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Preconception Care of Women on Prescribed Opioids

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ABSTRACT

PRECONCEPTION CARE OF WOMEN ON PRESCRIBED OPIOIDS

The landmark 2015 report from the Center for Disease Control (CDC) posited that too many women of reproductive age received prescribed opioids. This is significant because fetal exposure to a known teratogen can have catastrophic outcomes. Furthermore, women are often ambivalent about birth control and many pregnancies are unplanned. Fortunately, women identify interactions with health care providers as acceptable cues for preconception decision making. Data has shown that Medicaid populations are disproportionately prescribed opioids compared to insured populations. However, the CDC defines reproductive status by age only. Therefore, the purpose of this research project was to identify women's actual risk for pregnancy as defined by presence or absence of menopause, sterilization, or long-acting, reversible birth control (LARC).

Rebecca-Maria Norwick DNP-c, FNP-BC, BC-ADM
May 2017

PRECONCEPTION CARE OF WOMEN ON PRESCRIBED OPIOIDS

by

Rebecca-Maria Norwick DNP-c, FNP-BC, BC-ADM

A project submitted in partial
fulfillment of the requirements for the degree of
Doctor of Nursing Practice,
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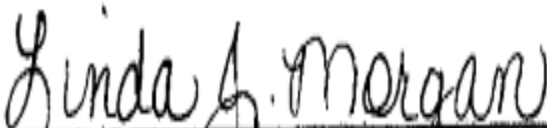
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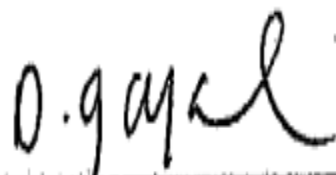
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CHAPTER 1: INTRODUCTION

The landmark 2015 report from the Center for Disease Control (CDC) posited that too many women of reproductive age received prescribed opioids (Ailes et al., 2015). This is significant because fetal exposure to a known teratogen can have catastrophic outcomes (Yazdy, Mitchell, Tinker, Parker, & Werler, 2013). Furthermore, women are often ambivalent about birth control and many pregnancies are unplanned (W. Mosher, Jones, & Abma, 2015). Fortunately, women identify interactions with health care providers as acceptable cues for preconception decision making. Data has shown that Medicaid populations are disproportionately prescribed opioids compared to insured populations (Ailes et al., 2015). However, the CDC defines reproductive status by age only. Therefore, the purpose of this research project was to identify women's actual risk for pregnancy as defined by presence or absence of menopause, sterilization, or long-acting, reversible birth control (LARC).

Background

Fetal exposure to opioids can have catastrophic consequences. Women taking opioids between one month before conception and two months post-conception risk miscarriage, birth defects, stillbirth, and newborn abstinence syndrome (Yazdy et al., 2013). The authors reported peri-conception opioid use in women correlating with a statistically significant 2.2-fold increase in risk of neural tube defects (or a prevalence of 5.9 per 10,000 live births). Broussard et al. (2011) revealed a statistically significant correlation between maternal opioid use and profound congenital cardiac, spinal, and intestinal pathology. Many pregnancies are not discovered until well after 4 weeks which greatly increases the chances of fetal exposure to opioids (Ailes et al., 2015). Weaning a pregnant woman off opioids can result in stillbirth (fetal abstinence syndrome)

so the standard of care is to switch her to methadone or buprenorphine and expect to wean the newborn off opioids (Cunningham, 2005; Yazdy et al., 2013).

The literature indicates that women are often ambivalent about birth control and many pregnancies are unplanned. Between 2006 and 2010, 37% of births in the United States were unintended and low income and less education correlated with higher rates (D. Mosher, Jones, & Abma, 2015). Borrero et al. (2015) found that women in one urban setting did not necessarily perceive that they had reproductive control nor clear pregnancy intentions. The benefits of a planned pregnancy were often not understood or valued. Women's behavior belied their intentions when actively seeking to avoid pregnancy. This mirrored qualitative work done in family planning clinics in the Midwest (Askelson, Losch, Thomas, & Reynolds, 2015).

Fortunately, women identify interactions with health care providers as acceptable cues for preconception decision making. The Health Belief Model (HBM), suggests that people will be more likely to change their health promotion activities when they identify obstacles to change and are prompted to have informed decision-making (Rosenstock, Strecher, & Becker, 1988). See Table 1 for the 6 basic constructs. The Expanded Health Belief Model (EHBM) was developed specifically to validate the Health Belief Model in the realm of preconception care of women with chronic disease (though with diabetes rather than chronic pain syndrome) (Charron-Prochownik et al., 2001).

Table 1

The six major cognitive constructs of (E)HBM.

1. Perceived susceptibility is an individual's belief of their own vulnerability to a problem.
2. Perceived severity is their belief about the seriousness of the problem.
3. Perceived benefits are an individual's belief that behavior change will result in a positive outcome.
4. Perceived barriers are an individual's belief in difficulties in implementing behavior change associated with a positive health outcome.
5. Self-efficacy is the confidence in one's ability to perform effective health behaviors.
6. Motivational cues represent triggers for the intention to change health behaviors.

Rich (2015)

Consider a 35-year-old female presenting to her advanced practice registered nurse (APRN) requesting treatment for severe sciatica. To change the patient's health promotion activity, the APRN can frame the interaction with the EHB (theory from Charron-Prochownik, 2001, case study by author). The patient is using the withdrawal method for birth control. As treatment for sciatica may include prescription of teratogenic medications (opioids and/or tricyclics), the APRN identifies the *intervention* as offering LARC to the patient. The individual perception is the patient's *perceived susceptibility* to pregnancy and *perception of the severity* (or serious nature) of an unplanned pregnancy (fetal withdrawal syndrome, birth defects) (Yazdy et al., 2013). Mediating and modifying factors include psychosocial factors, a religious objection to actively preventing pregnancy as well as *motivational cues* and the patient's rapport and trust in her APRN. Likelihood of action depends on the *perceived benefits of change* (initiating LARC or sterilization or titrating off the opioids), the patient's *self-efficacy* (does she defer to her husband on matters of reproduction?), and her *intent to change* her birth control method. The reproductive *health behavior outcome* is seeking preconception care as defined as willingness to engage in a conversation about her birth control method.

Studies have shown that women do, in fact, find shared decision-making with providers acceptable while provider driven or patient driven decision-making resulted in lower patient satisfaction in the process and the method chosen (C. Dehlendorf & Steinauer, 2012; C. Dehlendorf, Kimport, Levy, & Steinauer, 2014). The authors in both studies used the Four Habits Model for effective and efficient office visits and "investing in the end" was especially successful in improving the patient experience, even more so than Motivational Interviewing (C. Dehlendorf & Steinauer, 2012).

Behavior modification relates to both the APRN and her patient. Studies have shown that if clinicians are not confident in their LARC knowledge and skills, they are less likely to have high LARC adoption by their patients (C. Dehlendorf, Levy, Ruskin, & Steinauer, 2010). A meaningful interaction with her APRN can promote healthy behavior change in the patient by either choosing LARC or discontinuing the teratogenic medication. Furthermore, training providers in LARC improves LARC rates (Harper et al., 2015). Evidence based preconception care is important in chronic disease for the above reasons as well as those promoted by the Healthy People 2020 campaign: family planning improves the lives of women and children and permits teens and women to finish or advance their education; smaller families allow more investment in each child, resulting in improved educational and other outcomes (CDC, 2011).

Problem statement

The CDC looked at prescription claim data between 2008 and 2012 and found Medicaid opioid prescriptions significantly higher than private insurance opioid prescriptions in women between 15 and 44 years of age (Ailes et al., 2015). In the author's view, "All women who might become pregnant are at risk" (Ailes et al, 2015, pp. 1). The authors further went on to propose that too many women of reproductive age were receiving prescribed opioids. The 2016 CDC Guideline for Prescribing Opioids for Chronic Pain recommends discussing contraception and the impact of opioids on a pregnancy before starting opioid therapy in reproductive age women (Dowell, Haegerich, & Chou, 2016). However, the author's checklist for prescribing opioids for chronic pain does not mention reproductive health.

The county of the population of interest has a mandate to reduce the incidence of drug addicted newborns called Drug Free Redacted. A decade ago, nine drug addicted newborns were reported by the county every year. Between 2012 and 2014, it was approximately 25 newborns

every year (reference redacted). While this reflects national and state trends, it is twice the state average and likely due to county mandated universal screening questions for every pregnant woman (Tolia et al., 2015). There is no state requirement to drug test newborns or mothers. While much of this was illicit drug use, some was from diverted prescription opioids and maybe legally prescribed opioids (Warren, 2016). This is especially pertinent in the community health setting since the main finding of the Ailes et al (2015) research revealed that Medicaid populations are prescribed opioids at higher rates than insured. Furthermore, 41% of the births in the county are to women funded by MCAID (source redacted).

The Federal push for evidence based practice and opioid prescription is evidenced in their campaign: “Treating for Two” which endorses thoughtful prescription of medication before and during pregnancy (<http://www.cdc.gov/pregnancy/meds/treatingfortwo/index.html>). This is an outgrowth of the United States’ *Healthy People 2020* established family planning goal to promote pregnancy planning and spacing, and reduce unintended pregnancies (CDC, 2011).

A physician group with attention to preconception care of the chronically ill is the American Academy of Neurology (Fountain et al., 2015). Their Epilepsy Quality Measurement Set includes annual counseling for women of childbearing years. This could serve as a model for chronic pain guidelines around reproductive health. Unfortunately, their data shows that the guidelines are not being followed diligently with less than half of seizure patients receiving counseling on the effects of seizure medications on contraception (oral contraceptives become less effective) and pregnancy (birth defects and pregnancy complications). Neurologists themselves were unable to identify teratogenic medications (Fountain et al., 2015).

Purpose of Project

The purpose of this project was to analyze data from 145 female patients between the ages of 18 and 45 with a diagnosis of chronic pain syndrome. The research question was what percentage of these patients have received effective preconception care? Effective preconception care was defined not just by age but whether the woman had been prescribed LARC, was menopausal, or if she or her partner were sterilized. The population of interest were patients at a community health center on the West Coast of the United States of America. The institution is a large federally qualified health center (FQHC) that uses electronic medical records from which reproductive health data can be drawn. Overall, the FQHC patients were 51% Hispanic/Latino, 38% White, and 11% other. Eighty-two percent had incomes at or below the Federal Poverty Level, 39% were un-insured, and 41% had Medicaid (source redacted).

Uninsured men and women in this setting have access to free birth control (including sterilization) through the federal Title X program regardless of immigration status and LARC is available in-house. Male sterilization is available in-house and female sterilization is referred out: tubal ablation is same day surgery in the hospital and tubal occlusion in the gynecologist's office. Many of the unfunded patients are mono-lingual Spanish speaking immigrants from Mexico who work in the agriculture or service industry.

Low income women, minorities, and the less educated have much higher rates of pregnancies nationally (*Clinical preventive services for women: Closing the gaps*, 2011). Walker et al. (2010) found that low-income older minority patients have poorer access to health care due to higher out-of-pocket costs and transportation difficulties. The 2015 CDC report found the rate of opioid prescriptions filled for private insurers was significantly lower than those filled for Medicaid (Ailes et al., 2015) which replicated data from (Edlund et al., 2010).

One of the basic assumptions of the project was that long acting reversible contraception was the preferred choice for women on teratogenic medications. This was because of treatment adherence. Half of pregnancies in the United States are unintended and the rates are worse in women who are low income, minority, or less educated (Ailes et al., 2015). These unintended pregnancies correlate with birth control methods that are user dependent. Oral contraceptives are not very effective even when used perfectly and most women cannot remember to take a pill every day (Likis, 2014). Condoms are even less effective and are user dependent: incorrect use can cause them to break or slip off and they must be used for every sex act. The injectable contraceptive Depo-Provera requires that women return to the clinic every three months. On the other hand, while LARC requires specialized training for insertion and removal, it's use is not user dependent. The IUDs (3, 5, or 10 years) are as effective as surgical sterilization and the 3-year implant almost matches that. Importantly, women do not seem to mind this loss of control and the patient satisfaction rates are high and discontinuation rates are low (Likis, 2014).

Health Literacy

The population of interest is mostly high school educated, older white women on disability. This is relevant since the 2003 National Assessment of Adult Literacy found that a lower than average health literacy correlated with living below the poverty line and lower levels of educational achievement. Studies have also shown that lack of skills in health literacy results in adverse outcomes because of an inability to effectively manage chronic disease and difficulty taking medications as directed (Dickens, 2013). Hence, there is the need for birth control methods that do not require daily action on the part of the patient (e.g. LARC and sterilization).

On the other hand, researchers at Yale were looking at ways to increase community level awareness and approval of long-acting contraceptives (Anonymous, 2013). This study surveyed low income women and found that more than half were not sure that intra-uterine devices (IUDs) were safe or effective. Almost 75% didn't know if contraceptive implants were safe and effective (Anonymous, 2013). This contrasts with the international data on the popularity of LARC in developed countries outside the United States. The respondents in the study were more interested in LARC if they had a friend with the method. The researchers suggested social networks and peer educators as a good method for increasing community awareness and acceptance of LARC.

Legal and Ethical Issues

The treatment of chronic pain syndrome in women of reproductive age presents the ethical dilemma of prescribing a teratogenic medication to a woman who could become pregnant and the legal liability of catastrophic fetal outcomes. The ethical dilemma is that the rights of the individual demand that providers respect the patient's request for the opioid prescription. The rights of society demand that providers avoid exposing a fetus to opioids. The utilitarian view (hard paternalism) supports the CDC report of too many women of reproductive age on opioids but Kantian ethics promotes individual rights, informed consent, and patient autonomy and supports the argument that it is ethical and legal to prescribe a woman opioids when she has a reliable, first tier form of birth control (sterilization or LARC) (Rich, 2015). The greater good can still be served while respecting individual legal and ethical rights through a transparent conversation between the patient and her APRN.

Nature of the doctoral project

The research design for this DNP capstone project was a quantitative, descriptive, non-experimental, retrospective analysis of existing data. The Center for Disease Control (CDC) reported that too many women of reproductive age were receiving prescribed opioids (Ailes et al., 2015). The research question was: women of reproductive age who are receiving prescription opioids, what percentage have received effective preconception care? Data was analyzed using descriptive statistics.

Significance and Summary

The 2015 Ailes et al report from the CDC was a call to arms. APRN prescribers and others have the responsibility of safe and evidence based prescribing practices (Cronenwett et al., 2009) as well as comprehensive preconception counseling. Medicaid populations are disproportionately prescribed opioids compared to insured populations (Ailes et al., 2015). However, the CDC defines reproductive status by age only. This project seeks to identify women's actual risk for pregnancy as defined by presence or absence of menopause, sterilization, or long-acting, reversible birth control in an underserved patient population.

CHAPTER 2: LITERATURE REVIEW

The problem addressed in this doctoral project is based on the CDC report that too many women of reproductive age are receiving prescribed opioids (Ailes et al., 2015). The research question is “Of women of reproductive age who are receiving prescription opioids, what percentage have received effective preconception care in a community health setting?” In other words, the project expands the definition of reproductive state beyond just age and sex.

Ailes et al. (2015) performed a retrospective study of opioid prescription claims in Medicaid and insured populations from 2008 to 2012. They looked at millions of data points from women between the ages of 15 and 44 in the United States of America. The primary goal of this study was to determine the frequency and type of opioid prescription per patient. Descriptive statistics and a chi-square test were used for the analysis. Results showed that opioids were widely prescribed in women of reproductive age and there was a disparity between Medicaid and insured populations. The strength of this study was the sheer volume and validity of its data (not just opioids prescribed but picked up at the pharmacy) that replicated previous work. The weakness was the definition of reproductive status based on age alone without considering menopause, sterilization, or presence of long-acting birth control. This weakened their recommendations for further action. See Figure 1.

Ailes et al. (2015) was a retrospective analysis of data already collected by the Truven Health’s MarketScan Commercial Claims and Encounters and Medicaid data. This was a convenience sample of employed persons and their families as well as Medicaid data from 13 states. Geographic data was only available for private insurance claims and showed opioid use higher in reproductive age women in Southern United States than in the Northeast.

Women aged 15-44 years who filled a prescripti for an opioid medication, 2008-2012

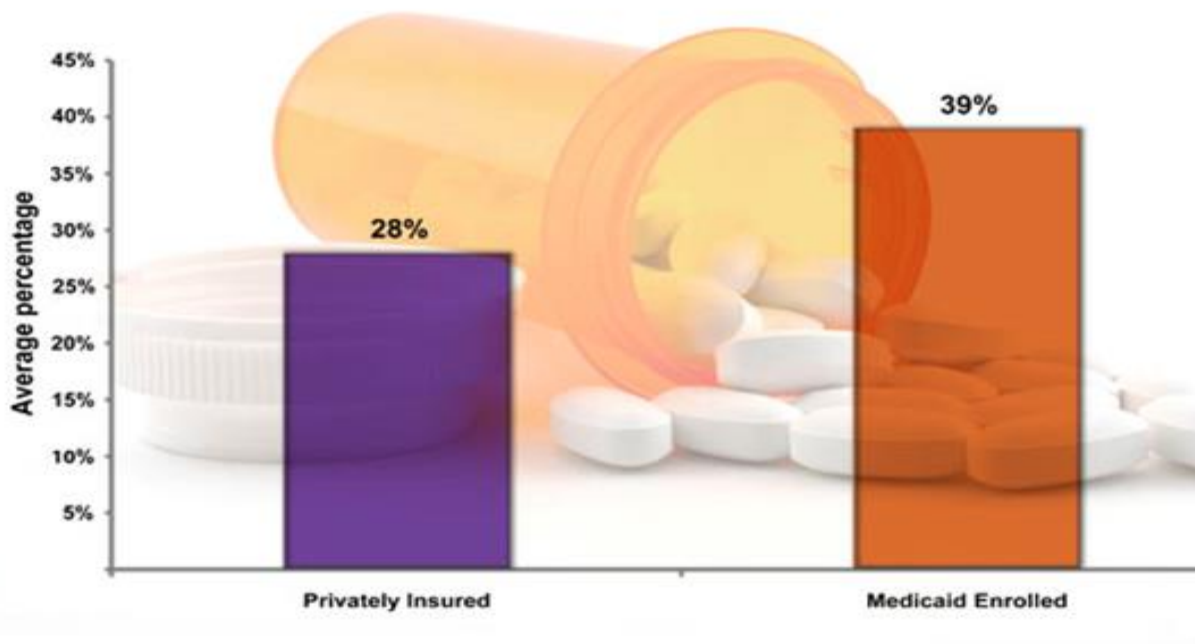


Figure 1. Ailes et al. (2015)

Ethnicity was only available for Medicaid claims which showed statistically significant higher rates of opioid prescription among white women as compared to black or Hispanic women. This validated previous work.

Askelson et al. (2015) published a qualitative study of 28 women (20-45 years of age) recruited via flyers in family planning clinics. Structured in-person and phone interviews done in 2012 in a rural mid-west state explored themes of ambivalence about unplanned pregnancy. Live coders, NVivo10 software, and the Braun and Clark process were used. The outcome showed that the women had both positive and negative feelings about pregnancy. Previous research had only revealed negative feelings. The authors elicited rich content from the participants but did not note if saturation was reached. Also, patients were prompted about having positive or negative feelings and the findings might not be applicable to more diverse, urban populations.

Broussard et al. (2011) performed a population-based case controlled study of infants from a national database (with birth defects versus without). A correlation was sought between unexplained birth defects (the outcome) and maternal prescription of opioids from 1 month preconception until the end of the third trimester. This was a very large, vigorous study including very specific correlations with distinct types of birth defects (more than 17,000 case mothers and 6,000 control mothers). However, the *n* for some birth defects was too small for strong statistical analysis. Demographics were collected so that the odds ratios could be adjusted. Mothers came from 10 states in the United States (West, East, and South) with most having not graduated from high school (82.2 %). Most were women between 20 and 40 years of age with 10.9% under 20 years and only 2.9% over 40 years. Ethnicity was 60% white and 23.2% Hispanic (black and other making up the rest) (Broussard et al., 2011). Multi-variable logistic regression analysis was

used to calculate the odds ratio and confirmed an association between opioid exposure and congenital heart defects.

Charron-Prochownik et al. (2001) conducted a multi-site, exploratory, case-controlled study of 80 female teens in diabetes clinics in Pennsylvania, New England, and the Midwest. Teens were reimbursed \$10 for completing a one hour phone interview examining their health care beliefs. Multi-linear regression and binary logistical regression of variables found that several major constructs of the expanded health belief model (EHBM) strongly correlated with behaviors and metabolic control (self-reported). Age was 16 to 20 years, most in school and coming from households with high school completion or higher. Most households had an income of \$20,000 or higher and the girls/women were insured 76.3% by private insurance and only 8.8% Medicaid (Charron-Prochownik et al., 2001). This validated previous work using EHBM but may not be applicable to other populations.

Christine Dehlendorf et al. (2014) used grounded theory techniques to examine the interaction between female patients and health care providers providing contraceptive counseling in family planning, primary care, and gynecology offices. They randomly chose and analyzed 50 interactions from a larger sample of 342 audio-recordings between 2009 and 2012 in the same region as the doctoral project. Live and computer-aided transcription (Atlas.ti) were utilized, reliability was determined by multiple coders, and thematic saturation was reached. The population was diverse but did not report whether the patients found their sessions helpful. Most patients had incomes at lower than 200% the national poverty rate (68%) and the birth control was covered by either publicly funded programs or private insurance. Most had education beyond high school (70%). The providers were all female and between 35-74 years and most were white (60%) (C. Dehlendorf et al., 2014). Three common styles of counseling approaches

were found: little discussion and method chosen by provider, informed choice, and shared decision making.

Harper et al. (2015) conducted a cluster randomized trial of long-acting reversible contraceptive use in 40 Planned Parenthood clinics in the Eastern United States (Pennsylvania). The outcomes were choice of IUD or implant as well as the pregnancy rates of 1500 women aged 18-25 years between 2011-2013. Generalized estimating equations were used for clustered data and survival analysis for the pregnancy rates. A large n and cluster format improved reliability and validity of results but the study may not be reproducible to other settings or provider types. This study was part of the Contraceptive CHOICE Program. Insurance of the patients was 30% private and 27.5% Medicaid with most having obtained a high school diploma or lower (73%). Ethnicity was 49.6% white, 27.2% Latina, and 14.8% black (Harper et al., 2015). The results were that pregnancy rates were reduced among patients whose providers (physicians/APRNs/PAs) received the intervention of extra training in LARC. This validated previous research.

The National Survey on Family Growth used data from >9000 women (15-44 years) sampled during the year 2002 and between 2006 and 2010 (W. Mosher et al., 2015). Their research sought to identify factors associated with non-use of contraception by women at risk of pregnancy using logistical regression analysis. The top three reasons for not using contraception were: not believing she could get pregnant, not minding becoming pregnant, and not planning on sexual intercourse. Fifty percent of Hispanic vs 29% of Black women cited the first reason which confirmed qualitative work (Borrero et al., 2015). Most of the women sampled had incomes below 300% of the national poverty rate. Fourteen percent were funded with private insurance and other or no insurance 40%. The researchers found that women 35 and older were less likely

to be using a method than between 20 – 34 years of age and the rate of non-use vs education level (low to high) was curvilinear.

Steinkellner (2010) examined retrospectively prescription medication claims for oral contraceptive pills (OCPs) in almost 500,000 American women 18-44 years of age. The outcome measured was compliance with OCPs with or without concurrent prescription of a category X medication. Multi-variable logistical regression was used to identify factors associated with adherence. Co-prescription of a category X medication did not positively correlate with compliance with OCPs. This study had a large *n* with reliable and valid data but did not include any correlation with health outcomes. Lower adherence was associated with income below \$20,000 a year, identifying as an ethnic minority, younger age, and less education. The data was taken from Medco Health Solutions in New Jersey but it was not clear the geographic demographics of the study participants. Furthermore, adherence to oral contraceptive regime varied from medication class to class and opioids were not specifically separated out (Steinkellner, 2010).

Yazdy et al. (2013) analyzed data from the Slone Epidemiology Center Birth Defects Study to answer the question: is maternal opioid use before and during pregnancy associated with neural tube defects such as spina bifida. It was an on-going, case controlled study utilizing telephone interviews of more than 20,000 mothers of non-malformed and malformed offspring from 1998-2010. The data was taken from urban hospitals in Massachusetts, New York, Canada (Toronto), and California. Of the neural tube cases, 59.7% were white, 19.7% Hispanic, and 11.5% black. Logistic regression models were used to estimate odds ratios. A statistically significant higher percentage of mothers of offspring with neural tube defects reported using an opioid medication than mothers of offspring in the nonmalformed control group. They concluded

that maternal periconception use of opioids increases the risk of neural tube defects more than 2-fold. The results may be confounded by recall bias though steps were taken to account for this.

The literature provided strong evidence for the underlying assumptions of this doctoral project. Fetal opioid exposure can be catastrophic (Yazdy et al., 2013), Medicaid women are prescribed opioids at higher rates than privately insured (Ailes et al., 2015), women are often ambivalent about preventing pregnancy (W. Mosher et al., 2015), and conversations with an APRN or other provider can be a cue for effective preconception care (C. Dehlendorf et al., 2014).

Summary and Gaps

The basic assumption of this project is that fetal exposure to opioids is strongly correlated with birth defects and this is supported by large, diverse, vigorous studies (Broussard et al., 2011; Yazdy et al., 2013). There is also strong evidence that for women of reproductive age, concurrent prescription of a category X medication (a strong teratogen) does not improve their adherence to OCPs (Steinkellner, 2010). This is significant since the qualitative research suggested that women are ambivalent about unplanned pregnancy (Askelson et al., 2015; W. Mosher et al., 2015) and that providers often do not always engage women in shared decision-making regarding contraception (C. Dehlendorf et al., 2014).

The 18-44 age range of this DNP Project is supported by Ailes et al. (2015), Broussard et al. (2011), Harper et al. (2015), W. Mosher et al. (2015), and Steinkellner (2010). Note that the study about lowering pregnancy rates by training providers in LARC used the 18-25 age range (Harper et al., 2015). The use of retrospective analysis for this kind of project is supported by Ailes et al. (2015), Broussard et al. (2011), and Steinkellner (2010).

The patient demographic at the CHC includes many low-income women who likely have less than a high school education, have publicly funded insurance or no insurance, and are for the most part white or Latina. The assumption that FQHC patients have health care disparities is supported by the Ailes et al. (2015) study that revealed female Medicaid patients are prescribed a disproportionately high rate of opioids. The assumption that women find pre-conception care acceptable has been elucidated and validated by the expanded health behavior model. A study of female teens with type I diabetes reported that healthcare provider advice to seek pre-conception care was a motivational cue that triggered action (Charron-Prochownik et al., 2001).

Further research was indicated, however, as the report from the CDC that gave us data on prescription opioid rates defined women's reproductive status by age rather than presence or absence of LARC, surgical sterilization or menopause (Ailes et al., 2015). Since these variables correlate with provider training and patient attitude towards health behaviors, more information is needed to clarify the best interventions. This DNP Project also sought to validate the CHOICE data showing that training health care providers in placement of long-acting contraception does reduce pregnancy rates (Harper et al., 2015).

CHAPTER 3: METHODOLOGY

The problem addressed in this doctoral project was based on the CDC report that states that too many women of reproductive age are receiving prescribed opioids (Ailes et al., 2015). The research question is of women who are of reproductive age who are receiving prescription opioids, what percentage have received effective preconception care in a community health setting? In addition, whether provider training in LARC correlates with high LARC rates (Harper et al., 2015).

Study Design

The research design for this DNP capstone project is a quantitative, descriptive, non-experimental, retrospective analysis of existing data. The purpose of this project is to identify what percentage of women of reproductive age who are receiving prescription opioids have received effective preconception care in this setting.

Non-experimental design has been identified as being appropriate to describe a phenomenon, especially when it would be unethical to manipulate the independent variable and is commonly used for this kind of research (Ailes et al., 2015; Broussard et al., 2011; Steinkellner, 2010). It also removes the need for informed consent since the data has already been collected. Although several studies define reproductive age as beginning at 15 years of age (Ailes et al., 2015; W. Mosher et al., 2015) or 16 years of age (Charron-Prochownik et al., 2001), because of the delicate nature of the topics and the need to protect the confidentiality of teens, the age was raised to 18 at the request of the internal review board at Fresno State University.

Definitions

“At risk” for pregnancy included no noted birth control method as well as less effective birth control methods such as condoms or oral contraceptives. “Not at risk” included long acting birth control, sterilization of patient or partner, menopause (surgical or physiologic). “Chronic use of opioids” was defined as either the diagnosis on the patient’s problem list or two or more refills of opioid prescriptions. “Acute use of opioids” was defined as one-time prescription of opioids. If the provider listed as the primary care provider (PCP) had seen the patient twice or less, the “PCP” was defined as either the provider who initiated the chronic opioid prescription or the provider who had seen the patient the most in the four-year period. This was relevant since the center had a three-year family medicine (physician) residency and a one year FNP residency resulting in a high turn-over of providers. Providers were family nurse practitioners, physician assistants, and physicians. “POPs” are progesterone only birth control pills.

Setting and Participants

Participants were a convenience sample from a community health center, seen between 2013 and 2016, female, between 18 to 45 years of age, with a diagnosis of chronic pain syndrome or taking long acting opioids, and not pregnant. Exclusion criteria included genetic males, being outside of the age range, lacking a diagnosis of chronic pain syndrome, not having been seen between 2013 and 2016, and/or pregnant. It was hypothesized by the author that it might be possible to predict preconception care by the presence or absence of LARC training (contraceptive implant) of the patient’s PCP.

Procedures/Data Collection

The data (including demographics and PCP) was taken from information already gathered in the electronic health records (EHR). The program was eClinicalWorks (ECW) and

the data was exported to an Excel spreadsheet on the community health center's servers which were password protected and accessible only by current employees or contractors. Permission was formally obtained from the community health center in the form of a letter from the Chief Medical Officer. When first submitted to the university, the project proposal included minors. Since teens are a protected population and the subjects of reproductive health and opioid use are both sensitive, the internal review board declined to waive formal review of the project. After revision, the doctoral project was approved on 08/18/2016 by the California State University at Fresno committee for protection of human subjects.

The promise of EHR to provide fingertip access to population data took longer than anticipated. Though in use for almost ten years at this CHC, obtaining data from the EHR in the form of meaningful reports has only been possible in the last few years and takes a team of people. Accurate information on reproductive status has been a struggle as there is no accurate report available. Birth control method might be based on historical entries rather than current data. Furthermore, menopause and permanent surgical sterilization are not structured, searchable fields and required manual chart reviews by the primary author to determine actual reproductive status for the project.

Search criteria for chronic pain syndrome, prescribed long acting opioids, and basic demographics provided robust data. The variables of age, and insurance status were likely valid and reliable, especially among the insured, since accuracy is needed for billing services. Race was self-reported by the patient and recorded by the medical receptionist for all new patients. The total data points drawn for the manual chart review were 145.

Descriptive research was used to explore relationships between the variables.

Disproving the null hypothesis that all women of reproductive age are at risk for pregnancy would disprove the assumption by Aimes et al (2015) that age correlates with risk of pregnancy.

CHAPTER 4: RESULTS

The CHC EMR search was for female patients seen between 2013 and 2016 with either a diagnosis of chronic pain or prescriptions for opioids. The variables were age, ethnicity, insurance type, primary care provider, and at risk or not for pregnancy.

The initial data drawn from the EMR had a sample size of 145 patients but a manual chart review showed that only 48 were chronically prescribed opioids and the rest received a one-time prescription for an acute visit. The acute visit patients were eliminated from the study. There was an increase in visits over the four years of the study (Figure 2). Insurance type was unfunded, Medicaid, Medicare, and private with only one patient with private insurance (See Figure 3). The demographics showed female patients ranging from 23 to 44 years of age, 90% Caucasian, 6% African American/Black, 4% Native American. Of the Caucasians, 28% were Hispanic (Figure 4). Four patients were receiving prescribed opioids for both chronic pain and addiction. PCPs had between one and four patients on the list and no one stood out as prescribing significantly more than others.

The manual chart review for actual reproductive status showed that 43% of participants had received effective preconception care (13% sterilized, 11% contraceptive implant, 17% IUD, none menopause). The remaining participants had not received effective preconception care (34% no method, 2% condom, 8% injection, 11% OCP, 2% POP). Two patients were actively seeking pregnancy while receiving prescribed opioids (Figure 5). Ailes (2015) claimed all women between 15 and 44 were at risk for pregnancy while this study found that in this setting in women from 18-44, only a little more than half were at risk. We were unable to validate the Ailes data regarding health disparities between Medicaid and private insurance since only one patient had private insurance. However, the finding of significantly higher rates of opioid

prescription among white women as compared to Hispanic women was validated. The LARC question was not elucidated since practically all providers were trained in LARC and each provider had so few patients.

Incidental findings and trends

Of the 90 acute visits in the original data set, 20 were the first and only visit for that patient. Most, but not all, of the prescribers for these visits worked in the homeless shelter or urgent care setting. Was this a function of the transient patient population of these settings or were the patients going to multiple prescribers? These results are pertinent because the community health center has a mandate to prevent diversion and misuse of opioids and a policy to defer opioid prescription in the absence of prior medical records. Another finding among the acute visits was that 17 prescriptions were from dentists. This is a reminder that opioid prescribing is not limited to physicians, physician assistants, and nurse practitioners.

Conclusions

While the CDC defines all women of reproductive age as at risk for pregnancy, this study found that almost half were not at risk due to sterilization, menopause, or effective birth control (LARC). No providers were over-represented as prescribers of chronic opioid medications. Most patients had Medicaid or no insurance and were predominantly white or Hispanic. LARC types were almost equally divided between IUD, contraceptive implant, and sterilization.

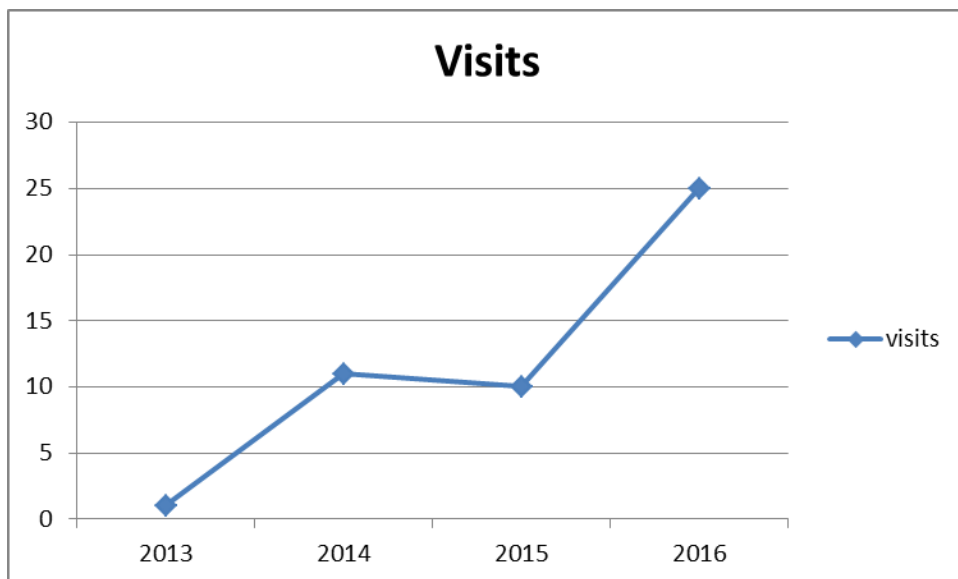


Figure 2. Female patient visits for chronically prescribed opioids.

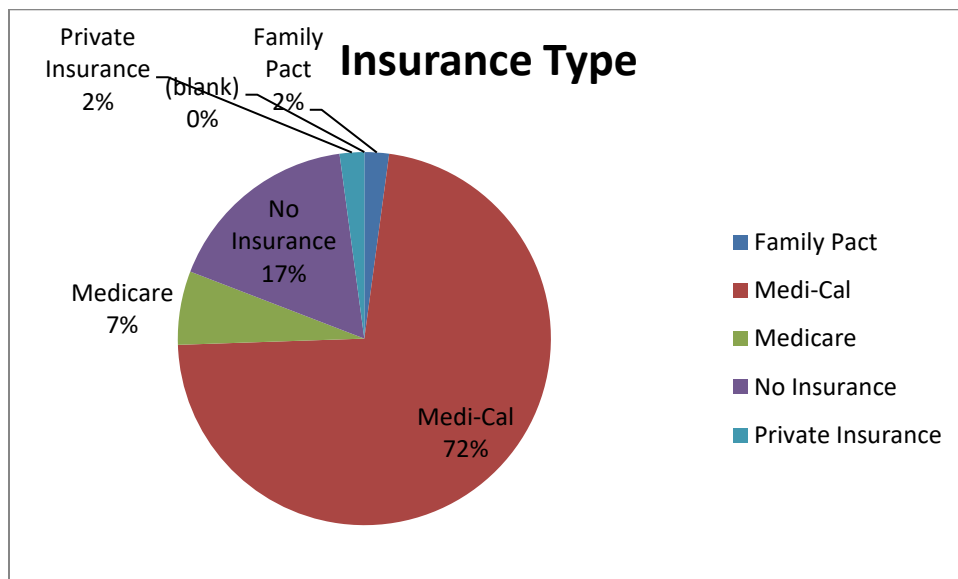


Figure 3. Insurance type.

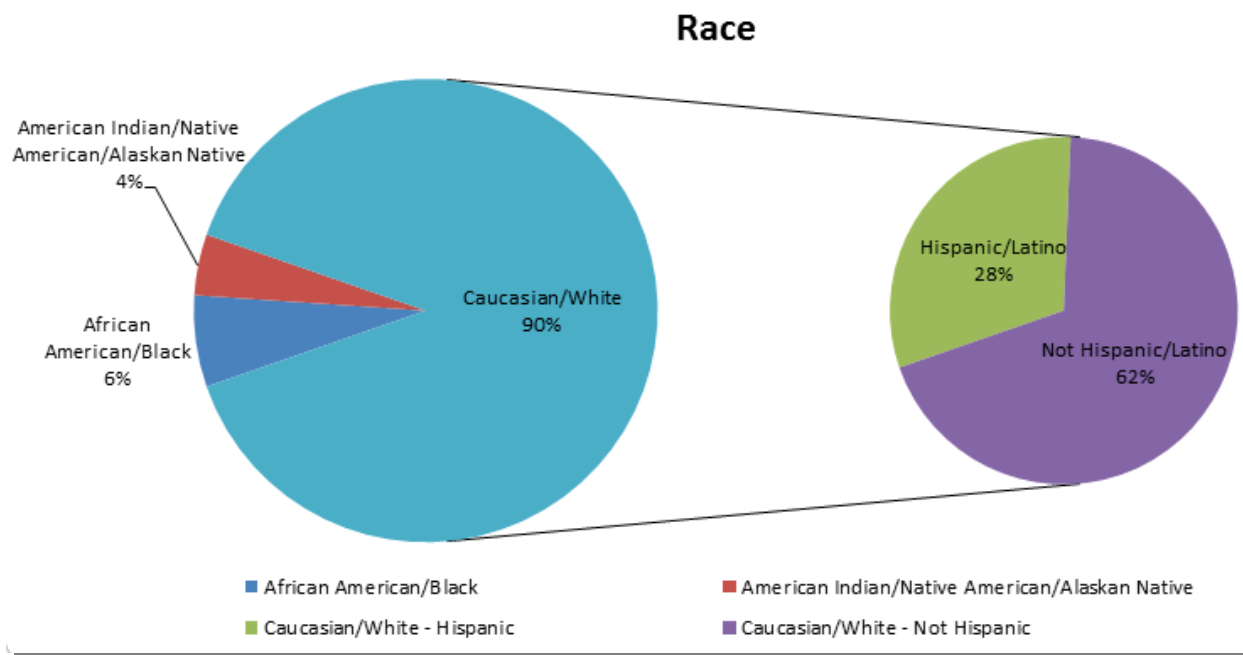


Figure 4. Race and ethnicity.

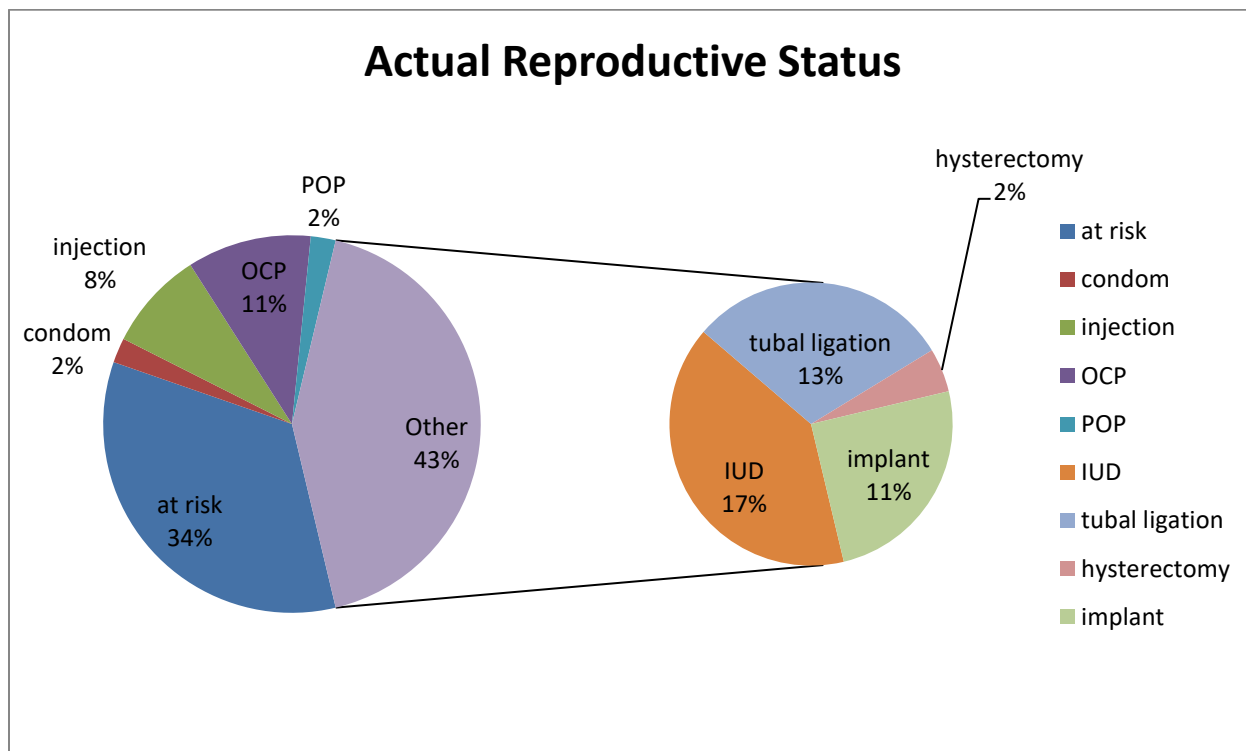


Figure 5. Actual reproductive status.

CHAPTER 5: DISCUSSION AND RECOMMENDATIONS

While disproving the null hypothesis that all women of reproductive age are at risk for pregnancy, the findings revealed there is still work to be done in the realm of preconception care of women on prescribed opioids. More than half of the women with chronic opioid prescriptions in the study had either no listed birth control or ineffective birth control. Given the catastrophic outcomes of peri-conceptive fetal exposure to opioids, this is not acceptable. The data was unable to validate the hypothesis that women on prescribed opioids are more likely to have effective preconception care if their PCP was trained in LARC.

However, by industry standards, a LARC rate of 43% is not that low. It matches, within one point, the Title X recommended goal for LARC utilization in a community health setting. In the CHC of this project, LARC utilization has been reported as only 13% but this possibly speaks to the accuracy of the manual chart review.

Limitations of this study included reproducibility as it required a manual chart review. Other health centers might lack the personnel hours to accomplish similar data acquisition. Determination of the reproductive status of the patient was weighted towards “at risk” to increase inter-rater reliability. If it was not immediately obvious from the problem list, medication list, or history, a further chart review was not done by the reviewer. Results may be skewed by lack of documentation and may have resulted in under-representation of menopause, abstinence, and partner sterilization. The study was also limited by a small sample size. However, results are likely generalizable to other CHCs with similar demographics of race and funding source.

The literature conclusively demonstrated that provider input is acceptable to patients when making decisions about contraception and preconception care (C. Dehlendorf et al., 2014). There may be special considerations for women receiving prescribed opioids which warrants

further study. Research also revealed prescribers' habits could be changed through audit and feedback, working most effectively when the message is delivered by a peer, given more than once, and has both measurable goals and a specific plan of action (Ivers et al., 2012). An excellent next step would be development of a systems solution to the problem of preconception care.

Next steps

Just as peers can influence prescriber practice, so can insurers. The region's Medicaid provider has been pressuring prescribers to lower the total dose of opioids for each of their patients. In that same manner, could they pressure providers to prescribe only to women not at risk for pregnancy? If at risk for pregnancy, specific, written patient consent would need to be documented. The Chief Medical Officer of the CHC is on good terms with the medical director of the Medicaid plan for the region and could provide guidance on this to the author.

For this CHC, focus could be made on Caucasian, non-Hispanic patients and those on Medicaid since they made up most of the chronic pain patients. The CHC should continue requiring contraceptive implant training for all prescribers, make reproductive status part of the chronic pain template in a structured field. Enforce medical assistant rooming standards requiring the notation of the birth control method of the patient. The chart review check list for chronic pain should include the reproductive status and the chronic pain database should include the variable of reproductive status.

This systematic documentation of the reproductive state should be spread to other chronic diseases. Chronic pain syndrome is not the only disease state that commonly uses teratogenic medications and hyperglycemia of diabetes can be teratogenic (Fountain et al., 2015; Yazdy et al., 2013). Population management can help improve LARC rates and the author is already

working with the EMR population management team on how to make reports on reproductive status more accurate. The CHC already employs clinicians to clean up data sets for colon cancer screening and other health maintenance so it would not be a stretch to add chronic pain syndrome as it is not an overwhelming number of patients.

Conclusion

The landmark 2015 report from the Center for Disease Control posited that too many women of reproductive age received prescribed opioids. This is significant because fetal exposure to a known teratogen can have catastrophic outcomes. Furthermore, women are often ambivalent about birth control and many pregnancies are unplanned. Fortunately, women identify interactions with health care providers as acceptable cues for preconception decision making. Data has shown that Medicaid populations are disproportionately prescribed opioids compared to insured populations. However, the CDC defines reproductive status by age only. Therefore, the purpose of this research project was to identify women's actual risk for pregnancy as defined by presence or absence of menopause, sterilization, or long-acting, reversible birth control.

When putting research into practice, it is important to assess how the data fits the specific patient population. In community health centers, rather than assuming all women of reproductive age are at risk for pregnancy, a more nuanced approach can help focus resources. In this case, population management to improve LARC rates overall and especially among the chronically ill is the best recommendation.

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