The Staha Project: promoting respectful and attentive care in Tanzania

Submission date	Recruitment status	Prospectively registered
25/09/2014	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
24/10/2014	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
17/07/2017	Pregnancy and Childbirth	

Plain English summary of protocol

Background and study aims

There is growing evidence that suggests that some women giving birth suffer disrespectful and abusive treatment at the hands of their health care providers and the health system in general. This includes, among other things, being shouted at, threats to withhold health care, physical abuse and leaving them to fend for themselves at time of need. This treatment violates the fundamental right of every woman to be treated with dignity within the health care system. It may stop women from seeking care at health facilities and undermine efforts to reduce the death rates of women who are having, or have recently had, a baby. The aim of this study is to identify the type of abuse experienced, the number of women affected, the root causes of the abuse and the consequences of it, in order to develop and test a evidence-based programme to prevent this treatment from happening.

Who can participate?

Females aged at least 15 who have given birth in the last year and live in the immediate catchment areas of the study facilities, or who have been discharged after a delivery in a health facility in the study facilities.

What does the study involve?

This project is run in two districts of Tanga region in northeastern Tanzania: Korogwe district (intervention district) and Muheza district (comparison district). In order to measure just how widespread the problem is, all women who have given birth discharged from one of the study facilities over a particular 4 month period are invited for an interview to talk about their experiences. A random number of these women are then followed up 6-8 weeks later. Focus groups and in-depth interviews are used for formative research as well as to examine perspectives on the nature and causes of the problem. Independent observations of deliveries in two of the facilities are also done and the women discharged after birth given exit questionnaires. After the collection and analysis of this baseline data, the evidence-based programme (intervention) takes place over a 12-18 month period in the Korogwe district. This involves the adaptation of a patient-provider charter and a quality improvement process which involves taking steps to improve respectful care. Muheza District, the comparison, are provided with the findings of the baseline research and participate only in the first planning meeting to interpret the data.

What are the possible benefits and risks of participating?

There will be no immediate direct benefit for the participants at the time of interview, but there should be future benefits if we can identify ways to reduce disrespectful and abusive treatment of women during childbirth. There will be minimal risks to women who agree to participate in focus group discussions, exit questionnaires and follow-up interviews. Patients requiring support following talking about any experience of depression, physical abuse, and rape are referred to mental health nurses located at nearby hospitals. To prepare for potential situations where the study observers may deem the safety or life of the patient to be endangered or where despite adequate care, the patient is deteriorating, observers will call senior staff for assistance.

Where is the study run from?

The study is conducted by Columbia University Mailman School of Public Health, Heilbrunn Department of Population and Family Health in partnership with the Ifakara Health Institute and local government in Korogwe and Muheza Districts of Tanzania.

When is the study starting and how long is it expected to run for? February 2011 to June 2011

Who is funding the study?

The Ministry of Foreign Affairs, Denmark and the American people through the United States Agency for International Development (USAID) and its Translating Research into Action (TRAction) Project.

Who is the main contact? Lynn Freedman lpf1@columbia.edu

Contact information

Type(s)

Scientific

Contact name

Prof Lynn Freedman

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

GG001823

Study information

Scientific Title

The Staha Project: promoting respectful and attentive care in Tanzania: a quasi-random, pre and post comparison group study

Acronym

Staha

Study objectives

This study hypothesizes that understanding the prevalence, nature, and severity of drivers of disrespect and abuse during childbirth will point to locally-feasible program activities which can reduce the incidence of this problem, thereby increasing health service utilization and ultimately improving maternal health outcomes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

- 1. Columbia University (USA), 1/3/2011, ref. IRB-AAAI1341
- 2. Ifakara Health Institute (Tanzania), 5/3/2011, ref. IHI/IRB/No: 05
- 3. National Institute of Medical Research (Tanzania), 11/5/2011, ref. NIMR/HQ/R.8a/Vol.IX/144

Study design

Quasi-random pre and post comparison group study

Primary study design

Interventional

Secondary study design

Quasi-random pre and post comparison group study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Disrespect and abuse experienced by women while delivering in health care facilities

Interventions

The intervention process involves two main, interacting components:

- 1. The adaptation of a patient-provider charter
- 2. A quality improvement (QI) process in the maternity ward in the district hospital. The duration of the intervention will be 12-18 months

The patient-provider charter in Tanzania was adopted at the national level and written in broad terms for further adaptation at local levels. Similar to other settings, the charter was never implemented at national level or adapted at local level. A small group of stakeholders from different district boards will be chosen to review and adapt the charter for district level. Then, each study facility (n=4) will perform its own adaptation of the charter with communities within the facilities catchment areas. Community leaders and health system managers will take actions to fulfill their obligations, including support to health providers

Intervention facilities will partake in a facility-based, modified quality improvement process to improve respectful care. The maternity team will use both the baseline data from the Staha project and the standards emerging from the charter as the criteria. Each 1-3 months, the maternity team will choose a new practice to adopt in relation to these standards. They will then work to implement and measure change for the chosen standard. Participants will include all health facility staff that work in the maternity ward and, depending on the standard being addressed, will include staff from other relevant parts of the facility.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Reported disrespect and abuse:

- 1. Single item measures:
- 1.1. Patients private health information shared in a way that others could hear
- 1.2. Patients private health information shared with others without patients consent
- 1.3. Lack of physical privacy
- 1.4. Shouting/scolding
- 1.5. Threat of withholding treatment
- 1.6. Threatening comments
- 1.7. Negative comments
- 1.8. Ignored when needed help
- 1.9. Delivered without attendant
- 1.10. Non-consent for tubal ligation
- 1.11. Non-consent for hysterectomy
- 1.12. Non-consent for cesarean section
- 1.13. Physical abuse (shouting, slapping, hitting, etc)
- 1.14. Sexual harassment
- 1.15. Rape
- 1.16. Detention in facility for failure to pay
- 1.17. Request for bribe

- 2. Categories of items:
- 2.1. Non-confidential care:
- 2.1.1. Patients private health information shared in a way that others could hear
- 2.1.2. Patients private health information shared with others without patients consent
- 2.1.3. Lack of physical privacy
- 2.2. Non-dignified care:
- 2.2.1. Shouting/scolding
- 2.2.2. Threat of withholding treatment
- 2.2.3. Threatening comments
- 2.2.4. Negative comments
- 2.3. Neglect:
- 2.3.1. Ignored when needed help
- 2.3.2. Delivered without attendant
- 2.4. Non-consented care:
- 2.4.1. Non-consent for tubal ligation
- 2.4.2. Non-consent for hysterectomy
- 2.4.3. Non-consent for cesarean section
- 2.5. Physical abuse:
- 2.5.1. Physical abuse (shouting, slapping, hitting, etc)
- 2.5.2. Sexual harassment
- 2.5.3. Rape
- 2.6. Inappropriate demands for payment:
- 2.6.1. Detention in facility for failure to pay
- 2.6.2. Request for bribe

3. Overall indicator:

Any reported disrespect and abuse: answering yes to any of the single item questions

Secondary outcome measures

- 1. Facility utilization
- 2. Satisfaction with delivery
- 3. Satisfaction with the health system
- 4. Perceived quality of care
- 5. Postpartum depression
- 6. Health seeking behaviors for mother, infant and other children postpartum
- 7. Recommendation of facility
- 8. Use of facility for child health visits
- 9. Intention to use same facility for next delivery
- 10. Intention to have more children
- 11. Self-rated health status

Overall study start date

28/02/2011

Completion date

30/06/2011

Eligibility

Key inclusion criteria

- 1. Exit interviews: All women 15 years or older discharged after a delivery in the study facilities during a four month period
- 2. Community follow-up interviews: Women randomly selected from those who complete an exit interview and consent to a follow-up interview in their home
- 3. Observations: Women who deliver at the 2 study hospitals and the health providers in the maternity wards during the month of observation
- 4. Qualitative interviews: health providers, community members, health managers, local government officials, regional and national health system stakeholders

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

Facility exit questionnaires: 1468 women; Follow-up interviews: 500 women; Observations: 200 deliveries

Key exclusion criteria

N/A

Date of first enrolment

28/02/2011

Date of final enrolment

30/06/2011

Locations

Countries of recruitment

Tanzania

United States of America

Study participating centre

Columbia University Mailman School of Public Health

New York United States of America 10032

Sponsor information

Organisation

Columbia University Mailman School of Public Health (USA)

Sponsor details

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Sponsor type

Government

Website

http://www.amddprogram.org

ROR

https://ror.org/00hj8s172

Funder(s)

Funder type

Government

Funder Name

Udenrigsministeriet

Alternative Name(s)

Ministry of Foreign Affairs of Denmark, Danish Ministry of Foreign Affairs

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Denmark

Funder Name

United States Agency for International Development Translating Research into Action (TRAction) Project (USA)

Alternative Name(s)

U.S. Agency for International Development, Agency for International Development, USAID

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	11/07/2017		Yes	No