Assessing the impact of an intervention to implement the referral care component of Integrated Management of Childhood Illnesses (IMCI) in district hospitals

Submission date
20/11/2008

Registration date
21/11/2008

Last Edited
15/01/2015

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Other

[_] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SSC911

Study information

Scientific Title
A randomised, parallel group trial of a multifaceted intervention to improve care of children in Kenyan district hospitals

Study objectives
That the quality of paediatric inpatient care at district hospitals in Kenya can be improved by an intervention over 18 months comprising evidence based guidelines, training, supervision, feedback and facilitation of local problem solving.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the KEMRI National Ethical Review Committee on 21st September 2005

Study design
Randomised, parallel, controlled intervention study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Quality of paediatric inpatient care

Interventions
Intervention arms:
Baseline survey followed by training, provision of guidelines and job aides (guideline booklets, standard admission record forms), external supervision and feedback after surveys and local facilitation provided over 18 months. Cross-sectional surveys conducted at 6, 12 and 18 months post-baseline.

Control arm:
Baseline survey followed by limited training, provision of guidelines and job aides (guideline booklets, standard admission record forms), written feedback after surveys over 18 months. Cross-sectional surveys conducted at 6, 12 and 18 months post-baseline.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Proportion of children with admission assessment, classification and treatment that is adherent to guidelines provided for pneumonia, diarrhoea/dehydration and malaria. Measurements will be available at 6, 12 and 18 months post-baseline with the primary endpoint being 18 months.

Secondary outcome measures

Proportion of key clinical signs documented for pneumonia, diarrhoea/dehydration and malaria admissions at 6, 12 and 18 months post-baseline with the primary endpoint being 18 months and will use a facility inventory to describe the proportion of items on a pre-specified checklist that are available at the time of the survey also at 6, 12 and 18 months post-baseline with the primary endpoint being 18 months.

Overall study start date

01/07/2006

Completion date

31/05/2009

Eligibility

Key inclusion criteria

1. Hospitals purposefully selected to represent diversity of Kenyan context and fulfilling minimum size requirements of 1,000 paediatric admissions per annum.
2. Random selection of all childhood admissions:
2.1. Aged 0 - 59 months, either sex
2.2. In participating hospitals with a diagnosis covered by inpatient IMCI guidelines (malaria, pneumonia, meningitis, malnutrition, diarrhoea/dehydration, neonatal sepsis, prematurity/low birthweight)

Participant type(s)

Patient

Age group

Child

Lower age limit

0 Months

Upper age limit

59 Months

Sex

Both

Target number of participants
Hospitals: intervention (n = 4) and control (n = 4). Childhood admissions: 12,800

Key exclusion criteria
Children aged 0 - 59 months in participating hospitals with non-IMCI diagnoses

Date of first enrolment
01/07/2006

Date of final enrolment
31/05/2009

Locations

Countries of recruitment
Kenya

Study participating centre
KEMRI/Wellcome Trust Programme
Nairobi
Kenya
00100

Sponsor information

Organisation
The Wellcome Trust (UK)

Sponsor details
215 Euston Road
London
United Kingdom
NW1 2BE
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Sponsor type
Charity

Website
http://www.wellcome.ac.uk/

ROR
https://ror.org/029chgv08

Funder(s)

Funder type
Charity

Funder Name
The Wellcome Trust (UK) (grant ref: 076827) - Senior Research Fellowship awarded to Dr. Mike English

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?
Other publications	discussion paper on study design	01/06/2008		Yes	No
Results article	results	25/11/2011		Yes	No
Results article	results	18/07/2014		Yes	No