CHAPTER 1

General introduction
and
research questions
INTRODUCTION

Neonatal intensive care
Neonatal intensive care units (NICUs) were designed in the 1950s and 1960s by paediatricians in order to provide better temperature support, isolation from infection risk, specialised feeding, and greater access to specialised equipment and resources. In the 1960, the development of mechanical ventilation of the newborn allowed for the survival of more premature newborns. In 1975, the American Board of Pediatrics established sub-board certification for neonatology. In the 1980s, the development of pulmonary surfactant replacement therapy further improved the survival of extremely premature infants and diminished bronchopulmonary dysplasia, one of the complications of mechanical ventilation. Over the past 25 years, developments in neonatal intensive care have led to dramatic decreases in infant mortality, and to improvements in quality of life for the infants who survive. In part, this is due to both the application of advanced monitoring and supporting technology, combined with improvements in understanding of the basic physiology of the newborn. However, illness severity, multiple complex interventions, and the high-technology environment of the 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. Thus, in the NICU, on the one hand there is a reduction in mortality due to advanced technology and ongoing knowledge, and on the other hand this reduction in mortality is threatened by an increased chance for harm due to errors in this high-technology environment. In the last decade, there have been several studies to assess the safety of ICU processes. However, the extent of this problem in neonatal intensive care units is not well known.

BACKGROUND

The development of patient safety
In the industrial sector it has been acknowledged that human errors will occur, and therefore systems are designed in such a way that errors are prevented or detected before they develop into an actual accident. 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 and technical and organisational (latent) failures. Reason presented his ideas as a Swiss Cheese model (Figure 1). In this model, an organisation’s defences against failure are modelled as a series of barriers, represented as slices of Swiss cheese (Emmenthal). The holes in the slices of cheese represent individual weaknesses in the individual parts of the system, and are continually varying in size and position in each slice. When all of the holes in each of the slices momentarily line up to permit ‘a trajectory of accident causation’, any hazard passing through the holes will lead to failures. In other words, a combination of several minor incidents might lead to a final (major) incident. Therefore, it is thought that preventive actions aimed at the system as a whole are more effective than actions aimed only at human error.

The aviation safety industry has been using Reason’s model for a long time to optimise safety. Likewise, in the chemical industry, much attention is paid to the safety of humans and processes. Therefore, safety management systems play an important role in the daily processes of these industries. In clinical practice, the magnitude of this problem has long been underestimated, despite several large studies confirming the occurrence of medical error with (possible) patient injury. In the past, a punitive approach to error predominated in health care, blaming individuals for their mistakes.

**Figure 1.** The Swiss cheese model of accident causation, adapted from the work of James Reason (1990).
Currently, more and more hospitals recognise that a system approach is needed to analyse incident reports.\textsuperscript{46} It is to the merit of the Institute of Medicine’s (IOM) report To Err is Human in 1999, that the importance of good patient safety management has been recognised by health-care workers all over the world.\textsuperscript{29} The IOM defines safety as ‘freedom from accidental injury’. Their report mentions that the problem of accidental injury is serious, and that patient safety must become a national priority. It was emphasised that the cause is not careless people but faulty systems. To achieve a better safety record, the report recommended a ‘four-tired approach’,\textsuperscript{29,30}

1. Establishing a national focus to create leadership, research, tools and protocols to enhance the knowledge base on safety;
2. Identifying and learning from errors by developing a nationwide public mandatory reporting system and by encouraging health-care organisations and practitioners to develop and participate in voluntary reporting systems;
3. Raising performance standards and expectations for improvements in safety through the actions of oversight organisations, professional groups, and group purchasers of health care;
4. Implementing safety systems in health-care organisations to ensure safety practices at the delivery level.

The IOM recommended that all health-care settings should establish comprehensive patient safety programs executed by trained personnel within a culture of safety, and emphasised that reporting systems are one of the key strategies for learning from errors and for monitoring progress in the prevention of their recurrence.\textsuperscript{30}

Established systems in non-medical industries share the following characteristics:

1. They focus on near misses;
2. They provide incentives for voluntary reporting;
3. They ensure confidentiality; and
4. They emphasise system approaches to error analysis.\textsuperscript{24}

According to the IOM, patient safety programs should encompass:

1. Case finding – identifying system failures;
2. Analysis – understanding the factors that contribute to system failures; and
3. System redesign – making improvements in care processes to prevent errors in the future.\textsuperscript{30}

Since the IOM report, there has been increasing interest in the development of such systems in health care.
Incident reporting systems

Adverse events versus near misses
At present, an incident is defined as any unintended event which (could have) reduced the safety margin for the patient.\textsuperscript{31} Recent efforts by the World Health Organization (WHO) to create an international patient safety taxonomy have resulted in the classification of three types of events, which is supported by other research:\textsuperscript{32,33}
- accident or adverse event: reached the patient and caused harm to the patient
- no harm event: reached the patient but did not cause harm to the patient
- near miss: did not reach the patient.

Thus, the true prevalence of events appropriate for incident reporting is impossible to estimate with any accuracy, as it includes actual adverse events as well as near misses and no harm events. The Aviation Safety Reporting System (ASRS), a USA national reporting system for near misses in the airline industry, processed approximately 30,000 reports annually, exceeding by many orders of magnitude the total number of airline accidents each year.\textsuperscript{34-36} The number of reports submitted to a comparable system in health care would presumably run in the millions if all adverse events, no harm events, and near misses were captured.\textsuperscript{37}

By contrast, over 6 years of operation, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Sentinel Event Database has captured only 1152 events, 62\% of which occurred in general hospitals.\textsuperscript{38} These statistics are clearly affected by underreporting and consist primarily of serious adverse events (76\% of events reported resulted in patient deaths), and not near misses.\textsuperscript{37,38} At this moment the JCAHO is actually revising its own sentinel event policy, in order to explicitly include near-misses and their error-recovery information.

Voluntary reporting
When incidents are reported on a voluntary basis, the database of reported incidents will probably not represent the actual number of incidents. Some incident types may be better represented in a database of voluntary reported incidents than others. Therefore, the actual number of incidents will be higher. However, the goal of incident monitoring is not to gather epidemiologic data \textit{per se}, but rather to gather qualitative data.\textsuperscript{37}

Several researchers found that voluntary, non-punitive reporting of incidents – including both adverse events and near misses – generates large volumes of valuable information on type, aetiology, outcome and preventability of incidents.\textsuperscript{4,31,39-41}

Moreover, a database of voluntary reported incidents gives a good interpretation of the
nature of incidents that one judges important enough to report. This may lead to better compliance to the implementation of future preventive strategies that are based on these incident reports.

Confidentiality
Non-punitive reporting was originally developed for the aviation industry.²³ It was thought that more information on airplane accidents and near misses would be revealed if personnel were encouraged to report errors ‘blame free’, instead of being punished for their mistakes. Several studies confirm that non-punitive reporting is effective in increasing the number of incident reports.⁴,⁵¹ However, there is much discussion on the term ‘blame free’, because it implies that a person will never be punished, even in case of criminal intent. Therefore, most researchers prefer to speak of ‘non-punitive reporting’. Several countries (most recently Belgium) have already introduced so-called ‘no-fault’ legislation in an attempt to separate financial compensation for injured patients from the delicate process of fact-finding for causal analysis.

With anonymous reporting, individuals can not be contacted for details of reported events.⁴² In case of non-anonymous reporting, one is able to obtain additional information on incidents in the event such information is needed for data analysis. On the other hand, the success of non-anonymous reporting of incidents strongly depends on the possibilities to create a non-punitive climate which allows staff to report incidents without disciplinary sanctions.⁴³ In other words, non-anonymous reporting might also be a barrier to reporting through a lack of personal protection, or because of a chance of being punished for reported mistakes. Therefore, in case of non-anonymous reporting, patient and staff confidentiality should be ensured by excluding personal identification from the final database.

Internal versus external reporting
A good internal reporting system makes all responsible health-care workers aware of the major hazards, and external reporting allows lessons to be shared so that others can avoid making the same mistakes. Also, external reporting systems will yield a larger sample size, increasing the potential to identify patterns of infrequent, yet striking errors. According to Leape, most of the benefits can be obtained with specialty-based or system-wide reporting programs.⁴ Specialty-based reporting systems can be used to collect incidents on a grand scale, to conduct benchmarking, and to identify areas for specialty-based improvement. Data exist regarding specialty-based reporting systems. The Australian Incident Monitoring System in Anaesthesia (AIMS-Anaesthesia) used
voluntary, anonymous incident reporting, which elicited large volumes of specific information about incidents that could be analysed for root causes and contributing factors.\textsuperscript{31,39,41,44} On the other hand, specialty-based systems also require standardised and reliable methods for the collection and analysis of incidents across different units.

The system approach: methods for systematic incident analysis
Several methods exist for analysis of incidents in health care. The Root Cause Analysis (RCA) method was first used in health care by the United States Veterans Affairs (VA) health administration, National Center for Patient Safety (NCPS).\textsuperscript{45} The goal of RCA is to find out (1) What happened; (2) Why did it happen; and (3) What to do to prevent it from happening again. It differs from troubleshooting and problem-solving in that these disciplines typically seek solutions to specific difficulties, whereas RCA is directed at underlying issues. It is a process that is part of the effort to build a culture of safety and move beyond the culture of blame. In RCA, basic and contributing causes are discovered in a process similar to diagnosis of disease – with the goal always in mind of preventing recurrence. RCA is:

1. Inter-disciplinary, involving experts from the frontline services;
2. Involving those who are most familiar with the situation;
3. Continually digging deeper by asking why, why, why at each level of cause and effect;
4. A process that identifies the changes that need to be made to the systems; and
5. A process that is as impartial as possible.\textsuperscript{45,46}

In 2005, RCA was made suitable for Dutch hospitals by the UMC Utrecht Patient Safety Center. In The Netherlands, it is called Systematic Incident Reconstruction and Evaluation (SIRE).\textsuperscript{47}

The Prevention and Recovery Information System for Monitoring and Analysis (PRISMA) method was originally developed to manage human error in the chemical process industry, but in the last decade it was also applied in the transportation sector, as well as in health care (PRISMA-Medical).\textsuperscript{25,48-52} This method is based on the system approach to the problem of human error.\textsuperscript{5,7} 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. Three main steps can be identified in the PRISMA-medical method:
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.

Causal trees provide a visual interpretation of the chain of events leading to an incident, without hypothesising about possible causes. They represent critical activities and decisions during the development of an incident in chronological order and show how activities and decisions are logically related to each other. Causal trees support the fact that nearly all incidents have more than one cause. By continuing to ask “why” regarding 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. In some incidents, recovery factors can also be identified (Figure 2). Root causes are subsequently classified by linking them to one of the categories of the ECM. The ECM includes both active failures and latent conditions (Appendix A). Active failures are mainly represented by human error. The human section of the model is based on the SRK-model developed by Rasmussen, who distinguishes three levels of behaviour: (1) skill-based behaviour; (2) rule-based behaviour; and (3) knowledge-based behaviour.

![Causal Tree incident description method](image)

Figure 2. Causal Tree incident description method (Adapted from MERS-TM).
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The medical version of PRISMA also distinguishes Patient-Related Factors. The latent conditions in the ECM involve technical and organisational errors. Technical and organisational factors are considered first when classifying root causes, and human failures are considered last. This sequence helps to counteract the tendency to start and stop analysis at the level of the end-user and leave the technical and organisational context of an incident unquestioned. The standardised classification of the causes of incidents through a coding system enables the analysis of multiple incident types or incidents from multiple units at the same time.50-52

The development of patient safety initiatives in The Netherlands

In 2003, the Dutch Ministry of Health, Welfare and Sport designated Rein Willems, at that time CEO of Shell Netherlands, as the ambassador of the so-called ‘Better Faster’ programme, to perform a study on the state of patient safety in The Netherlands. Based on extrapolation of data from the United States, it was estimated that yearly 1500–6000 patients die as a result of medical errors in The Netherlands.

In their final report, Shell stated that safety should have a higher priority among all professionals in the health-care sector in The Netherlands.55 In the meanwhile, a large record review study among 21 randomly selected Dutch hospitals reported that, when extrapolated to the national level, between 1482 and 2032 potentially preventable deaths occurred in Dutch hospitals in 2004.56 According to Shell, action was required on four fronts to get structural improvement in safety in health care:

1. Hospitals should introduce structural safety management;
2. Hospital managements should hold final responsibility for safety;
3. Health insurers should make safety and quality a permanent feature of their contract;
4. The Ministry should provide funding to facilitate the introduction of safety management systems.

In their report, Shell also referred to a pilot study by Molendijk and colleagues which was performed simultaneously with the ‘Better Faster’ programme in 2003. Molendijk and colleagues performed a pilot study on patient safety in the neonatal intensive care unit (NICU) in Zwolle, The Netherlands.57 In Dutch hospitals, the traditional approach to incidents is mandatory reporting of only incidents with significant patient harm or catastrophic incidents to a central hospital committee (MIP or FONA). Therefore, the impact of incidents is probably underestimated. The authors defined an incident as any unintended event which (could have) reduced the safety margin for the patient.31 They found that the introduction of voluntary, non-punitive incident reporting to a local NICU committee resulted in a 5-fold increase in the number of incident reports. Based
on their findings, they concluded that the impact of incidents in the NICU is probably much higher than previously known. The authors proposed a nationwide approach to incidents in the NICU through the introduction of a voluntary, non-punitive incident reporting system for Dutch NICUs.

NEOSAFE

**Aim and objectives of the study**
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 that could have reduced, or did reduce the safety margin for the patient’.31

Patient safety was defined as ‘the avoidance and prevention of patient injuries or adverse events resulting from the process of health-care delivery’.58

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 have become critical steps in handling the large number of incident reports.52

The main objectives were:

- To examine the characteristics of incidents reported after the introduction of a voluntary, non-punitive incident reporting system for NICUs in The Netherlands; and to investigate which types of reported incident 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 was not exactly known which aspects of the safety climate in the NICU influenced 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 an instrument for structural and systematic analysis of incidents. However, information on the validity and reliability of methods for the analysis of incidents in health care was lacking. Thus, little was known about the reliability and feasibility of the PRISMA-Medical method for systematic incident analysis in the NICU. This is an important issue to address if we want to use this method as a diagnostic technique to expose specialty-based system weaknesses.

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?

**OUTLINE OF THIS THESIS**

**Chapter 2** reviews the literature on the characteristics of incident reporting systems in NICUs in relation to type, aetiology, outcome and preventability of incidents. **Chapter 3** describes which aspects of safety culture predict incident reporting behaviour in Dutch NICUs, before and after implementation of a voluntary, non-punitive incident reporting system. In **Chapter 4** we examine the feasibility and reliability of the PRISMA-medical method for systematic, specialty-based analysis and classification of incidents in the NICU. **Chapter 5** describes the characteristics of incidents reported in Dutch NICUs during the first year after the introduction of NEOSAFE. We also describe which types of reported incident pose the greatest risk to patients in the NICU. In **Chapter 6** we
systematically investigate the causes and severity of incidents with inotropic agents in the NICU, in order to develop effective preventive strategies for the specialty of neonatal intensive care. Inotropes are indispensable drugs in any NICU due to their positive effects on cardiac output in haemodynamically unstable patients. However, errors in prescription, preparation, or administration of these drugs may cause severe damage to patients, such as persistent hypotension when underdosing and severe hypertension when overdosing. Chapter 7 describes the causes and severity of incidents with intravascular catheters and mechanical ventilation and discusses strategies for prevention. Finally, the major findings and methodological considerations of this thesis are discussed in Chapter 8. In addition, recommendations regarding patient safety in NICUs in The Netherlands, and directions for future research are proposed based on the findings of this thesis.
REFERENCES