Neonatal events of interest in low- and middle-income regions

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Introduction

- Maternal immunisation can greatly reduce the burden of respiratory and other diseases in infants.
- For a better interpretation of safety data from clinical trials, it is paramount to understand the background rates of pregnancy outcomes and neonatal events of interest.
- Yet, such data are scarce and their collection is not standardised in low- and middle-income (LMI) regions.

Objective

To evaluate the incidence of neonatal events of interest that may be considered adverse events if they occur following maternal vaccination in neonates born to mothers from LMI regions.

Methods

Prospective, multi-country, low-interventional (without administration of medicines), cohort study (NCT03614676)

Neonates born to healthy mothers aged 18–45 years — From — South Africa, Argentina, Thailand, Colombia, Philippines, Bangladesh, Brazil, Malaysia, Mexico, Panama — Enrolled between August 28 2019 – July 27 2021

Endpoint: percentage of neonates who experienced neonatal events of special interest — Evaluated from birth — 28 days of age — Using standardised, harmonised surveillance methodology and case definitions

Key findings

Overall, the most common neonatal events reported were low birth weight (LBW), preterm birth, small for gestational age and congenital anomalies.

Compared to the overall analysis, the percentage (%) of
- **LBW neonates** tended to be higher in the Philippines, Bangladesh and Malaysia
- **preterm birth** and **small for gestational age** was higher in Bangladesh
- **congenital anomalies** was higher in South Africa.

Conclusions

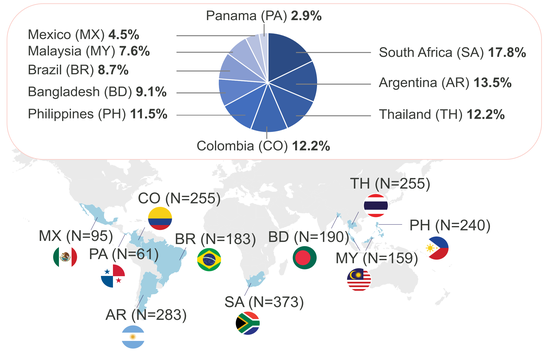
The **incidence of neonatal events of special interest** in neonates born to healthy women in LMI regions was established using a standardised and harmonised approach.

This study may facilitate the interpretation of safety outcomes in **maternal immunisation trials**.

Results

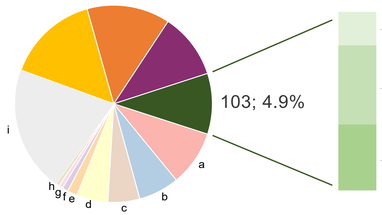
2094 neonates were included in the analyses (per-protocol set). Neonatal events of special interest were reported for **1034** of them.

Number of neonates included (N) by country



Neonatal events of special interest

(n; % of a total of 2094 neonates included in the per-protocol analyses)



Congenital anomalies
(n, % of a total of 2094 neonates included)

- functional defects (19; 0.9%)
- internal structural defects (46; 2.2%)
- major structural defects (38; 1.8%)

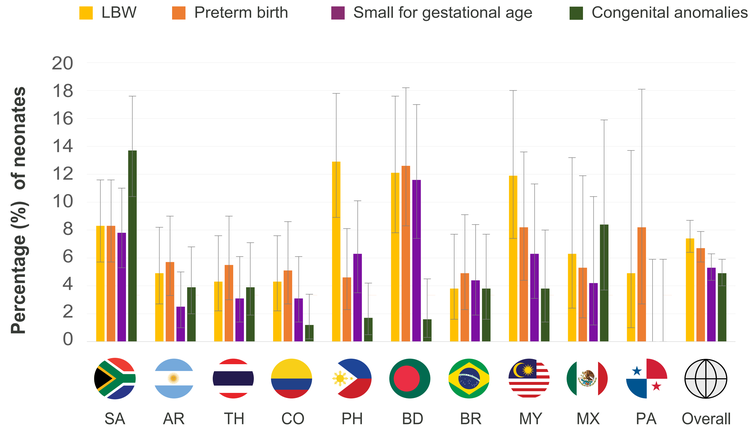
- LBW (156; 7.4%)
- Preterm birth* (141; 6.7%)
- Small for gestational age** (111; 5.3%)
- Congenital anomalies (103; 4.9%)
- [a] Respiratory distress in the neonate (94; 4.5%)
- [b] Neonatal infections (69; 3.3%)
- [c] Large for gestational age (54; 2.6%)
- [d] Macrosomia (53; 2.5%)
- [e] Congenital microcephaly (17; 0.8%)
- [f] Neonatal death (10; 0.5%)
- [g] Failure to thrive (7; 0.3%)
- [h] Neonatal encephalopathy (6; 0.3%)
- [i] Other event considered by the investigator to be of concern (213; 10.2%)

Neonatal deaths (10): in preterm live births 30% | 70% in (full-)term live births

n=number of infants with a specific event; **LBW**=low birth weight (<2500 g, including very LBW [<1500 g]); *at <37 completed weeks gestation; **birth weight <10th percentile for gestational age as assessed against a validated global, regional or local standard.

Percentage of neonates with the most common events of special interest

from birth through 28 days of age, overall and by country



Confidence intervals are depicted as error bars.

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