CHAPTER 7

Incidents associated with mechanical ventilation and intravascular catheters in neonatal intensive care: exploration of the causes, severity and methods for prevention

C. Snijders, R.A. van Lingen, T.W. van der Schaaf,

W.P.F. Fetter, A. Molendijk,

on behalf of the NEOSAFE study group

Arch Dis Child Fetal Neonatal Ed, accepted for publication

ABSTRACT

Objectives: To systematically investigate the causes and severity of incidents with mechanical ventilation and intravascular catheters in neonatal intensive care units (NICUs) in The Netherlands, in order to develop effective strategies to prevent these incidents in the future treatment of neonates.
Design: Prospective multicentre survey.
Methods: Inclusion criteria: incidents with mechanical ventilation and intravascular catheters that had been reported to a voluntary, non-punitive, incident-reporting system (NEOSAFE), and that had been systematically analysed using the PRISMA-Medical method. We describe the type, severity and identified causes of incidents reported from 1 July 2005 to 31 March 2007. We also describe the local interventions that were performed as a result of systematic analysis of incidents.
Results: 533 out of 1306 (41%) reported incidents with mechanical ventilation and intravascular catheters (n=339/856 and n=194/450, respectively) had been PRISMA-analysed and were included in the study. Four incidents resulted in severe harm, 18 in moderate harm, and 222 in minor harm. Tube-related incidents accounted for the greatest proportion of harm. In total, 1233 root causes were identified. Most root causes were classified as human error (55%). Organisational (20%), technical (16%), and patient-related (6%) failures accounted for the remainder of failures identified, whereas 4% of failures were unclassifiable. The majority of failures were rule-based errors.
Conclusion: Incidents with mechanical ventilation and intravascular catheters occur regularly in the NICU, and patients are frequently harmed by these incidents. Multicentre, systematic analysis increases our knowledge of these incidents. Although we stress the need for continuous training and education of all NICU personnel, preventive strategies in the NICU should be aimed at the whole system – including the technical and organisational environment – rather than at human failure alone.

INTRODUCTION

Patients in the intensive care unit (ICU) are usually subject to multiple complex interventions. It is known that complex interventions are prone to error, because they require several different steps which depend on technical, organisational, human, as well as patient-related factors.[1,2] To achieve favourable outcomes, these steps should occur in sequence and without errors.[3] In the last decade, several studies have been performed to assess the extent of incidents in ICU processes. A recent prospective cohort study in a paediatric ICU found an association between nursing workload and unplanned extubations.[4] Another study reported that patients in adult and paediatric ICUs are harmed by unintended and preventable incidents involving airway events, while important contributing factors in the patients include medical condition and age <1 year.[5] The same authors reported that patients are harmed by preventable line, tube and drain incidents, and that these incidents tend to occur more frequently in medically complex patients and in the paediatric population.[6] A study on incidents relating to arterial cannulation reported that for each incident report multiple contributing factors were selected, such as lack of knowledge, rule-based errors, high unit activity, and lack of supervision.[7] However, at present the impact of patient safety incidents in neonatal intensive care units is not well known. Studies of incidents in neonatal intensive care are scarce and the majority focus on medication errors.[8] In previous work concerning voluntary reported incidents in neonatal ICUs (NICUs) in The Netherlands, we identified 414 incidents with mechanical ventilation (9% of all reported incidents) and 245 incidents with intravascular lines (5%) in a one-year period. In terms of potential consequences and likelihood of reoccurrence, 52% of incidents with mechanical ventilation, and 39% of incidents with intravascular catheters were classified as (very) high-risk incidents.[9]

In order to develop effective strategies to prevent future incidents associated with mechanical ventilation and intravascular catheters in the treatment of neonates, we systematically investigated the causes and severity of these incidents in Dutch NICUs.

METHODS

Setting

From February through June 2005, a Neonatology System for Analysis and Feedback on medical Events (NEOSAFE) was implemented in eight of the ten Dutch tertiary care NICUs (14–24 beds per NICU) and one paediatric surgical ICU (14 beds, 15% neonates). It concerned a voluntary collaboration supported by the Dutch Association of Medical Specialists. In total, approximately 3500 neonates were admitted annually.

Data collection and handling

Voluntary, non-punitive incident reporting was introduced to establish specialty-based learning from incidents. Patient safety was defined as *the avoidance and prevention of patient injuries or adverse events resulting from the process of health-care delivery*.[10] An incident was defined as *any event which could have reduced, or did reduce the safety margin for the patient*.[11] A multidisciplinary patient safety committee (PSC) was formed in each unit. Personnel were asked to fill out an incident-report form immediately after the discovery of an incident. Incidents were either self-reported or reported by personnel who discovered the incident. We developed a standardised report form on the basis of recommendations from the Institute Of Medicine.[12] The report form included a section to be filled out by the PSC during analysis, including risk scores that were based on potential consequences and likelihood of reoccurrence (Appendix B, pp 134-135).[9] An interdisciplinary meeting provided consensus on incident categorisation and classification of (potential) severity. The PSCs managed an electronic database (Microsoft Access) of reported incidents and results of the subsequent analysis, which were forwarded to the central investigator (CS) on a monthly basis. Patient and staff confidentiality were ensured by excluding personal identification from the electronic database. The local medical research ethics committee (METC Zwolle) was consulted and they confirmed that this study did not require approval for implementation, as it only involved the registration of incidents.

Data analysis

Reported incidents with intravascular catheters and mechanical ventilation were systematically analysed by the local PSCs using the PRISMA-Medical method.[13] The main goal of PRISMA is to build a quantitative database of incidents (including near misses) and process deviations, in order to facilitate the development and evaluation of system-based preventive strategies. In the PRISMA-Medical method three main steps can be identified: (1) the Causal Tree incident description method; (2) classification of root causes by the Eindhoven Classification Model (ECM); and (3) formulation of structural measures for improvement (Classification/Action Matrix). Causal trees support the fact that nearly all incidents have more than one cause. By continuing to ask “why” of each event (beginning with the top event), a structure of causes and consequences arises, until the root causes are identified at the bottom of the tree. These root causes are subsequently classified by linking them to one of the categories of the ECM (Appendix A, pp 132-133). In some incidents, recovery factors can also be identified. In this study we focus on the failure factors. As both active failures (human error) and latent conditions (technical and organisational failures) of incidents are systematically considered with the PRISMA-Medical method, the results of this analysis can be used to provide a more realistic view of how the system is actually working.[14,15] Each PRISMA-analysis was conducted by two members of the local PSC, who were PRISMA-trained and familiar with the department and its processes. Test cases were performed to measure agreement at three levels of root cause classification. Interrater reliability was determined by calculating generalised κ values for each level of classification. Substantial agreement (κ 0.70–0.81) was reached at the main level of root cause classification of the test cases (discrimination between technical, organisational and human failure), and agreement among the committees at the second level (discrimination between subcategories of technical, organisational and human failure) was acceptable (κ 0.53–0.59). Discrimination between different types of rule-based errors (the third level of classification) was more difficult to assess (κ 0.40–0.47).[16] Therefore, we searched for the first two levels of root causes (Appendix A, pp 132-133). PSCs were encouraged to analyse incidents within 2 weeks after reporting. We describe the type, severity and identified causes of incidents with mechanical ventilation and intravascular catheters reported between 1 July 2005 and 31 March 2007. We also describe the interventions made in participating NICUs. Decisions for interventions were made by individual units following after PRISMA-Medical analysis of incidents. Descriptions of these interventions and the precipitating incident reports were monthly collected by the central investigator (CS).

RESULTS

During the study period, 1306 out of 9107 incident reports (14%) concerned incidents with mechanical ventilation and intravascular catheters. In total, 533 incidents (41%) were PRISMA-analysed and thus included in the study (Table 1).

Table 1. Incident subtypes and descriptions for mechanical ventilation (n=339) and intravascular catheter incidents (n=194)

Mechanical ventilation (n=339)	n	%	Intravascular catheters (n=194)	n	%
Incident subtype			**Incident subtype**		
Ventilator	147	43.4	Venous line	131	67.5
Endotracheal tube	98	28.9	Arterial line	56	28.9
Humidification	37	10.9	Both venous and arterial line	7	3.6
Ventilator tubing	22	6.5			
Other subtype	23	6.8			
Combination of subtypes	12	3.5			
Incident description			**Incident description**		
Wrong settings	125	36.9	Loosening	37	19.1
Unplanned removal	46	13.6	Unplanned removal	34	17.5
Mechanical failure	35	10.3	Wrong usage	31	16.0
Wrong usage	32	9.4	Wrong connection	17	8.8
Wrong connection	23	6.8	Occlusion	14	7.2
Loosening	17	5.0	Wrong settings	10	5.2
Unavailable	9	2.7	Material damage	8	4.1
Material damage	8	2.4	Subcutaneous infusion	4	2.1
Occlusion	6	1.8	Prolonged indwelling time	2	1.0
Other	38	11.2	Other	37	19.1

Mechanical ventilation

There were 856 reports of incidents associated with mechanical ventilation (variation between units n=42–318), of which 339 (40%) were PRISMA-analysed (variation between units n=8–59). Three incidents resulted in severe harm, and moderate harm was reported after 12 incidents. For instance, a machine defect during high-frequency oscillatory ventilation resulted in repeated bradycardia and desaturation of a patient; and necrosis of the nasal cartilage was reported in several tube-related incidents. Another 149 incidents resulted in minor harm. With respect to risk scores (based on potential consequences and likelihood of reoccurrence), 153 incidents (45%) were classified as (very) high-risk incidents.[9] Tube-related incidents accounted for the greatest proportion of harm (7% moderate harm, and 56% minor harm). They were also assigned the greatest proportion of (very) high-risk scores (62% of all tube-related incidents). Most tube-related incidents concerned unplanned extubation (both auto-extubation and accidental extubation by other means, n=44), malposition (either non-tracheal or too deep, n=15), or loosening of the fixation (n=13).

Out of 339 incidents associated with mechanical ventilation, 799 root causes were identified using the PRISMA-Medical method (2.4 root causes on each incident, variation between incident reports: 1–7 root causes). Most root causes were classified as human error (51%). Technical (20%), organisational (19%), and patient-related (5%) failures accounted for the remainder of failures identified, whereas 5% of failures were unclassifiable. Table 2 shows the distribution of root causes according to the ECM, and proposed actions to prevent their recurrence according to the Eindhoven Classification/Action matrix.[13] Most identified root causes were human-rule-based failures (47%). Technical external or design failures (9% and 8%, respectively), and protocol-related failures (8%) were also common. Table 3 outlines interventions made in individual NICUs as a result of analysing reported incidents. For instance, a double-check of the machine set-up was introduced after several reports on a wrong set-up of machines; and education and training with regard to general knowledge of mechanical ventilation was intensified after reports on wrong (written) orders by doctors.

Intravascular catheters

There were 450 reports of incidents associated with intravascular lines (variation between units n=27–102), of which 194 (43%) were PRISMA-analysed (variation between units n=11–48). One incident resulted in severe harm: vascular occlusion by an arterial line resulted in foot necrosis and subsequently plastic surgery. Moderate harm was reported after 6 incidents (for instance, a dislocated intravascular catheter leaking parenteral nutrition into the abdomen; another one leaking parenteral nutrition into the pleural cavity; and excessive bleeding after catheter disconnection). Another 73 incidents resulted in minor harm. With respect to risk scores (based on potential consequences and likelihood of reoccurrence), 82 incidents (42%) were classified as (very) high-risk incidents.

Out of 194 incidents associated with intravascular lines, 434 root causes were identified using the PRISMA-Medical method (2.2 root causes on each incident, variation between incident reports: 1–7 root causes). Most root causes were classified as human error (61%). Organisational (22%), technical (8%) and patient-related (7%) failures accounted for the remainder of failures identified, whereas 2% of failures were unclassifiable (Table 2). Most identified root causes were human-rule-based failures (55%). Protocol-related failures (11%) were also common. Interventions made in individual NICUs as a result of analysing reported incidents included adjusting of protocols on intravascular catheters after reports of faulty connections, blood loss after catheter removal, and an incorrect position of the arterial-line transducer, causing inadequate blood-pressure measurements (Table 3).

Table 2. Results of systematic analysis of incidents associated with mechanical ventilation (n=339) and with intravascular catheters (n=194)

Root cause classification[a]		**Mechanical ventilation (n=799 causes on 339 incident reports)**		**Intravascular catheters (n=434 causes on 194 incident reports)**		**Preventive actions**[b]
1st level[b]	**2nd level**[b]	**N**[c]	**%**	**N**[c]	**%**	
Technical	External	75	9.4	17	3.9	Escalation[d]
	Design	62	7.8	10	2.3	Technology / equipment
	Construction	10	1.3	1	0.2	Technology / equipment
	Materials	13	1.6	6	1.4	Technology / equipment
Organisational	External	8	1.0	4	0.9	Escalation
	Transfer of knowledge	24	3.0	15	3.5	Escalation
	Protocols	61	7.6	48	11.1	Procedures
	Management priorities	25	3.1	10	2.3	Escalation
	Culture	32	4.0	18	4.1	Reflection
Human	External	4	0.5	2	0.5	Escalation
	Knowledge-based behaviour	18	2.3	13	3.0	Information & communication[e]
	Rule-based behaviour	377	47.2	240	55.3	Training
	Skill-based behaviour	12	1.5	11	2.5	Technology / equipment[b]
Other factors	Patient-Related Factor	41	5.1	29	6.7	
	Unclassifiable	37	4.6	10	2.3	

[a] According to the PRISMA-Medical Eindhoven Classification Model.
[b] As proposed by the PRISMA-Medical Classification /Action Matrix[12].
[c] Number of identified root causes.
[d] Handling the problems at a higher organisational level.
[e] No motivation, as motivation of personnel only is an ineffective method in the prevention of human error[12].

Table 3. Interventions made in units following incident reports associated with mechanical ventilation or intravascular lines

Mechanical ventilation	Incident reports triggering the intervention	No. of units	Intravascular catheters	Incident reports triggering the intervention	No. of units
1. Training/procedures			**1. Training/procedures**		
Adjustment of protocols.	Drop-out of HFO-machine due to low pressure in combination with high amplitude.	1	Adjustment of protocols.	Faulty connection of infusion catheters, causing back stream of fluid.	1
	Several reports on adjustments of HFO-machine using the limitation button instead of the adjustment button.	2		Blood loss after removal of an arterial catheter.	1
				Several reports on wrong position of arterial catheter transducer, causing inadequate measurement of blood pressure.	1
Education and training regarding general knowledge of mechanical ventilation.	Non-functioning mechanical ventilation during transport. Wrong (written) orders by doctors.	1 3	New protocol describing the use of double lumen catheters.	Incorrect use of double lumen catheter (one lumen not connected and obstructed).	1
Double-check of machine set-ups (by second person). Checklist of set-up attached to machine. Mail to staff with manual of NO-machine. 'Report of the week'.	Faulty set-up of machine (high-frequency oscillation (HFO), nitrogen monoxide (NO)-circuit, connecting tubes, compressed air, humidification).	5	Adjustment of drug concentrations and drug combinations.	Precipitation of crystals and catheter occlusion because of high drug concentrations or incompetent drug combinations.	2
2. Reminders			**2. Reminders**		
Dutch names on control panel of HFO-machine.	Several reports on adjustments of HFO-machine using the limitation button instead of the adjustment button.	1	The use of different colours for securing of silestic catheters versus peripheral infusion catheters.	Accidental removal of a silestic catheter instead of the peripheral infusion catheter.	1
			E-mail to remind staff to use filters when administering inotropes.	Several reports describing the absence of filters when administering inotropes.	1
3. Forcing functions			**3. Forcing functions**		
The same pressure in every NO-bottle.	Difference in pressure between NO-bottles.	1	Highly concentrated solution of phenobarbital removed from stock.	Precipitation of crystals and catheter occlusion because of incorrect drug concentrations.	1
Emergency power on every socket.	Machines not attached to emergency power during power shutdown.	1			
4. Other			**4. Other**		
New plasters / foam material for securing of tubes.	Many auto-extubations because of tubes slipping through the plaster/foam material attached to the tube.	1	Consultation of the manufacturer of catheters for parenteral nutrition.	Frequent occlusion alarms, contaminated filters, loose seams.	1

DISCUSSION

Mechanical ventilation and intravascular catheters represent a substantial part of the daily processes in the NICU. Incidents with these treatments frequently harm our patients.

Tube-related incidents in particular are a threat to the NICU population, as these incidents carry a considerable risk for respiratory distress, i.e., desaturation and hypoxemia. Therefore, prevention of these incidents should become part of the daily routine activities in the NICU.

By performing systematic analysis, the errors that occurred or could occur in the different steps of NICU processes became more visible. We identified several weaknesses in the processes necessary for mechanical ventilation. First, many technical external failures were detected, which should be handled at a higher organisational level. Second, we found failures in design that should be discussed with technical experts. Third, there were many deficiencies in protocols which required adjustments. And finally, the majority of failures were human-rule-based errors, which should be followed by intensification of training and education. Incidents with intravascular catheters were also often the result of several process weaknesses. As with mechanical ventilation, there were many protocol-related failures. Patient-related failures were also prominent; frequently, unexpected patient movements caused loosening of catheters. However, again rule-based errors accounted for the greatest proportion of failures. In this light, we stress the need for continuous training and education, aimed at safer performance of tasks and procedures.

Looking at the local interventions executed during the study period as a result of systematic analysis, it can be concluded that several units already focused on training and education of personnel with respect to the theory and use of mechanical ventilation and intravascular catheters. This underlines the value of systematic analysis. It also demonstrates that these failures are not limited to one unit. Therefore, we propose that specialty-wide incident analysis should also lead to specialty-wide interventions instead of local interventions. Multidisciplinary, multicentre focus groups may contribute to more thorough investigations to accomplish powerful interventions. This may also lead to better compliance with the implementation of future preventive strategies. For instance, the results of our study can be used to initiate a collective (re-)education programme for paediatricians and residents in paediatrics with respect to the theory and practice of mechanical ventilation; and critical review of protocol-related failures might contribute to the creation of uniform procedures across NICUs.

On the other hand, specialty-wide analysis may also contribute to the prevention of superfluous searches for preventive actions that are already used in other units. For instance, one unit mentioned the implementation of different colours for the securing of catheters, after reports of accidental removal of a silestic catheter instead of the peripheral infusion catheter (Table 3). This type of intervention has already been used in other NICUs and has also been described earlier.[17] Although our study would allow comparison of incident types and identified root causes between different NICUs, we did not report this information for reasons of confidentiality.

This study has some limitations. First, several units reported shortage of time in handling the large number of incidents reported after the introduction of the voluntary reporting system. As a result, only 41% of all eligible reported incidents were analysed by PRISMA-Medical analysis. Although the units that had expected time-management problems had been instructed well ahead of time to analyse every third report so as to get a representative sample of PRISMA-analyses, selective analysis may have affected the final results. A review of all eligible incident reports (including all unselected cases) showed that mechanical ventilation incidents relating to humidification were relatively under-analysed, which may have affected the final profile of root causes. There was no significant difference between the proportion of analysed arterial line incidents and the proportion of analysed venous line incidents. In mechanical ventilation incidents, there was no significant difference between selected and unselected cases with respect to the level of actual harm. However, with respect to risk scores (based on potential consequences and likelihood of reoccurrence), there was a higher proportion of incidents with high-risk scores in unselected cases compared to selected cases (58% of unselected cases versus 47% of selected cases). Thus, in our final study, the severity of mechanical ventilation incidents in the NICU is possibly underestimated. In intravascular catheter incidents, there was no significant difference between selected and unselected cases with respect to the level of actual harm, or risk scores.

Second, analysing incidents with the PRISMA-Medical method is a retrospective way of incident analysis. We acknowledge the possibility that post-hoc analysis of incidents is subject to confirmation bias and other types of biases. Third, in spite of the systematic collection and analysis of incidents, there are many (known or unknown) co-factors, which make it difficult to assess the beneficial effects of system changes on patient safety in neonatal intensive care. However, improving even one of those factors might lead to safer conditions for patient care. Finding and preventing these factors remains an important issue for further studies.

CONCLUSIONS

Incidents with mechanical ventilation and intravascular catheters occur regularly in the NICU, and patients are frequently harmed by these incidents. Multicentre, systematic analysis increases our knowledge of these incidents. Although we stress the need for continuous training and education of all NICU personnel, preventive strategies in the NICU should be aimed at the whole system – including the technical and organisational environment – rather than at human failure alone.

REFERENCES

1. Leape LL. Reporting of adverse events. *N Engl J Med* 2002;347:1633−8.
2. Reason J. Human error: models and management. *BMJ* 2000;320:768−70.
3. Pronovost PJ, Wu AW, Sexton JB. Acute decompensation after removing a central line: practical approaches to increasing safety in the intensive care unit. *Ann Intern Med* 2004;140:1025−33.
4. Ream RS, Mackey K, Leet T et al. Association of nursing workload and unplanned extubations in a paediatric intensive care unit. *Pediatr Crit Care Med* 2007;8:366−71.
5. Needham DM, Thompson DA, Holzmueller CG et al. A system factors analysis of airway events from the intensive care unit safety reporting system (ICUSRS). *Crit Care Med* 2004;32:2227−33.
6. Needham DM, Sinopoli DJ, Thompson DA. A system factors analysis of 'line, tube and drain' incidents in the intensive care unit. *Crit Care Med* 2005;33:1701−7.
7. Durie M, Beckmann U, Gillies DM. Incidents relating to arterial cannulation as identified in 7525 reports submitted to the Australian incident monitoring study (AIMS-ICU). *Anesth Intensive Care* 2002;30:60−5.
8. Snijders C, van Lingen RA, Molendijk A et al. Incidents and errors in neonatal intensive care: a review of the literature. *Arch Dis Child Fetal Neonatal Ed* 2007;92:391–8. Epub 2007 March 21.
9. Snijders C, van Lingen RA, Fetter WPF et al. Specialty-based, voluntary incident reporting in neonatal intensive care: description of 4846 incident reports. Arch Dis Child Fetal Neonatal Ed 2009;94:210–5. Epub 2008 Oct 6.
10. Sorra JS, Nieva VF. Hospital Survey on Patient Safety Culture. (Prepared by Westat, under Contract No. 290-9609994). AHRQ Publication No. 04-0041. Rockville MD: Agency for Healthcare Research and Quality, 2004.
11. Beckmann U, Baldwin I, Hart GK et al. The Australian Incident Monitoring Study in Intensive Care: AIMS-ICU. An analysis of the first year of reporting. *Anaesth Intensive Care* 1996;24: 320 −9.
12. Aspden PH, Corrigan JM, Wolcott J. Patient safety: achieving a new standard for care. Washington DC: National Academy Press, 2004.
13. Van der Schaaf TW, Habraken MMP. PRISMA-Medical: a brief description. Eindhoven: Eindhoven University of Technology, 2005. Available at: http://www.who.int/patientsafety/taxonomy/PRISMA_Medical.pdf (accessed 26 August 2009).
14. Battles JB, Kaplan HS, van der Schaaf TW et al. The attributes of medical event-reporting systems. Experience with a prototype medical event-reporting system for transfusion medicine. *Arch Pathol Lab Med* 1998;122:231−8.
15. Kaplan HS, Battles JB, van der Schaaf TW et al. Identification and classification of the causes of events in transfusion medicine. *Transfusion* 1998;38:1071–81.
16. Snijders C, van der Schaaf TW, Klip H et al. Feasibility and reliability of PRISMA-medical for specialty-based incident analysis. *Qual Saf Health Care* 2009;18:486−91.
17. Singleton RJ, Webb RK, Ludbrook GL et al. The Australian Incident Monitoring Study. Problems associated with vascular access: an analysis of 2000 incident reports. Anaesth *Intensive Care* 1993;21:664−9.