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Abstract

In response to the demand for adequate treatment of pain, providers began prescribing more opiates in the 1990s. Methadone was soon recognized as a cheap, long acting pain reliever and was added to preferred drug lists in the United States. As methadone prescriptions increased, so did opioid related deaths, especially among Medicaid patients. In 2006 the CDC and FDA began issuing warnings against using methadone for the treatment of chronic pain; and in the years that followed methadone overdoses began to subside for individuals under 55 years of age. For those 55 and over, however, the methadone overdose rate has not declined. Methadone is a dangerous medication with a variable half life. Although methadone accounted for only 1% of all opioid prescriptions in the year 2014, it was involved in nearly one fourth of all prescription opioid related deaths. Moreover, many insurers continue to list methadone as a preferred drug, and health care providers continue to prescribe methadone. Research shows that Medicaid recipients are prescribed methadone at twice the rate of privately insured individuals. Prescribing a medication as dangerous as Methadone due to its lower cost violates the bioethical precept of justice. This article discusses the ethical considerations involved in prescribing methadone for the treatment of chronic pain.

Death by Methadone (DBM)

Methadone is a long acting opioid approved by the FDA for the treatment of heroin addiction as well as moderate to severe pain (FDA, 2006). Rates of DBM were highest from 2005 to 2007, and have since declined in response to the numerous warnings issued by the CDC and the FDA (Jones, Baldwin, Manocchio, White, & Mack, 2016). This overall decline, however, applies only to those under age 55. The DBM rate has actually held steady for the 55 to 64 year old cohort and has increased among persons 65 years and older (Rudd, Seth, David, & Scholl, 2016). A study of methadone distribution, diversion and overdose deaths from 2002 to 2014 revealed increased diversion and overdose in response to increased prescribing of methadone for pain (Jones et al., 2016). While methadone accounted for only 1% of opioid prescriptions in 2014, the drug was involved in approximately 23% of all opioid related deaths for that year (Faul, Bohm, & Alexander, 2017). Because of the high mortality rates associated with methadone, the CDC recommends that the drug be reserved strictly for the treatment of opiate addiction or cancer and palliative care pain (CDC, 2012). In 2015, the latest year for which data has been collected; methadone use resulted in 3,301 deaths in the United States (Rudd et al., 2016). It is important to note that the CDC has found that DBM primarily involves methadone prescribed for chronic pain; not the daily doses dispensed from methadone maintenance drug programs for the treatment of narcotic addiction (CDC, 2012). The ethical underpinnings of health care include the principles of justice, non-maleficence, beneficence, and autonomy. The intent of this article is to examine the ethical considerations related to the prescribing of methadone for non-cancer pain.

Background

First introduced in the 1960's as a treatment for heroin addiction, methadone continues to be a mainstay in the treatment of intravenous drug abuse (Woody, 2017). In the 1990s patient advocacy groups began raising awareness of the under treatment of pain in our society (Franklin, 2014). The Joint Commission for Hospital Accreditation then began to push healthcare providers to record pain levels as the fifth vital sign (Ballantyne & Fleisher, 2010). What followed was the "decade of pain control" from 2000 to 2010, as pharmaceutical companies increasingly marketed opioids to prescribers for the treatment of chronic pain (Perret & Rosen, 2011, p. 1364).
In response there was an increase in opiate prescribing. Beginning in the late 1990's methadone was increasingly prescribed for non-cancer pain due to its long half life, low cost, and effectiveness against resistant pain (Modesto-Lowe, Brooks, & Petry, 2010). In order to save money in the early 2000's state Medicaid plans began listing methadone as a preferred long acting drug for the treatment of pain. As methadone was increasingly prescribed for pain, statistical data revealed a concurrent increase in DBM rates (Substance Abuse and Mental Health Services Administration [SAMHSA], 2012). While overall DBM rates have experienced a downward trend since 2008, the methadone death rate is on the rise in persons 65 years and older (Rudd et al., 2016). Research has found that health care providers "are inadvertently serving as a significant source of abused prescription opioids" (Inciardi, Surratt, Cicero, & Beard, 2009, p. 547).

A dangerous drug

Statistical data gathered by the CDC surrounding opioid overdose has shown that methadone is unsafe for treating chronic pain (Jones et al., 2016). There is a direct correlation in the prescribing of methadone for non-cancer pain and the methadone death rate (CDC, 2012). The

variable half life of methadone is the primary reason that it is such a dangerous opioid (FDA, 2006). Depending on the individual, the methadone half life is 8 to 59 hours, yet the effects of pain relief end after only 4 to 8 hours (FDA, 2006). Thus, methadone metabolites build up in the body, placing the user at higher risks of respiratory arrest with each additional dose. A person in pain will want to take another pill earlier than recommended by the prescriber; unwittingly increasing the risk of overdose (Okolie et al., 2015). This is particularly dangerous in patients who are opiate naïve. Moreover, methadone is associated with prolonged QT intervals and torsades de point, a potentially lethal heart arrhythmia (Wedam & Haigney, 2013). Even at therapeutic levels methadone places users at risk of sudden death. A review of 177 cases of sudden death in patients that had taken opiates found that methadone was involved in 41 percent of the cases, while only 7 percent involved other opioids (Chugh et al., 2008). The FDA found that as more physicians began prescribing methadone for pain management, the DBM rate rapidly increased (FDA, 2006). Despite the FDA's warnings, many prescribers, however, continue prescribing the drug for chronic pain (Ray et al., 2015). In a study reviewing health care provider compliance to opioid prescribing guidelines, Khalid et al. (2015) found that prescribers were only partially compliant with established guidelines.

Ethics of prescribing

The ethical principle of beneficence is the obligation to do good and "contribute to the overall welfare of patients" (Peirce & Smith, 2013, p. 11). In keeping with this principle, methadone should be avoided in lieu of safer alternatives. Medical examiner data has shown that 75% of victims of DBM in 13 states were not participating in a methadone maintenance program (CDC, 2012). The Researched Abuse Diversion and Addiction Related Surveillance System found that 70 percent of DBM cases from 2003 to 2006 had no prescription and were not participating in a

methadone maintenance program (Center for Substance Abuse Treatment [CSAT], 2009). This demonstrates that methadone is associated with a high rate of diversion and should be prescribed in only the most desperate cases (Modesto-Lowe et al., 2010). In the CDC's July 2016 Morbidity and Mortality Weekly Report, Jones et al. (2016) found that the continued prescribing of methadone to treat chronic pain is directly related to the number of deaths from opioid use.

The principle of beneficence must also be followed by insurers. The CDC has recommended that Medicare part D (prescription drug coverage) insurers, as well as other major third party payers remove methadone from their respective preferred drug lists (CDC, 2012). Such an act by insurers across the United States would satisfy the principle of beneficence: to do good. Methadone, however, is cheaper than other long acting opioid analgesics (Modesto-Lowe et al., 2010). While many Medicaid plans have pulled methadone from their preferred drug list, a number of states and prescription drug plans continue to list methadone as a preferred long acting narcotic for the treatment of pain (Carefirst, 2017; Kaiser, 2017; Vestal, 2015). Although quantity limits are required, the preferred (tier one) designation allows the prescribing of methadone without prior authorization, and does not require step therapy. A 2014 review of opioid prescribing practices found that Medicaid recipients are prescribed methadone at twice the rate of commercially insured individuals (Faul et al., 2017). The Center for Medicaid and Medicare services issued an informational bulletin in 2016 indicating that Medicaid insured individuals are 3 to 6 times more likely to die of prescribed opiate overdose, in contrast to those with non-Medicaid insurance plans (Wachino, 2016). Such data reveals a violation of the ethical principle of justice, which consists of the fair and equal treatment of all people regardless of socioeconomic status (Peirce & Smith, 2013). The concept of prescribing a medication as dangerous as methadone simply because it is cheap is unjust.

The ethical principle of autonomy represents the right of self determination (Peirce & Smith, 2013). The increasing reports of opioid overdoses (Rudd et al., 2016), however, demonstrate that patients are not qualified to choose their own pain medication. Moreover, many patients decide to sell their prescription medication for profit, an illegal practice known as diversion (CSAT, 2009). Unfortunately, prescribers can rarely tell the difference between a patient who is sincerely requesting medication for pain and the patient who is intent on selling their medications (Inciardi et al., 2009). While patients do have the right to autonomy, they do not have the right to break the law and sell their narcotic pain medications. If healthcare providers continue prescribing methadone, then they become another link in the chain of diversion. Research has shown that diversion occurs in elderly patient populations (Inciardi et al., 2009). A survey of prescription drug dealers in Delaware revealed the deceptive tactics used by elderly patients who were easily able to obtain prescription narcotics from healthcare providers by complaining of pain, even if they had no pain (Inciardi et al., 2009). It was further noted that most of these elderly patients were diverting their medications as a means of extra income. The concept of diversion explains why SAMHSA (2012) found that 75 percent of DBM victims from 13 states in 2009 did not have a prescription for the medication within 60 days of lethal overdose. Moreover, the CDC has documented a “strong positive correlation” with respect to DBM and methadone distribution and diversion (Jones et al., 2016). According to Maumus (2015), patients who are abusing prescription medications are not able to act in their own best interest. While autonomy is the hallmark of ethics in healthcare, prescribers must employ paternalism to protect the patient from abusing and diverting opioid medications. In a paternalistic approach, the prescriber develops a treatment plan that is most beneficial to the patient, especially in situations where the patient

should not choose for themselves (Peirce & Smith, 2013). Prescribing must be guided by what is best for the patient, not necessarily by what the patient wants (Perret & Rosen, 2011).

Conclusion

There is a high rate of diversion with methadone prescribing, which contributes disproportionately to the opioid overdose rates in the United States (Jones et al., 2016). Moreover, it is a disturbing fact that DBM has a "disproportionate impact on Medicaid beneficiaries" (Wachino, 2016, p. 2). Despite mounting data against the use of methadone for non-cancer pain, there are drug plans that continue to list methadone on their preferred drug list (Carefirst, 2017; Kaiser, 2017). A number of state Medicaid plans also continue to list methadone as a preferred drug (Vestal, 2015). The increased prescribing of methadone in primary care and pain management has made the drug more accessible for increased diversion and abuse among individuals who have no prescription (SAMHSA, 2012). Therefore, action is needed to stop the continued prescribing of methadone for chronic pain. Both the CDC and the FDA have found that further policy changes are needed to end inappropriate prescribing of opioids (CDC, 2012; FDA, 2006).

In treating heroin addiction, a prescriber must register with the DEA in order to prescribe and dispense methadone from a narcotic treatment facility (Green, Kellogg, & Kreek, 2004). However, any health care provider who is approved to prescribe schedule II narcotics can prescribe methadone for chronic pain. As a point of reference, cough syrup with codeine, as well as oxycodone, hydromorphone, fentanyl, and morphine are also schedule II narcotics (CSA, 1970). Unfortunately, health care providers continue writing prescriptions for methadone to treat non-cancer pain (Jones et al., 2016). If an opioid medication is prescribed to the poor simply because it is cheaper, even though there are safer, albeit more expensive alternatives; then it

follows that the prescribing of the cheaper, but more dangerous medication is an unethical choice.

The FDA could revise the indications and usage of methadone to exclude chronic pain. Insurers could remove methadone from their preferred drug lists. Pharmacies could even refuse to fill prescriptions for methadone. This will not, however, relieve prescribers from the responsibility to prescribe morally and ethically. Most providers know that some patients will insist on opiate medications. Nonetheless, in each and every patient interaction there remains the responsibility of beneficence: to do good. As healthcare providers, please keep in mind that there is no obligation to provide a treatment that will do more harm than good, even if a patient is demanding it (Ballantyne & Fleisher, 2010).

Clinical Resources

1. CDC Guidelines for opiate prescribing: https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm

2. US Preventive Services Task Force: Screening in primary care setting for illicit drug use: www.uspreventiveservicestaskforce.org/Home/GetFile/1/559/drugsys/pdf

3. Harm Reduction coalition - Overdose prevention: http://harmreduction.org/issues/overdose-prevention/

4. Substance Abuse and Mental Health Services Administration : https://www.samhsa.gov/

5. National Institute on Drug Abuse: https://www.drugabuse.gov/

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