C-Safe summary

**Title**
C-Safe: Optimising maternal and perinatal outcomes through safe and appropriate caesarean sections in low- and middle-income countries (LMIC).

**Objectives**
To develop, implement, and evaluate a multi-faceted interventional strategy (C-Safe) targeting healthcare professionals, pregnant women and health systems to reduce maternal and perinatal mortality and morbidity following caesarean section (CS) in low- and middle-income countries (LMIC).

**Team**
Chief investigator: Prof Shakila Thangaratinam. Programme manager: Dr Amie Wilson.

Partners: WHO, Unicef, Jhpiego, Global Surgery Foundation, ELLY charity, University of Central Lancashire, London School of Hygiene and Tropical Medicine, University of Dar es Salaam, Muhimbili University, MRT Apoio Operacional e Informacoes Ltda, Fernandez Foundation, University of Nairobi, Bayero University & Founding Director of African Centre of Excellence in Population Health and Policy, Royal Free Teaching Hospital, Royal College of Obstetricians and Gynaecologists.

**Trial design**
i. Prioritisation of intervention and outcome components through Delphi surveys and consensus meetings.

ii. Development and refinement of intervention and implementation strategies through field testing using team-based training, learning, and mentoring; audit and feedback, ethnographic research, and further refinement based on the findings.

iii. Evaluating the C-Safe intervention through a hybrid effectiveness-implementation design stepped-wedge cluster randomised trial in India and Tanzania (process outcomes, implementation outcomes, clinical outcomes with mixed methods evaluation (focus groups, surveys, discussions).

**Participant population and sample size**
i. Obstetricians, midwives and nurses, anaesthetic providers, neonatologists, women - Delphi surveys and consensus.

ii. Stakeholders (women, family, HCP, policymakers) (2 hospitals – 1 in Tanzania and 1 in India – these will not be the trial sites in the cluster trial) – field testing.

iii. Healthcare professionals and pregnant woman, from 8 hospitals (4 in each country with a minimum of 4,000 births/ year (1,500 expected CS) totalling around 30,000 births and 10,000 CS) - cluster RCT. Healthcare professionals, individual women, communities, family members (partners and older female relatives), and policymakers - 48 focus groups, 240 interviews, 4000 survey responses - mixed methods evaluation.

**Setting**
i. India, Tanzania, Kenya, Nigeria, and Brazil - Delphi surveys.

ii. Two urban or peri-urban, secondary or tertiary-level public facilities (Tanzania, India) providing comprehensive emergency obstetric care - field testing.

iii. Eight urban or peri-urban, secondary or tertiary-level public facilities (Tanzania, India) providing comprehensive emergency obstetric care over 12 months – cluster RCT.

**Eligibility criteria**
All HCPs working in maternity will have access to the C-Safe intervention during the cluster RCT. All pregnant women accessing the facilities for delivery will encounter the C-Safe intervention during the cluster RCT.

**Interventions**
C-Safe framework incorporating C-Why, C-Op, C-Non packages. Control: Usual care with dissemination of the current guidelines on reporting of indications for CS, safe surgery, and labour management.

**Outcome measures**
Changes in clinical practice, process outcomes, implementation, acceptability, equity, cost and clinical outcomes.
Figure i. Work package flowchart

Figure ii. C-Safe trial flowchart