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Innovative management practices to enhance hospital quality and save lives in Malawi

Submission date	**Recruitment status**	[X] Prospectively registered
09/11/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/03/2023	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
12/09/2024	Other	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Every year 2.5 million newborns die. Most of these deaths happen in hospital and could be prevented. Babies in their first 28 days of life represent some of the most vulnerable users of the health system, as they can die quickly. Malawi has made good progress in reducing neonatal deaths but mortality rates for small and sick neonates admitted to hospitals are persistently high. Now that most births happen in health facilities, there is an urgent need to improve hospital care for newborns and their families. There is strong evidence that health technologies are a necessary ingredient for improving the survival of small and sick babies. However, in practice, babies do not always get these clinical interventions even when resources are available. Commonplace problems, such as poorly configured patient pathways, drug stockouts, staff shortages at critical times, and power outages, can be due to organisational failings rooted in poor management. Improving management practices – so that hospitals effectively manage and motivate staff, are data-driven in how they make decisions, and have in place systems to support quality improvement – offers the potential to turn the situation around. The aim of the study is to evaluate the impact of a co-designed multi-faceted management intervention on in-hospital neonatal mortality and the quality of clinical care for small and sick newborns.

Who can participate?
Government and faith-based hospitals in Malawi. The target population of the study is small and sick newborns admitted to the neonatal unit of the study hospitals.

What does the study involve?
The study hospitals are all part of the NEST360 programme, in which they receive a bundle of inputs and activities that include: the provision of affordable technologies to keep babies warm, help them breathe, treat jaundice and control infections; the training of technicians and clinicians; enhanced data systems; and support for regular quality improvement visits. Hospitals participating in the trial are then randomly allocated to one of two groups.
Those in the first group receive, in addition to the NEST360 activities, the following management components:
1. Identifying priority actions through a situation analysis;
2. Monitoring the adoption of management practices;
3. Facilitating the use of data for action by managers (including target setting and recognition

awards);
4. Implementing small tests of change;
5. Hospital peer-to-peer learning;
6. On-site management skills strengthening.
These core components are accompanied by several support strategies to: identify champions, engage the hospital leadership, and faciliate better communication between managers and clinical staff. Hospitals in the second group receive the existing NEST360 activities only.

What are the possible benefits and risks of participating?
Participating hospitals could benefit from better management practices, which in turn could improve the quality of clinical care they provide to small and sick newborns. There are no notable risks involved with taking part in the study.

Where is the study run from?
London School of Hygiene & Tropical Medicine (UK)

When is the study starting and how long is it expected to run for?
November 2022 to October 2024.

Who is funding the study?
National Institute for Health and Care Research (NIHR), UK.

Who is the main contact?
Prof. Timothy Powell-Jackson
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Study website
https://www.lshtm.ac.uk/research/centres-projects-groups/impress

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NIHR131237

Study information

Scientific Title
IMPRESS: A cluster randomised trial of the impact of a multi-faceted hospital management intervention on in-hospital mortality and the quality of clinical care for small and sick newborns in Malawi

Acronym
IMPRESS

Study objectives
The multi-faceted management intervention will increase the adoption of management practices in participating hospitals, leading to an improvement in the quality of care and a reduction in all cause in-hospital mortality amongst small and sick newborns.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 31/01/2023, College of Medicine Research and Ethics Committee (Kamzu University of Health Sciences, p/bag 360, Chichiri, Blantyre 3, Malawi), ref: P.01/23/3941
2. Approved 30/11/2022, London School of Hygiene and Tropical Medicine, Interventions Research Ethics Committee (Keppel Street, London, WC1E 7HT, UK), ref: 28255

Study design
Interventional cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not applicable

Health condition(s) or problem(s) studied
Quality of care for small and sick neonates

Interventions
The study hospitals all participate in NEST360 – they receive a bundle of inputs and activities that include: the provision of affordable technologies to keep babies warm, help them breath, treat jaundice and control infections; the training of technicians and clinicians; enhanced data systems; and support for regular quality improvement visits.

Participating hospitals in the trial are randomly allocated to one of two groups.
Hospitals are assigned to intervention or control in a ratio of 1:2 using stratified randomisation. Stratification ensures that the number of hospitals receiving intervention or control is well balanced within each stratum. The stratification variable is baseline all cause in-hospital mortality of patients admitted to the neonatal unit (10 strata). Hospitals are allocated to intervention or control using a computer generated randomisation list done by the trial statistician. Study hospitals will be informed of intervention assignment through in-person site visits. Specifically, the list will be used to prepare randomisation cards that are sealed in opaque envelopes. A member of the study team will explain how the randomisation was done and then open the envelope to reveal the randomisation card and treatment group assignment. Sealed envelopes provide a pragmatic, confidential and transparent method of implementing randomisation in the field.

Intervention group (arm A): hospitals receive a multi-faceted management intervention in addition to the existing NEST360 activities. The management intervention targets primarily middle management in the hospital and health staff in the neonatal unit. It includes the following core components:
1. Identifying priority actions through a situation analysis;
2. Monitoring the adoption of management practices;
3. Facilitating the use of data for action by managers (including target setting and recognition awards);
4. Implementing small tests of change;
5. Hospital peer-to-peer learning;
6. On-site management skills strengthening.
These core components are accompanied by several support strategies: identifying champions, engaging the hospital leadership and facilitating better communication between managers and clinical staff.

Control group (arm B): hospitals continue to receive the existing NEST360 activities only.

Intervention Type
Mixed

Primary outcome measure
All-cause in-hospital mortality of patients admitted to the neonatal unit of the study hospitals, measured over a 6-month period 9-15 months after the start of the management intervention using the Neonatal Inpatient Dataset, an electronic medical records information system.

Secondary outcome measures

Current secondary outcome measures as of 12/09/2024:

1. All cause in-hospital mortality over each of the third, fourth and fifth quarter-years of follow-up to track if the effect on mortality changes over time
2. All cause in-hospital mortality in each birthweight category (1001g-1500g, 1501g-2000g, 2001g-2500g, 2501g+), measured between month 9 and month 15 after the start of the management intervention
3. Proportion of newborns receiving pulse oximetry at admission, measured between month 9 and month 15 after the start of the management intervention
4. Proportion of newborns with their temperature taken at admission, measured between month 9 and month 15 after the start of the management intervention
5. Proportion of newborns with a glucose test taken at admission, measured between month 9 and month 15 after the start of the management intervention
6. Proportion of newborns that has all three diagnostics at admission assessment (pulse oximetry, temperature taken, glucose test completed), measured between month 9 and month 15 after the start of the management intervention
7. Proportion of newborns exclusively breastfed on discharge from the neonatal unit, measured between month 9 and month 15 after the start of the management intervention
8. Proportion of newborns with birthweight 1000g-1499g or those with birthweight 1500g-1999g and respiratory distress syndrome and hypoxia receiving Continuous Positive Airway Pressure (CPAP) during admission to neonatal unit, measured between month 9 and month 15 after the start of the management intervention
9. Proportion of newborns with clinical sepsis diagnosis given antibiotics during admission to neonatal unit, measured between month 9 and month 15 after the start of the management intervention
10. Proportion of newborns with clinical sepsis diagnosis that have a blood culture done, measured between month 9 and month 15 after the start of the management intervention
11. Proportion of newborns that have a blood culture done amongst those given antibiotics during admission to neonatal unit, measured between month 9 and month 15 after the start of the management intervention
12. Proportion of newborns that have a birthweight of <2500g receiving kangaroo mother care (KMC) during admission to neonatal unit, measured between month 9 and month 15 after the start of the management intervention
13. Proportion of newborns receiving a bilirubin test during admission amongst those showing jaundice at admission, measured between month 9 and month 15 after the start of the management intervention
14. Proportion of newborns with a clinical jaundice diagnosis or bilirubin test who received phototherapy at any time during their neonatal unit stay, measured between month 9 and month 15 after the start of the management intervention
15. Proportion of inborn newborns that had hypothermia (<36.5°C) at admission to neonatal unit, measured between month 9 and month 15 after the start of the management intervention
16. Proportion of inborn newborns <2500g that had hypothermia (<36.5°C) at admission to neonatal unit, measured between month 9 and month 15 after the start of the management intervention

The management-related and other secondary outcomes are:
17. Hospital management quality score, measured at month 12 after the start of the management intervention. This is an overall measure of the quality of management based on the Hospital Management Tool developed during the formative phase of research
18. Hospital management records score, measured at month 12 after the start of the management intervention. This is an overall measure of the adoption of management practices based on the Record Review Tool developed during the formative phase of research

19. Mean number of neonatal unit admissions per month, measured between month 9 and month 15 after the start of the management intervention using the Neonatal Inpatient Dataset
20. Experience of care index, measured at month 15 after the start of the management intervention. This is an overall measure of experience of care based on responses to the individual items in the Experience of Care Survey, calculated as a percentage of the maximum score.

Previous secondary outcome measures from 09/01/2024 to 12/09/2024:

1. All cause in-hospital mortality over each of the third, fourth and fifth quarter-years of follow-up to track if the effect on mortality changes over time
2. All cause in-hospital mortality in each birthweight category (1001g-1500g, 1501g-2000g, 2001g-2500g, 2501g+), measured between month 9 and month 15 after the start of the management intervention
3. Proportion of newborns receiving pulse oximetry at admission, measured between month 9 and month 15 after the start of the management intervention
4. Proportion of newborns with their temperature taken at admission, measured between month 9 and month 15 after the start of the management intervention
5. Proportion of newborns with a glucose test taken at admission, measured between month 9 and month 15 after the start of the management intervention
6. Proportion of newborns that has all three diagnostics at admission assessment (pulse oximetry, temperature taken, glucose test completed), measured between month 9 and month 15 after the start of the management intervention
7. Proportion of newborns exclusively breastfed on discharge from the neonatal unit, measured between month 9 and month 15 after the start of the management intervention
8. Proportion of newborns with birthweight 1000g-1499g or those with birthweight 1500g-1999g and respiratory distress syndrome and hypoxia receiving Continuous Positive Airway Pressure (CPAP) during admission to neonatal unit, measured between month 9 and month 15 after the start of the management intervention
9. Proportion of newborns with clinical sepsis diagnosis given antibiotics during admission to neonatal unit, measured between month 9 and month 15 after the start of the management intervention
10. Proportion of newborns with clinical sepsis diagnosis that have a blood culture done, measured between month 9 and month 15 after the start of the management intervention
11. Proportion of newborns that have a blood culture done amongst those given antibiotics during admission to neonatal unit, measured between month 9 and month 15 after the start of the management intervention
12. Proportion of newborns that have a birthweight of <2500g receiving kangaroo mother care (KMC) during admission to neonatal unit, measured between month 9 and month 15 after the start of the management intervention
13. Proportion of newborns receiving a bilirubin test during admission amongst those showing jaundice at admission, measured between month 9 and month 15 after the start of the management intervention
14. Proportion of newborns with a clinical jaundice diagnosis or bilirubin test who received phototherapy at any time during their neonatal unit stay, measured between month 9 and month 15 after the start of the management intervention
15. Proportion of inborn newborns that had hypothermia (<36.5°C) at admission to neonatal unit, measured between month 9 and month 15 after the start of the management intervention

16. Proportion of inborn newborns <2500g that had hypothermia (<36.5°C) at admission to neonatal unit, measured between month 9 and month 15 after the start of the management intervention

The management-related and other secondary outcomes are:
17. Hospital management quality score, measured at month 12 after the start of the management intervention. This is an overall measure of the quality of management based on the Hospital Management Tool developed during the formative phase of research
18. Hospital management records score, measured at month 12 after the start of the management intervention. This is an overall measure of the adoption of management practices based on the Record Review Tool developed during the formative phase of research
19. Mean number of neonatal unit admissions per month, measured between month 9 and month 15 after the start of the management intervention using the Neonatal Inpatient Dataset

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Previous secondary outcome measures:

The quality of clinical care outcomes, measured using the Neonatal Inpatient Dataset, are:
1. All cause in-hospital mortality over each of the third, fourth and fifth quarter-years of follow-up to track if the effect on mortality changes over time
2. All cause in-hospital mortality in each birthweight category (1001g-1500g, 1501g-2000g, 2001g-2500g, 2051g+), measured between month 9 and month 15 after the start of the management intervention
3. Proportion of newborns with respiratory distress syndrome and hypoxia and <2000g receiving Continuous Positive Airway Pressure (CPAP) during admission to neonatal unit, measured between month 9 and month 15 after the start of the management intervention
4. Proportion of newborns with clinical sepsis diagnosis given antibiotics during admission to neonatal unit, measured between month 9 and month 15 after the start of the management intervention
5. Proportion of newborns exclusively breastfed on discharge from the neonatal unit, measured between month 9 and month 15 after the start of the management intervention
6. Proportion of inborn newborns that had hypothermia at admission to neonatal unit, measured between month 9 and month 15 after the start of the management intervention
7. Proportion of newborns that have a birthweight of <2000g receiving kangaroo mother care (KMC) during admission to neonatal unit, measured between month 9 and month 15 after the start of the management intervention
8. Proportion of newborns that has all three diagnostics at admission assessment (pulse oximetry, temperature taken, glucose test completed), measured between month 9 and month 15 after the start of the management intervention
9. Proportion of newborns that have a blood culture done amongst those given antibiotics during admission to neonatal unit, measured between month 9 and month 15 after the start of the management intervention

The management-related and other secondary outcomes are:
10. Hospital management quality score, measured at month 12 after the start of the management intervention. This is an overall measure of the quality of management based on the Hospital Management Tool developed during the formative phase of research
11. Hospital management records score, measured at month 12 after the start of the management intervention. This is an overall measure of the adoption of management practices

based on the Record Review Tool developed during the formative phase of research
12. Mean number of neonatal unit admissions per month, measured between month 9 and month 15 after the start of the management intervention using the Neonatal Inpatient Dataset

Overall study start date
09/11/2022

Completion date
01/10/2024

Eligibility

Key inclusion criteria
Hospitals:
1. Part of the NEST360 network of hospitals in Malawi
2. More than 3,000 births per year
3. Government-owned hospital or Christian Health Association of Malawi (CHAM) hospital

Patients:
1. Baby admitted to the neonatal unit of a study hospital
2. Baby alive at admission to the neonatal unit

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
30 hospitals. 450 admissions per hospital.

Key exclusion criteria
Hospitals:
1. Central level hospitals

Patients:
1. Birthweight of baby is 1000g or less

Date of first enrolment
12/06/2023

Date of final enrolment
01/07/2024

Locations

Countries of recruitment

Malawi

Study participating centre
Kamuzu University of Health Sciences (KUHeS)
Private Bag 360, Chichiri
Blantyre
Malawi
BT3

Sponsor information

Organisation
London School of Hygiene & Tropical Medicine

Sponsor details
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Sponsor type
University/education

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

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Results will be written up for publication in an academic journal. Dissemination activities will include: one national dissemination meeting with policymakers and stakeholders in Malawi; three subnational dissemination meetings with zonal, district and hospital managers in Malawi; small meetings organised through established networks and participation in government technical working groups; conferences; policy briefs; webinars; and teaching materials.

Intention to publish date
15/12/2024

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 4.1	06/08/2024	12/09/2024	No	No