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Mitigating healthcare harm amongst vulnerable children in primary care: mixed methods  
analysis of national safety reports

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**Contributors statement page**

Dr Adhnan Omar carried out the primary coding, undertook the thematic analysis, drafted the initial manuscript, and reviewed and revised the manuscript.

Dr Alison Cooper completed the double coding, discussed coding queries at weekly team meetings, and reviewed and revised the manuscript.

Drs Huw Williams and Huw Evans discussed coding queries at weekly team meetings and reviewed and revised the manuscript.

Drs Philippa Rees, Peter Hibbert, Prof Meredith Makeham, Gareth Parry, Prof Sir Liam Donaldson, and Prof Adrian Edwards critically reviewed and revised the manuscript.

Dr Andrew Carson-Stevens conceptualised and designed the study, coordinated and supervised the project, acted as arbitrator in the double coding process and reviewed and revised the manuscript.

All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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**Abbreviations:** NRLS – National Reporting and Learning System; EDA – Exploratory Data Analysis; WHO – World Health Organisation

## **Mitigating healthcare harm amongst vulnerable children in primary care: mixed methods analysis of national safety reports**

### **Abstract**

#### **Purpose**

Patient safety failures are recognised as a global threat to public health, yet remain a leading cause of death internationally. Vulnerable children are inversely more in need of high quality primary health and social-care but little is known about the quality of care received. Using national patient safety data, this study aimed to characterise primary care-related safety incidents amongst vulnerable children.

#### **Methods**

This was a cross-sectional mixed methods study of a national database of patient safety incident reports occurring in primary care settings. Free-text incident reports were coded to describe incident types, contributory factors, harm, and incident outcomes. Subsequent thematic analyses of a purposive sample of reports was undertaken to understand factors underpinning problem areas.

## **Results**

Of 1,183 reports identified, 572(48%) described harm to vulnerable children. Socio-demographic analysis showed that included children had child protection-related (517, 44%); social (353, 30%); psychological (189, 16%) or physical (124, 11%) vulnerabilities. Priority safety issues included: poor recognition of needs and subsequent provision of adequate care; insufficient provider access to accurate information about vulnerable children, and delayed referrals between providers.

## **Conclusion**

This is the first national study utilising incident report data to explore unsafe care amongst vulnerable children. Several system failures affecting vulnerable children are highlighted, many of which pose internationally-recognised challenges to providers aiming to deliver safe care to this at-risk cohort. We encourage healthcare organisations globally to build on our findings and explore the safety and reliability of their healthcare systems, in order to sustainably mitigate harm to vulnerable children.

## **Introduction**

For almost two decades unsafe care has been recognised as a global threat to public health, yet healthcare-related harms remain a leading cause of death internationally.(1,2) Children are particularly at risk of poor quality care and subsequent healthcare harm: a US study highlights that only 47% of children receive high quality primary care; and in the UK 26% of child deaths have identifiable care failures.(3,4) Vulnerable patients such as those with disabilities, safeguarding concerns or those receiving social care, are at an even greater risk of unsafe healthcare, by virtue of their physical, psychological, social or child protection needs.(5–7)

Rates of placement in out-of-home care have increased internationally over the last two decades.(8) Each year, as many as 16% of children are physically abused, up to 10% experience penetrative sexual abuse and 10% are neglected or psychologically abused.(7) Almost a third of UK children either live in poverty, with disability, are on the child protection register or under the care of local authorities; all of which are widely accepted as markers of vulnerability.(9–11) These vulnerable children are inversely more in need of high quality health and social care, to counteract the lifelong deleterious impacts of adverse childhood experiences.(6,12,13) Despite growing populations of vulnerable children globally, there have been no studies of the burden of unsafe care amongst this cohort.(14,15)

Interrogation of incident report data can yield important learning.(16–18) Systematic identification of reported error patterns and their contributory factors, can highlight system issues amenable to redress – which can form the basis of targeted improvement efforts to effectively

improve safety.(19) We therefore aim to explore the safety of primary care provided to vulnerable children in the UK, by interrogating national patient safety data.

## **Method**

### **Study design**

This cross-sectional study used established mixed methods to analyse patient safety incident reports submitted to a national database. The mixed methods process involved three phases: coding reports; exploratory data analysis; and thematic analysis.

### **Data Source**

Data on vulnerable children seen in primary care were extracted from a database of patient safety incidents reports received from National Health Service facilities in England and Wales. This national database (the National Reporting and Learning System- NRLS) was established in 2003 and remains one of the largest national repositories of such data in the world. A patient safety incident is defined as: “Any unexpected or unintended incident[s] that could have, or did, lead to harm to one or more patients”.(20) Each report captures structured categorical information such as patient age, incident location, date of occurrence, and severity of harm outcome.(21) In addition, there are free-text fields where reporters describe what happened, why they think it happened, and how they think it could have been prevented.(22) It has been mandatory to report incidents resulting in severe harm or death since 2010, but healthcare professionals are expected to report all observed safety incidents.

### **Definition of vulnerability**

Our definition of vulnerability was informed by the literature (Appendix 1) and included “Children under the age of 18 years, who are more susceptible to welfare loss above the socially accepted norm if faced with adversity, without provision of additional support services.” This includes children who are as socially, psychologically or physically vulnerable; or vulnerable due to child protection risks. These categories are not mutually exclusive.

### **Study population**

The free-text of 270,000 reports exclusively from primary care settings was searched using a list of key terms to identify reports involving vulnerable children (Appendix 2). Reports were reviewed by one of the authors against the inclusion and exclusion criteria. Reports were included if involved children under 18 years old, occur in primary care and involved a child defined as vulnerable as above. Reports of patients beyond the allocated age group, without free-text description or Incidents occurring in secondary care but are reported in primary care were excluded.

### **Coding reports**

A classification system (a series of related coding frameworks), aligned with the WHO International Classification for Patient Safety, and previously developed by the Primary Care Patient Safety (PISA) Research Group at Cardiff University was used.(16,23) Codes were applied systematically to reflect the chronology of the described incident (see Figure 1). To model the sequence of events culminating and contributing to an incident we adhered to the framework of the Recursive Model of Incident Analysis.(24) Primary incidents included those proximal (chronologically) to the patient outcome, whereas contributory incidents included those



that contributed to the occurrence of another incident. Multiple codes for incident type, contributory factor, and incident outcome were applied to each report where possible to deconstruct free-text narratives of reports and capture what happened, perceived contributory factors and outcomes.(25) This permitted modelling of the steps preceding and leading to the incident which resulted in harm to the patient (Figure 1).(24)

Figure 1. Examples of codes from the classification system using the Recursive Model of Incident Analysis

Reports were coded by one of the authors, and for methodological rigor a random sample 20% of reports were independently double coded by another author for every 500 reports coded. If disagreements arose they were arbitrated at weekly meetings with the research team trained in root cause analysis and human factors.(26)

### **Exploratory Data Analysis**

We used Exploratory Data Analysis to describe and summarise data in order to inform hypotheses about the most frequent and harmful reported incidents, contributory factors, and outcomes.

### **Thematic analysis**

We identified priority areas for improvement based on exploring a purposive sample of the most frequently harmful incidents and those resulting in serious harm or death. Two of the authors (AO and ACS) independently re-read the reports and re-examined groups of similar incidents to

understand the underlying contextual issues. From this process, causal themes and subthemes of safety failures were identified within clusters of codes. These could not have been captured in the initial phase of coding. The potential interventions to improve unsafe situations were generated by reflecting on the nature of the factors contributing to them. Our theory for improvement – which is grounded in the data – is illustrated in a driver diagram (Fig 2).(27)

### **Ethical approval**

Aneurin Bevan University Health board research risk review committee waived ethical approval (ABHB R and D Ref number: SA/410/13).

### **Results**

The search strategy identified 2,015 reports, of which 1,183 met the inclusion criteria. Of the 1,183 vulnerable children whose care was the subject of a patient safety incident report, about half were reported to have suffered some degree of harm (n=572, 48% of reports).

Children who were the subject of child protection concerns (n=517, 90%) were most frequently reported as experiencing harm from unsafe care. Additional vulnerable children experiencing substandard care included orphans, migrants and looked-after children (n=353, 62%), children with poor mental health or learning difficulties (n=189, 16%) and children with physical disabilities (n=124, 11%)(Table 1). As Table 2 shows, there were three broad themes underpinning the healthcare harm experienced by these children: failure to recognise care needs and intervene appropriately (n=642, 54%); information transfer and documentation failures (295 reports, 25%); and referral failures between health and social care services (218 reports, 19%).

Table 1. Overview of included reports

Level of Harm of included reports	Number of reports n (% of total number of reports)
No harm	611 (52)
Low harm	462 (39)
Moderate harm	81 (6)
Severe Harm	27 (2)
Death	2 (0)
Type of vulnerability described in reports	
Child protection	517 (44)
Social	353 (30)
Psychological	189 (16)
Physical	124 (11)

Table 2. Amount of harm associated with different safety failures

Area of safety failure: broad themes within incident reports	Specific safety failures within incident reports: sub-themes	No Harm (% of sub-theme)	Harm (% of sub-theme)	Moderate or Severe (% of subtheme)	Total, n (% of total reports)
Failures to recognise care needs and intervene appropriately	Inadequate planning of health or social interventions	126 (68)	51 (27)	10 (5)	187 (16)
	Failure or delayed recognition of children in need	87 (53)	47 (29)	28 (18)	162 (14)
	Errors in completing standard assessments or investigations	45 (35)	65 (51)	18 (14)	128 (11)
	Treatment and medication: errors	23 (27)	45 (53)	18 (20)	86 (7)
	Difficulty accessing or engaging with healthcare providers	32 (65)	11 (23)	6 (12)	49 (4)
	Inadequate provision of essential equipment	13 (43)	17 (56)	0	30 (3)
Information transfer and documentation failures	Medical documentation errors	74 (67)	36 (32)	1 (2)	111 (9)
	Information sharing errors	64 (67)	29 (31)	2 (2)	95 (8)

	Poor management of patient healthcare appointments	35 (73)	12 (25)	(2)	48 (4)
	Communication errors (face to face)	7 (17)	29 (71)	5 (12)	41 (4)
Referral failures between health and social care services	Delayed or incomplete referral of patients between services	71 (42)	78 (46)	20 (12)	169 (14)
	Breaches of confidentiality	19 (39)	29 (59)	1 (2)	49 (4)
Other	Unprofessional conduct of healthcare providers	15 (54)	13 (46)	0 (0)	28 (2)
Total		611 (52)	462 (39)	110 (9)	1183 (100)

Poor recognition of vulnerable children's health and social care needs, and subsequent failure to meet these needs and provide adequate care was a commonly described issue (n=642, 54%). Many of these children were described as suffering subsequent harm including 80 cases of moderate or severe harm, and 236 cases of low harm. Failure to identify the needs of vulnerable children frequently stemmed from delays conducting essential health assessments such as the annual Looked-after Child review, a mandatory assessment required for all children living in social care (n=128). Consequently, the needs of vulnerable children including their safeguarding needs went un-assessed, undetected and unmet (n=162). For example, children with complex specialist care needs such as tracheostomy care or wheelchair access were sometimes unable to access these resources (n=30) (Table 3, Example 1). A range of contributory factors underpinned these failures: children had difficulty accessing the appropriate service (n=48), parents and carers had poor knowledge about which services they should access or how to access them (n=49), and this was compounded by language barriers for non-English speakers (n=76). Staff also had

varying knowledge of the local processes around accessing additional care (Example 2). This resulted in children suffering long delays waiting for appropriate assessment and care (n=53).

Poor information transfer between services (n=29, 25%) especially about child protection risk was a commonly reported issue. This resulted in harm to children including 9 cases of moderate/severe harm and 106 cases of low harm. Failures included transfer of incorrect patient information, such as children's status on the child protection register (n=67) (Example 3); and incomplete transfer of essential information such as child protection plans or details of clinical needs (n=295). These failures occurred during verbal information transfer/ communications such as multi-disciplinary case conferences (n=41) (Example 4) and via electronic and paper-based information transfer for example record sharing (n=95) (Example 5). Key contributory factors underpinning these failures were changes in patient address, particularly amongst looked-after children who often moved address several times, which led to difficulties registering for care and transferring medical records (n=45). Healthcare providers faced difficulty ensuring the presence of key health and social care staff at child protection case conferences (n=67), often due to shift constraints and excessive staff workload (n=39). These children consequently had delayed reviews and delayed creation of safeguarding plans (n=39), leaving them in the community with out-dated care and protection plans (n=127). In extreme cases at-risk children were left in unsafe environments with guardians who had previously had children removed from their care (Example 6,7).

Most reports describing failures in referrals between health and social care services (n=219, 19%), also described harm to children including 107 cases of low harm and 21 cases of moderate

or severe harms. The nature of these children’s health needs meant they were often involved with multiple social, health visiting and child protection services (n=106). Referrals from secondary services to community health visiting services (n=86) (Example 8), and from child protection service to community professionals (n=62) such as community nurses, were reported as incomplete, delayed or not received (n=66) (Example 9). The complex nature of these children’s needs was a key factor contributing to this problem (n=97) as they often required simultaneous involvement and collaboration of multiple providers. Paper-based referral systems were also culpable as paper referrals were frequently lost, completed illegibly, or sent to the wrong place (n=54). Whilst these referral issues were on-going, affected children deteriorated clinically (Example 10) and were left inadequately protected in vulnerable situations (n=67) (Example 11).

Table 3. Example reports

<p>Example 1. Discharged patient home following acute hemiparesis. Patient discharged without access to a wheelchair or appliances to improve mobility. Patient requires high level of rehabilitation that cannot be fully met by the community team.</p>
<p>Example 2. [Child’s Guardian] called about [patient] who had returned from a visit to her [parent’s home] with vaginal pain and offensive discharge. Her behaviour had altered over the past month crying a lot and having nightmares. [Guardian] concerned that she has been sexually abused. Call assessed by nurse [out of hours primary care centre] and sent through to a GP [out of hours primary care centre] but did not include a clinical summary for GP highlighting the concerns. No referral made to social services.</p>
<p>Example 3. Following discharge from hospital visit for bruising, on [date]. Child was not noted as ‘at risk’. The child’s health deteriorated and required subsequent re-hospitalization. Later checks identified the mother’s current partner has history of abusing children – no safeguarding measures had been undertaken in discharge planning.</p>
<p>Example 4. Information received from [Nurse] in safeguarding team that she attended an initial safeguarding conference on [date] which raised concerns of missed opportunities from health regarding the welfare and protection of a child. It was deemed the child was suffering chronic neglect and the [nurse] was concerned that this child had not had all possible opportunities explored. Procedures had not been adhered to regarding failed visits</p>

<p>and significant events, and subsequent seeking of supervision, which led to a delay in neglect being recognized and acted upon.</p>
<p>Example 5. Request for records received from [police] as part of investigation into serious assault on a child. On reviewing the child's record to fulfil the police request, concerns were raised that no child protection referral had been made for this call at the time it was taken and following the nurse assessment. The child was subsequently taken to hospital and found to have a number of non-accidental injuries.</p>
<p>Example 6. Due to mother's previous history it was decided the baby would be removed at birth for protection. From conference on [date] there has been no communication from Social Services regarding the mother and unborn child. Birth notification arrived from Child Health Dept and we have statutory obligation to visit. We are unaware of baby's whereabouts. Hospital contacted - stated baby has gone to [location] - no address available despite original planned interventions.</p>
<p>Example 7. Baby was brought to see GP by mother with several problems including a burn-like mark. Entry was made in clinical notes detailing 'burn-like' lesion with cause unknown. No further action was taken. Another member of staff saw the entry and realized the child had recently been taken off the child protection register and the mother had already had [several] children taken from her.</p>
<p>Example 8. Referral by midwives regarding cannabis use by a mother during pregnancy was received but not acted upon by health visitors. Baby went on to develop and die from a [cancer] which is recognized as being linked to recreational drug use in pregnancy. There is no record of baby being seen by health visitors after new birth visit; however, she was seen several times at the GP surgery for developmental checks at six-to-eight weeks and for primary immunizations. This omission was picked up during child protection supervision when records were reviewed following the baby's death.</p>
<p>Example 9. Informed on [date] by the children's community nursing team that [patient] had been discharged home from [hospital] with a nasogastric tube in situ. We had not been informed by the hospital dieticians or the ward, therefore we did not know what feed and equipment [the child] required and had not registered [the child] with [name of professional] for delivery of equipment for feeding via her nasogastric tube. Attempted to visit patient but could not gain access. On second visit, we discovered mum spoke no English and dad speaks very little. They had run out of syringes for feeding but were using syringes given to them by the community nurses. Both parents were very anxious about the situation.</p>
<p>Example 10. This patient has been waiting for 12 months to be seen in the enuresis clinic since referral. There has been another referral from another agency since the first referral. The patient's mother has informed me that enuresis problem is really affecting [the child] as it is worsening [the child's] behaviour problems and is currently [receiving care from] the Community Learning Disability Nurse. I have now apologized to mum for the long wait and have now managed to discharge a patient who is now dry and I have now given the patient an appointment for [date].</p>

**Example 11.**

While in a multi-agency meeting I identified that the child being discussed had been lost to follow up in pediatrics. Last seen in my clinic with four-month follow up recorded on system and letter. Went into system but no further appointments have been made. Has developmental issues, but also growth issues, that may need endocrine referral which potentially will have been delayed by this.

**Discussion**

This study is the largest analysis of patient safety incidents reports describing the nature and burden of unsafe primary care for vulnerable children. Our findings point to major areas of systemic weakness in the care provided. This puts children - who are already subject to the harmful impact of childhood adversity - at risk of further iatrogenic harm from unsafe care.

The comprehensive and detailed methods for analysing incident reports have also been applied to secondary care incident reports,(21) as well as other studies in primary care.(16,22) The quality and utility of safety incident reporting systems are heavily dependent on reporting staff, and underreporting is a well-acknowledged issue with the NRLS.(28) This study is therefore hypothesis generating and inductive in nature, requiring confirmation with further studies. However, the concurrent mixed method approach better enables prioritisation, understanding, and exploration of issues identified by frontline staff and offers important insights which can be interpreted alongside additional complementary data sources, to inform and target improvement efforts.(26,29)

All children are by their nature vulnerable, but from our study population, it is clear that the most pronounced reported healthcare-related harm relates to those with child protective service involvement. Case reviews of child deaths highlight that early recognition of needs and



safeguarding intervention can dramatically improve outcomes for vulnerable children by removing them from harmful and violent home environments and providing extra support in the home.(30) Terrell et al. highlight similar challenges with the provision of timely health assessments for looked-after children in the USA, as a result of issues coordinating care, incomplete and delayed referrals for assessment, documentation issues and appointment availability.(31)

Our study is consistent not just with previous studies of health and social care provision for children but also repeated criticisms of regulators and external reviews that failures occur because of inadequate information sharing between services. In the UK *The Health and Social Care Act* (32) resulted in better integration of information for adult users of health services, but not children, despite clear evidence from reviews of serious harm and death that this is a serious weakness.(10,33)

Vulnerable children, by virtue of their greater needs are involved with multiple services. The complexity of their care coordination is greater.(34) Our findings highlight the difficulty of interactions between hospital and community teams. Children often faced worse health outcomes because of poor quality referrals.(35) They could even be said to be victims of the “inverse care law”, because although they are more in need of safe care they are also less likely to receive it.(6,25)

Although patient safety incidents affecting children may seldom be fatal, in our study almost half caused some level of harm. There are calls to give these events in childhood as much importance as is given to other serious public health issues with lifelong sequelae.

From our analysis, exploring causation of patient safety incidents and the resulting harm, we moved to using improvement science methods and tools to identify a set of strategic actions to strengthen the care for this group of vulnerable children. These are shown (*primary drivers*) in the Driver Diagram (Figure 2). Recognising health and social care needs earlier, with better transfer of information across care and institutional boundaries, and improved efficiency of referrals, could reduce the risks of further harm to these vulnerable children. The secondary drivers denoted in the driver diagram – exemplify specific actionable recommendations that could help bring about the necessary improvements detailed in the primary drivers.

Figure 2. A driver diagram illustrating our theory for improving the safety of care for vulnerable children in primary care settings

Our findings support calls for shared and contemporaneous databases containing health and social records to mitigate harms from out-of-date and inadequate care plans that leave children in vulnerable situations. Referrals of at-risk children to the necessary services could be improved through the use of patient referral checklists(36) or where systems allow electronically generated and transmitted referrals containing agreed data items.(36,37) Training staff to identify signs of abuse or neglect and clarifying guidelines for assessing and managing at risk children alongside safeguard alerts and safety checklists will all allow earlier recognition and thus intervention for

children that are currently going undetected.(38–40) These represent higher-level recommendations that address healthcare systems rather than relying on humans who are more susceptible to error. Whilst these changes take longer to implement, in the short-term practitioners can utilise interventions such as screening tools or clinical decision support tools to test in practice until such time reliable system changes can be brought about.(39)

## **Conclusion**

This study highlights health system failures affecting a vulnerable paediatric population, in addition to the numerous challenges facing providers attempting to deliver safe care – many of which are echoed around the globe. Through the application of improvement science methods to our data, we have identified systemic priority areas for action to mitigate healthcare harm amongst vulnerable children. We encourage healthcare-organisations globally to explore the priority safety issues highlighted in this study in the context of their own patient safety data, to empirically inform their own quality improvement efforts to improve the safety of care provided to vulnerable children.

## **What is known on this subject:**

- For over two decades patient safety failures have been recognised as a global threat to public health.
- Vulnerable children are inversely more in need of high quality primary health and social care but national studies frequently demonstrate failures in care.
- At present little is known about the quality and safety of health and social care that vulnerable children receive.

### **What this study adds:**

- This is the first study of national incident report data for vulnerable children in primary care.
- Findings highlight system weaknesses that put children who are already subject to harmful impacts of childhood adversity at risk of further iatrogenic harm from unsafe care.
- Identified priority areas to mitigate harms include improving referrals, enabling greater care continuity and ensuring earlier recognition and intervention to meet child protection needs.

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