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AN ASSESSMENT OF THE SAFEGUARDS SURROUNDING THE OPIOID EPIDEMIC & HOW PUBLIC HEALTH STRATEGY CAN AID IN ITS CONSUMMATION

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ABSTRACT

Creating a fragmentary response to the opioid epidemic yields no change to the continuous damage being inflicted upon American society. This paper serves to assess the current federal and state safeguards that have been developed in response to the opioid crisis and the public health response that is missing in many communities. The research question addressed is, "Are the current state and federal safeguards regarding opioid use disorder in the United States adequate in their ability to end the opioid epidemic?" Because a multi-faceted approach must be taken to overcome the epidemic, analysis of the processes currently in place alongside evidence-based approaches that can be implemented is necessary to reach recommendations for progress. This paper will also include a multidimensional analysis of practices that public health departments and physicians can utilize to play a pivotal role in providing education to those in their respective communities. The analysis of the federal and state regulations along with the public health solutions surrounding opioid misuse will further reduce opioid overdoses, prevent problematic prescribing, and provide opportunities for patients to make informed decisions about their health.

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INTRODUCTION

Following the completion of a sixth-month shadowing program under Dr. Darren Freeman, a pain medicine physician serving the Inland Empire, I felt compelled to further my understanding of the United States opioid crisis and what safeguards are in place to prevent it from worsening. Pain medicine physicians specialize in the evaluation, diagnosis, and treatment of pain that is the result of illness or injury. Once the physician is able to diagnose the pain, they proceed by finding a therapy that is most suitable for the patient. When applicable, physicians are able to prescribe the patient multiple therapies that are to be used in synergy. Namely, the use of prescription medication ranging from injections to opioids may be used to alleviate pain. Although the use of said prescriptions is often seen within pain management offices, primary care physicians are often faced with patients experiencing pain and are tasked to find a solution. Throughout the time that I shadowed Dr. Freeman, I began to question the safeguards implemented by the federal government, the state, and providers themselves to prevent opioid use disorder. The following will include defining terms and concepts relevant to the paper which will allow for ease of reading. Opioids are defined as a class of drugs that are prescribed by physicians to treat moderate to severe pain. Examples include oxycodone, hydrocodone (Vicodin), morphine, and methadone. All of which can have serious risks and side effects including a potential dependence/addiction to opioids resulting from a troubling pattern of use. The laws and practices implemented to prevent opioid use disorder begin at the federal level and cease with patient education that can occur within the exam room or in the community through public health services.

A significant portion of this paper will focus on the effects of federal and state opioid-related regulations and their impact on the total number of opioid overdoses per year. Opioid overdoses are particularly important when discussing the crisis because they indicate whether or not the safeguards have been successful in their intended purpose. The impediments within the safeguards that the federal and state governments have deployed are essential in understanding the entirety of the crisis. Currently, the government continues to provide fragmentary solutions to this enduring epidemic. Oftentimes the safeguards are designed in a way to be unburdening to both prescribers and patients, which creates a completely flawed methodology. It is critical that safeguards become routine once proper training is provided. This makes it possible to track not only patient activity within and between medical offices, but ensures that problematic prescribing habits are not ensuing unknowingly. Furthermore, ensuring that the public is equipped with resources allows for a comprehensive plan and makes no assumption that abstinence is the only route to protect the public. Finally, by reinforcing federal and state regulations with a public health-based approach, social determinants of health can be addressed within every community to ensure that a patients health status is not disproportionately affected. If opportunities are available to make a lasting impact on opioid misuse and overdose, then the necessary measures must be taken to ensure that the epidemic is not enabled.

Ultimately, the longstanding goal proposed by this literature is to recommend a public health-based approach for the community to adopt in hopes of further minimizing opioid overdoses, preventing problematic prescribing by physicians, and implementing preventative education that allows patients to make informed decisions when it comes to their health. Regardless of the complexity that ensues by taking a multifaceted approach to the opioid crisis, it

is the most effective way to confront the epidemic while simultaneously prioritizing the safety and well-being of both patients and their prescribers.

UNDERSTANDING THE OPIOID EPIDEMIC

The Centers for Disease Control and Prevention have categorized the opioid epidemic as a triple-wave crisis. Initially starting in the 1990s, as there was a national increase in opioid prescriptions and overdoses in the United States (Centers for Disease Control and Prevention). There are two events that are said to be connected to the increase in opioid prescriptions. The first one, being the efforts made by the American Pain Society to treat pain as the "fifth vital sign," which would permit the use of prescription opioids for chronic, noncancerous pain. The four traditional vital signs include body temperature, blood pressure, heart rate, and respiratory rate. By including pain within this subset of vital signs, it was intended to heighten the quality of care that patients were receiving by treating pain as an equivalent to the aforementioned vital signs. This idea was supported by multiple healthcare systems including the Veterans Health Administration and the Joint Commission on Accreditation of Healthcare Organization. Although the idea of adding pain as the fifth vital sign was a virtuous attempt to emphasize the need for improved pain care, there were unintended consequences that ultimately led to the manifestation of the first wave. Increasing the availability of opioids inadvertently allows for greater misuse, which in its totality contributes to the epidemic. Upon having this realization, it was recommended that pain be removed as the fifth vital sign, but before this was executed, the sustained release formulation of semi-synthetic oxycodone was approved. It was released to the market in 1996 and by 2010 the sales had amounted to \$3.1 billion, making it one of the most misused prescription opioids available. As a result, manufacturers decided to reformulate

oxycodone in an attempt to deter abuse of the opioid via injection or snorting. Due to the reformulation, there was a growing desire for a less expensive and more highly available alternative that delivered the same effects as prescription opioids. Thus began the sudden increase in illegal substances such as heroin.

Shortly after the remanufacturing of oxycodone in 2010, the second wave began as a direct consequence to the uptake in heroin use. Heroin is an illegally manufactured opioid derived from morphine, a natural substance found in the seedpod of opium poppy plants. Not only were users desiring a more accessible and cheaper alternative to the reformulated oxycodone, but some were building a tolerance to their medication and a suitable solution to this issue could be found on the street in the form of heroin which carries a higher purity. Ultimately in 2013, the third wave emerged as synthetic opioid overdose deaths started. Most often, synthetic opioids contain fentanyl which is up to 50 times stronger than heroin and 100 times stronger than morphine (Centers for Disease Control and Prevention). Although fentanyl can be pharmaceutically made, the illegally made fentanyl that is available in the illegal drug market is extremely dangerous. Collectively, all three waves have contributed to the ongoing epidemic that has yet to find any form of resolution. Since the beginning of the first wave and up until present day, there have been more than 263,000 Americans that have died due to overdose. Currently, 187 people die from an opioid overdose including prescriptions and illicit opioids daily, proving that the opioid crisis has yet to subside regardless of the increase in safeguards (Centers for Disease Control and Prevention).

DEFINING OPIOID USE DISORDER

Opioid use disorder (OUD) is a chronic substance abuse disorder that results from misusing opioids. Millions of people in America are living with the disease and it can affect anyone regardless of social identities. The Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM 5-TR) denotes opioid use disorder as an individual that presents with a problematic opioid use and exhibits at least two of the following symptoms within a twelve month period (American Psychiatric Association):

- 1. Taking larger amounts or taking drugs over a longer period than intended.
- 2. Persistent desire or unsuccessful efforts to cut down or control opioid use.
- 3. Spending a great deal of time obtaining or using the opioid or recovering from its effects.
- 4. Craving, or a strong desire or urge to use opioids
- 5. Problems fulfilling obligations at work, school or home.
- 6. Continued opioid use despite having recurring social or interpersonal problems.
- 7. Giving up or reducing activities because of opioid use.
- Using opioids in physically hazardous situations such as driving while under the influence of opiates.
- Continued opioid use despite ongoing physical or psychological problem likely to have been caused or worsened by opioids.
- 10. Tolerance (i.e., need for increased amounts or diminished effect with continued use of the same amount)
- 11. Experiencing withdrawal (opioid withdrawal syndrome) or taking opioids (or a closely related substance) to relieve or avoid withdrawal symptoms.

Federal & State Regulations

Due to concerning trends regarding opioid use, both federal and state governments have attempted to implement various policies and safeguards in hopes of controlling the epidemic and aiding in its consummation. On a federal level, regulatory agencies are responsible for implementing and enforcing laws that are passed by Congress. Whereas, the individual states are tasked to find solutions that are unique to their respective matters of contention. It is essential to note that there is intense complexity that emanates when discussing the roles and capabilities of both the federal and state departments and outlining this exhaustive list is beyond the scope of this paper. It is crucial to understand that the subsequent examination of both federal and state-level safeguards is not all-encompassing. Rather this highlights the most notable safeguards used to prevent opioid misuse. The complexity of roles and capabilities within the two governments directly reflects the complexity that results from trying to end the opioid epidemic.

ASSESSMENT OF THE FOOD AND DRUG ADMINISTRATION

Due to the alarming statistics arising from the opioid crisis, the Food and Drug Administration (FDA) played a primary role in the federal response. Significantly, the FDA was tasked with playing a pivotal role in protecting both patients and prescribers. Not only did the FDA work to educate prescribers on proper prescribing techniques based on the medication, but they began implementing new requirements within the pharmaceutical market that would require strict labeling and marketing language to be used for any new opioid drug approved for market. Most significantly the FDA was tasked with increasing access to naloxone; a medication used to reverse an overdose from opioids. Soelberg al (2017) studied naloxone access in the United States in which they described a great need for changing naloxone to over-the-counter status in an effort to fight the current crisis. The FDA has been slow in its response to changing naloxone availability which resulted in states taking action themselves. More than 35 states worked to pass legislation that would allow for the drug to be dispensed without a prescription. They found that some states required additional safeguards including safety classes regarding signs of overdose and proper administration techniques in an effort to avoid any mishandling of the drug. Soelberg et al call for a liberalization of access laws by the FDA in an effort to keep the American publics best interest in mind. By implementing laws that increase access to life-saving medication, it allows for greater protection of those who are at risk of overdosing. Suppose data suggests a positive relationship between naloxone reversing the effects of an opioid overdose and overdose mortality. In that case, it is imperative that the FDA makes strides toward making naloxone available over the counter nationwide (Soelberg et al).

ASSESSMENT OF STATE-REGULATED PRESCRIPTION DRUG MONITORING PROGRAMS

In an effort to combat opioid use disorder, states have implemented electronic databases known as Prescription Drug Monitoring Programs (PDMP) to track the habits of both prescribers and patients. Alogaili et al studied the strengths and weaknesses of PDMP systems. They described a great need for improvement in the infrastructure setup, which has resulted in the low implementation and acceptance of PDMP regardless of its many advantages. The most prevalent and universally agreed upon advantage of implementing a PDMP system is its direct effect on combating drug abuse. Among those involved in the study, they concluded that having a PDMP is a "cornerstone in combating the abuse and misuse of scheduled drugs," due to the availability of information including prescription history which can provide insight into potential doctor shopping or problematic use (Alogaili et al). Doctor shopping can be understood as a practice by some patients in which they visit multiple physicians in an attempt to obtain multiple prescriptions that are most often highly addictive. Furthermore, history is also available for

physicians and pharmacies, which allows the state to monitor and track any signs of potentially problematic prescribing. By increasing the degree of transparency in relation to prescription history, prescribers, and pharmacists are able to play a more direct and educated role in preventing the misuse of opioids. Nevertheless, the current management of PDMP systems, which varies between states, does not allow for the system to be optimized. Currently, PDMP is not mandatory nationwide, which prevents a universal workflow from being established due to the lack of standards available. They found that by making PDMP mandatory across the 50 states, all physicians would be required to input reports for each patient regardless if probable suspicion was present, which would have a direct impact on reducing drug abuse. Alogaili et al call for a predetermined method to be established when implementing PDMP. A major weakness presented within the system is its inability to integrate with pre-existing healthcare operating systems. Since the system is decentralized, providers are relying on entities such as the Department of Health to provide proper training that would allow for the smooth implementation of PDMP, but this has yet to occur. It is imperative that the respective healthcare providers are afforded comprehensive training, allowing them to maximize their understanding and use of the system.

POTENTIAL PUBLIC HEALTH RESPONSES

Reducing morbidity and mortality associated with the opioid epidemic is essential in devising a large-scale public health approach. In their study of public health strategies, Beletsky et al. concluded that "policymakers are seeking solutions in the wrong places, and we believe that criminal penalties and a commitment to abstinence-only methods will cause more people to needlessly die of overdoses and will fail to keep the public safe." Based on their results, devising a plan that combines the efforts of local, state, and national governments is essential in

improving public health. The list of potential approaches allows individual communities to take part in ending the national crisis. In an effort to enable researchers to make guided decisions when it relates to the epidemic, is a need for improved data collection. Proper and extensive data collection would allow for tracking of at-risk populations, allowing local governments alongside physicians to identify resources in real-time that can be deemed essential. Although there are legal issues to be addressed, collecting data that is relevant to specific populations aids in ensuring that social determinants of health are not causing an added level of harm. Current data has allowed health officials to suggest the implementation of medication like Naloxone into the community and recognize that by widening the availability, there is a direct impact on lowering the total number of opioid deaths.

THE IMPACT OF NALOXONE

Naloxone, also known as Narcan, has become a critical component in combating the opioid epidemic since its introduction in 1971 when the United States Food and Drug Administration (FDA) approved Narcan as an injectable medication for use in hospitals and other medical settings to combat opioid overdoses. In 2015, the FDA approved a naloxone nasal spray which allows for easier administration in dire situations. Since then, the FDA has aimed to increase access to naloxone by widening the overall number of people that are able to access this life-saving medication. In some states, individuals are able to obtain naloxone from the pharmacy without a prescription. Whereas, others access the medication through community-based programs established by local emergency services that focus on proper training and distribution (Centers for Disease Control and Prevention). These programs permit users, friends, family, and other individuals to access the medication in case they find themselves in a life-threatening situation. Said individuals are able to access and administer the medication

while being protected by the Good Samaritan Law which allows for legal immunity when administering medical aid for someone experiencing an overdose. Ensuring the legal safety of concerned bystanders enables community members to play a critical role in the epidemic. Furthermore, in 2018 the FDA approved a naloxone auto-injector that can be used by people who have limited to no medical experience. Formulating the medication to be easy to use and increasing its availability to the United States public makes a direct impact on the number of lives that can be saved.

Narcan is an opioid antagonist which allows for binding to the same brain receptors that opioids affect but ultimately allows for the receptors to not be activated. By binding to said receptors, it blocks the opioids effect on the brain and reverses the potentially fatal hypoventilation that accompanies an opioid overdose. Opioids operate by attaching to receptors in the brain that control pain and pleasure. More specifically opioids affect the neurotransmitter that is responsible for dopamine releases. Instead, when naloxone is administered it works by competing with the opioids for those same receptors in the brain. Narcan has been formulated to have a higher affinity for those receptor sites, enabling the medication to bind more effectively than opioids. The successful binding of naloxone allows for the damaging respiratory effects that accompany an overdose to be reversed. Ultimately, the individual will return to a more state of breathing known as eupnea due to the opioid molecules being removed from said receptor sites. This complex neurochemical interaction can take effect very quickly, oftentimes within minutes, when the medication is administered promptly and correctly (Gould).

THE COST-EFFECTIVENESS OF NALOXONE

According to the CDC (2018), more than 27,000 overdoses that occurred between 1996 and 2014 have been reversed due to the use of naloxone. Based on a 2019 study published in the

Annals of Internal Medicine, in counties where naloxone was more widely available, they experienced 9.7% less opioid overdose deaths compared to counties with limited access. Beginning in 2010, a total of 188 community-based overdose prevention programs were created to distribute naloxone within 15 states and the District of Columbia. Overall, these programs were responsible for distributing 53,032 naloxone kits. The distribution of naloxone kits was deemed a cost-effective measure in preventing overdose deaths. In total, the estimated cost per quality-adjusted life year gained totaled \$2,680, with each kit distributed through these programs costing roughly \$18.80. When considering the cost of the kits in comparison to the reduction of mortality rates in communities universally, it is essential that prevention overdose programs continue to expand.

PHYSICIAN RESPONSES

CO-PRESCRIBING NALOXONE WITH OPIOIDS

Co-prescribing naloxone with opioids is known to have emerged as a vital harm-reduction strategy in preventing opioid-related deaths. Based on a study conducted by Walley et al. (2013) found that a naloxone distribution program in Massachusetts reduced opioid deaths without increasing initial opioid use by 11 percent (Walley et al). Furthermore, they found that opioid overdose deaths decreased by 47% among patients who had access to and received a naloxone prescription alongside their opioid prescription treatment plan. These findings spotlight the heightened potential of co-prescribing naloxone with opioids. Regardless of the known benefits that accompany co-prescribing, physicians continue to underutilize this tool when practicing. This is especially concerning considering how cost-effective and easy-to-use naloxone is considered. One potential reason for this could be the overall lack of awareness that healthcare providers have when it comes to the benefit of co-prescribing. There is no reason for the total number of opioid prescriptions to not equate to an equal number of co-prescribed Naloxone.

As a direct response to this issue, various initiatives have been launched to promote co-prescribing including the Opioid Safety Initiative (OSI) which was set in motion by the 2013 Veterans Health Administration. The Opioid Safety Initiative includes recommendations for proper patient prescribing, patient monitoring, and co-prescribing for patients that physicians may deem necessary. The OSI includes recommendations for opioid prescribing, patient monitoring, and co-prescribing naloxone for patients at high risk of overdose. Furthermore, co-prescribing naloxone with opioids can also help reduce health disparities in opioid overdose deaths. A study by Wermeling et al. (2010), indicates that naloxone co-prescribing can be particularly beneficial for populations that are at increased risk of opioid overdose, such as people who use drugs, those with a history of opioid misuse, and those with co-occurring mental health or medical conditions. Co-prescribing naloxone with opioids can also be an effective way to address the racial and ethnic disparities in opioid overdose deaths. A study by Green et al. (2019) found that in order to decrease opioid deaths among racial/ethnic groups by 81%, co-prescribing naloxone was seen as necessary. Regardless of the list of benefits that accompany the co-prescribing of naloxone with opioids, barriers continue to block physicians from fully implementing it into their practice. Even though naloxone has been considered cost-effective, for some patients are still unable to afford it. As a result, many states have taken measures to increase access to naloxone. As previously mentioned, in some states pharmacists are able to dispense the medication without a prescription. Furthermore, statistical modeling suggested that in communities where patients are unable to afford the drug, it was imperative for laypersons and

medical personnel to have access to this safe-saving medication. Townsend suggests that another 21% of opioid overdose deaths could be avoided by providing this medication specifically to laypersons within the community. This highlights the significance for others outside of emergency medical services to have access to naloxone but continues to spotlight that the most significant impact can be seen by co-prescribing said medication.

PATIENT EDUCATION

In order to effectively manage patients that use opioids for pain relief, it's important to note the crucial role that physicians play. A proper discussion between patients and their providers that educate patients in regards to the risks and benefits of using an opioid is imperative. Physicians should not limit themselves to speaking about potential addiction and overdose, but educate their patients on how to be safe and responsible to prevent dangerous mishandling of their medication. More specifically, talking to patients about the true purpose of taking an opioid and how tolerance can build by long-term use and improper medication dosage intake. Furthermore, ensuring that patients are prepared in case of an emergency is essential to decreasing overall mortality rates. According to a study published by the National Association of Orthapedic Nurses, patient education significantly improves patients' knowledge about opioid use and safety practices. The study found that patients who received education in regards to opioid safety had an overall better understanding of their medication and certain implications when it came to opioid disposal, use, and storage. According to a study by Green and colleagues, they found a direct correlation between those patients who received counseling and educational material, and a stark reduction in opioid misuse among their patients experiencing any level of chronic pain. Moreover, patient education can be utilized to reduce the stigma surrounding opioid use disorder. Physicians should encourage patients to create an open dialogue and ask any

questions they might have about opioids. Furthermore, patients should feel comfortable sharing any concerns they might have about their medication and receive answers to those concerns before they leave the examination room. It is important to note that opioid use disorder is a disease. Addiction often requires treatment, and it is important for patients to feel comfortable when seeking said resources. It is imperative that doctors have resource information readily available for patients experiencing chronic pain to ensure safe use is occurring. Altogether, patient education is an essential part of responsible opioid prescribing. Physicians are responsible for ensuring that when a patient leaves their examination room, they are equipped with accurate knowledge that will guide patients' decision-making.

CONCLUDING REMARKS AND FURTHER RESEARCH

Current literature is limited in understanding the opioid epidemic in its entirety and the expansion of solutions. Regardless, it is imperative that continuous strides be made to improve the management of pain with respect to both parties: patients and prescribers. A multifaceted and united approach is necessary to prevent the devastating epidemic from continuing. This approach can begin with a series of changes made to the federal and state policies currently in place.

During the 2020 Presidential campaign, the Biden administration vowed to play a key role in ensuring proper resources were allocated towards combating the nation's opioid crisis (The White House). His approach proposed several strategies, including expanding access to treatment, improving drug monitoring programs, funding research, and increasing access to lifesaving drugs like Naloxone. Most notably, Biden proposed investing \$4 billion to expand access to evidence-based addiction services, increasing support to housing services, national hotlines, and access to medication-assisted treatment. He proposed another \$1 billion to help strengthen prescription drug monitoring programs which would prevent over-prescribing and

potential doctor shopping. Finally, outlined his plan to increase the accessibility of Naloxone to first responders and other individuals at risk by allocating another \$1.5 billion. Biden has attempted to implement strategies that are multi-faceted, but data has yet to show if it has made a significant impact on the total mortality rate. Regardless, it is important that the government continues to allocate funds towards evidence-based programs that will help the nation overcome the epidemic.

With all this said, I think at the heart of the issues lies the need for a cultural shift within the United States. Opioid use disorder is a disease that is highly stigmatized within our society and oftentimes is viewed as a sign of weakness. The American public must shift our view when it comes to addiction and ensure that we are supporting practices that focus on rehabilitation and providing those who are suffering with the support they need. No one is immune to addiction; rather it affects people of all economic, racial, and social backgrounds, therefore finding a multifaceted approach is essential to ending the opioid crisis and challenging all factors that may be enabling it.

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