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Appropriate decision for caesarean section in Burkina Faso

Submission date
13/12/2013

Recruitment status
No longer recruiting

Registration date
12/02/2014

Overall study status
Completed

Last Edited
25/11/2022

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In Burkina Faso, population-based caesarean section rates are still very low (between 2% and 3.5% according to rural and urban settings). However, institutional caesarean section rates are growing quickly since the implementation of the caesarean section fee exemption policy in 2006. Excessive increase in caesarean section rates can have negative impacts on maternal and perinatal health. Many initiatives have been tested but not assessed rigorously. The aim of this study is to assess the effectiveness and analyze the introduction of a multi-faceted intervention to lower the rate of non-medically justified caesareans in Burkina Faso.

Who can participate?
Referral hospitals in Burkina Faso equipped with a functional operating room and women giving birth by caesarean section in those participating hospitals.

What does the study involve?
Hospitals are randomly allocated to one of two groups: an intervention group or a control group. For hospitals in the intervention group an intervention is introduced that combines three potentially effective approaches for reducing non-medically justified caesarean rates: training in best practices during labour and delivery to favor vaginal delivery for low-risk women; clinical audits based on objective criteria for the main indications for caesareans; and text message reminders to support decisions regarding clinically indicated caesareans. This lasts one year. For hospitals in the control group, there are no changes to normal practices.

What are the possible benefits and risks of participating?
According to previous studies, the approach under review could change future behaviors. There are no risks involved.

Where is the study run from?
22 centers (9 regional hospitals and 13 district hospitals) in Burkina Faso

When is the study starting and how long is it expected to run for?
March 2014 to December 2016

Who is funding the study?
1. Fonds Francais Muskoka Canal multi-latéral, UNICEF WHO/OMS - UNFPA ONU Femmes/UN Women
2. Canadian Institute for Health Research (CIHR)
3. French Embassy in Burkina Faso

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effectiveness of clinical audit combined with training in reducing the rate of abusive (not medically justified) caesarean sections in hospitals in Burkina Faso: a cluster randomized controlled trial

Acronym
DECIDE

Study objectives
Clinical audits combined with training and recalls reduce unjustified caesarean delivery by 50% compared to the control group (no external intervention).

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Ethics Committee of Burkina Faso, 05/02/2014

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Caesarean section

Interventions
Current interventions as of 09/05/2017:
This study combines a multicentre cluster randomized controlled trial with an implementation analysis in an mixed-methods approach. The evidence-based intervention will consist of three strategies to improve the competencies of maternity teams: 1) clinical audits based on objective criteria; 2) training of personnel; and 3) decision-support reminders of indications for caesareans via text messages. To analyze the intervention process, a longitudinal qualitative study consisting of deliberative workshops and individual in-depth interviews will be conducted.

1. Intervention group activities: The activities will be conducted from May 2015 to April 2016. The sequence of activities over the 12 months will be directly focused on developing local leadership and strengthening the obstetric teams' capacities. To achieve this goal, the intervention will be implemented in several stages. The intervention will begin with the training of local trainers on: 1) evidence-based standards for the management of labour, the reasoning used to diagnose the main indications for caesareans, and the quality of the surgical procedure; and 2) conducting clinical audits of indications for caesareans based on objective criteria (criteria-based clinical audits, CBCA). The trainers will create CBCA teams in their own hospitals and will organize training for obstetric teams on best practices. Thereafter, decision-support reminders of evidence-based criteria for diagnosing the main indications for caesareans, conveyed via SMS, will be used to supplement the staff training.
2. Control group: No external intervention is planned for this group.

Previous interventions:
Multi-factorial intervention combining education, clinical audit with feedback and reminders concerning the indications for caesarean section.
Methodology for each treatment arm:
1. Intervention group activities: Professionals from the intervention group will be first trained in evidence-based practice using algorithms for the decision of caesarean section and vignettes (one day). The initial training will target health professionals who provide obstetrical care, select women for caesarean section and/or perform caesareans. This training aims to improve the performance of health care personnel in managing four main clinical situations: women with previous caesarean section, pre-eclampsia, prolonged labor and fetal distress. With the support of an external facilitator (principal investigator), the audit process will be launched in each center in accordance with the approach proposed by WHO. Information on caesarean sections collected during the pre-intervention period will be analyzed according to the algorithms. A synthesis of the results will be addressed to the hospital director and the head of the maternity unit who will plan an audit meeting with the staff. Recommendations for action will be drawn and the implementation of each action will be monitored by the research team. Individual feedback of audit findings, recommendations to health care personnel and continuous training with vignettes will be implemented during one year using mobile phone (SMS).
2. Control group: No external intervention is planned for this group.

Randomization
The trial consists of a 6-month pre-intervention, a 1-year intervention period and a 6-month post-intervention period. After the 6-month pre-intervention data collection period (baseline), each hospital will be randomly assigned to either an intervention group or a control group. All participating hospitals will be simultaneously randomised, which minimize risks of allocation bias. To avoid level of care imbalance within each stratum, a computer blocked randomisation will be used to generate the allocation sequence. Each block will included two or four hospitals of similar level of care. Investigators will be informed of the allocation status of their hospital only after the baseline period and immediately before the implementation of the intervention in the intervention group.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

The effect of the intervention will be measured by the change in the rate of non-medically justified caesarean sections among all caesarean sections between the periods before and after the intervention. Data on caesarean sections will be collected for 6 months before the intervention period and 6 months after the intervention period. They relate to clinical information for judging the appropriateness of indications for caesarean section according to objective criteria approved by a committee of independent experts.

Secondary outcome measures
1. Knowledge score of health care professionals using specific vignettes
2. Quality scores for the practice of caesareans based on objective criteria (specific tasks)
3. Score of resource availability using the complexity index proposed by WHO
4. Fatality rate of caesarean sections (mother and child)
Each of these outcomes will be measured before and after the intervention period.

Overall study start date
01/03/2014

Completion date
31/12/2016

Eligibility

Key inclusion criteria
For the hospitals:
1. A minimum of 1000 deliveries per year
2. A minimum of 200 caesarean sections per year
3. The permanent availability of emergency caesarean section
4. The absence of current or recent experience in clinical audits for caesarean
5. Willingness to participate in the study is materialized by a written and signed ward agreement by the hospital director and the head of the maternity unit
6. District or regional hospital

For the patients:
We will include all women who deliver by caesarean section in selected hospitals during the study period: the first 100 caesarean sections for each center during the pre-intervention period (6 months) and the first 100 caesarean sections for each center in the post-intervention period.
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For the health professionals:
All health professionals involved in the decision making process for a caesarean section: obstetricians, general practitioners, nurses and midwives.

Participant type(s)
Mixed

Age group
Adult

Sex
Female

Target number of participants

The target number for this trial is 4400 women (2200 in each group)

Total final enrolment
4174

Key exclusion criteria
For the hospitals:
1. University hospitals
2. Private hospitals

For the patients:
Women admitted in a center participating in the study but whose caesarean section was performed in another center

Date of first enrolment
02/05/2014

Date of final enrolment
02/11/2016

Locations

Countries of recruitment
Burkina Faso

France

Study participating centre
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Sponsor information

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Sponsor type
Research organisation

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Funder(s)

Funder type
Charity

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Funder Name
UNICEF WHO/OMS UNFPA ONU Femmes/UN Women

Funder Name
French Embassy in Burkina Faso

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
01/12/2017

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	21/10/2016		Yes	No
Results article	results	02/05/2019	25/02/2021	Yes	No
Results article	Secondary analysis of the post-intervention phase	06/10/2022	25/11/2022	Yes	No