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

Submission date
17/05/2017

Recruitment status
No longer recruiting

Registration date
18/05/2017

Overall study status
Completed

Last Edited
26/11/2020

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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)
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2. Dr J. Lucian Davis (scientific)

Contact information

Type(s)
Scientific

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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 Technolog
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
Interventional

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
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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, , BO3, OMS

Funding Body Type
Private sector 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

Not provided at time of registration

Study outputs

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