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PUMA Paediatric early warning systems: Utility and Mortality Avoidance

Submission date 13/05/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 18/08/2015	**Overall study status** Completed	
Last Edited 20/10/2021	**Condition category** Other	

Plain English summary of protocol

Background and study aims

In 2011 a research study compared child health in the UK with other European countries. It was worrying that UK measures of child health were amongst the worst in Europe. It is not clear why that is and further work needs to be done to better understand this. In hospital staff try to quickly identify the children who are seriously ill or getting sicker, so that they receive rapid treatment to improve their condition. Despite training, sometimes children become sicker in hospital without staff noticing or they underestimate the severity of illness, or do not treat deterioration quickly enough, or get extra help. In these cases the very sick child might require emergency transfer to intensive care, or stop breathing, or die unexpectedly. This study aims to develop an understanding of a number of key pieces of information that could help to standardise monitoring of children in hospital, help to identify deterioration quickly so there is an urgent response to save the patient from harm and reduce premature death in hospitalised children across the UK. This research study will be conducted in four hospitals and aims to examine what key components should be included in a track and trigger score and early warning system, to help identify the children who are sicker and prevent them becoming more unwell, having a serious complication or dying. This will be the largest, most comprehensive study of paediatric early warning scores and systems, with the aim to improve patient safety and reduce mortality. Our findings will inform recommendations about safety processes that should be established in every hospital treating paediatric in-patients across the NHS.

Who can participate?

All children admitted to the four participating hospital's inpatient units general hospital wards (excluding high dependency and intensive care units), the parents of some of these children and the healthcare professionals looking after some of these children.

What does the study involve?

This study will develop a tool for healthcare professionals to use to monitor sick children. Before this is introduced we need to understand how staff currently monitor children, how they communicate with each other and how they record symptoms. We will observe and interview healthcare professionals working on paediatric wards and parents of children on the ward to see how best to develop a track and trigger tool to help monitor patients. We will use this information as well as published research literature to develop a track and trigger tool that can

be used to help staff monitor children who are getting sicker. We will continue to observe and interview staff and parents to see how well the new tool is accepted into working practice.

What are the possible benefits and risks of participating?
There are no direct benefits to the parents or healthcare professionals taking part in these discussions, but they may gain indirect benefit by talking about their experiences in a supportive environment. We hope that the study will help us to identify and better understand the best way to monitor children and identify when they get sicker. Our future aim is to use the findings from this project to roll out a national system. Observation and interviews will make certain demands on staff. We will be attentive to service issues and ensure that our study does not disrupt practice. The parents who agree to participate will only have the time burden of participating in an interview and if any parents who child has deteriorated chose to be interviewed, they may become upset when talking about their child and their experience.

Where is the study run from?
Alder Hey Hospital, Arrow Park Hospital, Children's Hospital of Wales and Morriston Hospital (UK).

When is the study starting and how long is it expected to run for?
From November 2014 to November 2018.

Who is funding the study?
NIHR - Health Services & Delivery Research Programme (UK).

Who is the main contact?
Dr Emma Thomas-Jones

Contact information

Type(s)
Scientific

Contact name
Dr Emma Thomas-Jones

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18842

Study information

Scientific Title
PUMA Paediatric early warning system (PEWS): Utilisation and Mortality Avoidance. A prospective, mixed methods, before and after study identifying the evidence base for the core components of an effective PEWS and the development of an implementation package for implementation and use in the UK

Acronym
PUMA

Study objectives
1. What is the evidence for the core components of a national paediatric track and trigger tool?
2. What is the evidence that the implementation of paediatric track and trigger tool in the UK NHS environment will reduce avoidable morbidity and mortality in hospitalised children?
3. What are the (micro, meso and macro) contextual features consequential for its success?
4. What factors are necessary to support successful implementation and normalisation?

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South West – Central Bristol, 13/04/2015, ref: 15/SW/0084

Study design
Non-randomised; Observational; Design type: Qualitative

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Other

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
Topic: Children; Subtopic: All Diagnoses; Disease: All Diseases

Interventions

Workstream 1 - The development of a track and trigger tool and an implementation package based on systematic review and expert consultation
A systematic review will be conducted in order to answer three interlinked questions:
1. How well validated are existing track and trigger scores for PEWS and their component parts?
2. How effective are PEWS (with or without track and trigger scores) at reducing mortality and critical events?
3. What socio-technical and contextual factors are associated with successful or unsuccessful PEWS (with or without track and trigger scores)?
Drawing on the evidence from the literature review, the PUMA study team will devise an optimal track and trigger tool, with the review informing the development of the items to be included in the score and the system that will inform how the score is used. This will be reviewed by key expert stakeholders to ensure face and internal validity and inform layout, format and feasibility. After development, the new tool will be field tested for feasibility. Feasibility testing will involve feedback from medical, nursing and support staff who use the tool to assess clarity and utility.

Workstream 2 - A prospective mixed method, before-and-after study design in four hospitals, with embedded case studies is proposed
These embedded case studies within the study at each phase will evaluate normal practice, the process of implementation and the use of the track and trigger tool post implementation.

Phase 1: Observe and record outcomes in current practice
Organisational case studies (one ward) will be undertaken in each hospital. Ethnographic methods will be deployed to explore the technical, social, and organisational factors consequential for PEW tool effectiveness at individual, team, unit and hospital level. Data will be generated pre-intervention and post-intervention in order to understand the impact of PEW tool implementation on practice and identify the micro, meso and macro contextual features consequential for effectiveness.

Phase 2: Implement the track and trigger tool based on best evidence, and the implementation package
An implementation strategy will be tailored to each organisation.
We anticipate developing an implementation package adopting a train the trainers approach. The implementation package will include a manual for implementation at an organisational level as well as a ‘user guide’ for staff directly using the tool and system.

Phase 3: Evaluate the system in use
Observational methods will be employed to describe and understand the implementation of the train the trainers programme in each of the four study sites to identify any significant variation in the delivery of the intervention, local issues that may surface in relation to the challenges of implementation, and any proposed adaptations and solutions.

Intervention Type

Mixed

Primary outcome measure

The primary outcome measure is the monthly collected rate of mortality and the following critical events:
1. Unplanned admission to Paediatric Intensive Care (PICU) or Paediatric High Dependency Unit (PHDU)
2. Cardiac arrest

3. Respiratory arrest
4. Medical emergencies requiring immediate assistance (arrest calls who were not respiratory or cardiac arrests)
5. Referrals for PICU review (in tertiary centres) or PICU retrieval (DGHs)
6. The Critical Deterioration (CD) metric

Secondary outcome measures
The secondary outcome measures are the monthly rates of each of the following critical events in each hospital:
1. Mortality
2. Unplanned admission to PICU or PHDU
3. Cardiac arrest
4. Respiratory arrest
5. Medical emergencies requiring immediate assistance
6. Referrals for PICU review (in tertiary centres) or PICU retrieval (DGHs)
7. CD metric
8. PIM3

Overall study start date
01/11/2014

Completion date
05/11/2018

Eligibility

Key inclusion criteria
1. All children admitted to the four participating hospital's inpatient units general hospital wards (excluding high dependency and intensive care units)
2. The parents of some of these children
3. The healthcare professionals looking after some of these children

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
Planned Sample Size: 66; UK Sample Size: 66

Key exclusion criteria
1. Preterm infants (<37 weeks gestation)
2. Adult patients >18 years of age
3. Patients not admitted to the hospital (e.g., those only seen in AED and discharged)
4. Patients admitted directly to PICU or HDU
5. Temporary or agency staff working in these departments

Date of first enrolment
01/04/2015

Date of final enrolment
01/04/2018

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Alder Hey Hospital
United Kingdom
L12 2AP

Study participating centre
Children's Hospital for Wales
United Kingdom
CF14 4XN

Study participating centre
Arrow Park Hospital
United Kingdom
CH49 5PE

Study participating centre
Morriston Hospital
United Kingdom
SA6 6NL

Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
NIHR - Health Services & Delivery Research Programme (HS&DR)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	25/07/2018		Yes	No
Other publications	hermeneutic systematic literature review and model development	14/11/2019	20/10/2021	Yes	No
Other publications	systematic review	05/05/2019	20/10/2021	Yes	No

HRA research summary	28/06/2023	No	No