C-Safe - Optimising maternal and perinatal outcomes through safe and appropriate caesarean sections in low- and middle-income countries (LMIC): stepped-wedge cluster randomised trial with mixed methods evaluation

Healthcare providers' training Information Sheet and Consent Form

Dear Healthcare provider,

We are conducting the C-Safe study to assess the impact of the C-Safe intervention. The intervention consists of three elements: 1) C-Why; promoting appropriate caesarean section (CS) through accurate reporting of CS indications for monitoring and feedback 2) C-Op; promoting safe caesarean section through perioperative interventions and 3) C-Non; promoting safe vaginal births, including assisted vaginal birth. The C-safe intervention will be delivered through an implementation strategy, focusing on simulation-based training, peer-assisted learning, local C-Safe champions, and feedback of actionable data to providers.

The facilities are chosen by a "cluster randomisation"; where providers working in the facilities selected to give the intervention receive the training (see figure 1 below). All facilities will receive the training at some point during the study, but the training will be received at different time points so we can understand the impact of the training. The C-Safe intervention is adapted to train providers in order to reduce unnecessary caesarean sections and improve the safety of the surgery/procedure. On-site support will be provided for the first week with remote support continuing throughout the intervention. A refresher session will take place 3-months after the initial training. As part of the training, observations will be conducted before and after training to observe how birth is managed.

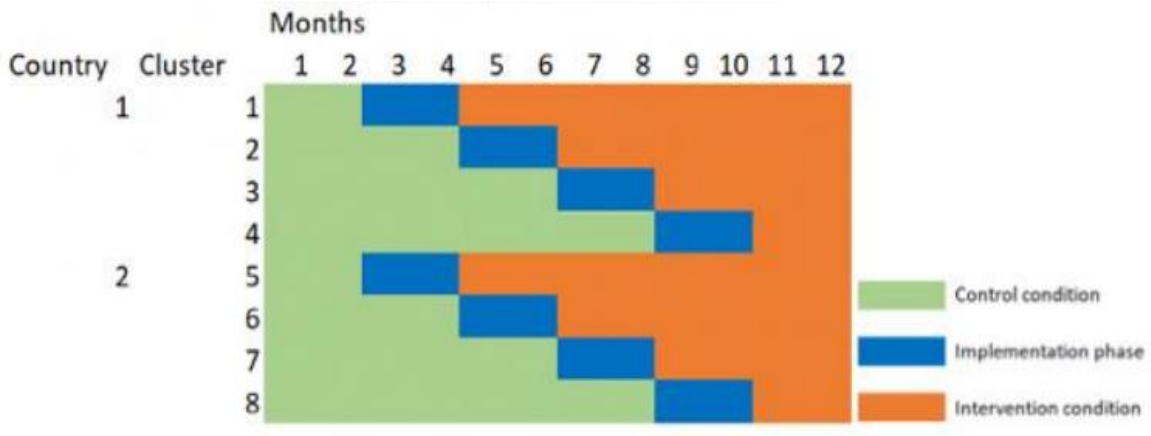

Figure 1: Cluster randomisation and delivery of the intervention.

Risks and benefits:

There are no direct risks involved in taking part in this study and you can choose not to take part in the training.

Confidentiality:

Your decision to participate in the training will help the research team, to determine the uptake rates of the training and will be kept confidential. We will collect scores from assessments including knowledge tests, observations and confidence assessments which will be anonymised and transferred to the University of Birmingham for safe storage. All data of this project will be held under the provisions of the 2018 Data Protection Act including the General Data Protection Regulation (GDPR) which sets a standard for participant rights regarding their data. Anonymised data will be stored in manual and/or electronic files in a secure format for up to 10 years.

Dissemination of results:

We will publish the results in the future as part of the overall study findings. You will not be identifiable in any publications.

Right to withdraw:

You have the right to refuse participation or withdraw from the training at any time. This will not bear any consequences to your current job.

If you have any questions about your rights, you may contact [insert country PI name and contact details].

Further information and clarification can be obtained from [insert additional contact here with contact details].

In case of concerns:

If you are concerned about any aspect of the research you can contact the team using the details above. If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, and you feel unable to discuss this with the research team then you may contact the University of Birmingham Research Ethics Team on +44 (0)121 414 8825 or by email ethics-queries@contacts.bham.ac.uk.

Organisation and funding of the research:

The study is being led by the University of Birmingham and is funded by the Medical Research Council.

Review of the research:

The University of Birmingham's Research Ethics Review Committee and local ethical review boards from each participating country: Tanzania and India have reviewed this study.

Participant agreement:

I have read the document describing the benefits, risks, and procedures for the research titled: "C-Safe - Optimising maternal and perinatal outcomes through safe and appropriate caesarean sections in low- and middle-income countries (LMIC): stepped-wedge cluster randomised trial with mixed methods evaluation." I have been allowed to ask any questions about the research answered to my satisfaction. I agree to participate in the training.

C-SAFE

Name: _____

Signature: _____

Date: ___ / ___ / _____

Health Facility Name:_____