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Gender-Related Considerations and Disparities in Pain and Substance Use Disorder Treatment

"Central to the unique issues women face in pain management are the differences between men and women with respect to pain sensitivity, response to pain medication, and predisposition to clinical pain conditions."

- Pain Management Best Practices Inter-Agency Task Force Report (May 23, 2019)

Gender Differences in Pain and Substance Use Disorder

Women are more likely than men to have <u>chronic pain</u> and be prescribed <u>higher doses</u> of opioid pain relievers for longer periods of time.

Studies indicate that women may be more likely than men to <u>misuse</u> prescription opioids for other problems such as anxiety and to take prescription opioids <u>without a prescription</u> to cope with pain. Women may also be more susceptible to <u>relapse</u> than men, which may be due to enhanced craving symptoms and stress related to withdrawal responses reported in women.

Additionally, treatment plans for <u>pregnant and parenting women</u> are often based on distinct standards of care.

In September 2018, the FDA held a <u>two-day meeting</u> to look at substance use disorder (SUD) through a gender lens. <u>Findings</u> included:

- Substance use in women is more often influenced by social factors, such as relationships with family, friends, and peers.
- Women are more likely to be caregivers than men, making them less likely to seek out and complete appropriate SUD treatment due to the constraints of caring for loved ones.
- Women are more likely to engage in "doctor shopping," seeking care from multiple prescribers simultaneously or pursuing treatment from practitioners known to liberally prescribe medications such as opioid pain relievers.

Gender-Related Barriers to Addiction Treatment

Increased Risk of Arrest and Criminalization

Fetal assault, chemical endangerment, and personhood laws have been used <u>to arrest and prosecute women with SUDs</u>.

- <u>Twenty-three states</u> and the District of Columbia consider substance use during pregnancy to be child abuse.
- <u>Twenty-four states</u> and the District of Columbia require health care professionals to report suspected prenatal drug use.
- <u>Three states</u> consider substance use during pregnancy grounds for involuntary hospitalization.
- In Tennessee, 100 women were <u>charged</u> under the "fetal assault" law between 2014 and 2016.
- In Alabama, 479 women were <u>prosecuted</u> between 2006 and 2015 under the "chemical endangerment" law, 89 percent of whom could not afford a lawyer.

Lack of Access to Medical Treatment

Only <u>19 states</u> have treatment programs specifically designed for pregnant women.

Only <u>10 states</u> prohibit publicly funded drug treatment programs from discriminating against pregnant women.

Women in rural areas can face <u>additional barriers</u> in accessing effective care, including a shortage of providers, lower quality of care within available health care systems, lack of transportation, and lack of financial resources.

Lack of <u>Childcare</u>

Under-Inclusive Research & Development Practices

Until the 1990s, medical research was conducted <u>almost exclusively</u> on men.

Until 1997, the <u>FDA banned</u> most women of "child bearing potential" from taking part in clinical research studies.

In 2001, <u>two-thirds</u> of clinical trials still excluded women.

Approximately <u>80 percent</u> of pain studies are conducted on males only.

Consequently, the <u>under-inclusion of women in research and</u> <u>development</u> practices may result in missed opportunities for prevention, incorrect diagnoses, misinformed treatments, sickness, and death.

Barriers to Health Care

The Substance Abuse and Mental Health Services Administration (SAMHSA) has published "<u>Clinical Guidance for Treating Pregnant and</u> <u>Parenting Women with Opioid Use Disorder and Their Infants</u>," which consists of 16 fact sheets on prenatal, infant, and maternal post-natal care.

Screening Recommendations

Practitioners should conduct pre-natal screenings for pregnant women for SUDs, including OUD with an emphasis on rapid referral and engagement in treatment.

The guidance also recommends screenings for mental health comorbidities, HIV/AIDS, and viral hepatitis inflection.

The standard of care for pregnant women with OUD is Medication-Assisted Treatment (MAT), which is pharmacotherapy with methadone or buprenorphine combined with evidence-based behavioral interventions.

• There is insufficient information about the safety of extended-release naltrexone during pregnancy or the intrauterine affects of exposure to extended-release naltrexone.

Current research has not identified an increased risk of birth defects associated with pregnant women's use of methadone or buprenorphine.

Neonatal Abstinence Syndrome

Neonatal abstinence syndrome (NAS) is a non-specific term used to describe when an infant is born dependent on drugs used by the mother during pregnancy. The infant experiences <u>withdrawal symptoms</u> such as tremors, diarrhea, fever, irritability, seizures, and difficulty feeding.

According to the National Institute on Drug Abuse, when neonatal abstinence syndrome (NAS) does occur in babies born to mothers receiving MAT, the NAS is <u>less severe</u> than in those babies born to mothers with OUD who are not on MAT.

Infants who have had <u>prenatal exposure to buprenorphine</u> required significantly less morphine for the treatment of NAS, a significantly shorter period of NAS treatment, and a significantly shorter hospital stay as compared to infants who have had prenatal exposure to methadone.

It should be noted that the more specific term, "<u>neonatal opioid</u> <u>withdrawal syndrome (NOWS)</u>," is becoming more widely used to more accurately identify and treat infants exposed to opioids in utero. NOWS expression and severity are not correlated with maternal dosages of methadone or buprenorphine.

Maternal Postnatal Care

SAMSHA recommends treatment providers focus on the postpartum period as an especially vulnerable time for return to substance use.

Upon delivery, women who are stable on methadone or buprenorphine should be advised to breastfeed, unless not recommended (e.g., the mother is HIV-positive or is hepatitis C-positive).

Alleviating Gender Disparities in Pain and Substance Use Disorder Treatment

The inclusion of women in research and development practices is critical for better understanding the differences in responses to medication between genders.

- In 2019, the FDA established the <u>Diverse Women in Clinical Trial</u> <u>Initiative</u> to raise awareness about the importance of participation of diverse groups of women in clinical research and to share best practices about clinical research design, recruitment, and subpopulation analyses.
- In 2018, The Task Force on Research Specific to Pregnant and Lactating Women (PRGLAC Task Force), established by the 21st Century Cures Act in 2016 and led by NIH, issued a <u>report</u> that made 15 recommendations for addressing gaps in knowledge and research on safe and effective therapies for pregnant women and lactating women.

The participation of OB/GYN providers in pain and OUD treatment is needed to more appropriately manage pain and OUD in women during pregnancy and the post-partum stage.