Development, implementation and evaluation of an early warning system improvement programme for children in hospital: the PUMA mixed-methods study

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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Scientific summary

The PUMA mixed-methods study

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Scientific summary

Background

The Paediatric early warning system Utilisation and Morbidity Avoidance (PUMA) study was commissioned to develop, implement and evaluate a paediatric track-and-trigger tool to address the problem of missed deterioration in hospitalised children. These aims were revised in the light of three systematic reviews, which showed limited effectiveness of paediatric track-and-trigger tools in isolation and instead showed evidence of multiple failure points in paediatric early warning systems.

Objectives

- Identify, through systematic literature review, evidence for the core components of effective paediatric track-and-trigger tools and paediatric early warning systems.
- Identify, through systematic literature review, contextual factors consequential for paediatric track-and-trigger tool and early warning system effectiveness.
- Develop and implement an evidence-based paediatric early warning system improvement programme (i.e. PUMA programme).
- Evaluate the effectiveness of the PUMA programme by examining clinical practice and core outcome trends.
- Identify the key ingredients of successful implementation and normalisation of the PUMA programme.

Methods

Workstream 1: evidence reviews and PUMA programme development

Quantitative reviews addressed the following questions:

1. How well validated are existing paediatric track-and-trigger tools and their component parts for predicting inpatient deterioration?
2. How effective are paediatric early warning systems (with or without a tool) at reducing mortality and critical events?

Papers reporting development or validation of a paediatric track-and-trigger tool were included for review 1. Papers reporting implementation of a 'paediatric early warning system intervention' were eligible for review 2. Both reviews considered a range of study designs involving inpatients aged 0–18 years. Outcome measures included mortality and critical events. Two people independently screened titles and abstracts. Full texts were reviewed independently by six reviewers and assigned to the relevant review question. Data extraction was carried out by two reviewers; discrepancies were resolved by discussion. Methodological quality and risk of bias was assessed using a modified version of the Downs and Black rating scale (Downs SH, Black N. The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non-randomised studies of health care interventions. *J Epidemiol Community Health* 1998;**52**:377–84).

A qualitative review addressed the following question:

3. What sociomaterial and contextual factors are associated with successful or unsuccessful paediatric early warning systems (with or without paediatric track-and-trigger tools)?

The review was informed by translational mobilisation theory and normalisation process theory and progressed through an iterative process of searching, analysis and interpretation of evidence. Eligibility criteria and key themes were refined through a scoping review. We undertook systematic searches of literature on paediatric and adult early warning systems, situational awareness and structured communication tools, and we undertook theory-driven searches on family involvement, observations and monitoring, and electronic systems. Papers were screened by title for eligibility and by full text to assess relevance. Evidential fragments and partial lines of inquiry formed the unit of analysis. Data extraction and quality appraisal were undertaken concurrently and checked by a second reviewer.

Intervention development

The PUMA programme is founded on OUTCOME, a novel approach to improvement, informed by translational mobilisation theory and normalisation process theory. Developed as part of the PUMA study, OUTCOME is designed to harness local expertise to implement contextually appropriate interventions to achieve an agreed goal. It comprises the following:

- an evidence-based and theoretically informed propositional model of a paediatric early warning system derived from systematic review 3 (PUMA Standard)
- visualisation of the model in the PUMA Wheel
- system assessment tools
- guidance to support improvement initiatives
- structured facilitation and ongoing support.

Workstream 2: implementation and prospective evaluation of the PUMA programme

The PUMA programme was implemented in two tertiary children's hospitals with onsite paediatric intensive care units (Alder Hey Children's Hospital and Noah's Ark Children's Hospital for Wales) and two district general hospitals (Arrowe Park Hospital and Morriston Hospital). Interrupted time series and ethnographic case studies were used to evaluate changes in outcomes and clinical practices. Qualitative methods were deployed in a process evaluation.

Interrupted time series

Analysis involved tracking aggregate monthly rates of mortality and morbidity outcomes for up to 18 months before, 12 months during and 12 months after implementation.

Data

The primary outcome was a composite metric, representing the aggregate number of children in each month that experienced at least one of these events:

- mortality
- cardiac arrest
- respiratory arrest
- unplanned admission to a paediatric intensive care unit
- unplanned admission to a high-dependency unit.

Secondary outcome measures were the aggregate number of children experiencing the following adverse events each month, with each event recorded individually as a separate outcome:

- mortality
- cardiac arrest
- respiratory arrest
- unplanned admission to a paediatric intensive care unit
- unplanned admission to a high-dependency unit
- other medical emergencies requiring immediate assistance
- reviews by paediatric intensive care unit staff.

Analysis

A separate interrupted time series model was fitted on data from each hospital. To model the trajectory for all pre-implementation, implementation and post-implementation periods, two intervention start points were considered:

1. start of the implementation period
2. start of the post implementation period.

Changes of level and of slope at the adjacent time points between pre-implementation, implementation and post-implementation phases were analysed to assess whether or not there was a statistically significant effect.

Exploratory analyses examined changes in level and slope of trajectory by (1) fitting the interrupted time series model on data from the pre- and post-implementation periods only and (2) fitting the interrupted time series model at each individual month of the implementation period to assess the pattern of changes in level and slope from the start of implementation phase until the end, given the potential for the different local initiatives to exert their effects over different time periods in different sites.

Ward case studies

Data

Qualitative data were generated in four ward case studies before and after implementation. This included > 300 hours of observations and 100 qualitative interviews with clinical staff and families.

Analysis

Data were used in a triangulating fashion to develop concrete descriptions of the paediatric early warning system in each ward; local principal investigators contributed to this sense-making process. Cross-case analysis was undertaken to explore relationship between the PUMA programme, context, mechanisms and outcomes.

Programme evaluation

Data

The delivery of and response to the PUMA programme were evaluated qualitatively, using observations, documents and interviews.

Analysis

Data were analysed thematically in relation to the core components of the PUMA programme.

Synthesis

Findings from the interrupted time series were analysed in relation to the qualitative data for each case.

Results

Workstream 1: evidence reviews and PUMA programme development

- Question 1: how well validated are existing paediatric track-and-trigger tools and their component parts for predicting inpatient deterioration?
  The review included 27 studies. Several track-and-trigger tools have been researched, although most are derived from a limited number of tools. No tool has been validated across different settings and many have been bench-tested only.

- Question 2: how effective are paediatric early warning systems (with or without a tool) at reducing mortality and critical events?
  The review included 19 studies. A few studies reported significant changes in mortality or arrests in hospitalised children as a result of a paediatric early warning system intervention; these are typically uncontrolled before-and-after studies, limiting confidence in findings. Three high-quality multicentre studies failed to find any significant reduction in mortality or arrests after paediatric early warning system interventions. There is moderate evidence that paediatric early warning system interventions may reduce unplanned transfers to a higher level of care, but corresponding reductions in hospital-wide or paediatric intensive care unit mortality have not been reported.
- Question 3: what sociomaterial and contextual factors are associated with successful or unsuccessful paediatric early warning systems (with or without paediatric track-and-trigger tools)?
  The review included 82 papers. There is strong evidence on barriers to successful paediatric early warning systems, but limited evidence to recommend the use of specific interventions to improve their effectiveness. Track-and-trigger tools have value but are not the sole solution and depend on certain preconditions for their use. Innovative approaches are needed to support family involvement. Professional judgement is important, but requires a supportive organisational culture. New technologies have widespread impacts on paediatric early warning systems.

Translational mobilisation theory was applied to the systematic review to develop a propositional model specifying the core functions and minimum sociomaterial requirements of a paediatric early warning system (the PUMA Standard). Informed by clinical experts and parents, this laid the foundations for the PUMA programme.

Workstream 2: implementation and prospective evaluation of the PUMA programme

All sites made changes to their paediatric early warning systems aligned with the PUMA Standard. Initiatives were often adjustments to current processes, rather than new, or externally developed, interventions. Teams found alternative approaches when their initial plans could not be implemented. Some initiatives were implemented but never embedded in practice and some initiatives were never implemented. In several cases, initiatives required the negotiation of organisational constraints outside the power of improvement teams. Implementing all selected initiatives was not possible within the available time scales, because of the need to implement them across multiple wards or because of other competing demands on the improvement team. At the close of the study, improvement work was ongoing in several sites.

All sites brought about system changes in reviewing sick children and planning for action so that there was a shared understanding of children at risk. Addressing equipment shortages was also significant in several sites. All sites identified initiatives to implement more systematic approaches to involving parents in detecting and acting on deterioration, but with limited success. Several initiatives that intended to improve situation awareness by enhancing interprofessional co-ordination between nursing and medical teams were abandoned.

Assessing the impact of the PUMA programme on quantitative outcomes was challenging because of the low event rates for hard clinical outcomes. Nevertheless, several of the clearer quantitative findings appeared to relate to qualitative observations. Alder Hey implemented multiple organisational-level changes, mandated in response to a critical Care Quality Commission report, which were associated with significant improvements in clinical outcomes. Morriston implemented several organisational-level system changes at an early stage in the study, which coincided with a decreased slope in adverse event rates. Arrowe Park introduced a safety huddle and electronic recording, which strengthened some aspects of the local system and weakened others. Quantitatively, there was no obvious ‘interruption’ to the adverse event rate over time. Very early in the pre-intervention period, there was a change in ward manager; the new ward manager was keen to reduce high-dependency unit transfers, which may have contributed to declining event rates over the course of the study. Noah’s Ark introduced several initiatives in certain wards, but no organisational-level changes.

The interrupted time series analysis gave a mixed picture; it may have produced a clearer trend if data had been collected over a longer period.

Implementation of the PUMA programme was not a one-shot event, and this created challenges for the interrupted time series in conceptualising the 'implementation' and 'post-intervention' periods. Although we conceptualised the 'implementation period' as being 12 months for each site for the purpose of the quantitative analysis, it is important to reflect that this probably varied between sites, and was less well defined than in some intervention studies.

Although the PUMA programme emphasises context-appropriate approaches to system improvement, certain common standards may have value. First, clinical expertise is an essential component of any paediatric early warning system, and staff turnover has potentially disruptive effects. Professional development is, thus, a critical component of all systems. Second, lack of access to appropriate equipment affects the system negatively. Ensuring that equipment is available and functioning is a prerequisite of any paediatric early warning system. Third, all sites recognised the importance of involving parents in detecting and acting on deterioration, but had limited success in implementing changes to the system. Parental involvement in the detection of deterioration is difficult to address outside wider strategies to facilitate parental involvement in children's care.

Although many of the changes implemented in Alder Hey were not formally identified as PUMA initiatives, they were in alignment with the areas of improvement identified in the site's self-assessment of their system and show how mandated organisational-level system change can have positive impacts. Other sites did not receive the same level of organisational sponsorship.

The study underlines the dynamic qualities of paediatric early warning systems, with several sites experiencing changes not formally included in their improvement programmes, but as a result of changes in the wider organisational context. These findings point to the value of regular assessment of system functioning.

Determining the impact and effectiveness of the PUMA programme using quantitative measures of inpatient deterioration was challenging. The findings lend weight to debates about the appropriateness of downstream individual-level outcome measures in this field and point to the need to reach agreement on upstream indicators of paediatric early warning system performance.

The PUMA programme was developed with reciprocal learning between the site leads and the research team informing the refinement of materials. Although this allowed us to adjust the programme in the light of experience, it created uncertainty for team leads in implementing the programme in their organisations, which required higher levels of facilitation than originally planned. The final version of the PUMA programme was piloted with three additional sites, adding confidence in the feasibility of the approach. However, the overall findings lend weight to the findings of others of the importance of investment in improvement skills in health care and in ensuring that teams have resources and organisational-level support.

Conclusions

Although there is little evidence for the effectiveness of any specific tool in reducing mortality or critical events, paediatric track-and-trigger tools do have value as mechanisms for co-ordinating action across clinical teams. Paediatric track-and-trigger tools depend on certain preconditions for their use, however, and should be implemented as part of a wider systems approach.

Locally led service improvement is challenging without adequate resources, skills and organisational support, and alternative outcome measures are required to support research and quality improvement

efforts in this context. The findings from Alder Hey, where system-level change was mandated in response to the Care Quality Commission report, show that organisational-level whole-systems change can bring about positive impacts on clinical outcomes.

The PUMA programme offers a framework for ongoing improvement of paediatric early warning systems. The OUTCOME approach has potential to be used more widely to address other areas of health care in which system complexity poses risks to service quality and patient safety.

Further research

- Consensus study to identify upstream indicators of paediatric early warning system performance.
- Evaluation of OUTCOME improvement approach in other clinical areas.
- Evaluation of a supernumerary nurse co-ordinator role in paediatric early warning systems.
- Evaluation of mandated system improvement.

Study registration

This study is registered as PROSPERO CRD42015015326.

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