

Method: Records of patient waiting times were examined via coding and bookings. Approved patient questionnaires were administered, regarding counselling, expectation and delivery of service, and follow-up. Trainees reported OSATs showing independent competency at the procedure. Complications were recorded by direct reporting to authors and inspection of clinical incident forms. Descriptive statistics are used to demonstrate changes pre-and post the service change.

Results: Data from the new service demonstrated an increase in provision of slots, and provision of teaching this core skill to trainees. Patient satisfaction data collection is ongoing. Changes in waiting times are reported, as well as waiting times for surgical management of miscarriage. Challenges of setting up the new service included ring-fencing of budget for Early Pregnancy care, streamlining the patient journey to ensure efficient use of time, staffing and equipment, and ensuring appropriate coding and recording was performed. **Conclusions:** MVA is now an established part of the core service of miscarriage management in this hospital. It is a procedure which trainee gynaecologists should be able to provide and is especially useful in emergency, non-starved patients. This evaluation revealed low numbers of complications, high staff and patient satisfaction rates, and a new opportunity for training, confirming the need for and success of the service.

EP.0096 | Neonatal events of interest in low- and middle-income regions

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Objective: This study aimed 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 low- and middle-income regions.

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

Method: Neonates born to healthy mothers aged 18–45 years were enrolled from Bangladesh, Malaysia, Philippines, Thailand, South Africa, Argentina, Brazil, Colombia, Mexico and Panama between 28 August 2019 and 27 July 2021. The percentage of neonates who experienced neonatal events of special interest occurring from birth up to 28 days of age is presented.

Results: Of the 2181 neonates enrolled, 2094 were included in the analyses (Bangladesh: 190, Malaysia: 159, Philippines: 240, Thailand: 255, South Africa: 373, Argentina: 283, Brazil: 183, Colombia: 255, Mexico: 95, Panama: 61). Overall, the most common neonatal events of interest were low birth weight (<2500 grams, including very low birth weight [<1500 grams]) reported in 156 (7.4%, 95% confidence interval [CI]: 6.4–8.7) neonates, preterm birth (<37 gestation-completed weeks) in 141 (6.7%, 95%CI: 5.7–7.9) neonates, small for gestational age (birth weight <10th percentile for gestational age) in 111 (5.3%, 95%CI: 4.4–6.3) neonates, and congenital anomalies in 103 (4.9%, 95%CI: 4.0–5.9) neonates (major external structural defects: 38 [1.8%] neonates, internal structural defects: 46 [2.2%], functional defects 19 [0.9%]). A total of 10 (0.5%) neonatal deaths were reported. The percentage of low birth weight varied across countries, from 3.8% (Brazil) to 12.9% (Philippines). Reporting rates of this event tended to be higher in Malaysia (11.9%, 95%CI: 7.4–18.0), Bangladesh (12.1%, 95%CI: 7.8–17.6) and Philippines (12.9%; 95%CI: 8.9–17.8) than the overall reporting rate. The percentage of preterm birth varied by country, from 4.6% (Philippines) to 12.6% (Bangladesh). Across countries, the rates of small for gestational age ranged from 0.0% (Panama) to 11.6% (Bangladesh). Reporting rates were higher in Bangladesh for preterm birth (12.6%, 95%CI: 8.3–18.2) and small for gestational age (11.6%, 95%CI: 7.4–17.0) than in the overall cohort. The reporting rate of congenital anomalies ranged from 0.0% (95%CI 0.0–5.9) in Panama to 13.7% (95%CI: 10.4–17.6) in South Africa, where the reporting rate was higher versus the overall reporting rate.

Conclusions: The results of this study contribute to establish the incidence of neonatal events of interest in neonates born to healthy women in low- and middle-income regions and may facilitate the interpretation of safety outcomes in maternal immunization trials.

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