

Evaluating alternative approaches to packaging evidence and exploring the influence of context in guideline development in Kenya

Submission date 01/03/2011	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 16/03/2011	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 22/03/2013	Condition category Other	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

SSC Protocol No. 1770 (Revised)

Study information

Scientific Title

Evaluating approaches to packaging evidence and exploring the influence of context in the process of developing evidence-informed guidelines for newborn care in rural hospitals in Kenya

Study objectives

Study 1 (randomised controlled trial) tests the null hypothesis that presenting research evidence using graded-entry summaries is not useful to those involved in national guideline development.

Study 2 (descriptive case study) involves description of deliberative processes involved in guideline development statement of a null hypothesis is consequently inappropriate.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Kenya Medical Research Institute National Ethical Review Committee on the 2nd March 2010 [ref. SSC Protocol No 1770 (Revised)].

Study design

Randomised controlled trial and a descriptive case study

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Child health: evidence-informed guidelines

Interventions

Study 1. Randomised controlled trial

Participants will be randomly allocated to receive the following graded-entry evidence summary formats.

A = Technical reviews + Systematic reviews (TR+SR)

B = Technical reviews + Systematic reviews + GRADE Summary of Findings table (TR+SR+SoF)

C = Technical reviews + Systematic reviews + Locally prepared mini-reviews with user- friendly front-ends (e.g. GRADE Summary of Findings table or SUPPORT-type summaries) placed under the abstract (TR+SR+MR+SoF)

The different evidence summary formats will be provided to participants as pre-reading materials one month before the national guideline development workshop.

Study 2. Descriptive case study

The usefulness of the linkage-exchange forum will be explored by conducting follow-up interviews with a sub-sample of the experts representing the spectrum of interest groups to, among other reasons, generate information on the opinions that shape stakeholder views on research evidence among different audiences for the guidelines.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Study 1. Randomised controlled trial

We will measure the impact of graded-entry evidence packs on participants understanding of key messages resulting from the evidence (tracer topic) summaries e.g. issues around persistent dilemmas on the timing (early or delayed) and rate of advancement (rapid or slow) of feeding volumes in prematurely born sick infants.

Study 2. Descriptive case study

Data collection will focus on documenting processes involved in knowledge exchange and in the application of GRADE grid in guideline development. Emerging themes following the application of GRADE grid will be presented to all the participants for further discussions to promote consensus on draft essential newborn care (ENC) recommendations.

Key secondary outcome(s)

We will measure the impact of graded-entry evidence packs on participants rating of their experience / satisfaction with the use of provided evidence packs.

Rating will be done using a 5-point Likert scale tool (used successfully in previous studies measuring 3 domains of their experience: usability (ease of use as indicated by average time spent looking for information), practical value (e.g. in tailoring research evidence) and barriers to use of evidence pack (accessibility).

Completion date

30/09/2010

Eligibility**Key inclusion criteria**

Participants will consist of a purposive sample of technical experts, practitioners and policy makers gathered to develop consensus guidelines during a planned 1 week neonatal stakeholder workshop.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/05/2010

Date of final enrolment

30/09/2010

Locations

Countries of recruitment

Kenya

Study participating centre

KEMRI/Wellcome Trust Research Programme

Nairobi

Kenya

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Sponsor information

Organisation

The Wellcome Trust (UK)

ROR

<https://ror.org/029chgv08>

Funder(s)

Funder type

Charity

Funder Name

The Wellcome Trust (UK) (grant ref: 084538)

Results and Publications

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?
Results article	results	01/02/2013		Yes	No