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The effect of giving feedback on maternal and newborn health services to community leaders and health providers in Uttar Pradesh, India

Submission date
10/09/2015

Recruitment status
No longer recruiting

Registration date
24/09/2015

Overall study status
Completed

Last Edited
16/07/2019

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
There are many medical services that can improve maternal and newborn health that are effective and cheap to deliver. Use of these interventions falls below global targets in many low- and middle-income countries. One reason for low coverage is that patients are often unaware of the type and quality of services that they are entitled to receive. Quality reporting to healthcare providers and public disclosure of this information has been widely used in the US and UK to give patients and providers better information on the performance of available health services. In contrast, very few initiatives have used feedback to improve accountability of health providers in low- and middle- income countries. This study aims to examine whether providing information on the performance of health services to healthcare providers and communities will improve the use of important maternal and newborn health services. The study will take place in Uttar Pradesh, India.

Who can participate?
Community representatives and healthcare providers.

What does the study involve?
We will create community (village) scorecards that show a community's performance in terms of coverage of five key maternal and newborn healthcare services. The scorecard will show the community's overall performance, and their performance against the best performing village in their district. We will test two methods for feeding back the scorecard. Either the scorecard will be given to individual healthcare providers operating in the local community (private feedback), or the scorecard will be fed back in open meetings with local leaders and persons of influence in the community (public feedback). Groups of participants will be randomly allocated to receive either private feedback, public feedback, both types of feedback, or no feedback. There will be two rounds of feedback over the course of the study.

What are the possible benefits and risks of participating?
The main benefit of participating in the study is improved coverage of maternal and newborn health services. There are no anticipated risks of participating in the study.

Where is the study run from?
The study has been set up by the London School of Hygiene and Tropical Medicine (UK), working in collaboration with Sambodhi Research and Communications (India).

When is the study starting and how long is in expected to run for?
September 2015 to June 2017.

Who is funding the study?
Merck Sharp & Dohme Corp (USA) through MSD for mothers.

Who is the main contact?
Dr Timothy Powell-Jackson
Timothy.Powell-Jackson@lshtm.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Timothy Powell-Jackson

ORCID ID
http://orcid.org/0000-0002-6082-3805

Contact details
15-17 Tavistock Place
London
United Kingdom
WC1H 9SH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Information, accountability, and the effect of feedback on the coverage of maternal and newborn health services: a cluster randomised controlled trial in Uttar Pradesh, India

Study objectives

This study tests two main hypotheses:
1. Private feedback to health providers encourages them to exert more effort towards maternal and newborn health services. This could be because some health providers are intrinsically motivated.
2. Public feedback to community members improves coverage of maternal and newborn health services. This could be because disclosing performance information increases the accountability of healthcare providers or raises demand for services as patients and other community members become more knowledgeable on the importance of maternal and newborn healthcare.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The Intervention Research Ethics Committee of the London School of Hygiene and Tropical Medicine, 03/07/2015, ref: 10006
2. The institutional review board of the Public Health Care Society in New Delhi, 18/04/2014

Study design
Single-centre cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Maternal and newborn health services

Interventions
There are 178 study clusters that will be allocated evenly across the four study arms, subject to integer constraints. Each cluster includes on average 30 women who have given birth in the previous two years. There is no specific target number of participants. In the clusters involving private feedback, all of the following providers will be targeted: ASHAs, public providers, social franchise private providers, private AYUSH, and private MBBS. In addition, a maximum of three private rural health providers that provided antenatal care in the past three months in the cluster will also be eligible. A list of potential eligible providers in each cluster will be created from a provider mapping survey conducted for another study. This will be used by fieldworkers as the starting point to identify providers. Fieldworkers will check with key informants in the cluster to confirm whether the list is complete. For private rural health providers, providers will be screened in order of proximity to the community. The first three rural health providers that

are eligible and give consent will participate. In the clusters involving public feedback, each cluster feedback session will involve 10-15 participants. At a minimum, at least two of PRI, Teacher, AWW or ASHA should be present for the feedback presentation to go ahead.

This study is a single-centre cluster randomised controlled trial. It has a two by two factorial design. Randomization will be stratified by receipt of a related social franchising intervention and baseline coverage of antenatal care. It is not possible to mask participants to allocation, but fieldworkers collecting outcome data will be masked to allocation. Allocation will also be masked for data analysis. Clusters will be randomly assigned to form four arms:
1. Private feedback to health providers
2. Public feedback to the community
3. Private and public feedback
4. No feedback

In the three intervention arms, the feedback intervention centres on a scorecard. This scorecard will be designed using data collected from a household survey, and will incorporate indicators of service coverage measured at the cluster (i.e. ward or village) level. The purpose of the scorecard is to communicate information on the performance of the village in a way that is simple to comprehend for those with low levels of literacy. The scorecard will show for each indicator both the absolute level of performance and the performance relative to the best performing cluster in the same district. The scorecard reports on five indicators:
1. Antenatal care four or more visits
2. Antenatal care counselling
3. Facility births
4. Immediate newborn breastfeeding
5. Newborn clean cord care

Two variants of the intervention are envisaged. In the first, the reporting of performance to the health providers is private in that the wider community is not privy to this information. The scorecard will be shared and communicated with health providers that offer maternal and newborn health services only. The information will be communicated to providers individually rather than organising meetings with groups of providers. During the feedback meetings, the facilitator will work with the health provider to develop an action plan for how they can help to improve service coverage in their community. In the second, the reporting of performance is made public during several organised meetings with community leaders, including elected representatives. During the meetings, a general presentation about the importance of the interventions covered in the scorecard will be presented, and then the community's scorecard will be discussed. We plan to use participatory methods with experienced facilitators to plan with community member on how improvements in performance can be established.

In both the public and private variations of the information feedback intervention, it is anticipated that providers or community members will alter their behaviour in response to the information that is fed back to them and that coverage of maternal and newborn health services will improve as a result. The feedback intervention is therefore envisioned to operate as a cycle. There will be two feedback cycles during the evaluation period, so that communities and providers can be informed of the effects of any actions they may have undertaken as a result of the first feedback cycle and adjust their behavior accordingly.

Intervention Type
Behavioural

Primary outcome measure

The proportion of women that received at least four antenatal care visits. The feedback intervention will take place October 2015 and September 2016. Outcomes will be measured at baseline (February 2015), then May 2016 (month 15), and then June 2017 (month 28). We will pool data from the second and third round of data collection when we analyse the impact of the intervention.

Secondary outcome measures
1. Proportion of women that gave birth at a health facility
2. Proportion of women that received counselling on all three danger signs (vaginal bleeding, convulsions, prolonged labour)
3. Proportion of newborns that were immediately breastfed within one hour of birth
4. Proportion of newborns that received clear cord care (clean instrument to cut, clean instrument to tie cord, nothing put on cord)
5. Proportion of women who received visit from ASHA during pregnancy
6. Proportion of women fully immunised with tetanus toxoid
7. Proportion of babies registered and received certificate

The feedback intervention will take place October 2015 and September 2016. Outcomes will be measured at baseline (February 2015), then May 2016 (month 15), and then June 2017 (month 28). We will pool data from the second and third round of data collection when we analyse the impact of the intervention.

Overall study start date
01/04/2014

Completion date
30/06/2017

Eligibility

Key inclusion criteria
Participants for the intervention will differ depending on whether they are allocated to the public or private reporting variant of the intervention.

Participants in study arms receiving private performance feedback will be providers of maternal, newborn and child health services operating within the cluster. Potential participants will be identified from a health provider census. Informed written consent will be obtained from providers, and project staff will schedule a meeting time for individual feedback at a time convenient for the provider.

Participants in the clusters receiving public feedback will be community members from the cluster. There will be up to two feedback sessions per cluster. Participants will be community leaders and persons with influence in the area of maternal and newborn health. Targeted participants include: PRI (rural) and ward members (urban), teachers, ASHA, AWW, health providers and religious leaders. Written consent will be obtained from the Pradhan of the Gram Panchayat or, if unavailable, an alternative community representative. We intend to leverage the cluster’s Gram Panchayat members to help identify relevant community stakeholders, including women.

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
There are 178 study clusters that will be allocated evenly across the four study arms, subject to integer constraints. Each cluster includes on average 30 women who have birth in the previous two years. The estimated number of participants that will receive public feedback is 900 (i.e. 10 participants per cluster X 90 clusters with public feedback), and the estimated number of participants that will receive private feedback is 534 (i.e. an average of 6 providers meeting inclusion criteria per cluster X 89 clusters with private feedback).

Total final enrolment
3133

Key exclusion criteria
In the clusters with private feedback:
1. Health providers that do not currently provide maternal or newborn health services
2. Private rural health providers beyond the target of three per cluster

In the clusters with public feedback:
1. People who do not have influence in the cluster over the uptake or provision of maternal and newborn health services

Date of first enrolment
30/09/2015

Date of final enrolment
30/11/2015

Locations

Countries of recruitment
India

Study participating centre
Sambodhi Research and Communications Limited
C-126, Sector-2
Noida, Uttar Pradesh
India
201301

Sponsor information

Organisation
London School of Hygiene and Tropical Medicine (UK)

Sponsor details
Keppel Street
London
England
United Kingdom
WC1E 7HT

Sponsor type
University/education

Website
www.lshtm.ac.uk

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Industry

Funder Name
Merck Sharp & Dohme Corp (USA) through MSD for Mothers

Results and Publications

Publication and dissemination plan
To be confirmed at a later date.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2019	16/07/2019	Yes	No