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Tabora Maternal and Newborn Health Initiative: Improving reproductive, maternal and newborn health in Tabora, Tanzania

Submission date
07/05/2018

Recruitment status
No longer recruiting

Registration date
11/05/2018

Overall study status
Completed

Last Edited
09/08/2023

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol
Background and study aims
Tanzania struggled to meet its Millennium Development Goal of reducing the number of maternal deaths down to 193 per 100,000 live births before the 2015 deadline. As part of the country's initiatives to improve maternal health outcomes, CARE Canada has been working in one of the poorest, most rural regions, Tabora, since 2012. The Tabora Maternal and Newborn Health Initiative (TAMANI) represents the second stage of reproductive, maternal, and newborn health (RMNH) programming, and will span from 2017-2021.
The protocol aims to evaluate the impact of the TAMANI program on reproductive, maternal and newborn health outcomes in Tabora. The key measures are the quality of health services around the time of birth, contraceptive use, and adolescent birth rate.
Due to practical constraints, TAMANI will be rolled out in phases. Each phase will move two districts paired together from untreated to treated status, and whose healthcare workers and community health workers will have received training. After each crossover period, a household survey will be given to eligible participants in randomly selected households in the community to collect data on RMNH experiences.

Who can participate?
The target population for the household survey are the community members benefiting from the interventions. Eligible participants are women aged 15-49 in selected households, as well as men also aged 15-49 in the same household.

What does the study involve?
The project aims to train health care workers to deliver basic and comprehensive emergency obstetric and newborn care in public health facilities, and train community health workers to deliver RMNH education and promote use of health care services in the community.

What are the possible benefits and risks of participating?
There are no direct benefits for a participant in the study. The results from the study will be used to assess how the project did over time and whether it achieved its goals. The information can be used to improve the delivery of services in the region. The risks of participation are

minimal as the information provided in the survey is kept private. During the survey, some questions or topics may be considered sensitive or uncomfortable by the participant.

Where is the study run from?
Tabora, Tanzania

When is the study starting and how long is it expected to run for?
November 2017 to July 2021.

Who is funding the study
Government of Canada - Global Affairs Canada

Who is the main contact
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
D-003063

Study information

Scientific Title
An evaluation of the Tabora Maternal and Newborn Health Initiative Protocol for a stepped-wedge trial

Acronym
TAMANI

Study objectives
It is hypothesized the project will have a positive impact on reproductive, maternal and newborn health outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
McGill University Faculty of Medicine Institutional Review Board, 03/11/2017, A10-B50-17B.

Study design
Stepped-wedge non-randomized cluster controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Effect of community health worker training on reproductive, maternal and newborn health

Interventions
Current interventions as of 16/04/2020:

The intervention is two-pronged and targets both the supply and demand side of health care provision in Tabora.
1. The supply side focuses on training and mentoring of health care workers in basic and comprehensive emergency obstetric and newborn health and reproductive health services (e.g.

family planning, respectful maternity care, adolescent friendly health services). Selected health professionals are trained within a 3-month period and returned to their health facilities to implement their skills along with provided job aids. Supportive supervision and mentoring activities take place post-training at specified 6-month and 12-month intervals.
2. The demand side focuses on training and equipping a total of 1,000 community health workers to provide quality maternal and newborn health education in their communities as well as promote utilization of health care services. The training period coincides with the same period interval as healthcare worker training.

At baseline, all districts are considered controls, defined as districts (or clusters) with no active intervention and no history of prior similar interventions. At each step, selected districts (in clusters of two) receive the intervention. Treated districts are defined as districts in which one or more interventions (within TAMANI) are in the process of implementation, currently active, and/or no longer active/being maintained by CARE. By the end of the project, all districts are considered treated.

The intervention activities take place for 3-month intervals in selected clusters, followed by a 3-month data collection period ('step') in all districts. Data collection is through a household survey in random sample of Tabora households in all districts. Participants meeting eligibility criteria in selected households will be asked to participate in the face-to-face survey on reproductive and maternal health and healthcare experiences. All intervention activities will have been completed in the July-September 2019 interval, with the final round of recruitment and data collection ('step 4') in October-December 2019.
The total duration of intervention implementation and follow-up time is 2 years, each consisting of 12 months of combined activity.

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Previous interventions:

The stepped wedge cluster randomized controlled trial design allows for a phased-in approach of interventions for districts. A pair of districts serves as a cluster. At specified periods of time, a cluster will cross-over from control status to treatment status. Treatment status refers to the implementation of specific intervention activities in those districts.
The intervention is two-pronged and targets both the supply and demand side of health care provision in Tabora.
1. The supply side focuses on training and mentoring of health care workers in basic and comprehensive emergency obstetric and newborn health and reproductive health services (e.g. family planning, respectful maternity care, adolescent friendly health services). Selected health professionals are trained within a 3-month period and returned to their health facilities to implement their skills along with provided job aids. Supportive supervision and mentoring activities take place post-training at specified 6-month and 12-month intervals.
2. The demand side focuses on training and equipping a total of 1,000 community health workers to provide quality maternal and newborn health education in their communities as well as promote utilization of health care services. The training period coincides with the same period interval as healthcare worker training.
The remaining districts or clusters serve as controls, where no intervention activities occur. By the end of the last intervention period, all districts will be considered treated.
The intervention activities take place for 3-month intervals in randomly selected clusters, followed by a 3-month data collection period ('step') in all districts. Data collection is through a household survey in random sample of Tabora households in all districts. Participants meeting eligibility criteria in selected households will be asked to participate in the face-to-face survey

on reproductive and maternal health and healthcare experiences. All intervention activities will have been completed in the July-September 2019 interval, with the final round of recruitment and data collection ('step 4') in October-December 2019.
The total duration of intervention implementation and follow-up time is 2 years, each consisting of 12 months of combined activity.

Intervention Type
Mixed

Primary outcome(s)
1. Availability of maternal and newborn health services as measured by the followed two indicators:
1.1 Percentage of women with unmet needs for family planning
1.2. Percentage of deliveries with a skilled birth attendant present
2. Increased utilization of maternal and newborn health services as measured by the following two indicators:
2.1. Percentage of women 15-49 with live birth attending antenatal care 4 or more times
2.2. Contraceptive prevalence rate, assessed as the proportion of women currently using, or whose sexual partner is currently using, at least one method of contraception, regardless of the method used
3. Adolescent birth rate as defined as number of births per 1,000 women aged 15-19 years
All outcomes will be measured by household survey (direct, face-to-face interviews) at baseline and measured again at each step in the stepped wedge design (the final step takes place approximately 2 years after the baseline survey).

Key secondary outcome(s))
Secondary outcomes will also be assessed among men. Specifically among men the outcomes are perceptions of women's health and reproductive rights, including: whether a woman is justified in refusing to have sex with her husband or partner in various situations (e.g., if she knows he has sex with other women, if she is tired or not in the mood); whether a woman has the right to go to the health facility without her husband's permission; and whether a woman can use family planning without her husband's permission.

Completion date
31/07/2021

Eligibility

Key inclusion criteria
1. All women aged 15-49 years residing in Tabora region throughout the TAMANI project lifespan (2017-2021)
2. All men aged 15-49 years residing in Tabora region throughout the TAMANI project lifespan (2017-2021)

Participant type(s)
All

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
15 years

Upper age limit
49 years

Sex
All

Total final enrolment
3895

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
13/11/2017

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
Tanzania

Study participating centre
Ifakara Health Institute
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Sponsor information

Organisation
CARE Canada

ROR

https://ror.org/01gg7p150

Funder(s)

Funder type
Not defined

Funder Name
Global Affairs Canada

Results and Publications

Individual participant data (IPD) sharing plan
The individual-level data, anonymized and stripped of any identifying information, will be published in a publicly available repository (https://dataverse.harvard.edu/dataverse/3po) after the trial has ended, approximately August 1, 2021.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		10/05/2023	09/08/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol (other)		05/08/2020	12/10/2022	No	No