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Register data on neonatal symptoms added to the Swedish knowledge base Janusmed Drugs and Birth Defects

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Introduction

- The Swedish knowledge base *Janusmed Drugs and Birth defects* provides risk assessments of medical drugs since 2001
- Analyses of Swedish national health register data are important when compiling the risk assessments. Previously, register data on drug exposure during pregnancy was only included from the Medical Birth Register (MBR). These data are collected at the first visits of pregnant women at the antenatal clinics and thereby focused on early pregnancy.
- To analyze outcomes associated with drug use during later stages of pregnancy, data from the Swedish Prescribed Drug Register (SPDR) are since 2025 included in the knowledge base. The SPDR covers prescriptions redeemed in Swedish pharmacies.

Method

- **Aggregated data** from the MBR and the SPDR are ordered from the National Board of Health and Welfare
- Data on drug exposure are extracted from both registers where they are registered according to the ATC code system
- The outcomes are extracted from the MBR and are, as previously: malformations, Apgar scores at 5 min<7, small for gestational age, large for gestational age and perinatal death
- Additionally, the following neonatal outcomes are added:

Neonatal outcomes	ICD-10 codes
Respiratory disorders	P220, P221, P228, P229, P293B, P240, P249
CNS-symptoms	P91
Withdrawal symptoms	P962
Neonatal convulsions	P90
Hypoglycemia	P703, P704
Feeding difficulties	P922, P925, P928, P929
Any of the above	

- The prevalence of the outcomes after exposure to different drugs are compared to the population. Chi-square tests or Exact Poisson distribution are used for significance level.

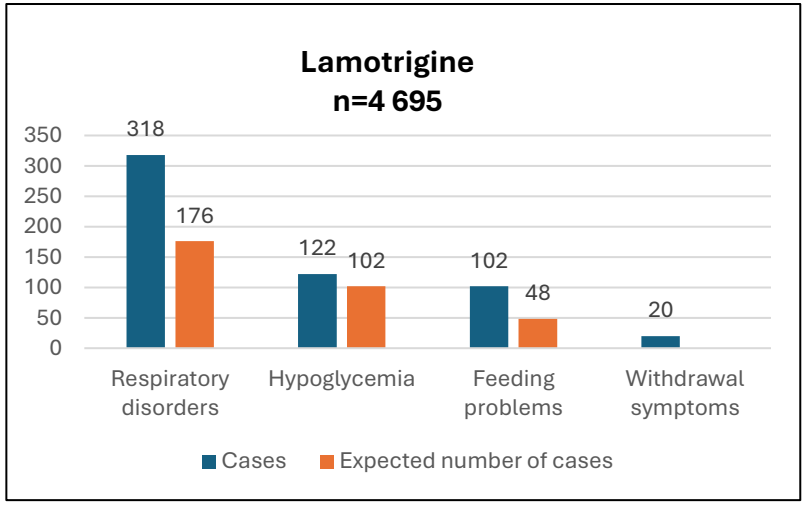
Method, continued

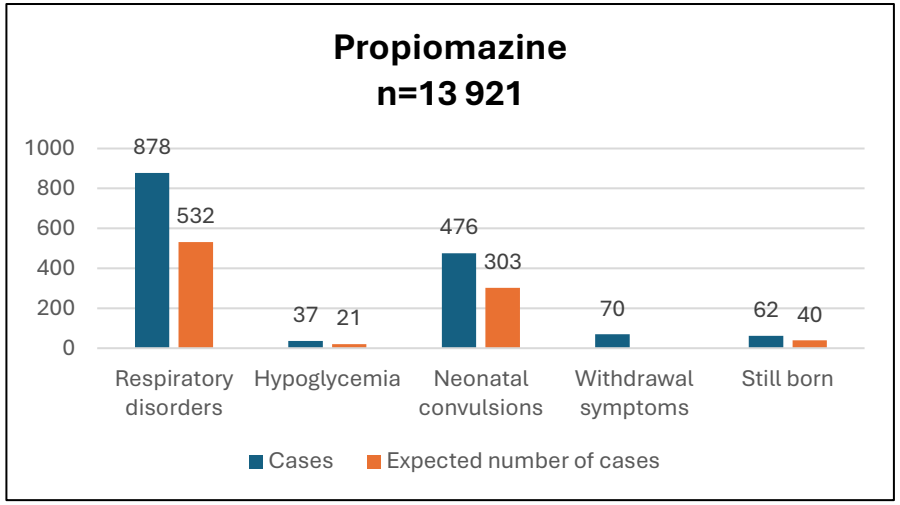
The analyses are carried out after early and late drug exposure according to the following definitions:

	Early pregnancy	Later stages of pregnancy
Exposure data	Self reported use of drugs at the first antenatal visit and prescriptions redeemed from 12 weeks before the start of the pregnancy through pregnancy week 12	Prescriptions redeemed from pregnancy week 13 or later

Results

Several drugs analyzed so far are clearly linked to higher rates of neonatal symptoms among infants exposed during later stages of pregnancy, e.g. lamotrigine, propiomazine, hydroxychloroquine and chlorzoxazone.





Conclusions

- The addition of the SPDR provides valuable data on neonatal disorders linked to drug use during later stages of pregnancy
- Since the results are prone to confounding, they must be carefully interpreted, and it must be explained to the users of *Janusmed Drugs and Birth Defects* that the data are not adjusted for background factors like exposure to other medical drugs and the disease per se
- The continuous analyses of aggregated data, work as an efficient signal detection method for areas that need further research
- In many instances, there are no findings in the literature of neonatal symptoms following maternal use of different drugs, whereas these data have the potential to fill important knowledge gaps
- Thank you from the editorial board of *Janusmed Drugs and Birth Defects*!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