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Community and District Empowerment for Scale-up (CODES)

Submission date	Recruitment status	[_] Prospectively registered
15/06/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/07/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/06/2021	Infections and Infestations	

Plain English summary of protocol

Background and study aims

Pneumonia and diarrhea are leading killers of children. Although a number of effective treatments exist, levels of preventive and treatment are virtually unchanged over the past decade and remain unacceptably low. As a result, few African countries, which have a substantial burden of these two diseases, will reach the Millennium Development Goal 4 of a two-thirds reduction in child mortality by 2015. UNICEF and the World Health Organization published the “Global Action Plan for the Prevention and Control of Pneumonia” in 2007 and “Diarrhea: Why Children Are Still Dying and What Can Be Done,” in 2009, which contained a comprehensive set of preventive, promotive and treatment interventions that capture exciting new advances for these two diseases. While countries have incorporated many of the key interventions into national policy and planning, and donors have contributed additional resources to implement some of these interventions, resources are insufficient and implementation has been limited, particularly among the poor and under served that experience the greatest mortality burden from both pneumonia and diarrhea. Previous studies have demonstrated that the failure to successfully scale up of interventions such as those proposed to decrease pneumonia and diarrhea deaths are essentially due to four factors: the lack of supportive policies, failure to prioritize those interventions that are most likely to prevent deaths, problems with the essential commodities for vaccination services and treatment of illnesses, and the absence of community-based health promotion activities (e.g., breastfeeding) and care (Bryce et al, 2010). While considerable gains have been made in the policy arena, the other three remain problematic. Furthermore, difficulties with prioritization, commodities, and community care for pneumonia and diarrhea have been compounded by an increasing decentralization of services, and a major challenge has been the support of implementation at the decentralized, district level. Analyses demonstrate that the root of many of these problems is poor management capacity, including the lack of local abilities and local data to prioritize and contextualize interventions, insufficient emphasis on results, the lack of identification of bottlenecks and of financial leeway to carry out context-specific managerial solutions, as well as failure to involve communities as active proponents in helping overcome obstacles to high coverage. New approaches are urgently needed to resolve the many obstacles to scaling up lifesaving interventions to prevent pneumonia and diarrhea deaths, which together account for more than a third of child deaths. We are therefore proposing an innovative new approach that will focus on identifying local needs, the obstacles to overcome them, and what evidence-based strategies are most likely to

work in a given context, focused on results. It will simultaneously focus on both demand- and supply side bottlenecks, and is designed to optimize learning. An approach consisting of a cycle of assessment, action, accountability, and analysis/re-analysis will be used to improve coverage for priority pneumonia and diarrhea interventions. Uganda, which has one of the highest child mortality rates in Africa and a highly decentralized health system, will be the case study for this approach. This project aims to demonstrate that a management strategy based on
1. Improved targeting of interventions to match disease burden, and better allocation of resources.
2. Regular review and improvement of district health team performance, and use of evidence-based management tools and focal funding to overcome management bottlenecks.
3. Community oversight and inputs will lead to improvements both coverage and quality of key interventions to reduce child deaths from diarrhea and pneumonia.

Who can participate?
All members of the district health teams in the intervention and control districts and local and political leaders.

What does the study involve?
This project consists of a 6 month preparatory period to identify participating districts, develop contracts with partners, and conduct an initial survey, followed by a two year initial implementation in a small number of districts, an additional two years of scale up in a larger number of districts if specific benchmarks are met in the first two years, and a 6 month period to conduct further advocacy and broadly share lessons learned. It represents a different and far more focused way of approaching two of the major causes of child death in Africa. If successful, this project has potential far-reaching applications in resource-limited settings and could be further scaled up in Uganda and other countries characterized by high pneumonia and diarrhea mortality and decentralized management. Led by UNICEF, the proposal will involve Uganda Ministry of Health supported by strong local implementing organizations, with monitoring and evaluation jointly by Makerere University, Uganda and Karolinska Institutet, Sweden.

What are the possible benefits and risks of participating?
There are no direct benefits to the individual respondents that will take part in this study. However the study will provide information to the district managers and other health partners on how to improve management for better service delivery. We hope that through this process districts will provide higher coverage and quality of care for the benefit of individuals. Since the study is a district management strengthening intervention, we don’t anticipate any risk that will be attributed to an individual for taking part in this study.

Where is the study run from?
UNICEF (Uganda Country Office)

When is the study starting and how long is it expected to run for?
October 2013 to September 2016

Who is funding the study?
Bill and Melinda Gates Foundation (USA)

Who is the main contact?
1. Dr Flavia Mpanga (public)
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2. Dr Peter Waiswa (scientific)
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Study website
http://ki.se/en/phs/codes-community-and-district-empowerment-for-scale-up

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PBA SC/2011/0258

Study information

Scientific Title
Community and District Empowerment for Scale-up (CODES): A complex district level intervention to improve child survival in Uganda-study protocol for a cluster randomized controlled trial

Acronym
CODES

Study objectives
Areas receiving CODES intervention will perform “better” and show accelerated “improvement” on the key protective, preventive, and curative quality coverage indicators for pneumonia, diarrhea and malaria compared to those that have not received the CODES intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Uganda National council for science and technology, 23/06/2011, ref: SS 2548

Study design
This is a single centre cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Child health with special focus on pneumonia, diarrhoea and malaria

Interventions
The CODES intervention package, which combines implementation of district-level diagnostic, management and evaluation tools, is evaluated for effect via a cluster randomized trial with eight districts as intervention and eight as comparison. Differences at a 2 year endline survey and changes between baseline and endline surveys in key child survival quality coverage indicators amongst target populations in the overall intervention and control districts will be compared. Implementation of the CODES intervention and all data collection is by the responsible local districts teams and/or local CBO who are supported in the supply and demand side implementation by two local NGOs. Additional information related to level of

implementation of the CODES package and contextual factors in each district is obtained based on reports from the local NGOs supporting the districts in the implementation activities as well as the from qualitative information solicited from the district. Analytical evaluation of the trial, the associated contextual factors and lessons learned is conducted by Makaerere University and Karolinka Institutet

Intervention Type
Other

Primary outcome measure
The status of the key protective, preventive and curative quality coverage indicators for pneumonia, diarrhea, and malaria

Measurements will be made in intervention and comparison districts at baseline and at endpoint two years (24 months) later

Secondary outcome measures
Prevalence of pneumonia, diarrhea, and malaria

Measurements will be made in intervention and comparison districts at baseline and at endpoint two years (24 months) later

Overall study start date
16/09/2010

Completion date
30/09/2016

Eligibility

Key inclusion criteria
1. All members of the district health teams in the intervention and control districts
2. District local and political leaders
3. We have no specific age limit so long as they are within the considered districts

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
21 districts

Total final enrolment
16

Key exclusion criteria
All districts outside the intervention and control arms

Date of first enrolment
01/10/2013

Date of final enrolment
30/09/2016

Locations

Countries of recruitment
Uganda

Study participating centre
UNICEF (Uganda Country Office)
Plot 9 George Street,
P.O.Box 7047
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Sponsor information

Organisation
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Sponsor type
Charity

Website
http://www.unicef.org/uganda/

ROR
https://ror.org/02dg0pv02

Funder(s)

Funder type
Research organisation

Funder Name
Bill and Melinda Gates Foundation

Alternative Name(s)
Bill & Melinda Gates Foundation, 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

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/03/2016		Yes	No
Results article		01/06/2021	10/06/2021	Yes	No