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Improving malaria treatment practices in children using mobile phone text-messaging in Kenya

Submission date
25/11/2008

Recruitment status
No longer recruiting

Registration date
27/11/2008

Overall study status
Completed

Last Edited
09/05/2013

Condition category
Infections and Infestations

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Implementation of the new artemether-lumefantrine treatment policy for uncomplicated malaria in Kenya is being compromised by poor treatment practices. This study aims to determine the effectiveness and cost of a new approach to improve the quality of paediatric outpatient malaria case-management using text-message reminders sent to health workers mobile phones.

Who can participate?
The study will include 108 government health facilities in two areas of Kenya, all health workers performing outpatient consultations and approximately 864 sick child consultations assessed during each round of evaluation.

What does the study involve?
Health facilities will be randomly allocated to either the intervention group, in which all health workers will receive text-messages on malaria case-management over 6 months, or a non-intervention control group. Three cross-sectional health facility surveys will be conducted to evaluate paediatric clinical practices: one before the intervention begins; one at 6 months, just after the end of the intervention to capture immediate effects of the intervention; and one 6 months later to assess retained effects.

What are the possible benefits and risks of participating?
The study will help us to better understand how new communication strategy may influence outpatient practices and, there is a hope, if intervention is successful, that the results of this research will help to improve the quality of malaria related care in Kenya in the future. No invasive procedures will be undertaken as a part of this study, and no costs will be incurred by caretakers or health workers as a result of their participation. Any child who has malaria according to national guidelines and does not receive adequate treatment during the consultation will receive an appropriate treatment free of charge by study teams.

Where is the study run from?
KEMRI/Wellcome Trust Research Programme in Kenya

When is the study starting and how long is it expected to run for?
The recruitment for the trial and evaluation is planned to take place between March 2009 and June 2010

Who is funding the study?
The Wellcome Trust

Who is the main contact?
Dr Dejan Zurovac
dzurovac@nairobi.kemri-wellcome.org

Contact information

Type(s)
Scientific

Contact name
Dr Dejan Zurovac

Contact details
KEMRI/Wellcome Trust Research Programme
PO Box 43 640
GPO 00100
Nairobi
Kenya
-
+254 (0)20 272 0163
dzurovac@nairobi.kemri-wellcome.org

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
OXTREC No 38/08

Study information

Scientific Title
Improving quality of paediatric outpatient malaria case-management using mobile phone text-messaging in Kenya

Study objectives

Null hypothesis:
The quality improvement intervention using reminders sent to health workers via mobile phone text-messaging has no effect on the quality of outpatient paediatric malaria case-management in Government health facilities in Kenya.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Oxford Tropical Medicine Research Ethics Committee (OXTREC) (UK) gave approval on the 26th August 2008 (ref: 38/08)
2. Kenya Medical Research Institute (KEMRI) Ethical Review Committee (ERC) gave approval on the 13th March 2008 (Scientific Steering Committee [SSC] ref: 1329)

Study design
Interventional, single-centre, pre-post cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
Malaria

Interventions
All Government facilities in two study districts were randomised to either the intervention group, in which all health workers will receive text-messages on malaria case-management over 6 months or a non-intervention control group.

The intervention is to send reminders on malaria case-management to health workers mobile phones via text-messaging. Key themes to be addressed are correct diagnosis, prescription, counselling, and drug dispensing. For each theme, 2 - 3 text messages will be generated, each less than or equal to 120 characters long. For 5 days each week, two text-messages will be sent to each health worker's mobile phone. This process will be repeated every week during the 6-month intervention period. Each message will be complemented with 40 characters of text providing information unrelated to malaria case-management that will be designed to be "attention-getting". Text messages will be sent from a phone connected to a personal computer running SMS delivery software. The software will be configured to distribute messages automatically to the approximately 160 intervention-group health workers' phone numbers at a

predetermined schedule. An automatic delivery report for each message will be received and archived.

Three cross-sectional health facility surveys will be conducted:
1. One before the intervention begins
2. One at 6 months, just after the end of the intervention to capture immediate effects of the intervention
3. One 6 months later to assess retained effects
After the last survey, in-depth interviews will be conducted with health workers in intervention facilities.

This is a pre-post randomised cluster controlled trial with 108 clusters (health facilities) randomly allocated to 54 control, and 54 intervention facilities in which all health workers will be exposed to intervention (approximately 160). During each evaluation survey we will need to collect data from all 108 control and intervention facilities, targeting 864 children across both arms.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
To determine the effectiveness of the mobile phone text-message reminders on the quality of outpatient diagnosis, prescription, counselling, and drug dispensing for children with uncomplicated malaria in Government facilities.

Timepoints for primary outcome:
Our primary comparison will be between baseline results and results of the second post-intervention survey. However, we will undertake an interim analysis and compare baseline results with the first post-intervention survey. If we are unable to demonstrate a 25 percentage point improvement attributed to the intervention, we will terminate the evaluation.

Secondary outcome measures
1. To determine qualitatively the factors that contribute to the effects of the intervention and influence outpatient malaria case-management practices
2. To determine the cost of the intervention using text-messaging of malaria case-management reminders to health workers mobile phones in government facilities

Overall study start date
01/02/2009

Completion date
31/10/2010

Eligibility

Key inclusion criteria
1. Health workers in intervention facilities prior to delivery of intervention are:
1.1. Working at Government dispensaries/health centres

1.2. Providing outpatient consultations
1.3. Providing informed consent

2. During the cross-sectional surveys, the health facility is:
2.1. Government facility
2.2. Dispensary/health centre level
2.3. Providing outpatient services

3. Health workers:
3.1. Any cadre providing outpatient services on the survey day
3.2. Providing informed consent

4. Children:
4.1. Below 5 years of age
4.2. Weighing 5 kg and above
4.3. Either sex
4.4. Coming for outpatient consultation on survey day
4.5. Mothers or guardians providing informed consent

Participant type(s)
Patient

Age group
Child

Upper age limit
5 Years

Sex
Both

Target number of participants
864 children

Key exclusion criteria
1. Health workers without mobile phones in intervention facilities
2. During cross-sectional surveys, the health facility is:
2.1. Private, mission or NGO facilities
2.2. Non-functional during the survey period
3. Health workers not attending enrolled patients on the survey day
4. Children with follow-up chronic diseases, traumas and burns

Date of first enrolment
01/02/2009

Date of final enrolment
31/10/2010

Locations

Countries of recruitment

Kenya

Study participating centre
KEMRI/Wellcome Trust Research Programme
Nairobi
Kenya
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Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
Clinical Trials and Research Governance
Manor House
John Radcliffe Hospital
Headington
Oxford
England
United Kingdom
OX3 9DZ
+44 (0)1865 743004
Heather.House@admin.ox.ac.uk

Sponsor type
University/education

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

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
The Wellcome Trust (UK) (grant ref: 084253)

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	27/08/2011		Yes	No