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dale russell
University of Lynchburg, daleeverett2002@yahoo.com

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Dale Russell, MPAS, PA-C

Abstract

There is a growing concern in America over the increasing morbidity and mortality associated with the use and abuse of opioid pain relievers. This alarming increase has led to the term "crisis" when referring to these facts. Addressing this crisis is multi-focused. The need to prevent and treat opioid addiction is on the forefront. These needs are seen in both the prescription of opioids as well as the illicit use of non-prescription opioids. Overprescribing opioids has led to an increase of abuse and addction to these substances[1]. This in turn has led to a rise in street use of illicit opioids and subsequent overdoses and deaths [2]. Pharmaceutical companies are to blame when it comes to putting out more potent opioids and thus pressuring prescribers to use these medications as a "reasonable" means to treat pain[3]. Patient education is needed. Prescriber responsibility must increase. Alternative pain treatment must be sought and lastly treatment for those already addicted must begin. A description of the scope of the opioid crisis will be addressed. Included will be the history of the crisis, factors contributing to the crisis, and statistics relating to addiction deaths due to overdose. Economic results will be evaluated and finally, interventions to solve this crisis will be assessed.

Keywords: Opioid Crisis, Opioid Addiction, Controlled Substance Abuse, Controlled Substance Addiction, Opioid Overdose, Heroin, Prescription Drug Abuse, Alternative Pain Management.

Introduction: How it all began

On the battlefield during the Civil War ca. 1861 a soldier is mortally wounded. Medics rush to his side to render aide and find him screaming in pain as he is missing two limbs. After applying tourniquets, they administer injectable morphine. It is titrated to near unconsciousness. The morphine will continue throughout this soldier's short life[4].

In 1898, in a typical American home a baby is crying in pain. Is it colic? Teething? The mother can no longer take the anguish and goes to the medicine cabinet for pain elixir, she grabs it and pours some in to the child's mouth, minutes later the infant is quiet, barely breathing in fact. The elixir is pure heroin extract. Relieved by the effects of this wonder drug the mother seeks it often to comfort her children during times of distress[5].

Sigmund Freud, an Austrian Neurologist and the Father of Psychoanalysis, in the late 1880's began to treat people for "dependence" on morphine. His method of treatment was to have them drink cocaine and alcohol elixirs which ultimately made their "dependence" worse[6]. Later Freud would coin the term addiction. Chemical addiction is defined as a substance dependence, a mal-adaptive pattern of substance use leading to clinically significant impairment or distress[7]. The worse characteristic of addiction then is an underlying change in brain circuitry beyond detoxification[7]. Opiate addiction can occur within just a few days of the first use and take up to a lifetime to recover[8]. Addiction itself is greatly dependent upon the person's underlying personality, stressors in life, socioeconomic status, and health status. Likewise, while the physical addiction can be recovered of in days, the psychological can take the rest of the person's life[9]. Our country has been using narcotics since the 1800's and it has been increasing at an alarming rate (see appendix 1, table 1). Opioid use in the U.S. is on the increase both medically and recreationally, potency has increased and in fact opioid overdoses now kill more Americans than guns, cars or HIV/AIDS[10]. Heroin has made a comeback and is a preferred abused opioid and due to being inexpensive and readily available, is on the increase[11]. Physicians and other

prescribers are under increasing pressure to satisfy their pain patients and hospitals and other institutions are now considering patient satisfaction placing them in the role of "customers". As such providers are now being evaluated on patient or customer satisfaction[12]. One common complaint against providers is they are not giving enough pain medication to control pain. Working with the pressure of patient satisfaction instead of doing only what is medically correct or necessary could then interfere with the Hippocratic Oath that physicians and many other providers take upon graduation from their training. The Hippocratic Oath essentially boils down to "do no harm". Appropriate medical care begins with compassion and ethics. Giving more pain medication solely on the basis or threat of a poor patient satisfaction score (and potential job threat), is a clear violation of ethics is and a potential breach of the Hippocratic Oath.
Some providers are putting their licenses in jeopardy over the prescribing of too potent, too many, or continuous refills of opioids[4,13]. Economy hits are seen when addiction and overdose numbers increase resulting in increased medical and insurance costs[14].

Methods

The following pages of this paper will describe in more detail the problem of the opioid crisis in America. Specifically, a look at the sources of the crisis, trends, patterns and effect on the culture and economy is reviewed. Literature is evaluated from the history of opioids in this country to the daily news of the statistics of deaths and costs. Due to the recent nature of this topic, literature includes published books, on-line sources, news feeds, blogs, as well as texts and authored articles. Presidential input is sought. Undeniable statistics are sited. Finally, resources dealing with solutions to the crisis, patient recovery, prevention, and economical restoration are reviewed.

Results

The Presidential Opioid Commission issued a report in July 2017 recommending that President Trump formally declare a national emergency. Specifically, he has issued a directive to his administration to use all "appropriate emergency and other authorities to respond to the crisis caused by the opioid epidemic"[15]. In addition, the National Institute on Drug Abuse has stated that the misuse of or an addiction to opioids including prescription

pain relievers, heroin, and synthetic opioids is a serious national crisis that effects public health as well as social economic welfare[16].

The primary responsibility of a provider is to do what is in the best interests of the patient. This ethic dates back to the time of Hippocrates and encompasses beneficence of preventing and removing harm. Treating pain is in this realm of "doing no harm". Treating pain to the point of dependence upon pain medication (addiction) is in fact doing harm and would therefore, go against this responsibility[17].

Morphine was readily used on the battlefields of the Civil War as a primary pain relief and Bayer marketed liquid pure heroin primarily as a childhood pain elixir[4,18]. Although both of these incidents in the American timeline were responsible for early addiction problems they were nevertheless, innocent attempts at pain control as addiction had not yet been defined or diagnosed[6]. Upon the diagnosis of addiction at the turn of the century, Heroin was removed from the market and replaced with none other than aspirin[19]. Table 1 in Appendix 1 gives an exhaustive list of opioid progression in the U.S. Beginning in the 1990's, pharmaceutical companies began marketing opioids as "all purpose" pain killers. The FDA approved Purdue Pharma to release Oxycontin, the most potent to date oral pain medication to be released[20]. At this time the market already contained less potent synthetic pain eds which were getting the job done. The result of the release of the Oxycontin was a 12-hour ore potent pain reliever which lasted longer and when stopped caused greater dependence and withdrawal. The Oxycontin release eventually made billions of dollars in revenue but at what cost to the patient population[20].

In 1996, the year after Oxycontin was marketed dr. James Campbell, president of the American Pain Society made a statement that "if pain were assessed with the same zeal as the other vital signs, it would have a much better chance of being treated properly"[21]. This new vital sign, unlike the traditional vital signs (bp, pulse, temp, resp rate) cannot be measured objectively. This lack of measurement leads patients to assign whatever severity to their pain that they wish. Therefore, one person's hang nail is a 10 on a 1-10 severity scale while someone with 3rd degree burns is an "8". This disparity was quickly identified as a problem as patients who are in the throes of addiction will continue to complain of a "10" pain and providers cannot

measure it. A standard was needed. By the early 2000's the AMA dropped pain as the 5th vital sign[22]. Along the lines of assessing pain came the patient care satisfaction surveys. In 1985 Medical Anthropologist Irwin Press and Sociologist Rod Ganey starter "Press Ganey", a survey design and administration that was adopted by medicine, primarily hospitals[23]. Hospitals adopted this survey as a way to improve patient satisfaction. Hospitals receive financial incentives from insurance companies for adopting these surveys[24]. These surveys inquire as to pain control as one of the questions. If a provider did not give the level of pain medications the patient desired a poor score could be reported. These poor reports would eventually get to the hospital administrators and then to the providers. Providers were then under pressure to serve their patients better in order to up their scores. More pain medication means better scores[25]. This led to stronger or more pain medications given to lesser complaints as a way to obtain higher scores or avoid lower scores thus protecting one's position[23-25]. The Press Ganey dilemma led providers to attempt to achieve good scores while using alternative pain medications as a way of not over-using opioids. However, the problem lies with the insurance companies and what they will or will not cover. Most insurance companies pay for nearly all the common narcotics especially if written generic. Those same insurance companies either do not cover non-narcotic alternatives which are newer and more expensive or will require prior authorization or a statement that narcotics have failed[26]. In addition, non-medicine pain therapies are rarely covered y most major insurance companies[27]. These facts may force a provider to yield to narcotic pain management. The effect on the provider as prescriber is one of attempting to do the right thing for the patient by treating pain as a vital sign while appeasing corporation mandates like patient satisfaction surveys. Staying in line with insurance companies to prescribe something covered would allow patient not to pay exorbitant fees out-of-pocket but may not be in line with "do no harm". Insurance companies' refusal of non-narcotic pain alternatives lead providers to choose controlled substances and that is where the statistic of increased narcotic scripts begins. Patients would begin to feel the effects.

The number of opioid prescriptions dispensed by providers steadily increased from 112 million in 1992 and peaked at 282 million in 2012 and by the end of 2016 rested at 236 million[18]

Some 11.5 million Americans aged 12 and older abused prescription opioids in 2016 and an Alarming 948,000 (0.3%) of those aged 12 and up used heroin in 2016[18]. The NIH has recorded the following startling statistics:[16]

29% of chronic pain patients misuse their opioids

12% develop opioid disorder

6% will transition to heroin use

80% of the heroin users were first prescription abusers and….

1 or of every 550 patients started on opioids dies from opioid causes after their first Prescription[28]

In 2015 2.7 million Americans suffered from opioid dependence of addiction[28]. Overdose is on the rise. In America, more than 115 people will die daily from an overdose of an opioid[16]. 2016 saw a 22% increase in opioid overdose deaths from the previous year totaling 64,000 deaths and has been on a steady increase yearly[10]. Opioid deaths grew over 100% from 2015 to 2016 and an astounding 533% from 2002-2016[18].

What does all this mean for the economy? Over 300,000 annual Emergency Department visits are for opioid overdose[28]. Another 200,000 people will visit the Emergency Department for non-overdose opioid injuries/illnesses[29]. In sum, the opioid crisis is producing an economic burden of $78 billion yearly of which health care and substance abuse programs contribute $28.9 billion. Of that 14% is funded by public health insurance while 25% by state and local government[30-31]. Included in these percentages are the costs to the judicial system and to employers[31.] The illegal drug trade is responsible for 18% of criminal activity revolving around obtaining addictive drugs[31]. In the job trade employers are paying higher insurance costs as well as higher rates for workers compensation due to employees who are opioid users missing work due to drowsiness, pain, and addiction[31].

Discussion

Solutions

We in America who want to see this crisis come to an end must realize it took decades to get where we are now, and it may take decades to fully reverse. Patience will be needed in

formulating a plan to unravel this disaster.

The first step is education. Education on the dangers of opioid abuse and addiction must start at a very young age since addiction and overdoses are seen in youth as young as 12[32]. Therefore, this education should begin in the latter stages of elementary school to include health classes focusing on the psychology of and consequences of opioid use/abuse[33]. Similarly, this training can be repeated up through high school graduation, adding material appropriate to age. The next phase would see implementation of opioid danger training in college that could be mandated, this would be especially helpful for health careers. We now see this getting under way in some states[34]. And finally, health career graduates can take an opioid danger awareness training to further bolster their awareness[35].

Practicing providers could do screening histories and exams geared toward identifying addictive tendencies prior to prescribing opioids[36]. Finding early red flags can allow a provider to recommend counsel before there is a problem and identify those patients already having difficulty with substance misuse/abuse. Furthermore, all medical/dental offices can run a pharmacy check on line to see what their opioid frequency, if any, is. The state of Michigan has implemented a system called M.A.P.S.[37]. M.A.P.S. is the Michigan Automated Prescription System and it gives a compiled list (years-worth) of all controlled substances the patient has received during the designated period of time sequestered. It shows what drug was prescribed, when it was prescribed, who prescribed it and how many pills were dispensed. This system allows providers to see if patients are “doctor shopping”, how many meds they receive and to see if they are being truthful. In addition to these fail-safes, providers can have patients sign agreement/contracts before receiving opioids[38]. These contracts cover why they are getting the medication chosen, what the side effects are, what the risks are for addiction, and the ramifications for misappropriating the medication (selling or giving it away). Also included would be a bold statement as to whether or not this medication can be expected to be refilled. For children, this form would be signed by a parent or guardian. As another safe guard, some states are now limiting the number of opioids allowable by prescription[39]. Increased public awareness of this topic has now led medical offices, pharmacies and law enforcement agencies

to carry Naloxone, the opioid overdose antidote[40,41]. This medication comes as oral, inhaled and injectable (intramuscular and intravenous), is inexpensive, and easy to use. The carrying of Naloxone will give comfort to all those who come in contact with those whom have either overdosed or overused and need immediate attention to prevent respiratory arrest or death. Taking this a step further, Naloxone is now becoming available to lay persons in order they administer the medication to themselves or others who are high risk[42].

In order to begin combatting and reversing this crisis there needs to be funding. We saw earlier that the crisis has cost this country $78 billion yearly[30,31]. That figure only accounted for medical costs. President Trump's Council of Economic Advisers estimated that the opioid drug epidemic cost our country $504 billion in 2015 alone, which includes lost lives, lost productivity, health care, criminal justice and miscellaneous costs[43]. Financial experts today have estimated fixing costs anywhere from $450 million yearly to $60 billion over 10 years[43]. The Energy and Commerce Committee has advanced 57 bills to combat the Opioid crisis[44]. In April of 2018 the bipartisan Senate health committee unanimously approved The Opioid Crisis Response Act of 2018[45]. The U.S. government will spend at least $4.6billion in 2018 which is part of a $1.3 trillion budget appropriation that President Trump signed[46]. It is glaringly apparent that this crisis is expensive beyond measure and will take the cooperation of all levels of government and society to correct.

Conclusion-Summary

The Opioid crisis in America has its roots as far back as the mid 1800's[4]. For a period of 134 years we saw control of opioids being attempted post-Civil War until 1995 when Oxycontin was marked by Purdue Pharma[4]. From that time to date the U.S. has been in an opioid crisis which has cost hundreds of thousands of lives and billions of dollars[29,32,33]. Many solutions have been implemented to combat this on the personal level. These solutions include education of the public and professionals[33-35], the administration of Naloxone to reverse opioid effects[40,41], limiting the number of pills and refills prescribed[39], monitoring numbers of prescriptions and prescribers[37], doing screening exams to detect addictive tendencies[36], and having patients sign opioid agreements/contracts[38].

The government has seen the passing of 57 bills to include the Opioid Crisis Response Act of 2018[44-46]. Billions have already been spent and more billions to be spent futuristically to begin the fix[46]. Only time will tell if and when we can get back to “doing no harm”.

Appendix

Table 1.[4] Historical Timeline of Narcotic Appearance in the U.S.

1861-5	Civil War Medics Use Morphine on battlefield as pain reliever
1898	Heroin is first produced commercially[5]
1914	Congress passes the Harrison Narcotics Act which requires doctors to write prescriptions for narcotic medications.
1924	The Anti-Heroin Act bans the production and sale of heroin in the U.S.
1970	The Controlled Substance Act becomes law. Groupings and Schedules appear.
1980	New England Journal of Medicine publishes a paper that looked at a very specific subset of patients in the hospital getting narcotic pain medication and incidences of addiction. They were closely monitored. This was not a study and the paper eventually became widely cited that narcotics were a safe treatment for chronic pain.
1995	Oxycontin, a long acting potent narcotic pain medicine is aggressively marketed as a safe pain pill.
2007	Federal government brings criminal charges against Purdue Pharma for misleadingly Advertising Oxycontin as safer and less addictive than other opioids.
2010	FDA approves an “abuse-deterrent” formulation to Oxycontin to help curb abuse.
2015	DEA announces the arrest of 280 people, including 22 doctors and pharmacists after a 15-month sting operation centered on health care providers who dispense large amounts of opioids.
2016	CDC publishes guidelines for prescribing opioids for patients with chronic pain.
2017	In March, President Trump signs an executive order calling for the establishment of the President’s Commission on Combatting Drug Addiction and the Opioid Crisis. In July, the White House Panel releases a report asking Trump to declare a national public health emergency to combat the ongoing crisis. In August, President Trump announces that a stronger law enforcement response is needed. In September, CVS pharmacy chain announces implementation of new restrictions on filling opioids and limits dispensing to 7-day supply. In October, Trump declares a national public health emergency to combat the crisis.

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