CHAPTER 8

General discussion,
implications for practice,
and directions for future research
GENERAL DISCUSSION

In the neonatal intensive care unit (NICU), a reduction in mortality has been accomplished due to ongoing knowledge and advanced technology, but this reduction in mortality is accompanied by an increased chance for harm as a result of errors in this high-technology environment. The aim of this study was to introduce a Neonatology System for Analysis and Feedback on medical Events (NEOSAFE) in The Netherlands in order to establish specialty-based learning from incidents, to prevent patient injury due to incidents in the future.

Incident reporting systems in neonatal intensive care (Chapter 2)

We reviewed the characteristics of incident reporting systems in NICUs in relation to type, aetiology, outcome and preventability of incidents. Previous data on voluntary, non-punitive, incident reporting systems in the NICU suggest that these reporting systems elicit much more incidents in the NICU than a mandatory system, yielding more information in a shorter period of time. These data also suggest that with the use of a system approach for incident analysis, repeated occurrence of incidents and contributing factors can be identified, thus facilitating their clarification and preventing their recurrence. However, the success of a voluntary incident reporting system strongly depends on the possibilities to create a non-punitive climate which allows staff to report incidents without disciplinary sanctions.

Safety culture and incident reporting behaviour (Chapter 3)

In this chapter we describe a study on the aspects of safety culture in relation to incident reporting. The results of our study demonstrate that certain aspects of safety culture explain incident reporting behaviour better than others. Moreover, these results suggest that safety culture dimensions adversely affect incident-reporting behaviour in the NICU in such a way that a non-punitive approach to error predicts an increase in the number of incident reports, while hospital management support for patient safety and employees’ perceptions of safety predict a decrease in the number of incident reports (‘feeling safe to report error’ versus ‘feeling safe’). Because the number of incident reports increased between 2005 and 2006 after the introduction of non-punitive incident reporting, it can be concluded that the increase in incident reports represents a short-term effect of a non-punitive safety climate. During our six-monthly NEOSAFE evaluation meetings, the local patient safety committees reported that the majority of participants felt safe to report incidents to the local committee, which was
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reflected by the high quantity of non-anonymously reported incidents. However, the effects of changes in other safety culture dimensions and implementations, such as improvement of procedures and systems, are expected to prevail in the long-run, hence eventually resulting in a decrease in the number of incident reports. The negative association between hospital management support for patient safety and the number of incidents reported suggests that frontline NICU-staff tend to report more incidents in response to a lack of safety support by the hospital’s management. A reverse causation hypothesis, that individuals’ experience of incidents influences their perceptions of management support for safety, seems less plausible, as reported by Clarke.10 Because in both survey years less than 36% of responders were positive regarding hospital management support for patient safety, we recommend initiatives to improve leadership support for patient safety in the NICU.11,12

Since our survey in the NICU, several researchers have been using the same culture survey to measure safety culture in hospitals. One study reported a lack of significant changes in safety culture dimensions over a one-year period.13 Another study reported that the overall safety culture was not related to safety outcomes.14 Although a good comparison between these studies and our study is difficult to assess due to differences in study setting and applied methodology, it can be argued if this survey is useful as a general tool for measuring the short-term effects of patient safety programs on safety culture in health care.15

Reliability and feasibility of the PRISMA-Medical method (Chapter 4)

The PRISMA-Medical method has great potential to contribute to the identification of system failures that lead to incidents in the NICU. When performing interrater reliability tests on PRISMA-Medical test cases, we found that 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 skill-based, rule-based and knowledge-based errors) was acceptable (κ 0.53–0.59). Similar results are reported in a recent study by Smits and colleagues.16 As both active failures (human failure) and latent conditions (technical and organisational failures) were discovered as the cause of the incident, the total profile of root causes identified through PRISMA-analysis can be used to provide a more realistic view of how the system is actually working. We found a variation in causal coding between incident categories, which suggests that for each incident category different approaches are needed to prevent recurrence. However, our practical experience also shows that feasibility of PRISMA-medical for specialty-based analysis strongly depends on the availability of time and
PRISMA-trained personnel. A possible solution to this problem is the selection and prioritisation of certain incident types, such as high-risk incidents, for PRISMA-analysis.\textsuperscript{17}

The value of PRISMA-medical for specialty-based incident analysis has been described previously. A USA study in blood transfusion medicine reported that PRISMA-Medical is a very useful tool in sense making of individual and specialty-based, aggregate causal data.\textsuperscript{17,19} The percentage of human causes in our study (64%) was rather high compared with that study (46%), and compared with a study on incidents reported to The Netherlands Health Care Inspectorate (42\%).\textsuperscript{19,20} Although this may reflect the actual situation in the NICU, it may also be due to remaining ‘person-oriented’ biases during the root cause analysis (the tendency to focus on human errors during incident analysis). If the latter is the case, one should expect to observe a decrease in the percentage of human errors after repeated PRISMA-education. Moreover, although several causes were identified for each incident, we did not test interrater reliability of the Causal Tree description method. In the meantime, methods have been developed to test the reliability of the Causal Tree description method as well. A recent study on this subject showed promising results.\textsuperscript{16}

In conclusion, with some restraints, PRISMA-Medical proves to be both feasible and acceptably reliable for specialty-based identification and classification of multiple causes of incidents in the NICU. Future research should study the effect of system-based interventions on the prevalence of system failures identified by PRISMA, as well as on patient harm. Moreover, future studies should examine the role of error recovery factors in the prevention of incidents.

\textbf{Incident types and risk scores (Chapter 5)}

In this study we found that incidents occur much more frequently in our NICUs than previously observed, and their impact on patient morbidity is considerable. The introduction of voluntary incident reporting generated large volumes of incident reports in all participating units. Two of these incidents were likely to have contributed to the death of a patient (a tenfold morphine overdose in a premature, unstable patient; and dysfunctional cerebral function monitoring which delayed the treatment of seizures). The majority of incidents had no actual severe consequences at the time of reporting. However, based on the expected frequency of recurrence and the potential for harm, the overall risk for patients was high. Thus, the introduction of voluntary, non-punitive incident reporting stimulated personnel to report a great number of high-risk incidents that were captured before they resulted in actual patient harm. The enormous amount
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of information collected through these near-miss incident reports can be very useful in the development of preventive strategies.21,22
We found that incidents relating to medication were most frequently reported. This is a common finding in the patient-safety literature.23,24 The greatest risk for the patient was found among incident reports pertaining to mechanical ventilation and blood products, followed by intravascular catheters and parenteral nutrition. The importance of these incident categories is supported by several studies outside the NICU.19,25-27
Interestingly, compared with all other reported incidents, the total group of medication incidents was less likely to classify into the highest risk scores, whereas a subgroup of the two most frequently reported medication incidents – wrong dose and wrong infusion rate – was more likely to classify into the highest risk scores. This finding is consistent with a recent study concerning proactive risk assessment of the medication use process in the NICU, where the highest risk procedures were found to occur in the administration stage, with common potential failures relating to error in dose and infusion pump settings.28 In our study, many incidents that resulted in actual severe or moderate harm related to one of the high-risk categories. Therefore, we propose that in voluntary incident reporting systems in the NICU, these high-risk incident categories are selected for analysis of fundamental causes, and prioritised in the development of preventive strategies.29 Moreover, since some incident categories – blood products for instance – were relatively rare but potentially very harmful, collection of incident reports on a specialty-based, nationwide level can reveal much more information regarding these incidents than local collection alone.7

Incidents with inotropes (Chapter 6)
Our study shows that incidents with inotropes are a serious hazard to patients in the NICU. By combining data from participating NICUs, we found that incidents with inotropes that occur rarely on a local level appear to have a serious impact on patient safety in the specialty of neonatology when studied nationwide. This finding shows that sampling of reports on high-risk, low-frequency incidents at a national level yields valuable information that cannot be found by sampling at a single hospital level. Besides human error, a great number of technical and organisational failures affect the safe use of inotropes in the NICU. This supports the theory of the system approach, which assumes that incidents are usually the result of a combination of human error as well as technical and organisational failures.
Failures in organisational culture as well as management priorities contributed to a substantial number of incidents with inotropes. With respect to the former problem, the current manner in which NICU personnel deals with safety should be evaluated in the
presence of NICU management, whereas the latter problem (management priorities) should be handled at a higher organisational level (‘escalation’).

However, despite the significant number of technical and organisational failures, the majority of incidents were still due to human error, in particular rule-based errors. Therefore, our advice would be that prevention should not only be focused on technical and organisational failures (the system approach), but also on the adequate training of personnel; such as instructing doctors how to prescribe, and practicing dose calculation and administration.\textsuperscript{29} Also, increased attention to information and communication is recommended to prevent knowledge-based errors (the inability of an individual to apply their existing knowledge to a novel situation).\textsuperscript{30,31} In this respect, we emphasise that motivation of personnel only is an ineffective method in the prevention of human error, as described in previous research.\textsuperscript{32,33} Moreover, it is important to be aware of the limits of human performance and the need to make system changes to accommodate these limits.\textsuperscript{34,35} Therefore, we recommend specific interventions with respect to the high incidence of dosing errors. First, uniform prescription of inotropes (for instance, dosage per minute) might contribute to the prevention of prescription and calculation errors, like 60-fold dosing errors.\textsuperscript{36,37} Second, information technology such as computed physician-order entry might contribute to a decrease in calculation errors.\textsuperscript{38,39} Third, a specialised NICU pharmacist might contribute to an earlier detection of prescription or preparation errors and thus to the prevention of injury.\textsuperscript{40,41} However, more research is needed to find more evidence for the effectiveness of this intervention.\textsuperscript{42}

**Incidents relating to mechanical ventilation and intravascular catheters (Chapter 7)**

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 have a great chance to cause respiratory distress, i.e. desaturation and hypoxemia. Therefore, prevention of these incidents should become part of the daily routine activities in the NICU.

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 manufacturers and technical experts. Third, there were many deficiencies in protocols, requiring adjustments. And finally, the majority of failures
were human rule-based errors, which should be followed by intensifying training and education. Likewise, incidents with intravascular catheters were 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. Therefore, besides aiming at latent failures, we stress the need for continuous training and education, aimed at safer performance of tasks and procedures.

Looking at the local interventions that were done 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-broad problems should also lead to specialty-broad interventions instead of local interventions.

**IMPLICATIONS FOR PRACTICE**

During our study, we noticed that it had already become more common to talk and think about patient safety in The Netherlands. This is supported by the open discussion on incidents in health care, which has gradually arisen on a local, regional as well as national level.\textsuperscript{43-45}

Our study demonstrates that local, voluntary reporting of incidents, and feedback after analysis of incident reports increase the risk awareness of personnel in the neonatal intensive care unit. Moreover, specialty-based, non-punitive reporting generates a great number of incident reports. Systematic analysis of these incidents on a national level increases our knowledge of incidents in neonatal intensive care. We found that incidents that occur rarely on a local level appear to have a serious impact on patient safety in the specialty of neonatology when studied nationwide. We have also noticed that specialty-based analysis generates interesting discussions, for example on the advantage or disadvantage of ad hoc interventions.

**RECOMMENDATION 1:** Specialty-based incident reporting and systematic analysis of incidents in neonatal intensive care should be continued.
The PRISMA-Medical method has proven to be a valuable instrument for this purpose. Although human errors are found to be the most common causes of incidents in neonatal intensive care, systematic analysis reminds us to look at the system as a whole, detecting also technical and organisational errors. This is important, because the system approach states that preventive actions should primarily aim at the structural (latent) system failures in order to prevent the often inevitable human failures. Our database provides a way to prioritise the most prominent factors as possible targets for error-reduction or recovery promotion interventions.46 For instance, failures in organisational culture that contributed to a substantial number of inotrope-related incidents should be evaluated in the presence of NICU management; and analysis of incidents with mechanical ventilation exposed failures in design that should be discussed with manufacturers and technical experts.

RECOMMENDATION 2: Preventive strategies in the NICU should be aimed at the whole system – including the technical and organisational environment – rather than at human failure alone.47

However, on the basis of our analyses, indicating that the majority of failures in the NICU were human rule-based errors, we stress the need for continuous training and education aimed at safer performance of tasks and procedures.

RECOMMENDATION 3: Doctors should be given clear instructions on how to prescribe, and practice dose calculation and administration. We also recommend initiating a collective (re-)education program for paediatricians and residents in paediatrics with respect to the theory and practice of mechanical ventilation.

The enormous numbers of incident reports require selection rules for analysis to be made on the basis of, for instance, incident frequency, risk for reoccurrence, or (potential) severity of incidents. Multidisciplinary, multi-centre focus groups, consisting of experts on one of the incident categories such as high-risk medication, blood products, or mechanical ventilation, may contribute to more thorough investigations to accomplish powerful, preferably evidence-based interventions. This may also lead to better compliance to the implementation of future preventive strategies. On the other hand, specialty-broad analysis may also contribute to the
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prevention of unnecessary searches for preventive actions that are already used in other units.

RECOMMENDATION 4: Selection rules have to be made to handle the enormous numbers of incident reports; and expert groups (neonatologists, NICU nurses, technicians, etc.) should be established for theme-focused incident investigations.

To enable quick exchange of information on incidents in the NICU, we propose that voluntary reporting and systematic analysis of incidents in neonatal intensive care, including database management, becomes part of the patient safety management program of the Dutch Association of Paediatrics.

RECOMMENDATION 5: Data obtained by specialty-based analysis should be managed in a professional database.

Finally, a favourable evolvement in the growing attention for patient safety is the development of a national patient safety program, including the obligation by the Ministry of Health, Welfare and Sport for hospitals to create a solid safety management system (VMS). The ultimate goal of the VMS is a 50% reduction of incidents in Dutch hospitals by 31 December 2012. With the NEOSAFE study, we have created a good basis towards a VMS on the level of the specialism of Neonatology. We should now aim for uniform leadership in all neonatal intensive care units in The Netherlands, and work towards failure-free execution of neonatal care time over time.

RECOMMENDATION 6: Following the VMS goals according to the Ministry of Health, we should strive for a 50% reduction of harmful incidents in neonatal intensive care by 31 December 2012.
DIRECTIONS FOR FUTURE RESEARCH

1. In this study, we identified the causes of incidents – both adverse events and near misses – associated with mechanical ventilation, intravascular catheters and inotropes. The next step is to implement system-based, if possible specialty-broad interventions that are based on these results; and to find evidence for the effectiveness of such interventions in preventing patient harm in the NICU.21,46

2. We also recommend to further examine the causes of high-risk incidents in the NICU (for instance, incidents with blood products and incidents with parenteral nutrition) in order to prevent these incidents in the future.

3. Future studies should examine how changes in safety culture relate to actual patient harm caused by incidents. This is an important issue to address because the long-term effects of our specialty-based patient safety program are expected to entail a substantial reduction in the number of harmful incidents due to changed attitudes, increased safety participation, and the development of strategies to improve patient safety.11

4. Studying patient safety in the NICU, we used voluntary incident reporting and retrospective analysis of incidents using PRISMA-Medical. We acknowledge the possibility that post-hoc analysis of incidents is subject to confirmation bias and other types of biases. Other methods that are already used in patient safety research besides root cause analysis include prospective risk analysis and medical chart review. We propose to combine these methods in future research to study the cumulative effect on identifying hazards and preventing harm in neonatal intensive care. Moreover, the role of the PRISMA Error Recovery Factors in the prevention of incidents should be examined.13

5. Further boosting of reporting near misses may be achieved if empirically it could be shown that the causal patterns of such near misses are indeed similar to those of actual adverse events. Therefore we recommend research into the so-called ‘Common cause hypothesis’, specifically for the NICU domain, and subsequently for other medical specialties as well.21

6. Families of NICU-patients are generally acquainted with the unit, because of the length of stay and intensity of treatment of their premature or severely ill newborns. Therefore, it would be interesting to investigate how families of NICU-patients can be involved in safety efforts.49
REFERENCES


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