# Rule of THUMB: A multi-centre cluster trial evaluating the implementation of a perioperative care complex intervention to improve outcomes from haemorrhage during and after caesarean section in African hospitals

**Protocol version 1.0**

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# Contents

## Trial summary

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| **Title** | **The Rule of THUMB trial** |
| **Project Office** | Department of Anaesthesia and Perioperative Medicine, Groote Schuur Hospital, University of Cape Town, South Africa. |
| **Trial Size** | Eight hospitals in four countries (Ethiopia, South Africa, Tanzania, and Uganda). |
| **Trial Design** | Multi-centre cluster trial evaluating the implementation of a perioperative care complex intervention to improve outcomes following haemorrhage during and after caesarean section. Mixed-methods process evaluation will be incorporated. |
| **Primary Objectives** | To evaluate whether implementation of the 'Rule of THUMB' perioperative complex intervention increases risk assessment and improves, diagnosis and compliance with proven interventions for haemorrhage during and after caesarean section, by evaluating the following:<br>1. Patient assessed as high-risk for postpartum haemorrhage<br>2. Administration of uterotonics intra- or postoperatively<br>3. Administration of tranexamic acid intra- or postoperatively<br>4. Uterine massage intra- or postoperatively after delivery of the baby<br>5. A postoperative clinician visit within four hours of discharge to the ward |
| **Secondary Objectives** | To evaluate the effect of the trial intervention on the following patient outcomes:<br>1. A diagnosis of postpartum haemorrhage<br>2. 30 day in-hospital mortality<br>3. Repeat laparotomy for suspected haemorrhage<br>4. Duration of hospital stay<br>5. Referral to higher level of care for further management of bleeding/resuscitation |
| **Inclusion Criteria** | Hospitals: Hospitals in participating countries that have an established maternity service that routinely perform caesarean section.<br>Patients: Any patient who requires a caesarean section. |
| **Exclusion Criteria** | Hospitals: Hospitals that do not consent to be part of the trial; hospitals that do not run a 24-hour caesarean section theatre service.<br>Patients: Patients who opt out of the trial will be excluded. |
| **Recruitment** | Eight hospitals in Ethiopia (2), South Africa (2), Tanzania (2), and Uganda (2). |
| **Trial intervention** | Control data will be collected at all hospitals over a two-week period (usual care phase). Thereafter, all hospitals will co-design and be trained for 2-6 weeks, as requires, on the intervention: comprising two mandatory risk assessments (preoperatively in theatre and postoperatively prior to discharge from the recovery area) which are linked to hospital-specific responses. Assessments for bleeding will occur intraoperatively (through direct vision, haemodynamic changes and/or measurement of blood loss) and postoperatively (with the use of the rapid assessment tool). If bleeding is diagnosed at any point, the THUMB checklist will be used to activate bundled care. On discharge from recovery, high-risk patients will be scheduled to receive a postoperative ward visit within four hours, where a further assessment for bleeding will occur.<br>Two intervention cycles will occur in each hospital. The initial intervention will be modified in accordance with data collected during the usual care phase, in conjunction with local stakeholders. Further intervention refinement will occur after each period |

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| | of data recruitment and analysis. All clusters do not have to commence this process on the same date. |
| **Trial duration** | Six months |

## Introduction and rationale

Obstetric haemorrhage is the leading cause of maternal death worldwide, 99% of which occurs in low- and middle-income countries.[1] A systematic review of studies between 1990 and 2017 reported that women in low- and middle-income countries who had a caesarean section were more likely to die, and one third died from postpartum haemorrhage.[2] Evidence from the recent African Surgical Outcomes Study (ASOS) shows that caesarean section is associated with maternal deaths in Africa, with postpartum haemorrhage contributing up to 25% of cases. Maternal mortality following caesarean section in this African study was 50 times higher than in high-income countries, and mostly driven by peripartum haemorrhage and anaesthesia complications.[3] In 2014, a World Health Organisation survey on global maternal deaths highlighted caesarean section as one of the key factors associated with the diagnosis of postpartum haemorrhage.[4]

Few complex interventions for perioperative maternal haemorrhage have been tested in caesarean section, and many studies not given due attention to processes of care, which may have a significant impact on outcomes in low- and middle-income countries. Despite the progress in postpartum haemorrhage research in these areas, there remains an important gap in the clinical evidence to define optimal care for patients at high risk of postpartum haemorrhage following caesarean section. Recent studies have examined a combination of interventions consisting of checklists, care bundles, or interlinked complex interventions. These interventions, mainly tested in patients having vaginal delivery or low-risk caesarean section, have shown positive results in reducing the incidence of complications and deaths due to postpartum haemorrhage.[5] A Delphi consensus study in 2022 found that many health professionals recommended a surgical safety checklist and routine risk assessment.[6]

The E-MOTIVE trial (a cluster randomised trial) showed that early detection of blood loss by objective measurement, combined with bundled care, improved patient outcomes following postpartum haemorrhage.[5] The intervention was developed through a robust process that outlined a “first response to postpartum haemorrhage” bundle, and a “response to refractory postpartum haemorrhage” bundle.[7] The E-MOTIVE trial showed improvement in the primary postpartum haemorrhage outcomes (a composite of severe postpartum haemorrhage, laparotomy, and death), in four sub-Saharan African countries. However, this trial included only patients who had undergone vaginal delivery, who were thought to represent a lower risk group than those undergoing caesarean section.

Anders et al reported a multi-stage intervention to prevent deaths from postpartum haemorrhage in Niger over a period of 72 months.[8] The intervention included prevention of postpartum haemorrhage, followed by staged treatment with misoprostol, intrauterine condom balloon tamponade and the use of non-inflatable anti-shock garment. Importantly, the intervention was based on a strong foundation of health care support with training and distribution of supplies, which are known to contribute to improvement in care. This reduced the rate of postpartum haemorrhage from 32% to 10% over a period of five years (2015 to 2020). It provided evidence that staged-care strategies can improve outcomes if based on a strong health care system that is equipped with resources and a trained workforce. Main et al suggested an “obstetric haemorrhage safety bundle” to standardise the multidisciplinary care for postpartum haemorrhage, through a consensus statement.[9] This bundle provides a framework for improved care of peri- caesarean section haemorrhage.

We developed a complex intervention to improve maternal outcomes for patients undergoing caesarean section based on early diagnosis of haemorrhage during and after surgery coupled to early treatment through first-responder protocolised treatment using a care bundle of five elements called the rule of THUMB. The intervention is essentially a quality improvement programme aimed at delivering better care, care that is already known to be effective in delivering better patient outcomes.

## Trial hypothesis

We propose to conduct a multicentre, investigator-initiated, prospective trial evaluating the implementation of a complex intervention designed to improve outcomes following haemorrhage during and after caesarean section, using a risk-stratification tool, and a perioperative care bundle package.

We hypothesise that preoperative risk stratification, earlier diagnosis of bleeding through improved diagnostic thresholds and active visitation of high-risk patients will result in an increase in diagnoses of bleeding and facilitate earlier delivery of care. The use of bundled care through checklists and the THUMB care bundle will also allow for improved delivery of recognised interventions for haemorrhage during and after caesarean section.

## Trial design

Multi-centre cluster trial evaluating the implementation of a perioperative care complex intervention to improve outcomes following hemorrhage during and after caesarean section. The trial will incorporate a mixed-methods process evaluation of the trial intervention.

## Objectives

**Primary objective**

To evaluate whether implementation of the 'Rule of THUMB' perioperative complex intervention increases risk assessment, and improves diagnosis and compliance with proven interventions for haemorrhage during and after caesarean section.

**Secondary objectives**

To evaluate the effect of the trial intervention on patient outcomes relevant to future trials.

# Trial outcomes

## Co-primary outcome measures

1. Patient assessed as high-risk for postpartum haemorrhage
2. Administration of uterotonics intra- or postoperatively
3. Administration of tranexamic acid intra- or postoperatively
4. Uterine massage intraoperatively after delivery, or postoperatively
5. A postoperative clinician visit within four hours of discharge to the ward

## Secondary outcome measures

1. A diagnosis of postpartum haemorrhage
2. 30 day in-hospital mortality
3. Repeat laparotomy for suspected haemorrhage
4. Duration of hospital stay (censored at 30 days)
5. Referral to higher level of care for further management of bleeding/resuscitation

A list of definitions is available in the 'Trial Definitions in Appendix 1.

# Trial setting

Maternity units of participating hospitals in four African countries (Ethiopia, South Africa, Tanzania, Uganda).

# Eligibility Criteria

## Hospital criteria

### Inclusion

Hospitals in participating countries that have an established maternity service that routinely performs caesarean section.

### Exclusion

Hospitals that do not consent to be part of the trial; hospitals that do not run a 24-hour caesarean section theatre service.

## Patient criteria

### Inclusion

Any patient who requires a caesarean section (regardless of anaesthetic technique).

### Exclusion

Patients who opt out of the trial will be excluded.

## Data collection and collation

This is a pragmatic trial in a resource-limited environment. As a result, a realistic data set will be fundamental to the success of the trial. We believe that these key data points will encourage hospitals to participate, as there will not be an excessive burden of data collection. Hospital-specific data will be collected once for each hospital, including: university or non-university hospital, number of hospital beds, number of theatres, number and level of critical care beds, and details about the reimbursement status of the hospital. Please see hospital case report form (*Appendix 2*) for more detail. A case report form will be completed for every eligible patient who undergoes caesarean section during the trial. Please see patient case report form (*Appendix 3*) for more detail. Patients will be followed up for 30 days. This information will then be entered into an electronic database. Access to the electronic data entry system will be protected by username and password, which will be delivered during the registration process, for individual local investigators. All electronic data transfer between participating hospitals and the coordinating hospital will be username and password protected. Each hospital will maintain a trial file including a protocol, local investigator delegation log, and ethics approval documentation. Pseudo-anonymised (coded) data may also be sent by mail to the coordinating hospital if necessary for event adjudication.

## Recruitment, consent and trial participation

This is an international trial in four African countries. We will include consecutive patients admitted to participating hospitals and undergoing caesarean section. The basis for participation in this trial is opt out i.e., patients will be included unless they ask not to be included. 'Broadcasting' through appropriate hospital notices and signage will inform patients and the public that the hospital is participating in the trial. The requirement for patient informed consent is expected to vary according to regulations of the participating nations. The national leaders will ensure that ethics approval is obtained from their respective countries and hospitals prior to participation. We will apply to all ethics committees for a waiver of consent for participating trial sites for the following reasons:

Firstly, the trial intervention is not only low risk but promotes the best standard of care every patient needs. Patients in the control phase will receive the current standard postoperative care. The intervention (a quality improvement programme) will then be implemented by the unit for all patients, aimed at delivering care that is already known to be effective in delivering better patient outcomes. All patients will thus be a part of the quality improvement programme, but will be allowed to opt out of data collection.

Secondly, the majority of obstetric surgery in Africa is urgent or emergency. Attempts to obtain traditional consent in the preoperative period in predominantly urgent and emergency surgery, may lead to non-consecutive patient enrolment in the trial. It is likely that this would lead to a biased sample, with artificially low estimates of adverse outcomes in these patients, and data not generalisable to the majority of African obstetric patients.

Thirdly, for these reasons, a waiver of consent is increasingly common around the world in both interventional and observational research involving time-sensitive procedures, such as surgery.

Fourthly, generating biased and poorly generalisable data would not address the research question, and thus would dishonour the contributions of the other included patients, and would be wasteful research, in a resource-limited environment.

Finally, we would use 'broadcasting' at participating sites to ensure that all patients and family members were aware that the surgical site was a participating surgical trial site, through appropriate signage, (*Appendix 4*) and a patient information sheet (*Appendix 5*). Where possible, preoperative assent will be obtained from participating patients.

## Ethical considerations

The study will be carried out in accordance with the ethical principles in the International Conference on Harmonisation and Good Clinical Practice. All members of the trial steering committee will declare conflicts of interest before joining the trial group.

Ethical approval will be obtained from the University of Cape Town with additional approvals in each country as required by national ethical committees, and from each hospital as required by local regulations. The Country Coordinators will be responsible for clarifying the need for ethical and regulatory approvals and for ensuring these are in place prior to data collection. Participating hospitals will not be permitted to record data without providing confirmation that the necessary ethical and regulatory approvals are in place. Full approval by the Research Ethics Committee as well as the participating hospital will be fully documented by letter to the Chief Investigator naming the trial site, the local Principal Investigator (who may also be the Chief Investigator) and the date on which the ethics committee deemed the trial permissible at that site. The translation of the trial protocol, 'broadcasting' documents and other trial documents will be completed if required by the local participating hospital, or at the discretion of the National Lead Investigator.

## Trial intervention: The Rule of THUMB

The intervention comprises two mandatory risk assessments (preoperatively in theatre and postoperatively prior to discharge from the recovery area) which are linked to hospital-specific responses. Assessments for bleeding will occur intraoperatively (through direct vision, haemodynamic changes and/or measurement of blood loss) and postoperatively (with the use of the rapid assessment tool). If bleeding is diagnosed at any point, the THUMB checklist will be used to activate bundled care. On discharge from recovery, high-risk patients will be scheduled to receive a postoperative ward visit within four hours, when a further assessment for bleeding will occur.

Staff at each hospital will collect data for the two-week usual care (control) phase describing usual perioperative care. This will be followed by a period of co-design and training (2-6 weeks, as required), and then implementation of the intervention phase for a further two weeks at each hospital. The initial intervention will be modified in accordance with data collected during the usual care phase, in conjunction with local stakeholders. Further intervention refinement will occur after each period of data recruitment and analysis. Two intervention cycles will occur. The intervention is

essentially a quality improvement programme aimed at delivering better care, care that is already known to be effective in delivering better patient outcomes. The intervention aims to improve compliance with recommended care for prevention and treatment of haemorrhage during and after caesarean section by creating a bundle of care that is delivered simultaneously (not sequentially) by first responders. It includes two mandated risk assessments before and after surgery, and implementation of the THUMB care bundle either in response to bleeding intraoperatively or in recovery or the ward through the rapid assessment tool. Please see the trial flow diagram (*Appendix 6*), rapid assessment tool (*Appendix 7*), THUMB diagram (*Appendix 8*) and THUMB recommendations document (*Appendix 9*) for more detail. Training and co-design will occur as outlined in *Appendix 10*, and how the process evaluation will be conducted, as detailed in *Appendix 11.* The participant consent for the process evaluation is *Appendix 12,* and the process evaluation interview topic guide is *Appendix 13.*

## Community Engagement and Involvement

Each of the participating sites will have opportunity to participate in the co-design of the intervention. This will allow for local modifications to the broad structure of the intervention – allowing for context-specific actions to occur in response to risk assessment or bleeding. The community will include consultation with healthcare workers (doctors [obstetric/anaesthetic/general], nurses [labour ward, theatre, postoperative wards]) and patients (ideally through patient-partners). We will initially discuss the trial with participating sites while collecting baseline data pertaining to usual care at that site. We will then aim to co-design a quality improvement programme at that site using a similar broad structure, but with local modifications. This will occur through meetings and one-on-one interviews. This intervention will then be tested at the site, and data collected. Following analysis of the intervention fidelity, a further round of consultation will be done in order improve the intervention. This improved intervention will then be tested in similar fashion. Further details of this process are provided in *Appendix 8*.

## Training of investigators

All investigators will complete training consistent with their national regulations for clinical research, as well as those in the country of the trial sponsor (South Africa). A representative of the national coordinating hospital for that country will conduct a site initiation at each site before patient recruitment commences, or conduct a remote electronic site initiation. The site initiation will include induction with respect to the trial protocol and procedures, the standardised assessment of outcome measures, and the trial database. When new investigators join the research team at a particular site during the course of the trial, the responsibility for induction training will fall to the local Principal Investigator.

# Statistical Methods

## Sample size calculation

We will include two hospitals from each of the four participating countries (total of eight hospitals). The expected delivery rate per month is between 500 – 1000. Given an average caesarean section rate of 30%, this will yield 150-300 caesarean sections per month, or 75-150 caesarean sections per two-week period. We therefore expect approximately 100 caesarean sections per hospital per two-week period. This will result in 800 caesarean sections for the control data collection period, and 800 caesarean sections for the transition period, and 800 for the intervention period. Total data set is expected to include approximately 2400 patients (800 in the control group, 800 in the transition period and 800 in the intervention group).

One-level clustering by hospital has been assumed, not accounting for clustering by countries separately. As no intra-cluster correlation (ICC) estimates are available, the resulting power for a range of ICCs is calculated. An ICC in the 0.01-0.1 range seems most likely.

All sample size calculations are for a one-sample proportion tests, testing against a fixed value and accounting for clustering. The fixed values are based on baseline estimates, however, choosing target values might be preferable. System optimisation step rates assumed not used in analyses.

**1. Administration of uterotonics intra- or postoperatively.**

Calculation based on i) a control rate of 90%, with ii) a post intervention compliance of 95% or 97.5%.

| N Clusters | Cluster size | N total | delta | p0 | pa | ICC | Power |
|---|---|---|---|---|---|---|---|
| 8 | 100 | 800 | .05 | .9 | .95 | 0.2 | .2959 |
| 8 | 100 | 800 | .05 | .9 | .95 | .1 | .5022 |
| 8 | 100 | 800 | .05 | .9 | .95 | .05 | .7581 |
| 8 | 100 | 800 | .05 | .9 | .95 | .01 | .9959 |
| 8 | 100 | 800 | .075 | .9 | .975 | 0.2 | .8460 |
| 8 | 100 | 800 | .075 | .9 | .975 | .1 | .9844 |
| 8 | 100 | 800 | .075 | .9 | .975 | .05 | .9998 |
| 8 | 100 | 800 | .075 | .9 | .975 | .01 | 1 |

**2. Administration of tranexamic acid intra- or postoperatively.**

Calculation based on i) a control rate of 2.5%, with ii) a post intervention compliance of 5% or 7.5%.

| N Clusters | Cluster size | N total | delta | p0 | pa | ICC | Power |
|---|---|---|---|---|---|---|---|
| 8 | 100 | 800 | .025 | .025 | .05 | 0.2 | .1097 |
| 8 | 100 | 800 | .025 | .025 | .05 | 0.1 | .1658 |
| 8 | 100 | 800 | .025 | .025 | .05 | 0.05 | .2649 |
| 8 | 100 | 800 | .025 | .025 | .05 | 0.01 | .6331 |
| 8 | 100 | 800 | .05 | .025 | .075 | 0.2 | .2178 |
| 8 | 100 | 800 | .05 | .025 | .075 | 0.1 | .3695 |
| 8 | 100 | 800 | .05 | .025 | .075 | 0.05 | .5953 |
| 8 | 100 | 800 | .05 | .025 | .075 | 0.01 | .9676 |

**3. Uterine massage intra- or postoperatively after delivery of the baby.**

Calculation based on i) a control rate of 90%, with ii) a post intervention compliance of 95% or 97.5%.

| N Clusters | Cluster size | N total | delta | p0 | pa | ICC | Power |
|---|---|---|---|---|---|---|---|
| 8 | 100 | 800 | .05 | .9 | .95 | 0.2 | .2959 |
| 8 | 100 | 800 | .05 | .9 | .95 | 0.1 | .5022 |
| 8 | 100 | 800 | .05 | .9 | .95 | 0.05 | .7581 |
| 8 | 100 | 800 | .05 | .9 | .95 | 0.01 | .9959 |
| 8 | 100 | 800 | .075 | .9 | .975 | 0.2 | .8460 |
| 8 | 100 | 800 | .075 | .9 | .975 | 0.1 | .9844 |
| 8 | 100 | 800 | .075 | .9 | .975 | 0.05 | .9998 |
| 8 | 100 | 800 | .075 | .9 | .975 | 0.01 | 1 |

**4. A postoperative clinician visit within four hours of discharge to the ward.**

Calculation based on i) a control rate of 5%, with ii) a post intervention compliance of 10% or 12.5%.

| N Clusters | Cluster size | N total | delta | p0 | pa | ICC | Power |
|---|---|---|---|---|---|---|---|
| 8 | 100 | 800 | .05 | .05 | .1 | 0.2 | .1785 |
| 8 | 100 | 800 | .05 | .05 | .1 | 0.1 | .2977 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 8 | 100 | 800 | .05 | .05 | .1 | 0.05 | .4891 |
| 8 | 100 | 800 | .05 | .05 | .1 | 0.01 | .9165 |
| 8 | 100 | 800 | .075 | .05 | .125 | 0.2 | .2903 |
| 8 | 100 | 800 | .075 | .05 | .125 | 0.1 | .4932 |
| 8 | 100 | 800 | .075 | .05 | .125 | 0.05 | .7485 |
| 8 | 100 | 800 | .075 | .05 | .125 | 0.01 | .9952 |

### Statistical analysis

Outcomes will be presented at a continental level. All hospital level data will be anonymised prior to publication. Categorical variables will be described as proportions and will be compared using chi-square tests. Continuous variables will be described as mean and standard deviation if normally distributed or median and inter-quartile range if not normally distributed. Comparisons of continuous variables between groups will be performed using t-tests, one-way ANOVA or equivalent non-parametric tests as appropriate.

Overall differences in outcomes will be compared between the intervention and control groups. All analyses will account for clusters. We will use logistic regression model to estimate the effect of the intervention, on the primary and secondary outcomes. We will calculate the odds ratios and their associated 95% confidence intervals. We will infer statistical significance if the computed 2-sided p-value is < 0.05. A single final analysis is planned at the end of the study.

## Trial management

### Hospitals

The main project office will the Clinical Research Hospital at Groote Schuur Hospital, Cape Town.

### Data management

Data entry and integrity verification will be done by independent investigators. Outcomes will be independently adjudicated. Data will be collected in individual hospitals on paper case report forms. These will be stored within a locked office in each hospital, as they will include identifiable patient data, in order to allow follow-up of clinical outcomes. Data will then be pseudo-anonymised by generation of a unique numeric code, and transcribed by local investigators onto an internet based electronic case report form. Each patient will only be identified on the electronic case report form by their numeric code; thus, the coordinating trial team will be unable to link data to an individual patient without contact with the local team. A participant (patient) list will be used in each hospital to match identifier codes in the database to individual patients, in order to record clinical outcomes and supply any missing data points. Access to the data entry system will be protected by username and password delivered during the registration process for individual local investigators. All

electronic data transfer between participating hospitals and the co-ordinating hospital will be encrypted using a secure protocol.

## Follow-up procedures

Follow-up data will be collected by a trial site investigator. Investigators will review a participant's in-hospital medical records (paper or electronic) until the time of hospital discharge.

## Process Evaluation

Theory-informed process evaluations alongside trials of complex interventions are now standard. The process evaluation will provide an understanding of how the trial results were achieved and how the intervention mechanisms did, or did not, work in practice. Process evaluation will firstly occur through evaluation of the following hard core (patient-facing) elements:

1. Preoperative postpartum haemorrhage risk assessment
2. Intraoperative early postpartum haemorrhage diagnosis
3. Post-recovery identification of the high risk patient
4. Postoperative surveillance and rapid assessment
5. Delivery of the THUMB bundle

Refer to Figure 1 for the trial flow process. Delivery of these components will be evaluated through collection of process measures in the main study, predominantly using quantitative data.

Secondly, it will occur through evaluation of the following soft periphery (staff-facing) elements:

1. Training on delivery of the THUMB care bundle
2. Co-design and team planning for how to adapt and implement the hardcore THUMB principles

This process evaluation will focus on evaluating these components through qualitative research methods. Please refer to *Appendix 9* for further details and explanation.

## Publication plan

Data will be presented and disseminated in a timely manner. The paper will be published in a peer-reviewed journal and will comply with the African Partnership For Perioperative And Critical Care Research (APPRISE) policy of trial authorship.

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# Appendices

## Appendix 1: Trial Definitions

**Definitions for co-primary outcomes**

**Patient assessed as high-risk for postpartum haemorrhage:** Risk assessment performed as per the preoperative PPH risk assessment tool (*Appendix 3)* and the patient documented to have one or more risk factors prior to commencement of caesarean section.

**Administration of uterotonics intra- or postoperatively:** Uterotonics were administered following delivery of the fetus in accordance with local policy.

**Administration of tranexamic acid intra- or postoperatively:** Tranexamic acid was administered following a diagnosis of postpartum haemorrhage.

**Uterine massage intraoperatively after delivery, or postoperatively:** Uterine massage following delivery of the fetus or diagnosis of postpartum haemorrhage in accordance with local policy.
**Postoperative clinician visit within four hours of discharge to the ward:** A documented postoperative visit by a clinician (designation of clinician as per local hospital capacity) within four hours of discharge to the ward.
**Definitions for secondary outcomes**

**A diagnosis of postpartum haemorrhage:** Postpartum haemorrhage following caesarean section is defined as blood loss of >500 mL. The diagnostic criteria for estimating that this threshold has been exceeded will be decided at each hospital during the co-design phase.
Some of the options that may be considered are: soaking of swabs (e.g., ≥ 3 soaked tape swabs), suction bottle >500 ml blood, haemodynamic instability (low SBP/high HR) as diagnosed by direct observation of significant/rapid bleeding by the anaesthetist and obstetric surgeon.

**30 day in-hospital mortality:** Death in-hospital, measured within 30 days following caesarean section. The day of the caesarean section shall be Day 0. Patients discharged prior to Day 30 will be marked as 'Alive'.

**Repeat laparotomy for suspected hemorrhage:** Did the patient undergo a laparotomy to obtain surgical control of bleeding following caesarean section?

**Duration of hospital stay (censored at seven days):** How long did the patient stay in hospital following caesarean section? The day of the caesarean section will be defined as day 0.

## Appendix 2: Hospital case report form


# Hospital case report form

### General

**Name of hospital:** _____ **University hospital:** Yes ☐ No ☐

**Total hospital beds:** ____ **Total ICU beds:** ____ **Total HCU beds:** ____

**Number of theatres:** ____ **Dedicated CS theatre:** Yes ☐ No ☐

**Level of care:** Primary ☐ Secondary ☐ Tertiary ☐

**Type of hospital:** Government ☐ Private ☐ Non-profit ☐

**Caesarean sections per month?** Total ____ Elective ____ Emergency ____

**Do you have or perform the following at your hospital?**

| | | |
|---|---|---|
| 24 hour staffed emergency theatre | Yes ☐ | No ☐ |
| Regular scheduled educational activities for staff | Yes ☐ | No ☐ |
| Simulation training for treatment of PPH | Yes ☐ | No ☐ |
| Written protocols for prevention and treatment of PPH | Yes ☐ | No ☐ |
| Written protocols for referral of woman to a higher level of care | Yes ☐ | No ☐ |
| Ambulance transport to and from centres with minimum delay | Yes ☐ | No ☐ |
| Preoperative risk assessment for PPH | Yes ☐ | No ☐ |
| Critical incident reviews of PPH cases (>1,5L blood loss)? | Yes ☐ | No ☐ |
| WHO surgical checklist perioperatively | Yes ☐ | No ☐ |

### Resources

**Do junior anaethetic doctors have specialist support?** (1= Always, 2= Sometimes, 3= Never)

| | | | | |
|---|---|---|---|---|
| During the day: | In person | 1☐ 2☐ 3☐ | Telephonic | 1☐ 2☐ 3☐ |
| After hours: | In person | 1☐ 2☐ 3☐ | Telephonic | 1☐ 2☐ 3☐ |

**Do junior obstetric doctors have specialist support?**

| | | | | |
|---|---|---|---|---|
| During the day: | In person | 1☐ 2☐ 3☐ | Telephonic | 1☐ 2☐ 3☐ |
| After hours: | In person | 1☐ 2☐ 3☐ | Telephonic | 1☐ 2☐ 3☐ |

**Do you have a blood bank:** On site ☐ Off site ☐ None ☐

**Do you have urgent access to?** (1= Always, 2= Sometimes, 3= Never)

| | | | |
|---|---|---|---|
| Emergency blood | 1 ☐ | 2 ☐ | 3 ☐ |
| Red cell concentrate | 1 ☐ | 2 ☐ | 3 ☐ |
| Whole blood | 1 ☐ | 2 ☐ | 3 ☐ |
| Fresh frozen plasma | 1 ☐ | 2 ☐ | 3 ☐ |
| Freeze-dried plasma | 1 ☐ | 2 ☐ | 3 ☐ |
| Cryoprecipitate | 1 ☐ | 2 ☐ | 3 ☐ |
| Platelets | 1 ☐ | 2 ☐ | 3 ☐ |
| Fibrinogen concentrate | 1 ☐ | 2 ☐ | 3 ☐ |

**Do you have the following available at your hospital?** (1= Always, 2= Sometimes, 3= Never)

| | | | |
|---|---|---|---|
| Oxytocin | 1 ☐ | 2 ☐ | 3 ☐ |
| Heat stable carbetocin | 1 ☐ | 2 ☐ | 3 ☐ |
| Misoprostol | 1 ☐ | 2 ☐ | 3 ☐ |
| Oxytocin-ergometrine fixed dose (e.g. syntometrine) | 1 ☐ | 2 ☐ | 3 ☐ |
| Ergometrine/methylergometrine | 1 ☐ | 2 ☐ | 3 ☐ |
| Tranexamic acid | 1 ☐ | 2 ☐ | 3 ☐ |
| Crystalloids | 1 ☐ | 2 ☐ | 3 ☐ |
| Colloids | 1 ☐ | 2 ☐ | 3 ☐ |
| Uterine artery embolisation | 1 ☐ | 2 ☐ | 3 ☐ |
| Intrauterine balloon tamponade device | 1 ☐ | 2 ☐ | 3 ☐ |
| Cell salvage | 1 ☐ | 2 ☐ | 3 ☐ |

CS= caesarean section, PPH = postpartum haemorrhage


**At CS**

**Do you have obstetric staff available onsite or standby who are skilled at performing the following:**

| | | | | |
|---|---|---|---|---|
| Uterine compression sutures? | Yes | ☐ | No | ☐ |
| Vessel ligations? | Yes | ☐ | No | ☐ |
| Hysterectomy? | Yes | ☐ | No | ☐ |

**Do you have anaesthetic staff available onsite or standby who are skilled at performing the following:**

| | | | | |
|---|---|---|---|---|
| Spinal anaesthesia | Yes | ☐ | No | ☐ |
| Epidural anaesthesia | Yes | ☐ | No | ☐ |
| General anaesthesia | Yes | ☐ | No | ☐ |

**Do you have or perform the following at caesarean section?**

| | | | | |
|---|---|---|---|---|
| Controlled cord traction for placenta removal | Yes | ☐ | No | ☐ |
| Delayed cord clamping if neonatal resuscitation not indicated | Yes | ☐ | No | ☐ |
| Uterine massage | Yes | ☐ | No | ☐ |
| A visual aid for the B-lynch suture procedure in theatre | Yes | ☐ | No | ☐ |

**Post CS**

**Do you have or perform the following postoperative in the recovery room?**

| | | | | |
|---|---|---|---|---|
| An equipped recovery area in theatre with dedicated staff | Yes | ☐ | No | ☐ |
| Protocol for specific observations and their frequency | Yes | ☐ | No | ☐ |
| Do you have a shortage of monitoring equipment | Yes | ☐ | No | ☐ |
| Criteria for discharge from theatre to the ward | Yes | ☐ | No | ☐ |

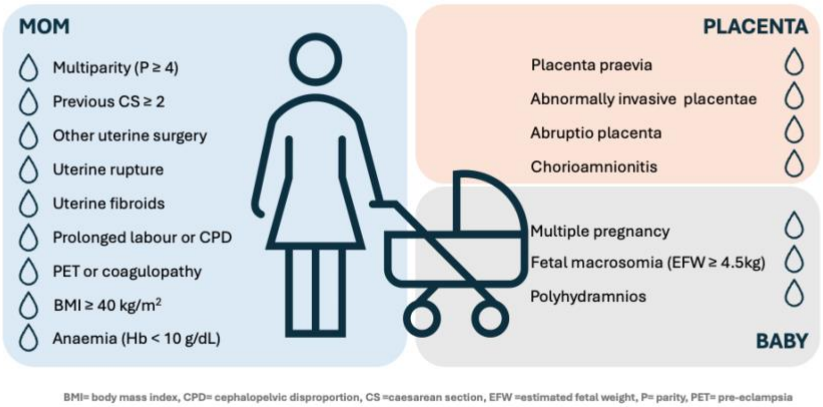
**Do you have or perform the following postoperative in the ward?**

| | | | | |
|---|---|---|---|---|
| A postoperative high care unit | Yes | ☐ | No | ☐ |
| An intensive care unit | Yes | ☐ | No | ☐ |
| Routine assessment of postpartum uterine tone | Yes | ☐ | No | ☐ |
| Routine haemoglobin level check | Yes | ☐ | No | ☐ |
| Protocol for specific observations and their frequency | Yes | ☐ | No | ☐ |
| Maternal early warning systems charts for observations | Yes | ☐ | No | ☐ |

## Control case report forms

| Patient details | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Age | _____ | Gravidity | _____ | Height | _____ cm | Preoperative haemoglobin | _____ g/dL |
| | ASA | _____ | Parity | _____ | Weight | _____ kg | Preoperative platelet count | _____ *$10^9$/L |

### Preoperative PPH Risk Assessment




BMI= body mass index, CPD= cephalopelvic disproportion, CS =caesarean section, EFW =estimated fetal weight, P= parity, PET= pre-eclampsia

NIHR National Institute for Health and Care Research | APPRISE

THUMB trial unique patient ID ☐☐☐☐☐☐

Patient name: _____
Hospital number: _____
DOB: _____

THUMB trial

### Intraoperative

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Single provider (anaesthesia and surgery)** | | | | Yes ❑ No ❑ | | | |
| **Anaesthesia** | Non-specialist ❑ | Specialist ❑ | Non-doctor ❑ | | | | |
| **Obstetrics** | Non-specialist ❑ | Specialist ❑ | Non-doctor ❑ | | | | |
| **Type of anaesthesia** | General ❑ | Spinal ❑ | Epidural ❑ | Sedation ❑ | | | |
| **Vasopressors** | Phenylephrine ❑ | Ephedrine ❑ | Adrenaline or noradrenaline ❑ | Other ❑ | | | |
| **SBP ≤ 80 mmHg** | Yes ❑ No ❑ | | **Duration of CS** _____minutes | | | | |

**Bleeding** → No ❑ / Yes ❑

| | |
|---|---|
| **≥ 500 mL in suction bottle** | Yes ❑ No ❑ |
| **≥ 3 soaked abdominal swabs** | Yes ❑ No ❑ |
| **Haemodynamic instability** | Yes ❑ No ❑ |
| **Observed significant/rapid blood loss** | Yes ❑ No ❑ |
| **Local predetermined criteria** | Yes ❑ No ❑ |
| **Estimated blood loss** | _____ mL |
| **Suspected cause of bleeding** | _____ |
| **Abnormal placentation at CS** | Yes ❑ No ❑ |

### Postoperative

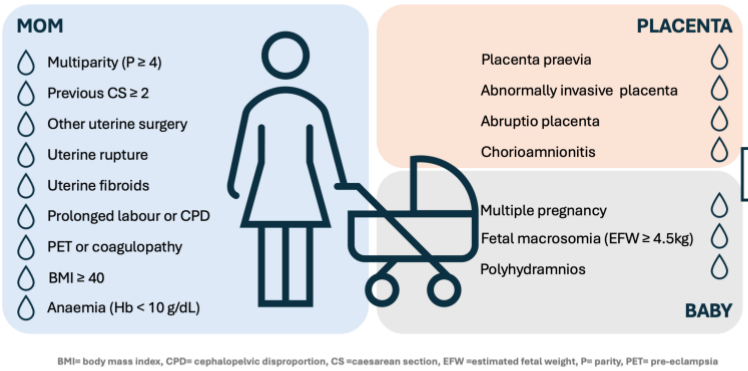
**Bleeding** → No ❑ / Yes ❑

| | |
|---|---|
| **Postoperative visit scheduled?** | Yes ❑ No ❑ |
| **Postoperative visit performed?** | Yes ❑ No ❑ |

# Intervention case report forms

| Patient details | | | | | | | |
|---|---|---|---|---|---|---|---|
| | Age | _____ | Gravidity | _____ | Height | _____ cm | Preoperative haemoglobin | _____ g/dL |
| | ASA | _____ | Parity | _____ | Weight | _____ kg | Preoperative platelet count | _____ *10⁹/L |

## Preoperative PPH Risk Assessment




BMI= body mass index, CPD= cephalopelvic disproportion, CS =caesarean section, EFW =estimated fetal weight, P= parity, PET= pre-eclampsia

THUMB trial

NIHR | National Institute for Health and Care Research

APPRISE

THUMB trial unique patient ID ☐☐☐☐☐☐☐

Patient name: _____
Hospital number: _____
DOB: _____

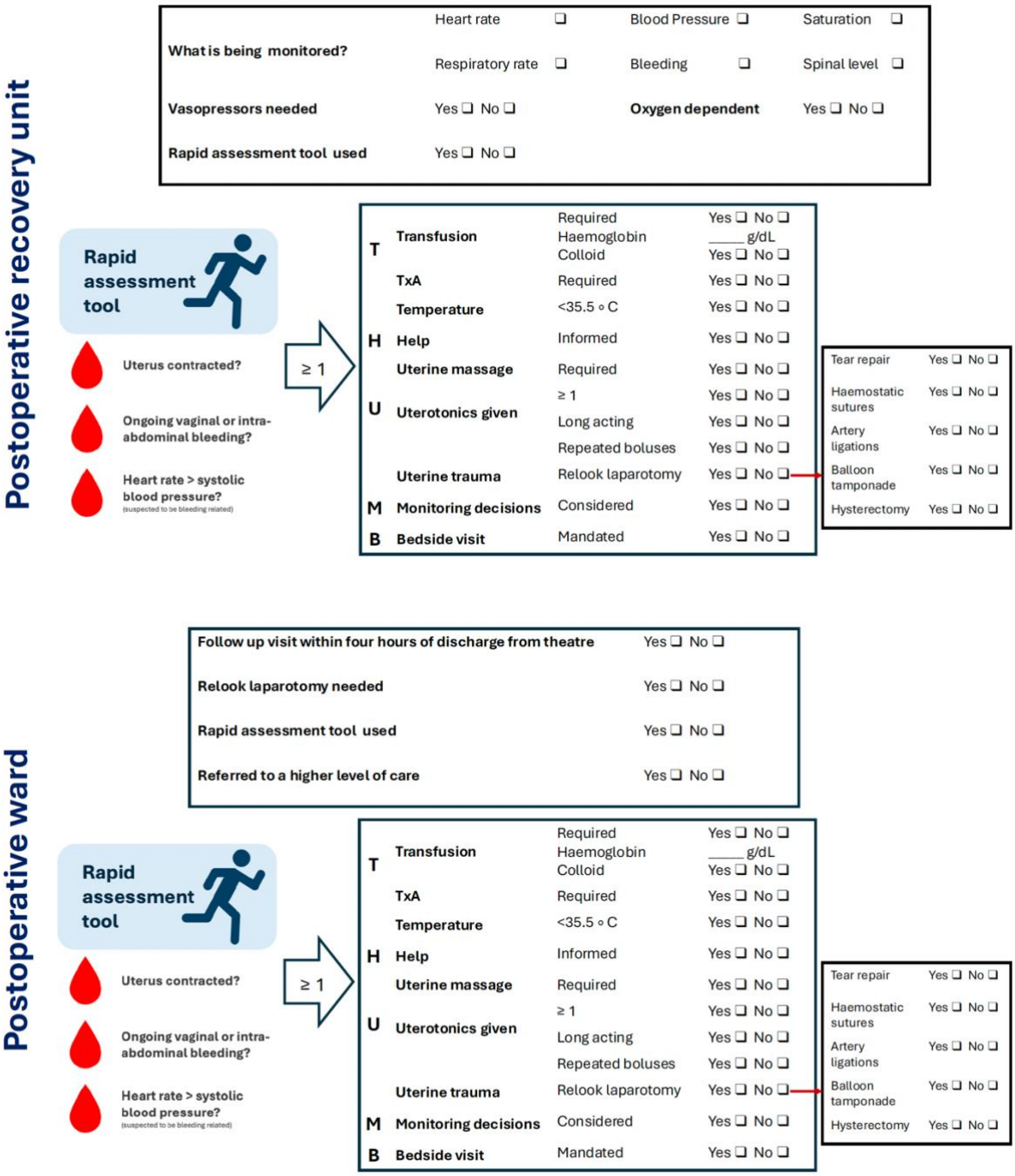
## Intraoperative

| | | | | |
|---|---|---|---|---|
| **Single provider (anaesthesia and surgery)** | | | | Yes ❑ No ❑ |
| **Anaesthesia** | Non-specialist ❑ | Specialist ❑ | Non-doctor ❑ | |
| **Obstetrics** | Non-specialist ❑ | Specialist ❑ | Non-doctor ❑ | |
| **Type of anaesthesia** | General ❑ | Spinal ❑ | Epidural ❑ | Sedation ❑ |
| **Vasopressors** | Phenylephrine ❑ | Ephedrine ❑ | Adrenaline or noradrenaline ❑ | Other ❑ |
| **SBP ≤ 80 mmHg** | Yes ❑ No ❑ | **Duration of CS** _____minutes | | |

**Bleeding** → No ❑ Move to postop CRF; Yes ❑

| | | |
|---|---|---|
| **≥ 500 mL in suction bottle** | Yes ❑ No ❑ | |
| **≥ 3 soaked abdominal swabs** | Yes ❑ No ❑ | |
| **Haemodynamic instability** | Yes ❑ No ❑ | |
| **Observed significant/rapid blood loss** | Yes ❑ No ❑ | |
| **Local predetermined criteria** | Yes ❑ No ❑ | |
| **Estimated blood loss** | _____ mL | |
| **Suspected cause of bleeding** | _____ | |
| **Abnormal placentation at CS** | Yes ❑ No ❑ | |
| **Surgical interventions** | | |
| B-Lynch ❑ | Artery ligations ❑ | Hysterectomy ❑ Tear repaired ❑ |
| Balloon tamponade ❑ | Haemostatic sutures ❑ | |

| | | | |
|---|---|---|---|
| T | **Transfusion** | Required<br>Haemoglobin<br>Colloid | Yes ❑ No ❑<br>_____ g/dL<br>Yes ❑ No ❑ |
| | **TxA** | Required | Yes ❑ No ❑ |
| | **Temperature** | <35.5 ∘ C | Yes ❑ No ❑ |
| H | **Help** | Informed | Yes ❑ No ❑ |
| | **Uterine massage** | Required | Yes ❑ No ❑ |
| U | **Uterotonics given** | ≥ 1<br>Long acting<br>Repeated boluses | Yes ❑ No ❑<br>Yes ❑ No ❑<br>Yes ❑ No ❑ |
| | **Uterine trauma** | Surgical intervention | Yes ❑ No ❑ |
| M | **Monitoring decisions** | Considered | Yes ❑ No ❑ |
| B | **Bedside visit** | Mandated | Yes ❑ No ❑ |


Postoperative recovery unit
What is being monitored?
Heart rate ❑
Blood Pressure ❑
Saturation ❑
Respiratory rate ❑
Bleeding ❑
Spinal level ❑
Vasopressors needed
Yes ❑ No ❑
Oxygen dependent
Yes ❑ No ❑
Rapid assessment tool used
Yes ❑ No ❑
Rapid assessment tool
Uterus contracted?
Ongoing vaginal or intra-abdominal bleeding?
Heart rate > systolic blood pressure?
(suspected to be bleeding related)
≥ 1
T Transfusion
Required
Haemoglobin
Colloid
Yes ❑ No ❑
_____ g/dL
Yes ❑ No ❑
TxA
Required
Yes ❑ No ❑
Temperature
<35.5 ∘ C
Yes ❑ No ❑
H Help
Informed
Yes ❑ No ❑
Uterine massage
Required
Yes ❑ No ❑
U Uterotonics given
≥ 1
Long acting
Repeated boluses
Yes ❑ No ❑
Uterine trauma
Relook laparotomy
Yes ❑ No ❑
M Monitoring decisions
Considered
Yes ❑ No ❑
B Bedside visit
Mandated
Yes ❑ No ❑
Tear repair
Yes ❑ No ❑
Haemostatic sutures
Yes ❑ No ❑
Artery ligations
Yes ❑ No ❑
Balloon tamponade
Yes ❑ No ❑
Hysterectomy
Yes ❑ No ❑
Postoperative ward
Follow up visit within four hours of discharge from theatre
Yes ❑ No ❑
Relook laparotomy needed
Yes ❑ No ❑
Rapid assessment tool used
Yes ❑ No ❑
Referred to a higher level of care
Yes ❑ No ❑
Rapid assessment tool
Uterus contracted?
Ongoing vaginal or intra-abdominal bleeding?
Heart rate > systolic blood pressure?
(suspected to be bleeding related)
≥ 1
T Transfusion
Required
Haemoglobin
Colloid
Yes ❑ No ❑
_____ g/dL
Yes ❑ No ❑
TxA
Required
Yes ❑ No ❑
Temperature
<35.5 ∘ C
Yes ❑ No ❑
H Help
Informed
Yes ❑ No ❑
Uterine massage
Required
Yes ❑ No ❑
U Uterotonics given
≥ 1
Long acting
Repeated boluses
Yes ❑ No ❑
Uterine trauma
Relook laparotomy
Yes ❑ No ❑
M Monitoring decisions
Considered
Yes ❑ No ❑
B Bedside visit
Mandated
Yes ❑ No ❑
Tear repair
Yes ❑ No ❑
Haemostatic sutures
Yes ❑ No ❑
Artery ligations
Yes ❑ No ❑
Balloon tamponade
Yes ❑ No ❑
Hysterectomy
Yes ❑ No ❑

**IMPORTANT PATIENT INFORMATION**

**A research study is being conducted at ……..Hospital.**

The research study is being done by Dr ……. from the Department of ……..

**Why is this research study being done?**

We have attempted to change the way we care for our patients during and after caesarean section by using a new system called “The rule of THUMB”

This project aims to improve how we categorise patients into high and low risk patients, how we recognise bleeding earlier, and how we can better deliver the care that is proven to work. Through this study we aim to understand whether this project will improve how our bleeding patients can be treated.

**Why are we telling you about this research study?**

All patients in this hospital who have a caesarean section are part of the research study. It is a requirement that some details of your clinical care will entered into a research study folder. All information will be used anonymously to understand how patients respond to the increased care given in the study.

**Will this research study affect my care while I am in hospital?**

Yes. We have designed a program that will ensure that proven effective care will be given earlier. For patients at risk of bleeding, you will be visited soon after your surgery by a doctor or nurse to check that you are not bleeding.

**Will my name or any personal details be kept by this research study?**

No. Your name and personal details will not be kept as part of this research study. All information from the study will be kept strictly confidential.

**Are there any risks or benefits associated with this project?**

No. There are no risks or direct benefits associated with this research study.

**Who should I contact if I have any questions or concerns?**

Please contact Dr …….. on telephone……..

If you have questions about your rights or welfare as a participant, please contact the UCT Faculty of Health Sciences Human Research Ethics Committee on +27 (0)21 406 6338.

# Patient Information Sheet

(To be read to all obstetric patients undergoing caesarean section)

A research study is being conducted at ……..Hospital.

The research study is being done by Dr ……. from the Department of …….

We hope to improve the care of patients during and after a caesarean section by using a new system called “The rule of THUMB”.

This system aims to help us recognise patients early, who may be developing bleeding during or after surgery, and then how we respond to provide increased care where it is needed.

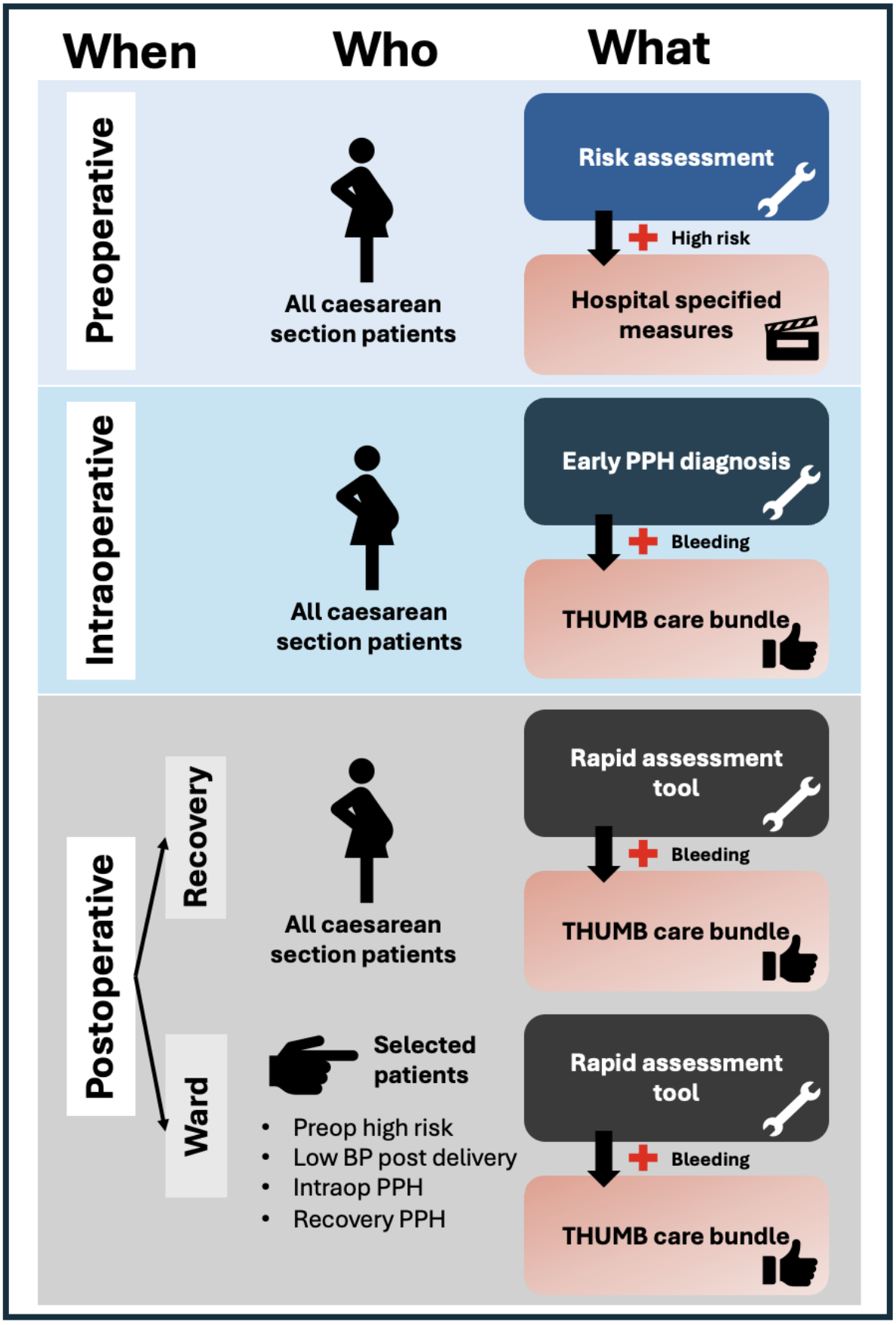
We are studying all our caesarean section cases to understand whether the “The rule of THUMB” system improves how our patients receive treatment for bleeding.

Some of the details of your clinical care will be entered into a research study folder. Information from this folder will be used anonymously to understand how surgical patients respond to the increased care given in the study.

Your name and personal details will not be kept as part of this research study. All information from the notes will be kept strictly confidential.

There are no risks or direct benefits associated with this research study.

## Appendix 6: Trial flow Process



**Explanation for each phase**

**Preoperative**

Team meeting (anaesthetist, obstetric surgeon, nursing) to assess risk of postpartum haemorrhage in the patient for caesarean section. The criteria for this risk assessment are detailed in Appendix 3. If ≥ 1 risk factor is present, then the team will answer the following questions:

1. Do we need more senior staff available?
2. Do we need better intravenous access?
3. Do we need blood products?
4. Should we be referring to a referral hospital or consulting ICU care?

Local responses to an increased risk of bleeding may be specified.

**Intraoperative**

*Trigger:*
A key principle is to diagnose postpartum hemorrhage as early as possible. The diagnostic criteria will be decided at each hospital during the co-design phase. Some of the options that may be considered are:

- ✓ Soaking of swabs (e.g., ≥3 soaked tape swabs)
- ✓ Suction bottle >500 ml blood
- ✓ Haemodynamic instability (low SBP/high HR) as diagnosed by the anaesthetist
- ✓ Obstetric surgeon direct observation of significant/rapid bleeding

The key to diagnosis is a *low threshold.* If the decision is in doubt/borderline, then the default response should be to treat as if postpartum haemorrhage is present. This is supported by recent findings from the E-MOTIVE trial.

*Action: THUMB*

See *Appendix 8*: THUMB recommendations document.

**Postoperative recovery**

*Trigger:*
Prior to discharge to ward, all patients should be evaluated with the Rapid Assessment Tool (*Appendix 7*) with 3 criteria:

- ✓ Is the uterus poorly contracted?
- ✓ Is there ongoing vaginal bleeding?
- ✓ Suspected intraabdominal bleeding?

- ✓ Is the heart rate higher than systolic blood pressure, due to haemorrhage?

If the answer is 'YES' to any of the preceding questions, then institute THUMB care bundle (see *Appendix 9*).

On discharge to the ward, a clear decision must be documented on whether a postoperative visit is required (must indicate on form). The following patients would need a postoperative visit:

- Preoperatively identified as high-risk
- Intraoperative diagnosis of PPH
- Postoperative bleed as per the rapid assessment tool
- Significant hypotension post-delivery (systolic blood pressure < 80 mmHg)

**Postoperative ward**

All patients selected for postoperative visit should be visited by a nominated healthcare worker. The level of the healthcare worker required will be decided at the co-design phase by the local staff. Importantly, the healthcare worker must be enabled to institute treatment if required, and to be able to access senior assistance rapidly, where needed.

At the postoperative visit, the Rapid Assessment Tool will be used to assess the patient's condition by checking four areas:

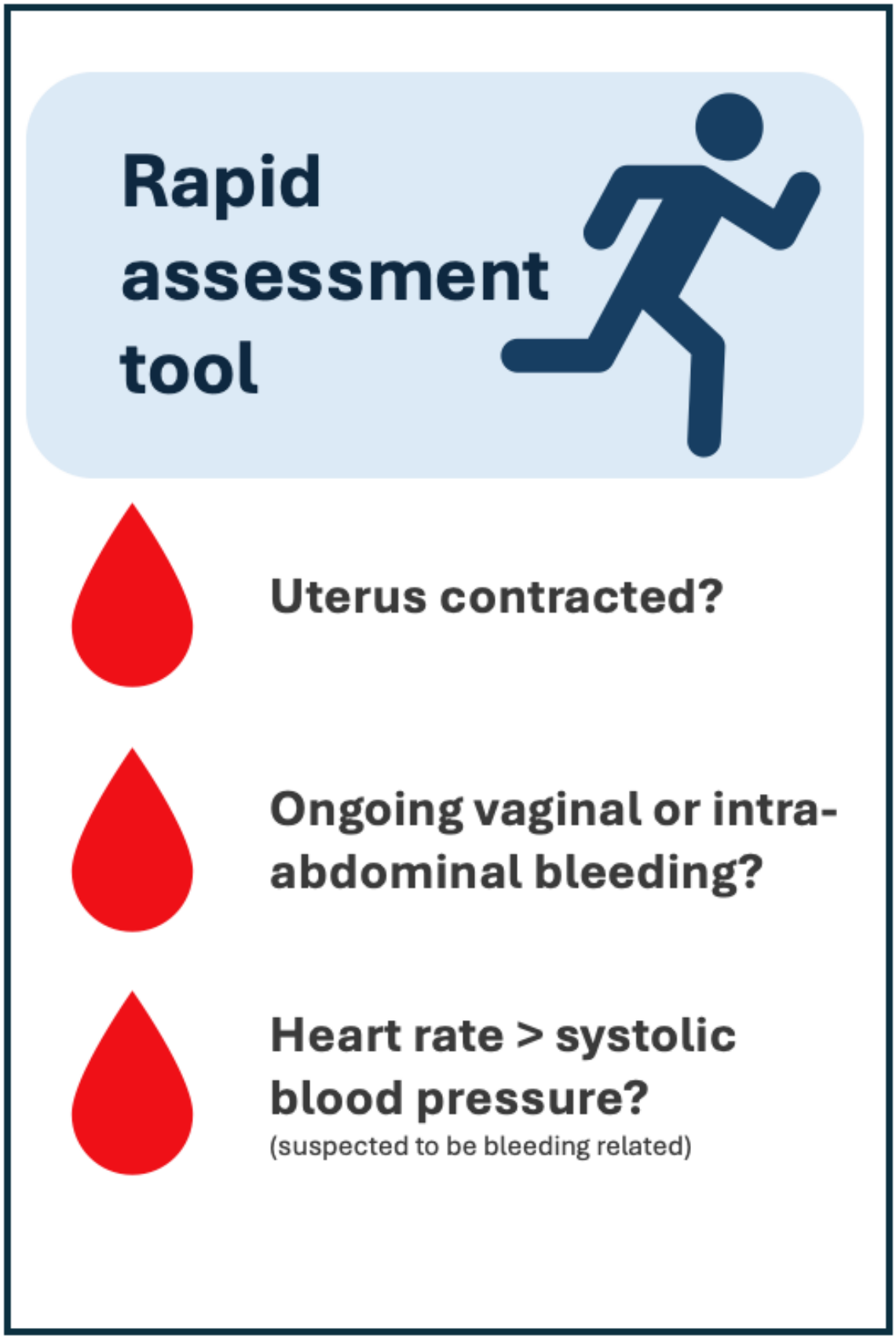
- ✓ Is the uterus poorly contracted?
- ✓ Is there ongoing vaginal bleeding?
- ✓ Suspected intraabdominal bleeding?
- ✓ Is the heart rate > systolic blood pressure, due to haemorrhage?

If the answer is 'YES' to any of the preceding questions, then institute THUMB care bundle (see *Appendix 9*).

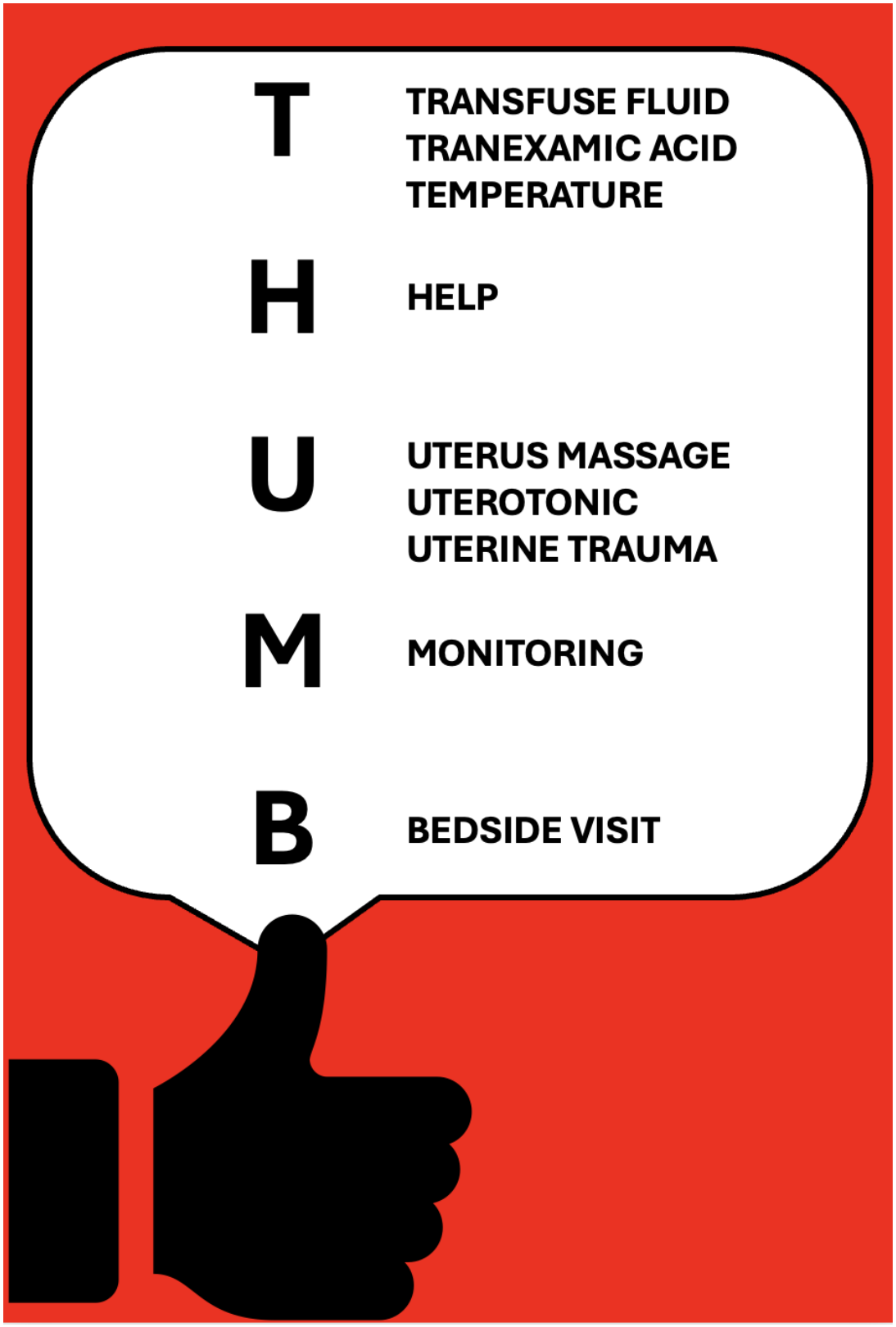
**Additional notes**

This is a proposed framework for regular assessment and appropriate responses through implementation of bundled care. Mandatory phases include the preoperative and postoperative risk assessments, implementation of the THUMB care bundle when bleeding is diagnosed, and scheduled postoperative visits for patients deemed to be at high risk of postoperative bleeding. The details of appropriate responses within each phase can be tailored to available resources and preferences of individual hospitals.

## Appendix 7: Rapid assessment tool



## Appendix 8: THUMB diagram



## Appendix 9: THUMB recommendations document

The intervention is a quality improvement initiative aimed at improved delivery of care, already known to be effective in improving patient outcomes. The intervention aims to improve compliance with recommended care for prevention and treatment of maternal haemorrhage by creating a bundle of care that is delivered simultaneously (not sequentially) by first responders.

| | | |
|---|---|---|
| T | **Transfuse fluid** | • Ensure adequate vascular access<br>• Draw the appropriate blood samples (should include a crossmatch)<br>• Fluid, blood or blood product administration as is clinically appropriate and available |
| | **Tranexamic acid (Txa)** | • 1g Txa IV/IM within 3 hours of the diagnosis of bleeding<br>• If the patient has received Txa and has ongoing bleeding, repeat the dose, if 2 hours since initial administration has elapsed |
| | **Temperature** | • Warm patient if possible |
| H | **Help** | • Declare the emergency and ensure extra hands come to assist<br>• Nurse to notify doctor<br>• Doctor to notify a senior colleague |
| U | **Uterus** | ○<br>• Uterine atony<br>○ Massage the uterus<br>○ Give a uterotonic if no contraindications<br>▪ Long acting uterotonic (oxytocin infusion or single dose ergometrine/ carbetocin/misoprostol)<br>▪ Additional uterotonic<br>▪ Repeat short acting boluses<br>• Uterine trauma<br>○ Repair surgical tears<br>○ Haemostatic sutures<br>○ Uterine compression sutures<br>○ Vessel ligation<br>○ Hysterectomy<br>○ Intrauterine tamponade device to be considered for a placental bed bleed<br>○ Re-open/laparotomy? |
| M | **Monitoring decisions** | • Where should the patient be monitored?<br>○ High care unit (HCU), intensive care unit (ICU), normal ward<br>○ Refer?<br>• What should be monitored?<br>○ Blood pressure, heart rate, saturation, respiration, level of consciousness, urine output, temperature, bleeding (vaginally and abdominal distention)<br>• Frequency of monitoring<br>• Advanced monitoring needed? |

| | | |
|---|---|---|
| | | ○ Central venous pressure line, arterial line and others<br>• Point of care testing<br>○ Blood gas, coagulation, haemoglobin (Hb) |
| B | **Bedside visit** | • Patient follow up withing 4 hours of bleeding episode |

This is a proposed bundle of care, to be implemented once bleeding has been diagnosed. The details of appropriate responses within each phase will be tailored by participating hospitals to their available resources and preferences, as well as the findings from the 2-week observational data.

## Appendix 10: Training and co-design

Improvement and implementation interventions are complex interventions. They can be seen as having both a hard core (the patient facing activities / processes that will directly improve patient outcomes) and a soft periphery (the staff / system facing activities / strategies required to get the hard core into routine use in a given clinical context. Complex interventions often require adaptation or tailoring to fit local context, whilst still maintaining enough of the 'active ingredients' of the proposed intervention to still be effective.

In our study we propose supporting clinical teams in study sites to adapt and tailor the Rule of THUMB intervention in the following ways:

The Rule of THUMB interventions (hard core / patient facing)

We will specify key objectives within our THUMB care bundle that will need to be achieved but allow teams to plan locally exactly how each objective will be achieved. The following are examples of this:

i. When a patient is assessed as "High Risk" preoperatively, the local institution will decide on the response to this assessment with respect to appropriate staff (seniority) and equipment (e.g. cell salvage) required.
ii. When a patient is assessed to require a postoperative visit based on risk, the local institution will decide on the level of staff required to perform this visit (nurse, doctoretc.) based on available staff.

We will encourage principles such as first-responder empowerment to act (in the example of a postoperative visit) but allow for local expressions of this principle. The co-design element of implementation will encourage local modifications that allow for contextual factors and which encourage buy-in from healthcare workers, using the scaffolding provided by the THUMB care bundle.

The implementation intervention (soft periphery / staff and system facing)

- Local clinical teams will be provided with an easy-to-use context assessment tool that will help them assess key barriers to- and facilitators of- THUMB delivery (Pragmatic Context Assessment Tool, see below)
- Teams will also be provided with a menu of practical evidence-based implementation activities and strategies that they can select from, based upon the barriers and facilitators identified. For example if staff knowledge about THUMB components is assessed as already good, clinical training would not be a suitable strategy. Conversely, if the local culture is assessed as often resistant to change, then 1) preparing local champions or role models may be effective as would 2) involving staff in the planning and problem-solving phases of the study preparation..
- Following baseline data collection teams will have 2-6 weeks to prepare for and start delivery of the THUMB intervention, following the above steps. The time period selected will be based on discussions with the local team.
- They will have online access to advice from the study team, including an implementation scientist, at this time.

- The study includes mid and end point data collection periods. Findings from this second (mid-point) round of data collection will be fed back to teams in timely manner and following best practice guidance for audit and feedback.
- Following the data feedback, teams will have a further 2-6 weeks to refine their THUMB care bundle delivery strategy before a final (end-point) 2 weeks of data collection.

**Example of a local Preface Question and Response Scale:**

| **Improvement to consider:**<br><br>1. **Routine preoperative risk assessment linked to action**<br>2. **Use of THUMB care bundle in response to bleeding**<br>3. **Postoperative risk assessment and monitoring plans**<br>4. **Postoperative visits within 4 hours for selected patients** | | |
|---|---|---|
| Indicate your agreement with this statement:<br><br>**1 – DISAGREE**: This means the item is a potential **barrier**<br><br>**2 – Neutral**<br><br>**3 – AGREE:** This means the item is a potential **facilitator** | This **barrier** will have…<br><br>This **facilitator** will have… | What is the likely effect of this barrier/facilitator on your ability to implement the improvement?<br><br>0 – Weak/no effect<br>1 – Strong effect<br><br>0 – Weak/no effect<br>1 – Strong effect |

The responses to this preface question are then recorded, using the Item Colour Mapping method shown below:

**Color key indicating CFIR Domain**: Innovation | Individuals | Inner Setting | Outer Setting | Process

| **Pragmatic Context Assessment Tool Question** | **2009 CFIR** | **Updated CFIR** |
|---|---|---|
| People here regularly seek to understand the needs of patients and make changes to better meet those needs. | **Patient Needs & Resources** | **Culture: Recipient-Centeredness** |

| | | |
|---|---|---|
| I have open lines of communication with everyone needed to make the change. | **Networks & Communications** | **Communications** |
| I have access to data to help track changes in outcomes. | **Reflecting & Evaluating** | |
| The change is aligned with leadership goals. | **Goals & Feedback** | **Mission Alignment** |
| The change is aligned with clinician values. | **Compatibility** | **Deliverer: Capability** |
| The change is compatible with existing clinical processes. | **Compatibility** | |
| The structures and policies in place here enable us to make the change. | **Structural Characteristics** | **SC: Work Infrastructure** |
| We have sufficient space to accommodate the change. | **Available Resources** | **AR: Space** |
| We have sufficient time dedicated to make the change. | | **Deliverer: Opportunity** |
| We have other needed resources to make the change (staff, money, supplies, etc.). | | **AR: Materials& Equipment, Funding** |
| People here see the current situation as intolerable and that the change is needed. | **Tension for Change** | |
| People here see the advantage of implementing this change versus an alternative change. | **Relative Advantage** | |
| Higher level leaders are committed, involved, and accountable for the planned improvement. | **Leadership Engagement** | **High-level Leaders: Motivation** |
| Leaders I work with most closely are committed, involved, and accountable for the planned improvement. | | **Mid-level Leaders: Motivation** |

Implementation strategies are then suggested using the Expert Recommendations for Implementing Change (ERIC) list of strategies.

**References**

Waltz, T.J., Powell, B.J., Matthieu, M.M. et al. Use of concept mapping to characterize relationships among implementation strategies and assess their feasibility and importance: results from the Expert Recommendations for Implementing Change (ERIC) study. Implementation Sci 10, 109 (2015). https://doi.org/10.1186/s13012-015-0295-0;

Powell, B.J., Waltz, T.J., Chinman, M.J. et al. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. Implementation Sci 10, 21 (2015). https://doi.org/10.1186/s13012-015-0209-1

## Appendix 11: Process evaluation framework

**Background**

The THUMB Trial has been developed to improve postpartum haemorrhage care in low-middle-income country settings. It brings together evidence-based interventions and care-bundle approaches to postpartum haemorrhage treatment with a focus on caesarean section, including: T: Transfuse/Tranexamic acid/Temperature, H: Help, U: Uterus (tone and trauma), M: Monitoring decisions and B: Bedside visits

The first phase of the study will be run as a quality improvement project in eight hospitals, two from each of the following countries: Uganda, South Africa, Tanzania and Ethiopia. (Refer to main study protocol for details). The complex intervention comprises two complementary elements, a) the hard core of the intervention that will be delivered to patients and b) the soft periphery of the intervention, designed to support implementation.

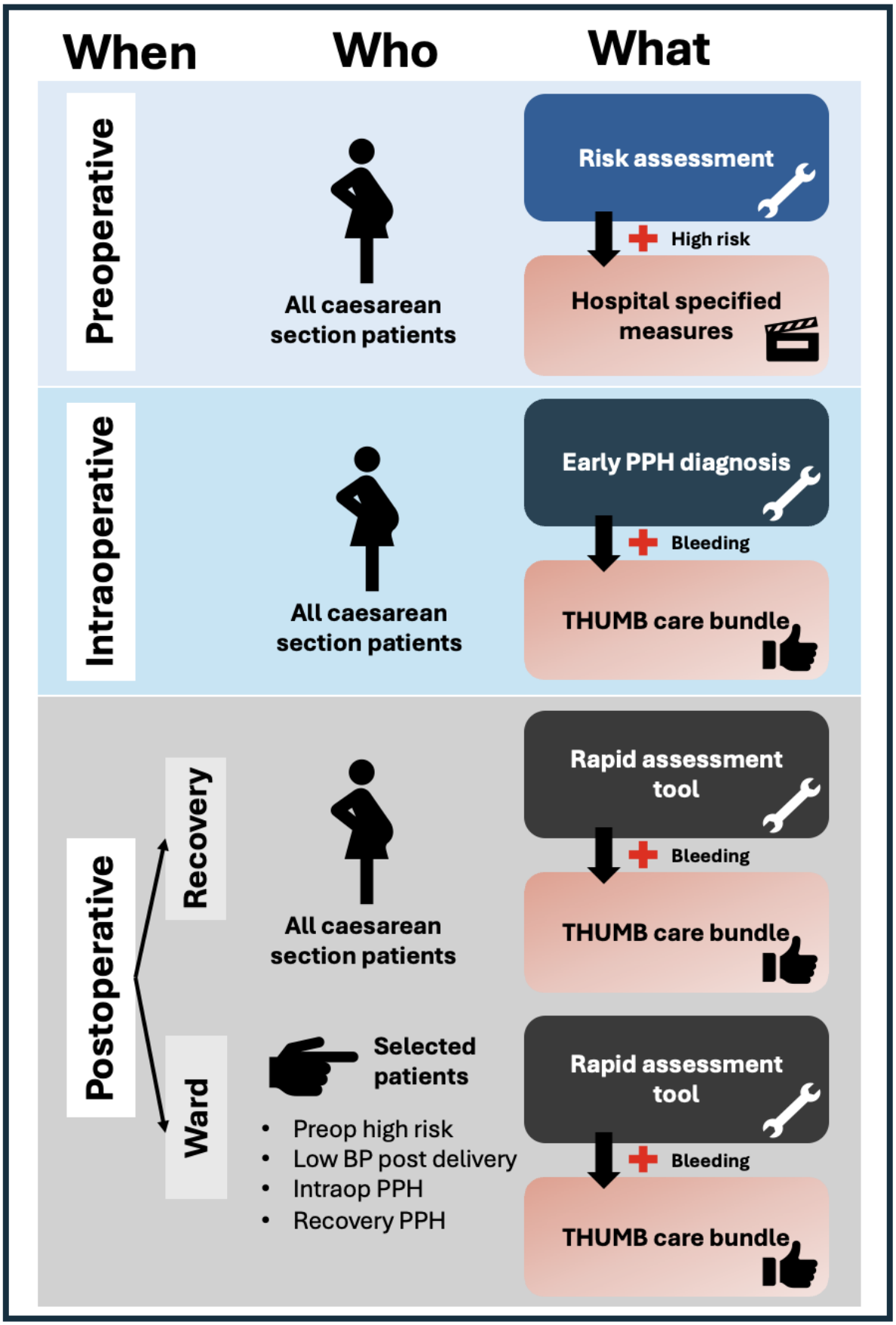
*Hard core (patient-facing) elements*

1) Preoperative postpartum haemorrhage risk assessment, 2) intraoperative early postpartum haemorrhage diagnosis, 3) post-recovery high risk patient identification, 4) postoperative surveillance and rapid assessment, 5) delivery of the THUMB care bundle. Refer to Figure 1 for the trial flow process. Delivery of these components will be evaluated through collection of process measures in the main study.

*Soft periphery (staff-facing) elements*

1) Training on delivery of the THUMB care bundle, 2) co-design and team planning for how to adapt and implement the hardcore THUMB principles. This process evaluation will focus on evaluating these components through qualitative research methods.

Figure 1: Trial flow process



**Study hypothesis for process evaluation**

A combination of adequate risk assessment before and after caesarean section, early identification of bleeding during and after caesarean section, and timely, and complete administration of the THUMB care bundle will lead improvement in postpartum haemorrhage outcomes at eight hospitals in Africa. We hypothesise that supporting local co-design, supporting team planning and preparation for implementation and data feedback on delivery as a trial midpoint will lead to effective implementation of the core components in hospitals in low-middle-income countries.

**Process evaluation scope**

The process evaluation is centred around the staff-facing interventions; namely co-design, training and team planning and how these influenced the delivery of the core THUMB care bundle. The goal is to generate evidence and recommendations that support the implementation of the core THUMB care bundle for caesarean sections in low-middle-income countries.

**Process evaluation objectives**

1- To describe how the delivery of the THUMB care bundle evolved through the lifecycle of the study, and what factors influenced the changes:

- To explore how the THUMB care bundle was planned to be delivered by local teams, including agreed strategies

- To examine how the THUMB care bundle was actually delivered by the local teams, including adaptations and modifications

2- To explain why the THUMB care bundle was implemented effectively or not, in the context in which it was applied, highlighting barriers and facilitators

**Process evaluation questions**

1- How closely did the implementation preparation phase for the core THUMB care bundle adhere to the recommended activities and strategies?

- What were the modifications and adaptations through the first phase of the THUMB study – both to the recommended strategies and to the plan agreed by the team?

- How useful was the mid-point data feedback and what further modifications and adaptations were made as result?

2- In what context (implementation environment) were the core THUMB care bundle delivered effectively? [What were the facilitators and barriers to delivery of the core THUMB care bundle?]

**Theory of change for the "Rule of THUMB" intervention**

Casual assumptions/ mechanism of change (reflected in the theory of change below). If we co-design the THUMB care bundle and train clinical teams on surveillance and assessment for bleeding risk before, during and after caesarean section, then they will 1) Identify mother undergoing caesarean

section who are at a higher risk of bleeding, 2) Identify bleeding early and 3) Deliver the THUMB care bundle when postpartum haemorrhage occurs.

In an established maternity service capable of providing caesarean sections 24 hours a day in a resource-constrained setting, if we can identify women who are likely to bleed during and after caesarean section (risk assessment), we can alert the team who will prepare to treat bleeding by gathering the required resources (senior clinicians, medicines and other supplies). If we can then identify the bleeding in a timely manner when it happens (intraoperative and postoperative) and immediately administer a bundle of evidence-based interventions as a "care package" the "THUMB", we can reduce deaths from bleeding. See theory of change below.

**Conceptual framework**

The process evaluation will be guided by the Consolidated Framework for Implementation Research from tool development to analysis and interpretation.

**Process evaluation methods**

We will directly observe delivery of the intervention and conduct one-on-one interviews of members of the clinical teams, selected using maximum variation sampling, including nurses or midwives, non-specialist doctors, obstetricians, anaesthetists, unit managers, and the hospital study leads from participating hospitals in Uganda, Tanzania, Ethiopia and South Africa. We will conduct interviews at two timepoints: 1) after study orientation, training and first phase of co-design, and 2) after study implementation. A total of 32 interviews (n= 4 hospitals x 2 timepoints x 4 participants per hospital). For consistency, the same persons will be interviewed for both interviews. Interviews will be guided by an adaptive interview guide, based on the Consolidated Framework for Implementation Research (CFIR) and reviewed by the study core group before use. The interview guide will include both broad open-ended questions and prompt questions structured around the domains of the CFIR and separated into two and three broad sections: background (only in the first interview guide), knowledge and perceptions, and evolution and context. We will use other materials from the main study during interviews as a visual guide. Interviews will be led by the national study co-ordinators who will interview in English either physically or virtually, with consent. All interviews will be audio-recorded. Hospital study leads will record their observations at least once a week during the THUMB intervention at each hospital.

**Analysis of Process evaluation data**

We will use inductive thematic analyse followed by deductive framework analysis based on the CFIR in the following steps: transcription (verbatim) and familiarisation of data, inductive thematic analysis and deductive framework analysis. Interview data will be triangulated with observation data. Interpretation, based on the CFIR: barriers and facilitators, contextual factors, local delivery adaptations and modifications.

## Appendix 12: Participant Information Sheet for the process evaluation

**Rule of THUMB: A multi-centre cluster trial evaluating the delivery of a complex intervention to improve outcomes from haemorrhage in patients during and after caesarean section in African hospitals**

**Introduction**

This Participant Information Sheet explains the research study and what taking part will mean. Knowing what is involved will help you decide if you want to take part in the study.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Participation in this research is voluntary and it is your choice to agree to be a part of the study or not. If you do not wish to take part, you do not have to. If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent (agree) to take part in the research project
- Consent to the research that is described

You will be given a copy of this Participant Information and Consent Form to keep.

**Background and purpose of this study**

You are invited to take part in this research project because you work at a hospital participating in the 'Rule of THUMB' project. You are a critically important voice in understanding the current status of managing haemorrhage during and after caesarean section at the hospital, what is required for clinical service improvement and capacity building, and the potential implications of this for yourself, your colleagues, and patients based on your experiences participating in 'Rule of THUMB' project.

Haemorrhage during and after caesarean section is the leading cause of death in mothers after caesarean section. Our research is designed to decrease this risk for mothers. Research is a very important part of surgical and clinical care and the healthcare system, and it includes a varied group of people. These people include patients, policymakers (all people involved in making decisions on how healthcare is provided to

patients), allied services (such as laboratories, pharmacy, biotechnology), and healthcare workers and administrators.

The ultimate goal of our research is to improve the outcomes of mothers having caesarean sections in the African region. The 'Rule of THUMB' study seeks to hear your perspective to inform how to adjust the initiative as we prepare to scale it to additional hospitals across Africa. Through talking about your experiences and exploring aspects of surgical capacity building at your hospital, we hope to understand some of the facilitators and barriers to improving care during and after caesarean section, and make the intervention more successful and easier to adopt.

This research is designed to directly benefit the patients of your hospital and wider community, but also to potentially provide a model for other African hospitals to improve their caesarean section services. In addition, taking part in this study could be important in helping the community to be more involved in healthcare and surgical delivery, for the benefit of the community in the future.

**What would taking part involve?**

One of the researchers will explain the study process to you and if you agree, to sign a consent form. You will then be asked a set of questions which will be audio-recorded and transcribed (copied word-by-word). The interview will either be done in person at your workplace, or if preferred, by video call (such as ZOOM). You will be asked a set of questions in a conversation with a member of the research team.

You will first be asked questions about your demographics, role and length of service. Further questions will be focused on your opinion of the current post-surgical service delivered at your hospital, and your perspective and recommendation of what might be required to improve, extend, and sustain these services. You will be asked to consider both positive and negative implications and to give us reasons for your answers. The interview will be conducted in English.

**Time commitment**

The time commitment will be 30-60 minutes. We will also ask you if you are interested in the research process, and if we can contact you in the future. This is entirely voluntary.

**Information to be collected, and stored confidentially**

The audio recordings and their transcripts will be stored securely. Any responses will be completely confidential; you will not be able to be identified from any research outputs.

**Who is organizing and funding the research?**

This research study has been conceived by the University of Cape Town's Department of Anaesthesia and Perioperative Medicine. The research is funded by the National Institute of Health Research (NIHR).

**Will I get paid to take part in this study?**

There is no reimbursement for this study.

**Consent**

It is up to you whether you decide to join the study. If you agree to take part, we will ask you to sign a consent form. You are free to leave the study at any time, without giving a reason. Whether or not you take part in the study, if you wish to complain, or have any concerns about any aspect of the way you have been treated during this study, you should ask to speak to your local lead researchers who will do their best to answer your questions (contact details are at the bottom of this form).

The UCT's Faculty of Health Sciences Human Research Ethics Committee can be contacted on 021 406 6338 in case you have any ethical concerns or questions about your rights or welfare as a participant in this research study.

**Contact details**

For any further information you may require, please contact Prof Bruce Biccard (021 404 5001).

## Appendix 13: Interview topic guide

# Topic guide – Healthcare staff interviews for "Rule of THUMB"

Thank you very much for taking the time to speak to me today. My name is [interviewer name], and I am one of the team members on the THUMB care bundle study in [country]. Before we begin, can I please confirm that you have received a copy of the study information sheet and consent form? And that you have consented to participate in the study?

As a reminder, this study aims to understand how and why the THUMB care bundle will be/is delivered effectively in [current hospital]. We are interested in hearing your views and experiences about what currently happens in practice, and what factors will influence or influence delivery of the THUMB care bundle. There are no right or wrong answers. Everything you say will be treated confidentially and will not be shared with any of your colleagues, or anyone outside of the THUMB study team. You are free to answer in as much or as little detail as you wish, to skip over any questions you do not wish to answer, and to pause or stop the interview at any time if needed.

This interview will take approximately one hour- depending on how much you have to say. Can I please check you are free now to talk for this amount of time?

I would also like to please record our conversation- so that I can capture your responses accurately, and so that I can listen to you rather than take many notes. Can I confirm you are happy for me to start recording?

NB: This is the [first / second] of two interviews that we will have with you. We request that you complete both so we can get a feel of how the implementation evolved from your side.

[If it's the first interview, get commitment to the second interview. If the second, thank them for honouring their invitation.]

Thank you.

Note to interviewer:

a. Please ask all questions in **BOLD**.
b. Wait before asking the *prompt questions (in italics)* until after the participants has responded to the question in bold.
c. Use the *prompt questions* to get more detailed information about **why** these personal views influence the delivery of the THUMB care bundle, in addition to how PPH is treated at the hospital, and who does what and when.

**During the interview**, please keep track of what's said about any of the following interventions mentioned by the participant when managing PPH:

***☐ Pre-operative risk assessment for bleeding ☐ Getting help or support during care ☐ Use of uterotonics ☐ Uterine massage ☐ Transfusion ☐ Use of Tranexamic acid ☐ C-section delivery ☐ Monitoring decisions ☐ Postpartum bedside monitoring/ visits ☐ Use of different interventions at the same time***

This information is required for questions about the THUMB care bundle delivery.

## First interview (Topic guide)

**Section 1: Background**

*We would like to start with understanding a bit about your role in your current job and the facility where you work:*

a. **What is your current position**?

Prompts: How long have you been a [doctor/midwife/nurse/ anaesthetist]? How long have you been in this position at this facility?

b. **Could you briefly tell me a bit about how the maternity department in your facility is set-up, including the operating theatre?**
*Prompts: Are there separate rooms for different stages of labour, who works where?*

c. **Which parts of the maternity department do you currently work on?**
*Prompts: Do you work in antenatal clinic, labour and delivery, postnatal?* Do you currently work in any other ward or theatre? Prompts: if yes, what do you do?

d. **Could you tell me a bit about your understanding and experience of postpartum haemorrhage (PPH) in your facility?**
Prompts: How much of an issue do you think PPH is among women giving birth for health care providers and for the hospital?
*Prompts around why, explore what is that makes it an issue or not an issue*

e. **How much is PPH a priority compared to your other clinical responsibilities in your current role?**

*Prompts: Why is that? Is there anything at a higher priority?*

f. **Could you describe how is PPH typically treated in this hospital?**

*Prompts: What is your role? Who else is involved? what do they do? where is PPH usually treated?*

g. **How would you describe the culture of your organization with respect to adopting new interventions?**

Prompt: How receptive is your organization to changes in practice and new interventions?

*Thank you for sharing. For the remainder of this interview, I would like to focus on discussing the planned or ongoing <u>delivery of the THUMB care bundle</u> in your hospital. For this research study, we are <u>not</u> interested in PPH from vaginal deliveries but only that associated with C-section delivery.*

***Show*** *the THUMB care bundle diagram to the participant if F2F or ask them to look at the diagram if using online to be either shared on PC screen or on WhatsApp if using a mobile phone.*

***READ*** *to the participant all the information about the THUMB care bundle below. Clearly state the treatment components of the package are to be performed ALL AT ONCE not sequentially.*

**Section 2: Knowledge and opinion about intervention**

a. **Have you participated in co-designing the THUMB care bundle at your hospital, together with the study team?**
   Prompts: To what extent do you feel the study team included the ideas from the hospital team? Can you describe the planning process for implementing the THUMB care bundle?
b. **Have you received training on the THUMB care bundle?**
   Prompts: When was the training? Where was the training? (in facility or external); what did the training cover; how was it delivered? (in classroom, online)
a. **Could you describe the core components of the THUMB care bundle for treating haemorrhage during or after CS?**
   Prompts: What does it involve? Who is involved? Where will the different components of the THUMB care bundle be applied?
c. **What is your perception of the evidence supporting components of the THUMB care bundle for treatment of haemorrhage during or after CS?**
   Prompts: In your opinion, are any of the treatments in the THUMB care bundle important than the others? Why is that?

d. **How helpful do you think delivering the THUMB care bundle would be for treatment of haemorrhage during or after CS by either yourself or team members?**
   Prompt: Why or why not? How does this compare to how haemorrhage during or after CS is currently detected in this facility?

e. **If you and your team were asked to use the THUMB care bundle when treating PPH, what would you need to help you do it?**
   Prompts: To what extent would you know what to do? To what extent would you need additional skills? To what extent do you have everything you need to perform the bundle?

f. **How would managing a haemorrhage during or after CS as described in the THUMB care bundle affect the ways you work as a team?**

**Section 3: Evolution and context**

a. **How does the THUMB care bundle compare to the way haemorrhage during or after CS is currently managed at your hospital.**
   Prompts: Can I please confirm which of the components of the THUMB care bundle you currently use in this facility? Which components do you use more often?

b. **Where do you think the THUMB care bundle could be adapted to suit most of your situations alluding to haemorrhage during or after CS?**

Prompts: what adaptations and modifications do you foresee in your hospital? Why?

c. **How would you describe the readiness of your organization to implement the THUMB care bundle for haemorrhage during or after CS?**
Prompt: Which resources do you think are not readily available to ensure effective implementation

d. **How will the organizational structures will support or hinder the implementation of the THUMB care bundle for haemorrhage during or after CS?**
Prompts: What challenges or complexities do you foresee in implementing the THUMB care bundle for haemorrhage during or after CS? [Physical Infrastructure, Information Technology Infrastructure, Work Infrastructure]

e. **How will external policies and incentives influence the implementation of the THUMB crae bundle?**
Prompts: What are the potential motivators for the care team to implement the THUMB care bundle?

**Finally, is there anything else that you would like to share with me about anything we discussed today?**

[Thank you for participating in this implementation study]

## Second interview (Topic guide)

**Section 1: Knowledge and opinion about intervention**

a. **How did you participate in the implementation of the THUMB care bundle for haemorrage during or after c-section delivery?**

Prompt: what was your role? What activities, clinical or organizational, did you participate in? When? How often did you play those roles?

b. **How were other key stakeholders involved in the delivery of the THUMB care bundle for PPH?**

Prompt: who delivered the THUMB care bundle, who played what role?

c. **Describe to me the commitment, and availability of all key staff in your hospital, during the implementation of the THUMB care bundle.**

Prompts: What were the potential motivators for the care team to implement the THUMB care bundle?

d. **How do you assess the effectiveness of the THUMB care bundle implementation, and what improvements have been identified in the care for haemorrhage during or following CSD?**

Prompts: What do you think are the potential benefits of managing PPH using the THUMB care bundle? What do you think are the potential disadvantages of managing PPH using the THUMB care bundle? To what extent do you think managing PPH as with the THUMB care bundle, is likely to help manage PPH more effectively?

e. **In your opinion, what do you think would happen if haemorrhage during or after CS was not managed by the THUMB care bundle in your facility?**

Prompts: Would there be any consequences? How much of a priority would a THUMB care bundle be in your hospital going forward?

**Section 3: Evolution and context**

a. **How would you describe the readiness of your organization before implementing the THUMB care bundle for haemorrhage during or after CS?**
Prompt: Which resources do you think were not readily available to ensure effective implementation? What organization support facilitated the implementation of the THUMB care bundle

b. **How do you think the THUMB care bundle was delivered in your hospital? What challenges and opportunities did you encounter as a team?**

   Prompts: How was the THUMB care bundle adapted within the care process of PPH care? What were the adaptations, modifications, innovations were used?

c. **Are you aware of any strategies that was used in your hospital to improve delivery of the THUMB care bundle for haemorrhage during or after CS treatment?**

   Prompt: If yes, please explain. In your opinion, how effective have these strategies been?

d. **What challenges or complexities have you encountered in implementing the THUMB care bundle for haemorrhage during or after CS?**

e. **What external policies or incentives impacted the implementation of the THUMB care bundle for haemorrhage during or after CS?**

**Finally, is there anything else that you would like to share with me about anything we discussed today?**

[Thank you for participating in this implementation study]

**Supplementary Material**

The following are the domains and constructs of Consolidated Framework for Implementation Research that relate to the process evaluation for the THUMB care bundle, with questions for consideration matched to the objectives of the process evaluation.

Table 1: Matrix for Process evaluation interview questions

| Construct/ domain | Potential interview questions | Objective matched to the question |
|---|---|---|
| I. INNOVATION DOMAIN | | |
| A. Innovation Source | | |
| B. Innovation Evidence-Base | What is your perception of the evidence supporting the effectiveness of the THUMB care bundle for PPH? | intervention |
| C. Innovation Relative Advantage | Could you describe how is haemorrhage during or after CS typically treated in this hospital?<br>- What is your role, who else is involved, what do they do, where is PPH usually treated?<br>Could you describe the core components of the THUMB care bundle for treating haemorrhage during or after CS?<br>- What does it involve?<br>- Who is involved?<br>- Where will the different components be applied?<br>How does the THUMB care bundle compare to the current standard practices for managing haemorrhage during or after CS?<br>What are the main advantages and disadvantages?<br>Can I please confirm which of the components of the THUMB care bundle you currently use in this facility?<br>Do you use some components in the bundle more often than others? Why is that? | Intervention<br>Evolution |
| D. Innovation Adaptability | How would the THUMB care bundle likely be adapted in your hospital? What do you think will need modification and why? | Evolution<br>intervention |

| | | |
|---|---|---|
| | How adaptable is the THUMB care bundle for the different clinical situations of haemorrhage during or after CS in your hospital?<br><br>Does your team currently use any of these components in the THUMB care bundle all at once? *If yes, ask:*<br>Do you and your team have to make any changes to deliver the THUMB care bundle all at once?<br>*Prompts: What were these changes?*<br>*Which components are used in combination or not?*<br>What are the challenges to using the components all at once?<br>*Prompts: what are the facilitators?* | context |
| E. Innovation Trialability | Are you aware of any strategies in your facility to try to improve delivery of the THUMB care bundle for haemorrhage during or after CS treatment?<br>If yes, please explain and in your opinion, how effective have these strategies been? | context |
| F. Innovation Complexity | What challenges or complexities do you foresee/have you encountered in implementing the THUMB care bundle for haemorrhage during or after CS? | Context |
| G. Innovation Design | In your opinion, are any of the treatments in the THUMB care bundle important than the others? Why is that?<br>Which of the components in the bundle are not currently used in your hospital? | context |
| H. Innovation Cost | | |
| II. OUTER SETTING DOMAIN | | |
| A. Critical Incidents | | |
| B. Local Attitudes | | |
| C. Local Conditions | | |
| D. Partnerships & Connections | | |
| E. Policies & Laws | How do external policies and incentives influence the implementation of the THUMB care bundle?<br><br>What external policies or incentives impact the implementation of the THUMB care bundle for haemorrhage during or after CS? | Context |

| | | |
|---|---|---|
| F. Financing | | |
| G. External Pressure | | |
| 1. Societal Pressure | | |
| 2. Market Pressure | What are the primary needs of the patients the THUMB care bundle aims to address?<br><br>How does the THUMB care bundle address the specific needs of patients experiencing haemorrhage during or after CS at your hospital? | Context |
| 3. Performance-Measurement Pressure | | |
| III. INNER SETTING DOMAIN | | |
| A. Structural Characteristics | What organizational structures support or hinder the implementation of the THUMB care bundle for PPH? Physical Infrastructure, Information Technology Infrastructure, Work Infrastructure | Context |
| 1. Physical Infrastructure | | |
| 2. Information Technology Infrastructure | | |
| 3. Work Infrastructure | | |
| B. Relational Connections | | |
| C. Communications | | |
| D. Culture | How would you describe the culture of your organization with respect to adopting new interventions? | Context |
| 1. Human Equality-Centeredness | | |
| 2. Recipient-Centeredness | | |
| 3. Deliverer-Centeredness | | |
| 4. Learning-Centeredness | | |

| | | |
|---|---|---|
| E. Tension for Change | In your opinion, what do you think would happen if haemorrhage during or after CS was not managed by the THUMB care bundle in your facility?<br><br>*Prompts: Would there be any consequences?* | Context |
| F. Compatibility | | |
| G. Relative Priority | How receptive is your organization to changes in practice and new interventions?<br><br>How much of a priority would a THUMB care bundle be in your hospital | Context |
| H. Incentive Systems | | |
| I. Mission Alignment | How helpful do you think delivering the THUMB care bundle would be for treatment of haemorrhage during or after CS by either yourself or team members?<br><br>*Prompt: Why or why not? How does this compare to how PPH is currently detected in this facility?* | context |
| J. Available Resources | If you and your colleagues were asked to use the THUMB care bundle when treating haemorrhage during or after CS, what would you need to help you do it?<br><br>- To what extent would you know what to do?<br>- To what extent would you need additional skills?<br>- To what extent do you have everything you need to perform the bundle?<br><br>What can you say about the resources required to implement the THUMB care bundle in your hospital?<br><br>How would you describe the readiness of your organization to implement the THUMB care bundle for haemorrhage during or after CS?<br><br>What resources and support systems are in place to facilitate the implementation of the THUMB care bundle? | Context |
| 1. Funding | | |
| 2. Space | | |
| 3. Materials & Equipment | | |

| | | |
|---|---|---|
| IV. INDIVIDUALS DOMAIN | | |
| A. High-level Leaders | | |
| B. Mid-level Leaders | | |
| C. Opinion Leaders | | |
| D. Implementation Facilitators | | |
| E. Implementation Leads | | |
| F. Implementation Team Members | | |
| G. Other Implementation Support | | |
| H. Innovation Deliverers | | |
| I. Innovation Recipients | | |
| A. Need | What are your personal beliefs about the effectiveness of, and need for the THUMB care bundle? | intervention |
| B. Capability | How confident do you feel in your ability to successfully implement this intervention?<br>How confident are the individuals in their ability to implement the THUMB care bundle? | intervention |
| C. Opportunity | Describe to me the commitment, and availability of all key staff in your hospital, to the implementation of the THUMB care bundle. | Context |
| D. Motivation | What are the potential motivators for the care team to implement the THUMB care bundle? | Context |
| V. IMPLEMENTATION PROCESS DOMAIN | | |
| B. Assessing Needs | | |
| 1. Innovation Deliverers | | |
| 2. Innovation Recipients | | |
| C. Assessing Context | | |

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|---|---|---|
| D. Planning | Can you describe the planning process for implementing the THUMB care bundle? | evolution |
| E. Tailoring Strategies | | |
| F. Engaging | How are key stakeholders engaged in the planning and organisation of the implementation process?<br><br>How are key stakeholders involved in the delivery of the THUMB care bundle for haemorrhage during or after CS? | evolution |
| 1. Innovation Deliverers | | |
| 2. Innovation Recipients | | |
| G. Doing | How was the intervention executed during the implementation period?<br><br>What changes, modifications and adaptations did you overserve during the implementations of the THUMB care bundle? | evolution |
| H. Reflecting & Evaluating | How do you assess the effectiveness of the THUMB care bundle implementation, and what improvements have been identified?<br><br>- What do you think are the potential benefits of managing PPH using the THUMB care bundle?<br><br>- What do you think are the potential disadvantages of managing PPH using the THUMB care bundle?<br><br>- To what extent do you think managing PPH as with the THUMB care bundle, is likely to help manage haemorrhage during or after CS more effectively? | intervention |
| 1. Implementation | How do you think the THUMB care bundle will be delivered in your hospital?<br><br>What challenges and opportunities do you foresee?<br><br>- How would managing a PPH as described in the THUMB care bundle affect the ways you work as a team? | evolution |
| 2. Innovation | What innovations have been applied to the delivery of the THUMB care bundle in your hospital? | evolution |
| I. Adapting | How was the THUMB care bundle adapted within the care process of PPH care? What were the adaptations? | Evolution |
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