

Opportunities For The Use Of Real World Data In Perinatal Pharmacoepidemiological Research: The PHARMO Perinatal Research Network (PPRN)

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Background

Clinical trials have well-known limitations to study drug safety in vulnerable populations, including pregnant women and their offspring. Real-world data and related observational population-based research have the potential to fill this gap as a non-invasive method for studies in these groups.

Objective

It was explored whether linkage of the PHARMO Data Network (PHARMO) and the Netherlands Perinatal Registry (Perined) would establish a valuable data source for perinatal pharmacoepidemiological studies in the Dutch population.

PHARMO Perinatal Research Network (PPRN)

Preconception	Pregnancy Birt	h Postpartum	Infancy	Childhood	Adulthood
 medication exposure comorbidities & diagnostics surgical procedures laboratory, pathology, malignancies 	 mode of conception pregnancy complications care provider gestational age 	 mode of delivery Apgar score birth weight birth defects 	 healthcare utilisation respiratory disease juvenile idiopathic arthritis cancer 	 patient journey laboratory tests neurodevelopment allergies 	 primary care specialist care birth control mental disorders

Maternal follow-up in Pregnancy Cohort & Child Cohort



Child follow-up in linked Child Cohort

Figure 1. Schematic overview of data captured in the PHARMO-Perined linked PPRN

Methods

- A new infrastructure was established on the record linkage of based PHARMO and Perined: the PHARMO Perinatal Research Network (PPRN).
- PHARMO represents a population-based data source with combined anonymous electronic healthcare data from different healthcare settings in the Netherlands.
- Perined is a nationwide registry containing

Table 1. Overview of record types available from the PPRN			
Record type	Description		
Pregnancy/neonatal	Maternal and neonatal characteristics and perinatal care captured by midwife practices, gynaecologists, paediatricians and neonatologists.		
Medication	General practitioner or specialist prescribed healthcare products (in- and outpatient) including information on type of product, date, strength, dosage regimen, route of administration, prescriber specialty and costs.		
General practitioner	Patient records registered by general practitioners including information on diagnoses and symptoms, laboratory test results, general practitioner visits and referrals to specialists.		
Laboratory tests	Results of laboratory tests performed on clinical specimens, requested by general practitioners or medical specialists including information on date and time of testing, test result, unit of measurement and type of clinical specimen.		
Hospital admissions	Hospital admissions (i.e. in-patient hospital records) for more than 24 hours and admissions for less than 24 hours for which a bed is required including information on hospital admission and discharge dates, discharge diagnoses and procedures.		
Ambulatory care	Ambulatory care (i.e. out-patient hospital records, e.g. by pediatrician), including diagnosis, number of visits, involved specialist.		
Pathology reports	Data on excerpts of histological, cytological and autopsy examinations, obtained		

maternal and neonatal characteristics and data on perinatal care.

- Pregnancies between 2000 and 2021 of women registered in Perined as well as PHARMO were included.
- Mother-child linkage in PHARMO was also assessed.

Results

- The PPRN included 744,675 pregnancies of 491,672 women (mean (±SD) age at delivery 31.2 (±4.8) years).
- Additionally, mother-child linkage was available for about one fifth of these pregnancies.
- PPRN contains preconceptional The information on maternal healthcare, as well as detailed pregnancy and neonatal data, extending into long-term follow-up after birth

through linkage with the national Pathology Registry.

Malignancies

Data on all newly diagnosed cancer cases including information on cancer diagnosis, tumour staging, tumour site, morphology and initial treatment, obtained through linkage with the national Netherlands Cancer Registry.

for both mother and child up to more than 20 years, with ongoing annual updates of the routinely collected data (see Figure 1 and **Table 1** for an overview of available records).

Conclusion

The PPRN provides a unique and rich data set facilitating in depth large-scale observational perinatal research. The patient-level linkage of many different healthcare data sources allows assessment of patient journeys of both mother and child during the preconception period, pregnancy, and after birth.

