

Making it Happen: reducing maternal and neonatal deaths in South Africa; healthcare facility level assessment of in-service training in emergency obstetric and early newborn care for staff working in maternity services in twelve districts in RSA

Submission date 26/08/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 08/09/2016	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/01/2020	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Globally, every year 303,000 women die due to pregnancy-related complications, 2.6 million babies are stillborn and a further 2.7 million die in the first month of life. Many of these deaths occur in low and middle income countries and the majority of them are preventable. Poor emergency care is one of the major contributors to the unacceptably high death rates for mothers and newborns in South Africa. Improving emergency care is known to reduce death rates. It is critical for healthcare providers to have up-to-date knowledge and skills. Short training programs are a recognised means of improving the quality of care for patients. This study aims to improve the knowledge and skills of healthcare workers in maternity services in South Africa through two packages: Essential Steps in Managing Obstetric Emergencies (ESMOE) and Emergency Obstetric Simulation Training (EOST).

Who can participate?

Staff from healthcare facilities providing emergency obstetric and newborn care in 12 districts in the Republic of South Africa

What does the study involve?

Healthcare providers at all facilities regularly have the EOST 'fire-drill' exercises (short, hands-on, participatory, on the job training) as a means of boosting their knowledge and skills. Additionally, all healthcare providers receive a one-off training using the ESMOE package (2- or 3-day training with a mix of teaching methods using theoretical and practical sessions). This training is introduced at different times to measure the effect of introducing the additional training and to find out how it affects patients and whether it reduces the number of deaths.

What are the possible benefits and risks of participating?

Staff taking part in the training benefit from refresher training which increases their ability to provide care to mothers and babies. There are no risks of taking part in the study.

Where is the study run from?

133 facilities in the selected districts in South Africa; all work is coordinated through the MRC departments at the University of Pretoria and the Centre for Maternal and Newborn Care at the Liverpool School of Tropical Medicine in the UK.

When is the study starting and how long is it expected to run for?

September 2011 to January 2018

Who is funding the study?

Department for International Development (DFID) UK and DFID South Africa

Who is the main contact?

Prof. Nynke van den Broek

Contact information

Type(s)

Scientific

Contact name

Prof Nynke van den Broek

ORCID ID

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Contact details

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Liverpool School of Tropical Medicine
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United Kingdom
L3 5QA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Making it Happen: reducing maternal and neonatal deaths in South Africa; healthcare facility level assessment of in-service training in emergency obstetric and early newborn care for staff working in maternity services in twelve districts in RSA

Study objectives

This study aims to identify the most effective method of providing in-service training in emergency obstetric and newborn care to help to reduce maternal and neonatal mortality in South Africa. With two approaches applied in the study, the null hypothesis is that in-service training in emergency obstetric and early newborn care delivered under Essential Steps in Managing Obstetric Emergencies (ESMOE) package is no different in terms of its effectiveness in reducing maternal and newborn mortality from delivering Emergency Obstetric Simulation Training (EOST) training in healthcare facilities.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Ethics Committee of the Faculty of Health Sciences, University of Pretoria, 30/05/2012, ref: 89/2012
2. Study granted an ethics review exemption by the Liverpool School of Tropical Medicine Research and Ethics Committee, 13/05/2016

Study design

Multicentre stepped-wedge cluster-controlled interventional study

Primary study design

Interventional

Secondary study design

Stepped-wedge randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

In-service training in emergency obstetric and early newborn care

Interventions

Two types of training approaches to be used to build capacity of healthcare providers in maternity services to provide emergency obstetric and early newborn care in twelve districts in the Republic of South Africa:

1. Emergency Obstetric Simulation Training (EOST) package: Training of trainers on ESMOE provided for lead doctor and midwife per participating facility. Having completed the training, those healthcare providers to act subsequently as facilitators of EOST in their workplaces by

organising regular 'fire-drill' sessions on selected aspects of emergency obstetric and newborn care for staff present in the ward during the time of the session.

2. Essential Steps in Managing Obstetric Emergencies (ESMOE) package: Training to be delivered in two forms: 2-day training for lower level cadres and 3-day for medical officers and above, with materials adjusted to meet the needs of specific types of participants. This training is to be delivered once per study period to staff in facilities designated to provide emergency care to mothers and babies in the selected twelve districts.

Both interventions to be delivered at all participating facilities; training of trainers to deliver EOST to be done at the start of the trial in all sites (and subsequently rolled out repeatedly to staff over the duration of the trial); ESMOE training delivered at different time points in the twelve districts based on the randomisation of districts (in line with stepped wedge design). All facilities within a district are to be trained a time period of ca. 6-8 weeks. Sufficient number of trainings on ESMOE to be provided to ensure a minimum of 80% of staff within a district have been trained (saturation approach) to ensure a critical mass of staff are trained.

Intervention Type

Other

Primary outcome measure

All outcomes are to be measured monthly in each facility (according to the stepped wedge design) over the study period (26 months):

1. Facility-level stillbirth rate (number of stillbirths per 1000 births)
2. Facility-level maternal case fatality rate for direct obstetric complications (number of maternal deaths due to direct obstetric complications per 100 cases of direct emergency obstetric complications)
3. Facility-level early newborn death rate (number of early newborn deaths per 1000 live births)
4. Facility-level maternal mortality ratio (number of maternal deaths per 100,000 live births)

Secondary outcome measures

Number of women seeking care in healthcare facilities measured in each facility each month (according to the stepped wedge design) over the course of the study period (26 months)

Overall study start date

30/09/2011

Completion date

31/01/2018

Eligibility

Key inclusion criteria

Note: Assessment of intervention done at healthcare facility level

1. Districts for the intervention were identified by the National Department of Health because of poor health outcomes measured by institutional maternal mortality ratio and district level stillbirth rate (within RSA). This is an externally-driven selection and is not representative of all regions in the Republic of South Africa. The final number of eligible districts is 12
2. Within the identified districts, all healthcare facilities designated to provide emergency obstetric and newborn care services as basic (BEmOC) and comprehensive (CEmOC) level in the districts to be included in the study (staff invited for training). The total number of such facilities identified is 136

3. Ultimate inclusion in the study based on ability to provide necessary data for monitoring the results of the intervention. The total number of such facilities is 133. (Other facilities meeting the first two criteria are eligible for inclusion in the training but not the measurement of effectiveness)

Participant type(s)

Health professional

Age group

Adult

Sex

Both

Target number of participants

In total, est. 3000 healthcare providers working in maternity services in the 12 districts to be trained in ESMOE; for the purpose of the facility level assessment, all staff at 133 healthcare facilities included in the study to be trained through both EOST and ESMOE training approaches

Key exclusion criteria

1. Facilities in non-selected districts
2. Facilities not designated to provide emergency obstetric and newborn care services as basic (BEmOC) or comprehensive (CEmOC) level
3. Facilities unable to provide data for assessing results of the intervention (this is only a criterion for inclusion in the facility-based assessment and does not exclude staff in those facilities being included in training)

Date of first enrolment

01/07/2012

Date of final enrolment

31/03/2015

Locations**Countries of recruitment**

England

South Africa

United Kingdom

Study participating centre

Liverpool School of Tropical Medicine

Centre for Maternal and Newborn Health

United Kingdom

L3 5QA

Study participating centre
University of Pretoria
Faculty of Health Sciences
South Africa

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Study participating centre
Connie Vorster-Hartswater Memorial Hospital
Francis Baard district
South Africa

-

Study participating centre
Galeshewe Day Hospital
Francis Baard district
South Africa

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Study participating centre
Jan Kemp Dorp Hospital
Francis Baard district
South Africa

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Study participating centre
Kimberley Hospital
Francis Baard district
South Africa

-

Study participating centre
Prof Z.K Matthews (Barclay West) Hospital
Francis Baard district
South Africa

-

Study participating centre

Warrenton Hospital
Francis Baard district
South Africa

-

Study participating centre
Bafokeng Health Centre
Bojanala district
South Africa

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Study participating centre
Bapong
Bojanala district
South Africa

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Study participating centre
Boitekong CHC
Bojanala district
South Africa

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Study participating centre
Chaneng
Bojanala district
South Africa

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Study participating centre
Hartebeesfontein Clinic
Bojanala district
South Africa

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Study participating centre

Ikhutseng Clinic (Klipgat)

Bojanala district

South Africa

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Study participating centre

Jst Hospital

Bojanala district

South Africa

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Study participating centre

Koster Hospital

Bojanala district

South Africa

-

Study participating centre

Letlhabile

Bojanala district

South Africa

-

Study participating centre

Mabieskraal

Bojanala district

South Africa

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Study participating centre

Mathibestad

Bojanala district

South Africa

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Study participating centre

Mogwase
Bojanala district
South Africa

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Study participating centre
Moretele
Bojanala district
South Africa

-

Study participating centre
Moses Kotane Hospital
Bojanala district
South Africa

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Study participating centre
Oukasie Maternity
Bojanala district
South Africa

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Study participating centre
Pella
Bojanala district
South Africa

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Study participating centre
Rekopantswe
Bojanala district
South Africa

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Study participating centre

Seaparankwe PHC

Bojanala district

South Africa

-

Study participating centre

Swartruggens Hospital

Bojanala district

South Africa

-

Study participating centre

Tlhabane Health Centre

Bojanala district

South Africa

-

Study participating centre

Amajuba Memorial Hospital

Gert Sibande district

South Africa

-

Study participating centre

Amsterdam CHC

Gert Sibande district

South Africa

-

Study participating centre

Badplaas CHC

Gert Sibande district

South Africa

-

Study participating centre

Bethal Hospital
Gert Sibande district
South Africa
-

Study participating centre
Carolina Hospital
Gert Sibande district
South Africa
-

Study participating centre
Elsie Ballot
Gert Sibande district
South Africa
-

Study participating centre
Embalenhle
Gert Sibande district
South Africa
-

Study participating centre
Embhuleni Hospital
Gert Sibande district
South Africa
-

Study participating centre
Ermelo
Gert Sibande district
South Africa
-

Study participating centre

Evander Hospital
Gert Sibande district
South Africa

-

Study participating centre
Paulinah Morapedi CHC
Gert Sibande district
South Africa

-

Study participating centre
Piet Retief Hospital
Gert Sibande district
South Africa

-

Study participating centre
Siyathemba
Gert Sibande district
South Africa

-

Study participating centre
Standerton Hospital
Gert Sibande district
South Africa

-

Study participating centre
Ellisras
Waterberg district
South Africa

-

Study participating centre

F.H. Odendaal
Waterberg district
South Africa
-

Study participating centre
George Masebe
Waterberg district
South Africa
-

Study participating centre
Mokopane
Waterberg district
South Africa
-

Study participating centre
Mookgopong Health Centre
Waterberg district
South Africa
-

Study participating centre
Thabaleshoba Health Centre
Waterberg district
South Africa
-

Study participating centre
Thabazimbi
Waterberg district
South Africa
-

Study participating centre

Voortrekker Hospital

Waterberg district

South Africa

-

Study participating centre

Warmbaths Hospital

Waterberg district

South Africa

-

Study participating centre

Witpoort Hospital

Waterberg district

South Africa

-

Study participating centre

Catherine Booth

Uthungulu district

South Africa

-

Study participating centre

Ekombe Hospital

Uthungulu district

South Africa

-

Study participating centre

Eshowe Hospital

Uthungulu district

South Africa

-

Study participating centre

Kwamagwaza
Uthungulu district
South Africa
-

Study participating centre
Lower Umfolozi District War Memorial Hospital (LUWMH)
Uthungulu district
South Africa
-

Study participating centre
Mbongolwane
Uthungulu district
South Africa
-

Study participating centre
Ngwelezana Clinic
Uthungulu district
South Africa
-

Study participating centre
Nkandla Hospital
Uthungulu district
South Africa
-

Study participating centre
Nseleni Community Health Centre
Uthungulu district
South Africa
-

Study participating centre

Thokozani Clinic
Uthungulu district
South Africa
-

Study participating centre
Appelsbosch Hospital
Umgungundlovu district
South Africa
-

Study participating centre
Bruntville CHC
Umgungundlovu district
South Africa
-

Study participating centre
East Boom
Umgungundlovu district
South Africa
-

Study participating centre
Edendale Hospital
Umgungundlovu district
South Africa
-

Study participating centre
Greys Hospital
Umgungundlovu district
South Africa
-

Study participating centre

Imbalenhle Community Health Centre

Umgungundlovu district

South Africa

-

Study participating centre

Northdale Hospital

Umgungundlovu district

South Africa

-

Study participating centre

Richmond Clinic

Umgungundlovu district

South Africa

-

Study participating centre

Gamalakhe

Ugu district

South Africa

-

Study participating centre

GJ Crookes Hospital

Ugu district

South Africa

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Study participating centre

Murchison Hospital

Ugu district

South Africa

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Study participating centre

Ntabeni Clinic

Ugu district
South Africa

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Study participating centre

Port Shepstone Hospital

Ugu district
South Africa

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Study participating centre

St Andrews Hospital

Ugu district
South Africa

-

Study participating centre

Turton CHC

Ugu district
South Africa

-

Study participating centre

Bertha Gxowa-Germiston Hospital

Ekurhuleni district
South Africa

-

Study participating centre

Esanyweni Mou

Ekurhuleni district
South Africa

-

Study participating centre

Far East Rand
Ekurhuleni district
South Africa
-

Study participating centre
J Dumane
Ekurhuleni district
South Africa
-

Study participating centre
Kwa-Thema Mou
Ekurhuleni district
South Africa
-

Study participating centre
Natalspruit
Ekurhuleni district
South Africa
-

Study participating centre
Nokuthela Ngwenya
Ekurhuleni district
South Africa
-

Study participating centre
O R Tambo
Ekurhuleni district
South Africa
-

Study participating centre

Philip Moyo
Ekurhuleni district
South Africa
-

Study participating centre
Phola Park
Ekurhuleni district
South Africa
-

Study participating centre
Pholosong Hospital
Ekurhuleni district
South Africa
-

Study participating centre
Ramakonop
Ekurhuleni district
South Africa
-

Study participating centre
Tembisa
Ekurhuleni district
South Africa
-

Study participating centre
Adelaide Hospital
Amathole district
South Africa
-

Study participating centre

Bedford Hospital
Amathole district
South Africa

-

Study participating centre
Bisho Hospital
Amathole district
South Africa

-

Study participating centre
Butterworth
Amathole district
South Africa

-

Study participating centre
Cathcart
Amathole district
South Africa

-

Study participating centre
Cecilia Makiwane Hospital
Amathole district
South Africa

-

Study participating centre
Dimbaza
Amathole district
South Africa

-

Study participating centre

Dutywa Health Centre

Amathole district

South Africa

-

Study participating centre

Dvdh

Amathole district

South Africa

-

Study participating centre

Elliotdale Health Centre

Amathole district

South Africa

-

Study participating centre

Empilweni Gompo CHC

Amathole district

South Africa

-

Study participating centre

Fort Beaufort Hospital

Amathole district

South Africa

-

Study participating centre

Frere Maternity

Amathole district

South Africa

-

Study participating centre

Middledrift Health Care

Amathole district

South Africa

-

Study participating centre

Nompumelelo Hospital

Amathole district

South Africa

-

Study participating centre

Nontyatyambo

Amathole district

South Africa

-

Study participating centre

Nqamakwe Health Centre

Amathole district

South Africa

-

Study participating centre

S. S. Gida Hospital

Amathole district

South Africa

-

Study participating centre

Stutterheim Hospital

Amathole district

South Africa

-

Study participating centre

Twafalofefe

Amathole district

South Africa

-

Study participating centre

Victoria

Amathole district

South Africa

-

Study participating centre

Willowvale CHC

Amathole district

South Africa

-

Study participating centre

Boitumelo Regional Hospital

Fezile Dabi district

South Africa

-

Study participating centre

Mafube District Hospital

Fezile Dabi district

South Africa

-

Study participating centre

Metsimaholo District Hospital

Fezile Dabi district

South Africa

-

Study participating centre

Parys Hospital
Fezile Dabi district
South Africa

-

Study participating centre

Tokollo
Fezile Dabi district
South Africa

-

Study participating centre

Dihlabeng Hospital
Thabo Mofuntsanyane district
South Africa

-

Study participating centre

Elizabeth Ross Hospital
Thabo Mofuntsanyane district
South Africa

-

Study participating centre

Itemoheng Hospital
Thabo Mofuntsanyane district
South Africa

-

Study participating centre

John Daniel Newberry District Hospital
Thabo Mofuntsanyane district
South Africa

-

Study participating centre

Mantsopa District Hospital
Thabo Mofuntsanyane district
South Africa

-

Study participating centre
Mofumahadi Manapo Mopeli Hospital
Thabo Mofuntsanyane district
South Africa

-

Study participating centre
Nketoane Hospital
Thabo Mofuntsanyane district
South Africa

-

Study participating centre
Phekelong
Thabo Mofuntsanyane district
South Africa

-

Study participating centre
Phumelela District Hospital
Thabo Mofuntsanyane district
South Africa

-

Study participating centre
Phuthuloha District Hospital
Thabo Mofuntsanyane district
South Africa

-

Study participating centre

Tebang Clinic

Thabo Mofuntsanyane district
South Africa

-

Study participating centre**Thebe Hospital**

Thabo Mofuntsanyane district
South Africa

-

Study participating centre**Bongani Hospital**

Lejweleputswa district
South Africa

-

Study participating centre**Katleho Hospital**

Lejweleputswa district
South Africa

-

Study participating centre**Mohau District Hospital**

Lejweleputswa district
South Africa

-

Study participating centre**Nala Hospital**

Lejweleputswa district
South Africa

-

Study participating centre

Thusanong Hospital
Lejweleputswa district
South Africa
-

Study participating centre
Winburg Hospital
Lejweleputswa district
South Africa
-

Sponsor information

Organisation
Liverpool School of Tropical Medicine

Sponsor details
Pembroke Place
Liverpool
England
United Kingdom
L3 5QA

Sponsor type
University/education

Website
<http://www.lstmed.ac.uk>

ROR
<https://ror.org/03svjbs84>

Funder(s)

Funder type
Government

Funder Name
Department for International Development

Alternative Name(s)
Department for International Development, UK, DFID

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

Intention to publish date

01/03/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Barbara Madaj (Barbara.Madaj@lstmed.ac.uk) or via the Centre's email address (cmnh@lstmed.ac.uk). Data will be accessible once the trial publication is published. The data dictionary with information on data available (variables and characteristics of variables) can be reviewed by interested parties. Use of data would need to be agreed in advance, following legal and ethical guidelines. Data in this trial relate to health facilities, not individual people, but the information on healthcare facilities will be suitably anonymised to protect the individual facilities. LSTM require data to be preserved for a minimum of five years, but there is no cap for how long the data would be stored.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/11/2019	27/01/2020	Yes	No