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A pre-post implementation study of a complex intervention to improve informed consent for caesarean section in Southern Malawi

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ABSTRACT

Objective

Informed consent is an essential component of respectful maternity care, but may be compromised by insufficient communication during the consent process prior to caesarean section (CS). This study aimed to improve women's recollection of information pertaining to informed consent for CS in a low-resource setting.

Setting

Rural 150-bed hospital in Southern Malawi.

Participants

Eighty postoperative women were interviewed both pre- and post-implementation.

Intervention

Based on observed deficiencies and input from local stakeholders, a complex intervention was created consisting of a standardised checklist, posters with a six-step guide for health workers in the maternity department and communication training. Using a pre-post implementation study and exit-interviews recollection of the informed consent process was assessed, for the following items: indication for CS, explanation of procedure, related risks, implications for future pregnancies and verbal enquiry of consent. Components were combined into a completeness score. Recollection of items and completeness scores were analysed using cross tabulation and independent sample t-test respectively.

Results

After implementation, the proportion of women who recollected being informed about procedure-related risks increased from 25/80(31.3%) to 47/80 (58.8%) (OR 3.13 [95% Confidence Interval 1.64-6.00]). Explanation of the procedure increased from 44/80 (55%) to 55/80 (68.8%) (OR 1.80[0.94-3.44]), implications for future pregnancy from 25/80 (31.3%) to 47/80 (58.8%) (1.69[0.89-3.20]) and recollection of consent enquiry from 67/80 (83%) to 73/80 (91.3%) (OR 2.02[0.73-5.37]). Mentioned indication was reported in 77/80 in both groups (OR 1.00[0.20-5.11]). Mean overall completeness scores increased from 3.20/5 to 3.79/5 (mean difference 0.58[0.19-0.96]). Proportion of women recollecting indication of CS increased from 70% to 82.5% (OR

2.02[0.96-4.27]). Mean proportion of recollected risks increased from 1.39/3 to 1.64/3 (mean difference 0.25[0.00-0.50]).

Conclusion

This complex intervention improved recollection of CS-related risks and increased completeness of the informed consent process. This contributes to improved and respectful maternity care.

KEYWORDS

Informed Consent, Caesarean Section, Low-resource setting, Respectful Maternity Care

ARTICLE SUMMARY

Strengths and limitations of this study

- Pre-post implementation analysis of complex intervention
- Assessed patients' recollection of informed consent with interviews
- Based on locally identified insufficiencies in clinical practice
- Limited sample size and no randomisation done

BACKGROUND

Women all over the world may experience disrespectful and abusive care during childbirth.[1-3] Non-consented care is a form of disrespect and abuse and a direct violation of the standards related to respectful maternity care. Valid informed consent is defined as being able to accept an intervention willingly after receiving adequate and comprehensible information about its risks and benefits, and is embedded in international standards such as the International Covenant on Civil and Political Rights.[4, 5] It is of great importance in many procedures including caesarean section (CS), the most frequently performed surgical procedure in many parts of the world.[6]

Several reports have recognised weaknesses in procedures to acquire informed consent prior to CS, like poor explanation of risks and the post-operative trajectory.[7-13] Women could feel pressured into undergoing CS when little information is provided or if information is not understood.[12] Women may experience informed

consent as a bureaucratic procedure not primarily serving their interests.[8] Sometimes, the emergency setting in which many informed consent processes prior to CS take place may not be conducive to information retention and shared decision-making.[8, 11, 13] If delaying the procedure would cause serious harm, consultations may be minimized.[14, 15] Still, even in emergency CS women should at least receive basic information prior to the procedure.[16, 17] Pain and anxiety in women giving birth should not automatically lead to the assumption that they lack capacity to consent.[18] Explanation of procedures and consent seeking are associated with improved ratings of birth services, while non-consented care is seen as a deterrent to skilled birth care utilization.[1, 19] Clinicians should improve women's ability to participate as fully as possible and as far as reasonably practicable.[20, 21]

A variety of prevalence studies and complex interventions focussing on respectful and non-abusive maternal care exists.[1, 22-27] On the contrary, studies promoting informed consent for surgical procedures (including CS) in our setting are scarce, with most literature focussing on elective procedures in high-income countries.[28] *Bowser and Hill* state that "there is a lack of routine patient information communication and consent protocols for obstetric procedures" in regions all over the world, as an explanation for observed shortfalls in informed consent practices.[1] Additional factors that inhibit these practices are women's low education levels, poor communication between health care workers and patients, extensive use of medical terminology and low level of knowledge of informed consent among doctors.[29, 30] Given these circumstances, standardisation of the informed consent process combined with health worker education may enhance its use and value for women giving birth.

Our objective was to assess the effect of implementing a complex intervention consisting of a checklist, a six-step informed consent guide and communication training for health workers involved in maternal health care. We aimed to improve completeness and women's recollection of the informed consent process and thereby promote respectful maternal care.

METHODS

Study design, setting and sample

This prospective pre-post implementation study was performed between January 1st, 2018 and June 1st, 2018 in a rural mission hospital the southern region of Malawi. The maternity staff comprised of locally trained midwives, associate clinicians and two Medical Doctors in Global Health and Tropical Medicine, trained in the Netherlands. The maternity department provides services free-of-charge and has an average of 200 births per month. All women who underwent CS were eligible for inclusion. Elective CS was defined as CS planned prior to onset of labour, while in unplanned CS the decision was made during the first or second stage of labour. Exclusion criteria were inability to participate due to poor clinical condition, referral or death, or unwillingness to participate. Informed consent consultation was done by the midwife on duty, a medical doctor or associate clinician. After CS had been performed, women were admitted for at least 72 hours in the postnatal ward for observation and discharged in case no complications arose.

Data collection

According to the pre-post implementation study design, 80 women were interviewed using a standardised questionnaire 48 to 72 hours after surgery before the intervention was implemented. Data related to timing of surgery, indication and whether it was an elective or emergency procedure were extracted from the records. After these initial two months, two weeks were allocated to intervention development and implementation. Subsequently, 80 additional women were included.

Development of the complex intervention

Based on the responses of the first 80 women and international standards, a complex intervention was designed addressing deficiencies in completeness and recollection of informed consent. Shortfalls were discussed among representatives of the maternity department, both clinical and nursing staff. The complex intervention consisted of the following:

1) *A standardised checklist.* This checklist for health workers encompassed five components of the informed consent process: indication for operation, elaboration on the procedure, discussion of associated risks, implications for future pregnancies and verbal consent enquiry. These components were based on the National Institute for Health and Care Excellence clinical guidelines on caesarean section.[31] We opted for this particular guideline because of its international recognition and clear outline on women-centred care. One

additional checkbox was dedicated to whether a woman's questions were addressed. The checklist was integrated into the facility's existing pre-operative form, thereby reassuring that the surgeon or midwife would bring the checklist along for consent enquiry. Definitions of each component are shown in table 1.

Table 1: Definition of primary outcomes *Completeness* and *Recollection*

Completeness – Which topics have been discussed preoperatively?	
Indication	Indication for CS.
Procedure	Transfer to theatre, lower abdominal incision, use of anaesthetics and possibly blood products.
Risk discussion	Information on commonly associated and serious risks.
Implications for future pregnancies	Need to deliver in secondary health facility in subsequent pregnancies. Strict advice of bilateral tubal ligation after third CS.*
Consent	Written and verbal consent has been collected.
Recollection – What information does the mother (or the woman) recollect?	
Recollection of indication	Woman names indication for CS as mentioned in her patient file.
Recollection of common complications	Score from 0 – 3, woman picks the following common complications out of a list of six options; - Extensive bleeding (>1000ml) - Infection (wound infection, endometritis, peritonitis) - Extended recovery time as opposed to vaginal birth (three-day hospital admission and no lifting for six weeks) - Other included options: leaving instruments in the abdomen, permanent paraplegia, maternal death

* Based on national consensus

2) *Posters with a six-step informed consent guide.* These posters were placed in every labour room at eye level and served as an additional reminder to maternity care providers for initiation of the informed consent discussion. Frequently occurring risks were separated from rarer risks, following consent advice from the Royal College of Obstetricians and Gynaecologists.[32] We emphasised that, although it was set up as a step by step guide, health workers should apply the information in accordance with women's needs and circumstances.

3) *Communication training.* We organized training sessions for clinical and nursing staff in the maternity department consisting of an introduction to the theory of informed consent and a respectful woman-centred approach during labour, followed by role-play in settings of both elective and unplanned CS and subsequent feedback from the other participants. We highlighted discussing information between contractions, addressing

uncertainties and questions, and the importance of acquiring verbal consent. Questions from participants were addressed and participants were invited to provide input to improve the consent guide.

Checklist and guide were discussed plenary with all hospital staff, providing an additional opportunity for adjustments. Health workers were provided with copies of the interventions and asked to evaluate its practical use.

Study tool

To assess primary outcomes, we designed an exit-questionnaire in English and Chichewa using forward- and subsequent backward-translation. An expert committee consisting of experienced clinicians and midwives working in the maternity department of SLH were involved in validating its content. This included how indications for CS should be grouped, which risks should be known by the women and what information is indispensable with regard to future pregnancies. Additionally, socio-demographic factors with potential influence on outcomes were identified. Use of medical terminology was reduced to ensure that all questions could easily be understood. A two-week qualitative pilot study was performed to assess women's input on questions, followed by an additional week using the tools' current answer options to examine its clarity. Interviews were performed by one of the authors (SZ), assisted by nursing college students working in the maternity department.

Study outcomes

Primary study outcomes were level of completeness, recollection of indication and recollection of risks (table 1). Level of completeness was defined as the number of discussed informed consent components according to the woman. Each of five topics was dichotomously scored (0 = not discussed, 1 = discussed) and rated as equally important. This resulted in a completeness score ranging from 0 to 5 for every individual. Recollection of indication was measured by the percentage of women who could describe the indication for CS as stated in the file, as a dichotomous value. To assess risk recollection a list with risks was provided, of which three were commonly associated with CS and three others were not. For every common risk mentioned, a point was given, making up a score from 0 to 3. Common risks deemed as essential knowledge for women in our setting were extensive bleeding of more than one litre, infections such as wound infection, endometritis or peritonitis and

an extended recovery time compared to vaginal birth. Three other choices were added to the list, based on risks named by women in two-week qualitative pilot study.

Analytic approach

To determine differences in overall completeness and risk recollection scores between pre- and post-intervention, we compared mean scores using independent samples t-tests. Additionally, simple bootstrap resampling was performed using 1000 samples, as validation parameter for potential violation of the assumption of normality and equal variances.[33] Effect size is expressed as the difference in means and p-values are provided. Each individual component of informed consent was compared between the pre- and post-intervention groups using Chi-squared tests with odds ratio's and 95% confidence intervals. For recollection, we also used Chi-squared tests to compare correct indication recall percentages. With regards to descriptive analyses, we used an unpaired t-test, Mann-Whitney U test or Chi-squared test accordingly. All analyses were performed with IBM SPSS 24.0. Alpha was set at 0.05. Analysis and interpretation of data adhered to SQUIRE 2.0 (Standards for Quality Improvement Reporting Excellence) guidelines [34].

Ethical consideration

The study received ethical approval by the National Health Sciences Research Committee of Malawi (approval number 1995) and a declaration of no-objection by the Leiden University Medical Centre Ethical Committee (reference number P18.027). Permission was granted by the hospital management to conduct the study. All participants were provided with an informed consent sheet either in English or Chichewa, with regard to the purpose of the study and women's rights. For women who were illiterate, the interview assistant read the consent form out loud and elaborated. Finger prints were accepted as signatures for women who did not know how to write. No names were included during data gathering to ensure confidentiality. Immediately after collection, data were stored in a locally encrypted database, only accessible by the primary investigators. All women were asked to give informed consent before inclusion.

Patient and public involvement

The importance of improving informed consent was highlighted in various hospital advisory committee meetings, in where local chiefs present the concerns of the hospital population. This laid the foundation for this

study. During the pilot phase patients were asked to comment on the study tools, in order to make them as understandable and applicable as possible.

RESULTS

During the study period, 163 women were eligible for inclusion, of whom 160 (98%) participated. One woman was discharged before the scheduled interview and two refused to participate. All participating women completed the interview.

Characteristics of women pre- and post-intervention are shown in table 2. Twenty-six (16.3%) procedures were elective, 134 (83.7%) were emergency CS. Of all women, 62 (38.8%) were primiparous. Median age was 24 years (IQR 21 – 30) and 22 (13.8%) women were 18 years or younger. Inability to read or write Chichewa was observed in 32 (20%) women. No statistically significant differences in indications for CS were found between the pre- and post-intervention groups. Commonest indication for the procedure was prolonged labour, occurring in 94 (58.8%) women. In the pre-intervention period, CS rate was 15.3% (54 out of 354 total births), compared to 19.3% (79/410) in the period after intervention. A statistically significant difference was observed in the attendance of medical doctors during CS, 12 CS (15%) in the pre-intervention group as compared to 37 CS (46.3%) in the post-intervention group.

Table 2. Participant and procedure characteristics for the pre- and post-intervention group

	Pre-intervention (N=80)	**Post-intervention (N=80)**	p-values
Median Age (IQR)	26 (21-30)	24 (21-30)	0.96
Parity (%)			0.83
- *1*	31 (38.8)	31 (38.8)	
- *2*	21 (26.3)	18 (22.5)	
- *>2*	28 (34.9)	31 (38.8)	
Prior CS %			0.24
- *1*	54 (67.5)	54 (67.5)	
- *2*	18 (22.5)	23 (28.8)	
- *3*	8 (10)	3 (3.8)	
Elective CS (%)	14 (17.5)	12 (15)	0.67
CS in nightshift (%)	34 (42.5)	29 (36.3)	0.42
Median number of antenatal consultations (IQR)	4 (3-4)	4 (3-4)	0.28
Illiteracy (%)	17 (21.3)	15 (18.8)	0.69

Attained high school (%)	37 (46.2)	40 (50)	0.64
HIV+ (%)	5 (6.3)	8 (10)	0.39
CS attended by Medical Doctors (%)	12 (15)	37 (46.3)	<0.05

Completeness of informed consent

Table 3 shows completeness scores and prevalence of individual components of informed consent for both pre- and post-intervention groups. In the post-intervention group 47 (58.8%) women stated they had received information on risks before surgery, as compared to 25 (31.3%) in the pre-intervention group (OR 3.13; 95% CI 1.64 – 6.00) . We observed increases in explanation of the procedure (OR 1.80; 95% CI 0.95 – 3.44), inclusion of implications for future pregnancies (OR 1.69; 95% CI 0.89 – 3.20), and verbal consent enquiry (OR 2.02; 95% CI 0.73 – 5.37) though none of these were statistically significant. The component 'indication for the procedure' was mentioned equally in both groups (96.3%). Mean completeness scores of pre-intervention and post-intervention were 3.2/5 and 3.8/5 (Table 3). Mean completeness score increased significantly after implementation of the interventions with a mean difference of 0.58 [95% CI 0.19 - 0.96]. Additional simple bootstrapped independent sample comparison provided a comparable mean difference of 0.58 [95% CI 0.21 – 0.96].

Table 3: Number of informed consent aspects discussed during preoperative counselling

	Pre-intervention (N=80)	**Post-intervention (N=80)**	Odds ratio (95% CI)
Mentioned indication (%)	77 (96.3)	77 (96.3)	1 (0.20 – 5.11)
Procedure explained (%)	44 (55)	55 (68.8)	1.80 (0.94 – 3.44)
Associated risks explained (%)	25 (31.3)	47 (58.8)	3.13 (1.64 – 6.00)
Need to deliver in hospital next time/ Need to deliver by CS next time / BTL (%)	43 (53.7)	53 (66.3)	1.69 (0.89 – 3.2)
Written and verbal consent (%)	67 (83.3)	73 (91.3)	2.02 (0.73 – 5.37)

Recollection of informed consent

Figure 1 shows the percentage of women able to name indications for CS as stated in the files. Prior to implementation, 56 (70%) named the correct indication. This increased post-implementation to 66 (82.5%),

with an odds ratio of 2.02 [95% I 0.96 – 4.27]. Table 4 shows an increase in the mean risk recollection score from 1.39/3 to 1.64/3 risks recollected (mean difference of 0.25 [95% CI 0.00 – 0.50]). Bootstrapped independent sample t-test resulted in an equal mean difference of 0.25 [95% CI 0.01 – 0.48].

Table 4: Completeness scores (0-5) for pre- and post-intervention group

	Pre-intervention	**Post-intervention**	Mean difference (95% CI)
Mean completeness score 0-5 (95% CI)	3.20 (2.92 – 3.48)	3.78 (3.50 – 4.05)	0.58 (0.19 - 0.96)
Simple bootstrap (N=1000)			0.58 (0.21 – 0.96)

DISCUSSION

Our complex intervention improved the level of completeness of the informed consent process by ensuring that essential components were systematically included. In the post-intervention group, a larger proportion of women stated to have received information on procedure-related risks. Women were also able to mention more commonly associated complications, indicating improved risk discussion. Risk discussions might have been included more frequently in the informed consent process in the post-intervention group, or improved structure of the risk discussion may have made it more understandable. Furthermore, the procedure was explained more frequently and more women were able to reproduce the indication for CS, although this trend was not statistically significant. An explanation could be that the informed consent consultation in the pre-intervention group already included an explanation of the proposed procedure and implications for future pregnancies in considerably large, although still deficient, proportions. Additional and more specific measures may be required to further improve recollection of these items. It was recognized that, the supplementary poster mainly focussed on the risk-discussion, possibly overlooking the other components. The significant increase in median completeness scores indicates that a complex intervention such as ours can improve the overall completeness of the informed consent process, or women's recollection thereof.

Several reports identified positive effects of standardisation on the informed consent process. *Firdousea et al.* implemented a checklist for informed consent in paediatric surgery, which increased inclusion of important items such as explaining alternative treatments, role of trainees and potential outcomes of conservative treatment.[35] As opposed to direct observations, our study used a questionnaire to measure patient's recollection instead. *Kondziolka et al.* also implemented a structured consent checklist for neurosurgical

procedures and found a high recall of diagnosis (100%), risks (97,4%) and alternative procedures (98,1%).[36] Recollection did not differ significantly immediately after consultation, compared to several months later. These findings suggest that a structured checklist may achieve high immediate recollection of information, but may also have a positive influence on long-term comprehension.

Standardised consent checklists carry the risk of reinforcing the 'repetitive nature' of the informed consent consultation for clinicians and thereby diminishing clinicians' and women's motivation and involvement, actually decreasing patient autonomy.[8, 37] Efforts were made to sustain motivation and participation in our intervention by including verbal consent as one of the five components and giving women and their guardians an opportunity to ask for clarifications. Involvement in the informed consent process may give women the feeling of being in control and enhance their relationship with healthcare providers. These are two facilitators of a positive birth experience.[38] Although, in an acute setting, there may not be time for an elaboration and questions, certainly in the elective setting these should be part of the consent process.

We opted for a prospective pre-post implementation study design because randomisation was not compatible with the study setting and pre-intervention data was necessary for the development and implementation of our complex intervention. Several limitations result from our study design. Outcomes could have been confounded by co-occurring contextual differences pre- and post-implementation.[39] The proportion of CS attended by the Dutch Medical Doctors Global Health and Tropical Medicine was higher post-implementation. Their practice around informed consent could have differed from Malawian colleagues. However, these medical officers were not directly involved in the informed consent process, since this was undertaken by midwives at the maternity ward. The availability of these doctors might have had an indirect positive influence on the quality of the informed consent process. There may also have been improved performance due to the presence of the research team, although the majority of this team consisted of hospital staff and the effect was minimized by a short time elapse between pre- and post-implementation phases. Additional limitations were incomplete validation of our self-designed questionnaire with regard to test-retest reliability, inter-rater reliability and the tool's responsiveness to changes in outcome, and existing language barriers between interviewer and participants. To diminish these effects, we designed the questionnaire to be simple and give little room for interpretation, with multiple choice and closed-ended questions. When necessary, translation was done by local nursing college students.

In future research, outcomes other than completeness of the consultation and women's recollection are worth investigating. New studies could explore influence of our standardised checklist on women's satisfaction, anxiety and long-term comprehension.

CONCLUSION

This complex intervention improved completeness of the informed consent process for CS by increased inclusion of essential components such as explanation of the procedure, risk discussion and implications on future pregnancies. Women left hospital more knowledgeable, mainly in risks associated with the procedure. These results suggest that standardisation and training may improve informed consent in a resource-poor setting, and thereby promote respectful maternity care.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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DATA STATEMENT

De-identified participant data and informed consent forms will be published online through the Dryad repository immediately after publication of the manuscript. The study protocol is attached as supplementary file.

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AUTHOR CONTRIBUTIONS

SZ and WB drafted the study protocol, with help of TvdA and JvR. FN and KK provided feedback on the study design and helped implementing the study in the facility. SZ and FN drafted the study tool. KK assisted in inclusion and logistics around the interviews. SZ conducted the interviews analysed the data together with WB. SZ and WB drafted the manuscript which was commented on by all authors and approved for submission.

CAPTIONS

Figure 1: Percentage of women who remembered their CS indication

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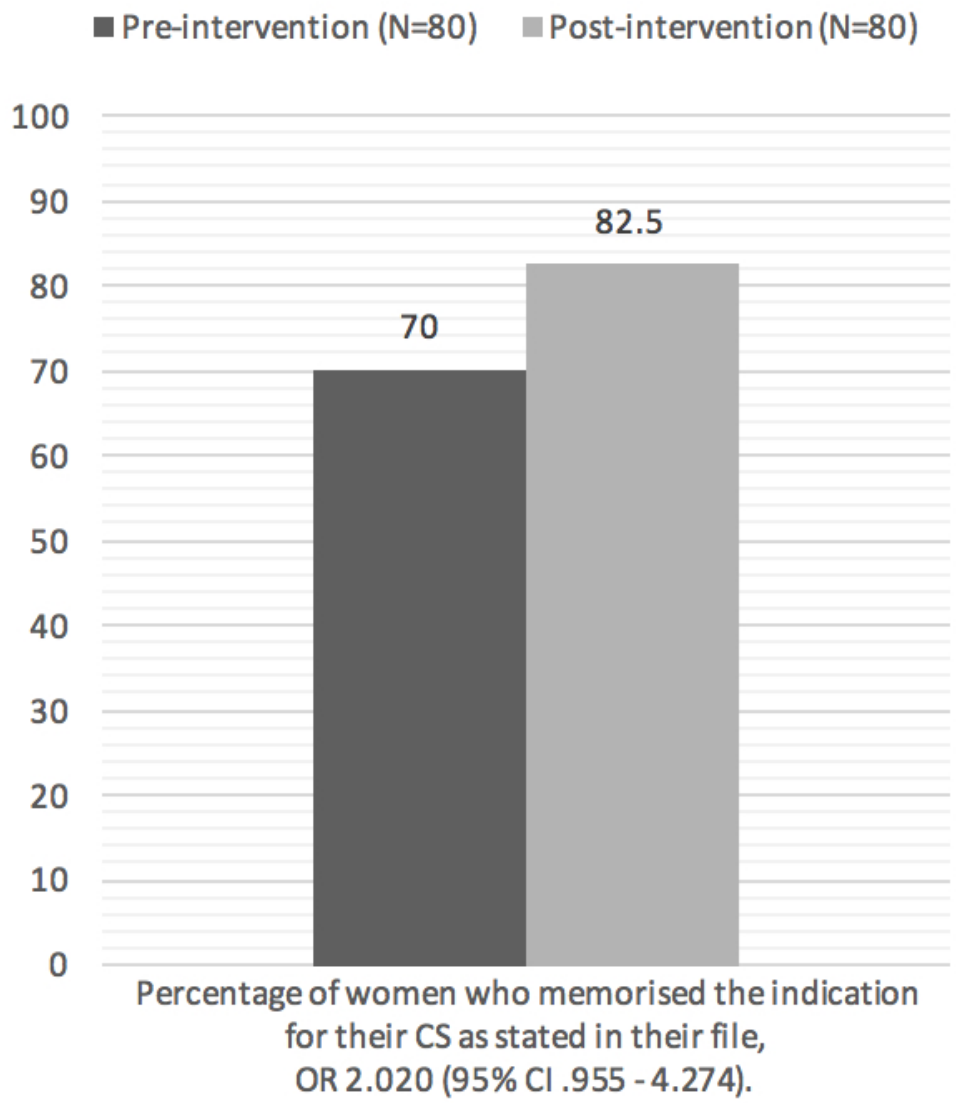


Figure 1: Percentage of women who remembered their CS indication

DECISION-MAKING AROUND CAESAREAN SECTION IN A RURAL HOSPITAL IN MALAWI

STUDY PROTOCOL

Study site: Saint Luke's Hospital, Malosa
Duration project: 1 February 2018 – 1 February 2019
Primary investigator: Wouter Bakker, Medical Officer
Email: bakker.stlukes@gmail.com Phone: +265991694212

Abstract

Research problem: Quality of care surrounding CS has to be investigated due to reports of disrespect and abuse in maternity health care. CS numbers are rising and some of them are performed unnecessarily. Health workers should ensure that the patient's right to information and consent are respected. Health worker perspectives on information transfer and gaining consent should be assessed to implement interventions accordingly and successfully. With this study, we assess the current quality of consultation for caesarean section and aim for improvement.

Objectives:

1. Analyse indications for caesarean sections and the use of interventions in labour.
2. Analyse the quality of the pre- and postoperative consultation for CS according to the patient's experience and recollection.
3. Identify circumstantial factors and patient characteristics which influence the informed consent process.
4. Analyse health worker perspectives on the use of informed consent prior to CS, in both emergency and elective settings.
5. Study the effectiveness of a standardized informed consent checklist.

Hypothesis: We hypothesize that the use of oxytocin and vacuum extractions can be improved in order to prevent unnecessary CS. We also hypothesize that the information transfer in consultation for CS is not according to accepted standards. Our proposed standardized informed consent checklist may aid us in reaching these standards. We also hypothesize that patients literacy, type of CS and performance of CS during night influence the effectiveness of our consultation. This may help in optimizing informed consent in specific groups.

Methods: A mixed-method approach, consisting of:

- Retrospective cohort analysis of all deliveries in 2015 and 2016 on indications for caesareans and the use of interventions in labour.
- Interview-administered questionnaire study (controlled before and after study) to identify the quality of informed consent prior to CS.
- Semi-structured interviews with health workers on the use of informed consent prior to CS.
- Implementation of intervention package to support a standardized informed consent checklist.

Benefits and Risks: No serious harm is inflicted to the patient by performing this study. Precautionary measures are taken to protect sensitive information of the study participants. No direct benefits are gained for the patient, other than an extra thorough explanation of risks of CS and post-CS care. However, this work lays the foundation for interventions which improve the quality of care in Saint Luke's Hospital.

Use of results: Primarily as foundation from where we can improve Respectful Maternity Care in Saint Luke's Hospital. Possibly presented during conferences in places in Malawi and the Netherlands. An effort will be made to submit an article to a Malawian peer reviewed journal. An article could be submitted to an international journal, after review by the NHSRC.

Table of contents

1. Proposal Summary

Title of Proposal	Decision-making around caesarean section in a low-resource setting.
Principal investigator	Wouter Bakker, MD

1. RESEARCH QUESTION TO BE ADDRESSED

How can we improve decision-making around caesarean sections in a rural hospital in Malawi and thereby reduce the amount of unnecessary caesareans, by looking at indications, interventions and informed consent?

2. RATIONALE FOR RESEARCH

Malawi currently has a population caesarean section (CS) percentage of 6.1%, of which 1.3% are elective procedures, and it has been slowly rising since 1992. [1] Hospital-based CS rates, however, are way higher. It is critical that this rise in CS is justified by the correct indications and is accompanied by an increase in awareness of the necessity of informed consent. Increasing the use of interventions in labour, like amniotomy, oxytocin administration and vacuum extraction could improve chances for vaginal delivery and prevent an unnecessary CS. Besides evidence based quality care, mothers deserve information and autonomy in their health, pregnancy and childbirth. Discussing the process and indications of caesareans thoroughly between clinicians and patients can assist in decision making. Several reports have recognised insufficiencies in the informed consent process prior to caesarean sections, as well as in the broader concept of RMC during facility-based deliveries in low-income countries. Despite its importance and being one of the most practical factors of the Bowser and Hill model to improve, the current state of informed consent for CS in Malawi has not be documented yet. Also, health staff perspectives on the need for informed consent and what it should accomplish might be helpful in improving informed consent and thus quality of care. This mixed-method study aims to give insight in the current practice of CS and its effectiveness in a low-income setting. Providing baseline data on the current state may present the need for improvement and lay the foundation for interventions, such as standardization of the consent process.

Based on our clinical experience, we hypothesize that a proportion of caesareans performed could be avoided and that use of interventions can be extended. We also hypothesize that the information transfer in consultation for CS might not always be according to accepted standards. However, health workers probably recognize the shortcomings in our consultation and may come up with suggestions how to overcome these barriers. We expect them to see the necessity and use of informed consent, and be open to possible additions. Our proposed informed consent checklist may aid us in reaching these standards.

OBJECTIVES

1. Identify indications for caesarean sections in order to find opportunities to prevent unnecessary caesareans to reduce maternal morbidity and mortality.
2. Determine use of evidence-based interventions in labour in our setting as amniotomy, oxytocin administration and vacuum extraction

3. Analyse the completeness and recollection of the pre- and postoperative consultation for CS, according to the patient's experience.
4. Identify circumstantial factors and patient characteristics which influence the informed consent process.
5. Analyse health worker perspectives on and experiences with the use of informed consent prior to CS, in both emergency and elective settings.
6. Study the effectiveness of an informed consent checklist on completeness of informed consent and patient recollection.

3. METHODS

The study will take place at Saint Luke's Hospital in Malosa, a rural CHAM facility. Maternity care here is free of charge for patients in the surrounding area.

This study project will make use of a mixed method approach, consisting of the following:

1. Retrospective data analyses of all vaginal births, vacuum extractions and caesarean sections over a two-year period: All patient data from the labour ward from the years 2015 and 2016 are collected. These files consist of partographs and information on admission and follow-up.
   a. Indications for caesareans done in this period will be extracted and compared to national protocols. The partographs will be assessed to see if the conditions for the indication are met and indications will be classified accordingly.
   b. All information concerning decisions during the labour process are collected: artificial rupture of membranes and induction or augmentation with oxytocin.
   c. All vacuum extractions will be evaluated on their indication, outcome and use before and after re-introduction and training.
2. Quantitative survey into quality and uptake of informed consent: In the period January – September 2018, a survey will be conducted into the quality of informed consent on caesarean sections. Exit-interviews with patients who underwent caesarean will be conducted, focused on their experiences and ability of information recall. An intervention to improve the quality of informed consent will be designed and assessed in the study period.
3. Qualitative analysis of perception of informed consent by health workers: To gain more insight in the use, functionality and challenges with informed consent in the setting, interviews with health workers will be conducted in the same period as stated above, following a semi-structured questionnaire. This will be combined with focus group discussions to get a clear picture on the perceptions of staff on informed consent.

4. RISKS & BENEFITS

Benefits and risks have been thoroughly discussed in the research group and are considered minimal. The patients undergoing exit-interviews might be at risk of being disadvantaged by health workers in future care, because of criticism on information transfer. This risk is minimized by anonymizing the questionnaire outcomes and administer the questionnaire on discharge in a separate room. Outcomes are only available to the independent researcher.

The health workers included in the qualitative in-depth interviews might be at risk of being criticized because of views not in accordance with hospital policy. This risk is minimized by anonymizing the collected interview data by an independent interviewer (SZ) and using a transcription for analysis, rather than the voice recording itself.
The performance of this study will increase awareness on the decision-making process around caesareans and the informed consent process. This may lead to a better health worker – patient relationship, of which staff and patients will benefit, and to a higher standard in quality of care and communication. Patients will receive an additional explanation of risks and implications on future pregnancies of their caesarean section, which might influence postoperative outcomes in a positive way.
Reviews of the ongoing study and the data collected will be conducted as per policies of the NHSRC. Any serious events will be reported promptly as required. This study does not involve any new therapies.

5. COSTS & COMPENSATION

Participants will not receive any direct compensation for participation in the study. However, they will receive additional consultation on post-operative risks and implications on future pregnancies associated with CS. Participants will not be asked to assume any out-of-pocket costs for their participation.

6. CONFIDENTIALITY ASSURANCES

All data, including study identification numbers, will be stored electronically under password protected software. All research paperwork including data collection forms, will be kept in a locked cabinet in the administration office of Saint Luke's Hospital; only the primary investigator will have access to it. Data will be anonymized to maintain strict protection of confidentiality. All members of the research team are well aware of issues related to confidentiality, especially with regards to HIV status. Furthermore, all personnel have been trained in subject protections and Good Clinical Practice. An independent ombudsman may be contacted by the patient if any wrongdoing has occurred. The patient information sheeth has been attached as a supplemental document to this application.

7. CONFLICT OF INTEREST

The research team does not have any conflicts of interest in performing this study.

8. COLLABORATIVE AGREEMENTS

The proposed study will be a collaboration between Saint Luke's Hospital and Leiden University Medical Centre. Letters of approval and support are provided as supplemental documents to this application.

9. INTENDED USE OF RESULTS

The results will be presented to the hospital staff and will hopefully assist in improving maternity care. Study results will be summarized and explained in an accompanying article. If the authors decide to publish the article, a copy will be send to the National Health Sciences Research Committee for review. An effort will be made to publish the findings in at least one local or international peer reviewed journal. Also, a final report will be send to the NHSRC after finishing the study.

The results can be a foundation for quality of care interventions, such as an informed consent checklist and focus group discussions with obstetric health staff. It may be presented in conferences in Malawi or internationally to address the importance of this subject. Furthermore, the whole project will give experience for the staff involved, which might motivate and assist them in their future career. Outcomes of this relatively small study project hopefully leads to more research being performed on the subject, for example in bigger multi-centre studies.

2. Main Proposal

Title of project	Decision-making around caesarean section in a low-resource setting.
Principal Investigator	Wouter Bakker, MD
Place of Study	Saint Luke's Hospital

1. BACKGROUND AND JUSTIFICATION

Unnecessary caesarean sections

Caesarean sections are rising worldwide, in both high- and low-income settings.(1–3) In their in 2015 updated statement on caesarean sections the WHO concluded that we should aim for a population based caesarean rate of 10%, with above that no significant improvement on maternal and neonatal outcome.(4) In a low-income setting as Malawi, caesarean section rates on population level still appear to be low, but on institutional level they are rising.(5) Caesarean sections are associated with severe maternal outcomes like hysterectomy, blood transfusion, need for ICU admission and death and this association is even higher Africa compared to Latin-America or Asia.(6–9) A study from South-Africa found a three times increased risk of maternal death after caesarean compared to vaginal birth, with haemorrhage as leading cause of death.(10) The risk on infections or uterine rupture in further pregnancies can also not be underestimated, especially not in a country where the average fertility rate is above five.(11–14) It remains therefore crucial to carefully select those cases eligible for surgical intervention and prevent to perform unnecessary procedures.(2) Where it used to be a problem of too little, too late and mothers and children died of not getting access to surgical care, we nowadays could also talk of too much, too soon. Critical evaluation of protocols, indications and individual cases could raise knowledge about necessary and unnecessary caesareans and assist in management of further cases. This can be done by audit of indications, group discussions and case evaluations. The World Health Organization advises to monitor CS rates on facility level.(4) There are many different classifications for caesareans described and a systematic review described the Robson classification as being the best suitable for identifying indications for caesareans.(15) This classification divides the indications for caesareans in different groups, but provides no means to compare indications to international standard protocols, to assess whether the decisions for performing an caesarean was based on correct grounds.(16) This could be useful at facility but also regional level, as a first step to identify pitfalls and work on reducing unnecessary procedures.

Interventions in labour

Analysing the indications of caesareans, we can identify in which area's we could improve to prevent ending up in unnecessary caesarean sections by using interventions in labour. These evidence based interventions are basic, broadly available and less risky than surgery. They require good monitoring of labour, for example using partographs. This is the case already in a big part of the world, although documentation is sometimes suboptimal.(17) Amniotomy and oxytocin administration should be available in every BEmOC setting, and should be used in case of poor progress of labour, if correctly identified.(18–20) Maintaining experience with this could prevent performing unnecessary caesarean sections. In the case of prolonged second stage of labour, forceps or vacuum extraction could provide assistance before opting for emergency caesarean section and local training

and support could improve its use.(21,22) Pro-active support of labour could also result in successful vaginal birth after caesarean, preventing complicated repeat caesareans.(13,23) Together, correct and indicated use of these evidence based interventions could assist further in preventing unnecessary procedures and deliver mothers the care they deserve.

Informed consent

Besides evidence based quality care, mothers deserve information and autonomy in their health, pregnancy and childbirth. Discussing the process and indications of caesareans thoroughly between clinicians and patients can assist in decision making. One of the universal rights for childbearing women is the right to information and informed consent. Being able to accept an intervention willingly after receiving adequate and comprehensible information about the risks and benefits of the suggested treatment and alternatives, is defined as valid informed consent.(24) In the Bowser and Hill model on disrespect and abuse, non-consented care is one of the categories and could lead to reduces accessibility of health facilities, risking complications in pregnancy, labour or the postnatal period.(25) Although forming a necessity, informed consent can be suboptimal, leading to questions, confusion and dissatisfaction with patients.(26,27) The use or misuse of informed consent is easily monitored at facility level and information on this could give insight in areas of improvement. Several reports have recognised insufficiencies in the informed consent process prior to caesarean sections (28-30), as well as in the broader concept of RMC during facility-based deliveries in low-income countries. (25, 31-33) Causes that inhibit informed consent practices are low level of education of the patient population, poor communication between doctor and patient, not enough time given for obtaining consent, extensive use of medical terminology and low level of knowledge of informed consent among doctors.(29) On a structural level, poor working conditions caused by system deficiencies leading to high workloads among practitioners, may also add to the problem.(34,35) The deficiencies in the informed consent process result in the preservation of false perspectives women have of caesarean sections. Prior counselling to C-sections with comprehensible information about the indication, procedure, common complications and implications on future pregnancies (36) might enhance women's understanding and thereby diminish misconceptions of the proposed surgery. As of yet, very few data is known on the use and quality of informed consent for surgical procedures in a low-resource setting. Identifying this and creating opportunities to improve the consent process can contribute to the decision-making and quality of care around caesarean sections.

2. HYPOTHESIS

We hypothesize that a significant amount of caesareans could be avoided and that there are opportunities during labour to do so. Also, we predict that the current the consultation prior to a caesarean section is suboptimal and that not all patients can reproduce their indication and the risks of a surgical intervention. Patient educational level and time of surgery might influence the information transfer effectiveness. Health workers might assist in identifying shortcomings and give insight in clinical practice of the consultation. With these inputs, an intervention package will be implemented consisting of a informed consent checklist, assessing the identified barriers and tackling them. We hypothesize that

with this approach we will improve the recollection of the patient and make the consultation more complete.

3. OBJECTIVES

The broad objective of this study is to improve the current informed consent consultation for caesarean section. This objective can be specified by the following objectives;

1. Identify indications for caesarean sections in order to find opportunities to prevent unnecessary caesareans to reduce maternal morbidity and mortality.
2. Determine use of evidence-based interventions in labour in our setting as amniotomy, oxytocin administration and vacuum extraction
3. Analyse the completeness and recollection of the pre- and postoperative consultation for CS, according to the patient's experience.
4. Identify circumstantial factors and patient characteristics which influence the informed consent process.
5. Analyse health worker perspectives on and experiences with the use of informed consent prior to CS, in both emergency and elective settings.
6. Study the effectiveness of an informed consent checklist on completeness of informed consent and patient recollection.

4. METHODOLOGY

Study site

The project will conducted in St. Luke's Hospital in Malosa, Malawi. The hospital is based in the southern region of Malawi. St. Luke's is a CHAM (Christian Health Association of Malawi) facility, working with a principle of minor user fees for their service. Maternity care is free of charge for the catchment population through the governments Service Level Agreement (SLA). The 150 bed rural hospital offers all types of care, including comprehensive emergency obstetric care for pregnancies from all gestational ages, with an average number of 2500 births per year. It serves a catchment population of roughly 30,000. The caesarean section rate was 19% in 2015 and 23% in 2016. This increase led to questions with hospital management and the request for further investigation. The principal investigator works full-time as a medical officer in St. Luke's since 2016 and has on the ground experience in the labour ward. He has close contact with management, hospital staff and patients and acquired insight in local problems and needs.

Study period

The whole study project will roughly take place between January 2018 and January 2019, but data of previous periods will be incorporated (from 2015 onwards).

Study design

The projects has a mixed-methods study design, consisting of a retrospective data analysis of all vaginal births, vacuum extractions and caesarean sections over a two-year period, a quantitative survey into quality and uptake of informed consent and a qualitative analysis of perceptions of health workers on informed consent . When shortcomings and barriers are identified, we propose to implement a structured informed consent checklist in

concordance with instructions on usage. The factors of influence we identified in both the analysis of the questionnaires and interviews, we will implement in the intervention.

Retrospective data analyses of all vaginal births, vacuum extractions and caesarean sections over a two-year period.

3500 case files of women who delivered in Saint Luke's Hospital between 1 January 2015 and 31 December 2016 will be collected and analysed retrospectively. Files consist of partographs and information on admission and follow-up. The information is collected in a database and statistical analysis on three major subjects will be done. The following information is gathered;

1. Indications for caesareans done in this period will be extracted and compared to national protocols. The partographs will be assessed to see if the conditions for the indication are met and indications will be classified accordingly.
2. All information concerning decisions during the labour process is collected: artificial rupture of membranes and induction or augmentation with oxytocin. The usage of these methods will be evaluated.
3. All vacuum extractions will be evaluated on their indication, outcome and use before and after re-introduction and training, which took place in first quarter of 2016

Quantitative survey into quality and uptake of informed consent.

Between January 2018 and September 2018 a structured exit-questionnaire will be administered to all patients delivering via CS in Saint Luke's Hospital. We aim to include 150 patients in total. The first 75 patients will be included for the analysis of the current status of the completeness and effectiveness of the informed consent consultation. The following 75 patients are included after implementation of an intervention, for measuring its effectiveness. Approximately 30 patients deliver by CS each month in the hospital. All consenting women who underwent CS can be included, either emergency operations or elective surgery. Exclusion criteria are non-consenting women and women not fit enough to participate due to post-operative complications. During the first months of the inclusions, the construction and implementation of the intervention takes place, based on the gathered data and identified shortcomings.

The quality of consultation is assessed by the completeness and recollection according to the patients' experience. In order to assess the completeness, the patient will be asked about several aspects of the consultation prior to CS. Based on international guidelines (36), the following information should be given to the patient:

1. Reason for the procedure.
2. What the procedure involves.
3. Associated risks.
4. Implications on future pregnancies.

Additionally, she should be asked verbally for consent of proposed procedure. We add one extra aspect for verbal consent gathering by health worker;

5. Asking for verbal consent.

Based on these five criteria, percentages of occurrence can be calculated and a mean score of completeness from 0 – 5 can be given.

The recollection of the patient will be assessed by two different measures;

a. The percentage of patients able to recollect the indication for their CS as mentioned in their patient file.
b. The percentage of patients able to recollect the most common risk factors of CS.

The checklists will be interview-administered, because additional explanation can be given to patients where necessary. The interviews will be performed by an independent interviewer, not involved in routine patient care (SZ). The interviewer will make clear to the patient that the questionnaire is voluntary and not part of routine care. Questionnaire administration takes place right before patients are discharged. Patient files will be analysed to gather patient demographics, including amount of antenatal consultations, HIV-status, time of surgery and presence of written consent. The rest of the socio-demographic data is gathered during the interview itself. This includes tribe-allocation, literacy, educational level, marital status and amount of previous deliveries and caesarean sections. The interviewer will work guided by the Chichewa questionnaire and will be assisted by a translator from the hospital, oriented on the study objectives and methods. This can either be a nurse, student or support staff, since the questions are straightforward and mostly multiple-choice. Data will immediately be entered in the databank, to assure the quality of the data entry. Analysis will be performed with IBM SPSS Statistics version 24. The database will be created during the study period. Descriptive analysis will be used to identify the percentage of criteria met in the total group. Pre- and post-intervention groups will be compared with either a Chi-square test or unpaired t-test.

Qualitative analysis of perception of informed consent by health workers.

Between April 2018 and July 2018, in-depth interviews will be held with health workers related to obstetric healthcare working in the antenatal clinic, maternity department or theatre. We aim to include 20 participants and have at least one focus group discussion. The interviews will encompass several aspects regarding informed consent for CS. The interview tool includes:

1. Personal experiences with informed consent.
2. Definition and goals of informed consent.
3. Daily practice of informed consent.
4. Barriers to informed consent.
5. Ethical considerations linked to informed consent.

Convenience and snowball sampling will be used and data will be collected until data saturation is reached. Interviews will be conducted by an independent researcher (SZ) to prevent courtesy bias, following a semi-structured questionnaire. The interviews will be recorded, transcribed and analysed with qualitative data analysis software MAXQDA. Coding will be done in order to identify themes around the subject. Data will be processed anonymously. No incentives are given for participation. The questionnaire and interview checklist are provided as supplemental documents to this application.

Sample size

Approximately 30 patients deliver by CS each month in the hospital. All consenting women who underwent CS can be included, either emergency operations or elective surgery. Exclusion criteria are non-consenting women and women not fit enough to participate due

to post-operative complications. Sample size is based on the amount of time available, but aimed at a total of 150 inclusions.
For the qualitative part, data will be collected until data saturation is reached, which we based on experience expect around 20 interviews, using convenience and snowball sampling. We aim to include at least one focus group discussion.
The retrospective review will include roughly 3500 records.

5. DISSEMINATION OF FINDINGS

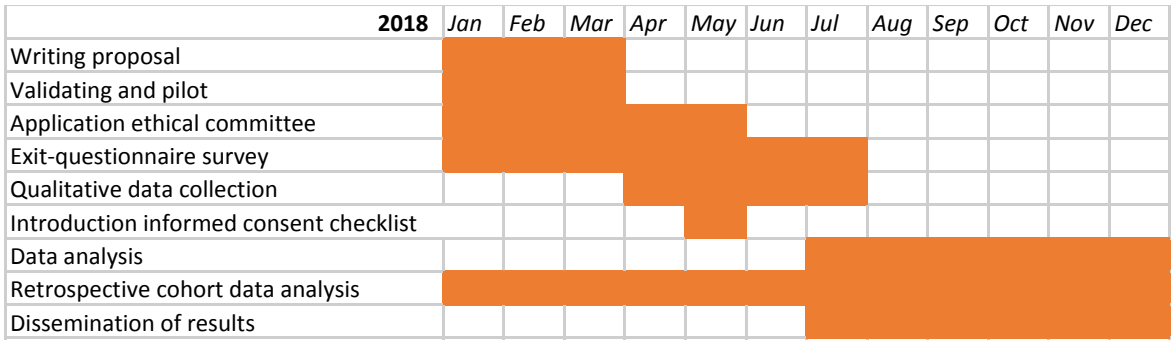
The direct aim of the project is quality improvement in the facility in the field of caesarean section indications, interventions in labour and informed consent. By focussing on these aspects of care, health workers have the opportunity to analyse their own practice and improve their skills, of which both health workers and patients will benefit. We hope identified barriers can lead to development of training packages of which all health workers and ultimately patients can benefit. All results will be presented on facility and if possible on district level. An effort will be made to publish the findings in at least one local or international peer reviewed journal, of which a copy will be send to the National Health Sciences Research Committee for review. Also, a final report will be send to the NHSRC after finishing the study. Outcomes of this relatively small study project hopefully leads to more research being performed on the subject, for example in bigger multi-centre studies.

6. PERSONNEL

Wouter Bakker, medical doctor, is the primary investigator and will lead the project.
Siem Zethof, master-student in medicine, will take responsibility of the data gathering for both the quality survey with exit-questionnaires and the interviews with health workers.
Felix Nansongole, clinical officer, is involved in the development of the research tools and patient approach.

7. WORK-PLAN

The project will take place in its entirety between January 2018 and January 2019. The first months are used for protocol writing and ethical approval. Practical approach is discussed and analysed in the facility. A small pilot was conducted to improve the questionnaire. In the first half of 2018 the first half of patients for the qualitative survey will be included. Also, the interviews with health workers will be held during this period of time. In April/May, the intervention checklist will be developed and applied. The second half of the survey, to evaluate the effectiveness of the proposed intervention, will be held after implementing the checklist. Data analysis will take place during the second halve of 2018. The cohort analysis will be performed throughout the year.



8. BUDGET

This research is not financed by any sponsors. Expected minor costs are as follows.

Printing costs	20.000 MWK
Hiring a translator for questionnaire	72.500 MWK
On-ground translator fees	20.000 MWK
10% NHSRC fee	11.250 MWK
Total budget	123.750 MWK

The costs will be paid out of the primary investigators personal account. It is thinkable that this project leads to more structurally funded research projects in the region.

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3. Informed Consent

Informed consent is gathered prior to administration of the questionnaire. The investigator gathering the informed consent will not have a treatment relationship with the individual. The aim of the research will be verbally explained and details about inclusion criteria and reasons for inclusion of the individual in particular, use of questionnaire, financial compensation, risks and benefits, confidentiality and contact details will be discussed in the Participant Information sheet. The patient will be informed that conduction of this research is not part of their routine care and completely voluntary. The individual is free to refuse to participate and will be free to withdraw from the research at any time without penalty or loss of benefits to which he or she would otherwise be entitled. Also, there will be touched upon the limits to the researchers' ability to guarantee confidentiality and the measures that are taken. Verbal informed consent will be gathered and additionally written explanation will be handed out to the patient, where another confirmation of consent is asked. The first page of the questionnaire is dedicated to informing the patient and asking for their written consent. Illiterate patients may give consent with a fingerprint.

Deliberately has been chosen to administer the participant information sheet verbally, because the information is very extensive and hard to understand all at once. We will give patients the option to ask questions and they will receive contact details for further explanation on study participation and progress. Also contact details of Saint Luke's Hospital personal have been included, who can link participants to an independent health advocate (ombudsman). Verbal explanation of this seems appropriate, because during pilot studies we found an illiteracy/bad understanding of Chichewa in 20% of patients. By doing this verbally and providing room for discussion, we make an effort to respect the autonomy of all patients viable for inclusion.

Considering the interviews with health workers, informed consent is gathered prior to interviews with the health workers. Verbally the scope of the research will be explained, the use of a recorder and the possible extraction of quotes. No names will be mentioned. None of the data can be linked to the included health personal. Numbers will be used for anonymization purposes.

The records of consent will be stored in the administration office of the hospital. The records are anonymous, but linked to admission numbers. An encrypted database, only accessible to the primary investigator, will link the admission numbers to the gathered data. This way we can link the informed consent form to an individual case. However, patient names are not recorded and cannot be traced.

3a. Informed Consent Exit-Questionnaire Survey

PATIENT INFORMATION SHEET **ENGLISH**

Study title:	*Decision-making around caesarean section in a low-resource setting.*		
Locality:	Saint Luke's Hospital	**Ethics committee ref.:**	National Health Science Research Ethics Committee
Primary investigator:	Wouter Bakker	**Contact phone number:**	**+265991694212**

CONSENT PAPER

These questions are part of the research study on quality safe motherhood.
They aim to see if you were properly informed before undergoing a caesarean section and if the health care personnel asked for your consent.
They also aim to see your current knowledge on caesarean section.
This research study will help us to identify shortcomings in the information provision prior to a caesarean section. This will help to improve safe motherhood.

RESEARCH METHODOLOGY
We will use questions.

ACTIVITIES DURING THE RESEARCH
If you accept to take part in this research, you will be asked questions and your part will end there. We will use your patient files to look at your HIV-status, amount of antenatal consults, parity, amount of caesarean sections and the indication for your current caesarean section.

ADVANTAGES AND DISADVANTAGES OF THIS RESEARCH
There is nothing to fear since there will be no new drugs or any kind of physical examination. There will be no direct advantages, but the results of the study will help to identify ways of strengthening patient education and respectful care given to pregnant women. You will receive an additional explanation of the risks of CS and its implications for future pregnancies.

THE RESEARCH STUDY IS NOT COMPULSORY
It is not compulsory to take part in the research study and to refuse to take part in this study will not affect the type of treatment that you are going to receive during this stay**.**

THE RIGHT TO WITHDRAW FROM THE STUDY
You have the right to withdraw from the study any time, without consequences.

CONFIDENTIALITY

We will make an effort to keep all information confidential, except when we have been asked by the law or the research bodies. Names shall not be used. Instead numbers shall be used. There will be no connection between your information and your identity.

THE RESULTS OF THE RESEARCH STUDY

You will be informed about the results of the study when we have finished scrutinizing them. You can contact the investigator any time for an update on the study results (see contact details).

RESEARCH POPULATION

Pregnant women who have undergone Caesarian Section are the ones required to take part in the study.

CONTACT DETAILS

If you have questions or comments concerning this research study, you can find the researcher:

Name, position:	Simon Zethof, co-investigator
Phone:	+265995661849
Email:	Siemzethof@hotmail.com

If you want to speak to an independent person you can find him on the address below;

Name, position	Mr J. Phiri, Senior Adminstrative Officer
Phone:	+0882010868 / 0999121039
Name, position	Mr P. Manjere, Human Resource Officer
Phone:	+0883377691 / 0999121039

You can also contact the National Health Science Research Ethics Committee

Name, position	Dr. Damson Kathyola, NHSRC representative
Phone:	+26 560 1726422, ask for Dr. Kathyola
Email:	directorgeneral@ncst.mw

Declaration by participant:
I hereby consent to take part in this study.

Participant's name: _____

Signature: _____ Date: _____

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____

PATIENT INFORMATION SHEET CHICHEWA

Study title:	*The quality of care for caesarean sections in Saint Luke's Hospital, Malawi: A mixed-method approach.*		
Locality:	Saint Luke's Hospital	**Ethics committee ref.:**	National Health Science Research Ethics Committee
Lead investigator:	Wouter Bakker	**Contact phone number:**	**+265995661849**

PEPALA LA CHILOLEZO

Mafunsowa akupanga mbali imodzi ya kafukufuku wa maphunziro a pamwamba a uchembere wabwino.
Zikukhudza ngati mwauzidwa moyenera musanapangidwe opareshoni ndiponso ngati a chipatala akufunsani zachilolezo chanu.
Zikhudzanso zomwe mukudziwa panopa za ma opareshoni.
Kafukufukuyu adzatithandiza kuona zofooka zimene zimapezeka popereka uthenga kwa mayi oyembekezera asanapangidwe opareshoni.

NDONDOMEKO YA KAFUKUFUKU

Ife tidzagwiritsa ntchito mafunso.

ZOCHITIKA MUKAFUKUFUKU AMENEYU

Ngati mutavomera kutenga mbali mukafukufukuyu,mudzafunsidwa mafunsondipo mbali yanu idzathera pomwepa. Tidzagwiritsanso ntchito ma fayilo anu popanga kafukufukuyu.

UBWINO NDIKUYIPA KWA KAFUKUFUKU AMENEYU

Palibe choopsa china chili chonse popeza sipadzakhala mankhwala achilendo kapena kuyezedwa kwina kulikonse.
Sipadzakhala ubwino wina uliwonse koma zotsatira zakafukufuku zizathandiza kupezera njira zolimbikitsa kudziwitsa ndi kuwonesetsa kuti zisankho za amayi apakati zikulemekezedwa.

KAFUKUFUKU AMENEYU SIWOUMILIZA

Kutengambali pakafukufuku ameneyu ndikosaumiriza ndipo kukanakutenga mbali pakafukufuku ameneyu sikudzakhudza chisamaliro chimene muyenera kulandira patsikuli.

UFULU OTULUKA MUKAFUKUFUKU AMENEYU

Muli ndi ufulu wonse kutuluka mukafukufuku ameneyu ndipo sipadzakhala chovuta china chili chonse.

KUSUNGA CHINSINSI

Tidzayetsetsa kusunga chinsinsi pa zonse zokhudza munthu wina aliyense kupatula pokhapokha ngati tafunsidwa ndilamulo kapena mabungwe oyang'anira kafukufuku. Mayina

sadzidzagwiritsidwa ntchito mmalo mwake manambala ndiamanene adzidzagwiritsidwa ntchito, sipadzakhala kugwirizana kwinakulikonse pa nkhani ndi mayina anu

ZOTSATIRA ZA KAFUKUFUKU
Mudzadziwitstsidwa zotsatira zakafukufuku ameneyu tikadzakamaliza kuunika bwinobwino

CHIWERENGERO CHA ANTHU OTENGAMBALI PAKAFUKUFUKU AMENEYU
Kafukufuku ameneyu adzafunika kwa amayi onse oyembekezera amene anapangidwa opaleshoni ndi amene adzatenge mbali.

MUNGATIPEZE BWANJI?
Ngati muli ndimafunso kapena ndemanga pokhudzana ndikafukufuku ameneyu, mukhoza kutifikira Kwa opanga kafukufuku;

Name, position:	Simon Zethof, co-investigator
Phone:	+265995661849
Email:	Siemzethof@hotmail.com

Ngati mukufuna kuyankhula ndi munthu wapadera mukhonza kumupeza pa keyala ili mmunsimu:

Name, position:	Mr J. Phiri, Senior Adminstrative Officer
Phone:	+0882010868 / 0999121039
Name, position:	Mr P. Manjere, Human Resource Officer
Phone:	+0883377691 / 0999121039

National Health Science Research Ethics Committee

Name, position	Dr. Damson Kathyola, NHSRC representative
Phone:	+26 560 1726422, ask for Dr. Kathyola
Email:	directorgeneral@ncst.mw

Ine…….. (Otengambali) ndawerenga zofunikirazi. Ndasankha kutenga mbali pakafukufuku ameneyu mosakakamizidwa. Ndamvetsetsa kuti ndili ndi ufulu kukana kuyankha funso komanso kutuluka mukafukufuku ameneyu nthawi ina iliyonse. Ndamvetsetsa kuti mayankho anga adzakhala achinsinsi

.

Kutsimikiza kwaotenga mbali	Tsiku
Umboni	Tsiku
Kutsimikiza Kwa opanga kafukufuku	Tsiku

CHALA

3b. Informed Consent Interview Health Workers

Research: Health Worker Perspectives on Informed Consent for Caesarean Sections.

Department	Obstetrics
Organization	Saint Luke's Hospital
Date	

Dear Sir, Madame,

The following interview will be conducted to gain insight in your perspectives on giving information to the patient and gaining her consent prior to CS. The interview will discuss personal experiences with informed consent, as well as thoughts about the information transfer, practical use of informed consent and ethical considerations.

- **The interviews are anonymous. The interviewee only states his/her function, age, gender, department and years of working experience.**
- **The interviews will be recorded and analyzed only by the interviewer.**
- **Comments may be used as quotes in the article. This, again, will be anonymous.**
- **The interview takes 30 minutes to 1 hour.**

By conducting interviews and analyzing them as one entity, the researcher tries to understand the process of informed consent and apply interventions were needed. This may improve the quality of care in Saint Luke's Hospital, but also may serve as an example for other health facilities.

This interview is not compulsory and will not affect your work in a negative way. The researcher may write during the interviews. The notations include observations and possible quotes.

I hereby give my consent for participating in this study

4. Data Collection Instruments

4a. Exit-Questionnaire

DATA COLLECTION SHEET **ENGLISH**

[Questionnaire: Quality of Consultation Caesarean Section**]**

Department	Obstetrics
Organization	Saint Luke's Hospital
Date	

Dear Madame,

This list of questions is part of a study on the quality of consultation in Safe Motherhood.
It will address whether or not you were informed sufficiently prior to your caesarean section and if healthcare providers asked for your consent.
It will also address your current knowledge of caesarean sections.
This study will enable us to identify shortcomings in the provision of information and improve Safe Motherhood for you and future patients.

- **If you find any of the questions hard to understand, you may ask the interviewer for clarification.**
- **If you find any of the questions offensive or do not want to answer them for any other reason, do not feel obliged to do so. Leave a blank space.**
- **The questionnaire should take 15 minutes to complete. You may quit the questionnaire anytime you like.**

The questionnaire is anonymous and will be analysed by an independent researcher.
Your answers will be confidential. Only the interviewer and researcher will take notice of them.
The filled-in answers will not affect the quality or accessibility of your healthcare in a negative way.
We will be using your patient records to identify the reason for your caesarean section as stated by the caregiver.

Part 1: Your social and demographic information

Instructions:

This part aims to collect information about your life.

When a line is depicted after a question, put your answer on the line.

Example question:

How many times have you been to Saint Luke's Hospital?

2

_____

When several options are given, pick one option (except when stated otherwise).

Example question:

Was your previous delivery a caesarean section?

a. Yes

b. No

Questions on patient demographics:

PICK ONE OPTION!

1. Are you able to read Chichewa?

a. Yes

b. No

2. Which tribe are you related to?

a. Yao-tribe

b. Chewa-tribe

c. Ngoni-tribe

d. Chotupa-tribe

e. Lomwe-tribe

3. How old are you? _____

4. Indicate your marital status:

a. married

b. single

c. relationship

5. Religion:

a. Christian
b. Muslim
c. Jehovah
d. Other
e. None

6. Occupation?

a. Employed
b. Business/self employed
c. Student/school
d. None
e. Farmer

7. Indicate your highest education level attained:

a. None
b. Primary school (Standard 1- 8)
c. Junior Secondary school (Form 1 and 2) - Junior Certificate of Education (JCE)
d. Senior Secondary school (Form 3 and 4) - Malawi Secondary Certificate of Education (MSCE)
e. College
f. University

8. How many times have you given birth? _____

9. How many caesarean sections did you have? _____

8. Which level of provider asked you for your consent prior to operation during your hospital stay?

a. Nurse/midwife
b. Doctor
c. Guardian
d. No one

Part 2: Received information and consent

Instructions:

Please answer these questions based on the counseling you have received for this C-section from the healthcare provider. The information should be received during THIS HOSPITAL STAY or antenatal consultations. It may either be mentioned before or after your C-section.

Example question.

Was your previous delivery a caesarean section?

a. Yes

b. No

1. Did someone from the hospital inform you of the reason for this caesarean section?

a. Yes

b. No

2. PICK ONE OPTION!

According to you, what was the reason for the caesarean section? PICK ONE OPTION!

a. Birth canal was too narrow for baby's head (CPD, obstructed labour, prolonged second stage, failed VBAC, macrosomia)

b. Problem with heart baby (Non-reassuring fetal status, fetal distress)

c. Problem with position of child (Fetal malpositioning, fetal malpresentation)

d. High blood pressure (Preeclampsia/eclampsia/HELLP syndrome)

e. Blood loss prior to labour (ante-partum hemorrhage, abnormal placentation, placenta praevia, placental abruption)

f. Cord was in front of the baby. (Funic presentation or cord prolapsed)

g. Uterine tear/rupture

h. Breech presentation in first pregnancy

i. 2 or more CS in history

j. Other _____

k. Don't know

3. Did someone from the hospital inform you on what a caesarean section involves? The doctor should have told you about the operation room (theatre) and the use of anesthetics (spinal block), and the possible complications of anesthetics?

a. Yes

b. No

4. Did someone from the hospital gave you information on the risks associated with a caesarean section during this stay?

a. Yes (go to question 5)

b. No (go to question 6)

5. PICK 3 OPTIONS!

Which of the following risks are MOST COMMON following a caesarean section? PICK 3 OPTIONS!

a. Increased risk of bleeding

b. Instruments left in abdomen

c. Maternal death

d. Infection

e. Extended recovery time

f. Becoming paralyzed

6. Did a healthcare provider explain that your future deliveries should be in the hospital, now that you've had a caesarean section?

a. Yes

b. No

c. Bilateral tubal ligation

7. Were you asked for your consent prior to this surgery?

a. Yes (go to question 9)

b. No (go to question 8)

8. Did you sign a consent form for this caesarean section?

a. Yes

b. No

9. If you were NOT asked for consent, why do you think this happened?

a. Doctor knows best

b. Women's feelings not considered

c. Unable to make decision due to drugs or complication

d. Sudden emergency

e. My guardian gave consent

f. High risk to baby

g. Other reason, fill in: _____

Part 3. Your Perspective on Hospital stay

Instructions:

The following instrument aims to give insight in your experiences of this hospital stay.
For each of the questions below, circle the response that best characterizes how you feel about the statement, where:
1 = Strongly Disagree, 2 = Disagree, 3 = Neither Agree Nor Disagree, 4 = Agree, 5 = Strongly Agree

Example:

	Strongly disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
I want Malawian healthcare to be the best.	1	2	3	4	5

	Strongly disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
I felt informed about my cesarean section during my hospital stay.	1	2	3	4	5
The provided information was hard to understand for me.	1	2	3	4	5
I had the chance to ask questions.	1	2	3	4	5
I want to receive more information on cesarean sections prior to surgery.	1	2	3	4	5
Asking for consent prior to cesarean section is important to me.	1	2	3	4	5

This is the end of the questionnaire. Your participation will be very helpful in our research for better obstetric care. Thank you for participating!!

DATA COLLECTION SHEET FOR INTERVIEWER

Number given by interviewer: _____

Handed out by: Interviewer/Student

Date of CS, time performed _____

Exact indication in patient records: _____

Written by consent: Patient/Guardian/No one

HIV-status: Positive/Non-reactive/Unknown

Amount of antenatal consultations: _____

Type of CS: Emergency / Elective

Any complications 3-days post CS? _____

Any long-term complications? _____

DATA COLLECTION SHEET **CHICHEWA**

[Mafunso: Ubwino wogawana nzeru pa nkhani za caesarean (operashoni)]

Department	Obstetrics
Organization	Saint Luke's Hospital
Date	

Zikomo Amai,

Mafunsowa akupanga mbali imodzi ya kafukufuku wa maphunziro a pamwamba a uchembere wabwino.
Zikukhudza ngati mwauzidwa moyenera musanapangidwe opareshoni ndiponso ngati a chipatala akufunsani zachilolezo chanu.
Zikhudzanso zomwe mukudziwa panopa za ma opareshoni.
Kafukufuku yu azatithandiza kuona zina zimene tingadziwe zothandiza uchembere wabwino.

- **Ngati pali mafunso ena amene musakuwamvetsa, muwafunse amene akukufunsani.**
- **Ngati pali mafunso amene pazifukwa zosiyanasiyana simungathe kuyankha, mutha kutsiya osayankha.**
- **Mafunso ayenera kutenga 15 minutes (mphindi 15). Mutha kutsiya nthawi ina iriyonse.**

Mafunso awa ndi achinsinsi azangoonedwa ndi wofufuza wa pa dera basi.
Mayankho anu azakhala achinsinsinso owonedwa ndi wokufunsani komanso wofufuza okhawo.
Mayankho anu sadzasintha chithandizo kapena kulandira chithandizo mochepera.
Tizigwiritsa zolembedwa zachipatala poona chifukwa cha opareshoni yanu monga analembera a dokotala.

Part 1: Za gulu lanu maphunziro, zakubadwa ndi kufa
Malangizo:
Mbali ino ndi yofuna kudziwa za moyo wanu.
Pakakhala mdzere pa funso mulembe yankho lanu pamdzere.

Chitsanzo:
Mwapitapo kangati ku Saint Luke's Hospital?

2

_____

Ngati pali mayankho ambiri, sankhanipo limodzi (kupatulapo ngati palembedwa zina).

Chitsanzo:
Kubereka kwanu komalizira Kunali kwa opareshoni/kong'amba?

c. Inde
d. Ayi

Mafunso okhudza kasinthidwe ka chiwerengero cha wodwala:

SANKHANIPO CHIMODZI!

1. Mungathe kuwelenga Chichewa?
a. Inde
b. Ayi

2. Mtundu wamu ndi chani?
a. Yao
b. Chewa
c. Chotupa
d. Ngoni
e. Lomwe

3. Muli ndi zaka zingati?

_____

4. Munakwatiwa:
a. Okwatiwa
b. Sindinakwatiwe
c. Ndili ndi chibwenzi

5. Mpingo:

a. Mkhilisitu

b. Musilamu

c. Mboni za Yehova

d. (Mpingo) wina

e. Palibe

6. Mumagwira ntchito?

a. Ndimagwira

b. Bizinesi/yandekha

c. Ndikuphunzira/ pa sukuhi sukulu

d. Palibe

e. Mlimi

7. Sukulu munalekedza mu chiyani?

g. Palibe / Sindinapite
h. Primary school (standard 1 – 8)
i. Junior Secondary school (Form 1-2) - Junior Certificate of Education (JCE)
j. Senior Secondary school (Form 3-4) - Malawi Secondary Certificate of Education (MSCE)
k. College
l. University / Yunivesite

8. Mwabereka kangati? _____

9**. Mwapangidwa opareshoni kangati?** _____

8**. Anakufotokozerani dongosolo la opareshoni yanu ndi ndani?**

a. A nasi / A namwina

b. A dokotala

c. Ondidikilira (guardian)

d. Palibe

Part 2: Zomwe ndinauzidwa ndi chilolezo

Malangizo:
Yankhani mafunso malinga ndi momwe mwauzidwira ndi a Chipatala zokhuzana ndi opareshoni. Izi ziyenera kulembedwa ulendo umene mwagonetsedwa uno kapena ku sikelo.
Chitsanzo:
Kodi mwana wanu omalidzira anali wa opareshoni?

a. Inde
b. Ayi

1. **Alipo ena a chiptala akudziwitsani chimene chimapangitsa opareshoni?**

a. Inde

b. Ayi

2. SANKHANIPO CHIMODZI!

Mukuganidzira kuti chimapangitsa ndichiyani? SANKHANIPO CHIMODZI!

l. Chifukwa cha kuchepa kwa njira kapena kukula kwa mutu wa mwana?

m. Mwana amabanika

n. Mwana sanagone bwino

o. BP yokwera/kuthamanga kwamagazi

p. Kutaya magazi kwambiri ndisanabereke

q. Kutsogoza mchombo wamwana.

r. Kung'ambika kuphulika kwa chiberekero

s. Kutsogoza matako amwana pamimba yoyamba

t. Kupangidwa opareshoni yamwana kawiri

u. China, -

_____

v. Sindikudziwa

3. Alipo wina wa chipatala amene anakudziwitsani zomwe zimachitika popanga opareshoni?

A dokotala/anesi amayenera kuudzani za chipinda cha opareshoni (fiyeta) ndi kagwiritsidwe ka mankhwala oletsa ululu komanno kwipa kwake.

a. Inde

b. Ayi

4. Alipo wina wa muchipatala amene wakuudzani za kuopsya kwa opareshoni?

a. Inde

b. Ayi

5. SANKHANI ZITATU MWA IZI!

Ndi zoopsya ziti mwa izi zimene zimachitika nthawi zambiri pa opareshoni? SANKHANI ZITATU MWA IZI!

a. kutaya magazi kwambiri

b. Kuyiwla zipangizo zogwiritsa ntichito m'mimba mwanga.

c. Imfa pobereka

d. Kuola kwa bala

e. Nthawi yaitali yochilira

f. Kufa kwaziwalo

6. Kodi a chipatala anakufotokodzerani kuti kubereka mtsoglo kuyenera kuchitikira muchiptala poti pano mwachitidwa opareshoni?

a. Inde

b. Ayi

c. Ndinatsekedwa

7. Munafunsidwa za chiloledzo chanu musanachitidwe opareshoni?

a. Inde

b. Ayi

8.Munasaina kalata yobvomeredza kuchitidwa opareshoni?

a. Inde

b. Ayi

9. Ngati simunafunsidwe za chiloledzo chanu, mukuganidzira kuti izi zinachitika chifukwa chiyani?

a. A dokotala akudziwa zonse bwino

b. Maganizo a azimai saganidziridwa.

c. Ndinalephera kupanga chiganizo chifukwa cha mankhwala kapena bvuto lina.

d. Mabvuto adzidzidzi

e. Amene amandiyang'anira anapereka chiloledzo.

f. Zoopsya kwa mwana

g. Chifukwa china, lembani: _____

Part 3. Malangizo omwe mungapereke okhuzana ndi chipatalachi

Malangizo:

Mafunso otsatira wa athandizira kuti mudzathandizidwe monga momwe mukufunira mukadzabweranso.

Pafunso linalililonse pali mayankho asanu, sankhani yankho limodzi lomwe mukuona kuti ndi loyenera. Muzungulize yankho loyeneralo.

1 = Kutsutsa kwambiri, 2 = Kutsutsa, 3 = Pakati ndipakati, 4 = Kubvomera, 5 = Kubvomera kwambiri

Chitsanzo:

	Kutsutsa kwambiri	Kutsutsa	Pakati ndipakati	Kubronera	Kubvomera kwambiri
Ndikufuna umoyo wabwino wa chimalawi kukhala opambana koposa.	1	2	3	4	5

	Kutsutsa Kwambiri	Kutsutsa	Pakati ndipakati	Kubvomera	Kubvomera Kwambiri
Ndinauzidwa za opareshoni nthawi imene ndinali muchipatala.	1	2	3	4	5
Chidziwitso chinaperekedwa chinali chobvuta kumvetsa.	1	2	3	4	5
Ndinali ndi mwai ofunsa mafunso.	1	2	3	4	5
Ndikufuna ~~€~~ chidziwitso chokwanira pa zong'amba thupi nthawi ya opareshoni isanakwane.	1	2	3	4	5
Kufunsa chiloredzo nthawi yong'amba thupi isanakwane ndi chofunikira kwa ine.	1	2	3	4	5

Apa ndi pamapeto a mafunso athu. Kutenga nawo gawo pa kafukufuku yu kutandizira kuti uchembere wabwino upite patsogolo. Zikomo kwambiri chifukwa chotenga nawo mbali.

DATA COLLECTION SHEET FOR INTERVIEWER

Number given by interviewer: _____

Handed out by: Interviewer/Student

Date of CS, time performed _____

Exact indication in patient records: _____

Written by consent: Patient/Guardian/No one

HIV-status: Positive/Non-reactive/Unknown

Amount of antenatal consultations: _____

Type of CS: Emergency / Elective

Any complications 3-days post CS? _____

Any long-term complications? _____

4b. In-depth interview guidance

Interview subject list: Informed Consent for Caesarean Section, Health Worker Perspective.

Introduction: **Scope of research, discuss informed consent.**
Interviewee characteristics: **Function, gender, age, current occupation, years of working experience.**

1. **Personal experiences with IC**
   a. In how many informed consent processes prior to CS have you been involved?
   b. Can you describe your last IC process prior to CS? Elaborate.
   c. Did any of the women ever refused the operation? Elaborate.
   d. Did you encounter a situation where a woman went to CS without gaining informed consent?
   e. Would you consider your experiences with informed consent positive or negative? Why?
2. **Definition of informed consent**
   a. Describe the definition of informed consent in a few sentences.
      i. Different aspects?
      ii. Purpose?
   b. What is the effect on the patient?
   c. What is the effect on the health worker?
3. **IC in clinical practice**
   a. How should a regular IC process for CS look like?
      i. Which points should be discussed?
      ii. Who should discuss it? Clinician or nurse?
      iii. Should it be discussed with patient or guardian?
      iv. Should the patient or guardian give consent?
      v. Situations where IC is unfavorable? Skip IC?
   b. What are the barriers for IC?
      i. Patient characteristics
      ii. Time management
      iii. Emergency setting
   c. How to overcome the barriers mentioned?
4. **Ethical considerations**
   a. Informed consent is a fictional approach, because:
      i. Most women do not have the medical expertise to comprehend the provided information.
      ii. Most patients expect the doctor to make a decision for them and do not want to be informed and involved in the decision making.
      iii. The clinician will provide selective information to coerce the patient into his option of choice.
      iv. A women giving no for an answer will not be tolerated. She will be forced to do whatever the clinician thinks is best under these circumstances.
   b. How do you assess the capability of a woman to consent? Is any woman in pain uncapable? Does it make a differences IC process involves the guardian rather than the patient?
   c. "Every women has the right to information, informed consent and refusal, and respect for her choices and preferences, including companionship during maternity care." What do you think of this statement? Is the right to informed consent a Human right? Is it usable in clinical practice?
   d. If a women refuses a CS, despite the damage to mother and child, should we respect this decision? Who should have the last word? Woman or clinician?
5. **Conclusion:**
   a. Definition of informed consent?
   b. Advantages?
   c. Disadvantages?
   d. Challenges?
   e. Want to add something?

5. Support Letter Institution

ANGLICAN DIOCESE OF UPPER SHIRE (ADUS)

HEALTH DEPARTMENT
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ZOMBA, MALAWI

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Tel : +265 9 99 121 039
Bishop: The Right Rev'd Brighton Vitta Malasa **: +265 8 84 478 897**

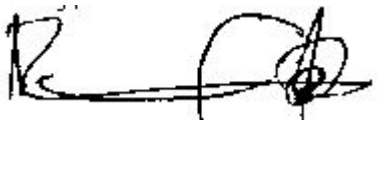
Dear members of the National Health Science Research Committee,

On behalf of St Luke's Hospital, I would like to offer my support to Dr. Wouter Bakker to conduct a study to visualize the theme of information transfer prior to a caesarean section.

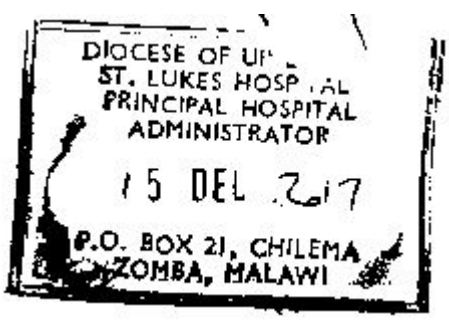
The study: The quality of care in caesarean sections in Saint Luke's Hospital, Malawi: A mixed-method approach, is not only of assistance to us as a hospital, but could serve a greater purpose as an example to improve on the patients right of information in obstetric health care.

Hereby I, endorse this study to investigate current practices of informed consent and stimulation of patient education.

Sincerely,



Winasi Boma, Principal Administrator St. Luke's Hospital.



Reporting checklist for quality improvement study.

Based on the SQUIRE guidelines.

Title: A pre-post implementation study of a complex intervention to improve informed consent for caesarean section in Southern Malawi

Authors: Zethof S, Bakker W, Nansongole F, Kilowe K, van Roosmalen J, van den Akker T

		Reporting Item	Page Number
	#1	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patientcenteredness, timeliness, cost, efficiency, and equity of healthcare)	1
	#02a	Provide adequate information to aid in searching and indexing	2
	#02b	Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions	2
Problem description	#3	Nature and significance of the local problem	3
Available knowledge	#4	Summary of what is currently known about the problem, including relevant previous studies	3,4
Rationale	#5	Informal or formal frameworks, models, concepts, and / or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work	4
Specific aims	#6	Purpose of the project and of this report	4
Context	#7	Contextual elements considered important at the outset of introducing the intervention(s)	4
Intervention(s)	#08a	Description of the intervention(s) in sufficient detail that others could reproduce it	5,6
	#08b	Specifics of the team involved in the work	5,6

Study of the Intervention(s)	#09a	Approach chosen for assessing the impact of the intervention(s)	6,7
	#09b	Approach used to establish whether the observed outcomes were due to the intervention(s)	7,8
Measures	#10a	Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability	7
	#10b	Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost	7
	#10c	Methods employed for assessing completeness and accuracy of data	7,8
Analysis	#11a	Qualitative and quantitative methods used to draw inferences from the data	7,8
	#11b	Methods for understanding variation within the data, including the effects of time as a variable	7,8
Ethical considerations	#12	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest	8
	#13a	Initial steps of the intervention(s) and their evolution over time (e.g., time-line diagram, flow chart, or table), including modifications made to the intervention during the project	N/A
	#13b	Details of the process measures and outcome	8,9
	#13c	Contextual elements that interacted with the intervention(s)	9
	#13d	Observed associations between outcomes, interventions, and relevant contextual elements	9
	#13e	Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s).	9
	#13f	Details about missing data	8
Summary	#14a	Key findings, including relevance to the rationale and specific aims	11
	#14b	Particular strengths of the project	11

Interpretation	#15a	Nature of the association between the intervention(s) and the outcomes	11
	#15b	Comparison of results with findings from other publications	11
	#15c	Impact of the project on people and systems	12
	#15d	Reasons for any differences between observed and anticipated outcomes, including the influence of context	12
	#15e	Costs and strategic trade-offs, including opportunity costs	N/A
Limitations	#16a	Limits to the generalizability of the work	12
	#16b	Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis	12
	#16c	Efforts made to minimize and adjust for limitations	12
Conclusion	#17a	Usefulness of the work	12,13
	#17b	Sustainability	12,13
	#17c	Potential for spread to other contexts	12,13
	#17d	Implications for practice and for further study in the field	12,13
	#17e	Suggested next steps	12,13
Funding	#18	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting	13

Comments:

#13a: With the intervention clearly described in text and the short timespan we felt a flow chart would not have any additional benefit

#15e: No cost analysis was done. The intervention had minimal costs and this was out of the scope of the research

BMJ Open

A pre-post implementation study of a multi-component intervention to improve informed consent for caesarean section in Southern Malawi

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Primary Subject Heading:	Obstetrics and gynaecology
Secondary Subject Heading:	Health policy, Ethics
Keywords:	Maternal medicine < OBSTETRICS, TROPICAL MEDICINE, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, MEDICAL ETHICS, Informed consent, Caesarean Section

TITLE: A pre-post implementation study of a multi-component intervention to improve informed consent for caesarean section in Southern Malawi

AUTHORS: Zethof S[1]*, Bakker W[2,3]*, Nansongole F[2], Kilowe K[2], van Roosmalen J[1,3], van den Akker T[1,3]

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WORD COUNT: 4019

ABSTRACT

Objective

Surgical informed consent is essential prior to caesarean section, but potentially compromised by insufficient communication. We assessed the effect of a multi-component intervention on women's recollection of information pertaining to informed consent for caesarean section in a low-resource setting, thereby contributing to respectful maternity care.

Design

Pre-post implementation study, conducted from January to June 2018, using exit-surveys.

Setting

Rural 150-bed mission hospital in Southern Malawi.

Participants

A total of 160 postoperative women were included: 80 pre- and 80 post-implementation.

Intervention

Based on observed deficiencies and input from local stakeholders a multi-component intervention was developed, consisting of a standardised checklist, wall poster with a six-step guide and on-the-job communication training for health workers.

Primary and secondary outcome measures

Individual components of informed consent were: indication, explanation of procedure, related risks, implications for future pregnancies and verbal enquiry of consent, which were compared pre- and post-intervention using $\chi 2$ test. Generalized linear models were used to analyse incompleteness scores and recollection of the informed consent process.

Results

The proportion of women who recollected being informed about procedure-related risks increased from 25/80 to 47/80 (OR 3.13 [95% Confidence Interval 1.64-6.00]). Recollection of an explanation of the procedure

increased from 44/80 to 55/80 (OR 1.80[0.94-3.44]), implications for future pregnancy from 25/80 to 47/80 (1.69[0.89-3.20]) and of consent enquiry from 67/80 to 73/80 (OR 2.02 [0.73-5.37]). After controlling for potential confounders, incompleteness scores were 26% lower post-intervention (Exp(β)=0.74; 95% CI 0.57 – 0.96). Recollection of common complications increased by 29% (Exp(β)=1.29; 95% CI 1.01 – 1.64). Recollection of the correct indication did not differ significantly.

Conclusion

Recollection of informed consent for caesarean section improved after implementing a multi-component intervention involving a standardized checklist, wall poster guide and on-site training of health workers. Obtaining informed consent for caesarean section is an essential component of respectful maternity care.

KEYWORDS

Informed Consent, Caesarean Section, Low-resource setting, Respectful Maternity Care

ARTICLE SUMMARY

Strengths and limitations of this study

- Based on locally identified insufficiencies in clinical practice
- Use of generalized linear models to quantify effect of intervention.
- Convenient study design with limited resources: limited sample size and follow-up and no quality control during implementation phase.
- Use of incompleteness rather than completeness score, to attain Poisson distribution.

BACKGROUND

Informed consent is key to medical practice and embedded in national and international standards such as the Code of Ethics and Professional Conduct of the Medical Council of Malawi, and the International Covenant on Civil and Political Rights.[1-3] Valid informed consent is defined as being able to accept an intervention willingly after receiving adequate and comprehensible information about risks and benefits.[4] It is a preoperative necessity for all surgical procedures including caesarean section (CS), the most frequently performed surgical procedure in many parts of the world.[5] In obstetrics, explanation of procedures and seeking consent are

associated with improved rating of birth experience, while non-consented care is seen as a deterrent to skilled birth care utilization.[3, 6]

Several reports have recognised weaknesses in the process of acquiring surgical informed consent for obstetric procedures, such as providing no explanation of the indication for surgery, procedure-related risks or the post-operative trajectory.[7-16] Women may feel pressured into undergoing surgery when little information is provided or information is not understood.[9, 14] At the same time, they may experience the provision of informed consent as a bureaucratic procedure not primarily serving their own interests.[8, 9] A variety of factors influence information transfer and retention, as well as shared-decision making. Poor communication between woman and health worker may be compounded by language barriers, a low education level on the side of the woman, but also by lack of consent-related knowledge or communication skills among health workers.[17-19] Additionally, emergency situations in which the informed consent process takes place may not be conducive to information retention due to shortage of time, physical limitations, anxiety and pain.[13, 20] To overcome such barriers, health workers must improve women's ability to participate in the decision-making process as fully as possible and as far as reasonably practicable.[21, 22] Information should be provided without use of medical terminology, adjusted to the language and understanding of the woman. It is preferentially given during pregnancy or, if at all during labour, between contractions.[17, 21]

Studies implementing interventions to improve informed consent for surgical procedures (including CS) in low-resource settings are scarce, with most literature focussing on elective procedures in high-income countries.[8, 23-25] However, there are examples of studies using multi-component interventions focussing on non-abusive and respectful maternity care.[26-30] The landscape analysis by *Bowser and Hill* identified non-consented care as one of the contributing factors to disrespect and abuse in childbirth, stating that "there is a lack of routine patient information, communication and consent protocols for obstetric procedures" in regions all over the world.[3] We postulated that a multi-component intervention standardizing the informed consent process could improve women's recollection of having consented to care and, in this way, their birth experience. Consenting to obstetric interventions including CS is an important element in the broader concept of respectful maternity care.

The objective of our study was to evaluate the effect of introducing a multi-component intervention consisting of a checklist, a six-step informed consent guide and communication training for health workers involved in maternity care.

METHODS

Study design, setting and participants

This prospective pre-post implementation study was performed between January 1st, 2018 and June 1st, 2018 in the maternity department of a rural mission hospital in the southern region of Malawi. Maternity staff comprised of locally trained midwives, associate clinicians (non-physician clinicians with a predominantly practical training of four years) and two Medical Doctors in Global Health and Tropical Medicine (MD GHTM), trained in the Netherlands.[31] The maternity department provides services free-of-charge and has an average of 200 births per month. CS rate in the study period was 15.7% (82 out of 523 total births) in the pre-intervention phase, and 19.5% (81/415) in the post-intervention phase. The hospital had one operating theatre available for all procedures. All women undergoing CS were eligible for inclusion. Elective CS was defined as CS planned prior to onset of labour, while in unplanned CS the decision was made during the first or second stage of labour. Exclusion criteria were inability to participate due to bad clinical condition, referral or death prior to survey, or unwillingness to participate. The informed consent process was initiated by the midwife on duty, a medical doctor or associate clinician. After CS had been performed, women were admitted for at least 72 hours in the postnatal ward for observation and discharged in case no complications arose. Figure 1 shows an overview of the study process. The study protocol is attached as a supplementary file (supplementary file 1).

Data collection

Prior to implementation, 80 women were surveyed between January 1st and March 15th 2018 using a standardised questionnaire. Surveys were performed on the day of discharge by one of the authors (SZ), assisted by rotating nursing college students who had not been involved in direct care for the woman. Data related to timing of surgery, indication and whether it was an elective or unplanned procedure were extracted from the records. After this initial period, two weeks were allocated to intervention development and implementation. Subsequently, 80 additional women were included between April 1st and June 1st 2018. Sample sizes were based on convenience and logistical possibilities.

Intervention development and implementation

Together with representatives of the maternity department, a multi-component intervention was designed consisting of a standardised checklist, wall poster with a six-step informed consent guide and communication training of health workers. The interventions aimed at addressing deficiencies observed in the pre-intervention period and brought forward by local stakeholders. This involved inadequacy of risk discussion, both in approach and content, and lack of women's involvement in decision-making. Interventions were supposed to reinforce one another by repeating important information and implementing checklist and poster into the training. The intervention consisted of the following:

1) *A standardised checklist (supplementary file 2).* Lack of informed consent protocols resulted in this checklist for health workers encompassing five components of the informed consent process: indication for operation with benefits of the proposed procedure, elaboration on the procedure, discussion of associated risks, implications for future pregnancies and verbal consent enquiry (table 1).Components were based on the National Institute for Health and Care Excellence clinical guidelines on caesarean section.[32] This particular guideline was used for its international recognition and clear outline on women-centred care. One additional checkbox addressed the opportunity given to the woman to ask questions. The importance of providing a woman with such opportunity was stressed in the communication training. The checklist was integrated into the facility's pre-operative form, thereby reassuring that the surgeon or midwife would bring the checklist along for consent enquiry. The original form only stated whether consent was given, without specifying what had been discussed during the consent process.

Table 1. Definition of primary outcomes

Completeness – Which topics have been discussed preoperatively?	
Indication	Indication for caesarean section.
Procedure	Transfer to theatre, lower abdominal incision, use of anaesthetics and possibly blood products.
Risk discussion	Information on commonly associated and serious risks.
Implications for future pregnancies	Need to deliver in secondary health facility in subsequent pregnancies. Advice to have bilateral tubal ligation after third caesarean section.*
Consent	Written and verbal consent has been collected.
Recollection – What information does the mother (or the woman) recollect?	

Recollection of indication	Woman names indication for caesarean section as mentioned in her medical records.
Recollection of common complications	Score from 0 – 3, woman picks the following common complications out of a list of six options; - Extensive bleeding (>1000ml) - Infection (wound infection, endometritis, peritonitis) - Extended recovery time as opposed to vaginal birth (three-day hospital admission and no lifting for six weeks) - Other included options: leaving instruments in the abdomen, permanent paraplegia, maternal death**

* Based on national consensus
** Extracted from *Litorp et al.* and pilot study.[11]

2) *Posters with a six-step informed consent guide (supplementary file 3).* These posters were placed in every labour room at eye level and served as an additional reminder to maternity care providers to initiate the informed consent discussion. The guide accentuated risk discussion due to its inadequacy in the pre-intervention period. Frequently occurring risks were separated from rarer risks, following consent advice from the Royal College of Obstetricians and Gynaecologists.[33] We emphasised that, although it was set up as a step-by-step guide, health workers apply information in accordance with women's needs and circumstances.

3) *Communication training.* In the second week of development and implementation, a training session for clinical staff in the maternity department was organized. The training was established by the research team (SZ, WB, FN, KK) and developed based on the Royal College of Obstetricians and Gynaecologists Clinical Governance Advice on obtaining valid informed consent, Medical Council of Malawi Code of Ethics and Professional Conduct and input from the clinical team.[2, 21] The training consisted of an introduction into the theory of informed consent and a respectful woman-centred approach during labour, followed by counselling methods, using the standardised checklist and poster. We highlighted timing of conversation, addressing uncertainties and questions and the importance of acquiring verbal consent. Role-play in settings of both elective and unplanned CS was performed and subsequent feedback given by other participants applying Pendleton's rules for professional feedback.[34] The single training session was attended by ten midwives, six associate clinicians and two MD GHTM. Not all rotating clinicians and midwives were present due to conflicting clinical duties. Questions from participants were addressed and participants invited to provide input into improving the consent guide.

Checklist and guide were discussed in a plenary session with all hospital staff, which provided an opportunity for additional adjustments. Health workers were then provided copies of checklist and guide. After the plenary session, posters were placed in the ward and use of the form with checklist started. No other interventions related to quality of care were implemented during the post-intervention period.

Study tool

For the pre- and post-implementation surveys, an exit questionnaire was created in English and Chichewa using forward and subsequent backward translation. (Supplementary file 4 and supplementary file 5) An expert committee consisting of experienced clinicians and midwives working in the maternity department of the hospital were involved in validating its content. This included how indications for CS should be grouped, which complications should be known to women and what information is indispensable with regard to future pregnancies. Additionally, participant and procedure related variables with potential impact on outcomes were identified. Use of medical terminology was reduced to ensure that all questions could easily be understood. A three-week pilot study was performed, whereby in the first week women were asked open-ended questions to obtain insight in probable answers. Mentioned risks related to CS were noted and used as answer options in the later version of the questionnaire. In the following two weeks, clarity of the study tools was examined and the order of questions and answer options adjusted in order to be easily understood by participants.

Outcome variables

Primary study outcomes were level of incompleteness and recollection of common complications and indication (table 1). Incompleteness was defined as the number of informed consent components not discussed according to the woman. For each component, the woman was asked whether it was discussed during the consent process. Each of five components was dichotomously scored (1 = not discussed, 0 = discussed) and rated as equally important. This resulted in an "incompleteness score" ranging from 5 (=none of the components discussed) to 0 (=all components discussed). An "incompleteness" rather than a "completeness" score was used, due to adoption of a Poisson distribution by the outcome variable. To assess recollection of common complications a list with complications was provided, of which three were commonly associated with CS and three were not. For every common complication mentioned, one point was given. Common complications deemed as essential knowledge for women in our setting were extensive bleeding of

more than one litre, infections such as wound infection, endometritis or peritonitis and an extended recovery time compared to vaginal birth. Three other choices were added to the list, based on complications named by women during the pilot study. Recollection of indication was measured by the percentage of women who described the indication for CS as stated in the medical records. Indications were categorised using plain, non-medical language such as "problem with heartrate of the child" or "high blood pressure".

Analytic approach

For descriptive analyses unpaired t-test, Mann-Whitney U test or $\chi 2$-test were used depending on the type of variable and normality of its distribution. For completeness, each individual component of informed consent was compared between the pre- and post-intervention groups using $\chi 2$-tests with odds ratio's and 95% confidence intervals. Additionally, generalized linear models were used to identify the attribution of the intervention on dependent variables: "incompleteness score", "number of recollected common complications" and "correct indication recall percentages". For the incompleteness scores a Poisson regression was adopted, due to a Poisson distribution of the dependent variable (one sample independent KS test ($p=0.57$)). The model's goodness of fit (Pearson $\chi 2/df$) was 0.96 and the omnibus test showed a significant difference between the model and intercept model ($p<0.001$). Number of recollected complications was normally distributed according to Jarque-Bera test of 1.44 (p-value >0.1) and a linear model was used. Goodness of fit was 0.61 and the omnibus test showed a significant difference ($p=0.03$). Binomial logistic regression was used with correct indication recall percentages as dependent variable. Goodness of fit was 1.06 and omnibus test showed no statistically significant difference ($p=0.14$). Type and timing of CS, antenatal consultations and prior CS were identified as explanatory variables based on the literature.[13, 33, 35] Additional explanatory independent variables were identified based on subsequent application of variables in the different models, and included when $p<0.05$. Exponentiated regression coefficients ($Exp(\beta)$) and their 95% confidence intervals were reported for the Poisson and logistic bivariate model, whereas for the linear model regression coefficient (β) were reported. All analyses were performed with IBM SPSS 24.0. Alpha was set at 0.05. Analysis and interpretation of data adhered to SQUIRE 2.0 (Standards for Quality Improvement Reporting Excellence) guidelines.[36]

Ethical consideration

The study received ethical approval by the National Health Sciences Research Committee of Malawi (approval number 1995) and a declaration of no-objection by the Leiden University Medical Centre Ethical Committee (reference number P18.027). Permission was granted by the hospital management to conduct the study. All participants were provided with an informed consent sheet either in English or Chichewa, regarding the purpose of the study, their right to stop participation at all times and a request to access their medical files. For women who were illiterate, the interview assistant read the consent form out loud and elaborated. Finger prints were accepted as signatures for women who did not know how to write. No names were included during data collection to ensure confidentiality. All women were asked to give informed consent before inclusion. Patient files were accessed only after approval was obtained. Patient records were brought with them to the exit-survey and extracted data was linked to their anonymised study number. Immediately after collection, data were stored in a locally encrypted database, only accessible by the primary investigators.

Patient and public involvement

The importance of improving informed consent was highlighted in various hospital advisory committee meetings, in which local chiefs present concerns of the community. This laid the foundation for this study. During the pilot phase, women were asked to comment on study tools, in order to make these as easily understandable and applicable as possible.

RESULTS

During the study period, 163 women were eligible for inclusion, of whom 160 (98%) participated. One woman was discharged before the scheduled interview and two refused to participate. All participating women completed the interview.

Participant- and procedure-related characteristics

The majority of women had had no previous CS; 54 (67.5%) pre- and post-intervention. (table 2). In both groups the highest percentage of women were aged between 20 and 24 years. Median age of the pre-intervention group was 26 (IQR 21-30) as compared to 24 (IQR 21-30; p=0.96) in the post-intervention group. Inability to read English or Chichewa was observed in 17 (21.3%) women pre-intervention and in 15 (18.8%) post-intervention. No statistically significant differences were found with regard to women's parity, antenatal consultations, highest educational level and religion. Daily occupation differed statistically significantly

(p<0.05), with more self-employed women in the pre-intervention group (21, 26.3%) compared to the post-intervention group (7, 8.8%). The majority of CS were unplanned in both groups, 66 (82.5%) and 68 (85%). A statistically significant difference was observed in the attendance of medical doctors during CS: 12 CS (15%) in the pre-intervention group compared to 37 CS (46.3%) in the post-intervention group. No statistically significant differences in timing of or indications for CS were found.

Table 2. Participant and procedure characteristics for the pre- and post-intervention group

	Pre-intervention [N=80] (%)	**Post-intervention [N=80] (%)**	p-values
Age			0.96
- 15 – 19	16 (20)	14 (17.5)	
- 20 – 24	22 (27.5)	29 (36.3)	
- 25 – 29	21 (26.3)	12 (15)	
- 30 – 34	15 (18.7)	14 (17.5)	
- 35+	6 (7.5)	11 (13.8)	
- Median Age <IQR>	26 <21-30>	24 <21-30>	
Parity			0.83
- 1	31 (38.8)	31 (38.8)	
- 2	21 (26.3)	18 (22.5)	
- >2	28 (34.9)	31 (38.8)	
Prior CS			0.24
- 0	54 (67.5)	54 (67.5)	
- 1	18 (22.5)	23 (28.8)	
- >1	8 (10)	3 (3.8)	
Inability to read English/Chichewa (%)	17 (21.3)	15 (18.8)	0.69
Highest educational level attained			0.06
- No formal education	7 (8.8)	6 (7.5)	
- Primary school	36 (45)	34 (42.5)	
- Junior secondary school	11 (13.8)	5 (6.3)	
- Senior secondary school	18 (22.5)	20 (25)	
- College/University	8 (10)	15 (18.8)	
Religion			0.84
- Christian	40 (50)	41 (51.3)	
- Jehovah's witness	2 (2.5)	1 (1.3)	
- Muslim	38 (47.5)	38 (47.5)	
Occupation			<0.05
- Employed	8 (10)	12 (15)	
- Business/self-employed	21 (26.3)	7 (8.8)	
- Student	3 (3.8)	3 (3.8)	
- Housewife	29 (36.3)	27 (33.8)	
- Farmer	19 (23.8)	31 (38.8)	
Mean number of antenatal consultations +/-SD	3.7 +/- 1.1	3.53 +/- 1.1	0.25

Timing of CS			0.42
- 8AM – 6PM	46 (57.5)	51 (63.7)	
- 6PM – 8AM	34 (42.5)	29 (36.3)	
Type of CS			0.67
- Elective CS	14 (17.5)	12 (15)	
- Unplanned CS	66 (82.5)	68 (85)	
Prevalence of indication categories			0.19
- Obstructed labour	45 (56.3)	49 (61.3)	
- Non-reassuring fetal status	7 (8.8)	3 (3.8)	
- Malposition/malpresentation	6 (7.5)	12 (15)	
- Preeclampsia/HELLP	2 (2.5)	1 (1.3)	
- Antepartum haemorrhage	3 (3.8)	0 (0)	
- Cord presentation/prolapse	2 (2.5)	2 (2.5)	
- Uterine rupture	2 (2.5)	1 (1.3)	
- ≥2 CS in history	8 (10)	3 (3.8)	
- Other*	5 (6.3)	9 (11.3)	
Surgeon performing CS			<0.05
- MD GHTM	12 (15)	37 (46.3)	
- Clinical Officer	68 (85)	43 (53.7)	

* Including (preterm) prelabour rupture of membranes, on woman's request.

Completeness of informed consent

In the post-intervention group 47 (58.8%) women expressed that they had received information on risks before surgery, as compared to 25 (31.3%) in the pre-intervention group (OR 3.13; 95% CI 1.64 – 6.00) (table 3). Changes in explanation of the procedure (OR 1.80; 95% CI 0.95 – 3.44), inclusion of implications for future pregnancies (OR 1.69; 95% CI 0.89 – 3.20), and verbal consent enquiry (OR 2.02; 95% CI 0.73 – 5.37) were noted, though none of these were statistically significant. The component "indication for the procedure" was mentioned equally in both groups (96.3%). Independent variable analysis showed "Age" and "Ability to read English/Chichewa" to be significantly associated with incompleteness scores. No correlation was found with type of surgeon or daily occupation. Incompleteness scores were 26% lower in women surveyed after implementation of the intervention (Exp(β)=0.74; 95% CI 0.57 – 0.96) (table 4). Age was associated with a 4% decrease per year (Exp(β) = 0.96; 95% CI 0.94 – 0.99). Inability to read English or Chichewa provided 30% higher incompleteness scores (Exp(β) = 1.3; 95% CI 1.02 – 1.83).

Table 3. Completeness of informed consent; number of informed consent aspects discussed during

preoperative counselling. Comparison between pre- and post-intervention group.

	Pre-intervention [N=80] (%)	Post-intervention [N=80] (%)	Odds ratio (95% CI)
Mentioned indication	77 (96.3)	77 (96.3)	1 (0.20 – 5.11)
Procedure explained	44 (55)	55 (68.8)	1.80 (0.94 – 3.44)
Associated risks explained	25 (31.3)	47 (58.8)	3.13 (1.64 – 6.00)
Need to deliver in hospital next time/ Need to deliver by CS next time / BTL	43 (53.7)	53 (66.3)	1.69 (0.89 – 3.2)
Written and verbal consent	67 (83.3)	73 (91.3)	2.02 (0.73 – 5.37)

Table 4. Generalized linear model: Poisson. Variables associated with incompleteness scores.

Variables		Exponentiated regression coefficiënt, β	95% CI	p-value
Group	Pre-intervention	1		
	Post-intervention	0.74	0.57 – 0.96	0.02
Type of CS	Unplanned	1		
	Elective	0.83	0.54 – 1.29	0.41
Timing of CS	Day-time (8AM – 6PM)	1		
	Night-time (6PM – 8AM)	1.24	0.95 – 1.62	0.12
Prior CS	0	1		
	1	0.92	0.66 – 1.28	0.62
	>1	1.53	0.93 – 2.52	0.09
Antenatal consultations		1.02	0.91 – 1.16	0.70
Age		0.96	0.94 – 0.99	0.00
Ability to read English/Chichewa	Yes	1		
	No	1.3	1.02 – 1.83	0.04

Recollection of informed consent

Multivariate Poisson regression analysis identified an increase of 0.25 recollected complication in the post-intervention group when corrected for other variables (β=0.25; 95% CI 0.01 – 0.49) (table 5). Age of participants was identified as an additional explanatory variable and associated with 0.02 more common complications recalled per year (β=0.02; 95%CI 0.00 – 0.04). Logistic binomial regression examined that women counselled post-implementation were 2.11 times more likely to recall the indication for CS (Exp(β)= 2.11; 95%CI 0.96 – 4.60). (Table 6) No additional explanatory variables were identified to be associated with correct indication recall percentages.

Table 5. Generalized linear model: Linear. Variables associated with number of recollected common complications.

Variables		Regression coefficiënt, β	95% CI	p-value
Group	Pre-intervention	0		
	Post-intervention	0.25	0.01 – 0.49	0.04
Type of CS	Unplanned	0		
	Elective	0.27	-0.09 – 0.63	0.14
Timing of CS	Day-time (8AM – 6PM)	0		
	Night-time (6PM – 8AM)	-0.02	-0.28 – 0.23	0.86
Prior CS	0	0		
	1	0.06	-0.23 – 0.34	0.69
	>1	-0.18	-0.68 – 0.33	0.49
Antenatal consultations		0.10	-0.14 – 0.21	0.09
Age		0.02	0.00 – 0.04	0.05

Table 6. Generalized linear model: Binary Logistic. Variables associated with correct indication recall percentages.

Variables		Exponentiated regression coefficiënt, β	95% CI	p-value
Group	Pre-intervention	1		
	Post-intervention	2.11	0.96 – 4.60	0.06
Type of CS	Unplanned	1		
	Elective	2.66	0.78 – 9.08	0.12
Timing of CS	Day-time (8AM – 6PM)	1		
	Night-time (6PM – 8AM)	1.63	0.72 – 3.71	0.25
Prior CS	0	1		
	1	0.58	0.24 – 1.41	0.23
	>1	0.27	0.07 – 1.14	0.08
Antenatal consultations		1.07	0.75 – 1.53	0.71

DISCUSSION

This study evaluated a multi-component intervention, consisting of an informed consent checklist, guide and training, providing standards and tools for the informed consent process prior to CS. The intervention had been developed and implemented in cooperation with clinical staff hoping to increase perceived acceptability, a necessary condition for effectiveness.[37] Other community or system related issues potentially influencing the intervention's effectiveness were normalisation of non-consented care, and lack of patient autonomy and legal redress mechanisms.[3] Although these issues were touched upon, the current intervention will not suffice as a complete solution. We opted for a prospective pre-post implementation study design because randomisation was not compatible with the study setting and pre-intervention data deemed to be necessary for development

and implementation of the multi-component intervention. No quality control measures were performed to assess concurrent acceptability during the implementation phase. Future research should aim to implement these measures as a means to identify obstacles that providers may experience while implementing this or similar tools, thereby increasing intervention adherence.

The percentage of women stated to have received information on procedure-related risks increased with 27.5% after implementation. Furthermore, the procedure was explained more frequently and more women were able to reproduce the indication for CS, although this trend was not statistically significant. An explanation for the latter not reaching the level of statistical significance could be that the informed consent consultation in the pre-intervention group already included an explanation of the proposed procedure and implications for future pregnancies in considerably large, although still deficient, proportions. Additional and more specific measures may be required to further improve recollection of these items. The supplementary poster mainly focussed on risk-discussion, possibly overlooking other components. Consent enquiry was incomplete in both groups, which in every case was explained by absence of verbal consent. This is a major concern, since surgery should not be performed without consent. After controlling for other explanatory independent variables, incompleteness scores were 26% lower in women counselled post-intervention. This implies that more components of informed consent were included after implementation. The variables "attended by MD GHTM" and "daily occupation" differed pre- and post-intervention, but no association with incompleteness scores were found in the multivariate model. A higher age of the woman, however, was associated with lower incompleteness scores, even after correcting for parity and the presence of prior CS. Possibly younger women experience discriminatory behaviour based on providers' prejudice, as has been reported previously.[3] Additionally, young women might be less involved in decision making when seniors are present to speak for them.[19, 38] Age and inability to read Chichewa or English resulted in higher incompleteness scores. This underlines the need for verbal explanation and consent enquiry in addition to the written consent form. Written consent forms should be made available in local languages.

Besides more risk discussions being included during the informed consent process, the multi-component intervention contributed significantly to recollection of common complications, with an increase of the number of recalled risks. Despite its statistical significance, the effect size was considered to be small. The intervention did result in higher correct indication recall percentages, although this did not reach the level of statistical

significance. It is important that information is reproducible. A signed consent form may not be valid if information has not been understood.[39, 40] Women's educational level, language competency and provider's effective communication of procedure, risks and recovery have previously been identified as important determinants to comprehend the informed consent process.[40, 41] Despite inclusion of more informed consent components post-implementation, major discrepancies may exist between provider and women's perspectives of the informed consent process.[42] Health workers could verify understanding by asking women to describe provided information in their own words.[23] Written material in women's vernacular may increase understanding, but written consent forms were previously found to be difficult to understand by women going for unplanned obstetric surgery.[9, 13] Use of audiovisual material before the start of the consent process has largely been studied in high-resource settings.[23] Future studies could investigate their effectiveness in resource- and time-limited circumstances comparable to ours.

Decisions regarding intervention design and outcome measurement may have had some undesirable consequences. Opting for standardised consent checklists carries the risk of reinforcing the 'repetitive nature' of the informed consent consultation for clinicians and of reducing clinicians' and women's motivation and involvement. In this manner, informed consent processes may actually decrease women's autonomy.[9, 43] Efforts were made to sustain motivation and participation by including verbal consent as one of the five components and giving women and their guardians an opportunity to ask for clarification. Involvement in the informed consent process may give women the feeling of being in control and enhance their relationship with healthcare providers. These are two facilitators of a positive birth experience.[44] In addition to standardization, we measured outcomes at patient level, which is an indirect reflection of interventions at health system level. Interference of woman related factors such as prior experiences, emotional barriers and physical impairment may occur, and may not be covered by our intervention. Nevertheless, the quality of informed consent is reflected in woman recollection.

Our study has several limitations. In order to use a Poisson regression analysis, "incompleteness" rather than "completeness" scores were used, increasing goodness-of-fit of the model. This makes it harder to interpret. Secondly, outcomes could have been confounded by co-occurring contextual differences pre- and post-implementation, because no control group was included.[45] However, no additional interventions were implemented at facility level and no interventions reported by local government at the time. Thirdly, informed

consent also may have improved due to the mere presence of the research team, although the majority of this team consisted of hospital staff and the effect was minimized by a short time elapse between pre- and post-implementation phases. Due to this short time elapse, however, we were not able to assess sustainability of the intervention. Additional limitations were incomplete validation of our self-designed questionnaire with regard to test-retest reliability, inter-rater reliability and the tool's responsiveness to changes in outcome, and existing language barriers between interviewer and participants. To diminish these effects, we designed the questionnaire to be simple and give little room for interpretation, with both multiple choice and closed-ended questions. When necessary, translation was done by local nursing college students. The presence of health workers might have led to socially desirable answers, although none of the participating students were involved in the consent process or birth.

In future research, outcomes other than completeness of the consultation and women's recollection are worth investigating. New studies could explore influence of our multi-component intervention on women's satisfaction, anxiety and long-term comprehension, and this intervention or similar context-specific interventions should be assessed in other settings.

CONCLUSION

Implementation of our multi-component intervention was associated with improved recollection of the informed consent process for caesarean section. Women stated more frequently to have received information on the procedure, possible complications and implications for future pregnancies. Recollection of common complications increased significantly following implementation. These results suggest that standardisation and training positively influence informed consent in a resource-poor setting, and thereby promote respectful maternity care.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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DATA STATEMENT

De-identified participant data and informed consent forms will be published online through the Dryad repository immediately after publication of the manuscript.

LICENCE STATEMENT

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AUTHOR CONTRIBUTIONS

SZ and WB drafted the study protocol, with help of TvdA and JvR. FN and KK provided feedback on the study design and helped implementing the study in the facility. SZ and FN drafted the study tool. KK assisted in

inclusion and logistics around the interviews. SZ conducted the interviews analysed the data together with WB.

SZ and WB drafted the manuscript which was commented on by all authors and approved for submission.

CAPTIONS

Figure 1: Flowchart of study design

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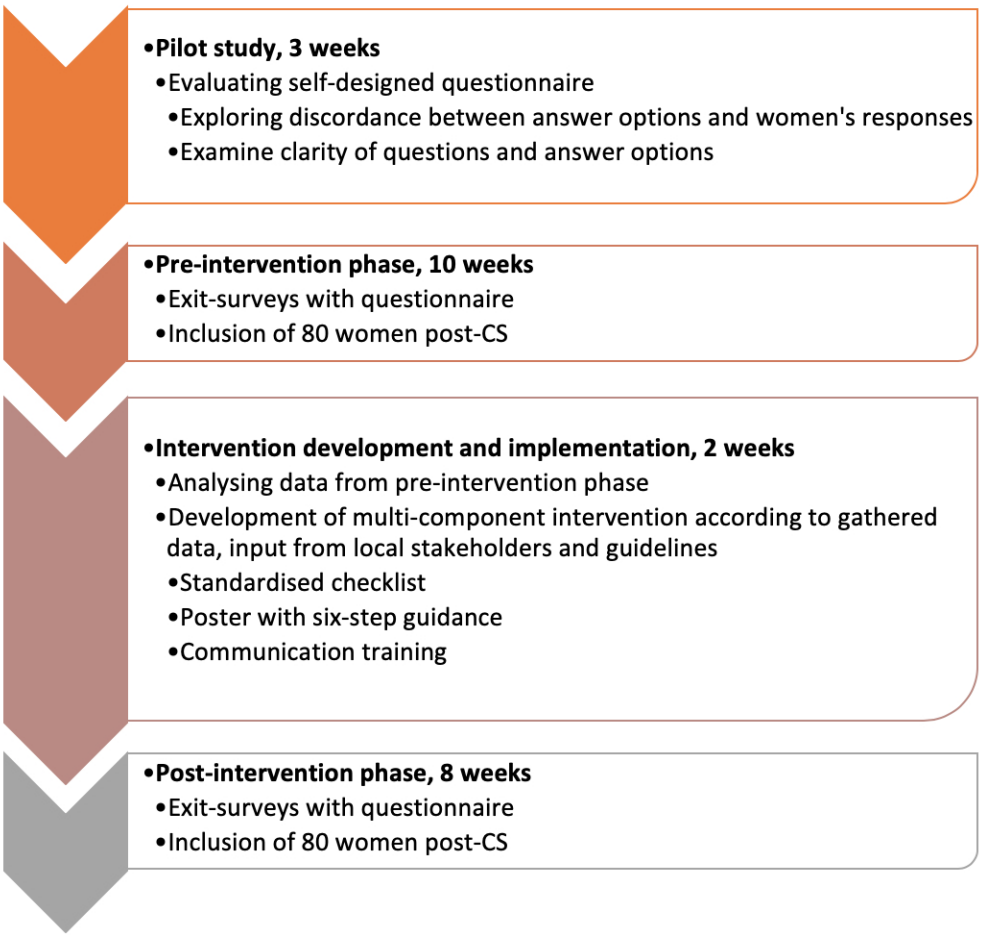

Figure 1: Flowchart of study design

DECISION-MAKING AROUND CAESAREAN SECTION IN A RURAL HOSPITAL IN MALAWI

STUDY PROTOCOL

Study site: Saint Luke's Hospital, Malosa
Duration project: 1 February 2018 – 1 February 2019
Primary investigator: Wouter Bakker, Medical Officer
Email: bakker.stlukes@gmail.com Phone: +265991694212

Abstract

Research problem: Quality of care surrounding CS has to be investigated due to reports of disrespect and abuse in maternity health care. CS numbers are rising and some of them are performed unnecessarily. Health workers should ensure that the patient's right to information and consent are respected. Health worker perspectives on information transfer and gaining consent should be assessed to implement interventions accordingly and successfully. With this study, we assess the current quality of consultation for caesarean section and aim for improvement.

Objectives:

1. Analyse indications for caesarean sections and the use of interventions in labour.
2. Analyse the quality of the pre- and postoperative consultation for CS according to the patient's experience and recollection.
3. Identify circumstantial factors and patient characteristics which influence the informed consent process.
4. Analyse health worker perspectives on the use of informed consent prior to CS, in both emergency and elective settings.
5. Study the effectiveness of a standardized informed consent checklist.

Hypothesis: We hypothesize that the use of oxytocin and vacuum extractions can be improved in order to prevent unnecessary CS. We also hypothesize that the information transfer in consultation for CS is not according to accepted standards. Our proposed standardized informed consent checklist may aid us in reaching these standards. We also hypothesize that patients literacy, type of CS and performance of CS during night influence the effectiveness of our consultation. This may help in optimizing informed consent in specific groups.

Methods: A mixed-method approach, consisting of:

- Retrospective cohort analysis of all deliveries in 2015 and 2016 on indications for caesareans and the use of interventions in labour.
- Interview-administered questionnaire study (controlled before and after study) to identify the quality of informed consent prior to CS.
- Semi-structured interviews with health workers on the use of informed consent prior to CS.
- Implementation of intervention package to support a standardized informed consent checklist.

Benefits and Risks: No serious harm is inflicted to the patient by performing this study. Precautionary measures are taken to protect sensitive information of the study participants. No direct benefits are gained for the patient, other than an extra thorough explanation of risks of CS and post-CS care. However, this work lays the foundation for interventions which improve the quality of care in Saint Luke's Hospital.

Use of results: Primarily as foundation from where we can improve Respectful Maternity Care in Saint Luke's Hospital. Possibly presented during conferences in places in Malawi and the Netherlands. An effort will be made to submit an article to a Malawian peer reviewed journal. An article could be submitted to an international journal, after review by the NHSRC.

Table of contents

1. Proposal Summary

Title of Proposal	Decision-making around caesarean section in a low-resource setting.
Principal investigator	Wouter Bakker, MD

1. RESEARCH QUESTION TO BE ADDRESSED

How can we improve decision-making around caesarean sections in a rural hospital in Malawi and thereby reduce the amount of unnecessary caesareans, by looking at indications, interventions and informed consent?

2. RATIONALE FOR RESEARCH

Malawi currently has a population caesarean section (CS) percentage of 6.1%, of which 1.3% are elective procedures, and it has been slowly rising since 1992. [1] Hospital-based CS rates, however, are way higher. It is critical that this rise in CS is justified by the correct indications and is accompanied by an increase in awareness of the necessity of informed consent. Increasing the use of interventions in labour, like amniotomy, oxytocin administration and vacuum extraction could improve chances for vaginal delivery and prevent an unnecessary CS. Besides evidence based quality care, mothers deserve information and autonomy in their health, pregnancy and childbirth. Discussing the process and indications of caesareans thoroughly between clinicians and patients can assist in decision making. Several reports have recognised insufficiencies in the informed consent process prior to caesarean sections, as well as in the broader concept of RMC during facility-based deliveries in low-income countries. Despite its importance and being one of the most practical factors of the Bowser and Hill model to improve, the current state of informed consent for CS in Malawi has not be documented yet. Also, health staff perspectives on the need for informed consent and what it should accomplish might be helpful in improving informed consent and thus quality of care. This mixed-method study aims to give insight in the current practice of CS and its effectiveness in a low-income setting. Providing baseline data on the current state may present the need for improvement and lay the foundation for interventions, such as standardization of the consent process.

Based on our clinical experience, we hypothesize that a proportion of caesareans performed could be avoided and that use of interventions can be extended. We also hypothesize that the information transfer in consultation for CS might not always be according to accepted standards. However, health workers probably recognize the shortcomings in our consultation and may come up with suggestions how to overcome these barriers. We expect them to see the necessity and use of informed consent, and be open to possible additions. Our proposed informed consent checklist may aid us in reaching these standards.

OBJECTIVES

1. Identify indications for caesarean sections in order to find opportunities to prevent unnecessary caesareans to reduce maternal morbidity and mortality.
2. Determine use of evidence-based interventions in labour in our setting as amniotomy, oxytocin administration and vacuum extraction

3. Analyse the completeness and recollection of the pre- and postoperative consultation for CS, according to the patient's experience.
4. Identify circumstantial factors and patient characteristics which influence the informed consent process.
5. Analyse health worker perspectives on and experiences with the use of informed consent prior to CS, in both emergency and elective settings.
6. Study the effectiveness of an informed consent checklist on completeness of informed consent and patient recollection.

3. METHODS

The study will take place at Saint Luke's Hospital in Malosa, a rural CHAM facility. Maternity care here is free of charge for patients in the surrounding area.

This study project will make use of a mixed method approach, consisting of the following:

1. Retrospective data analyses of all vaginal births, vacuum extractions and caesarean sections over a two-year period: All patient data from the labour ward from the years 2015 and 2016 are collected. These files consist of partographs and information on admission and follow-up.
   a. Indications for caesareans done in this period will be extracted and compared to national protocols. The partographs will be assessed to see if the conditions for the indication are met and indications will be classified accordingly.
   b. All information concerning decisions during the labour process are collected: artificial rupture of membranes and induction or augmentation with oxytocin.
   c. All vacuum extractions will be evaluated on their indication, outcome and use before and after re-introduction and training.
2. Quantitative survey into quality and uptake of informed consent: In the period January – September 2018, a survey will be conducted into the quality of informed consent on caesarean sections. Exit-interviews with patients who underwent caesarean will be conducted, focused on their experiences and ability of information recall. An intervention to improve the quality of informed consent will be designed and assessed in the study period.
3. Qualitative analysis of perception of informed consent by health workers: To gain more insight in the use, functionality and challenges with informed consent in the setting, interviews with health workers will be conducted in the same period as stated above, following a semi-structured questionnaire. This will be combined with focus group discussions to get a clear picture on the perceptions of staff on informed consent.

4. RISKS & BENEFITS

Benefits and risks have been thoroughly discussed in the research group and are considered minimal. The patients undergoing exit-interviews might be at risk of being disadvantaged by health workers in future care, because of criticism on information transfer. This risk is minimized by anonymizing the questionnaire outcomes and administer the questionnaire on discharge in a separate room. Outcomes are only available to the independent researcher.

The health workers included in the qualitative in-depth interviews might be at risk of being criticized because of views not in accordance with hospital policy. This risk is minimized by anonymizing the collected interview data by an independent interviewer (SZ) and using a transcription for analysis, rather than the voice recording itself.
The performance of this study will increase awareness on the decision-making process around caesareans and the informed consent process. This may lead to a better health worker – patient relationship, of which staff and patients will benefit, and to a higher standard in quality of care and communication. Patients will receive an additional explanation of risks and implications on future pregnancies of their caesarean section, which might influence postoperative outcomes in a positive way.
Reviews of the ongoing study and the data collected will be conducted as per policies of the NHSRC. Any serious events will be reported promptly as required. This study does not involve any new therapies.

5. COSTS & COMPENSATION

Participants will not receive any direct compensation for participation in the study. However, they will receive additional consultation on post-operative risks and implications on future pregnancies associated with CS. Participants will not be asked to assume any out-of-pocket costs for their participation.

6. CONFIDENTIALITY ASSURANCES

All data, including study identification numbers, will be stored electronically under password protected software. All research paperwork including data collection forms, will be kept in a locked cabinet in the administration office of Saint Luke's Hospital; only the primary investigator will have access to it. Data will be anonymized to maintain strict protection of confidentiality. All members of the research team are well aware of issues related to confidentiality, especially with regards to HIV status. Furthermore, all personnel have been trained in subject protections and Good Clinical Practice. An independent ombudsman may be contacted by the patient if any wrongdoing has occurred. The patient information sheeth has been attached as a supplemental document to this application.

7. CONFLICT OF INTEREST

The research team does not have any conflicts of interest in performing this study.

8. COLLABORATIVE AGREEMENTS

The proposed study will be a collaboration between Saint Luke's Hospital and Leiden University Medical Centre. Letters of approval and support are provided as supplemental documents to this application.

9. INTENDED USE OF RESULTS

The results will be presented to the hospital staff and will hopefully assist in improving maternity care. Study results will be summarized and explained in an accompanying article. If the authors decide to publish the article, a copy will be send to the National Health Sciences Research Committee for review. An effort will be made to publish the findings in at least one local or international peer reviewed journal. Also, a final report will be send to the NHSRC after finishing the study.

The results can be a foundation for quality of care interventions, such as an informed consent checklist and focus group discussions with obstetric health staff. It may be presented in conferences in Malawi or internationally to address the importance of this subject. Furthermore, the whole project will give experience for the staff involved, which might motivate and assist them in their future career. Outcomes of this relatively small study project hopefully leads to more research being performed on the subject, for example in bigger multi-centre studies.

2. Main Proposal

Title of project	Decision-making around caesarean section in a low-resource setting.
Principal Investigator	Wouter Bakker, MD
Place of Study	Saint Luke's Hospital

1. BACKGROUND AND JUSTIFICATION

Unnecessary caesarean sections

Caesarean sections are rising worldwide, in both high- and low-income settings.(1–3) In their in 2015 updated statement on caesarean sections the WHO concluded that we should aim for a population based caesarean rate of 10%, with above that no significant improvement on maternal and neonatal outcome.(4) In a low-income setting as Malawi, caesarean section rates on population level still appear to be low, but on institutional level they are rising.(5) Caesarean sections are associated with severe maternal outcomes like hysterectomy, blood transfusion, need for ICU admission and death and this association is even higher Africa compared to Latin-America or Asia.(6–9) A study from South-Africa found a three times increased risk of maternal death after caesarean compared to vaginal birth, with haemorrhage as leading cause of death.(10) The risk on infections or uterine rupture in further pregnancies can also not be underestimated, especially not in a country where the average fertility rate is above five.(11–14) It remains therefore crucial to carefully select those cases eligible for surgical intervention and prevent to perform unnecessary procedures.(2) Where it used to be a problem of too little, too late and mothers and children died of not getting access to surgical care, we nowadays could also talk of too much, too soon. Critical evaluation of protocols, indications and individual cases could raise knowledge about necessary and unnecessary caesareans and assist in management of further cases. This can be done by audit of indications, group discussions and case evaluations. The World Health Organization advises to monitor CS rates on facility level.(4) There are many different classifications for caesareans described and a systematic review described the Robson classification as being the best suitable for identifying indications for caesareans.(15) This classification divides the indications for caesareans in different groups, but provides no means to compare indications to international standard protocols, to assess whether the decisions for performing an caesarean was based on correct grounds.(16) This could be useful at facility but also regional level, as a first step to identify pitfalls and work on reducing unnecessary procedures.

Interventions in labour

Analysing the indications of caesareans, we can identify in which area's we could improve to prevent ending up in unnecessary caesarean sections by using interventions in labour. These evidence based interventions are basic, broadly available and less risky than surgery. They require good monitoring of labour, for example using partographs. This is the case already in a big part of the world, although documentation is sometimes suboptimal.(17) Amniotomy and oxytocin administration should be available in every BEmOC setting, and should be used in case of poor progress of labour, if correctly identified.(18–20) Maintaining experience with this could prevent performing unnecessary caesarean sections. In the case of prolonged second stage of labour, forceps or vacuum extraction could provide assistance before opting for emergency caesarean section and local training

and support could improve its use.(21,22) Pro-active support of labour could also result in successful vaginal birth after caesarean, preventing complicated repeat caesareans.(13,23) Together, correct and indicated use of these evidence based interventions could assist further in preventing unnecessary procedures and deliver mothers the care they deserve.

Informed consent

Besides evidence based quality care, mothers deserve information and autonomy in their health, pregnancy and childbirth. Discussing the process and indications of caesareans thoroughly between clinicians and patients can assist in decision making. One of the universal rights for childbearing women is the right to information and informed consent. Being able to accept an intervention willingly after receiving adequate and comprehensible information about the risks and benefits of the suggested treatment and alternatives, is defined as valid informed consent.(24) In the Bowser and Hill model on disrespect and abuse, non-consented care is one of the categories and could lead to reduces accessibility of health facilities, risking complications in pregnancy, labour or the postnatal period.(25) Although forming a necessity, informed consent can be suboptimal, leading to questions, confusion and dissatisfaction with patients.(26,27) The use or misuse of informed consent is easily monitored at facility level and information on this could give insight in areas of improvement. Several reports have recognised insufficiencies in the informed consent process prior to caesarean sections (28-30), as well as in the broader concept of RMC during facility-based deliveries in low-income countries. (25, 31-33) Causes that inhibit informed consent practices are low level of education of the patient population, poor communication between doctor and patient, not enough time given for obtaining consent, extensive use of medical terminology and low level of knowledge of informed consent among doctors.(29) On a structural level, poor working conditions caused by system deficiencies leading to high workloads among practitioners, may also add to the problem.(34,35) The deficiencies in the informed consent process result in the preservation of false perspectives women have of caesarean sections. Prior counselling to C-sections with comprehensible information about the indication, procedure, common complications and implications on future pregnancies (36) might enhance women's understanding and thereby diminish misconceptions of the proposed surgery. As of yet, very few data is known on the use and quality of informed consent for surgical procedures in a low-resource setting. Identifying this and creating opportunities to improve the consent process can contribute to the decision-making and quality of care around caesarean sections.

2. HYPOTHESIS

We hypothesize that a significant amount of caesareans could be avoided and that there are opportunities during labour to do so. Also, we predict that the current the consultation prior to a caesarean section is suboptimal and that not all patients can reproduce their indication and the risks of a surgical intervention. Patient educational level and time of surgery might influence the information transfer effectiveness. Health workers might assist in identifying shortcomings and give insight in clinical practice of the consultation. With these inputs, an intervention package will be implemented consisting of a informed consent checklist, assessing the identified barriers and tackling them. We hypothesize that

with this approach we will improve the recollection of the patient and make the consultation more complete.

3. OBJECTIVES

The broad objective of this study is to improve the current informed consent consultation for caesarean section. This objective can be specified by the following objectives;

1. Identify indications for caesarean sections in order to find opportunities to prevent unnecessary caesareans to reduce maternal morbidity and mortality.
2. Determine use of evidence-based interventions in labour in our setting as amniotomy, oxytocin administration and vacuum extraction
3. Analyse the completeness and recollection of the pre- and postoperative consultation for CS, according to the patient's experience.
4. Identify circumstantial factors and patient characteristics which influence the informed consent process.
5. Analyse health worker perspectives on and experiences with the use of informed consent prior to CS, in both emergency and elective settings.
6. Study the effectiveness of an informed consent checklist on completeness of informed consent and patient recollection.

4. METHODOLOGY

Study site

The project will conducted in St. Luke's Hospital in Malosa, Malawi. The hospital is based in the southern region of Malawi. St. Luke's is a CHAM (Christian Health Association of Malawi) facility, working with a principle of minor user fees for their service. Maternity care is free of charge for the catchment population through the governments Service Level Agreement (SLA). The 150 bed rural hospital offers all types of care, including comprehensive emergency obstetric care for pregnancies from all gestational ages, with an average number of 2500 births per year. It serves a catchment population of roughly 30,000. The caesarean section rate was 19% in 2015 and 23% in 2016. This increase led to questions with hospital management and the request for further investigation. The principal investigator works full-time as a medical officer in St. Luke's since 2016 and has on the ground experience in the labour ward. He has close contact with management, hospital staff and patients and acquired insight in local problems and needs.

Study period

The whole study project will roughly take place between January 2018 and January 2019, but data of previous periods will be incorporated (from 2015 onwards).

Study design

The projects has a mixed-methods study design, consisting of a retrospective data analysis of all vaginal births, vacuum extractions and caesarean sections over a two-year period, a quantitative survey into quality and uptake of informed consent and a qualitative analysis of perceptions of health workers on informed consent . When shortcomings and barriers are identified, we propose to implement a structured informed consent checklist in

concordance with instructions on usage. The factors of influence we identified in both the analysis of the questionnaires and interviews, we will implement in the intervention.

Retrospective data analyses of all vaginal births, vacuum extractions and caesarean sections over a two-year period.

3500 case files of women who delivered in Saint Luke's Hospital between 1 January 2015 and 31 December 2016 will be collected and analysed retrospectively. Files consist of partographs and information on admission and follow-up. The information is collected in a database and statistical analysis on three major subjects will be done. The following information is gathered;

1. Indications for caesareans done in this period will be extracted and compared to national protocols. The partographs will be assessed to see if the conditions for the indication are met and indications will be classified accordingly.
2. All information concerning decisions during the labour process is collected: artificial rupture of membranes and induction or augmentation with oxytocin. The usage of these methods will be evaluated.
3. All vacuum extractions will be evaluated on their indication, outcome and use before and after re-introduction and training, which took place in first quarter of 2016

Quantitative survey into quality and uptake of informed consent.

Between January 2018 and September 2018 a structured exit-questionnaire will be administered to all patients delivering via CS in Saint Luke's Hospital. We aim to include 150 patients in total. The first 75 patients will be included for the analysis of the current status of the completeness and effectiveness of the informed consent consultation. The following 75 patients are included after implementation of an intervention, for measuring its effectiveness. Approximately 30 patients deliver by CS each month in the hospital. All consenting women who underwent CS can be included, either emergency operations or elective surgery. Exclusion criteria are non-consenting women and women not fit enough to participate due to post-operative complications. During the first months of the inclusions, the construction and implementation of the intervention takes place, based on the gathered data and identified shortcomings.

The quality of consultation is assessed by the completeness and recollection according to the patients' experience. In order to assess the completeness, the patient will be asked about several aspects of the consultation prior to CS. Based on international guidelines (36), the following information should be given to the patient:

1. Reason for the procedure.
2. What the procedure involves.
3. Associated risks.
4. Implications on future pregnancies.

Additionally, she should be asked verbally for consent of proposed procedure. We add one extra aspect for verbal consent gathering by health worker;

5. Asking for verbal consent.

Based on these five criteria, percentages of occurrence can be calculated and a mean score of completeness from 0 – 5 can be given.

The recollection of the patient will be assessed by two different measures;

a. The percentage of patients able to recollect the indication for their CS as mentioned in their patient file.
b. The percentage of patients able to recollect the most common risk factors of CS.

The checklists will be interview-administered, because additional explanation can be given to patients where necessary. The interviews will be performed by an independent interviewer, not involved in routine patient care (SZ). The interviewer will make clear to the patient that the questionnaire is voluntary and not part of routine care. Questionnaire administration takes place right before patients are discharged. Patient files will be analysed to gather patient demographics, including amount of antenatal consultations, HIV-status, time of surgery and presence of written consent. The rest of the socio-demographic data is gathered during the interview itself. This includes tribe-allocation, literacy, educational level, marital status and amount of previous deliveries and caesarean sections. The interviewer will work guided by the Chichewa questionnaire and will be assisted by a translator from the hospital, oriented on the study objectives and methods. This can either be a nurse, student or support staff, since the questions are straightforward and mostly multiple-choice. Data will immediately be entered in the databank, to assure the quality of the data entry. Analysis will be performed with IBM SPSS Statistics version 24. The database will be created during the study period. Descriptive analysis will be used to identify the percentage of criteria met in the total group. Pre- and post-intervention groups will be compared with either a Chi-square test or unpaired t-test.

Qualitative analysis of perception of informed consent by health workers.

Between April 2018 and July 2018, in-depth interviews will be held with health workers related to obstetric healthcare working in the antenatal clinic, maternity department or theatre. We aim to include 20 participants and have at least one focus group discussion. The interviews will encompass several aspects regarding informed consent for CS. The interview tool includes:

1. Personal experiences with informed consent.
2. Definition and goals of informed consent.
3. Daily practice of informed consent.
4. Barriers to informed consent.
5. Ethical considerations linked to informed consent.

Convenience and snowball sampling will be used and data will be collected until data saturation is reached. Interviews will be conducted by an independent researcher (SZ) to prevent courtesy bias, following a semi-structured questionnaire. The interviews will be recorded, transcribed and analysed with qualitative data analysis software MAXQDA. Coding will be done in order to identify themes around the subject. Data will be processed anonymously. No incentives are given for participation. The questionnaire and interview checklist are provided as supplemental documents to this application.

Sample size

Approximately 30 patients deliver by CS each month in the hospital. All consenting women who underwent CS can be included, either emergency operations or elective surgery. Exclusion criteria are non-consenting women and women not fit enough to participate due

to post-operative complications. Sample size is based on the amount of time available, but aimed at a total of 150 inclusions.
For the qualitative part, data will be collected until data saturation is reached, which we based on experience expect around 20 interviews, using convenience and snowball sampling. We aim to include at least one focus group discussion.
The retrospective review will include roughly 3500 records.

5. DISSEMINATION OF FINDINGS

The direct aim of the project is quality improvement in the facility in the field of caesarean section indications, interventions in labour and informed consent. By focussing on these aspects of care, health workers have the opportunity to analyse their own practice and improve their skills, of which both health workers and patients will benefit. We hope identified barriers can lead to development of training packages of which all health workers and ultimately patients can benefit. All results will be presented on facility and if possible on district level. An effort will be made to publish the findings in at least one local or international peer reviewed journal, of which a copy will be send to the National Health Sciences Research Committee for review. Also, a final report will be send to the NHSRC after finishing the study. Outcomes of this relatively small study project hopefully leads to more research being performed on the subject, for example in bigger multi-centre studies.

6. PERSONNEL

Wouter Bakker, medical doctor, is the primary investigator and will lead the project.
Siem Zethof, master-student in medicine, will take responsibility of the data gathering for both the quality survey with exit-questionnaires and the interviews with health workers.
Felix Nansongole, clinical officer, is involved in the development of the research tools and patient approach.

7. WORK-PLAN

The project will take place in its entirety between January 2018 and January 2019. The first months are used for protocol writing and ethical approval. Practical approach is discussed and analysed in the facility. A small pilot was conducted to improve the questionnaire. In the first half of 2018 the first half of patients for the qualitative survey will be included. Also, the interviews with health workers will be held during this period of time. In April/May, the intervention checklist will be developed and applied. The second half of the survey, to evaluate the effectiveness of the proposed intervention, will be held after implementing the checklist. Data analysis will take place during the second halve of 2018. The cohort analysis will be performed throughout the year.

2018	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Writing proposal												
Validating and pilot												
Application ethical committee												
Exit-questionnaire survey												
Qualitative data collection												
Introduction informed consent checklist												
Data analysis												
Retrospective cohort data analysis												
Dissemination of results												

8. BUDGET

This research is not financed by any sponsors. Expected minor costs are as follows.

Printing costs	20.000 MWK
Hiring a translator for questionnaire	72.500 MWK
On-ground translator fees	20.000 MWK
10% NHSRC fee	11.250 MWK
Total budget	123.750 MWK

The costs will be paid out of the primary investigators personal account. It is thinkable that this project leads to more structurally funded research projects in the region.

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3. Informed Consent

Informed consent is gathered prior to administration of the questionnaire. The investigator gathering the informed consent will not have a treatment relationship with the individual. The aim of the research will be verbally explained and details about inclusion criteria and reasons for inclusion of the individual in particular, use of questionnaire, financial compensation, risks and benefits, confidentiality and contact details will be discussed in the Participant Information sheet. The patient will be informed that conduction of this research is not part of their routine care and completely voluntary. The individual is free to refuse to participate and will be free to withdraw from the research at any time without penalty or loss of benefits to which he or she would otherwise be entitled. Also, there will be touched upon the limits to the researchers' ability to guarantee confidentiality and the measures that are taken. Verbal informed consent will be gathered and additionally written explanation will be handed out to the patient, where another confirmation of consent is asked. The first page of the questionnaire is dedicated to informing the patient and asking for their written consent. Illiterate patients may give consent with a fingerprint.

Deliberately has been chosen to administer the participant information sheet verbally, because the information is very extensive and hard to understand all at once. We will give patients the option to ask questions and they will receive contact details for further explanation on study participation and progress. Also contact details of Saint Luke's Hospital personal have been included, who can link participants to an independent health advocate (ombudsman). Verbal explanation of this seems appropriate, because during pilot studies we found an illiteracy/bad understanding of Chichewa in 20% of patients. By doing this verbally and providing room for discussion, we make an effort to respect the autonomy of all patients viable for inclusion.

Considering the interviews with health workers, informed consent is gathered prior to interviews with the health workers. Verbally the scope of the research will be explained, the use of a recorder and the possible extraction of quotes. No names will be mentioned. None of the data can be linked to the included health personal. Numbers will be used for anonymization purposes.

The records of consent will be stored in the administration office of the hospital. The records are anonymous, but linked to admission numbers. An encrypted database, only accessible to the primary investigator, will link the admission numbers to the gathered data. This way we can link the informed consent form to an individual case. However, patient names are not recorded and cannot be traced.

3a. Informed Consent Exit-Questionnaire Survey

PATIENT INFORMATION SHEET ENGLISH

Study title:	*Decision-making around caesarean section in a low-resource setting.*		
Locality:	Saint Luke's Hospital	**Ethics committee ref.:**	National Health Science Research Ethics Committee
Primary investigator:	Wouter Bakker	**Contact phone number:**	**+265991694212**

CONSENT PAPER

These questions are part of the research study on quality safe motherhood.
They aim to see if you were properly informed before undergoing a caesarean section and if the health care personnel asked for your consent.
They also aim to see your current knowledge on caesarean section.
This research study will help us to identify shortcomings in the information provision prior to a caesarean section. This will help to improve safe motherhood.

RESEARCH METHODOLOGY

We will use questions.

ACTIVITIES DURING THE RESEARCH

If you accept to take part in this research, you will be asked questions and your part will end there. We will use your patient files to look at your HIV-status, amount of antenatal consults, parity, amount of caesarean sections and the indication for your current caesarean section.

ADVANTAGES AND DISADVANTAGES OF THIS RESEARCH

There is nothing to fear since there will be no new drugs or any kind of physical examination. There will be no direct advantages, but the results of the study will help to identify ways of strengthening patient education and respectful care given to pregnant women. You will receive an additional explanation of the risks of CS and its implications for future pregnancies.

THE RESEARCH STUDY IS NOT COMPULSORY

It is not compulsory to take part in the research study and to refuse to take part in this study will not affect the type of treatment that you are going to receive during this stay**.**

THE RIGHT TO WITHDRAW FROM THE STUDY

You have the right to withdraw from the study any time, without consequences.

CONFIDENTIALITY

We will make an effort to keep all information confidential, except when we have been asked by the law or the research bodies. Names shall not be used. Instead numbers shall be used. There will be no connection between your information and your identity.

THE RESULTS OF THE RESEARCH STUDY

You will be informed about the results of the study when we have finished scrutinizing them. You can contact the investigator any time for an update on the study results (see contact details).

RESEARCH POPULATION

Pregnant women who have undergone Caesarian Section are the ones required to take part in the study.

CONTACT DETAILS

If you have questions or comments concerning this research study, you can find the researcher:

Name, position:	Simon Zethof, co-investigator
Phone:	+265995661849
Email:	Siemzethof@hotmail.com

If you want to speak to an independent person you can find him on the address below;

Name, position	Mr J. Phiri, Senior Adminstrative Officer
Phone:	+0882010868 / 0999121039
Name, position	Mr P. Manjere, Human Resource Officer
Phone:	+0883377691 / 0999121039

You can also contact the National Health Science Research Ethics Committee

Name, position	Dr. Damson Kathyola, NHSRC representative
Phone:	+26 560 1726422, ask for Dr. Kathyola
Email:	directorgeneral@ncst.mw

Declaration by participant:
I hereby consent to take part in this study.

Participant's name: _____

Signature: _____ Date: _____

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____

PATIENT INFORMATION SHEET CHICHEWA

Study title:	*The quality of care for caesarean sections in Saint Luke's Hospital, Malawi: A mixed-method approach.*		
Locality:	Saint Luke's Hospital	**Ethics committee ref.:**	National Health Science Research Ethics Committee
Lead investigator:	Wouter Bakker	**Contact phone number:**	**+265995661849**

PEPALA LA CHILOLEZO

Mafunsowa akupanga mbali imodzi ya kafukufuku wa maphunziro a pamwamba a uchembere wabwino.
Zikukhudza ngati mwauzidwa moyenera musanapangidwe opareshoni ndiponso ngati a chipatala akufunsani zachilolezo chanu.
Zikhudzanso zomwe mukudziwa panopa za ma opareshoni.
Kafukufukuyu adzatithandiza kuona zofooka zimene zimapezeka popereka uthenga kwa mayi oyembekezera asanapangidwe opareshoni.

NDONDOMEKO YA KAFUKUFUKU

Ife tidzagwiritsa ntchito mafunso.

ZOCHITIKA MUKAFUKUFUKU AMENEYU

Ngati mutavomera kutenga mbali mukafukufukuyu,mudzafunsidwa mafunsondipo mbali yanu idzathera pomwepa. Tidzagwiritsanso ntchito ma fayilo anu popanga kafukufukuyu.

UBWINO NDIKUYIPA KWA KAFUKUFUKU AMENEYU

Palibe choopsa china chili chonse popeza sipadzakhala mankhwala achilendo kapena kuyezedwa kwina kulikonse.
Sipadzakhala ubwino wina uliwonse koma zotsatira zakafukufuku zizathandiza kupezera njira zolimbikitsa kudziwitsa ndi kuwonesetsa kuti zisankho za amayi apakati zikulemekezedwa.

KAFUKUFUKU AMENEYU SIWOUMILIZA

Kutengambali pakafukufuku ameneyu ndikosaumiriza ndipo kukanakutenga mbali pakafukufuku ameneyu sikudzakhudza chisamaliro chimene muyenera kulandira patsikuli.

UFULU OTULUKA MUKAFUKUFUKU AMENEYU

Muli ndi ufulu wonse kutuluka mukafukufuku ameneyu ndipo sipadzakhala chovuta china chili chonse.

KUSUNGA CHINSINSI

Tidzayetsetsa kusunga chinsinsi pa zonse zokhudza munthu wina aliyense kupatula pokhapokha ngati tafunsidwa ndilamulo kapena mabungwe oyang'anira kafukufuku. Mayina

sadzidzagwiritsidwa ntchito mmalo mwake manambala ndiamanene adzidzagwiritsidwa ntchito, sipadzakhala kugwirizana kwinakulikonse pa nkhani ndi mayina anu

ZOTSATIRA ZA KAFUKUFUKU
Mudzadziwitstsidwa zotsatira zakafukufuku ameneyu tikadzakamaliza kuunika bwinobwino

CHIWERENGERO CHA ANTHU OTENGAMBALI PAKAFUKUFUKU AMENEYU
Kafukufuku ameneyu adzafunika kwa amayi onse oyembekezera amene anapangidwa opaleshoni ndi amene adzatenge mbali.

MUNGATIPEZE BWANJI?
Ngati muli ndimafunso kapena ndemanga pokhudzana ndikafukufuku ameneyu, mukhoza kutifikira Kwa opanga kafukufuku;

Name, position:	Simon Zethof, co-investigator
Phone:	+265995661849
Email:	Siemzethof@hotmail.com

Ngati mukufuna kuyankhula ndi munthu wapadera mukhonza kumupeza pa keyala ili mmunsimu:

Name, position:	Mr J. Phiri, Senior Adminstrative Officer
Phone:	+0882010868 / 0999121039
Name, position:	Mr P. Manjere, Human Resource Officer
Phone:	+0883377691 / 0999121039

National Health Science Research Ethics Committee

Name, position	Dr. Damson Kathyola, NHSRC representative
Phone:	+26 560 1726422, ask for Dr. Kathyola
Email:	directorgeneral@ncst.mw

Ine…….. (Otengambali) ndawerenga zofunikirazi. Ndasankha kutenga mbali pakafukufuku ameneyu mosakakamizidwa. Ndamvetsetsa kuti ndili ndi ufulu kukana kuyankha funso komanso kutuluka mukafukufuku ameneyu nthawi ina iliyonse. Ndamvetsetsa kuti mayankho anga adzakhala achinsinsi

.

Kutsimikiza kwaotenga mbali	Tsiku
Umboni	Tsiku
Kutsimikiza Kwa opanga kafukufuku	Tsiku

CHALA

3b. Informed Consent Interview Health Workers

Research: Health Worker Perspectives on Informed Consent for Caesarean Sections.

Department	Obstetrics
Organization	Saint Luke's Hospital
Date	

Dear Sir, Madame,

The following interview will be conducted to gain insight in your perspectives on giving information to the patient and gaining her consent prior to CS. The interview will discuss personal experiences with informed consent, as well as thoughts about the information transfer, practical use of informed consent and ethical considerations.

- **The interviews are anonymous. The interviewee only states his/her function, age, gender, department and years of working experience.**
- **The interviews will be recorded and analyzed only by the interviewer.**
- **Comments may be used as quotes in the article. This, again, will be anonymous.**
- **The interview takes 30 minutes to 1 hour.**

By conducting interviews and analyzing them as one entity, the researcher tries to understand the process of informed consent and apply interventions were needed. This may improve the quality of care in Saint Luke's Hospital, but also may serve as an example for other health facilities.

This interview is not compulsory and will not affect your work in a negative way. The researcher may write during the interviews. The notations include observations and possible quotes.

I hereby give my consent for participating in this study ☐

4. Data Collection Instruments

4a. Exit-Questionnaire

DATA COLLECTION SHEET **ENGLISH**

[Questionnaire: Quality of Consultation Caesarean Section**]**

Department	Obstetrics
Organization	Saint Luke's Hospital
Date	

Dear Madame,

This list of questions is part of a study on the quality of consultation in Safe Motherhood.
It will address whether or not you were informed sufficiently prior to your caesarean section and if healthcare providers asked for your consent.
It will also address your current knowledge of caesarean sections.
This study will enable us to identify shortcomings in the provision of information and improve Safe Motherhood for you and future patients.

- **If you find any of the questions hard to understand, you may ask the interviewer for clarification.**
- **If you find any of the questions offensive or do not want to answer them for any other reason, do not feel obliged to do so. Leave a blank space.**
- **The questionnaire should take 15 minutes to complete. You may quit the questionnaire anytime you like.**

The questionnaire is anonymous and will be analysed by an independent researcher.
Your answers will be confidential. Only the interviewer and researcher will take notice of them.
The filled-in answers will not affect the quality or accessibility of your healthcare in a negative way.
We will be using your patient records to identify the reason for your caesarean section as stated by the caregiver.

Part 1: Your social and demographic information

Instructions:

This part aims to collect information about your life.

When a line is depicted after a question, put your answer on the line.

Example question:

How many times have you been to Saint Luke's Hospital?

2

_____

When several options are given, pick one option (except when stated otherwise).

Example question:

Was your previous delivery a caesarean section?

a. Yes

b. No

Questions on patient demographics:

PICK ONE OPTION!

1. Are you able to read Chichewa?

a. Yes

b. No

2. Which tribe are you related to?

a. Yao-tribe

b. Chewa-tribe

c. Ngoni-tribe

d. Chotupa-tribe

e. Lomwe-tribe

3. How old are you? _____

4. Indicate your marital status:

a. married

b. single

c. relationship

5. Religion:

a. Christian
b. Muslim
c. Jehovah
d. Other
e. None

6. Occupation?

a. Employed
b. Business/self employed
c. Student/school
d. None
e. Farmer

7. Indicate your highest education level attained:

a. None
b. Primary school (Standard 1- 8)
c. Junior Secondary school (Form 1 and 2) - Junior Certificate of Education (JCE)
d. Senior Secondary school (Form 3 and 4) - Malawi Secondary Certificate of Education (MSCE)
e. College
f. University

8. How many times have you given birth? _____

9. How many caesarean sections did you have? _____

8. Which level of provider asked you for your consent prior to operation during your hospital stay?

a. Nurse/midwife
b. Doctor
c. Guardian
d. No one

Part 2: Received information and consent

Instructions:

Please answer these questions based on the counseling you have received for this C-section from the healthcare provider. The information should be received during THIS HOSPITAL STAY or antenatal consultations. It may either be mentioned before or after your C-section.

Example question.

Was your previous delivery a caesarean section?

a. Yes

b. No

1. Did someone from the hospital inform you of the reason for this caesarean section?

a. Yes

b. No

2. PICK ONE OPTION!

According to you, what was the reason for the caesarean section? PICK ONE OPTION!

a. Birth canal was too narrow for baby's head (CPD, obstructed labour, prolonged second stage, failed VBAC, macrosomia)

b. Problem with heart baby (Non-reassuring fetal status, fetal distress)

c. Problem with position of child (Fetal malpositioning, fetal malpresentation)

d. High blood pressure (Preeclampsia/eclampsia/HELLP syndrome)

e. Blood loss prior to labour (ante-partum hemorrhage, abnormal placentation, placenta praevia, placental abruption)

f. Cord was in front of the baby. (Funic presentation or cord prolapsed)

g. Uterine tear/rupture

h. Breech presentation in first pregnancy

i. 2 or more CS in history

j. Other _____

k. Don't know

3. Did someone from the hospital inform you on what a caesarean section involves? The doctor should have told you about the operation room (theatre) and the use of anesthetics (spinal block), and the possible complications of anesthetics?

a. Yes

b. No

4. Did someone from the hospital gave you information on the risks associated with a caesarean section during this stay?

a. Yes (go to question 5)

b. No (go to question 6)

5. PICK 3 OPTIONS!

Which of the following risks are MOST COMMON following a caesarean section? PICK 3 OPTIONS!

a. Increased risk of bleeding

b. Instruments left in abdomen

c. Maternal death

d. Infection

e. Extended recovery time

f. Becoming paralyzed

6. Did a healthcare provider explain that your future deliveries should be in the hospital, now that you've had a caesarean section?

a. Yes

b. No

c. Bilateral tubal ligation

7. Were you asked for your consent prior to this surgery?

a. Yes (go to question 9)

b. No (go to question 8)

8. Did you sign a consent form for this caesarean section?

a. Yes

b. No

9. If you were NOT asked for consent, why do you think this happened?

a. Doctor knows best

b. Women's feelings not considered

c. Unable to make decision due to drugs or complication

d. Sudden emergency

e. My guardian gave consent

f. High risk to baby

g. Other reason, fill in: _____

Part 3. Your Perspective on Hospital stay

Instructions:

The following instrument aims to give insight in your experiences of this hospital stay.
For each of the questions below, circle the response that best characterizes how you feel about the statement, where:
1 = Strongly Disagree, 2 = Disagree, 3 = Neither Agree Nor Disagree, 4 = Agree, 5 = Strongly Agree

Example:

	Strongly disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
I want Malawian healthcare to be the best.	1	2	3	4	5

	Strongly disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
I felt informed about my cesarean section during my hospital stay.	1	2	3	4	5
The provided information was hard to understand for me.	1	2	3	4	5
I had the chance to ask questions.	1	2	3	4	5
I want to receive more information on cesarean sections prior to surgery.	1	2	3	4	5
Asking for consent prior to cesarean section is important to me.	1	2	3	4	5

This is the end of the questionnaire. Your participation will be very helpful in our research for better obstetric care. Thank you for participating!!

DATA COLLECTION SHEET FOR INTERVIEWER

Number given by interviewer: _____

Handed out by: Interviewer/Student

Date of CS, time performed _____

Exact indication in patient records: _____

Written by consent: Patient/Guardian/No one

HIV-status: Positive/Non-reactive/Unknown

Amount of antenatal consultations: _____

Type of CS: Emergency / Elective

Any complications 3-days post CS? _____

Any long-term complications? _____

DATA COLLECTION SHEET **CHICHEWA**

[Mafunso: Ubwino wogawana nzeru pa nkhani za caesarean (operashoni)]

Department	Obstetrics
Organization	Saint Luke's Hospital
Date	

Zikomo Amai,

Mafunsowa akupanga mbali imodzi ya kafukufuku wa maphunziro a pamwamba a uchembere wabwino.
Zikukhudza ngati mwauzidwa moyenera musanapangidwe opareshoni ndiponso ngati a chipatala akufunsani zachilolezo chanu.
Zikhudzanso zomwe mukudziwa panopa za ma opareshoni.
Kafukufuku yu azatithandiza kuona zina zimene tingadziwe zothandiza uchembere wabwino.

- **Ngati pali mafunso ena amene musakuwamvetsa, muwafunse amene akukufunsani.**
- **Ngati pali mafunso amene pazifukwa zosiyanasiyana simungathe kuyankha, mutha kutsiya osayankha.**
- **Mafunso ayenera kutenga 15 minutes (mphindi 15). Mutha kutsiya nthawi ina iriyonse.**

Mafunso awa ndi achinsinsi azangoonedwa ndi wofufuza wa pa dera basi.
Mayankho anu azakhala achinsinsinso owonedwa ndi wokufunsani komanso wofufuza okhawo.
Mayankho anu sadzasintha chithandizo kapena kulandira chithandizo mochepera.
Tizigwiritsa zolembedwa zachipatala poona chifukwa cha opareshoni yanu monga analembera a dokotala.

Part 1: Za gulu lanu maphunziro, zakubadwa ndi kufa
Malangizo:
Mbali ino ndi yofuna kudziwa za moyo wanu.
Pakakhala mdzere pa funso mulembe yankho lanu pamdzere.

Chitsanzo:
Mwapitapo kangati ku Saint Luke's Hospital?
2
_____

Ngati pali mayankho ambiri, sankhanipo limodzi (kupatulapo ngati palembedwa zina).

Chitsanzo:
Kubereka kwanu komalizira Kunali kwa opareshoni/kong'amba?

c. Inde
d. Ayi

Mafunso okhudza kasinthidwe ka chiwerengero cha wodwala:

SANKHANIPO CHIMODZI!

1. Mungathe kuwelenga Chichewa?
a. Inde
b. Ayi

2. Mtundu wamu ndi chani?
a. Yao
b. Chewa
c. Chotupa
d. Ngoni
e. Lomwe

3. Muli ndi zaka zingati?
_____

4. Munakwatiwa:
a. Okwatiwa
b. Sindinakwatiwe
c. Ndili ndi chibwenzi

5. Mpingo:

a. Mkhilisitu

b. Musilamu

c. Mboni za Yehova

d. (Mpingo) wina

e. Palibe

6. Mumagwira ntchito?

a. Ndimagwira

b. Bizinesi/yandekha

c. Ndikuphunzira/ pa sukuhi sukulu

d. Palibe

e. Mlimi

7. Sukulu munalekedza mu chiyani?

g. Palibe / Sindinapite
h. Primary school (standard 1 – 8)
i. Junior Secondary school (Form 1-2) - Junior Certificate of Education (JCE)
j. Senior Secondary school (Form 3-4) - Malawi Secondary Certificate of Education (MSCE)
k. College
l. University / Yunivesite

8. Mwabereka kangati? _____

9**. Mwapangidwa opareshoni kangati?** _____

8**. Anakufotokozerani dongosolo la opareshoni yanu ndi ndani?**

a. A nasi / A namwina

b. A dokotala

c. Ondidikilira (guardian)

d. Palibe

Part 2: Zomwe ndinauzidwa ndi chilolezo

Malangizo:
Yankhani mafunso malinga ndi momwe mwauzidwira ndi a Chipatala zokhuzana ndi opareshoni. Izi ziyenera kulembedwa ulendo umene mwagonetsedwa uno kapena ku sikelo.
Chitsanzo:
Kodi mwana wanu omalidzira anali wa opareshoni?

a. Inde
b. Ayi

1. Alipo ena a chiptala akudziwitsani chimene chimapangitsa opareshoni?

a. Inde

b. Ayi

2. SANKHANIPO CHIMODZI!

Mukuganidzira kuti chimapangitsa ndichiyani? SANKHANIPO CHIMODZI!

l. Chifukwa cha kuchepa kwa njira kapena kukula kwa mutu wa mwana?

m. Mwana amabanika

n. Mwana sanagone bwino

o. BP yokwera/kuthamanga kwamagazi

p. Kutaya magazi kwambiri ndisanabereke

q. Kutsogoza mchombo wamwana.

r. Kung'ambika kuphulika kwa chiberekero

s. Kutsogoza matako amwana pamimba yoyamba

t. Kupangidwa opareshoni yamwana kawiri

u. China, -

_____

v. Sindikudziwa

3. Alipo wina wa chipatala amene anakudziwitsani zomwe zimachitika popanga opareshoni?

A dokotala/anesi amayenera kuudzani za chipinda cha opareshoni (fiyeta) ndi kagwiritsidwe ka mankhwala oletsa ululu komanno kwipa kwake.

a. Inde

b. Ayi

4. Alipo wina wa muchipatala amene wakuudzani za kuopsya kwa opareshoni?

a. Inde

b. Ayi

5. SANKHANI ZITATU MWA IZI!

Ndi zoopsya ziti mwa izi zimene zimachitika nthawi zambiri pa opareshoni? SANKHANI ZITATU MWA IZI!

a. kutaya magazi kwambiri

b. Kuyiwla zipangizo zogwiritsa ntichito m'mimba mwanga.

c. Imfa pobereka

d. Kuola kwa bala

e. Nthawi yaitali yochilira

f. Kufa kwaziwalo

6. Kodi a chipatala anakufotokodzerani kuti kubereka mtsoglo kuyenera kuchitikira muchiptala poti pano mwachitidwa opareshoni?

a. Inde

b. Ayi

c. Ndinatsekedwa

7. Munafunsidwa za chiloledzo chanu musanachitidwe opareshoni?

a. Inde

b. Ayi

8.Munasaina kalata yobvomeredza kuchitidwa opareshoni?

a. Inde

b. Ayi

9. Ngati simunafunsidwe za chiloledzo chanu, mukuganidzira kuti izi zinachitika chifukwa chiyani?

a. A dokotala akudziwa zonse bwino

b. Maganizo a azimai saganidziridwa.

c. Ndinalephera kupanga chiganizo chifukwa cha mankhwala kapena bvuto lina.

d. Mabvuto adzidzidzi

e. Amene amandiyang'anira anapereka chiloledzo.

f. Zoopsya kwa mwana

g. Chifukwa china, lembani: _____

Part 3. Malangizo omwe mungapereke okhuzana ndi chipatalachi

Malangizo:

Mafunso otsatira wa athandizira kuti mudzathandizidwe monga momwe mukufunira mukadzabweranso.

Pafunso linalililonse pali mayankho asanu, sankhani yankho limodzi lomwe mukuona kuti ndi loyenera. Muzungulize yankho loyeneralo.

1 = Kutsutsa kwambiri, 2 = Kutsutsa, 3 = Pakati ndipakati, 4 = Kubvomera, 5 = Kubvomera kwambiri

Chitsanzo:

	Kutsutsa kwambiri	Kutsutsa	Pakati ndipakati	Kubronera	Kubvomera kwambiri
Ndikufuna umoyo wabwino wa chimalawi kukhala opambana koposa.	1	2	3	4	5

	Kutsutsa Kwambiri	Kutsutsa	Pakati ndipakati	Kubvomera	Kubvomera Kwambiri
Ndinauzidwa za opareshoni nthawi imene ndinali muchipatala.	1	2	3	4	5
Chidziwitso chinaperekedwa chinali chobvuta kumvetsa.	1	2	3	4	5
Ndinali ndi mwai ofunsa mafunso.	1	2	3	4	5
Ndikufuna ₡ chidziwitso chokwanira pa zong'amba thupi nthawi ya opareshoni isanakwane.	1	2	3	4	5
Kufunsa chiloredzo nthawi yong'amba thupi isanakwane ndi chofunikira kwa ine.	1	2	3	4	5

Apa ndi pamapeto a mafunso athu. Kutenga nawo gawo pa kafukufuku yu kutandizira kuti uchembere wabwino upite patsogolo. Zikomo kwambiri chifukwa chotenga nawo mbali.

DATA COLLECTION SHEET FOR INTERVIEWER

Number given by interviewer: _____

Handed out by: Interviewer/Student

Date of CS, time performed _____

Exact indication in patient records: _____

Written by consent: Patient/Guardian/No one

HIV-status: Positive/Non-reactive/Unknown

Amount of antenatal consultations: _____

Type of CS: Emergency / Elective

Any complications 3-days post CS? _____

Any long-term complications? _____

4b. In-depth interview guidance

Interview subject list: Informed Consent for Caesarean Section, Health Worker Perspective.

Introduction: **Scope of research, discuss informed consent.**
Interviewee characteristics: **Function, gender, age, current occupation, years of working experience.**

1. **Personal experiences with IC**
   a. In how many informed consent processes prior to CS have you been involved?
   b. Can you describe your last IC process prior to CS? Elaborate.
   c. Did any of the women ever refused the operation? Elaborate.
   d. Did you encounter a situation where a woman went to CS without gaining informed consent?
   e. Would you consider your experiences with informed consent positive or negative? Why?
2. **Definition of informed consent**
   a. Describe the definition of informed consent in a few sentences.
      i. Different aspects?
      ii. Purpose?
   b. What is the effect on the patient?
   c. What is the effect on the health worker?
3. **IC in clinical practice**
   a. How should a regular IC process for CS look like?
      i. Which points should be discussed?
      ii. Who should discuss it? Clinician or nurse?
      iii. Should it be discussed with patient or guardian?
      iv. Should the patient or guardian give consent?
      v. Situations where IC is unfavorable? Skip IC?
   b. What are the barriers for IC?
      i. Patient characteristics
      ii. Time management
      iii. Emergency setting
   c. How to overcome the barriers mentioned?
4. **Ethical considerations**
   a. Informed consent is a fictional approach, because:
      i. Most women do not have the medical expertise to comprehend the provided information.
      ii. Most patients expect the doctor to make a decision for them and do not want to be informed and involved in the decision making.
      iii. The clinician will provide selective information to coerce the patient into his option of choice.
      iv. A women giving no for an answer will not be tolerated. She will be forced to do whatever the clinician thinks is best under these circumstances.
   b. How do you assess the capability of a woman to consent? Is any woman in pain uncapable? Does it make a differences IC process involves the guardian rather than the patient?
   c. "Every women has the right to information, informed consent and refusal, and respect for her choices and preferences, including companionship during maternity care." What do you think of this statement? Is the right to informed consent a Human right? Is it usable in clinical practice?
   d. If a women refuses a CS, despite the damage to mother and child, should we respect this decision? Who should have the last word? Woman or clinician?
5. **Conclusion:**
   a. Definition of informed consent?
   b. Advantages?
   c. Disadvantages?
   d. Challenges?
   e. Want to add something?

5. Support Letter Institution

ANGLICAN DIOCESE OF UPPER SHIRE (ADUS)

HEALTH DEPARTMENT
P.O. BOX 21, CHILEMA
ZOMBA, MALAWI

E-mail :
stlukeshospitalmalosa@gmail.com

Tel : +265 9 99 121 039
Bishop: The Right Rev'd Brighton Vitta Malasa **: +265 8 84 478 897**

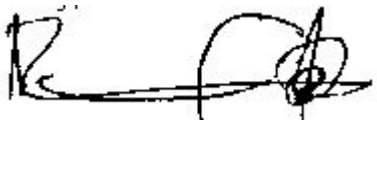
Dear members of the National Health Science Research Committee,

On behalf of St Luke's Hospital, I would like to offer my support to Dr. Wouter Bakker to conduct a study to visualize the theme of information transfer prior to a caesarean section.

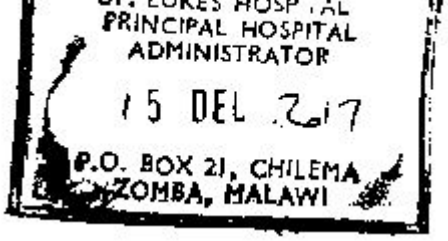
The study: The quality of care in caesarean sections in Saint Luke's Hospital, Malawi: A mixed-method approach, is not only of assistance to us as a hospital, but could serve a greater purpose as an example to improve on the patients right of information in obstetric health care.

Hereby I, endorse this study to investigate current practices of informed consent and stimulation of patient education.

Sincerely,



Winasi Boma, Principal Administrator St. Luke's Hospital.



Anglican Diocese of
UPPER SHIRE
ST LUKE'S MISSION HOSPITAL

CAESAREAN SECTION

DETAILS		
	Patient name	
	Next of kin	
	Contact details	

DECISION		
	Date and time	
	Made by	
	Indication	

INFORMATION (BY SURGEON)

Discuss the following topics with the patient

- ☐ Explained **INDICATION** for CS and **BENEFITS** of CS in current situation to the patient.
- ☐ Explained **PROCEDURE** of CS to the patient. *Including anaesthesia and possible use of blood products.*
- ☐ Explained the **RISKS** of CS to the patient. *Infection, hemorrhage, recovery time, serious and rare complications*
- ☐ Explain **IMPLICATIONS FOR FUTURE PREGNANCIES.** *Hospital delivery, trial of labour, risk of uterine rupture*
- ☐ Address **UNCERTAINTIES** and answer **QUESTIONS.**
- ☐ Gain **VERBAL CONSENT** from the patient.

I have explained the procedural nature and risks to the undersigned patient or person legally competent to give consent.

Surgeon: Signature: Date:

CONSENT (BY PATIENT)

I, the undersigned, hereby consent to the performance of, and understand the nature and risks of the procedure. The clinicians who perform the above may increase the reasonable scope thereof or carry out additional or alternative measures (including general anaesthesia) if considered necessary. I agree that a sample of my blood will be taken and tested for Hepatitis B and HIV should an incident of contamination of a health care worker by bodily fluids occur during the procedure. I grant consent to use of blood and/or blood products if needed.

Patient/guardian name: Signature: Date:
Relationship to patient (if applicable):

PRE-OPERATIVE			
☐	Ceftriaxone 2g IV stat	Signature:	Time:
☐	Foley's catheter and urinary bag	Signature:	Time:
☐	IV access (preferably grey cannula)	Signature:	Time:
☐	Preload with 1 liter NS or RL (remove bags with added Oxytocin!)	Signature:	Time:
☐	Urgent Hb | blood group | cross-match	Signature:	Time:

PROCEDURE AND FINDINGS				
	Surgeon		Signature	
	Time started		Time completed	
	Skin incision		Blood loss	
	Uterine incision		Complications	
	Fetal position			
	Liquor			
	Uterine closure			
	Tubal ligation			
	Fascia closure			
	Skin closure			

NEONAT				
	Midwife		Signature	
	Time delivery		Apgar scores	
	Resuscitation		Birth Weight	

ANAESTHETIC DETAILS				
	Anaesthetist		Signature	
	Medical history			
	Examination			
	Investigations			
	Technique			

MONITORING

200
180
160
140
120
100
80
60
40

POST-OPERATIVE	☐ Standard (see below)	☐ Adjusted (indicate below)	Signature
	Vitals: take blood pressure and pulse before patient is taken to the ward and again 30 minutes after arrival in the ward. For the first 24 hours vitals have to be taken 6 hourly, and 12 hourly for subsequent days. Check for possible bleeding (wound or vagina) and urinary output each time when taking vitals. **Analgesia**: pethidine 50-100mg IM 8 hourly for 1 day (PRN) and paracetamol 1g PO 8 hourly for 3 days. **Antibiotics**: only indicated in signs of infection. **IV fluids**: NS or RL 8 hourly for 1 day (depending on oral intake). **Intake**: may drink after 6 hours, may eat Phala after 12 hours and soft Nsima after 24 hours. **Hb**: if clinically indicated. **Ambulation**: as soon as possible. **Wound**: expose on day 1 or 2 post-op and leave open if clean. **Discharge**: by clinician after 3-4 days. **Sutures**: removal after 7 days if nylon.		

	Vitals (30 min)	BP	P	Bleeding	Time transfer	(only if stable!)
	Vitals (60 min)	BP	P	Bleeding	Ward nurse	

CARE PROTOCOL	Since operation	6h	12h	18h	24h	2nd day:		3rd day:		4th day:		5th day:	
	Actual time												
	Blood pressure												
	Pulse												
	Abnorm. bleeding												
	Urine output												
	Temp mother												
	Temp neonate												
	Pethidine IM					inform clinician if patient is still having pain							
	Paracetamol PO					ensure that patient has received PCM tablets							
	IV fluids (NS|RL)			stimulate oral intake									

Anglican Diocese of
UPPER SHIRE
ST LUKE'S MISSION HOSPITAL

Informed Consent in C-section

A Six-Step Guide

1) Explain **INDICATION** for CS and **BENEFITS** of CS in current situation to the patient.

2) Explain **PROCEDURE** of CS to the patient.
   - ***a.*** *What happens in theatre*
   - ***b.*** *Use of anaesthetics*
   - ***c.*** *Possibly use of blood products*

3) Explain the **RISKS** of CS to the patient.* **

FREQUENTLY OCCURRING RISKS	**INFECTION**	Wound infection or endometritis	*5 – 10%*
	EXTENSIVE BLEEDING	>1000 ml or in need of transfusion	*4 – 9%*
	EXTENDED RECOVERY TIME	3 days hospitalization (everyone), persistent wound and abdominal discomfort for >1 month	*9%*
SERIOUS RISKS	**EMERGENCY HYSTERECTOMY**	Due to uncontrolled bleeding, uterine rupture and placental problems	*0.7 – 0.8%*
	INTRA-ABDOMINAL INJURY DUE TO SURGERY	Ureteric, bladder or bowel damage	*0.2 – 0.5%*
	MATERNAL DEATH DUE TO CS	**Very rare. Depends on underlying factor that necessitate CS.**	***<0.1%***

** Make an effort to separate FREQUENTLY OCCURING and SERIOUS risks.*
*** Risks are increased in OBESITY, PREVIOUS SCAR, PRE-EXISTING MEDICAL CONDITION.*

4) Explain **IMPLICATIONS FOR FUTURE PREGNANCIES.**
   - ***a.*** *Need to deliver in hospital next time!*
   - ***b.*** *Increased risk of complications*
   - ***c.*** *Increased risk of CS in subsequent deliveries*

5) Address **UNCERTAINTIES** and answer **QUESTIONS.**

6) Gain **VERBAL** and **WRITTEN CONSENT** from the patient. *Ask the patient if she is ok with the procedure.*

Incidence percentages of complications were extracted from the RCOG consent advice, *Chilopora et al.* and the Saint Luke's Hospital annual reports.[1-3]

1. Royal College of Obstetricians and Gynaecologists. Consent Advice No. 7: Caesarean Section. 2009 [Available from: https://www.rcog.org.uk/en/guidelines-research-services/guidelines/consent-advice-7/ Accessed November 2018.
2. Chilopora, G., C. Pereira, F. Kamwendo*, et al.*, *Postoperative outcome of caesarean sections and other major emergency obstetric surgery by clinical officers and medical officers in Malawi*. Vol. 5. 2007. 17.
3. Saint Luke's Hospital, *St Lukes Hospital Annual Report* 2016-2017, Saint Luke's Hospital: Malosa. https://www.stlukesmalosa.org/hospital-reports/ Accessed March 2018.

[Questionnaire: Quality of Consultation Caesarean Section]

Department	Obstetrics
Organization	Saint Luke's Hospital
Date	

Dear Madame,

This list of questions is part of a study on the quality of consultation in Safe Motherhood.

It will address whether or not you were informed sufficiently prior to your caesarean section and if healthcare providers asked for your consent.

It will also address your current knowledge of caesarean sections.

This study will enable us to identify shortcomings in the provision of information and improve Safe Motherhood for you and future patients.

- **If you find any of the questions hard to understand, you may ask the interviewer for clarification.**
- **If you find any of the questions offensive or do not want to answer them for any other reason, do not feel obliged to do so. Leave a blank space.**
- **The questionnaire should take 15 minutes to complete. You may quit the questionnaire anytime you like.**

The questionnaire is anonymous and will be analysed by an independent researcher.

Your answers will be confidential. Only the interviewer and researcher will take notice of them.

The filled-in answers will not affect the quality or accessibility of your healthcare in a negative way.

We will be using your patient records to identify the reason for your caesarean section as stated by the caregiver.

Part 1: Your social and demographic information

Instructions:

This part aims to collect information about your life.

When a line is depicted after a question, put your answer on the line.

Example question:

How many times have you been to Saint Luke's Hospital? 2

When several options are given, pick one option (except when stated otherwise).

Example question:

Was your previous delivery a caesarean section?

a. Yes
b. No

Questions on patient demographics:

PICK ONE OPTION!

1. **Are you able to read English/Chichewa? (is able to read the introduction)**
   a. Yes
   b. No

2. **How old are you?** _____

3. **Indicate your marital status:**
   a. married
   b. single
   c. relationship

4. Religion:

a. Christian
b. Muslim
c. Jehovah
d. Other
e. None

5. Occupation?

a. Employed
b. Business/self employed
c. Student/school
d. Housewife
e. Farmer

6. Indicate your highest education level attained:

a. None
b. Primary school (Standard 1- 8)
c. Junior Secondary school (Form 1 and 2) - Junior Certificate of Education (JCE)
d. Senior Secondary school (Form 3 and 4) - Malawi Secondary Certificate of Education (MSCE)
e. College/University

7. How many times have you given birth? _____

8. How many caesarean sections did you have? _____

Part 2: Received information and consent

Instructions:

Please answer these questions based on the counseling you have received for this C-section from the healthcare provider. The information should be received during THIS HOSPITAL STAY or antenatal consultations. It may either be mentioned before or after your C-section.

Example question.

Was your previous delivery a caesarean section?

c. Yes
d. No

1. Did someone from the hospital inform you of the reason for this caesarean section?

a. Yes

b. No

2. According to you, what was the reason for the caesarean section?

a. Birth canal was too narrow for baby's head (CPD, obstructed labour, prolonged second stage, failed VBAC, macrosomia)

b. Problem with heart baby (Non-reassuring fetal status, fetal distress)

c. Problem with position of child (Fetal malpositioning, fetal malpresentation)

d. High blood pressure (Preeclampsia/eclampsia/HELLP syndrome)

e. Blood loss prior to labour (ante-partum hemorrhage, abnormal placentation, placenta praevia, placental abruption)

f. Cord was in front of the baby. (Funic presentation or cord prolapsed)

g. Uterine tear/rupture

h. 2 or more CS in history

i. Other _____

j. Indication has not been told (according to previous question)

3. Did someone from the hospital inform you on what a caesarean section involves? The doctor should have told you about the operation room (theatre) and the use of anesthetics (spinal block), and the possible complications of anesthetics?

a. Yes

b. No

4. Did someone from the hospital gave you information on the risks associated with a caesarean section during this stay?

a. Yes (go to question 5)

b. No (go to question 6)

5. Which of the following risks are MOST COMMON following a caesarean section? PICK 3 OPTIONS!

a. Increased risk of bleeding

b. Instruments left in abdomen

c. Maternal death

d. Infection

e. Extended recovery time

f. Becoming paralyzed

6. Did a healthcare provider explain that your future deliveries should be in the hospital, now that you've had a caesarean section?

a. Yes

b. No

c. Bilateral tubal ligation

7. Were you asked for your consent prior to this surgery?

a. Yes (go to question 9)

b. No (go to question 8)

8. Did you sign a consent form for this caesarean section?

a. Yes

b. No

This is the end of the questionnaire. Your participation will be very helpful in our research for better obstetric care. Thank you for participating!!

Fill in by interviewer:

Number given by researcher:

Exact indication in patient records:

Falls under which category:

Written consent file: Patient/Guardian/No one

Amount of antenatal consultations:

Emergency / Elective:

[**Mafunso:** Ubwino wogawana nzeru pa nkhani za caesarean (operashoni)]

Department	**Obstetrics**
Organization	Saint Luke's Hospital
Date	

Zikomo Amai,

Mafunsowa akupanga mbali imodzi ya kafukufuku wa maphunziro a pamwamba a uchembere wabwino.

Zikukhudza ngati mwauzidwa moyenera musanapangidwe opareshoni ndiponso ngati a chipatala akufunsani zachilolezo chanu.

Zikhudzanso zomwe mukudziwa panopa za ma opareshoni.

Kafukufuku yu azatithandiza kuona zina zimene tingadziwe zothandiza uchembere wabwino.

- **Ngati pali mafunso ena amene musakuwamvetsa, muwafunse amene akukufunsani.**
- **Ngati pali mafunso amene pazifukwa zosiyanasiyana simungathe kuyankha, mutha kutsiya osayankha.**
- **Mafunso ayenera kutenga 15 minutes (mphindi 15). Mutha kutsiya nthawi ina iriyonse.**

Mafunso awa ndi achinsinsi azangoonedwa ndi wofufuza wa pa dera basi.

Mayankho anu azakhala achinsinsinso owonedwa ndi wokufunsani komanso wofufuza okhawo.

Mayankho anu sadzasintha chithandizo kapena kulandira chithandizo mochepera.

Tizigwiritsa zolembedwa zachipatala poona chifukwa cha opareshoni yanu monga analembera a dokotala.

Part 1: Za gulu lanu maphunziro, zakubadwa ndi kufa

Malangizo:

Mbali ino ndi yofuna kudziwa za moyo wanu.

Pakakhala mdzere pa funso mulembe yankho lanu pamdzere.

Chitsanzo:

Mwapitapo kangati ku Saint Luke's Hospital? 2

Ngati pali mayankho ambiri, sankhanipo limodzi (kupatulapo ngati palembedwa zina).

Chitsanzo:

Kubereka kwanu komalizira Kunali kwa opareshoni/kong'amba?

a. Inde
b. Ayi

Mafunso okhudza kasinthidwe ka chiwerengero cha wodwala:

1. Mungathe kuwelenga English/Chichewa? (is able to read introduction)

a. Inde
b. Ayi

2. Muli ndi zaka zingati?

3. Munakwatiwa?

a. Okwatiwa
b. Sindinakwatiwe
c. Ndili ndi chibwenzi

4. Mpingo?

a. Mkhilisitu
b. Musilamu
c. Mboni za Yehova
d. (Mpingo) wina
e. Palibe

6. Ntchito?/ Mumagwira ntchito?

a. Ndimagwira
b. Bizinesi/yandekha
c. Ndikuphunzira/ pa sukuhi sukulu
d. Pa banja
e. Mlimi

7. Sukulu munalekedza mu chiyani?

a. Palibe / Sindinapite
b. Primary school (standard 1 – 8)
c. Junior Secondary school (Form 1-2) - Junior Certificate of Education (JCE)
d. Senior Secondary school (Form 3-4) - Malawi Secondary Certificate of Education (MSCE)
e. College/University (Yunivesite)

8. Mwabereka kangati? _____

9. Mwapangidwa opareshoni kangati? _____

Part 2: Zomwe ndinauzidwa ndi chilolezo

Malangizo:

Yankhani mafunso malinga ndi momwe mwauzidwira ndi a Chipatala zokhuzana ndi opareshoni. Izi ziyenera kulembedwa ulendo umene mwagonetsedwa uno kapena ku sikelo.

Chitsanzo:

Kodi mwana wanu omalidzira anali wa opareshoni?

a. Inde
b. Ayi

1. **Alipo ena a chiptala akudziwitsani chimene chimapangitsa opareshoni?**

   a. Inde

   b. Ayi

2. Mukuganidzira kuti chimapangitsa ndichiyani?

   a. Chifukwa cha kuchepa kwa njira kapena kukula kwa mutu wa mwana?

   b. Mwana amabanika

   c. Mwana sanagone bwino

   d. BP yokwera/kuthamanga kwamagazi

   e. Kutaya magazi kwambiri ndisanabereke

   f. Kutsogoza mchombo wamwana.

   g. Kung'ambika kuphulika kwa chiberekero

   h. Kupangidwa opareshoni yamwana kawiri

   i. China, _____

   j. Sindikudziwa (see question 1 = no)

3. Alipo wina wa chipatala amene anakudziwitsani zomwe zimachitika popanga opareshoni?

A dokotala/anesi amayenera kuudzani za chipinda cha opareshoni (fiyeta) ndi kagwiritsidwe ka mankhwala oletsa ululu komanno kwipa kwake.

a. Inde

b. Ayi

4. Alipo wina wa muchipatala amene wakuudzani za kuopsya kwa opareshoni?

a. Inde

b. Ayi

5. Ndi zoopsya ziti mwa izi zimene zimachitika nthawi zambiri pa opareshoni? SANKHANI ZITATU MWA IZI!

a. kutaya magazi kwambiri

b. Kuyiwla zipangizo zogwiritsa ntichito m'mimba mwanga.

c. Imfa pobereka

d. Kuola kwa bala

e. Nthawi yaitali yochilira

f. Kufa kwaziwalo

6. Kodi a chipatala anakufotokodzerani kuti kubereka mtsoglo kuyenera kuchitikira muchiptala poti pano mwachitidwa opareshoni?

a. Inde

b. Ayi

c. Ndinatsekedwa

7. Munafunsidwa za chiloledzo chanu musanachitidwe opareshoni?

a. Inde

b. Ayi

8.Munasaina kalata yobvomeredza kuchitidwa opareshoni?

a. Inde

b. Ayi

Apa ndi pamapeto a mafunso athu. Kutenga nawo gawo pa kafukufuku yu kutandizira kuti uchembere wabwino upite patsogolo. Zikomo kwambiri chifukwa chotenga nawo mbali.

Reporting checklist for quality improvement study.

Based on the SQUIRE guidelines.

Title: A pre-post implementation study of a multi-component intervention to improve informed consent for caesarean section in Southern Malawi

Authors: Zethof S, Bakker W, Nansongole F, Kilowe K, van Roosmalen J, van den Akker T

		Reporting Item	Page Number
	#1	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patientcenteredness, timeliness, cost, efficiency, and equity of healthcare)	1
	#02a	Provide adequate information to aid in searching and indexing	2
	#02b	Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions	2
Problem description	#3	Nature and significance of the local problem	3,4
Available knowledge	#4	Summary of what is currently known about the problem, including relevant previous studies	3,4
Rationale	#5	Informal or formal frameworks, models, concepts, and / or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work	3,4
Specific aims	#6	Purpose of the project and of this report	5
Context	#7	Contextual elements considered important at the outset of introducing the intervention(s)	4,5
Intervention(s)	#08a	Description of the intervention(s) in sufficient detail that others could reproduce it	6,7
	#08b	Specifics of the team involved in the work	5,6

Study of the Intervention(s)	#09a	Approach chosen for assessing the impact of the intervention(s)	8,9
	#09b	Approach used to establish whether the observed outcomes were due to the intervention(s)	8,9
Measures	#10a	Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability	8,9
	#10b	Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost	8,9
	#10c	Methods employed for assessing completeness and accuracy of data	8,9
Analysis	#11a	Qualitative and quantitative methods used to draw inferences from the data	8,9
	#11b	Methods for understanding variation within the data, including the effects of time as a variable	9
Ethical considerations	#12	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest	10
	#13a	Initial steps of the intervention(s) and their evolution over time (e.g., time-line diagram, flow chart, or table), including modifications made to the intervention during the project	5
	#13b	Details of the process measures and outcome	8,9
	#13c	Contextual elements that interacted with the intervention(s)	9
	#13d	Observed associations between outcomes, interventions, and relevant contextual elements	8,9
	#13e	Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s).	8,9
	#13f	Details about missing data	10
Summary	#14a	Key findings, including relevance to the rationale and specific aims	10,11
	#14b	Particular strengths of the project	14

Interpretation	#15a	Nature of the association between the intervention(s) and the outcomes	12,13
	#15b	Comparison of results with findings from other publications	14,15
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	#15e	Costs and strategic trade-offs, including opportunity costs	N/A
Limitations	#16a	Limits to the generalizability of the work	16,17
	#16b	Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis	16,17
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Conclusion	#17a	Usefulness of the work	14,15
	#17b	Sustainability	15
	#17c	Potential for spread to other contexts	16,17
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	#17e	Suggested next steps	16,17
Funding	#18	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting	17

Comments:

#15e: No cost analysis was done. The intervention had minimal costs and this was out of the scope of the research

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A pre-post implementation survey of a multi-component intervention to improve informed consent for caesarean section in Southern Malawi

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TITLE: A pre-post implementation survey of a multi-component intervention to improve informed consent for caesarean section in Southern Malawi

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ABSTRACT

Objective

Surgical informed consent is essential prior to caesarean section, but potentially compromised by insufficient communication. We assessed the association between a multi-component intervention and women's recollection of information pertaining to informed consent for caesarean section in a low-resource setting, thereby contributing to respectful maternity care.

Design

Pre-post implementation survey, conducted from January to June 2018, surveying women prior to discharge.

Setting

Rural 150-bed mission hospital in Southern Malawi.

Participants

A total of 160 postoperative women were included: 80 pre- and 80 post-implementation.

Intervention

Based on observed deficiencies and input from local stakeholders a multi-component intervention was developed, consisting of a standardised checklist, wall poster with a six-step guide and on-the-job communication training for health workers.

Primary and secondary outcome measures

Individual components of informed consent were: indication, explanation of procedure, common complications, implications for future pregnancies and verbal enquiry of consent, which were compared pre- and post-intervention using $\chi 2$ test. Generalized linear models were used to analyse incompleteness scores and recollection of the informed consent process.

Results

The proportion of women who recollected being informed about procedure-related risks increased from 25/80 to 47/80 (OR 3.13 [95% Confidence Interval 1.64-6.00]). Recollection of an explanation of the procedure

changed from 44/80 to 55/80 (OR 1.80[0.94-3.44]), implications for future pregnancy from 25/80 to 47/80 (1.69[0.89-3.20]) and of consent enquiry from 67/80 to 73/80 (OR 2.02 [0.73-5.37]). After controlling for other variables, incompleteness scores post-intervention were 26% lower (Exp(β)=0.74; 95% CI 0.57 – 0.96). Recollection of common complications increased by 29% (Exp(β)=1.29; 95% CI 1.01 – 1.64). Recollection of the correct indication did not differ significantly.

Conclusion

Recollection of informed consent for caesarean section changed significantly in the post-intervention group. Obtaining informed consent for caesarean section is one of the essential components of respectful maternity care.

KEYWORDS

Informed Consent, Caesarean Section, Low-resource setting, Respectful Maternity Care

ARTICLE SUMMARY

Strengths and limitations of this study

- Based on locally identified deficiencies in clinical practice
- Use of generalized linear models to quantify effect of intervention.
- Convenient study design with limited resources: limited sample size and follow-up, no control group
- Use of incompleteness rather than completeness score, to attain Poisson distribution.

BACKGROUND

Informed consent is key to medical practice and embedded in national and international standards such as the Code of Ethics and Professional Conduct of the Medical Council of Malawi, and the International Covenant on Civil and Political Rights.[1-3] Valid informed consent is defined as being able to accept an intervention willingly after receiving adequate and comprehensible information about risks and benefits.[4] It is a preoperative necessity for all surgical procedures including caesarean section (CS), the most frequently performed surgical intervention in many parts of the world.[5] In obstetrics, explanation of procedures and seeking consent are

associated with improved rating of birth experience, while non-consented care is seen as a deterrent to skilled birth care utilization.[3, 6]

Several reports have recognised weaknesses in the process of acquiring surgical informed consent for obstetric procedures, such as providing no explanation of the indication for surgery, procedure-related risks or the post-operative trajectory.[7-16] Women may feel pressured into undergoing surgery when little information is provided or information is not understood.[9, 14] At the same time, they may experience the provision of informed consent as a bureaucratic procedure not primarily serving their own interests.[8, 9] A variety of factors influence information transfer and retention, as well as shared-decision making. Poor communication between woman and health worker may be compounded by language barriers, low education level on the side of the woman, but also by lack of consent-related knowledge or communication skills among health workers.[17-19] Additionally, emergency situations in which the informed consent process takes place may not be conducive to information retention due to shortage of time, physical limitations, anxiety and pain.[13, 20] To overcome such barriers, health workers must improve women's ability to participate in the decision-making process as fully as possible and as far as reasonably practicable.[21, 22] Information should be provided without use of medical terminology, adjusted to the language and understanding of the woman. It is preferentially given during pregnancy or, if during labour, between contractions.[17, 21]

Studies implementing interventions to improve informed consent for surgical procedures (including CS) in low-resource settings are scarce, with most literature focussing on elective procedures in high-income countries.[8, 23-25] However, there are examples of studies using multi-component interventions focussing on non-abusive and respectful maternity care.[26-30] The landscape analysis by *Bowser and Hill* identified non-consented care as one of the contributing factors to disrespect and abuse in childbirth, stating that "there is a lack of routine patient information, communication and consent protocols for obstetric procedures" in regions all over the world.[3] We postulated that a multi-component intervention standardizing the informed consent process could improve women's recollection of having consented to care and, in this way, their birth experience. Consenting to obstetric interventions including CS is one of the important elements in the broader concept of respectful maternity care.

The objective of our study was to assess recollection of informed consent prior to and after introducing a multi-component intervention consisting of a checklist, a six-step informed consent guide and communication training for health workers involved in maternity care.

METHODS

Study design, setting and participants

This prospective pre-post implementation survey was performed between January 1st, 2018 and June 1st, 2018 in the maternity department of a rural mission hospital in the southern region of Malawi. Maternity staff comprised of locally trained midwives, associate clinicians (non-physician clinicians with a predominantly practical training of four years) and two Medical Doctors in Global Health and Tropical Medicine (MD GHTM), trained in the Netherlands.[31] The maternity department provides services free-of-charge and has an average of 200 births per month. CS rate in the study period was 15.7% (82 out of 523 total births) in the pre-intervention phase, and 19.5% (81/415) in the post-intervention phase. The hospital had one operating theatre available for all procedures. All women undergoing CS were eligible for inclusion. Elective CS was defined as CS planned prior to onset of labour, while in unplanned CS the decision was made during the first or second stage of labour. Exclusion criteria were inability to participate due to bad clinical condition, referral or death prior to survey, or unwillingness to participate. The informed consent process was initiated by the midwife on duty, a medical doctor or associate clinician. After CS had been performed, women were admitted for at least 72 hours in the postnatal ward for observation and discharged in case no complications arose. Figure 1 shows an overview of the study process. The study protocol is attached as a supplementary file (supplementary file 1).

Data collection

Prior to implementation, 80 women were surveyed between January 1st and March 15th 2018 using a standardised questionnaire. Surveys were performed on the day of discharge by one of the authors (SZ), assisted by rotating nursing college students who had not been involved in direct care for the woman. Data related to timing of surgery, indication and whether it was an elective or unplanned procedure were extracted from the records. After this initial period, two weeks were allocated to intervention development and implementation. Subsequently, 80 additional women were included between April 1st and June 1st 2018.

Intervention development and implementation

Together with representatives of the maternity department, a multi-component intervention was designed consisting of a standardised checklist, wall poster with a six-step informed consent guide and communication training of health workers. The interventions aimed at addressing deficiencies observed in the pre-intervention period and brought forward by local stakeholders. This involved inadequacy of risk discussion, both in approach and content, and lack of women's involvement in decision-making. Interventions were supposed to reinforce one another by repeating important information and implementing checklist and poster into the training. The intervention consisted of the following:

1) *A standardised checklist (supplementary file 2).* Lack of informed consent protocols resulted in this checklist for health workers encompassing five components of the informed consent process: indication for operation with benefits of the proposed procedure, elaboration on the procedure, discussion of associated risks, implications for future pregnancies and verbal consent enquiry (table 1).Components were based on the National Institute for Health and Care Excellence clinical guidelines on caesarean section.[32] This particular guideline was used for its international recognition and clear outline on women-centred care. One additional checkbox addressed the opportunity given to the woman to ask questions. The importance of providing a woman with such opportunity was stressed in the communication training. The checklist was integrated into the facility's pre-operative form, thereby reassuring that the surgeon or midwife would bring the checklist along for consent enquiry. The original form only stated whether consent was given, without specifying what had been discussed during the consent process.

Table 1. Definition of primary outcomes

Completeness – Which topics have been discussed preoperatively?	
Indication	Indication for caesarean section.
Procedure	Transfer to theatre, lower abdominal incision, use of anaesthetics and possibly blood products.
Risk discussion	Information on commonly associated and serious risks.
Implications for future pregnancies	Need to deliver in secondary health facility in subsequent pregnancies. Advice to have bilateral tubal ligation after third caesarean section.*
Consent	Written and verbal consent has been collected.
Recollection – What information does the mother (or the woman) recollect?	

Recollection of indication	Woman names indication for caesarean section as mentioned in her medical records.
Recollection of common complications	Score from 0 – 3, woman picks the following common complications out of a list of six options; - Extensive bleeding (>1000ml) - Infection (wound infection, endometritis, peritonitis) - Extended recovery time as opposed to vaginal birth (three-day hospital admission and no lifting for six weeks) - Other included options: leaving instruments in the abdomen, permanent paraplegia, maternal death**

* Based on national consensus
** Extracted from *Litorp et al.* and pilot survey.[11]

2) *Posters with a six-step informed consent guide (supplementary file 3).* These posters were placed in every labour room at eye level and served as an additional reminder to maternity care providers to initiate the informed consent discussion. The guide accentuated risk discussion due to its inadequacy in the pre-intervention period. Frequently occurring risks were separated from rarer risks, following consent advice from the Royal College of Obstetricians and Gynaecologists.[33] We emphasised that, although it was set up as a step-by-step guide, health workers apply information in accordance with women's needs and circumstances.

3) *Communication training.* In the second week of development and implementation, a training session for clinical staff in the maternity department was organized. The training was established by the research team (SZ, WB, FN, KK) and based on the Royal College of Obstetricians and Gynaecologists Clinical Governance Advice on obtaining valid informed consent, Medical Council of Malawi Code of Ethics and Professional Conduct and input from the clinical team.[2, 21] The training consisted of an introduction into the theory of informed consent and a respectful woman-centred approach during labour, followed by counselling methods, using the standardised checklist and poster. We highlighted timing of conversation, addressing uncertainties and questions and the importance of acquiring verbal consent. Role-play in settings of both elective and unplanned CS was performed and subsequent feedback given by other participants applying Pendleton's rules for professional feedback.[34] The single training session was attended by ten midwives, six associate clinicians and two MD GHTM. Not all rotating clinicians and midwives were present due to conflicting clinical duties. Questions from participants were addressed and participants invited to provide input into improving the consent guide.

Checklist and guide were discussed in a plenary session with all hospital staff, which provided an opportunity for additional adjustments. Health workers were then provided copies of checklist and guide. After the plenary session, posters were placed in the ward and use of the form with checklist started. No other interventions related to quality of care were implemented during the post-intervention period.

Study tool

For the pre- and post-implementation surveys, an exit questionnaire was created in English and Chichewa using forward and subsequent backward translation. (Supplementary file 4 and supplementary file 5) An expert committee consisting of experienced clinicians and midwives working in the maternity department of the hospital were involved in validating its content. This included how indications for CS should be grouped, which complications should be known to women and what information is indispensable with regard to future pregnancies. Additionally, participant and procedure related variables with potential impact on outcomes were identified. Use of medical terminology was reduced to ensure that all questions could easily be understood. A three-week pilot study was performed, whereby in the first week women were asked open-ended questions to obtain insight in probable answers. Mentioned risks related to CS were noted and used as answer options in the later version of the questionnaire. In the following two weeks, clarity of the study tools was examined and the order of questions and answer options adjusted in order to be easily understood by participants.

Outcome variables

Primary study outcomes were level of incompleteness and recollection of common complications and indication (table 1). Incompleteness was defined as the number of informed consent components not discussed according to the woman. For each component, the woman was asked whether it was discussed during the consent process. Each of five components was dichotomously scored (1 = not discussed, 0 = discussed) and rated as equally important. This resulted in an "incompleteness score" ranging from 5 (=none of the components discussed) to 0 (=all components discussed). An "incompleteness" rather than a "completeness" score was used, due to adoption of a Poisson distribution by the outcome variable. To assess recollection of common complications a list with complications was provided, of which three were commonly associated with CS and three were not. For every common complication mentioned, one point was given. Common complications deemed as essential knowledge for women in our setting were extensive bleeding of

more than one litre, infections such as wound infection, endometritis or peritonitis and an extended recovery time compared to vaginal birth. Three other choices were added to the list, based on complications named by women during the pilot study. Recollection of indication was measured by the percentage of women who described the indication for CS as stated in the medical records. Indications were categorised using plain, non-medical language such as "problem with heartrate of the child" or "high blood pressure".

Analytic approach

For descriptive analyses unpaired t-test, Mann-Whitney U test or $\chi 2$-test were used depending on the type of variable and normality of its distribution. For completeness, each individual component of informed consent was compared between the pre- and post-intervention groups using $\chi 2$-tests with odds ratio's and 95% confidence intervals. Additionally, generalized linear models were used to identify the attribution of the intervention on dependent variables: "incompleteness score", "number of recollected common complications" and "correct indication recall percentages". For the incompleteness scores a Poisson regression was adopted, due to a Poisson distribution of the dependent variable (one sample independent KS test ($p=0.57$)). The model's goodness of fit (Pearson $\chi 2/df$) was 0.96 and the omnibus test showed a significant difference between the model and intercept model ($p<0.001$). Number of recollected complications was normally distributed according to Jarque-Bera test of 1.44 (p-value >0.1) and a linear model was used. Goodness of fit was 0.61 and the omnibus test showed a significant difference ($p=0.03$). Binomial logistic regression was used with correct indication recall percentages as dependent variable. Goodness of fit was 1.06 and omnibus test showed no statistically significant difference ($p=0.14$). Type and timing of CS, antenatal consultations and prior CS were identified as explanatory variables based on the literature.[13, 33, 35] Additional explanatory independent variables were identified based on subsequent application of variables in the different models, and included when $p<0.05$. Exponentiated regression coefficients ($Exp(\beta)$) and their 95% confidence intervals were reported for the Poisson and logistic bivariate model, whereas for the linear model regression coefficients (β) were reported. All analyses were performed with IBM SPSS 24.0. Alpha was set at 0.05. Analysis and interpretation of data adhered to SQUIRE 2.0 (Standards for Quality Improvement Reporting Excellence) guidelines.[36]

Ethical consideration

The study received ethical approval by the National Health Sciences Research Committee of Malawi (approval number 1995) and a declaration of no-objection by the Leiden University Medical Centre Ethical Committee (reference number P18.027). Permission was granted by the hospital management to conduct the study. All participants were provided with an informed consent sheet either in English or Chichewa, regarding the purpose of the study, their right to stop participation at all times and a request to access their medical files. For women who were illiterate, the interview assistant read the consent form out loud and elaborated. Finger prints were accepted as signatures for women who did not know how to write. No names were included during data collection to ensure confidentiality. All women were asked to give informed consent before inclusion. Patient files were accessed only after approval was obtained. Patient records were brought with them to the exit-survey and extracted data was linked to their anonymised study number. Immediately after collection, data were stored in a locally encrypted database, only accessible by the primary investigators.

Patient and public involvement

The importance of improving informed consent was highlighted in various hospital advisory committee meetings, in which local chiefs present concerns of the community. This laid the foundation for this study. During the pilot phase, women were asked to comment on study tools, in order to make these as easily understandable and applicable as possible.

RESULTS

During the study period, 163 women were eligible for inclusion, of whom 160 (98%) participated. One woman was discharged before the scheduled interview and two refused to participate. All participating women completed the interview.

Participant- and procedure-related characteristics

The majority of women had had no previous CS; 54 (67.5%) pre- and post-intervention. (table 2). In both groups the highest percentage of women were aged between 20 and 24 years. Median age of the pre-intervention group was 26 (IQR 21-30) as compared to 24 (IQR 21-30; p=0.96) in the post-intervention group. Inability to read English or Chichewa was observed in 17 (21.3%) women pre-intervention and in 15 (18.8%) post-intervention. No statistically significant differences were found with regard to women's parity, antenatal consultations, highest educational level and religion. Daily occupation differed statistically significantly

(p<0.05), with more self-employed women in the pre-intervention group (21, 26.3%) compared to the post-intervention group (7, 8.8%). The majority of CS were unplanned in both groups, 66 (82.5%) and 68 (85%). A statistically significant difference was observed in the attendance of medical doctors during CS: 12 CS (15%) in the pre-intervention group compared to 37 CS (46.3%) in the post-intervention group. No statistically significant differences in timing of or indications for CS were found.

Table 2. Participant and procedure characteristics for the pre- and post-intervention group

	Pre-intervention [N=80] (%)	**Post-intervention [N=80] (%)**	p-values
Age			0.96
- 15 – 19	16 (20)	14 (17.5)	
- 20 – 24	22 (27.5)	29 (36.3)	
- 25 – 29	21 (26.3)	12 (15)	
- 30 – 34	15 (18.7)	14 (17.5)	
- 35+	6 (7.5)	11 (13.8)	
- Median Age <IQR>	26 <21-30>	24 <21-30>	
Parity			0.83
- 1	31 (38.8)	31 (38.8)	
- 2	21 (26.3)	18 (22.5)	
- >2	28 (34.9)	31 (38.8)	
Prior CS			0.24
- 0	54 (67.5)	54 (67.5)	
- 1	18 (22.5)	23 (28.8)	
- >1	8 (10)	3 (3.8)	
Inability to read English/Chichewa (%)	17 (21.3)	15 (18.8)	0.69
Highest educational level attained			0.06
- No formal education	7 (8.8)	6 (7.5)	
- Primary school	36 (45)	34 (42.5)	
- Junior secondary school	11 (13.8)	5 (6.3)	
- Senior secondary school	18 (22.5)	20 (25)	
- College/University	8 (10)	15 (18.8)	
Religion			0.84
- Christian	40 (50)	41 (51.3)	
- Jehovah's witness	2 (2.5)	1 (1.3)	
- Muslim	38 (47.5)	38 (47.5)	
Occupation			<0.05
- Employed	8 (10)	12 (15)	
- Business/self-employed	21 (26.3)	7 (8.8)	
- Student	3 (3.8)	3 (3.8)	
- Housewife	29 (36.3)	27 (33.8)	
- Farmer	19 (23.8)	31 (38.8)	
Mean number of antenatal consultations +/-SD	3.7 +/- 1.1	3.53 +/- 1.1	0.25

Timing of CS			0.42
- 8AM – 6PM	46 (57.5)	51 (63.7)	
- 6PM – 8AM	34 (42.5)	29 (36.3)	
Type of CS			0.67
- Elective CS	14 (17.5)	12 (15)	
- Unplanned CS	66 (82.5)	68 (85)	
Prevalence of indication categories			0.19
- Obstructed labour	45 (56.3)	49 (61.3)	
- Non-reassuring fetal status	7 (8.8)	3 (3.8)	
- Malposition/malpresentation	6 (7.5)	12 (15)	
- Preeclampsia/HELLP	2 (2.5)	1 (1.3)	
- Antepartum haemorrhage	3 (3.8)	0 (0)	
- Cord presentation/prolapse	2 (2.5)	2 (2.5)	
- Uterine rupture	2 (2.5)	1 (1.3)	
- ≥2 CS in history	8 (10)	3 (3.8)	
- Other*	5 (6.3)	9 (11.3)	
Surgeon performing CS			<0.05
- MD GHTM	12 (15)	37 (46.3)	
- Clinical Officer	68 (85)	43 (53.7)	

* Including (preterm) prelabour rupture of membranes, on woman's request.

Completeness of informed consent

In the post-intervention group 47 (58.8%) women expressed that they had received information on risks before surgery, as compared to 25 (31.3%) in the pre-intervention group (OR 3.13; 95% CI 1.64 – 6.00) (table 3). Changes in explanation of the procedure (OR 1.80; 95% CI 0.95 – 3.44), inclusion of implications for future pregnancies (OR 1.69; 95% CI 0.89 – 3.20), and verbal consent enquiry (OR 2.02; 95% CI 0.73 – 5.37) were noted, though none of these were statistically significant. The component "indication for the procedure" was mentioned equally in both groups (96.3%). Independent variable analysis showed "Age" and "Ability to read English/Chichewa" to be significantly associated with incompleteness scores. No correlation was found with type of surgeon or daily occupation. Incompleteness scores were 26% lower in women surveyed after implementation of the intervention (Exp(β)=0.74; 95% CI 0.57 – 0.96) (table 4). Age was associated with a 4% decrease per year (Exp(β) = 0.96; 95% CI 0.94 – 0.99). Inability to read English or Chichewa provided 30% higher incompleteness scores (Exp(β) = 1.3; 95% CI 1.02 – 1.83).

Table 3. Completeness of informed consent; number of informed consent aspects discussed during

preoperative counselling. Comparison between pre- and post-intervention group.

	Pre-intervention [N=80] (%)	Post-intervention [N=80] (%)	Odds ratio (95% CI)
Mentioned indication	77 (96.3)	77 (96.3)	1 (0.20 – 5.11)
Procedure explained	44 (55)	55 (68.8)	1.80 (0.94 – 3.44)
Associated risks explained	25 (31.3)	47 (58.8)	3.13 (1.64 – 6.00)
Need to deliver in hospital next time/ Need to deliver by CS next time / BTL	43 (53.7)	53 (66.3)	1.69 (0.89 – 3.2)
Written and verbal consent	67 (83.3)	73 (91.3)	2.02 (0.73 – 5.37)

Table 4. Generalized linear model: Poisson. Variables associated with incompleteness scores.

Variables		Exponentiated regression coefficiënt, β	95% CI	p-value
Group	Pre-intervention	1		
	Post-intervention	0.74	0.57 – 0.96	0.02
Type of CS	Unplanned	1		
	Elective	0.83	0.54 – 1.29	0.41
Timing of CS	Day-time (8AM – 6PM)	1		
	Night-time (6PM – 8AM)	1.24	0.95 – 1.62	0.12
Prior CS	0	1		
	1	0.92	0.66 – 1.28	0.62
	>1	1.53	0.93 – 2.52	0.09
Antenatal consultations		1.02	0.91 – 1.16	0.70
Age		0.96	0.94 – 0.99	0.00
Ability to read English/Chichewa	Yes	1		
	No	1.3	1.02 – 1.83	0.04

Recollection of informed consent

Multivariate Poisson regression analysis identified an increase of 0.25 recollected complications in the post-intervention group when corrected for other variables (β=0.25; 95% CI 0.01 – 0.49) (table 5). Age of participants was identified as an additional explanatory variable and associated with 0.02 more common complications recalled per year (β=0.02; 95%CI 0.00 – 0.04). Logistic binomial regression examined that women counselled post-implementation were 2.11 times more likely to recall the indication for CS (Exp(β)= 2.11; 95%CI 0.96 – 4.60). (Table 6) No additional explanatory variables were identified to be associated with correct indication recall percentages.

Table 5. Generalized linear model: Linear. Variables associated with number of recollected common complications.

Variables		Regression coefficiënt, β	95% CI	p-value
Group	Pre-intervention	0		
	Post-intervention	0.25	0.01 – 0.49	0.04
Type of CS	Unplanned	0		
	Elective	0.27	-0.09 – 0.63	0.14
Timing of CS	Day-time (8AM – 6PM)	0		
	Night-time (6PM – 8AM)	-0.02	-0.28 – 0.23	0.86
Prior CS	0	0		
	1	0.06	-0.23 – 0.34	0.69
	>1	-0.18	-0.68 – 0.33	0.49
Antenatal consultations		0.10	-0.14 – 0.21	0.09
Age		0.02	0.00 – 0.04	0.05

Table 6. Generalized linear model: Binary Logistic. Variables associated with correct indication recall percentages.

Variables		Exponentiated regression coefficiënt, β	95% CI	p-value
Group	Pre-intervention	1		
	Post-intervention	2.11	0.96 – 4.60	0.06
Type of CS	Unplanned	1		
	Elective	2.66	0.78 – 9.08	0.12
Timing of CS	Day-time (8AM – 6PM)	1		
	Night-time (6PM – 8AM)	1.63	0.72 – 3.71	0.25
Prior CS	0	1		
	1	0.58	0.24 – 1.41	0.23
	>1	0.27	0.07 – 1.14	0.08
Antenatal consultations		1.07	0.75 – 1.53	0.71

DISCUSSION

This study evaluated a multi-component intervention, consisting of an informed consent checklist, guide and training, providing standards and tools for the informed consent process prior to CS. The intervention had been developed and implemented in cooperation with clinical staff hoping to increase perceived acceptability, a necessary condition for effectiveness.[37] Other community or system related issues potentially influencing the intervention's effectiveness were normalisation of non-consented care, and lack of patient autonomy and legal redress mechanisms.[3] Although these issues were touched upon, the current intervention will not suffice as a complete solution. We opted for a prospective pre-post implementation study design because randomisation

was not compatible with the study setting and pre-intervention data deemed to be necessary for development and implementation of the multi-component intervention.

The percentage of women stated to have received information on procedure-related risks was 27.5% higher in the post-intervention group. Furthermore, the procedure was explained more frequently and more women were able to reproduce the indication for CS, although this trend was not statistically significant. An explanation for the latter not reaching the level of statistical significance could be that the informed consent consultation in the pre-intervention group already included an explanation of the proposed procedure and implications for future pregnancies in considerably large, although still deficient, proportions. Additional and more specific measures may be required to further improve recollection of these items. The supplementary poster mainly focussed on risk-discussion, possibly overlooking other components. Consent enquiry was incomplete in both groups, which in every case was explained by absence of verbal consent. This is a major concern, since surgery should not be performed without consent. After controlling for other explanatory independent variables, incompleteness scores were 26% lower in women counselled post-intervention. This implies that more components of informed consent were included after implementation. The variables "attended by MD GHTM" and "daily occupation" differed pre- and post-intervention, but no association with incompleteness scores was found in the multivariate model. A higher age of the woman, however, was associated with lower incompleteness scores, even after correcting for parity and the presence of prior CS. Possibly younger women experience discriminatory behaviour based on providers' prejudice, as has been reported previously.[3] Additionally, young women might be less involved in decision making when seniors are present to speak for them.[19, 38] Age and inability to read Chichewa or English resulted in higher incompleteness scores. This underlines the need for verbal explanation and consent enquiry in addition to the written consent form. Written consent forms should be made available in local languages.

Besides more risk discussions being included during the informed consent process, an increase of the number of recalled risks was observed post-intervention, suggesting an increased recollection of common complications. Despite its statistical significance, the effect size was considered to be small. Higher correct indication recall percentages were seen, although this did not reach the level of statistical significance. It is important that information is reproducible. A signed consent form may not be valid if information has not been understood.[39, 40] Women's educational level, language competency and provider's effective communication

of procedure, risks and recovery have previously been identified as important determinants to comprehend the informed consent process.[40, 41] Despite inclusion of more informed consent components post-implementation, discrepancies may exist between provider and women's perspectives of the informed consent process.[42] Written material in women's vernacular may increase understanding, but written consent forms were previously found to be difficult to understand by women going for unplanned obstetric surgery.[9, 13]

Efforts were made to sustain motivation and participation by including verbal consent as one of the five components and giving women and their guardians an opportunity to ask for clarification. Involvement in the informed consent process may give women the feeling of being in control and enhance their relationship with healthcare providers. These are two facilitators of a positive birth experience.[43] In addition to standardization, we measured outcomes at patient level, which is an indirect reflection of interventions at health system level. Interference of woman-related factors such as prior experiences, emotional barriers and physical impairment may occur, and may not be covered by our intervention. Nevertheless, the quality of informed consent is reflected in women's recollection.

Our chosen study design has several limitations. Firstly, given the uncontrolled pre-post study design conclusions with regard to causality between intervention and studied outcome are impossible. Study groups were different with regard to daily occupation and type of surgeon. Although these particular variables were not independently statistically significantly associated with the outcome, the latter could have been confounded by co-occurring contextual differences, such as policy changes and acquaintance with the research team.[44] Several potential confounders were included in the model and the research team was stable throughout the study period, therefore we think that residual confounding and researcher bias are limited, but these cannot be excluded. Time elapse between pre- and post-implementation phases was minimized, no additional interventions were implemented at facility level and no interventions were reported by local government at the time. While the limited time elapse between both groups may be beneficial to reduce the chance that concurring events influence outcomes, it may complicate assessing sustainability of the intervention, since the effect is measured shortly after implementation. Secondly, a sample size calculation was not performed due to absence of prevalence data on informed consent recollection in our setting or similar populations in the designing phase of the study. At the time of finalizing this paper, such data are available.[7, 8] Our sampling was based on convenience and logistical possibilities. Thirdly, due to the use of a Poisson

regression analysis, "incompleteness" rather than "completeness" scores were used, increasing goodness-of-fit of the model, but rendering interpretation possibly more difficult. Additional limitations were incomplete validation of our self-designed questionnaire with regard to test-retest reliability, inter-rater reliability and the tool's responsiveness to changes in outcome, and existing language barriers between interviewer and participants. To diminish these effects, we designed the questionnaire to be simple and give little room for interpretation, with both multiple choice and closed-ended questions. When necessary, translation was done by local nursing college students. The presence of health workers might have led to socially desirable answers, although none of the participating students were involved in the consent process or birth.

In future research, attribution of the intervention to the observed difference in recollection of informed consent has to be confirmed by including a control group in the study design. Outcomes other than completeness of the consultation and women's recollection are worth investigating. New studies could explore influence of our multi-component intervention on women's satisfaction, anxiety and long-term comprehension, and this intervention or similar context-specific interventions should be assessed in other settings.

CONCLUSION

After implementation of a multi-component intervention recollection of the informed consent process for caesarean section improved. Women stated more frequently to have received information on the procedure, possible complications and implications for future pregnancies. Recollection of common complications was significantly higher post-intervention. These results suggest that standardisation and training positively influence informed consent in a resource-poor setting, and thereby promote respectful maternity care.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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DATA STATEMENT

Extra data can be accessed via the Dryad data repository at http://datadryad.org/ with the doi: 10.5061/dryad.8sf7m0chd

LICENCE STATEMENT

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AUTHOR CONTRIBUTIONS

SZ and WB drafted the study protocol, with help of TvdA and JvR. FN and KK provided feedback on the study design and helped implementing the study in the facility. SZ and FN drafted the study tool. KK assisted in inclusion and logistics around the interviews. SZ conducted the interviews analysed the data together with WB. SZ and WB drafted the manuscript which was commented on by all authors and approved for submission.

CAPTIONS

Figure 1: Flowchart of study design

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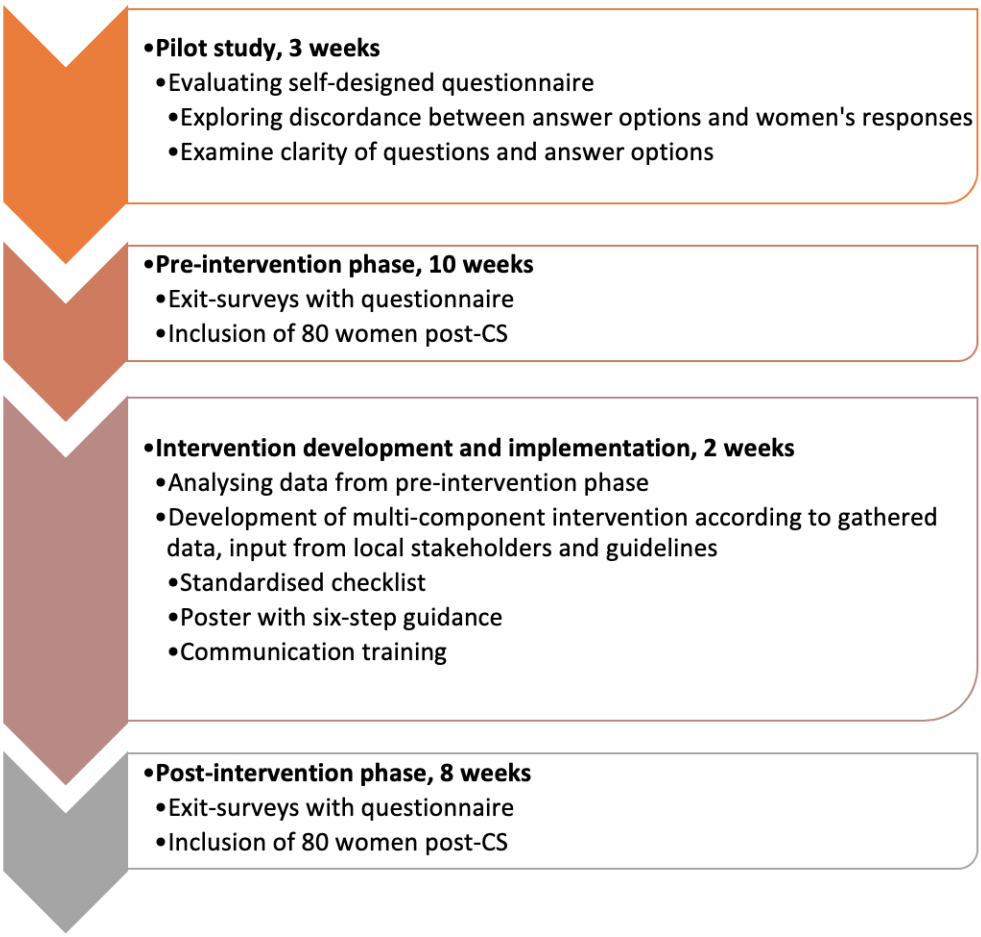

Figure 1: Flowchart of study design

DECISION-MAKING AROUND CAESAREAN SECTION IN A RURAL HOSPITAL IN MALAWI

STUDY PROTOCOL

Study site: Saint Luke's Hospital, Malosa
Duration project: 1 February 2018 – 1 February 2019
Primary investigator: Wouter Bakker, Medical Officer
Email: bakker.stlukes@gmail.com Phone: +265991694212

Abstract

Research problem: Quality of care surrounding CS has to be investigated due to reports of disrespect and abuse in maternity health care. CS numbers are rising and some of them are performed unnecessarily. Health workers should ensure that the patient's right to information and consent are respected. Health worker perspectives on information transfer and gaining consent should be assessed to implement interventions accordingly and successfully. With this study, we assess the current quality of consultation for caesarean section and aim for improvement.

Objectives:

1. Analyse indications for caesarean sections and the use of interventions in labour.
2. Analyse the quality of the pre- and postoperative consultation for CS according to the patient's experience and recollection.
3. Identify circumstantial factors and patient characteristics which influence the informed consent process.
4. Analyse health worker perspectives on the use of informed consent prior to CS, in both emergency and elective settings.
5. Study the effectiveness of a standardized informed consent checklist.

Hypothesis: We hypothesize that the use of oxytocin and vacuum extractions can be improved in order to prevent unnecessary CS. We also hypothesize that the information transfer in consultation for CS is not according to accepted standards. Our proposed standardized informed consent checklist may aid us in reaching these standards. We also hypothesize that patients literacy, type of CS and performance of CS during night influence the effectiveness of our consultation. This may help in optimizing informed consent in specific groups.

Methods: A mixed-method approach, consisting of:

- Retrospective cohort analysis of all deliveries in 2015 and 2016 on indications for caesareans and the use of interventions in labour.
- Interview-administered questionnaire study (controlled before and after study) to identify the quality of informed consent prior to CS.
- Semi-structured interviews with health workers on the use of informed consent prior to CS.
- Implementation of intervention package to support a standardized informed consent checklist.

Benefits and Risks: No serious harm is inflicted to the patient by performing this study. Precautionary measures are taken to protect sensitive information of the study participants. No direct benefits are gained for the patient, other than an extra thorough explanation of risks of CS and post-CS care. However, this work lays the foundation for interventions which improve the quality of care in Saint Luke's Hospital.

Use of results: Primarily as foundation from where we can improve Respectful Maternity Care in Saint Luke's Hospital. Possibly presented during conferences in places in Malawi and the Netherlands. An effort will be made to submit an article to a Malawian peer reviewed journal. An article could be submitted to an international journal, after review by the NHSRC.

Table of contents

1. Proposal Summary

Title of Proposal	Decision-making around caesarean section in a low-resource setting.
Principal investigator	Wouter Bakker, MD

1. RESEARCH QUESTION TO BE ADDRESSED

How can we improve decision-making around caesarean sections in a rural hospital in Malawi and thereby reduce the amount of unnecessary caesareans, by looking at indications, interventions and informed consent?

2. RATIONALE FOR RESEARCH

Malawi currently has a population caesarean section (CS) percentage of 6.1%, of which 1.3% are elective procedures, and it has been slowly rising since 1992. [1] Hospital-based CS rates, however, are way higher. It is critical that this rise in CS is justified by the correct indications and is accompanied by an increase in awareness of the necessity of informed consent. Increasing the use of interventions in labour, like amniotomy, oxytocin administration and vacuum extraction could improve chances for vaginal delivery and prevent an unnecessary CS. Besides evidence based quality care, mothers deserve information and autonomy in their health, pregnancy and childbirth. Discussing the process and indications of caesareans thoroughly between clinicians and patients can assist in decision making. Several reports have recognised insufficiencies in the informed consent process prior to caesarean sections, as well as in the broader concept of RMC during facility-based deliveries in low-income countries. Despite its importance and being one of the most practical factors of the Bowser and Hill model to improve, the current state of informed consent for CS in Malawi has not be documented yet. Also, health staff perspectives on the need for informed consent and what it should accomplish might be helpful in improving informed consent and thus quality of care. This mixed-method study aims to give insight in the current practice of CS and its effectiveness in a low-income setting. Providing baseline data on the current state may present the need for improvement and lay the foundation for interventions, such as standardization of the consent process.

Based on our clinical experience, we hypothesize that a proportion of caesareans performed could be avoided and that use of interventions can be extended. We also hypothesize that the information transfer in consultation for CS might not always be according to accepted standards. However, health workers probably recognize the shortcomings in our consultation and may come up with suggestions how to overcome these barriers. We expect them to see the necessity and use of informed consent, and be open to possible additions. Our proposed informed consent checklist may aid us in reaching these standards.

OBJECTIVES

1. Identify indications for caesarean sections in order to find opportunities to prevent unnecessary caesareans to reduce maternal morbidity and mortality.
2. Determine use of evidence-based interventions in labour in our setting as amniotomy, oxytocin administration and vacuum extraction

3. Analyse the completeness and recollection of the pre- and postoperative consultation for CS, according to the patient's experience.
4. Identify circumstantial factors and patient characteristics which influence the informed consent process.
5. Analyse health worker perspectives on and experiences with the use of informed consent prior to CS, in both emergency and elective settings.
6. Study the effectiveness of an informed consent checklist on completeness of informed consent and patient recollection.

3. METHODS

The study will take place at Saint Luke's Hospital in Malosa, a rural CHAM facility. Maternity care here is free of charge for patients in the surrounding area.

This study project will make use of a mixed method approach, consisting of the following:

1. Retrospective data analyses of all vaginal births, vacuum extractions and caesarean sections over a two-year period: All patient data from the labour ward from the years 2015 and 2016 are collected. These files consist of partographs and information on admission and follow-up.
   a. Indications for caesareans done in this period will be extracted and compared to national protocols. The partographs will be assessed to see if the conditions for the indication are met and indications will be classified accordingly.
   b. All information concerning decisions during the labour process are collected: artificial rupture of membranes and induction or augmentation with oxytocin.
   c. All vacuum extractions will be evaluated on their indication, outcome and use before and after re-introduction and training.
2. Quantitative survey into quality and uptake of informed consent: In the period January – September 2018, a survey will be conducted into the quality of informed consent on caesarean sections. Exit-interviews with patients who underwent caesarean will be conducted, focused on their experiences and ability of information recall. An intervention to improve the quality of informed consent will be designed and assessed in the study period.
3. Qualitative analysis of perception of informed consent by health workers: To gain more insight in the use, functionality and challenges with informed consent in the setting, interviews with health workers will be conducted in the same period as stated above, following a semi-structured questionnaire. This will be combined with focus group discussions to get a clear picture on the perceptions of staff on informed consent.

4. RISKS & BENEFITS

Benefits and risks have been thoroughly discussed in the research group and are considered minimal. The patients undergoing exit-interviews might be at risk of being disadvantaged by health workers in future care, because of criticism on information transfer. This risk is minimized by anonymizing the questionnaire outcomes and administer the questionnaire on discharge in a separate room. Outcomes are only available to the independent researcher.

The health workers included in the qualitative in-depth interviews might be at risk of being criticized because of views not in accordance with hospital policy. This risk is minimized by anonymizing the collected interview data by an independent interviewer (SZ) and using a transcription for analysis, rather than the voice recording itself.
The performance of this study will increase awareness on the decision-making process around caesareans and the informed consent process. This may lead to a better health worker – patient relationship, of which staff and patients will benefit, and to a higher standard in quality of care and communication. Patients will receive an additional explanation of risks and implications on future pregnancies of their caesarean section, which might influence postoperative outcomes in a positive way.
Reviews of the ongoing study and the data collected will be conducted as per policies of the NHSRC. Any serious events will be reported promptly as required. This study does not involve any new therapies.

5. COSTS & COMPENSATION

Participants will not receive any direct compensation for participation in the study. However, they will receive additional consultation on post-operative risks and implications on future pregnancies associated with CS. Participants will not be asked to assume any out-of-pocket costs for their participation.

6. CONFIDENTIALITY ASSURANCES

All data, including study identification numbers, will be stored electronically under password protected software. All research paperwork including data collection forms, will be kept in a locked cabinet in the administration office of Saint Luke's Hospital; only the primary investigator will have access to it. Data will be anonymized to maintain strict protection of confidentiality. All members of the research team are well aware of issues related to confidentiality, especially with regards to HIV status. Furthermore, all personnel have been trained in subject protections and Good Clinical Practice. An independent ombudsman may be contacted by the patient if any wrongdoing has occurred. The patient information sheeth has been attached as a supplemental document to this application.

7. CONFLICT OF INTEREST

The research team does not have any conflicts of interest in performing this study.

8. COLLABORATIVE AGREEMENTS

The proposed study will be a collaboration between Saint Luke's Hospital and Leiden University Medical Centre. Letters of approval and support are provided as supplemental documents to this application.

9. INTENDED USE OF RESULTS

The results will be presented to the hospital staff and will hopefully assist in improving maternity care. Study results will be summarized and explained in an accompanying article. If the authors decide to publish the article, a copy will be send to the National Health Sciences Research Committee for review. An effort will be made to publish the findings in at least one local or international peer reviewed journal. Also, a final report will be send to the NHSRC after finishing the study.

The results can be a foundation for quality of care interventions, such as an informed consent checklist and focus group discussions with obstetric health staff. It may be presented in conferences in Malawi or internationally to address the importance of this subject. Furthermore, the whole project will give experience for the staff involved, which might motivate and assist them in their future career. Outcomes of this relatively small study project hopefully leads to more research being performed on the subject, for example in bigger multi-centre studies.

2. Main Proposal

Title of project	Decision-making around caesarean section in a low-resource setting.
Principal Investigator	Wouter Bakker, MD
Place of Study	Saint Luke's Hospital

1. BACKGROUND AND JUSTIFICATION

Unnecessary caesarean sections

Caesarean sections are rising worldwide, in both high- and low-income settings.(1–3) In their in 2015 updated statement on caesarean sections the WHO concluded that we should aim for a population based caesarean rate of 10%, with above that no significant improvement on maternal and neonatal outcome.(4) In a low-income setting as Malawi, caesarean section rates on population level still appear to be low, but on institutional level they are rising.(5) Caesarean sections are associated with severe maternal outcomes like hysterectomy, blood transfusion, need for ICU admission and death and this association is even higher Africa compared to Latin-America or Asia.(6–9) A study from South-Africa found a three times increased risk of maternal death after caesarean compared to vaginal birth, with haemorrhage as leading cause of death.(10) The risk on infections or uterine rupture in further pregnancies can also not be underestimated, especially not in a country where the average fertility rate is above five.(11–14) It remains therefore crucial to carefully select those cases eligible for surgical intervention and prevent to perform unnecessary procedures.(2) Where it used to be a problem of too little, too late and mothers and children died of not getting access to surgical care, we nowadays could also talk of too much, too soon. Critical evaluation of protocols, indications and individual cases could raise knowledge about necessary and unnecessary caesareans and assist in management of further cases. This can be done by audit of indications, group discussions and case evaluations. The World Health Organization advises to monitor CS rates on facility level.(4) There are many different classifications for caesareans described and a systematic review described the Robson classification as being the best suitable for identifying indications for caesareans.(15) This classification divides the indications for caesareans in different groups, but provides no means to compare indications to international standard protocols, to assess whether the decisions for performing an caesarean was based on correct grounds.(16) This could be useful at facility but also regional level, as a first step to identify pitfalls and work on reducing unnecessary procedures.

Interventions in labour

Analysing the indications of caesareans, we can identify in which area's we could improve to prevent ending up in unnecessary caesarean sections by using interventions in labour. These evidence based interventions are basic, broadly available and less risky than surgery. They require good monitoring of labour, for example using partographs. This is the case already in a big part of the world, although documentation is sometimes suboptimal.(17) Amniotomy and oxytocin administration should be available in every BEmOC setting, and should be used in case of poor progress of labour, if correctly identified.(18–20) Maintaining experience with this could prevent performing unnecessary caesarean sections. In the case of prolonged second stage of labour, forceps or vacuum extraction could provide assistance before opting for emergency caesarean section and local training

and support could improve its use.(21,22) Pro-active support of labour could also result in successful vaginal birth after caesarean, preventing complicated repeat caesareans.(13,23) Together, correct and indicated use of these evidence based interventions could assist further in preventing unnecessary procedures and deliver mothers the care they deserve.

Informed consent

Besides evidence based quality care, mothers deserve information and autonomy in their health, pregnancy and childbirth. Discussing the process and indications of caesareans thoroughly between clinicians and patients can assist in decision making. One of the universal rights for childbearing women is the right to information and informed consent. Being able to accept an intervention willingly after receiving adequate and comprehensible information about the risks and benefits of the suggested treatment and alternatives, is defined as valid informed consent.(24) In the Bowser and Hill model on disrespect and abuse, non-consented care is one of the categories and could lead to reduces accessibility of health facilities, risking complications in pregnancy, labour or the postnatal period.(25) Although forming a necessity, informed consent can be suboptimal, leading to questions, confusion and dissatisfaction with patients.(26,27) The use or misuse of informed consent is easily monitored at facility level and information on this could give insight in areas of improvement. Several reports have recognised insufficiencies in the informed consent process prior to caesarean sections (28-30), as well as in the broader concept of RMC during facility-based deliveries in low-income countries. (25, 31-33) Causes that inhibit informed consent practices are low level of education of the patient population, poor communication between doctor and patient, not enough time given for obtaining consent, extensive use of medical terminology and low level of knowledge of informed consent among doctors.(29) On a structural level, poor working conditions caused by system deficiencies leading to high workloads among practitioners, may also add to the problem.(34,35) The deficiencies in the informed consent process result in the preservation of false perspectives women have of caesarean sections. Prior counselling to C-sections with comprehensible information about the indication, procedure, common complications and implications on future pregnancies (36) might enhance women's understanding and thereby diminish misconceptions of the proposed surgery. As of yet, very few data is known on the use and quality of informed consent for surgical procedures in a low-resource setting. Identifying this and creating opportunities to improve the consent process can contribute to the decision-making and quality of care around caesarean sections.

2. HYPOTHESIS

We hypothesize that a significant amount of caesareans could be avoided and that there are opportunities during labour to do so. Also, we predict that the current the consultation prior to a caesarean section is suboptimal and that not all patients can reproduce their indication and the risks of a surgical intervention. Patient educational level and time of surgery might influence the information transfer effectiveness. Health workers might assist in identifying shortcomings and give insight in clinical practice of the consultation. With these inputs, an intervention package will be implemented consisting of a informed consent checklist, assessing the identified barriers and tackling them. We hypothesize that

with this approach we will improve the recollection of the patient and make the consultation more complete.

3. OBJECTIVES

The broad objective of this study is to improve the current informed consent consultation for caesarean section. This objective can be specified by the following objectives;

1. Identify indications for caesarean sections in order to find opportunities to prevent unnecessary caesareans to reduce maternal morbidity and mortality.
2. Determine use of evidence-based interventions in labour in our setting as amniotomy, oxytocin administration and vacuum extraction
3. Analyse the completeness and recollection of the pre- and postoperative consultation for CS, according to the patient's experience.
4. Identify circumstantial factors and patient characteristics which influence the informed consent process.
5. Analyse health worker perspectives on and experiences with the use of informed consent prior to CS, in both emergency and elective settings.
6. Study the effectiveness of an informed consent checklist on completeness of informed consent and patient recollection.

4. METHODOLOGY

Study site

The project will conducted in St. Luke's Hospital in Malosa, Malawi. The hospital is based in the southern region of Malawi. St. Luke's is a CHAM (Christian Health Association of Malawi) facility, working with a principle of minor user fees for their service. Maternity care is free of charge for the catchment population through the governments Service Level Agreement (SLA). The 150 bed rural hospital offers all types of care, including comprehensive emergency obstetric care for pregnancies from all gestational ages, with an average number of 2500 births per year. It serves a catchment population of roughly 30,000. The caesarean section rate was 19% in 2015 and 23% in 2016. This increase led to questions with hospital management and the request for further investigation. The principal investigator works full-time as a medical officer in St. Luke's since 2016 and has on the ground experience in the labour ward. He has close contact with management, hospital staff and patients and acquired insight in local problems and needs.

Study period

The whole study project will roughly take place between January 2018 and January 2019, but data of previous periods will be incorporated (from 2015 onwards).

Study design

The projects has a mixed-methods study design, consisting of a retrospective data analysis of all vaginal births, vacuum extractions and caesarean sections over a two-year period, a quantitative survey into quality and uptake of informed consent and a qualitative analysis of perceptions of health workers on informed consent . When shortcomings and barriers are identified, we propose to implement a structured informed consent checklist in

concordance with instructions on usage. The factors of influence we identified in both the analysis of the questionnaires and interviews, we will implement in the intervention.

Retrospective data analyses of all vaginal births, vacuum extractions and caesarean sections over a two-year period.

3500 case files of women who delivered in Saint Luke's Hospital between 1 January 2015 and 31 December 2016 will be collected and analysed retrospectively. Files consist of partographs and information on admission and follow-up. The information is collected in a database and statistical analysis on three major subjects will be done. The following information is gathered;

1. Indications for caesareans done in this period will be extracted and compared to national protocols. The partographs will be assessed to see if the conditions for the indication are met and indications will be classified accordingly.
2. All information concerning decisions during the labour process is collected: artificial rupture of membranes and induction or augmentation with oxytocin. The usage of these methods will be evaluated.
3. All vacuum extractions will be evaluated on their indication, outcome and use before and after re-introduction and training, which took place in first quarter of 2016

Quantitative survey into quality and uptake of informed consent.

Between January 2018 and September 2018 a structured exit-questionnaire will be administered to all patients delivering via CS in Saint Luke's Hospital. We aim to include 150 patients in total. The first 75 patients will be included for the analysis of the current status of the completeness and effectiveness of the informed consent consultation. The following 75 patients are included after implementation of an intervention, for measuring its effectiveness. Approximately 30 patients deliver by CS each month in the hospital. All consenting women who underwent CS can be included, either emergency operations or elective surgery. Exclusion criteria are non-consenting women and women not fit enough to participate due to post-operative complications. During the first months of the inclusions, the construction and implementation of the intervention takes place, based on the gathered data and identified shortcomings.

The quality of consultation is assessed by the completeness and recollection according to the patients' experience. In order to assess the completeness, the patient will be asked about several aspects of the consultation prior to CS. Based on international guidelines (36), the following information should be given to the patient:

1. Reason for the procedure.
2. What the procedure involves.
3. Associated risks.
4. Implications on future pregnancies.

Additionally, she should be asked verbally for consent of proposed procedure. We add one extra aspect for verbal consent gathering by health worker;

5. Asking for verbal consent.

Based on these five criteria, percentages of occurrence can be calculated and a mean score of completeness from 0 – 5 can be given.

The recollection of the patient will be assessed by two different measures;

a. The percentage of patients able to recollect the indication for their CS as mentioned in their patient file.
b. The percentage of patients able to recollect the most common risk factors of CS.

The checklists will be interview-administered, because additional explanation can be given to patients where necessary. The interviews will be performed by an independent interviewer, not involved in routine patient care (SZ). The interviewer will make clear to the patient that the questionnaire is voluntary and not part of routine care. Questionnaire administration takes place right before patients are discharged. Patient files will be analysed to gather patient demographics, including amount of antenatal consultations, HIV-status, time of surgery and presence of written consent. The rest of the socio-demographic data is gathered during the interview itself. This includes tribe-allocation, literacy, educational level, marital status and amount of previous deliveries and caesarean sections. The interviewer will work guided by the Chichewa questionnaire and will be assisted by a translator from the hospital, oriented on the study objectives and methods. This can either be a nurse, student or support staff, since the questions are straightforward and mostly multiple-choice. Data will immediately be entered in the databank, to assure the quality of the data entry. Analysis will be performed with IBM SPSS Statistics version 24. The database will be created during the study period. Descriptive analysis will be used to identify the percentage of criteria met in the total group. Pre- and post-intervention groups will be compared with either a Chi-square test or unpaired t-test.

Qualitative analysis of perception of informed consent by health workers.

Between April 2018 and July 2018, in-depth interviews will be held with health workers related to obstetric healthcare working in the antenatal clinic, maternity department or theatre. We aim to include 20 participants and have at least one focus group discussion. The interviews will encompass several aspects regarding informed consent for CS. The interview tool includes:

1. Personal experiences with informed consent.
2. Definition and goals of informed consent.
3. Daily practice of informed consent.
4. Barriers to informed consent.
5. Ethical considerations linked to informed consent.

Convenience and snowball sampling will be used and data will be collected until data saturation is reached. Interviews will be conducted by an independent researcher (SZ) to prevent courtesy bias, following a semi-structured questionnaire. The interviews will be recorded, transcribed and analysed with qualitative data analysis software MAXQDA. Coding will be done in order to identify themes around the subject. Data will be processed anonymously. No incentives are given for participation. The questionnaire and interview checklist are provided as supplemental documents to this application.

Sample size

Approximately 30 patients deliver by CS each month in the hospital. All consenting women who underwent CS can be included, either emergency operations or elective surgery. Exclusion criteria are non-consenting women and women not fit enough to participate due

to post-operative complications. Sample size is based on the amount of time available, but aimed at a total of 150 inclusions.
For the qualitative part, data will be collected until data saturation is reached, which we based on experience expect around 20 interviews, using convenience and snowball sampling. We aim to include at least one focus group discussion.
The retrospective review will include roughly 3500 records.

5. DISSEMINATION OF FINDINGS

The direct aim of the project is quality improvement in the facility in the field of caesarean section indications, interventions in labour and informed consent. By focussing on these aspects of care, health workers have the opportunity to analyse their own practice and improve their skills, of which both health workers and patients will benefit. We hope identified barriers can lead to development of training packages of which all health workers and ultimately patients can benefit. All results will be presented on facility and if possible on district level. An effort will be made to publish the findings in at least one local or international peer reviewed journal, of which a copy will be send to the National Health Sciences Research Committee for review. Also, a final report will be send to the NHSRC after finishing the study. Outcomes of this relatively small study project hopefully leads to more research being performed on the subject, for example in bigger multi-centre studies.

6. PERSONNEL

Wouter Bakker, medical doctor, is the primary investigator and will lead the project.
Siem Zethof, master-student in medicine, will take responsibility of the data gathering for both the quality survey with exit-questionnaires and the interviews with health workers.
Felix Nansongole, clinical officer, is involved in the development of the research tools and patient approach.

7. WORK-PLAN

The project will take place in its entirety between January 2018 and January 2019. The first months are used for protocol writing and ethical approval. Practical approach is discussed and analysed in the facility. A small pilot was conducted to improve the questionnaire. In the first half of 2018 the first half of patients for the qualitative survey will be included. Also, the interviews with health workers will be held during this period of time. In April/May, the intervention checklist will be developed and applied. The second half of the survey, to evaluate the effectiveness of the proposed intervention, will be held after implementing the checklist. Data analysis will take place during the second halve of 2018. The cohort analysis will be performed throughout the year.

2018	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Writing proposal												
Validating and pilot												
Application ethical committee												
Exit-questionnaire survey												
Qualitative data collection												
Introduction informed consent checklist												
Data analysis												
Retrospective cohort data analysis												
Dissemination of results												

8. BUDGET

This research is not financed by any sponsors. Expected minor costs are as follows.

Printing costs	20.000 MWK
Hiring a translator for questionnaire	72.500 MWK
On-ground translator fees	20.000 MWK
10% NHSRC fee	11.250 MWK
Total budget	123.750 MWK

The costs will be paid out of the primary investigators personal account. It is thinkable that this project leads to more structurally funded research projects in the region.

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3. Informed Consent

Informed consent is gathered prior to administration of the questionnaire. The investigator gathering the informed consent will not have a treatment relationship with the individual. The aim of the research will be verbally explained and details about inclusion criteria and reasons for inclusion of the individual in particular, use of questionnaire, financial compensation, risks and benefits, confidentiality and contact details will be discussed in the Participant Information sheet. The patient will be informed that conduction of this research is not part of their routine care and completely voluntary. The individual is free to refuse to participate and will be free to withdraw from the research at any time without penalty or loss of benefits to which he or she would otherwise be entitled. Also, there will be touched upon the limits to the researchers' ability to guarantee confidentiality and the measures that are taken. Verbal informed consent will be gathered and additionally written explanation will be handed out to the patient, where another confirmation of consent is asked. The first page of the questionnaire is dedicated to informing the patient and asking for their written consent. Illiterate patients may give consent with a fingerprint.

Deliberately has been chosen to administer the participant information sheet verbally, because the information is very extensive and hard to understand all at once. We will give patients the option to ask questions and they will receive contact details for further explanation on study participation and progress. Also contact details of Saint Luke's Hospital personal have been included, who can link participants to an independent health advocate (ombudsman). Verbal explanation of this seems appropriate, because during pilot studies we found an illiteracy/bad understanding of Chichewa in 20% of patients. By doing this verbally and providing room for discussion, we make an effort to respect the autonomy of all patients viable for inclusion.

Considering the interviews with health workers, informed consent is gathered prior to interviews with the health workers. Verbally the scope of the research will be explained, the use of a recorder and the possible extraction of quotes. No names will be mentioned. None of the data can be linked to the included health personal. Numbers will be used for anonymization purposes.

The records of consent will be stored in the administration office of the hospital. The records are anonymous, but linked to admission numbers. An encrypted database, only accessible to the primary investigator, will link the admission numbers to the gathered data. This way we can link the informed consent form to an individual case. However, patient names are not recorded and cannot be traced.

3a. Informed Consent Exit-Questionnaire Survey

PATIENT INFORMATION SHEET ENGLISH

Study title:	*Decision-making around caesarean section in a low-resource setting.*		
Locality:	Saint Luke's Hospital	**Ethics committee ref.:**	National Health Science Research Ethics Committee
Primary investigator:	Wouter Bakker	**Contact phone number:**	**+265991694212**

CONSENT PAPER

These questions are part of the research study on quality safe motherhood.
They aim to see if you were properly informed before undergoing a caesarean section and if the health care personnel asked for your consent.
They also aim to see your current knowledge on caesarean section.
This research study will help us to identify shortcomings in the information provision prior to a caesarean section. This will help to improve safe motherhood.

RESEARCH METHODOLOGY
We will use questions.

ACTIVITIES DURING THE RESEARCH
If you accept to take part in this research, you will be asked questions and your part will end there. We will use your patient files to look at your HIV-status, amount of antenatal consults, parity, amount of caesarean sections and the indication for your current caesarean section.

ADVANTAGES AND DISADVANTAGES OF THIS RESEARCH
There is nothing to fear since there will be no new drugs or any kind of physical examination. There will be no direct advantages, but the results of the study will help to identify ways of strengthening patient education and respectful care given to pregnant women. You will receive an additional explanation of the risks of CS and its implications for future pregnancies.

THE RESEARCH STUDY IS NOT COMPULSORY
It is not compulsory to take part in the research study and to refuse to take part in this study will not affect the type of treatment that you are going to receive during this stay**.**

THE RIGHT TO WITHDRAW FROM THE STUDY
You have the right to withdraw from the study any time, without consequences.

CONFIDENTIALITY

We will make an effort to keep all information confidential, except when we have been asked by the law or the research bodies. Names shall not be used. Instead numbers shall be used. There will be no connection between your information and your identity.

THE RESULTS OF THE RESEARCH STUDY

You will be informed about the results of the study when we have finished scrutinizing them. You can contact the investigator any time for an update on the study results (see contact details).

RESEARCH POPULATION

Pregnant women who have undergone Caesarian Section are the ones required to take part in the study.

CONTACT DETAILS

If you have questions or comments concerning this research study, you can find the researcher:

Name, position:	Simon Zethof, co-investigator
Phone:	+265995661849
Email:	Siemzethof@hotmail.com

If you want to speak to an independent person you can find him on the address below;

Name, position	Mr J. Phiri, Senior Adminstrative Officer
Phone:	+0882010868 / 0999121039
Name, position	Mr P. Manjere, Human Resource Officer
Phone:	+0883377691 / 0999121039

You can also contact the National Health Science Research Ethics Committee

Name, position	Dr. Damson Kathyola, NHSRC representative
Phone:	+26 560 1726422, ask for Dr. Kathyola
Email:	directorgeneral@ncst.mw

Declaration by participant:
I hereby consent to take part in this study.

Participant's name:

Signature: Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name:

Signature: Date:

PATIENT INFORMATION SHEET CHICHEWA

Study title:	*The quality of care for caesarean sections in Saint Luke's Hospital, Malawi: A mixed-method approach.*		
Locality:	Saint Luke's Hospital	**Ethics committee ref.:**	National Health Science Research Ethics Committee
Lead investigator:	Wouter Bakker	**Contact phone number:**	**+265995661849**

PEPALA LA CHILOLEZO

Mafunsowa akupanga mbali imodzi ya kafukufuku wa maphunziro a pamwamba a uchembere wabwino.
Zikukhudza ngati mwauzidwa moyenera musanapangidwe opareshoni ndiponso ngati a chipatala akufunsani zachilolezo chanu.
Zikhudzanso zomwe mukudziwa panopa za ma opareshoni.
Kafukufukuyu adzatithandiza kuona zofooka zimene zimapezeka popereka uthenga kwa mayi oyembekezera asanapangidwe opareshoni.

NDONDOMEKO YA KAFUKUFUKU

Ife tidzagwiritsa ntchito mafunso.

ZOCHITIKA MUKAFUKUFUKU AMENEYU

Ngati mutavomera kutenga mbali mukafukufukuyu,mudzafunsidwa mafunsondipo mbali yanu idzathera pomwepa. Tidzagwiritsanso ntchito ma fayilo anu popanga kafukufukuyu.

UBWINO NDIKUYIPA KWA KAFUKUFUKU AMENEYU

Palibe choopsa china chili chonse popeza sipadzakhala mankhwala achilendo kapena kuyezedwa kwina kulikonse.
Sipadzakhala ubwino wina uliwonse koma zotsatira zakafukufuku zizathandiza kupezera njira zolimbikitsa kudziwitsa ndi kuwonesetsa kuti zisankho za amayi apakati zikulemekezedwa.

KAFUKUFUKU AMENEYU SIWOUMILIZA

Kutengambali pakafukufuku ameneyu ndikosaumiriza ndipo kukanakutenga mbali pakafukufuku ameneyu sikudzakhudza chisamaliro chimene muyenera kulandira patsikuli.

UFULU OTULUKA MUKAFUKUFUKU AMENEYU

Muli ndi ufulu wonse kutuluka mukafukufuku ameneyu ndipo sipadzakhala chovuta china chili chonse.

KUSUNGA CHINSINSI

Tidzayetsetsa kusunga chinsinsi pa zonse zokhudza munthu wina aliyense kupatula pokhapokha ngati tafunsidwa ndilamulo kapena mabungwe oyang'anira kafukufuku. Mayina

sadzidzagwiritsidwa ntchito mmalo mwake manambala ndiamanene adzidzagwiritsidwa ntchito, sipadzakhala kugwirizana kwinakulikonse pa nkhani ndi mayina anu

ZOTSATIRA ZA KAFUKUFUKU
Mudzadziwitstsidwa zotsatira zakafukufuku ameneyu tikadzakamaliza kuunika bwinobwino

CHIWERENGERO CHA ANTHU OTENGAMBALI PAKAFUKUFUKU AMENEYU
Kafukufuku ameneyu adzafunika kwa amayi onse oyembekezera amene anapangidwa opaleshoni ndi amene adzatenge mbali.

MUNGATIPEZE BWANJI?
Ngati muli ndimafunso kapena ndemanga pokhudzana ndikafukufuku ameneyu, mukhoza kutifikira Kwa opanga kafukufuku;

Name, position:	Simon Zethof, co-investigator
Phone:	+265995661849
Email:	Siemzethof@hotmail.com

Ngati mukufuna kuyankhula ndi munthu wapadera mukhonza kumupeza pa keyala ili mmunsimu:

Name, position:	Mr J. Phiri, Senior Adminstrative Officer
Phone:	+0882010868 / 0999121039
Name, position:	Mr P. Manjere, Human Resource Officer
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Phone:	+26 560 1726422, ask for Dr. Kathyola
Email:	directorgeneral@ncst.mw

Ine…….. (Otengambali) ndawerenga zofunikirazi. Ndasankha kutenga mbali pakafukufuku ameneyu mosakakamizidwa. Ndamvetsetsa kuti ndili ndi ufulu kukana kuyankha funso komanso kutuluka mukafukufuku ameneyu nthawi ina iliyonse. Ndamvetsetsa kuti mayankho anga adzakhala achinsinsi

.

Kutsimikiza kwaotenga mbali	Tsiku
Umboni	Tsiku
Kutsimikiza Kwa opanga kafukufuku	Tsiku

CHALA

3b. Informed Consent Interview Health Workers

Research: Health Worker Perspectives on Informed Consent for Caesarean Sections.

Department	Obstetrics
Organization	Saint Luke's Hospital
Date	

Dear Sir, Madame,

The following interview will be conducted to gain insight in your perspectives on giving information to the patient and gaining her consent prior to CS. The interview will discuss personal experiences with informed consent, as well as thoughts about the information transfer, practical use of informed consent and ethical considerations.

- **The interviews are anonymous. The interviewee only states his/her function, age, gender, department and years of working experience.**
- **The interviews will be recorded and analyzed only by the interviewer.**
- **Comments may be used as quotes in the article. This, again, will be anonymous.**
- **The interview takes 30 minutes to 1 hour.**

By conducting interviews and analyzing them as one entity, the researcher tries to understand the process of informed consent and apply interventions were needed. This may improve the quality of care in Saint Luke's Hospital, but also may serve as an example for other health facilities.

This interview is not compulsory and will not affect your work in a negative way. The researcher may write during the interviews. The notations include observations and possible quotes.

I hereby give my consent for participating in this study ☐

4. Data Collection Instruments

4a. Exit-Questionnaire

DATA COLLECTION SHEET **ENGLISH**

[Questionnaire: Quality of Consultation Caesarean Section**]**

Department	Obstetrics
Organization	Saint Luke's Hospital
Date	

Dear Madame,

This list of questions is part of a study on the quality of consultation in Safe Motherhood.
It will address whether or not you were informed sufficiently prior to your caesarean section and if healthcare providers asked for your consent.
It will also address your current knowledge of caesarean sections.
This study will enable us to identify shortcomings in the provision of information and improve Safe Motherhood for you and future patients.

- **If you find any of the questions hard to understand, you may ask the interviewer for clarification.**
- **If you find any of the questions offensive or do not want to answer them for any other reason, do not feel obliged to do so. Leave a blank space.**
- **The questionnaire should take 15 minutes to complete. You may quit the questionnaire anytime you like.**

The questionnaire is anonymous and will be analysed by an independent researcher.
Your answers will be confidential. Only the interviewer and researcher will take notice of them.
The filled-in answers will not affect the quality or accessibility of your healthcare in a negative way.
We will be using your patient records to identify the reason for your caesarean section as stated by the caregiver.

Part 1: Your social and demographic information

Instructions:

This part aims to collect information about your life.

When a line is depicted after a question, put your answer on the line.

Example question:

How many times have you been to Saint Luke's Hospital?

2

_____

When several options are given, pick one option (except when stated otherwise).

Example question:

Was your previous delivery a caesarean section?

a. Yes

b. No

Questions on patient demographics:

PICK ONE OPTION!

1. Are you able to read Chichewa?

a. Yes

b. No

2. Which tribe are you related to?

a. Yao-tribe

b. Chewa-tribe

c. Ngoni-tribe

d. Chotupa-tribe

e. Lomwe-tribe

3. How old are you? _____

4. Indicate your marital status:

a. married

b. single

c. relationship

5. Religion:

a. Christian
b. Muslim
c. Jehovah
d. Other
e. None

6. Occupation?

a. Employed
b. Business/self employed
c. Student/school
d. None
e. Farmer

7. Indicate your highest education level attained:

a. None
b. Primary school (Standard 1- 8)
c. Junior Secondary school (Form 1 and 2) - Junior Certificate of Education (JCE)
d. Senior Secondary school (Form 3 and 4) - Malawi Secondary Certificate of Education (MSCE)
e. College
f. University

8. How many times have you given birth? _____

9. How many caesarean sections did you have? _____

8. Which level of provider asked you for your consent prior to operation during your hospital stay?

a. Nurse/midwife
b. Doctor
c. Guardian
d. No one

Part 2: Received information and consent

Instructions:

Please answer these questions based on the counseling you have received for this C-section from the healthcare provider. The information should be received during THIS HOSPITAL STAY or antenatal consultations. It may either be mentioned before or after your C-section.

Example question.

Was your previous delivery a caesarean section?

a. Yes

b. No

1. Did someone from the hospital inform you of the reason for this caesarean section?

a. Yes

b. No

2. PICK ONE OPTION!

According to you, what was the reason for the caesarean section? PICK ONE OPTION!

a. Birth canal was too narrow for baby's head (CPD, obstructed labour, prolonged second stage, failed VBAC, macrosomia)

b. Problem with heart baby (Non-reassuring fetal status, fetal distress)

c. Problem with position of child (Fetal malpositioning, fetal malpresentation)

d. High blood pressure (Preeclampsia/eclampsia/HELLP syndrome)

e. Blood loss prior to labour (ante-partum hemorrhage, abnormal placentation, placenta praevia, placental abruption)

f. Cord was in front of the baby. (Funic presentation or cord prolapsed)

g. Uterine tear/rupture

h. Breech presentation in first pregnancy

i. 2 or more CS in history

j. Other _____

k. Don't know

3. Did someone from the hospital inform you on what a caesarean section involves? The doctor should have told you about the operation room (theatre) and the use of anesthetics (spinal block), and the possible complications of anesthetics?

a. Yes

b. No

4. Did someone from the hospital gave you information on the risks associated with a caesarean section during this stay?

a. Yes (go to question 5)

b. No (go to question 6)

5. PICK 3 OPTIONS!

Which of the following risks are MOST COMMON following a caesarean section? PICK 3 OPTIONS!

a. Increased risk of bleeding

b. Instruments left in abdomen

c. Maternal death

d. Infection

e. Extended recovery time

f. Becoming paralyzed

6. Did a healthcare provider explain that your future deliveries should be in the hospital, now that you've had a caesarean section?

a. Yes

b. No

c. Bilateral tubal ligation

7. Were you asked for your consent prior to this surgery?

a. Yes (go to question 9)

b. No (go to question 8)

8. Did you sign a consent form for this caesarean section?

a. Yes

b. No

9. If you were NOT asked for consent, why do you think this happened?

a. Doctor knows best

b. Women's feelings not considered

c. Unable to make decision due to drugs or complication

d. Sudden emergency

e. My guardian gave consent

f. High risk to baby

g. Other reason, fill in: _____

Part 3. Your Perspective on Hospital stay

Instructions:

The following instrument aims to give insight in your experiences of this hospital stay.
For each of the questions below, circle the response that best characterizes how you feel about the statement, where:
1 = Strongly Disagree, 2 = Disagree, 3 = Neither Agree Nor Disagree, 4 = Agree, 5 = Strongly Agree

Example:

	Strongly disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
I want Malawian healthcare to be the best.	1	2	3	4	5

	Strongly disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
I felt informed about my cesarean section during my hospital stay.	1	2	3	4	5
The provided information was hard to understand for me.	1	2	3	4	5
I had the chance to ask questions.	1	2	3	4	5
I want to receive more information on cesarean sections prior to surgery.	1	2	3	4	5
Asking for consent prior to cesarean section is important to me.	1	2	3	4	5

This is the end of the questionnaire. Your participation will be very helpful in our research for better obstetric care. Thank you for participating!!

DATA COLLECTION SHEET FOR INTERVIEWER

Number given by interviewer: _____

Handed out by: Interviewer/Student

Date of CS, time performed _____

Exact indication in patient records: _____

Written by consent: Patient/Guardian/No one

HIV-status: Positive/Non-reactive/Unknown

Amount of antenatal consultations: _____

Type of CS: Emergency / Elective

Any complications 3-days post CS? _____

Any long-term complications? _____

DATA COLLECTION SHEET **CHICHEWA**

[Mafunso: Ubwino wogawana nzeru pa nkhani za caesarean (operashoni)]

Department	Obstetrics
Organization	Saint Luke's Hospital
Date	

Zikomo Amai,

Mafunsowa akupanga mbali imodzi ya kafukufuku wa maphunziro a pamwamba a uchembere wabwino.
Zikukhudza ngati mwauzidwa moyenera musanapangidwe opareshoni ndiponso ngati a chipatala akufunsani zachilolezo chanu.
Zikhudzanso zomwe mukudziwa panopa za ma opareshoni.
Kafukufuku yu azatithandiza kuona zina zimene tingadziwe zothandiza uchembere wabwino.

- **Ngati pali mafunso ena amene musakuwamvetsa, muwafunse amene akukufunsani.**
- **Ngati pali mafunso amene pazifukwa zosiyanasiyana simungathe kuyankha, mutha kutsiya osayankha.**
- **Mafunso ayenera kutenga 15 minutes (mphindi 15). Mutha kutsiya nthawi ina iriyonse.**

Mafunso awa ndi achinsinsi azangoonedwa ndi wofufuza wa pa dera basi.
Mayankho anu azakhala achinsinsinso owonedwa ndi wokufunsani komanso wofufuza okhawo.
Mayankho anu sadzasintha chithandizo kapena kulandira chithandizo mochepera.
Tizigwiritsa zolembedwa zachipatala poona chifukwa cha opareshoni yanu monga analembera a dokotala.

Part 1: Za gulu lanu maphunziro, zakubadwa ndi kufa
Malangizo:
Mbali ino ndi yofuna kudziwa za moyo wanu.
Pakakhala mdzere pa funso mulembe yankho lanu pamdzere.

Chitsanzo:
Mwapitapo kangati ku Saint Luke's Hospital?
2
_____

Ngati pali mayankho ambiri, sankhanipo limodzi (kupatulapo ngati palembedwa zina).

Chitsanzo:
Kubereka kwanu komalizira Kunali kwa opareshoni/kong'amba?

c. Inde
d. Ayi

Mafunso okhudza kasinthidwe ka chiwerengero cha wodwala:

SANKHANIPO CHIMODZI!

1. Mungathe kuwelenga Chichewa?
a. Inde
b. Ayi

2. Mtundu wamu ndi chani?
a. Yao
b. Chewa
c. Chotupa
d. Ngoni
e. Lomwe

3. Muli ndi zaka zingati?
_____

4. Munakwatiwa:
a. Okwatiwa
b. Sindinakwatiwe
c. Ndili ndi chibwenzi

5. Mpingo:

a. Mkhilisitu

b. Musilamu

c. Mboni za Yehova

d. (Mpingo) wina

e. Palibe

6. Mumagwira ntchito?

a. Ndimagwira

b. Bizinesi/yandekha

c. Ndikuphunzira/ pa sukuhi sukulu

d. Palibe

e. Mlimi

7. Sukulu munalekedza mu chiyani?

g. Palibe / Sindinapite
h. Primary school (standard 1 – 8)
i. Junior Secondary school (Form 1-2) - Junior Certificate of Education (JCE)
j. Senior Secondary school (Form 3-4) - Malawi Secondary Certificate of Education (MSCE)
k. College
l. University / Yunivesite

8. Mwabereka kangati? _____

9**. Mwapangidwa opareshoni kangati?** _____

8**. Anakufotokozerani dongosolo la opareshoni yanu ndi ndani?**

a. A nasi / A namwina

b. A dokotala

c. Ondidikilira (guardian)

d. Palibe

Part 2: Zomwe ndinauzidwa ndi chilolezo

Malangizo:
Yankhani mafunso malinga ndi momwe mwauzidwira ndi a Chipatala zokhuzana ndi opareshoni. Izi ziyenera kulembedwa ulendo umene mwagonetsedwa uno kapena ku sikelo.
Chitsanzo:
Kodi mwana wanu omalidzira anali wa opareshoni?

a. Inde
b. Ayi

1. **Alipo ena a chiptala akudziwitsani chimene chimapangitsa opareshoni?**

a. Inde

b. Ayi

2. SANKHANIPO CHIMODZI!

Mukuganidzira kuti chimapangitsa ndichiyani? SANKHANIPO CHIMODZI!

l. Chifukwa cha kuchepa kwa njira kapena kukula kwa mutu wa mwana?

m. Mwana amabanika

n. Mwana sanagone bwino

o. BP yokwera/kuthamanga kwamagazi

p. Kutaya magazi kwambiri ndisanabereke

q. Kutsogoza mchombo wamwana.

r. Kung'ambika kuphulika kwa chiberekero

s. Kutsogoza matako amwana pamimba yoyamba

t. Kupangidwa opareshoni yamwana kawiri

u. China, -
_____

v. Sindikudziwa

3. Alipo wina wa chipatala amene anakudziwitsani zomwe zimachitika popanga opareshoni?

A dokotala/anesi amayenera kuudzani za chipinda cha opareshoni (fiyeta) ndi kagwiritsidwe ka mankhwala oletsa ululu komanno kwipa kwake.

a. Inde

b. Ayi

4. Alipo wina wa muchipatala amene wakuudzani za kuopsya kwa opareshoni?

a. Inde

b. Ayi

5. SANKHANI ZITATU MWA IZI!

Ndi zoopsya ziti mwa izi zimene zimachitika nthawi zambiri pa opareshoni? SANKHANI ZITATU MWA IZI!

a. kutaya magazi kwambiri

b. Kuyiwla zipangizo zogwiritsa ntichito m'mimba mwanga.

c. Imfa pobereka

d. Kuola kwa bala

e. Nthawi yaitali yochilira

f. Kufa kwaziwalo

6. Kodi a chipatala anakufotokodzerani kuti kubereka mtsoglo kuyenera kuchitikira muchiptala poti pano mwachitidwa opareshoni?

a. Inde

b. Ayi

c. Ndinatsekedwa

7. Munafunsidwa za chiloledzo chanu musanachitidwe opareshoni?

a. Inde

b. Ayi

8.Munasaina kalata yobvomeredza kuchitidwa opareshoni?

a. Inde

b. Ayi

9. Ngati simunafunsidwe za chiloledzo chanu, mukuganidzira kuti izi zinachitika chifukwa chiyani?

a. A dokotala akudziwa zonse bwino

b. Maganizo a azimai saganidziridwa.

c. Ndinalephera kupanga chiganizo chifukwa cha mankhwala kapena bvuto lina.

d. Mabvuto adzidzidzi

e. Amene amandiyang'anira anapereka chiloledzo.

f. Zoopsya kwa mwana

g. Chifukwa china, lembani: _____

Part 3. Malangizo omwe mungapereke okhuzana ndi chipatalachi

Malangizo:

Mafunso otsatira wa athandizira kuti mudzathandizidwe monga momwe mukufunira mukadzabweranso.

Pafunso linalililonse pali mayankho asanu, sankhani yankho limodzi lomwe mukuona kuti ndi loyenera. Muzungulize yankho loyeneralo.

1 = Kutsutsa kwambiri, 2 = Kutsutsa, 3 = Pakati ndipakati, 4 = Kubvomera, 5 = Kubvomera kwambiri

Chitsanzo:

	Kutsutsa kwambiri	Kutsutsa	Pakati ndipakati	Kubronera	Kubvomera kwambiri
Ndikufuna umoyo wabwino wa chimalawi kukhala opambana koposa.	1	2	3	4	5

	Kutsutsa Kwambiri	Kutsutsa	Pakati ndipakati	Kubvomera	Kubvomera Kwambiri
Ndinauzidwa za opareshoni nthawi imene ndinali muchipatala.	1	2	3	4	5
Chidziwitso chinaperekedwa chinali chobvuta kumvetsa.	1	2	3	4	5
Ndinali ndi mwai ofunsa mafunso.	1	2	3	4	5
Ndikufuna ~~C~~ chidziwitso chokwanira pa zong'amba thupi nthawi ya opareshoni isanakwane.	1	2	3	4	5
Kufunsa chiloredzo nthawi yong'amba thupi isanakwane ndi chofunikira kwa ine.	1	2	3	4	5

Apa ndi pamapeto a mafunso athu. Kutenga nawo gawo pa kafukufuku yu kutandizira kuti uchembere wabwino upite patsogolo. Zikomo kwambiri chifukwa chotenga nawo mbali.

DATA COLLECTION SHEET FOR INTERVIEWER

Number given by interviewer: _____

Handed out by: Interviewer/Student

Date of CS, time performed _____

Exact indication in patient records: _____

Written by consent: Patient/Guardian/No one

HIV-status: Positive/Non-reactive/Unknown

Amount of antenatal consultations: _____

Type of CS: Emergency / Elective

Any complications 3-days post CS? _____

Any long-term complications? _____

4b. In-depth interview guidance

Interview subject list: Informed Consent for Caesarean Section, Health Worker Perspective.

Introduction: **Scope of research, discuss informed consent.**
Interviewee characteristics: **Function, gender, age, current occupation, years of working experience.**

1. **Personal experiences with IC**
   a. In how many informed consent processes prior to CS have you been involved?
   b. Can you describe your last IC process prior to CS? Elaborate.
   c. Did any of the women ever refused the operation? Elaborate.
   d. Did you encounter a situation where a woman went to CS without gaining informed consent?
   e. Would you consider your experiences with informed consent positive or negative? Why?
2. **Definition of informed consent**
   a. Describe the definition of informed consent in a few sentences.
      i. Different aspects?
      ii. Purpose?
   b. What is the effect on the patient?
   c. What is the effect on the health worker?
3. **IC in clinical practice**
   a. How should a regular IC process for CS look like?
      i. Which points should be discussed?
      ii. Who should discuss it? Clinician or nurse?
      iii. Should it be discussed with patient or guardian?
      iv. Should the patient or guardian give consent?
      v. Situations where IC is unfavorable? Skip IC?
   b. What are the barriers for IC?
      i. Patient characteristics
      ii. Time management
      iii. Emergency setting
   c. How to overcome the barriers mentioned?
4. **Ethical considerations**
   a. Informed consent is a fictional approach, because:
      i. Most women do not have the medical expertise to comprehend the provided information.
      ii. Most patients expect the doctor to make a decision for them and do not want to be informed and involved in the decision making.
      iii. The clinician will provide selective information to coerce the patient into his option of choice.
      iv. A women giving no for an answer will not be tolerated. She will be forced to do whatever the clinician thinks is best under these circumstances.
   b. How do you assess the capability of a woman to consent? Is any woman in pain uncapable? Does it make a differences IC process involves the guardian rather than the patient?
   c. "Every women has the right to information, informed consent and refusal, and respect for her choices and preferences, including companionship during maternity care." What do you think of this statement? Is the right to informed consent a Human right? Is it usable in clinical practice?
   d. If a women refuses a CS, despite the damage to mother and child, should we respect this decision? Who should have the last word? Woman or clinician?
5. **Conclusion:**
   a. Definition of informed consent?
   b. Advantages?
   c. Disadvantages?
   d. Challenges?
   e. Want to add something?

5. Support Letter Institution

ANGLICAN DIOCESE OF UPPER SHIRE (ADUS)

HEALTH DEPARTMENT
P.O. BOX 21, CHILEMA
ZOMBA, MALAWI

E-mail :
stlukeshospitalmalosa@gmail.com

Tel : +265 9 99 121 039
Bishop: The Right Rev'd Brighton Vitta Malasa **: +265 8 84 478 897**

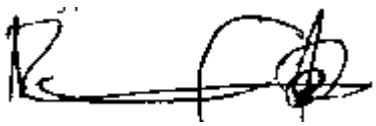
Dear members of the National Health Science Research Committee,

On behalf of St Luke's Hospital, I would like to offer my support to Dr. Wouter Bakker to conduct a study to visualize the theme of information transfer prior to a caesarean section.

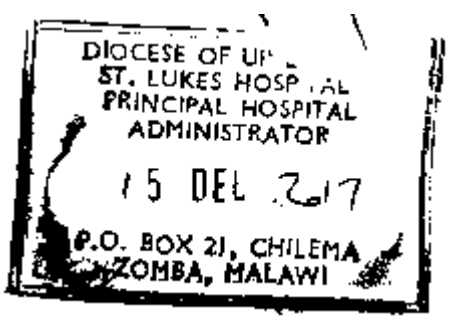
The study: The quality of care in caesarean sections in Saint Luke's Hospital, Malawi: A mixed-method approach, is not only of assistance to us as a hospital, but could serve a greater purpose as an example to improve on the patients right of information in obstetric health care.

Hereby I, endorse this study to investigate current practices of informed consent and stimulation of patient education.

Sincerely,



Winasi Boma, Principal Administrator St. Luke's Hospital.



Anglican Diocese of
UPPER SHIRE
ST LUKE'S MISSION HOSPITAL

CAESAREAN SECTION

DETAILS		
	Patient name	
	Next of kin	
	Contact details	

DECISION		
	Date and time	
	Made by	
	Indication	

INFORMATION (BY SURGEON)

Discuss the following topics with the patient

- ☐ Explained **INDICATION** for CS and **BENEFITS** of CS in current situation to the patient.
- ☐ Explained **PROCEDURE** of CS to the patient. *Including anaesthesia and possible use of blood products.*
- ☐ Explained the **RISKS** of CS to the patient. *Infection, hemorrhage, recovery time, serious and rare complications*
- ☐ Explain **IMPLICATIONS FOR FUTURE PREGNANCIES.** *Hospital delivery, trial of labour, risk of uterine rupture*
- ☐ Address **UNCERTAINTIES** and answer **QUESTIONS.**
- ☐ Gain **VERBAL CONSENT** from the patient.

I have explained the procedural nature and risks to the undersigned patient or person legally competent to give consent.

Surgeon: Signature: Date:

CONSENT (BY PATIENT)

I, the undersigned, hereby consent to the performance of, and understand the nature and risks of the procedure. The clinicians who perform the above may increase the reasonable scope thereof or carry out additional or alternative measures (including general anaesthesia) if considered necessary. I agree that a sample of my blood will be taken and tested for Hepatitis B and HIV should an incident of contamination of a health care worker by bodily fluids occur during the procedure. I grant consent to use of blood and/or blood products if needed.

Patient/guardian name: Signature: Date:
Relationship to patient (if applicable):

PRE-OPERATIVE			
☐	Ceftriaxone 2g IV stat	Signature:	Time:
☐	Foley's catheter and urinary bag	Signature:	Time:
☐	IV access (preferably grey cannula)	Signature:	Time:
☐	Preload with 1 liter NS or RL (remove bags with added Oxytocin!)	Signature:	Time:
☐	Urgent Hb | blood group | cross-match	Signature:	Time:

PROCEDURE AND FINDINGS				
	Surgeon		Signature	
	Time started		Time completed	
	Skin incision		Blood loss	
	Uterine incision		Complications	
	Fetal position			
	Liquor			
	Uterine closure			
	Tubal ligation			
	Fascia closure			
	Skin closure			

NEONAT				
	Midwife		Signature	
	Time delivery		Apgar scores	
	Resuscitation		Birth Weight	

ANAESTHETIC DETAILS				
	Anaesthetist		Signature	
	Medical history			
	Examination			
	Investigations			
	Technique			

MONITORING

200
180
160
140
120
100
80
60
40

POST-OPERATIVE	☐ Standard (see below)	☐ Adjusted (indicate below)	Signature
	Vitals: take blood pressure and pulse before patient is taken to the ward and again 30 minutes after arrival in the ward. For the first 24 hours vitals have to be taken 6 hourly, and 12 hourly for subsequent days. Check for possible bleeding (wound or vagina) and urinary output each time when taking vitals. **Analgesia**: pethidine 50-100mg IM 8 hourly for 1 day (PRN) and paracetamol 1g PO 8 hourly for 3 days. **Antibiotics**: only indicated in signs of infection. **IV fluids**: NS or RL 8 hourly for 1 day (depending on oral intake). **Intake**: may drink after 6 hours, may eat Phala after 12 hours and soft Nsima after 24 hours. **Hb**: if clinically indicated. **Ambulation**: as soon as possible. **Wound**: expose on day 1 or 2 post-op and leave open if clean. **Discharge**: by clinician after 3-4 days. **Sutures**: removal after 7 days if nylon.		

	Vitals (30 min)	BP	P	Bleeding	Time transfer	(only if stable!)
	Vitals (60 min)	BP	P	Bleeding	Ward nurse	

CARE PROTOCOL	Since operation	6h	12h	18h	24h	2nd day:		3rd day:		4th day:		5th day:	
	Actual time												
	Blood pressure												
	Pulse												
	Abnorm. bleeding												
	Urine output												
	Temp mother												
	Temp neonate												
	Pethidine IM					inform clinician if patient is still having pain							
	Paracetamol PO					ensure that patient has received PCM tablets							
	IV fluids (NS|RL)			stimulate oral intake									

Anglican Diocese of
UPPER SHIRE
ST LUKE'S MISSION HOSPITAL

Informed Consent in C-section

A Six-Step Guide

1) Explain **INDICATION** for CS and **BENEFITS** of CS in current situation to the patient.

2) Explain **PROCEDURE** of CS to the patient.
   - ***a.*** *What happens in theatre*
   - ***b.*** *Use of anaesthetics*
   - ***c.*** *Possibly use of blood products*

3) Explain the **RISKS** of CS to the patient.* **

FREQUENTLY OCCURRING RISKS	**INFECTION**	Wound infection or endometritis	*5 – 10%*
	EXTENSIVE BLEEDING	>1000 ml or in need of transfusion	*4 – 9%*
	EXTENDED RECOVERY TIME	3 days hospitalization (everyone), persistent wound and abdominal discomfort for >1 month	*9%*
SERIOUS RISKS	**EMERGENCY HYSTERECTOMY**	Due to uncontrolled bleeding, uterine rupture and placental problems	*0.7 – 0.8%*
	INTRA-ABDOMINAL INJURY DUE TO SURGERY	Ureteric, bladder or bowel damage	*0.2 – 0.5%*
	MATERNAL DEATH DUE TO CS	**Very rare. Depends on underlying factor that necessitate CS.**	***<0.1%***

** Make an effort to separate FREQUENTLY OCCURING and SERIOUS risks.*
*** Risks are increased in OBESITY, PREVIOUS SCAR, PRE-EXISTING MEDICAL CONDITION.*

4) Explain **IMPLICATIONS FOR FUTURE PREGNANCIES.**
   - ***a.*** *Need to deliver in hospital next time!*
   - ***b.*** *Increased risk of complications*
   - ***c.*** *Increased risk of CS in subsequent deliveries*

5) Address **UNCERTAINTIES** and answer **QUESTIONS.**

6) Gain **VERBAL** and **WRITTEN CONSENT** from the patient. *Ask the patient if she is ok with the procedure.*

Incidence percentages of complications were extracted from the RCOG consent advice, *Chilopora et al.* and the Saint Luke's Hospital annual reports.[1-3]

1. Royal College of Obstetricians and Gynaecologists. Consent Advice No. 7: Caesarean Section. 2009 [Available from: https://www.rcog.org.uk/en/guidelines-research-services/guidelines/consent-advice-7/ Accessed November 2018.
2. Chilopora, G., C. Pereira, F. Kamwendo*, et al.*, *Postoperative outcome of caesarean sections and other major emergency obstetric surgery by clinical officers and medical officers in Malawi*. Vol. 5. 2007. 17.
3. Saint Luke's Hospital, *St Lukes Hospital Annual Report* 2016-2017, Saint Luke's Hospital: Malosa. https://www.stlukesmalosa.org/hospital-reports/ Accessed March 2018.

[Questionnaire: Quality of Consultation Caesarean Section]

Department	Obstetrics
Organization	Saint Luke's Hospital
Date	

Dear Madame,

This list of questions is part of a study on the quality of consultation in Safe Motherhood.

It will address whether or not you were informed sufficiently prior to your caesarean section and if healthcare providers asked for your consent.

It will also address your current knowledge of caesarean sections.

This study will enable us to identify shortcomings in the provision of information and improve Safe Motherhood for you and future patients.

- **If you find any of the questions hard to understand, you may ask the interviewer for clarification.**
- **If you find any of the questions offensive or do not want to answer them for any other reason, do not feel obliged to do so. Leave a blank space.**
- **The questionnaire should take 15 minutes to complete. You may quit the questionnaire anytime you like.**

The questionnaire is anonymous and will be analysed by an independent researcher.

Your answers will be confidential. Only the interviewer and researcher will take notice of them.

The filled-in answers will not affect the quality or accessibility of your healthcare in a negative way.

We will be using your patient records to identify the reason for your caesarean section as stated by the caregiver.

Part 1: Your social and demographic information

Instructions:

This part aims to collect information about your life.

When a line is depicted after a question, put your answer on the line.

Example question:

How many times have you been to Saint Luke's Hospital? 2

When several options are given, pick one option (except when stated otherwise).

Example question:

Was your previous delivery a caesarean section?

a. Yes
b. No

Questions on patient demographics:

PICK ONE OPTION!

1. **Are you able to read English/Chichewa? (is able to read the introduction)**
   a. Yes
   b. No

2. **How old are you?** _____

3. **Indicate your marital status:**
   a. married
   b. single
   c. relationship

4. Religion:

a. Christian
b. Muslim
c. Jehovah
d. Other
e. None

5. Occupation?

a. Employed
b. Business/self employed
c. Student/school
d. Housewife
e. Farmer

6. Indicate your highest education level attained:

a. None
b. Primary school (Standard 1- 8)
c. Junior Secondary school (Form 1 and 2) - Junior Certificate of Education (JCE)
d. Senior Secondary school (Form 3 and 4) - Malawi Secondary Certificate of Education (MSCE)
e. College/University

7. How many times have you given birth? _____

8. How many caesarean sections did you have? _____

Part 2: Received information and consent

Instructions:

Please answer these questions based on the counseling you have received for this C-section from the healthcare provider. The information should be received during THIS HOSPITAL STAY or antenatal consultations. It may either be mentioned before or after your C-section.

Example question.

Was your previous delivery a caesarean section?

c. Yes
d. No

1. Did someone from the hospital inform you of the reason for this caesarean section?

a. Yes

b. No

2. According to you, what was the reason for the caesarean section?

a. Birth canal was too narrow for baby's head (CPD, obstructed labour, prolonged second stage, failed VBAC, macrosomia)

b. Problem with heart baby (Non-reassuring fetal status, fetal distress)

c. Problem with position of child (Fetal malpositioning, fetal malpresentation)

d. High blood pressure (Preeclampsia/eclampsia/HELLP syndrome)

e. Blood loss prior to labour (ante-partum hemorrhage, abnormal placentation, placenta praevia, placental abruption)

f. Cord was in front of the baby. (Funic presentation or cord prolapsed)

g. Uterine tear/rupture

h. 2 or more CS in history

i. Other _____

j. Indication has not been told (according to previous question)

3. Did someone from the hospital inform you on what a caesarean section involves? The doctor should have told you about the operation room (theatre) and the use of anesthetics (spinal block), and the possible complications of anesthetics?

a. Yes

b. No

4. Did someone from the hospital gave you information on the risks associated with a caesarean section during this stay?

a. Yes (go to question 5)

b. No (go to question 6)

5. Which of the following risks are MOST COMMON following a caesarean section? PICK 3 OPTIONS!

a. Increased risk of bleeding

b. Instruments left in abdomen

c. Maternal death

d. Infection

e. Extended recovery time

f. Becoming paralyzed

6. Did a healthcare provider explain that your future deliveries should be in the hospital, now that you've had a caesarean section?

a. Yes

b. No

c. Bilateral tubal ligation

7. Were you asked for your consent prior to this surgery?

a. Yes (go to question 9)

b. No (go to question 8)

8. Did you sign a consent form for this caesarean section?

a. Yes

b. No

This is the end of the questionnaire. Your participation will be very helpful in our research for better obstetric care. Thank you for participating!!

Fill in by interviewer:

Number given by researcher:

Exact indication in patient records:

Falls under which category:

Written consent file: Patient/Guardian/No one

Amount of antenatal consultations:

Emergency / Elective:

[**Mafunso:** Ubwino wogawana nzeru pa nkhani za caesarean (operashoni)]

Department	**Obstetrics**
Organization	Saint Luke's Hospital
Date	

Zikomo Amai,

Mafunsowa akupanga mbali imodzi ya kafukufuku wa maphunziro a pamwamba a uchembere wabwino.

Zikukhudza ngati mwauzidwa moyenera musanapangidwe opareshoni ndiponso ngati a chipatala akufunsani zachilolezo chanu.

Zikhudzanso zomwe mukudziwa panopa za ma opareshoni.

Kafukufuku yu azatithandiza kuona zina zimene tingadziwe zothandiza uchembere wabwino.

- **Ngati pali mafunso ena amene musakuwamvetsa, muwafunse amene akukufunsani.**
- **Ngati pali mafunso amene pazifukwa zosiyanasiyana simungathe kuyankha, mutha kutsiya osayankha.**
- **Mafunso ayenera kutenga 15 minutes (mphindi 15). Mutha kutsiya nthawi ina iriyonse.**

Mafunso awa ndi achinsinsi azangoonedwa ndi wofufuza wa pa dera basi.

Mayankho anu azakhala achinsinsinso owonedwa ndi wokufunsani komanso wofufuza okhawo.

Mayankho anu sadzasintha chithandizo kapena kulandira chithandizo mochepera.

Tizigwiritsa zolembedwa zachipatala poona chifukwa cha opareshoni yanu monga analembera a dokotala.

Part 1: Za gulu lanu maphunziro, zakubadwa ndi kufa

Malangizo:

Mbali ino ndi yofuna kudziwa za moyo wanu.

Pakakhala mdzere pa funso mulembe yankho lanu pamdzere.

Chitsanzo:

Mwapitapo kangati ku Saint Luke's Hospital? 2

Ngati pali mayankho ambiri, sankhanipo limodzi (kupatulapo ngati palembedwa zina).

Chitsanzo:

Kubereka kwanu komalizira Kunali kwa opareshoni/kong'amba?

a. Inde
b. Ayi

Mafunso okhudza kasinthidwe ka chiwerengero cha wodwala:

1. Mungathe kuwelenga English/Chichewa? (is able to read introduction)

a. Inde
b. Ayi

2. Muli ndi zaka zingati?

3. Munakwatiwa?

a. Okwatiwa
b. Sindinakwatiwe
c. Ndili ndi chibwenzi

4. Mpingo?

a. Mkhilisitu
b. Musilamu
c. Mboni za Yehova
d. (Mpingo) wina
e. Palibe

6. Ntchito?/ Mumagwira ntchito?

a. Ndimagwira
b. Bizinesi/yandekha
c. Ndikuphunzira/ pa sukuhi sukulu
d. Pa banja
e. Mlimi

7. Sukulu munalekedza mu chiyani?

a. Palibe / Sindinapite
b. Primary school (standard 1 – 8)
c. Junior Secondary school (Form 1-2) - Junior Certificate of Education (JCE)
d. Senior Secondary school (Form 3-4) - Malawi Secondary Certificate of Education (MSCE)
e. College/University (Yunivesite)

8. Mwabereka kangati? _____

9. Mwapangidwa opareshoni kangati? _____

Part 2: Zomwe ndinauzidwa ndi chilolezo

Malangizo:

Yankhani mafunso malinga ndi momwe mwauzidwira ndi a Chipatala zokhuzana ndi opareshoni. Izi ziyenera kulembedwa ulendo umene mwagonetsedwa uno kapena ku sikelo.

Chitsanzo:

Kodi mwana wanu omalidzira anali wa opareshoni?

a. Inde
b. Ayi

1. **Alipo ena a chiptala akudziwitsani chimene chimapangitsa opareshoni?**

   a. Inde

   b. Ayi

2. Mukuganidzira kuti chimapangitsa ndichiyani?

   a. Chifukwa cha kuchepa kwa njira kapena kukula kwa mutu wa mwana?

   b. Mwana amabanika

   c. Mwana sanagone bwino

   d. BP yokwera/kuthamanga kwamagazi

   e. Kutaya magazi kwambiri ndisanabereke

   f. Kutsogoza mchombo wamwana.

   g. Kung'ambika kuphulika kwa chiberekero

   h. Kupangidwa opareshoni yamwana kawiri

   i. China, _____

   j. Sindikudziwa (see question 1 = no)

3. Alipo wina wa chipatala amene anakudziwitsani zomwe zimachitika popanga opareshoni?

A dokotala/anesi amayenera kuudzani za chipinda cha opareshoni (fiyeta) ndi kagwiritsidwe ka mankhwala oletsa ululu komanno kwipa kwake.

a. Inde

b. Ayi

4. Alipo wina wa muchipatala amene wakuudzani za kuopsya kwa opareshoni?

a. Inde

b. Ayi

5. Ndi zoopsya ziti mwa izi zimene zimachitika nthawi zambiri pa opareshoni? SANKHANI ZITATU MWA IZI!

a. kutaya magazi kwambiri

b. Kuyiwla zipangizo zogwiritsa ntichito m'mimba mwanga.

c. Imfa pobereka

d. Kuola kwa bala

e. Nthawi yaitali yochilira

f. Kufa kwaziwalo

6. Kodi a chipatala anakufotokodzerani kuti kubereka mtsoglo kuyenera kuchitikira muchiptala poti pano mwachitidwa opareshoni?

a. Inde

b. Ayi

c. Ndinatsekedwa

7. Munafunsidwa za chiloledzo chanu musanachitidwe opareshoni?

a. Inde

b. Ayi

8.Munasaina kalata yobvomeredza kuchitidwa opareshoni?

a. Inde

b. Ayi

Apa ndi pamapeto a mafunso athu. Kutenga nawo gawo pa kafukufuku yu kutandizira kuti uchembere wabwino upite patsogolo. Zikomo kwambiri chifukwa chotenga nawo mbali.

Reporting checklist for quality improvement study.

Based on the SQUIRE guidelines.

Title: A pre-post implementation study of a multi-component intervention to improve informed consent for caesarean section in Southern Malawi

Authors: Zethof S, Bakker W, Nansongole F, Kilowe K, van Roosmalen J, van den Akker T

		Reporting Item	Page Number
	#1	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patientcenteredness, timeliness, cost, efficiency, and equity of healthcare)	1
	#02a	Provide adequate information to aid in searching and indexing	2
	#02b	Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions	2
Problem description	#3	Nature and significance of the local problem	3,4
Available knowledge	#4	Summary of what is currently known about the problem, including relevant previous studies	3,4
Rationale	#5	Informal or formal frameworks, models, concepts, and / or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work	3,4
Specific aims	#6	Purpose of the project and of this report	5
Context	#7	Contextual elements considered important at the outset of introducing the intervention(s)	4,5
Intervention(s)	#08a	Description of the intervention(s) in sufficient detail that others could reproduce it	6,7
	#08b	Specifics of the team involved in the work	5,6

Study of the Intervention(s)	#09a	Approach chosen for assessing the impact of the intervention(s)	8,9
	#09b	Approach used to establish whether the observed outcomes were due to the intervention(s)	8,9
Measures	#10a	Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability	8,9
	#10b	Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost	8,9
	#10c	Methods employed for assessing completeness and accuracy of data	8,9
Analysis	#11a	Qualitative and quantitative methods used to draw inferences from the data	8,9
	#11b	Methods for understanding variation within the data, including the effects of time as a variable	9
Ethical considerations	#12	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest	10
	#13a	Initial steps of the intervention(s) and their evolution over time (e.g., time-line diagram, flow chart, or table), including modifications made to the intervention during the project	5
	#13b	Details of the process measures and outcome	8,9
	#13c	Contextual elements that interacted with the intervention(s)	9
	#13d	Observed associations between outcomes, interventions, and relevant contextual elements	8,9
	#13e	Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s).	8,9
	#13f	Details about missing data	10
Summary	#14a	Key findings, including relevance to the rationale and specific aims	10,11
	#14b	Particular strengths of the project	14

Interpretation	#15a	Nature of the association between the intervention(s) and the outcomes	12,13
	#15b	Comparison of results with findings from other publications	14,15
	#15c	Impact of the project on people and systems	15,16
	#15d	Reasons for any differences between observed and anticipated outcomes, including the influence of context	15,16
	#15e	Costs and strategic trade-offs, including opportunity costs	N/A
Limitations	#16a	Limits to the generalizability of the work	16,17
	#16b	Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis	16,17
	#16c	Efforts made to minimize and adjust for limitations	17
Conclusion	#17a	Usefulness of the work	14,15
	#17b	Sustainability	15
	#17c	Potential for spread to other contexts	16,17
	#17d	Implications for practice and for further study in the field	16,17
	#17e	Suggested next steps	16,17
Funding	#18	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting	17

Comments:

#15e: No cost analysis was done. The intervention had minimal costs and this was out of the scope of the research