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Commentary

# Decision Science Can Help Policymakers to Identify and Evaluate Policies to Treat Opioid Use Disorder Among Pregnant Women

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## Opioid Use Disorder During Pregnancy: A Complex Clinical Problem Requiring Rigorous Analysis and Innovative Policy Strategies

Opioid misuse is the "intentional use of a medication without a prescription, in a way other than as prescribed, or for the experience or feeling that it causes" and it often progresses to opioid use disorder (OUD)—a "problematic pattern of opioid use leading to clinically significant impairment or distress" (Dunlap & Cifu, 2016). When it occurs during pregnancy, OUD is associated with poor maternal, fetal, and newborn outcomes (Committee on Health Care for Underserved Women, The American College of Obstetricians and Gynecologists, 2012; Kaltenbach, Berghella, & Finnegan, 1998). Public financing plays an important role in treating OUD among pregnant women. Sixty percent of childbearing women diagnosed with chronic opioid use were covered by Medicaid in 2009 (Patrick et al., 2012); whether these public dollars were spent effectively is unknown. Policymakers need strong evidence to guide decisions toward high-value public investments. The current state of practice for treating maternal OUD is to prescribe opioid agonist treatment; however, access to treatment is very limited, coverage for treatment varies across states and across settings, and there is no standard approach to determine how insurance coverage should be determined (Grogan et al., 2016; Substance Abuse and Mental Health Services Administration, 2014a; Terplan, McNamara, & Chisolm, 2012).

Decision science is a tool for producing evidence that policymakers may consider when making decisions about health care financing, benefits, and coverage design, as well as other aspects of regulation and management of health care delivery to optimize value. Unfortunately, rigorous, policy-relevant decision modeling strategies regarding treatment for substance abuse, such as OUD, have not been thoroughly addressed; this is especially true for substance use among pregnant women. There may be many reasons for this, including that women's health is often not prioritized by policymakers, and substance use during pregnancy is stigmatized. In addition, because the Patient Protection and Affordable Care Act prohibited the use of quality-adjusted life-years in research funded through the Patient Centered Outcomes Research Institute, it is possible that policymakers might be reluctant to use decision analyses as a basis for comparing interventions (Neumann & Weinstein, 2010; Patient Protection and Affordable Care Act of 2010).

Current attention on the opioid epidemic brings new opportunities to revisit health care policy and practice, and to revise them to efficiently and effectively address opioid misuse among pregnant women. The purpose of this commentary is to explain the importance of decision analyses methods and show how they may be used to improve women's health, with a specific focus on one example: how decision analysis might help identify best value treatment for OUD among pregnant women. Additionally, this example highlights how decision analysis methods may be used more broadly to improve women's health care access and outcomes. We begin with a description of what is currently known about the trade-offs of the two most common OUD therapies during pregnancy and why a decision analytic approach is needed in this space. Next, we offer suggestions for integrating these methods into policymaking and clinical

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practice to guide future work. We hope to inform and encourage future research aimed to identify best value treatments and policies for maternal OUD.

## OUD Treatment During Pregnancy: Recognizing Trade-offs

Foundational to the use of decision science tools is an understanding of the trade-offs between different therapies. The American College of Obstetricians and Gynecologists (ACOG) recommends methadone maintenance therapy (MMT) and buprenorphine maintenance therapy (BMT) for the treatment of maternal OUD (ACOG Committee on Health Care, 2012; Saia et al., 2016). Although both methadone and buprenorphine are forms of opioids, they are administered through managed programs and act as opioid substitutes to alleviate the symptoms associated with opioid withdrawal so that users do not relapse back to using other opioids (Schuckit, 2016). In clinical trials, pregnant women on MMT and BMT were less likely to relapse, overdose, contract human immunodeficiency virus and hepatitis C, or have a preterm birth (Jones et al., 2010; Zedler et al., 2016). Although not always available, linkage to clinical and community support services are recommended in conjunction with MMT and BMT (Center for Substance Abuse Treatment, 2009; Kampman & Jarvis, 2015). In special cases, supervised withdrawal may also be an option, but it is generally not recommended (ACOG Committee on Health Care, 2012). Here, we discuss the trade-offs in availability, administration, and effectiveness of MMT and BMT for maternal OUD.

### *Access*

MMT is available in specialty centers, Opioid Treatment Programs, which have strong federal regulations. Unfortunately, specialty treatment centers can be difficult to access, particularly in rural areas. For example, Montana, Idaho, and Nebraska all have fewer than five centers, and none operate in Wyoming (Substance Abuse and Mental Health Services Administration, 2014b). Furthermore, not all MMT centers will treat pregnant women. Alternatively, BMT—prescribed by trained physicians with specific waivers—does not require daily visits to specialty treatment centers. Yet, access to BMT for pregnant women is also limited. In 2014, only 2.2% of physicians had obtained the necessary waivers to prescribe it and it is unclear what proportion of waivered physicians also care for pregnant women (Rosenblatt, Andrilla, Catlin, & Larson, 2015). When using a decision model in circumstances of limited availability, therapies should only be compared if they are available. Alternatively, a decision analytic model could also be used to investigate the costs and benefits of increasing access to unavailable therapies.

### *Treatment Administration*

MMT doses are adjusted throughout pregnancy to avoid withdrawal. Treatment is given daily and is ideally combined with prenatal care, counseling, and other medical and psychosocial services (ACOG Committee on Health Care, 2012). It is important that women with OUDs have access to a full range of services because they are less likely to seek prenatal care and more likely to suffer from other medical conditions (Krans, Cochran, & Bogen, 2015). A decision model would need to account for these additional benefits associated with MMT. BMT also requires a period of dose adjustment, but it is not usually paired with the same ancillary services as MMT and resources vary by provider. Here, a model could determine if the additional benefits associated with MMT make it a better option than BMT.

### *Effectiveness*

As mentioned, MMT and BMT work as opioid substitutes to prevent withdrawal during pregnancy. Although the effectiveness of each treatment varies from person to person, on average, clinical trials have found that the retention of patients on BMT were lower than those on MMT (Connock et al., 2007). Clinical trials also showed that pregnant women who stayed on BMT delivered higher-weight infants with less severe neonatal abstinence syndrome (Jones et al., 2010). A decision model may be especially helpful in this situation, because it would account for the trade-off between a higher risk of relapse and less severe neonatal abstinence syndrome, for BMT compared with MMT.

## Using Decision Science to Address OUD During Pregnancy

The first step to decision modeling is to identify all possible treatment options. For OUD during pregnancy, treatment options could include MMT and BMT. Next, a state-transition model (STM) can be constructed. STMs conceptualize clinical situations into a set of health states and health events, which are represented as transitions between health states over a specified timeframe (Siebert et al., 2012). Individuals populate the STM and transition between health states according to so-called transition probabilities, which may vary based on treatment status, current health status, or demographic factors like age. Costs (measured in dollars) and benefits (measured in quality-adjusted life-years) are accrued over time, and vary according to how long or how often individuals reside in, or transition between, each health state.

Figure 1 is an example of an STM to evaluate OUD during pregnancy. It consists of five main health states: pregnant, treated OUD, pregnant, untreated OUD, treated OUD, untreated OUD, and dead. For this example, we assume that all women start pregnant and on treatment (pregnant, treated OUD state). A number of events may cause a woman to transition from one state to another. For example, pregnant women on treatment may relapse (to pregnant, untreated OUD state), give birth (to treated OUD state), or die (to dead state). Pregnant women who have relapsed and are no longer on treatment could restart treatment (to pregnant, treated OUD state), give birth (to untreated OUD state), or die (to dead state). This STM could also be expanded to predict adverse events associated with OUD in pregnancy, including preterm birth, fetal loss, and neonatal abstinence syndrome.

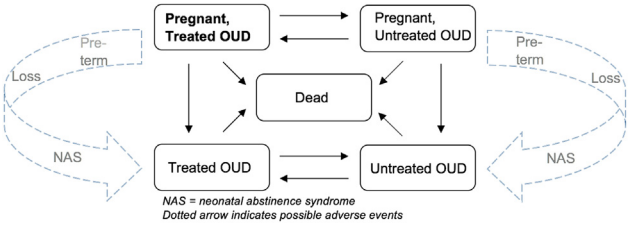


**Figure 1.** State-transition model to measure cost and effect of treatment for opioid use disorder (OUD).

After the identification of treatment options and model construction, all consequences of decisions should be identified, measured, and valued—based on existing research—while also considering the uncertainty that exists about the outcomes and the limitations of available research. Patient characteristics are incorporated into decision science models as well. A useful model would contain detailed information about the population of women it is evaluating. Specific measures of interest in this case include sociodemographic and clinical factors, as well as timing, type, and extent of opioid use. The parameters of the model should be specific to the population at hand, because these characteristics can influence how women transition through the model. Currently, data on the type and extent of opioid use during pregnancy are limited, making it difficult to conduct research. Furthermore, because population characteristics are accounted for in the model, it is important to note that the intervention the model identifies as the best value should only be recommended for that specific population; for other populations, another model should be created and used, perhaps by modifying the original.

Policymakers should bear in mind the following when using decision analyses to inform care: 1) results are based on the treatment options analyzed, and it is important to ensure all viable treatment options are included; 2) the model is only as good as its inputs; ask if the most up-to-date and best measures on treatment costs and benefits are used, or consult experts in the field to estimate them; 3) model stability matters for how certain the results are; take into account sensitivity analyses on all measures of costs and benefits, paying special attention to parameters that are unknown or assumed in the models; 4) look at the whole financial picture; be sure that cost estimates include all relevant costs from a societal perspective, including costs of patient travel to obtain care and the costs of therapies to the patient, payer, and employer; and finally, 5) decision analysis evaluates efficiency, but does not account for equity, or who is most deserving of care; such decisions need to be made through thoughtful consideration (Sanders et al., 2016).

## Conclusions

Using decision science to guide policy in women's health may offer innovative, helpful information, and may inform effective value-based decision making. It may be particularly useful in the complex context of the current opioid crisis, especially as it pertains to pregnant women, an understudied population that is deeply affected by the opioid epidemic. To the best of our knowledge, decision science has not yet been used to identify a best value treatment of OUD among pregnant women. A decision science model is one of the few research tools that can integrate many sources of data, such as clinical trials, expert opinion, and health care utilization information, to provide a data-driven recommendation. It allows for therapies to be compared to each other in a quantitative approach and incorporates the unique characteristics of the population that may be otherwise understudied or uniquely vulnerable to the adverse outcomes associated with the opioid epidemic, or other exposures. Findings from decision science can help policymakers to determine which therapies could have the greatest impact on health, and inform decisions about the financing and organization of health care delivery through public programs like Medicaid, and via regulation of health insurance, clinic, and health care delivery systems. Importantly, sensitivity analyses can highlight areas of uncertainty, including where better data are needed, and identify the variables that most influence outcomes, which can be used to inform policy decisions as well as further studies.

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