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Dynamic electronic tracking and escalation to reduce critical care transfers

Submission date
03/06/2019

Recruitment status
No longer recruiting

Registration date
07/06/2019

Overall study status
Completed

Last Edited
03/07/2024

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Missed clinical deterioration in children in hospital is a challenging problem in the NHS, which can lead to emergency transfer to critical care (PICU or HDU), and at worst, death. Children who require emergency transfer to critical care are sicker, need more intensive treatment and have a longer stay than planned admissions. This study will evaluate whether using SMART digital technology, incorporating a paediatric early warning score (PEWS) and sepsis screening, can help staff to identify signs of deterioration earlier, so that urgent treatment can be given, and if this prevents emergency admission to critical care. Careflow Vitals (previously known as VitalPAC) is Health IT software which runs on electronic handheld devices (iPods and iPads) and allows staff to document routinely collected vital signs, calculate the PEWS and screen for signs associated with sepsis. It prompts staff to take caution when PEWS are elevated or there are clinical concerns of deterioration, including sepsis. The information is immediately available to the entire clinical team, regardless of where they are in the hospital, to provide shared team situation awareness of the status of patients. VitalPAC has been shown to improve serious illness recognition and reduce deaths in adults. There is potential for similar benefits for children. However, the device used in adults is unsuitable for children because:
1. Signs of serious illness in children differ from those seen in adults.
2. Vital signs (heart rate, breathing and blood pressure) change markedly throughout childhood and into adulthood, so the measures used to flag concern must be age specific.
3. Children become seriously ill quicker than adults, particularly when they have severe infections (sepsis). Consequently, there is greater urgency to act quickly to stabilise them.
This study will focus on three main elements:
1. Exploring the clinical effectiveness of this type of active monitoring at reducing critical deterioration in children in hospital
2. Explore the clinical utility of the technology; does it help doctors and nurses to recognise and respond to deteriorating children earlier and what is the acceptability of this technology to children and their families
3. Explore whether this type of technology is cost-effective for use in the NHS

Who can participate?
All in-patients under the age of 18 at the participating site

What does the study involve?
The bedside nurse directly inputs vital signs into Careflow Vitals on a handheld device. It automatically charts the values and calculates the PEWS, eliminating calculation error. It incorporates NICE sepsis screening. The vital signs, PEWS and sepsis screening are immediately uploaded to the network so they are instantly visible to the doctors and nurses. Higher PEWS scores indicate deterioration and trigger an automated alert. Senior nurses and doctors carrying a device are alerted, via Careflow Connect, without the bedside nurse having to leave the patient's bedside. They can respond quickly to provide urgent treatment to stabilise the child.

What are the possible benefits and risks of participating?
The care provided to children in hospital continues as normal. This study aims to discover if the SMART technology, used in this study, which is portable and available to all ward nurses and doctors, improves the availability of real-time information without the need to log into a computer. The researchers will explore whether this technology speeds up the process of spotting sicker patients and treating them. They cannot guarantee 100% that this technology will improve care, but it will not make it worse. Improved understanding of the signs predictive of serious illness could help children in hospital in the future, and could help hospitals to be more efficient. Feedback from patients and families will inform future product development. There are no disadvantages to joining the study.

Where is the study run from?
Alder Hey Children's NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for
March 2018 to August 2023

Who is funding the study?
Department of Health, UK via the NIHR i4i (invention for innovation) funding scheme

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
36022

Study information

Scientific Title
Dynamic Electronic Tracking and Escalation to reduce Critical Care Transfers (DETECT study)

Acronym
DETECT

Study objectives
All-cause child mortality in the UK has not maintained improvement, in line with other European countries. A CEMACH report 'Why children die', identified that 25% of in-hospital deaths had identifiable failures in direct care and potentially avoidable factors in 43%. It is recognised that detection of early signs of deterioration is challenging. Paediatric Early Warning Systems have been advocated as a mechanism to identify deterioration, however, the evidence base underpinning their use is weak. To date published PEWS studies in the UK NHS environment have been single site using historical controls. Developing the PEWS evidence base has been hampered by the use of paper-based charting of vital signs. Progress on developing and calibrating PEWS risk models have been limited by the challenge in achieving compliance with the intervention and human factors confounding hospital safety processes. Smart technology can potentially address this by using process control and compliance monitoring to standardise active monitoring of children. The software under development includes prompts to ensure that deteriorating children are escalated for urgent clinical review. With large datasets captured electronically, sophisticated models can be applied to ensure a PEWS which is robust at identifying early deterioration and sepsis across all paediatric ages.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/01/2018, North West - Liverpool East Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ; Tel: +44 (0)207 104 8019; Email: nrescommittee.northwest-liverpooleast@nhs.net), ref: 17/NW/0533

Study design
Non-randomised; Interventional; Design type: Validation of investigation /therapeutic procedures

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Deterioration in all sick children in hospital, regardless of the underlying condition or diagnosis

Interventions
The interventional component uses Health IT technology to improve the screening of patients to identify early signs of deterioration, including sepsis with the aim of prompting enhanced clinical care delivery to prevent the progression of deterioration to become critical. There is active monitoring, because the entered data calculates the Paediatric Early Warning score (PEWS) and prompts associated actions. If there are concerns regarding sepsis further actions are prompted including bundled management of sepsis to comply with the NICE sepsis guidelines. The compliance with PEWS and sepsis active monitoring is continually evaluated and reported back to the ward teams and clinical teams to drive behaviour change and demonstrate improved organisational safety.

The observational component focuses on the collection of vital signs (physiological measurements and clinical assessments for the PEWS calculation and sepsis screening, to allow modelling of the components to improve predictive performance) and the clinical course of patients who did or did not deteriorate, so that the cost of care delivery for patients who have a critical deterioration can be explored. The total period of observation is 30 months. There is no follow up included in the study.

This is a stepped-wedge prospective mixed methods study exploring the clinical effectiveness, clinical utility and cost-effectiveness of a pro-active electronic physiological surveillance system to screen paediatric patients for early signs of serious deterioration or sepsis.
Participants: Infants, children and young people under the age of 18 years, admitted to hospital
Intervention: An Electronic Physiological Surveillance System; Careflow Vitals and Connect
Comparison: Standard care; where children are monitored and have vital signs recorded in the Electronic Patient Record, which has an in-built Paediatric Early Warning score
Outcome: Unplanned Critical Care Transfer (PICU or HDU)

The bedside nurse directly inputs vital signs into Careflow Vitals on a handheld device. It automatically charts the values and calculates the PEWS, eliminating calculation error. It incorporates NICE sepsis screening. The vital signs, PEWS and sepsis screening are immediately uploaded to the network so they are instantly visible to the doctors and nurses. Higher PEWS scores indicate deterioration and triggers an automated alert. Senior nurses and doctors carrying a device are alerted, via Careflow Connect, without the bedside nurse having to leave the patient's bedside. They can respond quickly to provide urgent treatment to stabilise the child. The research will focus on three main elements:
1. Exploring the clinical effectiveness of this type of active monitoring at reducing critical deterioration in children in hospital
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Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Health IT technology

Primary outcome measure
Measured at baseline and 1 year post intervention:
1. Emergency transfers to Critical Care (PICU/HDU); number of unplanned admissions from in-patient ward, prevalence per 1,000 hospital admissions
1.1. Total bed days; total bed days or part bed calendar days in PICU or HDU used for unplanned admission from in-patient ward
1.2. Severity of illness (PIM3); unplanned admission from in-patient ward to PICU only, PIM3 taken at first contact with PICU team
1.3. Length of stay; PICU or HDU length of stay (individual and combined critical care length of stay)/days or part calendar days
2. Sepsis identification and response; screening questions all in-patients
2.1. Could this be sepsis? Number yes (denominator number of screenings), in the yes cohort stratification of risk: moderate or high, treat as sepsis confirmed by clinician, bundled management of sepsis
3. Interventions (days):
3.1. Mechanical ventilation; calendar days or part days invasively ventilated
3.2. Non-invasive ventilation; calendar days or part days non-invasive respiratory support
3.3. Inotropes; calendar days or part days of inotropes
3.4. Dialysis; calendar days or part days non-invasive respiratory support

Secondary outcome measures
Measured at baseline and 1 year post intervention:
1. Prevalence of Critical Deterioration Events per 1,000 hospital admissions (as defined by

Bonafide 2012); a subsection of unplanned in-patient transfers to HDU or PICU from within the same hospital, who require organ support immediately preceding transferor within the following 12 hours
2. Cardiac arrests, respiratory arrests, any activation of resuscitation team; number of activations of the resuscitation team, stratified by mechanism
3. Mortality (all cause). Patients from study areas in-patient wards only. Deaths of patients who were never admitted to a study ward are excluded (e.g direct admissions to PICU from ED)
4. Critical care activity: total PICU and HDU admissions, the total PICU and HDU bed days or part bed days for any admission to PICU or HDU:
4.1. Severity of illness; All cause PICU admissions PIM3, at first contact with PICU team
4.2. Length of stay; All cause PICU and HDU length of stay/calendar days or part days
4.3. Internal/external refused emergency admissions; Refused request for a PICU or HDU bed as bed not available (excludes bed not clinically warranted); number of refusals within the hospital or for external transfers in
4.4. Cancellations of major elective surgery requiring an HDU or PICU bed; Surgery cancelled because a PICU or HDU bed was bed not available, number of cancelled
5. Hospital activity: total (ward) admissions, total bed days/month, median length of stay

Overall study start date
01/03/2018

Completion date
31/08/2023

Eligibility

Key inclusion criteria
1. Hospital ward in-patient
2. Age 0-18 years

Participant type(s)
Patient

Age group
Child

Lower age limit
0 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
38,500

Key exclusion criteria

1. Day case patients or outpatients
2. Young adults >18 years
3. Patients already in PICU

Date of first enrolment
30/05/2019

Date of final enrolment
31/08/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Alder Hey Children's NHS Foundation Trust
Eaton Road
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Sponsor information

Organisation
University of Liverpool

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Sponsor type
University/education

ROR

https://ror.org/04xs57h96

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: II-LA-0216-20002

Results and Publications

Publication and dissemination plan
1. The study protocol should be published before the end of 2019.
2. The study findings are expected to be published in a high-impact peer-reviewed journal in late 2021.

Intention to publish date
30/06/2024

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made 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 article	protocol	17/10/2019	23/10/2020	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Costs-effectiveness observational component results	04/07/2023	05/07/2023	Yes	No
Other publications	Survey developed by the research team was piloted before use	31/08/2023	01/09/2023	Yes	No