While the literature exploring patient safety for children in the inpatient setting is limited, it is recognized that children have unique susceptibilities regarding safety and risk in hospital environments.¹⁻⁴ For children in an inpatient setting, safety and quality issues in hospital care are likely to be compounded for those with complex health care needs and conditions influencing the length of admissions and susceptibility to preventable harms.²⁻⁴ Furthermore, children with intellectual disability have inequities regarding their health care in terms of physical and mental health compounded by...
poorer social determinants. These children are known to experience increased frequency and length of admissions, which makes them more vulnerable to poor experiences of care. While parents and carers have reported the poor care experiences of children and young people with intellectual disability in hospital, there is limited research regarding clinical incidents relating to these children in a hospital context.

Incident data containing contextual factors that may have predisposed, perpetuated, or precipitated the event and concurrent patient safety issues embedded in the reports have not yet been explored and require further investigation. Furthermore, how these risks are identified, reported, and responded to within incident management systems are also unknown.

Incident reporting in hospitals is today routine in most high-income countries including Australia, Canada, Denmark, Ireland, Japan, New Zealand, the Netherlands, Sweden, the UK, and USA. In 2004, an electronic system for incident reporting was introduced in New South Wales (NSW) hospitals. This was based on the Australian Patient Safety Foundation’s Advanced Incident Management System model, replacing past models and adapted to the NSW context. The NSW Incident Management System operates in a similar manner to those from the USA and UK with approximately 64,000 clinical incidents reported annually in NSW. Patient safety incidents are defined as unplanned events resulting in, or having the potential for, injury, damage, or loss, including near misses. Reported incidents are managed by local health district clinical governance units and are aggregated at a statewide level. The aggregated data are then used at a local or state level to identify improvement opportunities and design interventions to prevent incidents reoccurring, thus reducing the risk of harm to patients and improving their care.

This qualitative study used data collected from the incident management system used across two tertiary children’s hospitals within one organization in a metropolitan area, comparing rates of reported clinical incidents in children with and without intellectual disability. An earlier quantitative study, which examined the same data, reported that children with intellectual disability were more likely to have an admission with at least one reported clinical incident, compared to children without intellectual disability. Incident types were extracted from the system by means of a drop-down box of clinical incident types selected by staff when lodging incident reports. The top three reported primary clinical incident types for children with intellectual disability were: (1) medication errors; (2) issues with documentation; and (3) clinical management. In contrast, the top three primary incident types for children without intellectual disability were: (1) medication errors; (2) clinical management; and (3) blood products. The open-ended text components of the incident management reports from the Mimmo et al. study forms the basis of the current study.

This study used qualitative content analysis to examine the open-ended text components of incident reports completed by health care staff for children with and without intellectual disability admitted to hospital for longer than 23 hours.

METHOD

Participants and setting

Open text sections of incident management reports were extracted from a retrospective chart review of electronic medical records that was conducted for 1021 randomly selected patients from a total of 21,337 patients aged 0 to 18 years admitted for longer than 23 hours to two tertiary children’s hospitals in NSW, Australia in 2017. Randomization (1:16 patient) and the process for allocating patients into each cohort (with and without intellectual disability) are described in the original study. The sex and age at admission in children with and without intellectual disability were reported as: 83 (43.7%) versus 507 (43.1%) females and 107 (56.3%) versus 670 (56.9%) males, p = 0.875. Median age was similar for the two groups; children with intellectual disability had a median age of 3 years (IQR: 1–8; range: 0–18). Children without intellectual disability had a median age of 4 years (IQR: 0–10; range: 0–18), p = 0.122. There were 190 admissions of children with intellectual disability (n = 125) and 1177 admissions of (n = 893) children without intellectual disability identified through data extraction. Of these, 211 incident reports were made, 44 for the group with intellectual disability and 164 for the group without intellectual disability. Research ethics approval was granted by the organization’s human research ethics committee (reference no. 2020/ETH2040).

Sample

The sample consisted of 44 reports for children with intellectual disability and 167 reports for children without intellectual disability. A small number of reports (n = 3) not related to clinical care processes were excluded in the group without intellectual disability, leaving a total of 164 reports.
Analysis

Latent content analysis is defined as interpreting what is hidden deep within the text. The researcher’s role is to discover the implied meaning in participants’ experiences. An independent data analysis process was undertaken from the open text sections of the report to identify categories and themes, as well as any similarities or differences that may exist within the context of children with intellectual disability and those without, which was not done in the previous study and are explained further in the text that follows. Text entries were extracted from the hospital incident management system for content analysis. The open-ended texts were analysed by the primary author (NO) using the latent pattern form of content analysis. This method enables the understanding of written clinical information and the inference of clinically significant meaning from these texts from a safety and quality perspective within a paediatric health setting. The primary author also had significant experience working in the hospital setting (20y) with a background in general and specialist paediatric medicine (subspecializing in neurodevelopmental disorders), which allowed her to interpret the reports by applying the lens of paediatric developmental medicine. The reflexivity of the primary author was acknowledged through a bracketing exercise. Bracketing is a method used in qualitative research to mitigate the potentially deleterious effects of preconceptions that may taint the research process.19 A second coder (DB) experienced in qualitative analysis participated in an independent parallel coding process after the initial set of condensed meaning units was derived and the code book created by the primary author. Any discrepancies were discussed and resolved through discussion with the wider research team.

An abductive approach was used. First, after reading each body of text several times for familiarization, an open coding exercise was conducted to derive a set of initial codes (code book using an inductive approach). Subsequent coding using the code book was conducted using a deductive approach. Using an inductive followed by a deductive approach constitutes the abductive approach.20 Table 1 contains the definitions of the terms used in the coding process.

The process was as follows: step 1: the decontextualization stage. Condensed meaning units were derived from the text and then further condensed into codes; step 2: the recontextualization stage. The initial list of codes was used to develop a code book that was subsequently applied to the rest of the data. Additional codes were subsequently derived; step 3: the categorization stage. These codes were subsequently organized into subcategories and categories by the primary author in discussion with the second coder; step 4: the theme generation stage. The underlying meaning and interpretation was sought from the codes, subcategories, and categories (Table 2). Themes emerged from this synthesis (Table S1). The results were discussed with the wider research team and consensus was achieved through a series of discussions. The terms used were based on the taxonomy of unsafe acts.25

Table 1 Terms used in the content analysis and their definitions

| Term                  | Definition                                                                 |
|-----------------------|-----------------------------------------------------------------------------|
| Data immersion        | First, the body of text is read through several times. This is then followed by several iterative rounds of coding |
| Condensed unit of meaning | Several words, a phrase, or a sentence that represents an idea or concept that is condensed and retains the original meaning |
| Coding                | A succinct group of words that represent or describes aggregated condensed units of meaning |
| Category              | Grouping of several codes that are related in either content or context. With larger quantities of codes, subcategories can be used as an intermediate level of grouping |
| Theme                 | Organization of categories that represent an underlying meaning. Themes describe behaviours, experiences, or emotions that emanate from categories |

Table 2 Example of an analysis schedule (open-ended text from an incident management report)

| Category          | Description                                                                 |
|-------------------|-----------------------------------------------------------------------------|
| Meaning unit      | Team charted 150mg lacosamide (daily dose) as per mother’s instructions (antecedent). Dose given at 17:00 on the 30th April 2017 (event). Mother was then present at bedside this morning (1st May 2017) and stated to me that his correct dose at home is 100mg lacosamide (daily dose) (problem identified). Team notified and dose corrected (feedback and resolution) |
| Condensed meaning unit | Team charted medication in error. Medication was given. Mother stated wrong dose and informed team of correct dose. Team corrected the dose |
| Code              | Medication charted and given in error. Mother picked up error. Team corrected the dose |
| Subcategory       | Medication error identified by parent. Issue corrected by staff |
| Category          | Medication error |
| Theme             | Parents identify medication errors. Team are responsive in correcting parent-reported errors |

Results

Categories of clinical incidents

From the process of developing condensed meaning units and codes, 31 subcategories of reported clinical incidents in the group with intellectual disability and 59 in the group without intellectual disability were derived. These
subcategories were subsequently further grouped into categories. Finally, from 11 categories, 10 themes were generated. The Cohen’s kappa coefficient was calculated as 0.96 between the primary author and secondary coder. Table 3 is a summary of the categories ranked from the highest to the lowest numbers and percentages for both groups.

From the analysis, the top three categories for the group with intellectual disability were medication-intravenous fluid issues, communication failures, and equipment issues. The top three categories for the group without intellectual disability were medication-intravenous fluid issues, delayed, wrong, or missed diagnosis, or treatment and communication failure.

When comparing the two groups, medication-intravenous fluid issues (43.18% vs 35.97%), communication failure (15.91% vs 11.38%), deterioration of state (6.81% vs 2.99%), and care issues identified by the parent (13.63% vs 4.79%) were higher in the group with intellectual disability. The percentage of reports of delayed, wrong, or missed diagnosis or treatment was higher for the group without intellectual disability (13.63% vs 18.56%).

However, when subjected to the $\chi^2$ test, we did not find differences between the two groups apart from the care issues identified by the parent category.

In the 44 reports for children with intellectual disability, there were 58 individual clinical incidents with 31.81% of the reports having more than one reported clinical incident. In contrast, in the children without intellectual disability, the percentage was lower, with 22.7% reporting multiple events. A closer examination of the reports showed that the multiple reported clinical incidents were described as co-occurring series of latent and active failures running parallel in a snowball effect. These events can occur contingent on one another but eventuating in multiple adverse events. For example, an infant with abdominal distention and fasted arrived at the ward unbeknown to the staff (active failure/lapse in communication). Therefore, a series of active failures continued to occur: no intravenous line sited for fluids; unable to provide bed space and order tests. Another example involved the receiving ward staff not being informed of a deteriorating patient (active failure), teams in disagreement as to where the patient should be located (latent failure/poor application of transfer policy), which led to delays in patient transfer and timely treatment (active failures).

In relation to closing the loop when a near miss was identified, two reports, one in each group, reported failure to provide feedback after a near miss was found. A near miss can be defined as a hazardous condition where the event sequence can lead to an accident if not interrupted. In the report for both groups (with intellectual disability and without), the section on contributing factors was not consistently completed, for example, 23 out of 44 (52.27%, group with intellectual disability) versus 105 out of 167 (62.87%, group without intellectual disability).

**Themes emerging from the content analysis**

Ten themes emerged from the aggregated condensed meaning units, subcategories, and categories. It was not surprising to observe that there were no differences in the derived themes between the two groups. It was not possible to see if a child’s diagnosis of intellectual disability had any impact on the type and nature of the reported incident. Some themes were more highly represented in one than the other group but overall these themes emerged from both groups. These are listed in Table S1.
DISCUSSION

This study describes an analysis of open text data of incident management reports and the results using latent content analysis. The results show consistency in the highest incidents reported and themes derived for both groups (with and without intellectual disability). The parent-identified clinical incidents were significantly higher in the group with intellectual disability compared to the group without. These findings are not surprising given the similar results with the previous study, which did not find differences in the types of adverse events for the group with intellectual disability compared to the group without. However, what is currently reported is probably an underestimation of the true number of clinical incidents involving children with intellectual disability because of under-reporting. It is interesting that despite this limitation, the category of care issues identified by parents was significantly higher in the group with intellectual disability, further supporting the assertion from the literature reporting parent experience of the role of parental presence in protecting children with intellectual disability from inpatient harms due to clinical incidents. While we have also found similar trends across categories between our data and the results of the previous study, it was not possible to reliably make a comparison given the difference in deductive (Mimmo et al.) and abductive (current paper) methods of categorization.

For both groups, the most reported incident was related to medication or intravenous fluid errors. Our findings suggest that most of the medication errors occurred as a result of errors in prescribing and administration in the context of single medication mistakes in dose, frequency, and duration. Some of the medication errors also occurred in the context of slips (forgot to hand over), equipment (technical glitches in electronic medical health records), errors in documentation and administration influenced by communication, supply and storage, workload, equipment, patient factors, interruptions and distractions, in line with a systematic review of medication errors done by Keers et al. However, we did not have enough information to determine if some of these errors were knowledge-based mistakes or deliberate violations.

Regarding parents identifying clinical incidents, evidence in the literature cites parental reports about being unable to leave a child unaccompanied because of fears that patient safety events may occur in their absence. Parents see themselves as a protective factor to prevent such occurrences from happening. In this study, we found that reports containing parent-identified clinical incidents (total n=14) were found in both groups but were higher in the group with intellectual disability.

While it is known from parent experience reported in the literature that a lack of parent-staff partnerships often contributed to patient safety and risk in this population, this was not highly featured in the reports. While the reason for this is not entirely clear, this could be related to bias since staff may not have considered their issues to be near misses or reportable incidents or were fearful of disciplinary action.

Involving parents and carers in the decision-making process and care of their child in hospital and having staff who are informed and skilled have protective effects. In a narrative synthesis of academic and grey literature by Louch et al., people with learning disabilities experienced poorer safety outcomes in hospital. However, these were ameliorated when family and carers were involved and informed staff were able to meet the needs of people with intellectual disability. A scoping review conducted by Kokorelias et al. found that using a family-centred care approach improved the well-being of those with illness and/or disability and their family/caregivers through mutual inclusion, communication, and partnerships.

A small proportion of reports related to lack of cohesion or disagreements between staff from different departments was observed in both groups. This included staff not wanting to document a procedure or review a patient when requested by another staff member, disagreements about the appropriate care setting of a deteriorating patient, and ignoring requests to adhere to policy despite being informed. This may be related to work cultures within healthcare disciplines. Nurses tend to follow policy and procedures, but medical staff tend to be more discretionary and this discordance plays out in these reports.

While it is important and standard practice to report well-recognized and accepted minor safety incidents, this should not bias staff towards not reporting more serious or major incidents or incidents that do not typically fit patient safety event classifications. The under-reporting of patient safety incidents can reduce the ability of health care systems to accurately measure and affect harm reduction. Reporting mechanisms provide a framework to address issues to prevent them from recurring.

Within an incident management system, the field for entering contributing factors would prompt reflection on the factors that may have led to the event. This was not always completed, thus limiting the understanding of the context and interpretation of the event and increasing the challenge of putting preventative measures or reasonable adjustments in place.

In this study, we observed the relative absence of parent-reported issues particularly around the attitudes of staff, communication, and lack of role negotiation with parents from staff, which dominates the patient and carer experience literature. While an incident management system may not be designed to capture this type of data, more work needs to be done in providing multiple mechanisms to further explore the health care experiences of these children with intellectual disability as a unique group. This would then lead to an enhancement and understanding of health care quality and safety deficiencies for this group and for children generally, providing a variety of ways to raise issues of patient safety in this population.

Only a small number of reports attributed blame towards the patient or parent, for example, a non-verbal or immobile patient contributing to the issue of pressure injury, that the parent was distracted when the fall occurred etc. These attributions seem to neglect the need to look at broader system or
protective factors that may have been absent, and may have played a role in not preventing the incident from occurring. This needs to be examined further in terms of examining prevailing attitudes of staff towards parents and children with intellectual disability. 39

There were variations in results compared to the earlier quantitative study using the same data; the former study used preset categories while the latter study derived data from the open text fields. This could be a result of the capture of classification of primary events that does not fully cover co-occurring events. For example, a report cited a nurse’s request for a medical review, which resulted in a discrepancy in their views on the management of a patient. The surgical on-call team was not informed and the treatment plan was not documented. While this event would be classified under clinical management as the primary incident, it fails to highlight that a significant part of the event also involved communication and documentation failures. This would explain the discrepancies with the percentages derived from the inbuilt clinical incident type classification versus the percentages calculated from the coding process.

Another finding was that there were multiple events in a single report. Higher rates of multiple issues were reported in the group with intellectual disability than the group without. This finding is supported by the literature highlighting the complex nature of health care issues for children with intellectual disability, their higher cost and length of stay in hospital. While the data for increased risk of more than one reported clinical incident in this group were not significant in the Mimmo et al. 17 study, this study supports this finding through its independent analysis.

Study limitations

Since this was a study conducted by a small team of researchers, the methodology chosen was what could be effectively achieved in the time period and with limited resources. In addition, sample sizes were relatively small. More cases and resources to extract and analyse more recent data, including outcome data, are required to look at whether these patterns reach significance and if better ways of addressing these issues need to be developed.

We found that causes or contributing factors were either described superficially or absent, which made it challenging in some reports to establish error causation maps to further understand the data and the relationships between active failure and potential latent failures. 39

There was limited content in the reports of peculiar issues relating to patients in the group with intellectual disability. For example, there was no explanation given for a patient with intellectual disability having no identification band in place. A plausible explanation could be the presence of a sensory issue precluding the patient from accepting the identification band. Finding ways to mitigate the risk by using an alternative identification process could have been put into place with greater clarity of the data.

Conclusions

This study provides contextual insights into clinical incidents as reported in an electronic mandatory reporting system. These events are a combination of active and latent failures interfacing with the clinical incident and patient safety event. Overall, children with or without intellectual disability are vulnerable in hospitals. This study highlights the types of issues identified through qualitative analysis, a range and pattern of adverse events that suggests that certain types of events may be more dominant in the group of children with intellectual disability because of the complexity of their health care needs or their added vulnerability in the hospital setting. Under-reporting may be contributing to the non-significant comparisons.

This highlights the need to raise awareness of improving incident reporting in the context of caring for children with intellectual disability and having better identification systems for staff to mitigate and prevent these issues in the future. The differences found in the parent-identified care issues need to be further explored looking at addressing system and human factor deficiencies to enable reasonable adjustments in clinical practice. In addition, health care staff training and education should include considerations of making incident reports in relation to these issues. When these issues are made visible in the system, authentic and sustained improvements for children with intellectual disability can be embedded into the health care system.

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The data that support the findings of this study are available upon reasonable request from the corresponding author. The data are not publicly available because of privacy or ethical restrictions. Open access publishing facilitated by The University of Sydney, as part of the Wiley - The University of Sydney agreement via the Council of Australian University Librarians.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author.

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SUBJECT INFORMATION
The following additional material may be found online:

Table S1: Content analysis themes and quotes from the incident reports.

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