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HEALTHCARE PRACTICES RELATED TO NEONATAL ABSTINENCE
SYNDROME

by
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A thesis submitted to the faculty of The University of Mississippi in partial fulfillment of
the requirements of the Sally McDonnell Barksdale Honors College.

Oxford
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ABSTRACT

The incidence of Neonatal Abstinence Syndrome (NAS) is abounding in hospitals across the nation due to the recent surge in opioid abuse. This thesis explores the variation in protocols and guidelines used by healthcare practitioners concerning NAS. This study consisted of a literature review as well as observations and interviews with healthcare practitioners in Neonatal Intensive Care Units (NICUs). The literature review revealed there has been a greater increase in NAS among rural areas, and there is currently no national standardized protocol for the treatment of NAS. Field notes taken during the interviews and observations confirmed the literature in that each NICU's protocol varied, although they were similar in many aspects. Five main themes were identified from the field notes, as well. In conclusion, it may prove beneficial to look into the development process of similar disease protocols such as Fetal Alcohol Syndrome (FAS) to gain insight to aid in the creation of a standardized protocol for NAS.

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INTRODUCTION

The opioid epidemic is one of the most serious issues facing America today. Over the past decade or so, as addiction rates have skyrocketed and garnered the attention of media outlets both local and national, several questions have emerged about the origins of and possible solutions to the crisis. While it is occurring across race, class, and geographic lines, the opioid problem is affecting populations well outside the stereotypical scope of Americans' traditional views of drug abuse, as it has taken root in predominantly white rural communities and branched out into suburban, middle class areas (Cicero, Ellis, Surratt, & Kurtz, 2014). The effects of the crisis are being felt across the nation but perhaps most strongly in the waiting rooms of America's rural hospitals, where people are being treated for overdoses. Additionally, a phenomenon often overlooked in news stories is the occurrence of Neonatal Abstinence Syndrome (NAS). NAS is a "drug-withdrawal syndrome that most commonly occurs after in utero exposure to opioids" and "manifests in the first few days of life as hypertonia, autonomic instability, irritability, poor sucking reflex, impaired weight gain, and less commonly, seizures" (Tolia et al., 2015, p. 2118-2119). According to data collected in 2014, a newborn was diagnosed with NAS every fifteen minutes, which resulted in a total of approximately 32,000 infants being diagnosed (Honein, Boyle, & Redfield, 2019). The headlines and soundbites are loud, but how did we get here?

In 1990 the president of The American Pain Society, Dr. Max Mitchell, claimed that doctors were not adequately treating patients' pain. Mitchell stated that "addiction is

rare in medical patients with no history of addiction,” an observation based on a single publication in 1980 that included no information on how it was conducted (Porter & Jick, 1980, p. 1). One year after Dr. Mitchell’s declaration, The American Pain Society issued new quality assurance standards for the treatment of acute pain and cancer pain. A decade passed, and the medical community’s philosophy of pain treatment continued to evolve.

To help physicians overcome their “opiophobia”, physician-spokespersons for opioid manufacturers informed prescribers that addiction was rare and cited flawed studies to emphasize the claim that the risk of addiction was less than 1% (Kolodny et al., 2015). Between 1996 and 2002, Purdue Pharma funded more than 20,000 pain-related educational programs and issued a campaign to encourage long-term use of opioids for chronic non-cancer pain. In addition, they gave financial contributions to the American Pain Society, the American Academy of Pain Medicine, the Federation of State Medical Boards, the Joint Commission, and many others. As a result, these organizations began pushing for “more aggressive identification and treatment of pain, especially use of opioid pain relievers” (Kolodny et al., 2015, p. 562).

In 2000, The Joint Commission, the nation’s leading health care accreditation group, released standards for organizations to better treat patients with pain by quantitatively measuring pain on a ten-point scale (Baker, 2017). Essentially, pain became known as the “fifth vital sign,” in addition to body temperature, pulse rate, respiration rate, and blood pressure (Baker, 2017). Hospitals began using treatment protocols and algorithms based on patients’ responses to questions regarding their pain level. This became a cause for concern among health care practitioners as the incidence of over-sedation by opioids increased from 11.0 to 24.5 per 100,000 inpatient hospital

days after the numerical pain treatment algorithm was put in place (Baker, 2017).

Realizing the implications of the numerical pain scale, The Joint Commission took measures to fully remove the phrase “pain as the fifth vital sign” from the accreditation standards manual by 2004. In 2009, The Joint Commission also removed the previous standard that all patients’ pain levels be measured, regardless of the nature of their visit, except for patients in behavioral health care. However, a study found that from 2009 to 2010, physicians prescribed opioids, often in high doses, in more than 50% of 1.14 million adult nonsurgical hospital admissions (Herzig, Rothberg, Cheung, Ngo, & Marcantonio, 2014).

The Joint Commission continued to modify the pain treatment protocol, and in 2011, placed an emphasis on the range of options, both pharmacological and nonpharmacological, that could be used in treating pain. Today, The Joint Commission is still working to mitigate the effects of the 2000 standards. Draft standards were released in 2017 with recommendations to consider patients’ psychosocial background as well as include the patient’s input in treatment planning and closely monitor the use of prescription opioids (Baker, 2017). Despite The Joint Commission’s efforts, opioid addiction rates have continued to rise unabated.

In the United States from 2000 to 2012, the rates of Neonatal Abstinence Syndrome (NAS) and maternal opioid abuse increased nearly 5-fold (Villapiano, Winkelman, Kozhimannil, Davis, & Patrick, 2017). Perhaps no one could have predicted the harmful effects that the alarming increase in opioid addicts would have on the future generations of infants. NAS is a fairly new phenomenon, and there is still a plethora of new research that needs to be conducted to better the lives of both mother and baby

dealing with the devastating effects of drug addiction. This study investigates healthcare practitioners' treatment of NAS in order to provide insight to aid in the creation of a national standardized treatment protocol for NAS.

LITERATURE REVIEW

Opioid Definition

According to the National Institutes of Health (NIH), opioids are a class of drugs that activate opioid receptors throughout the nervous system that result in relief from pain. Opioids include illegal street drugs such as heroin, synthetic drugs such as fentanyl, and legal prescription drugs used for pain relief (NIH, n.d.). The most commonly prescribed opioids include methadone, codeine, hydrocodone, oxycodone, propoxyphene, fentanyl, tramadol, hydromorphone, morphine, and levorphanol (Mistry, Bawor, Desai, Marsh, & Samaan, 2014). Opioids are prescribed for pain management in both acute and chronic conditions. These include non-cancer chronic pain, post-surgical treatment, and musculoskeletal pain. Because opioids belong to an addictive class of narcotics, abuse often leads to “the development of tolerance, dependence, and overdose” (Mistry et al., 2014, p. 156).

History of the Opioid Epidemic

Deaths by opioid overdose have skyrocketed since the national standards urged physicians to treat pain by use of prescription opioids. Since 1999, the number of deaths from prescription opioid overdose have quadrupled, surpassing the number of deaths involving cocaine and heroin combined by 2007 (Keyes, Cerdá, Brady, Havens, & Galea, 2014). Drug addiction as a public health problem itself is not a new phenomenon, but the sources of that addiction have changed dramatically. Research indicates that increased availability and ease of access are significant contributors to this epidemic (Keyes et al.,

2014). Pressured by evolving treatment protocols, physicians were tasked with better treatment of pain. As a result, there was a marked increase in the availability of prescription drugs. For example, methadone sales increased thirteen-fold between 1997 and 2007 (Keyes et al., 2014). By 2010, there were enough prescription opioids to administer five milligrams of hydrocodone every four hours to every single adult in the United States for one month (Keyes et al., 2014). As the number of people with a prescription for an opioid medication has risen, access to such medications has become proportionately easier. Researchers have found that most nonmedical opioid users obtain the drugs from friends, family members, or street dealers (Keyes et al., 2014).

Opioids Across the Rural - Urban Continuum

The increase in opioid deaths has been nationwide, but there are notable regional pockets of even greater incidences of overdose. Largely rural populations in states such as Kentucky, West Virginia, Alaska, and Oklahoma have experienced the opioid crisis to a more severe extent than others (Keyes et al., 2014). The reasons for this phenomenon are unclear, but researchers have begun to identify some of the risk factors that explain why rural populations are more likely to abuse prescription opioids. In concert with the national trend, the availability of prescription opioids has increased throughout rural areas in recent years. OxyContin™, in particular, was more heavily marketed in rural areas surrounding Appalachia (Keyes et al., 2014), which may explain some of the increase. A generally higher level of chronic pain itself may also be an explanation (Keyes et al., 2014). Rural populations also tend to be more elderly than urban populations, which would be associated with more chronic pain and more chronic pain-related opioid prescriptions (Keyes et al., 2014). Finally, rural populations also experience more chronic

pain and injury related to rural industries, such as coal mining and other heavy labor professions (Keyes et al., 2014). According to Keyes et al. (2014), there also seems to be an emigration of young adults from rural areas. For example, West Virginia's percentage of adults aged older than 65 is twice that of those aged 18 to 24 (Keyes et al., 2014). This demographic phenomenon has two effects that work in concert. Primarily, this creates an aging workforce which leads to poor economic infrastructure and development.

Communities with substandard economies and workforces may become more vulnerable and succumb to the use of nonprescription opioids, along with other substances. The secondary effect may lead to an increase in opioid abuse among the young adults who stay in these rural communities. Young adults who remain in these areas may have a greater risk of drug abuse and may be more likely to become drug dependent at a young age (Keyes et al., 2014).

Although the specific reasons for increased drug abuse rates among rural areas is unclear, there is an interesting political correlation. According to Monnat's (2016) study, Trump over performed in the 2016 Presidential Election in counties that experienced the highest drug, alcohol, and suicide mortality rates. The study also noted that these "deaths of despair" are higher among non-Hispanic whites and that it has raised the overall mortality rate for middle-aged non-Hispanic whites, most notably those lacking a college degree living in small cities and rural areas. Economic distress and the presence of a working class appear to account for the relationship between Trump's success in these areas with high rates of "deaths of despair". These areas include Appalachia, the Industrial Midwest, and New England. All of these areas have experienced increased

unemployment rates in manufacturing and are considered economically distressed (Monnat, 2016).

Compared to urban areas, communities in rural areas tend to have larger families and higher fertility rates (Keyes et al., 2014). Taking this into account and the increase in opioid abuse among rural populations, one might reasonably speculate that there has been an increase in Neonatal Abstinence Syndrome (NAS) in these communities as well. The occurrence of NAS across the United States nearly tripled from 2000 to 2009, and patients are requiring longer inpatient treatments with the median length of stay increasing from 13 to 19 days from 2004 to 2013 (Tolia et al., 2015). As with the greater increase in opioid abuse among rural areas, there also seems to be a greater increase in NAS among rural communities when compared to urban areas. From 2004 to 2013, NAS occurrences in rural infants increased from 1.2 to 7.5 per 1,000 hospital births whereas NAS occurrences in urban infants increased from 1.4 to 4.8 per 1,000 hospital births (Villapiano et al., 2017). In correlation, deliveries complicated by maternal opioid abuse increased more drastically among rural mothers (1.3 to 8.1 per 1,000 hospital deliveries) compared to urban mothers (1.6 to 4.8 per 1,000 hospital deliveries) (Villapiano et al., 2017). Although there has been an increase in nonmedical prescription opioid morbidity and mortality across all areas, these phenomena have been concentrated in states with largely rural populations (Keyes et al., 2014). The occurrence of maternal opioid use and NAS have increased disproportionately in rural counties when compared to urban counties as well (Villapiano et al., 2017).

This drastic comparison emphasizes the need for better healthcare and drug prevention measures in rural communities across the United States. Specifically, rural

counties are in dire need of hospitals with the capability of caring for and treating opioid affected mothers and infants (Villapiano et al., 2017). Currently, there is no standard treatment protocol for NAS, and treatments are varied in children's hospitals across the United States (Patrick, Kaplan, Passarella, Davis, & Lorch, 2014).

Nonpharmacological Treatments

While a standardized treatment protocol is lacking, most all hospitals use nonpharmacological measures as a first line of treatment. These treatments alone may successfully treat the neonate in mild cases of withdrawal. Nonpharmacological treatments are “easily acceptable, less expensive, and less controversial” (Kocherlakota, 2014, p. e553). The goal is to promote an environment of low stimulation to help calm the infant and minimize withdrawal symptoms. Swaddling is very important in keeping the infant calm and undisturbed. It is shown to decrease stimulation and crying and promote good sleeping habits. Skin-to-skin contact and pacifiers may also help soothe the child. Trained volunteer cuddlers are used in many hospitals to hold and comfort infants when family members and nurses are unable to do so. This human touch is especially important for babies born addicted to drugs such as opioids (Hilton, 2018). There are also nontraditional treatments such as massage therapy, music therapy, and non insertive acupuncture. Studies show that active maternal participation is the “best nonpharmacologic care” (Kocherlakota, 2014, e553). It is very important that the mother be treated with respect and that healthcare practitioners possess a nonjudgmental attitude towards the mother. If the mother feels like she is not being judged for the choices she has made, she may be more likely to participate in the care of her child. Supportive care

is essential in properly treating the infant and can lead to an earlier discharge from the hospital as well (Kocherlakota, 2014).

Rooming-In

Perhaps one of the most effective nonpharmacological treatments for opioid exposed infants and NAS is the rooming-in approach. Rooming-in occurs when the mother stays in the same room with her baby throughout the length of the hospital stay. Rooming-in of both mother and baby has remarkably profound benefits for both parties involved; it is a major part in the baby's recovery and decreases the severity of withdrawal symptoms (Abrahams et al., 2007). The traditional method of treating NAS has been a two-fold approach involving a low-stimulation environment with feeding of a high calorie formula and administration of a narcotic or central nervous system suppressant aimed at decreasing the infant's withdrawal symptoms. It has often been deemed necessary that the mother and infant be separated so that the infant can be closely monitored and observed; however, separation of mother and baby in normal situations can lead to detrimental outcomes including difficulties in bonding and attachment and can even result in abandonment. These issues are already closely associated with mothers who experience substance abuse (Abrahams et al., 2007). According to Abrahams et al. (2007), opioid exposed infants who roomed-in with their mothers were more likely to have a decreased length of stay in the hospital and were more likely to go home in the custody of their mothers. These infants were also less likely to need treatment for NAS (Abrahams et al., 2007). Rooming-in helps the mother feel more involved and also facilitates the act of breastfeeding which is readily encouraged, if possible. Breastfeeding may "decrease the incidence of NAS, the need for pharmacological treatment, and the

length of the hospital stay” (Kocherlakota, 2014, p. 555). However, breastfeeding is not conducive if the mother has illicit drug and/or polydrug abuse or is infected with HIV (Kocherlakota, 2014). Overall, the rooming-in of mother and baby is an effective tool that should be used when possible and helps both individuals transition more easily into their new lives.

Infant Seat

There are several hospitals that are using a new, innovative technology that soothes the infant by simply placing him/her in an infant seat. It is called the 4moms mamaRoo and includes five different settings. These settings include car ride, kangaroo, tree swing, rock-a-bye, and wave. The seat bounces up and down and sways side to side which closely mimics the soothing sensation of being rocked. Through a pilot study conducted by the National Perinatal Association (NPA) and 4moms, researchers concluded that babies were more physiologically stable after thirty minutes in the swing. The babies had lower heart and respiratory rates and were in calmer behavioral states. Healthcare practitioners have advocated that mamaRoo is an effective nonpharmacological treatment for opioid exposed infants and those with NAS suffering with withdrawal symptoms. This is a great tool to help ease the discomforts of withdrawal and soothe the babies, especially when the parents, other family members, nurses, or volunteers are unavailable to comfort the infant. The mamaRoo is currently in 375 hospitals across the nation (4moms & NPA, 2018).

Criminalization

There is currently a major controversy over the criminalization of pregnant women with substance abuse history. The first obstacle is accurate identification of in

utero drug exposure. There are many methods of identification including interview, self-administered questionnaires, intake history, urine testing of mother and infant, and hair and meconium testing of the infant. Self-reporting is often a difficult task for many mothers for fear of involvement of Child Protective Services (CPS) and/or because it is socially unacceptable. There is also the issue of how society sees maternal drug use. Some view it as a public health crisis that needs compassion and understanding while others see it as a criminal act that deserves legal punishment. However, both the Supreme Court and the medical field see addiction as a disease (Lester, Andreozzi, & Appiah, 2004). According to Lester et al. (2004), there were no statutes criminalizing drug use during pregnancy; therefore, many courts in the past have prosecuted women under child abuse, assault, murder, drug dealing, or delivery of drugs to a minor charges. However, according to the Guttmacher Institute, as of February 1, 2019, there are twenty-three states and the District of Columbia that consider substance abuse during pregnancy as child abuse, and three consider it grounds for civil commitment. Even if the mother is not criminally prosecuted, CPS can remove the child from the mother based on positive toxicology screens at the time of birth or confirmed reports of drug use in the home (Lester et al., 2004). After the child has been removed, CPS is required to ensure that the mother receives the opportunity for treatment for her substance abuse addiction through a plan formulated by the court system. If the mother refuses to comply, custody rights can be terminated, and the child will be eligible for adoption. Although every state has variations of laws mandating the report of child abuse and neglect, not every state has a law mandating the report of drug use during pregnancy (Lester et al., 2004). However, there are twenty-five states and the District of Columbia that require reporting of

suspected prenatal drug use by healthcare professionals. Eight states require them to drug test those individuals suspected of prenatal drug use (Guttmacher Institute, 2019). While it is a complex battle, many states are leaning towards treatment of the mother. Nineteen states have either created or funded drug treatment programs targeted specifically for pregnant women, and seventeen states and the District of Columbia have laws giving priority to pregnant women for state-funded drug treatment programs (Guttmacher Institute, 2019).

Research

Despite the increase in opioid addiction rates and subsequent rise in the number of NAS diagnoses, there is a lack of published research concerning this disease. Hospitals across the nation are in need of a standardized treatment protocol for NAS and proper education and funding for nonpharmacological treatment options. Community resources should also be made more available to mothers recovering from addiction, and if these resources are lacking in a community, arrangements should be attempted to help both mother and baby. Perhaps research could be conducted to see which types of community resources are most effective at assisting new parents struggling with addiction.

Healthcare practitioners are needed in the development of a protocol, and their insight and knowledge is crucial in creating a protocol that will be effective and implemented to the fullest extent. These gaps in the literature led me to ask the question: What treatment protocols, community resources, and advocacy are healthcare practitioners who serve patients (including those from rural areas) in the South employing to better treat the influx of patients with NAS? There also seems to be a disconnect between the various national medical organizations and the healthcare practitioners who are actually

diagnosing and treating these infants. There are several organizations that have published guidelines in treating this disease, yet the protocols vary in hospitals across the nation. How are healthcare practitioners navigating these protocols and implementing them in their practice?

METHODS

In conducting this research on healthcare practitioners' treatment of Neonatal Abstinence Syndrome (NAS), I performed a comparative case study by observing in hospital Neonatal Intensive Care Units (NICUs) and interviewing healthcare practitioners who treat infants diagnosed with NAS. The comparative case study was conducted at two different urban hospital NICUs located in the southern United States that serve patients from across their states, including rural populations. The study involved observation, interviews, and document reviews. NICUs in the southern U.S. were chosen due to the recent increase of NAS occurrence among rural areas. Due to the lack of availability of many types of healthcare in rural areas, patients are often forced to seek treatment in larger, more urban cities, especially for the specialized care required from high risk pregnancies. An interview with a registered nurse who works in a rural NICU was also conducted.

The documents obtained include hospital treatment protocols, NAS scoring sheets, and informational pamphlets on NAS. Although most, if not all, NICUs/hospitals have a treatment protocol for NAS, there is no standardized policy for treatment (Patrick et al., 2014). Several national medical organizations have released guidelines/position statements concerning the treatment of NAS. To supplement these sources, I conducted research to explore and investigate the various protocols being practiced in hospitals today and the effectiveness of the different policies.

Before I could interview or observe in the NICUs, I submitted an abbreviated

application to the Institutional Review Board at the University of Mississippi. I submitted my application and was approved in early April of 2018. I was also required to submit an additional application to the External Review Board for the first NICU I observed in. This application was approved in late July right before I conducted my observations and interviews at this particular NICU.

I spent a total of two days, approximately 12 hours, at the first NICU I observed. This NICU is a Level IV facility with 96 beds. I was referred to this specific neonatologist by my thesis advisor and contacted her through email. I shadowed the attending neonatologist and her team. The team consisted of the attending as well as a neonatal fellow, pediatric resident, two neonatal nurse practitioners, a dietitian, and a speech pathologist. I observed and took field notes when applicable during the morning rounds. During rounds, the team presented on each of their patients and made changes to the treatment plan based on any new findings that had been made since the previous day's rounds. Afterwards, I sat with the residents and fellows in the resident workroom. The residents did their charting, and I asked several questions pertaining to NAS such as how the NAS scoring sheet worked and the medication they used if pharmacological treatment was needed. The following day, I conducted my interview with the neonatologist and asked several questions about NAS. We discussed the diagnostic process, pharmacological and nonpharmacological treatments, and the rate of occurrence. This particular hospital had 19 infants diagnosed with NAS in 2016 compared to 58 in 2017. I also asked about the placement of the infants, whether they were placed in the NICU, nursery, with the mother, etc. I took field notes on a legal pad throughout the interview. Afterwards, I observed morning rounds again and saw the daily routine of the

NICU. Once morning rounds were complete, I shadowed the neonatal fellow and followed him as he went to deliveries. During my observation, I did not witness interactions between providers and babies specifically diagnosed with NAS. There were two patients that received narcotics and required the NAS scoring scale; however, this was due to prolonged ventilation, not intrauterine drug exposure.

For the second hospital I observed, I spent a total of approximately 16 hours over two consecutive days in early August of 2018. This particular NICU is a Level IV facility with 98 beds. I chose this NICU because of the large rural population it serves, and I had also previously shadowed in this facility. I contacted the neonatologist through email. I was required to complete paperwork and submit a background check prior to my observation. I began the first day by shadowing a NICU nurse. I watched as she cared for her two patients and charted. She talked with me about my project and gave me several documents which included treatment protocols on NAS. She also gave me the pamphlet they provide to the parents of a baby diagnosed with NAS which explains how to care for the infant and create a low-stimulation environment. I then shadowed one of the attending neonatologists and his team on morning rounds. The team consisted of the neonatologist, a neonatal nurse practitioner, dietitian, as well as a fellow observer. I followed them throughout rounds and took notes when applicable. Afterwards, I got a chance to ask the attending several questions about NAS treatment and his research on this topic. I took field notes on a legal pad during the questioning. That afternoon, I was able to sit in on a care team meeting. The care team provides support for opioid-exposed infants and consists of many different professions including physicians, nurses, social workers, child life specialists, lactation consultants, and care providers. During the meeting, they

discussed the successes of the program and its progress, reviewed and edited a new parent information pamphlet, and presented results from an internal survey on Trauma Informed Care, an initiative to educate nurses about addiction and its effects on mothers. On the second day, I shadowed a lactation consultant who works for the care team. I interviewed her and asked the same questions I asked the previous neonatologists. Follow-up questions were also asked such as the benefits of breastfeeding and how it helps in the recovery of the infant. We also discussed the different medications that the moms are prescribed during pregnancy which help with the withdrawal symptoms they experience when they come off the substance they were abusing. Likewise, I took field notes throughout this process. Afterwards, I observed her as she cared for an infant that had been exposed to drugs in utero but never developed signs of withdrawal. She brought the baby back to the room where the mother was staying and did a lactation consultation. She explained how to properly breastfeed the baby and encouraged her to do so; however, she also assured her that it was perfectly normal if she was not able, or it was too difficult. The mother was having a difficult time trying to get the baby to breastfeed, but the lactation consultant gave her advice on how to increase production of milk and how to get the baby to latch to feed for a sufficient amount of time. Although this baby had not been diagnosed with NAS, this experience was very helpful in my understanding of the care for drug-exposed infants. During my observation, I did not observe any interactions between providers and infants formally diagnosed with NAS.

To analyze the data obtained from the observations/interviews, I initially read all my field notes and the documents received after the observations at each hospital. I then identified three specific themes that were prominent at each hospital. These themes

include both pharmacological and nonpharmacological treatments as well as advocacy/community resources. After I determined the broad, overarching ideas, I conducted a detailed analysis based on each specific theme. The detailed analysis includes examples such as quotes and stories and generalizations for each topic based on my observations, interviews, and document reading.

I could not find a clear, exact treatment protocol for NAS that was issued by a national organization/association; however, I did find three national organizations that released treatment guidelines/position statements. I conducted a web search of various national medical organizations and Neonatal Abstinence Syndrome to see if any guidelines had been posted for that particular organization. I then followed several of the supporting articles that had been cited for additional information. These three organizations and their guidelines/position statements are addressed in the “Findings” chapter.

FINDINGS

Throughout my observations, interviews, and document reviews, I was able to identify five main themes related to Neonatal Abstinence Syndrome (NAS) that were apparent in all three NICUs. Although the protocols were somewhat varied, each NICU has a treatment plan in place that includes morphine as the first line of treatment if pharmacological measures are needed. Likewise, each NICU implements nonpharmacological measures first, if possible, to prevent the infant from being subjected to narcotics. These protocols witnessed during the observations were compared to treatment guidelines issued by three national medical organizations. Lastly, there are community resources available for mothers struggling with opioid addiction who have recently given birth to an opioid exposed infant. As well as helping connect mothers with nearby resources, healthcare practitioners are fervently advocating for a national standardized treatment protocol for NAS which would help healthcare professionals across the country better treat infants diagnosed with this disease.

Nonpharmacological Treatment

Based on my observations and literature research, there seems to be a consensus that the first line of treatment for NAS should be nonpharmacological measures if possible. However, if the infant has extreme withdrawal and receives a high score on the NAS Scoring Sheet, nonpharmacological measures are not sufficient, and medication will be used to try and alleviate the symptoms. There are many different techniques that can be used to administer nonpharmacological treatment, but the main goal is to reduce

stimulation and light exposure and provide adequate comfort and support for the infant (Hudak, Tan, The Committee on Drugs, & The Committee on Fetus and Newborn, 2012). According to *Neonatology for Primary Care*, only 25% of infants who display withdrawal symptoms will need pharmacological treatment (Ostrea, Alviedo, Banadera, Cortez, & De Jesus, 2015, p. 469); therefore, it is extremely important that supportive, nonpharmacological treatments are readily available and implemented properly.

All three NICUs in question agreed that nonpharmacological measures should be implemented first before medication is considered. These measures include but are not limited to skin-to-skin contact, breastfeeding, reduction in stimuli (light, touch, and sound), skin protection, and swaddling. The second hospital I observed in provided me with the information pamphlet they provide to the parents. The recommendations they provided include keeping the lights low, turning off the TV, setting any phones to a low ring or silent, touching the baby gently and speaking in a low voice, keeping visitors to a minimum, waking the baby only for feeding, and caring for the baby without a lot of handling or touching. The pamphlet also recommended using skin-to-skin contact and swaddling. The second hospital I observed at also stated that the practice of rooming-in has been very effective. The rooming-in approach allows the mother to bond with the infant and learn how to properly care for her infant. The lactation consultant I shadowed noted that “keeping the mom and baby together increases bonding and helps mom feel needed, necessary, and successful.” While shadowing the lactation consultant, she was caring for an opioid-exposed infant and was encouraging the mother to attempt breastfeeding and keep the baby with her as much as she could. She explained the benefits of skin-to-skin contact and breastfeeding and that these were extremely helpful

in preventing withdrawal symptoms for the baby. The nurse I interviewed from the rural hospital agreed that she thinks the rooming-in approach would work well in her hospital. This hospital does not currently implement this practice. The first hospital I observed at also implements the rooming-in approach as long as the infant does not require any acute care which would require him/her to be placed in the NICU. All three hospitals treat infants with nonpharmacological measures as a first line of treatment before medication is used. Pharmacological treatments are used only when nonpharmacological treatments are unsuccessful in maintaining the infant's withdrawal scores at a low level.

Although there is no standardized treatment plan for NAS, each hospital I observed agrees that nonpharmacological measures should be taken before any medication is prescribed to alleviate withdrawal symptoms. There is not one single method that works best for this first line of treatment; it is simply based on placing the infant in a low stimulation environment that will nurture and promote infant growth and comfort.

Pharmacological Treatment

Pharmacological treatment of NAS includes medications prescribed to infants who express symptoms of withdrawal to help reduce the effects which can be fatal. Medications used to treat NAS are opioids (tincture of opium, neonatal morphine solution, methadone, and paregoric), barbiturates (phenobarbital), benzodiazepines (diazepam, lorazepam), clonidine, and phenothiazines (chlorpromazine) (Hudak et al., 2012). Morphine, clonidine, and phenobarbital were all included in the treatment protocols I received from the hospitals I observed. There is currently no standardized

treatment protocol for NAS to guide healthcare practitioners on which medications and dosages to prescribe (Patrick et al., 2014).

While interviewing the various healthcare practitioners and reading the documents/protocols given to me, I noticed a stark similarity between the hospitals' pharmacological treatment plans. The nurse I interviewed from the rural women's hospital gave me a copy of the hospital's protocol for assessment and treatment of NAS. They use the Modified Finnegan Neonatal Abstinence Scoring Tool which the other hospitals use as well. The Modified Finnegan Scoring Tool measures three different areas of the infant's overall health including central nervous system/neurologic excitability, autonomic signs, and gastrointestinal dysfunction. CNS/neurologic excitability includes tremors, irritability, increased wakefulness/sleep disturbance, high-pitched crying, increased muscle tone, hyperactive deep-tendon reflexes, seizures, frequent yawning and sneezing. Autonomic signs include sweating, nasal stuffiness, fever/temperature instability and mottling. Poor feeding, uncoordinated and constant sucking, vomiting, diarrhea, dehydration, and poor weight gain are symptoms of gastrointestinal abnormalities. The infant is scored every three to four hours. Morphine sulfate is given if two consecutive scores are greater than 8. The first hospital I observed in also implements oral clonidine if morphine alone is not sufficient. The second hospital I observed also initially uses morphine and adds oral clonidine then phenobarbital if morphine alone does not help lower the infant's scores.

At the first NICU I observed, there was an infant who had to be scored using the NAS tool during each of the baby's care sessions. This particular baby did not have NAS but had to be treated with narcotics due to prolonged ventilation. The nurse scored the

baby by examining him while she changed his diaper and made sure he was comfortable in his crib. I watched as she charted and scored him using the electronic score sheet. The baby was not very fussy and had not been displaying signs of withdrawal; therefore, he was not given any narcotics at that time.

Based on my observations/interviews, morphine seems to be the most common medication prescribed to infants experiencing drug withdrawals. However, the hospitals use different secondary medications if the first line of pharmacological treatment is insufficient. Considering the recent increase in NAS, there is a dire need for a national standardized medication protocol that is implemented by each hospital. Without a national standardized protocol, treatments and clinical outcomes may vary widely across hospitals in the U.S. (Hearing on H.R. 1462, 2015).

Discharge Policy

During my interviews and observations, specific details regarding discharge were never fully discussed, but the general process was laid out. According to my interview, the rural hospital typically discharges the patient from the NICU within two to four weeks, and the patient follows up with a pediatrician or the NICU outpatient clinic, depending on the physician's orders. The first hospital I observed discharges infants after they have stopped pharmacological treatment, and the infant scores below a certain number on the NAS scoring form. The baby is then seen in the new baby clinic within 48-72 hours after discharge while also following up with a pediatrician. Discharge policy was not discussed at the second hospital I observed in.

The American Academy of Pediatrics' (AAP) Committee on Fetus and Newborn released proposed guidelines for hospital discharge of the high-risk neonate in 1998 and

again in 2008. The 2008 guidelines were reaffirmed in 2011 (AAP, 2012). There have been no recent guidelines published since then. In the 2008 guidelines, the AAP classified infants with parents who committed substance abuse as high-risk infants due to family issues. The guidelines proclaimed that the infant was put at higher risk due to “adverse effects on the developing fetus in utero and because of possible postnatal exposure to drugs through breastfeeding or by inhalation” (Committee on Fetus and Newborn, 2008, p. 1121). The behavior of the parents was also concern for the child’s home environment. The Committee stated that effective strategies for ensuring the safety of the infant have been difficult to find. Most of them have included follow-up observations such as home visits; however, the success of these visits is not entirely evident (Committee on Fetus and Newborn, 2008). Although parental drug use is mentioned in the article, there is no mention of NAS. This lack of literature on discharge of NAS infants by the AAP is further proof that more research is critically needed.

National Organizations’ Guidelines/Position Statements

Just as the treatment protocols of the hospitals I shadowed in vary, the guidelines/position statements of national medical organizations differ, as well. The National Perinatal Association (NPA) issued a position statement in 2017 concerning NAS treatment. The position statement expressed support for comprehensive treatment programs for parents and encouraged continued research of rooming-in practices for mother and infant. The NPA also encouraged health care access with prenatal and substance abuse treatment in one facility (Goyer, Hoppe, Milford, & Puccio, 2017). The AAP issued a policy in 2012 expressing support for the modified Neonatal Abstinence Scoring System which assesses twenty-one different symptoms/signs that are observed

during presentation of NAS. The AAP stated that infants at risk for NAS should be kept in the hospital and observed. The length of stay is variable and depends on the mother's substance use history. The first line of treatment should be nonpharmacological measures aimed at reducing stimulation and maximizing the infant's comfort. Breastfeeding is also encouraged in that it has been "associated with less severe NAS that presents later and less frequently requires pharmacologic intervention" (Hudak et al., 2012, p. 548). The AAP urges every nursery to have a NAS protocol and to train staff on how to properly conduct a NAS assessment. The AAP does not encourage pharmacological treatment unless the infant has failed to respond to nonpharmacological treatments, and medication is deemed absolutely necessary. It should be used in these cases to prevent complications such as fever, weight loss, and seizures. The AAP did not issue a precise protocol in this policy on which medication to use or dosage amounts. The policy stated that the majority of clinicians in the United Kingdom and the United States use an opioid (either morphine or methadone) (Hudak et al., 2012). In the AAP's policy released in 1998, no dosage amounts were given for morphine; however, methadone was stated to be given in initial doses of 0.05 to 0.1 mg/kg every 6 hours, "with increases of 0.05 mg/kg given until signs are controlled" (Committee on Drugs, 1998, p. 1084).

The Joint Commission also released an information piece on the management of NAS. The Joint Commission stated that the Finnegan Scoring System is widely recommended to assess infants' withdrawal severity. Infants should be scored every 3 to 4 hours until 48 hours after medication has been stopped. The Joint Commission also stated that breastfeeding support should be given, and if possible, rooming-in should occur. The organization agrees that pharmacological treatments are only to be used when

nonpharmacological measures have not been sufficient and/or the infant is experiencing severe complications. The document states that “no single medication or regimen is considered suitable for every patient,” and “there are no standardized regimens for pharmacological management of NAS” (The Joint Commission, 2016, p. 1-2). The Joint Commission also maintains that morphine is the most common drug used to treat NAS. They issued that the goal for NAS management is for infants to exhibit normal eating and sleeping patterns, weight gain, maintenance of stable withdrawal scores, and termination of withdrawal symptoms (The Joint Commission, 2016).

Advocacy/Community Resources

Because there is currently no standardized treatment protocol for NAS, the interviewees agreed that advocacy for legislative changes is essential in creating and passing a national standard for the treatment of NAS. Accessibility of community resources is also very crucial in providing adequate support for mothers and discharged infants who have no safe environment to return to. Both of these aspects combined can lead to a brighter future for both infants diagnosed with NAS and the mothers of these babies.

Community resources play a vital role in helping suppress the rise in diagnosis of NAS. Addiction treatment programs and rehabilitation homes are crucial in helping women suffering from drug abuse and infants who have been diagnosed with NAS. The Rainbow (Residential Rehabilitation for Pregnant and Postpartum Women) Program is a great example of a community resource aimed at helping these two populations. The Rainbow Program employs licensed professionals who specialize in addiction treatment and pre- and post-natal care. They also offer a wide variety of services that include

residential and outpatient treatment and many social and physical amenities such as food, clothing, shelter, transportation, and training/counseling (Meharry Medical College: Rainbow, n.d.).

Advocacy and community resources are two essential aspects of helping alleviate the surge in opioid-exposed and NAS diagnosed infants. With the help of healthcare practitioners and rehabilitation programs, hospitals across the country may one day implement a national standardized treatment protocol as well as see a decline in the number of infants exposed to opioids.

Fetal Alcohol Syndrome: Aid in Creation of NAS Protocol

Although NAS does not have its own national standardized protocol, there are guidelines for other infant diseases such as Fetal Alcohol Syndrome (FAS). To help in the creation and development of a protocol for NAS, it might prove helpful to look at these other guidelines and gather information such as formatting and diagnostic requirements which could aid in the writing of a NAS protocol.

In 2002, U.S. Congress mandated that the Centers for Disease Control and Prevention (CDC) acting through the National Center on Birth Defects and Developmental Disabilities (NCBDDD) Fetal Alcohol Syndrome (FAS) Prevention Team and in coordination with the National Task Force on Fetal Alcohol Syndrome and Fetal Alcohol Effect (NTFFAS/FAE), other federally funded FAS programs, and appropriate nongovernmental organizations would develop guidelines for the diagnosis of FAS, incorporate these guidelines into curricula for students in medical programs and practitioners, seek to have them recognized by professional organizations and accrediting boards, and distribute curricula to and provide training for students and practitioners

regarding these guidelines. The diagnostic criteria were developed over a two-year period and includes facial dysmorphia (smooth philtrum and thin vermilion border ranking 4 or 5 on the University of Washington Lip-Philtrum Guide and small palpebral fissures at or below 10th percentile), growth problems (confirmed prenatal or postnatal height or weight at or below the 10th percentile), and Central Nervous System abnormalities (structural, neurological, and/or functional). For an infant to be diagnosed with FAS, the infant must display and have documentation of all three of the above defects. These guidelines were created to ensure a more consistent diagnosis of FAS (NCBDDD, CDC, & HHS, 2004).

The early development of the CDC's protocol for FAS resembles the stage in which NAS is currently experiencing. When this report was first published in 2004, there were no proper criteria for diagnosing FAS and there was a "lack of knowledge and misconceptions among primary care providers" (NCBDDD et al., 2004, p. 3). Many healthcare professionals believed the mother had to be an alcoholic for the baby to contract FAS. There were also misconceptions that FAS only occurs among low-income and/or racial minority groups (NCBDDD et al., 2004). As with NAS, this is not true. For example, NAS does seem to occur more frequently in rural areas which may be low-income but occurs predominantly in Caucasian households. FAS is also difficult to distinguish from other alcohol-related conditions (NCBDDD et al., 2004). As with NAS, the diagnosis can oftentimes be tricky due to the spectrum of conditions that each entails. For example, a baby that experienced prenatal drug exposure may show no signs of drug withdrawal throughout the hospital stay; therefore, the infant is not diagnosed with NAS. However, he/she could potentially begin withdrawing after discharge.

After Congress mandated that FAS guidelines be issued for diagnosis, the CDC created an internal team that conducted preplanning meetings to help develop the best way to create all aspects of the guidelines. Each aspect of the guidelines was created by reviewing literature and having discussions with consultants, clinicians, researchers, and parents of affected children (NCBDDD et al., 2004). If these steps were taken, the medical community may be able to develop a standardized NAS protocol that could be implemented across the country and that it would lead to a more consistent diagnosis and treatment of NAS.

There are three basic steps for the diagnosis of FAS and include initial identification, referral, and diagnosis. Initial identification for FAS may be recognized later in life during early school-age years. Parents may recognize differences between the child and siblings or daycare staff may notice the child experiencing difficulty. Pediatricians are also some of the first to detect and screen for problems. Obstetricians may refer a newborn if they suspect the mother may have a substance abuse problem. Unlike FAS, symptoms of NAS are recognized within the first few hours of life until approximately six months of age.

After a clinician begins to suspect an alcohol-related disorder, he/she will gather the necessary documentation and may refer the child to a multidisciplinary team for a confirmed diagnosis. The team will then diagnose the child using more thorough FAS diagnostic procedures to evaluate dysmorphia and growth parameters as well as look at neurodevelopmental evaluation data. Likewise, to diagnose NAS, healthcare practitioners use the NAS scoring sheet to monitor and document the presence and/or severity of the infant's withdrawal symptoms.

When the child is officially diagnosed with FAS, a plan is developed and includes many specialists such as dysmorphologists, developmental pediatricians, psychiatrists, psychologists, social workers, and educational specialists (NCBDDD et al., 2004). Similarly, an infant diagnosed with NAS has a team of specialists including social workers, lactation specialists, child life specialists, and speech, occupational, and physical therapists; however, it is unclear how long the infant has these services.

Once an infant with NAS is discharged, they are typically seen in a follow-up clinic for developmental concerns. If developmental deficits or physical abnormalities are observed, it is often difficult to distinguish which substance is the specific cause due to many mothers using multiple drugs including alcohol, tobacco, and prescription and/or street drugs; therefore, it is oftentimes unclear which drug causes which symptoms/deficits. For example, infants exposed to alcohol and methadone, a replacement drug often prescribed to pregnant women to lessen use of other opiates and illicit drugs, failed to habituate to a novel tone at 7 months of age; however, infants exposed to methadone alone did not demonstrate this pattern. According to researchers, opioid-exposed children scored significantly lower on the Mental Development Index (MDI) at 12 and 18 months. Infants exposed to methadone were also found to display “increased motor rigidity, dysregulated motor patterns and decreased activity” (Logan, Brown, & Hayes, 2013, p. 189). Additional studies are still needed to further identify and confirm specific long-term developmental outcomes for opioid-exposed infants.

DISCUSSION

There is no standardized treatment protocol for NAS; therefore, it is critical to understand how healthcare practitioners are treating these patients as well as navigating the various treatment guidelines issued by national medical organizations. According to my findings from the observations, interviews, and document reviews, it is clear that there is an evident need for a standardized treatment protocol. Although all three NICUs had a different treatment protocol for infants diagnosed with NAS, they all contained many similarities and closely resembled the guidelines issued by the national medical organizations. However, the lack of a standardized protocol is apparent and could be contributing to possible variations in patient treatment and outcome. Morphine was the first line of treatment for all three units, but they varied in the second line of medication. The lack of documents on dosage for the medications is also a concern for the need of a standardized protocol especially for units who may not experience a frequent number of infants with this disease. With a national protocol, there would be less uncertainty on the right plan of treatment, and regardless of unit location, each infant would receive the same care based on his/her condition.

Variation in the nonpharmacological treatment such as the placement of the infant, whether it be with the mother or in the NICU, is also a concern for standardization. Studies have shown that the practice of rooming in is beneficial for both mother and baby. If all units were required to implement this practice, healthcare practitioners may see a reduction in the length of stay and in the number of patients who

require medication. This would also remove all patients from the NICU which is not the best place for a NAS infant to properly heal and recover. If acute care is not needed that would require the infant to be placed in the NICU, the infant should be placed in a quiet room, if possible. Oftentimes, the NICU is a bright, loud environment filled with a multitude of people and lots of beeping noises. If the patient was placed in a room with the mother, the baby would be in the ideal environment to heal as well as have the opportunity to bond with the mother.

A standardized protocol should also have other nonpharmacological treatments outlined such as the 4moms mamaRoo. The mamaRoo has shown to calm fussy infants experiencing withdrawal symptoms and is useful when the parents are not present and the healthcare provider is unable to rock/soothe the baby. The mamaRoo looks promising; however, additional studies are warranted to further prove its effectiveness. The company offers a product discount to hospitals and health care centers and is currently used in over 350 maternity wards, NICUs, and pediatric units across the U.S (4moms & NPA, 2018). Having a standardized protocol that included nonpharmacological treatments would help guide healthcare practitioners on the right plan of action and would ensure that the infant received the best care available.

Other protocols, such as Fetal Alcohol Syndrome (FAS), should be looked at to help in the creation of a standardized NAS protocol. Just as FAS was once addressed as a phenomenon in need of diagnosis and treatment protocols, the treatment of NAS is experiencing some of the same struggles as the treatment of FAS once did. Lawmakers and healthcare practitioners could gain useful insight by looking at the development and creation process of the FAS treatment protocol and lessons learned from such efforts. In

order to create a protocol that will be implemented accurately and treat babies affected by NAS successfully, there needs to be a variety of people with different perspectives and backgrounds involved in the development process. During the creation of the FAS protocol, many people gave their insight and knowledge to help create the protocol. These people included clinicians, researchers, parents of affected children, and many more. The development process could benefit greatly if similar groups of people were used in the creation of a NAS protocol.

There were several limitations to this study as well as ways in which this study could be improved. Because I conducted personal observations and interviews, the number of NICUs I was able to observe was low. In contrast, if someone performed a survey concerning the treatment plans of NICUs, he/she would be able to collect data from units across the country. This would give the researcher a much larger pool of data from which to compare the protocols and would give a better image of how varied treatment protocols are across the nation. However, this particular study was very intimate, and I was able to personally observe the different treatment protocols in action. The rich data this kind of observational and interview study provides, it can provide insights that a survey alone would miss.

The information gathered in this study could help inform the creation of new policies to not only implement a national standardized treatment plan but help lawmakers decide on which plan of care to include that would best treat this disease. This study also sheds light on the gaps that are present in this area of research. More research needs to be conducted on the causes of the recent increase in NAS and why, in particular, rural areas. Healthcare practitioners should also be more involved in the legislative process and

inform law makers of implemented protocols that are achieving success in their own hospitals.

Neonatologists who are involved in the research and practice of treating NAS are fervently advocating for a national standardized protocol for NAS treatment. Healthcare practitioners such as Drs. Stephen Patrick, Sean Loudin, and Tony Napolitano are researching, advocating for, and developing guidelines for the treatment of NAS. Dr. Stephen Patrick's research is funded by the National Institute on Drug Abuse and focuses on "improving outcomes for opioid-exposed infants and women with substance-use disorder and evaluating state and federal drug control policies" (Vanderbilt University SOM Faculty Profiles, n.d., p. 1). He has served as Senior Science Policy Advisor to the White House Office of National Drug Control Policy and has testified before Congress on the recent increase of infants being diagnosed with NAS. During his testimony before Congress, he explained the results of the recent opioid epidemic which has led to an increase in the number of opioid-exposed infants. Due to the lack of a standardized national protocol for NAS treatment, there is a wide variation in treatment and clinical outcomes throughout hospitals in the US. The Protecting Our Infants Act of 2015's primary goal is to help people better understand the problem and fill knowledge and service gaps (Hearing on H.R. 1462, 2015). The Act asks the Department of Health and Human Services (HHS) to "conduct a study and develop recommendations for preventing and treating prenatal opioid abuse and neonatal abstinence syndrome" and calls on the Centers for Disease Control and Prevention to "coordinate and improve surveillance systems for NAS and to craft a public health response to the syndrome" (Hearing on H.R. 1462, 2015, p. 5-6). Former President Barack Obama signed the bill into law on

November 25, 2015. In a report to Congress released in 2017, the HHS recommended that evidence-based protocols be established to identify and manage NAS and that breastfeeding and nonpharmacological treatments be promoted. The strategy developed by the HHS, once finalized, will be used to inform policy and planning; however, full implementation will be contingent upon funding (Behavioral Health Coordinating Council Subcommittee on Prescription Drug Abuse, 2017). Without the research and advocacy of healthcare practitioners like Dr. Patrick, the bill's passage would not have been likely.

NAS is a unique disease in that it was internally created by the healthcare industry itself. If physicians had never been pushed to prescribe opioids in excess, NAS may have never been a nationally recognized phenomenon, and the need for a national standardized protocol would be nonexistent. Because of its peculiar history and origin, the research approach used for this particular disease could be applied in the research of other medical illnesses. Additional analysis and research using this approach could lead to valuable insight into many other areas of disease in medicine.

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APPENDIX

Interview Questions

1. Are you over the age of 18 and consent to the observation/shadowing and interview as described in the information sheet?
2. What percentage of infants admitted to this hospital are diagnosed with Neonatal Abstinence Syndrome (NAS)?
3. Are these infants placed in the Neonatal Intensive Care Unit (NICU)? If not, are they placed with the mothers, in the nursery, etc.?
4. What is the standard treatment protocol, and are any experimental options, such as music therapy, being implemented?
5. What do you think is the best treatment plan for an infant diagnosed with NAS?
6. Does this hospital implement the “rooming-in” approach? If so, do you think this method has improved the quality of life for the baby, the mother, or both?
7. Considering many babies admitted to the NICU are transferred from another hospital, do a disproportionate number of these patients come from a particular area or region?
8. What factors do you think contribute to the recent increase in NAS, specifically in rural areas?
9. Do these infants experience any developmental complications in early childhood due to NAS?

10. After the patient is released, what kind of outpatient care does the infant receive, if any?
11. Do the infants have varying intensities of NAS depending on which drug the mother was taking? If so, which drug causes the most severe degree of NAS?
12. Are there any complications in pregnancy, in utero, or during birth related to NAS?