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How Good Intentions Contributed to Bad Outcomes: The Opioid Crisis

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Abstract

The opioid crisis that exists today developed over the past 30 years. The reasons for this are many. Good intentions to improve pain and suffering led to increased prescribing of opioids, which contributed to misuse of opioids and even death. Following the publication of a short letter to the editor in a major medical journal declaring that those with chronic pain who received opioids rarely became addicted, prescriber attitude toward opioid use changed. Opioids were no longer reserved for treatment of acute pain or terminal pain conditions but now were used to treat any pain condition. Governing agencies began to evaluate doctors and hospitals on their control of patients' pain. Ultimately, reimbursement became tied to patients' perception of pain control. As a result, increasing amounts of opioids were prescribed, which led to dependence. When this occurred, patients sought more in the form of opioid prescriptions from providers or from illegal sources. Illegal, unregulated sources of opioids are now a factor in the increasing death rate from opioid overdoses. Stopping the opioid crisis will require the engagement of all, including health care providers, hospitals, the pharmaceutical industry, and federal and state government agencies.

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For editorial comment, see page 269

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There is no debate that the United States is in the midst of an opioid crisis. Between 1999 and 2014, drug overdose deaths nearly tripled.[1] In 2016, more than 60,000 people died from drug overdoses, and opioids were responsible for most of these deaths.[2] For the first time since 1999, life expectancy decreased for US citizens compared with citizens of other developed countries, and opioid overdoses were a factor.[3]

This crisis includes both prescription and nonprescription (illegal) use of opioid drugs. Prescription opioids include natural and semisynthetic opioids such as codeine and morphine, and synthetic opioids such as methadone, fentanyl, and tramadol. Many of the synthetic agents such as fentanyl are manufactured and distributed illegally. With the increased availability of both prescribed and illegally obtained opioids over the past 30 years, there has been an increase in misuse and deaths (Figure).[4]

Various opioids have been available for more than a century, and opioid misuse has occurred during that time. Following the Civil War, veterans who suffered severe injuries were given morphine for pain relief. In the late 1800s, pharmaceutical companies began producing synthetic opioids, at which time heroin became available. At the same time it became clear that these derivatives of opium were addictive, and the United States restricted the importation of opium for medical purposes only.[5] In 1912, the United States and other countries signed the International Opium Convention, which controlled the import, manufacture, and sale of morphine.[6] In 1924, because of misuse of heroin, the Heroin Act prohibited manufacturing, importation, and possession of heroin, even for medical purposes.[7] However, opioid problems continued to surface especially following war. Veterans were given opioids for relief of acute pain associated with combat injures but many continued to use and then misuse opioids once the immediate crisis was over. By the 1970s, additional opioids such as oxycodone and hydrocodone were developed and marketed for relief of acute and cancer pain.

Opioid use impacts all ages, sexes, ethnic and socioeconomic backgrounds, and especially those in rural settings.[8] According to a study in *Annals of Internal Medicine*, nearly one-third of US adults currently use prescription opioids.[9] The United States leads the world in opioid use, consuming roughly

80% of all the world's opioids.[10] According to former Surgeon General Vivek H. Murthy, MD, MBA, the substance use disorder problem, which includes opioids, is now more prevalent than common medical diseases such as diabetes and is 1.5 times more prevalent than all cancer diagnoses combined.[11] More people use prescription opioids than use tobacco.[11] Substance misuse disorder in the United States costs $442 billion a year in health care, criminal justice costs, and lost productivity.[11] The opioid crisis alone skyrocketed to more than $78 billion a year.[12]

With increased opioid misuse, drug overdoses have become the leading cause of death for Americans younger than 50 years and a growing problem for those aged 15 to 24 years.[3] By 2016, more die per year than from influenza, pneumonia, and kidney disorders, as well as from motor vehicle and firearm deaths.[2] Unfortunately, only a fraction of those impacted by substance misuse, with some estimates indicating only 10%, are able to access services and get help for their condition.[13]

Opioids have been available for some time, so why are we now seeing a tremendous increase in opioid misuse and deaths? The reasons for this are complex. It appears that some good intentions to improve pain and suffering have contributed to some of the bad outcomes we are experiencing today with the opioid crisis.

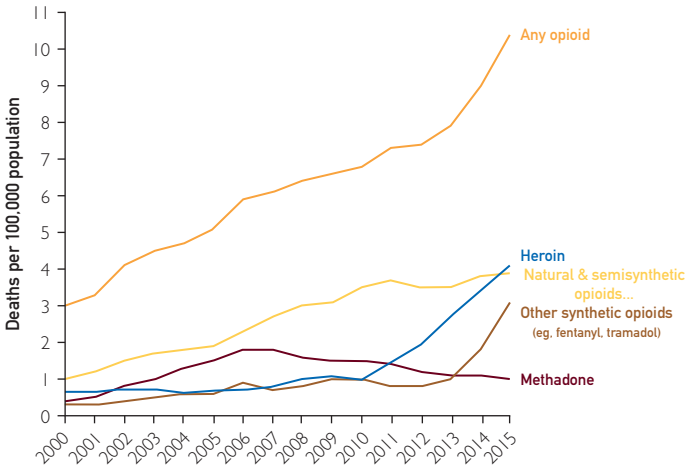

FIGURE. Overdose deaths involving opioids by type of opioid, United States, 2000-2015. From *CDC/NCHS National Vital Statistics System, Mortality*, with permission.[4]

ADDRESSING CHRONIC PAIN

In the past, opioid medications were prescribed primarily for acute pain due to injury or surgery or severe pain related to cancer or a terminal illness. Physicians were reluctant to prescribe opioids for other conditions because there was no evidence to support wider prescribing practices, and there was a concern for addiction. In addition, physicians feared investigation and state board disciplinary action if they did prescribe opioids more liberally.[14-16] In 1980, a 1-paragraph letter to the editors of the *New England Journal of Medicine* challenged the practice of using opioids only for relief of acute pain.[17] The authors of the letter, after a retrospective review of their records, stated that only 4 of 11,882 patients who had pain and were given opioids became addicted to them. Subsequently, this 5-sentence letter was referenced over 600 times in support of using opioids for chronic pain.[18]

A number of physicians and pain organizations, including the World Health Organization, began advocating for more aggressive use of opioids for pain control for anyone who had "pain."[19] A study published in 1986 in the journal *Pain*, based on only 38 patients, concluded that "opioid maintenance therapy can be a safe, salutary and a more humane alternative to the options of surgery or no treatment in those patients with intractable non-malignant pain."[20] In the textbook *Narcotic Analgesics in Anesthesiology*, Arthur Taub similarly indicated that continuing opioid therapy in patients with nonmalignant pain was not associated with substance abuse or psychological dependence.[21] Consequently, opioids were no longer limited to acute pain and pain associated with terminal illnesses but were also used to treat chronic pain.

This led to a slow but steady expansion of opioid use in the 1980s for anyone having "pain." In 1996, the American Academy of Pain Medicine and the American Pain Society issued a consensus statement that opioids should have a role in the treatment of patients with chronic noncancer pain.[22] Subsequently, many states passed Intractable Pain Acts that removed sanctions for physicians who

prescribed long-term opioid therapy. Opioid prescribing began to increase.[23] From 1990 to 1995, prescriptions for opioids increased by 2 million to 3 million each year.[24] Then in 1995 OxyContin, produced by Purdue Pharma, was approved by the US Food and Drug Administration (FDA). In 1998, the pharmaceutical company began aggressively marketing the drug for the treatment of chronic pain, particularly to primary care physicians.[25] The company created and distributed to physician offices more than 15,000 copies of the video called "I Got My Life Back" that chronicled 6 patients treated with OxyContin for chronic, noncancer pain.[25] The promotional message encouraged prescribers to use this opioid as an ongoing treatment for chronic pain and highlighted the lack of side effects. Subsequently, the annual number of prescriptions for OxyContin increased from 670,000 to 6.2 million between 1997 and 2002, and the total number of opioid prescriptions increased by 45 million.[26] In 2007, a federal court found that the promotion provided false information about the addiction potential of OxyContin and fined Purdue Pharma $634.5 million.[27] However, the combination of consensus statements and deceptive marketing had resulted in increased opioid prescribing.

With both the push for treatment of chronic pain with opioids and the promotion by pharmaceutical companies that the new opioids were safe for use in chronic pain, the number of opioid prescriptions increased from 2 million to 3 million a year in 1990 to 8 million a year in 1996, and 11 million in 1999.[24] Nearly 62 million patients had at least 1 opioid prescription filled in 2016.[28] These good intentions to relieve all pain led governing organizations, which set and monitor standards for medical practice, to develop new standards for doctors and hospitals to monitor and treat pain.

MONITORING PAIN

The impetus for more aggressive pain treatment came from numerous studies published in the 1990s indicating that cancer and noncancer pain were ineffectively treated. In 1998, a study examining a national database of elderly patients in a nursing home with cancer found that pain was prevalent and often untreated.[29] Another study of more than 1000 outpatients with metastatic cancer treated between 1990 and 1991 reported that 42% did not receive adequate pain therapy.[30] Inadequate pain therapy was also reported in other patient populations such as ambulatory patients with AIDS and hospitalized critical care trauma patients.[31,32]

In 2001, the Joint Commission, an organization that monitors quality and sets standards for hospitals and medical centers, announced new standards for monitoring and treating pain that emphasized the need to perform systematic assessments of patients' pain levels regularly and frequently while hospitalized. It advocated for pain to be monitored similarly to how vital signs are monitored. Consequently, pain monitoring increased dramatically and became known as the "5th vital sign." With "pain" increasingly surveilled and endorsed, opioid administration increased. Although the Joint Commission later revised and then in 2009 deleted these recommendations in response to concerns of overtreatment, the practice continued.[33] The good intention to closely monitor and treat pain on the basis of patients' direct input increased the use of opioids, which has further contributed to today's opioid crisis.

Using Patient Satisfaction as a Proxy for Quality Care

In 2001, the Institute of Medicine (IOM) in *Crossing the Quality Chasm: A New Health System for the 21st Century* stated that the "US delivery system does not provide consistent, high-quality medical care to all people." The IOM called for improvement in 6 areas: safety, effectiveness, patient centeredness, timeliness, efficiency, and equitableness.[34] The IOM called for processes to monitor and track these 6 aims at improving the patient experience for which patient satisfaction became a proxy.[34] Shortly thereafter, Congress directed the Center for Medicare & Medicaid Services (CMS) and the Agency for Healthcare Research and Quality to create the Hospital Consumer of Healthcare Providers and Systems (HCAHPS)[35] Survey that incorporated patient satisfaction data and became a proxy for quality care. Three of the 25 survey questions concerned pain control, intended to measure how well hospital providers manage patients

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with pain. The laudable goal to measure and improve patient experience was well intended, but no evidence existed that equates patients' perception of their health care including pain control with quality of care.

REIMBURSING FOR PATIENT SATISFACTION

The Deficit Reduction Act of 2005 required hospitals to participate in the HCAHPS Survey by submitting the results of the survey as a part of the Inpatient Prospective Payment System. The hospitals that submitted patient satisfaction data received full annual payment; those that did not incurred a 2% penalty for nonsubmission.[36] By 2010, the Patient Protection and Affordable Care Act of 2010 expanded the role of patient satisfaction as a payment incentive by including the HCAHPS Survey scores as a part of the Hospital Value Based Purchasing program.[37] This program was intended to reward hospitals for high-quality care by requiring measures of clinical processes, outcomes, and patient experience. The patient experience domain comprised 30% of the total performance score in this calculation. Therefore, the scores on the patients' perception of pain control had a big influence on reimbursement under the Inpatient Prospective Payment System.

Although there is some evidence that patient satisfaction with care is correlated with adherence to treatment recommendations, multiple studies show that patient experience scores do not relate to quality of care or to significantly improved outcomes.[38-42] In spite of this, reimbursement from CMS was in part related to patient satisfaction and pain control. The 3 questions included in the HCAPS Survey were as follows: (1) During this hospital stay, did you need medicine for pain? (2) During this hospital stay, how often was your pain well controlled? (3) During this hospital stay, how often did hospital staff do everything they could to help you with your pain?[43] As a result many clinicians felt obliged to address patients' pain more aggressively to satisfy the patient.[44,45] Opioids were now given in situations involving acute pain from minor procedures as well as for chronic pain.

On the other hand, many conscientious physicians received poor patient satisfaction scores for not providing opioids and other controlled substances when requested. A recent study showed the denial of a patient request for pain medication was associated with lower patient satisfaction scores.[46] This has discouraged some of the best and most caring physicians who try to provide quality care. Although the Joint Commission, IOM, and CMS had good intentions of involving patients in their care, some of the ramifications were that patients received more opioids and other controlled substances when requested.

PROVIDING LARGER AMOUNTS AND MORE POTENT PAINKILLERS

Pharmaceutical companies, medical governing agencies, insurance companies, and retail pharmacies also had good intentions of improving patient care and decreasing cost, but these intentions also indirectly contributed to the opioid crisis. Physicians and dentists wrote prescriptions for larger supplies of opioids after procedures to not only aggressively treat pain but also limit refill requests. Some retail pharmacies and insurance companies inadvertently contributed to the opioid problem by charging less for prescriptions of larger numbers of pills rather than smaller ones that would require refills to obtain the same number of pills. In addition, some insurance companies restricted higher priced, less addictive agents to control pain, leading providers to prescribe opioids when nonopioid pain medications may have been just as helpful.[47] A recent study published in *JAMA* indicated that there was no clinical or statistical difference in pain reduction for acute extremity injury between opioid and nonopioid pain medication.[48] As a result of this prescribing practice, many patients received large amounts of potent opioids when only a few or none were needed.

This prescribing practice increased the risk for dependence. A study showed that 80% of opioid abusers had a prescription for opioids before the start of the addiction.[49,50] When patients could no longer obtain prescription refills, the illegal opioid market was available with more potent and cheaper agents such as heroin and fentanyl. Even if patients did not take all the prescribed medication, the remaining pills could be misused by other family members, become a target for theft, or sold illegally. Fifty percent of opioid abusers who

did not have a previous opioid prescription had a family member who did.[49,50]

Opioid prescribing rose at alarming rates from 1995 until 2012. In 2006, 72.4 opioid prescriptions were written per 100 people. This rate continued to increase annually until 2012. By 2016, it declined to 66.5 opioid prescriptions per 100 people, but despite this drop, the death rates from opioid overdoses did not decline. Although prescription opioid pain relievers were initially driving the crisis, by 2015 there were an equal number of deaths caused by illicit, synthetic opioids, which included heroin and fentanyl as well as methadone. As prescription opioid deaths level off, deaths from the illicit, synthetic agents continue to rise.[28] Unfortunately, the good intentions to improve patient satisfaction, reduce the need for refills, and reduce medication costs have inadvertently contributed to the opioid crisis.

SUMMARY

Many good intentions leading to specific actions contributed to the opioid crisis. It began with underestimating the addictive potential of opioids in treating chronic pain and the advocacy of opioids to treat all pain issues. The implied message was that pain, which is part of the human condition, is a vital sign that should be treated similar to abrupt changes in temperature and blood pressure. Concurrently, pain control assessments included in patient satisfaction surveys became a measure of patient-centered care. The financial incentive for both doctors and hospitals to have high patient satisfaction scores only escalated the growing opioid crisis. Finally, the less expensive cost of opioids compared with that of less addictive agents to treat pain fueled an already smoldering problem. There is no single group or organization that is responsible for what has occurred over the past 30 years. Together we created the opioid crisis that exists today and together we must address it.

POSSIBLE NEXT STEPS

To address the opioid crisis, there are a number of groups attempting to set goals, guidelines, and regulations including the IOM, the Joint Commission, the Department of Health and Human Services, the CMS, the FDA, the Centers for Disease Control and Prevention, and other federal and state government agencies. In 2011, the IOM published "Relieving Pain in America," which advocates for a multidisciplinary and multimodal approach to pain management, and includes emphasis on prevention, not just treatment.[51] Over the past decade, the Joint Commission reexamined and modified its view of the standard of pain management starting with the elimination of assessments as a fifth vital sign in 2009.[33] The Department of Health and Human Services and the CMS worked together to set priorities including addressing opioid prescribing practices and implementing more effective person-centered and population-based strategies to reduce risk of opioid disorders, expanding use of naloxone, increasing use of medication-assisted treatments to reduced opioid disorders, and encouraging the use of evidence-based practices for acute and chronic pain management.[52,53] The CMS also is transitioning to new questions regarding pain in the HCAPHS Survey. Starting in January 2018, the new questions are as follows: (1) During this hospital stay did you have pain? (2) During this hospital stay did the hospital staff talk with you about how much pain you had? and (3) During this hospital stay, how often did hospital staff talk with you about how to treat your pain?[52]

Many are recommending investment in research to better understand the neurobiology of pain and opioid use disorders to find better nonopioid treatments and other interventions that identify unique factors for specific opioid using populations.[54] The Centers for Disease Control and Prevention has developed guidelines for prescribing opioids for chronic pain.[55] States are also addressing the crisis. Most states have databases that can be accessed by providers that show previous opioid prescriptions dispensed to patients. This measure is associated with a modest and sustained decrease in opioid prescriptions as has been found by the mandatory prescribing drug monitoring program on opioid prescriptions by dentists in New York.[56,57] In April 2017, federal legislation was introduced to limit the supply of opioid prescription for acute pain to 7 days.[58] By August 2017, 24 states have enacted legislation with a limit,

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guidance, or requirement related to opioid prescribing.[59]

Despite these advances, there are still gaps that need to be addressed. Reimbursing physicians and hospitals for patient pain control and satisfaction data, that neither reflect quality nor consistently reward those who are providing the best care, needs to be reevaluated. Insurance companies and retail pharmacies should also reassess how opioid medications are supplied to patients and how the cost of opioid versus nonopioid pain medications is determined. Potent, synthetic illegal opioids such as heroin, carfentanil, and many others entering the United States from outside markets must be eliminated.

CONCLUSION

Over the past 30 years, the intentions to address and control pain and to have patients directly involved in their care were well-meaning, but the measures taken to achieve these goals contributed to the opioid crisis. Pain is not an opioid-deficient condition but a human, multidimensional disorder often involving more than just physical pain. Because it encompasses emotional, social, and spiritual, as well as physical components, it cannot be eliminated by a single drug. If we continue to approach pain in a unidimensional way, the current opioid crisis will likely continue, and the suffering will persist. Suffering will be alleviated only when, in addition to physical pain relief, emotional turmoil is calmed, social conflicts are lessened, and spiritual peace is found.

Abbreviations and Acronyms: **CMS** = Centers for Medicare & Medicaid Services; **FDA** = Food and Drug Administration; **HCAHPS** = Hospital Consumer Assessment of Healthcare Providers and Systems; **IOM** = Institute of Medicine

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