SUMMARY
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BACKGROUND AND AIMS OF THE STUDY

Over the past 25 years, developments in neonatal intensive care have led to a dramatic decrease in infant mortality, and to improvement in the quality of life for the infants who survive. In part, this is due to the application of advanced monitoring and supporting technology, combined with improvements in understanding the basic physiology of the newborn. However, illness severity, multiple complex interventions, and the high-technology environment of the neonatal intensive care unit (NICU) require very careful and continuous monitoring of patients compared to other hospital units. It is known that complex interventions are prone to error, because they are the result of several different steps which depend on technical, organisational, human, as well as patient-related factors. To achieve favourable outcomes, these steps must occur in sequence and without errors.

The so-called system approach to the problem of human error was originally proposed by psychologist James Reason in 1990. It assumes that incidents are usually the result of a combination of human (active) error as well as technical and organisational (latent) failures. Therefore, it is thought that preventive actions aimed at the system as a whole are more effective than actions aimed at human error alone. In the last decade, there have been several studies to assess safety of ICU processes. However, the extent of this problem in neonatal intensive care units is not well known.

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.

An incident was defined as ‘any event which could have reduced, or did reduce the safety margin for the patient’.

Patient safety was defined as ‘the avoidance and prevention of patient injuries or adverse events resulting from the process of health-care delivery’.

In Chapter 2, we reviewed the characteristics of incident reporting systems in Neonatal Intensive Care Units (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 many 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, the repeated occurrence of incidents and their contributing factors can be identified, thus facilitating their clarification and preventing their recurrence.

Based on the available NICU data from 2002–2004, the average number of incidents reported to a MIP in The Netherlands was 13 per 100 NICU admissions. With the expected increase in reported incidents after the introduction of a voluntary reporting system, selection and prioritisation for in-depth analysis become critical steps in handling the large number of incident reports.

The main objectives of the NEOSAFE study were:

- To examine the characteristics of incidents reported after the introduction of a voluntary, non-punitive incident reporting system for NICUs in The Netherlands (NEOSAFE); and to investigate which types of reported incidents pose the highest risk to patients in the NICU.

- To systematically investigate the causes and severity of incidents with three important NICU processes: high-risk medication, intravascular catheters and mechanical ventilation in the NICU, in order to develop effective strategies to prevent future incidents in the treatment of neonates.

Although we expected an increase in the number of incident reports after the introduction of voluntary, non-punitive reporting to a local safety committee, it is not exactly known which aspects of the safety climate in the NICU influence the incident reporting behaviour. Therefore, an extra study question was formulated:

- Which aspects of safety culture predict incident reporting behaviour in the NICU, before and after implementation of a voluntary, non-punitive incident reporting system?

On the basis of several studies reporting the advantages of the PRISMA-Medical method, we decided to use this method as a diagnostic technique to expose specialty-based system weaknesses.

However, little is known on the reliability and feasibility of the PRISMA-Medical method for systematic incident analysis in the NICU.

Therefore, we added a fourth study question:

- Is the PRISMA-medical method a feasible and reliable method for systematic, specialty-based analysis and classification of incidents in the NICU?
MAIN FINDINGS

Safety culture and incident reporting behaviour (Chapter 3)
Safety culture assessments are increasingly used to evaluate patient safety programs. However, it is not clear which aspects of safety culture are most relevant in understanding incident reporting behaviour, and ultimately improving patient safety. We examined which aspects of safety culture predict incident reporting behaviour in the NICU, before and one year after implementation of a voluntary, non-punitive incident reporting system. We performed a survey study among all personnel in the participating NICUs. The study was based on a translated, validated version of the AHRQ Hospital Survey on Patient Safety Culture. This survey incorporates two outcome measures, eleven dimensions of patient safety culture as well as demographic data.

The primary outcome was the number of self-reported incidents in the past 12 months. The overall response rate was 80% (n=700) at t=0, and 76% (n=670) at t=1 year. The results of our study, which was based on a multivariate multilevel regression prediction model, 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’). The relation between these aspects of safety culture and patient outcome requires further scrutiny and therefore remains an important issue to address in future research.

Reliability and feasibility of the PRISMA-Medical method (Chapter 4)
The main goal of PRISMA-Medical 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 this method, the causes of an incident are described in a causal tree, and the root causes (at the bottom of the tree) are subsequently classified using the Eindhoven Classification Model.

In this study, we examined the feasibility and reliability of the PRISMA-Medical method for systematic, specialty-based analysis and classification of incidents in the NICU. Following the introduction of NEOSAFE, multidisciplinary unit patient safety committees started using PRISMA-Medical to identify root causes of voluntary reported incidents. Committee members were PRISMA-trained and familiar with the...
SUMMARY

department and its processes. We describe the results of PRISMA-analysis of incidents reported during the first year.
At t=3 months and t=12 months after introduction, test cases were performed to measure agreement at three levels of root cause classification using PRISMA-Medical. Interrater reliability was determined by calculating generalised k values for each level of classification. During the study period, 981 out of 1786 eligible incidents (55%) were analysed for underlying root causes. In total, 2313 root causes were identified and classified, giving an average of 2.4 root causes for every incident. Although substantial agreement 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, discrimination between rule-based errors (the third level of classification) was more difficult to assess. We conclude that with some restraints, PRISMA-Medical proves to be both feasible and acceptably reliable to identify and classify multiple causes of incidents in the NICU.

Incident analysis (Chapters 5, 6 and 7)

Incident types and risk scores (Chapter 5)
The objective of this prospective multi-centre survey was to examine the characteristics of incidents reported after introduction of NEOSAFE; and to investigate which types of reported incident pose the highest risk to patients in the NICU. Multidisciplinary, unit-based patient safety committees systematically collected and analysed incident reports, and assigned risk scores to each reported incident. Data were centrally collected for specialty-based analysis. We describe the characteristics of incidents reported during the first year. Bivariate logistic regression analysis was conducted to identify high-risk incident categories.
There were 5225 incident reports on 3859 admissions, of which 4846 were eligible for analysis. Medication incidents were most frequently reported (27%), followed by laboratory (10%) and enteral nutrition (8%) incidents. Severe harm was described in 7 incident reports, and moderate harm in 63 incident reports. 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). Incidents with mechanical ventilation and blood products were most likely to be assigned high-risk scores, followed by parenteral nutrition, intravascular lines and medication dosing errors. We conclude that incidents occur much more frequently in our NICUs than previously observed, and that their
impact on patient morbidity is considerable. In our study, reported incidents concerning mechanical ventilation, blood products, intravascular lines, parenteral nutrition, as well as medication dosing errors pose the highest risk to patients in the NICU.

**Incidents with inotropes (Chapter 6)**

Inotropes are indispensable drugs in any intensive care unit (ICU), due to their positive effects on cardiac output in hemodynamically unstable patients. However, they are also high-risk drugs, as errors with these drugs may cause severe damage to patients. We systematically investigated the causes and severity of incidents with inotropes in NICUs, in order to develop effective strategies to prevent future incidents with inotropes in the treatment of neonates. Moreover, we investigated whether nationwide sampling would reveal information that could not be obtained by sampling on hospital level. We performed a prospective multi-centre survey and included inotrope-related incidents that were reported to NEOSAFE, and that were 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.

In total, 114 incidents with inotropes were identified from the NEOSAFE database. Although most incidents were discovered before they actually caused any injury, 54% of incidents were classified as (very) high-risk incidents. Dosing and concentration errors were frequently reported. An average of 2.4 root causes were identified on each incident analysed. Most root causes were classified as human error (67%). Organisational (23%), technical (6%) and patient-related (6%) failures accounted for the remainder of errors identified. Concluding, by combining data from several NICUs, we found that incidents with inotropes that occur rarely on a local level appear to have a serious impact on safety in neonatal intensive care when studied nationwide. Besides human error, a great number of technical and organisational failures affect the safe use of inotropes in the NICU. Preventive strategies aimed at the whole system are therefore probably most effective. However, given the great number of human rule-based errors, we stress the need for adequate training of personnel regarding the prescription and administration of inotropes.

**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, but are also prone to error. We systematically investigated the causes and severity of incidents with mechanical ventilation and intravascular catheters in the NICU. We included incidents with mechanical ventilation and
intravascular catheters that had been reported to NEOSAFE between 1 July 2005 and 31 March 2007, and that had been systematically analysed using the PRISMA-Medical method. We also describe the local interventions made in individual NICUs as a result of analysing reported incidents.

In total, 533 out of 1306 (41%) reported incidents with mechanical ventilation and intravascular catheters 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. Incidents related to endotracheal tubes 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. In conclusion, incidents with mechanical ventilation and intravascular catheters frequently harm our patients. Although the variety of causes endorse a system approach, we stress the need for continuous training and education of all NICU personnel in an effort to decrease the substantial number of human errors.

FUTURE PERSPECTIVES

Implications for practice (Chapter 8)

During our study, we noticed that an open discussion on incidents in health care has gradually arisen on a local, regional as well as national level. Our study demonstrates that local, voluntary reporting of incidents, and feedback after analysis of incident reports increase the participation of personnel in patient safety activities in the neonatal intensive care unit. Moreover, specialty-based, non-punitive reporting generates a great number of incident reports, and systematic analysis of these incidents on a national level increases our knowledge of incidents in neonatal intensive care. 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. Therefore, we recommend specialty-based incident reporting and systematic analysis of incidents in neonatal intensive care to 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. Therefore, preventive strategies in the NICU should be aimed at the whole system – including the technical and organisational environment – rather than at human failure alone. Our database provides a way to prioritise the most prominent factors as possible targets for error-reduction or recovery promotion interventions.

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. We recommend clear instructions for doctors on how to prescribe, and practice of dose calculation and administration. We also recommend initiating a collective (re-)education program for paediatricians and residents in neonatal intensive care 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 in one of the high-risk incident categories, 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 prevention of unnecessary searches for preventive actions that are already used in other units.

To enable the 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.

Finally, a favourable evolution in the growing attention for patient safety is the obligation by the Ministry of Health, Welfare and Sport for hospitals to create a solid safety management system (VMS). With the NEOSAFE study, we have created a good basis towards a VMS on the level of the specialism of Neonatology.
SUMMARY

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.

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.

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.

5. Further boosting of reporting near misses may be achieved if it could be shown empirically 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.

6. Families of NICU-patients are generally acquainted with the unit, due to the length of stay and insensitivity 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.