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Improving maternal and newborn health using the HIV/AIDS program platform in Tanzania

Submission date
05/03/2013

Recruitment status
No longer recruiting

Registration date
18/03/2013

Overall study status
Completed

Last Edited
07/12/2016

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Even though there have been many maternal health interventions over the past 50 years, maternal mortality continues to be very high in Tanzania. There is a known package of interventions that can prevent most maternal and newborn deaths: high quality antenatal care, delivery by a skilled attendant, access to emergency obstetric care (obstetrics means care during pregnancy, childbirth, and the postnatal period) for complications, and basic newborn resuscitation and care. Separately, in recent years there has been a dramatic and successful scale-up of HIV services in Tanzania. The model used by the HIV programs focused on strengthening the health system. This study will test whether the HIV program strategy can be used to improve the quality of care of maternal and newborn health in dispensaries in the Pwani Region, Tanzania. It will also test whether this strategy leads to more women using the health system. The study's findings can help guide Tanzanian policy regarding maternal and newborn health and also aid donors in making decisions about supporting maternal and newborn health quality improvement projects.

Who can participate?
The study is taking place in 24 dispensaries in the Pwani Region, Tanzania. Health care providers from these dispensaries are invited to participate in yearly surveys. In addition, we will conduct three household surveys, at which time all women living in the official catchment areas of the 24 dispensaries who delivered in the past year and are 15 years old or older will be invited to participate in a survey.

What does the study involve?
The intervention will be carried out in 12 dispensaries which are chosen by a process called 'randomization', which is like a coin toss. The intervention includes training of health care providers in labor, delivery, and newborn care, continuing medical education activities, supportive supervision of health care providers monthly by the study obstetrician, minor renovations to the facilities, peer outreach, and provision of essential equipment, supplies, and medications when the facilities need them. The intervention will take place over four years. The research activities include three household surveys which are in-person interviews with women who have recently had a baby. These surveys will take place before the intervention begins, after two years of the intervention, and at the end of the study. Women are eligible for each

individual survey if they had a baby in the year before the survey, so women may take part in one, two, or all three surveys depending on when they have children. There will also be discussions with groups of men and women before the study begins to learn more about people s preferences for health care. Providers in the facilities will be invited to participate in a series of surveys every year that measure their knowledge of obstetric and newborn care, their satisfaction and motivation with their work, and their attitudes toward maternal and newborn health care. In addition we will collect information from patient records in the participating dispensaries.

What are the possible benefits and risks of participating?
This study, if successful, can help the study participants living near program facilities immediately by improving the quality of maternal and newborn health services available to them. In the medium-term, if the results of the study indicate improvements in uptake, satisfaction, as well as the quality of care of maternal and newborn health services, the implementation support approach being tested here could be expanded with international and Tanzanian government funding to other health centers. Indeed, the entire focus of this study is to ensure that quality improvements at the facility actually reach and respond to the needs of real women in the community. We anticipate no risk or less than minimal risk to participants of this study.

Where is the study run from?
The study is overseen by Columbia University in New York, USA. The intervention is run by Tanzania Health Promotion Support (THPS) in Tanzania and the research activities are run by Ifakara Health Institute (IHI) in Tanzania.

When is the study starting and how long is it expected to run for?
The study began in August 2011 and is expected to run for five years, through to August 2016.

Who is funding the study?
The study is funded by the National Institute of Allergy and Infectious Diseases

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1R01AI093182 - 01A1

Study information

Scientific Title
Improving maternal and newborn health using the HIV/AIDS program platform in Tanzania: a cluster randomized implementation research for health system strengthening

Acronym
MNH+

Study objectives
It is hypothesized that it is possible to adapt and expand a health system support strategy originally developed for HIV programs to strengthen maternal and newborn health services and outreach and increase the quality and utilization of essential maternal, newborn, and HIV services among women in Pwani Region, Tanzania.

The null hypothesis is that pregnant women who live within the catchment area of facilities that receive the health system intervention will utilize the health system and receive the same quality of care as women living in the catchment areas of control facilities. This could happen if theintervention is not implemented effectively, or if the intervention is not successful in both improving the quality of care provided and reaching out to women to notify them that the quality of care has improved.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Columbia University Medical Center Institutional Review Board, 02/06/2011, protocol IRB-AAAI1696
2. Ifakara Health Institute Review Board, 06/06/2011, IHI/IRB/No.23
3. National Institute of Medical Research (Tanzania), 29/07/2011

Study design
Cluster randomized implementation science single-site study

Primary study design

Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Quality of life

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 and newborn health

Interventions
The intervention will be implemented for four years in 12 dispensaries and 12 dispensaries will continue with care as usual.

The intervention includes training of health care providers in basic emergency obstetric and newborn care, continuing medical education activities, supportive supervision of health care providers monthly by the study obstetrician, minor renovations to the facilities, peer outreach, and stop-gap provision of essential equipment, supplies, and medications. The intervention is at the health system level.

The control health facilities will continue with care as usual.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
All measures will be collected at baseline. Provider and facility indicators will be measured yearly. Population characteristics will be measured again after two years of implementation and at endline. Measures of facility functioning will be repeated monthly. Measures will compare the intervention facilities to the control facilities.

There are three primary outcome measures: utilization, quality, and extent of implementation and unintended consequences of implementation. These will be measured in many ways:

Utilization
1. Proportion of women in the study facilities' official catchment area with a facility delivery (coverage)
2. Number of women utilizing the study facilities for delivery (volume)

Quality
1. Women's satisfaction with services, measured using a four-point Likert scale ranging from 1, 'very satisfied' to 4 'very unsatisfied'
2. Service quality as perceived by women, measured using a five-point Likert scale ranging from 1, 'excellent' to 5, 'poor'
3. Processes of care: services received by the women (including proportion of women receiving a uterotonic and proportion of women receiving IV antibiotics)
4. Services delivered by the facility measured both through the registers and interviews with providers (including performance of obstetric signal functions in past three months, proportion of partographs completely and properly filled out, proportion of deliveries where active management of third stage of labor was performed)
5. Morbidity (including distribution of mothers' EQ-5D and MUAC within one year post-delivery)

Implementation
Dose of the intervention
1. Dose delivered (including: number of providers trained, number of equipment delivered, number of supportive supervision visits, number of peer outreach workers trained, number of peer outreach visits conducted)
2. Provider knowledge (measured through provider knowledge tests and provider vignettes)
3. Women's experience of outreach (e.g. proportion of women receiving peer outreach visits, proportion of women with knowledge of danger signs in pregnancy)
4. Fidelity (planned versus actually conducted activities)

Unintended consequences
1. Provider motivation measured using an adapted version of the Nursing Work Index. Most questions ask providers to state their level of agreement with statements regarding their work environment on a four-point Likert scale from 1, 'strongly agree' to 4, 'strongly disagree'
2. Utilization and quality of other services, such as HIV, Family planning, outpatient care (e.g. number of family planning visits per month, number of outpatient visits per month, proportion of women in antenatal care who are offered an HIV test)
3. Changes in support from other organizations (number of organizations working in the facility, amount of nongovernmental money in facility)

Secondary outcome measures

Secondary outcome measures will be collected at baseline. Provider and facility indicators will be measured yearly. Population characteristics will be measured again after two years of implementation and at endline. Measures of facility functioning will be repeated monthly. These measures will look at issues surrounding the main aims, women's delivery experiences, and implementation of the intervention. They will include:

1. Extent and indications of bypassing (e.g. proportion of women bypassing for delivery, characteristics of bypassers, experiences of bypassers)
2. Preferences for delivery care (measured through discrete choice experiments and focus group discussions)
3. Cost of the intervention and cost effectiveness
4. Mortality (measured through the case fatality rate in facilities as well as the number of maternal and newborn deaths in the catchment areas)
5. Level of functioning of the facilities (measured through facility assessments of indicators measuring infrastructure, human resources, availability of drugs, equipment, and supplies, e.g. proportion of facilities with no stockouts of essential maternal drugs in the past 90 days, proportion of essential labor and delivery equipment available at the facility)

Overall study start date
01/08/2011

Completion date
01/08/2016

Eligibility

Key inclusion criteria
Household survey:
1. Reside within the official catchment area of one of the study health facilities at time of interview.
2. Age >= 15 years
3. Delivered a child within 12 months of interview

Provider surveys:
1. Working in one of the study health facilities at time of interview
2. For the knowledge surveys, providers need to be skilled in deliveries (e.g. medical doctors, clinical officers, and nurses)

Focus group discussions:
1. Age >= 15 years
2. Delivered a child in the past year
3. Lived in the study districts, but not in the official catchment areas of the study dispensaries

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
Household survey: 3,000; Provider surveys: 90; Focus group discussions: 60

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/08/2011

Date of final enrolment
01/08/2016

Locations

Countries of recruitment
Tanzania

United States of America

Study participating centre
Columbia University
New York
United States of America
10032

Sponsor information

Organisation
National Institute of Allergy and Infectious Diseases (NIAID) (USA)

Sponsor details
NIAID Office of Communications and Government Relations
6610 Rockledge Drive
MSC 6612
Bethesda
United States of America
20892

Sponsor type
Government

Website
http://www.niaid.nih.gov

ROR
https://ror.org/043z4tv69

Funder(s)

Funder type
Government

Funder Name
National Institute of Allergy and Infectious Diseases (USA) (R01AI093182)

Alternative Name(s)
Instituto Nacional de Alergias y Enfermedades Infecciosas, National Institute of Allergy & Infectious Diseases, NIAID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/08/2014		Yes	No
Results article	results	18/10/2014		Yes	No
Results article	results	01/02/2017		Yes	No