

Maternal mortality and obstetric care

Submission date 04/12/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/12/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/05/2017	Condition category Neonatal Diseases	<input type="checkbox"/> Individual participant data

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?

1. Dr Alexandre Dumont (scientific)

alexandre.dumont@ird.fr

2. Dr Pierre Fournier (scientific)

pierre.fournier@umontreal.ca

3. Dr Idrissa Diop (public)

hygea@sentoo.sn

4. Dr Mamadou Konate (public)

Mamadou.konate@caref.org

Contact information

Type(s)

Scientific

Contact name

Dr Pierre Fournier

Contact details

Université de Montréal

3875 St Urbain

Montreal

Quebec

Canada

H2W 1V1

+1 (0)514 890 8000 ext. 15926

Pierre.fournier@umontreal.ca

Type(s)

Scientific

Contact name

Dr Alexandre Dumont

Contact details

Université de Montréal

Montréal

Canada

-

+221 (0)33 820 78 16

alex.dumont@orange.sn

Type(s)

Public

Contact name

Dr Idrissa Diop

Contact details

HYGEA Senegal

-

Senegal

-

-

hygea@sentoo.sn

Type(s)

Public

Contact name

Dr Mamadou Konate

Contact details

CAREF Mali

-

Mali

-

-

Mamadou.konate@caref.org

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

Quebec

Canada

H2W 1V1

Sponsor information

Organisation

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

Sponsor details

c/o Sylvie Cossette

3175 Cote Sainte Catherine

Montreal

Quebec

Canada

H3T 1C5

+1 (0)514 345 4931 ext. 5657

sylvie.cossette@recherche-ste-justine.qc.ca

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?
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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