ISRCTN42996612 https://doi.org/10.1186/ISRCTN42996612

# 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

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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 |