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An affordable solution for strengthening the backbone of maternal care during childbirth

Submission date
28/03/2017

Recruitment status
No longer recruiting

Registration date
11/05/2017

Overall study status
Completed

Last Edited
11/05/2017

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Pakistan has one of the highest maternal mortality rates in the world, with 260 deaths per 100,000 live births. Punjab is the largest province, where 56% of the total population of Pakistan lives. Rural health centers (RHCs) are a critical component of emergency care during pregnancy and are where 59% of all deliveries in the province take place. Households choose to deliver at the RHCs due to financial and cultural reasons. In many cases, these facilities are not well prepared to provide this care. The aim of this study is to find out whether increasing knowledge about emergency care services for pregnant women can help to reduce maternal death rates.

Who can participate?
All maternal care health workers and all pregnant women at participating facilities.

What does the study involve?
Participants are randomly allocated to receive two study conditions in a random order, six months apart. The first condition involves health workers taking part in a one-day refresher workshop to provide them with basic training. The second condition involves the refresher workshop with the addition of mentoring visits through post graduate doctors. These visits involve onsite discussions and demonstration of emergency obstetric care methods. Participants in both groups are followed up for 12 months through reviewing clinical management notes compiled from monthly facility records.

What are the possible benefits and risks of participating?
Maternal care health workers in treatment groups benefit from receiving training that could help them provide better emergency care in the future. Pregnant women who take part may benefit from an improved standard of care. There are no notable risks involved with participating.

Where is the study run from?
The study is run from King Edward Medical University and takes place in 72 health facilities in rural areas (Pakistan)

When is the study starting and how long is it expected to run for?
June 2013 to April 2017

Who is funding the study?
International Food Policy Research Institute (USA)

Who is the main contact?
Dr Musharraf Cyan
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
H14055

Study information

Scientific Title
Priming rural facilities for optimal service delivery

Study objectives
The aim of this study is to test that whether an intervention to prime rural health facilities by institutionalizing readiness protocols for emergency obstetric care through training visits by postgraduate trainee physicians offers an affordable solution for strengthening the backbone of maternal care during childbirth in rural Pakistan.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Susan Laury Experimental Economics Center, Shelia L. White Office of Research Integrity, Georgia State University, 18/12/2014, ref: 331304

Study design
Randomised cross over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Maternal health

Interventions
Participants are randomized to receive the two study conditions in a random order using a randomization command in Stata. All the participating facilities are randomly assigned to eight groups and two time periods. All participants in a facility receive the treatment exposure or control treatment assigned to the facility. Groups are balanced with 9 facilities in each group. During time period 1, the first 6 months of the study, facilities in Groups 1, 2 and 3 receive 6 visits (1 monthly mentoring visit for 6 months) , 3 visits (1 mentoring visit once in 2 months), and 1 mentoring visit at the start of the time period, respectively. Facilities in Group 4, 5, 6, 7 and 8 do not receive any mentoring visit during the first 6 months. At 6 months, Groups 5, 6 and 7 are exposed to treatment while Groups 1, 2 and 3 move into control. Facilities in Group 5, 6 and 7 receive 6, 3 and 1 mentoring visit during time period 2. Facilities in Group 1, 2, 3, 4 and 8 are not exposed to mentoring visits in time period 2.

Control: Participants undergo basic training of health care workers. This involves a one-day refresher workshop on EmoC conducted by OBGYN specialists.

Intervention: Participants undergo the same basic training of health care workers as the control group, with the addition of mentoring visits through post graduate doctors. These visits involve onsite discussions and demonstration of EmOC methods.

Follow up takes place after 12 months and involves review of clinical management notes compiled from monthly facility records.

Intervention Type
Supplement

Primary outcome measure
Rate of application of emergency obstetric care management options is assessed by reviewing clinical management notes from baseline to 12 months.

Secondary outcome measures
1. Rate of application of appropriate diagnosis is assessed by reviewing clinical management notes from baseline to 12 months
2. Usage of parental antibiotics is assessed by reviewing clinical management notes from baseline to 12 months
3. Usage of uterotonic drugs is assessed by reviewing clinical management notes from baseline to 12 months
4. Knowledge, attitudes, and practices (KAP) scores are assessed by reviewing clinical management notes at 6 and 12 months

Overall study start date
01/06/2013

Completion date
30/04/2017

Eligibility

Key inclusion criteria
1. All maternal care health workers in the 72 health facilities
2. All pregnant women who applied to the 72 health facilities

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
1. 360 health workers 2. 25920 pregnant women

Key exclusion criteria
1. No pregnant women attending rural health facilities
2. Women attending health facilities for ANC visits
3. Health workers at the health facilities not tasked with maternal care and/or EmOC services

Date of first enrolment
01/03/2014

Date of final enrolment

28/02/2015

Locations

Countries of recruitment
Pakistan

Study participating centre
King Edward Medical University
Nelagumbad Mayo Hospital Road
Lahore
Pakistan
54000

Sponsor information

Organisation
Georgia State University

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Sponsor type
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Organisation
Georgia State University

Sponsor details

Sponsor type
Not defined

Website
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ROR
https://ror.org/03qt6ba18

Funder(s)

Funder type
Research organisation

Funder Name
International Food Policy Research Institute

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal in 2-3 months after the trial end date.

Intention to publish date
30/08/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Mushrarraf Rasool Cyan (cyan@gsu.edu)

IPD sharing plan summary
Available on request