

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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United Kingdom
L3 5QA

Additional identifiers

Protocol serial number

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

Study type(s)

Other

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(s)

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)

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

South Africa

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

-

Study participating centre

Connie Vorster-Hartswater Memorial Hospital

Francis Baard district

South Africa

-

Study participating centre

Galeshewe Day Hospital

Francis Baard district

South Africa

-

Study participating centre

Jan Kemp Dorp Hospital

Francis Baard district

South Africa

-

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

-

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

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Study participating centre

Lethabile

Bojanala district

South Africa

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Study participating centre

Mabieskraal

Bojanala district

South Africa

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Study participating centre

Mathibestad

Bojanala district

South Africa

-

Study participating centre

Mogwase

Bojanala district

South Africa

-

Study participating centre

Moretele

Bojanala district

South Africa

-

Study participating centre

Moses Kotane Hospital

Bojanala district

South Africa

-

Study participating centre

Oukasie Maternity

Bojanala district

South Africa

-

Study participating centre

Pella

Bojanala district

South Africa

-

Study participating centre

Rekopantswe

Bojanala district

South Africa

-

Study participating centre

Seaparankwe PHC

Bojanala district

South Africa

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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

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Study participating centre

Evander Hospital

Gert Sibande district
South Africa

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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

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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

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Study participating centre

Mokopane

Waterberg district
South Africa

-

Study participating centre

Mookgopong Health Centre

Waterberg district

South Africa

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Study participating centre

Thabaleshoba Health Centre

Waterberg district

South Africa

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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

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Study participating centre

Witpoort Hospital

Waterberg district

South Africa

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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

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Study participating centre

Nkandla Hospital

Uthungulu district

South Africa

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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

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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

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Study participating centre

Richmond Clinic

Umgungundlovu district

South Africa

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Study participating centre

Gamalakhe
Ugu district
South Africa
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Study participating centre
GJ Crookes Hospital
Ugu district
South Africa
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Study participating centre
Murchison Hospital
Ugu district
South Africa
-

Study participating centre
Ntabeni Clinic
Ugu district
South Africa
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Study participating centre
Port Shepstone Hospital
Ugu district
South Africa
-

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

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Study participating centre
Far East Rand
Ekurhuleni district
South Africa

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Study participating centre
J Dumane
Ekurhuleni district
South Africa

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Study participating centre
Kwa-Thema Mou
Ekurhuleni district
South Africa

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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

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Study participating centre

Tembisa
Ekurhuleni district
South Africa

-

Study participating centre

Adelaide Hospital
Amathole district
South Africa

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Study participating centre

Bedford Hospital
Amathole district
South Africa

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Study participating centre

Bisho Hospital
Amathole district
South Africa

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Study participating centre

Butterworth
Amathole district
South Africa

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Study participating centre

Cathcart

Amathole district

South Africa

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Study participating centre

Cecilia Makiwane Hospital

Amathole district

South Africa

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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

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Study participating centre

Empilweni Gompo CHC

Amathole district

South Africa

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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

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Study participating centre

Nontyatyambo

Amathole district

South Africa

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Study participating centre

Nqamakwe Health Centre

Amathole district

South Africa

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Study participating centre

S. S. Gida Hospital

Amathole district

South Africa

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Study participating centre

Stutterheim Hospital

Amathole district

South Africa

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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

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

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