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Maternal mortality and obstetric care

Submission date 04/12/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/12/2007	**Overall study status** Completed	
Last Edited 25/05/2017	**Condition category** Neonatal Diseases	

Plain English summary of protocol

Background and study aims
Maternal and perinatal mortality (death of mother/newborn baby) are major problems for which progress in sub-Saharan Africa has been inadequate, although childbirth services are available even in the poorest countries. Reducing these deaths is the aim of two of the main Millennium Development Goals. There have been many initiatives to remedy this situation, such as the Advances in Labour and Risk Management (ALARM) International Program, whose purpose is to improve the quality of obstetric services in low-income countries. However, few interventions have been tested in this context with rigorous methods for analysing effectiveness in terms of health outcomes. The aim of this study is to assess the effectiveness of the ALARM International Program (AIP) at reducing maternal mortality in referral hospitals in Senegal and Mali.

Who can participate?
Pregnant women from 12 to 45 years old who deliver in one of the participating hospitals

What does the study involve?
Participating hospitals are randomly allocated to the intervention group or the control group. The intervention group hospitals receive a combination of two approaches aimed at improving the performance of health personnel: educational outreach visits and the introduction of facility-based maternal death reviews. The intervention lasts 2 years. The control group hospitals do not receive the intervention. Maternal mortality rates, resource availability, quality of care, maternal morbidity (illness), perinatal mortality, and health personnel satisfaction are compared between the two groups.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Université de Montréal (Canada)

When is the study starting and how long is it expected to run for?
March 2007 to November 2011

Who is funding the study?
Canadian Institutes of Health Research (CIHR) (Canada)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MCT-82503

Study information

Scientific Title
Quality of care, risk management and obstetrical techniques in developing countries (QUalité des soins, gestion du RIsque et TEchniques obstétricales dans les pays en développement [QUARITE])

Acronym
QUARITE

Study objectives
Principal hypothesis:
The program ALARM international reduces by 30% the global case fatality rate, measured in the hospitals during the post-intervention period, compared to the control group.

Secondary hypotheses:
1. Reduction of stillbirth and early neonatal mortality
2. Improvement in the quality of care by a better utilisation of local resources and changes in

professional practices
3. Increase in health workers satisfaction

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Research Ethic Committee, Saint Justine's Hospital (Le comité d'éthique de la recherche, l'Hôpital Sainte-Justine), Montréal, Québec (Canada), 20/11/2006, ref: # 2425
2. Ministry of Health and Preventive Medicine, Health Directorate, Republic of Senegal (Ministère de la santé et de la prévention médicale, Direction de la santé, République du Sénégal), 10/05/2007, ref: # 0869 MSPM/DS/DER
3. National Ethics Committee for health and life sciences, Ministry of Health, Republic of Mali (Comité national d'éthique pour la santé et les sciences la vie [CNESS], Ministère de la santé, République du Mali), 18/06/2007, ref: # 034/MS-SG-CNESS

Study design
Multicentre international two-arm randomised cluster trial of educational nature

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Maternal mortality/neonatal mortality

Interventions
Training of opinion leaders to optimal professional practices and to maternal deaths audits (training of trainers):
1. Training of obstetric team in hospital
2. Implementation of audit in hospitals
3. External facilitators visits
4. Recertification of opinion of the leaders

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Global case fatality rate measured in the hospitals in post intervention period (year 4)

Secondary outcome measures
1. Distribution of principal causes of maternal morbidity and mortality
2. Case fatality rates for obstetric complications
3. Mortinatality rate in hospital
4. Early neonatal mortality in hospital
5. Obstetric interventions rate
6. Emergency obstetric care availability score
7. Human resources satisfaction score

Overall study start date
01/03/2007

Completion date
01/11/2011

Eligibility

Key inclusion criteria
At the hospital level:
1. Public referral hospital (district, department, regional or national)
2. Availability of surgical theatre
3. Annual number of deliveries greater than 800
4. Consent form signed by the maternity director and hospital director to participate in the study

At the individual level:
1. Women admitted for delivery including those referred to the hospital or who died in the transport to hospital
2. Pregnant women from 12 to 45 years old

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
174 688 women nested in 44 hospitals

Key exclusion criteria
At the hospital level:
1. Private hospital
2. Public hospital with less than 800 deliveries per year
3. Surgical theatre not operational

4. Hospitals where the maternal deaths audit were already implemented
5. No signed consent form directors of maternity and hospital

At the individual level:
1. Women admitted not pregnant
2. Women admitted for complications during the first quarter of pregnancy (miscarriage, ectopic pregnancy)
3. Women admitted after 42 days after the end of pregnancy
4. Late maternal deaths or deaths from accidental causes

Date of first enrolment
01/03/2007

Date of final enrolment
01/11/2011

Locations

Countries of recruitment
Canada

Mali

Senegal

Study participating centre
Université de Montréal
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Sponsor information

Organisation
Sainte-Justine Hospital Research Centre (CHU Sainte-Justine) (Canada)

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Sponsor type
Hospital/treatment centre

Website
http://www.recherche-sainte-justine.qc.ca/en

ROR
https://ror.org/01gv74p78

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (ref: MCT-82503)

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	results	18/09/2009	Yes	No
Results article	results	29/10/2012	Yes	No
Results article	results	25/01/2013	Yes	No
Results article	results	13/07/2013	Yes	No