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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/03/2011	**Overall study status** Completed	
Last Edited 22/03/2013	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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

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 measure
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.

Secondary outcome measures
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).

Overall study start date
01/05/2010

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

Age group
Adult

Sex
Both

Target number of participants
36-40 technical experts, practitioners and policy makers

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
00100

Sponsor information

Organisation
The Wellcome Trust (UK)

Sponsor details

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Sponsor type
Charity

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ROR
https://ror.org/029chgv08

Funder(s)

Funder type
Charity

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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