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# Introducing Community Health Agents (CHA) to Accelerate Achievement of MDGs 4 and 5 in Tanzania: The Connect Project

**Submission date**
29/03/2012

**Recruitment status**
No longer recruiting

**Registration date**
21/06/2012

**Overall study status**
Completed

**Last Edited**
22/09/2023

**Condition category**
Other

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

## Plain English summary of protocol

Background and study aims
Maternal and child mortality (death) remains high in Tanzania especially for people in rural areas wholack adequate access to primary and emergency health care services. The aim of this project is to test innovative district health system strategies to solve this problem. Using community health agents (CHAs) with the necessary system supports and district-level emergency referral systems, to remote village locations where the burden of maternal, newborn and child mortality is severe could be very helpful to these areas. CHAs are trained in the components of primary health care prevention, community case management of major childhood causes of death as well as in community mobilization. The aim of this study is to see if introducing community health agents (CHA) into the Tanzania will result in reduction of child mortality, particularly newborn mortality, and produce efficiencies and cost-savings in the health system.

Who can participate?
Adults who live in the area and whose households include women of reproductive age (15-49 years old) or are the primary care takers for at least one five year old if they are aged over 49, non-English speaking. Health care workers who work in the area can participate as well.

What does the study involve?
This is a two-celled randomised cluster trial in which entire villages are being randomized. Individuals living in these villages are exposed to the CHA model of service delivery over the course of the study. However, they will never be individually asked to seek CHA health services. The CHA try to provide primary care through routine household visits and community education sessions about various topics. To assess the success of the CHA health care, participants can take part in focus group discussions and in-depth interviews about family planning, after birth care and health and care seeking behaviour of women who are pregnant or while during delivery.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
The project will be conducted by the Heilbrunn Department of Population and Family Health (HDPFH) at Columbia University (USA) and Ifakara Health Institute (IHI) in Tanzania.

When is the study starting and how long is it expected to run for?
July 2010 to July 2014

Who is funding the study?
1. Doris Duke Charitable Foundation DDCF (USA)
2. Comic Relief (UK)

Who is the main contact?
Dr James Phillips

# Contact information

### Type(s)
Scientific

### Contact name
Dr James Phillips

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
N/a

# Study information

### Scientific Title
Introducing Community Health Agents (CHA) to Accelerate Achievement of MDGs 4 and 5 in Tanzania: The Connect Project

### Acronym
The Connect Project

### Study objectives

The research will test the hypothesis that introducing the community health agents (CHA) cadre into the Tanzanian health system and the necessary system supports, and emergency referral systems, will result in reduction of child mortality, particularly newborn mortality, and produce efficiencies and cost-savings in the health system. It has an experimental design to measure the impact of the CHA intervention and also systems and operations research to test the approaches and costs.

Tanzania has a comprehensive primary healthcare program that provides a wide range of essential preventive and curative services. However, the system also has gaps in the services, particularly at community level, that prevent it from achieving its full potential.
To address these problems, Connect aims to strengthen the capacity of the health system by introducing the CHA with the necessary systems support structures to function most effectively. The project will be guided in these efforts by a framework created by the World Health Organization. The framework has identified the six areas of focus that have been shown to be critical to effective health systems development (HSD):
1. Integrated primary healthcare interventions that are known to reduce morbidity and mortality;
2. A health workforce that is trained, deployed, and accessible for addressing healthcare needs;
3. Essential information that is required for healthcare workers to provide appropriate services;
4. Essential supplies, equipment, and facilities for providing basic healthcare operations;
5. Resources and social protection mechanisms to finance and ensure economic accessibility of services;
6. Mechanisms of leadership and governance that provide direction to health system operations.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
1. Columbia University IRB, Jan 2012, ref: IRB-AAAF3452
2. National Institute for Medical Research (NIMR), Aug 2012
3. Ifakara Health Institute, June 2010

## Study design
Two-celled randomized cluster trial

## Primary study design
Interventional

## Secondary study design
Cluster randomised trial

## Study setting(s)
Community

## Study type(s)
Prevention

## 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

Infant and child mortality, maternal mortality

## Interventions
The health workers will participate in focus group discussions and in-depth interviews on issues related to job satisfaction and retention and their expectations, reservations and ideas regarding the introduction of the CHA.

Connect is a randomized controlled trial by village cluster that contains a total of 101 villages  50 treatment and 51 control. Assignment of villages to the treatment or control arm followed probability proportionate to size sampling procedures which ensured that each arm was comparable with regards to the population size of the villages in them. No other variable was used in the sampling frame. Within the treatment arm the number of CHA assigned to each village also followed probability proportionate to size methods whereby intervention villages with fewer than 1000 population received 1 CHA; villages with 1000-3999 population received 2 CHA; villages with 4000  6999 population received 3 CHA and villages with over 7000 population received for 4 CHA.

The CHA intervention integrates various primary health care functions into a single community-based work package that includes all stages of the oft-cited continuum of care: routine household visits and community education sessions focused on (a) general primary healthcare education and promotion; (b) comprehensive family planning including distribution of condoms and oral contraceptives, and education and focused referral for long term and permanent acting methods; (c) focused referral for antenatal care for pregnant women; (d) birth planning and referral assistance to ensure institutional delivery; (e) essential newborn care education and promotion and referral assistance for sick newborns; (f) community case management for malaria, diarrhea, and pneumonia; (g) general first aid other community health promotion functions; (h) HIV/STI prevention education, including condom distribution. The number of sessions is variable according to the various contextual and individual factors that affect CHA performance and this is followed through program monitoring processes.

There will be 12 focus group discussions on this issue (120 participants) and 12 in-depth interviews (12 subjects). The focus group discussions with community members will be about:
1. Family planning
2. Postnatal care and service seeking behavior, and
3. Health and care-seeking behaviors of women during pregnancy and delivery.

The family planning discussions will be held with men (married, aged 30-49) and women (married, aged 25-49) groups separately. The latter two types of focus group discussions will enroll women that had newborns in the past 12 months. For each of these focus group discussion types there will be the same number of subjects as laid down in the above discussion of health workers (120 focus group subjects and 48 in depth interview subjects).

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome measure
The following discussion provides a subject population description for the three components of phase 1:

1. Sampling Research: This involves the use archival de-identified summary data that reflects the subject accrual of some 350,000 people in the Ifakara and Rufiji health and demographic surveillance system (HDSS). The catchment area of these HDSS areas is comprised of the village clusters that we will randomize into our study by the end of this phase. The Connect project will not enroll these people, but will use de-identified summary statistics that reflect on this population in order to inform our randomization.
2. Baseline Research (3000 subjects total, see below): this will involve the accrual of human subjects that reside within the catchment population of the Ifakara and Rufiji HDSS. The household survey will include roughly 3000 households. Households can be included only if they are among those accrued in the Ifakara and Rufiji HDSS and have women of reproductive age (15-49 years of age) and be the primary care takers of at least one under-five year old child. The population to be enrolled as participants in the household survey will, in most cases, be non-English speaking, educationally- and economically disadvantaged. Kiswahili is the national language of Tanzania and residents of rural villages are typically impoverished and with limited means to adequate schooling. An additional special populations that will figure prominently in this survey are pregnant women, which stands to reason given the objectives of Connect and its core impact and outcome indicators which are well explained in the attached protocol and study description. No children or minors will be enrolled.
3. Formative Research: With respect to the formative research, it will be conducted amongst health workers and members of the study population. The health workers will participate in focus group discussions and in-depth interviews on issues related to job satisfaction and retention and their expectations, reservations and ideas regarding the introduction of the CHA. The family planning discussions will be held with men's (married, aged 30-49) and women's (married, aged 25-49) groups separately. The latter two types of focus group discussions will enroll women that had newborns in the past 12 months.

### Secondary outcome measures
1. Maternal mortality
2. Cause of death, fertility
3. Childhood morbidity
4. Burden of disease life years gained and key maternal and child health behaviors

Additional, key secondary outcomes cover a range of relevant reproductive, maternal, newborn and child health seeking and service utilization behaviors and are gathered at baseline and end-line using a sub-HDSS panel survey which is linked to the HDSS using shared respondent IDs. Baseline data were collected between May and July 2011 and the end-line data will be collected during the same period in 2015.

### Overall study start date
01/07/2010

### Completion date
31/07/2014

## Eligibility

### Key inclusion criteria
1. Human subjects that reside within the catchment population of the Ifakara and Rufiji HDSS.
2. The household survey will include roughly 3000 households. Households can be included only if:
2.1. Have women of reproductive age (WRA) (15-49 years of age) or be the primary care takers of

at least one under-five year old child for women more than 49 years old.
2.2. The population to be enrolled as participants in the household survey will, in most cases, be non-English speaking, educationally- and economically disadvantaged. Kiswahili is the national language of Tanzania and residents of rural villages are typically impoverished and with limited means to adequate schooling. No children under the age of 15 will be enrolled. All WRA will be enrolled as subjects.
3. Health workers  Any Community Health Agents and government health employees within the study districts.

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
3664

### Key exclusion criteria
Does not meet inclusion criteria

### Date of first enrolment
01/07/2010

### Date of final enrolment
31/07/2014

## Locations

### Countries of recruitment
Tanzania

United States of America

### Study participating centre
**60 Haven Ave**
New York
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## Sponsor information

**Organisation**
Columbia University (USA)

**Sponsor details**
Mailman School of Public Health
Heilbrunn Department of Population and Family Health
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**Sponsor type**
University/education

**ROR**
https://ror.org/00hj8s172

# Funder(s)

**Funder type**
Charity

**Funder Name**
Doris Duke Charitable Foundation DDCF 2009058 (USA)

**Alternative Name(s)**
Doris Duke Charitable Foundation, Inc., DDCF Trust, Doris Duke Foundation, DDCF

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Trusts, charities, foundations (both public and private)

**Location**
United States of America

**Funder Name**
Comic Relief (UK)

# 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? |
|---|---|---|---|---|---|
| Protocol article | protocol | 01/01/2013 | | Yes | No |
| Results article | results | 08/07/2016 | | Yes | No |
| Results article | results and and qualitative process evaluation | 19/09/2023 | 22/09/2023 | Yes | No |