10/13/2020

To whom it may concern:

I am a licensed psychologist, who has certification in Addiction Medicine and have taken training in pain management. I had been a clinical director of a recovery program in Lancaster, Ohio (please find my resume enclosed).

I have evaluated and followed up many of Dr. Leon Margolin's patients (including all the patients in the patient list enclosed), however, I am not an employee, colleague, or social friend of Dr. Margolin. I did not receive any payment for this review.

As described in my prior letters (dated October 10, 2019 and May 16, 2019), based on my experience of more than 20 years in the field of pain and addiction, I fully endorse the use of the SBIRT (G codes) and addressing psychological factors in EMG testing for the patients in the list enclosed. I think Dr. Margolin has created one of the best SBIRT programs in the state of Ohio which is medically necessary and fully compliant.

I fully endorse his publication in collaboration with the Cleveland Clinic Foundation published in a peer-reviewed journal:

https://www.gavinpublishers.com/assets/articles_pdf/1595045423article_pdf1130015263.pdf

There are several independent publications by American Medical Association, HHS, National Institute for Drug Abuse, Society for Addiction Medicine and other agencies that have recently endorsed similar findings. Dr. Margolin's SBIRT program is even more relevant and needed during the COVID-19 pandemic.

For example, Dr. Nora D. Volkow, Director, National Institute on Drug Abuse, National Institutes of Health (USA) recently (September, 2020) published the enclosed article calling for increase in screening of the pain and addiction patients, especially since this population is at increased risk for COVID-19.

American Medical Association (AMA) published the enclosed urgent brief on August 4th, 2020 marking Ohio as an area of a sharp increase in opioid mortality:

"Policymakers need to act to remove barriers to evidence-based care for patients with pain and those with a substance use disorder or the epidemic will continue to worsen." (AMA report below page 4):
https://www.ama-assn.org/system/files/2020-07/opioid-task-force-progress-report.pdf

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The opioid crisis has become an epidemic within the COVID-19 (see enclosed):

https://www.painmedicinenews.com/Multimedia/Article/08-20/Panel-COVID-19-Compounds-Opioid-Public-Health-Emergency/59293

It is absolutely clear to me that any denial of the SBIRT (G codes) or other services rendered by Dr. Margolin or marking them as "unallowed" and any recoupment of funds from Dr. Margolin's practice would not only contradict the acceptable national and state guidelines but in effect constitute a public health hazard that puts hundreds if not thousands of Ohioans at the risks of disability and death.

Such policies must be stopped to prevent danger to thousands of people in Ohio and nationwide as reflected by the HHS, AMA, National Institute for Drug Abuse (NIDA) policies and publications. Ohio is one of the most affected area devastated by the crisis, therefore urgent actions are required.

Sincerely,
William Vasilakis, Psy.D.
Dr. William Vasilakis, Psy.D

Clinical Psychologist #5481

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Patient list: last name/ first name initials (article example are in **bold**)

PE	JA
HS	
BBK	
HL	
CC	
MR	
LB	
ST (example 5)	
AE	
PV	
SM (example 6)	
CJ	
TD	
II	
HR	
PT	
MG	
SD (example 1)	
RL	
MT	
LA	
FG	
SR	
EA	
WG	
KT	
KI	
BD	
MJ (example 4)	
EH	
MC	
CA	
HW	
KW	
LJ	
PB	
CJ	
FA	
TC	
MF	
SW	
AM	
AG	
WR	
WK	
HL (example 2,3)	

APEX

· Counseling Services ·

Addendum – October 10, 2019:

I would also like to clarify that each time the patient is defined as "low risk" or a "good candidate for narcotic medication" this assessment is based on the history and the data reported by the patient. There it is mandatory to continue SBRIT (G0397) protocol attached.

Literature shows that some patients will develop aberrant drug seeking behavior despite an initial recommendation to be a "good candidate for narcotic medication" or "low risk", that's why the guidelines mandate the SBRIT (G0397) monitoring that Dr. Margolin implemented in his practice.

Based on my clinical experience of 20+ years in this field of pain and addiction psychology, serving as the head of the Department of Addiction Medicine in the Lancaster Hospital, I think Dr. Margolin has created one of the best SBIRT programs in Ohio and maybe nationwide. Dr. Margolin's practice is located in the epicenter of the opioid epidemic and sub-specialized in the screening for drug and alcohol of high risk patients that require high frequency of such screening. Dr. Margolin receives referral for the screening for drug and alcohol of high risk patients from hospitals including OSU, Riverside, Mount Caramel, and University Hospital in Cleveland, OH and even from other pain management clinics in the area because of the outstanding quality of his SBRIT (G0397) protocol for screening high risk patients for drugs and alcohol.

My understanding is that he has presented his experience at the 2019 national meeting and is invited to present his SBIRT experience at the Case Western School of Medicine continuous medical education event.

Respectfully,

William H. Vasilakis, Psy.D.

William H. Vasilakis, Psy.D.

Clinical Psychologist

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Patient Name: **INS:** **DOB:** **Date:**

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:

_____

_____

_____

_____

Leon Margolin MD, PhD / Jing Liu CNP

APEX

· Counseling Services ·

May 16, 2019

To Whom It May Concern:

I am a licensed psychologist, who has certification in addictions medicine and have taken training in pain management. I had been a clinical director of a recovery program in Lancaster, Ohio before transitioning to a hospital.

I have been working with the Comprehensive Pain Management Institute, LLC (CPMI) for several years now, but I am not employed by them and receive no compensation for services from them or Dr. Margolin for analysis.

I reviewed Dr. Margolin's voluntary practice improvement, submitted and approved to ABPMR.

After evaluating the patients I noticed that most of the patients in the sample (as well as many other high risk patients treated by CMPI) have psychological co-morbidities such as: anxiety, depression or concerns of aggressive/manipulative behavior (such as demanding a sharp increase in medications in response to an invasive test). The tests include EMG but because of higher risk patients, there is a chance of increasing psychopathology, like verbal aggression, therefore, a patient is required to give verbal consent.

These risks are clearly and objectively documents in the records as reflected in the initial follow-up evaluations. This includes urine drug screens, prescription monitoring program reports (OARRS), SOAPP-R, PADT, ORT and other assessment tools and referring provider records. All the patients on the list were treated in the framework of screening and brief intervention (SBIRT) approach which requires diagnostic testing. This includes nerve conduction studies within the framework of the Interventional Pain Management according to the state and federal guidelines.

Taking these factors into consideration, in my professional opinion Dr. Margolin made the correct clinical judgement within the framework of Interventional Pain Medicine by avoiding the needle EMG testing (for patients in sample two and in general of all CPMI patients) in case of lack of cooperation or clear understanding by the patient and/or concern of the aberrant behaviors described above.

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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 UN1VERSITY
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.

Molecular Psychiatry
https://doi.org/10.1038/s41380-020-00880-7

IMMEDIATE COMMUNICATION

COVID-19 risk and outcomes in patients with substance use disorders: analyses from electronic health records in the United States

Quan Qiu Wang[1] · David C. Kaelber[2] · Rong Xu[1] · Nora D. Volkow[3]

Received: 22 June 2020 / Revised: 20 August 2020 / Accepted: 3 September 2020

Abstract

The global pandemic of COVID-19 is colliding with the epidemic of opioid use disorders (OUD) and other substance use disorders (SUD) in the United States (US). Currently, there is limited data on risks, disparity, and outcomes for COVID-19 in individuals suffering from SUD. This is a retrospective case-control study of electronic health records (EHRs) data of 73,099,850 unique patients, of whom 12,030 had a diagnosis of COVID-19. Patients with a recent diagnosis of SUD (within past year) were at significantly increased risk for COVID-19 (adjusted odds ratio or AOR = 8.699 [8.411–8.997], $P < 10^{-30}$), an effect that was strongest for individuals with OUD (AOR = 10.244 [9.107–11.524], $P < 10^{-30}$), followed by individuals with tobacco use disorder (TUD) (AOR = 8.222 ([7.925–8.530], $P < 10^{-30}$). Compared to patients without SUD, patients with SUD had significantly higher prevalence of chronic kidney, liver, lung diseases, cardiovascular diseases, type 2 diabetes, obesity and cancer. Among patients with recent diagnosis of SUD, African Americans had significantly higher risk of COVID-19 than Caucasians (AOR = 2.173 [2.01–2.349], $P < 10^{-30}$), with strongest effect for OUD (AOR = 4.162 [3.13–5.533], $P < 10^{-25}$). COVID-19 patients with SUD had significantly worse outcomes (death: 9.6%, hospitalization: 41.0%) than general COVID-19 patients (death: 6.6%, hospitalization: 30.1%) and African Americans with COVID-19 and SUD had worse outcomes (death: 13.0%, hospitalization: 50.7%) than Caucasians (death: 8.6%, hospitalization: 35.2%). These findings identify individuals with SUD, especially individuals with OUD and African Americans, as having increased risk for COVID-19 and its adverse outcomes, highlighting the need to screen and treat individuals with SUD as part of the strategy to control the pandemic while ensuring no disparities in access to healthcare support.

Introduction

Coronavirus disease 2019 (COVID-19) is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and has rapidly escalated into a global pandemic [1]. The global pandemic of COVID-19 is colliding in the United States (US) with the epidemic of opioid use disorders (OUD) and overdose mortality [2–4]. Currently, there is little if any quantitative analysis of the risks and outcomes for COVID-19 infection in individuals suffering from an OUD and those suffering from other substance use in the US. In addition, there is minimal data on how race and other demographic factors affect the risk and outcomes of COVID-19 among patients with SUD including OUD.

It is estimated that more than 70,000 people will die in the US from an overdose in 2019 mostly from opioid overdoses, which are driven by the respiratory depressant effects of opioids. Considering that COVID-19 affects pulmonary function this combination could be particularly lethal. Additionally, ~10.8% of adults in the US have a substance use disorders (SUD) including alcohol (AUD) and tobacco (TUD) [5]. To the extent that chronic use of tobacco, alcohol and other drugs is associated with cardiovascular (arrhythmias, cardiac insufficiency, and myocardial infarction), pulmonary

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[3] National Institute on Drug Abuse, National Institutes of Health, Bethesda, MD, USA

Published online: 14 September 2020

(COPD, pulmonary hypertension), and metabolic diseases (diabetes, hypertension) [6–10] all of which are risk factors for COVID-19 infection and for worse outcomes [11–13] one can also predict that individuals with SUD including OUD would be at increased risk for adverse COVID-19 outcomes [2]. Preliminary reports regarding higher risk for adverse outcomes with COVID-19 and smoking have been inconclusive [14–16]. Currently there is little research on the effects of other drugs including opioids, cannabis, cocaine and alcohol on the susceptibility to COVID-19 infection and to adverse outcomes [2].

Material and methods

Database description

We performed a retrospective case-control study using de-identified population-level electronic health record (EHR) data collected by the IBM Watson Health Explorys from 360 hospitals and 317,000 providers across 50 states in the US since 1999 [17]. The EHRs are de-identified according to the Health Insurance Portability and Accountability Act and the Health Information Technology for Economic and Clinical Health Act standards. After the de-identification process, curation process normalizes the data through mapping key elements to widely-accepted standards [18]. Specifically, disease terms are coded using the Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT), a global standard for health terms that provides the core general terminology for EHRs [19]. Previous studies showed that with this large-scale and standardized EHR database, large case-control studies can be undertaken efficiently [20–24], including our recent studies [23, 24].

Study population

At the time of this study (June 15, 2020), the study population consisted of 73,099,850 unique patients, including 7,510,380 patients with a diagnosis with SUD (diagnosis made within the past year or prior) of whom 722,370 had been recently diagnosed with SUD (diagnosed within past year), 12,030 patients diagnosed with COVID-19, 1880 patients with lifetime diagnosis of SUD and COVID-19, and 1050 with recent SUD diagnosis and COVID-19. The status of COVID-19 was based on the concept "Coronavirus infection (disorder)" (SNOMED-CT Concept Code 186747009) and we further limited the diagnosis time frame to within the past year to capture the timing of new cases arising during the COVID-19 pandemic. The outcome measures were COVID-19 diagnosis, rates of death, and hospitalization. The specific types of SUD examined included alcohol use disorder (AUD), OUD, tobacco use disorder (TUD), cannabis use disorder (CUD), and cocaine use disorder (Cocaine-UD). Other types of SUDs were not investigated due to their small number of COVID-19 cases.

The status of "SUD" was based on diagnosis of "Drug dependence (disorder)" on SNOMED-CT Concept Code 191816009, or of "Substance abuse (disorder)" on SNOMED-CT Concept Code 66214007. The status of "AUD" was based on the diagnosis of "Alcohol dependence (disorder)" on Concept Code 66590003, or of "Alcohol abuse (disorder)" on Concept Code 7200002. The status of "CUD" was based on the diagnosis of "Cannabis dependence (disorder)" on Concept Code 85005007 or of "Cannabis abuse (disorder)" on Concept Code 37344009. The status of "Cocaine-UD" was based on the diagnosis of "Cocaine dependence (disorder)" on SNOMED-CT Concept Code 31956009, or of "Cocaine abuse (disorder)" on Concept Code 78267003. The status of "OUD" was based on diagnosis of "Opioid dependence (disorder)" on Concept Code 75544000, or of "Nondependent opioid abuse (disorder)" on Concept Code 191909007. The status of "TUD" was based on diagnosis of "Nicotine dependence (disorder)" on Concept Code 56294008. In our study, patients with SUD were categorized into two groups: patients with a lifetime diagnosis of SUD (diagnosed within past year or prior) and patients with a "recent" SUD (diagnosed within the past year). The first group represents patients with any SUD diagnosis (active or recovered). The second group is a subset of the first group but more likely consists of patients with active SUD. Through this manuscript we use the term SUD, following DSM-5 [25], which combines the prior categories of substance abuse and substance dependence from DSM-4.

The following analyses were performed: (1) we examined if patients diagnosed with SUD were at increased the risk for COVID-19, adjusted for age, gender, race, and insurance type. The exposure groups were patients diagnosed with SUD, the unexposed groups were patients without SUD, and the outcome measure was diagnosis of COVID-19. Separate analyses were done for patients with a lifetime SUD diagnosis and for patients with a recent SUD. Separate analyses were done for subtypes of SUD. (2) We examined how demographic factors affected COVID-19 risk among patients with recent diagnosis of SUD. The case groups were patients with SUD and one of the following demographic factors: female, senior, African American. The comparison groups were patients with SUD and one of the following corresponding demographic factors (male, adult, Caucasian). The outcome measure was diagnosis of COVID-19. (3) We examined rates of death and hospitalization among patients with COVID-19 and SUD and compared outcomes of African Americans to those of Caucasians with SUD.

Statistical analysis

The adjusted odds ratio (AOR), 95% CI and *P* values were calculated using the Cochran–Mantel–Haenszel method [26] by controlling for age groups (juniors age <18 years, adults age 18–65 years, senior age > 65 years), gender (female, male), race (Caucasian, African American), and insurance type (private, medicare, medicaid, self pay). Other demographic groups were not included due to insufficient sample sizes for COVID-19 cases. Two-sided, 2-sample test for equality of proportions with continuity correction were used to compare prevalence of comorbidities and outcomes. Statistical tests were conducted with significance set at *P* value < 0.05 (two sided). All analyses were done using R, version 3.6.3.

Results

Patient characteristics

The baseline characteristics of the study population (as of June 15, 2020) are presented in Table 1. Among 73,099,850 patients, 7,510,380 patients had lifetime SUD (diagnosed within the last or prior years) (10.27% of study population), including 1,264,990 with AUD (1.73% of study population), 222,680 with Cocaine-UD (0.30%), 490,420 with CUD (0.67%), 6,414,580 with TUD (8.77%), and 471,520 with OUD (0.65%). Among 73,099,850 patients, 722,370 had recent SUD (diagnosed within the last year) (0.99% of total population), including 83,100 with AUD (0.11%), 14,800 with Cocaine-UD (0.02%), 27,650 with CUD (0.04%), 611,750 with TUD (0.84%), and 43,160 with OUD (0.06%).

Among 12,030 patients diagnosed with COVID-19, 1880 patients had lifetime SUD (15.63% in COVID-19 population), including 320 with AUD (2.66%), 70 with Cocaine-UD (0.58%), 80 with CUD (0.67%), 1470 with TUD (12.22%), and 210 with OUD (1.75%). Among 12,030 patients diagnosed with COVID-19, 1050 had recent SUD (8.73% in COVID-19 population), including 130 with recent AUD (1.03%), 30 with Cocaine-UD (0.25%), 30 with CUD (0.25%), 840 with TUD (6.98%), and 90 with OUD (0.75%).

Risk associations between SUD and COVID-19

Patients with recent SUD diagnosis had significantly higher risk of developing COVID-19 compared to patients without recent SUD diagnosis, after adjusting for age, gender, race, and insurance types. The AOR between recent SUD diagnoses and COVID-19 was 8.699 [8.411–8.997]. Among patients with SUD subtypes, individuals with OUD had the largest risk (AOR = 10.244 [9.107–11.524]), followed by TUD (AOR = 8.222 ([7.925–8.530]), AUD (AOR = 7.752 [7.04–8.536]), Cocaine-UD (AOR = 6.53 [5.242–8.134]) and CUD (AOR = 5.296 [4.392–6.388]) (Fig. 1a).

Patients with lifetime SUD diagnosis had significantly higher risk of developing COVID-19 compared to patients without SUD, after adjusting for age, gender, race, and insurance types. The AOR between those with lifetime SUD and COVID-19 was 1.459 [1.421–1.499]; for whom, individuals with OUD had the largest risk (AOR = 2.42 [2.247–2.607], followed by cocaine-UD (AOR = 1.57 [1.393–1.77], AUD (AOR = 1.417 [1.335–1.504], and TUD (AOR = 1.332 [1.294–1.372]. Among 7,510,380 patients with lifetime SUD diagnosis, 722,370 had recent diagnosis (9.6%) (Fig. 1b).

Patients with SUD often have multiple comorbidities, including cardiovascular, pulmonary, metabolic diseases, and increased susceptibility to infections [6–10], which are also risk factors for COVID-19 [11–13]. We then examined prevalence of these known COVID-19 risk factors among adult patients with recent diagnosis of SUD and compared them to adult patients without recent SUD diagnosis. As shown in Table 2, patients with recent diagnosis of SUD had significantly higher prevalence of asthma, chronic kidney disease, chronic obstructive pulmonary disease, diabetes, cancer, HIV, chronic liver disease, cardiovascular diseases including hypertension, and obesity as compared to patients without recent SUD diagnosis of SUD. Patients with recent diagnosis of OUD had higher risk of COVID-19 than other SUD subtypes, however, the prevalence of risk factors for COVID-19 was not higher than for other SUD subtypes.

Individuals with OUD had the greatest risk for COVID-19 among patients with SUD (Fig. 1) but they did not have more comorbidities (known COVID-19 risk factors) than those with other SUDs. We then examined if medications used to treat OUD (MOUD), including methadone (though when used for OUD its dispensed through methadone clinics and not regular prescriptions), buprenorphine (which is also prescribed for pain management) and naltrexone, affected the risk of patients with OUD in getting COVID-19. There was no significant difference in risk for COVID-19 between OUD patients who were not prescribed methadone, buprenorphine or naltrexone vs. those that were (AOR = 1.064, [0.871–1.3], *P* value = 0.578) after adjusting for age, gender, race, and insurance types. These results indicate that these opioid medications had no significant effects on OUD patients' risk for COVID-19. However, a limitation in this analysis is that the EHR dataset does not capture methadone given through methadone clinics, which is the authorized way when used for the treatment of OUD. Regardless, our results did not show differences in COVID risk for OUD patients prescribed methadone, buprenorphine

Table 1 Patient characteristics.

Patient	Study population	SUD (All)	SUD (Recent)	COVID-19	COVID-19 + SUD (All)	COVID-19 + SUD (Recent)
Total	73,099,850	7,510,380	722,370	12,030	1880	1050
Gender						
Female	39,215,260 (54%)	3,528,890 (47%)	351,760 (49%)	7160 (60%)	920 (49%)	510 (49%)
Male	33,388,310 (46%)	3,972,450 (53%)	366,960 (51%)	4840 (40%)	950 (52%)	540 (51%)
Unknown	497,080 (1%)	9040 (<1%)	3640 (<1%)	30 (<1%)	10 (<1%)	0 (0%)
Age						
Adult (18–65)	43,797,300 (60%)	5,458,840 (73%)	502,770 (70%)	8180 (68%)	1200 (64%)	670 (64%)
Senior (>65)	17,810,980 (24%)	2,034,850 (27%)	217,380 (30%)	3160 (26%)	670 (36%)	380 (36%)
Junior (<18)	10,547,380 (14%)	21,970 (<1%)	3670 (1%)	700 (6%)	10 (<1%)	0 (0%)
Race						
Caucasian	40,065,790 (55%)	5,505,640 (73%)	525,560 (73%)	5500 (46%)	1050 (56%)	610 (58%)
African American	7,523,880 (10%)	1,206,150 (16%)	144,950 (20%)	5470 (45%)	770 (41%)	410 (39%)
Asian	1,184,420 (2%)	63,610 (1%)	5000 (1%)	130 (1%)	0 (0%)	0 (0%)
Hispanic/ Latino	1,055,220 (1%)	69,790 (1%)	5090 (1%)	10 (<1%)	0 (0%)	0 (0%)
Unknown	8,995,110 (12%)	832,070 (11%)	65,090 (9%)	530 (5%)	150 (8%)	110 (10%)
Insurance						
Private	25,775,370 (35%)	3,389,040 (45%)	339,900 (47%)	2020 (17%)	480 (26%)	330 (31%)
Medicare	7 7,598,120 (10%)	1,618,980 (22%)	184,940 (26%)	580 (5%)	300 (16%)	210 (20%)
Medicaid	6,094,580 (8%)	1,292,880 (17%)	149,690 (21%)	530 (4%)	160 (9%)	110 (10%)
Self pay	4,904,960 (7%)	806,110 (11%)	40,410 (6%)	160 (1%)	50 (3%)	30 (3%)
Unknown	6,157,570 (8%)	604,540 (8%)	33,340 (5%)	180 (1%)	60 (3%)	40 (4%)

Number of cases and percentage (%) are shown.

or naltrexone compared to those who did not receive those medications.

Effects of demographics on risk of COVID-19 among patients with recent SUD

Among patients with a recent diagnosis of SUD, seniors were more likely to develop COVID-19 compared to adults (AOR = 1.307 (1.207–1.416]) and African Americans were more likely to develop COVID-19 compared to Caucasians (AOR = 2.173 [2.01–2.349], after adjusting for age, gender and insurance types. Gender had no significant effects, after adjusting for age, race, and insurance types. Of the three demographic factors examined, race had the largest effect on COVID-19 risk, which was true across individuals with SUD, AUD, OUD, and TUD with the largest effects for patients with recent diagnosis of OUD. Among patients with recent diagnosis of OUD, African Americans had significantly higher risk of COVID-19 than Caucasians (4.162 [3.13–5.533], after adjusting for age, gender, and insurance types (Fig. 2). We examined prevalence of known COVID-19 risk factors among African Americans and Caucasians with recent diagnosis of SUD (and its subtypes). We showed that African Americans with recent diagnosis of SUDs had higher prevalence of asthma, chronic kidney disease, type 2 diabetes, hypertension, obesity, and HIV compared to Caucasians, while prevalence of COPD, chronic liver disease, cardiovascular disorders, and cancer was similar or lower (data not shown).

Rates of deaths and hospitalizations in COVID-19 patients with SUD

Among 12,030 COVID-19 patients, 790 died (6.57%). African Americans with COVID-19 had a death rate of 7.50%, significantly higher than for Caucasians who had a rate of 6.18% ($P = 0.007$). Among 1,880 COVID-19 patients with lifetime SUD, 180 died (9.57%), a rate significantly higher than the death rate of 6.57% for all COVID-19 patients ($P < 0.0001$). African Americans with COVID-19 and lifetime SUD had a death rate of 12.99%, significantly higher than the rate of 8.57% for Caucasians

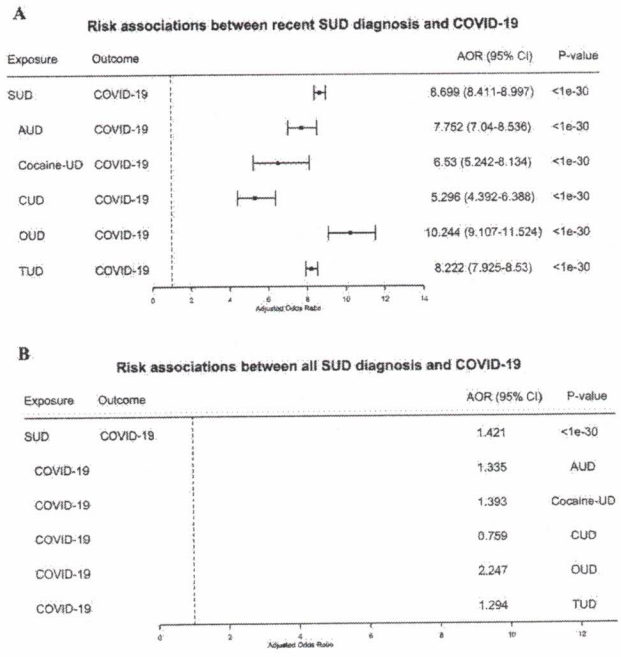

Fig. 1 **a** Risk associations of recent (diagnosis made in the last year) SUD diagnoses (and its subtypes) with COVID-19; **b** Risk associations of lifetime (diagnosed in the last year or prior) SUD diagnoses (and its subtypes) with COVID-19. SUD substance use disorder, AUD alcohol use disorder, Cocaine-UD cocaine use disorder, CUD cannabis use disorder, OUD opioid use disorder, TUD tobacco use disorder. Subtypes without sufficient sample sizes for COVID-19 cases are not shown.

with COVID-19 and lifetime SUD ($P = 0.003$). Among 1050 COVID-19 patients with recent diagnosis of SUD, 100 died (9.52%), a rate significantly higher than that for general COVID-19 patients ($P = 0.003$) and similar to that for COVID-19 patients with lifetime SUD (9.57%). Death rates for patients with COVID-19 and a recent diagnosis of SUD did not differ significantly between African Americans (12.20%) and Caucasians (9.84%) ($P = 0.276$) (Fig. 3a). The death rates for SUD subtypes were not examined due to their small sample sizes.

Among 12,030 COVID-19 patients, 3620 were hospitalized (30.09%) and the rate was significantly higher among the African Americans (35.56%) than the Caucasians (26.36%) ($P < 0.0001$). Among 1880 COVID-19 patients with lifetime SUD, 770 were hospitalized (40.96%), a rate significantly higher than for all COVID-19 patients (30.09%) ($P < 0.0001$) and also significantly higher among the African Americans (50.65%) than the Caucasians (35.24%) ($P < 0.0001$). Among 1050 COVID-19 patients with recent diagnosis of SUD, 460 were hospitalized (43.81%), a rate significantly higher than for general COVID-19 patients (30.09%) ($P < 0.0001$) and similar to that for COVID-19 patients with lifetime SUD (40.96%) ($P = 0.144$). Hospitalization rates for COVID-19 patients with a recent diagnosis of SUD were significantly higher for African Americans (53.66%), than for Caucasians (37.70%) ($P < 0.0001$) (Fig. 3b).

Table 2 Prevalence of known risk factors for COVID-19 among adult patients with recent diagnosis of SUD (and its subtypes) ("Y") versus adult patients without recent diagnosis of SUD (and its subtypes) ("N").

	Asthma (%)	CKD	COPD (%)	T2D (%)	CLD (%)	CVD (%)	HP (%)	Obesity (%)	HIV	Cancer (%)
SUD										
Y	22.11	6.25	18.86	18.60	8.26	72.67	48.99	30.12	1.75	15.06
N	6.89	1.03	1.63	4.64	1.20	23.34	13.02	7.23	0.27	3.83
AUD										
Y	17.86	5.77	16.86	14.91	12.61	73.61	53.77	21.38	2.35	14.41
N	7.05	1.09	1.80	4.79	1.27	23.83	13.37	7.47	0.29	3.95
Cocaine-UD										
Y	25.77	10.09	22.03	20.73	16.34	75.45	51.33	25.56	4.90	10.37
N	7.06	1.09	1.82	4.80	1.28	23.89	13.42	7.49	0.29	3.96
CUD										
Y	23.89	5.32	11.23	11.98	5.32	61.65	34.41	23.60	2.36	9.18
N	7.05	1.09	1.82	4.80	1.09	23.89	13.42	7.49	0.29	3.96
OUD										
Y	23.93	7.60	17.63	17.44	7.60	71.49	46.35	26.75	1.70	15.98
N	7.05	1.09	1.81	4.79	1.09	23.87	13.40	7.48	0.28	3.85
TUD										
Y	23.16	6.56	21.13	19.93	7.891	74.89	50.89	32.37	1.70	15.98
N	6.91	1.04	1.64	4.66	1.22	23.42	13.07	7.26	0.28	3.85

CKD chronic kidney disease, *COPD* chronic obstructive pulmonary disease, *T2D* diabetes mellitus type 2, *CLD* chronic liver disease, *CVD* cardiovascular diseases, *HP* hypertension.

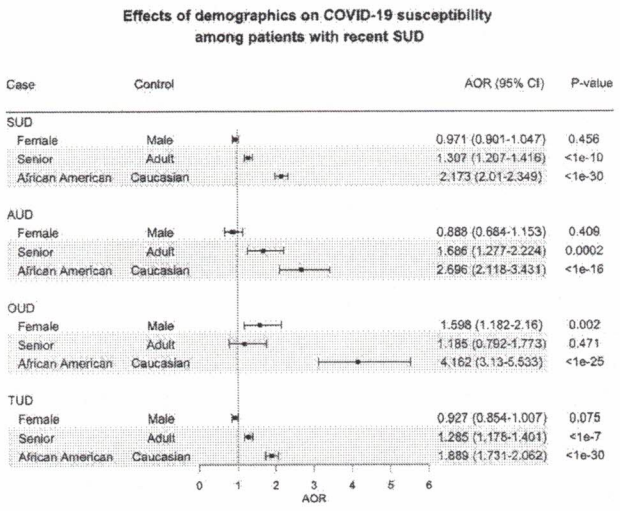

Fig. 2 Effects of demographics on COVID-19 susceptibility among patients with recent SUD and its subtypes. Cocaine-UD and CUD were not examined due to insufficient sample sizes of COVID-19 for stratifications. Senior (age > 65 years). Adult (age 18–65 years).

Discussion

Based on EHR patient data in the US we show that individuals with SUD, particularly recent OUD, were at increased risk for COVID-19 and these effects were exacerbated in African Americans compared to Caucasians. The higher prevalence of kidney, pulmonary, liver, cardiovascular, metabolic, and immune-related disorders in COVID-19 patients with SUD and also in African Americans are likely contribute to their higher risk. These findings identify individuals with SUD as a vulnerable population, especially African Americans with SUDs, who are at significantly increased risk for COVID-19 and its adverse outcomes, highlighting the need to screen and treat SUD as part of the strategy to control the pandemic while ensuring that there are no disparities in access to healthcare support for African Americans.

In the Explorys EHR database, 10.3% of the study population had a diagnosis of SUD, which is similar to the reported prevalence of 10.8% among people aged 18 or older in the US according to the 2018 National Survey on Drug Use and Health (NSDUH) [5]. However the prevalence rates for SUD subtypes from the Explorys EHR database was lower than for NSDUH (12 years or older population) except for OUD and Cocaine-UD. For TUD the rate was 10.40%, which is also lower than 13.7% of current cigarette smokers in the US adult population [27]. These discrepancies are likely to be caused by the failure of the health system to adequately screen for and accurately diagnose SUDs, which could have significantly under-estimated the risk of patients with SUD for COVID-19 illness and adverse outcomes.

The analyses showed that a recent diagnosis of SUD significantly increased the risk of COVID-19 that was highest for recent diagnosis of OUD followed by TUD, AUD and Cocaine-UD, and lowest for CUD. Patients with both SUD and COVID-19 also had significantly worse outcomes (death, hospitalization) than general COVID-19 patients. Compared to patients without SUD, patients with recent SUD had significantly higher prevalence of chronic kidney, liver, lung diseases, cardiovascular diseases, type 2 diabetes, obesity and cancer. However, the prevalence of known risk factor for COVID-19 among patients with OUD was not higher than patients with other types of SUD. These results suggest that while comorbidities associated with SUD likely contributed to the increased risk of COVID-19 and to worse outcomes among SUD patients, specific pharmacological effects of drugs of abuse (e.g., opioid induced respiratory depression) as well as behavioral and socioeconomic factors could facilitate COVID-19 infection and increase risk for adverse outcomes.

Among patients with recent diagnosis of SUD, African Americans had significantly higher risk of COVID-19 than Caucasians, an effect that was strongest for African Americans with OUD and they also had worse outcomes (death and hospitalizations). This is consistent with data from states and counties across the US showing that the coronavirus affects African Americans at a disproportionately high rate and that the they suffer a greater death toll [28–31]. We showed that adult African Americans with recent diagnosis of SUDs had higher prevalence of asthma, chronic kidney disease, type 2 diabetes, hypertension, obesity and HIV compared to adult Caucasians. These enriched comorbidities in African Americans with SUD could underly their higher susceptibility to COVID-19 and their risk for adverse COVID outcomes along with socioeconomic disparities. However, these comorbidities alone may not be sufficient to explain the observed several-fold increase of COVID-19 diagnosis in African Americans as compared to Caucasians or their increased death rates. Other factors including access to healthcare, socioeconomic status and other social adversity components may have contributed negatively to their increased risk of COVID-19 as well as to the adverse outcomes.

Consistent with other reports [12, 13], our study showed that seniors were more likely to develop COVID-19 than adults, which was also expected since hypertension, diabetes, obesity, cardiovascular diseases, and weakened immune function are more common in seniors than in adults. No disparity was observed for gender.

Our study is based on retrospective analysis of patient EHR data. Patient EHR data have been widely used and accepted for observational studies including health utilization, drug utilization, epidemiology (incidence/prevalence), risk factors, and safety surveillance [32–34]. However patient EHR data have inherent limitations when used for research purposes: data are collected for billing purposes,

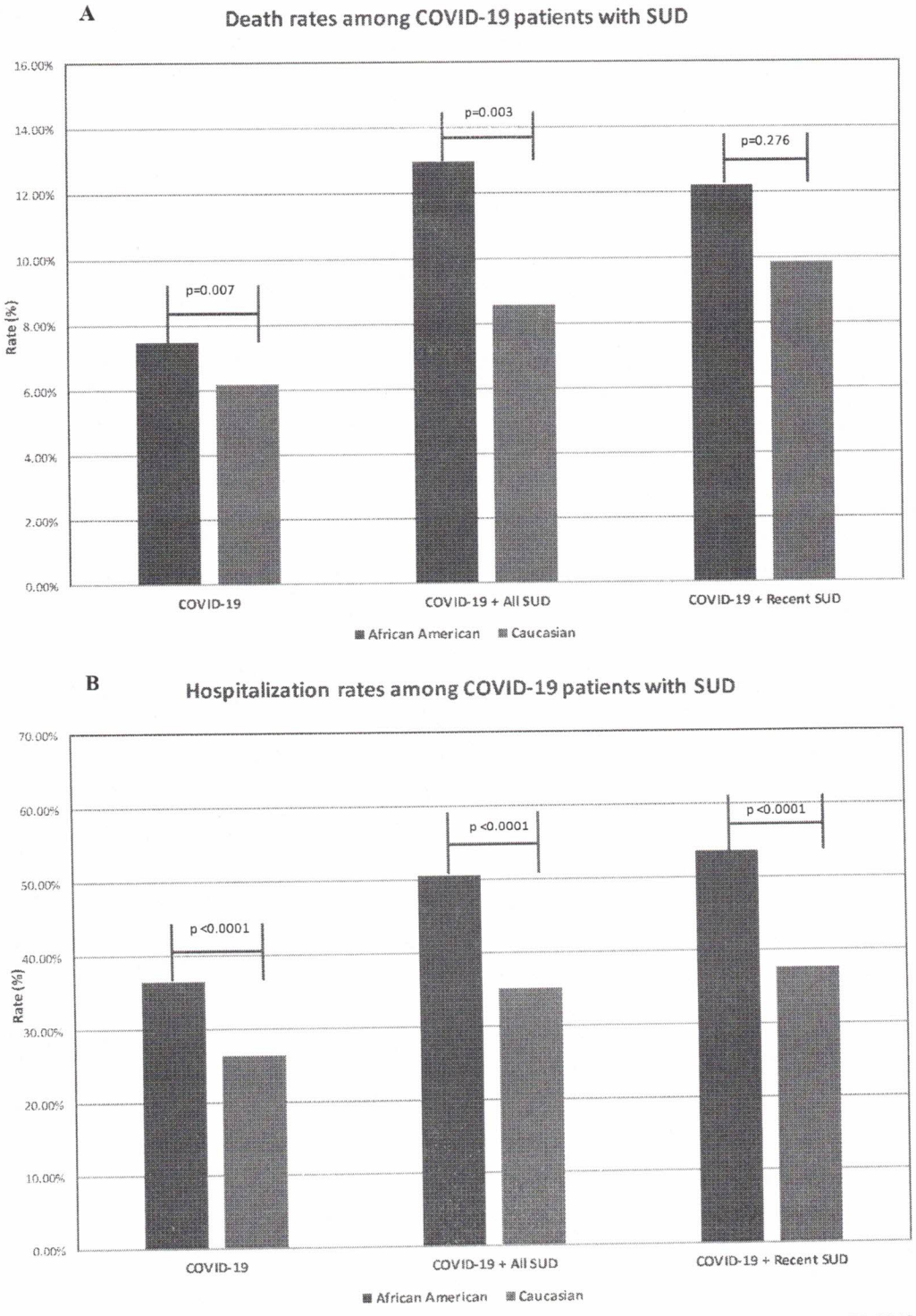

Fig. 3 Outcomes in patients with COVID-19 and SUD. **a** Death rates among patients with COVID-19 and SUD (African American vs. Caucasians); **b** Hospital admission rates among patients with COVID-19 and SUD (African American vs. Caucasians). The SNOMED-CT concepts "Hospital admission (procedure)" (ID 32485007) was used to obtain hospitalization status from patient EHRs. Explorys regularly imports from the Social Security Death index for the "deceased" status.

often suffer from under, over, or misdiagnosis, do not include all confounding factors, have limited time-series information, limited information of medication adherence and patient outcomes, among others. The Explorys EHR Database collects data from multiple health information systems. Since EHR adoption and health IT use generally lags in rural areas due to lack of financial and technical resources, patients from rural areas are likely less

represented in our study population. In our study, disease diagnoses in the patient EHR data were coded using SNOMED-CT terminology and for SUD these differ from categories used by DSM-5. A further limitation of our study is that "COVID-19" (Concept ID 840539006) was not yet included the Explorys EHRs database at the time of this study. This new concept was first included in the March 2020 SNOMED-CT International Edition Interim Release, with a planned update in July, 2020 [35]. At the time of this study, this update has not been yet incorporated in Explorys EHRs. Despite these limitations, this large nationwide database allows us to assess a wide population helping us identify large trends (not necessarily for accurate prevalence estimation) in risks, disparities and outcomes of COVID-19 in SUD patients engaged with healthcare systems.

A major limitation for this and other studies of COVID-19 has been the limited number of individuals who are tested for COVID-19, which can underestimate prevalence in the general population. For our study this is further confounded by the likelihood that patients with pulmonary, cardiac, metabolic or immune conditions, many of which are co-morbid with SUD, might have been more likely to be tested. It is also confounded by the likelihood that patients with specific SUDs (e.g., Cocaine-UD and OUD) might have been less likely to be tested due to socioeconomic factors or stigma. Widespread accessibility to COVID-19 testing in the future will allow more accurate comparisons of COVID prevalence between those with and without SUD.

Additional limitations for this study include: (1) possible ascertainment bias as illicit SUD might have been under-reported and individuals with SUD particularly illicit SUD are less likely to access healthcare, which would result in their lower representation in EHR, (2) the EHR database did not encode for current or active drug use, which is why we relied on a recent SUD diagnoses assuming that those patients were more likely to be active drug users, and (3) due to limited information of socioeconomic information on the EHR data, we were unable to assess the effects of social adversity and its interaction with medical conditions to COVID-19 risk, race disparity and adverse outcomes among patients with SUD. Social adversity is likely to have contributed not only to the higher risk for COVID-19 among patients with SUD but also to the even higher risk among African Americans patients with SUD.

In our study, we showed that patients with SUDs has significantly higher prevalence of comorbidities, which are known risk factors for COVID-19, as compared to patients without SUDs. Our study did not control for these comorbidities when assessing the risk associations between SUD and COVID-19 for two main reasons. First, the central hypothesis of this study was that comorbidities associated with SUD, including type 2 diabetes, hypertension, heart disease, chronic kidney, lung, and liver diseases, largely contributed to patients' risk to COVID-19 and its adverse outcomes. Second, due to limited sample sizes for COVID-19 cases among patients with SUD (1880 cases for all SUD and 210 for OUD), the large number of SUD-associated comorbidities, as well as inter-dependency among comorbidities (e.g., diabetes, hypertension, and obesity), we are currently unable to control for these comorbidities as well as their associated medications, behaviors and other socio-economic factors in order to assess the direct effects of addictive drugs or of SUD as a disease entity on COVID-19 risk. As more COVID-19 related data will be captured by EHR databases in the future, we will be able to investigate how SUD contributes to COVID-19 risk and outcomes in finer-grained details.

In summary, our findings at a macroscopic level provide evidence that SUD should be considered a condition that increases risk for COVID-19, a comorbidity that has particularly deleterious effects to African Americans. This has implication to healthcare as it relates to expanding testing and making decisions of who might need hospitalizations. Similarly, when vaccine or other treatments become available, this has implication for deciding who is at greater risk. They also highlight the exacerbation of healthcare disparities from COVID-19 driven by social and economic factors that place certain groups at increased risks for both SUD as well as risk and adverse outcomes from COVID-19. Finally, our findings also underscore the importance of providing support for the treatment and recovery of individuals with SUD as part of the strategy to control the COVID pandemic.

Data availability

All the data are publicly available at http://nlp.case.edu/public/data/COVID_SUD/.

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Funding The funder of the study had no role in study design, data collection, data analysis, data interpretation, and writing of the report. The corresponding author (RX) had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Author contributions QW, RX, and NDV conceived the study, designed the study, and authored the paper. QW and RX conducted the analysis. DK contributed to Explorys EHR database-related search

questions and medical informatics-related questions. All authors approved the paper. QW and RX had access to the original data.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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PAINMEDICINE NEWS

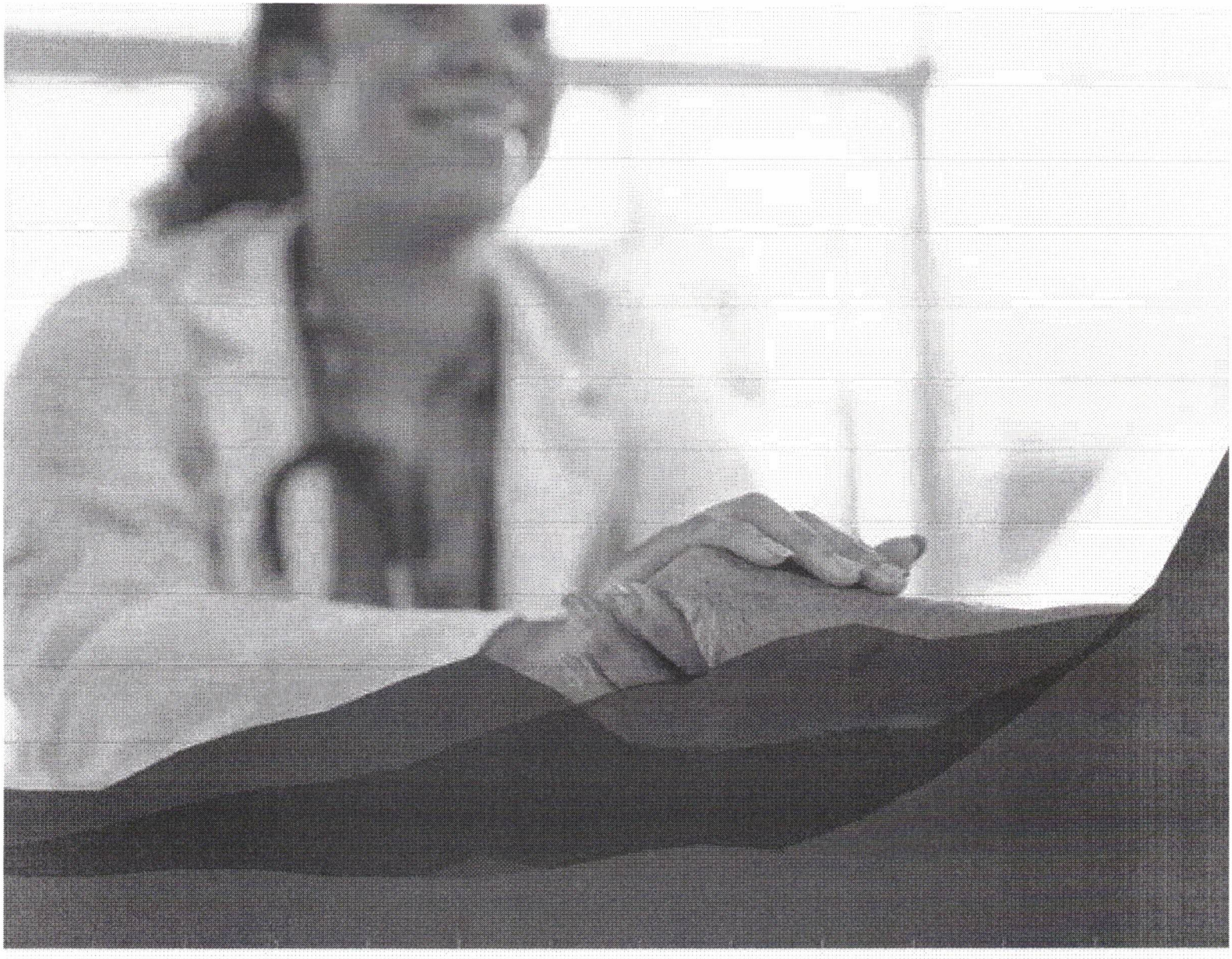
AUGUST 12, 2020

Panel: COVID-19 Compounds Opioid Public Health Emergency

The opioid crisis has become an epidemic within the COVID-19 pandemic, a panel of public health experts said during a recent webinar.

Some people with opioid use disorder have turned to alcohol or benzodiazepines as a temporary substitute for lack of access to opioids, and suicides due to depression and/or unemployment are occurring, according to a panel discussion of how the COVID-19 pandemic is impeding efforts to prevent and treat opioid use disorder.

AMA
AMERICAN MEDICAL ASSOCIATION



OPIOID TASK FORCE 2020 PROGRESS REPORT

Physicians' progress toward ending the nation's drug overdose and death epidemic

END-OVERDOSE-EPIDEMIC.ORG

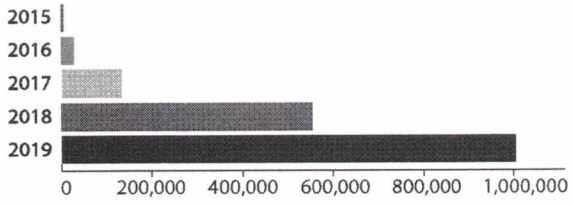
The nation's continuing increase in drug overdoses is fueling the evolution of a more dangerous and complicated epidemic.

In 2014, the American Medical Association convened the AMA Opioid Task Force—more than 25 national, specialty and state medical associations committed to providing evidence-based recommendations and leadership to help end the opioid epidemic.

To date, the task force's recommendations have led to significant progress:

37.1% decrease in opioid prescriptions from 244.5M in 2014 to 153.7M in 2019[1]

1M+ naloxone prescriptions in 2019 —up from 6,588 in 2015[2]

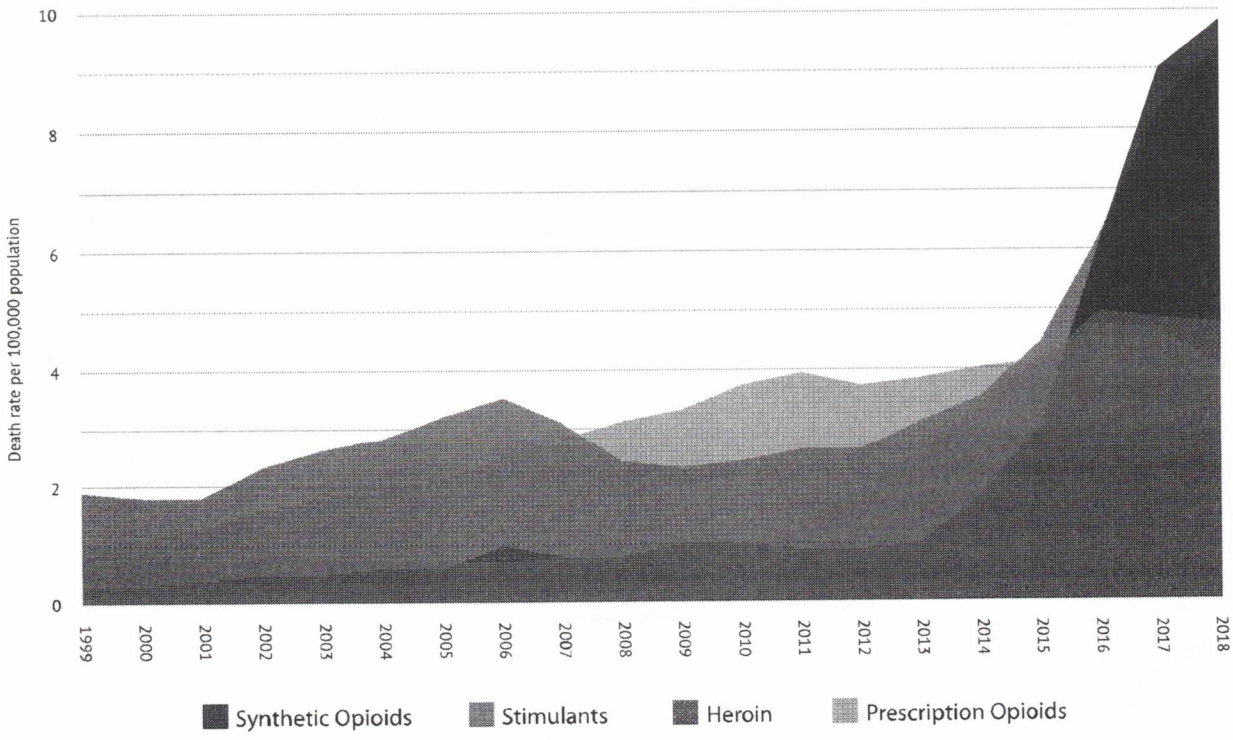


64.4% increase in the use of state prescription drug monitoring programs in the past year—to 739M queries in 2019[3]

Hundreds of thousands of physicians accessing continuing medical education and other courses on substance use disorders, treating and managing pain, and more

85,000+ physicians and health care professionals certified to prescribe buprenorphine in-office—an increase of nearly 50,000 since 2017[4]

Despite these efforts, illicitly manufactured fentanyl, fentanyl analogues and stimulants (e.g. methamphetamine, cocaine) are now killing more Americans than ever. The use of these illicit drugs has surged and their overdose rate increased by 10.1% and 10.8%, respectively.



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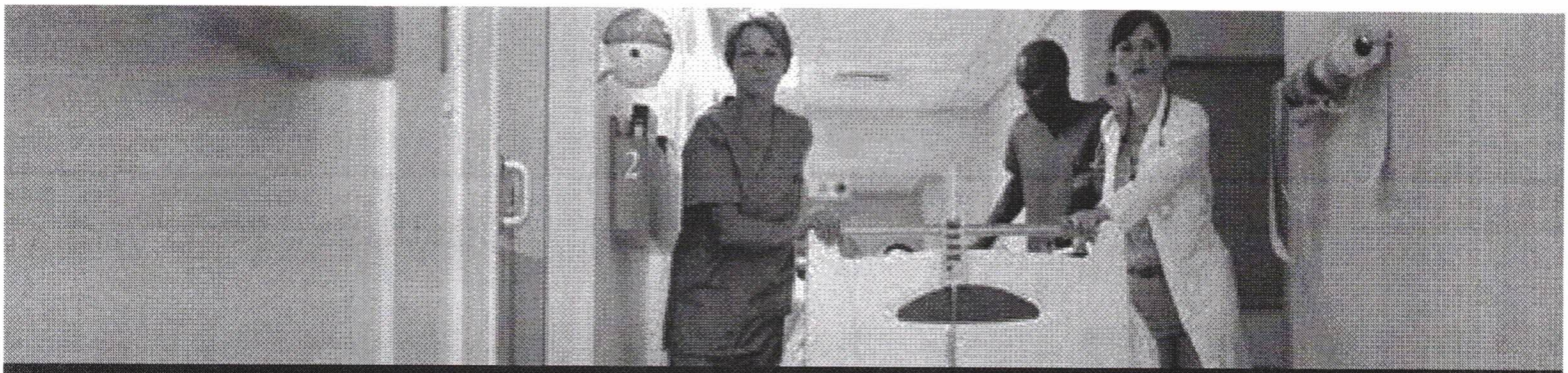
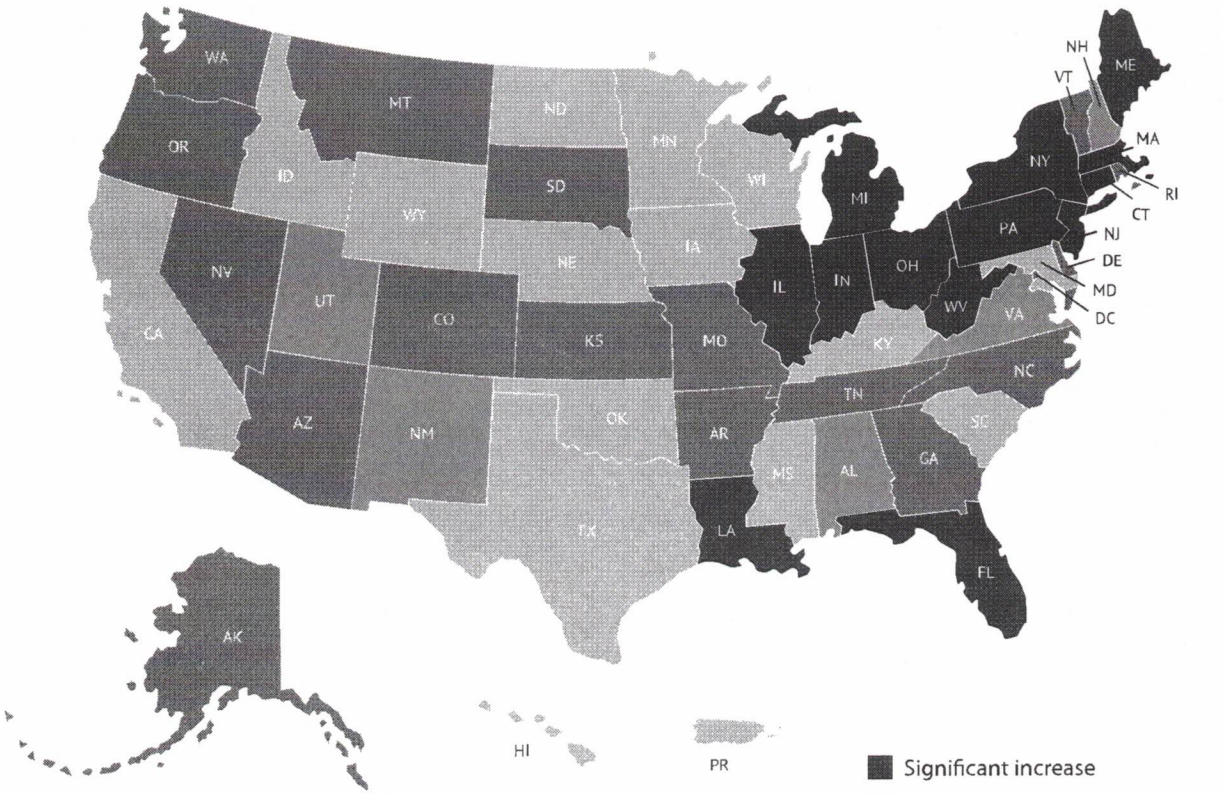


This transformation has rapidly changed the opioid epidemic into a more complicated drug overdose epidemic.

There are hopeful signs that overdoses related to prescription opioids are decreasing slightly. However, the number of drug overdoses will continue to rise unless more is done to help the more than 2 million Americans with an untreated substance use disorder.

Research shows that people who have had at least one overdose are more likely to have another.[5] Removing the barriers for patients to receive evidence-based treatment is a critical first step to helping end the epidemic.

Change in non-fatal drug overdoses (January 2019–January 2020)



Reference: CDC's Drug Overdose Surveillance and Epidemiology (DOSE) System

Policymakers need to act to remove barriers to evidence-based care for patients with pain and those with a substance use disorder or the epidemic will continue to worsen.

Health insurance companies continue to delay and deny access to non-opioid pain care and evidence-based treatment for opioid use disorder, while pharmacy chains, pharmacy benefit managers and state laws continue to inappropriately use arbitrary guidelines to restrict access to legitimate medication that some patients need to help manage their pain.

- **92% of pain medicine specialists said that they have been required to submit a prior authorization** request for non-opioid pain care. Physicians and their staff spend hours per day on such requests.[6]
- **72% of pain medicine specialists said that they—or their patients**—have been required to reduce the quantity or dose of medication they have prescribed.[7]

Only 21 states and the District of Columbia have enacted laws that limit public and/or private insurers from imposing prior authorization requirements on a [substance use disorder] service or medication.[8] The AMA helped support passage of more than one dozen of those laws in 2019 alone. Health plans fight bitterly to oppose these laws.

Mental health and substance use disorder parity laws require health insurers to provide the same level of benefits for mental health and substance use disorder treatment and services that they do for medical/surgical care. However, only a few states (e.g., Arizona, California, Colorado, Delaware, Illinois, Massachusetts, Pennsylvania, Rhode Island) have taken meaningful action to enact or enforce those laws.

Landmark ruling sets precedent for parity coverage of mental health and addiction treatment –Stat News

Report: Health insurers biased in treating mental-health –Providence Journal

PA: Aetna violated parity laws in substance abuse coverage –Bucks County Courier Times

AG Healey reaches $1 million settlement with 7 companies to increase behavioral health access –WBUR

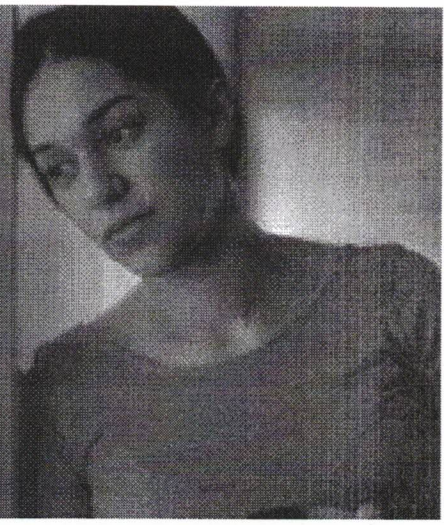
New law requires mental health insurance transparency –Delaware Public Media

Every lawmaker in Arizona just voted for better mental health care. That's a big deal –AZ Central

In 2019, the AMA partnered with Manatt Health to publish a state policy roadmap to provide tangible actions for policymakers to take meaningful action on parity and other areas necessary to end the epidemic.

Treating the nation's drug overdose epidemic demands a far more proactive and coordinated approach focused on evidence-based, public health solutions.

To date, efforts to combat the epidemic have largely fallen into a reactionary "crisis framework," which has created too many one-size-fits-all strategies that are less than effective. Going forward, physicians, public health officials, policymakers and health insurance companies must work together to create an integrated, sustainable, predictable and resilient public health system.



What we do today:
"Crisis framework"

Evolve to prevention framework

Prioritize preventing and treating substance use disorders

Employ effective surveillance strategies

Better identify patients at risk of an overdose and those who have overdosed in the past

Implement proven public health solutions

Take an evidence-based approach to prevention and treatment

What we must do tomorrow:
Integrated, sustainable, predictable and resilient public health system

Improving the collection and use of data is critical to evolving the nation's efforts to combat the epidemic. For example, currently, overdose-related data collection practices are not consistent across the United States. Modernizing and adapting data collection will allow stakeholders to develop more effective solutions tailored to the needs of individuals and their community.

Policies and treatments must consider that patients are not identical. They must account for drug type, gender, race, age and social determinants of health.

The nature of the epidemic and its evolution are not the same across the country. They are not even the same within a state. **Their solutions must be equally as varied.**

The AMA urges policymakers and other stakeholders to take meaningful action to remove barriers and increase patients' access to evidence-based care to save lives and help end the epidemic.

1. Remove prior authorization, step therapy and other inappropriate administrative burdens or barriers that delay or deny care for FDA-approved medications used as part of medication-assisted treatment for opioid use disorder.

2. Support assessment, referral and treatment for co-occurring mental health disorders as well as enforce meaningful oversight and enforcement of state and federal mental health and substance use disorder parity laws, including requiring health insurance companies to demonstrate parity compliance at the time of their rate and form filing.

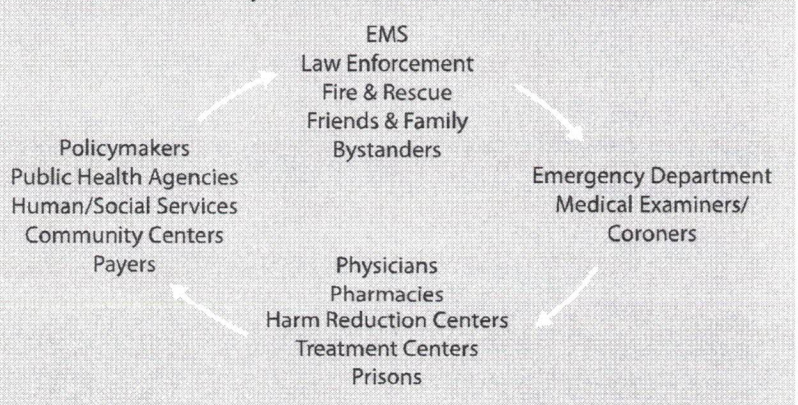
> "Physicians' progress alone will not end the epidemic. Policymakers, health insurance companies, pharmacy chains and others must move beyond words; they must take meaningful action to remove barriers to evidence-based care. We all need to work together, but the status quo is killing far too many of our loved ones and wreaking havoc in our communities."
>
> –Patrice A. Harris, MD, MA
> Chair, AMA Opioid Task Force

3. Remove administrative and other barriers to comprehensive, multi-modal, multidisciplinary pain care and rehabilitation programs.

4. Support maternal and child health by increasing access to evidence-based treatment, preserving families and ensuring that policies are non-punitive.

5. Support increased efforts to expand sterile needle and syringe services programs as well as reforms in the civil and criminal justice system that help ensure access to high quality, evidence-based care for opioid use disorder, including medication-assisted treatment.

More stakeholders must come together and work collaboratively to act on these recommendations.



6. Implement systems to accurately track overdose and mortality trends to provide equitable public health interventions that include comprehensive, disaggregated, racial and ethnic data collection related to testing, hospitalization and mortality associated with opioids and other substances.

1 IQVIA Xponent market research services. ©IQVIA 2020. All rights reserved.

2 Emergent Biosolutions; Xponent IQVIA. Data received June 8, 2020. On file with author.

3 AMA Fact sheet: Physicians' and health care professionals' use of state PDMPs increases 64.4 percent from 2018 to 2019; 739 million queries in 2019.The state-by-state data is available at https://end-overdose-epidemic.org/wp-content/uploads/2020/07/AMA-Fact-Sheet-PDMP-use-and-registration-increase-2014-2019-FINAL.pdf

4 www.samhsa.gov/medication-assisted-treatment/training-materials-resources/practitioner-program-data, accessed June 30, 2020.

5 Suffoletto B, Zeigler A. Risk and protective factors for repeated overdose after opioid overdose survival. Drug and Alcohol Depend. 2020;209:107890.

6 American Board of Pain Medicine, "Second Annual Survey of Pain Medicine Specialists Highlights Continued Plight of Patients with Pain, And Barriers To Providing Multidisciplinary, Non-Opioid Care." Available at http://abpm.org/component/content/article/296

7 Id.

8 "Spotlight on Legislation Limiting the Use of Prior Authorization for Substance Use Disorder Services and Medications." Legal Action Center and Center on Addiction. Available at https://www.lac.org/resource/spotlight-on-legislation-limiting-the-use-of-prior-authorization-for-substance-use-disorder-services-and-medications

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