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Pregnancy and infant outcomes following the use of asthma medicines with an unknown risk classification

Maartje Conijn[1], Anne-Marie J.M.P. van Gorp[1], Benedikte-Noël Cuppers[1], Saar Nederveen[2], Veronique Y.F. Maas[1]*

[1]Netherlands pharmacovigilance centre Lareb, The Netherlands
[2]Deventer Hospital, The Netherlands

*Presenting author: v.maas@lareb.nl

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Background

- **Adequate control of asthma during pregnancy** is important to prevent complications including low birth weight, premature birth and maternal hospitalization.
- To achieve this, it may be necessary to use medication for which **limited safety information** is available.
- The objective of this study was **to describe the use of asthma medicines with limited to no safety information and the associated pregnancy and infant outcomes**.

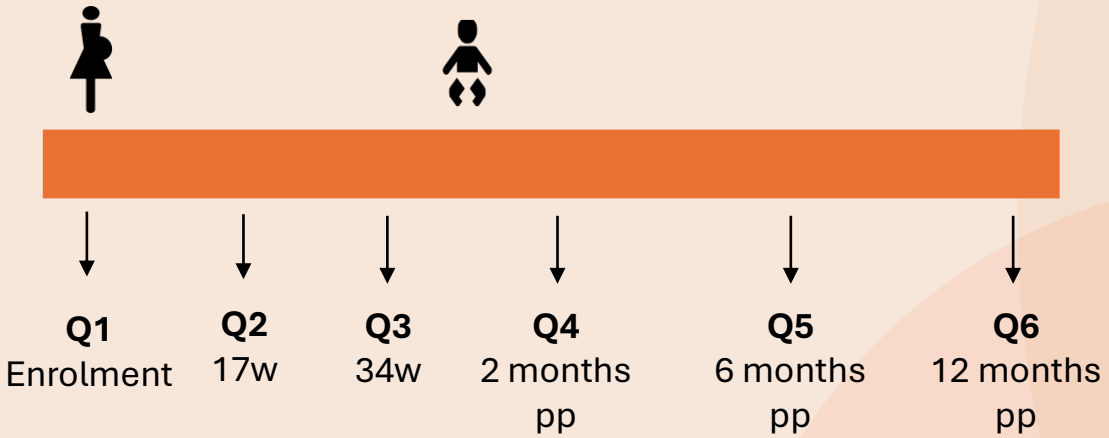

Figure 1. Questionnaire distribution schedule of the DPDR.
Abbreviations; pp = postpartum, Q = questionnaire, w = weeks of gestation

Methods

- Data of the **Dutch Pregnancy Drug Register** (DPDR) between January 2021 and October 2024 was used.
- In this ongoing prospective cohort study, women self-report through a **maximum of six online questionnaires** on their health, medication use and the outcomes of their pregnancy and child(ren) (**Figure 1**).
- All women who reported a **medical history of asthma at baseline** were selected for this study.
- The medicines they reported to use for their **asthma** were evaluated.
- Medicines that were registered to treat asthma and were classified as **'risk unknown'** on the website of the Dutch Teratology Information Service (TIS) were included for analysis.
- **Data** was collected on;
  - pattern of medication use
  - pregnancy complications and outcomes
  - congenital malformations.
  - infant health
  - Effect after exposure to breastfeeding
- **Descriptive analyses were performed.**

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Results

- Of the 17,023 women in the DPDR, **6.8% reported a medical history of asthma (Figure 2).**
- To treat their asthma, 67.8% of them used one or more medicines during pregnancy or in the month prior to conception.
- A total of **79 (10.1%) women used one or more medicines that were classified as 'unknown risk'**.
- **Pregnancy outcomes were available for 39** of these women, with 53 exposures of interest.
- There were **35 first trimester exposed pregnancies,** with a total of 48 exposures of interest (**Table 1**, next slide).
- Among the first trimester exposures, **two miscarriages were reported**. One after **ipratropium** and **vilanterol** exposure and one following **glycopyrronium** use.
- One **tiotropium** exposed pregnancy was **terminated after the diagnosis of a genetic syndrome.**
- **Four first trimester exposed infants (3x ciclesonide and 1x ciclesonide and tiotropium)** were born with a **congenital malformation** (one major and three minor based on the EUROCAT classification).
- **No specific patterns** of congenital malformations were observed.
- During the post-partum follow-up**, infant health problems were reported for 14 of the 36 infants** who were exposed at some point during pregnancy. In five of these infants this concerned infectious disease (i.e. eye and airway infections).
- 18 infants were exposed to 'unknown risk' asthma medication during **breastfeeding**, **no effects** on the child or breastfeeding were reported.

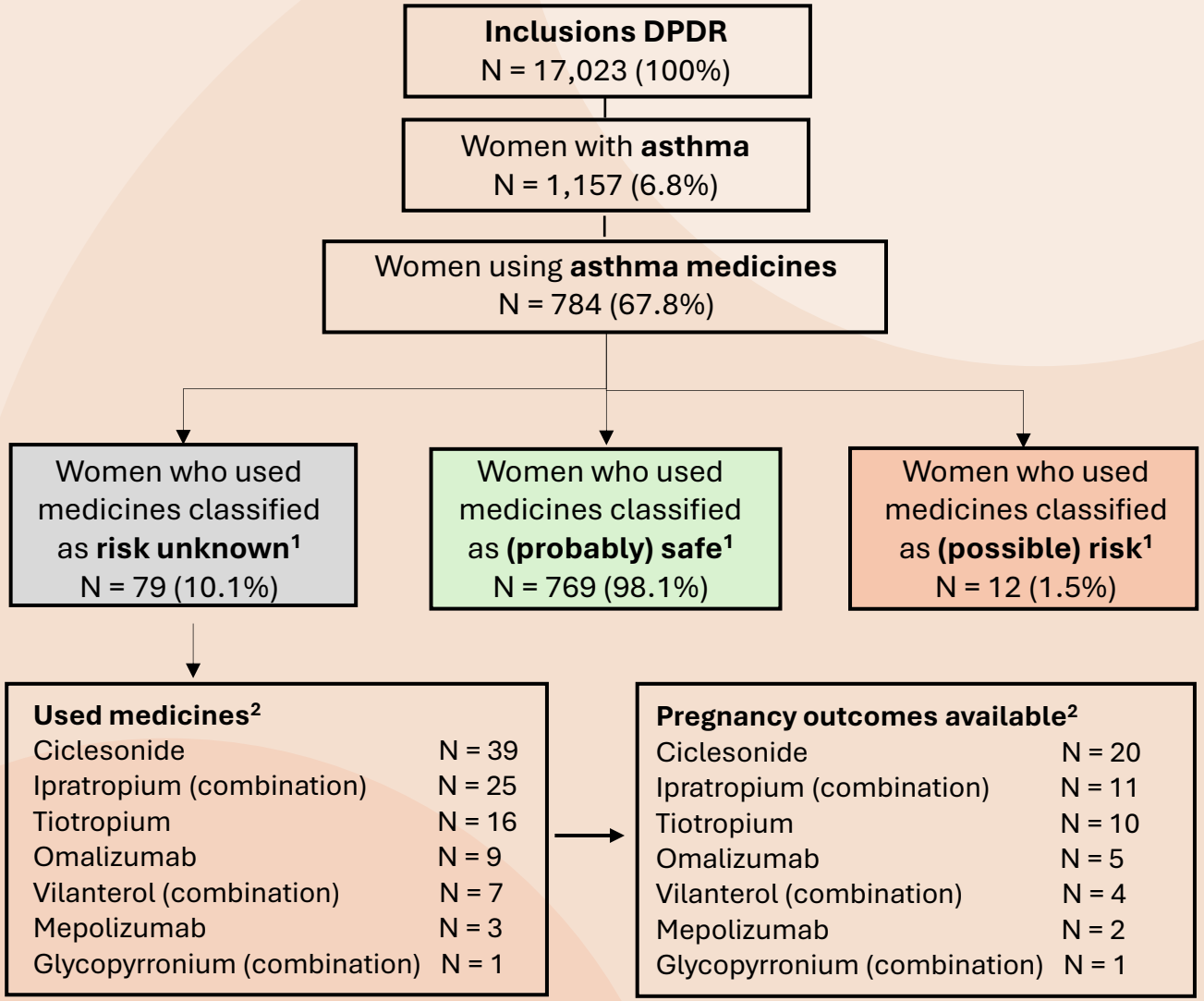

Figure 2. Flowchart of participants and selected 'unknown' risk medication.
Abbreviations; Dutch Pregnancy Drug Register. [1]Women can use medicines in multiple risk categories; [2]Multiple medicines can be used by the same participant

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Table 1. Pregnancy outcomes after exposures to 'unknown risk' asthma medication

	First trimester exposed				Exposed at any point during pregnancy					Breastfeeding	
	Exposed	Miscarriage	Induced abortion	Congenital malformation	Exposed	Liveborn	GA < 37 weeks	SGA	Infant health problems	Exposed	Reported effects
Unique cases	35	2	1	4	39	36	2	3	14	18	0
Cases per exposure[1]											
Ciclesonide	20	0	0	4^	20	20	0	1	10	11	0
Ipratropium	9	1#	0	0	11	10	0	0	3	4	0
Tiotropium	9	0	1*	1$	10	9	1	2	3	4	0
Vilanterol	3	1#	0	0	4	3	1	0	1	1	0
Omalizumab	4	0	0	0	5	5	0	0	3	3	0
Mepolizumab	2	0	0	0	2	2	0	0	1	0	0
Glycopyrronium	1	1	0	0	1	0	0	0	0	0	0

Abbreviations: GA: Gestational age; SGA: Small for gestational age.
[1]Infants may be exposed to multiple medications of interest and may therefore be in this table multiple times;
[#]Same infant exposed to both ipratropium and vilanterol;
**Termination of pregnancy due to a genetic syndrome;*
^Reported congenital malformations; hypospadias (major), hip dysplasia (minor), inguinal hernia (minor) and ankyloglossia (minor);
[$]Reported congenital malformations inguinal hernia (minor), this infant was exposed to both tiotropium and ciclesonide.

Conclusion

- This study provides **preliminary reassurance** on the safety of less commonly used asthma medications during pregnancy.
- **The cases show no specific pattern of malformations.**
- Based on the low number of exposures, no definite conclusions on the safety of these medicines can be drawn.