

A multi-modal intervention to improve care of the severely ill in Uganda

Submission date 17/05/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/05/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/11/2020	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Globally, there is a high burden of severe illness and associated deaths in low-income countries. To improve management of severely ill patients in hospital in low-income settings, the World Health Organization (WHO), through its program on the Integrated Management of Adolescent and Adult Illness, established a triage tool (a tool used to help decide the order of treatment) called "Quick Check" to provide clinicians with a rapid, standardised approach to identifying patients with severe illness based on recognising of abnormal vital signs. The aims of this study are to determine the impact of the WHO QuickCheck+ training program and the Severe Illness Management System (SIMS) program on how well severely ill patients can be identified and to identify and test methods of improving the way in which best care for severely ill patients can be followed in low-income settings.

Who can participate?

Patients aged 14 years and over who have been admitted to the general medical wards through the casualty department at participating hospitals.

What does the study involve?

The study involves an intervention designed to improve health worker performance of vital sign collection and diagnosis of severe illness conditions. Intervention components include clinical mentoring by an expert in severe illness care, collaborative improvement meetings with external support supervision, and continuous audits of clinical performance with structured feedback. All health facilities in the study will receive the intervention but at different times.

What are the possible benefits and risks of participating?

Participants could benefit from improved identification of their illness so that they can be better managed in hospital. There are no notable risks involved with participating.

Where is the study run from?

The study is taking place at four inpatient health facilities in one district of western Uganda.

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

August 2014 to May 2015

Who is funding the study?

1. World Health Organization (Switzerland)
2. Cooperative Biological Engagement Program (USA)
3. IMAI Alliance (USA)
4. Anonymous European Family Foundation

Who is the main contact?

1. Dr. Shevin Jacob (scientific)
shevin@walimu.org
2. Dr J. Lucian Davis (scientific)

Contact information

Type(s)

Scientific

Contact name

Dr Shevin Jacob

ORCID ID

<https://orcid.org/0000-0003-2425-9394>

Contact details

University of Washington School of Medicine
1959 NE Pacific Street
Seattle
United States of America
-

Type(s)

Scientific

Contact name

Dr J. Lucian Davis

ORCID ID

<https://orcid.org/0000-0002-8629-9992>

Contact details

Yale University
School of Public Health
60 College Street
New Haven
United States of America
06510

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

SIMS 1.0

Study information

Scientific Title

A complex intervention to improve implementation of World Health Organization guidelines for diagnosis of severe illness in low-income settings: a quasi-randomized trial from Uganda

Study objectives

The overall aim of this project is to improve the management of severely ill patients at four hospitals in western Uganda.

The specific aims of this project are:

1. To determine the impact of the WHO QuickCheck+ training program and the Severe Illness Management System (SIMS) program on process measures related to the identification of severely ill patients
2. To identify and test methods of improving adherence to evidence-based care for severely ill patients in low-income settings

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. The Makerere University School of Public Health Higher Degrees, Research, and Ethics Committee
2. The Uganda National Council for Science and Technology
3. The University of California San Francisco Committee on Human Research
4. The Human Investigation Committee, Yale University

Study design

Stepped-wedge quasi-randomized trial

Primary study design

Intentional

Secondary study design

Stepped wedge quasi-randomized trial

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Severe illness conditions as defined by WHO Quick Check+ (shock, sepsis, severe respiratory distress, altered mental status)

Interventions

This study consists of a behavioral intervention to improve health care worker performance. The intervention is comprised of three modalities: clinical mentoring by an expert in severe illness care, collaborative improvement meetings with external support supervision, and continuous audits of clinical performance with structured feedback. There is no follow up. The intervention is implemented using a quasi-randomised, stepped-wedge design. The sequence for introducing the intervention is randomly assigned, with a new site launching approximately every six weeks and an a priori plan to launch two sites simultaneously.

Intervention Type

Behavioural

Primary outcome measure

Vital sign collection and diagnosis of severe illness conditions, determined via review of medical charts, at time of hospital admission

Secondary outcome measures

Vital status, specifically mortality, determined via review of medical charts, at the time of hospital discharge

Overall study start date

01/05/2014

Completion date

01/09/2015

Eligibility

Key inclusion criteria

1. Aged 14 years and over
2. Admitted to the general medical wards through the casualty department at each health facility

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

6000

Total final enrolment

5759

Key exclusion criteria

Those whose primary admitting diagnosis is an emergent surgical or obstetrical condition.

Date of first enrolment

01/08/2014

Date of final enrolment

31/05/2015

Locations**Countries of recruitment**

Uganda

Study participating centre**Walimu**

Plot 5-7, Coral Crescent

Kololo

Kampala

Uganda

N/A

Sponsor information**Organisation**

Walimu

Sponsor details

Plot 5-7

Coral Crescent

Kololo

Kampala

Uganda

-

+256 772 711 439

info@walimu.org

Sponsor type

Other

Funder(s)

Funder type

Research organisation

Funder Name

World Health Organization

Alternative Name(s)

, , Всемирная организация здравоохранения, Organisation mondiale de la Santé, Organización Mundial de la Salud, WHO, , ВОЗ, OMS

Funding Body Type

Government organisation

Funding Body Subtype

International organizations

Location

Switzerland

Funder Name

Cooperative Biological Engagement Program

Funder Name

IMAI Alliance

Funder Name

Anonymous European Family Foundation

Results and Publications

Publication and dissemination plan

Planned for presentation at international conferences and publication in a high-impact peer-reviewed journal.

Intention to publish date

31/12/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr J. Lucian Davis (lucian.davis@yale.edu).

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	06/11/2017	26/11/2020	Yes	No