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Impact of health professionals' training in primary health care facilities on maternal and neonatal health

Submission date
16/06/2015

Recruitment status
Stopped

Registration date
27/07/2015

Overall study status
Stopped

Last Edited
11/12/2018

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The causes of maternal and neonatal deaths identified in Mali suggest that the situation can be improved since the complications leading to death can be diagnosed and successfully treated in a health system with skilled personnel and facilities able to handle emergency cases and provide postpartum care (that is, care just after having a baby). Early detection followed by management of high blood pressure (hypertension), diabetes, intrauterine growth restriction (that is, where the unborn baby is smaller than it should be) (IUGR), pre-eclampsia, and other conditions can help prevent obstetric complications and/or premature birth. This and ensuring that basic and comprehensive emergency obstetric and neonatal care are both available and accessible may reduce the number of Maternal and neonatal deaths.
Identifying IUGR or preterm birth requires knowledge of gestational age, but it is usually loosely estimated in West Africa. Moreover, in rural areas, most health agents are not trained for detection and management of pregnancy complications and newborn health issues. Thus, we plan to implement an intervention that would:
1. Increase the number of pregnant women who know their date of last menstruation, therefore the number of pregnancies for which the gestational age is known
2. Improve the detection of premature delivery, post-term delivery, and intrauterine growth retardation
3. Improve decisions making as to place of birth and the care of newborns and pregnant women at risk of complications
4. Reduce excess perinatal mortality (stillbirths and death of newborn within the first week of life) that results from the impossibility of determining gestational age at delivery (e.g. IUGR, prematurity)

Who can participate?
Any woman who comes to the participating health centres for prenatal care or delivery and every woman referred from one of them for at risk pregnancy/delivery. Also included will be all health professionals working at the participating health centres.

What does the study involve?
Health centres participating in this study are randomly allocated to the intervention or control group. Participants attending intervention centres receive the study intervention. Participants attending control centres act as controls for the study and receive usual care. The study compares women and health workers in the health centres of the intervention group to those of the control group. The intervention covers four aspects:
1. Training of health workers to the use of the sandwich method for the determination of date of last menstruation.
2. Training of health workers in good practices when it comes to monitoring of pregnancy (detection and management of complications / possible pathologies), delivery and care of the newborn.
3. Overseeing teams for the implementation of best practices.

What are the possible benefits and risks of participating?
By enrolling in this study, participants will help in identifying new ways to improve the situation of maternal/neonatal health. If training and supervision have a positive impact on health workers' practices and maternal/neonatal health care, the results of this trial will help in identifying that. There is no risk in participating in this trial as there is no invasive action taken and data collected will anonymous.

Where is the study run from?
The trial will be run in the 76 community health centres of three Malian districts: Diéma Bafoulabé and Yélimané and none of them will be considered as a lead centre.

When is the study starting and how long is it expected to run for?
September 2015 to August 2018

Who is funding the study?
The trial will be funded by three sources:
1. PEERS program, a scientific collaboration and fund transfer agreement between the IRD and URFOSAME
2. InfoDos program, a research agreement between UNICEF and the IRD

Who is the main contact?
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Study website
https://groups.google.com/forum/?hl=fr#!forum/quahor

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Improving the quality of obstetric and neonatal care in primary health care facilities in rural Mali through health workers' training

Study objectives
Current hypothesis as of 20/10/2015:
1. Main hypothesis: Training / supervision of health care professionals to the use of the sandwich method increases the proportion of health care professionals who use this method to estimate the date of last menstruation during first antenatal care visit.
2. Secondary hypotheses: Training / supervision of health care professionals to the use of the sandwich method and optimal care allow:
2.1. To estimate gestational age, and thus secure pregnancy monitoring,
2.2. To improve the diagnosis and management of premature child, small for gestational age or post-term infants
2.3. To reduce neonatal mortality

Previous hypothesis:
1. Main hypothesis: Training / supervision of health care professionals to the use of the sandwich method increases the proportion of women who know their date of last menstruation (DLM).
2. Secondary hypotheses: Training / supervision of health care professionals to the use of the sandwich method and optimal care allow:
2.1. To estimate gestational age, and thus secure pregnancy monitoring
2.2. To improve the diagnosis and the management of premature child, small for gestational age or post-term infants
2.3. To reduce neonatal mortality

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Pragmatic two arms cluster randomized trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Maternal and neonatal health

Interventions
Our Intervention consists in three complementary activities:
1. Training health workers to the use of the sandwich method
2. Training health workers in obstetric and neonatal optimal care
3. Supervision of obstetric teams for the implementation of best practices

Intervention Type
Mixed

Primary outcome measure
Current primary outcome measure as of 20/10/2015:
Proportion of health workers who use the sandwich method to estimate the date of last menstruation during first antenatal care visit.

Previous primary outcome measure:
Proportion of women who know the date of last menstruation.

Secondary outcome measures
Current secondary outcome measures as of 20/10/2015:
1. The proportion of women who know the date of last menstruation
2. The knowledge score of the health care professionals
3. The health workers' satisfaction score regarding their working conditions
4. The rate of transfer of pregnant women to a higher-level structure during pregnancy
5. The rate of transfer of women to a higher-level structure after delivery
6. The rate of transfer of newborn to a higher-level structure after delivery
7. The proportion of newborns diagnosed pre-term, small for gestational age or post-term
8. Perinatal mortality rate

All outcome measures will be measured one time before intervention and one time after intervention. Two rounds of supervision will be carried out.

Previous secondary outcome measures:
1. The proportion of health professionals that determine the date of last menstruation using the sandwich method
2. The knowledge score of the health care professionals
3. The health workers' satisfaction score regarding their working conditions
4. The rate of transfer of pregnant women to a higher-level structure during pregnancy
5. The rate of transfer of women to a higher-level structure after delivery
6. The rate of transfer of newborn to a higher-level structure after delivery
7. The proportion of newborns diagnosed pre-term, small for gestational age or post-term
8. Perinatal mortality rate

All outcome measures will be measured thus:
1. One year of pre-intervention data collection
2. One year of intervention implementation
3. One year of post-intervention data collection

Overall study start date
01/09/2015

Completion date
31/08/2018

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
Patients:
1. Pregnant women presenting in one of the participating health facilities for antenatal care
2. Women who give birth in one of the participating health facilities or were referred to a higher-level facility during childbirth

Health professionals:
All the general practitioners, obstetric nurses, midwives, health technicians and midwives who provide care to pregnant women and newborns in the participating health centres of Diema will be included in the study.

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
Patients: 1600; Health professionals: 228

Key exclusion criteria
Women who have given birth at home and used postpartum healthcare services in one of the participating health centers

Date of first enrolment
01/09/2016

Date of final enrolment
31/08/2017

Locations

Countries of recruitment
Mali

Study participating centre
Community health centres
Diéma, Bafoulabé and Yélimané
Mali
-

Sponsor information

Organisation
Institute of Research for Development, UMR 216

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Sponsor type
Research organisation

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ROR
https://ror.org/05q3vnk25

Funder(s)

Funder type
Government

Funder Name
PEERS program (scientific and fund transfer collaboration agreement between IRD and URFOSAME)

Funder Name

Results and Publications

Publication and dissemination plan
The final results of this study will be disseminated to the community health centres and the policy makers so that they are aware of the effectiveness of such intervention in April/June 2018. Project's final report and scientific articles will also be published between March and June 2018

Intention to publish date
30/06/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available