

Evaluation of an intervention to increase utilisation of primary maternal, newborn, and child health services in Ethiopia

Submission date 14/12/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 19/12/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/01/2025	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Ethiopia has significantly reduced under-five mortality, but utilisation of primary maternal, newborn and child health services is still low. Concerted efforts are needed for continued improvements in maternal, newborn and child health and survival. UNICEF and PATH in collaboration with the Federal Ministry of Health have developed a complex intervention based on an analysis of barriers to the utilization of primary maternal, newborn and child health services. The intervention includes components to engage the community, strengthen the capacity of primary care workers, and reinforce the local ownership and accountability of the primary maternal, newborn and child health services. The evaluation has a pragmatic trial design with intervention and comparison areas across four Ethiopian regions. The primary outcomes are increased care seeking and appropriate treatment for probable pneumonia and diarrhea in children below the age of five years, and neonatal sepsis. Baseline and end line surveys covering household, facility, and health worker modules will be performed in intervention and comparison areas across Amhara, Southern Nations Nationalities and Peoples, Oromia, and Tigray regions. The effectiveness of the intervention will be assessed by difference-indifferences analysis, controlling for cluster design and relevant confounders. A process evaluation follows the guidelines of the UK Medical Research Council. It will describe and analyze the activities, the recipient, cost, and fidelity of the intervention, dose, reach, and contextual factors. The results will form the basis for possible scale-up in Ethiopia, and inform policy and efforts in other settings to engage communities and improve ownership and accountability for increased primary care service utilization.

Who can participate?

Children aged 0-59 months and their caretakers.

What does the study involve?

Areas are randomly allocated to either being an intervention or comparison area. Intervention areas engage with the community in the primary care services, strengthening the capacity of the primary care workers, and increasing the ownership and accountability of the health system stakeholders in the programs for newborn and child health care and treatment. Participating

caretakers are randomly selected to fill out a questionnaire about the utilization of services, and quality of services for newborn serious infections, probable pneumonia, and diarrheal diseases (the three main killers). The results from those in the intervention areas are compared to those in the comparison areas.

What are the possible benefits and risks of participating?

The potential benefits for the participants in intervention areas are increased care utilization and improved quality of care. If the result is promising, the intention by the Federal Ministry of Health is to scale-up the interventions to increase the demand for care and improved quality of care to other parts of the country. Neither those engaged in the interventions, nor the participants (children) in the evaluation of outcome are exposed to any risk by this study.

Where is the study run from?

This study is being run by the London School of Hygiene & Tropical Medicine (UK) and takes place in partnership with universities in Ethiopia.

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

October 2015 to October 2020

Who is funding the study?

Bill and Melinda Gates Foundation (USA)

Who is the main contact?

1. Professor Joanna Schellenberg (Scientific)

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2. Professor Lars Åke Persson (Scientific)

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Contact information

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Scientific

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Additional identifiers

Protocol serial number

OPP1132551

Study information

Scientific Title

Evaluation of a complex intervention aiming at increased utilisation of primary maternal, newborn, and child health services in Ethiopia

Acronym

Dagu

Study objectives

An increased demand of primary maternal, newborn, and child health services, improved availability and quality of integrated community case management and community-based newborn care services, and improved ownership and accountability of these services would lead to an increased and sustained use of these services, which ultimately would further reduce neonatal and under-five mortality.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. The Ethiopian Scientific and Ethical Review Committee
2. The London School of Hygiene & Tropical Medicine Ethical Review Committee, 06/06/2016, ref: 11235

Study design

Pragmatic trial design with intervention and comparison districts in four regions in Ethiopia.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

The focus of the study is primary care utilization for the main causes of under-five mortality in Ethiopia, i.e., neonatal conditions, pneumonia, and diarrheal diseases

Interventions

A complex intervention including activities aiming at community engagement in primary care services, capacity building of health extension workers and "Women's Development Army" members (a type of community health volunteers), and efforts to increase ownership and accountability within the health system for community-based newborn care and integrated community case management of childhood diseases. The total duration of these interventions is 24 months. These interventions are only performed in intervention areas in four regions of Ethiopia, not in comparison areas.

The interventions are performed in the community, and in the primary care services. The study unit for the evaluation of effect of this intervention is the child below the age of five years in intervention areas and comparison areas. All children aged 0-59 months and their caretakers in randomly selected households in these areas are invited to participate in baseline and endline surveys.

Intervention Type

Behavioural

Primary outcome(s)

Care seeking and provision of appropriate treatment for probable pneumonia and diarrheal diseases in children below the age of five years, and neonatal sepsis. This is measured through baseline (before) and endline (after) surveys in interventions and comparison areas in four regions in Ethiopia by household interviews and interviews and observations in health posts in these areas. The estimation of effectiveness will be performed by the difference-in-differences methodology, with adjustments for the cluster design and confounding factors.

Key secondary outcome(s)

Coverage of antenatal visits, institutional delivery, postnatal first week home visit, quality of care provided by health extension worker (observation, re-examination), use of prevention (bed-nets, immunization). This will be assessed through baseline and endline surveys in intervention and comparison areas in four regions in Ethiopia.

Completion date

31/10/2020

Eligibility

Key inclusion criteria

1. All community members, invited to the different engagement activities
2. Health extension workers and women's development army members participating in capacity

building activities

3. Stakeholders within the district health services who are invited to ownership and accountability creation activities

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Key exclusion criteria

Participants outside the intervention areas.

Date of first enrolment

01/12/2016

Date of final enrolment

31/12/2018

Locations

Countries of recruitment

United Kingdom

England

Ethiopia

Study participating centre

London School of Hygiene & Tropical Medicine

Keppel Street

London

United Kingdom

WC1E 7HT

Study participating centre

Ethiopian Public Health Institute

Addis Ababa

Ethiopia

n/a

Study participating centre

University of Gondar

Gondar
Ethiopia
n/a

Study participating centre**Mekelle University**

Mekelle
Ethiopia
n/a

Study participating centre**Jimma University**

Jimma
Ethiopia
n/a

Study participating centre**Hawassa University**

Hawassa
Ethiopia
n/a

Sponsor information**Organisation**

Bill and Melina Gates Foundation

ROR

<https://ror.org/0456r8d26>

Funder(s)**Funder type**

Charity

Funder Name

Bill and Melinda Gates Foundation

Alternative Name(s)

Bill & Melinda Gates Foundation, Gates Foundation, Gates Learning Foundation, William H. Gates Foundation, BMGF, B&MGF, GF

Funding Body Type

Government organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United States of America

Results and Publications

Individual participant data (IPD) sharing plan

A data sharing committee has been established comprised of each of the universities and Ethiopian Public Health Institute. Any requests will be reviewed by this committee and if requests are granted data will be shared without any identifiers. Request for data can be made to Yemisrach B. Okwaraji (Yemisrach.Okwaraji@lshtm.ac.uk) or Desta Wolassa (desta.wolassa@lshtm.ac.uk).

Previous publication and dissemination plan:

The baseline report is available: Community-based child care: household and health facility perspectives.

<https://www.slideshare.net/DaguProject/dagu-baseline-survey-report-ethiopia-december-2016-february-2017>.

We plan a number of papers in high-impact journals. These are some of the planned publications with

tentative dates of submission to journals:

The study protocol will be submitted to journal around 01/03/2018

The process evaluation report will be submitted around 31/01/2019

The effectiveness report will be submitted around 01/07/2019

IPD sharing statement:

The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/09/2020	17/09/2020	Yes	No

Results article	results	12/03/2021	15/03/2021	Yes	No
Results article		16/02/2023	17/02/2023	Yes	No
Results article		11/08/2020	21/01/2025	Yes	No
Protocol article	protocol	01/12/2020	28/04/2020	Yes	No
Other publications		17/06/2020	21/01/2025	Yes	No
Other publications		25/09/2020	21/01/2025	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes