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Treatment Outcomes for Opiate Addicted Pregnant Women

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Final DNP Practice Inquiry Project Report

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Introduction

The problem of opiate addiction is complex enough but compounded when the patient is pregnant. Substance use during pregnancy produces harmful and costly effects to both the mother and the fetus (Veilleux, Colvin, Anderson, York & Hines, 2010). The rate of opiate addiction among pregnant women in the U.S. has been increasing in epidemic numbers since the beginning of the 21st century. This paper looks at research on the origin of the problem, the demographics of the average pregnant opiate addicted patient, the effects on the woman and her unborn child, and available treatment options.

Preparation at the practice doctorate level includes advanced education to help become a change agent for populations in need, such as pregnant opiate addicted women and their unborn children. The DNP prepared nurse is well positioned to assist this vulnerable population by using expert knowledge to influence health care outcomes for the pregnant opiate addicted patients. This specific population is often ostracized and stigmatized which can deter their seeking available treatment. As an example, in 2014, a law was passed in Tennessee that allows women to be criminally charged with an assaultive offense for the illegal use of a narcotic drug while pregnant or if her child is born addicted to or harmed by the narcotic drug; and for criminal homicide if her child dies as a result of her illegal use of a narcotic drug taken while pregnant. A felony assault charge can subject such woman up to 15 years in prison in Tennessee.

Further, pregnant opiate addicted women face stigma from healthcare professionals. As an example, a systematic review of 28 studies examining stigma by

healthcare professionals toward patients with substance use disorders concluded that negative attitudes of healthcare professionals toward patients with substance use disorders are common and contribute toward suboptimal outcomes (Van Boekel, Brouwers, Van Weeghel, and Garretson, 2013). The DNP prepared nurse has a unique opportunity to contribute to positive treatment outcomes by providing direct care and assist with the management of care for these individuals. In addition, the DNP prepared nurse can develop and implement healthcare policies to enhance access to often sparsely available and expensive care.

Application of the DNP Essentials led to the development of this project. In examining DNP Essential Number V, Health Care Policy for Advocacy in Health Care, it became apparent that this Essential would be instrumental in making effective changes for the population at hand. Therefore a thorough investigation of the policy underlying drug addiction treatment methods and availability was conducted.

DNP Essential III, Clinical Scholarship and Analytical Methods for Evidence-Based Practice was also used to develop this project and find solutions for the treatment needs of the population. The population of pregnant opiate addicted women is an area where a gap in literature exists, in terms of their experience and their needs for treatment. Information on the effects of the use of drugs on the fetus is readily available but not on preferred treatment methods and treatments that actually work for this group of women.

This practice inquiry project will further present three manuscripts that explore the issue of opiate drug addiction. The first manuscript is an integrative review of the literature regarding pregnancy and opiate addiction. It examines research that focuses on the issues faced by pregnant women who use and abuse opiates, such as access to care,

drug replacement therapy, and neonatal abstinence syndrome.

The second manuscript analyzes the role of the advanced practice nurse in the treatment of addiction disorders and how these nurses are uniquely suited to advocate and be leaders and lobbyists to influence public policy for this population. The third manuscript is based on a retrospective chart review of data from 161 pregnant women with opiate addiction admitted to an inpatient psychiatric facility over a one year period and describes their treatment needs and prn usage in relation to their disposition at discharge. The combined information from these three manuscripts will be used as a blueprint to offer evidence-based practice recommendations for primary care and psychiatric care providers to enhance their practices with this population.

Manuscript #1

Pregnancy and Opiate Addiction: A Review of the Literature

Abstract

This paper is a review of 12 research articles, published between 1997 and 2014, which investigate the treatment of pregnant women with opiate addiction. The significance of the problem of opiate addiction and pregnancy and the resulting neonatal abstinence syndrome cannot be overestimated. By identifying effective treatment strategies for this population to treat opiate withdrawal symptoms management and addiction treatment options, the quality of life for these women and unborn children can be enhanced.

Keywords: opiates, pregnancy, addiction

Opiate Addiction, Pregnancy and Treatment Modalities: A Review of the Literature

The use and misuse of both prescription and illegally obtained opiates has become an epidemic and costly public health problem among pregnant women in the United States. Martin, Longinaker, and Terplan, (2014) reported that during the period from 1992-2012, 2% to 28% of pregnant women in the United States sought treatment for abuse of prescription opioids and that 1% to 19% were admitted for treatment of prescription opioids. According to the Substance Abuse and Mental Health Services Administration (SAMHSA) combined data for 2007 and 2008, 5.1% of pregnant women ages 15–44 reported past month use of illegal drug use which could include abuse of prescription medications obtained "on the street" (SAMHSA, 2009). The rate of current illicit drug use of all types in combined data from SAMHSA (2013) was 14.6 percent among pregnant women aged 15 to 17, 8.6 percent among women aged 18 to 25, and 3.2 percent among women aged 26 to 44.

Treatment options for pregnant women with opiate addictions include detoxification or drug replacement therapy with methadone or buprenorphine. Regardless of the treatment approach, withdrawal from opiates is difficult for pregnant women. An important research question is: Which treatments are available to hospitalized pregnant women with opiate addiction and what are their options for treatment when discharged from the hospital setting? Nursing care can be improved and tailored to fit the needs of the patient population when the effectiveness of current treatment methods are researched and examined.

Substance use during pregnancy is associated with harmful effects to both the mother and fetus. According to Patrick (2012), from 2000 to 2009 the number of newborns with neonatal abstinence syndrome resulting from the mother's use of drugs during pregnancy tripled and the number of mothers using opiates at delivery increased five-fold from 1.10 to 5.63 per 1,000 births. Jackson and Shannon (2012) report that one of the most devastating prenatal effects of using opiates is the repeated periods of intoxication and withdrawal which can result in life threatening complications for the fetus as well as postnatal complications of neonatal abstinence syndrome.

Opiate addicted pregnant women are a very specific population with specific needs. Standard of care would necessitate a universal substance use screening during pregnancy and referral to treatment such as maintenance therapy if warranted. When a woman is identified as pregnant and opiate addicted, evidence-based practice guidelines and research recommend referral for short term hospitalization for opiate detoxification, followed by then treated with methadone or buprenorphine as a safer substitute on a maintenance basis. However, according to Martin et al. (2014), only about a third of the women hospitalized when pregnant for opiate addiction are placed on medication assisted therapy despite the standard of care for opioid abuse in pregnancy. A comprehensive, standard of care program regimen improves maternal and neonatal outcomes as well as reduces associated adverse health consequences (Jones, O'Brady, Malfi, & Tuten, 2008; Kaltenbach & Finnegan, 1998).

Significance/Morbidity/Mortality

The significance of the problem of opiate addiction and pregnancy and the resulting neonatal abstinence syndrome cannot be overestimated. The recent trends in opioid use with women are alarming. The overall rate of heroin initiation increased for women from 0.06% in 2002-2004 to 0.10% in 2009-2011 (SAMHSA, 2013). There has been a 50% increase in persons 12 and older who are dependent on heroin from 180,000 in 2007 to 360,000 in 2011 (SAMHSA, 2013). There has been greater than a 500% increase among women in opioid pain reliever overdose deaths since 1999 with opioid overdoses surpassing motor vehicle accidents as a leading cause of death (CDC, 2014). In addition, in the U.S., 25% or more of all pregnant women admitted for treatment report prescription opioid use (CDC, 2014).

Neonatal Abstinence Syndrome (NAS), which is observed in infants of a mother who has been using opiates, occurs in 55-94% of exposed infants with medication required in approximately 50% of the cases (Kahila, Saisto, Kivitie-Kallio, Haukamaa, & Halmesmaki, 2007). The mean length of stay for infants with NAS is 16.4 days at an average cost of $53,000.00 per infant (Martin, Longinaker, & Terplan, 2014). Complications from NAS include dysfunction in feeding, gastrointestinal dysfunction, autonomic dysfunction, failure to thrive, seizures, low birth weight for gestational age, and respiratory problems (Martin, et al., 2014). The abuse of heroin or other opiates during pregnancy is associated with a 600% increase in prenatal obstetric complications (SAMSHA, 2013). Babies who are born to opiate-abusing mothers have lower birth weights, and these infants are at greater risk of sudden infant death syndrome (SIDS). Opiate-abusing mothers tend to have decreased health and poor nutrition, are less likely

to get adequate prenatal care, and are more likely to abuse other dangerous substances (SAMSHA, 2013).

The purpose of this paper is to summarize findings from a literature review that focused on treatment preferences and needs of opiate addicted pregnant women and research on current treatment. In addition, this paper will examine the gaps in research, and make recommendations for evidenced based practice to improve the quality of life for this unique population of women and children.

Review of the Literature

Search Methodology

An integrative review of literature relating to treatment needs of pregnant opiate addicts was conducted. The online databases used for the search included the Cumulative Index to Nursing and Allied Health Literature (CINAHL), PsycINFO Psychology Information, MEDLINE, the Cochrane Database of Systemic Reviews, Article First and Elsevier. Key words used in the search were pregnant, opiate addicts, users, dependence and women. In additions, retrieved studies were graded on the strength of evidence based on the Strength of Recommendation Taxonomy (SORT) criteria (see Annotated Bibliography).

Inclusion and Exclusion Criteria

Initial inclusion criteria comprised any study that contained information regarding both opiate addiction in general and pregnant women with opiate addiction and treatments for this population that met quality and evidence grading standards published in the 5-year period prior to 2012. The literature was screened to make sure that it represented the population of opiate addicted pregnant women whenever possible.

Following this initial review of articles obtained in the search, exceptions were made because two studies older than the 5-year mark had a strong evidence rating. In addition, some articles were not excluded even though they addressed opiate addiction as a whole because they were landmark studies of high quality involving opioid addiction. Exclusion criteria encompassed studies focused on addiction in general (not specific to opioids) or the physiological effects on the newborns of addicted women.

Findings

Twelve studies focused on the criteria mentioned above and were included in this evidence review. The twelve studies can be categorized into studies which focused solely on opiate addiction and pregnancy from a drug replacement therapy perspective, and those that investigated both pharmacologic treatment and other factors determined to be equally important to treatment success.

Treatment Modalities

Drug Replacement Therapy

A significant amount of research has examined the effects of opiate addiction on the developing fetus and on the infant after birth. In addition a large amount of research has been completed which favors drug replacement therapy in lieu of detoxification for the pregnant opiate addicted woman.

The studies focusing on drug replacement therapy for the opiate addicted pregnant woman recommend either methadone or buprenorphine as the drug of choice to prevent opiate abuse in women during pregnancy. Some researchers conclude that methadone is superior while others claim buprenorphine is, yet some state either will be equally efficacious.

In an example of a study that recommends methadone as the drug of choice, Burns, Mattick, Lim, and Wallace (2007) reported on a systematic review of descriptive studies using record linkage in the U.S. There were 2993 births to women on methadone at delivery; these increased from 62 in 1992 to 459 in 2002. The authors concluded that continuous methadone treatment during pregnancy was associated with earlier antenatal care and improved neonatal outcomes. Early engagement in methadone treatment by pregnant women with opiate addiction was identified as essential. Study limitations include the fact that due to the cross sectional nature of the reviewed studies cause and effect could not be determined. The study controlled only for confounding variables on main neonatal outcomes and future work would need to examine relationships between variables in more detail. Another limitation is that the study did not have information on methadone dosage or treatment policies, critical knowledge affecting retention and outcomes.

Another study, which supported methadone maintenance, was a Cochrane systematic review of multiple randomized clinical trials among opiate addicted individuals in different countries by Mattick, Breen, Kimber, and Davoli (2009). This study, although not specific to pregnant women was included because of its significance and the large number of subjects (n=1969). The authors found that methadone maintenance treatment had superior treatment effectiveness as compared to treatments that did not involve opioid replacement therapy such as detoxification, drug rehabilitation or placebo medications. In this study, methadone maintenance treatment was shown to retain patients in treatment, which is considered paramount to treatment effectiveness. The theme of treatment retention was prevailing in the studies for success of treatment.

However, a retrospective case series study of 23 infants born to 22 pregnant women in the U.S. by O'Conner, Alto, Musgrave, Gibbons, Llatno, and Karnes (2011) found that buprenorphine was the best available practice for opioid dependent pregnant women and the early identification and treatment of this at risk population is essential to reduce complications and decrease withdrawal for the neonate. In agreement with the O'Conner et al.'s (2011) study, Kahila, Saisto, Kivitie-Kallio, Haukamaa, and Halmesmaki (2007) conducted a case-control study among 66 pregnant women in Finland and buprenorphine was again found as the preferred treatment option for opioid addicted pregnant women. This study mentioned that drug replacement therapy such as the use of buprenorphine prevents relapses, raises social status of the women and helps avoid infectious disease transmission, overdose death and criminality associated with street drugs. Their findings also state that it improves overall maternal health and life circumstances and thus decreases the risk to the fetus.

An earlier high quality RCT performed by Mattick et al. (2002) with a sample of 405 opioid dependent subjects in the U.S., found that both methadone and buprenorphine were effective in treating opioid dependence by producing significant reductions in drug use. Changes in well-being and social functioning were also noted as significant.

Drug Replacement and a Holistic Approach

Studies involving treatment interventions reiterated the importance of drug replacement therapy but suggested that something else was needed for treatment success. In a review of opiod dependence among pregnant women in different countries, Unger, Metz, and Fischer (2012) found that using opioid agonist maintenance treatment was the best option for the majority of women, noting that few opioid addicted women could

handle abstinence from opioids. They mention that treatment, however, should involve more than just replacement therapy and should be an interdisciplinary team approach that includes social workers, nurses, psychologists, psychiatrists, gynecologists, anesthesiologists and pediatricians. They also recommend the treatment of comorbid psychiatric conditions and addressing the financial, legal and housing aspects as well as offering psychosocial support. A review of the literature by Veilleux, Covlin, Anderson, York, and Heinz, (2010) reiterated the need for psychosocial interventions and specifically mentioned outreach counseling and brief outpatient therapy to decrease relapse and retain the individuals in treatment. In a case series study in the U.S. by Jones, Martin, Heil, Kaltenback, Selby, Coyle, Stein, Arria, and Fischer (2008), the study authors stated that the optimal treatment approaches for opioid dependent pregnant women should be tailored to the needs of each patient and such tailored treatment needs to be further investigated. Jones et al. (2008) also noted that opioid dependent pregnant women face huge stigma from family and society and that health care providers can mitigate this source of stress by directly addressing the patient's fears, guilt and treatment resistance.

Lack of Treatment Accessibility

In a case review study of 420,665 cases in the U.S., Martin et al. (2014) looked at recent trends in treatment admissions for prescription opioid abuse during pregnancy. A significant finding in this study was that only a small proportion of the women with opioid addiction were receiving medication-assisted therapy. The researchers note that mediation-assisted therapy is the standard of care for opioid dependent pregnant women, indicating that it leads to improved maternal medical status, decreased fetal morbidity

and increased utilization of prenatal care. The authors attribute the lack of access to the medication-assisted therapy, stating that only 9% of substance abuse treatment facilities in the US offer medication-assisted therapy (Martin et. al, 2014).

Gaps in literature

There is a plethora of research supporting the use of drug replacement therapy in opiate addicted individuals (Mattick et al., 2006; O'Conner et al., 2011; Kahila et al., 2007; Mattick et al., 2009; and Veilleux et al., 2010). These same studies give scientific support for the use of opioid replacement therapy in opiate addicted pregnant women. The gaps in the literature involve the following questions:

1) What is the preferred method of treatment for opiate addicted pregnant women when identified as pregnant, detoxification from opiates or drug replacement therapy? Do they prefer buprenorphine or methadone if they prefer drug replacement therapy?

2) Why are women not being offered drug replacement therapy when pregnant and opiate addicted if it is known to be the standard?

3) What type, if any, of comprehensive approaches to treatment have shown to achieve long-term effects with this vulnerable population?

Implications for Future Research

The research included in this review suggests that drug replacement therapy is the standard in treatment for opioid addicted pregnant women. Some research further suggests that giving methadone or buprenorphine alone is inadequate. Rather, many of the researchers point out that there is a need for a multidisciplinary approach beyond drug replacement therapy to create lasting change and make a difference in the lives of the

women and newborn children. Perhaps longitudinal studies of these women and their children would provide a blueprint and help guide clinicians further in other areas that could promote increased quality of life for the women and children.

Nursing Practice Change Recommendations

According to Young, Borden and Shea (2014) in their webinar presentation on treatment needs for opiate addicted mothers in the U.S., barriers to best practice for this unique population include: 1) the variation in the child welfare response, 2) the lack of medication availability, 3) the lack of collaboration between social services, healthcare professionals, state, local agencies and law enforcement, 4) the lack of sufficient comprehensive, long term treatment for women and their children and5) the knowledge and practice gaps in best practices in screening and assessment of addiction in pregnancy, post pregnancy, and neonatal abstinence syndrome.

Advanced practice nurses are in a unique position to assist in the development and implementation of this type of collaborative approach, in which a team would develop a plan to identify women with opioid use during pregnancy and engage them in prenatal care, medical care, substance use treatment and other needed services, (AACN DNP Essentials, 2006). This approach is believed to reduce the number of crises at birth for women, babies and the system (Young et al, 2014).

Conclusion

There are immediate benefits of opioid replacement therapy for pregnant women addicted to opiates. Through treatment with either methadone or buprenorphine, the woman is able to remain off unsafe street drugs and health risks to the unborn child are reduced, although neonatal abstinence syndrome is still likely. The risk to the fetus and

mother is reduced as indicated by several groups of researchers who have explored the topic (Mattick et al. 2009; Kahila et al. 2007; Martin et al. 2014). Further research is needed to help determine what would enable pregnant women addicted to opiates to remain off of street drugs and enhance her ability to remain drug free. Further studies on what constitutes effective lasting treatment and that would have long-term positive impact on the lives of the women and their children would be optimal.

Annotated Bibliography

Author/Year/Journal/Title Reference Information	Burns, L, Mattick, R.P., Lim, K & Wallace, C./2007/Addiction 102: 264-270/Methadone in pregnancy: treatment retention and neonatal outcomes
Type of Literature/Design	Cross Sectional; SR of Descriptive Studies using Record Linkage
Sample	2993 births in 10 year period from 1992 – 2002.
Purpose of Article	Examine the association between retention in methadone treatment during pregnancy and key neonatal outcomes.
Findings	Continuous methadone treatment during pregnancy is associated with earlier antenatal care and improved neonatal outcomes.
Implications	Innovative techniques for early engagement in methadone treatment by pregnant opioid women or those planning to become pregnant should be identified and implemented.
Evidence Level	2
Grade	Strength A

Author/Year/Journal/Title Reference Information	O'Connor, A., Alto, W., Musgrave, K, Gibbons, D., Llatno, L., Holden, S., & Karnes, J./2011/J Am Board Fam Med 24: 104-201/Observational study of buprenorphine treatment of opioid-dependent pregnant women in a family residency: reports on maternal and infant outcomes
Type of Literature/Design	Observational study; Retrospective case studies
Sample	23 infants born to 22 women
Purpose of Article	To investigate the outcomes of infants who were exposed to a range of doses of buprenorphine in utero and to determine how closely observed maternal/fetal outcomes match those previously reported in the literature
Findings	The findings were consistent with earlier studies in that early identification and treatment of opioid dependent pregnant women is essential because it reduces potential complications from recurrent intoxication and withdrawal from opioids for both fetus and mother.
Implications	Buprenorphine, a replacement for opioids, is the best available practice for opioid dependent pregnant women.
Evidence Level	3
Grade	Strength C

Author/Year/Journal/Title Reference Information	Unger, A., Jung, E., Winklbaur, B. & Fischer, G./2010/Journal of Addictive Diseases 29, 217-230/Gender issues in the pharmacotherapy of opioid-addicted women: buprenorphine
Type of Literature/Design	Case Series
Sample	NA
Purpose of Article	Purpose is to increase awareness for the need to take gender into consideration when making treatment decisions in an effort to optimize services and enhance the quality of life of women suffering from substance abuse.
Findings	There are significant gender-related differences in the epidemiology of opioid dependence and maintenance treatment. Evidence has suggested that neonatal abstinence following intrauterine exposure to buprenorphine may be less severe than associated with methadone. Buprenorphine is gaining recognition as an effective treatment for opioid dependence. Significant psychiatric co-morbidity such as mood disorders, PTSD and eating disorders add to challenge of attaining treatment success in women with substance abuse problems.
Implications	Data governing the use of buprenorphine is limited thus significant gender-related difference in the epidemiology of opioid dependence and maintenance treatment require more investigation. Optimizing treatment outcomes in terms of retention and completion requires consideration of barriers to treatment access and entry that are specific to women such as lack of services for pregnant women, fear of losing custody when the baby is born and fear of prosecution. Public funded studies and pharmaceutical support drug trials are needed to provide a better understanding of gender-related differences in response to meds. .
Evidence Level	Level 3
Grade	Grade B

Author/Year/Journal/Title Reference Information	Kahila, H., Saisto, T., Kivitie-Kallio, S., Haukamaa, M., Halmesmaki, E./2007/Acta Obstetricia et Gynecologica 86: 185-190. A prospective study on buprenorphine use during pregnancy: effects on maternal and neonatal outcomes
Type of Literature/Design	Case control study, subjects followed prospectively in outpatient multidisciplinary antenatal setting
Sample	67 pregnancies of 66 buprenorphine users from 2002 to 2005
Purpose of Article	To determine via case-study the effects of buprenorphine use during pregnancy on maternal and neonatal outcome
Findings	Buprenorphine is more suitable for opioid maintenance therapy and toxicologically is safer than methadone. It has no adverse effect on pregnancy and labor or immediately neonatal well-being. The main problem with buprenorphine use is NAS. The pregnancies and deliveries of buprenorphine-using women were uneventful but severe NAS and need for morphine replacement therapy was seen in 57% of buprenorphine exposed newborns.
Implications	Replacement therapy with buprenorphine for opioid dependence during pregnancy is recommended in light of the fact that it prevents relapses, raises social status of the women and helps avoid infectious disease transmission, overdose death, and criminality associated with street drugs. It also improves maternal health and life circumstances and probably decreases risks to fetus.
Evidence Level	Level 2 Case Control
Grade	Strength A

Author/Year/Journal/Title Reference Information	Mattick, R.P., Breen, C. Kimber, J. & Davoli, M./2009/Cochrane Collaboration Issue 3/Methadone maintenance therapy versus no opioid replacement therapy for opioid dependence (review)
Type of Literature/Design	SR of Multiple RCTs
Sample	1969 participants
Purpose of Article	Purpose – To evaluate the effects of methadone maintenance treatment compared with treatments that did not involve opioid replacement therapy (detoxification, offer of drug free rehabilitation, placebo medication, wait list controls) for opioid dependence.
Findings	Methadone is an effective maintenance therapy intervention for the treatment of heroin dependence as it retains patients in treatment and decreases heroin use better than treatments that do not utilize opioid replacement therapy. It did not show a statistically significant superior effect on criminal activity or mortality.
Implications	Methadone maintenance treatment can keep people who are dependent on heroin in treatment programs and reduce their use of heroin. The review found that people withdraw from trials when they are assigned to a drug free program.
Evidence Level	Level 1
Grade	Strength A

Author/Year/Journal/Title Reference Information	Mattick, R.P., Ali, R., White, J.M., O'Brien, S., Wolk, S. & Danz, C./2002/Addiction 98, 441-452/Buprenorphine versus methadone maintenance therapy: a randomized double blind trial with 405 opioid-dependent patients
Type of Literature/Design	Randomized double-blind trial
Sample	405 opioid-dependent patients seeking treatment
Purpose of Article	To assess the efficacy of buprenorphine compared with methadone maintenance therapy for opioid dependence in a large sample
Findings	Buprenorphine did not differ from methadone in its ability to deter heroin use but treatment retention was 10% less in the group receiving it. The decreased percentage could be attributed to the method in which the medication was induced in treatment.
Implications	The results indicate that both methadone and buprenorphine are effective in treating opioid dependence by producing significant reductions in drug use. Changes in addicts' well-being and social functioning were noted also.
Evidence Level	Level 1, high quality RCT
Grade	Grade A

Author/Year/Journal/Title Reference Information	Unger, A., Metz, V. & Fischer, G./2012/Obstetrics and Gynecology International/Opioid dependent and pregnant: what are the best options for mothers and neonates
Type of Literature/Design	Review Article
Sample	NA
Purpose of Article	Update health professionals in the field of gynecology and obstetrics on the latest optimal treatment approaches for mothers suffering from opioid dependence and their neonates.
Findings	Women with opioid addiction are a highly vulnerable group and at risk of adverse pregnancy outcomes and perinatal complications. Opioid agonist maintenance treatment is the best option for the majority of women. Few opioid addicted women can handle abstinence from opioids and rapid detoxification is not recommended from a medical standpoint.
Implications	Early and closely monitored treatment in interdisciplinary team approach that includes social workers, nurses, psychologists, psychiatrists, gynecologists, anesthesiologists and pediatricians should be provided. The treatment of co morbid psychiatric conditions and the resolution of financial, legal, housing issues and psychosocial support have significant effect on optimizing pregnancy outcom
Evidence Level	Level 3
Grade	Grade C

Author/Year/Journal/Title Reference Information	Jones, H.E., Martin, P.R., Heil, S.H., Kaltenback, K., Selby, P., Coyle, M., Stine, S., O'Grady, K., Arria, A. & Fischer, G. /2008/Journal of Substance Abuse Treatment 35, 245-259/Treatment of opioid dependent pregnant women: clinical and research issues
Type of Literature/Design	Case Series
Sample	NA
Purpose of Article	To address common question that clinicians face when treating pregnant women with opioid dependence.
Findings	Pregnant women often receive agonist maintenance treatment because the benefits supersede the risks. The mother and child are now both considered equally important instead of making the mother "bad" and the baby the only reason for treatment.
Implications	Optimal treatment approaches that are tailored to the needs of each opioid dependent pregnant patient need to be investigated. Opioid dependent pregnant women face huge stigma from family and society. Health care providers can mitigate this source of stress by directly addressing the patient's fears, guilt and treatment resistance.
Evidence Level	Level 3
Grade	Grade C

Author/Year/Journal/Title Reference Information	Veilleux, J., Colvin, P., Anderson, J., York, C. & Heinz, A./2010/Clinical Psychology Review 30, 155-166/A review of opioid dependence treatment: pharmacological and psychosocial interventions to treat opioid addiction
Type of Literature/Design	Review of Literature with focus drawn by experts in the field
Sample	
Purpose of Article	Up to date review of the literature on opioid dependence treatment, with focus on conclusions drawn by experts in the field (Cochrane reviews meta-analyses and methodological rigorous studies such as randomized controlled trials. They describe the major classes of drug treatments available, in the context of detoxification and long term treatment options. They reviewed the state of the literature regarding prevention of opioid overdose and discuss co morbidity among opioid dependent populations.
Findings	Treatment retention is extremely important in successful outcomes with opioid addiction. Two psychosocial interventions, outreach counseling and brief outpatient therapy plus contingency management resulted in lower relapse rates and higher treatment retention at baseline. Further research on psychopharmacological medications is needed.
Implications	Many treatment options for opioid dependence are available and many work fairly well. Opioid addiction, however, is found to be chronic and unrelenting and often people drop out of treatment which exposes them to an at- risk lifestyle and decreased quality of life. Hopefully generalizing the outcome research to real patient outcomes will assist in combating this addiction.
Evidence Level	Level 3, Expert Consensus
Grade	Grade C

Author/Year/Journal/Title Reference Information	Pritham, U., Paul, J. & Hayes, M./2012/Association of Women's Health, Obstetric and Neonatal Nurses 41, 180-190/Opioid dependency in pregnancy and length of stay for neonatal abstinence syndrome
Type of Literature/Design	Retrospective descriptive study
Sample	152 opioid dependent pregnant women
Purpose of Article	To examine opioid replacement therapy in pregnancy and neonatal outcomes, length of stay for neonatal abstinence syndrome.
Findings	Replacement therapy with either methadone or buprenorphine maintenance therapy caused prolonged hospital stays for neonates. Breastfed neonates had shorter length of stay. Prenatal exposure to methadone caused longer length of stay for neonate than infants with prenatal exposure to buprenorphine.
Implications	Harm reduction strategies for opioid dependent pregnant women should include guidance on daily treatment doses and recommendations to avoid concomitant use of benzos in order to lessen neonatal abstinence syndrome. Breastfeeding should be recommended. Understanding perinatal and neonatal outcomes of pregnant women on replacement therapy will help identify optimal treatment for opioid dependency with pregnancy.
Evidence Level	Level 2
Grade	Strength C

Author/Year/Journal/Title Reference Information	Crome, I., Khaled, M.K.Ismail, Ghetau, E., McAuley, R., Bloor, R., Jones, P. & O'Brien, P.M.S./2005/Drugs: Education, Prevention and Policy 12 (6) 431-436/Opiate misuse in pregnancy; finding of a retrospective case note series
Type of Literature/Design	Retrospective Case Series
Sample	50 pregnant opiate addicted women
Purpose of Article	To identify the obstetric and neonatal characteristics of high-risk pregnancies of opiate addicts, the level of contact with the offered service and the relationship between level of attendance in the service and pregnancy outcome.
Findings	Birth weights of 27 of 39 babies in the study were < or = to10th percentile for gestational age. Positive association between attending the treatment services offered at least 70% and birth weight. Retention in treatment is associated with improved outcomes in pregnant drug users.
Implications	Participation in treatment programs for opiate addiction may give the stability needed in the life of an opiate addict. It gives them the opportunity for substitution medication and also helped to resolve housing, employment and other social issues. A program of research should be developed to examine the impact of maternal drug use on the children at birth to adolescence and evaluate interventions aimed at improving their health and well-being both short and long term.
Evidence Level	Level 3
Grade	Grade C Problem with study is that it is difficult to draw conclusion based on retrospective analysis of relatively small sample size.

Author/Year/Journal/Title Reference Information	Martin, C., Longinaker, N., Terplan, M. /2014/Journal of Substance Abuse Treatment/Article in Press retrieved from: http://dx.doi.org./10.1016/j.jsat.2014.07.007. Recent trends in treatment admissions for prescription opioid use during pregnancy
Type of Literature/Design	Case Review via TEDS Admissions Data
Sample	420,665 cases reviewed
Purpose of Article	Examine trends in opioid pregnant women treatment admissions
Findings	Overall there were 420,665 substance abuse treatment admissions from 1992 to 2012. Among pregnant admissions the proportion reporting any abuse of opiates rose from 2% in 1992 to 28% in 2012.
Implications	The small amount of opioid admissions receiving medication-assisted therapy is alarming. The demand for treatment of prescription opioids during pregnancy has increased in recent years parallel to the increase in abuse among the general population. As opioid abuse increases there is a need for increase services with a multidimensional approach to preventing its impact
Evidence Level	Level 2
Grade	Strength B

Manuscript #2

The Role of the Advanced Practice Nurse in the Treatment of Addiction Disorders: Advocacy, Leadership, and Lobbying to Influence Public Policy

Abstract

This paper explores the role of the Advanced Practice Nurse in the treatment of addiction at the policy making level. By using the strengths inherent in the Advanced Practice Role such as advocacy, leadership and lobbying, the DNP graduate can shape policy to create change. Policy change is explored through the Kingdon Conceptual Framework. The problem of opiate addiction in Kentucky is examined and current attempts to change the State legislative policy for the treatment of opiate addiction is presented with emphasis on the difference the Advanced Practice Nurse can make in implementing change.

Keywords: opiates, Naloxone, policy

The Role of the Advanced Practice Nurse in the Treatment of Addiction Disorders: Advocacy, Leadership, Lobbying to Influence Public Policy

Epidemic increases in the use of opiates and heroin throughout Kentucky are consistent with opiate use trends in the United States as a whole (Substance Abuse and Mental Health Services Administration [SAMHSA], 2010). In addition, increased use has contributed to increased deaths from heroin and opiate overdose in the past decade. This paper explores how advanced practice nurses can influence the treatment of addiction in the policy arena by taking on the roles of advocate, leader and lobbyist. One such way would be to help facilitate policy that would mandate the availability of Medicaid funding for inpatient opiate addiction treatment and increase the availability of naloxone to address the problems of opiate addiction and heroin deaths. In this paper, the policy perspective for opiate and heroin addiction problems will be analyzed using Kingdon's multiple streams theory. A case study involving the introduction of Senate Bill 5, which involved increasing the availability of naloxone to overdosed heroin substance abusers and increasing treatment options to this population, and was unsuccessfully presented before the Kentucky legislature in the spring of 2014, will be highlighted.

Background and Significance of Opiate Addiction Problem

Opiate drug abuse costs lives, affects the health of newborn infants born to abusing mothers and has a negative impact on epidemic numbers of individuals in the United States (SAMHSA, 2010). The Network for Public Health Law (2014) states that fatal drug overdoses haves increased six-fold over the past three decades with 15,000 of these deaths attributed to opiates alone. In 2010, The Centers for Disease Control estimated that over 78% of drug overdoses were unintentional, and those that were opiate

induced could have been prevented by an opioid antagonist such as naloxone. Opiate overdose can be easily and inexpensively reversed through the timely administration of naloxone and emergency care (Wermerling, 2010), yet access to naloxone is limited due to laws and regulations that predate the overdose epidemic era.

The problem exists on a national scope as well as statewide. According to Kerlikowske (2012), drug induced deaths are the leading cause of injury death in the United States. A 2009 SAMHSA report on substance abuse suggests that 19% of women ages 15 to 44 are addicted to opiates. These data are critical when viewed within the context of consequences for women of childbearing age. According to Patrick (2012), from 2000 to 2009 the number of newborns with neonatal abstinence syndrome resulting from the mother's use of drugs during pregnancy tripled and the number of mothers using opiates at delivery increased fivefold from 1.10 to 5.63 per 1,000 births.

Opiates, including prescription drugs, are the most commonly used drugs among primary drug treatment admissions in the state of Kentucky (SAMHSA, 2012). According to the Office of National Drug Control Policy (2012), Kentucky was one of the top ten states for rates attributed to non-medical use of pain relievers among persons aged 12-17. Reports for 2010-2011 indicated that approximately 161,000 Kentuckians ages 12 and older used pain relievers for non-medical reasons (SAMHSA, 2012). Overdose deaths attributed to the use of heroin accounted for nearly one-fifth, or 19.56%, of all Kentucky Medical Examiner drug overdose cases in 2012. In 2011 the rate was 3.22%. Of the 1,004 overdose deaths in 2011, 888 were found to be unintentional (Office of Drug Control Policy, State of Kentucky, 2012).

Addressing the Problem: Advanced Practice Nurse Responsibilities

"Health policy influences multiple care delivery issues, including health disparities, cultural sensitivity, ethics, the internationalization of health care concerns, access to care, quality of care, health care financing, and issues of equity and social justice in the delivery of health care" AACN (2006, p. 13). According to the Institute of Medicine's hallmark 2001 report, DNP graduates are "prepared to design, influence, and implement health care policies that frame health care financing, practice regulation, access, safety, quality and efficacy" (AACN, 2006, p. 13). DNP graduates are especially capable, according to the AACN (2006), of addressing issues of social justice and equity in health care due to their powerful practice experience, which can translate into strong influence on policy formation. Thus DNP-prepared nurses are able to integrate their experience into effective action in the policy arena and help their patients receive access to care and equity in care. According to Goudreau and Smolenski (2013), advanced practice nurses "are already taking action to create better practice environments and conditions, investigating how they can work to define positive change for their patients/ clients, and how they can have an impact on the health of communities and the nation through the health policy process" (p. 305).

The Advocate Role of the APN in Opiate Addiction Treatment

Nursing as a discipline tends to resist political involvement; many nurses prefer to focus on helping patients directly. Lobbying in particular has developed a bad connotation and nurses historically avoid it. According to Hall-Long (2009) in her article on nursing and public policy, nurses will get involved to a point but are still not as actively involved in the legislature as many other health professionals. However, as

nurses enter into advanced practice, they are beginning to understand that sometimes taking care of a patient means serving as patient advocates, which may encourage them to leave the bedside comfort zone and venture into the political arena. Nurses can draw upon the bedside experience to influence public policy to better serve the needs of the patients they wish to help (Maryland & Gonzalez, 2012). According to Maryland and Gonzalez (2012), nurses can influence public policy through advocacy by providing real life examples to illustrate the needs of patients and the outcomes of public policy on patient morbidity and mortality. Nurses can advocate for increased access to care, which is certainly needed in the case of the patients who are addicted to opiates.

There is a lack of services available to those with opiate addiction, a lack of treatment facilities and a lack of access to emergency measures such as naloxone to families and non-physicians, despite the fact that these individuals are most likely to come into contact with an individual who has overdosed. Since healthcare costs, access and quality outcomes are a large part of many political agendas, the nurse is in a perfect position to influence these agendas due to the inherent trust the public and patients have in the nursing profession (Maryland & Gonzalez, 2012). "When nurses have the ability to share experiences and insights with public and elected officials, they can advocate for patients and families effectively and become a powerful force in the policy-making process" (Maryland & Gonzalez, 2012, p.2).

The Leadership Role of the APN in Opiate Addiction Treatment

The APN leadership role in health policy can be effective at an individual level or through groups of APNs who share a common interest or goal in patient outcomes. According to Filipovich (2013), "Leadership in any form requires current knowledge of

the issues that affect nursing and health care as well as how policy decisions pertaining to those issues are made" (Kindle Locations 3746-3748). The APN is ideally positioned to take a leadership role in policy due to the knowledge base required at that level of practice. In the case of opiate addiction, effective advocacy on the part of the APN requires assuming a leadership role and knowing effective strategies to promote legislation that would increase treatment options for those addicted to opiates. Assuming a leadership role would mean organizing efforts to lobby politicians, creating a coalition to fight for the increased treatment option availability for addicts and organizing the vast scientific research that backs the efforts of increasing naloxone availability to families of people addicted to opiates and emergency personnel that come into contact with the overdosed individual. The APN has the expertise needed to spearhead efforts to teach family members about the safe administration of naloxone, as well as prevention, treatment and aftercare of an overdose.

Advanced practice nurses make ideal leaders because they are educated for a political journey, according to Hall-Long (2009). She asserts that the skills she gained from her nursing education, such as communication, advocacy, listening, problem-solving, and reflection, have proven to be essential in times of political compromise. These skills have made her an effective leader who eventually became a Delaware legislator. Nurses are excellent communicators, listeners and multitaskers and receive a high level of public respect, positioning them effectively in leadership.

The Lobbyist Role of the APN in Opiate Addiction Treatment

According to Milstead (1997), the clinical expertise of APNs translates well into the political arena. Milstead (1997) states that bringing a problem to the attention of the

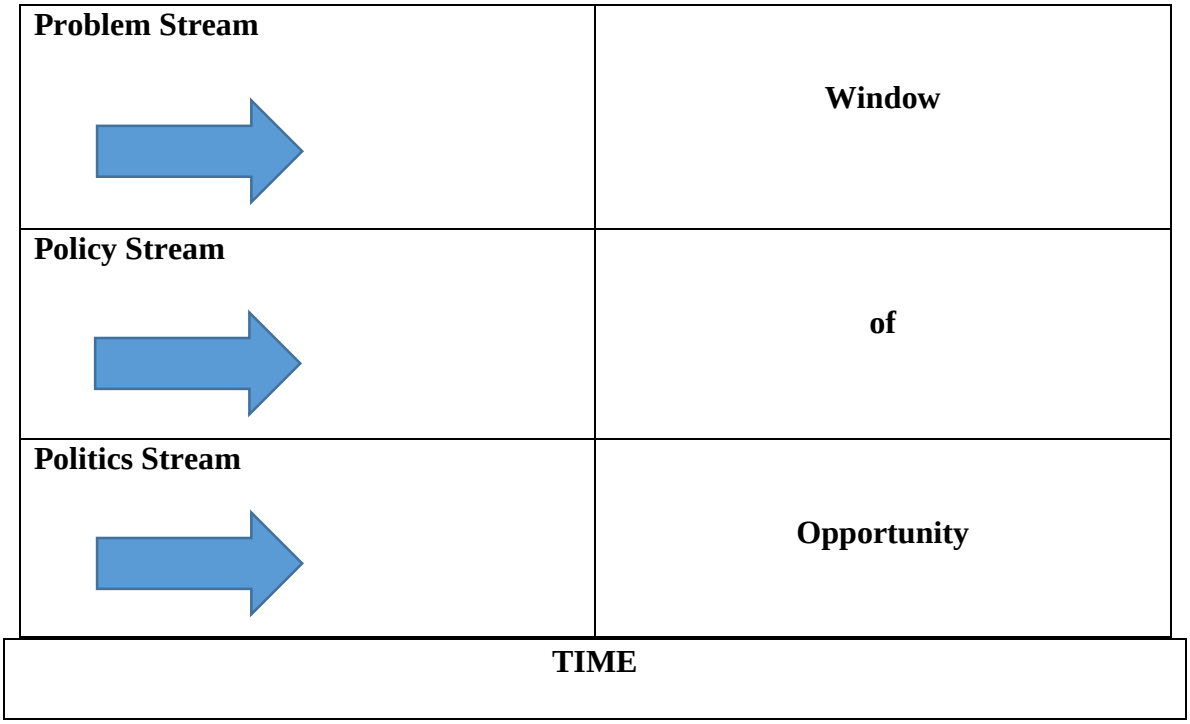
government is often the first step in solving it. APNs can use their expertise to provide fact sheets, statistics and personal experiences to bring a problem to the attention of legislatures (Milstead, 1997). APNs have expert knowledge to share and are skilled at synthesizing the available research on a topic in order to lead an evidence-based discussion of the issue. APNs know how to tap into available resources within communities, and they know what services are available and needed. APNs can look at the multifaceted scope of a problem and approach it from an evidence-based perspective. In reference to opiate addiction the APN is able to share the experiences of treating those with opiate addiction and provide the statistics on relapse, lack of treatment resources and mortality rates due to overdose. In addition to evidence, the APN can provide personal experiences with individuals with opiate addiction who want to detoxify from opiates but have neither the willpower to do so on their own nor the money for a private drug rehabilitation treatment facility. The APN can share the stories of families who worry daily whether they will find their son or daughter dead from a heroin overdose and who would have some relief if they had naloxone on hand to administer in an emergency.

Conceptual Framework

Kingdon (2012) developed the streams metaphor to describe how issues become part of policy-making agendas, emphasizing that this occurs when the problem, policy and political streams merge at the same moment, thus creating a window of opportunity for change to occur. The problem stream describes the issue or problem at hand. It involves the process of persuading those in power to view a certain problem as the one that should get their attention at a specific time when there are always competing problems for the agenda. It also involves convincing lawmakers that the problem can be

reduced or eradicated by the policy presented instead of the other solutions or alternative approaches. According to Kingdon, the policy stream encompasses all possible solutions to the problem that the lawmakers could pursue within the timeframe and political climate present. Within that climate, Kingdon observes that streams converge and may create a window of opportunity for a policy to become a law. Strategies include focusing events in order to bring problems to the public forefront, thus making it an issue that is ripe for the "window of opportunity" (Kingdon, 2011). Heroin overdose and opiate addiction are reaching epidemic proportions and overdose deaths of celebrities bring the issue into the public eye; thus the problem is being brought to the public forefront. Now may be the perfect time for APNs to offer solutions to the problems and to lobby for increased treatment options and access to treatment for opiate addicts.

Kingdon's Streams Model (Figure 1)



Application of Kingdon's concepts to promote policy change requires a clear understanding of the problem of opiate addiction and how it came about in the United States.

The Problem of Opiate and Heroin Addiction

Historical Perspective

Opiate addiction originated in this country around the time of the Civil War (Courtwright, 2001). Why then? Around 1840 New Englanders brought the first 24,000 pounds of opium into the United States. Since then, the face of opiate addiction has changed many times in the populations affected, prompting a response from the country's social, political, legal and medical communities (Courtwright, 2001). Opioid addiction has been primarily viewed through two different lenses: (1.) it is an incurable disease requiring long term maintenance with drug replacement therapy and (2.) it is caused by a personality flaw or lack of moral character and is best treated by abstinence or by punitive measures in the criminal justice system. Stigma and empathy toward people addicted to opiates have waxed and waned depending on the population most affected. For example, in the late nineteenth century an estimated 300,000 persons with opiate addiction were mostly either female upper class or disabled war veterans, thus this population was treated with empathy (Courtwright, 2001). The population changed, however, with the introduction of heroin as a "cough suppressant" and injectable forms of drugs which contributed to increased use among street criminals, changing the attitude of empathy to one of disdain and stigma (Courtwright, 2001).

Post World War II, the population of those with opiate addictions shifted to the inner city ghetto areas and the attitudes toward this population seemed to shift towards stigmatization and further away from empathy. During the subsequent period, 1960-1980, approximately 500,000 Americans of all social and economic backgrounds used opioids, thus creating a major medical problem and a social "hot button" topic (Courtwright, 2001). According to SAMHSA data on drug use for 2012 approximately 898,000 people in the United States were using heroin, treatment admission rates for addiction to opioid analgesics more than doubled between 1992 and 2001, and emergency room visits related to opiate abuse increased 117 percent between 1994 and 2001 (SAMHSA, 2012).

Some medical problems are more prevalent in people addicted to opioids than in the general population. Many of the problems include infections that can be life threatening, such as cellulitis, wound botulism, necrotizing fasciitis, and endocarditis. Diseases that are transmissible pose serious public health threats, such as HIV/AIDS, hepatitis, syphilis, and tuberculosis (TB). Many patients in medication-assisted treatment (MAT) for opioid addiction have chronic diseases such as diabetes, asthma, or hypertension, as well as conditions such as severe dental problems or seizure disorders, which may have been neglected or poorly managed for years. Some patients have chronic obstructive pulmonary disease (COPD), hypertension, coronary artery disease, or other illnesses related to long-term heavy tobacco use. Management of chronic pain for patients in MATs is particularly challenging because of the role of opioids in pain treatment. In addition, opioid intoxication may result in head trauma or other bodily injury. Criminal activity may produce severe physical injuries such as gunshot wounds.

While methadone, buprenorphine and naltrexone are all used to assist with treating the chronic addiction to opiates, there still remain issues with lack of access to these treatment options. Moreover, current public opinion still vacillates between blaming those with addiction and following a punitive approach versus recognizing addiction as a disease to be treated. As Olsen and Sharfstein (2014) point out, "First, the understanding of opioid use disorder as a medical illness is still overshadowed by its misconception as a moral weakness or a willful choice" (p.1393). Even in the substance use treatment community, many still believe that recovery depends solely on the willpower to abstain from all opioids, including methadone and buprenorphine (Olsen & Sharfstein, 2014). Furthermore, many treatment facilities require those who receive drug replacement therapy to taper off or discontinue and detox to be considered a success at treatment (Olsen & Sharfstein, 2014). As such, "Reimbursement for treatment may cover only the most basic services, including medication delivery and a weekly professional encounter" (Olsen & Sharfstein, 2014, p. 1394). Since opiate detoxification is not considered life threatening, most insurance companies and hospitals refuse patients based on the sole admitting diagnosis of opiate detoxification. Moreover, the patient usually has to have suicidal ideation or a co-morbid condition for admission. Olsen and Sharfstein (2014) have also noted that the language used to describe opiate addiction is stigmatizing. For example, the active user is called "dirty" while those who are not using are described as "clean." "Junkie" is still a popular term to describe both opiate and heroin addicts (Olsen & Sharfstein, 2014).

The history of how opiates came into the country and how they created the opportunity for addiction across all socioeconomic spectrums is fascinating. Next,

Kingdon's model recommends an examination of possible solutions to the problem of opiate addiction within the present timeframe and current political climate to determine the likelihood of the three streams converging to create the window of opportunity (Kingdon, 2007).

The Policy of Opiate and Heroin Addiction

Application of the Kingdon policy stream concept calls for exploration of all potential solutions to the problem that are available to decision makers (Goshin & Byrne, 2009). Therefore, it is important to begin the exploration by recognizing that opiate addiction is typically viewed as either a medical illness or disease and treated with interventions or it is viewed as a moral weakness with incarceration. If treated, four options are generally available: detoxification, methadone maintenance, buprenorphine replacement therapy and naltrexone (aversion therapy). However, due to lack of insurance coverage and lack of availability of treatment facilities available to those without funds, these treatment options may not necessarily be available to those who are addicted to the drug. Legislative efforts can address the problem, and the APN is in a position to help enact effective legislation to help the treatment of those with opiate addiction.

Legislative approaches

Senate Bill 5 is an example of a recent legislative approach in the state of Kentucky to increase the treatment options available to those with opiate addictions. Although legislation is not intended to completely resolve the problem, it is an important approach for easing the burden of opiate overdose in Kentucky. In addition, it addresses

an important public issue related to the hundreds of fatal heroin overdoses in Kentucky during the past three years as well as the crimes committed by those suffering from heroin addiction, for the money required for their drugs. The proposal for the bill included use of Medicaid programs in the state to cover several inpatient and outpatient options for people with opiate addiction and it encompassed heroin and prescription drug abuse problems as well. The bill specified expansion of treatment programs for the opiate addicted population because Kentucky currently has only about 2,400 treatment beds for those addicted to substances. The deficit in available treatment beds results in wait lists of six months or longer for treatment – a time frame that is untenable for those who need help. Senate Bill 5 also sought to increase the availability of naloxone and make it available to families of those with addictions and emergency workers.

Treatment options

Methadone is a limited treatment option because it is only available through specialized treatment clinics (National Institute of Health, 2010). Also, use of methadone replacement therapy is often met negative opinions and stigma. Patients undergoing this treatment may be made to feel that they are just replacing one drug for another, that they are somehow morally, physically, or spiritually weak for not being able to be completely free of all substances. Another option is buprenorphine which is used for detoxification and relapse and does not require inpatient admission. Two types of this medication exist. Suboxone (buprenorphine), gives the euphoria and feeling of well-being similar to the abused drug of choice but at a safe prescription level and dosage, simultaneously blocking any opiate receptors in case the patient were to use opiates while on the drug. Subutex, is purely an opiate agonist which does not give the euphoria or

feeling of well-being. Therefore, subutex is often favored as the drug to give, yet those with addictions are often not as adherent with this therapy. Naltrexone is an opioid receptor blocker that not only blocks heroin overdose but in the depot injection form of Vivitrol® can be effective for long periods, diminish opioid use, reduce craving and promote patient adherence to treatment (National Institute of Health, 2010). However, Vivitrol® is expensive and therefore cost prohibitive to a large percentage of those with addictions.

The Politics of Opiate and Heroin Addiction

The politics stream involves the political climate and the public opinion about the issue and policy solution being presented. With the current administration, Kingdon's window of opportunity on a national level is wide open. The window was open nationally for a bill like Senate Bill 5 to be successfully passed, but would it be in the state of Kentucky? According to Schambra (2009), "Both his ambition and his unique style of issue management show that Obama is emphatically a policy approach president" (p.127). Schambra (2009) states that Obama's policy approach looks at long term problems of healthcare, taking into account the whole and avoiding attempts to solve the problem in small pieces. Obama has demonstrated an approach to the national drug problem by looking at objective evidence, scientific facts and expert counsel by the formulation a Nation Drug Control Strategy in 2010.

On a national scale, the Obama administration has attempted to change drug abuse treatment and perspective through development of new policy based on scientific research instead of ideology in his administration. The 2013 National Drug Control Strategy emphasized that government policy has shifted from that of incarceration

focused solutions to a drug prevention approach incorporating strategies informed by science, research and evidence. The strategies emphasize prevention instead of incarceration. The strategy also empowers health care professions to intervene early before a condition becomes chronic thus creating access to treatment a reality. In addition, the strategy gives a voice to those in addiction recovery, and reinforces the idea that the United States cannot arrest and incarcerate its way out of a drug crisis. Rather, it views drug issues as being a global problem in "the spirit of shared responsibility" (Office of National Drug Control Policy, 2012).

Political viewpoints

Two political viewpoints on drug addiction that are prevalent in America today. One viewpoint maintains that addiction is a disease that needs to be treated with prevention, education, medical intervention and rehabilitation efforts. In contrast, the other view is based on personal responsibility and the idea that addiction is a path chosen by persons who lack fortitude or character. Some politicians argue that if drug use is a voluntary activity in which the risk is known, then responsibility falls on the person engaged in the activity (Winkler, 2002). These same individuals would argue that the government should not put money and effort into treatment for the opiate and heroin addicted population.

Policy Options and Outcomes

The political climate in Kentucky regarding opiate addiction is favoring treatment for those with addictions through drug replacement therapy combined with rehabilitation efforts. In an editorial for the Lexington Herald-Leader, Eblen (2008), pointed out that

more than 375,000 Kentuckians need drug or alcohol treatment. He argues that for an investment of $1 spent on treatment, $7 is saved in health care and criminal justice costs. One could try other options such as legislation that would mandate drug testing before a patient receives Medicaid, disability or other governmental assistance; yet it would likely fail because it would be extremely costly to enforce. Another option could be promotion of abstinence in the school systems as a preventative measure. However, previous Just Say No campaigns have not proven to be effective in curbing the appeal of drugs (Rosenbaum, 1998). One could also continue the current approach of prosecuting the drug dealers, especially in areas where the drug abuse problem is rampant. However, that approach does not appear to be working at this time. According to Kleiman (2001), "Neither current drug policies nor current correctional policies offer any real hope of substantially reducing drug consumption by user/offenders" p. 171. Other options include incentives to those addicted who remain drug free, which is what was done with some success in a study of pregnant opiate users by Svikis, Lee, Haug, and Stitzer (1997), but that would not be cost effective and again, it would be difficult to enforce.

Case Study: Senate Bill 5

The legislation proposed for enactment of Senate Bill 5 would have furthered the goals of the current National Drug Control Strategy. For example, Senate Bill 5 would have amended current legislation and redirected a portion of the recaptured savings from criminal justice reforms be directed to funding of treatment programs for those suffering from opiate addiction. It would have created a new section of Kentucky Revised Statute (KRS) by specifying that controlled substance treatment services be offered under Medicaid and would thus increase treatment availability to opiate addicted populations.

It would have also amended the current KRS 217.186 by allowing for the availability of naloxone for use as a rescue drug for narcotic overdose situations. This would save lives in the case of overdose emergency situations and create a safe harbor by enacting a new section of KRS Chapter 218A to provide immunity for persons seeking emergency help in drug overdose situations.

The goals proposed by Senate Bill 5 would have moved away from a punitive approach of opiate drug addiction toward a recovery based treatment modality based on the evidence of scientific research as the most effective approach in the treatment of addiction. Furthermore, goals of the bill were consistent with the National Drug Control Strategy set in 2010, which based its strategy on scientific research and inquiry.

Senate Bill 5 did not garner sufficient votes to be passed into law. An apparent filibuster in the Kentucky House in the final hour of the General Assembly session prevented it from passing. The three streams converged and the "window of opportunity" seemed to be conducive to the possibility of passing the bill. The concepts contained within the bill are still valid, worth reconsidering and fighting for by APNs interested in promoting treatment options and decreased mortality rates for opiate-addicted individuals.

Conclusion

The problem of opiate drug addiction and death from overdose will require a comprehensive solution that will include input and a multidisciplinary approach from healthcare providers, policy makers, public health officials, law enforcement and legislators. However, much evidence suggests that an effective strategy to reduce the

number of deaths from overdose is to remove the legal barrier to obtaining naloxone (Wermeling, 2010). The APN is in the position to advocate for families of those with addiction themselves, to provide some relief from worry. The "window of opportunity" appears to be ripe for the APN to lobby on behalf of this vulnerable population and save lives.

Addendum from Senator Stine

Sponsor of Senate Bill 5

When asked if she was going to pursue this issue the next legislative session she responded with this email:

" Thank you for your email about last session's SB5. I am not running for re-election so I will not be a member of the Senate when it convenes in January because my present term will have ended at the end of 2014. In these last days of my term I have been traveling around the state visiting treatment centers, community leaders and law enforcement officials trying to raise consciousness about the real threat that heroin poses to our state. It is a tragedy that the House chose to ignore this important legislation until the last day of the session and then load it down with "ripper" amendments so that they ran out of time and failed to pass SB5 in the session. Please encourage your legislators in your part of the state to take action. Unfortunately people are dying due to this inaction. If this many lives were lost due to some unknown virus or natural disaster there would be a huge response and

outcry. Why are blind eyes being turned toward the heroin epidemic and its terrible cost in Kentucky lives?

Thanks again for contacting me."

Senator Katie Stine

Manuscript 3

Effective Inpatient Treatment Methods for Opiate Addicted Pregnant Women:

A Retrospective Chart Review Study

ABSTRACT

This paper explores the treatment needs of opiate addicted pregnant women by assessing their preferred method of treatment when hospitalized on an inpatient behavioral unit at a large medical center in a southeastern state of the United States. The period of assessment was a one year time frame and the study is a retrospective case review of charts from 161 patients who were hospitalized at that time. The research questions to be answered included what is the preferred method of treatment for opiate addicted pregnant women when they are initially hospitalized and how is frequency of prn usage during treatment associated with their disposition at discharge? Findings from this study may initiate discussions on what retains a patient in treatment, what is important to do for the patient while in treatment, and what could be the long-term treatment needs to maintain drug abstinence and improve quality of life.

Problem Statement

Opiate addiction among pregnant women is a national epidemic that has risen sharply since 2000 (Patrick, 2012). The number of newborns with neonatal abstinence syndrome (NAS) defined as the withdrawal syndrome of the newborn of an opiate addicted mother, tripled between 2000 and 2009 and the number of mothers using opiates at delivery increased five-fold (Patrick, 2012). Additionally, maternal opiate use at the time of delivery in the United States increased from 1.19 to 5.63 per 1,000 births during the years 2000 to 2009 (Patrick, 2012). The costs of treating NAS in 2009 was 720 million dollars; 77.6% of this cost is paid by state Medicaid programs (Patrick, 2012).

According to Stone (2015), pregnant women who misuse substances are positioned at the center of public health and criminal justice intervention. "The impact of their substance use on their personal health and the health of their fetuses is a public health concern, as professionals in this field are dedicated to improving maternal and infant health" (Stone, 2015, p. 1). This places the woman at a disadvantage since as she is subject to criminal prosecution, increased surveillance, loss of custody of her child, and prosecution if she seeks assistance for her addiction issues and is an active user.

The overall goal of this Doctor of Nursing Practice (DNP) program practice inquiry project was to determine the most effective inpatient treatment methods for opiate addicted pregnant women. The immediate objective was to conduct a retrospective chart review of previously hospitalized opiate addicted pregnant women to ascertain the treatment preferences of the women and to see if there was a correlation in prn usage and

disposition at discharge. This type of analysis has the potential to help clinicians create a blueprint for effective treatment of this special population and thereby increase treatment retention and success. In addition, this group of women is a very specific population with specific needs. Most of them, when identified as pregnant and opiate addicted, are referred for short term hospitalization for opiate detoxification or treated with methadone or suboxone as a safer substitute (Veilleux, Colvin, Anderson, York, & Heinz, 2010). They often have difficulties withdrawing from opiates whether they are placed on detoxification or whether a drug replacement with methadone or suboxone is utilized (Veilleux et al., 2010). This study was designed to uncover which treatment modality is utilized most often by the women in general and what, if any, differences are found in need for adjunct medication for each treatment approach.

Research Questions

What is the preferred method of treatment for opiate addicted pregnant women when they are initially hospitalized and how is frequency of prn usage during treatment associated with their disposition at discharge?

Background and Significance

Illicit drugs were consumed by 5.1% of pregnant women in the United States in the year 2009, compared to 9.3% of women in the general population (Young, 2009). The prevalence rates of substance abuse during pregnancy ranged from 1.3 to 18% during the 1990s, with the rates increasing over the past two decades (Bertsch, Mullins, & Chaffin, 2006). It is important to note that the infants of women with opiate addiction were born with NAS, which resulted in significant respiratory distress, low birth weight, feeding difficulties and seizures. Also, the newborns with NAS were more likely to be

covered by Medicaid. According to Patrick (2012), mean hospital charges for these infants rose from $39,400 to $53,400 between 2000 and 2009, compared with a rise from $6,600 to $9,500 for all other hospital births over the same period. Solutions to decrease the number of opiate users and newborns exposed to opiates should be of utmost concern and priority due to the risks it poses to the newborn child and the high healthcare costs associated with treating the newborn with NAS.

Theoretical Framework

The study's theoretical framework is the Disease Model of Addiction. The Disease Model of Addiction proposes that addiction of any kind has biological, neurological, genetic, and environmental sources of origin. The disease model involves set factors that make a person susceptible to addiction be it either genetic predisposition or psychological damage that occurred during childhood or both factors (Peele, 1988). When this susceptible person is exposed to drugs and or environmental stress then drug addiction is likely to result which then leads to a host of other problems. This model fits when applied to the women in this study as the majority of the women reported a family member with addiction issues and a large majority of the women also reported a history of sexual abuse as a child or adolescent and current physical abuse in relationships.

Design and Methods

DESIGN:

The proposed study was based on a descriptive retrospective medical record review of opiate addicted pregnant women hospitalized on a behavioral unit at a large medical center in a southeastern state of the United States and that all study procedures were approved by the medical review board of the sponsoring institution.

SAMPLE:

The convenience sample consisted of all pregnant opiate addicted women hospitalized at Samaritan Hospital Behavioral Health from January 1, 2012 to December 31, 2012.

MEASURES/INSTRUMENTS:

Demographic Variables: Demographic variables included years of age, ethnicity, educational level, marital status, and presence of existing psychiatric disorder and type of opiate used (heroin, oxycodone etc.), age of first use, years of use, number of previous detoxification attempts, whether they are a tobacco smoker, gestational age of fetus and how many living children they had currently not counting present pregnancy.

Outcome variables: The primary outcome variable was preferred method of treatment (detoxification, methadone maintenance, subutex) as stated by the patient upon admittance to the inpatient facility. The secondary outcome measure was amount of PRNs used (in counts) from day 1 to day 5 of inpatient hospitalization. In addition, the average prn usage (across the 5 days of admission) were determined. Finally, information on discharge disposition [detoxification vs. methadone maintenance vs. suboxone (buprenorphine) vs left Against Medical Advice (AMA)] was obtained from the charts**.**

PROCEDURE:

The sources of research material were obtained from the medical charts of previously admitted patients on a behavioral health unit who had a diagnosis of opiate addiction and pregnancy. Since this study involves a retrospective chart review of existing data, no subjects were recruited. No identifiers were obtained from subject charts and each chart reviewed was given a unique code. An official letter of support

from the major medical center granting access to the charts for this research purpose was granted, giving permission for this research record review. Medical record personnel were utilized to obtain the charts once IRB permission was granted. The IRB approval processes were followed and the procedure for a Medical Expedited Exempt IRB Review was followed. Once the research study was approved, data was securely stored on removable device kept with the researcher. The sample included medical records of all pregnant women with opiate addiction hospitalized at Samaritan Behavioral Health during a specific time period (Jan 2012 to Dec. 31, 2012).

DATA ANALYSIS:

The primary outcome measure was an analysis of the preferred method of treatment as stated by the patient upon admittance to the inpatient facility. Differences in treatment completion were calculated using chi-square analyses for categorical and ordered categorical values (with Fisher's exact test for cells with lower than expected cell count), and using t-tests or Mann-Whitney U tests for continuous variables (which did not meet the assumption of equality of variance based on Levine's equality of variance test).

The secondary outcome measure was amount of PRNs used from day 1 to day 5 of inpatient hospitalization and how it related to disposition at discharge. Analysis of Variance (ANOVA) tests were used to assess mean differences in total and average (across the 5 days) prn usage by disposition at discharge (i.e., detox vs. methadone maintenance vs. suboxone (buprenorphine) vs left AMA).

Results

Sample Characteristics

The sample included 161 women. The sample was primarily white (96.3%), 26.4 years of age, high school or GED (65.8%). One-half of the sample were single and not in a relationship and were an average at 19.7 weeks of gestation. The majority were tobacco users (91.3%) and using opiates in general (42.2%) or a combination of opiates and other illicit drugs (34.8%). On average women started using opiates at age 19.3 and had been using for nearly 7 years. More than one-third of the women had a co-morbid psychiatric illness. Of those attending the methadone inpatient program, 80.7% completed (stayed 5 days). There were no significant differences in patient characteristics between those who completed and did not complete the program (See Table 1).

Preferred Method of Treatment During Hospitalization

When women were asked their preferred method of treatment, the majority preferred detoxification (see figure 1). The preference for method of treatment did not vary by demographic or other patient characteristics.

Association between PRN use and Discharge Disposition

There were significant differences in the frequency of PRN use by patients' disposition at discharge. Patients who left before treatment was complete/AMA, had significantly lower scores on total PRN use and average PRN use as compared to those who preferred to be detoxed from opiates or who had plans to be maintained on subutex or methadone upon discharge. Specifically, patients who left early/AMA or before the 5 days of treatment used less PRNs (Mean amount of total prn use = 5.6) whereas

participants who stayed the entire 5 days of treatment and did not leave AMA used more PRNs (Mean amount of total prn use = 13.2). Patients who left before treatment was complete/AMA, had significantly lower scores on total PRN use and average PRN use as compared to those who preferred to be detoxed from opiates or who had plans to be maintained on suboxone, subutex or methadone upon discharge (see Table 3). As indicated in Table 3, average PRN use among non-completers/AMA was lower compared to completers or those who were detoxed from opiates or chose maintenance medications

Discussion

The standard of care for an opiate addicted pregnant woman would necessitate a universal substance use screening during pregnancy and referral to treatment such as maintenance therapy if warranted (Mattick et al., 2009). Evidence based practice and a review of the literature suggests that when identified as pregnant and opiate addicted, women are referred for short term hospitalization for opiate detoxification and then treated with methadone or suboxone as a safer substitute on a maintenance basis (Martin et al., 2014: Kahila et al., 2007). A comprehensive, standard of care program regimen improves maternal and neonatal outcomes as well as reduces associated adverse health consequences (Jones, O'Grady, Malfi & Tuten, 2008; Kaltenbach & Finnegan, 1998). Methadone, Suboxone and Subutex treatments, also known as drug replacement therapy, is the preferred alternative to detoxification according to most research, as research has shown that it is safer and more effective for the addicted mother and fetus.

The treatment needs as expressed by the study sample did not match what the standard of care suggests. Greater than 90% desire to detoxify from drugs completely as verbalized by the patient (see Figure 1). No other study, known to this author, have asked patients

their preference for treatment. Addicted women who completely detox often relapse if they do not go to extended treatment and receive drug replacement therapy (Kahila et al., 2007). However treatment and drug replacement therapy is often difficult to obtain and afford, which may have affected the participants' stated choice of "detox." In addition they may have endorsed detox because participants felt that it was the "right" thing for their unborn child. Nonetheless, this finding is consistent with the findings according to Martin et al., (2014), who state that only about a third of the women hospitalized when pregnant for opiate addiction are placed on medication assisted therapy despite the standard of care for opioid abuse in pregnancy.

Alternatively, the poor endorsement of drug replacement therapy at discharge by the study sample may reflect the lack of available and accessible treatment facilities to for this population and the financial limitations that come with such treatment. This is consistent in other studies that highlight the multiple barriers pregnant women with addition problems face with a lack of suitable treatment options and challenges in finding and accessing treatment (Stone, 2015). These potential barriers necessitate the further expansion of treatment programs and social services to meet the needs of substance-using women (Stone, 2015). This need is highlighted by a qualitative study with 30 cocaine using women that found that optimizing the benefit of comprehensive services for addicted women requires their provision within a multilevel model of substance abuse treatment, including long- and short-term residential and intensive outpatient settings (Kaltenbach and Finnegan, 1998).

In addition, in the current study, PRN use was significantly associated with discharge disposition. The more the study sample received PRNs, the more likely they

were to stay the entire detoxification period and not leave against medical advice. Those who left against medical advice received the fewest PRNs; this finding was significant when examining both total PRN usage and when examining PRN usage based on the total stay. This could suggest that comfort level of the patient may be a factor in the patient completing treatment. Those who ask for and receive PRNs may be trying to decrease their discomfort while those who are not may have lower tolerance for withdrawal or be less motivated to engage in treatment. Often those patients who left AMA were patients who returned again once or twice for detox during the same pregnancy. This is consistent with other studies which reported that few opioid addicted women can handle abstinence from opioids (Unger et al., 2010; Martin et al., 2009).

Limitations

The limitations in this study include the small sample size (161) and the fact that it encompasses a geographic region that may not capture true demographics typical of the population at large. In this study, for example, 96.3% of the participants were White, which may lead a researcher to believe it is not a problem for other ethnicities.

An additional limitation is that since this study is a retrospective analysis of existing data, there could have been different study variables which could have affected the outcomes of the study that were unavailable. For example, the data on participants' withdrawal scores were unreliable because there were too many missing records from the charts. In other words, often times opiate withdrawal checks were not done the requisite or ordered times that they were supposed to be done. In addition, participant's motivation for detox was not measured. As a result, it is not possible to tell if those who left AMA were less motivated to complete treatment as compared to those who completed treatment. Future

studies may assess patient motivation as a possible predictor of discharge disposition and treatment completion.

A strength of this study is that it is the first of its kind. Opiate addiction among pregnant women is a subject which has been reviewed extensively for neonatal abstinence effects and the effects of drug replacement therapies but it has not been reviewed in terms of the patient experience, preference for treatment and success of treatment long term for the woman and her children.

Implications for Practice

This study can be used as a beginning blueprint for investigating what pregnant women with opiate addiction need for treatment from an inpatient perspective. It can begin the discussion on what retains a woman in treatment, what is important to do for the woman while she is in treatment, and what could be her treatment needs long term in order for her to remain drug free and improve her quality of life? It can help healthcare workers examine the stigma they place on the opiate pregnant addicted woman and shape attitudes and practice.

Table 1. Sample characteristics by program completion

	Total (N =161)		Completed (n = 130)		Not Completed (n = 31)	
	N	**%**	*n*	%	*n*	%
Ethnicity						
White	155	96.3	124	95.4	31	100.0
African American	4	2.5	4	3.1	0	0.0
Hispanic	1	0.6	1	0.8	0	0.0
Other	1	0.6	1	0.8	0	0.0
Education Level (missing=12)						
Less than High School	51	34.2	44	34.9	7	30.4
High School/GED or greater	94	63.1	79	62.7	15	65.2
College Graduate	4	2.7	3	2.4	1	4.3
Marital Status						
Single, not in relationship	82	50.9	73	56.2	9	29.0
Divorced/Separated	18	11.2	14	10.8	4	12.9
Non-Married, Living with Partner	37	23.0	25	19.2	12	38.7
Married	19	11.8	13	10.0	6	19.4
Non-Married, estranged from Partner	2	1.2	2	1.5	0	0.0
In relationship, not living with Partner	3	1.9	3	2.3	0	0.0
Type of Illicit Drug Use						
Heroin	10	6.2	7	5.4	3	9.7
Opiates in General	68	42.2	55	42.3	13	41.9
Oxycodone/OxyContin	23	14.3	18	13.8	5	16.1
Suboxone	2	1.2	0	0.0	2	6.5
Methadone	2	1.2	2	1.5	0	0.0
Combination of Many	56	34.8	48	36.9	8	25.8
Tobacco Use						
Yes	147	91.3	118	90.8	29	93.5
No	14	8.7	12	9.2	2	6.5
Co-Morbid Psychiatric Illness						
Yes	60	37.3	52	40.0	8	25.8
No	101	62.7	78	60.0	23	74.2
Number of Detox Attempts						
None	70	43.5	54	41.5	16	51.6
1 to 3	69	42.9	57	43.8	12	38.7
Greater than 3	22	13.7	19	14.6	3	9.7

Table 2

	Mean	SD	Mean	SD	Mean	SD
Age (years)	26.4	4.4	26.3	4.5	27.0	3.7
Gestational Age of Fetus (Weeks)	19.7	8.0	20.1	7.9	17.9	8.4
How Many Living Children	1.5	1.9	1.5	1.9	1.5	1.8
Age of First Use of Opiates in Years(missing = 4)	19.3	4.4	19.2	4.3	19.9	5.0
Duration of Use in Years (missing = 4)	6.9	4.9	6.8	4.8	7.3	5.6

*** Differences are calculated using chi-square analyses for categorical and ordered categorical values (with Fisher's exact test for cells with lower than expected cell count), and using t-tests or Mann-Whitney U tests for continuous variables (which did not meet the assumption of equality of variance based on Levine's equality of variance test).

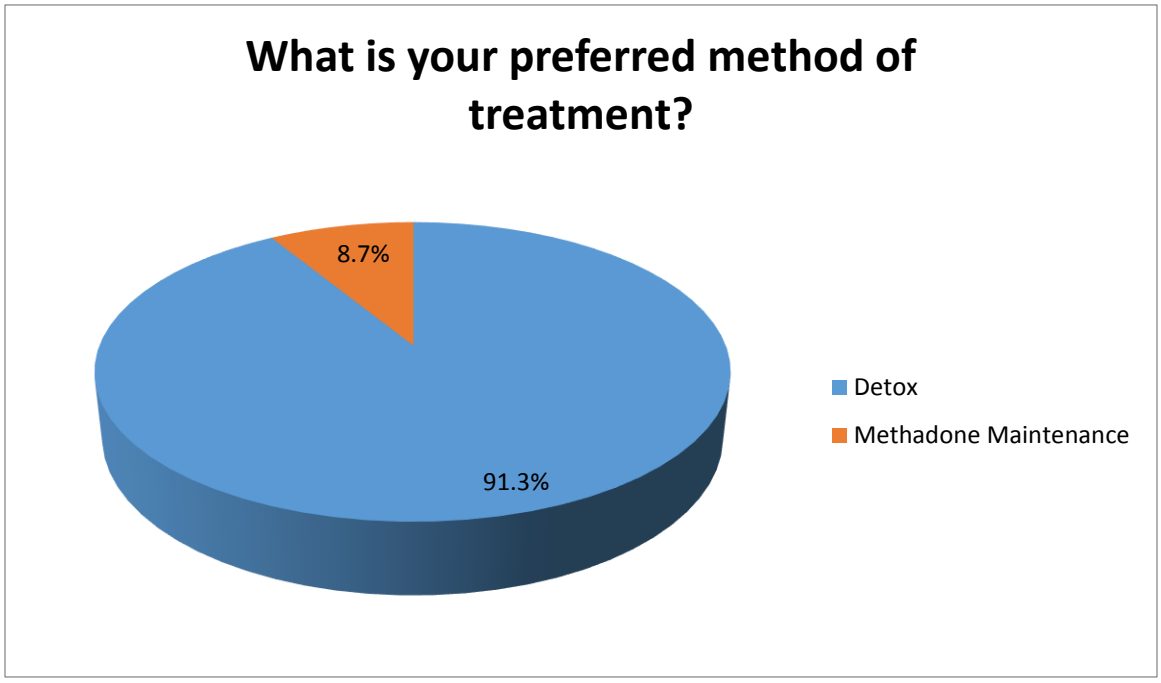


Figure 2 Preferred Method of Treatment

Table 3. Differences in Frequency of PRN use by Disposition at Discharge and Completion of Treatment

	Total PRN			
	Mean	**SD**	**F Statistic (DF)**	**P-Value**
Disposition at Discharge			7.0	<.0001
Methadone Maintenance (n=20)	12.3	7.9		
Detox from Opiates (n=101)	14.2	8.5		
Maintenance on Subutex (n=15)	13.2	10.5		
Left on no RX/AMA (n=25)	5.6	6.5		

	Average PRN*			
	Mean	**SD**	**F Statistic (DF)**	**P-Value**
Disposition at Discharge			3.7	.013
Methadone Maintenance (n=20)	2.5	1.6		
Detox from Opiates (n=101)	2.9	1.7		
Maintenance on Subutex (n=15)	2.8	2.2		
Left on no RX/AMA (n=25)	1.7	1.4		

Average PRN use is defined by the total PRN use/length of stay

Practice Inquiry Project Conclusions

Opiate addiction is a complex multidimensional disease that affects every aspect of the afflicted person's life. This problem becomes more urgent during pregnancy, because another life is involved. The evidence based literature has demonstrated the degree to which opiate addiction and pregnancy has escalated in scope in this country. The literature has also described the attempts at treatments for women who are pregnant and opiate addicted with an emphasis on the utilization of drug replacement therapy as the safest alternative for the woman and the child. However, the problems that opiate addictions encompass go beyond the pregnancy and expand into psychosocial, physiological, psychological, financial, legal and ethical realms. Thus this problem needs the focus of an APN to tackle some of its issues from the policy arena in order to create long term lasting effects for the health of this vulnerable population. The access to treatment is limited, and funding for standard drug replacement therapies is lacking. The women then attempt to detox off of all drugs and more often than not fail in that attempt. The result even with a woman who receives adequate drug replacement therapy is an infant born with neonatal abstinence syndrome, a costly expense to the system. Women who do seek treatment are often stigmatized by society and even by the healthcare workers they seek treatment from. In addition, they often face legal consequences of their drug use which could include losing custody of their children when they admit to needing help with their drug addiction.

Why are so many young women abusing drugs? What are their stressors in life? Why do they use drugs when others don't? Is prevention a possibility here? In the meantime how do we effectively treat these women in a manner that is consistent with

what they want and need? This research has basically raised several more important questions, and this researcher would like to go to the source for the answer, the women themselves.

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