ORIGINAL ARTICLE



Systematic analysis of adverse incident reports revealed the need for improvements in the neonatal unit

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Abstract

Aim: The aims were to characterise adverse incident reports and recommendations to avoid the reoccurrence of adverse incidents and detect a possible increase in incidents outside of office hours and on vacation season.

Methods: Analysis of adverse incidents reported at the neonatal intensive care unit of Tampere University Hospital in Finland between 2013 and 2020.

Results: Analysis of 925 fully processed adverse incident reports revealed that 36.3% of the reports were related to medication, fluid management and blood products, and 34.8% of these were administering errors. Nurses reported 828 (89.5%) adverse incidents and physicians reported 37 (4.0%). Near misses constituted 35.3% of nurses' and 21.6% of physicians' reports. There were significantly more adverse incident reports on day shifts, on Thursdays and, Saturdays and in June, November and December than at other times. The interventions recommended were to inform the staff or other parties after 673 (72.7%) reports and to recommend improvements after 56 (6.0%) reports.

Conclusion: Analysis of adverse incident reports can reveal the need for improvements in existing protocols in the neonatal intensive care unit.

KEYWORDS

adverse incident, adverse reports, near miss, neonatology, patient safety

1 | INTRODUCTION

The Institute of Medicine published *To Err is Human* in the year 2000 creating awareness of the magnitude of medical errors and the effect of errors on mortality and morbidity in healthcare settings. Since then, several incident reporting systems (IRS) have been developed to improve patient safety and enhance learning from adverse

incidents.²⁻⁴ IRS help healthcare institutions develop changes to prevent further adverse incidents.⁵

Adverse incidents in healthcare are either errors or near miss incidents that can potentially cause harm to the patient.³ In near miss incidents, the chain of events is corrected before harm can come to a patient.³ However, reported near miss incidents can provide information on the risk factors for errors and on the need for improvements.^{6,7}

Abbreviations: HaiPro, Electronic Reporting System for Safety Incidents in Health Care Organisations in Finland; IRR, incidence rate ratio; IRS, incident reporting system; IT, information technology; NICU, neonatal intensive care unit.

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There are differences in the safety incident profiles between different medical specialties⁸ and between paediatric subspecialties.⁹ There are high-risk incidents in neonatal intensive care units (NICU), for instance because of the use of mechanical ventilation, medications and invasive lines.⁶ Earlier reports have suggested that neonates born before 28–32 weeks of gestation are especially exposed to errors in treatment.^{10,11} For these reasons, it is essential to study adverse incidents in NICU settings. The data on the timing of reported adverse incidents is scarce^{5,12,13} and information from recent years is lacking.

The aims of the present study were to (1) characterise adverse and near miss incidents in a tertiary-level NICU, (2) analyse whether the reported incidents occurred more frequently outside of office hours and during vacation seasons than during office hours, (3) study the contributory factors of the incidents and (4) study the recommendations given to prevent reoccurrence of the incidents.

2 | METHODS

This is a retrospective descriptive study of the adverse incidents reported in 2013–2020 at the tertiary-level NICU of Tampere University Hospital. The hospital is one of five university hospitals in Finland. In this hospital, there are approximately 4500 live births each year and approximately 1000 admissions to the neonatal unit, including about 350 admissions to neonatal intensive care.

The Electronic Reporting System for Safety Incidents in Health Care Organisations (HaiPro) was launched in Finland in 2007 and is used in approximately 200 healthcare organisations. ¹⁴ Reporting is done by healthcare personnel, and the system is voluntary, anonymous and separate from patients' medical records.

The person reporting the incident fills a structured form with both categorical and narrative fields. The incident is described, and information is provided about the timing, location and circumstances of the incident. It is possible to give suggestions on how to prevent similar incidents in the future.

Adverse incident reports are processed at the local level by appointed staff members who are well accustomed to the unit's practices. The person processing the reports can further categorise incidents into subcategories and determine the contributory factors of the incident. An incident that was recognised before it reached the patient is classified as a near miss incident, here as opposed to incidents that happened to the patient. There are national guidelines on the HaiPro system on the processing of reports, and for instance, on classifying incidents that happened to the patient into four categories: no harm, and minor, moderate or significant harm. Incidents are also classified according to their consequences to the healthcare unit. Persons processing adverse incident reports may propose interventions to prevent a similar incident from reoccurring.

2.1 | Data selection

A data search of the HaiPro reporting system database was performed for adverse incident reports from the NICU of Tampere

Key notes

- Medication errors seem to be the most common type of reported adverse incidents, and most administering errors seem to cause adverse events to the patient.
- The frequency of adverse incident reports may increase towards the end of the week and during vacation seasons.
- Analysis of adverse incident reports and recognition of contributory factors may help in developing interventions to improve patient safety.

University Hospital. Before 2007 and during the first years of HaiPro, a separate local reporting system was still in use. We excluded the data from the transition years from the previous system to HaiPro and included data from 2013 to 2020.

2.2 | Statistical analysis

Data processing was carried out with IBM SPSS Statistics for Windows, version 28.0 (IBM Corp.).

 X^2 test was used when categorical variables were analysed. We used a significance level of 0.05 for the p-value.

Poisson regression analysis was used for analysis of the total amounts of adverse incident reports during different days, months and working shifts. The incidence rate ratio (IRR) was calculated using the time of the lowest frequency of reports as a reference. Eventually, for days of the week, for months and for working shifts, Wednesday, February and night, respectively, were used as the reference group.

3 | RESULTS

Between 2013 and 2020, a total of 1090 adverse incidents reports were recorded. We excluded 165 reports because of their unfinished state of processing, so a total of 925 reports were included in the analysis.

3.1 | Characteristics of the incidents

One third of the incidents were related to medication, fluid management and blood products, and a third of these were classified as near miss (Table 1). Nursing practice and monitoring was the second most common type of incidents, followed by communication and device-related incidents, respectively. The most common subcategories of medication, fluids and blood products incidents were administering errors, followed by preparation errors and dispensing errors, while 9.8% were prescription errors (Table 1). There were 144 reports where a specific medicinal product was mentioned, 87 reports regarding fluid

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TABLE 1 Adverse incident types and their distribution between near miss incidents and incidents that happened to the patient.

Type of the incident					
	Near miss	Happened to patient	All		
	n (%)	n (%)	n (%)	% Within category	
All	330 (35.7)	595 (64.3)	925 (100)		
Invasive/operative procedure	5 (19.2)	21 (80.8)	26 (2.8)		
Hygiene	15 (50.0)	15 (50.0)	30 (3.2)		
Other	22 (44.9)	27 (55.1)	49 (5.3)		
Diagnostic study	23 (25.3)	68 (74.7)	91 (9.8)		
Devices	42 (35.6)	76 (64.4)	118 (12.8)		
Communication	68 (50.0)	68 (50.0)	136 (14.7)		
Nursing practice and monitoring	71 (32.7)	146 (67.3)	217 (23.5)		
Medication, fluids, blood products	111 (33.0)	225 (67.0)	336 (36.3)	100	
Administering error	8 (6.8)	109 (93.2)	117	34.8	
Preparation error	21 (37.5)	35 (62.5)	56	16.7	
Dispensing error	29 (55.8)	23 (44.2)	52	15.5	
Prescribing error	17 (51.5)	16 (48.5)	33	9.8	
Documentation error	10 (45.5)	12 (54.5)	22	6.5	
Other/not specified ^a	26 (46.4)	30 (53.6)	56	16.7	

^aIncludes errors related to storage, ordering or delivery from the pharmacy, adverse reactions and if a subcategory was not specified.

management, and four reports related to blood products. Paracetamol (18), morphine (12), iron sulphate (9), vancomycin (7) and insulin (7) were the most frequently reported medicines. A minority of the administering and preparation errors were near misses.

Approximately two thirds of the reported incidents happened to the patient, and 189 of these caused harm to the patient (Table 1). Harm to a patient was minor in 165 cases. As a result of 23 adverse incidents, a patient suffered moderate harm. One incident, with a misplaced nasogastric catheter, caused major harm and the death of the patient.

Nursing staff reported 828 (89.5%) incidents, other staff members reported 60 (6.5%) incidents, and 37 (4%) were reported by physicians. Within physicians' reports, eight (21.6%) were near misses, while 292 (35.3%) of nurses' reports and 30 (50%) of the other professionals' reports were near misses.

3.2 | Timing of incidents

In 22 incident reports, the time when the incident happened was not known, and consequently 903 reports were analysed for the timing of the incidents. The lowest numbers of reported incidents happened on Wednesdays (109), and the incident reports were the most numerous (158) on Thursdays (IRR 1.45, 95% CI 1.14–1.85), followed by 144 reports from Saturdays (IRR 1.32, 1.03–1.69) (Figure 1A).

The total number of reported incidents was the lowest in February (59). Compared with February, there were significantly more reports in June (96, IRR 1.63, 1.18–2.25), November (86, IRR 1.46, 1.04–2.03) and December (89, IRR 1.51, 1.08–2.10) (Figure 1B).

There were 359 reports (43.6%) from the day shift from 7a.m. to 3p.m., 259 incident reports (31.4%) from the evening shift from 3p.m. to 9p.m. and 206 (25%) from the night shift from 9p.m. to 7a.m. The most frequently reported incidents occurred during the day shift (IRR of 1.74, 1.47–2.06) compared with the night (Figure 1C).

The proportions of near miss incidents and incidents that happened to a patient, remained the same during different weekdays, months and working shifts (Figure 1).

3.3 | Contributory factors of the incidents

There were several contributory factors for some of the incidents, which were recognised in 449 (48.5%) reports. The most common factors were the following: working practices in 166 (17.9%) of the reports, work environment, tools and resources in 131 (14.1%), and the communication or transfer of information in 129 (13.9%). The education, orientation or competence of personnel was insufficient in 74 (8%). Patient or family contributed to the incidents in seven reports (0.8%).

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FIGURE 1 Total number of reported adverse incidents and incident distribution between near miss and happened to the patient during different weekdays (A), months (B) and working shifts (C).

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TABLE 2 Recommendations to prevent reoccurrence of the adverse incident.

	n = 925 ^a (%)
Discussion with or informing of	673 (72.8)
Staff in the ward	561 (60.6)
A party outside the ward	67 (7.2)
Other involved sectors	13 (1.4)
Improvement regarding	56 (6.0)
Standard operating procedures	25 (2.7)
Information technology, technical systems, devices, equipment	11 (1.2)
Communication	5 (0.5)
Education	6 (0.6)
Other improvement	9 (1.0)
Report transferred to the head of the department	7 (0.8)
No recommendation	205 (22.2)

^aAfter the 925 incident reports were processed, there were 736 recommendations. Some reports resulted in several recommendations and 205 reports did not lead to any recommendations.

3.4 | Recommendations

Most of the reports prompted one or more recommendations to prevent the reoccurrence of the incident (Table 2). There were no recommendations after 205 (22.2%) reports. The most common (60.6%) intervention after an incident report was to discuss or inform the unit staff. After 80 (8.6%) reports, informing a party or actor outside the NICU was recommended.

Fifty-six (6%) reports resulted in one or more recommended improvements. These included training of the staff and creating new checklists, and standard operating procedures. Furthermore, malfunctioning devices were updated or replaced. After an incident in which milk was infused to a false route, nasogastric tubes were changed to a type not connectable to other infusion routes. In Appendix S1, there is a comprehensive list of recommended improvements further categorised according to a classification from previous literature. ^{15,16}

4 | DISCUSSION

This is the first study to analyse adverse incidents from a tertiary-level NICU in Finland. The main findings are as follows: (1) medication and fluid management errors were the most common safety incidents, and a minority of adverse incidents were reported by physicians. Among the medication errors, administering errors were the most frequently reported. (2) Some statistically significant differences were detected in the numbers of reports between weekdays and months, and incidents were most often reported during the day shift. (3) Deficiencies in the working practices, work environment, tools, resources and communication or transfer of information were

the most frequent contributory factors. (4) After a reported incident, the most common intervention was to inform or discuss the matter with the staff, but further improvements were planned as well.

In several studies, medication errors have been the most common type. 5,6,17 Likewise, in the present study, medication and fluid management errors were the most frequently reported errors. In Finnish healthcare organisations across all medical fields, the most common medication errors were dispensing errors (34%), followed by administering (25%) and documentation errors (17%). ¹⁸ In a paediatric medication error study, Nydert et al. observed rates of 36.3% administering errors, 35.6% prescribing errors, and 27.5% dispensing errors. 19 The rate of administering errors in our study was similar to previous research, but the rates of other types of errors were lower. A computerised physician order entry system can reduce prescription errors, 20 and it is likely that it impacted the low proportion of prescribing errors in this NICU. More than half of prescribing and dispensing errors were noticed before administering a medicinal product to the patient. The existing double-checking procedures in place at various steps may have reduced this type of error. Most of the preparation and administering errors happened to the patient.

High-alert medications are related to a risk of significant harm to patients, and they are often associated with harm in both paediatric and neonatal care. Along with several of the most frequently reported medications in our study, parenteral nutrition preparations have appeared on the list of high-alert medications in acute care settings, which was composed by the Institute for Safe Medication Practices.

In the research from many medical fields, it has been reported that physicians report only small proportions of adverse incidents, but they report severe incidents more often than other professionals. 5,6,23-25 Fukami et al. discussed that the nature of physicians' adverse incident reports may reveal more complex system problems. 24 Studies have shown that the lack of training and feedback on adverse incident reporting are significant barriers to reporting incidents. 23,24 Similar to previous research, in our study, a minority of the incidents were reported by physicians, indicating there is a need for interventions to increase physician reporting activity.

Previous data on when adverse incidents happen are scarce and contradictory. 12,13 We hypothesised that there would be more adverse incident reporting during the vacation seasons and outside of office hours. Indeed, there were more adverse incident reports on Saturdays and in June and December, but there was also an increase on Thursdays and in November, while there was no significant increase on Sundays and in July. The observed increase on Thursdays may be attributed to the several scheduled meetings for physicians and nurses on Thursdays at this NICU, which leaves less time to complete clinical work meticulously. There is no clear explanation for the discrepancy in the results on incident report numbers between Saturday and Sunday. Meanwhile, in Finland, most substitutes for vacation seasons start working in May or June and in November or December. It is possible that the increase in report numbers during these months is related to the presence of less experienced staff members, who may be more prone to make mistakes. Nearly,



half of the incidents reported in our study are from the day shift when there is more staff and more planned procedures than during other shifts. Interestingly, the number of reported incidents during the night shift was the lowest, although the duration of the shift was longer than the duration of the other shifts. The low number of staff members and of routine procedures during the night shift may explain this finding. The aforementioned differences between the incident report rates between certain weekdays and months would not have been detected without statistical analysis of the large number of reports and these results can give a reason to makes changes to the weekly working schedule in this neonatal unit. The planning of the vacation schedule for the regular staff was revised when the adverse incidents reports were initially processed, which is mentioned in Appendix S1.

Van der Starre et al. ¹⁶ reported that in a paediatric hospital, 22% of contributory factors were team and task related, 20% were provider factors, 19% were related to work environment, and patient-related factors only rarely contributed to the occurrence of adverse incidents. They also concluded that improvements for system factors can be more effective than for provider factors. In our study, contributory factors were recognised in less than 50% of the reports. Nevertheless, the detection of contributory factors can help plan interventions to improve patient safety.

Analysis of adverse incidents can reveal the need for improvements, but it is difficult to study the effect of the improvements on patient safety. ¹⁶ In our study, interventions were recommended after nearly 80% of the incident reports. The most common intervention was to discuss with or inform the staff. The study data do not include information on whether the discussions resulted in creating new improvement interventions. A limitation of the present study is that it was not possible to assess the effect of the improvements on patient outcomes.

There are limitations to the current study. With a voluntary reporting system, some of the incidents are not reported, and the true incidence of adverse incidents remains unknown. ^{10,11} In this hospital, there is a mandatory reporting process only for sentinel events, so it was not possible to determine the total number of adverse incidents. Another limitation is that the quality of information given in each report varies depending on how comprehensive the originally submitted report was. Anonymous reporting systems restrict the possibility of requesting further information on the incident, and consequently, some of the issues related to the incidents may not be recognised.

A strength of the present study is that the large data size allows statistical analysis of reports and the detection of the trends related to the incidents. Additionally, a long study period can diminish the effect of possible temporary issues such as understaffing and composition of the staff at the time of the incidents. These aspects of the study data can make the results more applicable to other neonatal units.

In conclusion, the present study supports the previous findings that medication errors are the most common type of reported adverse incidents and that most administering errors cause adverse events to the patient. The frequency of adverse incident reports varies depending on time and it is possible that there is an increase

in the number of adverse incidents towards the end of the week and during vacation seasons. Recognising the contributing factors of adverse incidents may help in the planning of improvements.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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