

# Pregnancy and Perinatal Outcomes Following Exposure to Medications for Opioid Use Disorder: An Analysis of FAERS (FDA Adverse Event Reporting System)

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## Background

- The opioid epidemic in the United States has seen an increase in opioid use, even during pregnancy [1].
- Methadone and buprenorphine are currently approved for treating opioid use disorder (OUD) in pregnancy.
- However, these medications have been reported to be associated with neonatal abstinence syndrome, low birth weight, and premature delivery [2].

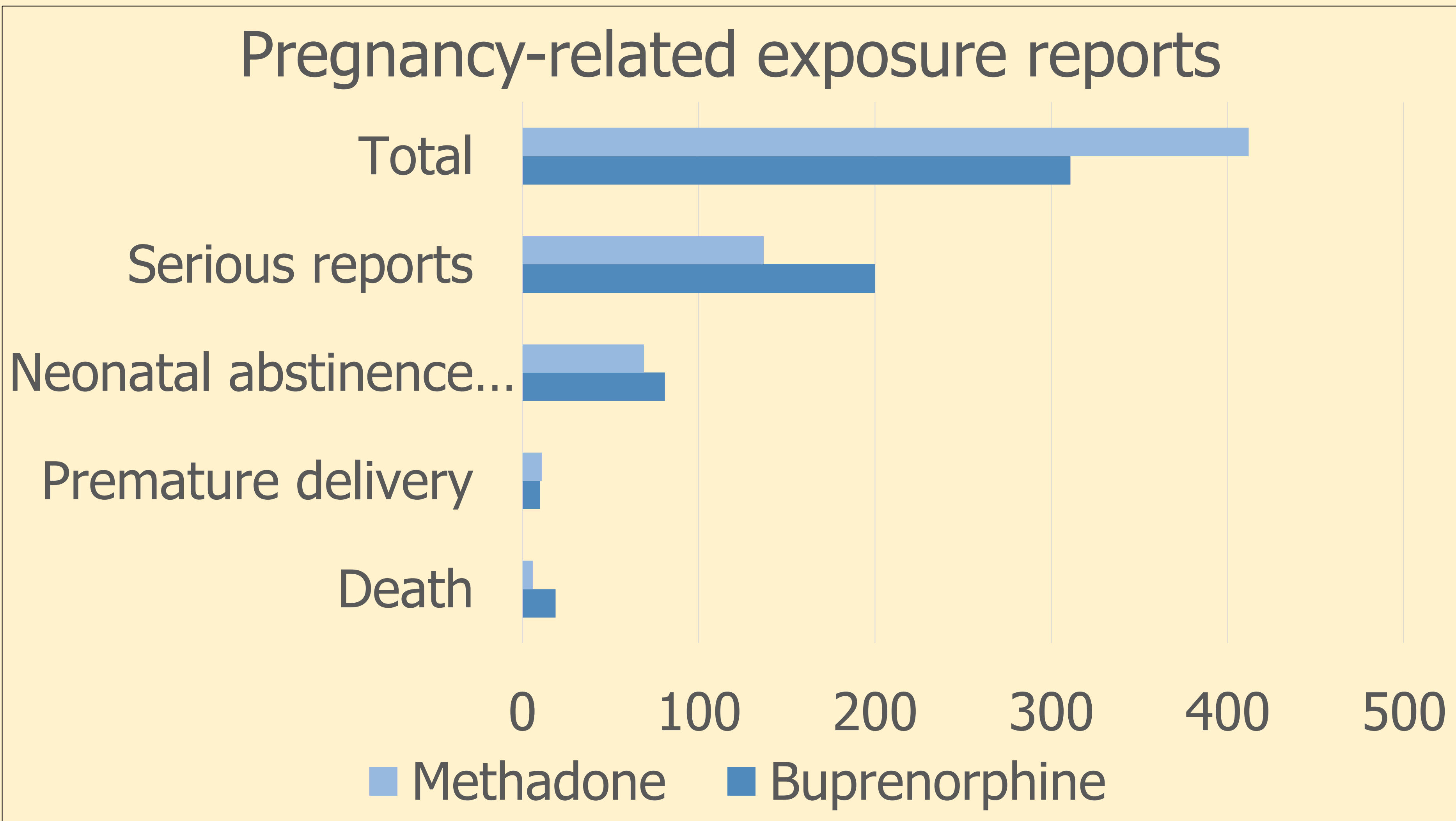
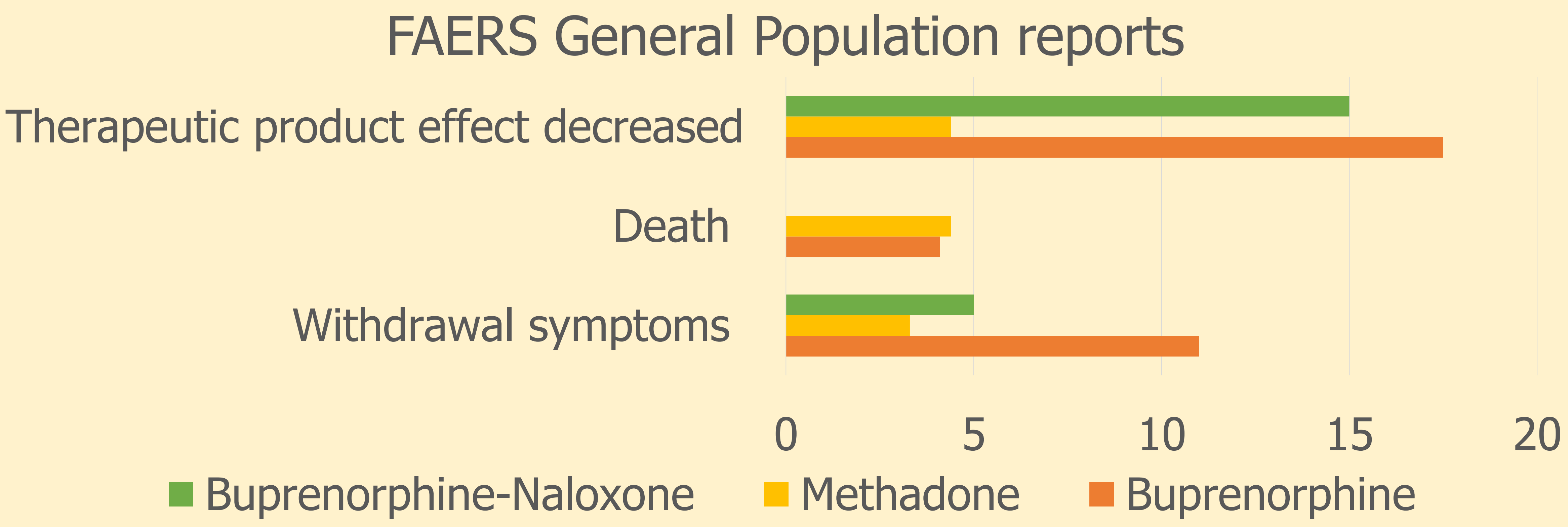
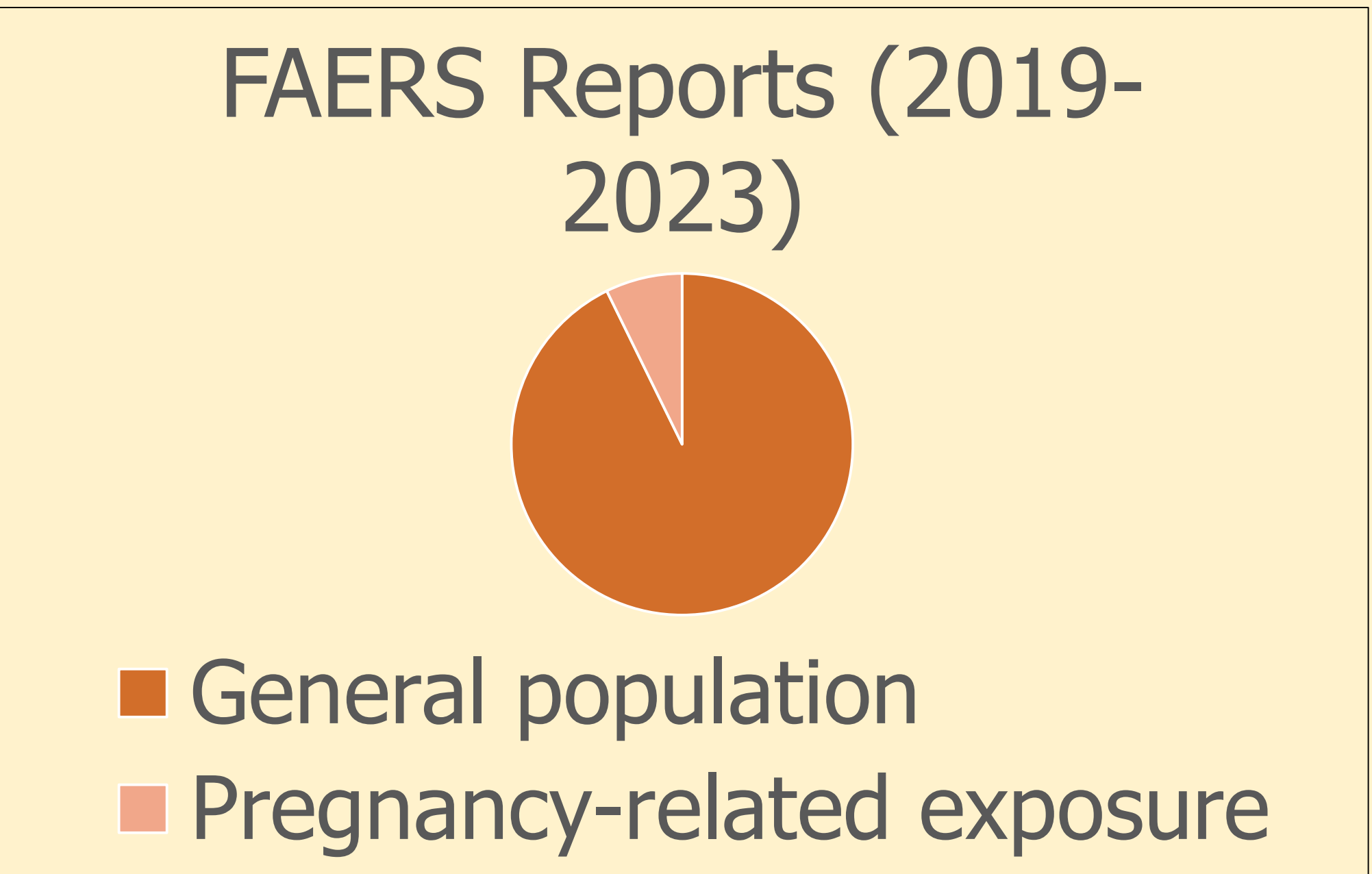
## Objective

This study aims to examine and compare FAERS reports related to the use of methadone, buprenorphine, buprenorphine-naloxone, and naloxone in the general population and during pregnancy, thus assessing their comparative safety.

## Methods

- The FAERS database was searched for adverse events (AEs) related to the use of methadone, buprenorphine, buprenorphine-naloxone, and naloxone.
- AEs reported over a five-year period from the first quarter of 2019 to the third quarter of 2023 were included.
- The AEs were coded using Medical Dictionary for Regulatory Activities (MedDRA) Preferred Terms (PTs), and the findings were presented using descriptive statistics.

## Results



- The study analyzed 10,110 cases, identifying 735 pregnancy-related cases with 1,718 reactions.
- Despite a higher number of cases reported with methadone (412 vs. 311 for buprenorphine):
  - ❑ Buprenorphine was linked to a higher incidence of serious reports (64.3%), compared to methadone (33.3%).
  - ❑ Buprenorphine was linked to a higher rate of neonatal mortality (4.8%) and more reports of neonatal drug withdrawal syndrome (26%).

## Conclusion

- While medications for OUD are linked to adverse outcomes during pregnancy, these risks are less severe than those arising from untreated OUD.
- It is important to educate and counsel patients about these potential outcomes, but this should not deter them from seeking treatment.
- Further research is necessary to determine if any of the currently recommended medications are preferable in specific contexts.

## References

- [1] Haight SC, Ko JY, Tong VT, Bohm MK, Callaghan WM. Opioid Use Disorder Documented at Delivery Hospitalization - United States, 1999-2014. MMWR Morb Mortal Wkly Rep. 2018;67(31):845-9. Epub 20180810. doi: 10.15585/mmwr.mm6731a1. PubMed PMID: 30091969; PubMed Central PMCID: PMC6089335.
- [2] Suarez EA, Huybrechts KF, Straub L, Hernández-Díaz S, Jones HE, Connery HS, et al. Buprenorphine versus Methadone for Opioid Use Disorder in Pregnancy. N Engl J Med. 2022;387(22):2033-44. doi: 10.1056/NEJMoa2203318. PubMed PMID: 36449419; PubMed Central PMCID: PMC9873239.