

# 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

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

<https://orcid.org/0000-0001-8523-2684>

### Contact details

Centre for Maternal and Newborn Health  
Liverpool School of Tropical Medicine  
Pembroke Place  
Liverpool  
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

-

**Study participating centre**

**Boitekong CHC**  
Bojanala district  
South Africa

-

**Study participating centre**

**Chaneng**  
Bojanala district  
South Africa

-

**Study participating centre**

**Hartebeesfontein Clinic**  
Bojanala district  
South Africa

-

**Study participating centre**

**Ikhutseng Clinic (Klipgat)**  
Bojanala district  
South Africa

-

**Study participating centre**

**Jst Hospital**  
Bojanala district  
South Africa

-

**Study participating centre**

**Koster Hospital**  
Bojanala district  
South Africa

-

**Study participating centre**

**Lethabile**

Bojanala district  
South Africa

-

**Study participating centre****Mabieskraal**

Bojanala district  
South Africa

-

**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

-

**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  
-

**Study participating centre**  
**Murchison Hospital**  
Ugu district  
South Africa  
-

**Study participating centre**  
**Ntabeni Clinic**  
Ugu district  
South Africa  
-

**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  
-

**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

**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? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>               | results                       | 10/11/2019   | 27/01/2020 | Yes            | No              |
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |