C-SAFE

UNIVERSITY OF BIRMINGHAM

WHO CC GLOBAL WOMEN'S HEALTH BIRMINGHAM

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.

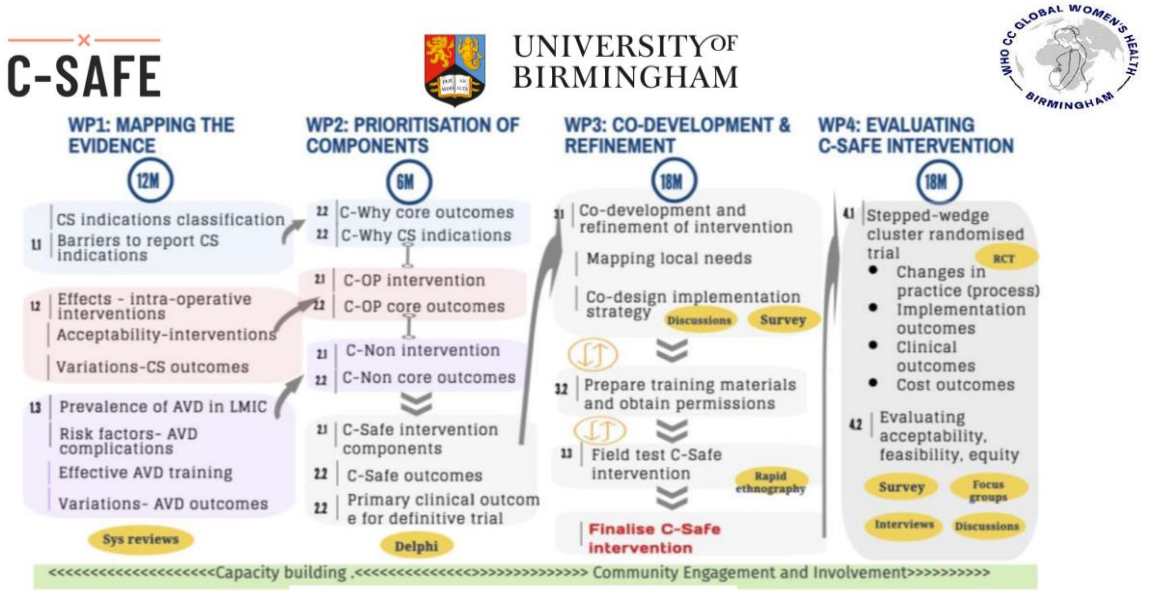

Figure i. Work package flowchart

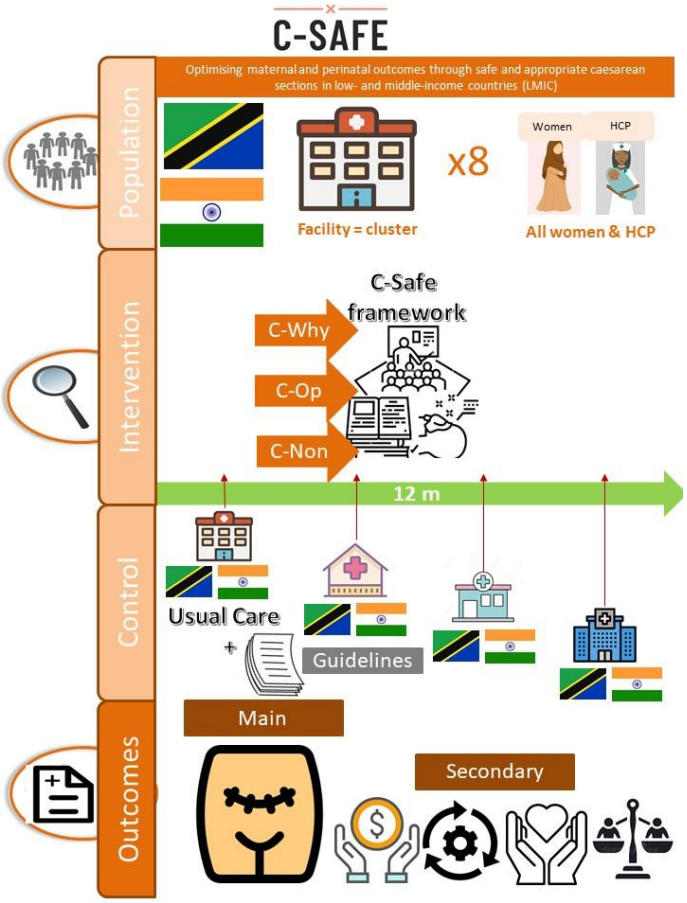

Figure ii. C-Safe trial flowchart