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CONTRACEPTIVE COUNSELING PRACTICES AMONG PROVIDERS PRESCRIBING OPIATES TO WOMEN OF CHILDBEARING AGE

by

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A Thesis Submitted in Partial Fulfillment of the Requirements for a Degree with Honors (Nursing)

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Abstract

Opiate use has reached epidemic levels in the United States, resulting in 28,647 deaths in 2014 alone. Prenatally, opioids are used for both pain management and to assist with opiate dependency. The level of risk associated with the use of opiates is much higher for pregnant women, and women of childbearing age, due to the detrimental effects opiates have on the developing fetus including, neonatal abstinence syndrome (NAS). Maine is leading the nation in the number of NAS births with incidence rates of greater than 30 per 1,000 hospital births. Pregnancy prevention is an upstream approach to reduce unintended pregnancy and prevent NAS. The purpose of this study is to examine providers' preconception counseling processes among women of childbearing age who are prescribed opiates. This descriptive study followed survey research design. The survey questions were developed based upon the evidence based practice framework, which involves assessment of patient values, application of best available evidence, and clinical judgement. Data from this study will provide preliminary information about the current preconception counseling processes provided to women of childbearing age who are prescribed opioid analgesics. The long-term goal of this research is to reduce the number of unintended pregnancies among women who are prescribed opioid analgesics. This will help to promote public health, and reduce the detrimental effects that the opiate epidemic has on the community.

Keywords: neonatal abstinence syndrome, contraception, addiction

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List of Abbreviations

- AAP-American Academy of Pediatrics
- AMA-American Medical Association
- ACOG-American College of Obstetricians and Gynecologists
- APS-American Pain Society
- CDC- Centers for Disease Control and Prevention
- DHHS- Department of Health and Human Services
- EBP- Evidence-based practice
- IUD- Intrauterine device
- LARC- Long acting reversible contraception
- NAS-Neonatal abstinence syndrome
- NGC- National Guideline Clearinghouse
- NIDA-National Institute on Drug Abuse
- WHO- World Health Organization

Contraceptive Counseling Practices Among Providers Prescribing Opiates to Women of Childbearing Age in the United States

In the United States, the increasing use of opiates, both prescription medications and illicit drugs, has reached epidemic proportions. Over the past fifteen years, drug overdose deaths have nearly tripled, leading to 28,647 deaths in 2014 alone (CDC, 2016 December). The risks associated with opiate use are much higher for pregnant women due to the detrimental effects on the developing fetus, including NAS. Symptoms of NAS include: mottled skin, high-pitched crying, hyperactive reflexes, irritability, poor feeding, rapid breathing, tremors and seizures, and occur because the baby is withdrawing from the opiates they were exposed to in utero. Forty to eighty percent of neonates who are exposed to opiates develop NAS, requiring prolonged hospitalization and pharmacotherapy. (Yazda, Desai, & Brogly, 2015). Amongst women using opiates, 86% of pregnancies are unintended (Barfield, 2016). It is important to understand that NAS can result from the use of both illicit drugs and prescription medications. Although the detrimental effects of this epidemic can be seen across the country, certain states are more heavily affected than others. On average, one person died every day from a drug overdose in Maine in 2016. (Maine Attorney General, 2017). The rate of NAS in Maine is also higher than the national average, with a prevalence rate of than 30 per 1,000 hospital births (Barfield, 2016).

Literature Review

History of the Issue

Several factors have contributed to this epidemic, including the aggressive marketing of OxyContin. When Purdue Pharma introduced OxyContin in 1996 it was aggressively marketed, resulting in sales growth from \$48 million in 1996 to almost \$1.1 billion in 2000 (Van Zee, 2009). Rural states with unsophisticated primary care, including Maine, were targeted. From 1995 to 2001, the number of patients in Maine being treated for opioid abuse increased by 460% (Van Zee, 2009). Another factor that contributed to the over prescribing of opiates was the emergence of "pain as the 5th vital sign". In 1996, the APS introduced this in order to improve pain assessment and management (National Pharmaceutical Council, 2006). This initiative emphasized that the pain assessment was an important aspect of a patient assessment, and that physicians need to act when a patient reports pain. By 2000, the rate of prescribing OxyContin in Maine was 5 or 6 times higher than the national average, which was one of the highest in the country (Van Zee, 2009).

Current evidence on prescribing opiates to women of childbearing age

There are two main uses of prescription opioids in pregnancy: pain management and opioid dependency treatment. Pain is commonly reported in pregnancy, with prevalence rates of low back and pelvic pain between 68-72%. Both opioid analgesics and non-steroidal anti-inflammatory drugs (NSAIDs) are used as pharmacological treatments for acute pain. However, guidelines published from the APS recommend minimal, or no use, of opioids during pregnancy. The Food and Drug Administration (FDA) classifies these drugs as Pregnancy Category C, which indicates evidence of

potential harm to the fetus. Despite documented evidence of adverse effects on fetal development, there are consistency high documented rates of prenatal use; pregnant women from 47 states with Medicaid insurance reported that 21.6% of women filled at least one opioid prescription during their pregnancy (Yazda, Desai, & Brogly, 2015).

Addiction is classified by the four "C" s: impaired control over drug use, compulsive use, continued use despite harm, and craving (Seikel, 2012). The use of injection drugs, such as heroin, during pregnancy is associated with poor nutrition and anemia, high risk of infectious diseases such as HIV and hepatitis, inadequate prenatal care, and expose the patient to a significant risk of overdose (Newman, 2017). In 2014, the World Health Organization (WHO) published guidelines for the identification and management of substance use and substance use disorders in pregnancy. These were developed primarily as a tool for health care providers who manage women from conception to birth, during the postnatal periods, and their infants. These evidence-based recommendations allow health care providers to apply scientific principles when identifying and managing substance use disorders in pregnant women. There are five overarching principles of the guideline: prioritizing prevention, ensuring access to prevention and treatment services, respecting patient autonomy, providing comprehensive care, and safeguarding against discrimination and stigmatization (WHO, 2014). Although this guideline addresses the importance of ensuring access to resources, as of 2010 only 19 U.S. states had drug treatment programs for pregnant women and only 9 gave priority access to pregnant women (Patrick, et al., 2012).

Methadone maintenance therapy (MMT) has been used in the United States since the 1960's and is now considered to be the standard of treatment for opioid dependency

during pregnancy (Yazda, Desai, & Brogly, 2015). The goals of pharmacotherapy include: prevention or reduction of withdrawal symptoms and craving, prevention of relapse to use of illicit drugs, restoration of physiological function disrupted by drug use, and a blockade of the euphoric effects of illicit self-administered opiates (Seikel, 2012). Benefits of MMT include improved prenatal care adherence, reduced fetal death rates, and higher infant birth rates compared to illicit drug use alone. Although MMT has been proven to be the gold standard of treatment, only 37% of pregnant women reporting opioid abuse at admission to a substance treatment center received this therapy (Yazda, Desai, & Brogly, 2015). There are many significant obstacles to implementing methadone treatment, including the stigma associated with pharmacological treatment of and misconceptions regarding the nature of addiction.

Current evidence on contraception and counseling

In 2014, the CDC published recommendations for providing quality family planning services. One of the recommendations states that "providers should use a tiered approach to presenting a broad range of contraceptive methods (including [LARC] such as intrauterine devices and contraceptive implants), in which the most effective methods are presented before less effective methods," (NGC, 2014, page 6). LARC devices have the ability to prevent unintended pregnancy because of the ease of use, safety, and efficacy associated with their use. There are several different types of LARC devices including a copper IUD, a hormonal IUD, and an implant. The hormonal IUD releases progestin, and has been approved for use for three to five years. The copper IUD does not contain hormones and can remain in the body for up to ten years. The implant is a flexible rod which releases progestin into the body, and once inserted into the upper arm,

can remain for up to three years. During the first year of typical use fewer than 1 in 100 women using an IUD or an implant will become pregnant (ACOG, 2016). This is the same efficacy rate as sterilization, but these options are completely reversible. An assessment of the 2006-2010 National Survey of Family Growth data was conducted and found that 13% of postpartum women using short-acting hormonal contraception had a pregnancy within 18 months compared to 0.5% of LARC users (Turok, Gawron, & Lawson, 2016). There are many other benefits to LARC including the fact that it does not depend on patient compliance to function properly. Unlike other birth control options, once it is in place the patient does not have to do anything further to prevent pregnancy.

Although LARCs are currently the most effective form of contraception, there is opposition to their use. There is a misconception that having an IUD increases the risk for developing upper genital tract infections. However, this is an outdated belief which is not supported by evidence and should not be considered a barrier to utilization (Turok, Gawron, & Lawson, 2016). There has also been concern regarding the safety of LARC use in pediatric patients. However, a recommendation in the 2014 NGC guidelines states that, "education about contraceptive methods should include an explanation that LARC is safe and effective for nulliparous women, including adolescents," (NGC, 2014, page 9). Both the AAP (AAP, 2014) and the ACOG (ACOG, 2012) support LARC methods as first-line choices for adolescents, and recommend LARC without restriction for nulliparous women. There are two important concepts regarding LARC use in clinical practice: reducing cost barriers to IUDs and implants, and improving patient counseling on the superior efficacy and satisfaction associated with these devices (Turok, et al., 2016).

Assumptions/biases surrounding substance use during pregnancy

From 2000 to 20009, the number of delivering mothers using or dependent on opioids rose nearly five-fold, and annual rates of NAS diagnosis increased almost 3-fold (Patrick, et al., 2012). There have been adequate and extensive studies into the effects of opiate use during pregnancy in order to gain a better understanding of the problem and initiate change. There are many factors associated with unplanned pregnancy and increased risk factors when substance use is involved. Women using opiates are reported to begin antenatal care late, tend to have underlying medical conditions, and a higher incidence of obstetric complications (Harding, 2003). There is an inaccurate perception of risk of pregnancy documented amongst opiate users. Opiate use can cause amenorrhea, a lack of a menstrual period, which is one reason why women using opiates may believe they cannot become pregnant (Harding, 2003). Due to this inaccurate perception, there is a high percentage of sexually active women prescribed methadone and other opiates who report using no contraception or less reliable methods. In order to develop a personalized plan of care, health care providers need to assess each woman's perceived pregnancy risk and desire for future pregnancies, along with including a discussion about contraception methods (Harding, 2003).

For pregnant women, there is a lot of fear and stigma surrounding addiction treatment. There are four factors that contribute to the stigma surrounding addiction and treatment (Olsen & Sharfstein, 2014). First, there is a misunderstanding that addiction is not a medical illness, but instead a moral weakness or willful choice. However, the NIDA classifies addiction as a chronic disease, similar to other chronic diseases such as type 2 diabetes, cancer, and cardiovascular disease (NIDA, 2016). The separation of addiction

treatment from the rest of health care has also contributed to this stigma. This separation means that physicians who are treating these patients aren't necessarily considering other substance abuse disorders, mental health conditions, and their overall physical health (Olsen & Sharfstein, 2014). The language used to discuss addiction mirrors and perpetuates this stigma, for example, urine test results are often called "clean" or "dirty," rather than "positive" or "negative" (Olsen & Sharfstein, 2014). The criminal justice system's treatment of addiction often fails to defer to medical judgement. For example, when incarcerated, people relying on methadone or buprenorphine replacement therapy are not always allowed to continue their treatment. It is estimated that 15% of people entering America's prison system each year are addicted to heroin, with many of those enrolled in methadone treatment at the time of their arrest (Mitchell, et al., 2010). Although this highlights a need for safe and effective treatment, or continuation of treatment for those enrolled, the majority of U.S. prisons and jails reported that they do not provide any medications for opioid detoxification (Mitchell, et al., 2010).

The stigma surrounding addiction is a barrier to care, because if women are too afraid to advocate for themselves they will not receive the resources they need. Seventy three percent of women reported that during their pregnancies they were afraid of testing positive for substances at prenatal visits or delivery, losing custody of their newborns, and experiencing criminal justice consequences (Stone, 2015). This fear is one of the reasons why many women using opiates report receiving late or inadequate antenatal care, which is linked to many poor health outcomes for the fetus. A cohort study was conducted using data from the Center for Disease Control and Prevention's (CDC, 2016) Linked Birth-Infant Death and Fetal Death data on all deliveries in the United States

between 1995 and 2002. Results from this study show that the risks of prematurity, stillbirth, early and late neonatal decease, and infant death increased linearly with decreasing care (Patridge, Balayla, Holcroft, & Abenhaim, 2012).

State Responses to the Issue

States vary in their approach to substance exposure in pregnancy. Eighteen states consider substance abuse during pregnancy to be child abuse. Tennessee is the only state that allows for assault charges to be filed against a pregnant woman who uses substances (Guttmacher Institute, 2014). However, both the AMA (AMA, 1990) and ACOG (ACOG, 2005) both oppose legislation criminalizing maternal drug addiction, as it leads to reduced prenatal care. A report from the AMA states, "pregnant women will be likely to avoid seeking prenatal or open medical care for fear that their physician's knowledge of substance abuse or other potentially harmful behavior could result in a jail sentence rather than proper medical treatment" (AMA, 1990). In many states, including Maine, pregnant women have priority access to substance abuse treatment programs (Guttmacher Institute, 2014). Although it is important that pregnant women have access to these services, a concern with giving them priority is that women will become pregnant to avoid the long wait lists at clinics.

Theoretical Framework

The questions in the survey are based upon the EBP framework, which includes best available research, patient values, and clinical judgement. The purpose of this framework is to move from a health care delivery system based on tradition, intuition and authority, to one that is guided and justified by the best available evidence (Leech, 2006).

Purpose

This descriptive study aimed to understand current preconception counseling practices among providers who prescribe opiates to women of childbearing age.

Method

Participant Population

Providers at primary care and pediatric institutions within Penobscot Community Health Care and Centers for Family Medicine in Penobscot County, Maine were targeted because primary care providers account for about half of opioid pain relievers dispensed and care for women (Daubresse et al., 2013).

Measurement

The questions aimed to assess provider's application of current evidence about contraception and counseling, the provider's assessment of patient values, and provider's clinical judgement. Each question addressed different components of the EBP framework.

- I. Provider's application of current evidence about contraception and counseling
 - i. When prescribing opiates to a woman of childbearing age, how likely are you to recommend contraception?

- ii. When discussing contraception, how likely are you to recommend long acting reversible contraception (LARC)?
- iii. When discussing LARC, how likely are you to recommend this method to adolescents and nulliparous women?
- II. Provider's assessment of patient values
 - Please rate the degree to which you agree or disagree with the following statement: "Providing patients with educational materials relating to the effects of opiates on pregnancy and recommending LARC would decrease the number of substance dependent babies born in Maine"
 - Please rate the degree to which you agree or disagree with the following statement: "Providing women with education about the effects of opiates on pregnancy will influence the patient's decision to take them."
- III. Provider's clinical judgement
 - i. When prescribing opiates to a woman of childbearing age, how likely are you to provide information about the risks of preconception, antenatal, and postnatal use of opiates?
 - ii. What do you think is the most significant barrier to LARC use?

Procedure

The practice director at each location was contacted via e-mail to determine their willingness to participate. The survey was sent electronically via Qualtrics survey research software to each practice director, who then distributed it amongst the providers of their organization. The responses to the survey remained anonymous. Data was stored into a spreadsheet within Qualtrics on the University of Maine Server system with strong privacy controls. Resulting data was accessible only to the research team. All data was deleted after completion of the study.

Results

Of the 29 providers who participated in the survey, 16 were physicians, 7 were resident physicians, and 6 were nurse practitioners. Twenty-one of the participants were female, and 8 were male. The participants ranged in age from 25 to 65+. When prescribing opiates to women of child-bearing age, 37.93% of providers responded as extremely likely to provide education about the risks and benefits of their use, while only 6.90% were extremely unlikely (Table 1). Providers were much more likely to provide contraception counseling, with 51.72% of providers responding as extremely likely (Table 2). Although the majority of providers are discussing LARC (Table 3), the most significant barrier to their use is patient understanding of safety and efficacy (Table 7). Results of the study show that although 41.38% of providers strongly agree that providing educational materials will decrease the rate of NAS (Table 5), only 24% of providers agree that providing improved education will influence the patient's decision to use opiates (Table 6).

Conclusion

Maine is being heavily impacted by the effects of the opiate epidemic, especially in regards to the prevalence of NAS. This can occur as the result of both illicit drugs and prescription medications, which drives the need for further public education. When prescribed opiates, women of child bearing age need to be informed of the risks related to their use, along with the benefits of contraception. Contraception counseling can be improved using tools developed by ACOG, which specifically address LARC. LARC is the most effective form of contraception, which requires no patient compliance and poses no safety risks. When providing patient education, health care providers need to determine each patient's level of health literacy to determine which learning style would be most effective. Improving contraception counseling will help to reduce the rate of unintended pregnancies amongst women taking opiates and decrease the number of babies born with NAS.

Nursing Implications

The results of this study highlight the need for improved patient education on LARCs. Fifty one percent of providers stated the most significant barrier to use was patient understanding of safety and efficacy (Table 7). This is an important nursing intervention, as providing patient education is one of the most important roles of the nurse. Health literacy is defined as, "the degree to which individuals can obtain, process, and understand the basic health information and services they need to make appropriate health decisions" (Berkman, et al., 2011). Only 12% of adults in the United States have proficient health literacy, and over a third of adults would have difficulty with common health tasks, such as following directions on a prescription drug label (DHHS, 2008).

Health literacy is lowest among those with lower education, racial and ethnic minorities, the uninsured and publicly insured, and the elderly (Berkman, et al., 2011). Before performing patient teaching, each patient's level of health literacy needs to be assessed to determine barriers to learning. Incorporating the use of educational materials such as brochures and handouts is one way to improve patient teaching. The American Congress of Obstetricians and Gynecologists (ACOG) website has several different patient resources that providers can utilize. ACOG has specifically developed a LARC program which has a variety of resources including clinical guidance and educational materials for patients. The purpose of this program is to help reduce unintended pregnancy by providing improved information and resources on LARC. (ACOG LARC Program, 2017).

Although improving education tools and resources will increase the patient's understanding of the risks, it doesn't necessarily mean it will influence the patient's decision. The American Nurses Association (ANA, 2015) has published ethical principles of nursing, which include autonomy and beneficence amongst others. Autonomy is defined as the, "agreement to respect another's right to self-determine a course of action," while beneficence is defined as "taking action to help others" (American Nurses Association 2015). When providing education, nurses and providers need to be mindful to present the information in an open and unbiased way. Although LARC is the most effective form of contraception for women using opiates, it is ultimately the patient's decision to choose the option that is right for them. When providing options counseling, the nurse or provider should explain the reasoning behind their recommendations, which is the purpose of the EBP framework. Providers need to utilize their best clinical

judgement to provide patient education that is based upon the best available research and focused on the individual values of the patient.

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APPENDIX

When prescribing opiates to a woman of childbearing age, how likely are you to provide information about the risks of preconception, antenatal, and postnatal use of opiates?

Response	Number of Responses	<u>%</u>
Extremely likely	11	37.93%
Somewhat likely	7	24.14%
Neither likely nor unlikely	6	20.69%
Somewhat unlikely	3	10.34%
Extremely unlikely	2	6.90%

Table 2

When prescribing opiates to a woman of childbearing age, how likely are you to recommend contraception?

Response	Number of Responses	<u>%</u>
Extremely likely	15	51.72%
Somewhat likely	6	20.69%
Neither likely nor unlikely	3	10.34%
Somewhat unlikely	3	10.34%
Extremely unlikely	2	6.90%

When discussing contraception, how likely are you to recommend long acting reversible contraception (LARC)?

Response	Number of Responses	<u>%</u>
Extremely likely	23	79.31%
Somewhat likely	3	10.34%
Neither likely nor unlikely	3	10.34%
Somewhat unlikely	0	0%
Extremely unlikely	0	0%

Table 4

When discussing LARC, how likely are you to recommend this method to adolescents and nulliparous women?

Response	Number of Responses	<u>%</u>
Extremely likely	19	65.52%
Somewhat likely	5	17.24%
Neither likely nor unlikely	5	17.24%
Somewhat unlikely	0	0%
Extremely unlikely	0	0%

Please rate the degree to which you agree or disagree with the following statement: "Providing patients with educational materials relating to the effects of opiates on pregnancy and recommending LARC would decrease the number of substance dependent babies born in Maine"

Response	Number of Responses	<u>%</u>
Strongly agree	12	41.38%
Somewhat agree	10	34.48%
Neither agree nor disagree	4	13.97%
Somewhat disagree	3	10.34%
Strongly disagree	0	0%

Table 6

Please rate the degree to which you agree or disagree with the following statement: "Providing women with education about the effects of opiates on pregnancy will influence the patient's decision to take them."

Response	Number of Responses	<u>%</u>
Strongly agree	12	41.38%
Somewhat agree	10	34.48%
Neither agree nor disagree	4	13.97%
Somewhat disagree	3	10.34%
Strongly disagree	0	0%

What do you think is the most significant barrier to LARC use?

Response	Number of Responses	<u>%</u>
Provider's education	2	6.90%
Cost	2	6.90%
Health Care Access Barriers	10	34.48%
Patient understanding of safety and efficacy	15	51.72%