



BMJ Open Family role in paediatric safety incidents: a retrospective study protocol

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ABSTRACT

Introduction Healthcare-associated harm is an international public health issue. Children are particularly vulnerable to this with 15%–35% of hospitalised children experiencing harm during medical care. While many factors increase the risk of adverse events, such as children's dependency on others to recognise illness, children have a unique protective factor in the form of their family, who are often well placed to detect and prevent unsafe care. However, families can also play a key role in the aetiology of unsafe care.

We aim to explore the role of families, guardians and parents in paediatric safety incidents, and how this may have changed during the pandemic, to learn how to deliver safer care and codevelop harm prevention strategies across healthcare settings.

Methods and analysis This will be a retrospective study inclusive of an exploratory data analysis and thematic analysis of incident report data from the Learning from Patient Safety Events service (formerly National Reporting and Learning System), using the established Patient Safety classification system. Reports will be identified by using specific search terms, such as *parent* and *mother*, to capture narratives with explicit mention of parental involvement, inclusive of family members with parental and informal caregiver responsibilities.

Paediatricians and general practitioners will characterise the reports and inter-rater reliability will be assessed. Exploratory descriptive analysis will allow the identification of types of incidents involving parents, contributing factors, harm outcomes and the specific role of the parents including inadvertent contribution to or mitigation of harm.

Ethics and dissemination This study was approved by Cardiff University Research Ethics Committee (SMREC 22/32). Findings will be submitted to a peer-reviewed journal, presented at international conferences and presented at stakeholder workshops.

INTRODUCTION

Healthcare-associated harm is a protracted public health issue.^{1–3} Children are particularly vulnerable to this, with approximately 15%–35% of hospitalised children coming to harm as a result of receiving medical care, known as an adverse event.⁴ This vulnerability to healthcare-associated harm is considered to be the result of a complex interplay of

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This is the first national study exploring the parental role in paediatric safety incidents across healthcare settings.
- ⇒ It will employ a rigorous methodological approach with trained clinicians systematically coding reports using an internationally established patient safety classification system.
- ⇒ A new mitigatory factors framework will be created to capture and classify this important and understudied component of paediatric safety.
- ⇒ The limitations of incident report data such as under-reporting, varying quality and detail in the reports, reporting bias and being written mostly by healthcare professionals may limit the breadth of safety incidents available for analysis and learning and does not capture the parental perspective
- ⇒ Reports relating to mitigating parental factors may be less likely to be reported if no subsequent incidents or related harm occurred.

factors, including children's dependency on others to recognise illness, seek healthcare input, recognise unsafe care and advocate for them. In addition, the diverse nature of paediatrics encompassing neonates to adolescents, and the reduced physiological reserve of children, complicates care further.^{5,6} Despite these vulnerabilities to healthcare-associated harm, children have a unique protective factor in the form of their families, parents and guardians.⁷

Families have the potential to play key roles in the nature of unsafe care. For example, studies from the USA and UK highlight that medication errors in the community setting, such as accidentally administering the wrong dose of a drug, often involve parents.^{8–10} Conversely, parents are well placed to detect errors due to their continuous presence, overview of any care received, and extensive knowledge of the child's diagnoses and management plans.^{6–8,11} Khan *et al* have demonstrated the



capability of parents to report errors and highlighted that where parents are permitted to submit safety incident reports, error detection (and reporting) increases and a greater breadth of errors are detected.¹² Similarly, as parents detect errors that may not otherwise be apparent to healthcare professionals, they can provide a differing yet essential perspective on safety.¹² Detecting such incidents also enables parents to prevent errors from reaching and harming their child (so called 'near misses'). A reliance on parents became increasingly relevant throughout the COVID-19 pandemic,¹³ and places them in a unique position to promote and protect paediatric safety.

Measures during the COVID-19 pandemic placed pressure on already constrained care systems. With school closures, remote working for many social services, and altered access to healthcare throughout the UK, support systems in place for children were disrupted.^{14 15} There were reports of substantial delays in accessing specialist input (eg, the proportion of children with a new diagnosis of cancer waiting over 2 weeks to see a consultant more than doubled to 15.7%), increased incidence of child maltreatment, increased childhood obesity particularly for those of low socioeconomic status, and deteriorating mental health among the paediatric population.^{14 16 17} There were reports at a national level of children and families having increased difficulty accessing support for their healthcare^{15 18} resulting in children, young people and their families carrying more responsibility for managing their own health and care than ever before. It is therefore imperative that we better understand the parental role within paediatric safety given the increasing responsibility placed on parents in recent years.

Our experience in critically reviewing patient safety incident reports highlights that there is a vast amount of rich data about what contributed to, and could potentially prevent future similar incidents (eg, contributory and mitigatory factors, respectively). Safer paediatric care must be co-delivered with families. To do this effectively, we need to better understand the current role of families, guardians and parents in paediatric healthcare safety. Understanding the breadth of the family role within paediatric safety is necessary to build effective strategies to tackle their contributory roles, while learning from their ability to prevent harms, and in turn improve the safety of care for children in all settings.

Aim

To explore the parental/family role in paediatric safety incidents reported across care settings in England and Wales.

The objectives of the study are, to:

- ▶ Characterise the nature of parental/family roles described in paediatric safety incident reports, specifically their contribution to incidents and/or their role in identifying and mitigating harm from incidents.

- ▶ Identify and characterise the types of incidents with parental involvement, the level of resultant harm and other clinical outcomes.
- ▶ Corroborate findings with stakeholders to create recommendations around working collaboratively with families to develop harm detection and prevention strategies.

METHODS

Overview

A retrospective study incorporating an exploratory data analysis followed by thematic analysis will be undertaken. This will involve systematically coding incident report data by using and building on the Patient Safety (PISA) framework previously established by Cardiff University,¹⁹ characterising key patterns within the coded data, and thematically analysing a purposive sample of reports to identify explanatory themes. Coding of the reports began in December 2022, with an estimated end date of December 2023.

National reporting and learning system

The National Reporting and Learning System (NRLS (now called the Learn From Patient Safety Events service in England only)) was a national centralised repository of patient safety incident reports from National Health Service (NHS) organisations across all care settings in England and Wales.²⁰ The NRLS received in excess of 65 000 paediatric safety incident reports annually.⁶ Incident reports include both categorical and free-text information capturing key characteristics such as patient age, incident date, incident location, and severity of harm; and descriptions of 'what happened', why reporters think these incidents happened, and how the incidents may have been prevented.

Inclusion criteria and definitions

We will sample reports about patients and service users aged less than 18 years of age. This definition of a child is in keeping with the United Nations Convention on the Rights of the Child and civil legislation in England and Wales. A patient safety incident, defined as 'any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving healthcare'.²¹

Our definition of parent is inclusive of any family member/guardian with parental or caregiving responsibilities. Parental or family 'involvement' in reported incidents includes any role family members are reported to play in the patient safety incident itself, for example, as contributors or mitigators. This includes the mention of parents in recommendations for future incident prevention; parents advocating for their child (eg, by making a complaint when a patient safety incident has occurred or chasing and following-up on appointments); parents distressed by a patient safety incident, including the specific mention of harm outcomes to parents, for example, psychological parental harm from

being contacted about a child death inappropriately; and parents providing additional information about the care their child received to better understand a patient safety incident. This does not include parental involvement by virtue of genetics, for example, incidents related to inherited conditions, parents bringing their children to appointments or parents providing routine medical history (unless this is related to an incident). Finally, involvement does not include parents being informed of a patient safety incident, or safeguarding referrals involving parents (that do not relate directly to a patient safety incident).

Sampling

A study-specific search and sampling strategy has been designed to best meet our aims and objectives. Our study sample is restricted to incident reports submitted between September 2014 and September 2020 across England and Wales involving children aged less than 18 years of age. Reports from primary and secondary care settings are included. To identify reports involving parents we used the search terms below (inclusive of wildcards):

- ▶ *parent*
- ▶ *mother*
- ▶ *father*
- ▶ *mum*
- ▶ *mam*
- ▶ *dad*
- ▶ guardian
- ▶ carer

These searches produced a sample of 205 659 reports. To augment the specificity of our search strategy further, a random sample of 500 reports (taken from the larger sample) were reviewed and only 42.4% (n=201) were included. The findings helped to inform our inclusion criteria and the search strategy was updated as follows:

- ▶ carer (removed as a search term as not sufficiently specific)
- ▶ family (removed as a search term as not sufficiently specific)
- ▶ *parent* NOT apparent*
- ▶ *mum* NOT maximum*
- ▶ *mum* NOT minimum*
- ▶ *mum* NOT optimum*
- ▶ *mother* NOT chemotherap*
- ▶ *parent NOT *parenteral nutrition*

We also excluded search hits for the following phrases:

- ▶ [search term e.g. mother] informed
- ▶ [search term e.g. mother] were informed
- ▶ [search term e.g. mother] has been informed
- ▶ [search term e.g. parents] have been informed
- ▶ [search term e.g. mother] made aware
- ▶ apolog* to [search term e.g. mother]

We also excluded the following categories of reports as they consistently failed to meet our inclusion criteria (using database categorical fields: IN05_lv11 and IN05_lv12).

- ▶ IVI incidents classed as patient accidents.

- ▶ IVI2 incidents classed as slips, trips and falls.
- ▶ IVI2 absconder/missing patient.
- ▶ IVI1 disruptive, aggressive behaviour (includes patient to patient).
- ▶ IVI1 self-harming behaviour.
- ▶ IVI2 self-harm.

This amended search strategy (see online supplemental appendix) produced 133 849 reports submitted between 2014 and 2020 involving children less than 18 years of age. To comprehensively explore the role of families/parents in paediatric safety across care settings and for different groups of paediatric patients, four weighted subsamples (each with approximately 4000 reports) will be created to identify reports from (1) the community setting, (2) the emergency department, (3) in-patient care and (4) the neonatal unit. Each subsample will contain similar proportions of children from different age groups (less than 1 year, 1–12 years, 12–18 years), except the neonatal unit sample which will only contain those less than 1 year of age. All reports of death, severe harm and moderate harm will be included within each subsample and the remaining sample will consist of reports of low harm and no harm in a ratio of 2:1. A fifth subgroup specific to General Practice yielded 1157 reports. To maximise the number of available reports for analysis, this subsample will include incidents submitted up to the end of 2022.

Data coding

All incident reports will be coded according to Recursive Model of Incident Analysis rules.²² This model is used routinely alongside the PISA classification system and supports a structured approach for capturing the content of incident reports systematically.^{19 22} This classification approach permits the application of multiple codes to capture factors contributing to incidents, the chronology and inter-relationship of incidents, and the apparent outcomes.

The PISA frameworks were iteratively developed by the PISA Research Group at Cardiff University and aligns with the WHO International Classification for Patient Safety.¹⁹ This multiaxial classification system is composed of four inter-related frameworks that can be applied to each report to capture the incident types (contributory and principal incident types), contributory factors, incident outcomes and harm severity.^{6 19} The existing PISA contributory factors framework will be expanded to incorporate a parent-specific contributory factors strand.

A new mitigatory factors framework will also be developed for this project. To develop these frameworks, we will employ the same constant comparative method²³ used to develop the original PISA frameworks.^{6 19} Coders will familiarise themselves with a sample of reports, and parental mitigatory factors identified will be discussed at fortnightly team meetings. The framework will be developed, updated and iterated concurrently throughout the study. Additionally, where possible, we will capture the diagnoses of the children included in the incident reports using the International Classification of Diseases-11, and



any medications involved in medication incidents will be classified as per the British National Formulary for Children.⁶

There will be free-text boxes for coders to highlight reports with particularly rich or context-specific information pertinent to the aims and objectives of the study, in addition to enabling us to identify reports where COVID-19 is implicated. These reports, identified concurrently, will undergo a separate thematic analysis to identify new insights and context-specific learning, such as how the COVID-19 pandemic may have impacted the role of parents in paediatric safety incidents. These reports will be reread for familiarisation by two clinicians, and new codes will be created to capture contextual, semantic and latent insights. These will be grouped into themes and subthemes to supplement learning from the wider dataset.

All coders will receive in-house method and Human Factors training specific to this project, including how to code incident report data using the Recursive Model for Incident Analysis²² and use of the PISA multiaxial coding frameworks. All reports will be coded by a healthcare professional working within either primary care or paediatrics.

Inter-rater reliability checks will take place between the coders for each subgroup, whereby a random 10% sample of each coder's reports are allocated to another coder for double-coding,¹⁹ ensuring consistency and validity of coding. The kappa coefficient statistic (applied to the principal incident type) will be used. We would aim for a k statistic of >0.7 and where the k statistic drops below this level, discrepancies would be highlighted for discussion and resolution at the team meeting. There is an established fortnightly team meeting where coders can discuss difficult reports, resolve any double-coding discrepancies, suggest the creation of new codes, discuss amending the definitions of codes and discuss themes or patterns emerging from the results.

Data analysis

The coded data will be described and summarised. Exploratory data analysis techniques will be employed to explore patterns in the data and the relationship between codes, for example, by using cross-tabulations.⁶ The presence and frequency of these patterns will be used to determine key learning points on the role of parents in paediatric safety. Recommendations will be developed to specifically target problem priority areas identified and to learn from and spread positive examples of parental involvement in paediatric safety. Recommendations will be informed by the literature, insights about the parental contributory and mitigatory factors for specific types of incidents, and discussions with our patient and public involvement and engagement (PPIE) and stakeholder groups.

Patient and public involvement and engagement

Healthcare safety is a parental priority as evidenced by its inclusion in the Core Outcomes in Neonatology which

was co-produced with parents.²⁴ This was also apparent through our discussions with parents on the expert patient advisory group previously assembled for the PISA study (NIHR HS&DR 12/64/118).

The findings of our previous paediatric studies (utilising NRLS data) were discussed and corroborated with a parent advisory panel. A key message from these consultations was the need to explore further the role of parents in paediatric safety since this was a recurring theme. The FRIEND study was conceived from those consultations. The PISA methods (to be employed in this study) were co-developed with a patient advisory group convened for the PISA study (NIHR HS&DR 12/64/118).

This protocol has also been developed in partnership with PPIE representatives (recruited through Health and Care Research Wales), all of whom have experience of accessing healthcare services while caring for children. Their guidance has ensured the perspectives and experiences of the public have been incorporated into our work. This has been essential in improving the relevance and quality of our research. They will help advise on the development of stakeholder workshops for the study, which will include parents with differing experiences of paediatric healthcare (from the community, primary care, hospital and neonatal care settings). PPIE advisory meetings will be held quarterly to explore study results as they emerge, ensure that the parental voice is present in the interpretation of results and in the generation of recommendations during workshops and in any study outputs and dissemination plans.

Corroboration of findings with stakeholders

Findings from the incident report analysis and recommendations will be presented at stakeholder workshops, including parents, children, healthcare staff, patient safety experts and policy representatives. Stakeholders will discuss the prioritisation and implementation of recommendations around utilising family partnership to improve paediatric healthcare and to formulate a dissemination strategy.

Anticipated outcomes and impact

This will be the first national study of the role of parents, family, and guardians within paediatric patient safety. It will provide an understanding of the priority areas for partnership with parents to improve the safety of children receiving healthcare. This study will highlight key contributory roles of parents for redress, and underscore the various ways that parents successfully promote and protect their children from healthcare-associated harms. We anticipate that this will provide specific learning about how to better work with and support parents to promote paediatric safety for children of different ages, with different conditions and in different care settings. This will become increasingly important as the NHS recovers from the COVID-19 pandemic and future-proofs services to return to and surpass prepandemic provision. The FRIEND study will enable the generation of

recommendations for parents, healthcare professionals, healthcare services and professional bodies, such as the Royal College Paediatric and Child Health (RCPCH) and the Royal College of General Practitioners (RCGP), about how to partner with parents to improve paediatric safety.

We will develop and use a mitigatory factors framework to better understand how we can leverage positive examples of parental involvement to improve safety on a wider scale.¹⁸ This will represent a considerable methodological advancement in the field of patient safety and pave the way for further studies to use this approach when analysing incident report data in the future.

Dissemination

The learning from this study will be disseminated via a range of routes to target a variety of different stakeholders. The results will be published in an open-access journal with a view to reaching healthcare professionals, patient safety experts and people working in the field of quality improvement. Key findings and recommendations will be presented at national and international conferences to raise awareness among stakeholders, and we will work closely with the NHS to disseminate the findings.

We will co-create materials, such as infographics, lay summaries and short videos, with our PPIE advisory panel and formulate a plan for their circulation to reach parents and children. These materials will also be circulated to key organisations, such as the RCPCH and the RCGP. We envisage developing educational materials for parents like the online booklet ‘When should I worry?’,²⁵ developed by PRIME Centre Wales which is used in general practitioner practices. We will work with and seek endorsement from organisations, such as the RCGP, to create, implement and evaluate learning materials, which could be made available to members.

Lay summaries and infographics will be disseminated via social media and press-releases, highlighting key study findings to the general media. We will work closely with the Cardiff University and University College London knowledge dissemination and impact leads to raise awareness of the study with the public.

Ethics

This study has been approved by Cardiff University Research Ethics Committee. SREC reference: SMREC 22/32.

Data protection and management

A data sharing agreement between Cardiff University and NHS England is in place for this study. Procedures are in place to anonymise the data sent to the study team by NHS England. All data generated or analysed during this study will be available from the authors on reasonable request.

Twitter Thomas Purchase @T_Purchase_GP

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Contributors PR and AC-S developed the study concept. PR and AC-S designed the report data extraction strategy and analysed the initial data. PR, AC-S and TP developed the study design and methods. SH managed the data retrieval. PR and TP prepared the initial draft of the manuscript. All authors reviewed and commented on the design and methodology. All authors read and approved the final manuscript. PR and TP contributed equally to this paper.

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