U.S. Opioid Epidemic: Challenges and Opportunities for Evidence-based Policies

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U.S. Opioid Epidemic: Challenges and Opportunities for Evidence-based Policies

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U.S. Opioid Epidemic: Challenges and Opportunities for Evidence-based Policies

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To God Almighty be all the Glory and Honor!
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Signature of Author: ______________
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ABSTRACT

Recent data from the Centers for Disease Control and Prevention (CDC) indicated that on average, 130 Americans die every day from opioid-related overdose.\textsuperscript{1,2} For the first time, more Americans are dying from opioids than from guns, car accidents or breast cancer.\textsuperscript{3} “Every 8 minutes, someone in America dies from a drug overdose; usually from opioids such as, heroin, illicit fentanyl, or oxycodone, hydrocodone, morphine and hydromorphine prescribed by doctors.”\textsuperscript{3} Specifically, prescription opioids account for approximately 40\%-70\% of fatal and non-fatal overdoses, and are frequently the first opioids encountered by individuals before transitioning to illicit drugs.\textsuperscript{4,5}

In response to this public health epidemic, a number of policies have been enacted to mitigate the problem. However, some policies may “prevent patients who need opioids from getting them, turn providers into policemen when patients seek opioids, and police providers themselves when they prescribe opioids.”\textsuperscript{6} Difficulty of accessing prescription opioids may contribute to increased demand for illegal narcotics, such as heroin and illicitly manufactured fentanyl (IMF).\textsuperscript{6} Herein lies the challenge of reversing the opioid epidemic while ensuring access to safe opioid treatment.

This document reviews policy approaches to addressing the epidemic, and considers opportunities for evidence-based strategies.
1. INTRODUCTION

1.1 Background

The CDC reported that over 13.2 million people were affected by drug-related disorders or overdose deaths in 2017. Of this figure, approximately 70,000 people died from drug overdose (with nearly 48,000 linked to opioids), 2.1 million had opioid use disorder (OUD) and 11.1 million misused prescription opioid pain medications. Additionally, an estimated 900,000 people used heroin or other illicit narcotics, further highlighting the enormous scale of the problem. The Drug Enforcement Administration (DEA) estimated that in the 7-year interval between 2006 and 2012, the U.S. was flooded with ~76 billion opioids, mainly oxycodone and hydrocodone. As a direct consequence, mortality rates linked to opioids quadrupled during this period. Relative to the national average of 4.6 deaths per 100,000 residents, mortality from opioid overdoses were approximately 3 to 8 times higher in communities flooded with opioid pills. In Norton County Virginia, opioid overdose accounted for 83 deaths (18 times above the national average). The opioid epidemic cuts across both urban and rural America.

How do opioids work and why are they so addictive? According to the National Institute on Drug Abuse (NIDA), opioids are a class of drugs that include illegal narcotics, synthetic opioids (such as, fentanyl) and pain relievers available legally by prescription (e.g. oxycodone <OxyContin®>, hydrocodone <Vicodin®>, codeine, morphine, etc.). This policy review focuses on prescription opioids. Generally, opioids dull pain and boost dopamine, which provides some high or euphoria that can easily lead to addiction. Opioids fall under a class of drugs that mimic the body’s naturally occurring endorphins released during injury. Therefore, routine opioid use can result in decreased production of endorphins and dependency on synthetic drugs. Due to
the body’s tolerance to opioids, higher doses may be required to achieve the same level of relief.\textsuperscript{12}

In response, several policies have been enacted to address the complex and multiple issues related to the epidemic, including prevention, management and treatment of addiction or drug overdose. For example, prescription drug monitoring programs (PDMPs), which is a statewide electronic database that tracks prescriptions of all controlled substances has been adopted by most states.\textsuperscript{5,13} Additional strategies, such as supervised injection facilities (SIFs) and access to clean syringes focus on harm reduction. However, harm mitigation initiatives are better suited to addressing illicit drug use rather than prescription opioids, which is the major focus of this review.

Strategies that limit access to opioids may results in unintended consequences. For example, efforts aimed at reducing overdose deaths due to OxyContin promoted transition to heroin and fentanyl by dependent users.\textsuperscript{14} Therefore, policies addressing the epidemic needs to balance safe-prescription practices and effective monitoring with increased access to treatment of addiction and substance use disorder.\textsuperscript{13} This policy review provides an analysis of what is working, what is not working and where there are areas for improvement. Findings from the report are intended as a resource for state and federal policymakers, physicians, researchers, pharmaceutical companies, regulators, patients, the criminal justice system and the general population.

1.2 Opioid Epidemic and Policies: Setting the Stage

A Google search conducted on August 16, 2019 with key words “state opioid policies” returned almost 48 million hits within 0.64 seconds. The widespread nature of the crisis and
potential impact on millions of people elicited a forceful response by political leaders. Several factors contributed to the current public health opioid epidemic (Figure 1). For years, the pharmaceutical industry ignored or violated laws that required them to report suspicious orders of opioids and not ship them. In one example, a drug company flagged over 37,000 suspicious orders but held back only 33.

**Figure 1:** Opioid policies targeting prevention and treatment strategies are important; however, several factors contribute to the epidemic.

While manufacturers and aggressive marketing strategies have come under the spotlight, at the heart of the crisis is a systemic failure that include several major actors, including over-prescribing practices by physicians, dispensing by pharmacies, ineffective monitoring by
regulators and abuse by consumers. A recent Kaiser Health News (KHN) report on opioid-prescribing habits among surgeons indicated that amounts of prescribed opioids were significantly higher than actually required for several post-surgical procedures, with many prescriptions unfilled by patients.15

1.3 Human and Economic Costs of the Opioid Epidemic

Why should policy-makers worry about economic costs of the opioid epidemic? Economic cost estimates are important for several reasons, namely: it serves as a valuable tool for understanding the scope of the problem; aids in identifying areas of society most affected by the crisis; and enables evidence-based interventions to address the issue.16 Economic implications of the opioid epidemic greatly impacts families, businesses and local communities. While economic costs of the opioid crisis on society may be difficult to accurately quantify, various studies have provided estimates.16,17 A 2018 analysis by Altarum, a nonprofit health research and consulting institute estimated that economic costs of the crisis exceeded a trillion dollars between 2001 and 2017, and projected costs to increase by $500 billion by 2020.16 Increasing use of prescription pain medications among a younger population, and switch from prescription opioids to synthetic illicit drugs contributed to increased economic costs.16

The NIDA estimates that the total "economic burden" of prescription opioid misuse alone in the United States is $78.5 billion a year.2,5 A breakdown of the costs indicated that almost two-thirds of the amount was associated with health care, substance abuse treatment, and lost productivity for nonfatal cases.5 Total health care spending, including substance abuse treatment accounted for over $28 billion.5 The economic burden is largely borne by federal, state and local governments, with over 14 percent of the cost funded by public health insurance programs, such
as Medicare and Medicaid.\textsuperscript{5} Expenditures related to the criminal justice system gulps $7.7 billion, with approximately 96 percent ($7.3 billion) directly funded by states.\textsuperscript{5} At the community level, increased crime rates and domestic violence contributed to decreased property value.\textsuperscript{17,18} Taken together, approximately 25 percent of aggregate economic burden is funded by public sources, with some portion of lost earnings borne by the public sector in the form of forgone tax revenues.\textsuperscript{5} \textbf{Figure 2} shows four main channels that account for nonfatal opioid costs, adapted from a recent article by Scavette.\textsuperscript{17}

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{figure2.jpg}
\caption{Accounting for nonfatal opioid costs. Nonfatal costs flow through four main channels.}
\end{figure}
1.4 Distribution of the Opioid Epidemic by Race/Ethnicity, Age and Gender

Out of approximately 47,600 opioid overdose deaths that occurred in 2017, non-Hispanic Whites accounted for 37,113 (78%), non-Hispanics Blacks, 5,513 (12%) and Hispanics, 3,932 (8%), respectively\(^{(19,20)}\) (Table 1). Based on age distribution, 24 - 34 years were at the most risk of opioid-overdose deaths, with males (32,337) disproportionately affected relative to females (15,263)\(^{(19,20)}\) (Table 1). Recent CDC data indicated the mortality rate for drug overdoses for all Americans, (accidental or intentional) in 2016 was 19.8 per 100,000, up from 16.3 per 100,000 the previous year.\(^{(20)}\) In comparison, the mortality rate from car crashes is 11.7 per 100,000.\(^{(20)}\) As depicted in Figure 3, drug overdose disproportionately impacts non-Hispanic Whites.\(^{(20)}\) Between July 2016 and September 2017, opioid overdose jumped by 30% among men relative to 24% in women.\(^{(21)}\) On average, opioid overdose increased by 30% in most states, but increased by 70% in the Midwest.\(^{(21)}\) Current opioid policies appear broadly targeted rather than tailored to specific or at-risk race/ethnicity, age or gender.

Table 1: Opioid overdose deaths by race/ethnicity, age and gender.

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>Whites</th>
<th>Blacks</th>
<th>Hispanics</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deaths</td>
<td>37,113</td>
<td>5,513</td>
<td>3,932</td>
<td>46,558</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age</th>
<th>0 – 24</th>
<th>25 – 34</th>
<th>35 – 44</th>
<th>45 – 54</th>
<th>55+</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deaths</td>
<td>4,173</td>
<td>13,181</td>
<td>11,149</td>
<td>10,207</td>
<td>8,874</td>
<td>47,584</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gender</th>
<th>Female</th>
<th>Males</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deaths</td>
<td>15,263</td>
<td>32,337</td>
<td>47,600</td>
</tr>
</tbody>
</table>
Medicaid expansion has increased access to health coverage, especially within minority populations; this is critical in accessing treatment for opioid-related disorders. In fact, association between state Medicaid eligibility thresholds and reduced deaths due to substance use disorder (SUD) have been reported.\textsuperscript{22} SUD is defined as recurring use of alcohol and/or drugs that causes significant clinical and functional impairment.\textsuperscript{22} Findings showed that state Medicaid coverage correlated with access to Medication-Assisted Treatment (MAT).\textsuperscript{22} Paradoxically, opioid overdose deaths have been highest in the Medicaid-expansion states of West Virginia, Pennsylvania and Ohio.\textsuperscript{23,24} However, whether increased health coverage due to Medicaid expansion directly contributed to increased access to prescription opioids, and hence addiction or overdose deaths remain unclear. Conversely, lack of health coverage and access to prescription pain medications may promote the use of illicit drugs. Therefore, differences in opioid overdose and mortality rates
between states may be multi-factorial. However, the presence or absence of Medicaid expansion and direct influence on the opioid epidemic warrants further investigation.

1.5 Context and Rationale of the Study

Inherent risks and dangers associated with misuse of prescribed pain medications are evident by adverse effects of the opioid epidemic. The epidemic is a present and immediate danger to the health and well-being of the American people. States have initiated policies tailored to their unique challenges, including prioritization of the problem and availability of resources. This review of state-level opioid policies highlight the impact and outcomes of specific policy actions.

1.6 Research Questions

To investigate and provide analysis of evidence-based opioid policies, the following questions were posed:

- What types of policies have states enacted to address the opioid crisis?
- What are objective measures of successful opioid policies?
- What are the potential unintended consequences resulting from opioid policies?
- What opportunities exist for actionable opioid policies?

1.7 Relevant Definitions

**Synthetic Opioids:** According to the CDC, “synthetic opioids are a class of drugs that are designed to provide pain relief, mimicking naturally occurring opioids such as codeine and morphine.” Methadone is also a synthetic opioid; however, deaths involving this drug are tracked separately from deaths involving other synthetic opioids. Opioids can be further classified broadly as prescription or illicit drugs. Qualified and licensed physicians usually prescribe the former for the
management of acute or chronic pain conditions. Conversely, illicit drugs, such as illicitly manufactured fentanyl (IMF) and heroin are procured from illegal sources, such as street-dealers or the internet.

**Opioid Epidemic:** Used interchangeably in this report, opioid epidemic or opioid crisis refers to the elevated levels of drug overdose, addiction and death attributed to the misuse of prescription opioid pain medications.

**Opioid Use Disorder (OUD):** The NIDA defines OUD as “problematic pattern of opioid use.”² OUD is a “diagnosis based on specific criteria, such as unsuccessful efforts to cut down or control use, or use resulting in social problems and a failure to fulfill obligations at work, school, or home, among other criteria.”²⁵

**Medication-Assisted Treatment (MAT):** This includes a combination of medications, counseling and behavioral therapies for treatment of substance use disorder.²¹,²⁶ Predominantly includes methadone and buprenorphine as effective treatment for OUD.¹⁴

**Chronic Pain:** According to the CDC Guideline for Prescribing Opioids for Chronic Pain in the US, chronic pain is defined as “pain conditions that typically last >3 months or past the time of normal tissue healing in outpatient settings outside of active cancer treatment, palliative care, and end-of-life care.”²⁷

**Opioid Policy:** This relates to legislation or laws intentionally designed to address issues related to the crisis, such as addiction and overdose deaths associated with opioids. Opioid policies come in different forms, and mainly target prevention and treatment strategies.

**Opioid Crisis Stakeholders:** This includes all parties that are impacted by the crisis. While not an exhaustive list, stakeholders may include government agencies, patients, social services,
community groups, professional associations, providers, patients, advocacy groups, people with SUD and their families, insurance companies, pharmacies, manufacturing, distribution, criminal justice system and regulators.
2. LIST OF REVIEWED MATERIALS AND SOURCES

2.1 Opioid Prescription Guidelines

During the course of this project, information was synthesized from a number of sources including textbooks, peer-reviewed studies, reports from government agencies, and publicly available databases. Published findings by centers of excellence, academic “think tanks,” and state health organizations were reviewed. Additional materials, including agendas and bills from state legislatures, case studies and white papers on the opioid crisis, as well as community resources were included. The review of diverse sources of information helped to ensure a broad representation of policies and perspectives related to the subject matter.

An estimated 13 million prescription opioids are dispensed every month in the United States. Over-prescription of opioids represent a major contributor to the crisis, and many state policies have focused on addressing this problem. While appropriate use of opioids exist in clinical settings, guidelines serve as recommendations for some specific pain conditions. However, guidelines are not legally mandated, and the extent of use and direct impact on opioid prescribing is difficult to ascertain. While opioids are primarily used to treat pain, the severity, frequency, duration and individual sensitivity or tolerance to pain varies. Although pain is broadly classified as acute or chronic, varying degrees or shades of pain exist within each category. Highlighted in Figure 4 are examples of acute and chronic pain conditions. Strict adherence to opioid prescribing guidelines is therefore a complex issue.
Figure 4: Pain treatment is complex. Opioid prescribing guidelines are not legally mandated and fail to fully capture all shades of acute or chronic pain.

The CDC Guideline for Prescribing Opioids for Chronic Pain acknowledges the importance of appropriate pain treatment; and emphasizes careful consideration of the benefits and risks of treatment options.27 “This guideline provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. The guideline addresses 1) when to initiate or continue opioids for chronic pain; 2) opioid selection, dosage, duration, follow-up, and discontinuation; and 3) assessing risk and addressing harms of opioid use. CDC developed the guideline using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) framework, and recommendations are made on the basis of a systematic review of the scientific evidence while considering benefits and harms, values and preferences, and resource allocation. CDC obtained input from experts, stakeholders, the public, peer reviewers, and a federally chartered advisory committee.”27 The National Heart, Lung and Blood Institute (NHLBI) has published evidence-
based guidelines for management of sickle cell disease (SCD) with extensive input by health care professionals.\textsuperscript{28} It specifically targets people living with SCD and ensures they receive appropriate care by providing the “best science-based recommendations to guide practice decisions.”\textsuperscript{28}

The American Medical Association (AMA) has also issued position statements on opioid treatment. The association recommends “developing sound treatment plans based on individual patient needs, rather than a one-size-fits-all approach of hard thresholds.”\textsuperscript{29} It opposes pharmacies, pharmacy benefit management (PBM) companies and insurers using “high prescriber” lists – without due process – to keep physicians from writing prescriptions for controlled substances and preventing patients from filling prescriptions at their pharmacy of choice.\textsuperscript{29}

Based on in-house study conducted in 2009, Kaiser Permanente (KP) of Southern California found the most frequently prescribed drugs among its physicians were opioid painkillers and highly addictive narcotics.\textsuperscript{30} In 2010, the group began implementing several efforts to reduce opioid prescribing that included adherence to prescribing and dispensing policies, monitoring and follow-up of patients, as well as clinical coordination through electronic health record integration.\textsuperscript{30} By July 2017, the group had recorded a 30% reduction in prescribing opioids in high doses, 98% reduction in number of prescriptions with greater than 200 pills, 90% decrease in opioid prescriptions with benzodiazepines and carisoprodol, 72% reduction in prescribing of Long Acting/Extended Release opioids and 95% reduction in prescribing of brand name opioid-acetaminophen products.\textsuperscript{30}
2.2 Additional Sources

2.2.1 U.S. Department of Health and Human Services (HHS)

HHS is comprised of federal government health agencies and institutes, including the CDC, National Institutes of Health (NIH) and Substance Abuse and Mental Health Services Administration (SAMHSA). Materials that support the HHS 5-point strategy to combat opioid crisis were evaluated. The HHS 5-point strategy includes:

1. Better addiction prevention, treatment, and recovery services;
2. Better data;
3. Better pain management;
4. Better targeting of overdose reversing drugs and
5. Better research.

HHS’s five major priorities focus on:

1. improving access to treatment and recovery services
2. promoting use of overdose-reversing drugs
3. strengthening our understanding of the epidemic through better public health surveillance
4. providing support for cutting-edge research on pain and addiction
5. advancing better practices for pain management

2.2.2 National Institutes of Health (NIH)

The NIH is assisting with discovery of new and better ways to prevent opioid misuse, treatment of opioid use disorders and alternative pain management strategies. As part of these
efforts, the NIH met with pharmaceutical companies and academic research centers in the summer of 2017 to discuss:

1. safe, effective, non-addictive strategies to manage chronic pain
2. new, innovative medications and technologies to treat opioid use disorders
3. improved overdose prevention and reversal interventions to save lives and support recovery

In April 2018, the NIH announced the launch of HEAL (Helping to End Addiction Long-term) initiative, an aggressive, trans-agency effort to speed scientific solutions to stem the national opioid public health crisis.31

2.2.3 Substance Abuse and Mental Health Services Administration (SAMHSA)

SAMHSA provides a number of services and programs that directly address the opioid crisis, substance use disorders and mental health.32

Reviewed training materials for practitioners include:

- Technology Transfer Centers (TTC) Program
- State Targeted Response Technical Assistance (STR-TA)
- Providers' Clinical Support System for Medication Assisted Treatment (PCSS-MAT)
- Clinical Support System for Serious Mental Illness (CSS-SMI)
- Suicide Prevention Resource Center (SPRC)
- Rural Opioid Technical Assistance (ROTA)
3. METHODS

3.1 Analysis

Analysis of opioid prevention and treatment policies included outcomes related to opioid prescribing and dispensing, overdose deaths, access to the overdose-reversing drug, naloxone, as well as utilization of MAT by OUD patients.

To understand enacted policies in clinical settings, physicians that provide emergency or continuity care to patients at Grady Memorial Hospital in downtown, Atlanta were interviewed. The interaction is presented under appendices.
4. RESULTS

4.1 Overview of Opioid Policies

Opioid policies have largely focused on prevention and treatment strategies. Within these broad categories are several initiatives that target specific opioid-related issues. For example, prescribing practice limits aim to reduce the number of pills prescribed and dispensed, while medication-assisted treatment (MAT) focus on OUD.

Between 2015 and 2017, approximately 33 states enacted some form of legislation related to the opioid epidemic.13 With the exception of ~20 states (including Georgia), most states have legislation that limits opioid prescription, including first-time prescriptions, dosage limits (MMEs) and number of days’ supply.13 These limits mainly apply to treatment of acute pain, with exceptions for chronic pain conditions.13 Additionally, a few states set limits specifically for minors.13 A summary of state policies related to the opioid epidemic is presented below.

4.2 Categories of State Opioid Policies

4.2.1 Opioid Prevention Policies

Prescription Drug Monitoring Programs (PDMPs): Virtually every U.S. state has a PDMP, which according to the CDC is a “statewide electronic database that tracks all controlled substance prescriptions.”33 PDMPs followed a 2011 recommendation by the U.S. Office of National Drug Control Policy that encouraged states to develop an active tool to monitor and minimize overprescribing of opioids.8,33 Statewide electronic opioid databases allow physicians to access prescription history, including the type and amount of specific medications dispensed.33 According to the CDC, PDMPs improve patient safety by allowing clinicians to:

• Identify patients who are obtaining opioids from multiple providers.
• Calculate the total amount of opioids prescribed per day (in MME/day).
• Identify patients who are being prescribed other substances that may increase risk of opioids—such as benzodiazepines.

In addition to enacting bills that mandate PDMP registration by providers, legislation established who can access PDMPs, time period within which dispensed prescriptions must be reported, and requirements for checking PDMPs before prescribing. With 49 of the 50 states having PDMPs, only recently have several states began mandating its use by health professionals due to the opioid epidemic. In a systematic review of 11 studies published between 1/1/2000–5/31/16, the authors concluded that evidence for the impact of state-level PDMPs were mixed. Specifically, opioid prescribing behavior, opioid diversion and supply, opioid misuse, and/or opioid-related morbidity/mortality presented mixed and variable results across different states. Among Medicare beneficiaries, states with more complete and timely monitoring achieved greater reductions in overdoses relative to states with less comprehensive programs.

Variability of PDMPs across different states include checking and reporting requirements, monitored controlled substances and resource availability, such as websites, educational videos and support helplines. In Wisconsin, Utah and a few other states, recent changes to the program have included information on overdose rescues, hospitalizations for drug-related conditions and drug-related arrests — that can help physicians determine when to curtail a patient’s drug use. Kentucky, Ohio, Virginia and Wisconsin now include referral information for addiction treatment, and at least 47 states have started adding drug monitoring data from neighboring states to enable physicians determine whether patients are receiving medications
from prescribers in other states. Future state-by-state comparisons may provide direct evidence on the impact of these new measures.

**Prescribing Practice Limits:** Prescription limits of narcotics are influenced by a number of factors, including age (e.g. under 18 years), and whether making an initial or continuing prescription. Opioid prescription limits enacted by states range from 3 – 7 days, 10 days, 14 – 18 days or even 30+ days of opioid supply. In several states, 7-day supply limit on initial prescriptions was most common with exceptions for chronic pain treatment. Prescriptions were typically represented as morphine milligram equivalent (MME) rather than actual number of pills, and ensured prescription of minimum opioid doses. Lower MME have been shown to correlate with decreased risks of opioid misuse, dependency and addiction.

**4.2.2 Opioid Treatment Policies**

**Medication-Assisted Treatment (MAT):** According to SAMHSA, the standard of care for OUD is medication-assisted treatment (MAT), which combines one of three medications (methadone, buprenorphine, or naltrexone) with counseling and other support services. With respect to Medicaid programs, all states cover at least one medication used as part of MAT and most cover all three of these medications. The effectiveness of medications such as methadone and buprenorphine resulted in policies that allowed physicians obtain a DEA waiver to prescribe buprenorphine in their own practices. While physicians with waivers were initially allowed to treat only 30 patients simultaneously, this grew rapidly to 100 patients and then to 275 patients. This increased potential access to MAT, especially in rural areas where methadone clinics are scarce. However, available data suggest that approved physicians are nowhere close to treating their allowable number of patients. Although the reasons are unclear, insufficient
reimbursement, and stigma are among possible factors that inhibit buprenorphine treatment.\textsuperscript{14} Direct evidence of expanded access to MAT with increased utilization and impact on OUD are mixed and highly variable across different states.

**Naloxone:** The effectiveness of naloxone, an overdose-reversing drug contributed to widespread support for increased distribution and access. State policies include immunity for carrying, dispensing or administering naloxone, third-party prescriptions and dispensing without prescription.\textsuperscript{13} In addition to first-responders, family-members and friends of at-risk population, law enforcement, community-based organizations and school personnel are allowed to carry naloxone.\textsuperscript{13}

Variations exists across different states with respect to naloxone co-prescribing policies. Based on Medicare Part D data between 2016-2017, Vermont mandated naloxone co-prescribing when patients received opioids at dosages of 90 MME/d or greater or concomitant benzodiazepines, while Virginia mandated co-prescribing at dosages of 120 MME/d or greater or concomitant benzodiazepines.\textsuperscript{40} 2018 data showed that naloxone dispensing rates were highest among metropolitan counties (206.3 per 100,000) and in the South (195.0) and lowest in rural counties (147.4) and in the Midwest (139.9).\textsuperscript{41} However, between 2012 and 2018, naloxone dispensing from retail pharmacies increased substantially in all states, including urban and rural areas.\textsuperscript{41} Based on gender, naloxone dispensing rates were higher among female recipients (187.7 per 100,000) than for males (151.6), with persons aged 60–64 years (362.8) receiving higher rates of naloxone prescriptions than for any other age group in 2018.\textsuperscript{41} While the study failed to differentiate between OUD treatment or overdose-related events, the rate of naloxone prescriptions per 100 high-dose opioid prescriptions was lowest among surgeons (0.2), pain
medicine physicians (1.3), physician assistants (1.3), primary care physicians (1.5), and nurse practitioners (2.3). Among all specialty groups, psychiatrists had the highest rate of naloxone prescriptions dispensed for every 100 high-dose opioid prescriptions (12.9), followed by addiction medicine specialists (12.2) and pediatricians (10.4). Within the same interval, persons with commercial insurance (51.1%) received the largest percentage of dispensed naloxone prescriptions, followed by Medicare (35.9%), Medicaid (10.7%), and self-pay (2.4%).

**Pain Clinics:** Pain clinics are described as facilities that specialize in the treatment of chronic pain, and may prescribe pain medications to patients. The CDC classifies opioid-regulating laws into seven groups, four of which directly target patients and prescribers. These include laws that provide immunity from prosecution for persons seeking help during an overdose, prohibit patients from receiving opioids from multiple providers without the prescribers’ knowledge, require a physical examination before prescribing, and mandate the use of tamper-resistant prescription forms. The remaining laws regulate pharmacies and pain management clinics, and include setting prescription drug limits, require patient identification before dispensing, and impose registration and strict oversight for pain management clinics.

Virtually all states require pain management clinics to register or obtain a license or certificate. Oversight of pain management clinic laws include legal provisions establishing state inspection authority. In some states, inspections are mandated at regular intervals and may include review of patient records to ensure compliance with license/administrative regulations. However, if financial gain (rather than medical needs) is the primary factor, pain clinics may have greater incentives to over-prescribe pain medications. While pain clinics promote access to treatment, utilization and impact on addiction outcomes are unclear.
4.3 Measures of Successful Opioid Policies

What does a successful opioid policy outcome look like? Success is a relative term, and in this context refers to specific opioid policies that have decreased opioid prescriptions, increased number of people on MAT and resulted in negligible adverse impact on patients’ access to opioid pain medications.

Reducing opioid prescribing and dispensing especially among primary physicians are key goals of prescribing practice limits. Emerging data suggest that fewer patients are receiving opioids plus lower initial doses, which result in shorter treatment duration.\textsuperscript{31,44} Likewise, several states have modified PDMPs to include additional resources, such as information on overdose rescues, hospitalizations for drug-related conditions and drug-related arrests.\textsuperscript{37} While these changes are either being implemented or undergoing further modifications, reduction in prescribed opioid will likely result from a combination of several strategies.

Opioid policies targeted at treatment of addiction and/or overdose demonstrate mixed results. With respect to MAT, the overall increase in SUD-related deaths between 2002 and 2015 is projected to have been greater had the average eligibility threshold for Medicaid not increased over this period.\textsuperscript{22} Indeed, expanding eligibility for Medicaid coverage may help reduce SUD-related deaths.\textsuperscript{22} However, for non-Medicaid coverage, increasing the number of physicians that prescribed buprenorphine, and the number of patients they treated did not translate into increased access and utilization.\textsuperscript{14} Potential obstacles to increased MAT utilization include challenges with reimbursements, counselling for individuals receiving buprenorphine and guidelines for the use of buprenorphine in clinically complex patients.\textsuperscript{14}
In recent years, several states have supported policies aimed at increasing access and dispensing of naloxone. For example, immunity for carrying, dispensing or administering naloxone without prescription, and third-party prescriptions may increase access; however evidence-based outcomes with respect to overdose deaths remain to be seen. In addition to overdose treatment, utilization of naloxone during MAT may amplify benefits for OUD patients.

4.4 Non-Opioid Approaches

Non-opioid alternatives range from over-the-counter medications to medicinal marijuana or meditation techniques (e.g. yoga). However, many of these options are not covered by insurance, and therefore physicians are unlikely to prescribe them. Physicians may also lack access or adequate training to prescribe these alternatives. In a recent study, Giannitrapani et al., identified availability and access as two major obstacles facing the use of non-opioid alternatives in pain management. Barriers included geographical (patient distance from service), financial (out-of-pocket cost to patient), temporal (treatment time delays), cultural (belief of increased provider workload, perception of insufficient training, perceptions of patient resistance to change, confrontation avoidance, and insufficient leadership support), and digital (measure used for pain assessment, older patients hesitant to use technology, providers overwhelmed by information). While non-opioid alternatives may offer potential value, evidence-based scientific data of comparable benefits to opioids are lacking.

4.5 Unintended Consequences of Opioid Policies

The opioid epidemic has been aptly characterized as an ecosystem, and policies targeting one part of the system may have unintended consequences. Policies affect demand and supply of opioids. Prescribing practice limits (rationing) and PDMPs focus on supply, but fail to address
demand for opioids which may promote transition to illicit narcotics, and increased risk of addiction and overdose deaths. Patients with chronic pain conditions routinely use opioid pain medications and may be impacted by policies that ration drugs. Chronic pain treatment is complex, and significant variability remain in the rates of opioid misuse, abuse and addiction.\textsuperscript{46}

Adult sickle cell disease (SCD) patients fall into this category, and examined below are effects of policy decisions focused on SCD.

\textbf{4.6 Opioid Policies and Relevance to Sickle Cell Disease (SCD)}

Described as “the most common severe genetic disease,” SCD affects about 100,000 Americans.\textsuperscript{47-51} The condition affects approximately one in 365 Black or African-American births, and 1 in 13 babies carry the trait.\textsuperscript{50} Among Hispanic-Americans, the disease occurs in about 1 out of every 16,300 births.\textsuperscript{50} Race/ethnicity may contribute to bias, stereotyping or stigmatization associated with drug-seeking behaviors. However, SCD patients do not pose a higher risk of addiction or drug overdose compared to the general population. In agreement with this assessment, studies by Kaiser Permanente and others have indicated that only \textasciitilde{}3\% of SCD patients become addicted to opioid pain medications, which is well below the national average of between 8 and 12\%.\textsuperscript{29,52,53} State policies rationing opioid prescriptions typically include exceptions for chronic pain conditions,\textsuperscript{13} and there is no direct evidence to suggest SCD patients face additional challenges filling opioid prescriptions. State policies that limit opioid prescriptions for 7, 10 or even 14 days may compel increased hospital visits and frequency to pharmacies.\textsuperscript{13} For a subset of chronic pain patients, for example in rural areas, this may pose significant challenges. Whether such challenges result in the use of illicit drugs, and increased addiction, overdose deaths, utilization of MAT or ER visits remain unclear.
To ensure that SCD patients receive appropriate care, the NHLBI has provided evidence-based recommendations to guide practice decisions. The guide assists health care professionals in the management of common issues, including routine health maintenance, recognition and treatment of common acute and chronic complications and comorbidities of SCD, as well as indications for monitoring of hydroxyurea and blood transfusion therapy. It further addresses the care of infants, children, adolescents, and adults with SCD, however the guideline is not mandated, and degree of application unknown.
5. DISCUSSION AND CONCLUSION

5.1 Promoting Effectiveness of Opioid Policies

Analysis of state opioid policies clearly demonstrated varying levels of effectiveness with respect to evidence-based outcomes. From an access standpoint, physicians exert significant control over prescription of opioid pain medications. *Mere existence of policies that set limits on prescribed opioids, does not necessary translate into adherence by physicians.* Therefore, opioid prescribing limits should be supported by monitoring and compliance mechanisms. Consultation of PDMPs increased from less than 35% to above 90% after mandatory requirement by some states, and correlated with a decline in overall opioid prescribing, as well as drug-related hospitalizations and overdose deaths.\(^{37}\) Additionally, PDMPs promotes greater oversight, coordination of care and deployment of resources to at-risks individuals or communities.

Opioid pain medications are prescribed by licensed physicians and dispensed at pharmacies but also diverted and sold illegally. Therefore, pharmacists and pharmacies should actively participate in the implementation of existing policies. However, policies need to consider the demand side of the epidemic, especially given addictive property of opioids. Therefore, in addition to expanding access to MAT, increasing utilization by OUD population is equally important. Treatment of OUD within community clinics by primary care physicians have been shown to be both feasible and effective.\(^{14}\) Therefore, integrating treatment of OUD into primary care may increase utilization and improve outcomes.\(^{14}\)

5.2 Opportunities for Additional Opioid Policies

**Drug Take-Back Programs:** This effort is led by the U.S. Drug Enforcement Administration (DEA), and sponsors a National Prescription Drug Take-Back Day in communities nationwide.\(^{46}\) The
initiative facilitates appropriate disposal of unused or excess medicines. Drug take-back initiatives or DEA-authorized collectors may exist within communities; some pharmacies provide mail-back programs or disposal kiosks for unused medicines.\textsuperscript{46} However, specific state policies that compliment these efforts are unclear, and presents an excellent opportunity of reducing amounts of opioids in circulation.

**Educational Training:** Continuing medical education (CME) is mandated for physicians, and an effective avenue of gaining best-in-practice training on opioid prescribing.\textsuperscript{36} Policies that extend pain management training among health professionals, including pharmacists, caregivers and community-based organizations will benefit patients and at-risk populations.

**Harm Reduction:** Patients that routinely use prescribed opioids may be at greater risk of switching to illicit narcotics, especially when faced with rationing.\textsuperscript{5} Therefore, policies that mitigate harm, such as supervised injection facilities (SIFs) and access to clean syringes should be expanded. As demonstrated by the CDC, policies or regulations that support access to clean needles correlate with decreased HIV and hepatitis C incidence.\textsuperscript{54}

5.3 Implications of Findings

Policies that improve quality of care and increased health coverage will strongly benefit at-risk individuals unable to afford treatment. Currently, 36 states and Washington DC have adopted Medicaid expansion which provides funding, and behavioral health waivers for not just treatment of OUD patients, but also expansion of community-based initiatives.\textsuperscript{24} Based on 2017 National Survey on Drug Use and Health by Kaiser Family Foundation (KFF), Medicaid provided coverage for nearly four in ten (38%) nonelderly adult.\textsuperscript{24} Therefore, government programs that improve benefits and coverage, such as Medicare, Medicaid or 1115 waivers should be expanded
rather than curtailed. Imposing restrictions to Medicaid or 1115 waivers (e.g. work status requirement for Medicaid coverage) will affect access to treatment, thereby impacting policies aimed increasing utilization of MAT.

5.4 Strengths and Limitations of the Study

**Strengths:** A major strength of the study was reliance on multiple, varied and authoritative sources of literature, which identified differences and consensus on policy actions undertaken by states. The report identified policies directed at specific areas of the epidemic, including prevention and treatment strategies. Variations of state policy outcomes, including addiction and overdose deaths were noted. Importantly, measurable impact related to specific policies, challenges and areas of improvement were reported. Finally, unintended consequences of opioid policies with specific reference to sickle cell disease was examined. Taken together, the document provides a comprehensive review of state policies related to the opioid epidemic.

**Limitations:** One limitation of the study was reliance on secondary sources of data. With the exception of direct interviews with physicians at Grady Memorial Hospitals in Atlanta, most of the data were collected from government sources, and peer-reviewed published literatures. This may have resulted in limited control over specific variables linked to opioid policies. Evidence-based effectiveness of reviewed policies were influenced by several factors, including insurance coverage, Medicaid programs, coverage and access variability across states, regulations and monitoring requirements. Therefore, policy effectiveness were often mixed and variable across the states. Outcomes based on a specific policy or set of policies were difficult to directly quantify and likely due to several strategies.
5.5 Conclusion

The opioid epidemic has reverberated across the nation and impacted hundreds of communities across every single state. In response, various policies were enacted to address the crisis. However, the opioid ecosystem involves many players, and disruption in one area may compensate in another. Therefore, uncoordinated policy actions that lack input from major stakeholders may provide only marginal benefits. In order to frame effective policies, law-makers should engage extensively with a wide range of groups, including subject matter experts. Some states, like Massachusetts, Washington and Oklahoma put together broad-based coalitions that included law enforcement, medical professionals, community-based organizations, patients and policymakers to find innovative solutions to the crisis.\textsuperscript{55-58} Input from diverse groups of stakeholders present better opportunities of designing effective policies that are relevant, actionable and with reduced risk of unintended consequences.

Beyond providers and patients, the influence of drug companies, including aggressive marketing strategies should be addressed. Incentives by the pharmaceutical industry can influence physicians prescribing behavior,\textsuperscript{59} and policies designed to prevent or limit such exposures are imperative. Furthermore, effective policies should include specific and measurable outcomes. Policy interactions, responsiveness to changing situations and direct or indirect impact on the epidemic should be monitored. In conclusion, policies that improve access to preventive and treatment strategies, collaborative and multidisciplinary efforts, plus evidence-based outcomes may present the best opportunities of reversing the opioid epidemic.
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APPENDICES

Interaction with physicians at GRADY Memorial Hospital, Atlanta.

Meeting with Dr. McLemore on 4/3/2019

According to Dr. McLemore, “when patients are under excruciating pain, they simply want the pain fixed.” However, as a physician, “I need to assess the immediate and overall status of a patient’s health, and carefully plan the best cause of action.” Pain episodes due to SCD can be difficult to manage effectively; and factors that exacerbate the condition are sometimes not easily determined. On an individual level, social factors, such as commuting distance to attend hospital visits or drug-seeking behavior are better captured by having a proactive relationship with patients.

A direct impact of opioid prescription guidelines includes efforts to prescribe minimum required amounts, plus closer monitoring of patients. Concerns regarding opioid prescriptions appear to come from insurance companies who observe that a patient is getting narcotics but are not fully aware of his or her medical condition, and hence sometimes question prescriptions. Pharmacies are also hesitant to maintain large stocks of narcotics, which means that patients may have to visit multiple pharmacies or locations in order to fill their prescription. For some patients, this can pose significant hurdles to accessing prescribed pain medicines. In addition, patients in rural areas may have difficulty with frequent hospital visits or filing prescriptions. In these situations, providing large amounts of pain medications may be logical and help minimize patients’ hospital visits.
Meeting with Dr. Rassi on 4/11/2019

Vaso-occlusive complications associated with SCD lead to acute or chronic pain episodes that require prescription of pain medications. However, it is important to note that opioids do not treat (and are not a treatment for) SCD but are primarily used to manage pain. Treatment for SCD typically includes hydroxyurea, and recently, efforts have expanded to include clinical trials of new genetic therapies.

Hydroxyurea was initially used as a treatment for cancer patients, and getting SCD patients to take hydroxyurea pills and stay on the treatment can be challenging. This is because hydroxyurea does not provide immediate pain relief; it could take 2 to 4 months of treatment before its pain-relieving effects kick-in. Opioid prescriptions for SCD allow for some degree of flexibility; for example, doctors may begin with small amounts of opioids, balancing between short-acting and long-acting pain medications. Alternating non-steroidal anti-inflammatory drugs (NSAIDs), such as Motrin and Naproxen with short-acting narcotics, such as Morphine may provide relieve. Inflammation also contributes to pain in SCD, hence the use of anti-inflammatory medicines in addition to opioids.

SCD population face several obstacles in accessing standard treatments and care. This subset of patients require prolonged care and take up a lot of time, and hospitals do not make money treating them. Grady system is subsidized by the state of Georgia, and better resourced to provide adequate care. On average, patients are hospitalized for ~6 days but hospitals are reimbursed for only 4 days. Readmission rates are high for SCD patients, and based on Medicaid 30-day readmission policy, hospitals are not compensated for readmissions that occur within the time interval. On a positive note, the national focus on opioids and related policies have been
helpful in some ways. For example, statewide and national databases are now available, and track patients’ prescription history within the last one year. Furthermore, increased focus on the issue has improved closer monitoring of patients, coordination of care and outcomes for SCD patients.
FIGURES AND TABLE

Figure 1: Contributions to the opioid epidemic.

Figure 2: Nonfatal costs of opioid epidemic.

Figure 3: Drug overdose (per 100,000) by drug type and race/ethnicity in the U.S. in 2016.

Figure 4: Pain treatment is complex.

Table 1: Opioid overdose deaths by race/ethnicity, age and gender.