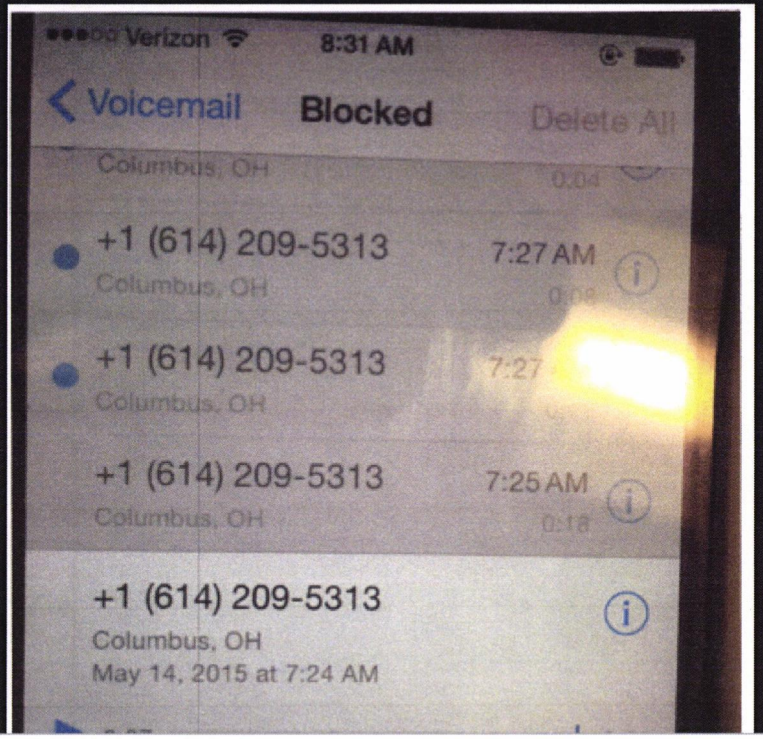


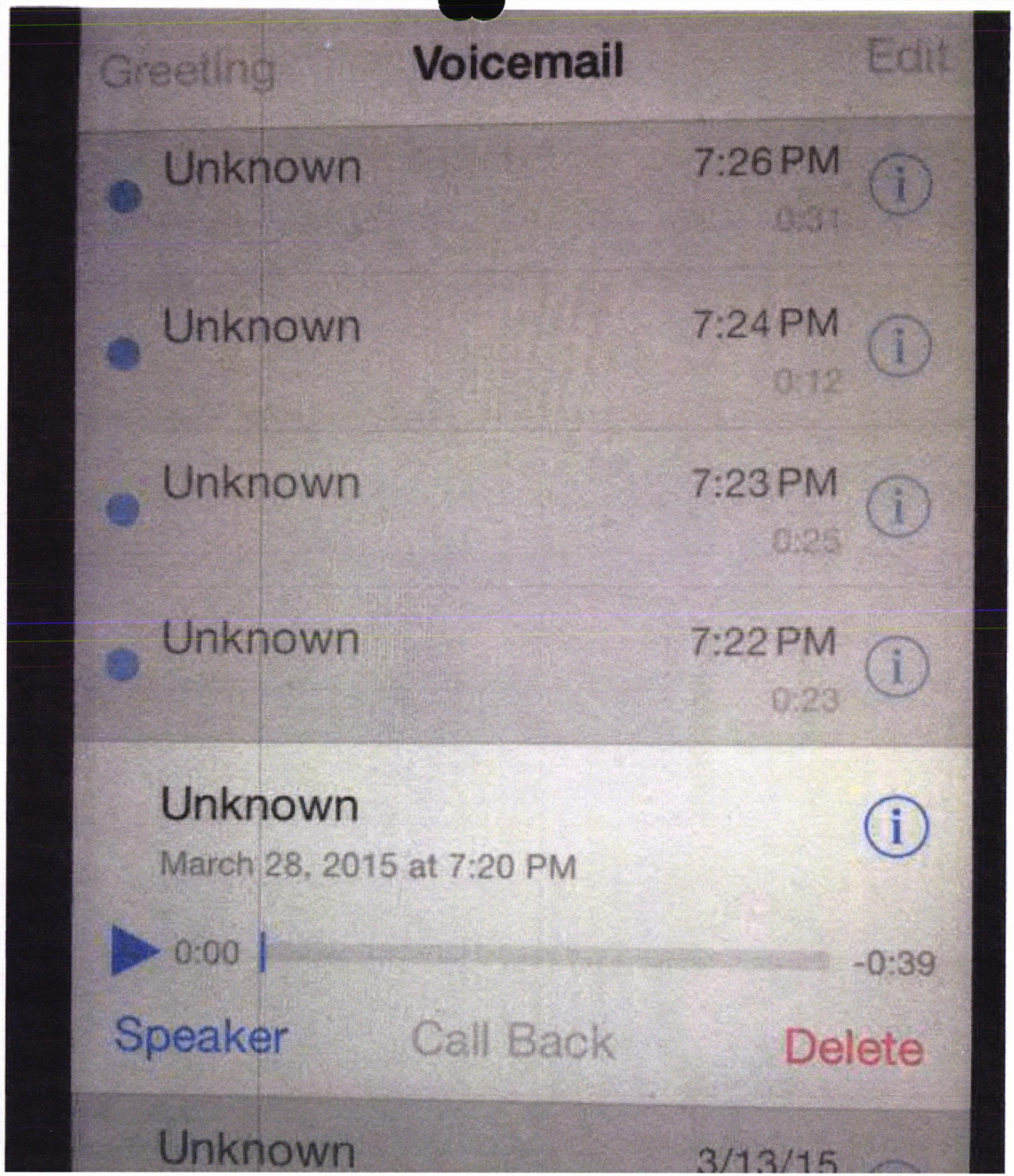
Assault by a drug seeking patient



- Difficult Pts – examples harassing messeges and calls on my personal cell


Verizon
Voicemail
Blocked
Delete All
+1 (614) 209-5313
Columbus, OH
7:31 AM
0:18
+1 (614) 209-5313
Columbus, OH
7:30 AM
0:04
+1 (614) 209-5313
Columbus, OH
7:30 AM
0:13
+1 (614) 209-5313
Columbus, OH
7:30 AM
0:03
+1 (614) 209-5313
Columbus, OH
7:29 AM
0:09
+1 (614) 209-5313
Columbus, OH
7:29 AM
0:19
+1 (614) 209-5313
7:29 AM


Verizon
8:31 AM
Voicemail
Blocked
Delete All
Columbus, OH
+1 (614) 209-5313
Columbus, OH
7:27 AM
+1 (614) 209-5313
Columbus, OH
7:27
+1 (614) 209-5313
Columbus, OH
7:25 AM
+1 (614) 209-5313
Columbus, OH
May 14, 2015 at 7:24 AM


Greeting
Voicemail
Edit
Unknown
7:26 PM
0:31
Unknown
7:24 PM
0:12
Unknown
7:23 PM
0:25
Unknown
7:22 PM
0:23
Unknown
March 28, 2015 at 7:20 PM
0:00
-0:39
Speaker
Call Back
Delete
Unknown
3/13/15

B

Franklin County Municipal Court

ori M. Tyack, Clerk of Court 375 S. HIGH ST., COLUMBUS, OHIO 43215

tate of Ohio
ounty of Franklin
ity of Columbus
THER JURISDICTION

V: [redacted]
DEFENDANT

TIME STAMP

FRA... MUNIC... COU...

COMPLAINT

Complainant, being duly sworn, states that the above named defendant, at Franklin County / Columbus, Ohio, on or about the 2nd day of December, 20 19 did: did knowingly cause or attempt to cause physical harm to Leon Margolin, to wit: did hit Leon Margolin about the head with his hand, and/or choke Leon Margolin by placing his hand around Leon Margolin's neck, causing injury.

in violation of section 2303.13(A) ☒ City Code ☐ O.R.C., a ☐ Misdemeanor ☐ Felony of the first degree.

Complainant [signature] Leon Margolin
SIGNATURE PRINT FULL NAME BADGE NUMBER

3082 Elbern Avenue | Columbus | OH | 43209
ADDRESS OR AGENCY & ASSIGNMENT | CITY | STATE | ZIP CODE

Sworn to and subscribed before me, this
23 day of January, 2020

Lori M. Tyack
Clerk of the Franklin County Municipal Court

By [signature]
CLERK / DEPUTY CLERK / NOTARY PUBLIC / PEACE OFFICER

Notary Seal & Expiration Date

☒ ARREST WARRANT

To any law enforcement officer of the State of Ohio:
You are hereby commanded to arrest the above named defendant and bring him/her before the Franklin County Municipal Court without unnecessary delay, to answer to the complaint hereon. WHEN APPLICABLE, IN ACCORDANCE TO CRIMINAL RULE 4(A), THE WARRANT HAS BEEN ISSUED BEFORE THE DEFENDANT HAS APPEARED AND THE BAIL PROVISION CRIMINAL RULE 46 SHALL APPLY. ARRAIGNMENT COURT IS HELD IN COURTROOM 4C AT 9:00 A.M., MONDAY THROUGH FRIDAY.

Lori M. Tyack
Clerk of the Franklin County Municipal Court

State # _____ Control # _____

By [signature] DEPUTY 1/23/2020 DATE

☐ SUMMONS:

C

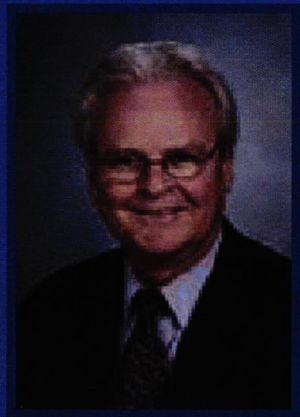
The Complete Guide to Communication Skills in Clinical Practice© *including*:



- Breaking Bad News
- Addressing Emotions
- Discussing Medical Errors
- Cultural Competence
- Challenging Emotional Conversations with Patients & Families
- Effective Communication in Supervision

Walter F. Baile, M.D.
Professor, Behavioral Science & Psychiatry
Director,
Interpersonal Communication And Relationship Enhancement
(I*CARE) Program

MD Anderson
I*CARE
Interpersonal Communication And
Relationship Enhancement



Many clinicians have not had the opportunity to develop their skills in managing difficult patient encounters where there are strong emotions, stressed families or uncomfortable conversations. This may be more so when transitioning a patient to palliative care or discussing end of life. This pocket guide was created to help you hone your communication skills in clinical practice.

The protocols (step-wise modules) in this guide can be used in many situations and were created and developed by the late Robert F. Buckman, MD, PhD, Medical Oncologist and myself and in collaboration with other communication skills experts (Antonella Surbone, MD, PhD, FACP, Daniel Epner, MD, and Rebecca Walters, MS, LMHC, LCAT, TEP). Creative contributions and editing were provided by the Interpersonal Communication And Relationship Enhancement (I*CARE) Program Project Director, Cathy Kirkwood, MPH. The guide is designed to be used as a quick reference and can be carried in your lab coat so you can review the information quickly before you begin a challenging conversation. It is our hope that the information provided will assist you in extending your role beyond treating disease to establishing a therapeutic and supportive alliance with the patient and family members.

Walter F. Baile, M.D.
Professor of Behavioral Science and Psychiatry
Distinguished Teaching Professor
Director, Program for Interpersonal Communication
*And Relationship Enhancement (I*CARE)*
Department of Faculty & Academic Development

Table of Contents

C-L-A-S-S	A protocol for all medical interviews	2
S-P-I-K-E-S	A protocol for breaking bad news to patients and family members	8
C-O-N-E-S	A protocol for discussing a medical error with patients and family members	14
E-V-E	A sub-protocol for any encounter when there are emotions present	18
B-U-S-T-E-R	A protocol for challenging conversations with patients and family members	20
B-A-L-A-N-C-E	A protocol for cultural competence	24
T-I-M-E-R	A protocol for effective communication in supervision	28

The C-L-A-S-S Protocol

The C-L-A-S-S Protocol

Five Key Steps for Clinical Interviews

C - CONTEXT	The physical set up of the area you choose for the interview
L - LISTENING SKILLS	How to be an effective listener
A – ACKNOWLEDGE	How to validate, explore and address emotions and concerns
S - STRATEGY	How to provide a management plan that the patient can understand
S - SUMMARY	How to summarize and clarify the conversation ensuring comprehension

C-Context (setting)

A private area with no distractions

Physical Space

- Choose an area where you can have a private conversation.
- Your eyes should be at the same level as the patient and/or family member (sit down if you need to).
- There should be no physical barriers between you.
- If you are behind a desk, have the patient and/or family members sit across the corner.
- Have a box of tissues available.

Family Members/Friends

- The patient should be seated closest to you.

Body Language

- Present a relaxed demeanor.
- Maintain eye contact except when the patient becomes upset.

Touch

- Only touch a non-threatening area (hand or forearm).
- Be aware of cultural issues that may not allow touching.

L - LISTENING SKILLS

Be an effective listener.

Open Ended Questions

- ***"How did you manage with the new treatment?"***
- ***"Can you tell me more about your concerns?"***
- ***"How have you been feeling?"***

Facilitating

- Allow the patient to speak without interrupting them.
- Nod to let the patient know you are following them.
- Repeat a key word from the patient's last sentence in your first sentence.

Clarifying

- ***"So, if I understand you correctly, you are saying…"***
- ***"Tell me more about that."***

Time & Interruptions

- If there are time constraints, let the patient know ahead of time.
- Pagers and phone calls – don't answer, but if you must, apologize to the patient before answering.
- Try to prepare the patient if you know you will be interrupted.

A -ACKNOWLEDGE EMOTIONS

Explore, identify, and respond to the emotion.

The Empathic Response

- Identify the emotion.
- Identify the cause of the emotion.
- Respond by showing you have made the connection between the emotion and the cause.
  "That must have felt terrible when..."
  "Most people would be upset about this."
- You don't have to have the same feelings as the patient.
- You don't have to agree with the patient's feelings.

S –STRATEGY

Propose a plan that the patient will understand

The Plan

- Appraise in your mind or clarify with the patient their expectations of treatment and outcome.
- Decide what the best medical plan would be for the patient.
- Recommend a strategy on how to proceed.
- Evaluate the patient's response.
- Collaborate and agree on the plan.

S -SUMMARY

Closing the interview

Final Thoughts

- Summarize the discussion in a clear and concise manner.
- Check the patient's understanding.
- Ask if the patient has any other questions for you.
- If you don't have time for further questions, suggest that they can be addressed at the next appointment.
- Make a clear contract for a follow up visit.

L

The S-P-I-K-E-S Protocol

SPIKES
Breaking Bad News

The S-P-I-K-E-S Protocol

S Setting Up the Conversation

P Perception

I Invitation

K Knowledge

E Emotions

S Strategy and Summary

S – SETTING - Secure an appropriate area for the discussion.

- Have the conversation in a quiet undisturbed area.
- Prepare for what to say and anticipate the patient/family reaction.
- Have the key people (whom the patient wants) in the room.
- Seat the patient closest to you and have no barriers between you.
- Sit down, try to be calm, make eye contact.

P – PERCEPTION - Assess the patient's understanding of the seriousness of their condition.

- Ask what the patient and family already know.
  "Tell me what you understand about your condition so far."
  "What did the other doctors tell you?"
  "I'd like to be sure we are on the same page with understanding your condition, so can you tell me…"
- Assess the patient and family members' level of understanding.
- Take note of discrepancies in the patient's understanding and what is actually true.
- Watch for signs of denial.

I – INVITATION - Get permission to have the discussion.

"ASK BEFORE YOU TELL."

- Set goals for the discussion - ask the patient if they want to know the details of the medical condition/treatment.
  "I'd like to go over the results, would that be ok?"
  "Today my plan is to discuss…is that okay?"
- Accept the patient's right not to know.
- Offer to answer any questions the patient/family member may have.

K – KNOWLEDGE - Explaining the facts

- **Avoid** medical jargon by explaining the facts in a manner that the patient will understand.
  NOT: *"You have a nuclear grade 1ER/PR positive spiculated 4-centimeter lesion."*
  BETTER: *"You have a fairly good sized tumor in your breast."*
- Fill in any gaps that were evident in the "Perception" stage.
- Present the information in small chunks.
- After each chunk, verify the patient's understanding.
  "Are you with me so far?"

E – EMOTIONS - The Empathic Response – Be Supportive

- Deal with emotions as they occur
  (patients who are very emotional will not comprehend what you say).
- Use open-ended and direct questions to explore what the patient is feeling.
  "Can you tell me more about how you feel?" "Did that make you angry?"
- Respond to emotions with empathic and affirming statements.
  "I can see you weren't expecting this."
  "Most people would be upset finding this out."
- Use ***"tell me more"*** statements.
  PT: ***"I don't know how I'm going to tell my kids."***
  MD: ***"Tell me more about that."***
- Try to keep your own emotions from taking over.
- **AVOID** responding with false reassurance such as:
  "Everything will be fine."
  "I've seen lots of miracles happen."

Note: You don't have to have the same feelings as the patient nor do you have to agree with the patient.

S – STRATEGY & SUMMARY - Closing the interview

Strategy

- Decide what the best medical plan would be for the patient.
- Appraise in your mind or clarify with the patient their expectations of treatment and outcome.
- Recommend a strategy on how to proceed.
- Collaborate and agree on the plan.
- Ask the patient to repeat to you their understanding of the plan.
- Have a clear treatment plan in writing for the patient to take home with them.

Summary

- Summarize the conversation.
- Offer to answer questions. (be prepared for tough questions):

  PT: ***"Does this mean I'm going to die?"***
  MD: ***"Tell me more about what concerns you?"***
  PT: ***"Can I be cured?"***
  MD: ***"I'm sorry to say that it is unlikely. Our goal is to keep it in check."***
  PT: ***"How long do I have to live?"***
  MD: ***"I can discuss that with you, but first tell me why you ask?"***

References

Baile WF, Buckman R, Lenzi R, Glober G, Beale EA, Kudelka AP. SPIKES-A six-step protocol for delivering bad news: Application to the patient with cancer. The Oncologist 5(4):302-11, 2000.

The C-O-N-E-S Protocol

The C-O-N-E-S Protocol

When You Have to Tell

C Context

O Opening Shot

N Narrative

E Emotions

S Strategy & Summary

Use the C-O-N-E-S Protocol when:

- Disclosing that a medical error has occurred
- There is a sudden deterioration in the patient's medical condition
- Talking to the family about a sudden death

NOTE: The news should be delivered by the most senior person on the patient's treatment team.

C – Context

- Prepare for what to say and anticipate the patient/family reaction.
- Have the conversation in a quiet undisturbed area.
- Seat the patient closest to you and have no barriers between you.
- Sit down, try to be calm, maintain eye contact.
- Have a box of tissues available.

O – Opening Shot

- Alert the patient/family member of important news.

  "This is difficult. I have to tell you what I found out about why your mother is so ill." "This is hard, but I have some information to give you that is important." "I must talk to you about your condition."
  "Thanks for coming in. I must tell you what is going on with your father."

N – Narrative Approach

- Explain the chronological sequence of events.

  "As you know, your mother came in back in…"
  "Then, we gave her… and there was little improvement."
  "Last night we….and I just found out that …"
  "In other words, she received too much chemotherapy."

- Avoid assigning blame and/or making excuses.
- Emphasize that you are investigating how the error occurred.

  "We started investigations and by the end of today I hope to be able to answer your questions as clearly as possible."
  "I hope by the end of today she will turn the corner and start improving."

- Offer a clear apology.

  "I am really sorry that this has happened."

E – Emotions

- Address strong emotions with empathic responses.
- Use the E-V-E protocol as soon as strong emotion occurs.

  "I know it's upsetting for you and it's awful for me too."

"I know this is awful."
"It's very rare, but it does happen and I'm sorry to say that it did."

- Beware of being pushed into making promises you can't deliver.
- Avoid reassuring the person that there's going to be a good outcome or that no harm was done.

S – Strategy & Summary

- Summarize the discussion and make specific plans for follow up.
- Let them know the situation is a priority.

"I am the doctor responsible for your mother so it is important that I found out what happened."
"I'll be open and honest with you when I have all the facts."
"I can guarantee we will do our best." "Here is what I propose we do."
"Let's meet at the end of today or I can call you when I know more."

- If you don't know the answer, say so and that you will attempt to find out.
- Disclosing medical errors is now a standard. It's not optional.
- Sensitive disclosures have a favorable impact on malpractice claims.

The E-V-E Protocol

The E-V-E Protocol

Three elements to use any time strong emotion occurs

E Explore the Emotion

V Validate the Emotion

E Empathic Response

E – Explore

- Explore and identify the emotion (anger, sadness, etc.).
- Find out more about the emotion and what is causing it.
  "Can you tell me more about how you feel?"
- Acknowledge the emotion.
  "I can see that made you very angry."

V – Validate

- Let the person know you understand the emotion was appropriate.
  "I can understand how that would make you angry."
  "Most people would feel that way."

E – Empathic Response

- Respond in a way that shows you have seen the emotion and that you can understand it.
  "I'm sorry this has happened and I understand how it would make you feel that way." "I hear what you're saying. That must have been very difficult."
  "I get your point. It was obviously very upsetting."

Challenging Emotional Conversations with Patients & Families



Challenging Emotional Conversations with Patients & Families

A guide to forming a therapeutic alliance with patients and families

Walter F. Baile, MD
Rebecca Walters, MS, LMHC, LCAT, TEP

MD Anderson

I*CARE

Interpersonal Communication And Relationship Enhancement

"Emotional Labor is the mental work used to recognize and minimize emotions so they don't rule the conversation."

When you feel like saying ***"Hey Buster, this is how it is,"*** take a step back and use the protocol below instead.

Be prepared

Use non-judgmental listening

Six second rule

"**T**ell me more" statements

Empathize and validate

Respond with a wish statement

Be Prepared

- **Expect emotions** (your own and theirs) to come your way.
- **Have a plan** for how you will do it (especially if you have to give bad news).
- **Monitor what you think and feel** (awareness of your communication can make you more effective).
- **Practice self regulation** – Keep your own emotions in check when your buttons are pushed.
- Aim to **turn the confrontation into a conversation.**
- **Know when NOT to have conversation** (when emotions are too intense).

Use Non-Judgmental Listening

- **Remember it's not about you**, but about the other's disappointments, fears, anxiety, etc. which often underlie the anger, blame or denial on the surface.
- **Maintain eye contact**.
- **Listen** without interrupting only making clarifying statements and paraphrasing.
  "So let me see if I understand…"
  "What I hear you saying is…"
- **Put your own agenda aside** until the other person is finished.
- **Avoid** trying to make a situation better when it is grave.
  "I'm sure things will not be as bad as you think."

Six Second Rule

Avoid escalation of conversation.

- When your own emotions start to boil (especially in response to anger or blame), **wait at least 6 seconds** or

more if needed for them to calm down.

- **Avoid being defensive/blaming** *"Well it didn't work because you waited too long to get help."*
- **Gather your thoughts** and use skills such as *"tell me more"* or empathic/validating responses.

Tell Me More

Invite the person to expand on what they are saying.

"Tell me more about your husband."
"What happened after that?"
"What other concerns do you have?"

Empathizing and Validating to acknowledge and diminish emotions.

Acknowledge emotions by empathizing:

"I can see you weren't expecting this."
"This isn't easy to talk about, is it?"
"It's very stressful, isn't it?"
"It must be hard to come here every week."
"I can see how difficult it is for you."

Respond with a Wish Statement

Let the other person know you hear them and acknowledge that the goal may be desirable, but…

"I wish I had better news…"
"I wish I didn't have to tell you this…"
"I wish we had a more effective treatment."
"I wish things had worked out better."

Important Tips

- **Stay calm.**
- **Avoid** phrases such as:
  "I know how you feel." "I feel your pain."
  "It's going to be alright."
- **When emotions/behaviors escalate and you feel threatened/unsafe, end the interaction.**
  "This conversation is making me feel uncomfortable right now."
  "I don't feel safe right now and can't continue this conversation."

Resources

The six-second rule
Goleman D. Emotional Intelligence 1995, Bantam Books

Walter F. Baile, M.D.,
Professor of Behavioral Science
Director, Interpersonal Communication And Relationship Enhancement (I*CARE) Program
Department of Faculty & Academic Development
The University of Texas MD Anderson Cancer Center

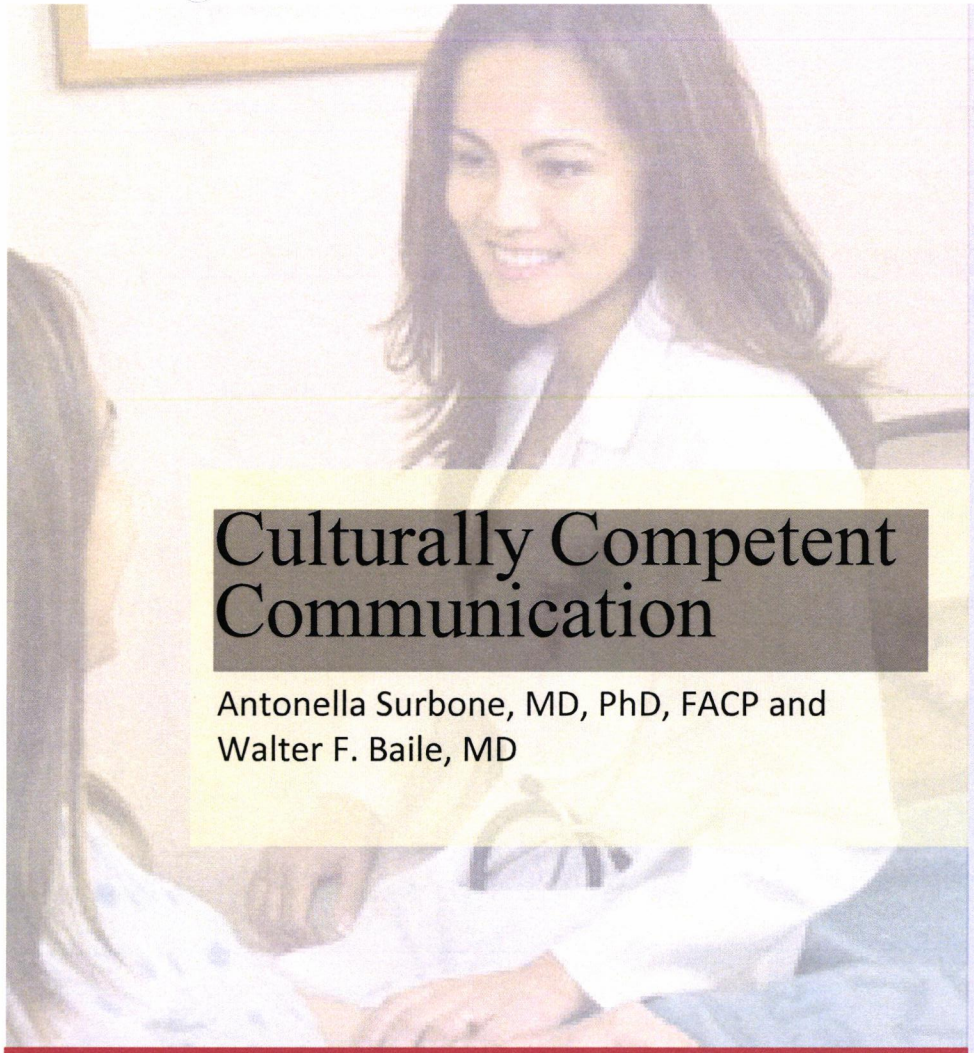
Rebecca Walters, MS, LMHC, LCAT, TEP
Director, Hudson Valley Psychodrama Institute
I*CARE Faculty

Cathy Kirkwood, MPH I*CARE Project Director Department of Faculty & Academic Development The University of Texas MD Anderson Cancer Center Email: icare@mdanderson.org

For video demonstrations of these techniques, please visit our Web site at:
www.mdanderson.org/icare

Free online CME available

Culturally Competent Communication



Culturally Competent Communication

Antonella Surbone, MD, PhD, FACP and
Walter F. Baile, MD

MD Anderson
I*CARE
Interpersonal Communication and Relationship Enhancement

Fundamental Principles:

- Cross-cultural medical encounters are increasing in multi-ethnic societies.
- Cultural factors influence cancer survival rates and patient/family quality of life.
- Cultural competence is a set of attitudes, skills and knowledge that can be acquired.
- Respecting cultural diversity is key to delivering comprehensive cancer care across the illness trajectory.
- Cultural competence promotes patient-centered care through sensitive negotiation of therapeutic goals.

The following vary across cultures:

- role of autonomy in decision making,
- support available to help patients cope,
- role expectations of sick persons,
- beliefs about cancer causation,
- EOL preferences (AD, DNR, hospice),
- patient/clinician/institution relationships.

Why Cultural Competence Can Help You Plan the Patient's Care

- Discussion of cancer is a taboo in some cultures where the word "cancer" is still associated with death or guilt & shame.
- Patients from diverse cultures rely on different healing practices that can often be incorporated into care plans.
- Ethnic/genetic/cultural differences can affect treatment response directly or through lifestyles.

Where You Need Cultural Competence Most

- Truth-telling about diagnosis, prognosis and risks
- Discussion of death and EOL choices
- Issues related to:
  - family involvement in information and decision making
  - use of alternative and complementary cancer treatments
  - reliance on spirituality and religion for healing
  - attitudes toward psychological and behavioral counseling
  - concerns regarding clinical trials

7 Areas to Cover in Taking a Cultural History -"BALANCE"

B Beliefs & Values (that influence perceptions of illness)

A Ambience (living situation and family structure)

L Language & Health Literacy (role of interpreters, accuracy of translation, metaphoric meanings)

A Affiliations (community ties, religious & spiritual beliefs)

N Network (social support system)

C Challenges (cancer-related risks of home, work & life conditions)

E Economics (socioeconomic status & community resources)

Pearls of Wisdom

- Sensitivity to cultural issues enhances trust between patients and doctors.
- Initial time investment avoids later misunderstandings and/or bedside ethical conflicts.
- Personalized cancer care incorporates patients' and families' culture and draws on community resources.

.....

- Learn about the cultural groups most frequently treated at your institution.
- Incorporate cultural into social history.
- Be prepared to briefly describe your own cultural background.

Pearls of Wisdom *(cont'd.)*

- Always clarify your institutional and ethical norms in matters of truth- telling and decision making.
- Recognize your own biases toward some cultural attitudes and practices.
- Be aware how different families involve themselves in decision making.
- Be sensitive to different cultural meanings of suffering and caregiving.
- Open your mind to different ways to promote health and cope with illness.

Resources

Cancer, Culture, and Health Disparities: Time to Chart a New Course?
Marjorie Kagawa-Singer, Annalyn Valdez Dadia, Mimi C.Yu & Antonella Surbone, CA Cancer J Clin 2010; 60: 12-39

For more information visit:

www.mdanderson.org/icare

Antonella Surbone, M.D., Ph.D. F.A.C.P.
Lecturer in Bioethics
Professor of Medicine
New York University Medical School
I*CARE Program Faculty

Walter F. Baile, M.D.,
Professor of Behavioral Science
Director, Interpersonal Communication And Relationship Enhancement (I*CARE) Program
Department of Faculty & Academic Development
The University of Texas MD Anderson Cancer Center

Cathy Kirkwood, MPH
I*CARE Project Director

© The University of Texas MD Anderson Cancer Center 2014

Effective Communication in Supervision



Effective Communication in Supervision

Giving Corrective Feedback – The good, the bad and the ugly

Walter F. Baile, MD
Rebecca Walters, MS, LMHC, LCAT, TEP

MD Anderson

I*CARE

Interpersonal Communication And Relationship Enhancement

Set your **TIMER** for a Successful Conversation!

- **T**hink Through the Encounter (ahead of time)
- **I**ntroduce Issues
- **M**anage the Discussion
- **E**stablish a Plan and Expectations
- **R**evisit and Give Feedback

Think Through the Encounter (ahead of time)

- Be sure you **have the right information/data** you need.
- **Run it by others** if you need a reality check or advice.
- Have the **endorsement** of the "one up" (upper management) to avoid being undermined.
- **Rehearse** what you will say – Don't let your thinking get catastrophic (focused on the worst possible outcome).
- Put on your "**Feedback Hat**." (Strive to help the person improve performance.)

Introduce the Issues

- **Meet on their turf**, if possible (being "called into the office" may not lead to productive conversation).
- **Clearly state the issue** using **"I Statements"** (tends to decrease defensiveness in others).

  "I'm worried about your getting to clinic late…" "I'm concerned about your interaction with…" "I have something important to discuss about…"
- **Provide Facts** – avoid personal stuff.

  "In going over your attendance, I see that…"
- **Maintain eye contact**.

Manage the Discussion

- Try to **stay calm**.
- **Focus** on what the other is saying.
- Try to **be nonjudgmental** and personal. It's about changing behavior.
- Use **"Tell me more"** to clarify.

  "When you say you feel treated unfairly, can you tell me more?"
- Use the "**Six Second Rule**" - when your emotions boil, wait 6 seconds or until calm before responding.
- **Reaffirm** the other person's issue.

  "So what I hear you saying is…"
- **Align** with the person **by acknowledging and validating** emotions with empathy.

  "I can see you weren't expecting this."
  "I know this is hard for you to hear."
  "I see your point."
  "This isn't easy to talk about, is it?"
- Use "**Wish Statements**"

  "I wish I could change that." "I wish I had better news."
  "I wish that I did not have to revisit the issue."

Establish a Plan and Expectations

- When emotions subside, **work on the problem together**.
- **State your expectations**.

  "It's important that we resolve this."
- **Collaborate/Negotiate/Brainstorm**.

  "What are your ideas for how we can…?"
- **State your goals**.

  "I'd like to see you try to…"
- Set **SMART** Goals:

  S=Specific
  M=Measureable
  A=Achievable
  R=Resourced
  T=Timed
- **Summarize**

  "So this is what we've decided."

Revisit and Give Feedback

- **State purpose of meeting.**

  "I wanted to meet with you to follow upon…"
- **Review** agreed upon goals/agreements.
- Get their **perception.**

  "How are things going?"
- **Praise Effort**.

  "I appreciate the work you put in to…"
- **Give Feedback**.

  "You've really improved on…"
  "I think you've struggled with…"
- **Brainstorm** to further improve performance.

  "What will it take for you to bump this up a notch?"

Feedback

– when things have NOT changed.

- **State the problem.**
  "I am concerned that you are still coming to work late."
- **Explore the problem.**
  "I'm wondering what's gotten in the way of your following through with our agreement?"
- **Deal with emotions as they occur.**
  "It sounds frustrating."
- **Restate the need to improve.**
  "This is really important so let's brainstorm some more as to how we can fix this."
- **State consequences.**
  "I'm trying to avoid this being moved to a higher level."

Resources

Walter F. Baile, M.D.,
Professor of Behavioral Science
Director, Interpersonal Communication
And Relationship Enhancement
(I*CARE) Program
Department of Faculty & Academic Development
The University of Texas MD Anderson Cancer Center

Rebecca Walters, MS, LMHC, LCAT, TEP
Director, Hudson Valley Psychodrama Institute
I*CARE Faculty

Cathy Kirkwood, MPH
I*CARE Project Director
Department of Faculty & Academic Development
The University of Texas MD Anderson Cancer Center
Email: icare@mdanderson.org

For video demonstrations of these techniques, please visit our Web site at:

www.mdanderson.org/icare

Free online CME available

© The University of Texas MD Anderson Cancer Center 2014

NOTES

Notes

Notes

To view video demonstrations of these protocols and our Telly Award winning program "Crossroads," please visit our Web site at: **www.mdanderson.org/icare**
Free online Continuing Medical Education (CME Ethics & Professional Responsibility) available

To order copies, please contact:

Cathy Kirkwood, MPH
Project Director, Academic Affairs
Interpersonal Communication And Relationship Enhancement (I*CARE) Program
MD Anderson Cancer Center - Faculty & Academic Development
The University of Texas MD Anderson Cancer Center
Mailing Address: PO Box 301407, Unit 1726, Houston Texas 77230-1407
Deliveries: 7007 Bertner Ave., 1MC17.2106, Houston, TX 77230-1407
Tel: 713-745-3138
Fax: 713-794-4236
cdkirkwood@mdanderson.org

Designed and Produced by Medical Graphics & Photography 2014

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center
Making Cancer History®

I herby confirm my participation in the CPMI patient communication, difficult patient management, bedside manners and professional ethic review workshop based on the I*CARE (The Complete Guide to Communication Skills by MD Anderson enclosed). I am aware of the electronic copy of the CPMI compliance and ethical policies and the HIPPA materials available to me in the office email. The free online link to the I*CARE is:

https://www.mdanderson.org/documents/education-training/icare/pocketguide-texttabscombined-oct2014final.pdf

-I was given the opportunity to ask questions and all of my questions have been answered.

08/16/24

NAME (Print): **NAME (Sign):**

Emily J Gonzalez [signature]

Shanee Houston [signature]

Leon Mangalan [signature]

Sosena Moges [signature]

I herby confirm my participation in the CPMI patient communication, difficult patient management, bedside manners and professional ethic review workshop based on the I*CARE (The Complete Guide to Communication Skills by MD Anderson enclosed). I am aware of the electronic copy of the CPMI compliance and ethical policies and the HIPPA materials available to me in the office email. The free online link to the I*CARE is:

https://www.mdanderson.org/documents/education-training/icare/pocketguide-texttabscombined-oct2014final.pdf

-I was given the opportunity to ask questions and all of my questions have been answered.

11/13/23

NAME (Print): **NAME (Sign):**

SOSena Moges

Emily Gonzalez

JING CUI

D

The University of Texas MD Anderson Cancer Center

certifies that

Leon Margolin, MD

has participated in the enduring material activity titled

Achieving Communication Excellence (ACE) Lecture Series

'Preventing Breakdowns and Mitigating Harm'

MEMV 1135-2

completed on April 20, 2015

and is awarded 1.25 *AMA PRA Category 1 Credits™*

Shirley A. Roy, MPH
Director, CME/Conference Management

The University of Texas MD Anderson Cancer Center is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The University of Texas MD Anderson Cancer Center designates this enduring material for a maximum of 1.25 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

This activity is designated for 1.25 *AMA PRA Category 1 Credits™* in the area of medical ethics and/or professional responsibility.

Please retain this document for your records. An administrative fee will be charged for replacement certificates.

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Making Cancer History®

The University of Texas MD Anderson Cancer Center
certifies that

Leon Margolin, MD

has participated in the enduring material activity titled

Achieving Communication Excellence (ACE) Lecture Series 2011

'Psychobiology of Communication Skills and Doctor-Patient Relationships'

MEMV 1131-3

completed on May 15, 2015

and is awarded 1.25 *AMA PRA Category 1 Credits™*

Shirley A. Roy, MPH
Director, CME/Conference Management

The University of Texas MD Anderson Cancer Center is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The University of Texas MD Anderson Cancer Center designates this enduring material for a maximum of 1.25 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

This activity is designated for 1.25 *AMA PRA Category 1 Credits™* in the area of medical ethics and/or professional responsibility.

Please retain this document for your records. An administrative fee will be charged for replacement certificates.

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Making Cancer History®

The University of Texas MD Anderson Cancer Center
certifies that

Leon Margolin, MD

has participated in the enduring material activity titled

Achieving Communication Excellence (ACE) Lecture Series

'Making Connection: The Art and Science of Compassion'

MEMV 1131-7

completed on May 15, 2015

and is awarded 1.25 *AMA PRA Category 1 Credits™*

Shirley A. Roy, MPH
Director, CME/Conference Management

The University of Texas MD Anderson Cancer Center is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The University of Texas MD Anderson Cancer Center designates this enduring material for a maximum of 1.25 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

This activity is designated for 1.25 *AMA PRA Category 1 Credits™* in the area of medical ethics and/or professional responsibility.

Please retain this document for your records. An administrative fee will be charged for replacement certificates.

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Making Cancer History®

The University of Texas MD Anderson Cancer Center

certifies that

Leon Margolin, MD

has participated in the enduring material activity titled

Achieving Communication Excellence (ACE) Lecture Series 2013

'What's Therapeutic about Clinician-Patient Communication'

MEMV 1123-3

completed on April 20, 2015

and is awarded 1.25 *AMA PRA Category 1 Credits™*

Shirley A. Roy, MPH
Director, CME/Conference Management

The University of Texas MD Anderson Cancer Center is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The University of Texas MD Anderson Cancer Center designates this enduring material for a maximum of 1.25 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

This activity is designated for 1.25 *AMA PRA Category 1 Credits™* in the area of medical ethics and/or professional responsibility.

Please retain this document for your records. An administrative fee will be charged for replacement certificates.

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Making Cancer History®

The University of Texas MD Anderson Cancer Center

certifies that

Leon Margolin, MD

has participated in the enduring material activity titled

Achieving Communication Excellence (ACE) Lecture Series

'How Does the Neuroscience of Empathy Inform Clinical Practice'

MEMV 1135-3

completed on April 2, 2015

and is awarded 1.25 *AMA PRA Category 1 Credits™*

Shirley A. Roy, MPH
Director, CME/Conference Management

The University of Texas MD Anderson Cancer Center is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The University of Texas MD Anderson Cancer Center designates this enduring material for a maximum of 1.25 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

This activity is designated for 1.25 *AMA PRA Category 1 Credits™* in the area of medical ethics and/or professional responsibility.

Please retain this document for your records. An administrative fee will be charged for replacement certificates.

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Making Cancer History®

The University of Texas MD Anderson Cancer Center

certifies that

Leon Margolin, MD/PhD

has participated in the enduring material activity titled

Basic Principles in Communication Skills for Clinical Oncology
MEMV 1127

On March 28, 2015

and is awarded 2.00 *AMA PRA Category 1 Credit(s)™*.
Of the total number of credits, 2.00 have been claimed in the area of medical ethics and/or professional responsibility.

Shirley A. Roy, MPH
Director, CME/Conference Management

The University of Texas MD Anderson Cancer Center is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The University of Texas MD Anderson Cancer Center designates this enduring material for a maximum of 2.00 *AMA PRA Category 1 Credit(s)™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

This activity is designated by The University of Texas MD Anderson Cancer Center for 2.00 *AMA PRA Category 1 Credit(s)* ™ in the area of medical ethics and/or professional responsibility.

Please retain this document for your records. An administrative fee will be charged for replacement certificates.

61327169

THE UNIVERSITY OF TEXAS
MD Anderson
Cancer Center

Making Cancer History®

The University of Texas MD Anderson Cancer Center

certifies that

Leon margolin, MD/PhD

has participated in the enduring material activity titled

Crossroads
MEMV 1140

On March 26, 2015

and is awarded 1.25 *AMA PRA Category 1 Credit(s)*™.
Of the total number of credits, 1.25 have been claimed in the area of medical ethics and/or professional responsibility.

Shirley A. Roy, MPH
Director, CME/Conference Management

The University of Texas MD Anderson Cancer Center is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The University of Texas MD Anderson Cancer Center designates this enduring material for a maximum of 1.25 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

This activity is designated by The University of Texas MD Anderson Cancer Center for 1.25 *AMA PRA Category 1 Credit(s)* ™ in the area of medical ethics and/or professional responsibility.

Please retain this document for your records. An administrative fee will be charged for replacement certificates.

90594452

THE UNIVERSITY OF TEXAS
MD Anderson
Cancer Center

Making Cancer History®

The University of Texas MD Anderson Cancer Center

certifies that

Leon Margolin, MD/PhD

has participated in the enduring material activity titled

Managing Difficult Communication: Your Father Has Died; I Will Not Take Tamoxifen; Discontinuing Ventilation, Euthanasia
MEMV 11286

On April 07, 2015

and is awarded 1.00 *AMA PRA Category 1 Credit(s)™*.
Of the total number of credits, 1.00 have been claimed in the area of medical ethics and/or professional responsibility.

Shirley A. Roy, MPH
Director, CME/Conference Management

The University of Texas MD Anderson Cancer Center is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The University of Texas MD Anderson Cancer Center designates this enduring material for a maximum of 1.00 *AMA PRA Category 1 Credit(s)™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

This activity is designated by The University of Texas MD Anderson Cancer Center for 1.00 *AMA PRA Category 1 Credit(s)* ™ in the area of medical ethics and/or professional responsibility.

Please retain this document for your records. An administrative fee will be charged for replacement certificates.

10660595

THE UNIVERSITY OF TEXAS
MD Anderson
Cancer Center

Making Cancer History®

The University of Texas MD Anderson Cancer Center

certifies that

Leon Margolin, MD/PhD

has participated in the enduring material activity titled

Managing Difficult Communication: Genetic Counseling
MEMV 11288

On April 07, 2015

and is awarded 1.50 *AMA PRA Category 1 Credit(s)*™.
Of the total number of credits, 1.50 have been claimed in the area of medical ethics and/or professional responsibility.

Shirley A. Roy, MPH
Director, CME/Conference Management

The University of Texas MD Anderson Cancer Center is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The University of Texas MD Anderson Cancer Center designates this enduring material for a maximum of 1.50 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

This activity is designated by The University of Texas MD Anderson Cancer Center for 1.50 *AMA PRA Category 1 Credit(s)* ™ in the area of medical ethics and/or professional responsibility.

Please retain this document for your records. An administrative fee will be charged for replacement certificates.

45129582

THE UNIVERSITY OF TEXAS
MD Anderson
~~Cancer~~ Center

Making Cancer History®

The University of Texas MD Anderson Cancer Center

certifies that

Leon Margolin, MD/PhD

has participated in the enduring material activity titled

Managing Difficult Communication: How Much Time Have I Got; Patient Is Angry; Telephone Conversations
MEMV 11287

On March 29, 2015

and is awarded 1.00 *AMA PRA Category 1 Credit(s)™*.
Of the total number of credits, 1.00 have been claimed in the area of medical ethics and/or professional responsibility.

Shirley A. Roy, MPH
Director, CME/Conference Management

The University of Texas MD Anderson Cancer Center is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The University of Texas MD Anderson Cancer Center designates this enduring material for a maximum of 1.00 *AMA PRA Category 1 Credit(s)™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

This activity is designated by The University of Texas MD Anderson Cancer Center for 1.00 *AMA PRA Category 1 Credit(s)* ™ in the area of medical ethics and/or professional responsibility.

Please retain this document for your records. An administrative fee will be charged for replacement certificates.

95865651

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Making Cancer History®

The University of Texas MD Anderson Cancer Center

certifies that

Leon Margolin, MD/PhD

has participated in the enduring material activity titled

Managing Difficult Communication: Mr. Carter
MEMV 11281

On April 07, 2015

and is awarded 1.00 *AMA PRA Category 1 Credit(s)*™.
Of the total number of credits, 1.00 have been claimed in the area of medical ethics and/or professional responsibility.

Shirley A. Roy, MPH
Director, CME/Conference Management

The University of Texas MD Anderson Cancer Center is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The University of Texas MD Anderson Cancer Center designates this enduring material for a maximum of 1.00 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

This activity is designated by The University of Texas MD Anderson Cancer Center for 1.00 *AMA PRA Category 1 Credit(s)* ™ in the area of medical ethics and/or professional responsibility.

Please retain this document for your records. An administrative fee will be charged for replacement certificates.

73011437

THE UNIVERSITY OF TEXAS
MD Anderson
Cancer Center

Making Cancer History®

The University of Texas MD Anderson Cancer Center

certifies that

Leon Margolin, MD/PhD

has participated in the enduring material activity titled

Managing Difficult Communication: Mrs. Wright
MEMV 11283

On April 07, 2015

and is awarded 1.00 *AMA PRA Category 1 Credit(s)*™.
Of the total number of credits, 1.00 have been claimed in the area of medical ethics and/or professional responsibility.

Shirley A. Roy, MPH
Director, CME/Conference Management

The University of Texas MD Anderson Cancer Center is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The University of Texas MD Anderson Cancer Center designates this enduring material for a maximum of 1.00 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

This activity is designated by The University of Texas MD Anderson Cancer Center for 1.00 *AMA PRA Category 1 Credit(s)* ™ in the area of medical ethics and/or professional responsibility.

Please retain this document for your records. An administrative fee will be charged for replacement certificates.

37518466

THE UNIVERSITY OF TEXAS
MD Anderson
Cancer Center

Making Cancer History®

The University of Texas MD Anderson Cancer Center

certifies that

Leon Margolin, MD/PhD

has participated in the enduring material activity titled

Managing Difficult Communication: An Error Has Occurred, I'm Going to Mexico, My Mother is Not To Be Told, Don't Give Up On My Mother
MEMV 11285

On March 27, 2015

and is awarded 1.00 *AMA PRA Category 1 Credit(s)*™.
Of the total number of credits, 1.00 have been claimed in the area of medical ethics and/or professional responsibility.

Shirley A. Roy, MPH
Director, CME/Conference Management

The University of Texas MD Anderson Cancer Center is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The University of Texas MD Anderson Cancer Center designates this enduring material for a maximum of 1.00 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

This activity is designated by The University of Texas MD Anderson Cancer Center for 1.00 *AMA PRA Category 1 Credit(s)* ™ in the area of medical ethics and/or professional responsibility.

Please retain this document for your records. An administrative fee will be charged for replacement certificates.

39557867

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Making Cancer History®

The University of Texas MD Anderson Cancer Center

certifies that

Leon Margolin, MD/PhD

has participated in the enduring material activity titled

Managing Difficult Communication: Mrs. Anderson
MEMV 11282

On April 07, 2015

and is awarded 1.50 *AMA PRA Category 1 Credit(s)™*.
Of the total number of credits, 1.50 have been claimed in the area of medical ethics and/or professional responsibility.

Shirley A. Roy, MPH
Director, CME/Conference Management

The University of Texas MD Anderson Cancer Center is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The University of Texas MD Anderson Cancer Center designates this enduring material for a maximum of 1.50 *AMA PRA Category 1 Credit(s)™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

This activity is designated by The University of Texas MD Anderson Cancer Center for 1.50 *AMA PRA Category 1 Credit(s)* ™ in the area of medical ethics and/or professional responsibility.

Please retain this document for your records. An administrative fee will be charged for replacement certificates.

87934193

THE UNIVERSITY OF TEXAS
MD Anderson
Cancer Center

Making Cancer History®

The University of Texas MD Anderson Cancer Center

certifies that

Leon Margolin, MD/PhD

has participated in the enduring material activity titled

Non-Verbal Communication Skills
MEMV 1130

On March 28, 2015

and is awarded 1.00 *AMA PRA Category 1 Credit(s)*™.
Of the total number of credits, 1.00 have been claimed in the area of medical ethics and/or professional responsibility.

Shirley A. Roy, MPH
Director, CME/Conference Management

The University of Texas MD Anderson Cancer Center is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The University of Texas MD Anderson Cancer Center designates this enduring material for a maximum of 1.00 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

This activity is designated by The University of Texas MD Anderson Cancer Center for 1.00 *AMA PRA Category 1 Credit(s)* ™ in the area of medical ethics and/or professional responsibility.

Please retain this document for your records. An administrative fee will be charged for replacement certificates.

45813430

THE UNIVERSITY OF TEXAS
MD Anderson
~~Cancer~~ Center

Making Cancer History®

The University of Texas MD Anderson Cancer Center

certifies that

Leon Margolin, MD

has participated in the enduring material activity titled

Achieving Communication Excellence (ACE) Lecture Series 2013 Online

'Improving Physician Communication Skills at a Large Academic Medical Center: The Cleveland Clinic Experience'

MEMV 1123-4

completed on April 20, 2015

and is awarded 1.25 *AMA PRA Category 1 Credits™*

Shirley A. Roy, MPH
Director, CME/Conference Management

The University of Texas MD Anderson Cancer Center is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The University of Texas MD Anderson Cancer Center designates this enduring material for a maximum of 1.25 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

This activity is designated for 1.25 *AMA PRA Category 1 Credits™* in the area of medical ethics and/or professional responsibility.

Please retain this document for your records. An administrative fee will be charged for replacement certificates.

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Making Cancer History®