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Comparison of Buprenorphine-Naloxone and Buprenorphine Monotherapy in Opioid Dependent Pregnant Women

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Abstract

- The purpose of this literature review is to compare the use of buprenorphine-naloxone combination therapy to buprenorphine monotherapy as medication assisted therapy (MAT) for opioid dependent pregnant women.
- Outcomes compared in this study include maternal and neonatal safety, neonatal abstinence syndrome, and peripartum pain management.
- This review included electronic search databases: PubMed, Clinical Key, and Cochrane Library from September 1, 2019 to March 1, 2020. The search included randomized control trials, systematic reviews, and meta-analysis. Sources excluded included those published >25 years ago, those with poor study design, and those with primary focus on methadone.
- Current research shows evidence to support both buprenorphine monotherapy and buprenorphine-naloxone combination therapy as MAT in opioid dependent pregnant women, however at this time there is insufficient evidence to declare one therapy superior compared to the other. Many studies discuss the complications and limitations of medication trials in pregnant and opioid dependent populations.
- Ultimately, more research and clinical trials are needed in order to claim the one buprenorphine product preferable, in terms of safety and efficacy, as medication assisted therapy in pregnant women with opioid dependence.
- **Key terms:** buprenorphine in pregnancy, buprenorphine-naloxone in pregnancy, naloxone in pregnancy, buprenorphine safety, suboxone, Subutex, buprenorphine and neonatal abstinence syndrome, pain management buprenorphine, peripartum pain management buprenorphine.

Introduction

- From 1999 to 2014 the number of women with opioid use disorder at the time of delivery has quadrupled (CDC, 2019).
- Opioid agonist pharmacotherapy, also referred to as medication assisted treatment (MAT) may be a solution.
- The goal of MAT during pregnancy is to prevent maternal opioid withdrawal, prevent relapse, reduce neonatal opioid exposure, and improve fetal outcomes.
- Primary concern of opioid use and MAT is neonatal abstinence syndrome (NAS). Neonatal abstinence syndrome is a range of symptoms that may result from chronic maternal opioid use during pregnancy and can occur in 30-80% of MAT mothers.

Statement of the Problem

- As opioid use and MAT becomes more prevalent, more primary care providers are encouraged to become certified in prescribing MAT.
- As a provider it is important to understand the different MAT medications and how to select the proper treatment.
- The FDA has approved two medications for use of opioid dependent pregnant women, methadone and buprenorphine. Furthermore, buprenorphine can be used as monotherapy or combination therapy with naloxone.
 - Suboxone = buprenorphine + naloxone
 - Subutex = buprenorphine

Research Question

- In opioid dependent pregnant women how does use of buprenorphine-naloxone compare to buprenorphine monotherapy in maternal and neonatal safety?
- In opioid dependent pregnant women how does use of buprenorphine-naloxone compare to buprenorphine monotherapy in reduction of NAS?
- In opioid dependent pregnant women how does use of buprenorphine-naloxone compared to buprenorphine monotherapy effect management of peripartum pain?

Literature Review

Buprenorphine-naloxone compared to buprenorphine monotherapy in maternal and neonatal safety.

- Regarding adverse effects, results showed no differences between Apgar scores and caesarean rates between buprenorphine-naloxone exposure and no opioid exposure. suggests use of buprenorphine-naloxone during pregnancy poses low risk to mother and baby. Furthermore mothers using buprenorphine-naloxone had higher birth-weight babies (Juma, 2016)
- Regarding adherence and risk of withdrawal, Tran et al. 2017 found buprenorphine mono-product more favorable due to risk of abuse in precipitating withdrawal and neonatal naloxone exposure. On the contrary, Zoorob et al. 2018 found buprenorphine-naloxone combination product preferred due to its lower risk of misuse by inclusion of naloxone.

Use of buprenorphine-naloxone compare to buprenorphine monotherapy in reduction of Neonatal Abstinence Syndrome.

- Debelak (2013) conducted a retrospective chart review, assessed measured gestational age at delivery, 1- and 5-minute Apgar scores, head circumference, length and weight at birth, treatment for NAS, length of hospital stay. All neonates were born full-term within normal birth parameters, and 40% experienced NAS. Outcomes were similar to that of buprenorphine monotherapy.
- Nguyen (2018) found of 26 mothers using buprenorphine-naloxone, only 19% of neonates required pharmacological treatment for NAS.
- Mullins et al. 2019 found that infants exposed to buprenorphine in utero experienced higher rate of NAS (54.6%), compared to infants exposed to buprenorphine-naloxone in utero experiencing NAS (35.3%).

Buprenorphine-naloxone compared to buprenorphine monotherapy in management of peripartum pain.

- Hoyt et al. 2018 observational study to support use of non-opioid medication for labor related pain in patients taking buprenorphine, using clonidine + bupivacaine epidural solution.
- Pan et al. 2017, MAT should be continued through delivery.
- No studies found directly comparing pain management between buprenorphine and buprenorphine + naloxone in peripartum pain management. However, if the medication is use appropriately, there is poor oral absorption of naloxone making it essential non-existent systemically, therefore should not interact with systemic or neuraxial pain medications.

Discussion

MATERNAL AND NEONATAL SAFETY

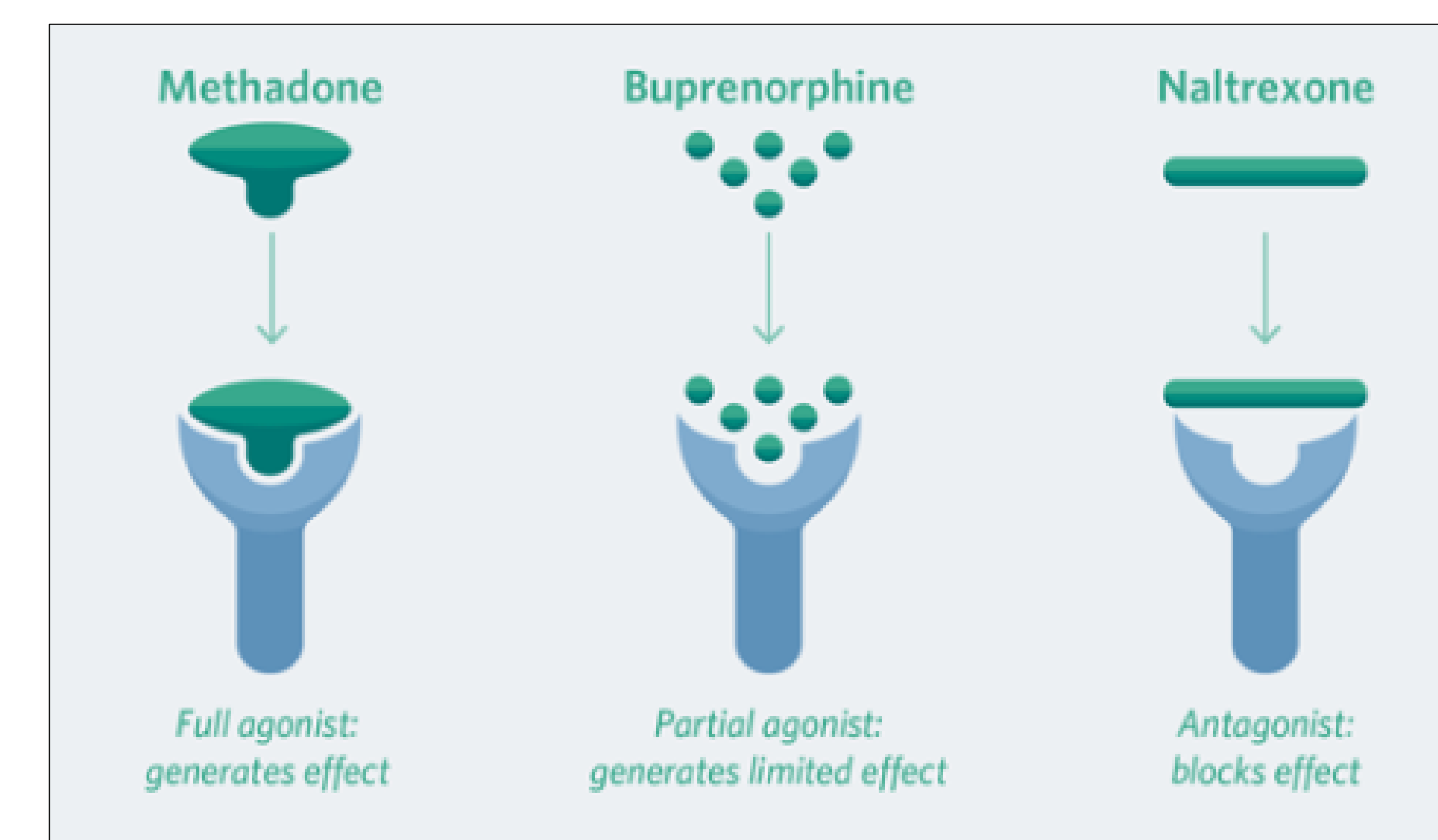
- Buprenorphine has been well studied and has demonstrated improved maternal and neonatal outcomes compared to opioid use.
- However, both monotherapy and combination therapy have risk for abuse and misuse, therefore providers should be well educated on both potential adverse effects and decide based each unique patient

NEONATAL ABSTINENCE SYNDROME

- When comparing combination therapy and monotherapy in reduction of NAS, very few studies have identified significant difference. Mullins et al. 2019 found that combination therapy did have a lower rate of NAS when compared to monotherapy. With this information providers can reassure mothers that between monotherapy and combination therapy, no significant difference has been found in reduction of NAS. The decision should be ultimately made to best suit the mother, as evaluated and decided by the trained provider.

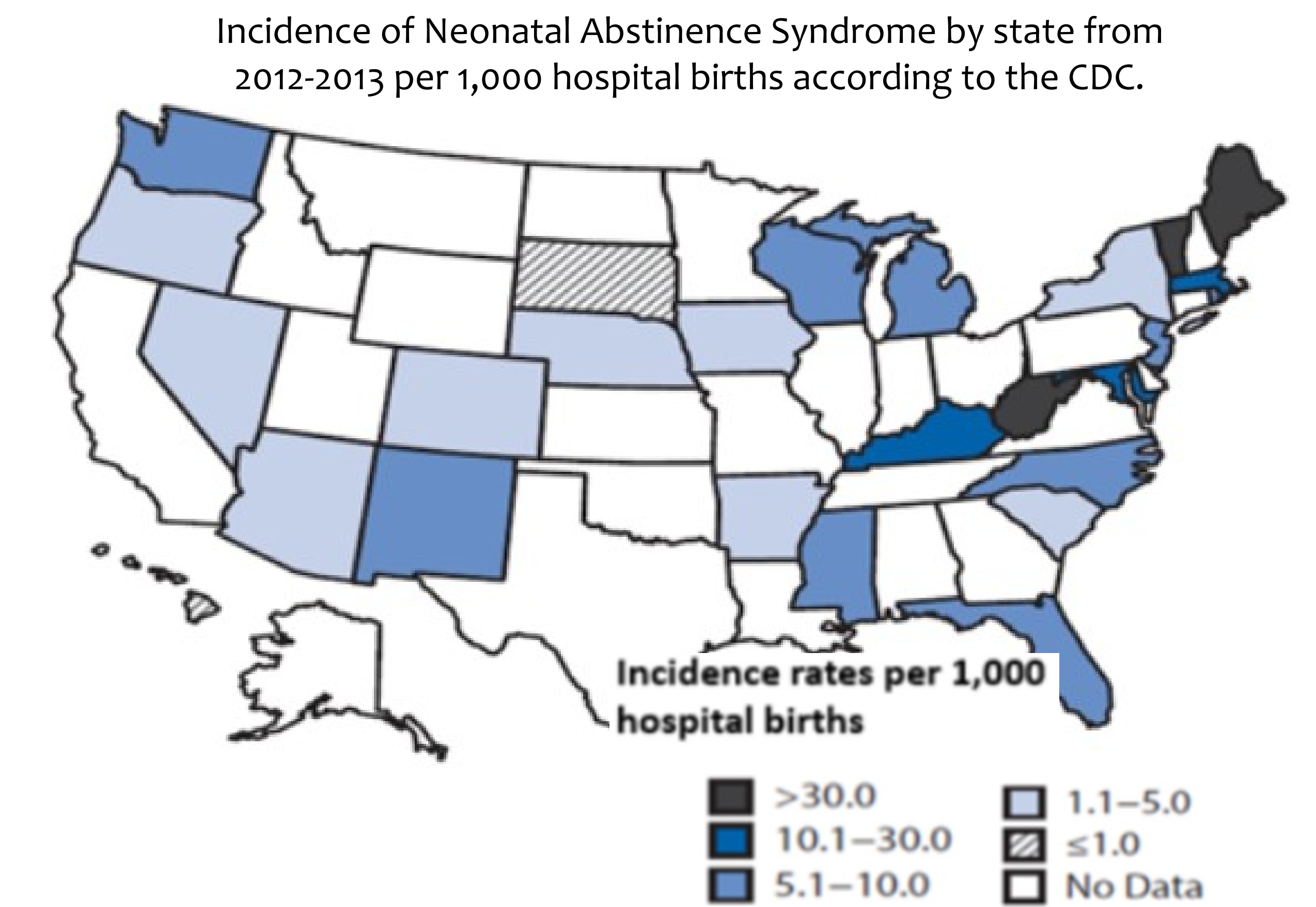
PERIPARTUM PAIN MANAGEMENT

- Few specific studies were found that evaluated inclusion of naloxone in MAT and assess postpartum pain management. The primary take away from the research done on MAT mothers and managing peripartum pain, is that these patients' pain is more difficult to manage. Both providers and anesthesia should be aware of this unique population and educated on how to best provide them with pain management.



Applicability to Clinical Practice

- As more providers becoming trained in prescribing MAT, it will be important to understand what form best fits the patient based on their lifestyle and needs.
- With the information provided in the literature review, the medical provider will be able to make the safest and most efficacious decision for management of opioid dependence in pregnant women or women of childbearing age.
- MAT during pregnancy has several layers of complexity, as it is researching a low compliance population, but also researching medication use during pregnancy which many mothers are opposed to.
- However, the evidence is sufficient in comparing MAT to opioid use in pregnancy for both maternal and neonatal outcomes



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