MANAGEMENT AND OUTCOMES OF CONGENITAL ANOMALIES IN LOW-, MIDDLE-, AND HIGH-INCOME COUNTRIES: PROTOCOL FOR A MULTI-CENTRE, INTERNATIONAL, PROSPECTIVE COHORT STUDY

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Aim: Congenital anomalies have risen to become the 5th leading cause of death in under 5-year olds globally yet limited literature exists from low- and middle-income countries where the majority of these deaths occur. 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 anorectal malformation, intestinal atresia, oesophageal atresia, gastroschisis, exomphalos, congenital diaphragmatic hernia, and Hirschsprung’s disease for a minimum of 30-consecutive days between Oct 2018 - April 2019. Data will be captured using the online data collection tool REDCap.

Results: Primary outcome will be all-cause in-hospital mortality. Secondary outcomes will be post-intervention complications. Data will be collected on patient demographics, clinical status, interventions and outcome. Chi-squared analysis will be used to compare mortality between LM&HICs. Multivariate logistic regression analysis will be used to identify factors affecting outcomes. Funding has been granted by the Wellcome Trust. Ethical approval will be sought from all participating centres.

Conclusion: 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.