Implementation and Evaluation of Nonclinical Interventions for Appropriate Use of Cesarean Section in Low- and Middle-income Countries: Protocol for a Multisite Hybrid Effectiveness-implementation Type III Trial

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Abstract

**Background:** While cesarean sections (CSs) are a life-saving intervention, an increasing number are performed without medical reasons in low- and middle-income countries (LMICs). Unnecessary CS diverts scarce resources and thereby reduces access to healthcare for women in need. Argentina, Burkina Faso, Thailand and Vietnam are committed to reducing unnecessary CS, but many individual and organizational factors in healthcare facilities obstruct this aim. Nonclinical interventions can overcome these barriers by helping providers improve their practices and supporting women's decision-making regarding childbirth. Existing evidence has shown only a modest effect of single interventions on reducing CS rates, arguably because of the failure to design multifaceted interventions effectively tailored to the context. The aim of this study is to design, adapt and test a multifaceted intervention for the appropriate use of CS in Argentina, Burkina Faso, Thailand and Vietnam.

**Methods:** We designed an intervention (QUALity DECision-making - QUALI-DEC) with four components: (1) opinion leaders at healthcare facilities to improve adherence to best practices among clinicians, (2) CS audits and feedback to help providers identify potentially avoidable CS, (3) a decision-analysis tool to help women make an informed decision on the mode of birth, and (4) companionship to support women during labor. QUALI-DEC will be implemented and evaluated in 32 hospitals (8 sites per country) using a pragmatic hybrid effectiveness-implementation design to test our implementation strategy, and information regarding its impact on relevant maternal and perinatal outcomes will be gathered. The implementation strategy will involve the participation of women, healthcare professionals and organizations and account for the local environment, needs, resources and social factors in each country.

**Discussion:** There is urgent need for interventions and implementation strategies to optimize the use of CS while improving health outcomes and satisfaction in LMICs. This can only be achieved by engaging all stakeholders involved in the decision-making process surrounding childbirth and addressing their needs and concerns. The study will generate robust evidence about the effectiveness and the impact of this multifaceted intervention. It will also assess the acceptability and scalability of the intervention and the capacity for empowerment among women and providers alike.

**Trial registration:** ISRCTN67214403

**Background**

Despite the short- and long-term risks associated with cesarean section (CS)\(^1\), the proportion of births by CS continues to increase\(^2\). This trend is not confined to high-income countries, but it widely affects low- and middle-income countries (LMICs), where the overuse and underuse of CS coexist, widening health inequalities and diverting scarce resources\(^3\). When clinically indicated, a CS can effectively prevent maternal and perinatal mortality and morbidity; however, there is no evidence of the benefits of a CS for women and infants who do not need the procedure, and as with any surgery, there are risks associated that are higher in LMIC settings\(^4–6\). Women with a single fetus in cephalic presentation who have reached
at least 37 weeks’ gestation and with no previous CS – a group considered low-risk - are major contributors to the growing prevalence of CS\textsuperscript{7}. This pattern has also been described in LMICs. Unnecessary CS may be particularly prevalent among low-risk women since these women account for approximately half of all CS.

The present evidence on care for women during childbirth has been summarized in the World Health Organization (WHO) recommendations on intrapartum care for a positive childbirth experience\textsuperscript{8} and may enhance the appropriate use of CS if used systematically by health care professionals. However, overuse of CS can no longer be seen only as the result of suboptimal clinical practices during childbirth. Nonclinical factors, such as social, cultural and organizational influences, have emerged as potential drivers and need to be considered to effectively optimize the use of CS\textsuperscript{9}. Nonclinical interventions that address these factors are defined as those applied independently of a clinical encounter between a healthcare provider and a woman in the context of patient medical care and have been shown to safely reduce CS rates, predominantly in high-income settings\textsuperscript{10}. They may target providers who are involved in CS decision-making (physicians, nurses and midwives), women and families, or healthcare organizations or facilities.

The effectiveness of nonclinical interventions to reduce unnecessary CS has also been summarized by the WHO \textsuperscript{10,11}. Table 1 shows the randomized trials conducted to implement nonclinical interventions with the aim of safely reducing CS rates, evaluated as providing moderate to high-certainty evidence. Among interventions targeted at providers, the implementation of guidelines combined with audit and feedback as well as mandatory secondary opinion or physician education by local opinion leaders are the most promising approaches \textsuperscript{12–14}. The relative reduction in CS rates varies between the effect size is higher among low-risk women (reduction by 20%) than among high-risk women (relative effect not reported or not statistically significant). The evidence suggests little or no difference in CS rates between usual care (defined in each study) and antenatal education/support programs for pregnant women \textsuperscript{15–17}. Paper-based or computer-based decision aids targeted at women with previous CS (high-risk women) present moderate-certainty evidence of an increased number of women choosing a trial of labor when eligible for vaginal birth \textsuperscript{18,19}, but the effect on repeat elective CS rates is not statistically significant. Evidence on the effects of other nonclinical interventions targeted at healthcare organizations shows that promoting companionship during labor may improve the outcomes for women and infants, including increased spontaneous vaginal births and a relative reduction of 25% in CS rates\textsuperscript{11}. However, there are uncertainties regarding the feasibility of these nonclinical interventions in LMICs, and the evidence relating to the effects of multifaceted interventions combining multiple nonclinical interventions is limited. Prioritized research areas were identified for the WHO recommendations on nonclinical interventions to reduce the prevalence of unnecessary CS\textsuperscript{20}.

In this context, we designed a multifaceted intervention called QUALI-DEC to improve decision-making regarding CS (Appropriate use of cesarean section through QUALity DECision-making by women and providers). Four components constitute QUALI-DEC: (1) Opinion leaders (OLs) at healthcare facilities to
implement best practices, (2) CS audits and feedback to help providers identify areas for improvements in medical practices; (3) a decision analysis tool (DAT) to help women make an informed decision on the mode of birth, and (4) companionship to support women during labor. The theoretical framework shown in Figure 1 and Table 2 describes how these four mutually reinforcing components targeted at women, providers and health facilities may reduce unnecessary CS by improving the decision-making of women and providers regarding the mode of birth.

In this study, we designed, adapted and evaluated a strategy to implement the four components of the QUALI-DEC intervention. Our primary hypothesis is that the implementation of quality decision-making supported by a local OL, continuous CS audit and feedback, use of the DAT during antenatal care and companionship during labor could reduce CS rates among low-risk women. The specific objectives of the study are as follows:

1. To evaluate the QUALI-DEC strategy at the health professional and health system levels in terms of participation, acceptability, implementation, scalability and empowerment of providers through the audit approach, costs at the organization level, and scalability.
2. To evaluate the QUALI-DEC strategy at the women's level in terms of participation in activities targeting them, acceptability, scalability and the empowerment of women in decision-making regarding the planned mode of birth and satisfaction with care.
3. To assess the effect of the multifaceted intervention on CS rates and maternal and perinatal outcomes.
4. To conduct extended cost-effectiveness analyses of implementing QUALI-DEC interventions from women's perspective and the health system perspective, using both health and nonhealth outcomes.

**Methods**

**Description**

**Study design**

We will use a pragmatic hybrid effectiveness-implementation type III design to test our implementation strategy while observing and gathering information on the QUALI-DEC intervention's impact on relevant outcomes. Using a quasi-experimental design (interrupted time series and before-after study), we will assess effectiveness and safety outcomes. A process evaluation will be carried out using mixed qualitative and quantitative approaches. The evaluation will account for the policy context, remuneration and organization of care, hospital characteristics, readiness to change and acceptability among healthcare providers and organizations. The evaluation will also consider the societal context, women's preferences for mode of birth, acceptability, knowledge improvement, birth experience and satisfaction among women, and out-of-pocket expenditures linked to maternity care. We used the Standards for Reporting Implementation Studies (STaRI) checklist to report our research protocol.

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Context

The multifaceted intervention will be implemented in facilities in Argentina, Burkina Faso, Thailand and Vietnam. These four countries illustrate various degrees of rates in LMICs (Table 3) and present specific challenges for QUALI-DEC implementation. Within these four countries, Argentina has the highest level of CS at national level and, more generally, of the biomedicalization of childbirth. Thailand has very low fertility, which may add pressure in favor of CS. A favorable socioeconomic context may also facilitate the preference for CS. Vietnam is interesting for its demographic impact (size of the population) and its performance in health indicators given its level of national income. However, the national CS rate has been continuously increasing over the past few decades, exceeding any reasonable level for medical needs and large inequalities in the use of CS. Burkina Faso has a low CS rate at national level that may hide inequalities and that suggests a great potential for further increase and consequently represents an opportunity to prevent the phenomenon before it aggravates. There is leverage power given the consequences of CS for nulliparous women in a context where fertility is so high. Risk of impoverishing expenditure for surgical care is high in Burkina Faso and Vietnam where financial protection is still developing. Evidence from our previous experience and the existing literature has shown that the skills and beliefs of healthcare providers, access to information and emotional support of low-risk women, leadership and commitment to use evidence-based guidelines at the organizational and system levels are important drivers of the CS rate in these four countries.

Targeted sites and participants

The study will be conducted from January 2020 to December 2024 in 32 healthcare facilities (8 per country) with high CS rates. Facilities were selected purposely with country investigators to reflect the range of contexts, such as secondary and tertiary levels of care, public and private hospitals, and teaching and nonacademic facilities (Table 4). There is a wide variation in the number of deliveries among the different institutions. In Vietnam, the number of annual births in some hospitals exceeds 20,000 births per year, while in other countries, the number ranges between 1200 and 7500 births per year. Facility-based CS rates range from 21% (district hospital in Burkina Faso) to 62% (tertiary hospital in Argentina) across countries.

The intervention directly targets healthcare providers involved in obstetric care and all women who give birth in the participating hospitals during the study period. We have defined providers as obstetricians and nurses/midwives working in the maternity ward in the study facilities. Women will be eligible if they give birth to a newborn (birthweight $\geq 500$ g in Argentina and Vietnam or $\geq 1000$ g in Burkina Faso and Thailand), alive or dead, and with or without malformations. The intervention does not target patients admitted for abortion or miscarriage or those who delivered at home or in another facility that is not a participating hospital.

Intervention
A multifaceted intervention was developed based on existing evidence (Table 1) and WHO recommendations on nonclinical interventions to reduce unnecessary CS. Baseline formative research informed by the ecological framework will be conducted to improve our understanding of the different levels of factors affecting CS rates and to adapt the multifaceted intervention to each country. The four components of QUALI-DEC will be implemented simultaneously in each participating hospital during the 2-year implementation period (Figure 1):

Component 1 – Opinion leader (OL) – One OL in each facility will be identified by peers and local authorities. OLs will be gynecologists-obstetricians with proven communication skills and a reputable influence on their colleagues. OLs will lead the process of selection of evidence-based clinical protocols for CS decision-making and train on-site collaborators charged with implementing audit and feedback, decision aid and companionship during labor.

Component 2 – Audit and feedback (A&F) – A&F involves the analysis of medical practices by the practitioners themselves (physicians, nurses/midwives) according to the evidence-based clinical protocols selected by the providers in each facility and subsequent advice as to whether the decision for CS was the most appropriate. The audit concerns several medical records, and as an output, it provides a conclusive analysis that will be presented to the rest of the medical staff (feedback). Audit cycles will be implemented monthly by the local committees following the different steps presented in Figure 2.

Component 3 – Decision analysis tool (DAT) – The DAT is adapted to each country and developed to be used during antenatal care (after 28 weeks of gestation) by women with a singleton pregnancy, without a previous CS and eligible for a trial of labor. It includes two sections: (i) an information section, providing a description and an explanation of the risks and benefits of each mode of birth (planned vaginal birth vs. planned CS); and (ii) an exercise section, allowing women to clarify and summarize their values and preferences with their clinician and indicate what aspects of the mode of birth are important to them. The DAT will be available as a paper booklet and an interactive web/smartphone application.

Component 4 – Companionship during labor – This component will be implemented using a tailored labor companionship model that will include information on (i) eligibility criteria for women and companions, (ii) identification of healthcare providers who will invite the chosen and eligible labor companion from the waiting area into the labor room, (iii) identification of healthcare providers who will deliver the messages to the laboring woman and her companion, (iv) how many people are allowed and when they are allowed to act as companions, (v) how physical space of the labor ward may need design modifications to accommodate a companion, and (vi) educational tools for companions on how to support women during labor and birth.

Pregnant women may benefit from the DAT, which can help them become more informed and active in their care and may reduce the likelihood of healthcare workers’ preferences dictating their care pathway. Women in labor may benefit from the support of a companion who can enhance their feelings of control.
and competence, which might reduce their reliance on medical interventions, such as pain relief. Healthcare providers who receive feedback from the audit on CS may be able to change their practice and clinical management in response to the feedback, with the support of local OLs. Providers may also benefit from the labor companion intervention, as the labor companion will help them better support women. They may also benefit from the DAT, as it could help them discuss and clarify women's perspectives and preferences on the mode of birth.

**Implementation strategy**

The implementation strategy is aligned within the usual model of care in participating healthcare facilities. The main implementers are the local OLs and healthcare providers who are involved in the program and are supported by the country-level study coordinator. Formative research in the baseline period will assess the main drivers and barriers, and a meeting will be held among all stakeholders to discuss implementation issues. Parliamentarians and representatives of women's associations will be involved in this meeting to consider women's views. Then, the intervention will be introduced in each country with a 5-day training workshop addressed to OLs to mobilize their awareness of the power/interaction model of interpersonal influence and to help them learn and practice intervention tools and techniques. The 5-day training session represents the beginning of the implementation phase of the QUALI-DEC project. A re-fresher 3-day training session will take place after one year to update OLs on the process of the intervention, discuss their roles, share their experiences and confirm their capacity to provide leadership in their clinical settings. OLs will receive financial incentives during the intervention period to compensate for the loss of revenues related to the decrease in their clinical activities. Trained OLs will create and train the local QUALI-DEC committee in each hospital charged to implement the intervention. The composition of this committee will be defined during the 5-day training workshop. It will include the OL, the data collector for the Robson classification (Ten Group Classification System) and the audit of CS indication, representatives of physicians, nurses/midwives and representatives of the hospital's administration.

The QUALI-DEC committee will launch the audit cycles, DAT and companionship in their hospital. They will encourage antenatal care providers to deliver the DAT booklet to eligible pregnant women. This will require a series of on-site meetings in all relevant facilities to inform and motivate providers and to obtain their formal commitment. In addition, a DAT application will be developed for smartphones and made available in the settings in which it is considered culturally appropriate and most acceptable and convenient for women. Posters will be displayed on the wall of the waiting room of antenatal care centers with the QR code to access the web/smartphone application. Other information, educational and communication (IEC) materials, such as flipcharts or posters, will be developed to facilitate the briefing of healthcare providers, companions and laboring women. These IEC materials will include reminders about the importance of labor companionship, the role of companions and the regulations of the labor wards. The country-level coordinator will conduct quarterly visits to each participating hospital during the 2-year implementation period to identify further barriers for the implementation process and possible strategies to overcome those barriers, verify data quality and document and report on the study's progress.
Methods: Evaluation

Outcomes

The primary endpoint measure is the monthly CS rate in participating hospitals among women with a singleton pregnancy, with a fetus in cephalic presentation and at least 37 weeks of gestation, and with no previous CS (Groups 1-4 of the Robson classification). We will use the Ten Groups Classification System (TGCS) (also known as the Robson classification) to monitor CS rates at the hospital level. The TGCS classify women into prospective mutually exclusive and totally inclusive groups of women based on a few obstetric variables which are easily obtained and most women themselves would know. Trained data collectors will gather information about each eligible woman using existing routine health information systems (paper-based or electronic records). The information includes five main variables to classify each woman into the TGCS: parity, fetal presentation, previous CS, number of fetuses and gestational age. Once each woman is classified, the data collector will enter the monthly number of vaginal and cesarean deliveries across the ten groups into a secure web application for building and managing online surveys and databases (REDCap). The system will automatically produce monthly hospital summary statistics according to the TGCS classification: group size, CS rate by group and the absolute contribution of each group to the overall CS rate. We will consider the monthly rate of CS before the onset of intervention (12-month period), during the implementation phase (24-month period), and after the implementation phase (24-month period) to assess the effects of the intervention.

As secondary endpoints, the following outcome measures will be assessed: assisted vaginal delivery; time of CS (before or during labor); third- or fourth-degree perineal laceration; antibiotics and uterotonics use; transfusion; admission of the mother or the newborn to intensive care unit; uterine rupture, hysterectomy, maternal or neonatal death; time of breastfeeding initiation; woman's satisfaction with care and her birth experience; payment for medical care; indirect costs of care for childbirth (e.g., cost of transportation to hospital); and loss of earnings. A cross-sectional survey among a representative sample of postpartum women will be established at two time points: at baseline and at the end of the intervention period. All births occurring in the participating hospitals during two weeks in Argentina and Burkina Faso and one week in Thailand and Vietnam will be covered in each survey. The data collection includes a face-to-face interview with women after childbirth and before they leave the maternity ward (facility-exit interview) and the collection of information from the women's medical records, including socioeconomic characteristics of the mother, reproductive history, antenatal and intrapartum care, time and indication of CS, if any, satisfaction with birth experience, breastfeeding practices, out-of-pocket costs, maternal and neonatal outcomes.

Process evaluation

We will use the UK Medical Research Council (MRC) process evaluation framework\textsuperscript{24} to describe how the intervention works (or does not work) along the pathway of implementation, including the internal dynamics of the four components of the QUALI-DEC strategy. The process evaluation also explores the roles, perceptions and coping strategies of actors, adaptation of the interventions based on the local
context, and any unintended effects, with a view to understand the mediating effect of the context\textsuperscript{30}. Figure 3 presents the key functions of the QUALI-DEC process evaluation and the relations among them, while Figure 4 shows the data collection and analysis methods.

To align the intervention and the implementation strategy to the local context, we conduct qualitative research, document review at the country level and a readiness assessment of each participating facility. The qualitative research will include semistructured interviews with women, potential companions and healthcare providers to obtain a comprehensive understanding of the health system and societal context in each country\textsuperscript{27}. Additional interviews with policy-makers and representatives of women’s and professional associations (gynecologists-obstetricians and nurses/midwives) will allow us to complete the stakeholder mapping and analysis. Following the context assessment and inconsultation with QUALI-DEC developers and implementers, we will define assumptions on what may need to happen (mechanisms of change), and we will hypothesize about how change will happen at the individual level (healthcare providers, women and companions), at the organizational level (healthcare facility) and through the interaction of participants. Discussions and meetings will be held by videoconference with country researchers and during face-to-face meetings with high-level stakeholders and local OLs in each country. To further assess the potential scalability of the intervention within the countries, we will include a participative scalability assessment in the in-country meetings to summarize early opportunities and challenges for scale up\textsuperscript{31}.

We will construct a theory of change to guide the process evaluation. We will define indicators of fidelity (whether the intervention was delivered as intended), dose (the quantity of intervention implemented) and reach of intervention (whether women and providers came into contact with each relevant component of QUALI-DEC)\textsuperscript{24}. These indicators will be measured at the individual and organizational levels in all facilities. During the quarterly monitoring visits at each hospital, the coordinator will use a checklist to rate the level of implementation for each component of QUALI-DEC and identify barriers/facilitators and adaptation strategies to overcome these barriers. Using data from the postpartum cross-sectional survey, we will be able to assess the proportion of women who used the DAT during antenatal care or chose a companion during labor. Interviews with providers and women will provide more detailed information on the perceptions and views of both stakeholders.

We will conduct in-depth case studies in a subset of four hospitals per country to investigate the details of what worked, why and why not. Study sites will be purposively selected based on indicators of fidelity, dose and reach to reflect the diversity of implementation across participating hospitals. Structured observations of each site and on-site meetings will be held with the members of the local committee, maternity ward staff and facility administrator. We will conduct in-depth individual interviews (IDIs) with key stakeholders at the end of the intervention period (months 24-30). The study instrument for IDIs with healthcare providers will be a semistructured interview guide covering the following topics: communication; interprofessional interaction; acceptability of the CS audit and feedback, DAT and labor companionship; and decision-making, including aspects of position/seniority, gender, weighing of alternatives and their implications, and information-sharing. The study instrument for IDIs with women
and their companions will be a semistructured interview guide covering the following topics: process of and factors affecting the decision-making to use DAT; process of and factors affecting decision-making to use labor companionship; perceptions of the DAT and labor companionship related to knowledge, experiences, and support in choosing the mode of childbirth; perceptions and experiences of the relationship between themselves and providers; perception and experiences of how use of the DAT and/or labor companionship influenced trust, self-esteem, empowerment, and the relationship with providers. All interviews will take place in a private setting and will be audio recorded.

**Economic evaluation**

The cost-effectiveness of the QUALI-DEC intervention and the financial risk protection provided are important factors for decision-makers considering implementing new strategies to reduce unnecessary CS. Therefore, an economic analysis of the QUALI-DEC strategy will be conducted to inform decision-makers about the implementation of the QUALI-DEC intervention in relevant healthcare facilities. The impact of QUALI-DEC will be estimated in three domains across women in distinct wealth strata: (i) health gains (e.g., reduced CS rates), (ii) women's out-of-pocket (OOP) expenditures averted by reducing unnecessary CS, and (iii) total net cost of the intervention to the implementer.

We will use an extended cost-effectiveness analysis (ECEA) approach to evaluate the cost-effectiveness of the QUALI-DEC intervention. The ECEA follows the same principles as the traditional cost-effectiveness analysis; however, ECEA allows policy-makers to account for both health and nonhealth outcomes when making decisions and thus to more effectively direct scarce healthcare resources towards specific policy objectives. Furthermore, ECEA assesses the health and financial consequences of policies, including financial risk protection and other disaggregated outcomes per a specific population stratum of interest.

Information on intervention costs will be collected at the national and facility levels. Information on individual costs will be collected from women in relation to the postpartum survey. Intervention costs will be assessed at two levels: (i) the national level (development of guidelines and training materials, quarterly visits, and coordination costs) and (ii) the healthcare facility level (time spent by health professionals and OLs on training activities, A&F, consumables, equipment, overheads, and capital costs) and collected during the intervention implementation. OOP costs will also be collected from women in relation to activities performed in evaluating effectiveness outcomes (postpartum survey) and will include the following: the formal and informal direct payment for medical care, direct nonmedical costs (i.e., transportation costs to seek care), and indirect costs (i.e., time and productivity losses, which can be translated into wages and foregone income). Costs for the eventual scale-up of the intervention will also be calculated. Health gains will be determined by evaluating changes in CS practices and perinatal outcomes and fed into the ECEA.

The ECEA will provide two main outputs: the *incremental cost-effectiveness ratio (ICER)* – the net costs per reduction in CS among low-risk women – will be computed; and *OOP averted* – this output can be referred to as ‘expenditures crowded out’ in the sense that the implementation of the QUALI-DEC intervention may lead to the ‘crowding out’ of these individual OOP costs. The distributional
consequences (i.e., outputs) will be analyzed across distinct strata of the populations (e.g., socioeconomic status and geographical setting).

**Sample size**

Limited guidance is available on sample size calculation for time series analyses, and many of the recommendations focus on the need for sufficient time points pre- and postintervention to precisely ascertain trends and levels\textsuperscript{33,34}. Our analysis on the primary outcome (monthly CS rates among low-risk women) will include 12 time points preintervention, 24 time points during the intervention phase, and 24 time points during the follow-up phase.

The approach for calculating the required number of participants for the postpartum cross-sectional survey is that used for a “before-after” noncontrolled study design. We estimated that a sample of 470 women at baseline and 470 women at the end of the intervention period will ensure 90% statistical power to detect an effect size of 0.3 standard deviations or greater in satisfaction scores with a two-sided 5% significance level\textsuperscript{35}. The calculation accounted for the clustered nature of the data by hospitals with a design effect of 2. Allowing for a 20% nonresponse rate, we aim to recruit 564 women in each phase. The proposed sample size (i.e., 564) can be achieved with two weeks of data collection in Argentina and Burkina Faso and with one week of data collection in Thailand and Vietnam. This sample size will be for each country and will allow to draw conclusions independently for each country and produce individual country interpretations. We estimated that 3980 births will occur during this data collection period in all participating hospitals of the four countries. This overall sample size for the cross-sectional survey will ensure accurate measurements of other secondary outcomes (maternal and perinatal morbidity, time of breastfeeding initiation). Estimations of outcomes at each time point will fluctuate within a 95% confidence interval with the following bounds: 10% rate ± 1% (example: postpartum hemorrhage); 20% rate ± 1.3% (example: second degree perineal trauma); 40% rate ± 1.5%; (examples: overall CS rate, breastfeeding within one hour of birth).

**Analysis**

*Quantitative analysis*

We will use different methods to evaluate the effectiveness of the QUALI-DEC intervention\textsuperscript{22,23}. For the primary outcome, interrupted time series analysis (ITSA) based on segmented regression will estimate the mean changes in the level (immediate change) and trend (sustained change) of monthly CS rates across all participating hospitals in relation to their baseline level and pre-existing trend. For secondary outcomes, we will use a before and after cross-sectional design that will include medical records and women’s interviews. We will compare the outcomes between the two periods of the cross-sectional survey, adjusting for hospital and woman characteristics, to evaluate changes in satisfaction with the birth experience, breastfeeding and medical practices, and maternal/perinatal morbidity. For implementation
outcomes, checklist ratings during monitoring visits will be used to compute average scores of the fidelity, dose and reach of the intervention. Parametric tests will be used to assess changes over time for each facility and differences between study sites.

**Qualitative analysis**

Qualitative data from observations and IDIs will be analyzed and interpreted using a thematic analysis approach. Interview transcripts will be analyzed in the local language at the country level. Final themes and key quotations will be translated into English for sharing with the researchers of the QUALI-DEC consortium. Framework analysis will be used to provide an in-depth understanding of acceptability by providers and women/companions and the empowerment of both stakeholders to act on CS decision-making. We will define acceptability as the perception of providers and women that the QUALI-DEC intervention is agreeable, entails an acceptable burden, is ethical and economically feasible, and leads to positive outcomes. We aim to understand the extent to which each component of the intervention and its process are both socially and technically accepted in each context. Empowerment can be understood as a process but also as an outcome to assess whether the intervention has helped providers and women act on CS decision-making. The analysis will focus on the individual empowerment of women and providers. We anticipate that our intervention will enhance providers’ empowerment by presenting them with monthly statistics promoting reflexivity on their practices, and this increased awareness of clinical practices will, in turn, enhance obstetricians’ and midwives’ sense of agency and self-determination in deciding on interventions during labor and delivery. From the women’s point of view, the study will detail the self-empowerment and professional support provided to women to choose the mode of delivery that better suits their needs. We will analyze the effect of the intervention on women’s self-esteem, knowledge and sense of empowerment when deciding on the mode of delivery. In our analysis of empowerment, particular attention will be paid to the gender dimension, including the gender dynamics between different categories of provider and between providers and women and how gender norms shape values and decisions related to childbirth.

**Subgroup analyses**

The integration of quantitative process measures into outcome datasets will contribute to understanding how implementation variability affects outcomes (on-treatment analyses) and to testing hypotheses arising from qualitative analyses. For example, time series models with multigroup comparisons will enable us to conduct formal statistical tests comparing the level and slope of the primary outcome between different categories of healthcare facilities reflecting different levels of implementation, thereby quantifying the variation of effect size between subgroups and revealing the mechanisms of impact. Additionally, outcomes between women in different socioeconomic categories (in terms of education, place of residence, place of birth and wealth index) and between periods will be compared to assess the equity of the QUALI-DEC intervention.

**Knowledge transfer**
In consultation with key stakeholders in each participating country, we will develop an innovative evidence-based knowledge transfer strategy, adapted to each context. The key ingredients of this strategy will be training, implementation and evaluation of a knowledge broker in each country who will facilitate the adaptation, dissemination and exploitation of QUALI-DEC findings by key stakeholders (ref). As the implementation of knowledge brokering is very innovative, it will be the subject of an in-depth evaluation in order to generate knowledge about its processes and effectiveness. A specific research protocol for this part of the QUALI-DEC project will be published later.

Discussion

There is an urgent need for interventions and implementation strategies that optimize the use of CS while improving health outcomes and satisfaction in LMICs. QUALI-DEC aims to test whether the audit and feedback, decision aid and patient-centered care approaches supported by local OLs improve the quality of decision-making and perinatal outcomes.

Innovation and potential impact

The components of the QUALI-DEC intervention have been tested in randomized controlled trials (RCTs) aiming to reduce the overuse of CS. However, the research reported to date has shown only modest effectiveness in reducing CS rates (Table 1). The reasons behind the limited success include the failure to acknowledge the multifactorial and complex nature of CS overuse and, accordingly, the failure to design multifaceted interventions. In addition, not enough emphasis has been given to the evaluation of the implementation strategies, which is a critical component underpinning effectiveness, particularly regarding complex and behavioral driven interventions. Our project will go beyond the state-of-the-art for the following reasons. First, it will provide an exhaustive description of the barriers and facilitators to implementing the four components of the QUALI-DEC intervention in various settings under a rigorous formative research phase. This information will help identify and systematically structure specific determinants associated with implementation success. Second, it will help explain what influences implementation outcomes and provide information on the overuse of CS in settings where the performance in terms of CS decision-making is currently undocumented. Third, it will integrate qualitative and quantitative data to strengthen the internal validity of the results. Combining the merits of multiple theoretical approaches, the QUALI-DEC project will offer a more complete understanding by providing a theory of change that could be adapted to different settings. Fourth, it will analyze the scalability and transferability of the intervention to other contexts, a pressing issue considering the global rise in CS in the past few decades. Importantly, QUALI-DEC focuses on LMICs, where addressing the challenge of overuse has become a priority.

Methodological considerations

Because the QUALI-DEC intervention has a strong evidence base, it is appropriate to prioritize the maximization of external validity through process evaluation and scalability assessment. However,
because QUALI-DEC has not yet been evaluated in LMICs, it is crucial to assess the safety and effectiveness outcomes in these settings. Due to the infeasibility of obtaining the consent of individual women for each component of the intervention and randomization, the assessment of QUALI-DEC outcomes will rely on a quasi-experimental design through interrupted time series and before-after analyses\textsuperscript{22,23}. This design was chosen because it provides an acceptable degree of internal validity given the pragmatic constraints.

The evaluation will help determine the resources needed to implement and administer the QUALI-DEC intervention, especially in the context of usual care in participating hospitals. This approach will enable the use of existing human resources as clinical OLs and healthcare providers. Attention to external validity considerations will result in a sustainable program that can be run on a national scale, which may mean building on the existing healthcare organization, rather than focusing on the QUALI-DEC intervention in isolation.

We will combine quantitative data on key process variables from all sites with in-depth qualitative data from samples purposively selected along dimensions expected to influence the functioning of the QUALI-DEC intervention. This approach will help us reduce the volume of data. We also planned to collect information at multiple time points to inform intervention developers and implementers on problems, unplanned needs or unexpected reactions from stakeholders that can be rectified and addressed as the evaluation progresses. These regular assessments and adaptations will be a crucial feature of QUALI-DEC and a step towards reconciling rigorous research with the pragmatism necessary for cost-effective implementation given the dynamic and changing nature of the interaction between complex interventions and the context\textsuperscript{44}.

Process analysis will be conducted before the outcome analysis to avoid biased interpretation of the process data. Following this approach, the process data will provide prospective insights into why evaluators might subsequently expect to see positive or negative overall effects and generate hypotheses about how variability in outcomes may emerge.

Particularly for complex interventions, such as QUALI-DEC, rigorous research is warranted to determine an efficient and effective scaling-up strategy. Our project will incorporate scalability considerations through the high integration of impact and process evaluation, stringent definition and measurement of scale-up objectives, and outcome evaluation plans that allow for the comparison of effects at different stages of scale-up. We reviewed and synthesized existing scale-up frameworks to identify relevant dimensions and available scalability assessment tools\textsuperscript{31}. Based on these, we defined our scalability assessment process and adapted existing tools for our study.

Our project will perform an extended cost-effectiveness evaluation of the intervention to account for both health and nonhealth outcomes. The findings are essential to understand how the QUALI-DEC strategy will contribute to the financial risk protection of women in different contexts where OOP expenditure for medical care, particularly CS, can contribute to impoverishing circumstances\textsuperscript{45}. Protection from the
financial risks associated with healthcare expenses has emerged as a critical component of universal health coverage\textsuperscript{46}.

In conclusion, the findings from this pragmatic evaluation will be highly applicable to practitioners, service managers and policy-makers who are tasked with implementing nonclinical intervention to reduce unnecessary CS in LMICs. In addition, the findings will determine the effectiveness and cost-effectiveness of an innovative implementation strategy tailored to the needs of the local setting. This strategy aims to implement four active components that are expected to improve quality decision-making for the mode of birth so that only the women who need to have a CS undergo the procedure. The strategy will involve women, healthcare professionals and organizations and will focus on how to best and most effectively implement these components, considering the local needs and resources in each country. Overall, our project will improve the appropriate use of CS and address several sustainable development goal targets, including improving maternal and neonatal health and reducing inequalities within and between countries.

**List Of Abbreviations**

| Abbreviation | Description |
|--------------|-------------|
| A&F          | Audit and feedback |
| CS           | Cesarean section |
| DAT          | Decision Analysis Tool |
| ECEA         | Extended Cost-Effectiveness Analysis |
| ICER         | Incremental Cost-Effectiveness Ratio |
| IDI          | In-depth individual interview |
| IEC          | Information, Education, Communication |
| ITSA         | Interrupted Time Series Analysis |
| LMIC         | Low- and Middle-Income Countries |
| MRC          | Medical Research Council |
| OL           | Opinion Leader |
| OOP          | Out-Of-Pocket |
| QUALI-DEC    | QUALity DECision-making by women and providers |
| REDCap       | Research Electronic Data Capture |
**Declarations**

**Ethical approval and consent to participate**

Ethical clearance for the study was obtained from the local and institutional review boards from the Centro Rosarino de Estudios Perinatales of Rosario, Argentina (Record Notice N° 1/20), Pham Ngoc Thach University of Ho Chi Minh city in Vietnam, Khon Kaen University in Thailand, the Ethics Committee for Health Research of Burkina Faso (Decision N° 2020-3-038), the Research Project Review Pannel (RP2) in the UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (WHO study N° A66006) and the French Research Institute for Sustainable Development (coordinator of QUALI-DEC project).

**Consent for publication**: Not applicable

**Availability of data and material**

The data produced and published during the QUALI-DEC project will be accessible in Zenodo (https://www.zenodo.org/), a general-purpose open-access repository developed under the European OpenAIRE program and operated by the European Organization for Nuclear Research (CERN). Zenodo will allow the deposition of datasets, reports and any other digital artifacts related to research. For each repository, a persistent DOI will be created to easily cite the stored items. The metadata of each record will be indexed and searchable directly in Zenodo's search engine immediately after publishing.

**Competing interests**

The authors declare that they have no competing interests.

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**Authors' contributions**
All authors and members of the QUALI-DEC research group participated in developing the project. AD was responsible for the scientific aspects of the project and the coordination of all work packages. The following authors were responsible for specific work packages: RE – Coordination of intervention implementation; APB - Evaluation of QUALI-DEC at the women's level; CH – Evaluation of QUALI-DEC at the health system level; MR – Monitoring CS rates, maternal and perinatal outcomes; VR – knowledge transfer. KSA participated in developing the economic evaluation of QUALI-DEC, and the following coauthors were responsible for adaptation to the corresponding study country: GC – Argentina; CK – Burkina Faso; PL – Thailand; MQNH – Vietnam. AD wrote the first version of the study protocol and, with APB and CH, coordinated its development and approved the final version. AD, APB, CH, MR, RE, GC, CK, PL, and MQNH obtained the funding for the project. All authors provided feedback and made revisions to the manuscript.

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The QUALI-DEC research Group

The QUALI-DEC research group is a Consortium of researchers and implementers of nine institutions across Europe, Argentina, Burkina Faso, Thailand and Vietnam. This group developed the QUALI-DEC project and is responsible for the implementation and the evaluation of the multifaceted intervention. The composition of the group is as follows.

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Appendix

- European Commission - Grant Agreement Data Sheet
- Ethical approvals
- StaRI checklist

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**Tables**
## Table 1
Published randomized controlled trials with moderate- to high-certainty evidence

| Study             | Study design | Type of intervention                                                                 | Overall CS rate in % | Relative effect (95% CI) |
|-------------------|--------------|---------------------------------------------------------------------------------------|----------------------|--------------------------|
| Lomas, 1991 (12)  | Cluster RCT  | Opinion leader education Audit and feedback                                            | - 53.7* - 69.7* 66.8* | Not reported             |
| Althabe, 2004 (13)| Cluster RCT  | Mandatory second opinion                                                               | 26.3 24.7 24.6 24.9  | ARR -1.9 (-3.8 to -0.1) |
| Chaillet, 2015 (14)| Cluster RCT | Audit and feedback                                                                     | 22.5 21.8 23.2 23.5  | ARR -1.8 (-3.8 to -0.2) |
|                   |              |                                                                                       |                      | ARR -1.7 (-3.0 to -0.3)  |
| Mansoumi, 2016 (15)| RCT          | Antenatal education program for physiologic childbirth                                  | - 45.0 - 43.7 45.0   | RR 1.03 (0.72 to 1.49)  |
| Bergstrom, 2009 (16)| RCT         | Antenatal education on natural childbirth preparation with training in breathing and relaxation techniques | - 59.9* - 63.0* 63.0* | RR 0.95 (0.58 to 1.56)  |
| Fraser, 1997 (17)  | RCT          | Individualized prenatal education and support program versus written information in pamphlet | - 21.3 - 23.7 23.7  | RR 0.90 (0.74 to 1.11)  |
| Montgomery, 2007 (18)| RCT        | Computer-based decision aids (information program, decision analysis)                 | - 48.6* - 49.6* 49.6* | RR 0.98 (0.82 to 1.18)  |
| Shorten, RCT       |              | Decision aid booklet during antenatal                                                  | - 49.4* - 52.2* 52.2* | Not reported             |
| Bohren, 2017 (11) | Meta-analysis | Companionship during labor | - | 12.3 | - | 15.0 | RR 0.75 (0.64 to 0.88) |

RCT = randomized controlled trial with intervention at the woman's level; cluster-RCT = randomized controlled trial with intervention at the hospital or healthcare provider level

* The selected outcome is the elective repeat cesarean section rate among high-risk women (women with previous CS)

** The selected outcome is the overall CS rate among low-risk women (single pregnancy with cephalic presentation without any complication)

For RCTs, risk ratio (RR) = (mean rate intervention/mean rate control) with 95% confidence intervals.

For the meta-analysis of RCTs, the relative effect is the summary risk ratio with 95% confidence intervals.

For cluster-RCTs, absolute risk reduction (ARR) = (rate change in intervention group) - (rate change in control group) with 95% confidence intervals.
Table 2
Definition, theory and assumptions of each component of the QUALI-DEC intervention

| Component | Definition | Theoretical stance | Assumption |
|-----------|------------|--------------------|------------|
| **Opinion leaders**<sup>47</sup> | Healthcare leaders are identified by their colleagues or local authorities in participating healthcare facilities as being respected clinicians and effective communicators. | Power/interaction model of interpersonal influence<sup>48</sup> | Adherence to guidelines and clinical audit are reinforced through the interaction and influence of reputable culture change agents. |
| **Audit and feedback**<sup>49</sup> | Indications of CS and CS practice among low-risk women are audited by a local committee, with timely feedback to all healthcare professionals. | Constructivist learning<sup>50</sup> | The way knowledge is absorbed, processed and retained results from cognitive, emotional and environmental influences, and change occurs through the active involvement of professionals in analyzing their practices. |
| **Decision analysis tool (DAT)**<sup>28</sup> | A meaningful dialogue between providers and women on preferences, options, concerns, risks and benefits of planned CS vs. planned vaginal delivery leads to an informed and more satisfactory decision for both parties. | Decision theory<sup>51</sup> | A decision aid benefits women and healthcare workers by facilitating a process of informed decision-making, in the context of improved knowledge and overt consideration of women's individual fears, values and needs surrounding birth. |
| **Companionship during labor**<sup>11</sup> | Through the process of implementation, professionals decide on the modification of existing systems, structures, or tasks to offer women and their relatives the possibility of having a companion of choice during labor and childbirth. | Convoy model of social relations<sup>52</sup><sup>49</sup> | Overuse of CS can be prevented by improving the design of health systems and processes to better respond and adapt to the needs of women and their relatives regarding social support during labor and childbirth. |
Table 3
Main health indicators and characteristics of participating hospitals by country

| Indicator, 2017-2019* | Argentina | Burkina Faso | Thailand | Vietnam |
|-----------------------|-----------|--------------|----------|---------|
| Population (millions) | 44.9      | 20.3         | 66.4     | 95.7    |
| Total fertility rate  | 2.3       | 5.3          | 1.5      | 2.0     |
| Maternal mortality ratio | 39       | 320          | 37       | 43      |
| Neonatal mortality rate, | 6.4       | 24.7         | 5.0      | 10.6    |
| Institutional delivery rate | 100% | 80%          | 99%      | 94%     |
| Cesarean section rate | 36%       | 3%           | 33%      | 27%     |
| Risk of impoverishing expenditure for surgical care | 3.9% | 75.9% | 6.3% | 27.4% |
| GDP per capita (PPP international $) 2018 | 20,611 | 1,985 | 19,051 | 7,478 |
| Income group of the country | Upper-middle income | Lower income | Upper-middle income | Middle income |

* Latest estimation according to the following source of information: (1) WHO Statistical Information System: https://www.who.int/whosis/indicators/en/; (2) World Bank national accounts data: https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD

Maternal mortality ratio: number of maternal deaths per 100,000 live births

Neonatal mortality rate: number of newborn deaths per 1000 live births

Impoverishing expenditure is defined as direct out-of-pocket payments for surgical and anaesthesia care which drive people below a poverty threshold (using a threshold of $1.25 PPP/day).

Risk of impoverishing is the proportion of population at risk of impoverishing expenditure when surgical care is required
Table 4
Characteristics of participating hospitals by country

| Characteristic                  | Argentina | Burkina Faso | Thailand | Vietnam |
|--------------------------------|-----------|--------------|----------|---------|
| Type of hospital               |           |              |          |         |
| Public without private ward    | 8         | 8            | 0        | 2       |
| Public with private wards      | 0         | 0            | 8        | 4       |
| Private                         | 0         | 0            | 0        | 2       |
| Level of reference             |           |              |          |         |
| Tertiary                       | 4         | 2            | 6        | 2       |
| Secondary                      | 4         | 4            | 2        | 4       |
| Primary                        | 0         | 2            | 0        | 2       |
| Teaching hospital              |           |              |          |         |
| Yes                             | 8         | 3            | 8        | 4       |
| No                              | 0         | 5            | 0        | 4       |
| Type of medical records        |           |              |          |         |
| Electronic                      | 8         | 0            | 4        | 1       |
| Paper-based                     | 0         | 8            | 4        | 7       |
| Range of annual births         | 1200-5600 | 2500-6000    | 2500-7500 | 2800-42000 |
| Range of CS rates               | 23%-38%   | 21%-48%      | 36%-56%  | 23%-54% |

Figures
**Figure 1**

Quality decision-making (QUALI-DEC) by women and healthcare providers for appropriate use of cesarean section

**Figure 2**

Audit cycle to change medical practice
Figure 3

Key functions of the process evaluation and the relations among them (adapted from Moore 2015)\textsuperscript{24}

Figure 4

Data collection and analysis methods for process evaluation

Supplementary Files
This is a list of supplementary files associated with this preprint. Click to download.

- BurkinafasoMoHApprovalMarch2020.pdf
- CREPapprovalJanuary2020.PDF
- StaR!checklistcompleted.docx
- GrantAgreementDataSheet.pdf
- CRECThailandApprovalMarch2020.pdf
- IRDAapprovalApril2020.pdf
- PNTVietnamApprovalMarch2020.pdf
- RP2WHOApprovalApril2020.pdf