

# Management and outcomes of congenital anomalies in low-, middle-, and high-income countries: protocol for a multi-centre, international, prospective cohort study

*Global PaedSurg Research Collaboration*

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## Abstract

**Background:** Congenital anomalies have risen to become the 5th leading cause of death in children under 5-years of age globally, yet limited literature exists from low- and middle-income countries where most of these deaths occur.

**Aim:** This collaboration aims to undertake a multi-centre prospective cohort study of congenital anomalies across the globe to compare outcomes between low-, middle- and high-income countries (LM&HICs).

**Methods:** The Global PaedSurg Research Collaboration will be established consisting of children's surgical care providers from around the world to participate in the study; collaborators will be co-authors of resulting presentations and publication(s). Data will be collected on patients presenting primarily with seven congenital anomalies (anorectal malformation, intestinal atresia, oesophageal atresia, gastroschisis, exomphalos/omphalocele, congenital diaphragmatic hernia, and Hirschsprung's disease) for a minimum of 30 consecutive days between Oct 2018 - April 2019. Data will be collected on patient demographics, clinical status, interventions and outcome. Data will be captured using the online data collection tool REDCap.

The primary outcome will be all-cause in-hospital mortality and the secondary outcomes will be occurrence of post-operative complications. Chi-squared analysis will be used to compare mortality between LM&HICs and multivariate logistic regression analysis to identify factors affecting outcomes.  $P < 0.05$  will be deemed significant. Ethical approval will be sought from all participating centres. Funding has been granted by the Wellcome Trust.

**Outcomes:** The study aims to be the first large-scale, geographically comprehensive, multi-centre prospective cohort study of a selection of common congenital anomalies across the globe to define current management and outcomes, aid advocacy and global health prioritisation, and inform future interventional studies aimed at improving outcomes.