Patient Safety in Pediatrics

A DEVELOPING DISCIPLINE

Cynthia van der Starre

Patient Safety in Pediatrics

A DEVELOPING DISCIPLINE

Promotiecommissie

Promotor:	Prof. dr. D. Tibboel
Overige leden:	Prof. dr. J. Klein Prof. dr. W.P.F. Fetter Prof. dr. J.B. van Goudoever
Copromotor:	dr. M. van Dijk

CIP-gegevens Koninklijke Bibliotheek, Den Haag

ISBN: 978-94-6169-156-9

Vormgeving: Estay reclame-adviesbureau - Zwijndrecht - www.estay.nl
Drukwerk: Optima Grafische Communicatie - Rotterdam

MIX
Papier van verantwoorde herkomst
FSC® C004472

Patient Safety in Pediatrics:

A DEVELOPING DISCIPLINE

Patiëntveiligheid in de kindergeneeskunde: een vakgebied in ontwikkeling

Proefschrift ter verkrijging van de graad van doctor
aan de Erasmus Universiteit Rotterdam
op gezag van de rector magnificus
Prof. dr. H.G. Schmidt
en volgens besluit van het College voor Promoties.

De openbare verdediging zal plaatsvinden op
woensdag 23 november 2011 om 15.30 uur
door

Cynthia van der Starre
geboren te Spijkenisse

ERASMUS UNIVERSITEIT ROTTERDAM

TABLE OF CONTENTS

INTRODUCTION

The publication of the breakthrough report "To Err is Human" by the Institute of Medicine was the launch of patient safety initiatives all over the world. In the intensive care unit (ICU) of the Erasmus MC-Sophia Children's Hospital this resulted in the institution of a multimodal patient safety management system under the name Safety First in 2005. This system now includes nine major elements, representing monitoring and intervention activities. In this thesis we report on the results and the implementation of the patient safety management system called Safety First.

Outline of this thesis

In part I the concept of patient safety and the Safety First project are introduced. The rationale for selecting the elements of the patient safety management system is explained. As preventable mortality and morbidity are the public focus as outcome parameters for quality and safety of care, we have studied very long stay patients in our ICU (chapter 2). The goal of this study was to determine characteristics and mortality in these patients as well as modes of death. Chapter 3 presents an evaluation of potentially preventable deaths in our ICU. An important question was whether five years of patient safety efforts had resulted in fewer potentially preventable deaths.

Part II reflects on the difficulties in monitoring adverse events. In chapter 4 we present numbers and types of adverse events identified with real time physicians' registration during a 3-month period in general pediatric practice. The next chapter is a study into adverse events in the surgical pediatric ICU in a 2-year period. We combined the physicians' registration with the Trigger Tool methodology as developed by the Institute for Healthcare, Boston, USA. The goals were to determine the rate and nature of the adverse events and to compare the two methods.

In part III a number of elements of Safety First are described, as well as other studies into patient safety issues relevant to bedside ICU care. Chapter 6 brings the results of critical incident analysis with a focus on the factors contributing to the incident and the resultant recommendations. The next study evaluated the availability and reliability of drug formularies used in our ICU, which are crucial in safe drug prescription. In chapter 8 we discuss the safety of routine MRI scans in preterm infants at 30 weeks gestational age, as reflected by safety incidents and adverse events. In the next chapter, safety focused Mortality and Morbidity conference reports were scrutinized for numbers and types of recommendations stemming from these meetings. Chapter 10 is a study about nursing protocol violations established with the Critical Nursing Situation Index.

Part IV describes a study of safety culture in the ICU, as it emerged from a safety attitude questionnaire administered to all staff. We aimed to compare findings to benchmark data and explore any deficiencies.

In the general discussion in part V the results of the studies are commented on and future directions are given, including guidelines for optimal implementation of a patient safety management system and future benchmarking.

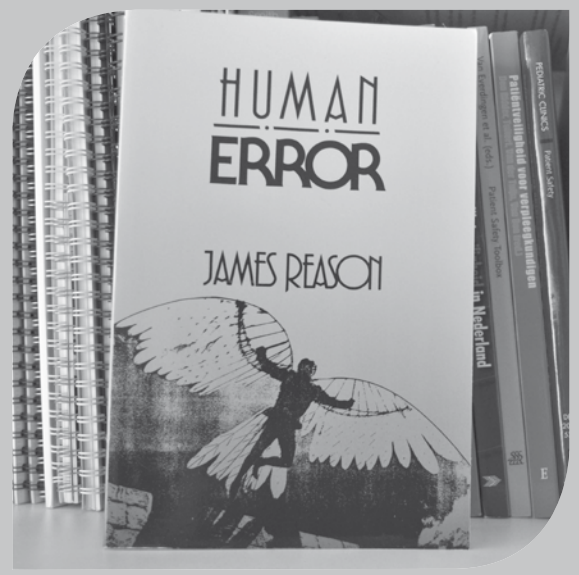
LARA'S STORY: PART 1

Our first child!

Thomas and Melissa are going to be parents! They are expecting their first child, a girl, and she will probably be born this night. However, she will be premature as she is due to be born after 9 more weeks. Also, they are extremely worried because something was very wrong at the first ultrasound. There was too much amniotic fluid, and further echo images showed a birth defect called esophageal atresia. This means her esophagus has not grown normally and is blocked, so that swallowed fluid cannot pass through to the stomach. Thomas and Melissa have been counseled on what to expect after birth. They have been told that their daughter will be admitted to the ICU and that she will need an operation to correct the defect. Of course they are very anxious and worried, how will their girl be after birth? What will happen to her? How will the operation go? Will the doctors know what to do and how to take care of their daughter? How will they know they have chosen the right hospital?

Part 1

The why and how of the Safety First project



CHAPTER 1

Safety First: Patient Safety Management in a pediatric ICU

Based on: *Patient Safety Management System in Pediatric ICUs Van der Starre C, Van der Tuijn Y, Tibboel D. In: Vincent JL, editor. Yearbook of Intensive Care and Emergency Medicine: Springer; 2006. p. 745-754.*

SAFETY FIRST: PATIENT SAFETY MANAGEMENT IN A PEDIATRIC ICU

Based on:
Patient Safety Management System in Pediatric ICUs
Van der Starre C, Van der Tuijn Y, Tibboel D.
In: Vincent JL, editor. Yearbook of Intensive Care and Emergency Medicine: Springer; 2006.
p. 745-754.

Background

Patient safety has become a subject of greater attention since the beginning of the century in health-care organizations all over the world. The report "To Err is Human" from the Institute of Medicine in the United States triggered awareness for the importance of safer practices in health care. [1] As an illustration, the Harvard Medical Practice study found that 4.7% of patients in US hospitals had suffered adverse events. [2-3] A number of studies in other countries have identified adverse events ranging from 2.9% to 16.6%. [4-9] With regard to adult and pediatric intensive care, from 8% to 62% of patients were found to have suffered at least one adverse event during their ICU stay. [10-15] Adverse events are not only detrimental to the patient, but also give rise to longer hospital stay and greater hospital costs. [16-18]
In 2001, the Institute of Medicine released the following statement:
"The biggest challenge to moving toward a safer health system is changing the culture from one of blaming individuals for errors to one in which errors are treated not as personal failures, but as opportunities to improve the system and prevent harm".

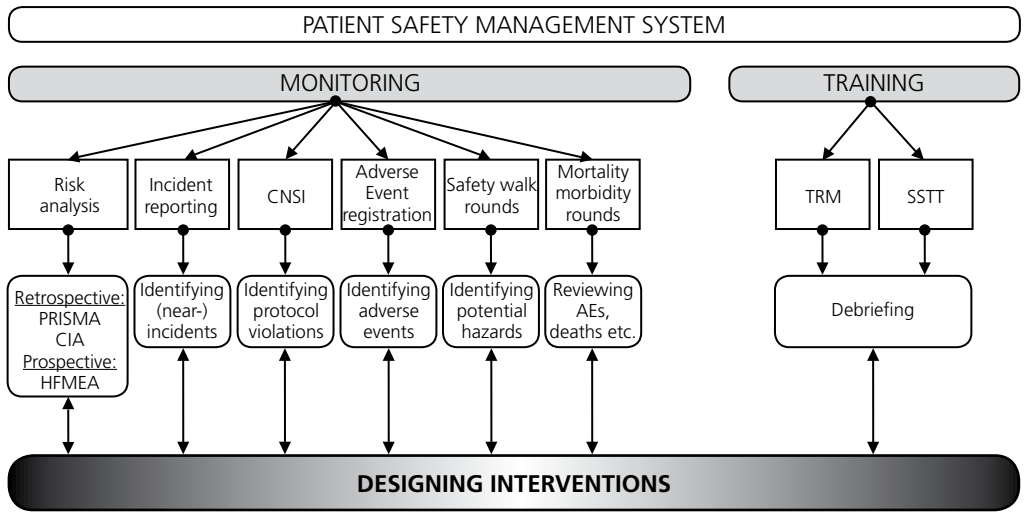
It has indeed been recognized that healthcare providers have to step away from the 'blame and shame' culture that prevents learning from errors. [19-22] Cultural changes are also necessary to successfully implement innovations that are designed to improve patient safety. [21, 23]
The Dutch Ministry of Health instructed hospitals and healthcare institutions to have a patient safety management system (PSMS) in place by January 1st 2008. The Paediatric Association of the Netherlands in collaboration with the Dutch Order of Medical Specialists thereupon decided to initiate patient safety projects. Apart from local initiatives, this has so far resulted in two nationwide projects, an adverse event registration for pediatrics and the so-called Neosafe® project for blame free incident reporting in neonatal ICUs. [24]

Our achievements: Safety First Project

The level 3 surgical PICU of the Erasmus MC-Sophia Children's Hospital in Rotterdam, the Netherlands, is one of the eight academic PICUs in the Netherlands and admits around 550 patients per year. Children with the following disorders are admitted to the surgical PICU: major congenital anomalies, traumatic brain injury or major trauma, neurosurgery, scoliosis surgery, and renal transplants. In addition, the unit has a supraregional function for craniofacial surgery and extracorporeal membrane oxygenation (ECMO). In 2008 the surgical PICU integrated with the medical PICU and since then provides all types of intensive care including cardiothoracic surgery, heart transplants and pediatric ECMO.

In 2004, we started a patient safety project which we named 'Safety First'. The first components to be implemented were adverse event (AE) registration (2005), Safety First reports (blame free incident reporting) (2004), Critical Nursing Situation Index (CNSI) (2005), and Team Resource Management (TRM) (2005). Other elements have consecutively been added: retrospective incident analysis (PRISMA) (2006), prospective risk analysis (HFMEA) (2007), Safety Walk Rounds (2007), safety focused Mortality and Morbidity conferences (2007), and Simulation training (2007). (Figure 1).

Figure 1 The Patient Safety Management System



Abbreviations:
AEs adverse events
CIA critical incident analysis
CNSI Critical Nursing Situation Index
HFMEA Healthcare Failure Mode and Effect Analysis
PRISMA Prevention and Recovery Information System for Monitoring and Analysis
SSTT Sophia Simulation team training
TRM Team Resource Management

Adverse events registration started as a pilot study in general pediatric wards, wards in referral hospitals in academic centers, and neonatal/pediatric ICUs. Adverse events were defined as "any unfavourable and unintended injury resulting from or contributed to by medical treatment during the hospital stay that resulted in adjustment of medical management or damage to the patient". Registration was aimed not only at quantifying the adverse events, but also at getting insight into their nature, as a means to direct preventive measures. Incidents were defined as "any unintended and unexpected occurrence that could have led or did actually lead to harm for the patient". In May 2004 all unit staff members were invited to report from now on anything that would qualify as an incident as it did not proceed as it should have or that went wrong. The blame free reporting of all incidents would generate more data on preventable causes of adverse events than would looking at the actual adverse events alone. Retrospective analysis of incidents using the PRISMA methodology was started in 2005; the first few critical incident analyses were performed in 2005 as well.

The Critical Nursing Situation Index is a validated method to detect nursing protocol violations in ICUs and was introduced in 2005 with a twofold aim: scrutinizing and updating nursing protocols and analyzing whether (non-) adherence to nursing protocols had any impact on incidents/adverse events. Team Resource Management is a training method, adapted from the world of aviation, aimed at improving communication and cooperation between team members. In 2005 all physicians, nurses, managers, and technicians in the unit were trained by the Centre for Man and Aviation. Subsequently, the aviation based training was adapted for the healthcare setting. Prospective risk assessment using the Healthcare Failure Mode and Effect analysis was first applied in 2007. Safety Walk Rounds were introduced in 2007 in an effort to advance discussion on safety topics between front line staff and executives. Mortality and Morbidity conferences were reinstated in 2007 with an added focus on patient safety aspects. Next to TRM, a program for simulation team training was developed and implemented in 2008.

Data Analysis

Adverse event registration

We undertook this study to improve quality of care by introducing adverse events as subjects for discussions, education and for directing the safety efforts. During a 3-month period, the medical and nursing staff reported on all possible adverse events, which then in turn were evaluated by a study group of the Paediatric Association of the Netherlands. The numbers and nature of adverse events were registered and the minimum dataset was also determined, i.e., what patient data, treatment data, context, etc. are needed for adequate adverse event registration. Over 3 months we recorded 122 adverse events (8.1 per 100 admission days).

Safety First Reports

A new reporting system was created in 2005 to gain more insight into the prevalence of incidents. An incident was defined as any unintended and unexpected occurrence that could have led or did actually lead to harm for the patient. Underreporting of errors is a serious problem in healthcare [25-27] and nurses are more likely to report incidents than is medical staff. A blame free environment for health care workers is a necessity for a successful voluntary incident reporting system. [28] The 'classical' reporting system in many hospitals in the Netherlands was a voluntary reporting system of faults or near accidents (FONA). Within this system, only 50-60 incidents per year were reported in our department. We introduced a new reporting form in 2004, based on that used in The Hospital for Sick Children, Toronto. [29] We set up a so-called Safety First Committee for the assessment of all the reports. They received a staggering amount of reports, i.e. each month 100-150 forms, a 30-fold increase compared to the FONA reports.

Table 1 Numbers and categories of incident reports 2005-2010

Category	2005	2006	2007	2008	2009	2010	Total	%
Medication	508	557	341	928	649	481	3464	30.6
PDMS*	340	339	199	768	485	329	2460	21.7
Equipment	188	169	112	464	255	199	1387	12.2
Catheters, tubes	194	281	154	237	173	135	1174	10.4
Work environment	139	115	56	176	107	61	654	5.8
Nursing care	51	117	70	202	119	80	639	5.6
Communication	24	40	35	187	123	138	547	4.8
Laboratory	50	72	53	90	34	34	333	2.9
Nutrition	55	57	31	77	35	35	290	2.6
Skin care	11	15	18	35	28	30	137	1.2
Radiology	5	9	3	3	2	4	26	0.2
Fall	0	6	2	2	2	1	13	0.1
Other	35	19	42	62	27	20	205	1.8
	1600	1796	1116	3231	2039	1547	11329	100

*PDMS: Patient Data Management System

More than one third of the reports pertained to medication errors, for instance dosing errors, wrong infusion rate and omission errors (medication either not prescribed or not given). Ventilator related incidents were reported in approximately 20% of incidents, varying from accidental extubation to wrong ventilator settings. Apart from the nature and number of incidents we also studied the consequences for the patients with the aid of a risk assessment matrix. The person who reports an incident is asked to rate the anticipated consequences as either none, minor, major, serious, or unknown. A minor consequence is defined as minimal discomfort, without damage, longer stay, or intervention needed. A major consequence is discomfort or temporary damage, with minimally longer ICU stay or minimal intervention. Serious consequences are considerable discomfort, permanent damage, greatly prolonged stay, major intervention (i.e., resuscitation, surgery) or death. The Safety First Committee assesses the actual consequences within 2 weeks after the report is submitted. We found that only 7% of the incidents resulted in actual major or serious consequences.

Table 2 Numbers of potential and actual consequences of reported incidents in 2005-2010.

Consequences	Potential (n)	%	Actual (n)	%
None	1290	11.4	9069	80.1
Minor	4711	41.6	1369	12.1
Major	4144	36.6	781	6.9
Serious	1137	10.0	16	0.1
Unknown/ missing	47	0.4	94	0.8
Total	11329	100	11329	100

A possible reason for underreporting in our unit under the FONA system, but also in other hospitals, was the lack of feedback to the 'reporters'. The sheer number of reports made it impossible, however, to give personal feedback. As an alternative, we published a monthly Safety First Journal presenting the top 5 incidents, results of the analysis of major incidents and the preventive strategies selected to reduce the incidents. This type of feedback helped to sustain staff motivation to report incidents.

Detailed analysis of the incidents helped to understand how and why incidents occur. PRISMA analysis has been validated in the nationwide project Neosafe® [24], which promotes blame free incident reporting on neonatal ICUs. [30] This method has been adapted from incident analysis systems used in aviation and the petrochemical industry. It categorizes factors contributing to incidents in human, technological, organizational, and patient related factors. As a rule each incident has causes in at least two different categories. Insight into the root causes of the incidents will help to reduce incidents and develop preventive strategies. A total of 203 PRISMA analyses have been performed from 2005 to 2011.

Critical Nursing Situation Index

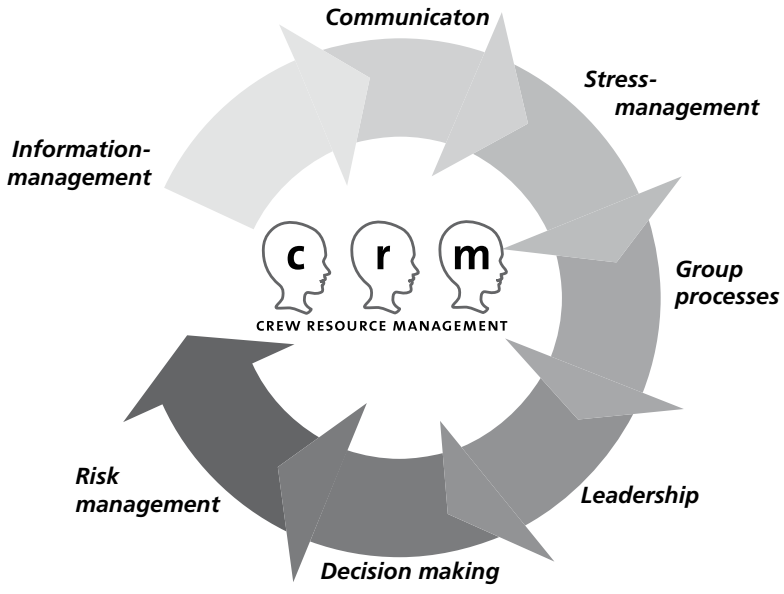
A Critical Nursing Situation is any observable situation which deviates from good clinical practice and which may potentially lead to an adverse event. The CNSI was originally developed and validated for an adult ICU by Binnekade et al. [31] It is a list of items to be checked at the bedside of patients. Each item represents an element from a nursing protocol. Each protocol was checked for being up-to-date, evidence based, and/or according to 'good clinical practice'. When found inadequate, a protocol was revised by two experienced PICU nurses and approved by one of the pediatric intensivists. The result was an adapted list of 192 items. Ten PICU nurses volunteered to test the new CNSI-picu for interrater reliability and usefulness on the unit. Paired scoring of 30 CNSIs showed a good inter-rater reliability: Cohen's kappa 0.76. This pilot study made clear that many nurses were afraid to be "caught making mistakes" when their patients were scored. A second pilot study was performed in which one of the CNSI trained nurses every day scored a randomly assigned patient. A monthly report on the most frequent protocol violations was published and appropriate action was undertaken, for instance education, protocol revision, etc.

Team Resource Management

Crew Resource Management (CRM) is a training method that has evolved in aviation over recent decades. Aviation has a longstanding history of collecting and analyzing safety data. Over a 7 year period, Billings and Reynard analyzed 35,000 reports and found that nearly half resulted from flight crew errors [32] Root cause analysis of these incidents revealed that insufficient communication and cooperation between team members contributed largely to the errors. CRM training programs are now widely used to improve teamwork of flight crews. [33] In a cross sectional survey Sexton and colleagues compared 1033 operating room personnel and more than 30,000 flight crew members on several items, mainly dealing with attitude towards teamwork, attitude about error and safety, and perceptions of stress and fatigue. [34] Medical respondents were more likely to agree to the item "even when fatigued, I perform effectively during critical times ", compared to flight crews (60 versus

26%). There was also a remarkable difference in preference for flat hierarchies. While 55% of the consultant surgeons advocated flat hierarchies, as many as 94% of cockpit crews indicated this to be their preferred model. This study and other analyses suggest that team training as used in aviation may also be useful in health care. CRM applications have been incorporated in various health care settings, e.g., the operating room, the emergency department, and obstetric units. This required adjustment of the training approaches to better cover the areas in which human factors contribute to errors in health care. Our project aims to assess the applicability of CRM for (pediatric) ICUs. Together with the Center for Man and Aviation, a tailored Team Resource Management training course was developed for health care workers. All employees are to participate in the training course.

Figure 2 Representation of the topics of the team resource management training, adapted from the Center for Man and Aviation.



Although CRM has been adopted in the aviation industry without objective data as to its effectiveness, we feel it has a high potential in health care. A number of studies have shown its effect on team behaviour and some have reported on positive effects on outcomes for patients.

Evaluation

Medical and nursing staff, but also hospital administrators and managers, need to work together to create a safe environment in which reporting and discussing of incidents is a routine procedure. Creating this safe and blame free working environment is the first step towards safer patient care. The next step constitutes eliciting the potential hazards, the adverse events and the outcomes related to the adverse events. Then, analysis of adverse events and (near) incidents must lead to interventions to prevent errors/incidents and to mitigate the effect of errors/incidents that do occur.

The patient safety management system developed in our unit is a growing and evolving system. There are still controversies about the effects and effectiveness of any strategy to improve patient safety. We believe that collecting and studying reports on "everything that did not go as it should have gone" will reveal all potential hazards and provide baseline data for individual units. After implementation of goal directed strategies we hopefully will be able to see a reduction in adverse events. So far our nursing and medical staffs have been very motivated to contribute to the Safety First project. Furthermore, the involvement of other disciplines has proved to be very useful. For instance, good cooperation with the hospital pharmacy and medical technology and radiology departments helped reduce the occurrence of incidents.

Conclusion

The multidisciplinary approach applied in the Safety First project aims to improve patient safety by continuous quality assessment and modification guided by real time data. Cost effectiveness of patient safety management systems is an important issue, especially in relation to the increasing costs of health care; it should be considered as an integral part of such a system and needs to be researched.

Acknowledgements: Peter N. Cox, MB ChB, Department of Critical Care Medicine, Hospital for Sick Children, University of Toronto, Canada

References

1. Institute of Medicine. To Err is Human: Building a Safer Health System. Kohn LT, Corrigan JM, Donaldson MS, editors. Washington, D.C.: National Academy Press; 2000.
2. Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. N Engl J Med. 1991;324(6):370-376
3. Leape LL, Brennan TA, Laird N, et al. The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. N Engl J Med. 1991;324(6):377-384
4. Wilson RM, Runciman WB, Gibberd RW, et al. The Quality in Australian Health Care Study. Med J Aust. 1995;163(9):458-471
5. Thomas EJ, Studdert DM, Burstin HR, et al. Incidence and types of adverse events and negligent care in Utah and Colorado. Med Care. 2000;38(3):261-271
6. Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. BMJ. 2001;322(7285):517-519
7. Davis P, Lay-Yee R, Briant R, et al. Adverse events in New Zealand public hospitals I: occurrence and impact. N Z Med J. 2002;115(1167):U271
8. Baker GR, Norton PG, Flintoft V, et al. The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. CMAJ. 2004;170(11):1678-1686
9. Zegers M, de Bruijne MC, Wagner C, et al. Adverse events and potentially preventable deaths in Dutch hospitals: results of a retrospective patient record review study. Qual Saf Health Care. 2009;18(4):297-302
10. Rothschild JM, Landrigan CP, Cronin JW, et al. The Critical Care Safety Study: The incidence and nature of adverse events and serious medical errors in intensive care. Crit Care Med. 2005;33(8):1694-1700
11. Resar RK, Rozich JD, Simmonds T, et al. A trigger tool to identify adverse events in the intensive care unit. Jt Comm J Qual Patient Saf. 2006;32(10):585-590
12. Stambouly JJ, McLaughlin LL, Mandel FS, et al. Complications of care in a pediatric intensive care unit: a prospective study. Intensive Care Med. 1996;22(10):1098-1104
13. Tibby SM, Correa-West J, Durward A, et al. Adverse events in a paediatric intensive care unit: relationship to workload, skill mix and staff supervision. Intensive Care Med. 2004;30(6):1160-1166
14. Larsen GY, Donaldson AE, Parker HB, et al. Preventable harm occurring to critically ill children. Pediatr Crit Care Med. 2007;8(4):331-336
15. Agarwal S, Classen D, Larsen G, et al. Prevalence of adverse events in pediatric intensive care units in the United States. Pediatr Crit Care Med. 2010;11(5):568-578
16. Thomas EJ, Studdert DM, Newhouse JP, et al. Costs of medical injuries in Utah and Colorado. Inquiry. 1999;36(3):255-264
17. Miller MR, Elixhauser A, Zhan C. Patient safety events during pediatric hospitalizations. Pediatrics. 2003;111(6 Pt 1):1358-1366
18. Hoonhout LH, de Bruijne MC, Wagner C, et al. Direct medical costs of adverse events in Dutch hospitals. BMC Health Serv Res. 2009;9:27
19. Medicine Io. Crossing the Quality Chasm; A New Health System for the 21st Century. Washington D.C.: National Academy Press; 2001.
20. Mills PD, Weeks WB. Characteristics of successful quality improvement teams: lessons from five collaborative projects in the VHA. Jt Comm J Qual Saf. 2004;30(3):152-162
21. Pronovost PJ, Berenholtz SM, Goeschel C, et al. Improving patient safety in intensive care units in Michigan. J Crit Care. 2008;23(2):207-221
22. Sexton JB, Berenholtz SM, Goeschel CA, et al. Assessing and improving safety climate in a large cohort of intensive care units. Crit Care Med. 2011;39(5):934-939
23. Nieva VF, Sorra J. Safety culture assessment: a tool for improving patient safety in healthcare organizations. Qual Saf Health Care. 2003;12 Suppl 2:ii17-23
24. 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(5):F391-398
25. Rowin EJ, Lucier D, Pauker SG, et al. Does error and adverse event reporting by physicians and nurses differ? Jt Comm J Qual Patient Saf. 2008;34(9):537-545
26. Taylor JA, Brownstein D, Christakis DA, et al. Use of incident reports by physicians and nurses to document medical errors in pediatric patients. Pediatrics. 2004;114(3):729-735
27. Taylor JA, Brownstein D, Klein EJ, et al. Evaluation of an anonymous system to report medical errors in pediatric inpatients. J Hosp Med. 2007;2(4):226-233

28. Snijders C, Kollen BJ, van Lingen RA, et al. Which aspects of safety culture predict incident reporting behavior in neonatal intensive care units? A multilevel analysis. Crit Care Med. 2009;37(1):61-67
29. Snijders C, van Lingen RA, Klip H, et al. Specialty-based, voluntary incident reporting in neonatal intensive care: description of 4846 incident reports. Arch Dis Child Fetal Neonatal Ed. 2009;94(3):F210-215
30. 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(6):486-491
31. Binnekade JM, de Mol BA, Kesecioglu J, et al. The Critical Nursing Situation Index for safety assessment in intensive care. Intensive Care Med. 2001;27(6):1022-1028
32. Billings CE, Reynard WD. Human factors in aircraft incidents: results of a 7-year study. Aviat Space Environ Med. 1984;55(10):960-965
33. Helmreich RL, Wilhelm JA, Gregorich SE, et al. Preliminary results from the evaluation of cockpit resource management training: performance ratings of flightcrews. Aviat Space Environ Med. 1990;61(6):576-579
34. Sexton JB, Thomas EJ, Helmreich RL. Error, stress, and teamwork in medicine and aviation: cross sectional surveys. BMJ. 2000;320(7237):745-749

Part 1

The why and how of the Safety First project

CHAPTER 2

Mortality in very long-stay pediatric intensive care unit patients and incidence of withdrawal of treatment.

Naghib S, van der Starre C, Gischler SJ, Joosten KF, Tibboel D. Mortality in very long-stay pediatric intensive care unit patients and incidence of withdrawal of treatment. Intensive Care Med. 2010 Jan; 36(1): 131-136.

MORTALITY IN VERY LONG-STAY PEDIATRIC INTENSIVE CARE UNIT PATIENTS AND INCIDENCE OF WITHDRAWAL OF TREATMENT.

Abstract

Background: The mortality for children with a prolonged stay in Pediatric Intensive Care Units (PICU) is much higher than the overall mortality. The incidence of withdrawal or limitation of therapy in this group is unknown.
Purpose: To assess mortality and characteristics of children admitted for at least 28 days to our ICU and to describe the extent to which limitations of care were involved in the terminal phase preceding death.
Methods: From the period 2003 to 2005 clinical data were collected retrospectively of children with prolonged stay (defined as ≥ 28 days) in a medical/surgical PICU of a University Children's Hospital.
Results: In the PICU 4.4% of the children (116/2607, equal gender, mean age 29 days) had a prolonged stay. Median (range) stay was 56 (28-546) days. These children accounted for 3% of total admissions and occupied 63% of total admission days. Mortality during admission for this group was 5 times higher (22%) than the average PICU mortality rate of 4.6%. Withdrawal or limitation of therapy preceded 70% of deaths.
Conclusions: Children with prolonged stay at the PICU have a significant high risk of mortality. Death is typically preceded by limitation of care.

Introduction:

Critical appraisal of the effectiveness of different modes of treatment and the demands for more cost-efficient hospital processes has focused attention upon the duration of care in an intensive care unit (ICU), an environment which necessarily provides high levels of care and therefore requires substantial operating budgets. [1-3] Median stay for most patients is two days [4, 5], but a small minority need to stay much longer and use resources in excess of their numeric proportions. [6] Long stay in the pediatric ICU is usually defined as stay longer than 12-13 days. [1, 3, 7] A special subgroup is formed by patients with very prolonged stay, longer than 30 days. [7, 8]

The few reports available on outcomes of long-stay pediatric ICU patients demonstrate higher mortality and morbidity, compared with short-stay patients. [3, 6, 9, 10] Withdrawal and limitation of medical care is associated with 14-75% of deaths in neonatal and pediatric intensive care. [11-12] These issues have been extensively discussed in the past decade [8, 11, 13-16] and have been subject to ongoing public discourse. The extent to which limitations of care actually contribute to death in very long-stay pediatric ICU patients is not known. The aim of the present study was to assess characteristics and mortality of very long-stay patients in our unit and to describe how often treatment was limited and/or withdrawn.

Methods

Data collection and definitions: The ICU of the Erasmus MC-Sophia Children's Hospital, Rotterdam, is a level III interdisciplinary intensive care unit for children in the Netherlands, providing all

pediatric and surgical subspecialties (except direct cardiopulmonary bypass). All patients including newborns with major congenital anomalies admitted from 1 January 2003 until 31 December 2005 were retrospectively identified using the computerized patient data management system. Long-stay patients were defined as those admitted for at least 28 continuous days. The reason for this cut-off point was that 28 days is three times the median length of stay in our unit. Whenever a long-stay patient was re-admitted, only the first admission was included in the study. The following clinical data: age, sex, presence and number of congenital malformations, reason for admission, and diagnosis were collected from hospital medical records and our patient data management system. Both data systems are used by nursing and medical staff.

Primary outcome was death during admission. Deaths during operations or other procedures were classified as intensive care deaths. Cause of death was categorized as [12]: Brain death, Do-not-resuscitate, failed cardiopulmonary resuscitation, withdrawal or limitation of therapy. [17-20] Retrospectively, every patient's death was classified according to four categories. Brain death (BD): when criteria for brain death were fulfilled. Do not resuscitate (DNR): when a previously ordered DNR document was available. Failed resuscitation (RES): when failed advance life support. Withdrawal or limitation of therapy (W/LT): when by agreement between family and medical staff, present level of life-sustaining treatment (LST) was limited and/or inotropes/mechanical ventilation removed.

Main diagnoses were categorized in six groups: disorders of the respiratory system, gastrointestinal disorders, multiple congenital abnormalities, neurological disorders, cardiac disease and others. Data on survival, limitations of therapy and withdrawal of therapy were collected. Decisions regarding do-not-resuscitate (DNR), limiting or withdrawing life sustaining therapy (W/LT) were taken by a multidisciplinary team (W/LT). As described earlier [21, 22] families were involved in all cases.
Severity of illness on admission was measured by the PRISM III score according to Pollack et al published in 1996, which was calculated from physiological data that included the most abnormal values in the first 12 and second 12 hrs of PICU stay.
In the terminal phase patients were not transferred to a different ward. Instead optimal palliative care was offered in a separate part of the intensive care unit. When needed or requested by the medical team and/or parents, the institutional Ethics Review Board was consulted. Approval from this Board for the present study was waived due to its retrospective character.

Setting: The setting for this study was a 34-bed multidisciplinary tertiary level III pediatric ICU with ECMO facilities, including a 6 bed step-down unit. This ICU is part of a 250-bed pediatric university hospital with a referral area of 4.000.000 and full-time staffed by intensive care specialists with basic training in pediatrics or anesthesiology.
Data Analysis: Data are presented as mean SD or median (IQR or range) where appropriate and have been analyzed with SPSS software (SPSS for windows, version 12.0, 2005, Chicago, Ill).

Results

During the study period 2607 patients were admitted on 3700 occasions with a total of 16013 admission days. Of this group 4.4 % (116/2607) patients were identified as very long-stay patients, responsible for 3.4 % (126/3700) of total admissions and consuming 63 % (10055/16013) of admis-

sion days. One hundred and six long-stay patients were admitted once, seven twice, and three were admitted three times. Demographic and care characteristics of long-stay patients are summarized in table 1. Clinical diagnoses were: disorders of the respiratory system 29 (25%), gastrointestinal disorders 23 (20 %), multiple congenital abnormalities 19 (16%), neurological disorders 18 (15%), cardiac disease 18 (15%) and others 9 (8%).

Table 1 Demographic characteristics of long-stay patients

Demographic characteristics	long-stay patients N = 116	Long-stay nonsurvivors N = 25	Long-stay survivors N = 91
Admissions	126	25	111
Fraction of total admissions (%)	3	2.6	0.6
Males (%)	57	60	58
Age median (months) (IQR25)	1	1	1
Mean age (months)	29	29	29
Mortality (%)	22	-	-
Surgical patients (%)	37	36	34
Median ventilation (days) (IQR25)	30	33	45

Their median length of stay was 56 (IQR 37-108) days. Distribution as to length of stay is shown in Fig 1. Outliers were three patients admitted for more than 300 days, the longest stay was 546 days. PRISM III scores are shown in Fig. 2. The majority of the long stay patients (58%) had a PRISM III score between 0 and 5. Ninety four patients (81%) had a maximum PRISM III score of 10.

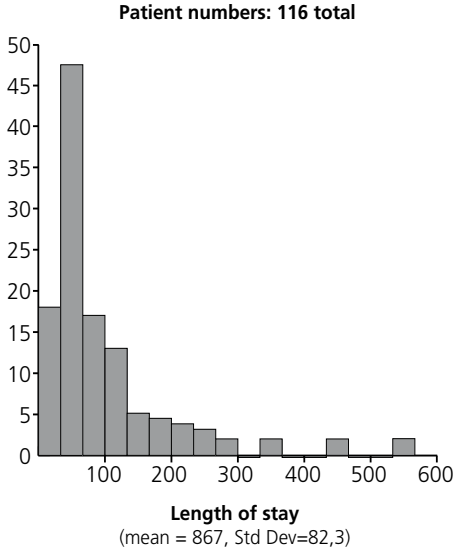
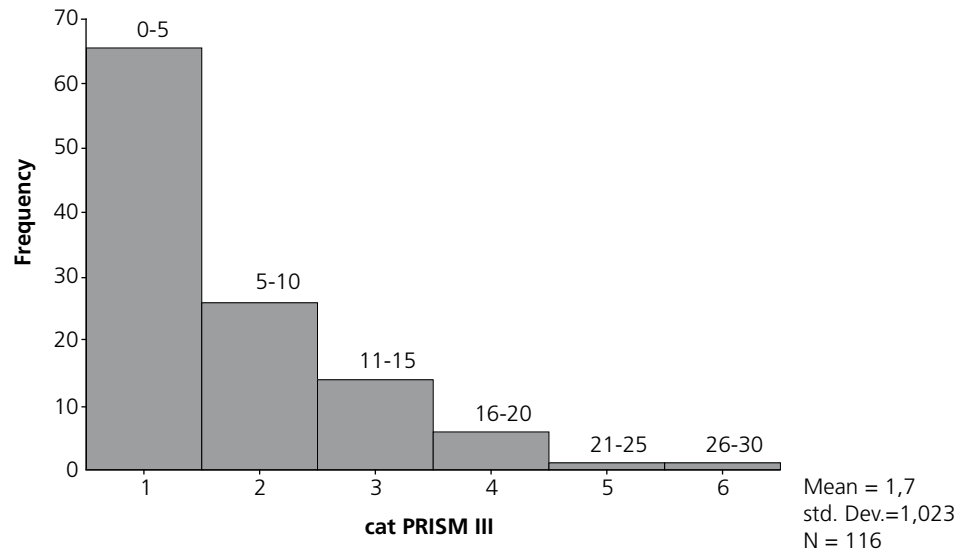


Fig. 1
Length of intensive care unit stay in days for a total of 116 long-stay patients

Fig. 2 PRISM III score among long-stay patients



During the study period 4.6% (120/2607) of the total patient group died during admission, 21% (25/120) of them were very long-stay patients. The mortality rate of long-stay patients was higher compared to short-stay patients (22% (25/116) vs.3.8% (95/2491) (p<0.001)). The characteristics of long-stay survivors and non-survivors are shown in table 2. Neonates accounted for half of the patient population in both groups. The most common diagnoses among the long stay non-survivors were multiple congenital anomalies (7/25: 28%) and cardiovascular disease (7/25: 28%). Multiple congenital anomalies was the most frequent diagnosis among the long stay survivors as well (25/91; 27%), followed by diseases of the respiratory system (22/91; 24%).

Table 2 Characteristics of nonsurvivors and survivors

Variables	Nonsurvivors	Survivors
Patient numbers	25	91
Patients no./total admissions	25	91/101
Male (%)	60	58
Median age (days)	29	34
Median length of stay (days)	67	54
Patient admission days	2538	7517
Neonate (%)	52	47
Ex-premature (%)	8	5
Diagnosis (%)		
Resp.	2/25 (8%)	22/91 (24%)
Cardio.	7/25 (28%)	7/91 (8%)
Gastro.	4/25 (16%)	17/91 (18%)
Neuro.	4/25 (16%)	14/91 (15%)
Others	1/25 (4%)	6/91 (7%)
MCA *	7/25 (28%)	25/91 (27%)

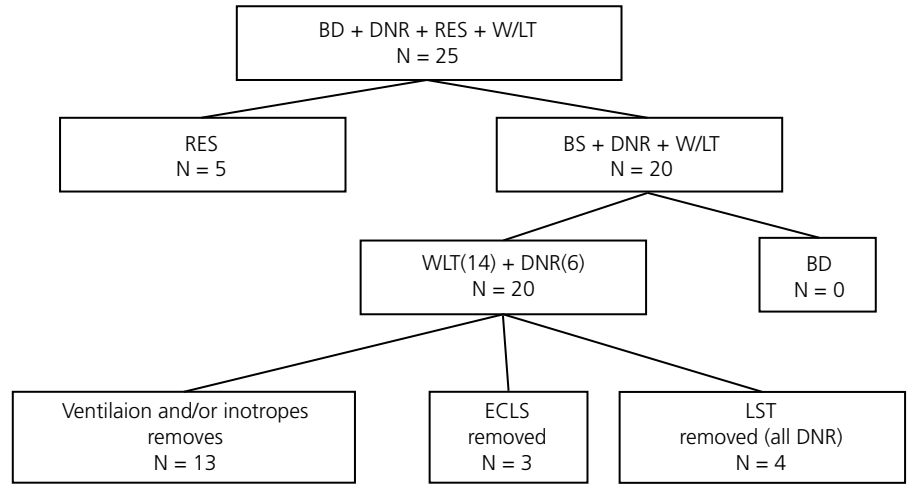
* multiple congenital anomalies

The specific primary diagnoses which lead to long stay are demonstrated in table 3.
A total of 101 readmissions were counted for 91 survivors. Comparing different diagnosis between survivors and non-survivors showed no statistical significance (p = 0.999)

Table 3 Specific primary diagnosis among long-stay patients

Primary Diagnosis	Nonsurvivors	Survivors
Dilated/restricted cardiomyopathy	2	1
Congenital heart disease	7	6
Acquired arrhythmia	0	1
Congenital airway/pulmo. disease	1	4
Acquired airway/pulmo. disease	0	5
Congenital gastrointestinal malformations	3	12
Acquired gastrointestinal disease	0	4
Congenital hypotonia	1	5
Status epilepticus (therapy resist)	1	1
Acquired neurological disease	0	1
Central hypoventilation	0	1
Infantile encephalopathy	1	3
Psychomotor retardation eci	1	1
Metabolic disease	1	2
Trauma	0	1
Sepsis	0	1
Malignancy	0	4
Multiple congenital anomalies	7	25
Congenital diaphragmatic hernia	0	12
Hematological/vascular disease	0	1
Total	25	91

Figure 3 demonstrates a flow diagram in which end-of-life categories are shown in non-survivors.
No patients were included in the category brain death. In 25 deaths, 6 patients had DNR status. Active withdrawal of support occurred in 12 patients; 2 with DNR orders and 10 without. Three patients were removed from extracorporeal life support (ECLS), one patient after 12 days ECMO and 2 cardiac patients with refractory shock.



RES: resuscitation
BD: brain death
DNR: do not resuscitate
W/LT: withdrawal/limitation of therapy
LST: life-sustaining treatment
ECLS: extracorporeal life support

Figure 3 Nonsurvivors end-of-life flow diagram in different patient groups, in which all nonsurvivors are categorized according to mode of death. RES: resuscitation, BD: brain death, DNR: do not resuscitate, W/LT: withdrawal/limitation of therapy, LST: life-sustaining treatment, ECLS: extracorporeal life support. In addition the W/LT and DNR group (n=20) is categorized by different ICU depedent treatment which they had been receiving.

Table 4 summarizes characteristics in modes of death categories and end-of-life treatments.
All end-of-life meetings between the medical team and family which resulted in limitations of treatment, DNR or withdrawal were documented. The cause of death was well-documented in all the charts, including an electronic patient data management system which has been used by both nursing and medical staff members. Consensus between caregivers and medical team regarding the end-of life meetings was reached in all cases. All parents were physically present with their child when passing away, except one parent couple who with respect to their religious restrictions unfortunately could not be present at the time of death.

Table 4 Characteristics in mode-of-death categories

	BD	DNR	W/LT	RES
Number	0	6	14	5
Age (years) mean (SD)		2.3 (4.9)	2.5 (5.6)	2.4 (5.3)
Age (years) median (range)		0.0 (0.0-3.9)	0.0 (0.0-1.5)	0.0 (0.0-6.0)
LOS (days) mean (SD)		82 (72)	102 (134)	123 (51)
LOS (days) median (range)		48 (39-136)	62 (33-107)	131 (75-167)
Initial ICU admission diagnosis (n)				
Resp		3	7	-
Cardiac		-	4	-
Resp + Cardiac		-	1	-
Resp + Surgery		2	2	-
Neuro		1	-	-
End-of-life treatments and characteristics				
Ventilated patients (n)		6	14	-
Ventilation days 80-100%		4	12	-
Tracheostomy		2	4	-
Non-invasive ventilation		-	-	
Multiple congenital anomaly		4	5	-
Dialysis		-	-	-

DNR do not resuscitate
RES (failed) resuscitation
W/LT withdrawal/limitation of therapy
BD brain death

Discussion

In this study the group very long-stay patients (LOS ≥ 28 days) forms only a small proportion of the total cohort (3%), but they are responsible for a considerable part of admission days (63%). The mortality rate for this group was five times higher than that for the total cohort.
We found that our very long stay patients consumed a high proportion of total admission days which is consistent with earlier studies performed in adult and pediatric ICUs (LOS > 12 days) [3, 7, 20]
The overall mortality rate in our ICU is comparable to the reported mortality rates from European and North American studies. [1, 4, 12] We reported a much higher mortality rate in very long stay patients (defined as ≥ 28 days) compared to short-stay patients. It is difficult to compare this mortality with earlier reports, as these were studies of long-stay patients (defined as: 7-30 days). [3, 6, 9, 10]
However, it is still lower than the ICU mortality documented among adults following very long stay (32%) [7]
Previous analysis by Marcin et al [1] of diverse PICUs in the United States indicates that among other factors, a PRISM III score between 10-33 was predictive of long stay in their population. Given that the PRISM III score has not been evaluated amongst European long-stay patients, we considered these scores in our study sample. The majority (81%) of our long-stay patients did have a PRISM III score between 0-10, which is at the lower range of the score and might be explained by the unique case mix of our ICU and the PRISM III score not being population independent.
The few studies available of adults who required at least 28-30 days of ICU care, generally report reasonable to relatively good chance of hospital and long-term survival, with some disability during daily activities. [7, 23-27] Friedrich et al. [7] reported a 32 % ICU mortality and a 58 % hospital survival rate among their very long-stay patients. Most survivors were discharged to their previous place of residence, which was considered as an important indicator of quality of life.

A high proportion of deaths in this study were preceded by end-of-life discussions, resulting in withdrawal or limitation of life-sustaining treatment. So far, however, there are no guidelines or protocols to facilitate the decision making process when establishing appropriate boundaries concerning the extent of medical care. Once certainty about the diagnosis and prognosis has been obtained, it is vital that a prominent member of the interdisciplinary teams informs the parents and evaluates whether the treatment given is in the child's best interest. [13, 16, 28, 29] If disagreement occurs between the parents and the view held by the medical team, this conflict can be mediated according to the guidelines of the Paediatric Association of the Netherlands which have been reported in the early 90's and available to all its members. Fortunately disagreement did not occur in our patient group.
Optimal palliative care was provided in a separate part of the intensive care without transferring the patient to a different ward. In the holistic approach towards our patients we appreciate continuous care given by same care providers. Carrying for families with a child awaiting the end of life creates a situation where an inevitable death demands the involved care providers to continue close relationships, especially when a long stay has been involved

The retrospective character of the study is a limitation. It was conducted in a mixed ICU population, which limits the generalisability and application to other centers. Moreover, our unit's infrastructure and the lack of separate high-dependency units within our hospital may have had a decisive influence on our findings. Generalisability, given the different population and institutional setting, has also been raised by Friedrich et al. in 2006 when evaluating an adult ICU population. [7] They described the unique character of their data, which may not be applicable to other centers with a different view on health care organization. [7] Having an intermediate/step-down unit and long term ventilatory facilities apart from the intensive care might bring other results (for example shorter ICU length of stay). The 28 days' minimum length of stay we defined may limit the applicability of our findings to other patient populations with severe congenital malformations with shorter length of stay, but also a high mortality.

Notwithstanding the limitations of this type of investigation, we believe that our data of very long-stay patients will raise awareness of this matter and contribute towards the improvement and establishment of appropriate goals of care. Long-term survival, functional outcomes and quality of life are important aspects of PICU patients that need more study. Pediatric follow-up data in long-stay patients are limited and contradictory. [3, 6]
In conclusion, the high mortality rate and frequent application of a "withholding" approach shown in this study emphasizes the necessity of timely care assessment, when a patient's stay in the pediatric ICU exceeds 28 days. A multidisciplinary team should then discuss possibilities of cure and care based on current and predicted future suffering. We recommend the use of a transparent individualized protocol to guide the treatment team towards boundaries of care.

Ongoing investigation is needed to point out the different indications and justifications of limita-

tions of treatment for pediatric ICU patients with a prolonged length of stay. Early identification of patients at risk of very long stay and recognition of their high risk of mortality and potential consequences for future therapeutic modalities should be incorporated into the activities of teams working at the pediatric ICU.

References

1. Marcin JP, Slonim AD, Pollack MM, et al. Long-stay patients in the pediatric intensive care unit. Crit Care Med. 2001;29(3):652-657
2. Slonim AD, Marcin JP, Pollack MM. Long-stay patients: are there any long-term solutions? Crit Care Med. 2003;31(1):313-314
3. Pollack MM, Wilkinson JD, Glass NL. Long-stay pediatric intensive care unit patients: outcome and resource utilization. Pediatrics. 1987;80(6):855-860
4. Gemke RJ, Bonsel GJ. Comparative assessment of pediatric intensive care: a national multicenter study. Pediatric Intensive Care Assessment of Outcome (PICASSO) Study Group. Crit Care Med. 1995;23(2):238-245
5. Ruttimann UE, Pollack MM. Variability in duration of stay in pediatric intensive care units: a multiinstitutional study. J Pediatr. 1996;128(1):35-44
6. van der Heide P, Hassing MB, Gemke RJ. Characteristics and outcome of long-stay patients in a paediatric intensive care unit: a case-control study. Acta Paediatr. 2004;93(8):1070-1074
7. Friedrich JO, Wilson G, Chant C. Long-term outcomes and clinical predictors of hospital mortality in very long stay intensive care unit patients: a cohort study. Crit Care. 2006;10(2):R59
8. Tibballs J. Legal basis for ethical withholding and withdrawing life-sustaining medical treatment from infants and children. J Paediatr Child Health. 2007;43(4):230-236
9. Kanter RK, Bove EL, Tobin JR, et al. Prolonged mechanical ventilation of infants after open heart surgery. Crit Care Med. 1986;14(3):211-214
10. Gemke RJ, Bonsel GJ, van Vught AJ. Long-term survival and state of health after paediatric intensive care. Arch Dis Child. 1995;73(3):196-201
11. Levetown M, Pollack MM, Cuerdon TT, et al. Limitations and withdrawals of medical intervention in pediatric critical care. JAMA. 1994;272(16):1271-1275
12. Garros D, Rosychuk RJ, Cox PN. Circumstances surrounding end of life in a pediatric intensive care unit. Pediatrics. 2003;112(5):e371
13. Hazebroek FW, Tibboel D, Mourik M, et al. Withholding and withdrawal of life support from surgical neonates with life-threatening congenital anomalies. J Pediatr Surg. 1993;28(9):1093-1097
14. Gill M. PICU Prometheus: Ethical issues in the treatment of very sick children in pediatric inteinsive care. Mortality. 2005;10(4):262-275
15. Mink RB, Pollack MM. Resuscitation and withdrawal of therapy in pediatric intensive care. Pediatrics. 1992;89(5):961-963
16. Verhagen AA, Sauer PJ. End-of-life decisions in newborns: an approach from The Netherlands. Pediatrics. 2005;116(3):736-739
17. Parker BL, Frewen TC, Levin SD, et al. Declaring pediatric brain death: current practice in a Canadian pediatric critical care unit. CMAJ. 1995;153(7):909-916
18. Guidelines for the diagnosis of brain death. Patient Care Policy. Toronto, Ontario, Canada: Hospital for Sick Children (Report No. 2.25); 1987.
19. Guidelines for the Appropriate Use of Do-Not-Resuscitate Orders. Council on Ethical and Judicial Affairs, American Medical Association. JAMA. 1991;265(14):1868-1871
20. Do not resuscitate (DNR) order. Policy and Procedure Manual Hospital for Sick Children. Toronto, Ontario, Canada; 1994. pp. 1-3
21. Hazebroek FW, Bouman NH, Tibboel D. The neonate with major malformations: experiences in a university children's hospital in the Netherlands. Semin Pediatr Surg. 2001;10(4):222-229
22. Caniano DA, Hazebroek FW, DenBesten KE, et al. End-of-life decisions for surgical neonates: experience in The Netherlands and United States. J Pediatr Surg. 1995;30(10):1420-1424
23. Gracey DR, Naessens JM, Krishan I, et al. Hospital and posthospital survival in patients mechanically ventilated for more than 29 days. Chest. 1992;101(1):211-214
24. Montuclard L, Garrouste-Orgeas M, Timsit JF, et al. Outcome, functional autonomy, and quality of life of elderly patients with a long-term intensive care unit stay. Crit Care Med. 2000;28(10):3389-3395
25. O'Brien BP, Butt W, Suhr H, et al. The functional outcome of patients requiring over 28 days of intensive care: a long-term follow-up study. Crit Care Resusc. 2006;8(3):200-204
26. Rimachi R, Vincent JL, Brimioulle S. Survival and quality of life after prolonged intensive care unit stay. Anaesth Intensive Care. 2007;35(1):62-67
27. Hughes M, MacKirdy FN, Norrie J, et al. Outcome of long-stay intensive care patients. Intensive Care Med. 2001;27(4):779-782
28. Bondi SA, Gries D, Faucette K. Neonatal euthanasia? Pediatrics. 2006;117(3):983; author reply 983-984
29. Verhagen E, Sauer PJ. The Groningen protocol--euthanasia in severely ill newborns. N Engl J Med. 2005;352(10):959-962

Part 1

The why and how of the Safety First project

CHAPTER 3

Does a patient safety management system in pediatric intensive care result in fewer preventable deaths?

Van der Starre, van Dijk, Naghib, Gischler, de Hoog, Tibboel. Submitted

DOES A PATIENT SAFETY MANAGEMENT SYSTEM IN PEDIATRIC INTENSIVE CARE RESULT IN FEWER PREVENTABLE DEATHS?

Abstract

Objective:
To determine whether 5 years of patient safety activities would have reduced the number of potentially preventable deaths in a single tertiary care intensive care unit in a university children's hospital.
Design:
An observational study with a before-after design.
Setting:
A level III 28-bed intensive care unit in a university children's hospital. A patient safety management system has been in place since 2005.
Patients:
Children who died in the ICU in the years 2001-2002 (before introduction of Patient Safety Management System); and 2006-2007 and 2009.
Measurement:
Numbers of potentially preventable deaths, numbers and types of potentially preventable adverse events contributing to death and demographic data of these patients.
Main results:
31 of 255 deaths (12%) were classified by five pediatric intensivists independently as potentially preventable. A median of 2 adverse events were identified in these 31 cases (interquartile range 2-3; total 100). The most frequent adverse events were blood stream infections (35%) and neurological damage (14%). Patients in the potentially preventable death group were statistically significantly younger (p= 0.003) and had a longer length of stay (p<0.001) than the other deceased patients. Numbers of preventable deaths did not significantly change over the time periods studied.
Conclusion:
There was no detectable reduction in potentially preventable mortality after 5 years of patient safety efforts. Harm resulting from adverse events would be a more useful measure to evaluate patient safety.

Introduction

Since the publication of the ground breaking report "To Err is Human" concerning the high incidence of preventable deaths in US hospitals, efforts have been directed toward diminishing these avoidable deaths. [1] Some of the most striking examples are the "Saving 100k Lives" campaign by the Institute for Healthcare Improvement in the USA [2] and "Patient Safety First" by the National Patient Safety Agency in the UK. [3]
A Dutch review estimated that approximately 1700 patients, excluding children under 1 year of age, die each year in Dutch hospitals from avoidable adverse events. [4] Like in other countries, campaigns have been launched in the Netherlands to reduce the preventable mortality. The Ministry of Health and the Healthcare Inspectorate have stimulated nation wide patient safety guidelines; the Dutch Technical Agreement on Patient Safety delineates requirements for hospital patient safety management. In the literature, pediatric intensive care units (PICUs) have been recognized as high-risk environments where patients are at considerable risk of suffering harm from their care management. [5-7] In these studies, though not exactly quantified, some of the incidents and adverse events were considered to have contributed to fatal outcomes for these children.
The aim of this study is to determine whether 5 years of patient safety activities in our tertiary care pediatric intensive care unit has succeeded in reducing the number of potentially preventable deaths.

Materials and Methods

Eligible subjects were all children who died in the Erasmus MC - Sophia ICU over three time periods: January 2001 to December 2002 (before introduction of a patient safety management system (PSMS) in 2005), January 2006 to December 2007 (shortly after the PSMS was introduced) and January 2009 to December 2009 (five years after introduction). Excluded were children whose medical records were incomplete.

Setting and description
The Erasmus MC - Sophia Children's Hospital is a tertiary care university hospital with a 28 bed intensive care unit and a 6 bed step-down unit. The ICU provides all types of intensive care, such as transplant surgery, neonatal and pediatric ECMO, cardiac surgery and care for newborns with major congenital anomalies and admits approximately 1400 patients per year. The medical staff consists of 8 fully trained pediatric intensivists, one neonatologist and one pediatric anesthesiologist, with fellows in training for pediatric intensive care and pediatric anesthesiology. There is full time attendance of a medical team of at least 1 resident, 1 fellow and 1 pediatric intensivist at consultant level. The three time periods were selected to represent the before and after situation, as the PSMS was launched in 2004. The first components of the PSMS were voluntary incident reporting [8], team resource management training [9-10], scoring of nursing protocol violations [11] and registration of adverse events. In order to fully implement and further develop the PSMS a physician (CvdS) and nurse (AvdB) were trained in patient safety at the Institute for Healthcare Improvement, Boston, USA and appointed as patient safety officers. Subsequently, safety walk rounds [12], critical incident analysis [13], patient safety oriented mortality and morbidity conferences, prospective risk analysis [14] and simulation training were introduced since 2007.
Data analysis
The medical records were reviewed for adverse events by two investigators. For the purpose of this study we defined patients whose deaths were potentially preventable as patients who suffered adverse events that contributed to their death and that were potentially preventable, in line with a former publication. [15] Adverse events were defined as unintended and unwanted injuries or complications caused by healthcare management. An event was deemed potentially preventable if known interventions could have reduced the risk of its occurrence. As the goal of the study was to determine the effectiveness of safety measures on the PICU, we excluded the deaths attributable to adverse events that occurred outside of the PICU setting. A neonatologist (CvdS) and an intensivist (DT), with 5 and 26 years working experience, respectively, independently reviewed the medical records and scored the deaths as 'potentially preventable' or 'not potentially preventable'. Consensus was reached in a subsequent meeting. To improve classification reliability, the records of all deceased

patients were randomly distributed among 3 other consultants, pediatric intensivists (MdH, SG,SN) with 15, 16 and 4 years of experience, who independently classified the deaths as potentially preventable or not. Consensus between all was achieved in a separate meeting.

Statistical analysis

Interrater reliability of classifying potentially preventable deaths was determined with the unweighted Cohen's kappa. A value between 0.61 and 0.80 is considered good. [16] Normally distributed variables are presented as mean (standard deviation) and non-normally distributed variables as median (interquartile range). Mann Whitney tests were used to compare background characteristics of the potentially preventable deaths to those of the other deaths.

Results

Over the three study periods there were 5462 discharges of which 257 patients died; thus the overall mortality rate was 4.7%. Two cases were excluded because the medical records were incomplete. The Cohen's kappa coefficient for the two consultants who first independently classified the 255 deaths was low (0.36), after a consensus meeting they reached consensus on 35 deaths being preventable. A second consensus meeting in which the classification by three others was considered resulted in consensus on 31 patients (12.1%). Kappa coefficient between the results of the first and second consensus meeting was 0.76. There was no significant decline in the number of potentially preventable deaths in the consecutive years before and after the introduction of the PSMS (p=0.18) (table 1).

Figure 1 Numbers of deaths reviewed

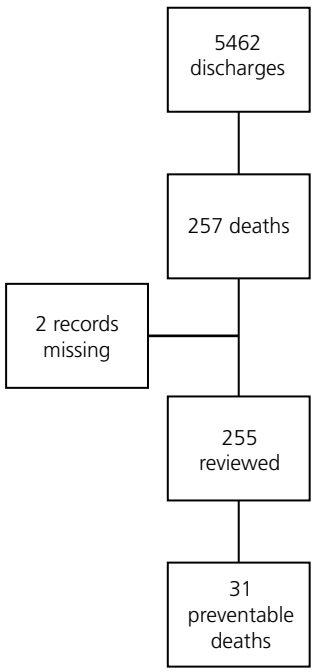


Table 1 Numbers of deaths and potentially preventable deaths per year.

Year	2001	2002	2006	2007	2009	Total
New admissions*	1023	1042	1196	1192	1189	5642
Number deaths	51	63	45	46	50	255
Number preventable deaths (%)	5 (9.8)	5 (7.9)	10 (22.2)	5 (9.8)	6 (10.9)	31 (12.1)
reason admission preventable deaths	CDH 4 sepsis 1	resusc 2 CDH 1 MCA 1 abd/surg 1	card 4 CDH 2 MCA 1 resp 1 ECMO 1 neur 1	resp 2 CDH 1 card 1 abd/surg 1	resp 2 CDH 1 card 1 MCA 1	

* Admissions may include repeated admissions of the same patients
Abbreviations: CDH congenital diaphragmatic hernia; MCA major congenital anomalies; resusc resuscitation; abd/surg abdominal/surgical; card cardiac/circulatory; resp respiratory insufficiency; neur neurological; ECMO extracorporeal membrane oxygenation

Table 2 Background characteristics of potentially preventable deaths and other deaths

	Preventables N=31	**Others** N=224	**p-value**
Boy/girl, N (%) (%)	18/13 (58/42)	112/112 (50/50)	0.40
Age at admission (months)			
Median	1.5	13.0	0.003
IQR	0 -19.4	1.1 – 69.0	
Length of stay (days)			
Median	19	4	<0.001
IQR	8 - 51	2 -14	
Reasons for admission (%)			
- resp insufficiency	5 (16.1)	65 (29.0)	
- cardiac/circulatory	6 (19.3)	36 (16.1)	
- resuscitation	2 (6.4)	26 (11.6)	
- MCA, including CDH (10 resp 13)	13 (41.9)	25 (11.1)	
- neurological	1 (3.2)	17 (7.6)	
- sepsis	1 (3.2)	17 (7.6)	
- trauma	-	17 (7.6)	
- ECMO	1 (3.2)	7 (3.1)	
- drowning	-	6 (2.7)	
- abdominal/surgical problem	2 (6.4)	5 (2.2)	
- suffocation	-	3 (1.3)	

Abbreviations:
IQR: interquartile range; MCA: major congenital anomalies; CDH; congenital diaphragmatic hernia; ECMO: extracorporeal membrane oxygenation

The number of preventable deaths in 2006 (n=10) was higher than that in all other years (n=5 or 6). The children who died of potentially preventable adverse events were statistically significantly younger than the other deceased children (p=0.003). Their median length of stay was statistically significantly longer (19 days versus 4 days respectively, p<0.001). The primary reasons for admission are listed in table 2. Of the preventable death patients, 13 (42%) were admitted because of major congenital anomalies. Ten of these (32% of all) had a congenital diaphragmatic hernia.
100 adverse events were identified that contributed to all preventable deaths and were potentially preventable The number of adverse events per patient ranged from 1 to 22 with a median of 2 per patient (IQR 2 to 3), significantly higher than the median of 0 (IQR 0-1) for the non-preventable deaths (p < 0.001). The patient with 22 adverse events was an outlier; she had trisomy 21 with a congenital heart defect, pulmonary hypertension, necrotizing enterocolitis with short bowel syndrome and tracheal stenosis; was admitted for 529 days; suffered 17 distinct episodes of blood stream infections, cholestatic liver insufficiency; and had 3 unplanned returns to surgery. She died from a Candida septicemia complicated by intractable pulmonary hypertension. A number of the adverse events she suffered occurred in 2005, but for this study they were recorded in 2006, as she died in that year. The most frequent occurring adverse events were blood stream infections (35%) and neurological damage (14%); the latter comprised hemorrhage, ischemia and hypoxic damage of the brain (table 3).

Table 3 numbers and types of potentially preventable adverse events.

Adverse events	**total**
Blood stream infections*	35
Neurological damage†	14
Thrombosis	8
Bleeding	7
Other infections	6
Unplanned return to surgery	5
Technical/procedural problem	4
Pleural effusion	4
Resuscitation	3
Pneumothorax/-mediastinum	3
Renal insufficiency	2
Arrhythmia	2
Other††	7
Total	**100**

* 1 patient suffered 17 episodes of blood stream infections
† neurological damage: ischemia, bleeding, hypoxic encephalopathy
†† in the category "other": accidental extubation, severe skin necrosis, myocardial ischemia, medication error, diagnostic delay, cholestatic liver insufficiency, pericardial effusion

Discussion

This study in a single high volume level III PICU does not show a decrease of potentially preventable deaths 5 years after the introduction of a patient safety management system.
The percentage of preventable deaths is lower (12.1%) than that reported in a study on the then surgical PICU in our hospital in 1991, in which over a 10 year period 22% of the investigated deaths were classified as preventable. [15] The latter study, however, also took into account adverse events outside the PICU.

The relative high number of potentially preventable deaths in 2006 appears to be a coincidence, as there were no significant changes in patient numbers and characteristics, or in staffing, work environment and protocols. There is a notable over-representation of patients with major congenital anomalies, in particular congenital diaphragmatic hernia, in the entire group of preventable deaths. A possible explanation is that these patients undergo highly technological interventions, such as Extra Corporeal Membrane Oxygenation (ECMO). Thus, the nature of the disease and the inherent exposure to invasive interventions, implicate that these children are at high risk of adverse events.

Most of the public attention for patient safety has focused on preventable mortality and there is an increasing demand for results after years of safety initiatives. The high proportion of preventable deaths in our unit in earlier years (22%) was the rationale for investigating whether we could demonstrate any such results. There are several explanations for the stable numbers of preventable deaths over the years. First, the overall mortality in PICUs reached a plateau, around 6% elsewhere [17-18] and 4.7% in this study. Therefore, it becomes more difficult to observe trends in mortality rates in a single unit. Second, the number of potentially preventable deaths is very low, thus making it even harder to achieve a significant decrease.
Also, due to the small numbers, it is impossible to apply multivariate analysis to identify the relevance of contributing factors such as patient or healthcare management problems. Third, the patient safety management system had been in place for a relatively short period (5 years). Landrigan et al reported in 2010 that 6 years of patient safety activities had not yet resulted in a measurable decrease of patient harm in 2341 admissions in acute care hospitals in North Carolina, USA. [19] We would argue therefore that incidence of preventable deaths is not a very useful outcome measure of safe care in pediatric intensive care settings. Another argument against it lies in the difficulties in determining preventability. In our study the interrater reliability was not very high, despite the clear definitions published by our group in 1991. Other studies into preventable adverse outcomes have also reported low interrater reliability. In our opinion it is more relevant to measure harm in the form of adverse events and the consequences they carry in terms of patient/parent suffering, length of stay and costs. Furthermore, sharing data on numbers and types of these adverse events will enable benchmarking, thus facilitating learning from each other.

A number of studies have looked into preventable mortality in children. In 2010 Pearson et al reported on the deaths of all children in a large region of the UK in 2006. [20-21] Avoidable factors could be identified in 26% of the deaths, and potentially avoidable factors in 43%, in contrast to the 12.1% in the present study. Their data also contained trauma, suicide, drowning and other non-healthcare

factors. They did show, however, that the largest clusters of avoidable factors occurred in hospitals, and that the problems were mostly related to pre-PICU issues. Monroe et al recently (2011) studied the pre-hospital and hospital management of critically ill children dying in the PICU. [22] They reported that adverse events contributing to death had occurred in 36% of 47 deceased children. Ninety-one percent of the adverse events had occurred in pre-PICU hospital care, 9% in pre-hospital management. They did identify critical incidents in the PICU, but none were judged to have contributed to death. The difference with our study is that we have focused on adverse events occurring in the PICU, thus, our results can not be compared with the Monroe study. Another difference is that we have studied multiple time-periods, in an effort to evaluate the effects of the patient safety management system.

A limitation of our study is the lack of risk of scores for disease severity, as it might be argued that the most critically ill are more likely to die if an adverse event occurred. These data were not available for the years 2001, 2002 and 2006. However, the case mix of the patients appears to be a representation of all types of patients admitted to our PICU, and not a selection of the most severely ill. Another limitation to the study is the difficulty we experienced in achieving good inter-rater reliability. After the review by the original investigators, the interrater reliability was poor. This appeared to be caused by the difficulty in determining whether an adverse event had contributed to the death, as causality between adverse events and outcome is hard to establish. Also determining the degree of preventability was a challenge.

The information in the medical records quite often had to be complemented with information retrieved from the memory of the investigators. This also increases the risk of hindsight bias, as with most retrospective studies. [23] The risk of hindsight bias could be reduced by performing retrospective review with a team of trained caregivers complemented with medical experts from outside the hospital. Preferably this would be a two-step review, where investigators first review cases independently and then review the cases together. Reviewing mortality is by its very nature retrospective and at risk of several methodological weaknesses. Even though preventable deaths are not adequate as outcome parameters, we believe its value in uncovering flaws in the care management outweighs these counterarguments, and we would like to argue that reviewing deaths needs to remain part of intensive care practice. For instance, thoroughly investigating the preventable deaths in Mortality and Morbidity conferences provides opportunities for exploring the adverse events and ways to prevent them in the future.

Conclusion

Preventable mortality is not an adequate outcome measure for patient safety activities in pediatric intensive care units; preventable adverse events might be a better marker. The number of potentially preventable deaths per year in our single large PICU was small and did not decrease after the introduction of a patient safety management system. Larger projects, such as the Dutch Pediatric Intensive Care Evaluation Project (in which annual data of all 8 designated PICUs in the Netherlands are collected) are necessary to analyze trends in preventable and non-preventable mortality.

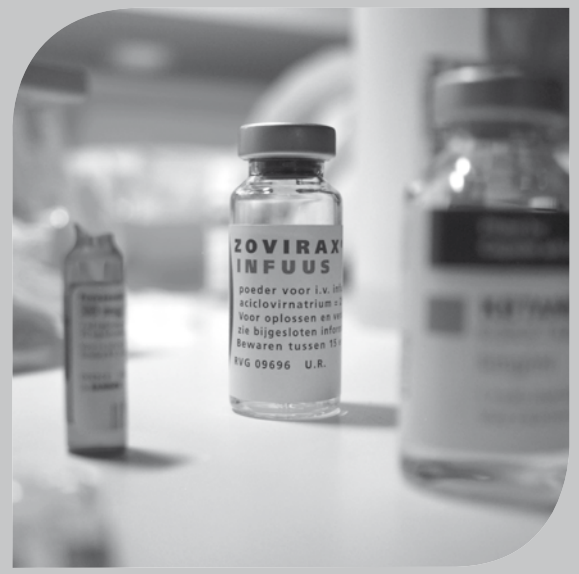
References

1. Institute of Medicine. To Err is Human: Building a Safer Health System. Kohn LT, Corrigan JM, Donaldson MS, editors. Washington, D.C.: National Academy Press; 2000.
2. Berwick DM, Calkins DR, McCannon CJ, et al. The 100,000 lives campaign: setting a goal and a deadline for improving health care quality. JAMA. 2006;295(3):324-327
3. NHS. Patient Safety First. 2008 [updated 2008; cited 2011 august 9]; Available from: www.patientsafetyfirst.nhs.uk/content.aspx?path=/
4. Zegers M, de Bruijne MC, Wagner C, et al. Adverse events and potentially preventable deaths in Dutch hospitals: results of a retrospective patient record review study. Qual Saf Health Care. 2009;18(4):297-302
5. Frey B, Kehrer B, Losa M, et al. Comprehensive critical incident monitoring in a neonatal-pediatric intensive care unit: experience with the system approach. Intensive Care Med. 2000;26(1):69-74
6. Tibby SM, Correa-West J, Durward A, et al. Adverse events in a paediatric intensive care unit: relationship to workload, skill mix and staff supervision. Intensive Care Med. 2004;30(6):1160-1166
7. Agarwal S, Classen D, Larsen G, et al. Prevalence of adverse events in pediatric intensive care units in the United States. Pediatr Crit Care Med. 2010;11(5):568-578
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(5):F391-398
9. Morey JC, Simon R, Jay GD, et al. Error reduction and performance improvement in the emergency department through formal teamwork training: evaluation results of the MedTeams project. Health Serv Res. 2002;37(6):1553-1581
10. Dunn EJ, Mills PD, Neily J, et al. Medical team training: applying crew resource management in the Veterans Health Administration. Jt Comm J Qual Patient Saf. 2007;33(6):317-325
11. Binnekade JM, de Mol BA, Kesecioglu J, et al. The Critical Nursing Situation Index for safety assessment in intensive care. Intensive Care Med. 2001;27(6):1022-1028
12. Montgomery VL. Impact of Staff-Led Safety Walk Rounds (Vol. 3: Performance and Tools). 2008;
13. Vincent C, Taylor-Adams S, Chapman EJ, et al. How to investigate and analyse clinical incidents: clinical risk unit and association of litigation and risk management protocol. BMJ. 2000;320(7237):777-781
14. van Tilburg CM, Leistikow IP, Rademaker CM, et al. Health Care Failure Mode and Effect Analysis: a useful proactive risk analysis in a pediatric oncology ward. Qual Saf Health Care. 2006;15(1):58-63
15. Hazebroek FW, Tibboel D, Leendertse-Verloop K, et al. Evaluation of mortality in surgical neonates over a 10-year period: nonpreventable, permissible, and preventable death. J Pediatr Surg. 1991;26(9):1058-1063
16. Altman DG. Practical statistics for medical research. London: Chapman and Hall; 1991.
17. Garros D, Rosychuk RJ, Cox PN. Circumstances surrounding end of life in a pediatric intensive care unit. Pediatrics. 2003;112(5):e371
18. Sands R, Manning JC, Vyas H, et al. Characteristics of deaths in paediatric intensive care: a 10-year study. Nurs Crit Care. 2009;14(5):235-240
19. Landrigan CP, Parry GJ, Bones CB, et al. Temporal trends in rates of patient harm resulting from medical care. N Engl J Med. 2010;363(22):2124-2134
20. Pearson GA, Ward-Platt M, Harnden A, et al. Why children die: avoidable factors associated with child deaths. Arch Dis Child. 2010;
21. Pearson G. Why cildren die: the report of a pilot confidential enquiry into child death by CEMACH (Confidential Enquiry into Maternal and Child Health). Clinical Risk. 2008;14(5):166-168
22. Monroe K, Wang D, Vincent C, et al. Patient safety factors in children dying in a paediatric intensive care unit (PICU): a case notes review study. BMJ Qual Saf. 2011;
23. Thomas EJ, Lipsitz SR, Studdert DM, et al. The reliability of medical record review for estimating adverse event rates. Ann Intern Med. 2002;136(11):812-816

LARA'S STORY: PART 2

Lara was born!

The doctors said she did very well after birth; she was crying and could breathe on her own. They put an iv-line in her hand and took her to the ICU. She weighs only 1700 grams but the nurse said that's good for her age. Now Thomas and Melissa will have to wait and see how Lara will do. The doctors and nurses are keeping a close eye on her, and they are going to do blood tests and X-rays. A couple of hours later, Thomas is getting worried about Lara's breathing. She keeps blowing bubbles and she has to work really hard to breathe. The nurse will call the doctor to have a look. Also they are going to check if the tube in her nose that has to keep the fluid out of her esophagus isn't blocked.



CHAPTER 4

Real time registration of adverse events in Dutch hospitalized children in general pediatric units: first experiences

Van der Starre, van Dijk, Tibboel
Accepted for publication by European Journal of Pediatrics

REAL TIME REGISTRATION OF ADVERSE EVENTS IN DUTCH HOSPITALIZED CHILDREN IN GENERAL PEDIATRIC UNITS: FIRST EXPERIENCES.

Abstract

The objective of this study to describe number and nature of adverse events occurring in general pediatric practice; to describe factors contributing to the occurrence of these adverse events; and to report on the experience of pediatricians with reporting adverse events. It is a prospective study on 11 pediatric units in a three month period; adverse events were registered for all newly admitted patients. Ninety-four adverse events were registered in 88 of 5669 patients, amounting to a 1.6 per 100 admissions rate and a 0.4 per 100 patient days rate. Ninety percent of the adverse events did not cause serious harm. Failed diagnostic procedures were most common.
Conclusion:
Adverse event registration in general pediatric practice is a first step in assessing quality and safety of care. It yields a considerable number of adverse events. Compliance to adverse event registration in daily practice is difficult but also key to optimal monitoring of quality of care.

Introduction

Since the publication of the report "To Err is Human" [1], quality and safety of care have been improved to decrease harm and adverse events. Nevertheless, a recent report showed little progress in reducing harm for adult patients in 10 acute care hospitals in North Carolina. [2] Annual adverse event rates of 1 to 3.4 % for hospitalized children have been reported in the US. [3-6] Adverse event rates for Dutch hospitalized children cannot be determined from available databases.
The Dutch Ministry of Health decreed that by January 1st 2008 all Dutch hospitals were to have a working patient safety management system. The Dutch Health Care Inspectorate subsequently established adverse event registration as a quality indicator for Dutch healthcare. These developments triggered the Pediatric Association of the Netherlands in collaboration with the Dutch Order of Medical Specialists to develop an easy-to-use reporting system for adverse events. The goal is to establish the exact rate and nature of adverse events in pediatric practice. The pediatric registration system is modeled after the surgical adverse event registration system and is intended to be used by all pediatricians in the Netherlands, so it can serve as a benchmarking tool for patient safety management. A previous study by Van den Beuken et al tested the design of the registration system [7]; the system was subsequently approved by the Paediatric Association of the Netherlands. In this study we report the first experience with prospective voluntary registration of adverse events in general pediatric units in Dutch hospitals. We describe the numbers and nature of the adverse events, the contributing factors and consequences of the adverse events and report on the findings of the pediatricians using this registration system.

Methods

Study design
We conducted a prospective study in 11 general pediatric units in the Netherlands, geographically evenly distributed over the Netherlands, and recruited by open invitation. During a 3 month period pediatricians collected general data and adverse events for all newly admitted patients on general pediatric units.
Setting
The units employed an average of 9 pediatricians (range 6 to 15) and a changing number of residents in training for pediatrics or not in training. Ten units were located in regional hospitals; one was a general pediatric unit in a university hospital, providing the same level of care as the non-academic units. Four of the ten regional hospitals are pediatric teaching hospitals. The mean number of beds in the regional hospitals was 556 (median 570, range 267 – 1070).
All the pediatricians in each unit agreed to participate in the study and one to three in each unit volunteered to be the primary contacts for the study.
Registration
The general data collected were patient details (name, date of birth, sex, hospital ID) and dates of admission and discharge). An adverse event was defined as any harm inflicted on the patient by medical care, whether or not the result of an error, with consequences such as adjustment of medical management, (permanent) scarring, or lengthening of hospital stay. As a first step in the registration, the localization is recorded, i.e. the body site or organ involved, and second the nature of the event, i.e. what actually happened. Furthermore, potentially contributing factors are registered, for instance placement of a nasogastric tube or administration of medication. Thus, pneumonia due to aspiration caused by vomiting during placement of a nasogastric tube would be registered as a respiratory adverse event (pneumonia) with placement of nasogastric tube as contributing factor. Finally, the consequence of the adverse event was registered. An adverse event was considered to have a serious consequence if it resulted in longer hospital stay (≥ 1 day), (temporary) disability or death. If a consequence was adjustment of medical management or temporary discomfort (e.g. extra blood sampling) it was deemed minor. The adverse events could be registered in handheld computers, in computer databases or on paper.
All 21 participating pediatricians (1 to 3 per unit) were assembled twice and instructed on what constitutes an adverse event and were trained in the use of the registration system. Formal testing of inter-rater reliability on the assessments of adverse events was not performed. The participants were requested to register all adverse events in newly admitted patients in the stated period. They were recommended to ask nursing and medical staff during daily rounds and handovers about occurrences of adverse events. It was left to the participants how the adverse events would be brought to their attention, at what time they registered the event and whether or not to invite others to register adverse events as well. At the end of the study period, the data were collected by the author and imported in a database. The adverse events were reviewed by the author with the pediatricians and in cases where there was doubt whether an event was actually validly registered as an adverse event, consensus was reached after discussing the adverse event. The adverse events were then classified in the categories "diagnostic", "therapeutic", "medication", "non-surgical procedure" and "other". Four weeks after the study all participating units received evaluation forms

by mail including both multiple choice and open questions on the use of the registration.

Results

In three months, 94 adverse events were registered for 88 of 5669 newly admitted patients. Thus, the mean adverse event rate was 0.0165 per admission (range 0.004-0.046, median 0.015) and 0.4 adverse events per 100 patient days (range 0.05-0.9, median 0.3). The distribution over the participating units is detailed in table 1; the rates vary widely, with the number of adverse events per unit ranging from 1 to 29.

Table 1 Number of adverse events, % advers events per discharge and number adverse events per 100 patient days per unit.

	Unit A (n=546)	Unit B (n=629)	Unit C (n=602)	Unit D (n=528)	Unit E (n= 535)	Unit F (n=543)
Adverse events (% of AEs per discharge)	5 (0.9%)	29 (4.6%)	3 (0.5%)	10 (1.9%)	5 (0.9%)	4 (0.7%)
Number AEs / 100 patient days	-*	0.9	-*	0.4	0.2	0.1

	Unit G (n=274)	Unit H (n=785)	Unit I (n=493)	Unit J (n=482)	Unit K (n=252)	Total (n=5669)
Adverse events (% of AEs per discharge)	6 (2.2%)	12 (1.5%)	10 (2.0%)	9 (1.9%)	1 (0.4%)	94 (1.65%, median 1.5%)
Number AEs / 100 patient days	0.3	0.3	0.5	0.4	0.05	0.4 (median 0.3)

* Missing data
Abbreviations: AE adverse event
AEs adverse events

The localizations of the adverse events are listed in table 2. The localization "other" (n=54) related to the adverse event of "pain" in 27 cases and to "other adverse event" in 26 cases, for instance failures in diagnostic procedures. The categories of the adverse events are detailed in table 3. Most were of a diagnostic nature. These include blood sampling failure (n=13), lumbar puncture failure (n=6) urine sampling failure (n=6) and missed diagnosis (3 cases of appendicitis and one case of urosepsis).

Table 2 Distribution of adverse events in localization, n (%)

Localization	number	%
Other	54	57.4
Biochemistry	12	12.8
Skin	9	9.6
Respiratory system	8	8.5
Gastro-enterologic system	5	5.3
Circulatory system	3	3.2
Haematological system	2	2.1
Urinary tract	1	1.1
Total	94	100

Table 3 Classification of adverse events

Category	N=94 (100%)
Diagnostic	38 (40.4%)
Therapewutic	20 (21.3%)
Medication	19 (20.2%)
Non surgical procedures	11 (11.7%)
Other	6 (6.4%)

Potentially contributing factors to the occurrence of the adverse event were registered in 48 of the 94 adverse events (51.8%) (table 4). In 16 cases (17.2%) a failure in the medication process; in 6 cases lumbar puncture (in 5 cases a dry tap and in 1 case the liquor sample was lost). A urinary catheter or catheterization was related to an adverse event in 5 cases: 3 catheterizations failed, 1 urine sample was lost; and 1 patient developed urinary tract infection while having a urinary catheter in situ.

Chapter 4

Table 4 Specification of potentially contributing factors to adverse events

External factor	No	% of AEs	Corresponding adverse events	No
Medication failure	16	17.2	Hypoglycemia Hyperglycemia Hyponatriemia Hypokaliemia Bleeding Other	3 2 2 1 1 7
Lumbar puncture	6	6.4	Diagnostic failure	6
Urinary catheter	5	5.4	Diagnostic failure Cystitis	4 1
Peripheral venous access	5	5.4	Phlebitis Hypoglycemia	4 1
Suprapubic aspiration	4	4.3	Diagnostic failure	4
Endotracheal tube	3	3.2	Hypoxia	3
External heater	2	2.2	Burn	2
Central venous line	2	2.2	Bleeding Hypoglycemia	1 1
Mechanical ventilation	1	1.1	Hypoxia	1
Nasogastric tube	1	1.1	Aspiration	1
SpO_2 sensor	1	1.1	Burn	1
pH probe	1	1.1	Diagnostic failure	1
Other (scissors) *	1	1.1	other	1
Total	48	51.8%		

* father cut umbilical cord below umbilical clamp

As to the consequences, medical management was adjusted in 51% of the adverse events. The consequences were serious in 18 cases (20%): 16 patients needed to stay longer in hospital, with a median lengthening of 1 day, one was readmitted and one died due to a Gram-negative sepsis. The consequences classified as 'other' (n=28, 30%) ranged from scarring following a burn, intensified monitoring after a fall, to discomfort from extra blood sampling.

Eight of the 11 participating units returned the evaluation forms. Five of 8 units had no adverse event registration system in place before the study. At the time of the study 7 units used a voluntary incident reporting system. The adverse events were mostly registered during daily rounds (in 5 of the 8 units), but also upon discovery, during hand overs or weekly multidisciplinary rounds. In 4 units a designated pediatrician registered the adverse events whereas in the other four units all physicians (pediatricians and residents) participated in registering. In 2 units the adverse events were registered directly in the handheld computer; in 5 units a paper registration was used and the adverse events were later entered in the handheld computer. Two units had initiated improvements: a protocol was reviewed and a different type of oxygen sensors was purchased because burns had occurred with the previously used type.

Discussion

In this study, adverse event registration as part of standard care in general pediatric practice yielded a considerable number of adverse events. Most adverse events registered were of a diagnostic nature. The adverse events resulted in longer hospital stay for 1 in 6 of the patients that suffered an adverse event.

This study is the first to register real time data on adverse events in general pediatric practice in the Netherlands. Most of the earlier studies used administrative data to retrospectively evaluate harm to hospitalized children. Miller and Zahn studied the 2000 Healthcare Cost and Utilization Project Database that included 5.7 million pediatric discharges. [8] Using the AHRQ's Patient Safety Indicators [9] they uncovered 1.2 adverse events per 100 discharges [8], including events related to birth, procedures and surgery in all children, whereas our study was limited to general pediatric units, and birth trauma and surgical or anesthetic adverse events were not recorded. Woods et al found an adverse event rate of 1 per 100 discharges by retrospectively analyzing 3719 pediatric hospitalizations in the Colorado and Utah Medical Practice Study. [10] Again, in that study most adverse events occurred in newborns and were birth related; 16% of the adverse events were surgical. Dunn and colleagues found an adverse event rate of 0.26 per 100 discharges in a retrospective review of 1612 selected records. [11]

The rate of 0.0165 adverse events per admission in our study is higher than the rates of adverse events in those studies – even though obstetrical and surgical adverse events were not registered in our study. This may be due to the prospective nature of our study and the commitment of the participating pediatricians. Also, our study used real time data, whereas previous studies used administrative data to identify adverse events, a method which is neither highly sensitive nor specific. [12] A striking finding is the wide range of numbers of registered adverse events by the different units (1 to 29). We speculate this to be a reflection of the zeal of the involved pediatricians, rather than of a difference in level of care, number of admissions or severity of sickness of the patients. Part of the differences between units can be explained by the fact that some physicians felt all events resulting in harm for the patient were to be considered adverse events, where others would consider such an event an anticipated result of a procedure (for instance a dry tap during a lumbar puncture). It was argued that in some of these cases, the adverse event might have occurred because of poor supervision of inexperienced residents and thus should be registered. Another reason for the differences between the units could be that some participants felt that any adjustment of management after an event (for instance loss of a blood sample, necessitating more drawing of blood samples, thus causing pain to the patient) needed to be registered, where others considered this to be (an unfortunate) part of pediatric practice.

A limitation to this study is the lack of a gold standard for detecting adverse events, and several methods have been proven to underestimate the actual occurrences of adverse events. Probably not all adverse events were detected with the real time registration, and we did not compare the results of the registration with other promising new methods such as the trigger tool methodology. [13]

Another limitation to this study is the lack of inter-rater reliability testing. Still, participants were taught that only events that led to harm and necessitated a change in medical management were to be registered.

Chapter 4

However, a number of advantages to real time registration can be identified. Real time registration as applied in our study is thought more reliable in detecting actual harm than voluntary incident reporting. In incident reporting it is encouraged to also report near-misses, which did not reach the patient and thus did not cause any harm or errors that did reach the patient but did not lead to harm. Also, voluntary reporting is well known for its underreporting, especially of more serious events such as nosocomial infections or diagnostic failures. [14-17] Nevertheless, incident reporting has been introduced in Dutch pediatric practice under the name NEOSAFE Project and is widely used. [18] The NEOSAFE study by Snijders et al reported significant harm in 70 of 4846 incidents reports (1.4%), a considerably lower rate than the serious consequences for the patients with adverse events in our study (n=18 in 88 patients, 20%).

Herein lies one of the arguments for direct registration of adverse events by the pediatricians themselves. By registering adverse events locally, underreporting might be less of an issue. Also, by gathering data locally, as opposed to centrally in a national database, the number and nature of the adverse events are very accessible and thus provide direct feedback to the pediatricians of the quality of the care delivered in their unit and hospital. Moreover, this direct registration provides information on the causes of the adverse event and on contributing factors that may be helpful in giving direction to improvement initiatives. Last but not least, it allows the focus of further investigations to be directed away from the role of the individual in the origin of the event towards the whole care delivery system as the source of the adverse event. [17, 19-20]

Another limitation of this study was to keep the physicians engaged in registering adverse events. Participants were very motivated, though, but quite often found that their colleagues were less likely to report adverse events. This can partially explain the large differences in numbers of adverse events per unit. Underreporting prevents good benchmarking of quality of care, so this issue should be addressed by each physician, unit or hospital committed to improving quality of care. Prospectively registering adverse events could well be a means to engage physicians and convince them that studying the adverse events and their causes can guide improvement programs and help assess the effects of those programs. [21] Nevertheless, very few improvement initiatives were reported in the evaluation forms. A number of pediatricians told they were going to deploy initiatives after the study. The prospective registration of adverse events was likely an important step, and for some units a first step, in creating awareness of quality and safety issues.

Conclusion

We believe that prospective registration of adverse events is a first step towards good monitoring of quality of care in general pediatric practice. A nationwide used registration system allows benchmarking within pediatrics. The registration system described in this study could be a useful tool, provided it is integrated in the daily practice of everybody working in pediatric units: nurses, residents and pediatricians. Prevalence, effects and causes of adverse events need to be further researched so that the findings may serve to develop programs for the prevention of adverse events in hospitalized children.

Acknowledgements

We thank the paediatric units of ***Albert Schweitzer Ziekenhuis Dordrecht; Catharina Ziekenhuis Eindhoven; Diakonessenhuis Utrecht; Flevo Ziekenhuis Almere; Groene Hart Ziekenhuis Gouda; Martini Ziekenhuis Groningen; Maxima Medisch Centrum Veldhoven; Medisch Spectrum Twente Enschede; Zaans Medisch Centrum Zaanstad; Zuiderzeeziekenhuis Lelystad; Wilhelmina Kinderziekenhuis Utrecht.***

References

1. Institute of Medicine. To Err is Human: Building a Safer Health System. Kohn LT, Corrigan JM, Donaldson MS, editors. Washington, D.C.: National Academy Press; 2000.
2. Landrigan CP, Parry GJ, Bones CB, et al. Temporal trends in rates of patient harm resulting from medical care. N Engl J Med. 2010;363(22):2124-2134
3. Meurer JR, Yang H, Guse CE, et al. Medical injuries among hospitalized children. Qual Saf Health Care. 2006;15(3):202-207
4. Miller MR, Elixhauser A, Zhan C. Patient safety events during pediatric hospitalizations. Pediatrics. 2003;111(6 Pt 1):1358-1366
5. Slonim AD, LaFleur BJ, Ahmed W, et al. Hospital-reported medical errors in children. Pediatrics. 2003;111(3):617-621
6. Woods DM, Holl JL, Klein JD, et al. Patient safety problems in adolescent medical care. J Adolesc Health. 2006;38(1):5-12
7. van den Beuken MGA, Schulpen TWJ, te Pas E, et al. Complicatieregistratie in de kindergeneeskundige praktijk. Tijdschrift voor Kindergeneeskunde. 2006;74(6):106-113
8. Miller MR, Zhan C. Pediatric patient safety in hospitals: a national picture in 2000. Pediatrics. 2004;113(6):1741-1746
9. Agency for Healthcare Research and Quality. Measures of Patient Safety Based on Hospital Administrative Data- The Patient Safety Indicators. McDonald KM, Romano PS, Geppert JJ, Davies SM, Duncan BW, Shojania KG, et al., editors. Rockville (MD); 2002.
10. Woods D, Thomas E, Holl J, et al. Adverse events and preventable adverse events in children. Pediatrics. 2005;115(1):155-160
11. Dunn KL, Reddy P, Moulden A, et al. Medical record review of deaths, unexpected intensive care unit admissions, and clinician referrals: detection of adverse events and insight into the system. Arch Dis Child. 2006;91(2):169-172
12. Landrigan CP. The safety of inpatient pediatrics: preventing medical errors and injuries among hospitalized children. Pediatr Clin North Am. 2005;52(4):979-993, vii
13. Matlow AG, Cronin CM, Flintoft V, et al. Description of the development and validation of the Canadian Paediatric Trigger Tool. BMJ Qual Saf. 2011;20(5):416-423
14. Capuzzo M, Nawfal I, Campi M, et al. Reporting of unintended events in an intensive care unit: comparison between staff and observer. BMC Emerg Med. 2005;5(1):3
15. Espin S, Wickson-Griffiths A, Wilson M, et al. To report or not to report: a descriptive study exploring ICU nurses' perceptions of error and error reporting. Intensive Crit Care Nurs. 2010;26(1):1-9
16. Evans SM, Berry JG, Smith BJ, et al. Attitudes and barriers to incident reporting: a collaborative hospital study. Qual Saf Health Care. 2006;15(1):39-43
17. Sharek PJ, Horbar JD, Mason W, et al. Adverse events in the neonatal intensive care unit: development, testing, and findings of an NICU-focused trigger tool to identify harm in North American NICUs. Pediatrics. 2006;118(4):1332-1340
18. Snijders C, van Lingen RA, Klip H, et al. Specialty-based, voluntary incident reporting in neonatal intensive care: description of 4846 incident reports. Arch Dis Child Fetal Neonatal Ed. 2009;94(3):F210-215
19. Resar RK, Rozich JD, Simmonds T, et al. A trigger tool to identify adverse events in the intensive care unit. Jt Comm J Qual Patient Saf. 2006;32(10):585-590
20. Takata GS, Mason W, Taketomo C, et al. Development, testing, and findings of a pediatric-focused trigger tool to identify medication-related harm in US children's hospitals. Pediatrics. 2008;121(4):e927-935
21. Michel P, Quenon JL, de Sarasqueta AM, et al. Comparison of three methods for estimating rates of adverse events and rates of preventable adverse events in acute care hospitals. BMJ. 2004;328(7433):199

Part 2

Finding the right outcome to study patient safety

CHAPTER 5

Monitoring patient harm in a paediatric intensive care unit: What is the best method

Van der Starre, van Dijk, Tibboel
Submitted to BMJ Quality and Safety

MONITORING PATIENT HARM IN A PAEDIATRIC INTENSIVE CARE UNIT: WHAT IS THE BEST METHOD?

Abstract

Objectives:
To determine the best method to detect and monitor adverse events in paediatric intensive care units and to identify and characterize events causing harm.
Design:
A 2 year observational study using an electronic database review process for the presence of triggers and adverse events compared with real time voluntary adverse event registration by physicians.
Setting:
A 14-bed level III paediatric surgical intensive care unit in a university children's hospital that admits approximately 550 patients per year and delivers all types of intensive care, including extracorporeal membrane oxygenation, but excluding cardiothoracic surgery.
Main outcome measure:
Numbers and types of adverse events detected with the trigger tool in electronic databases and those registered by physicians during daily rounds. Adverse events were defined as any unfavourable and unintended injury resulting from or contributed to by medical treatment during the intensive care unit stay that necessitated adjustment of medical management or resulted in harm for the patient.
Results:
The two methods together detected 804 adverse events in 279 of 1223 admitted patients (22.8%), i.e. 0.66 adverse events per patient. The trigger tool alone detected 70% (n=560) of the adverse events; the physician registration 35% (n=282) and 38 events (4.7%) were detected with both methods. The most frequently detected adverse events with either method were uncontrolled pain and nosocomial infection.
Conclusion:
Application of the trigger tool methodology using electronic databases as a source yielded a high number of adverse events but had missed relatively many events, i.e. those reported by the physicians only, representing 30% of all adverse events detected with the two methods combined. These are the ones that can be prevented. Thus, voluntary reporting, preferably by both physicians and nurses, remains indispensable next to the trigger tool methodology.

Introduction

Ever since the first reports on patient harm caused by healthcare management [1-5], initiatives have been launched to reduce preventable mortality and morbidity. [6-8] Adverse events leading to patient harm occur regularly in paediatrics [9-12] and paediatric and neonatal intensive care in particular. [13-17] Detecting and monitoring adverse events in a reliable way is difficult. Methods such as voluntary incident reporting, identifying indicators from electronic databases, and medical record review all are suspected of underestimating the actual rate of the adverse events. [18-21] Recently, the trigger tool methodology developed by the Institute for Healthcare Improvement [22-24] has been shown to

identify high numbers of adverse events. The Global Trigger Tool has been adapted for various paediatric settings resulting in amongst others the PICU Trigger Tool and the NICU Trigger Tool. [14-15, 17, 25-26] The trigger tool is a list of 'clues' or 'flags' that are identified by a targeted search of a sample of medical records. If a trigger is found, further evaluation should clarify if it was related to an adverse event, and, if so, whether this adverse event has caused harm to the patient. For instance the administration of naloxon is a trigger that can identify an adverse event such as morphine overdose. Events that caused no change, or only a minor change in the patient's physical condition or medical management, are not considered to be adverse events.
Applying the trigger tool to computerized data rather than medical records is suggested to be more efficient and reliable. [22, 27] All admitted patients can then easily be reviewed, instead of only a sample, thus providing a more complete picture of adverse events on a ward.
The goal of our study was to determine numbers and types of adverse events in a single paediatric surgical intensive care unit by applying the trigger tool methodology and to compare findings with those obtained with the method of real time reporting by the unit's physicians.

Methods

Design
This study is a combined approach of evaluation of electronic database data and physicians' registration of adverse events in all patients admitted to the paediatric surgical intensive care unit (PSICU) in a 2 year period (2006-2007). Adverse events were defined as "any unfavourable and unintended injury resulting from or contributed to by medical treatment during the intensive care stay that necessitated adjustment of medical management or resulted in harm for the patient ". Adverse events occurring elsewhere prior to the ICU admission were not included.
Setting
At the time of the study, the PSICU is a 14 bed level III unit in a university children's hospital, with around 550 admissions per year. It serves a referral region of 4 million inhabitants and delivers intensive care for all surgical subspecialties, except cardiothoracic surgery. Apart from the care for newborns with major congenital anomalies, the facilities also include transplant surgery, orthopaedic and craniofacial surgery, trauma care and extracorporeal membrane oxygenation. The medical staff consists of 3 paediatric intensivists, 1 paediatric anaesthiologist-intensivist, 1 paediatrician-neonatologist, 2-3 fellows paediatric intensive care and 5-7 residents.
A patient safety management system is in place since 2005, which now has come to include adverse event registration, voluntary incident reporting [28], scoring of nursing protocol violations [29], team resource management training [30], retrospective incident analysis [31], prospective risk analysis [32], safety walk rounds [33], simulation team training, and safety oriented mortality and morbidity conferences.
Data collection
Real time adverse event registration
Since November 2005, the fellow or consultant in charge recorded details of any adverse event that was brought to the attention during the daily rounds. Details included the patient's personal data, date of the adverse event, description of the adverse event, and the effects of the adverse event (e.g. adjustment of management, temporary scarring, contributing to death).
If data were not clear or inconsistent, the investigator (CvdS) questioned the involved staff member

to resolve these issues.

Retrospective trigger tool application

Because of the specific case mix of the PSICU, including newborns with congenital anomalies, we used the PICU Trigger Tool complemented with 4 triggers from the NICU Trigger Tool: "pneumatosis intestinalis" (for the adverse event necrotizing enterocolitis), "abnormal cranial imaging" (hemorrhage, ischemia, and infarction), "octreotide use" (pleural effusion/chylothorax) and "out of range levels of antibiotics" (medication error).

Using the tool we searched for triggers in the hospital electronic database that contains all the data on admission and discharge dates, laboratory results, pathology results, microbiology lab results, radiology reports, surgery reports and discharge letters to the referring doctors and the general practitioners. In addition, the patient data management system (PDMS), which records all vital signs, pain scores, nursing notes, fluid/medication administration and other relevant nursing care information. was screened for the presence of triggers.

For any trigger found, we further searched the electronic databases for evidence of adverse events. For example, as a trigger for resuscitation, we would search the PDMS-database for administration of epinephrine, followed by reviewing the discharge letter and PDMS nursing notes for the occurrence of resuscitation.

Two triggers included in the original tool were not searched for: "hypotension" and "drop in hemoglobin/hematocrite". It is hard to define abnormal values due to the wide range of ages, weights and diseases in our ICU. Also, the PDMS contains numerous false values, i.e. when failing invasive or non-invasive measurements of blood pressure were recorded as actual real values. The trigger "drop in hemoglobin/hematocrite" (for the adverse event "bleeding") was replaced by the trigger "bleeding" as a search term in discharge letters and PDMS nursing notes.

Statistical analysis

Numbers and types of the adverse events are presented as median with interquartile ranges. Background characteristics of patients with and patients without adverse events were compared using the chi square test or Mann Whitney test when appropriate. A p-value of 0.05 (two-sided) was deemed statistically significant.

Results

The number of admissions in the study period was 1491, concerning 1223 patients. The number of patient days was 11101. The two different methods (trigger tool and physician registration) yielded 804 adverse events in 279 patients (22.8% of all patients). Thus the adverse event rate is 0.66 per patient or 7.2 per 100 patient days. The trigger tool yielded 560 adverse events (69.7%); the physician registration 282 (35.1%); the overlap was 38 (4.7%; detected with both methods).

Table 1a Numbers of adverse events found with either method per patient and per 100 admission days.

	Combined (n=804)	Trigger tool (n=560)	Physician registration (n=282)
AEs/patient	0.66	0.46	0.23
% patients ≥1 AE	22.8%	19.2%	10.8%
AEs/100 days	7.2	5.0	2.5

Table 1b Numbers of adverse events detected with 2 methods and their overlap.

		Trigger tool AEs (n (%))		
		yes	no	
Physician registration AEs (n(%))	yes	38 (4.7)	244 (30.3)	282 (35.1)
	no	522 (64.9)	-	522 (64.9)
		560 (69.7)	244 (30.3)	804 (100)

AE= Adverse Event

The patients in whom adverse events occurred, were statistically significantly younger (median 3.3 months versus 12.2 months, (p<0.001)) and were admitted longer than the others (median 11 days versus 2 days (p<0.001)).

The most frequent adverse events were uncontrolled pain (26.3%), nosocomial infection (15.8%), constipation (9.3%) and malpositioning of endotracheal tube (4.8%). Table 2 lists all occurrences of adverse events, broken down by detection method. The top 3 adverse events detected with the trigger tool are uncontrolled pain, nosocomial infections and constipation, and these were poorly detected with physician registration. Of the adverse events only detected with physician registration, catheter complications (n=30), nosocomial infections (n=26), metabolic disturbances (n=19), medication error (n=16) and accidental extubation (n=15) were the most frequent.

Chapter 5

Table 2 Number of adverse events, number of triggers, number (%) detected with trigger tool, numbers (%) detected with registration, numbers (%) detected with both methods.

Rank	Adverse events	No. trig	No. AE	TT (%)	AER (%)	Overlap (%)
1	Uncontrolled pain	405	**212**	210 (99.1)	2 (0.9)	-
2	Nosocomial infections	660	**128**	102 (80.3)	43 (33.9)	17 (13.4)
3	Constipation	124	**75**	69 (92.0)	6 (8.0)	-
4	Malposition endotracheal tube	158	**37**	37 (94.9)	-	-
5	Catheter complication	9	**31**	1 (3.2)	30 (96.8)	-
6	Hypoglycemia (insulin Rx)	48	**27**	24 (88.9)	4 (14.8)	1 (3.7)
7	Accidental extubation	12	**25**	10 (40.0)	21 (84.0)	6 (24.0)
8	Bleeding	30	**23**	11 (47.8)	12 (52.2)	-
9-10	Metabolic dysregulation Postextubation stridor/tracheal lesion	- 42	**19** **19**	- 11 (57.9)	19 (100) 10 (52.6)	- 2 (10.5)
11	Pleural effusion	12	**18**	14 (77.8)	8 (44.4)	4 (22.2)
12	Decubitus/pressure ulcers	16	**17**	10 (58.8)	8 (47.1)	1 (5.9)
13-14	Medication error Pneumothorax	61 11	**16** **16**	- 10 (62.5)	16 (100) 8 (50.0)	- 2 (12.5)
15	Thrombosis	52	**14**	10 (71.4)	7 (50.0)	3 (21.4)
16-17	Narcotic overdose/oversedation Atelectasis	12 -	**12** **12**	11 (91.7) -	1 (8.3) 12 (100)	- -
18	Respiratory distress	-	**10**	-	10 (100)	-
19	Withdrawal	9	**9**	7 (77.8)	2 (22.2)	-
20	Resuscitation	7	**8**	4 (50.0)	4 (50.0)	-
21-24	Brain damage Hyperglycemia Thrombopenia Diagnostic failure	22 - - -	**6** **6** **6** **6**	6 (100) - - -	1 (16.7) 6 (100) 6 (100) 6 (100)	1 (16.7) - - -
25-26	Unplanned readmission Renal failure	9 175	**5** **5**	4 (80.0) 3 (60.0)	1 (20.0) 2 (40.0)	- -
27	Hypotension	-	**4**	-	4 (100)	-
28-32	Allergic reaction Unplanned return to surgery Fluid overload Skin burn Hypertension	68 7 - - -	**3** **3** **3** **3** **3**	3 (100) 2 (66.7) - - -	- 2 (66.7) 3 (100) 3 (100) 3 (100)	- 1 (33.3) - - -
33-36	Seizures Anemia Agitation/delirium Osteopenia	- - - -	**2** **2** **2** **2**	- - - -	2 (100) 2 (100) 2 (100) 2 (100)	- - - -
37-51	Miscellanous (n=15)	90 (pulm edema)	**15**	1 (100) (pulm edema)	1 (100)	-

Abbreviations: AE adverse event, TT trigger tool, AER adverse event registration, Rx therapy

Miscellaneous: Pulmonary edema, fall, right ventricular hypertrophia, developmental delay, hypothyreoidy, cholestasis, compartment syndrome, dehiscence post laparotomy, diaphragm paralysis, corneal lesion, surgical failure, bowel perforation, pericardial effusion, esophageal perforation, diarrhoea

Discussion

The electronic trigger tool methodology and physician registration together detected a large number of adverse events. However, the physicians missed 65% of the adverse events; the trigger tool methodology 30%. Physician underreporting was found as well in other studies in adult medical and surgical settings [18, 34-35] It is hard to estimate how many adverse events might have been missed by applying the electronic search only instead of searching the paper medical records. Adverse events such as accidental extubation or catheter complications (accidental removal, blockage, malpositioning) tend to be recorded in medical records but may be hard to find with the trigger search of our electronic databases.

The number of adverse events identified with the combined approach (0.66 per patient) was smaller than in the studies by Larsen et al [15] and Agarwal et al [17] (1.96 and 2.03 per patient, respectively) (Table 4).

Table 4 Numbers of adverse event rates in the literature.

Study (year)	Setting	AE rate / patient	% patients with ≥ 1 AE	AEs / 100 days	Methodology
Agarwal et al (2010)	15 PICUs	2.03	62%	28.6	PICU trigger tool
Larsen et al (2007)	1 PICU	1.96	59%	53	PICU Trigger tool
Sharek et al (2006)	15 NICUs	0.74	-	3.2	NICU trigger tool
Silas et al (2010)	1 PICU	0.71	26%	-	Systematic review and voluntary reporting (incl no-little harm events)
Tibby et al (2004)	1 PICU	0.35	22%	6.0	Voluntary event reporting (incl near-misses)
Stambouly et al (1996)	1 PICU	0.11	8%	2.7	Daily survey for AEs
Van der Starre et al (2011)	1 surg PICU	0.66	23%	7.3	Adapted PICU trigger tool and AE registration

Abbreviations: AE adverse event
PICU paediatric intensive care unit
NICU neonatal intensive care unit

A focused review of a sample of patient records compared with a search through an electronic database of all admissions is likely to yield a higher number of adverse events. Silas et al reported a comparable rate of adverse events as in our study, but included events with little or no harm, which we excluded. Our detection rate is higher than that in the prospective studies by Stambouly et al [13] (0.11 AE/patient) and Tibby et al [36] (0.35 AE/patient), so the addition of the trigger methodology to prospective reporting clearly has an added value, as appears also from the studies by Sharek, Larsen and Agarwal. [14-15, 17] The Global Trigger Tool has been adapted for different paediatric settings, and we found it necessary to adapt the PICU version because of the specific case mix of our unit.

Chapter 5

As advocated by Resar et al [22] it is a flexible methodology, which allows collection of data in different environments so individual units can apply the adapted version that best fits their case mix. The same trigger tool must be used, however, for benchmarking purposes.

In our study, the physician registration yielded relevant additional adverse events that are likely to be missed by searching only medical records or electronic databases, such as respiratory distress, bleeding or atelectasis. Also, especially those adverse events that are potentially preventable are registered, such as catheter complications, medication errors and accidental extubations, as was found in the study by O'Neil as well. [18] The most effective and reliable way to monitor patient harm seems to be a combination of methods, as advocated by previous studies. Silas et al reported a similar small overlap of detection of adverse events. Only 9% of the adverse events in a PICU were detected by both voluntary incident reporting and systematic review by a physician actively searching for adverse events. [16] Naessens et al performed a retrospective chart review in three general hospitals, and found very little overlap between 3 different methods for detecting harm (global trigger tool, patient safety indicators from the AHRQ and provider reports). [35] Another argument in favour of physician registration is that physicians tend to report the most noteworthy and often serious adverse events – those that often leave an impression with the care providers. Finally, having physicians reporting on (serious) adverse events may make them more aware of the importance of providing safe care.

The combined methodology in the present study yielded the same types of adverse events as those reported in other PICU adverse event studies. [13, 15, 17] Noteworthy are the high incidence of uncontrolled pain and the fact that this was underreported by physicians. The trigger uncontrolled pain was defined by scores on two validated pain assessment instruments, the COMFORT behaviour scale and the VAS. [37-39] The trigger was positive if scores were too high at two consecutive time points with at least two hours interval. One of the explanations for the high incidence of uncontrolled pain may be the fact that the scores had actually been recorded in a high number of patients, (1567 distinct episodes) and the high numbers of surgical patients in our unit. These high numbers of occurrences of uncontrolled pain underline the importance of urgent interventions to address this issue. Nosocomial infections also ranked high, as in other pediatric intensive care settings. [15, 17] Also, as in previous studies the younger patients were at higher risk of adverse events. This might be explained by their great vulnerability and the more hazardous technical interventions they are subjected to. Also, our population included a high percentage of newborns with congenital malformations who had undergone surgery, which has been shown to increase the likelihood of adverse events. [17] Adverse events have been associated with longer PICU stay. [13, 15, 17] It remains unresolved, however, whether the adverse events cause longer stay, or whether longer stay increases the risk of adverse events. For example, surgical treatment of a major congenital anomaly is associated with a lengthy hospital stay in itself; it would be hard to tell whether a nosocomial infection would actually increase length of hospital stay.

Limitations

Several limitations of this study should be addressed. First, the lack of a gold standard to determine the number and nature of adverse events limits any study on adverse events. Second, determining whether a trigger has led to an adverse event or not may have been subjective. By adhering to the definition of an adverse event, that is, an event resulting in an adjustment of medical management or harm to the patient, we excluded near-misses and thus detected only actual adverse events.

Conclusion

Monitoring adverse events is best done with multiple methods, for example the trigger tool methodology combined with physicians' registration. The development of new triggers could be helpful in detecting the adverse events that were solely identified with physicians' registration. The types of adverse events registered by physicians (catheter complications, medication errors and accidental extubations) are prominently those that could be prevented with targeted interventions. While new triggers are developed, further research should also be aimed at improving engagement of physicians in registering adverse events; this could be helpful to maximize yield of adverse event monitoring.

References

1. Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. N Engl J Med. 1991;324(6):370-376
2. Leape LL, Brennan TA, Laird N, et al. The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. N Engl J Med. 1991;324(6):377-384
3. Thomas EJ, Studdert DM, Burstin HR, et al. Incidence and types of adverse events and negligent care in Utah and Colorado. Med Care. 2000;38(3):261-271
4. Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. BMJ. 2001;322(7285):517-519
5. Zegers M, de Bruijne MC, Wagner C, et al. Adverse events and potentially preventable deaths in Dutch hospitals: results of a retrospective patient record review study. Qual Saf Health Care. 2009;18(4):297-302
6. World Health Organization. WHO Patient Safety campaigns. [cited 2011 march 28]; Available from: www.who.int/patientsafety/campaigns/en/
7. Institute for Healthcare Improvement. Overview of the 100,000 Lives Campaign. [cited 2011 march 28]; Available from: www.ihi.org/IHI/Programs/Campaign/100kCampaignOverviewArchive.htm
8. APSF. Australian Patient Safety Foundation. [cited 2011 march 29]; Available from: www.apsf.net.au/
9. Miller MR, Elixhauser A, Zhan C. Patient safety events during pediatric hospitalizations. Pediatrics. 2003;111(6 Pt 1):1358-1366
10. Woods D, Thomas E, Holl J, et al. Adverse events and preventable adverse events in children. Pediatrics. 2005;115(1):155-160
11. Slonim AD, LaFleur BJ, Ahmed W, et al. Hospital-reported medical errors in children. Pediatrics. 2003;111(3):617-621
12. Meurer JR, Yang H, Guse CE, et al. Medical injuries among hospitalized children. Qual Saf Health Care. 2006;15(3):202-207
13. Stambouly JJ, McLaughlin LL, Mandel FS, et al. Complications of care in a pediatric intensive care unit: a prospective study. Intensive Care Med. 1996;22(10):1098-1104
14. Sharek PJ, Horbar JD, Mason W, et al. Adverse events in the neonatal intensive care unit: development, testing, and findings of an NICU-focused trigger tool to identify harm in North American NICUs. Pediatrics. 2006;118(4):1332-1340
15. Larsen G, Grant MJ. Pediatric patient safety: identification and characterization of adverse events, adverse drug events, and medical error. Pediatr Crit Care Med. 2004;5(2):189-191
16. Silas R, Tibballs J. Adverse events and comparison of systematic and voluntary reporting from a paediatric intensive care unit. Qual Saf Health Care. 2010;19(6):568-571
17. Agarwal S, Classen D, Larsen G, et al. Prevalence of adverse events in pediatric intensive care units in the United States. Pediatr Crit Care Med. 2010;11(5):568-578
18. O'Neil AC, Petersen LA, Cook EF, et al. Physician reporting compared with medical-record review to identify adverse medical events. Ann Intern Med. 1993;119(5):370-376
19. Localio AR, Weaver SL, Landis JR, et al. Identifying adverse events caused by medical care: degree of physician agreement in a retrospective chart review. Ann Intern Med. 1996;125(6):457-464
20. Thomas EJ, Petersen LA. Measuring errors and adverse events in health care. J Gen Intern Med. 2003;18(1):61-67
21. Murff HJ, Patel VL, Hripcsak G, et al. Detecting adverse events for patient safety research: a review of current methodologies. J Biomed Inform. 2003;36(1-2):131-143
22. Resar RK, Rozich JD, Classen D. Methodology and rationale for the measurement of harm with trigger tools. Qual Saf Health Care. 2003;12 Suppl 2:ii39-45
23. Resar RK, Rozich JD, Simmonds T, et al. A trigger tool to identify adverse events in the intensive care unit. Jt Comm J Qual Patient Saf. 2006;32(10):585-590
24. Rozich JD, Haraden CR, Resar RK. Adverse drug event trigger tool: a practical methodology for measuring medication related harm. Qual Saf Health Care. 2003;12(3):194-200
25. Takata GS, Mason W, Taketomo C, et al. Development, testing, and findings of a pediatric-focused trigger tool to identify medication-related harm in US children's hospitals. Pediatrics. 2008;121(4):e927-935
26. Matlow AG, Cronin CM, Flintoft V, et al. Description of the development and validation of the Canadian Paediatric Trigger Tool. BMJ Qual Saf. 2011;20(5):416-423
27. Landrigan CP, Parry GJ, Bones CB, et al. Temporal trends in rates of patient harm resulting from medical care. N Engl J Med. 2010;363(22):2124-2134
28. 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(5):F391-398
29. Binnekade JM, de Mol BA, Kesecioglu J, et al. The Critical Nursing Situation Index for safety assessment in intensive care. Intensive Care Med. 2001;27(6):1022-1028
30. Morey JC, Simon R, Jay GD, et al. Error reduction and performance improvement in the emergency department through formal teamwork training: evaluation results of the MedTeams project. Health Serv Res. 2002;37(6):1553-1581
31. Vincent C, Taylor-Adams S, Chapman EJ, et al. How to investigate and analyse clinical incidents: clinical risk unit and association of litigation and risk management protocol. BMJ. 2000;320(7237):777-781
32. van Tilburg CM, Leistikow IP, Rademaker CM, et al. Health Care Failure Mode and Effect Analysis: a useful proactive risk analysis in a pediatric oncology ward. Qual Saf Health Care. 2006;15(1):58-63
33. Montgomery VL. Impact of Staff-Led Safety Walk Rounds (Vol. 3: Performance and Tools). 2008;
34. Marang-van de Mheen PJ, van Hanegem N, Kievit J. Effectiveness of routine reporting to identify minor and serious adverse outcomes in surgical patients. Qual Saf Health Care. 2005;14(5):378-382
35. Naessens JM, Campbell CR, Huddleston JM, et al. A comparison of hospital adverse events identified by three widely used detection methods. Int J Qual Health Care. 2009;21(4):301-307
36. Tibby SM, Correa-West J, Durward A, et al. Adverse events in a paediatric intensive care unit: relationship to workload, skill mix and staff supervision. Intensive Care Med. 2004;30(6):1160-1166
37. van Dijk M, de Boer JB, Koot HM, et al. The reliability and validity of the COMFORT scale as a postoperative pain instrument in 0 to 3-year-old infants. Pain. 2000;84(2-3):367-377
38. Ista E, van Dijk M, Tibboel D, et al. Assessment of sedation levels in pediatric intensive care patients can be improved by using the COMFORT "behavior" scale. Pediatr Crit Care Med. 2005;6(1):58-63
39. Valkenburg AJ, Boerlage AA, Ista E, et al. The COMFORT-Behavior scale is useful to assess pain and distress in 0- to 3-year-old children with Down syndrome. Pain. 2011;152(9):2059-2064

LARA'S STORY: PART 3

Something went wrong!

Thomas and Melissa were rushed to the ICU after Lara had been resuscitated. She was taken to the operation room and now they are waiting for the surgeon. The IC doctors explained that Lara was having more and more trouble breathing on her own and that they had to intubate her to help her breathing. Then, Lara's condition worsened very quickly, and they had to use chest compressions and medication to keep her alive. Melissa and Thomas wonder: what has happened? What went wrong? And why? Are they going to make sure it won't happen again, not to Lara and not to any other baby? But most of all: how will Lara be after all that?

Part 3

Finding the right interventions to improve patient safety

CHAPTER 6

Pediatric critical incident analysis: worth the effort?

C van der Starre, M van Dijk, A van den Bos, E Dekker, H Pas, D Tibboel
Submitted to BMJ Quality and Safety

PAEDIATRIC CRITICAL INCIDENT ANALYSIS: WORTH THE EFFORT?

Abstract

Objective:
To identify causal and contributing factors of serious patient safety incidents in a paediatric university hospital; to report recommendations stemming from incident analyses; to describe barriers to incident analysis.
Methods:
Possible causal and contributing factors identified in 17 incident analysis procedures were classified according to a classification by Vincent and colleagues. Proposed recommendations were classified accordingly and degrees of implementation were established.
Results:
A median of 5 causal and contributing factors per incident were identified (range 2-10; total 85). Team factors and task factors each comprised 22% of all factors, provider factors 20%, work environment 19%, organizational factors 11%, and patient factors 6%. A median of 5 recommendations per analysis were formulated (range 1-8; total 84). Most recommendations related to task factors (36%), followed by team factors (21%), organizational factors (19%), work environment factors (15%), and provider factors (8%). Patient-related recommendations were not given. The time load of each analysis was a mean of 27 hours. One third of the recommendations have been acted upon, mostly those related to task factors and team factors.
Conclusion:
Incident analysis is time-consuming but yields valuable information on causal and contributing factors, presenting numerous opportunities for quality improvement. Failure to put the recommendations into practice diminishes the value of these analyses. It is therefore crucial that senior management and clinical leaders act adequately upon recommendations.

Introduction

Reports on paediatric patient safety [1-5] have made clear that children in intensive care units are at high risk of incidents and adverse events. Incidents are defined as events that could or did lead to harm in patients. As an illustration, voluntary incident reporting in Dutch NICUs yielded 1.3 incidents per admission [6]; and Agarwal and colleagues reported adverse events in almost two thirds of PICU patients in the USA. [5] Other studies have reported from 2.5 to 10 incidents and adverse events per admission. [5, 7-12] Patient safety programs [13-16] suggest we first need to learn from the incidents before effective preventive measures can be taken.
Seeking answers to the following three questions is central here: what has actually occurred? What causes and circumstances contributed to allow the incident to occur? What measures and interventions could prevent recurrence? Root cause analysis may be able to answer these questions [15, 17-18], notably Reason's systems approach. [19-20] Errors are usually the result of a chain of events; they occur not only because of human failure, but also because there may be no or ineffective barriers to prevent an error from reaching its unfortunate endpoint. Reason's approach focuses on the flaws in the system rather than on human failure, and is applied because interventions to avoid the first are more effective. [21]
The paediatric and neonatal intensive care units in the Erasmus MC - Sophia Children's Hospital have been patient safety pioneers in this hospital. They were the first to implement voluntary incident reporting [6] and incident analysis. The PICU later also put in place adverse event registration and scoring of nursing protocol violations. [22] In 2005 the entire PICU staff received crew resource management training from the Dutch Centre for Man and Aviation. The patient safety officers have adapted this training course to the medical setting and since then have been training new PICU employees and all NICU staff. Other patient safety activities implemented in the PICU are: critical incident analysis [23], prospective risk analysis [24], safety walk rounds [25], simulation training, and safety-focused mortality and morbidity conferences. The other departments in our hospital have adopted voluntary incident reporting, but so far few of the other patient safety elements have spread to other units. We present the results of in-depth analysis of seventeen critical incidents in our hospital, focusing on the causal and contributing factors and recommendations stemming from the analyses.

Methods

Setting
Erasmus MC-Sophia is a 215-bed university children's hospital, including a 37-bed obstetrics department, a 28-bed paediatric ICU with a 6 bed high care unit, and a 27-bed neonatal ICU with a 6 bed HC unit. A voluntary incident reporting system has been introduced in 2005 in the ICU units, and in 2008 in the medical and surgical medium care units.

Design
Retrospective review of critical incident analyses in the period 2005-2010.

Patients
All patients admitted to the children's hospital, including the obstetrics department were eligible for incident analysis.

Procedural information
A physician (CvdS), a nurse manager (AvdB) and rotating nurses investigate critical incidents on the request of the departmental heads of the intensive care units or other departments. The physician and nurse manager both have completed the patient safety officer executive development program from the Institute for Healthcare Improvement. [26] The rotating nurses are not involved in the actual care of the individuals concerned, and have attended a training course in root cause analysis. [19]

The incidents in this study had been reported to the heads of the departments because staff considered them severe; structured reporting to management of serious incidents was not yet in place at the time of the study. The departmental heads subsequently requested investigation. The patient safety officers of the PICU interviewed all staff involved with the incident to supplement the information provided in the incident report. If thought helpful, parents were interviewed as well. Causal and contributing factors were identified by means of a cause-and-effect diagram or a causal tree analysis. [23] The investigating team then proposed recommendations based on the identified causal and contributing factors, and the report was sent to the requester and all interviewed parents and employees.

For this study, we classified the identified factors according to Vincent et al [23], in the categories institutional context, organizational and management factors, work environment factors, team factors, provider factors, task factors, and patient factors. The recommendations were classified accordingly.

Results

Eight of the 17 critical incidents occurred on the PICU, 6 on the neonatal ICU and 3 in other departments in Erasmus MC-Sophia. The 8 incidents on the PICU had been reported in the voluntary incident reporting system, and 6 (75%) had actually caused serious harm. In the study period 11327 incidents on the PICU had been reported, of which 480 (4.2%) were classified as potentially critical and thus eligible for analysis. In the NICU, 773 of 8683 reported incidents (8.9%) were classified as potentially causing serious harm and thus eligible for analysis. Data on the numbers of incidents and their severity in the other units are not available as they did not yet employ a voluntary incident reporting system.
Figure 1 gives an example of an incident reconstruction; Table 1 provides the causal and contributing factors identified in this example and the recommendations made.

Figure 1 Result of analysis of clonidine overdose, presented in the 'Swiss Cheese' model developed by James Reason. (CPOE: computerized physician order entry system) (Read from right to left)

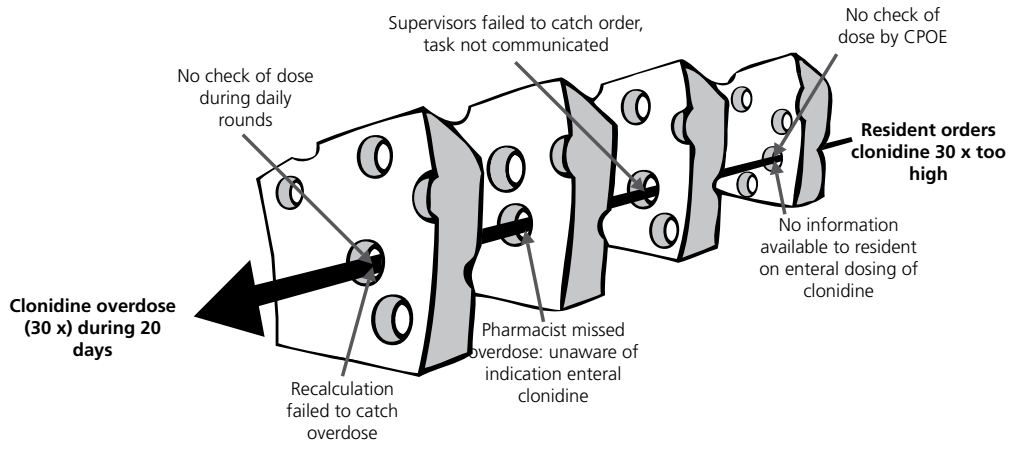


Table 1 Case example: clonidine overdose (30 fold) during 20 days

Case	Factors
A patient with esophageal atresia had been receiving IV sedatives (midazolam and clonidine) for three months. During a weekend round it was decided to change the clonidine route of administration from intravenous to enteral. The attending resident ordered a daily dose through the computerized physician order entry system (CPOE) which later appeared to be a 30 fold overdose. In retrospect the patient had been very sleepy the first days of getting the high dose. The overdose went unnoticed for 20 days, and was discovered by the community pharmacist when preparing patient's discharge home. The patient had been home one hour and was readmitted for monitored weaning of the clonidine.	
Causal and contributing factors:	
- resident could order overdose because: 1. CPOE does not check dose for weight 2. supervisors failed to communicate who was supervising the resident at the time of prescription 3. information on enteral dosing of clonidine for sedation in neonates was not available to the resident at the time	 Work environment factor Team factor Task factor
- every 24 hrs a pharmacist checks all newly prescribed medication; this dose was within range for children for treatment of hypertension; there was a failure to catch the overdose because not being informed on the indication (different dose advice for sedation vs hypertension), the pharmacist approved the order	Team factor
- multiple intensivists and residents did not check the order during consecutive rounds because recalculating a dose is not common practice	Provider factor
- after transfer from IC to HC unit, nurses calculated the number of vials to be opened for this dose but did not check if the dose itself was correct, so the recalculation failed to catch the overdose	Provider factor
Recommendations:	
- improve communication between physicians on task distribution (task: supervising the resident)	Team factor
- purchase software/ICT to enable medication check in CPOE	Organizational factor
- change preset order in CPOE and insert dose advice	Work environment factor
- pharmacists should check new orders more frequently	Organizational factor
- provide formulary with recommended doses of uncommon drugs	Task factor
- improve medical record keeping	Team factor

CPOE: computerized physician order entry

The incidents were reconstructed from a median of 6 interviews (range 3-15; total 112). In two incident analyses parents were interviewed. Time spent on the interviews, analysis and preparing a report amounted to 27 hours per incident.

The 17 incidents are listed in Table 2. In 7 of the incidents the patient in question died during admission; in 3 of these, death was unanticipated and was the incident under investigation.
One unanticipated death related to a failure to resuscitate a newborn with meconium aspiration syndrome; the second concerned a patient with aplasia cutis who died from unnoticed bleeding during the night shift; the third was an intra-uterine death due to arrhythmia and hydrops foetalis. Causality between incident and death was established in two of the other 4 cases. In the first, a 1000-fold overdose of alprostadil led to uncontrollable hypotension and pulmonary hypertension,

Chapter 6

followed by death 6 hours post-incident. In the second, ECMO cannulation caused a tear in the right atrium followed by bleeding. This was quickly discovered and the tear was surgically repaired, but resuscitation failed.

Table 2 description of incidents, units where the incident occurred and patient outcomes

Type of incident	Unit	Patient outcome
Medication errors		
Clonidine: overdose 30x	PICU	Longer hospital stay
Alprostadil: overdose 1000x	PICU	Death
Paracetamol: overdose 10x	PICU	No harm
Desmopressin: IV instead of enteral administration	PICU	Temporary harm
Morphine: overdose 35x	NICU	Death
Fluconazol: overdose 9x	NICU	Temporary harm
Procedural		
Tear right atrium at ECMO canulation	PICU	Death
Severe skin burn at insertion umbilical lines	NICU	Death
Chest drain wrong side in pneumothorax	NICU	Temporary harm
Dislocation septal occluder in pulmonary artery	Other	Permanent harm
Unanticipated death		
Failed resuscitation, ET obstructed in MAS	NICU	Death
Intra-uterine foetal arrhythmia	Other	Death
Unnoticed haemorrhage in aplasia cutis	Other	Death
Unexpected resuscitation		
Respiratory insufficiency in oesophageal atresia	PICU	Temporary harm
Nursing care		
Near strangulation with nasogastric tube	PICU	No harm
Severe skin lesions due to stoma care	NICU	Temporary harm
Disconnection ventilator tubing	PICU	Temporary harm

Abbreviations:
IV intravenous
ECMO extra corporeal membrane oxygenation
ET endotracheal tube
MAS meconium aspiration syndrome
PICU paediatric intensive care unit
NICU neonatal intensive care unit

Of the two patients in whom a clear causal relation between death and incident was not established, one had a previously diagnosed untreatable metabolic disorder and it was decided to withdraw life support. However, he had been given a 35-fold morphine overdose 12 hours earlier. The other was a premature infant who was severely burned when umbilical lines were inserted (the sterile cotton covering became soaked in blood and stuck to the skin, upon which the heat from the external heater

caused a severe burn) and died 6 days post partum due to necrotizing enterocolitis and sepsis. Six other patients were (temporarily) harmed, e.g. skin lesions; chest drain inserted on the wrong side.
One of these 6 patients needed longer hospitalization, and one suffered permanent severe neurological damage. Two incidents, near-strangulation with a nasogastric tube during sleep and paracetamol overdose, apparently caused no harm.
A median of 5 causal and contributing factors per incident were identified (range 2 -10; total 85). Team factors (e.g. loss of information on shift handover or resident's work not supervised by intensivist) and task related factors (e.g. ambiguous protocols) were most frequent: both 19 out of 85 (22%). Seventeen factors (20%) related to individual providers, e.g. calculation errors or failing to adhere to protocol. Sixteen factors (19%) related to work environment, such as a defective IV pump. Nine (11%) were organizational factors, such as lack of medication dose check in the computerized physician order entry system. The remaining 5 factors related to patient features, such as turning during sleep and bleeding from aplasia cutis.
A total of 84 recommendations were formulated, a median of 5 per analysis (range 1-8). Twenty-eight of the recommendations (33%) were actually implemented. Recommendations relating to organizational factors were least implemented, only 3 of 16 (19%); recommendations pertaining to task factors most frequently: 12 of 30 (40%); these were mostly improvements in protocols and guidelines. In 5 analyses none of the recommendations (n=16) was followed up.

Discussion

Our analyses provide useful information on the factors that caused or contributed to these serious incidents and enabled the investigators to formulate corrective recommendations. However, no more than a disappointing one third of the recommendations were actually taken up.
The median number of 5 causal and contributing factors per incident is more than double that reported by others. [27-28] As a possible explanation: most studies on the causes of incidents in paediatrics are based on anonymous reports. If relevant information on how and why the incident occurred is lacking, it is inherently impossible to retrieve this information. We were able to gather more information as reports are not anonymous and everyone involved is interviewed. Furthermore, "latent factors" contributing to incidents, such as management decisions or organizational policies impacting patient safety, may have been left out of consideration, which was not the case in our study.
Only 6% of the contributing factors in our study were ascribed to patient-related circumstances, versus 45% in 462 paediatric incidents in the ICUSRS database [29], and 32% in 2075 incident reports in adult and paediatric ICUs analyzed by Pronovost et al. [27] Bagian et al [30] found that incident analysis in general yielded much smaller proportions of patient factors than did focused review (10% vs. 43%). Root cause analysis by Snijders et al [28] also yielded a low percentage of patient factors (3%) contributing to incidents in NICUs. In the present study, none of the patient factors could have been prevented, and there was no reason to recommend preventive measures.
In our study, only 20% of the causal and contributing factors were related to performance of care providers. Frey et al. reported that provider performance assumedly played a role in 63% of the incidents in NICUs and PICUs. [31] A study of incident analysis in Dutch NICUs concluded that provider performance played a role in 64% of incidents. [28] Nevertheless, two other studies both reported that – like in our study – only 20% of contributing factors were provider factors. [27, 29] Measures to

Chapter 6

counter failures of individual providers are hardly effective; e.g. recommending greater attention to medication preparation will not be permanently effective to prevent errors.
Improvements on 'systems' factors are more likely to be effective in this respect. Team factors and task factors were the most frequent contributing factors found in our analyses. The team factors are clear examples of issues that could be addressed by team resource training, i.e. communication, situational awareness, and leadership and followership roles. Most of the employees interviewed had not yet received team resource training, with the exception of the involved PICU staff other than the residents. This training course may prevent faulty teamwork if the team members are continually reminded of the principles of teamwork.
Implementing recommended measures is known to be a difficult undertaking. [17, 32-34] In our hospital, only one third of recommendations were acted upon. Recommendations aimed at organizational (redesign of processes) and work environment factors (equipment changes) are thought to have the highest likelihood of successful prevention of incidents; those aimed at providers (general education) and task factors (guideline development) have a lesser likelihood. [17] However, no more than three (of 16) recommendations aimed at organizational factors were implemented in our hospital. The recommendations not taken up included monitoring of vital signs on a medium care unit and purchasing smart pump technology. [35] As a possible explanation, organizational changes are not easily achieved in a single care unit in a large university hospital. Another possible explanation is that acting upon the recommendations was left to the discretion of the departmental heads who commissioned the investigations. A lesson to be learned from this is the necessity of appointing a responsible person for the implementation of the recommendations. Failure to act on these serious incidents can be very discouraging. Staff can easily perceive this as a sign that the management does not give priority to patient safety, thus hampering the development of a culture of learning from errors that is essential to improve patient safety.
A limitation in this report is the small number of incidents analyzed. Apart from these 17 incidents, 12 other incidents in the PICU had actually caused serious harm. These had not been reported to the departmental head, however, and critical incident analysis had therefore not been performed. Analysis of all reported critical incidents in the PICU (480 with potentially serious consequences) was also not feasible due to time constraints. It seems worthwhile to set up a structure that allows for fast detection of serious incidents and enables management to respond quickly and request analysis. Analyzing critical incidents should become routine procedure, and not remain coincidental activities.

Conclusion

In this report we describe the results of seventeen critical incident analyses conducted in an academic children's hospital by a team of patient safety officers and frontline staff familiar with the working conditions. This setup increases the likelihood of identifying all possible factors involved in an incident and thus allows articulating recommendations that might prevent similar incidents. Only few recommendations were taken up, however, so the worth of critical incident analysis is still undecided. To determine whether it really is worth the effort, we need to reach a stage at which more incidents are analyzed and more recommendations are implemented. Then we can monitor their effectiveness and decide whether incident analysis improves patient safety.

Acknowledgements

We thank Ko Hagoort for editorial assistance.

References

1. Miller MR, Elixhauser A, Zhan C. Patient safety events during pediatric hospitalizations. Pediatrics. 2003;111(6 Pt 1):1358-1366
2. Woods D, Thomas E, Holl J, et al. Adverse events and preventable adverse events in children. Pediatrics. 2005;115(1):155-160
3. Landrigan CP. The safety of inpatient pediatrics: preventing medical errors and injuries among hospitalized children. Pediatr Clin North Am. 2005;52(4):979-993, vii
4. Sharek PJ, Classen D. The incidence of adverse events and medical error in pediatrics. Pediatr Clin North Am. 2006;53(6):1067-1077
5. Agarwal S, Classen D, Larsen G, et al. Prevalence of adverse events in pediatric ICUs in the United States*. Pediatr Crit Care Med. 2010:568-578
6. Snijders C, van Lingen RA, Klip H, et al. Specialty-based, voluntary incident reporting in neonatal intensive care: description of 4846 incident reports. Arch Dis Child Fetal Neonatal Ed. 2009;94(3):F210-215
7. Stambouly JJ, McLaughlin LL, Mandel FS, et al. Complications of care in a pediatric intensive care unit: a prospective study. Intensive Care Med. 1996;22(10):1098-1104
8. McBride SC, Chiang VW, Goldmann DA, et al. Preventable adverse events in infants hospitalized with bronchiolitis. Pediatrics. 2005;116(3):603-608
9. Sharek PJ, Horbar JD, Mason W, et al. Adverse events in the neonatal intensive care unit: development, testing, and findings of an NICU-focused trigger tool to identify harm in North American NICUs. Pediatrics. 2006;118(4):1332-1340
10. Larsen GY, Donaldson AE, Parker HB, et al. Preventable harm occurring to critically ill children. Pediatr Crit Care Med. 2007;8(4):331-336
11. Ligi I, Arnaud F, Jouve E, et al. Iatrogenic events in admitted neonates: a prospective cohort study. Lancet. 2008;371(9610):404-410
12. Silas R, Tibballs J. Adverse events and comparison of systematic and voluntary reporting from a paediatric intensive care unit. Qual Saf Health Care. 2010;
13. Institute of Medicine. To Err is Human: Building a Safer Health System. Kohn LT, Corrigan JM, Donaldson MS, editors. Washington, D.C.: National Academy Press; 2000.
14. Leape LL, Woods DD, Hatlie MJ, et al. Promoting patient safety by preventing medical error. JAMA. 1998;280(16):1444-1447
15. Bagian JP, Lee C, Gosbee J, et al. Developing and deploying a patient safety program in a large health care delivery system: you can't fix what you don't know about. Jt Comm J Qual Improv. 2001;27(10):522-532
16. Leape L, Berwick D, Clancy C, et al. Transforming healthcare: a safety imperative. Qual Saf Health Care. 2009;18(6):424-428
17. Taitz J, Genn K, Brooks V, et al. System-wide learning from root cause analysis: a report from the New South Wales Root Cause Analysis Review Committee. Qual Saf Health Care. 2010;19(6):e63
18. Smits M, Janssen J, de Vet R, et al. Analysis of unintended events in hospitals: inter-rater reliability of constructing causal trees and classifying root causes. Int J Qual Health Care. 2009;21(4):292-300
19. Reason J. Human error. 1 ed. Cambridge: Cambridge University Press; 1990.
20. Reason J. Human error: models and management. BMJ. 2000;320(7237):768-770
21. Vincent CA. Analysis of clinical incidents: a window on the system not a search for root causes. Qual Saf Health Care. 2004;13(4):242-243
22. Binnekade JM, de Mol BA, Kesecioglu J, et al. The Critical Nursing Situation Index for safety assessment in intensive care. Intensive Care Med. 2001;27(6):1022-1028
23. Vincent C, Taylor-Adams S, Chapman EJ, et al. How to investigate and analyse clinical incidents: clinical risk unit and association of litigation and risk management protocol. BMJ. 2000;320(7237):777-781
24. van Tilburg CM, Leistikow IP, Rademaker CM, et al. Health Care Failure Mode and Effect Analysis: a useful proactive risk analysis in a pediatric oncology ward. Qual Saf Health Care. 2006;15(1):58-63
25. Montgomery VL. Impact of Staff-Led Safety Walk Rounds (Vol. 3: Performance and Tools). 2008;
26. Institute of Healthcare Improvement. Patient Safety Executive Development Program. [cited 2011 march 28]; Available from: www.ihi.org/IHI/Programs/ProfessionalDevelopment/PatientSafetyProgramSeptember2011.htm
27. Pronovost PJ, Thompson DA, Holzmueller CG, et al. Toward learning from patient safety reporting systems. J Crit Care. 2006;21(4):305-315
28. 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(6):486-491
29. Skapik JL, Pronovost PJ, Miller MR, et al. Pediatric safety incidents from an intensive care reporting system. J Patient Saf. 2009;5(2):95-101
30. Bagian JP, Gosbee J, Lee CZ, et al. The Veterans Affairs root cause analysis system in action. Jt Comm J Qual Improv. 2002;28(10):531-545
31. Frey B, Kehrer B, Losa M, et al. Comprehensive critical incident monitoring in a neonatal-pediatric intensive care unit: experience with the system approach. Intensive Care Med. 2000;26(1):69-74
32. Braithwaite J, Westbrook MT, Mallock NA, et al. Experiences of health professionals who conducted root cause analyses after undergoing a safety improvement programme. Qual Saf Health Care. 2006;15(6):393-399
33. Wallace LM, Spurgeon P, Adams S, et al. Survey evaluation of the National Patient Safety Agency's Root Cause Analysis training programme in England and Wales: knowledge, beliefs and reported practices. Qual Saf Health Care. 2009;18(4):288-291
34. Iedema R, Jorm C, Braithwaite J. Managing the scope and impact of root cause analysis recommendations. J Health Organ Manag. 2008;22(6):569-585
35. Trbovich PL, Pinkney S, Cafazzo JA, et al. The impact of traditional and smart pump infusion technology on nurse medication administration performance in a simulated inpatient unit. Qual Saf Health Care. 2010;19(5):430-434

Part 3

Finding the right interventions to improve patient safety

CHAPTER 7

Evaluation of drug formularies for pediatric intensive care

Ceelie I, van der Starre C, Tibboel D, Stol K, Koren G, de Wildt SN. Evaluation of drug formularies for pediatric intensive care. Pediatr Crit Care Med. 2011 Jan;12(1):e14-19.

EVALUATION OF DRUG FORMULARIES FOR PEDIATRIC INTENSIVE CARE

Abstract

Objectives:
To evaluate availability and reliability of pediatric drug dosing guidelines in selected formularies for intensive care patients. Most drugs used in the pediatric intensive care unit are prescribed off-label, often on the guidance of limited information from commonly used drug formularies.
Design:
Availability of dosing information on prescribed drugs in a Dutch intensive care unit from January 1, 2005 to December 31, 2006 was compared among four selected formularies (Micromedex, Lexi-Comp, Drug Formulary for Children, Drug Doses). Reliability of dosing guidelines was assessed by evaluating labelling status and literature data for the three most (midazolam, acetaminophen, and amoxicillin/clavulanic acid) and the three least (bosentan, ketanserin, and iloprost) prescribed drugs.
Measurements and Main Results:
The selected formularies covered 68% to 86% of all 257 prescribed drugs. Guidelines differ widely on daily doses per kilogram, dose description, dosing regimen, and age ranges. For the three most prescribed and one of the least prescribed drugs (bosentan), dosing guidelines adequately reflected labelling status and existing (but scarce) literature. No dosing guidelines were available for iloprost, and only one dosing guideline was available for ketanserin.
Conclusions:
This study shows that four commonly used drug formularies give few and widely differing dosing guidelines for drugs prescribed in the intensive care unit. If guidelines exist, they seem to reflect labelling status (if present) and limited literature available. Findings from this study likely reflect the scarcity of drug studies in this population. Physicians should be aware of the limitations of these formularies for daily practice in this group of vulnerable patients.

Introduction

Reducing medication errors is an important means for improving patient safety, for which clinicians are expected to follow the "the five rights": the right drug; the right dose; the right route; the right time; and the right patient. [1] Getting the dose right is especially challenging in pediatric patients, as it needs to be age-appropriate. Also, off-label (outside the terms of the product license) and unlicensed (not licensed for the use in children) use of drugs in pediatric intensive care units (ICUs) is a reason for concern, as these patients' lives often depend on adequate treatment. A 2002 study in general practices and general pediatric wards and ICUs in the Netherlands showed, however, that 30% to 68% of drugs prescribed to children were off-label or unlicensed. [2, 3] Both staff and trainees prescribe such drugs on the guidance of dosing guidelines from drug formularies. Although widely used all over the world, the availability and reliability of these sources of information have received little attention in the current debate on drug prescription in children. Yet, "getting the dose right" depends on the availability of adequate dosing guidelines. The objective of the present study was to determine the availability and reliability of drug dosing guidelines for pediatric intensive care patients in selected drug formularies.

Materials and methods

Availability of Information
Two pediatric residents independently searched four drug formularies for dosing guidelines on all drugs prescribed in the ICU of the Erasmus MC Sophia Children's Hospital, Rotterdam, Netherlands, in 2005 and 2006, excluding intravenous fluids and feeds. This 28-bed, level 3 ICU admits all pediatric categories of patients, except direct postoperative cardiopulmonary bypass. Information on the drugs used was retrieved from the Patient Data Management System. The four study formularies were selected from hundreds of formularies as a convenience sample as they are often used in our ICU. Selection criteria were easy accessibility/user-friendly format, different geographic origin (Netherlands,
United States, and Australia), and different funding sources (commercial vs. public). The selection includes Drug Doses [4], Drug Formulary for Children [5], Lexi-Comp (Lexi-Comp, Hudson, Ohio; www.utdol.com/home/index.html), and Micromedex (Denver, Colorado; www.micromedex.com/products/hcs/). Characteristics are given in Table 1.

Table 1 As of March 2008, after we performed the actual study, the Drug Formulary for Children formulary dosing guidelines are incorporated in the Dutch National Formulary, which is available free online (www.kinderformularium.nl).

	Drug Doses	**Drug Formulary for Children***	**Lexi-Comp**	**Micromedex**
Country of origin	Australia	The Netherlands	USA	USA
Consulted version	Booklet	Booklet	Online- via UptoDate®	Online
Target patient group	Pediatric intensive care	Office pediatrics	General Medicine + Pediatrics	General Medicine
Information sources (as presented in the actual formulary)	Practice based	N/A	Literature references	Literature references
Book/online/PDA	Book/online/pda	Book/pda*	Online/pda	Online/pda
Costs	≈15 USD (PDA) <10 USD (book) Free:online	≈ 20 USD	Institutional subscription	Institutional subscription

N/A not available

All information retrieved by the two residents was counter-checked to ensure no errors were made in copying the data. If a formulary recommended a >100% higher daily dose per kilogram than the lowest dose recommended in the other formularies, the drug in question was tagged as "different dosing per kilogram." A drug was tagged as "different description" on the basis of differences in e.g., mg/kg in "x" doses vs. mg/kg/day, in "x" doses or every "x" hrs, mg/kg/hr vs. µg/kg/min, and amount per kg vs. amount per square meter. [m2] "Differences in regimen" refers to e.g., bolus vs. not bolus, bolus-dosing vs. continuous, and differences in the number of doses per day and differences in routes of administration. "Differences in age range" refers to differences in recommended age ranges or the absence of age ranges. Finally, "lack of pediatric data" was assigned when there was no

guideline at all, or when no pediatric dosing guideline was available in any of the formularies. These "tags" were dichotomized (0 or 1) so that percentages could be calculated. The list of all prescribed drugs was divided into quartiles with respect to number of prescriptions. Quartile 1 referred to the most frequently prescribed drugs; quartile 4 to the least frequently prescribed drugs. Number of prescriptions (following the quartiles) was related to both the availability of dosing guidelines and variation of drug doses.

Reliability of Information

As the availability of information on pediatric drug doses is only a quantitative measure to determine a formulary's usefulness, we assessed quality of the dosing guidelines for the three most and the three least prescribed drugs. To that end, we performed exploratory literature searches in PubMed (www.ncbi.nlm.nih.gov/sites/entrez) and EMBASE (www.embase.com). The search strategies were similar. The initial search consisted of drug name, followed by the limits Humans, English, and Child (0–18 yrs). For the three most prescribed drugs, the search was further limited to Newborn, Infant, Preschool child, and Child, and clinical trial or pharmacokinetics or pharmacodynamics. To reduce the number of initial, less relevant hits, the search was repeated, using extensive MeSH terms in PubMed; drug name, restricted to administration and dosage, pharmacokinetics, pharmacology, therapeutic use, and the previously mentioned limits (Humans, English, and Newborn, Infant, Preschool child, and Child) for each drug. Extended EMBASE search was performed with limits randomized clinical trial, humans, English, Newborn, Infant, Preschool child, and School child for all years. Relevance of the hits was evaluated by the availability of used drug doses, as described in the abstract; when of interest, "related articles" were searched. Dosing information was preferably obtained from randomized controlled trials (RCTs) that supported the efficacy and safety of the drug in question. If RCTs were not available, dosing information from pharmacokinetic studies, case series, etc. was used. Information regarding Food and Drug Administration (FDA) labelling status was retrieved from the Website www.accessdata.fda.gov/ scripts/cder/drugsatfda/index.cfm (last accessed December 1, 2008), to evaluate if approval status was reflected in the availability of dosing guidelines. Drug doses reported in studies and drug labels were compared with the dosing guidelines from the formularies.

Statistics

Availability of dosing guidelines of the formularies was compared for all prescribed drugs, by calculating the percentage of covered drugs for each formulary. Similarly, percentages for the other variables (differences in doses/kg, regimen, administration, age range, lack of pediatric data) were calculated. The relationship between number of prescriptions (following the quartiles) and availability of dosing guidelines was tested by Kruskal-Wallis test. The variation of drug doses per kilogram in relationship to the number of prescriptions was also tested by Kruskal-Wallis test. The calculations were performed, using Statistical Package for the Social Sciences (SPSS) version 15.0 (SPSS, Chicago, IL).

Results

Availability of Information

A total of 257 unique drugs had been prescribed during the study period. For 9.4% of all drugs, none of the four formularies provided a pediatric dosing guideline. For 34.7% of drugs, the guideline for the daily dose differed by >100% compared with the formulary for the lowest daily dose. For 61.0% of drugs, dose descriptions differed between formularies, whereas for 53.4%, the dosing regimen guidelines differed. Finally, for 34.5% of drugs, recommended age ranges differed. For each drug formulary, the availability of dosing guidelines correlated significantly with prescription frequency in our ICU (p=0.033). We did not find a relationship between prescription frequency and dose variation (p=0.293).

Availability of Information for the Three Most and the Three Least Prescribed Drugs

The three most prescribed drugs were acetaminophen (14,330 prescriptions), midazolam (1646 units for multiple use), and amoxicillin/clavulanic acid (5174 units). The least prescribed drugs were bosentan, iloprost, and ketanserin (each prescribed only once). Table 2 shows the dosing guidelines for these drugs in the four studied formularies. The dosing guidelines for the three most prescribed drugs were provided in all formularies and were largely in agreement. In contrast, only two formularies provided dosing guidelines for bosentan, none for iloprost, and one for ketanserin.

Reliability of Information

For the three most prescribed drugs, the dosing guidelines in the formularies adequately reflected the FDA labelling guidelines (www.fda.gov). The literature search results are shown in Table 3. The doses of midazolam [6, 7], acetaminophen [8–10], and amoxicillin/clavulanic acid [11, 12] used in clinical trials or pharmacokinetic/pharmacodynamic studies (>20 for each drug) also corresponded with the drug dosing guidelines in the formularies. The amoxicillin/clavulanic acid dosing guidelines can be potentially confusing and are prone to error. In the Micromedex, Lexi-Comp, and Drug Doses formularies, the daily dose of amoxicillin/clavulanic acid is only based on amoxicillin properties and not on the combination.

As the formulation in the United States and Australia differs from the formulation prescribed in the Netherlands (amoxicillin/clavulanic acid ratio in the Netherlands 4:1 vs. 7:1 elsewhere), recommendations on dosing differ. These differences disappear once the dose is corrected for clavulanic acid. In contrast to the frequently used drugs, no FDA approval for pediatric use has been granted for ketanserin, bosentan, and iloprost. For bosentan, dosing guidelines in two formularies reflected similar doses used in a small number of retrospective reports and open-label studies. [13] This only provides limited evidence for dosing; we did not find pharmacokinetic- pharmacodynamic studies or RCTs. Similarly, for iloprost, a number of relevant papers [14, 15] for use in children are available, but these do not include clinical trials. Finally, the ketanserin study [16] provided information only on transplacental passage of the drug to the fetus and no data on pediatric use (Table 3).

Chapter 7

Table 2A The 3 most prescribed drugs in 2005/2006 on the ICU and their dosing guidelines following the four studied formularies. For each drug the recommended dose was converted to a dose for 24 hours for easier comparison.

Drug	*Drug Formulary for Children*	*Micromedex*	*Drug Doses*	*Lexi-Comp*
Acetaminophen	Oral 60-90 mg/kg/day in 4-6 doses, first doses double dose Rectal 60-90 mg/kg/d in 3 doses	Oral 10-15 mg/kg/dose every 4-6H Rectal (1-3y) 80 mg every 4H	Oral 20 mg/kg stat then 15 mg/kg/dose 4H Rectal 40 mg/kg stat then 30 mg/kg/dose 6H	Oral 10-15 mg/kg/dose every 4-6H Rectal 10-20 mg/kg/dose every 4-6H
Acetaminophen dose calculated per mg/kg/day (mg/kg/d)	Oral 60-90 mg/kg/d Rectal 60-90 mg/kg/d	Oral 40-90mg/kg/d Rectal 30-50 mg/kg/d	Oral 90 mg/kg/d Rectal 120 mg/kg/d	Oral 40-90 mg/kg/d Rectal 40-120 mg/kg/d
Midazolam	0.05-0.2 mg/kg/h	0.06-0.12 mg/kg/hour	1-4 mcg/kg/min	0.4-6 mcg/kg/min
Midazolam dose calculated per mg/kg/day	*1.2-4.8 mg/kg/d*	*1.44-2.88 mg/kg/d*	*1.44-5.76 mg/kg/d*	*0.58-8.64 mg/kg/d*
Amoxicilin/ Clavulanic Acid	Oral 50/12.5-100/25 mg/kg/d in 3 doses	Oral 25-45 mg/kg/day divided every 12H (child <40 kg ascertain appropriate formulation)	Amoxi component 10-25 mg/kg/dose 8H iv im oral	Oral (child <40 kg) 20-40 mg/kg/day every 8H (amoxicillin component)
Amoxicillin/ Clavulanic acid dose calculated per calculated per mg/ kg/day	*50-100 mg/kg/d*	*25-45 mg/kg/d*	*30-75 mg/kg/d*	*20-40 mg/kg/d*

Table 2B The 3 least prescribed drugs in 2005/2006 on the ICU and their dosing guidelines following the four studied formularies. For each drug the recommended dose was converted to a dose for 24 hours for easier comparison. When no dosing guideline was available this was noted as such.

Drug	*Drug Formulary for Children*	*Micromedex*	*Drug Doses*	*Lexi-Comp*
Ketanserin	0.5-5 mcg/kg/min Max 150 mg/day	Not available	Not available	Not available
Ketanserin dose calculated per mg/ kg/day	*0.72-7.2 mg/kg/d max 150mg/day*	Not available	Not available	Not available
Bosentan	Not available	Not available	Oral; 1 mg/kg/dose 12H for 1-4 wk then 2 mg/kg/dose 12H Iv half oral dose	Oral <10 kg 15.6 mg daily to 15.6 twice daily 10-20 kg 31.25 mg daily to twice daily >20-40 kg 31.25 mg twice daily to 62.5 mg twice daily >40 kg 62.5 mg twice daily to 125 mg twice daily
Bosentan dose calculated per mg/ kg/day	Not available	Not available	2-4 mg/kg/d	1.6-4 mg/kg/d
Iloprost	Not available	Not available	Not available	Not available
Iloprost dose calculated per mg/ kg/day	Not available	Not available	Not available	Not available

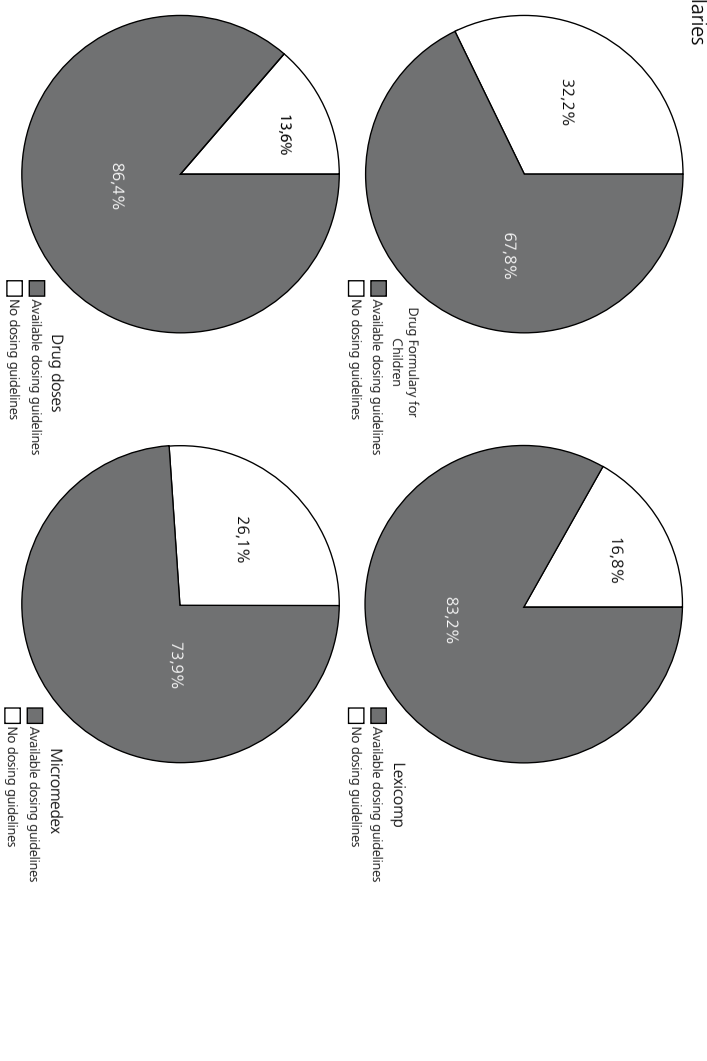
Table 3 Number of hits following the literature search as performed in PubMed and EMBASE.

Medication	Pubmed (01-04-2008)	+ limits (humans, english, all child 0-18 yr)	+ limits (human, English, newborn, infant, preschool child, school child) + (clinical trial, or pharmacokinetics or pharmacodynamics	+ MeSH (administration and dosage, pharmacokinetics, + limits)	Embase (02-05-2008) all years	All years + human	+ limits (RCT, English, human, all years, newborn, infant, preschool child, school child)	Number of formularies that agree with literature
Midazolam	7859	1109	829	24	20576	17864	109	4 of 4
Augmentin	2242	368	206	2	16000	13065	76	4 of 4
Acetaminophen	12517	1340	1021	43	40513	29680	111	4 of 4
Ketanserin	4374	23	18	0	6978	2614	1	0 of 0
Bosentan	1235	44	31	31 (substance name + limits)	2652	1292	1	2 of 2
Iloprost	1949	44	31	1	3721	2705	0	0 of 0

Discussion

This study shows that the four selected drug formularies give dosing guidelines from 67.8% to 86.4% of the 257 drugs prescribed in our ICU (Fig. 1). These guidelines diverge widely on various aspects. They reflect FDA status for the most and least frequently prescribed drugs. The coverage of drugs was associated with the number of prescriptions, with more information available for more frequently prescribed drugs and less variation between drug formularies with respect to the drug doses. An important limitation is, however, that not all studies that are used as basis for drug dosing guidelines are performed in the (sub)population of patients admitted to the ICU. For example, the dosing guidelines of the FDA on midazolam are based on a study [7] performed in pediatric patients undergoing computed tomography scans, a different population than the critically ill patients admitted to the ICU. In addition, even for frequently used drugs, there are few pediatric studies. For example, analgesics have been evaluated by no more than one or two RCTs, which often lack power. [17, 18] Although it has been recognized that further research is needed, pediatric drug research still faces financial, regulatory, practical, and scientific challenges. [19] In recent years, both American and European legislation has aimed to stimulate the study of medicines for use in children. Still, one cannot expect that the information gap will be closed soon. In this context, we believe that specific pediatric formularies, based on the latest evidence and expert opinions, are mandatory. They will enable physicians to provide the most effective and safe drug therapy in children.

Figure 1 Availability of dosing guidelines of the 257 prescribed drugs in the intensive care unit, in the four used formularies



They may also serve to protect physicians legally when prescribing urgently needed drugs to children. [20] The formularies studied were developed for different user groups. The focus on the Drug Formulary for Children is office based pediatrics, whereas Drug Doses focuses on ICUs. This may perhaps explain the larger differences between these two as well as the higher total doses per 24 hrs in Drug Doses. Micromedex and Lexi-Comp were not specifically developed for pediatric use, although both now have a large pediatric component. The geographical origin of the formularies differs, resulting in different marketing and labelling strategies as well as different "culturally determined" prescribing preferences (e.g., rectal formulations are less common in North America than in Europe). Also, the formularies differ with regard to evidence supporting the dosing guidelines. The Drug Formulary for Children and Drug Doses do not provide literature references at all. A partial solution to this issue could be setting up a database of the literature references on which the dosing guidelines are based. It should be freely accessible, preferably online. The content would also allow physicians to create a personal formulary as advised by the World Health Organization in their Guide to Good Prescribing. [21]

In addition to literature references, the rationale for the dosing guidelines should be given, as well as contact information to facilitate information sharing. Further needed research could then be anticipated according to evident knowledge gaps. It would also reduce the need for individual hospitals to perform time-consuming and costly literature search and to schedule Drug and Therapeutic committee meetings. Recently, the Dutch Knowledge Centre for Pediatric Pharmacotherapy launched a government-sponsored, free online pediatric formulary in the Netherlands, largely based on these principles (www.kinderformularium.nl/search/index.php). Dosing guidelines are initially derived from the Drug Formulary for Children. In the near future, they will all be verified against existing evidence, adjusted if needed, and provided with the relevant literature references. In case of absence of evidence to support the guidelines, expert opinion is used to decide on dosing guidelines. Currently, general consensus is reached in face-to-face meetings with a panel of experts (e.g., pediatric subspecialists, pharmacists, clinical pharmacologists, and epidemiologists). Alternatively, Delphi surveys could aid this process of decision making. [22] Similarly, the British National Formulary for Children is a collective publication by the Royal College of Pediatrics and Child Health, British Medical Association, Neonatal and Pediatric Pharmacists Group, and the Royal Pharmaceutical Society of Great Britain. [20] As the British National Formulary for Children explicitly states that its main focus is not tertiary care, we did not include it in our analysis. Even when FDA or other government labelling is available based on sufficient pediatric data, age restrictions are not always mentioned. Thus, there is a risk that drugs are prescribed to children younger than the age group they are intended for. Pediatric data used to label drugs in children may not be applicable to the patient population that is to receive the drug, such as critically ill patients. Furthermore, physicians should realize that data on less commonly used drugs often have been derived from retrospective case series or open-label studies. Our study may be limited in that we only searched four formularies. Nevertheless, as our selection represents a wide variety of properties (e.g., pocket book vs. digital, international coverage, commercial vs. academic, referenced vs. "experience-based," pediatric-specific vs. nonpediatric-specific), we believe that our findings may be generalized to other formularies. Another possible limitation is that we determined reliability of dosing guidelines for only the three most and three least prescribed drugs. Also, we did not perform a complete systematic review for these six drugs. We do believe, however, that this exploratory search provides a relevant overview of reliability of dosing guidelines in these formularies.

To our knowledge, no systematic reviews or RCTs have been published that unequivocally determine optimal drug dosing for drugs used in pediatric intensive care covering all ages. Our search more or less reflects what a physician would do in limited time, at the same time juggling all other demands in a busy clinical practice.

Conclusions

In conclusion, this study points at challenges in the availability and reliability of pediatric drug dosing guidelines in present drug formularies. Physicians should be aware of the limitations of the use of these formularies in daily practice. The lack of adequate and evidence based dosing recommendations for pediatric intensive care patients reflects the lack of drug studies in this population. Many others have made a plea, too, for studies in this population that might improve the current practice of off-label and unlicensed prescription.

Chapter 7

References

1. Benjamin DM. Reducing medication errors and increasing patient safety: case studies in clinical pharmacology. J Clin Pharmacol. 2003;43(7):768-783
2. 't Jong G, Eland IA, Sturkenboom MC, et al. Unlicensed and off label prescription of drugs to children: population based cohort study. BMJ. 2002;324(7349):1313-1314
3. 't Jong GW, Vulto AG, de Hoog M, et al. A survey of the use of off-label and unlicensed drugs in a Dutch children's hospital. Pediatrics. 2001;108(5):1089-1093
4. Shann F. Drug Doses. 12th ed. Parkville, Australia: Collective Pty Ltd; 2003.
5. Kimpen JLL, Rademaker CMA, Doesburg PBC, et al. Geneesmiddelenformularium voor kinderen. Wilhelmina Kinderziekenhuis. Edition 2003. Utrecht: Universitair Medisch Centrum; 2003.
6. de Wildt SN, de Hoog M, Vinks AA, et al. Pharmacodynamics of midazolam in pediatric intensive care patients. Ther Drug Monit. 2005;27(1):98-102
7. Reed MD, Rodarte A, Blumer JL, et al. The single-dose pharmacokinetics of midazolam and its primary metabolite in pediatric patients after oral and intravenous administration. J Clin Pharmacol. 2001;41(12):1359-1369
8. Anderson BJ, van Lingen RA, Hansen TG, et al. Acetaminophen developmental pharmacokinetics in premature neonates and infants: a pooled population analysis. Anesthesiology. 2002;96(6):1336-1345
9. Anderson BJ, Woollard GA, Holford NH. A model for size and age changes in the pharmacokinetics of paracetamol in neonates, infants and children. Br J Clin Pharmacol. 2000;50(2):125-134
10. Prins SA, Van Dijk M, Van Leeuwen P, et al. Pharmacokinetics and analgesic effects of intravenous propacetamol vs rectal paracetamol in children after major craniofacial surgery. Paediatr Anaesth. 2008;18(7):582-592
11. Reed MD. Clinical pharmacokinetics of amoxicillin and clavulanate. Pediatr Infect Dis J. 1996;15(10):949-954
12. Sanchez Navarro A. New formulations of amoxicillin/clavulanic acid: a pharmacokinetic and pharmacodynamic review. Clin Pharmacokinet. 2005;44(11):1097-1115
13. Barst RJ, Ivy D, Dingemanse J, et al. Pharmacokinetics, safety, and efficacy of bosentan in pediatric patients with pulmonary arterial hypertension. Clin Pharmacol Ther. 2003;73(4):372-382
14. Ivy DD, Doran AK, Smith KJ, et al. Short- and long-term effects of inhaled iloprost therapy in children with pulmonary arterial hypertension. J Am Coll Cardiol. 2008;51(2):161-169
15. Rimensberger PC, Spahr-Schopfer I, Berner M, et al. Inhaled nitric oxide versus aerosolized iloprost in secondary pulmonary hypertension in children with congenital heart disease: vasodilator capacity and cellular mechanisms. Circulation. 2001;103(4):544-548
16. Hanff LM, Visser W, Roofthooft DW, et al. Ketanserin in pre-eclamptic patients: transplacental transmission and disposition in neonates. BJOG. 2004;111(8):863-866
17. Playfor S, Jenkins I, Boyles C, et al. Consensus guidelines on sedation and analgesia in critically ill children. Intensive Care Med. 2006;32(8):1125-1136
18. Twite MD, Rashid A, Zuk J, et al. Sedation, analgesia, and neuromuscular blockade in the pediatric intensive care unit: survey of fellowship training programs. Pediatr Crit Care Med. 2004;5(6):521-532
19. Abdel-Rahman SM, Reed MD, Wells TG, et al. Considerations in the rational design and conduct of phase I/II pediatric clinical trials: avoiding the problems and pitfalls. Clin Pharmacol Ther. 2007;81(4):483-494
20. Stephenson T. The medicines for children agenda in the UK. Br J Clin Pharmacol. 2006;61(6):716-719
21. De Vries TP, Henning RH, Hogerzeil HV, et al. Guide to Good Prescribing. Geneva: World Health Organization; 1994.
22. Couper MR. The Delphi technique: characteristics and sequence model. ANS Adv Nurs Sci. 1984;7(1):72-77

Part 3

Finding the right interventions to improve patient safety

CHAPTER 8

Safety of routine early MRI in preterm infants

Annemarie Plaisier, Marlou M.A. Raets, Cynthia van der Starre, Monique Feijen-Roon, Paul Govaert, Maarten H. Lequin, Anneriet M. Heemskerk, Jeroen Dudink
Submitted to Archives of Disease in Childhood

SAFETY OF ROUTINE EARLY MRI IN PRETERM INFANTS

Abstract

Objective:
Preterm infants are at risk for brain injury and consequent neurodevelopmental impairment. Routine cerebral Magnetic Resonance Imaging (MRI) at 30 weeks gestational age (GA) is performed as part of our standard clinical care to screen for possible brain injury. Our aim was to evaluate safety of these MRI procedures.
Methods:
We retrospectively collected data on patient safety and adverse events in 52 infants who underwent routine MRI scans at 30 weeks GA. MRI procedures were carried out according to a guideline covering all disciplines involved. This included time-out procedures and documentation of vital parameters and adverse events related to the procedure.
Results:
Mean GA and weight at image acquisition were 30.1 weeks (29 4/7 - 30 4/7) and 1133 grams (659-1580), respectively. Vital parameters remained stable during the procedure. Minor adverse events were common. The MRI was terminated in 3 infants (5.8%) because of respiratory instability. Increased respiratory support within 24 hours after the MRI was necessary for 12 infants (23.1%) and was significantly correlated with GA, birth weight and the mode of respiratory support. Hypothermia (core temperature <36˚C) occurred in 9 infants (17.3%). Temperature drop was significantly correlated with weight at image acquisition.
Conclusions:
Although scanning at 30 weeks gestational age is relatively safe for preterm infants, adverse events in our study were common and should not be underestimated. A dedicated guideline for MRI procedures in preterm infants, including documentation of patient data, time-out procedures and critical incident review is essential, and these guidelines should be re-evaluated systematically.

Introduction

In preterm infants, early recognition of neonatal brain injury and assessment of risks of later impairment is a challenging goal of current neuroimaging studies. [1-3] Magnetic resonance imaging (MRI) provides clinicians and researchers objective, high-quality, in vivo information about brain anatomy, pathology and, due to recent advances, functional and physiological characteristics. [4-10] Early cerebral MRI scans at 30-weeks postmenstrual age and at term-equivalent age are increasingly being incorporated into standard care for very low birth weight (VLBW) infants. This provides early biomarkers for studying preterm brain injury related to neurodevelopmental outcome. These early determinants may contribute to the design of pharmacological and behavioral interventions to improve future outcome. [6-7, 11-12]
MRI is considered a safe imaging technique. No evidence exists of serious harm to human tissue, besides loud acoustic noise, tissue heating and peripheral nerve stimulation. [13-16] Performing early MRI scans in VLBW infants is challenging, as they frequently require respiratory support and are vulnerable to hemodynamic instability. Consequently, early MRI scans of VLBW infants should be performed in a safe and controlled environment with the use of a dedicated protocol. Studies on the methods that promote patient safety and health care quality are ongoing. Previous studies regarding safety of MRI in VLBW infants suggest that MRI procedures are safe. [17-19] However, population size and maturity range varied widely in these studies, and in some works, only adverse events during the scan were assessed. [17-18]
Our aim was to study the safety of routine MRI scans in preterm infants at a postmenstrual age of 30 weeks. To accomplish this, we collected data of these infants regarding safety incidents and (avoidable) adverse events over a long time period: 24 hours before and 24 hours following the MRI scan.

Methods

Description of the guideline:
A tailored, center-specific guideline for MRI procedures in VLBW infants was developed in collaboration with representatives from the radiology and neonatology departments as well as a patient safety officer from the Erasmus Medical Center – Sophia's Children Hospital. The guideline was based on the MR safety literature and our own experiences and was adjusted using the principles of the 'plan-do-study-act' quality improvement, [20] an iterative process, to improve outcomes (figure 1, see appendix).
Study participants
As part of standard clinical care practices, MRI scans were performed on VLBW infants with a gestational age (GA) < 29 weeks. These scans were performed at a postmenstrual age of 30 weeks (29 4/7 – 30 4/7 weeks). In all patients, the MRI procedure was carried out according to our multi-disciplinary guideline (see appendix). Data regarding patient safety, such as vital parameters, mode of respiratory support, number of episodes of bradycardia, apnea or oxygen desaturation and (avoidable) adverse events, were retrospectively collected from our electronic patient data management system. These data were sampled at fixed times: 24, 16 and 8 hours before the MRI scan, during the MRI procedure itself and 8, 16 and 24 hours after the MRI scan. The definitions of major and minor adverse events are listed in table 1.

Table 1 Definitions of adverse events

Major adverse events	Respiratory compromise resulting in intubation
	Circulatory compromise resulting in need for inotropic agents
	Cardiac resuscitation
	Death
Minor adverse events	Respiratory instability during the procedure
	Respiratory compromise resulting in minor increased respiratory support
	Increased hemodynamic instability
	Increased hemodynamic instability resulting in sepsis work-up
	Hypothermia

Image acquisition

All MRI scans were performed using a 1.5-T GE Echo Speed scanner (General Electronics Medical Systems, Milwaukee, Wisconsin.). The standard imaging protocol included the following: axial T1-w spin echo, axial T2-w dual spin echo, sagittal T1-w spin echo, axial 3DT1-SPGR and echo planar diffusion tensor imaging. Total acquisition time was approximately 39 minutes.

Statistical analysis

Statistical analysis was performed using SPSS v17.0.2. A repeated measures ANOVA using Wilk's Lambda test was conducted to test the stability of vital parameters during the MRI procedure. Correlations of adverse events with GA, birth weight, weight at image acquisition, gender, temperature drop, mode of respiratory support and total acquisition time were tested. Pearson's correlation coefficients were used for continuous variables. A one-way ANOVA and Pearson's chi-squared test were used for categorical variables, as appropriate. A p-value of <.05 (two-sided) was considered statistically significant.

The study was approved by the medical ethical committee of the Erasmus Medical Centre Rotterdam, the Netherlands.

Results

Infant characteristics

A total of 158 infants were eligible for inclusion in the study. Among these, 32 infants died, 36 infants were transferred to other hospitals before the MRI scan could be performed and 38 infants were not hemodynamically stable enough for MRI scanning. Thus, 52 infants (30 boys) underwent a cerebral MRI scan. Patient characteristics are listed in table 2.

Table 2 Patient characteristics

Gestational age at birth, mean ± SD, wk		26.8 ± 1.4
Birth weight, mean ± SD, g		967 ± 247
Postmenstrual age at MR acquisition, mean ± SD, wk		30.1 ± 0.3
Weight at MR acquisition, mean ± SD, g		1133 ± 197
Male gender, n (%)		30 (57.7)
Mode of respiratory support during MRI, n (%)		
	Nasal prongs	10 (19.2)
	CPAP	27 (51.9)
	Non-invasive ventilation	11 (21.2)
	Mechanical ventilation	4 (7.7)

Hemodynamic (in)stability

Compared to 24 hours before the MRI scan, vital parameters (heart rate, breathing rate and oxygen saturation) remained stable during the 24 hours after the scan (figure 2). Repeated measures ANOVA using Wilk's Lambda test was used to test this stability (data not shown).

Increased hemodynamic instability, defined as an increase of >5 episodes of bradycardia (heart rate <100/min), apnea (>20 seconds) or oxygen desaturation (saturation <85%) within the first 24 hours after the MRI compared with the 24 hours before the scan, occurred in 14 infants (26.9%) (table 3).

Table 3 Minor adverse events related to MRI procedure

Increased hemodynamic instability	14 (26.9)
Cancellation of MRI because of respiratory instability	3 (5.8)
Obstruction of central venous catheter after MRI	1 (1.9)
Increased respiratory support necessary within 24 hours after MRI	12 (23.1)
Hypothermia (< 36.0°) after MRI	9 (17.3)
Temperature drop after MRI, mean ± SD, degrees Celsius	0.5 ± 0.6

Adverse events

No adverse events occurred in 26 infants. However, in 26 infants (preventable) incidents and minor adverse events were encountered (table 3). The MRI scan was cancelled for 3 infants (5.8%) because of respiratory instability. In another infant, obstruction of the central venous catheter occurred after the scan, although its cause is unclear. Twelve infants (23.1%) needed increased respiratory support within 24 hours after the MRI; this was defined as increased inspiratory pressure, increased positive end expiratory pressure or increased frequency of ventilation. For one infant, this might have been due to being transported twice to the MR scanning room because of technical problems with the magnet. Hypothermia (core temperature <36°C) occurred in 9 infants (17.3%). On average, the infants' core temperature dropped 0.5 degrees after the MRI scan. Wilk's Lambda test for repeated measures ANOVA showed that temperature significantly decreased after MRI scanning (figure 3).

A required increase in respiratory support after the MRI scan was significantly correlated with GA, birth weight and mode of respiratory support; infants that required increased respiratory support after the scan were born at a significantly lower GA, were born with a lower birth weight and/or more frequently received non-invasive ventilation during the scan (table 4). Temperature drop was significantly correlated with weight at image acquisition; infants with a lower weight showed an increased temperature drop after the scan ($p< 0.03$).

Chapter 8

Table 4 Correlation of increased respiratory support with other variables

Parameter	Need for increased respiratory support		p
	No	Yes	
Gestational age at birth, mean ± SD, wk	27.1 ± 1.3	25.8 ± 1.4	<0.01[a]
Birth weight, mean ± SD, g	1007 ± 244	831 ± 210	0.03[a]
Weight at MR acquisition, mean ± SD, g	1146 ± 210	1091 ± 148	NS
Temperature drop after MRI procedure, degrees Celsius	0.5 ± 0.6	0.5 ± 0.5	NS
Male gender, n	21	9	NS
Mode of respiratory support during MRI, n			<0.01[b]
Nasal prongs	10	0	
CPAP	22	5	
Non-invasive ventilation	4	7	
Mechanical ventilation	4	0	

[a]Pearson's T-test, [b]Pearson's chi-squared test

NS: Not Significant

Discussion

Our study stresses the importance of providing a controlled environment for early MRI procedures for preterm infants. Despite the presence of a multi-disciplinary guideline specifically designed for preterm infants, minor adverse events, such as hypothermia and the need for increased respiratory support after the scan, were encountered regularly (17.3% and 23.1%, respectively). Therefore, caution needs to be taken regarding the safety of VLBW infants during MRI procedures. Critical incident review and continuous re-evaluation of the guidelines are essential in this process.

MRI is becoming increasingly important for accurately evaluating brain injuries and the consequent effects on neurodevelopment in preterm infants. [9, 11, 21-22] Compared with cranial ultrasonography, MRI has proven to be more sensitive for the detection of diffuse white matter injury (DWMI), [3, 23-24] and allows objective quantification of brain injury at a micro-structural level. [4, 25] MRI is considered a safe imaging technique, independent of ionizing radiation, and it enables high-resolution neuroimaging in a non-invasive manner. [26] The use of MRI scanning is limited in preterm infants because of their cardio-respiratory instability and predisposition to hypothermia. [17, 26-28] Performing an MRI scan in this vulnerable population requires a comprehensive guideline that includes all the essential elements: good preparation, optimal monitoring of vital parameters, open communication between the involved parties, individualized care and continuous efforts to improve the quality of care. Neonatal intensive care must obviously be maintained throughout the procedure, which requires the use of MR-compatible equipment that ensures optimal monitoring of vital parameters without causing injuries, such as burning, or image degradation as a result of radiofrequency interference with the static magnetic field.

Because of the increased risk of respiratory and circulatory compromise, sedation is not often used in preterm infants. To reduce motion artifacts, other strategies to comfort the infant are used, such as those according to the principles of the Newborn Individualized Developmental Care and Assessment Program. [29-30]

Safety incidents in (neonatal) health care are generally related to poor preparation, equipment failure and human error. [31-32] Studies on interventions to improve healthcare quality, such as staff training, implementation of a time-out-procedure (TOP) and the use of checklists and tailored guidelines, have shown that such preventable incidents can be reduced. [33-35] In addition, adverse events should always be reported in order for the guideline to be adjusted. [31] Comparable to operative procedures, a systematic pre-procedural briefing, such as a TOP, can be implemented for MR procedures as well. A pre-procedural TOP ensures that all involved caregivers agree that the correct procedure is being carried out properly for the correct patient.

We have shown that adverse events related to MRI scans are common. This is in contrast to other studies, [17-19] in which no significant adverse events were found. However, these studies primarily investigated serious adverse events that occurred during the scan itself, and the MRI scans had short acquisition times, [17] or a lower field strength (1 T), [19] or the study population consisted of patients with a wide range of gestational ages. [17-18] In contrast, the results of the current study only include data on VLBW infants with a mean postmenstrual age of 30 weeks ± 4 days. In addition, total acquisition time was approximately 39 minutes, and we collected data for the 48 hours surrounding the MRI procedure. Even though vital parameters remained stable during the MRI scan itself, increased hemodynamic instability occurred within the following 24 hours in some infants.

The limitations of this study include its retrospective design and the lack of temperature measurement during the MRI scan. Because of the increased incidence of hypothermia, we propose using an optical temperature probe to measure temperature continuously during the scan. Another limitation could be selection bias, as our data consist only of infants considered hemodynamically stable enough for a MRI scan. This implies that the incidence of adverse events might increase if more critically ill preterm infants are scanned, emphasizing the importance of a comprehensive guideline with staff training to ensure the safe execution of MR procedures.

Although minor adverse events were encountered more frequently after the MRI scan, it is not with certainty established that this in fact can be attributed to having undergone a MRI scan. However, due to the lack of evidence against causality and in the context of patient safety, we argue that each adverse event should be considered as a result of the procedure. Moreover, in order to avoid this possible bias, vital parameters, mode of respiratory support and the number of episodes of bradycardia, apnea or oxygen desaturation that occurred within 24 hours before the MRI scan were compared with the same details occurring within 24 hours following the MRI scan of each infant individually.

Finally, no serious adverse events occurred during the procedures, but the clinical significance of minor adverse events for future neurodevelopmental outcome remains unclear. Until empirical evidence shows that these events do not adversely affect neurodevelopment, we argue that adverse events should always be considered potentially harmful, and maximal efforts to prevent them must be undertaken.

In conclusion, adverse events within 24 hours after routine MRI procedures in VLBW infants at 30 weeks gestational age are common. Our findings illustrate the importance of providing a safe environment for early MRI procedures in preterm infants. Considering the increased application of MR imaging as part of the standard clinical care for preterm infants, a multi-disciplinary-based approach with continuous re-evaluation of the guidelines is necessary to ensure optimal safety for this population.

Chapter 8

References

1. Dyet LE, Kennea N, Counsell SJ, et al. Natural history of brain lesions in extremely preterm infants studied with serial magnetic resonance imaging from birth and neurodevelopmental assessment. Pediatrics. 2006;118(2):536-548
2. Debillon T, N'Guyen S, Muet A, et al. Limitations of ultrasonography for diagnosing white matter damage in preterm infants. Arch Dis Child Fetal Neonatal Ed. 2003;88(4):F275-279
3. Inder TE, Anderson NJ, Spencer C, et al. White matter injury in the premature infant: a comparison between serial cranial sonographic and MR findings at term. AJNR Am J Neuroradiol. 2003;24(5):805-809
4. Huppi PS, Murphy B, Maier SE, et al. Microstructural brain development after perinatal cerebral white matter injury assessed by diffusion tensor magnetic resonance imaging. Pediatrics. 2001;107(3):455-460
5. Dudink J, Kerr JL, Paterson K, et al. Connecting the developing preterm brain. Early Hum Dev. 2008;84(12):777-782
6. Ment LR, Hirtz D, Huppi PS. Imaging biomarkers of outcome in the developing preterm brain. Lancet Neurol. 2009;8(11):1042-1055
7. Boardman JP, Craven C, Valappil S, et al. A common neonatal image phenotype predicts adverse neurodevelopmental outcome in children born preterm. Neuroimage. 2010;52(2):409-414
8. Dubois J, Benders M, Borradori-Tolsa C, et al. Primary cortical folding in the human newborn: an early marker of later functional development. Brain. 2008;131(Pt 8):2028-2041
9. Rutherford MA, Supramaniam V, Ederies A, et al. Magnetic resonance imaging of white matter diseases of prematurity. Neuroradiology. 2010;
10. Seghier ML, Lazeyras F, Huppi PS. Functional MRI of the newborn. Semin Fetal Neonatal Med. 2006;11(6):479-488
11. Ramenghi LA, Rutherford M, Fumagalli M, et al. Neonatal neuroimaging: going beyond the pictures. Early Hum Dev. 2009;85(10 Suppl):S75-77
12. Dudink J, Lequin M, van Pul C, et al. Fractional anisotropy in white matter tracts of very-low-birth-weight infants. Pediatr Radiol. 2007;37(12):1216-1223
13. Schenck JF. Safety of strong, static magnetic fields. J Magn Reson Imaging. 2000;12(1):2-19
14. Schenck JF. Physical interactions of static magnetic fields with living tissues. Prog Biophys Mol Biol. 2005;87(2-3):185-204
15. Collins CM, Wang Z. Calculation of radiofrequency electromagnetic fields and their effects in MRI of human subjects. Magn Reson Med. 2011;
16. McJury M, Shellock FG. Auditory noise associated with MR procedures: a review. J Magn Reson Imaging. 2000;12(1):37-45
17. Benavente-Fernandez I, Lubian-Lopez PS, Zuazo-Ojeda MA, et al. Safety of magnetic resonance imaging in preterm infants. Acta Paediatr. 2010;
18. Merchant N, Groves A, Larkman DJ, et al. A patient care system for early 3.0 Tesla magnetic resonance imaging of very low birth weight infants. Early Hum Dev. 2009;85(12):779-783
19. Battin M, Maalouf EF, Counsell S, et al. Physiological stability of preterm infants during magnetic resonance imaging. Early Hum Dev. 1998;52(2):101-110
20. Speroff T, O'Connor GT. Study designs for PDSA quality improvement research. Qual Manag Health Care. 2004;13(1):17-32
21. Arthur R. Magnetic resonance imaging in preterm infants. Pediatr Radiol. 2006;36(7):593-607
22. Counsell SJ, Rutherford MA, Cowan FM, et al. Magnetic resonance imaging of preterm brain injury. Arch Dis Child Fetal Neonatal Ed. 2003;88(4):F269-274
23. Maalouf EF, Duggan PJ, Counsell SJ, et al. Comparison of findings on cranial ultrasound and magnetic resonance imaging in preterm infants. Pediatrics. 2001;107(4):719-727
24. Roelants-van Rijn AM, Nikkels PG, Groenendaal F, et al. Neonatal diffusion-weighted MR imaging: relation with histopathology or follow-up MR examination. Neuropediatrics. 2001;32(6):286-294
25. Counsell SJ, Edwards AD, Chew AT, et al. Specific relations between neurodevelopmental abilities and white matter microstructure in children born preterm. Brain. 2008;131(Pt 12):3201-3208
26. Stokowski LA. Ensuring safety for infants undergoing magnetic resonance imaging. Adv Neonatal Care. 2005;5(1):14-27; quiz 52-14
27. Mathur AM, Neil JJ, McKinstry RC, et al. Transport, monitoring, and successful brain MR imaging in unsedated neonates. Pediatr Radiol. 2008;38(3):260-264
28. van Wezel-Meijler G, Leijser LM, de Bruine FT, et al. Magnetic resonance imaging of the brain in newborn infants: practical aspects. Early Hum Dev. 2009;85(2):85-92
29. Als H. NIDCAP: testing the effectiveness of a relationship-based comprehensive intervention. Pediatrics. 2009;124(4):1208-1210
30. Legendre V, Burtner PA, Martinez KL, et al. The Evolving Practice of Developmental Care in the Neonatal Unit: A Systematic Review. Phys Occup Ther Pediatr. 2011;
31. Moss SJ, Embleton ND, Fenton AC. Towards safer neonatal transfer: the importance of critical incident review. Arch Dis Child. 2005;90(7):729-732
32. Lim MT, Ratnavel N. A prospective review of adverse events during interhospital transfers of neonates by a dedicated neonatal transfer service. Pediatr Crit Care Med. 2008;9(3):289-293
33. Nguyen YL, Wunsch H, Angus DC. Critical care: the impact of organization and management on outcomes. Curr Opin Crit Care. 2010;16(5):487-492
34. Schlack WS, Boermeester MA. Patient safety during anaesthesia: incorporation of the WHO safe surgery guidelines into clinical practice. Curr Opin Anaesthesiol. 2010;23(6):754-758
35. Chassin MR, Loeb JM. The ongoing quality improvement journey: next stop, high reliability. Health Aff (Millwood). 2011;30(4):559-568

Appendix

Description of the guideline:

Preparation

The medical team (attending neonatologist, pediatric radiologist and nursing staff) decides whether the infant is medically stable enough to undergo an MRI scan and whether the scan is indicated.

A multidisciplinary approach with close communication is essential.

A checklist is used to prepare the infant and equipment for the procedure; this checklist ensures a minimal risk of adverse events related to incorrect execution of the procedure.

An MR-compatible incubator is used, which provides controlled temperature and humidity as well as MR-compatible pulse oximetry and ventilation. The MR-compatible incubator is checked as follows: the temperature is set correctly; nonmagnetic air and oxygen tanks are present with sufficient capacity; and equipment for ventilation support is available and working.

A resuscitation bag with all necessary equipment for acute interventions is checked and available during the procedure.

All devices attached to the infant and implants (e.g., ECG leads, pulse oximetry probe, temperature probe, intravascular catheters, ductus arteriosus clips and ventriculo-peritoneal shunts as well as metal-containing infant clothing and bracelets) are checked for MR compatibility (www.mrisafety.com). MR-compatible ECG electrodes and pulse oximetry probe are attached to the infant to monitor heart rate and oxygen saturation during the scan.

The infant is protected against noise with moldable earplugs and neonatal earmuffs.

Infusion lines are sufficiently extended such that the infant can undergo an MRI scan while the infusion pumps remain outside the scanning room, or MR-compatible infusion pumps can be used.

The infant is placed in the MR incubator in a comfortable and secure way to encourage sleep and reduce movement. As sedation can cause respiratory and circulatory compromise, sedation is not desirable and often not needed.

Transport

A time-out procedure is performed before leaving the NICU such that a quick re-check is conducted and all involved parties agree on the following: the correct infant has been properly prepared, the MR incubator is set correctly, the infant is stable and comfortable and the MR department is ready to scan the infant.

Transport is accompanied by trained staff, and physiological stability is monitored during transport.

During the acquisition

Staff trained in neonatal life support remain present throughout the MRI scan.

A room near the MR suite with equipment, supplies and guidelines for neonatal resuscitation is checked and available during the MRI scan.

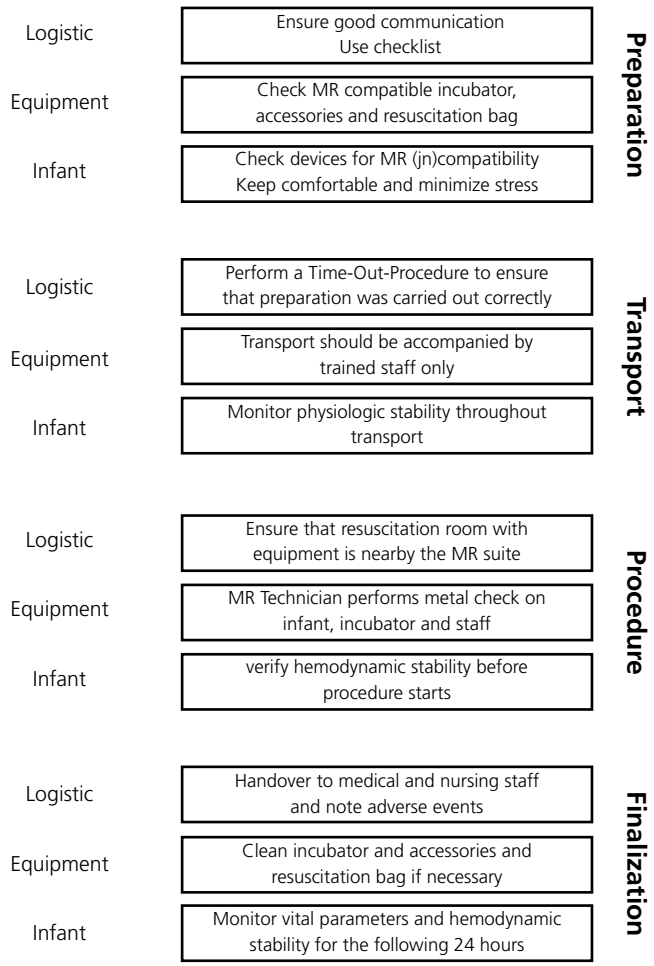
The technician at the MR suite performs a metal check on the infant, incubator, oxygen and air tanks and accompanying staff before entering the MR suite. Because of the potential hazards associated with the strong electromagnetic field, MR safety training for all accompanying staff is recommended.

Before the actual MR procedure starts, the presence of adequate respiratory support, hemodynamic stability and the infant's comfort are verified. Hemodynamic stability is closely monitored from the console room. The MRI procedure should be interrupted if hemodynamic stability is compromised or if there is any doubt about it.

After the MRI scan

After the acquisition, the infant's hemodynamic stability and respiratory support are checked again before returning to the NICU. Upon arrival to the NICU, a handover of the procedure to medical and nursing staff takes place, and possible adverse events are noted. The MR-compatible incubator and accessories are cleaned, and the resuscitation bag is refilled if necessary. During the subsequent 24 hours, the infant's vital parameters and hemodynamic stability are monitored continuously.

Figure 1 Guideline for safe execution of MRI procedures in preterm infants (see also addendum).



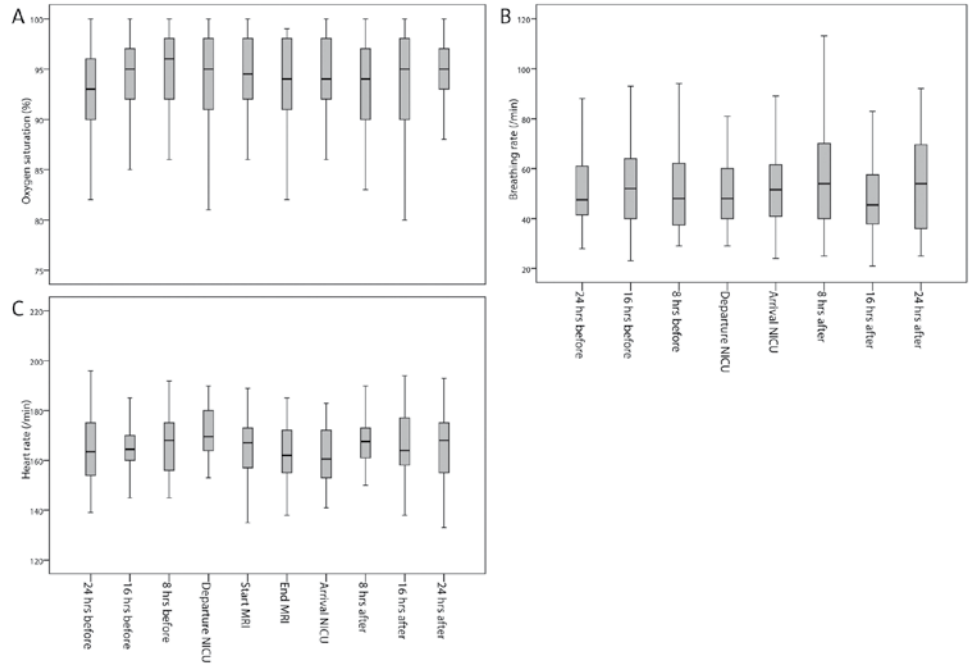


Figure 2 Trend of oxygen saturation (A), breathing rate (breathing rate was not measured during the MRI scan) (B) and heart rate (C) during the 48 hours surrounding the MRI scan. Note that these parameters remained stable.

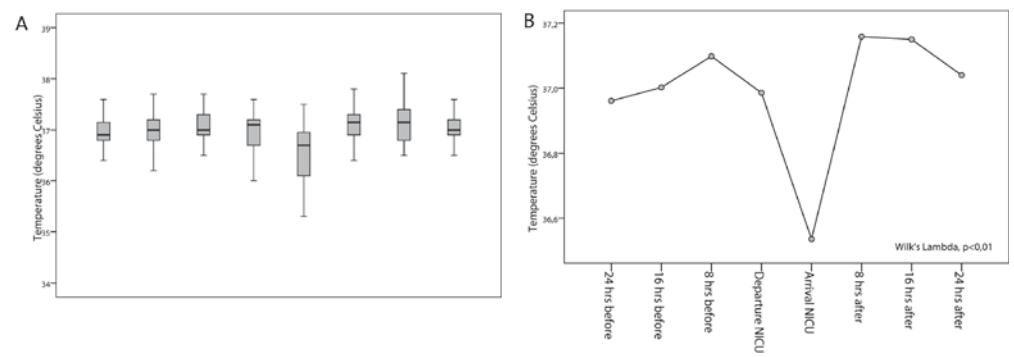


Figure 3 Temperature dropped significantly after the MRI scan. A: trend of temperature during the 48 hours surrounding the MRI scan. B: Repeated measures ANOVA shows that temperature dropped significantly after the MRI scan.

Part 3

Finding the right interventions to improve patient safety

CHAPTER 9

Integration of patient safety issues in Mortality and Morbidity conferences, does it make sense?

Van der Starre, van Dijk, van den Bos, Tibboel
Submitted to BMJ Quality and Safety

INTEGRATION OF PATIENT SAFETY ISSUES IN MORTALITY AND MORBIDITY CONFERENCES, DOES IT MAKE SENSE?

Abstract

Objective:
Mortality and Morbidity discussions in our institution were adapted to integrate patient safety issues. The focus was on recommendations to improve patient safety. The objective of the study was to describe the outcomes of these discussions over a 3 year period (2008 - 2010).
Design:
a retrospective descriptive study.
Setting:
A level III 28-bed intensive care unit in a university children's hospital. A patient safety management system has been in place since 2005.
Patients:
The unit admits patients from birth to 18 years, and serves as the ICU for all specialties. During 3 years, 85 patients were discussed in the conferences.
Interventions:
Reports of the conferences over a 3 year period were analyzed. Recommendations for improvement were identified and categorized.
Measurement:
We evaluated how many proposed recommendations had in fact been implemented.
Main results:
Patient safety issues related to death or serious adverse events were analyzed in 85 of the 93 conferences. Most of the 148 proposed recommendations concerned team (32.4 %) and individual provider performance (23.6%). Thirty one recommended interventions have been carried out so far.
Conclusions:
These conferences should be considered a promising addition to patient safety programs. Low implementation rates of recommendations are a well known problem that needs to be addressed to improve the yield from safety focused M&M conferences.

Introduction

Various studies have made clear that safety of healthcare leaves much to be desired. [1-3] Medical errors and adverse events are not uncommon, and pediatric patients in particular are at a high risk. [4-9] Both multinational and national initiatives have been launched to improve patient safety. [10-12] They are based on the notion that it is essential to create a culture in which staff feels safe to discuss any shortcomings without fear of "blaming and shaming" and to learn from errors. [3, 13, 14]
Mortality and morbidity (M&M) conferences were introduced in the 20th century in surgery and anesthesiology residency programs [15-18], and have since spread to other fields of medicine. [19-23] Traditionally, the goals of the M&M conferences were educational [24], with a focus on peer review and open discussion of adverse clinical events. The Accreditation Council for Graduate Medical Education in the United States has included quality improvement and patient safety in the core competencies for residency programs [25] and has advocated M&M conferences for that purpose. In recent years, the conferences have come to include ways to discuss and implement preventive measures as well. [23, 26-30] So far, only 2 publications on patient safety focused M&M conferences are available in the pediatric literature, both not in an ICU setting. [27, 31] In 2007 we started to integrate safety aspects in the M&M conferences in our ICU. We describe the nature of these conferences, the resulting recommendations, the problems with implementation and the lessons learned to improve effectiveness of the conferences.

Materials and Methods

Setting and description
The ICU is a 28 bed tertiary care intensive care unit in an academic children's hospital, with 1400 admissions per year. It serves a referral region of 4 million and provides all types of intensive care, such as transplant surgery, Extra Corporeal Membrane Oxygenation, cardiac surgery and care for newborns with major surgical anomalies. The ICU employs 15 certified intensivists with a background in pediatrics or anesthesiology; 4 fellows; 8 residents; and 120 FTE nursing staff. In 2005 a patient safety management system was introduced, with voluntary incident reporting, adverse event registration, scoring of protocol violations, and team resource management as its cornerstones. [32-34] A nurse (AvdB) and a physician (CvdS) have completed the Patient Safety Officer Executive Development Program from the IHI [35] and together with a nurse-safety manager are responsible for patient safety.
In 2007, weekly mortality, morbidity and safety (MMS) conferences were implemented, focusing on what went wrong and how errors could have been prevented. These are attended by ICU nurses, physicians and, if cases call for it, subspecialty physicians and nurses or other stakeholders. The MMS conferences are led by patient safety officers or senior clinical leaders when possible. Cases are usually presented by intensivists or fellows, and concern ICU deaths and serious adverse events. Others, too, may suggest topics, e.g. the ventilation practitioner (nurse specialist) presenting a case of difficult ventilation management. Furthermore, issues that are not directly patient related may be discussed, e.g. feedback from the incident reporting system, unnatural cause of death, or recognition of child abuse. Each conference is expected to be concluded with recommendations for improvement of care and prevention of the same or similar adverse events. The number and disciplines of attendees are recorded and minutes are taken.
Data collection
For this study, recommendations were identified from the minutes and categorized according to the contributing factors framework for incidents as developed by Vincent et al. [-] In this framework, adverse events are the result of a chain of events and these events are influenced by working conditions and organizational context. The 7 "levels" of contributing factors are patient factors, task, provider, team factors, working environment factors, organizational and management factors and institutional factors. Patient's factors can directly influence his condition and thus contribute to an event; in our study no recommendations pertaining to patients factors were established. Task factors are the availability and utility of protocols and test results. An example was the fact that a geneticist was not consulted in a patient with major congenital anomalies before she died; the protocol for diagnostic workup of these patients was outdated and not easily accessible.

Provider factors include the knowledge, skills and experience of each employee. An example would be the recommendation to consider rescue ECMO therapy in case of cardiac arrest and in-hospital resuscitation. The way an individual is influenced by other members of the team and the way they communicate, support and supervise each other are team factors. The recommendation to improve medical record keeping was classified as a team factor, as the issue was lack of communication of treatment plans etc and it was not aimed at a single provider but all members of medical staff (recommended 10 times). The working environment factors concern the physical environment and factors which affect staff ability to work effectively, such as defective equipment. Examples would be to mark ECMO cannulas as arterial and venous before insertion, or improve the redistribution of workload in case of deteriorating patients. The organisational factors include policies for continuing education, training and supervision and the availability of equipment and supplies. The request for better after-care for employees after stressful events or the suggestion to install rapid response teams were classified as organizational factors. The organisation is affected by the institutional context, including financial constraints, external regulatory bodies and the broader economic and political climate. Two recommendations were deemed institutional: earlier involvement of external expertise in conversations with parents and improve feedback on the outcome of cases of unnatural cause of death. The data are presented as numbers, medians and percentages.

Results

From January 2008 to January 2011 ninety-three MMS conferences were held. Seventy-seven (82.8%) conferences dealt with patient death; 8 (8.6%) with serious adverse events; 4 (4.3%) with general feedback from other patient safety activities; and 4 on other topics (e.g. unnatural cause of death, recognition of child abuse). Patient demographics are presented in Table 1. The minutes of 12 conferences do not completely record the number and type of attendees. The other 81 conferences were attended by a median of 17 participants (range 6-28, SD 5), mostly nurses (median 10); intensivists or fellows (median 3) and residents (median 2).

Table 1 Demographics of patients presented during MMS conferences.

Sex n (%)	
boys	45 (53%)
girls	39 (46%)
Age at admission n (%)	
Median	1 yr
IQR	45 days – 6 yrs
0-1 months	20 (23.8%)
1-12 months	28 (33.3%)
1 yr-12 yrs	23 (27.4%)
≥ 12 yrs	13 (15.5%)
Diagnoses n (%)	
Cardiac disease	19 (22.6%)
Neurological	14 (16.7%)
Congenital anomaly	13 (15.5%)
Post CPR	9 (10.7%)
Respiratory	7 (8.3%)
Oncological	6 (7.1%)
Infection	5 (6.0%)
Trauma	4 (4.8%)
Other	7 (8.3%)
Length of stay (days)	
Median	10
IQR	3-30

* N = 84, data on 1 case missing
Abbreviations: CPR; cardiopulmonary resuscitation, IQR; interquartile range

An illustrative case is shown in Table 2. The case presented was a 15-year-old patient with neurotrauma who died within 24 hours after admission to the PICU. All trauma casualties are stabilized in the adult Emergency Room, where the adult trauma expert is the team leader and the pediatric intensivist is consulted when deemed necessary. After stabilization the patient is handed over to the pediatric intensivist and transported to the children's hospital (a 15 minute walk). The normal policy is to first stabilize patients in the emergency department and then evaluate the neurologic status on the PCIU. The ED and PICU physicians did not decide treatment was likely to be futile considering the neurological status of the patient. However, the patient was not stabilized properly before being transported to the PICU. It is not likely this has changed the outcome for this patient, as the cerebral hemorrhaging and swelling was so severe that death was inevitable.

Table 2 Example case:

Chronological case description
A 15 year old boy was hit by a car and severely wounded. On site he was successfully intubated and resuscitated. In the ED he was respiratory and circulatory stable but neurological examination revealed dilated non-responsive pupils. After CT scan of head and pelvic area he was transferred to PICU; transport from ED to the PICU via the CT took over 1 hour. No central lines were inserted, no lab checks were done in that period and transfusion units were not ordered. Upon arrival on the PICU, his Hb had dropped from 6.3 to 2.4 mmol/L and he was hypotensive. CT scans showed massive intracranial hemorrhage and multiple bleeding fractures of the pelvis. Appropriate interventions to increase blood pressure, decrease intracranial pressure and stabilize the pelvis were carried out. In spite of these, brain death was declared shortly after.
Discussion points
- Transfer from the ED to the PICU took too much time, during which there was suboptimal monitoring of the vitals and no monitoring of laboratory values, amongst others due to long distance between units and staff shortage. - Communication and team structure was suboptimal because the adult trauma expert was the team leader and not the pediatric intensivist (as a rule, in all trauma cases trauma experts are teamleader). Stabilization of the fractured pelvis was not prioritized over head CT scan, and not discussed in the ED - Transfusion units were not ordered in advance on the ED, because a quick transfer to the PICU was foreseen.
Recommendations
- Increase speed of transfer to PICU (organizational factor) - Pediatric intensivist should speak up and discuss with team leader necessity of stabilization of fractured pelvis (provider factor) - If large bones are fractured, transfusion units should be ordered immediately (task factor)

Abbreviations: ED: emergency department
CT: computer tomography
PICU: pediatric intensive care unit
Hb: hemoglobin

In 85 conferences 148 recommendations were formulated (median 2; range 0-4). Fifteen conferences (17.6%) were concluded without recommendations; they dealt with unavoidable adverse outcomes or deaths where no errors in management could be identified, for instance inoperable congenital malformation or brain death after high energetic trauma.
The recommendations are categorized in Table 3. Only two (1.4%) related to institutional factors; 48 (32.4%) related to team factors. Thirty-one recommendations (21%) have been implemented so far, for example the use of a list of available materials and equipment and the establishment of a support team for employees experiencing traumatic events. The team factors recommendations were taken up as topics for the team resource management and team simulation trainings.

Table 3 Recommendations categorized according to Vincent's framework.

N (%)	adopted	Category	Example of recommendation
2 (1.4)	-	Institutional context	Create guideline for feedback on unnatural deaths from forensic department/police.
22 (14.9)	1	Organizational and management factors	Improve psychological support for patient/parents/ employees; set up rapid response team.
16 (10.8)	6	Work environment factors	Improve visibility of lab results during CPR in ED; mark ECMO cannulas arterial/venous before insertion.
48 (32.4)	18	Team factors	Improve communication and reporting on DNR policy.
35 (23.6)	3	Provider factors	Early CT scan in case of visible head injury; consider rescue ECMO for cardiac arrest.
25 (16.9)	3	Task factors	Have end-tidal CO_2 measurement ready before intubation.
148 (100)	**31 (21)**		

Abbreviations:
CPR cardiopulmonary resuscitation
ED emergency department
ECMO extra corporeal membrane oxygenation
DNR do not resuscitate
CT computer tomography

Discussion

Our patient safety focused M&M conferences in a pediatric ICU environment resulted in many recommendations – indicative of systems failures on the one side, and opportunities for improvement on the other side. However, only 21% of the recommendations have been taken up so far. A number of lessons can be learnt from this. First of all, in the conferences that were not chaired by the patient safety officers or senior leaders, recommendations were either not formulated or not specified enough to develop an intervention. Second, in a large number of conferences, nobody was appointed as responsible for the further development and implementation of the recommendations, thus the tasks were not taken up by anybody. Also, some of the recommendations were difficult to bring into practice, such as addressing "medical record keeping needs to be improved". Especially addressing the organizational recommendations was difficult. These were often related to collaboration with other disciplines such as surgeons and cardiologists that were not involved with the safety improvement initiatives and thus more difficult to convince of the necessity of organizing multidisciplinary rounds etc. At the start of the conferences, the focus was on creating awareness of patient safety issues and the system's approach towards errors and adverse outcomes. Thus, appointing responsibilities and assignments was not a priority in the beginning. Later, this proved to be very difficult as the attendees considered taking up the task of acting on the recommendations to be optional and not an obligation.
Formats of M&M conferences, their goals, topics and impact on education have been reported extensively. [15, 17, 18, 36, 37] Lately, we have seen a shift from peer review of individual performance and review of "(educationally) interesting" cases to multidisciplinary open discussions of adverse events and system failures. [23, 26-30]

Chapter 9

Two previous studies have reported on safety focused M&M conferences in a pediatric setting. One identified 33 improvement items resulting from19 conferences in a children's hospital, of which 23 had been implemented, such as a structured communication technique. [31] The other, in a pediatric psychiatry department, identified improvement opportunities in 80% of cases presented during 2 years of monthly conferences, e.g. additional education and communication guidelines. [27] Our study, however, is the first of its kind focusing on patient safety in a pediatric intensive care setting.

M&M conferences have also been implemented as a tool for the advancement of patient safety in other settings. Bechtold et al identified 121 system improvement recommendations in an internal medicine department in 11 months. [26] Szekendi et al. and Sultana and Baxter both describe that patient safety focused M&M rounds were successful in identifying potential system improvements. [23, 28] Ksouri reported that M&M conferences on the adult ICU resulted in three major system improvements: a standardized procedure for sepsis in neutropenic patients, standardized prescription of mechanical ventilation, and definition of roles of nursing staff in cardiac or respiratory arrest. [29]

An important feature of the safety focused M&M meetings – and a likely key to their success – is application of the systems approach to adverse outcomes, as opposed to the approach in which individuals are blamed. A detailed discussion of the care process and the inadequacies therein, can direct attention towards factors such as management decisions or work environment that may have contributed to the adverse outcome. [28, 37] In our safety focused M&M conferences, no more than 23.6% of the recommendations were aimed at individual performance (provider factors). Thus we have come a long way to achieving the systems approach.

Another key element of successful M&M conferences is the multidisciplinary nature. [26, 27, 29, 38] From the introduction of M&M conferences in our department, both nurses and physicians have contributed, allowing different viewpoints to be expressed and a broader range of improvements to be suggested. The conferences were scheduled in the afternoon so that both day and evening shifts nurses could attend.

Other studies have reported that lack of time and resources may hinder good preparation of these conferences. [20, 38] Without proper preparation, motivation of attendees to contribute to the discussion will decrease and pointing out opportunities for improvement will be more difficult. Therefore it may be necessary to select cases more purposefully, i.e. solely cases where something went wrong.

An impediment was the lack of consistent leadership of the meetings, as the patient safety officers or senior clinical leaders were not always present. We believe this has hampered identifying contributing factors and successful implementation of recommendations. Furthermore, maximum yield of safety focused M&Ms can only be obtained when specific persons are assigned the task to implement the recommendations.

The lessons we learned is that roles and responsibilities of participants, presenters, chairpersons, patient safety officers and senior management should be defined and formalized right from the start. In addition, all participants should agree on the contents of the conferences, the open way in which matters are discussed, and the nature of the recommendations to be made. Every conference could start with feedback on the recommendations from previous meetings, so that implementation can be augmented and quality and safety of care further improved.

Conclusion

Frequently held multidisciplinary mortality and morbidity conferences with a focus on patient safety have great potential, especially when attention is shifted away from individual failures and errors. They stimulate an open discussion of unsafe practices among care providers and provide leads for system-based safety interventions. Successful implementation largely depends on prior definition of roles and responsibilities of the participants, and on unwavering public support from clinical leaders and management.

References

1. Leape LL, Brennan TA, Laird N, et al. The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. N Engl J Med. 1991;324(6):377-384
2. Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. N Engl J Med. 1991;324(6):370-376
3. Institute of Medicine. To Err is Human: Building a Safer Health System. Kohn LT, Corrigan JM, Donaldson MS, editors. Washington, D.C.: National Academy Press; 2000.
4. Dominguez TE, Chalom R, Costarino AT, Jr. The impact of adverse patient occurrences on hospital costs in the pediatric intensive care unit. Crit Care Med. 2001;29(1):169-174
5. Agarwal S, Classen D, Larsen G, et al. Prevalence of adverse events in pediatric ICUs in the United States*. Pediatr Crit Care Med. 2010:568-578
6. Miller MR, Elixhauser A, Zhan C. Patient safety events during pediatric hospitalizations. Pediatrics. 2003;111(6 Pt 1):1358-1366
7. Landrigan CP. The safety of inpatient pediatrics: preventing medical errors and injuries among hospitalized children. Pediatr Clin North Am. 2005;52(4):979-993, vii
8. Larsen GY, Donaldson AE, Parker HB, et al. Preventable harm occurring to critically ill children. Pediatr Crit Care Med. 2007;8(4):331-336
9. Woods D, Thomas E, Holl J, et al. Adverse events and preventable adverse events in children. Pediatrics. 2005;115(1):155-160
10. World Health Organization. WHO Patient Safety campaigns. [cited 2011 march 28]; Available from: www.who.int/patientsafety/campaigns/en/
11. Institute for Healthcare Improvement. Overview of the 100,000 Lives Campaign. [cited 2011 march 28]; Available from: www.ihi.org/IHI/Programs/Campaign/100kCampaignOverviewArchive.htm
12. APSF. Australian Patient Safety Foundation. [cited 2011 march 29]; Available from: www.apsf.net.au/
13. Leape L, Berwick D, Clancy C, et al. Transforming healthcare: a safety imperative. Qual Saf Health Care. 2009;18(6):424-428
14. Vincent C. Understanding and responding to adverse events. N Engl J Med. 2003;348(11):1051-1056
15. Veldenz HC, Dovgan PS, Schinco MS, et al. Morbidity and mortality conference: enhancing delivery of surgery residency curricula. Curr Surg. 2001;58(6):580-582
16. Gore DC. National survey of surgical morbidity and mortality conferences. Am J Surg. 2006;191(5):708-714
17. Prince JM, Vallabhaneni R, Zenati MS, et al. Increased interactive format for Morbidity & Mortality conference improves educational value and enhances confidence. J Surg Educ. 2007;64(5):266-272
18. Aboumatar HJ, Blackledge CG, Jr., Dickson C, et al. A descriptive study of morbidity and mortality conferences and their conformity to medical incident analysis models: results of the morbidity and mortality conference improvement study, phase 1. Am J Med Qual. 2007;22(4):232-238
19. Orlander JD, Fincke BG. Morbidity and mortality conference: a survey of academic internal medicine departments. J Gen Intern Med. 2003;18(8):656-658
20. Friedman JN, Pinard MS, Laxer RM. The morbidity and mortality conference in university-affiliated pediatric departments in Canada. J Pediatr. 2005;146(1):1-2
21. Miller DC, Filson CP, Wallner LP, et al. Comparing performance of Morbidity and Mortality Conference and National Surgical Quality Improvement Program for detection of complications after urologic surgery. Urology. 2006;68(5):931-937
22. Seigel TA, McGillicuddy DC, Barkin AZ, et al. Morbidity and Mortality conference in Emergency Medicine. J Emerg Med. 2010;38(4):507-511
23. Sultana CJ, Baxter JK. A resident conference for systems-based practice and practice-based learning. Obstet Gynecol. 2011;117(2 Pt 1):377-382
24. Biddle C, Oaster TR. Investigating the nature of the morbidity and mortality conference. Acad Med. 1990;65(6):420
25. Accreditation Council for Graduate Medical Education. Outcome Project: General Competency and Assessment Common Program Requirements. 2007 [updated 2007; cited 2011 april 1]; Available from: www.acgme.org/outcome/comp/compCPRL.asp
26. Bechtold ML, Scott S, Nelson K, et al. Educational quality improvement report: outcomes from a revised morbidity and mortality format that emphasised patient safety. Qual Saf Health Care. 2007;16(6):422-427
27. Goldman S, Demaso DR, Kemler B. Psychiatry morbidity and mortality rounds: implementation and impact. Acad Psychiatry. 2009;33(5):383-388
28. Szekendi MK, Barnard C, Creamer J, et al. Using patient safety morbidity and mortality conferences to promote transparency and a culture of safety. Jt Comm J Qual Patient Saf. 2010;36(1):3-9
29. Ksouri H, Balanant PY, Tadie JM, et al. Impact of morbidity and mortality conferences on analysis of mortality and critical events in intensive care practice. Am J Crit Care. 2010;19(2):135-145; quiz 146
30. Berenholtz SM, Hartsell TL, Pronovost PJ. Learning from defects to enhance morbidity and mortality conferences. Am J Med Qual. 2009;24(3):192-195
31. Deis JN, Smith KM, Warren MD, et al. Transforming the Morbidity and Mortality Conference into an Instrument for Systemwide Improvement (Vol. 2: Culture and Redesign). In: Henriksen K, Battles JB, Keyes MA, Grady ML, editors. Advances in Patient Safety: New Directions and Alternative Approaches. 2011/01/21 ed. Rockville (MD): Agency for Healthcare Research and Quality; 2008
32. Snijders C, van Lingen RA, Klip H, et al. Specialty-based, voluntary incident reporting in neonatal intensive care: description of 4846 incident reports. Arch Dis Child Fetal Neonatal Ed. 2009;94(3):F210-215
33. Binnekade JM, de Mol BA, Kesecioglu J, et al. The Critical Nursing Situation Index for safety assessment in intensive care. Intensive Care Med. 2001;27(6):1022-1028
34. Van der Starre C, Van der Tuijn Y, Tibboel D. Patient Safety Management System in Pediatric ICUs. In: Vincent JL, editor. Yearbook of Intensive Care and Emergency Medicine: Springer; 2006. pp. 745-754
35. Institute of Healthcare Improvement. Patient Safety Executive Development Program. [cited 2011 march 28]; Available from: www.ihi.org/IHI/Programs/ProfessionalDevelopment/PatientSafetyProgramSeptember2011.htm
36. Murayama KM, Derossis AM, DaRosa DA, et al. A critical evaluation of the morbidity and mortality conference. Am J Surg. 2002;183(3):246-250
37. Risucci DA, Sullivan T, DiRusso S, et al. Assessing educational validity of the Morbidity and Mortality conference: a pilot study. Curr Surg. 2003;60(2):204-209
38. Kravet SJ, Howell E, Wright SM. Morbidity and mortality conference, grand rounds, and the ACGME's core competencies. J Gen Intern Med. 2006;21(11):1192-1194

Part 3

Finding the right interventions to improve patient safety

CHAPTER 10

Nursing protocol violations: detect, correct and communicate

Harma te Beest, Cynthia van der Starre, Dick Tibboel, Monique van Dijk
Submitted to intensive care nursing

NURSING PROTOCOL VIOLATIONS: DETECT, CORRECT AND COMMUNICATE

Abstract

Introduction

The Critical Nursing Situation Index (CNSI) is a tool to detecting nursing protocol violations.

Objectives: The objective of this study was to determine incidences and severities of different types of protocol violations and to check whether actions were taken to correct the protocol violations.

Methods

Prospective observational study in the intensive care unit of the Erasmus MC-Sophia Children's Hospital.

A checklist adapted from a previously published version of the CNSI was applied in the period February 2009 to February 2010 by 14 nurses who had been trained to use the CNSI and whose interrater reliability was sufficient. The checklist addressed nine domains of nursing care; Basic Care, Circulation, Respiration, Digestive tract, Infection, Invasive catheters, Medication, ECMO, and Central nervous system.

Results

238 observations in 126 patients were carried out, in which 21512 items were checked. In 986 out of 8107 applicable items (12.2%) the protocol was violated. More than fifty percent (53.4%) of all protocol violations were corrected in the same shift. Nurses' classification of the severity of the protocol violations was not reliable, with linearly weighted kappa varying from 0 to 0.33.

Conclusions

The CNSI is a useful tool to monitor and to correct nursing protocol violations.

Relevance to clinical practice: Timely identification of protocol violations enables to rectify them which will improve safety. Furthermore, this study made us aware that protocol violations may be justifiable in clinical practice. The reasons and durations of these should be well communicated among the nursing staff.

Introduction

The risk of errors and adverse events may be considerable in high-technology departments such as a pediatric intensive care unit (PICU). Several tools are available to monitor adverse events in the PICU setting but the role of the nurse in this area so far has been limited to voluntary incident reporting [1-3]. Adverse events registration has evolved with the use of trigger tools to identify adverse events [4-5] but it is mainly physicians who apply trigger tools. It is thought that no instrument is ideal to identify all adverse events.

Of course it would be best to prevent errors in the first place. Important in this respect is continuity of care and adherence to evidence based nursing protocols. To check adherence to protocols, Binnekade et al. developed the Critical Nursing Situation Index (CNSI), a checklist to identify protocol violations. [6] De Neef et al. developed a modified version for use in a general PICU. [7] Binnekade et al. found an incidence of 13 protocol violations in 100 "items at risk" in an adult ICU. "Items at risk" are those CNSI items that are applicable; for instance items that concern mechanical ventilation will be items at risk for ventilated patients but not for spontaneously breathing patients. The incidence was statistically significantly higher when nursing time at bedside was shorter. The latter finding was not replicated by de Neef et al in a paediatric intensive care population. [7] In this study the incidence was 18 per 100 items at risk.

The objective of our study was 1) to determine the incidences and severities of different types of protocol violations and to check whether actions were taken to correct the protocol violations; and 2) to investigate how often nurses deviate from the protocol for justifiable reasons.

Methods

Patients and setting

All patients aged 0 to 18 years at the ICU of the Erasmus MC-Sophia Children's Hospital are eligible for CNSI assessment of nursing care. The ICU is a level III unit with 28 beds and a step down unit of 6 beds with an average of 1400 admissions a year. The number of nurses is around 130. The Erasmus MC Medical Ethical Review Board waived informed consent because CNSI assessment is part of our Patient Safety Management System, which has been in place since 2005 and furthermore incorporates voluntary incident reporting, team resource training and adverse events registration.

Study design

Prospective observational study.

CNSI instrument

In 2003 we tested the CNSI tools of Binnekade et al [6] and de Neef et al [7] both in 15 patients. Most items (69% and 83%, respectively) proved not suitable for our setting. [8] From October 2003 to August 2004, the 96 nursing protocols of our unit, that provide the basis of the CNSI, were each independently screened by two nurses, and if necessary, adapted and rewritten. Final approval was obtained from a paediatric intensivist. CNSI Items were added for neurotrauma patients and patients on Extra Corporeal Membrane Oxygenation (ECMO). A new update was prepared in 2009 (see Figure 1). Our CNSI now contains 181 items divided into 9 categories (Appendix 1). Each item of the CNSI represents an element of a nursing protocol.

There are three possible responses to the item statements: "True" which indicates that the protocol was violated; "False", which indicates that care was by protocol, and "Not applicable", which indicates that this item does not apply to this patient. A considerable number of CNSI items may not be applicable in for instance a patient without mechanical ventilation.

Severity of protocol violations was established as follows. Seven nurses each independently scored the severity of 32 randomly selected protocol violations; i.e. hypothetically. Because the interrater reliability was low we continued with a second step. The nurses scored the same protocol violations again, but now after having been given information about patients in the current study for whom the protocol violations were noted, such as age, body weight and severity of illness. Severity was scored on a 1 to 5 scale: 1 Without adverse effects; 2 Possible minimal discomfort; no harm, no interventions necessary; 3 Moderate: Possible discomfort, temporary harm; 4 Serious: Possible serious discomfort; permanent harm; serious clinical interventions 5 Unknown: Possibility of future harm or interventions, but the potential is unknown by now.

Procedure

Fourteen nurses were trained in CNSI assessment during two 3-hours sessions followed by bedside scoring. Each nurse made 10 assessments in alternating pairs with a colleague. Interrater reliability of all nurses was excellent (Cohen's Kappa 0.93-0.99). These nurses were asked to apply the CNSI at least once a week to keep their skills and to collect sufficient data for this study. A patient would be randomly selected and the bedside nurse would be informed. After the assessment, the bedside nurse and the nurse who scored the CNSI would go through the list to discuss any protocol violation encountered. The nurse who scored also recorded if violations were discussed with the bedside nurse and corrected either immediately or later in the same shift; and if protocol violations were justifiable.

The CNSI score form also includes date and time of admission; reason for admission; observation date and time; and IC or High Care patient. The total list of 181 items is divided into two sub lists to reduce assessment time. The odd numbered ones were placed on an 'A' list, the even numbered ones on the 'B' list.

Data were collected from February 2009 to January 2010. CNSI assessments continued afterwards as standard of care with an average of 3-4 weekly CNSI sores.

Statistical analysis

The incidence of 'critical nursing situations', which we shall further refer to as 'protocol violations' was the quotient of items scored as 'true' and the total number of applicable items and is expressed as the rate per 100 items at risk. Interrater reliability of the severity scores was calculated with the linearly weighted Cohen's kappa. A kappa of 0.61 or higher was deemed acceptable. We calculated a mean (SD) severity score to compare the items.

Results

In the study period 238 assessments were performed in 126 out of the 1081 patients (11.6%) admitted during that period. In 110 assessments the A form (92 items) was used; in 128 times the B form (89 items). Patients' background characteristics are given in Table 1. Eighty percent were under the age of 4 years and their median length of stay was 19 days (IQR 9 to 40).

Table 1 Patient characteristics (N=126)

Background characteristics	N (%) unless stated otherwise
Girls	57 (45.2)
Boys	69 (54.8)
Age group	
Neonates	50 (39.7)
1 month -1 year	31 (24.6)
1 - 4 year	20 (15.9)
5 - 17 year	23 (18.2)
18 year and older	2 (1.6)
Diagnosis	
Cardiac disorders	29 (23.0)
Respiratory disorders	29 (23.0)
Gastrointestinal disorders	16 (12.7)
Neurological disorders	15 (11.8)
CDH	14 (11.0)
Sepsis/H1N1	9 (7.1)
Syndromes and other	14 (11.1)
PRISM-II and PIM-II in mean (SD)	
PRISM II (n=119)	14.8 (8.5)
PIM-II (n=119)	– 3.14 (1.59)
Length of stay in median (IQR) days	19 (9 to 40)
Type of patient	
IC	96 (76.2 %)
HC	30 (23.8 %)
Number of CNSI observations per patient in median (IQR)	1 (1 to 2)

Of all 21512 items, 8107 (37.7%) were at risk for a protocol violation. Of these, 986 were scored as 'true' (12.2%), resulting in an overall incidence of 12 protocol violations per 100 items at risk (Figure 1). The incidence of protocol violations per subscale varied from 5 (Medication) to 26 (Digestive tract) as shown in Table 2.

Actions taken upon protocol violations

Table 3 gives the response to the protocol violations. More than fifty percent (53.4%) of all protocol violations were directly or later corrected by the bedside nurse. This percentage varied between 31.8% for ECMO related protocol violations to 64% for Digestive tract related violations. Protocol violations were justifiable in 22.3% of all, ranging from 10.9% for Digestive tract to 40.9% for ECMO related protocol violations (Table 3). The most frequent justifiable protocol violation was 'Incorrect vital functions alarm settings on the monitor' (32 times). Alarm settings may be tailored to suit a specific patient. Refraining from weighing (item 3) or position not changed regularly (item 9) was noted respectively 11 and 10 times in case of instable patients.

In almost one quarter (24.3%) of cases the violations were not discussed (e.g. because the assessment was performed in a next shift) or not recorded on the case record form.

Figure 1

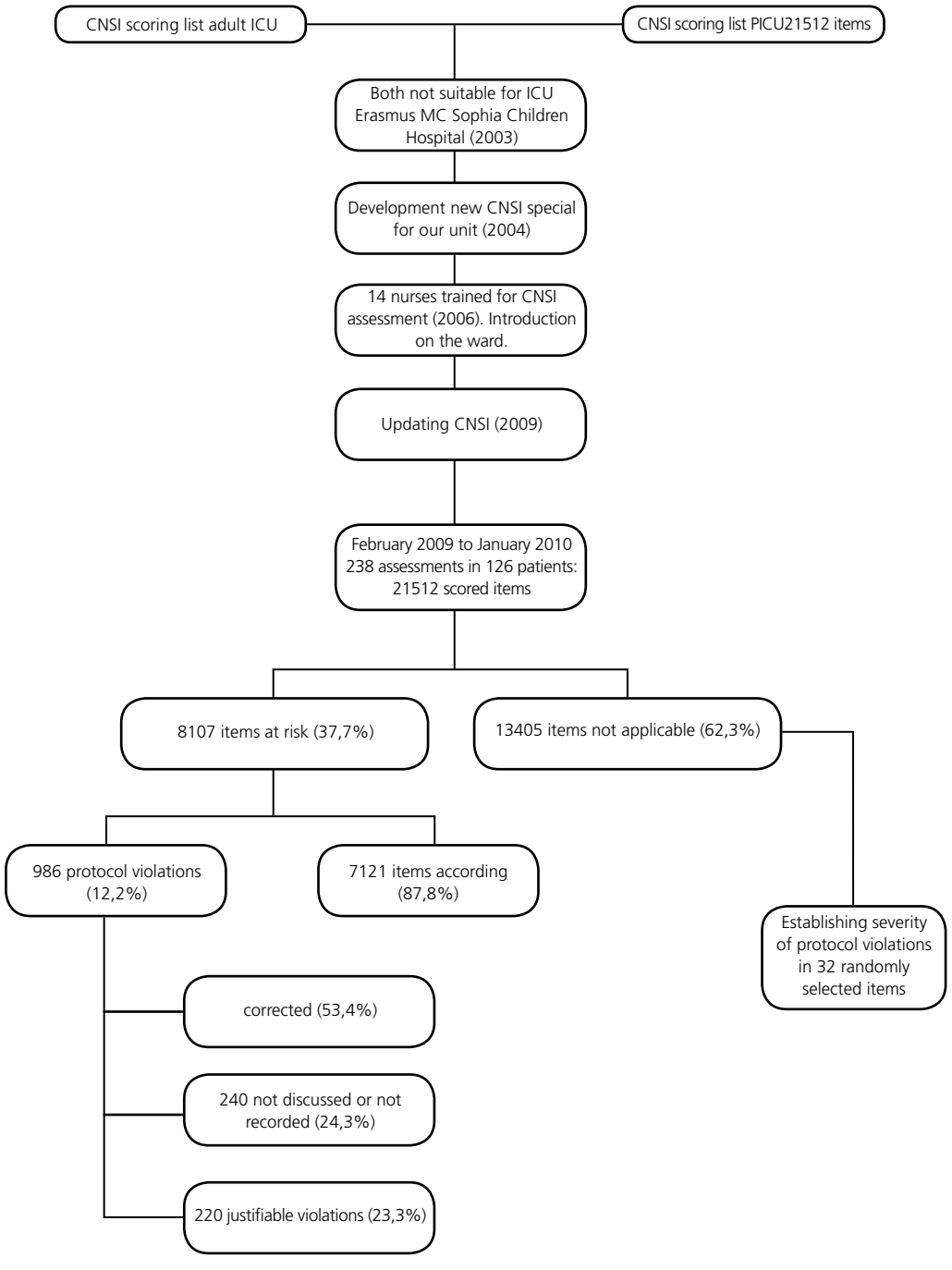


Table 2 Protocol violations, items at risk and incidence of protocol violations per 100 items at risk with the highest CNSI item score in each subscale

Subscale	Protocol violations	Items at risk	Incidence	Item per subscale with the highest CNSI score
Basic care	180	1473	12	50.9% (29/57) item 21 *No first responsible nurse selected for patient, although indicated*
Circulation	140	1178	12	54.4% (68/125) item 24 *Incorrect vital functions alarm settings on the monitor*
Respiration	149	1742	9	51.1% (24/47) item 65 *$EtCO_2$ is not monitored in patient at Servo-I respirator*
Digestive tract	128	495	26	51.4% (55/107) item 68 *Insertion date of nasogastric- and/or duodenal tube is not noted in PDMS*
Infection	113	742	15	39.1% (27/69) item 84 *PVC nasogastric tube is not renewed every 10 days*
Invasive catheters	181	1279	14	54.3% (50/92) item 106 *Insertion date of the central venous or arterial line not noted in PDMS*
Medication	26	515	5	8.3% (9/109) item 114 *Syringe with intravenous medication does not show label when in Perfusor pump*
ECMO	45	560	8	33.3% (6/18) item 127 *Membrane and coil kidney pressure device settings deviate from recommended setting*
CNS	24	123	19	50% (5/10) item 183 *Urine labstick test not performed twice daily in case of dexamethasone administration.*
Total	986	8107	12	

Table 3

Subscale	Protocol violations	Corrected directly or later	Authorized violation	Not discussed or unknown
	n	n (%)	n (%)	n (%)
Basic care	180	83 (46.1%)	43 (23.8%)	54 (30%)
Circulation	141	63 (44.6%)	46 (32.6%)	32 (22.6%)
Respiration	149	85 (57%)	32 (21.4%)	32 (21.5%)
Digestive tract	128	82 (64%)	14 (10.9%)	32 (25%)
Infection	113	62 (54.9%)	21 (18.5%)	30 (26.5%)
Invasive catheters	182	114 (63.3%)	35 (19.4%)	33 (18.3%)
Medication	26	12 (46.1%)	7 (26.9%)	7 (26.9%)
ECMO	44	14 (31.8%)	18 (40.9%)	12 (27.2%)
CNS	24	12 (50%)	4 (16.6%)	8 (33.3%)
Total	986	527 (53.4%)	220 (22.3 %)	240 (24.3%)

Severity of protocol violations

Seven nurses scored the severity of 32 randomly selected protocol violations. Their scores varied from 1 to 4; score 5 (unknown harm) was not assigned. The mean severity score across the 32 items varied from 1.7 for item 89 'continuous enteral feeding system not renewed every 24 hours' to 3.4 for item 121 'Marking stickers on intravenous infusion incorrect or unreadable'. The linearly weighted kappa was poor, ranging from 0 to 0.33. In the second step, after patient information had been provided, the mean severity scores for the 32 items with varied from 1.4 for item 65 'EtCO2 is not monitored in patient at Servo I respirator' to 3.8 for item 3 'Weight on resuscitation form not up-to-date'. The linearly weighted kappa now was poor to moderate, ranging from 0.12 to 0.46. For example, severity scores ranged from 1 to 4 for item 53 'Saturation limits of premature born not adapted to gestational age' and from 2 to 4 for item 37 'Discrepancy between selected and actual ventilation settings'.

Discussion

In this study the incidence of protocol violations was 12 per 100 items at risk. More than half of the protocol violations were effectively corrected either directly or at the end of the shift. Assessing the severity of the critical nursing situation proved unreliable.

The incidence of protocol violations was comparable to that found in an adult ICU [6] and lower than the incidence of 18 per 100 critical incidents in the single pediatric study available in the literature. [7] It is hard to draw conclusions, however, because the nature of the protocols and the numbers of CNSI items differed. Healthcare is a rapidly changing environment and protocols need to be regularly adjusted with these changes, it follows that the CNSI instrument requires updates as well.

On a subscale level, the incidence of protocol violations in the Medication subscale was low in view of the high percentages of medication errors found with voluntary incident reporting. [2, 9] As a possible explanation, voluntary incident reporting obviously takes place after an incident has occurred, whereas CNSI assessment is performed at random moments, implying that theoretically a certain number of incidents are missed.

Although the CNSI was originally designed to merely monitor the incidence rates of predefined observable protocol violations, we saw major value in the fact that more than half of incidents could be corrected. There is room for improvement considering that in a quarter of all incidents corrective actions were unknown. Interestingly, in almost one quarter of incidents the protocol deviations were justified. We feel that this reflects the essence of working according to protocol: being open for situations in which it would be better to deviate from protocol. A prerequisite is, however, that these justifiable violations are well communicated with co-workers and recorded in the patient data management system.

Protocols ensure continuity of care and should be kept up-to-date and preferably be evidence-based, which means that the nursing profession should be stimulated to perform research.

De Neef et al pointed out that the safety risk for the patient differs per CNSI item and we agree. [7] We were surprised, however, to find that agreement about the severity of protocol violations was so low. The low interrater reliability coefficients indicated large discrepancies between nurses. Our study was the first to try and classify the severity of the protocol violations. In future we should look at different approaches to establish the severity of protocol violations, for example in consensus meetings.

When the CNSI was introduced in 2006, nurses felt they were checked upon and were nervous about the results. Over the years these feelings have changed and nurses more and more consider CNSI assessments as a useful way to correct possible flaws. Occasionally, they even ask for CNSI assessment for patients they take care of. We publish the results in newsletters and highlight protocols for which many violations were seen. Giving feedback about frequent protocol violations is very important. Our nursing staff includes 130 nurses, some part-timers, and not all nurses read these newsletters. We will therefore also monthly publish frequent protocol violations in strategically placed posters, and post them on the hospital's Intranet.

Recommendations

Since many items often are not applicable we recommend using a short CNSI version or tailor-made versions for specific patient groups and units. Also, assessment within 24 hours after admission would allow timely corrections of flaws in protocol compliance. All units that want to develop a unit-specific CNSI should first evaluate the evidence base of existing protocols.

References

1. Sharek PJ, Classen D. The incidence of adverse events and medical error in pediatrics. Pediatr Clin North Am. 2006;53(6):1067-1077
2. Snijders C, van Lingen RA, Klip H, et al. Specialty-based, voluntary incident reporting in neonatal intensive care: description of 4846 incident reports. Arch Dis Child Fetal Neonatal Ed. 2009;94(3):F210-215
3. Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. BMJ. 2001;322(7285):517-519.
4. Agarwal S, Classen D, Larsen G, et al. Prevalence of adverse events in pediatric intensive care units in the United States. Pediatr Crit Care Med. 2010;11(5):568-578
5. Sharek PJ, Horbar JD, Mason W, et al. Adverse events in the neonatal intensive care unit: development, testing, and findings of an NICU-focused trigger tool to identify harm in North American NICUs. Pediatrics. 2006;118(4):1332-1340
6. Binnekade JM, de Mol BA, Kesecioglu J, et al. The Critical Nursing Situation Index for safety assessment in intensive care. Intensive Care Med. 2001;27(6):1022-1028.
7. de Neef M, Bos AP, Tol D. Safety as a criterion for quality: the critical nursing situation index in paediatric critical care, an observational study. Intensive Crit Care Nurs. 2009;25(6):341-347
8. Vlug G, Groenewegen R, van der Tuijn Y, et al., editors. Validation of the Critical Nursing Situation Index in the Pediatric Surgical Intensive Care Unit. 15th ESPNIC Medical and Nursing Annual Congress Paediatric and Neonatal Critical Care - "Art or Science?"; 2004; London.
9. Skapik JL, Pronovost PJ, Miller MR, et al. Pediatric safety incidents from an intensive care reporting system. J Patient Saf. 2009;5(2):95-101

Appendix with all CNSI items

Basic care

1	Bed environment not according to guideline (complete monitoring setting, set for manual ventilation, suction equipment, necessities for basic care).
2	Resuscitation orders are missing or not up to date.
3	Weight on resuscitation form not up to date.
4	Nursing-or family report from previous shift is lacking.
5	Hospital stay review not updated (at least 2 times a week) and/or events not registered in PDMS.
6	Bed safety fences not up (fences up if there is any possibility the child will sit or stand up independently).
7	Heated bed or incubator switched off.
8	Heat shield is not properly installed (minimal distance 60 cm).
9	Posture not in agreement with instructions (position changing every 4 hours).
10	Drain(s) and/or catheter(s) not fully secured in place (post-operative drains, Broviac and other venous catheters, supra pubis catheter, pyelum catheters).
11	Patients weight control not according to physician's instructions.
12	Surgical wounds not observed and bandaged according to protocol (bandages to be changed 24-48 hours after surgery. Observation surgical wounds must be recorded in PDMS every 2-3 hours, after 48 hours every 6 hours).
13	Postoperative checks not according to protocol (Protocol: first hour after surgery every 15 min; 2 hours every 30 min; 3 hours once an hour; every 2 hours).
14	Phototherapy conditions not according to protocol (eye protection, covered SpO_2 adhesive sensor, 40-60 cm. distance from child to lightsource).
15	No urinary catheter for patient with inguinal line.
16	Oral care not according to protocol.
17	Eye care not according to protocol.
18	No subcutaneous indwelling catheter present although indicated.
19	Neonatal hearing test not performed/scheduled after removing endotracheal tube.
20	Subcutaneous indwelling catheter not renewed according to protocol.
21	No first responsible nurse selected for patient, although indicated.
22	Comfort score not assessed or registered in PDMS according to protocol.

Circulation

23	Sound alarms of one or more parameters switched off (unless agreed with physician).
24	Incorrect vital functions alarm settings on the monitor.
25	Heart rate inadequately registered on the monitor.
26	Peripheral circulation and color of patient not recorded in PDMS (I.C. patient every 2 hours; if plaster cast present: first 6 hours every 60 minutes; 24 hours every 3 hours; 2 times daily).
27	NIBP not measured according to protocol (Protocol: when no IBP: NIBP control according to doctor's orders when hypo- or hypertension, instable patient, cor vitium, use of medication which can affect the blood pressure).
28	Body temperature checked and registered less frequent than prescribed.
29	Transfusion form filled out incompletely.
30	Blood group not recorded in PDMS.
31	Fluid loss compensation recorded incorrectly (gastric fluid every 6 hours; drains every 2 hours; in case of electrolyte disturbance every hour).
32	Prescribed venous line is absent.
33	Urinary catheter is obstructed.
34	Traction on urinary-, supra pubic- or renal catheter.
35	No "low-resistance system" installed on the urinary catheter of children < 3 years (unless catheter removed < 24 hours).

Respiration

36	Tube size and tube length not registered in PDMS.
37	Discrepancy between agreed upon and actual ventilation settings.
38	Discrepancy between agreed upon and actual tube cuff pressure (Protocol: continuous pressure control).
39	Endotracheal tube is fixed inadequately.
40	Humidifying system for respirator is empty.
41	Humidifier for respirator is switched off.
42	No closed suction system connected to endotracheal tube.
43	Respirator system not set up according to guidelines.
44	Color and consistency of sputum not recorded in PDMS.
45	Closed suction system not changed every 48 hours.
46	Suction system container filled for more than ¾.
47	Optiflow not set according to protocol.
48	Amount of NO in cylinder recorded incorrectly in PDMS.
49	Supply tubing and/or NO measuring point connected incorrectly.
50	Saturation is inadequately registered on monitor.
51	No double suction tube connected between child on respirator and the suction container.
52	Patient on respirator has no gastric tube.
53	Saturation limits of preterm patient not adapted to gestational age (<32 weeks 88%-94%; >32 weeks 92%-96%; neonates with NO-administration 94%-100%).
54	Drain system incorrect positioned relative to chest drain (fixed on chest, drains on the other side).
55	Thoracic drain settings not according to protocol or as agreed on.
56	Trachea cannula size not registered in PDMS.
57	Clamp missing when patient has chest drain.
58	Emergency tracheostomy set is missing or incomplete (contents: Spare cannula + 1 smaller cannula; mayo tube; fixation bandage).
59	Changing date for trachea cannula not registered in PDMS.
60	FiO_2 supply by nasal cannula or nasal catheter not as agreed upon.
61	Patient on NPT fails to reach PEEP limit.
62	Suction depth not or incorrect recorded in PDMS.
63	Renewal of expiration filter not recorded in PDMS.
64	Pressure gauge at Jackson Reese or Waterset is lacking.
65	$EtCO_2$ is not monitored in patient at Servo I respirator.
66	Cuff pressure of endotracheal tube is not checked every 4 hours.
67	Nebulizer is used incorrectly.

Digestive tract

68	Introduction date of gastric tube is not noted in PDMS.
69	Discrepancy between actual and agreed upon amount and type of nutrition.
70	Trans-anastomosis nasal-gastric tube inadequately marked.
71	Nasal gastric tube and/or duodenum tube not secured according to protocol.
72	Gastric retention not measured as agreed upon.
73	Hands of child with an trans-anastomosis nasal-gastric tube are not restrained.
74	Insertion site of gastric drain not managed according to protocol.
75	Gastric retention not as agreed upon.
76	Suction on replogle tube not as agreed upon.
77	Replogle tube not flushed every hour.
78	Replogle tube is not replaced every 24 hours or more frequently if necessary (obstruction).
79	Belly width not measured at the times agreed upon.
80	Rectal cannulas not applied at the times agreed upon.
81	Stoma care is inadequate.
83	Neonatal screening not performed or scheduled.

Infectious

82	Times when infusion systems are renewed are not recorded in PDMS.
84	PVC nasal gastric tube is not renewed every 10 days.
85	Infusion system touches the floor.
86	Nasal cannula or -catheter for FiO2 supply visibly contaminated.
87	Blood or ESDEP not renewed every 6 hours.
88	No isolation prescriptions mounted if indicated.
89	Continuous enteral feeding system not renewed every 24 hours
90	One or more caps missing from venous access.
91	Medical- or nursing devices not renewed according to protocol.
92	Biopatch on insertion site central venous or arterial line is absent.
93	Bandage of central venous-, arterial- or peripheral line visibly contaminated.

Invasive lines

94	Discrepancy between actual and agreed upon ml/h for continuous intravenous medication.
95	Puncture site of peripheral line is fully covered and therefore not visible.
96	I.V. lock not flushed with NaCl 0.9% every 6 hours.
97	Peripheral administration of glucose > 10%.
98	T.P.N. not connected on lumen close to patient.
99	T.P.N. continued at body temperature > 38°.
100	No flush line on I.V. infusion system for administration of medication.
101	Ramp of 4 three way stopcocks absent in the presence of > 2 extra connectors on I.V. infusion system.
102	No caution mark on flush line on cardiovascular medication.
103	Caps on I.V. infusion system are absent.
104	Broviac catheter is not secured according to protocol.
105	I.V.3000 bandage of CVC, arterial catheter or peripheral infusion inadequately secured.
106	Date of introduction of the central venous or arterial line not noted in PDMS.
107	Pressure system(s) not calibrated.
108	No caution mark on arterial or central venous catheter.
109	A Grasebuy pump is connected next to an I.V. line for administration of cardiovascular medication.
110	I.V. system for administration of cardiovascular medication incorrectly set up.
111	Cardiovascular agents are not connected on the proximal lumen of the venous catheter.
113	< 2 ml fluid per hour administered on one of the lumen of the C.V.C.
115	C.V.P. measurement not connected to distal lumen of the central venous line.

Medication

112	Prescribed medication not administered or initialed by nurse on duty.
114	Syringe with intravenous medication does not show label when in perfusor.
116	Furosemide and Sodium Nitroprusside are not protected against day light.
117	Prescribed medication not administered within one hour after agreed time.
119	Medication for solitary intravenous infusion combined with other medication.
121	Marking stickers on intravenous infusion incorrect or unreadable.

ECMO

118	ECMO system is not checked every 4 hours.
120	Tie-strips on connections are lacking.
122	Cables or gas pipes uncovered on the floor.
123	ECMO management policy checklist not complete.
124	Pigtails in use are not daily renewed.
125	ECMO cannulas are badly secured.
126	Pressure devices of membrane and coil kidney not changed every 4 days.
127	Membrane and coil kidney pressure device settings are not as agreed upon.
128	Disconnection of the ECMO system should be preceded by disinfection.
129	Raceway not repositioned once a week without informing intensivist.
130	There are no 2 syringes on blood sample point. (One 1 ml and one 2.5 ml.)
131	Pigtails that are **not** in use are not renewed every 3rd day.
132	Post membrane blood gas assessment not according to protocol (6.00 - 14.00 - 22.00).
133	The person who disconnects the ECMO system does not wear gloves.
134	Pre- and post ductal saturation are measured incorrectly.
135	The daily blood culture at 6.00 p.m. is not performed.
136	ACT is not assessed every hour.
137	Blood bag for emergencies missing or expired.
138	During platelets transfusion oxygen administration is not fully100%.
139	Name of "back-up" nurse has not been registered in PDMS.
140	After platelet administration the pigtail used has not been renewed.
141	Venous bloodgas values have not been manually registered in PDMS.
142	After platelet transfusion the oxygen administration level has not been reset to original values.
143	Heparin administration not adjusted to ACT values.
144	Fontanel not performed and recorded in PDMS. (Only for neonatal ECMO)
145	An extra bolus of heparin not administered halfway through platelet transfusion.
146	Respirator treatment in emergencies isnot or incorrectly detailed.
147	Pupillary reflex has not been checked and/or registered in PDMS.
148	Auscultation and chest excursions have not been noted in PDMS.
149	Platelets not administered correctly.(Pediatric ECMO directly to patient, neonatal ECMO on heater)
150	Set bubble detector switched off.
151	Label detailing emergency respiration treatment is not present on respirator or is incorrect.
152	Biopatch on cannula insertion site is lacking.
153	Blood flow and blood temperature have not been checked after clamp from coil kidney.
154	Discrepancy between actually administered and prescribed ml/h of pre-dilution fluid.
155	Set bladder is switched off.
156	Venous blood gas assessment not according to protocol (6.00 - 14.00 - 22.00)
157	< 0.6 ml/h heparin 100 i.E./ml administered on the pressure device of coil kidney.
159	Discrepancy between actual withdrawn and registered ml/h fluid from coil kidney.
161	Nursing care of patient on ECMO not as prescribed.

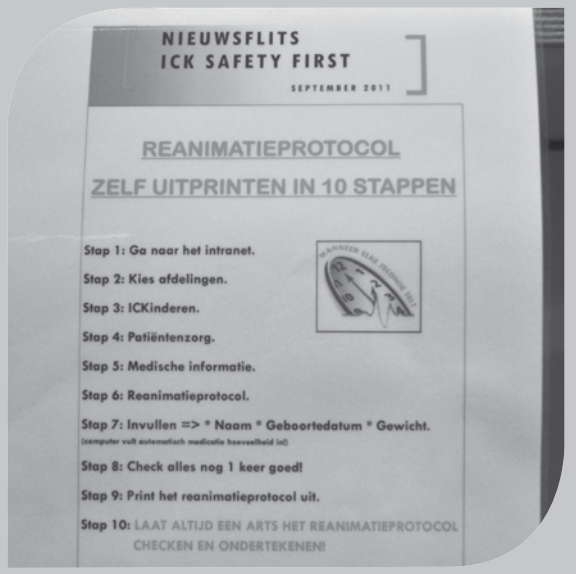
Central nervous system

158	Alarm settings of ICP, CPP and SvO_2 are incorrect.
160	Calibration number of ICP express missing in PDMS and on ICP extension.
162	Bulbus jugular line not calibrated every shift.
163	Monitor modules plugged in, in wrong order.
164	Extension of bulbus jugular is found in bed.
165	SvO_2, $PtiO_2$ and/or brain temperature not manually registered in PDMS.
166	External ventricle drainage system positioned at wrong height.
167	PDMS is not set at 15 minutes intervals.
168	Glasgow Coma Scale assessment not carried out as agreed upon.
169	Orange "DO NOT FLUSH" label missing on bulbus jugular catheter.
170	Upon admission neurologic trauma patient is not immediately assigned a special bed.
171	Catheters and cables of measuring instruments have not been secured.
172	Patient has not been given a "first-step mattress" after 48 hours.
173	Liquor production limit not indicated in PDMS.
174	Insertion site of ICP not taken care of according to protocol.
175	Medical Research Council strength score not carried out according to protocol.
176	Patient with body temperature > 38° is not on cooling mattress.
177	Patient lies not flat in bed and/or head is not in midline.
178	VISS assessment not performed as agreed upon and/or not registered in PDMS.
179	Elbows and ankles not bandaged when patient is on standard bed.
181	Pupillary reflex has not been checked in patient in Sodium Pentobarbital coma.
183	Urine labstick test not performed twice daily in case of Dexamethason administration.

LARA'S STORY: PART 4

Lara is back on the ICU!

The surgeon told Thomas and Melissa the operation went well. The esophagus has been repaired, and they found that the esophagus and the trachea had been connected by a so-called fistula. This explains that at intubation the air blown into the tube went through the fistula to the stomach instead of to the lungs, and that's why Lara deteriorated so quickly. Now that the fistula has gone, this will not happen again. Although very relieved that Lara is now doing better, Thomas and Melissa still wonder how this could have happened. The next day they the head of the department tells them that Lara's resuscitation and the circumstances leading up to it will be investigated. They are assured that the patient safety team on the unit will make recommendations to prevent this from happening again to other children in the ICU.


NIEUWSFLITS
ICK SAFETY FIRST
SEPTEMBER 2011

REANIMATIEPROTOCOL
ZELF UITPRINTEN IN 10 STAPPEN

Stap 1: Ga naar het intranet.
Stap 2: Kies afdelingen.
Stap 3: ICKinderen.
Stap 4: Patiëntenzorg.
Stap 5: Medische informatie.
Stap 6: Reanimatieprotocol.
Stap 7: Invullen => * Naam * Geboortedatum * Gewicht.
(computer vult automatisch medicatie hoeveelheid in!)
Stap 8: Check alles nog 1 keer goed!
Stap 9: Print het reanimatieprotocol uit.
Stap 10: LAAT ALTIJD EEN ARTS HET REANIMATIEPROTOCOL CHECKEN EN ONDERTEKENEN!

Our first child > Lara was born > Something went wrong > **Lara is back on the ICU** > Lara is home > Conclusion

CHAPTER 11

The Patient Safety Culture on a Dutch Pediatric Surgical Intensive Care Unit: An Evaluation Using the Safety Attitudes Questionnairre

Poley MJ, van der Starre C, van den Bos A, van Dijk M, Tibboel D. Patient safety culture in a Dutch pediatric surgical intensive care unit: An evaluation using the Safety Attitudes Questionnaire. Pediatr Crit Care Med. 2011 May 12.

THE PATIENT SAFETY CULTURE ON A DUTCH PEDIATRIC SURGICAL INTENSIVE CARE UNIT: AN EVALUATION USING THE SAFETY ATTITUDES QUESTIONNAIRE

Abstract

Objective:
Nowadays, the belief is widespread that a safety culture is crucial to achieving patient safety. Yet, there has been virtually no analysis of the safety culture in pediatric hospital settings so far. Our aim was to measure the safety climate on our unit, compare it with benchmarking data, and identify potential deficiencies.
Design:
Prospective longitudinal survey study, at two points in time.
Setting:
Pediatric surgical intensive care unit at a Dutch university hospital.
Subjects:
All unit personnel.
Interventions:
To measure safety climate, the Safety Attitudes Questionnaire (SAQ) was administered to physicians, nurses, nursing assistants, pharmacists, technicians, and ward clerks both in May 2006 and May 2007. This questionnaire assesses caregiver attitudes through using the 6 following
scales:
teamwork climate, job satisfaction, perceptions of management, safety climate, working conditions, and stress recognition. Earlier research showed that the SAQ has good psychometric properties, and produced benchmarking data that can be used to evaluate strengths and weaknesses in a given clinical unit against peers.
Measurements and Main Results:
The response rate for the SAQ was 85% (May 2006) and 74% (May 2007). There were mixed findings regarding the difference between physicians and nurses: on three scales (i.e., teamwork climate, safety climate, and stress recognition), physicians scored better than nurses at both points in time. On another two scales (i.e., perceptions of management and working conditions), nurses consistently had higher mean scale scores. Probably due to the small number of physicians, only some of these differences between physicians and nurses reached the level of statistical significance. Compared to benchmarking data, scores on perceptions of management were higher than expected ($P < 0.01$), whereas scores on stress recognition were low ($P < 0.001$). The scores on the other scales were somewhat above (job satisfaction), close to (teamwork climate, safety climate), or somewhat below (working conditions) what was expected based on benchmarking data, but no persistent significant differences were observed on these scales.
Conclusions:
Although on most domains the safety culture in our unit was good when compared to benchmark data, there is still room for improvement. This requires us to continue working on interventions intended to improve the safety culture, including Crew Resource Management trainings, safety briefings, and senior executive walk rounds. More research is needed into the impact of creating a safety culture on patient outcomes.

The Patient Safety Culture on a Dutch Pediatric Surgical Intensive Care Unit: An Evaluation Using the Safety Attitudes Questionnaire

Nowadays, improving patient safety is widely considered an important priority of our health care system. One factor crucial to achieving patient safety falls under the term "safety culture". This term was first used in the aftermath of the Chernobyl nuclear disaster of 1986. [1] Later, it found its way to other high-hazard industries, such as aviation and chemical manufacturing, and eventually also to the health care sector. In 1999, the US Institute of Medicine recommended that healthcare organizations should work to enhance their safety culture. [2] Since then, it is increasingly believed that safety culture is a major determinant of patient safety. While an exact definition of a safety culture does not exist, it is generally described as including the following components: 1) acknowledgment of the high risk, error-prone nature of an organization's activities, 2) blame-free environment where individuals are able to report errors or near misses without punishment, 3) expectation of collaboration across ranks to seek solutions to vulnerabilities, and 4) willingness on the part of the organization to direct resources to address safety concerns. [3] Without the right safety culture, initiatives to improve patient safety, such as blame-free incident reporting and root cause analysis, are far less likely to succeed. It can be assumed that health care organizations have ample room for improvement. For example, a pervasive culture of blame that impedes acknowledgment of error and barriers to communication against the authority gradient are traditionally regarded as obstacles to a safety culture within health care. [3]

The field of pediatric health care is showing increasing interest in safety culture. [4, 5] Yet, there has been virtually no analysis of the safety culture in pediatric hospital settings so far, despite the development and psychometric assessment in recent years of instruments to measure safety culture. [6, 7] There are a few notable exceptions. Grant and co-workers documented poor recognition of the adverse effects of stress and fatigue, but high levels of job satisfaction among staff members of a children's hospital. [8] This result is in line with a study among pediatric trainee physicians by Parry and colleagues, who further found that trainee physicians are not fully comfortable with their ability to act interdependently (i.e., to care for patients in situations where they interact with another group of providers). [9] In a study of the safety culture in pediatric cardiac surgery teams, Bognár et al. concluded that many team members considered it difficult to raise safety concerns and felt that teams lack the power to prevent safety events. [10] Khoshbin and co-workers found that the introduction of operating room briefings was associated with an improvement in patient safety attitudes among nursing staff. [11] Finally, Snijders et al., who analyzed the safety culture in neonatal ICUs, showed that a nonpunitive approach to error, hospital management support for patient safety, and overall perceptions of safety predicted incident reporting behavior. [12]
This study sought to add to the scarce evidence on the safety culture in pediatric intensive care settings. Our three-fold aim was to measure the safety climate on our pediatric surgical intensive care unit (PSICU), to compare it with benchmarking data, and to identify potential deficiencies.

Materials and methods

Setting

The study was carried out in the PSICU of the Sophia Children's Hospital (Erasmus MC), a level III hospital serving a referral area of 4 million inhabitants with 44,000 births each year. At the time of this study, our PSICU had a capacity of 14 beds and admitted 550 patients each year, with ages ranging from newborn to 18 years (>65% below the age of 3). The PSICU serves as the ICU for all surgical specialties, with the exception of open-heart surgery patients. Consequently, it treats children with a wide variety of congenital anomalies and acquired diseases, among others traumatic brain injury, renal transplants, craniofacial surgery, and scoliosis. It also provides extracorporeal membrane oxygenation (ECMO).

A comprehensive unit-based patient safety management system has been established on our PSICU beginning in 2003 to improve the safety culture, and patient safety. [13, 14] Among its main components are: incident reporting, critical nursing situation index (CNSI), complication registration, and crew resource management (CRM) training. These components may be briefly described as follows. First, medical and nursing staff are asked to report any incidents, including near-incidents, during each shift. This goes together with applying a risk assessment matrix and with systematic in-depth analysis of underlying causes. [15-17] Second, the CNSI represents a tool to assess adherence to standards and protocols in ICU nursing care. [18] Third, complication registration involves medical staff registering all unintended and undesirable medical events or conditions during the daily rounds. [19] Fourth, CRM training concentrates on subjects such as human errors, stress management, communication, group dynamics, leadership, decision making, and risk management. Practically, CRM programs typically include educating staff about the limitations of human performance, videotaping of actual mishaps, simulation trainings, and debriefing sessions. [20-22]

Data collection

The Safety Attitudes Questionnaire (SAQ) was used to measure safety climate, a term that generally refers to the measurable components of safety culture. It assesses caregiver attitudes by using the following 6 scales: teamwork climate, job satisfaction, perceptions of management, safety climate, working conditions, and stress recognition (Table 1). [23] The SAQ-ICU version used in this study comprised 64 items, each of which is answered using a five-point Likert scale: Disagree Strongly (a score of 0), Disagree Slightly (25), Neutral (50), Agree Slightly (75), and Agree Strongly (100). Each scale score was calculated as the mean score of its component items, and thus was calibrated from 0 to 100. Negatively worded items were reverse scored, so that higher scores indicated better safety climate.

Table 1 Safety Attitudes Questionnaire scales and example items

Scale	Example items
Teamwork climate: perceived quality of collaboration between personnel	– Disagreements are appropriately resolved (i.e., not who is right, but what is best for the patient) – Our doctors and nurses work together as a well coordinated team
Job satisfaction: positivity about the work experience	– I like my job – This ICU is a good place to work
Perceptions of management: approval of managerial action	– Management supports my daily efforts in this ICU – Management is doing a good job
Safety climate: perceptions of a strong and proactive organizational commitment to safety	– I would feel perfectly safe being treated here – ICU personnel frequently disregard rules or guidelines
Working conditions: perceived quality of the work environment and logistical support (staffing, equipment etc.)	– Our levels of staffing are sufficient to handle the number of patients – The equipment in this ICU is adequate
Stress recognition: acknowledgement of how performance is influenced by stressors	– I am less effective at work when fatigued – When my workload becomes excessive, my performance is impaired

Table borrowed from Sexton et al. [23]

An additional section of the SAQ is a scale to evaluate the quality of collaboration and communication between employee groups. This section of the survey uses a five-point Likert scale with response choices of Very Low, Low, Adequate, High, and Very High. Finally, an open-ended section asks responders to write their top three recommendations for improving patient safety. These responses were categorized by theme. Basic demographic information included age, sex, job status, years of experience, and time with the organization. Each participant was asked if he or she had ever followed a CRM training, either in our hospital or elsewhere. Finally, we asked each participant how many events he or she had reported in the past month.

The SAQ has been shown to have good psychometric properties. [23] Sexton et al. administered the SAQ ICU version to 8,646 health care providers at 179 ICUs in three countries (United Kingdom, New Zealand, and United States of America). [23] This resulted in benchmarking data that clinical units can use to understand their strengths and weaknesses against peers and to identify appropriate interventions.

Developed in the USA, the original language of the SAQ is English. With the help of the tool's original developers, its linguistic validation into Dutch was undertaken. To ensure conceptual equivalence and respondent acceptance, the translation process followed well-established methods, comprising the following six steps: forward translation, reconciliation, backward translation, harmonization, pre-testing and cognitive interviewing, and finalization. For a full description of the translation process, please see supplemental Table 1, available on the PCCM website.

Design

This was a prospective longitudinal survey study. To track possible changes in safety culture over time, the SAQ was administered at two points in time (in May 2006 and May 2007).

Apart from the ongoing activities as part of our patient safety management system, such as incident reporting, complication registration, and CRM training, there were no specific events on our unit between these two dates that likely could have affected the safety culture. These surveys were the starting point of our current standard practice to administer the SAQ once every one or two years. This standard practice was developed because we feel that regular measurements at set time intervals provide essential information in this respect, considering that safety culture may fluctuate over time and considering that human behavior is a fundamental issue in the implementation of safety measures.

Eligible were both full- and part-time staff members working on our ICU for at least one month, including employees not based in the unit, but with a significant work commitment to it. This implies that all physicians, nurses, nursing assistants, pharmacists, technicians, and ward clerks were invited to participate. The questionnaires were handed over during CRM meetings. Staff members not present at the meetings received the questionnaires in their mailboxes. Completed questionnaires could be left in a closed box at the ward. Hospital staff were not identified on the data collection instrument.

Statistical analyses

We collapsed nurse and physician subcategories into all nurses and all physicians and compared scale scores between these two professions (Mann-Whitney U test). The comparisons between professions mainly focused on nurses and physicians, and not on the group 'other', because the last-mentioned group was heterogeneous. To analyze possible changes over time, the scores at the two points in time were compared. Although the samples were correlated, we had to use Student's t-test for independent samples, because the observations could not be matched due to the anonymity of the questionnaires. This statistical test was also used to evaluate differences between our sample and the benchmark group. [23] The relationship between the number of reported events and the perceived safety culture was examined using Spearman's rank correlation coefficient. The Chi-square test with Yates' correction for continuity was used to test for differences in the ratings of collaboration and communication between nurses and physicians. Trying to explain particularly low or high scores (at both points in time) on a given scale, we performed linear regression analyses. Results were considered statistically significant if they were below the 0.05 level of probability.

Results

Table 2 lists basic information on the response rate and the responders. The response rate was 85% (May 2006) and 74% (May 2007), yielding an overall response rate of 79%. At both measurement dates, responders were approximately 40 years of age on average, and were predominantly female (a little less than 90%). In May 2006, responders included nurses (71%), physicians (13%), and a group 'other' (16%). One year later, this distribution was 84%, 7%, and 9%, respectively. This distribution of age, sex, and profession is a good reflection of the total staff employed in our unit, with a slight underrepresentation of physicians. Consider that in May 2006, of the total staff (i.e., all 89 staff members who were asked to complete the SAQ) 71% (n = 63) were nurses and 20% (n = 18) were physicians. In May 2007, these numbers were 76% (n = 73) and 15% (n = 14), respectively. The levels of the physicians and nurses, as well as the composition of the group 'other', are broken down in Table 2. At the time of the first survey, 74% of the responders had ever followed a CRM training. At the 2007 survey, this proportion had increased up to 80%.

Table 2 Information on the response rate and the responders

	May 2006	May 2007
Response rate		
No. of surveys distributed	89	96
No. of surveys returned	76	71
Response rate	85% (76/89)	74% (71/96)
Responders		
Sex (% male)	12%	11%
Mean age (interquartile range)	39.4 (10)	40.8 (10)
Profession (%)		
- physician	10 (13%)	5 (7%)
pediatrician/intensivist	3	3
ICU fellow pediatrician	1	1
ICU fellow anesthesiologist	1	1
resident	5	-
- nurse	54 (71%)	56 (84%)
coordinating nurse	4	4
unit head nurse	1	1
IC senior nurse	29	37
IC nurse	9	4
student IC nurse	2	2
nurse practitioner	1	1
pediatric/high-care nurse	8	7
- other	12 (16%)	6 (9%)
nursing assistant/care assistant	5	2
ward clerk	3	4
other	4[a]	-
Job status (%)		
full-time	25 (33%)	20 (28%)
part-time[b]	48 (64%)	51 (72%)
other (on an agency or 'flexible' contract basis)	2 (3%)	-
Mean no. of years of experience in discipline (SD)	12.4 (9.4)	12.2 (8.6)
Mean no. of years worked in this ICU (SD)	8.5 (7.9)	9.0 (7.6)
Ever followed a CRM training (%)	56 (74%)	56 (80%)
No. of events reported in the past month (%)		
none	14 (18%)	15 (21%)
1 to 2	20 (26%)	23 (33%)
3 to 5	24 (32%)	21 (30%)
6 to 10	10 (13%)	8 (11%)
more than 10	8 (11%)	3 (4%)

Abbreviation: SD, standard deviation.

[a] This group includes one medical technician. In the remaining three cases, the subcategory was not specified by the responder.
[b] Part-time staff are defined as those staff that work anything less than full-time.

We calculated mean scale scores for both measurement dates, with a distinction between three professions (physicians, nurses, and other) (Table 3). On three scales (i.e., teamwork climate, safety climate, and stress recognition), physicians scored better than nurses at both points in time. Regarding teamwork climate for example, at the first measurement date 80% (n = 8) of the physicians (slightly) agreed with the statement "Disagreements in this ICU are resolved appropriately (i.e., not who is right, but what is best for the patient)", versus 44% (n = 24) of the nurses. At the second measurement date, these proportions were 60% (n = 3) in physicians and 50% (n = 28) in nurses. On another two scales (i.e., perceptions of management and working conditions), nurses consistently had higher mean scale scores. For example, at the first measurement date 25% (n = 13) of the nurses (slightly) agreed with the statement "Hospital administration supports my daily efforts", as compared to 10% (n = 1) of the physicians (at the second measurement date: 16% (n = 9) and 0% (n = 0), respectively). Statistical testing revealed that, at the first measurement date, physicians had higher levels of stress recognition than nurses (P = 0.003). At the second measurement date, the difference in perceptions of management – in favor of the nurses – reached the level of statistical significance (P = 0.04), though especially at this point in time the number of physicians included in the comparison was small

Table 3 Main results of the Safety Attitudes Questionnaire (by profession)

	May 2006			
Mean scale scores (SD)	Physicians (n = 10)	Nurses (n = 54)	Other (n = 12)	Total (n = 76)
Teamwork climate	72.9 (11.7)	68.6 (12.1)	68.3 (8.1)	69.1 (11.5)
Job satisfaction	68.5 (11.6)	70.4 (13.2)	76.5 (13.6)	70.9 (13.1)
Perceptions of management	48.8 (16.1)	56.1 (10.8)	57.5 (18.1)	55.3 (12.9)
Safety climate	68.3 (14.1)	66.9 (11.5)	63.5 (10.4)	66.7 (11.6)
Working conditions	49.4 (13.6)	56.9 (11.6)	54.2 (7.0)	55.6 (11.6)
Stress recognition	71.3 (16.7)	51.2 (16.7)	56.3 (17.2)	54.7 (17.9)
	May 2007			
Mean scale scores (SD)	Physicians (n = 5)	Nurses (n = 56)	Other (n = 6)	Total (n = 71)
Teamwork climate	77.5 (9.6)	68.0 (12.7)	74.3 (5.5)	69.0 (12.1)
Job satisfaction	72.0 (10.4)	63.8 (13.9)	79.2 (5.8)	65.6 (13.9)
Perceptions of management	43.8 (9.9)	55.7 (13.3)	60.4 (7.6)	55.4 (12.7)
Safety climate	73.6 (13.7)	68.8 (14.7)	73.6 (14.4)	69.4 (14.2)
Working conditions	47.5 (10.5)	54.8 (12.0)	58.8 (8.4)	54.4 (11.8)
Stress recognition	60.0 (18.0)	51.3 (16.7)	56.3 (17.2)	52.2 (16.4)

Higher scores indicate better safety climate.

We were interested to know whether there were statistically significant associations between the number of patient safety events reported and the scale scores. There appeared to be a weak negative correlation between job satisfaction and the number of events reported in the past month, both at the first (rho = -0.28; P = 0.02) and the second measurement date (rho = -0.26; P = 0.03). Overall, the mean score on job satisfaction decreased from May 2006 to May 2007 (70.9 v 65.6; P = 0.02) (Table 3).

The mean score on safety climate appeared to improve from May 2006 to May 2007, whereas the scores on working conditions and stress recognition seemed to show a decrease from 2006 levels. However, the differences on all these three domains were not statistically significant.
Table 4 presents the results of the SAQ compared to the benchmark. At both points in time, scores on the perceptions of management scale appeared to be higher than would be expected from benchmarking data (P < 0.01), whereas scores on stress recognition were relatively low (P < 0.001). The mean scores on the other scales were somewhat above (job satisfaction), close to (teamwork climate, safety climate), or somewhat below (working conditions) benchmarking scores, but no persistent significant differences were observed on these scales.

Table 4 Results of the Safety Attitudes Questionnaire compared to benchmarking data

Mean scale scores (SD)	Benchmarking scores[a]	PSICU Sophia Children's Hospital	
		May 2006	May 2007
Teamwork climate	70.7 (18.6)	69.1 (11.5)	69.0 (12.1)
Job satisfaction	63.4 (21.6)	70.9 (13.1)**	65.6 (13.9)
Perceptions of management	48.0 (20.3)	55.3 (12.9)**	55.4 (12.7)**
Safety climate	67.7 (17.0)	66.7 (11.6)	69.4 (14.2)
Working conditions	58.6 (20.4)	55.6 (11.6)	54.4 (11.8)
Stress recognition	65.9 (20.2)	54.7 (17.9)***	52.2 (16.4)***

Higher scores indicate better safety climate.
* Statistically significantly different from the benchmarking scores at P < 0.05.
** Statistically significantly different from the benchmarking scores at P < 0.01.
*** Statistically significantly different from the benchmarking scores at P < 0.001.
[a] Benchmarking scores of the SAQ ICU version (n = 8,646) as published by Sexton et al. [23]

In an attempt to explain the scores on stress recognition and perceptions of management, we performed linear regression analyses, with the following independent variables: sex, age, profession, job status, number of years worked in this ICU, and ever followed a CRM training (data not fully shown). Regarding stress recognition, at the first measurement date the fact whether the responder had ever followed a CRM training was the only variable that made a significant contribution to the regression (P = 0.006). Surprisingly, those who had ever followed a CRM training (n = 55; score = 51.3) had poorer levels of stress recognition than those who did not (n = 17; score = 65.8). At the second measurement date, only the number of years that the responder had worked in this ICU significantly contributed to explaining stress recognition (P = 0.03): as the number of years worked in this ICU increased, the level of stress recognition decreased (as also reflected by a negative Pearson's correlation coefficient of -0.29). Regression analysis revealed that, with the available data, it was not possible to explain the relatively high scores on perceptions of management at both measurement occasions: none of the independent variables were found to make a significant contribution to predicting perceptions of management.
At the first measurement date, 8% of the nurses and 60% of the physicians rated the quality of collaboration and communication with physicians as high or very high (P < 0.001).

The quality of the collaboration and communication with nurses was rated as high or very high by 50% of the nurses and 50% of the physicians (P = 1.00). These differences in the evaluation of the collaboration with physicians were also found when the SAQ was administered for the second time (although it should be taken into account that the number of physicians surveyed was small at that time, which is why no statistical testing was done for these results): 7% of the nurses and 20% of the physicians rated the quality of collaboration with physicians as high or very high, whereas the quality of the collaboration with nurses was rated as high or very high by 30% of the nurses and 25% of the physicians.

Regarding the questionnaires handed out in May 2006, 67% (51 of 76) of responders together wrote 127 patient safety recommendations. One year later, 54% (38 of 71) of responders wrote 80 patient safety recommendations. Considering all 207 recommendations, the top four recommendations fell within the themes of: "Improve communication (e.g., between nurses and physicians)" (15%); "Improve the training and supervision of interns" (15%); "Report, analyze, and take action on incidents, complications, and deaths (including debriefings)" (10%); and "Provide trainings (e.g., CRM trainings) and/or continuing medical education" (9%). There were only small differences between May 2006 and May 2007 in the recommendations most frequently mentioned (data not shown).

Discussion

This article has focused attention on the safety culture on our PSICU, as measured by personnel attitudes across six different scales. The results reveal that the scale scores were, by and large, in line with benchmarking scores. Yet, another finding, which was consistent over time, was that the perceptions of management were higher than would be expected from benchmarking data, whereas scores on stress recognition were relatively low.

In this study, we choose to use the SAQ, which provides a snapshot of a clinical unit's safety climate. The SAQ is among the most rigorously tested instruments to measure safety climate. [6] For example, Sexton and co-workers have administered the SAQ to >200 clinical units across three countries. [23] Another strong point of our study was the good response rate (79%). Other studies using the SAQ had response rates of 58 to 77%. [8, 9, 23-34] It should be acknowledged that the SAQ was created primarily with adult practitioners in mind, whereas we applied it to pediatric physicians and nurses. Given the different approaches to patient care used in adult and pediatric ICUs, it is important that efforts to apply the SAQ to pediatric settings are continued and that the evidence base on safety culture in pediatrics is broadened. This study was meant to be a step in that direction.

Even though the benchmarking data were collected in ICUs (that is, adult ICUs) from other countries than our own – ICUs that may differ from our unit in characteristics such as nurse-to-physician ratio and full-time/part-time ratio – we draw the following conclusions from the comparison with benchmarking data. The staff members surveyed displayed relatively poor recognition of the effects of stress and fatigue on performance. This feeling of invulnerability is part of several professional cultures. It has been found in the aviation industry, and seems even more prevalent in health care settings. [35]

Our findings that medical staff do not fully appreciate the effects of stress and fatigue echo the findings of other studies in tertiary care pediatric centers [8, 9], as well as studies in, for example, anesthetists [36] and members of air medical teams. [37] The perception that people make good decisions no matter what stress they are under is not true however: stress, high workload, and sleep deprivation do decrease performance and raise medical error occurrence. [38-41]

Although above benchmark scores, the perceptions of management found in this study were fairly low. Perceptions of management are high when management favors open communication, supports team work, allocates appropriate resources, rewards reporting, and visibly acts to remedy problems. [42] One way to improve the staff's perceptions of management, and thereby the safety culture, is by senior executive walk rounds, which are intended to demonstrate senior leadership commitment to patient safety. Building on the examples set by several other hospitals [5, 43-45], we implemented senior executive walk rounds in our unit in the year 2007. Importantly, patient safety walk rounds indeed seem to fulfill their promise to improve the safety culture. [43-45]

The comparisons of the patient safety attitudes between physicians and nurses need to be interpreted with some caution, because the number of physicians was small (reflecting the staff composition typically seen in a PSICU in the Netherlands). Nevertheless, the following conclusions may be presented. There were mixed findings regarding the differences in patient safety attitudes between physicians and nurses. A number of previous studies provided insight in these differences, with equivocal results. In the study of Pronovost et al. [46], who used a derivation of the full SAQ, physicians gave lower scores than nurses for most items. On the contrary, in other studies nurses generally had the lowest scores. [27, 47] Using the SAQ or its predecessor, six previous studies all found that nurses had lower scores on teamwork climate than physicians. [8, 27, 32-34, 47] This is consistent with our findings. Moreover, in this study, when asked to rate the quality of collaboration and communication, relatively few nurses rated collaboration and communication with physicians as high or very high, while many more physicians rated collaboration and communication with nurses as high or very high. This finding mirrors the similar results found by others. [28, 31, 34, 35] Next to this, the patient safety recommendation most frequently given in the open-ended section of the SAQ was to improve communication, particularly between nurses and physicians. It is important to remedy this situation, for several reasons. First, breakdowns in communication and collaboration are a cause of incidents. This was demonstrated by data from the Joint Commission on Accreditation of Healthcare Organizations: problems in communication were a root cause in approximately 65% of the 2,966 sentinel events reported to the Joint Commission from 1995 to 2004. [48] Second, as Thomas et al. mention, poor teamwork may be a significant source of nurses' dissatisfaction with their profession that has led to a critical nursing shortage. [34] Third, empirical research suggested several other benefits of good teamwork, such as less sickness absence among physicians [49] better quality of care as assessed by nurses [50], and lower patient mortality rates or ICU readmission rates. [51, 52] All this highlights the need to invest in initiatives that have the potential to improve the teamwork climate, such as team training in the form of CRM and the use of daily goals sheets. [53, 54]

This study analyzed safety culture by measuring the attitudes of staff members - a practical and efficient method of collecting safety climate data. However, attitudes and real behavior are not the same thing.

It would be worth employing a triangulation methodology, combining staff attitudes surveys with alternative methods to study safety culture, such as peer observations, group discussions, analysis of an organization's incident history, and audits of the safety management system. [55] So far, this has largely been ignored in studies on safety culture. There is still much to learn about how data obtained from different methods are related and how to combine these data to get the most complete view of safety culture.

Creating a safety culture is a widely heralded goal, but an important question is whether this has an effect on the bottom line — that is, patient outcomes. The value of creating a safety culture is difficult to link to better patient outcomes. There is however some evidence that safety culture, as measured by the SAQ, can be improved in health care and that survey scores are related to patient safety outcomes. In a study of Pronovost et al., a comprehensive unit-based safety program led to an improved safety climate, and at the same time to a reduction in nursing turnover, in medication errors, and in length of stay. [56] A study by McCulloch and colleagues showed that CRM training resulted in an improvement in safety climate and in team performance, as well as in a decline in both technical and procedural errors. [57] Plainly, further research using more rigorous designs is needed into the relationship between safety culture and variables such as staff turnover, staff sickness rates, incident rates, length of stay, and patient outcomes such as mortality and morbidity.

Conclusions

Safety culture is increasingly recognized as one of the primary conditions for patient safety. Assessing the status quo is a critical first step to improving safety culture. This study showed that on most domains the safety culture in our PSICU was good when compared to benchmark data. It is hard to quantify exactly to what degree this was a result of the interventions we introduced to improve the safety culture, including CRM trainings. Despite their face validity, the effectiveness of such interventions and causal relationships are difficult to prove. Nevertheless, we will continue working on interventions to improve the safety culture, among which are CRM trainings, safety briefings, and senior executive walk rounds. To monitor progress, this will go together with administration of the SAQ at regular intervals, along with other methods that can be used in attempts to assess the effectiveness of patient safety initiatives, such as analyzing reported incidents and studying adverse events by means of a PICU-focused trigger tool. [58-60]

Acknowledgements

The authors gratefully acknowledge E.J. Thomas, S. Adams and W.K. Redekop for their excellent help in translating the SAQ.

References

1. International Atomic Energy Agency: Safety culture: a report by the International Nuclear Safety Advisory Group (Safety series No.75-INSAG-4). Vienna, International Atomic Energy Agency, 1991
2. Kohn LT, Corrigan JM, Donaldson MS (Eds): To err is human: building a safer health system (Institute of Medicine report). Washington, DC, National Academy Press, 1999
3. Pizzi LT, Goldfarb NI, Nash DB: Promoting a culture of safety. In: Making health care safer: a critical analysis of patient safety practices (Evidence report/technology assessment, number 43). Shojania KG, Duncan BW, McDonald KM, et al (Eds). Rockville, MD, Agency for Healthcare Research and Quality, 2001
4. Alton M, Mericle J, Brandon D: One intensive care nursery's experience with enhancing patient safety. Adv Neonatal Care 2006; 6:112-119
5. Verschoor KN, Taylor A, Northway TL, et al: Creating a safety culture at the Children's and Women's Health Centre of British Columbia. J Pediatr Nurs 2007; 22:81-86
6. Colla JB, Bracken AC, Kinney LM, et al: Measuring patient safety climate: a review of surveys. Qual Saf Health Care 2005; 14:364-366
7. Flin R, Burns C, Mearns K, et al: Measuring safety climate in health care. Qual Saf Health Care 2006; 15:109-115
8. Grant MJC, Donaldson AE, Larsen GY: The safety culture in a children's hospital. J Nurs Care Qual 2006; 21:223-229
9. Parry G, Horowitz L, Goldmann D: Patient safety attitudes of paediatric trainee physicians. Qual Saf Health Care 2009; 18:462-466
10. Bognár A, Barach P, Johnson JK, et al: Errors and the burden of errors: attitudes, perceptions, and the culture of safety in pediatric cardiac surgical teams. Ann Thorac Surg 2008; 85:1374-1381
11. Khoshbin A, Lingard L, Wright JG: Evaluation of preoperative and perioperative operating room briefings at the Hospital for Sick Children. Can J Surg 2009; 52:309-315
12. Snijders C, Kollen BJ, Lingen RAv, et al: Which aspects of safety culture predict incident reporting behavior in neonatal intensive care units? A multilevel analysis. Crit Care Med 2009; 37:61-67
13. Hazebroek FWJ: Quality improvement in pediatric surgery: the Rotterdam experience. J Pediatr Surg 2006; 41:617-623
14. Starre Cvd, Bos-Boon Avd, Tuijn Yvd, et al: Multidisciplinary care of patient's safety at the child intensive care [in Dutch]. Ned Tijdschr Geneeskd 2009; 153:334-339
15. Snijders C, Lingen RAv, Klip H, et al: Specialty-based, voluntary incident reporting in neonatal intensive care: description of 4846 incident reports. Arch Dis Child Fetal Neonatal Ed 2009; 94:F210-F215
16. Shell Netherlands: You work safely here, or you don't work here at all. Better faster - Safety in health care [in Dutch]. The Hague, Shell Netherlands, 2004
17. Snijders C, Schaaf TWvd, Klip H, et al: Feasibility and reliability of PRISMA-Medical for specialty-based incident analysis. Qual Saf Health Care 2009; 18:486-491
18. Binnekade JM, Mol BAd, Kesecioglu J, et al: The Critical Nursing Situation Index for safety assessment in intensive care. Intensive Care Med 2001; 27:1022-1028
19. Beuken MGAvd, Schulpen TWJ, Pas Et, et al: Complication registration in pediatrics [in Dutch]. Tijdschr Kindergeneeskd 2006; 74:106-113
20. Mearns K, Flin R, O'Connor P: Sharing 'worlds of risk'; improving communication with crew resource management. Journal of Risk Research 2001; 4:377-392
21. Oriol MD: Crew resource management: applications in healthcare organizations. J Nurs Adm 2006; 36:402-406
22. Pizzi LT, Goldfarb NI, Nash DB: Crew resource management and its applications in medicine. In: Making health care safer: a critical analysis of patient safety practices (Evidence report/technology assessment, number 43). Shojania KG, Duncan BW, McDonald KM, et al (Eds). Rockville, MD, Agency for Healthcare Research and Quality, 2001
23. Sexton JB, Helmreich RL, Neilands TB, et al: The Safety Attitudes Questionnaire: psychometric properties, benchmarking data, and emerging research. BMC Health Serv Res 2006; 6:44
24. Deilkås ET, Hofoss D: Psychometric properties of the Norwegian version of the Safety Attitudes Questionnaire (SAQ), Generic version (Short Form 2006). BMC Health Serv Res 2008; 8:191
25. Holden LM, Watts DD, Walker PH: Patient safety climate in primary care: age matters. J Patient Saf 2009; 5:23-28
26. Holden LM, Watts DD, Walker PH: Communication and collaboration: it's about the pharmacists, as well as the physicians and nurses. Qual Saf Health Care 2010; 19:169-172

27. Huang DT, Clermont G, Sexton JB, et al: Perceptions of safety culture vary across the intensive care units of a single institution. Crit Care Med 2007; 35:165-176
28. Makary MA, Sexton JB, Freischlag JA, et al: Operating room teamwork among physicians and nurses: teamwork in the eye of the beholder. J Am Coll Surg 2006; 202:746-752
29. Modak I, Sexton JB, Lux TR, et al: Measuring safety culture in the ambulatory setting: the Safety Attitudes Questionnaire - ambulatory version. J Gen Intern Med 2007; 22:1-5
30. Pronovost PJ, Berenholtz SM, Goeschel C, et al: Improving patient safety in intensive care units in Michigan. J Crit Care 2008; 23:207-221
31. Relihan E, Glynn S, Daly D, et al: Measuring and benchmarking safety culture: application of the Safety Attitudes Questionnaire to an acute medical admissions unit. Ir J Med Sci 2009; Doi: 10.1007/s11845-009-0352-2
32. Sexton JB, Holzmueller CG, Pronovost PJ, et al: Variation in caregiver perceptions of teamwork climate in labor and delivery units. J Perinatol 2006; 26:463-470
33. Sexton JB, Makary MA, Tersigni AR, et al: Teamwork in the operating room: frontline perspectives among hospitals and operating room personnel. Anesthesiology 2006; 105:877-884
34. Thomas EJ, Sexton JB, Helmreich RL: Discrepant attitudes about teamwork among critical care nurses and physicians. Crit Care Med 2003; 31:956-959
35. Sexton JB, Thomas EJ, Helmreich RL: Error, stress, and teamwork in medicine and aviation: cross sectional surveys. Br Med J 2000; 320:745-749
36. Flin R, Fletcher G, McGeorge P, et al: Anaesthetists' attitudes to teamwork and safety. Anaesthesia 2003; 58:233-242
37. Fisher J, Phillips E, Mather J: Does crew resource management training work? Air Med J 2000; 19:137-139
38. Barger LK, Ayas NT, Cade BE, et al: Impact of extended-duration shifts on medical errors, adverse events, and attentional failures. PLoS Med 2006; 3:e487
39. Landrigan CP, Rothschild JM, Cronin JW, et al: Effect of reducing interns' work hours on serious medical errors in intensive care units. N Engl J Med 2004; 351:1838-1848
40. Lockley SW, Barger LK, Ayas NT, et al: Effects of health care provider work hours and sleep deprivation on safety and performance. Jt Comm J Qual Patient Saf 2007; 33:7-18
41. Scott LD, Rogers AE, Hwang WT, et al: Effects of critical care nurses' work hours on vigilance and patients' safety. Am J Crit Care 2006; 15:30-37
42. Firth-Cozens J: Organisational trust: the keystone to patient safety. Qual Saf Health Care 2004; 13:56-61
43. Frankel A, Grillo SP, Pittman M, et al: Revealing and resolving patient safety defects: the impact of leadership WalkRounds on frontline caregiver assessments of patient safety. Health Serv Res 2008; 43:2050-2066
44. Campbell DA, Thompson M: Patient safety rounds: description of an inexpensive but important strategy to improve the safety culture. Am J Med Qual 2007; 22:26-33
45. Thomas EJ, Sexton JB, Neilands TB, et al: The effect of executive walk rounds on nurse safety climate attitudes: a randomized trial of clinical units. BMC Health Serv Res 2005; 5:28
46. Pronovost PJ, Weast B, Holzmueller CG, et al: Evaluation of the culture of safety: survey of clinicians and managers in an academic medical center. Qual Saf Health Care 2003; 12:405-410
47. France DJ, Greevy RA, Liu X, et al: Measuring and comparing safety climate in intensive care units. Med Care 2010; 48:279-284
48. Croteau RJ: The Joint Commission's Sentinel Event Database: 10 years of digging at the roots. Available online at: www.ihi.org/Ihi/Files/Forum/2005/Handouts/M18-d-NursingComplexity.pdf. Accessed January 26, 2011
49. Kivimäki M, Sutinen R, Elovainio M, et al: Sickness absence in hospital physicians: 2 year follow up study on determinants. Occup Environ Med 2001; 58:361-366
50. Rafferty AM, Ball J, Aiken LH: Are teamwork and professional autonomy compatible, and do they result in improved hospital care? Qual Health Care 2001; 10:ii32-ii37
51. Baggs JG, Schmitt MH, Mushlin AI, et al: Association between nurse-physician collaboration and patient outcomes in three intensive care units. Crit Care Med 1999; 27:1991-1998
52. Wheelan SA, Burchill CN, Tilin F: The link between teamwork and patients' outcomes in intensive care units. Am J Crit Care 2003; 12:527-534
53. Narasimhan M, Eisen LA, Mahoney CD, et al: Improving nurse-physician communication and satisfaction in the intensive care unit with a daily goals worksheet. Am J Crit Care 2006; 15:217-222
54. Phipps LM, Thomas NJ: The use of a daily goals sheet to improve communication in the paediatric intensive care unit. Intensive Crit Care Nurs 2007; 23:264-271
55. Cooper MD: Towards a model of safety culture. Saf Sci 2000; 36:111-136

56. Pronovost P, Weast B, Rosenstein B, et al: Implementing and validating a comprehensive unit-based safety program. J Patient Saf 2005; 1:33-40
57. McCulloch P, Mishra A, Handa A, et al: The effects of aviation-style non-technical skills training on technical performance and outcome in the operating theatre. Qual Saf Health Care 2009; 18:109-115
58. Agarwal S, Classen D, Larsen G, et al: Prevalence of adverse events in pediatric intensive care units in the United States. Pediatr Crit Care Med 2010; 11:568-578
59. Takata GS, Mason W, Taketomo C, et al: Development, testing, and findings of a pediatric-focused trigger tool to identify medication-related harm in US children's hospitals. Pediatrics 2008; 121:e927-e935
60. Landrigan CP, Parry GJ, Bones CB, et al: Temporal trends in rates of patient harm resulting from medical care. N Engl J Med 2010; 363:2124-2134

Supplemental digital content

Supplemental Table 5 The six-steps methodology used to translate the Safety Attitudes Questionnaire into Dutch

Step		Explanation
1)	Forward translation	Two translators, who were native speakers of the target language and fluent in the source language, undertook two independent forward translations (that is, translations from the original language into the target language).
2)	Reconciliation	Based on these two translations, a reconciled third version of the instrument was developed by a translation team composed of different experts.
3)	Backward translation	As a quality-control check, two independent translators who were native speakers of the source language and fluent in the target language and who had no knowledge of the questionnaire then did a backward translation of the reconciled version (that is, translated the tool back into the original language).
4)	Harmonization	The backward translation and the original were compared and any discrepancies (i.e., instances where the underlying concepts of the original version were subverted) were discussed. The process of forward and backward translation was iterated as many times as needed until a satisfactory version was reached.
5)	Pre-testing and cognitive interviewing	The instrument was pre-tested on individuals (not involved in the translation process) representative of those who were administered the questionnaire. Pre-test respondents were administered the instrument and debriefed using personal interviews. For example, this debriefing asked respondents what they thought the items were asking and whether there were any words they did not understand.
6)	Finalization	Based on all the steps described above, a final version of the instrument in the target language was produced.

LARA'S STORY: PART 5

Lara is home!

After those first hectic days on the ICU she quickly improved and now she is even drinking her bottles. And it appears that the resuscitation procedure did not bring any harm, so Melissa and Thomas are confident about her future….

Part 5

General discussion and summary

CHAPTER 12

General Discussion

GENERAL DISCUSSION

Towards a nation-wide patient safety program

The last decade has seen a wealth of studies about preventable mortality and morbidity in hospitals. [1-8] On average one in 12 patients suffered a serious adverse event due to their medical treatment. The conclusions attracted intense public attention, and made healthcare managers and providers aware that patient safety should be an indispensable part of healthcare management. Several patient safety campaigns were launched in countries such as the USA, Australia and the UK. [9-11] The Dutch Ministry of Health decreed that all hospitals and healthcare facilities should have a patient safety management system in place by January 1, 2008. In 2007 the Dutch Technical Agreement on patient safety management was published, which delineates the requirements for hospital patient safety management. A Dutch government-supported collaboration of Dutch hospitals, physicians and nurses resulted in the launch of the Dutch Patient Safety Program ("VMSZorg", www.vmszorg.nl) in 2008. Simultaneously three centers for expertise on patient safety were founded – in Utrecht, Zwolle and Rotterdam – and a professorial chair of patient safety was established in Rotterdam in 2010. So far these initiatives have resulted in 3 PhD theses on patient safety. [12-15]
Anticipating these developments, the Paediatric Association of the Netherlands established a Patient Safety Committee in 2005. Guided by this Committee an adverse event registration system for pediatric practice was developed and made available to Dutch pediatricians on the website of the Paediatric Association of the Netherlands. At the same time the Neosafe® project was launched, a nation-wide initiative for voluntary incident reporting in neonatal intensive care units. [16] The Patient Safety Committee next organized patient safety courses and developed an e-learning module on patient safety specifically for pediatricians (www.medschool.nl/patientveiligheid). Furthermore, in august 2011 the Paediatric Association of the Netherlands has distributed guidelines on six major pediatric patient safety issues, such as prevention of central line associated infections and early recognition of deterioration, among all Dutch pediatricians.
Younger children have been overlooked to some extent in patient safety research. As an illustration, the Dutch study on preventable adverse events [8] excluded patients under 1 year of age. Interventions to improve patient safety are usually designed for the adult setting and cannot just be copied to pediatrics for lack of evidence in this setting. For example, a combination of measures to prevent central line associated infections in adults, which was proven very effective by Pronovost et al [17], was found not effective in the PICU setting. [18]

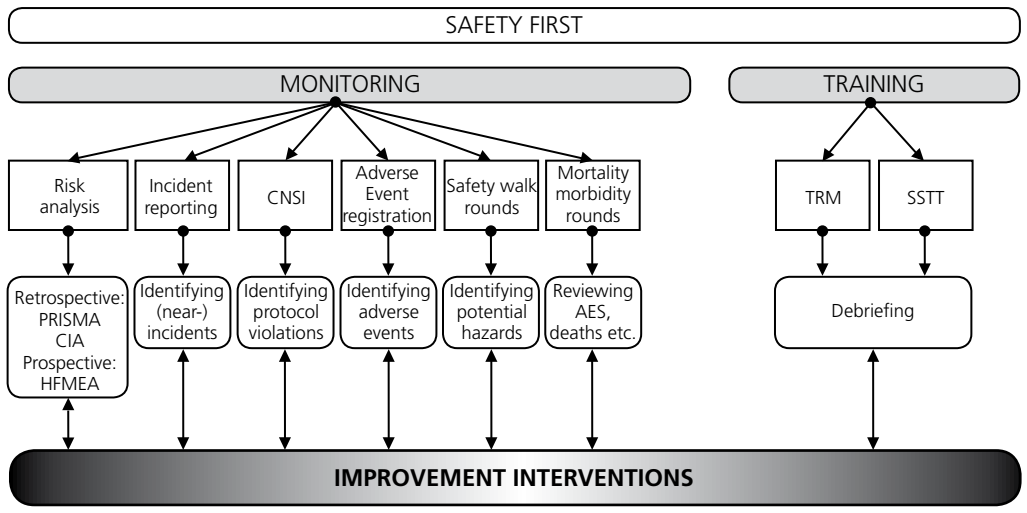
Why patient safety in pediatric intensive care?

Tailored interventions for hospitalized children need to be developed and tested. Patients in intensive care units, as in operating rooms and emergency departments, are at a higher risk of incidents and adverse events than are medium care patients or outpatients. They are more critically ill and undergo more high-tech interventions. Safety management systems for intensive care settings should be developed with these factors kept in mind.
The PICU in the Erasmus MC -Sophia Children's Hospital has developed and implemented such a patient safety management system (PSMS). It potentially serves as a role model for the other seven PICUs in academic hospitals in the Netherlands. In this thesis we reported on the patient safety activities employed in the past 6 years, the results of evaluations, and consequences for future patient safety management.

The Patient Safety Management System: Safety First

In 2004, we started a patient safety project under the name 'Safety First' (fig 1). The first components to be implemented were adverse event registration (2005), Safety First reports (blame-free incident reporting) (2004), Critical Nursing Situation Index (CNSI) (2005), and Team Resource Management (TRM) (2005). Since 2006 other elements have been added: retrospective incident analysis (PRISMA) (2006), prospective risk analysis (HFMEA) (2007), Safety Walk Rounds (2007), safety focused Mortality and Morbidity conferences (2007), and Simulation training (2007).

Figure 1 Elements of the Safety First patient safety management system



Abbreviations:

AEs	adverse events	SSTT	Sophia Simulation team training
CIA	critical incident analysis	TRM	Team Resource Management
CNSI	Critical Nursing Situation Index		
HFMEA	Healthcare Failure Mode and Effect Analysis		
PRISMA	Prevention and Recovery Information System for Monitoring and Alalysis		

A number of elements of the Safety First project have been studied and the findings are reported in this thesis. To asses the effectiveness of the Safety First project, we aimed at determining the rates of preventable mortality before and after the introduction of the project. We concluded, however, that mortality is not a useful outcome measure for a number of reasons, of which the low mortality rate in pediatric ICUs is the main one. So effectiveness of the safety management system in reducing preventable mortality has not yet been proven. Comparable data from other pediatric ICUs in the Netherlands are not available. Studies of preventable mortality in children are few. [19]

Studies on adverse events reported that some adverse events had contributed to death, but the incidence was very low. [20] Sharing of data on outcome and preventable events is indispensable for reliable benchmarking with similar ICU units. The Vermont Oxford Network (www.vtoxford.org) is an example of how sharing data can lead to the spread of best practices.

The incidences and nature of adverse events in both general pediatrics and pediatric intensive care were studied by means of physician registration. In addition we applied the trigger tool methodology to detect adverse events in the PICU. The Paediatric Association of the Netherlands has facilitated registration of adverse events for all pediatric units, but so far no studies have been reported. A number of studies have looked at adverse events in hospitalized children in other countries, using different methodologies. The most promising method appears to be the trigger tool, both for general pediatrics [21] and the intensive care settings. [20, 22-23] However, in our study 30% of adverse events were not detected with the trigger tool, so a combined approach is necessary. We recommend further development of triggers to increase the yield from electronic searches. Until that is accomplished, physician registration of adverse events needs to be facilitated and stimulated by developing easy-to-use registration systems and by providing regular detailed feedback.

The usefulness of critical incident analysis in detecting causal and contributing factors is described in this thesis. The methodology was adapted from critical incident analysis in high risk industries such as aviation, nuclear and chemical industry. Van de Schaaf et al adapted risk analysis to the medical setting and this has been applied in the Neosafe study by Snijders et al. [16, 24] No other study of incident analysis in pediatrics in the Netherlands is available. A number of studies described results of incident analysis in pediatric ICUs, most using a voluntary web-based incident reporting system. [25-28] The incidents were reported anonymously and could not be investigated as thoroughly as in our critical incident analysis. All different methods of incident analysis succeeded in identifying the contribution to the incident of factors beside the patient and the care provider, but we believe critical incident analysis results in the highest numbers of contributing factors. Because it is time-consuming however, it should be applied to cases where the patient suffered serious harm.

Our safety focused Mortality and Morbidity (M&M) conferences resulted in a large number of recommendations for improvement. No studies have been reported for similar initiatives in the Netherlands. A number of international publications describe integration of patient safety aspects in M&M conferences, of which two in a pediatric setting. [29-30] The experiences were similar to our experiences, even though they were in quite different settings (one pediatric hospital and 1 pediatric psychiatry ward). As in our safety focused M&M rounds, theirs had resulted in recommendations for system improvements, and we believe they are an important component of a PSMS.

The Critical Nursing Situation Index [31] has been applied in our unit for 5 years and in one other PICU and in two adult ICUs in the Netherlands. The first advantage of using this instrument was the assessment of all nursing protocols: are they actually evidence-based? How up-to-date are our protocols? The next step, reevaluating existing protocols and creating new ones, was also beneficial for nursing care. Lately we have seen a shift in use of this checklist, from monitoring to intervention, as protocol violations can be corrected immediately upon discovery. However, we would argue to keep the monitoring function as well, to identify which protocols are not or poorly followed.

We reported on the results of two consecutive Safety Attitude Questionnaire surveys. This questionnaire is a validated instrument for assessment of safety climate. [32] The safety climate in the surgical PICU was comparable to benchmark data from ICUs in the USA, UK and New Zealand.

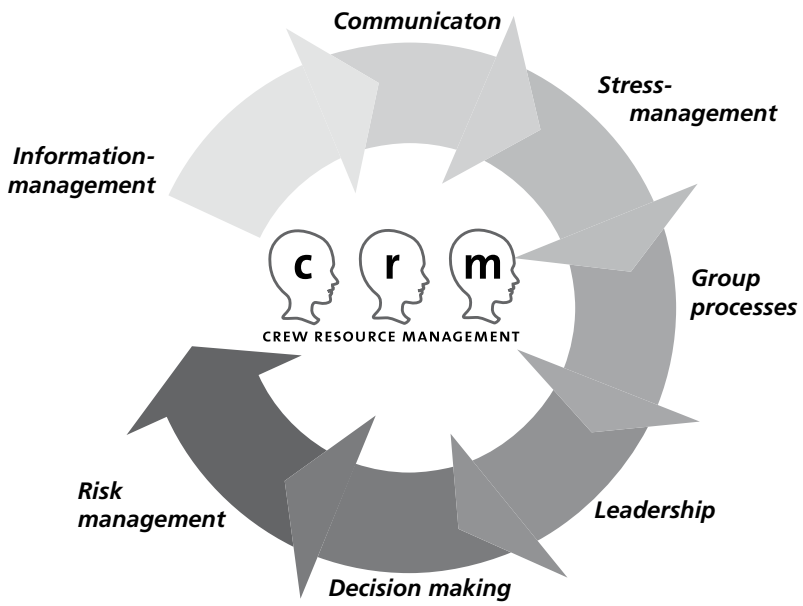
Except the Neosafe project, no comparable studies in Dutch pediatrics have been reported. [33] There is one other study on safety culture in 19 Dutch hospitals. [34] It used the Hospital Survey on Patient Safety Culture and concluded that this questionnaire represented the group culture rather than individual attitudes. A large number of studies have assessed safety climate both in nationwide surveys or in local surveys of a single unit, but few of them have focused on pediatrics. [35-38] The main findings in these studies are that a positive safety culture positively impacts on teamwork and perception of safety, so monitoring it is a valuable instrument for safety management. Another conclusion is that relations between safety culture, teamwork, and patient outcomes are worth investigating. [39]

An instrument we have introduced in 2007 to improve the leadership aspect of patient safety is Safety Walk Rounds. [40] This implies that the executives and senior management join the patient safety officers on visits to the wards and discuss safety issues with staff and parents. An additional benefit is that staff will realize that the management is concerned with safety issues. Responsibilities for any improvement actions are assigned and feedback is given at the next round. Monthly Safety Walk Rounds across all wards in the children's hospital start October 2011.

Team Resource Management training (TRM) is another intervention with a potential positive impact on safety culture. [41-44] All employees in the PICU and NICU of our hospital have taken this training course and are required to attend follow-up training once every 2 years. The focus is on interaction between participants: what goes well and what could be improved on the unit and how will that be achieved? (figure 2).

The TRM courses were supplemented with simulation team training sessions in which TRM skills and knowledge are tested. Ten physicians and nurses have learned how to set up simulation training by attending a course in the Center for Advanced Pediatric & Perinatal Education at Stanford University, Los Angeles, USA. [45-46] A designated patient area has been made available for training sessions in our own unit, which all physicians and nurses are required to attend two days per year. TRM and simulation training have thus become part of our continuous education program. Next to studies on the effects of these trainings on teamwork we plan to set up a regional training center.

Figure 2 Topics of Team Resource Management training, adapted from the Center for Man and Aviation.



Suggestions for improvement

A number of suggestions on improving the PSMS can be identified.

- As Monroe and colleagues [47] demonstrated, preventable adverse events contributing to death mainly occur before admission to the PICU itself. Promising preventive interventions are setting up the Pediatric Early Warning System [48-51] and rapid response teams (RRT) of intensive care consultants and nurses who can be consulted when a patient is deteriorating. The introduction of RRTs has decreased in-hospital arrests and lowered in-hospital mortality in a number of pediatric studies. [49, 52-57]

- For monitoring of adverse events it would be best to avoid relying on registration of adverse events by care providers only, as underreporting remains an issue difficult to resolve. We would argue to apply the trigger tool to the electronic databases every month in combination with the voluntary incident reporting. Also new triggers need to be developed to specifically target the adverse events that are hard to detect with the current triggers.

- A redesign of the incident reporting system is needed so that management is notified almost immediately after serious incidents occur. For every recommendation stemming from incident analysis or M&M conferences someone needs to be appointed as being responsible for further development and implementation of the recommended action. More employees should be trained in incident analysis so that more incidents can be investigated, more information on system factors is gained,

and more system-wide preventive measures can be developed. Another important improvement would be feedback on the recommendations: what has been done and has it worked? Not just to the involved parties but also to management and other units in the hospital.

- Improvement of medication safety can be achieved by adaptation of the computerized physician order entry (CPOE) systems. It would involve adding, for example, dose monitoring, reminders of dangerous drug-drug interactions, and suggestions for better choices of drugs. The use of standardized solutions for IV pumps combined with barcode scanning and smart pump technology would be a next step. These techniques check if the right drug is given to the right patient at the right time and at the right pump rate. Bar code scanning should be applied to single dose administration as well. [58-59] Collaboration of front line staff with pharmacists, ICT specialists and human factor engineers is critical to achieve foolproof medication safety.

- Focusing the Critical Nursing Situation Index on specific protocols, such as ECMO or ventilatory support, assessing each patient within 48 hours after admission, and providing prompt feedback to the nursing team will promote protocol adherence.

- The Safety Attitudes Questionnaire as well could be put to better use. For instance the divergent responses from doctors and nurses to statements such as "decision making is a team effort in our unit", with nurses less inclined to agree, is a clear indication that decision making needs to be addressed. The Safety Attitudes Questionnaire could be used as a monitoring tool for employee satisfaction and management perception, administering it more frequently and studying the results in greater detail.

- Teamwork could be improved by applying the TRM principles in daily practice. The use of briefings and debriefings, daily goals sheets and the use of time out procedures (before interventions such as intubation or placement of central venous line) will lead to better communication and feedback and better teamwork. These tools are not just applicable to intensive care settings, but other settings as well.

Cost-effectiveness

A number of studies concluded that the costs of adverse events are high, due to longer stay, extra medication and extra procedures related to the adverse events. A Dutch study found an average amount of €4555. [60] Interestingly, regarding the 10 children in that study, the extra costs involved in adverse events were estimated at approximately €600. Except for a few studies on specific targeted interventions (infection control or fall prevention) evidence for cost effectiveness of patient safety is very limited, and no studies have yet looked into the cost-effectiveness of a patient safety management system; further research into this is slowly getting under way.

Chapter 12

Education

With the growing awareness that poorly designed systems may cause adverse events, the awareness of current inadequacies in medical and nursing education has spread. [61] Systems theory, safety science and improvement science are usually not incorporated in educational programs. Only by teaching patient safety can we prepare future doctors and nurses for the task of improving the systems of healthcare delivery developed by their predecessors. We also should realize that standard medical research is not suitable to study improvement strategies. [62] It is imperative we understand how to develop and introduce better practices in the absence of randomized trials. Therefore academic leaders need to embrace patient safety and safety research, so that patient safety becomes a genuine academic discipline.

Conclusion

The Safety First project as developed in our ICU can serve as a framework for patient safety management in both general and university pediatric healthcare. It meets the requirements for a patient safety management system as established in the Dutch Technical Agreement. Multidisciplinary teams on unit level are needed to develop and implement good patient safety measures. Such teams must include physicians to facilitate data acquisition and interpretation, improvement development, and promoting safety awareness among colleagues. Support from management and leaders is indispensable for success, the more so as safety programs involve considerable costs. The safety teams need to be educated not only in the many aspects of patient safety, but also in implementation. We would recommend the Patient Safety Officer Executive Development Program from the Institute for Healthcare Improvement in Boston, USA. [63] As detailed in the first requirement for safety management in the Dutch Technical Agreement and required by the Ministry of Health in the Dutch Patient Safety Program, support from the Boards of Directors is crucial to all patient safety programs. The various institutions should share all patient safety related data to facilitate benchmarking and to identify best practices, which requires the use of the same measurement instruments. The Paediatric Association of the Netherlands is the most suitable organization to facilitate setting up national databases on incidents and adverse events and disseminating best practices proven to improve patient safety topics. Another important duty for the Paediatric Association of the Netherlands lies in providing education on patient safety, as is being done presently. Finally, up-to-date guidelines and protocols are important means to improve quality of care.

Patient safety should be integrated in everyday healthcare. The Patient Safety Management System in our intensive care unit has made a promising start. If the principles of safety are embraced more widely, the likelihood of improving safety will increase, as every care provider is aware of his/her accountability for the care he/she provides. Against the background of "To Err is Human" [64] it seems justified to say that promoting patient safety is not just the task and responsibility of patient safety officers, quality managers or Boards of Directors, but of everybody involved in healthcare.

References

1. Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG, et al. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. N Engl J Med. 1991 Feb 7;324(6):370-6.
2. Leape LL, Brennan TA, Laird N, Lawthers AG, Localio AR, Barnes BA, et al. The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. N Engl J Med. 1991 Feb 7;324(6):377-84.
3. Wilson RM, Runciman WB, Gibberd RW, Harrison BT, Newby L, Hamilton JD. The Quality in Australian Health Care Study. Med J Aust. 1995 Nov 6;163(9):458-71.
4. Thomas EJ, Studdert DM, Burstin HR, Orav EJ, Zeena T, Williams EJ, et al. Incidence and types of adverse events and negligent care in Utah and Colorado. Med Care. 2000 Mar;38(3):261-71.
5. Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. BMJ. 2001 Mar 3;322(7285):517-9.
6. Davis P, Lay-Yee R, Briant R, Ali W, Scott A, Schug S. Adverse events in New Zealand public hospitals I: occurrence and impact. N Z Med J. 2002 Dec 13;115(1167):U271.
7. Baker GR, Norton PG, Flintoft V, Blais R, Brown A, Cox J, et al. The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. CMAJ. 2004 May 25;170(11):1678-86.
8. Zegers M, de Bruijne MC, Wagner C, Hoonhout LH, Waaijman R, Smits M, et al. Adverse events and potentially preventable deaths in Dutch hospitals: results of a retrospective patient record review study. Qual Saf Health Care. 2009 Aug;18(4):297-302.
9. APSF. Australian Patient Safety Foundation. [cited 2011 march 29]; Available from: www.apsf.net.au/.
10. Institute for Healthcare Improvement. Overview of the 100,000 Lives Campaign. [cited 2011 march 28]; Available from: www.ihi.org/IHI/Programs/Campaign/100kCampaignOverviewArchive.htm
11. NHS. Patient Safety First. 2008 [cited 2011 august 9]; Available from: www.patientsafetyfirst.nhs.uk/content.aspx?path=/.
12. Kessels-Habraken M, De Jonge J, Van der Schaaf T, Rutte C. Prospective risk analysis prior to retrospective incident reporting and analysis as a means to enhance incident reporting behaviour: a quasi-experimental field study. Soc Sci Med. 2010 May;70(9):1309-16.
13. Kessels-Habraken M, Van der Schaaf T, De Jonge J, Rutte C. Defining near misses: towards a sharpened definition based on empirical data about error handling processes. Soc Sci Med. 2010 May;70(9):1301-8.
14. Snijders C. Voluntary reporting and systematic analysis of incidents in neonatal intensive care: the NEOSAFE study. Amsterdam2010.
15. Leistikow I. Patientveiligheid, de rol van de bestuurder. Utrecht2010.
16. Snijders C, van Lingen RA, Klip H, Fetter WP, van der Schaaf TW, Molendijk HA, et al. Specialty-based, voluntary incident reporting in neonatal intensive care: description of 4846 incident reports. Arch Dis Child Fetal Neonatal Ed. 2009 May;94(3):F210-5.
17. Pronovost P, Needham D, Berenholtz S, Sinopoli D, Chu H, Cosgrove S, et al. An intervention to decrease catheter-related bloodstream infections in the ICU. N Engl J Med. 2006 Dec 28;355(26):2725-32.
18. Miller MR, Griswold M, Harris JM, 2nd, Yenokyan G, Huskins WC, Moss M, et al. Decreasing PICU catheter-associated bloodstream infections: NACHRI's quality transformation efforts. Pediatrics. 2010 Feb;125(2):206-13.
19. Pearson GA, Ward-Platt M, Harnden A, Kelly D. Why children die: avoidable factors associated with child deaths. Arch Dis Child. 2010 Jun 8.
20. Agarwal S, Classen D, Larsen G, Tofil NM, Hayes LW, Sullivan JE, et al. Prevalence of adverse events in pediatric intensive care units in the United States. Pediatr Crit Care Med. 2010 Sep;11(5):568-78.
21. Matlow AG, Cronin CM, Flintoft V, Nijssen-Jordan C, Fleming M, Brady-Fryer B, et al. Description of the development and validation of the Canadian Paediatric Trigger Tool. BMJ Qual Saf. 2011 May;20(5):416-23.
22. Larsen G, Grant MJ. Pediatric patient safety: identification and characterization of adverse events, adverse drug events, and medical error. Pediatr Crit Care Med. 2004 Mar;5(2):189-91.
23. Sharek PJ, Horbar JD, Mason W, Bisarya H, Thurm CW, Suresh G, et al. Adverse events in the neonatal intensive care unit: development, testing, and findings of an NICU-focused trigger tool to identify harm in North American NICUs. Pediatrics. 2006 Oct;118(4):1332-40.
24. Snijders C, van der Schaaf TW, Klip H, van Lingen RA, Fetter WP, Molendijk A, et al. Feasibility and reliability of PRISMA-medical for specialty-based incident analysis. Qual Saf Health Care. 2009 Dec;18(6):486-91.

25. Skapik JL, Pronovost PJ, Miller MR, Thompson DA, Wu AW. Pediatric safety incidents from an intensive care reporting system. J Patient Saf. 2009 Jun;5(2):95-101.
26. Needham DM, Sinopoli DJ, Thompson DA, Holzmueller CG, Dorman T, Lubomski LH, et al. A system factors analysis of "line, tube, and drain" incidents in the intensive care unit. Crit Care Med. 2005 Aug;33(8):1701-7.
27. Needham DM, Thompson DA, Holzmueller CG, Dorman T, Lubomski LH, Wu AW, et al. A system factors analysis of airway events from the Intensive Care Unit Safety Reporting System (ICUSRS). Crit Care Med. 2004 Nov;32(11):2227-33.
28. Pronovost PJ, Thompson DA, Holzmueller CG, Lubomski LH, Dorman T, Dickman F, et al. Toward learning from patient safety reporting systems. J Crit Care. 2006 Dec;21(4):305-15.
29. Deis JN, Smith KM, Warren MD, Throop PG, Hickson GB, Joers BJ, et al. Transforming the Morbidity and Mortality Conference into an Instrument for Systemwide Improvement (Vol. 2: Culture and Redesign). 2008 Aug.
30. Goldman S, Demaso DR, Kemler B. Psychiatry morbidity and mortality rounds: implementation and impact. Acad Psychiatry. 2009 Sep-Oct;33(5):383-8.
31. Binnekade JM, de Mol BA, Kesecioglu J, de Haan RJ. The Critical Nursing Situation Index for safety assessment in intensive care. Intensive Care Med. 2001 Jun;27(6):1022-8.
32. Sexton JB, Helmreich RL, Neilands TB, Rowan K, Vella K, Boyden J, et al. The Safety Attitudes Questionnaire: psychometric properties, benchmarking data, and emerging research. BMC Health Serv Res. 2006;6:44.
33. Snijders C, Kollen BJ, van Lingen RA, Fetter WP, Molendijk H, Group NS. Which aspects of safety culture predict incident reporting behavior in neonatal intensive care units? A multilevel analysis. Crit Care Med. 2009 Jan;37(1):61-7.
34. Smits M, Wagner C, Spreeuwenberg P, van der Wal G, Groenewegen PP. Measuring patient safety culture: an assessment of the clustering of responses at unit level and hospital level. Qual Saf Health Care. 2009 Aug;18(4):292-6.
35. Colla JB, Bracken AC, Kinney LM, Weeks WB. Measuring patient safety climate: a review of surveys. Qual Saf Health Care. 2005 Oct;14(5):364-6.
36. Nieva VF, Sorra J. Safety culture assessment: a tool for improving patient safety in healthcare organizations. Qual Saf Health Care. 2003 Dec;12 Suppl 2:ii17-23.
37. Sorra JS, Dyer N. Multilevel psychometric properties of the AHRQ hospital survey on patient safety culture. BMC Health Serv Res. 2010;10:199.
38. Vlayen A, Hellings J, Claes N, Peleman H, Schrooten W. A nationwide Hospital Survey on Patient Safety Culture in Belgian hospitals: setting priorities at the launch of a 5-year patient safety plan. BMJ Qual Saf. 2011 Jul 18.
39. Pronovost PJ, Berenholtz SM, Goeschel C, Thom I, Watson SR, Holzmueller CG, et al. Improving patient safety in intensive care units in Michigan. J Crit Care. 2008 Jun;23(2):207-21.
40. Montgomery VL. Impact of Staff-Led Safety Walk Rounds (Vol. 3: Performance and Tools). 2008 Aug.
41. Morey JC, Simon R, Jay GD, Wears RL, Salisbury M, Dukes KA, et al. Error reduction and performance improvement in the emergency department through formal teamwork training: evaluation results of the MedTeams project. Health Serv Res. 2002 Dec;37(6):1553-81.
42. Jain M, Miller L, Belt D, King D, Berwick DM. Decline in ICU adverse events, nosocomial infections and cost through a quality improvement initiative focusing on teamwork and culture change. Qual Saf Health Care. 2006 Aug;15(4):235-9.
43. Dunn EJ, Mills PD, Neily J, Crittenden MD, Carmack AL, Bagian JP. Medical team training: applying crew resource management in the Veterans Health Administration. Jt Comm J Qual Patient Saf. 2007 Jun;33(6):317-25.
44. Mazzocco K, Petitti DB, Fong KT, Bonacum D, Brookey J, Graham S, et al. Surgical team behaviors and patient outcomes. Am J Surg. 2009 May;197(5):678-85.
45. Zabari M, Suresh G, Tomlinson M, Lavin JP, Jr., Larison K, Halamek L, et al. Implementation and case-study results of potentially better practices for collaboration between obstetrics and neonatology to achieve improved perinatal outcomes. Pediatrics. 2006 Nov;118 Suppl 2:S153-8.
46. Kaempf JW, Campbell B, Sklar RS, Arduza C, Gallegos R, Zabari M, et al. Implementing potentially better practices to improve neonatal outcomes after reducing postnatal dexamethasone use in infants born between 501 and 1250 grams. Pediatrics. 2003 Apr;111(4 Pt 2):e534-41.
47. Monroe K, Wang D, Vincent C, Woloshynowych M, Neale G, Inwald DP. Patient safety factors in children dying in a paediatric intensive care unit (PICU): a case notes review study. BMJ Qual Saf. 2011 May 19.
48. Parshuram CS, Hutchison J, Middaugh K. Development and initial validation of the Bedside Paediatric Early Warning System score. Crit Care. 2009;13(4):R135.

49. Kotsakis A, Lobos AT, Parshuram C, Gilleland J, Gaiteiro R, Mohseni-Bod H, et al. Implementation of a multicenter rapid response system in pediatric academic hospitals is effective. Pediatrics. 2011 Jul;128(1):72-8.
50. Duncan H, Hutchison J, Parshuram CS. The Pediatric Early Warning System score: a severity of illness score to predict urgent medical need in hospitalized children. J Crit Care. 2006 Sep;21(3):271-8.
51. Akre M, Finkelstein M, Erickson M, Liu M, Vanderbilt L, Billman G. Sensitivity of the pediatric early warning score to identify patient deterioration. Pediatrics. 2010 Apr;125(4):e763-9.
52. Nowak JE, Brilli RJ. Pediatric rapid response teams: is it time? JAMA. 2007 Nov 21;298(19):2311-2.
53. Sharek PJ, Parast LM, Leong K, Coombs J, Earnest K, Sullivan J, et al. Effect of a rapid response team on hospital-wide mortality and code rates outside the ICU in a Children's Hospital. JAMA. 2007 Nov 21;298(19):2267-74.
54. Brilli RJ, Gibson R, Luria JW, Wheeler TA, Shaw J, Linam M, et al. Implementation of a medical emergency team in a large pediatric teaching hospital prevents respiratory and cardiopulmonary arrests outside the intensive care unit. Pediatr Crit Care Med. 2007 May;8(3):236-46; quiz 47.
55. Hanson CC, Randolph GD, Erickson JA, Mayer CM, Bruckel JT, Harris BD, et al. A reduction in cardiac arrests and duration of clinical instability after implementation of a paediatric rapid response system. Qual Saf Health Care. 2009 Dec;18(6):500-4.
56. Tibballs J, Kinney S. Reduction of hospital mortality and of preventable cardiac arrest and death on introduction of a pediatric medical emergency team. Pediatr Crit Care Med. 2009 May;10(3):306-12.
57. Avent Y, Johnson S, Henderson N, Wilder K, Cresswell J, Elbahlawan L. Successful use of a rapid response team in the pediatric oncology outpatient setting. Jt Comm J Qual Patient Saf. 2010 Jan;36(1):43-5.
58. Poon EG, Cina JL, Churchill W, Patel N, Featherstone E, Rothschild JM, et al. Medication dispensing errors and potential adverse drug events before and after implementing bar code technology in the pharmacy. Ann Intern Med. 2006 Sep 19;145(6):426-34.
59. Poon EG, Keohane CA, Yoon CS, Ditmore M, Bane A, Levtzion-Korach O, et al. Effect of bar-code technology on the safety of medication administration. N Engl J Med. 2010 May 6;362(18):1698-707.
60. Hoonhout LH, de Bruijne MC, Wagner C, Zegers M, Waaijman R, Spreeuwenberg P, et al. Direct medical costs of adverse events in Dutch hospitals. BMC Health Serv Res. 2009;9:27.
61. Leape L, Berwick D, Clancy C, Conway J, Gluck P, Guest J, et al. Transforming healthcare: a safety imperative. Qual Saf Health Care. 2009 Dec;18(6):424-8.
62. Morath JM, Hain PD, Deshpande JK, Gitlin JD, Churchwell KB. Patient safety as an academic discipline. J Pediatr. 2009 Sep;155(3):303-4.
63. Institute of Healthcare Improvement. Patient Safety Executive Development Program. [cited 2011 march 28]; Available from: www.ihi.org/IHI/Programs/ProfessionalDevelopment/PatientSafetyProgramSeptember2011.htm.
64. Institute of Medicine. To Err is Human: Building a Safer Health System. Kohn LT, Corrigan JM, Donaldson MS, editors. Washington, D.C.: National Academy Press; 2000.

Chapter 12

Part 5

General discussion and summary

CHAPTER 13

Summary

SUMMARY

The rationale for the patient safety management system in our pediatric and intensive care units is explained from the increasing attention to patient safety, both in the public and medical domain, since the ground breaking report "To Err is Human" by the Institute of Medicine in the US. For Dutch hospitals, the number of yearly preventable deaths in 2004 was estimated at 1735, but excluding children less than 1 year of age. Information on preventable deaths in pediatrics is still lacking for the Netherlands.
The Dutch regulatory bodies required hospitals and healthcare facilities to have a functional patient safety management system (PSMS) in place by January 1, 2008. In our pediatric surgical ICU a PSMS was already in place prior to this date and in 2008 we introduced it in the general pediatric ICU. Voluntary incident reporting was introduced in 2004, scoring of nursing protocol violations and team resource management training in 2005 and adverse event registration in 2006. Subsequently other elements were introduced: retrospective incident analysis, prospective risk analysis, safety walk rounds, safety focused mortality and morbidity conferences, and simulation training.

Part I: The why and how of the Safety First project
In a study in 2004 we found that 4.5% of patients had been admitted more than 25 days, which in half of them was related to adverse events. Chapter 2 focuses on details of these so-called long-stay patients (admitted longer than 28 consecutive days) collected over three years (2003-2005). They comprised 4.4% of all admitted patients and accounted for 63% of total admission days. As a striking finding in these patients, mortality was 5 times higher than that in the others.
Chapter 3 deals with potentially preventable mortality; i.e. hospital deaths in which a potentially preventable adverse event has contributed to the death. Preventable mortality has been an important focal point in the media and in many patient safety campaigns. Thirty-one of 255 deaths in our ICU (12%) in three time periods (2001-2002, 2005-2006, 2009) were identified as potentially preventable, a median of 5 deaths per year. After the implementation of the PSMS the number of preventable deaths did not decrease.

Part II: Finding the right outcome to study patient safety
Studies in the United States have applied retrospective reviews of administrative databases, and found adverse event rates of 1 to 3.4% for hospitalized children. In chapter 4 we present a prospective study on 11 general pediatric units across the Netherlands in which local pediatricians registered adverse events over a 3 month period. The adverse event rate was 0.016 per patient, which is higher than reported in previous studies. Most adverse events occurred in neonates and infants. Diagnostic failures (e.g. loss of blood sample, failed lumbar puncture) were most frequent but did not cause serious physical harm. However, they increased length of hospital stay with a median of 1 day.
In Chapter 5 we studied the adverse events in the pediatric surgical ICU in 2006 and 2007. Numerous methods to detect and monitor adverse events have been advocated, but there is no gold standard. The Institute for Healthcare Improvement, Boston, USA, has developed the trigger tool methodology. The trigger tool uses "clues" found in a sample of medical records for a targeted search for adverse events. So far, this has resulted in higher detection rates than obtained with incident reporting, physician reporting, or chart review. We applied a modified version of the trigger tool to the electronic databases of 2006 and 2007. In the same period the physicians registered adverse events during the daily rounds. The two methods combined yielded an adverse events rate of 0.66 per patient. One or more adverse events occurred in 23% of patients; these patients were significantly younger than the other patients and their length of stay was longer. Comparison of the two methods showed that the trigger tool identified 70% of the adverse events; the physician registration 35%. There was only a 4.7% overlap of the two methods (4.7%). Catheter complications, accidental extubations and medication errors were sometimes not detected with the trigger tool. We concluded that the modified PICU trigger tool is a good method to detect adverse events, but should be used in combination with other methods, to assure the least possible number of adverse events is missed.

Part III: Finding the right interventions to improve patient safety
Since the medical community realized that errors in health care are common, costly and sometimes detrimental for patients, they turned to other high risk industries to learn how to deal with this. One of the main principles of safety management is learning from errors. To analyze errors it is essential to look beyond the individual committing an error and closely examine all factors contributing to the incident. This provides a window on the system in which individuals work that also allows for more effective improvements. Chapter 6 describes the results of 17 incidents that were thoroughly investigated with the SIRE (Systematic Incident Reconstruction and Evaluation) approach. The incidents varied from near-strangulation, with no permanent harm to the patient, to a medication error contributing to death. The resulting causal and contributing factors were classified in contextual categories (e.g. work environment factors, provider factors, patient factors), as were the recommendations stemming from the incident analyses. On average, we could identify 5 factors per incident and formulate 5 recommendations. The contributing factors were mostly team factors (such as communication, loss of information) and task factors (no protocol available). The most frequent recommendations were about task factors (improve protocol) and team factors (improve communication).
Chapter 7 focuses on medication safety. In both adult and pediatric studies the most frequent reported incidents are medication errors. The PICU is no exception to this rule, as medication errors continue to account for one third of all incidents. We investigated the available dosing information for 6 drugs that were most (n=3) and least (n=3) frequently prescribed. For none of them consistent guidelines were available, which might have contributed to the occurrence of medication errors in our PICU.

MRI scanning of preterm infants requiring respiratory support is associated with a high risk of adverse events. In Chapter 8 we retrospectively collected data on adverse events occurring during and after MRI scanning of 52 infants at 30 weeks gestational age. Adverse events such as increased respiratory instability or hypothermia occurred in half of these infants. Analysis of the adverse events led to the introduction of time out procedures for MRI scanning and systematic incident review for future prevention of adverse events.

Chapter 9 describes experiences gained from our so-called Patient Safety focused Mortality and Morbidity conferences over 3 years (2008-2010). Focusing on patient safety implied that participants addressed what went wrong and considered opportunities for improvement. Most of the recommendations related to team work (e.g. improve communication) and individual staff (e.g. check medication prescription). However, only 31 of 148 recommendations had been acted upon. Safety focused M&M conferences can be a valuable addition to a PSMS, provided that individual staff is made responsible to implement the recommendations.
Next to voluntary incident reporting, scoring of nursing protocol violations was implemented. In chapter 10 the Critical Nursing Situation Index was applied 238 times; the mean percentage of protocol violations was 12.2% (SD 7.4%). More than fifty percent (53.4%) of all protocol violations could be timely corrected. Severity of the protocol violations could not be assessed in a reliable manner; the assessors' interrater reliability was poor and it was not possible to reach consensus.

Part IV: Culture, leadership and teamwork
A PSMS will only be effective if a number of basic requirements are met. An important feature is establishing a culture in which discussing errors is welcomed, in contrast with a culture of "blaming and shaming". Chapter 11 evaluates the Safety Attitudes Questionnaire, administered to all employees of the pediatric surgical ICU in 2006 and in 2007, and inquiring after safety aspects such as teamwork and stress recognition. The response rates were 85% and 74% respectively. From a comparison to benchmark data we concluded that the safety culture was good enough. There is room for improvement, however, but so far it is unknown how to achieve this and how this would improve patient care and health outcomes.

Discussion
The general discussion in chapter 12 regards the findings in a broader view. The main conclusions are:
- preventable mortality cannot serve as an indicator for quality and safety of care in a single pediatric (intensive care) unit;
- measuring (preventable) harm to patients will remain difficult;
- more of the recommendations stemming from incident analysis, Mortality and Morbidity conferences, and Safety Walk Rounds should be implemented and their effectiveness should be monitored;
- reliable measurement tools for the effect of team training need to be developed and tested;

A number of recommendations are presented on how to proceed with patient safety in the ICU, in the children's hospital and in pediatrics in general:
- the use of the Pediatric Early Warning Score and so-called Rapid Response Teams for the timely detection and treatment of deteriorating patients outside of the ICU;
- the application of the trigger tool in electronic databases every month, complemented with voluntary incident reporting; new triggers need to be developed to detect as many adverse events as possible;
- the incident reporting system needs to be redesigned so that management is rapidly informed after the occurrence of serious incidents;
- more personnel needs to be trained in critical incident analysis;

- more feedback is required on the implementation of recommendations and their effectiveness;
- the use of computerized physician order entry (CPOE) systems can improve medication safety; standard iv solutions, barcode scanning and smart pump technology can further increase safety; for this, intense collaboration between paediatricians, pharmacists, IT specialists and human factors engineers is indispensable;
- the CNSI can be put to more effective use by developing scoring lists for specific patient categories and then using them within 48 hours after admission for each patient;
- the Safety Attitudes Questionnaire can be used more effectively by studying the divergent responses from different disciplines such as doctors and nurses in more detail; the Questionnaire can also be applied to monitor employee satisfaction;
- teamwork can be improved by using instruments from the TRM training such as briefings and debriefings, daily goals sheets and time out procedures;
- determining cost-effectiveness of patient safety interventions is difficult, more research into this topic is required;
- patient safety needs to become an integral part of the education of both doctors and nurses.

Appendices
In chapter 15 the multidisciplinary approach to patient safety management as implemented in the pediatric surgical ICU is described for Dutch physicians. It explains the different elements of the PSMS and the preliminary results: on average 125 incidents were reported per month, one in every 5 patients suffered an adverse event and on average 5 nursing protocols per patient were violated.
Chapter 16 deals with our experiences with simulation team training. From 272 evaluation forms of 10 training days it became clear that 89% of the participants felt they had things under control during the sessions and 79% expected to feel more in control during actual work events in the future.

Chapter 13

Part 5

General discussion and summary

CHAPTER 14

Samenvatting

SAMENVATTING

De rationale voor de ontwikkeling en invoering van het patiëntveiligheidsmanagementsysteem (PVMS) op onze afdeling Intensive Care voor Kinderen (IC Kinderen) hangt samen met de toenemende aandacht voor patiëntveiligheid, zowel in de publieke opinie als in de medische wereld, sinds de publicatie van het baanbrekende rapport "To Err is Human" van het Institute of Medicine in de Verenigde Staten. Voor de Nederlandse ziekenhuizen is de jaarlijks vermijdbare sterfte geschat op 1735, maar hierbij werden dossiers van kinderen onder 1 jaar niet onderzocht. Gegevens over vermijdbare sterfte in de kindergeneeskunde ontbreken nog in Nederland.
De Nederlandse overheid heeft bepaald dat alle ziekenhuizen en zorginstellingen per 1 januari 2008 een functionerend PVMS dienen te hebben. Op de kinderchirurgische IC was het PVMS al voor deze datum ingevoerd en in 2008 werd het geïntroduceerd op de IC Kinderen. Vrijwillige incidentmelding was geïntroduceerd in 2004, scoren van verpleegkundige protocolschendingen en team resource management training in 2005, en complicatieregistratie in 2006. Vervolgens werden andere elementen toegevoegd: retrospectieve incidentanalyse, prospectieve risicoanalyse, safety walk rounds, mortaliteit-, morbiditeit- en veiligheidbesprekingen en simulatietraining.

Deel 1: Het waarom en hoe van het Safety First project
Uit een studie in 2004 bleek dat 4.5% van de patiënten meer dan 25 dagen opgenomen was geweest, en dat dit bij de helft daarvan gerelateerd was aan complicaties. Vervolgens hebben we over de jaren 2003 tot en met 2005 gekeken wat de kenmerken waren van deze zogenaamde long-stay patiënten (langer dan 28 opeenvolgende dagen opgenomen). Ze vormden 4.4% van alle opgenomen patiënten en waren goed voor 63% van het totaal aantal opnamedagen (Hoofdstuk 2). Een opvallende bevinding was dat in deze patiënten de sterfte 5 keer hoger was vergeleken met de andere patiënten.
Hoofdstuk 3 gaat over de potentieel vermijdbare sterfte; oftewel overlijden in het ziekenhuis waarbij een mogelijk vermijdbare complicatie bijgedragen heeft tot het overlijden. Dit is een belangrijk aandachtspunt in zowel de media als in vele patiëntveiligheidsprojecten. We kwamen tot de conclusie dat bij 31 van de 255 overleden kinderen op onze IC in 2001-2002, 2005-2006, en 2009 mogelijk te voorkomen complicaties hadden bijgedragen tot het overlijden. Het gemiddelde aantal van 5 per jaar nam niet af na de invoering van het PVMS in 2005.

Deel 2: Op zoek naar de goede uitkomstmaat voor het meten van patiëntveiligheid.
Onderzoekers in de Verenigde Staten kwamen na het achteraf bestuderen van administratieve gegevens tot de conclusie dat bij 1 tot 3,4 % van de kinderen opgenomen in een ziekenhuis een complicatie was ontstaan. In hoofdstuk 4 presenteren we de resultaten van ons prospectief onderzoek gedurende 3 maanden naar complicaties in 11 algemene kinderafdelingen verspreid over Nederland. Het percentage complicaties was 1,6%, hoger dan in eerdere onderzoeken. De meeste complicaties kwamen voor bij pasgeborenen en baby's. Procedurefouten kwamen het meest voor, zoals het kwijt raken van bloedmonsters of het niet lukken van een ruggenprik, en die veroorzaakten weinig lichamelijke schade. Maar ze maakten wel een langer ziekenhuisverblijf (gemiddeld 1 dag) noodzakelijk.

Hoofdstuk 5 beschrijft ons onderzoek naar complicaties op de kinderchirurgische IC in 2006 en 2007. Er zijn verschillende methodes om complicaties te ontdekken en bij te houden, maar een gouden standaard is er niet. Het Institute for Healthcare Improvement, Boston, USA, heeft de trigger tool methodologie ontwikkeld. De trigger tool maakt gebruik van bepaalde aanwijzingen in het medisch dossier voor een gerichte zoektocht naar complicaties. Tot nu toe worden hiermee meer complicaties opgespoord dan methodes zoals incidenten melden, registratie door artsen, of gewoon dossieronderzoek. We hebben een aangepaste versie van de trigger tool gebruikt met de elektronische gegevens van 2006 en 2007. In diezelfde periode werden de complicaties ook door de artsen bijgehouden tijdens de dagelijkse visiterondes. Kijkend naar alle opgenomen patiënten in deze 2 jaar leverden de twee methodes samen 0,66 complicaties per patiënt op. Een of meer complicaties kwamen voor bij 235 van de 1223 patiënten; deze kinderen waren jonger dan de kinderen zonder complicaties en lagen langer op de IC. Bij vergelijken van de methodes bleek dat de trigger tool 70% van de complicaties had gevonden en de registratie door artsen 35%. Er was 4,7% overlap van die 2 methodes. Problemen met intraveneuze lijnen, met beademingsbuizen en medicatiefouten werden met de trigger tool veel gemist. Onze conclusie was dat de aangepaste versie van de trigger tool een goede mogelijkheid biedt om complicaties op te sporen, maar dat die het beste gecombineerd kan worden met nog andere methodes om zo weinig mogelijk complicaties te missen.

Deel 3: Op zoek naar de goede interventies om de veiligheid te verbeteren.
Sinds de gezondheidszorg doordrongen is van het feit dat fouten in de zorg veel voorkomen, kosten met zich meebrengen en soms ernstige gevolgen hebben voor de patiënt, is gekeken naar hoe andere bedrijfstakken hiermee omgaan. Eén van de beginselen van veiligheidsmanagement is het leren van fouten. Het is van groot belang om niet alleen te kijken naar de individuele medewerker die een fout heeft gemaakt, maar naar alle factoren die hebben bijdragen. Hiermee krijg je zicht op het systeem waarbinnen mensen werken en kunnen effectievere verbeteringen bedacht worden. Hoofdstuk 6 beschrijft wat we vonden bij het grondig uitzoeken van 17 incidenten met de SIRE benadering (Systematische Incident Reconstructie en Evaluatie). De incidenten varieerden van bijna-wurging door een maagsonde zonder uiteindelijke schade voor de patiënt, tot een medicatiefout die bijdroeg aan het overlijden. De mogelijk veroorzakende en bijdragende factoren werden in categorieën ingedeeld (bijvoorbeeld betrekking hebbende op de werkomgeving, een individuele zorgverlener, of de patiënt zelf), en ook de aanbevelingen uit de analyses werden op die manier ingedeeld. Gemiddeld konden we 5 factoren per incident identificeren en 5 aanbevelingen benoemen. De meeste bijdragende factoren hadden betrekking op samenwerking in het team (zoals onvoldoende communicatie, verloren gaan van informatie) en protocol of procedure gerelateerde factoren (geen protocol aanwezig). De meeste aanbevelingen gingen inderdaad over deze zaken: verbeteren van communicatie, en ontwikkelen/verbeteren van protocollen.
Hoofdstuk 7 richt zich op medicatieveiligheid. Zowel bij volwassenen als bij kinderen zijn medicatiefouten de meest voorkomende incidenten. De IC Kinderen is geen uitzondering op die regel, want medicatiefouten vormen nog steeds één derde van alle incidenten. We hebben gekeken naar de informatie over de dosering van de drie medicijnen die het meest, en de drie die het minst werden voorgeschreven. Voor geen van de zes waren consequente richtlijnen te vinden, wat kan hebben bijgedragen aan het optreden van medicatiefouten op de IC Kinderen.

Het maken van MRI-scans bij te vroeg geboren kinderen die beademd worden kent een hoog risico op complicaties. In hoofdstuk 8 hebben we informatie verzameld over incidenten en complicaties tijdens en na het maken van een MRI-scan bij 52 kinderen van 30 weken zwangerschapsduur. Bij de helft waren complicaties opgetreden, zoals toegenomen ademhalingsproblemen of onderkoeling. Naar aanleiding van een analyse van de complicaties hebben we time out procedures ingevoerd vóór de MRI-scan en worden eventuele incidenten systematisch beoordeeld zodat ze in de toekomst voorkomen kunnen worden. .

Hoofdstuk 9 beschrijft de ervaringen opgedaan met de zogenaamde Mortaliteit, Morbiditeit en Veiligheid besprekingen. De laatste drie jaar waren die speciaal gericht op patiëntveiligheid, wat betekent dat de deelnemers bespraken wat er niet goed was gegaan en hoe dat verbeterd kon worden. De meeste aanbevelingen betroffen teamwerk (bijvoorbeeld verbeteren communicatie) en individuele zorgverleners (bijvoorbeeld beter checken van medicatievoorschrift). Er waren echter maar 31 van de 148 aanbevelingen uitgevoerd. Deze besprekingen kunnen een waardevolle aanvulling zijn op een PVMS, maar dan moeten er wel verantwoordelijken aangewezen worden voor het uitvoeren van de aanbevelingen.
Behalve het vrijwillig melden van incidenten werd ook een systeem ingevoerd om het niet volgens verpleegkundig protocol werken te registreren: de Critical Nursing Situation Index. In hoofdstuk 10 wordt beschreven dat uit 238 observaties bleek dat gemiddeld 12.2% (SD 7.4%) van de voorschriften waren geschonden. In meer dan de helft van de gevallen kon dit op tijd recht gezet worden. Een aantal verpleegkundigen was gevraagd in te schatten hoe ernstig de protocolschendingen waren. De inschattingen liepen echter ver uiteen; de inter-beoordelaar betrouwbaarheid was laag en het lukte niet om consensus te bereiken.

Deel 4: Cultuur, leiderschap en teamwerk
Een PVMS kan alleen goed werken als aan een aantal basisvoorwaarden is voldaan. Een belangrijke voorwaarde is het creëren van een cultuur waarin het bespreken van fouten verwelkomd wordt, in tegenstelling tot een cultuur van "blaming and shaming". Hoofdstuk 11 evalueert de Safety Attitudes Questionnaire, afgenomen bij alle medewerkers van kinderchirurgische IC in 2006 en 2007, die veiligheidsonderwerpen als teamwork en stressherkenning in kaart brengt. De deelname was 85% en 74% respectievelijk. Na vergelijking met benchmarkgegevens konden we besluiten dat de veiligheidscultuur goed genoeg was. Er is echter wel ruimte voor verbetering, maar het is moeilijk te zeggen hoe dit te bereiken en of dit inderdaad tot betere patiëntveiligheid leidt.

Discussie
De discussie in hoofdstuk 12 plaatst de bevindingen in een breder perspectief. De belangrijkste conclusies zijn:
- vermijdbare sterfte kan niet als kwaliteits- of veiligheidsindicator gebruikt worden voor een kindergeneeskundige (IC) afdeling;
- het inzicht krijgen in de gevallen van mogelijk vermijdbare schade aan patiënten zal moeilijk blijven;

- meer van de aanbevelingen die voortkomen uit de incidentanalyses, de mortaliteit en morbiditeit besprekingen en safety walk rounds moeten ingevoerd worden en daarna worden getest op hun effectiviteit;
- betrouwbare meetinstrumenten voor de effecten van teamtraining moeten ontwikkeld en getest worden.
De volgende aanbevelingen worden gepresenteerd over hoe verder te gaan met patiëntveiligheid op de IC, in het kinderziekenhuis en in de kindergeneeskunde algemeen:
- het gebruik van de Pediatric Early Warning Score en zogenaamde Rapid Response Teams om op tijd achteruitgang bij patiënten te ontdekken en te kunnen behandelen;
- het gebruik van de trigger tool in de elektronische database op maandelijkse basis, aangevuld met vrijwillige incidentmeldingen, waarbij nieuwe triggers ontwikkeld dienen te worden om zoveel mogelijk complicaties te vinden;
- het incidentmeldingen systeem moet zo aangepast worden dat het management na ernstige incidenten snel op de hoogte wordt gebracht;
- meer medewerkers moeten geschoold worden in incident analyse;
- er moet meer feedback gegeven worden over wat met de aanbevelingen is gedaan en of ze effectief zijn;
- door het gebruik van zgn computerized physician order entry (CPOE) systemen kan de medicatieveiligheid worden verbeterd. Ook kunnen standaard oplossingen voor intraveneuze medicijnen, barcode scanning en zgn smart pump technologie hierbij helpen. Intensieve samenwerking tussen de kinderartsen, de apothekers, ICT deskundigen en industrieel ontwerp specialisten is hierbij onmisbaar;
- de CNSI kan effectiever gebruikt worden door het gericht op bepaalde soorten patiënten te maken en dan binnen 48 uur na opname elke patiënt te scoren;
- de Safety Attitudes Questionnaire kan ook beter gebruikt worden door in meer detail de uiteenlopende antwoorden van bv artsen en verpleegkundigen met elkaar te vergelijken. De Safety Attitudes Questionnaire kan ook gebruikt worden om medewerker tevredenheid bij te houden;
- teamwerk kan verbeterd worden door gebruik te maken van instrumenten uit de TRM training zoals briefings en debriefings, daily goals sheets en time out procedures;
- kosten-effectiviteit van patiëntveiligheid interventies is moeilijk te bepalen, dit moet verder onderzocht worden;
- patiëntveiligheid dient opgenomen te worden in het onderwijs van zowel artsen als verpleegkundigen.

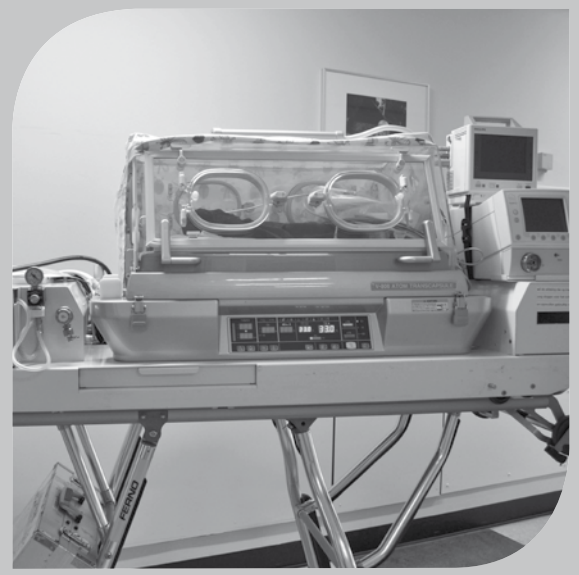
Bijlagen
In hoofdstuk 15 wordt de multidisciplinaire aanpak van patiëntveiligheid, zoals op de kinderchirurgische IC ingevoerd, voor Nederlandse artsen uitgelegd. De verschillende onderdelen van het PVMS komen aan bod en de eerste resultaten worden beschreven: per maand worden gemiddeld 125 incidenten gemeld, 1 op de 5 patiënten krijgt een complicatie, en er worden gemiddeld 5 verpleegkundige protocollen per patiënt geschonden.
Hoofdstuk 16 meldt onze ervaringen met simulatie-teamtraining. Uit 272 evaluatieformulieren bleek dat 89% van de deelnemers zich zeker voelde tijdens het uitvoeren van de scenario's en 79% verwachtte in de toekomst zich in echte werksituaties ook zekerder te voelen.

Chapter 14

Conclusion

When Lara was about to be discharged from the hospital the safety officers told Thomas and Melissa about the results of the investigation they did. The work protocols for children with esophageal atresia were updated and all staff had been especially instructed on things that could go wrong. Also the rules and guidelines for acutely worsening patients were put up on the screensavers and posters all over the unit. Thomas and Melissa feel that what had happened to their daughter had been taken seriously and tell the safety officers they hope the next baby with esophageal atresia will benefit from all these improvements.

Part 6 Appendices



CHAPTER 15

Multidisciplinaire aanpak van patiëntveiligheid op de kinder-IC

van der Starre C, van den Bos-Boon A, van der Tuijn Y, Maas I, Molendijk AH, Offringa M, et al. Multidisciplinaire aanpak van patientveiligheid op de kinder-IC. Ned Tijdschr Geneeskd. 2009 Feb 21;153(8):334-339.

MULTIDISCIPLINAIRE AANPAK VAN PATIËNTVEILIGHEID OP DE KINDER-IC

Abstract

Doel: Verbetering van de patiëntveiligheid en daarmee van de kwaliteit van zorg op een kinderchirurgische niveau 3 Intensive Care in een universitair centrum met ongeveer 550 opnames per jaar.
Opzet: Beschrijvend onderzoek.
Methode: Verschillende meetmethoden voor het melden van incidenten, registratie van complicaties, evaluatie van protocollen en protocollair werken, en gestructureerde trainingen werden geïntroduceerd. Er werden 3 verschillende analysemethoden van incidenten gebruikt.
Resultaten: Er werden gemiddeld 125 incidenten per maand gemeld; ongeveer 25% van de patiënten liep 1 of meer complicaties op; per patiënt werden gemiddeld 5 verpleegkundige protocollen niet nageleefd.
Conclusie: Het blijkt goed mogelijk een effectief veiligheidsmanagementsysteem te introduceren op een klinische afdeling, overeenkomstig de door het Nederlands Normalisatie-Instituut opgestelde norm, mits er een veilige en open afdelingscultuur wordt gecreëerd. Onderrapportage van incidenten en complicaties is desalniettemin nog een probleem. De cultuurverandering is een langzaam verlopend proces en de implementatie van gerichte verbeteringen heeft nog niet aantoonbaar geleid tot betere zorg, voornamelijk door de korte tijd dat het project loopt.

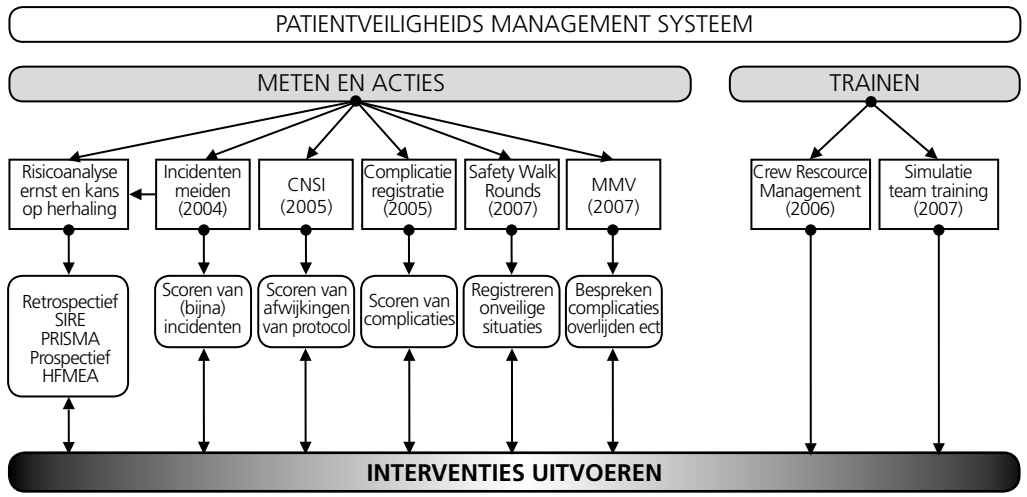
Introductie

Volgens onderzoek zouden er in Nederland per jaar zo'n 1700 mensen overlijden door fouten in ziekenhuizen. [1] Overheid, ziekenhuizen, verpleegkundigen en specialisten zien patiëntveiligheid als één van de belangrijke punten van verbetering van de zorg. Dat heeft de afgelopen jaren geresulteerd in projecten zoals 'Sneller beter', waarbij gestreefd wordt naar grotere transparantie, doelmatigheid en kwaliteit in de curatieve zorg (www.snellerbeter.nl), maar ook in de verplichting om per 1 januari 2008 een werkend veiligheidsmanagementsysteem te hebben. Het Nederlands Normalisatie-Instituut heeft samen met 36 andere partijen de minimumeisen voor een dergelijk systeem vastgelegd in de Nederlandse Technische Afspraak (NTA 8009:2007). [2] De ontwikkeling van deze norm verloopt volgens een groeimodel, waarbij in 2011 een nieuwe versie als Nederlandse norm zal verschijnen.
In oktober 2003 werd op de kinderchirurgische Intensive Care van het Erasmus MC-Sophia Kinderziekenhuis te Rotterdam een project gestart, genaamd 'Safety first',met als doel de patiëntveiligheid te verbeteren. Het uitgangspunt was dat dit project uiteindelijk zou moeten
leiden tot minder incidenten en complicaties, en daardoor tot een lagere mortaliteit en morbiditeit, en een kortere opnameduur. Een belangrijke voorwaarde voor het verbeteren van de patiëntveiligheid is dat medewerkers zich bewust worden van de risico's en gevaren van hun handelen in de dagelijkse praktijk. Deze bewustwording moet samengaan met een cultuurverandering: in plaats van reactief om te gaan met voorgevallen incidenten en de daaropvolgende schuldvraag ('blaming and shaming') moet men incidenten en complicaties gaan melden zonder angst voor repercussies ('blame-free'), en risico's proactief analyseren. Een stimulerende rol is hierbij weggelegd voor de leiders van de afdeling.

In dit artikel bespreken wij de verschillende onderdelen van het door ons opgezette veiligheidsmanagementsysteem 'Safety first', zoals risico-inventarisatie, risicoanalyse en teamtraining. Ook worden de samenhang tussen de verschillende onderdelen en de ontwikkelingen in de tijd weergegeven, naast de resultaten over de periode 2005-2007.

Gegevens en methoden

Het project 'Safety first' vond plaats op de kinderchirurgische Intensive Care, een multidisciplinaire IC van niveau 3 met ongeveer 550 opnames per jaar. De opgenomen patiënten zijn vooral kinderen met ernstige aangeboren afwijkingen, kinderen met neuro- of multitrauma, kinderen die een craniofaciale of orthopedische operatie hebben ondergaan en kinderen die behandeld worden met extracorporele membraanoxygenatie. [3] Er werken ongeveer 120 verpleegkundigen, 5 intensivisten, 4 fellows en 7 arts-assistenten. Sinds januari 2008 zijn deze afdeling en de Intensive Care Pediatrie samengevoegd tot de Intensive Care Kinderen. In ons project gebruikten wij een aantal methoden om de patiëntveiligheid te verbeteren, zoals het melden en bespreken van incidenten, protocollair werken en trainingen om het personeel bewust te maken van patiëntveiligheidsaspecten (figuur).



Samenwerking en training

Optimale samenwerking in teamverband is van groot belang voor de kwaliteit en de veiligheid van de geleverde zorg. Omdat analyse van ongevallen en incidenten in de luchtvaart heeft aangetoond dat in 70% van de gevallen ontoereikende communicatie en samenwerking een rol speelden, [4] startten wij met 'Team resource management' (TRM)-training, een van de luchtvaart afgeleide veiligheidstraining op het gebied van samenwerking voor personeel in de gezondheidszorg. Zowel de medische als de verpleegkundige staf volgde een tweedaagse training onder andere gericht op menselijk gedrag en fouten, effecten van stress op handelen en perceptie, en op communicatie tussen teamleden.

Inmiddels volgen ook alle nieuwe medewerkers deze training en wordt een herhalingstraining voorbereid. In 2007 werd een programma van simulatietrainingen opgezet dat met name gericht was op het samenwerken in teamverband. Na instructie in het Center for Advanced Pediatric and Perinatal Education aan de Stanford University in Californië voerde het team regelmatig praktijkscenario's uit die werden gefilmd. Na het bekijken van iedere opname vond een nabespreking plaats, waarbij de TRM-principes aan de orde kwamen. Om de betrokkenheid van het hoger management en van de medewerkers bij de patiëntveiligheid te bevorderen, werden veiligheidsvisiterondes ('safety walk rounds') georganiseerd. Deze hielden in dat vertegenwoordigers van het ziekenhuis- en afdelingsmanagement (zowel het medisch als het verpleegkundig management) samen met de veiligheidsfunctionarissen van de kinder-IC de afdeling halfjaarlijks bezochten. Tijdens dit bezoek konden de deelnemers en de medewerkers, evenals de ouders van de kinderen op de afdeling, incidenten en situaties benoemen die zij als risicovol ervoeren.

Incidenten, complicaties en protocollair werken

Het 'Vrijwillig incidentmeldingssysteem' (of 'Veilig incidentmeldingssysteem') is een alom gebruikt instrument om potentiële risico's op te sporen en gericht interventies te ontwikkelen om fouten en incidenten te voorkomen. De bereidheid om fouten te melden, wordt negatief beïnvloed door angst voor represailles, het ontbreken van feedback over ondernomen acties en door de hoeveelheid tijd die met een melding gemoeid is. [5,6] Voor het melden van (bijna-)incidenten werd een eigen formulier ontwikkeld, in overleg met een klankbordgroep bestaande uit vertegenwoordigers van verschillende disciplines werkzaam op de ic-afdeling, zoals van de apotheek en het laboratorium. Het hoe en waarom van het melden van incidenten werd in voorlichtingsbijeenkomsten aan alle medewerkers uitgelegd. De definitie van 'incident' is: 'onbedoelde gebeurtenis in het zorgproces die tot schade voor de patiënt heeft geleid dan wel had kunnen leiden', maar de medewerkers werd gevraagd 'alles te melden wat niet ging zoals de bedoeling was'. Er werd een brainstormgroep van een tiental verpleegkundigen in het leven geroepen om een breed draagvlak voor het melden te creëren. Terugkoppeling aan de medewerkers vond plaats via het maandelijkse 'Safety First journaal', waarin de 5 meest voorkomende meldingen van de afgelopen maand worden beschreven, maar ook door het doorvoeren van verbeteringen door middel van interventies. Twee leden van de 'Safety First'-projectgroep (een verpleegkundige Kwaliteit en een stafarts) beoordeelden wekelijks de meldingen. Dit gebeurde aan de hand van een risicomatrix om zodoende zowel de potentiële als de feitelijke ernst van het (bijna-)incident te beoordelen en de kans op herhaling ervan in te schatten. De uitkomst van deze beoordeling bepaalde vervolgens of nadere analyse van het incident zou plaatsvinden. De 'Critical nursing situation'-index (CNSI) werd geïntroduceerd als indicator voor het al dan niet protocollair werken door verpleegkundigen. Een 'critical nursing situation' is een observeerbare situatie die afwijkt van geprotocolleerde zorg en die kan leiden tot een incident of complicatie. [7] Inzicht in het aantal en het soort situaties waarbij er niet volgens protocol gewerkt wordt, kan richting geven aan verbeteringen, zoals het aanpassen van protocollen of het geven van scholing. In de zomer van 2004 werden alle verpleegkundige protocollen geactualiseerd en bekwaamden 10 verpleegkundigen (vrijwilligers) zich in het scoren van de index. Om de betrouwbaarheid van de waarnemingen vast te stellen, werd de overeenstemming tussen de beoordelaars gemeten.
Deze was voldoende (kappa = 0,69), waarna in 2005 het gebruik van de CNSI werd ingevoerd.

De scoorders verrichtten eenmaal per dienst een CNSI bij een willekeurig gekozen patiënt. Complicatieregistratie dient, behalve als kwaliteitsindicator voor ziekenhuizen op gezag van de Inspectie voor de Gezondheidszorg, ook voor risico-inventarisatie. De definitie van 'complicatie' zoals deze door de Orde van Medisch Specialisten en de Inspectie gehanteerd wordt, luidt: 'Een onbedoelde en ongewenste gebeurtenis of toestand, tijdens of volgend op medisch-specialistisch handelen, die voor de patiënt zodanig nadelig is dat aanpassing van het medisch (be)handelen noodzakelijk is, dan wel dat er sprake is van onherstelbare schade.' Na deelname aan 2 pilotstudies naar de bruikbaarheid van de complicatieregistratie [8] werd daadwerkelijk gestart met registreren. De complicaties werden geclassificeerd in verschillende assen met bijbehorende codering, zoals eerder door Marang-van de Mheen in dit Tijdschrift beschreven. [9] Sinds 1 januari 2007 werden tweewekelijks zogenaamde mortaliteit-, morbiditeit- en veiligheidsbesprekingen gehouden in multidisciplinair verband. Naar aanleiding van overlijdensgevallen, complicaties of andere ernstige (bijna-)incidenten die zich voordeden, werden beheers- en verbetermaatregelen voorgesteld. Voorbeelden hiervan zijn richtlijnen die werden opgesteld voor de preventie van trombose, voor sedatiebeleid en voor het fixeren van maagsondes, diepe veneuze lijnen en endotracheale tubes op uniforme wijze.

Analyses

(Bijna-)incidenten die matig of ernstig letsel hadden kunnen veroorzaken, werden geanalyseerd met behulp van de 'Prevention and recovery information system for monitoring and analysis'(PRISMA)-methode. Hierbij wordt een oorzakenboom opgesteld, zodat men tot de basisoorzaken komt. Deze zijn in te delen in menselijke, technologische en organisatorische factoren. [10] Bij een ernstig incident werd een 'Systematische incident reconstructie en evaluatie'(SIRE)-analyse verricht. [11] Bij deze methode wordt niet alleen naar oorzaken gezocht, maar vooral ook naar mogelijke maatregelen die het incident hadden kunnen voorkomen; drempels die in het systeem ingebouwd moeten worden ter preventie van incidenten. De aanbevelingen die voortkwamen uit deze analyses werden maandelijks besproken met de medische en de verpleegkundige staf. Prospectieve analyses van de risico's – dus niet analyses naar aanleiding van bijvoorbeeld een incidentmelding – werden uitgevoerd met behulp van de 'Healthcare failure mode effect analysis' (HFMEA;www.va.gov/NCPS/SafetyTopics.html). Hierbij wordt preventief gezocht naar mogelijke oorzaken van het falen van processen. Vervolgens wordt bepaald waar drempels opgeworpen kunnen worden die de kans op fouten verkleinen, en daarop worden gerichte interventies ontwikkeld.

Resultaten

Informatie uit bovenstaande bronnen werd gebruikt om gerichte interventies te ontwikkelen en uit te voeren. Door continu alle binnenkomende informatie te verwerken, konden aanpassingen gedaan worden, zowel in het beleid voor de patiëntenzorg als in het veiligheidsbeleid.

Training

De onderwerpen van de TRM-training werden door een multidisciplinaire werkgroep in de praktijk gebracht op de afdeling en verschenen als screensavers op de computerterminals op de afdeling. Waar nodig werden maatregelen ter verbetering geïntroduceerd.

Chapter 15

Voorbeelden hiervan zijn: het elkaar aanspreken op onvoldoende handhygiëne, het verminderen van geluidsoverlast en het nabespreken van ernstige incidenten of acute situaties met de betrokkenen. Incidenten, complicaties en protocollair werken. Van 1 januari 2005 - 31 december 2007 werden 4512 (bijna-)incidenten gerapporteerd, een gemiddelde van 125 per maand. De 5 frequentste meldingen staan in tabel 1 beschreven. Meldingen met betrekking tot medicatie kwamen het meest voor (31% van alle meldingen), zoals de toediening van een verkeerde dosis of een onjuiste infuusstand.

Tabel 1 De 5 meest voorkomende incidenten in de periode 2005-2007

aard incident	n (%)							
	2005 (n=1600)		2006 (n=1796)		2007 (n=1116)		2005-2007 (n=4512)	
medicatiefout	512	32%	557	31%	340	30%	1409	31%
fout PDMS	339	21%	338	19%	198	18%	875	19%
probleem lijnen, katheters, tubes	195	12%	279	16%	155	14%	629	14%
probleem apparatuur	192	12%	169	9%	112	10%	473	10%
fysieke omgeving*	144	9%	115	6%	55	5%	314	7%

* onder "fysieke omgeving" werd een scala aan incidentmeldingen verstaan, bijvoorbeeld het ontbreken van verpleegartikelen bij de bedplaats, het niet omhoog staan van de bedhekken, of het in bed aan treffen van infuusdopjes.
PDMS: patient data management system

In het eerste volledige jaar dat de CNSI gebruikt werd (2006), werd de CNSI bij 247 patiënten bepaald. Er werd 1232 keer niet volgens een verpleegkundig protocol gewerkt, wat neerkomt op een gemiddelde van 5 maal per patiënt per dag. De 5 handelingen die het vaakst niet volgens protocol verricht werden, waren: plaatsing of verschoning van centrale lijnen of infuussystemen, plaatsing of verschoning van maag- of duodenumsondes, mondverzorging, het invullen van het transfusieformulier, en het instellen van de beademing of het maken van afspraken hierover.
Van 1 december 2005 - 28 februari 2006 werden 120 complicaties geregistreerd bij 46 van de 181 opgenomen patiënten. Dit houdt in dat een kwart van de opgenomen patiënten 1 of meer complicaties opliep; anders gezegd ging het om 8 complicaties per 100 verpleegdagen. De 5 meest vóórkomende complicaties waren: medicatiefouten, hypoxie (voornamelijk bij accidentele extubatie), sepsis (vooral bij aanwezigheid van een centrale lijn), problemen met een centraal-veneuze of arteriële lijn en atelectase. Uit tabel 2 wordt duidelijk dat er verband bestaat tussen de resultaten van deze 3 onderdelen van het veiligheidsmanagementsysteem. Zo is te zien dat zorgprocessen waarbij medicatie, beademing, intraveneuze en intraarteriële lijnen, beademingstubes of katheters, en apparatuur een rol spelen, een hoog veiligheidsrisico hebben.

Tabel 2 de top 5 van meest vóórkomende meldingen per onderdeel van het veiligheidsmanagementsysteem

Top 5	complicatieregistratie	incidentmeldingen	afwijkingen van protocol (CNSI)
1	medicatiefout	medicatiefout	aanleggen of hantering van lijnen
2	hypoxie	fout PDMS	inbrengen of verzorgen van sondes
3	sepsis	probleem met lijnen, katheters, tubes	mondverzorging
4	probleem met veneuze of arteriële lijn	probleem met apparatuur	invullen transfusieformulier
5	atelectase	fysieke omgeving	afspraken over, of instellingen beademing

* onder "fysieke omgeving" werd een scala aan incidentmeldingen verstaan, bijvoorbeeld het ontbreken van verpleegartikelen bij de bedplaats, het niet omhoog staan van de bedhekken, of het in bed aan treffen van infuusdopjes.
PDMS: patient data management systeem

Analyses
In 2005 en 2006 werden 157 PRISMA-analyses verricht, waarbij 464 basisoorzaken benoemd konden worden. In tabel 3 is de onderverdeling van de basisoorzaken in de verschillende categorieën weergegeven. Menselijke factoren speelden een belangrijke rol bij de meeste incidenten, maar ook werden veel technische en organisatorische basisoorzaken gevonden. Sinds de zomer van 2006 werden 8 SIRE-analyses verricht, die gemiddeld 14 manuren in beslag namen. De aanbevelingen hieruit betroffen technische aspecten, zoals het aanpassen van het elektronisch medicatievoorschrijfsysteem, en menselijke factoren, zoals afspraken over supervisie. In 2006 werd een prospectieve HFMEA-analyse verricht van de orale toediening van clonidine. Deze analyse kostte 30 manuren. Hierna konden 8 verschillende aanbevelingen gedaan worden om 13 risicovolle processtappen te verbeteren.
Succes- en faalfactoren
Meerdere factoren droegen bij tot het slagen van de verschillende onderdelen van het veiligheidsmanagementsysteem, zoals een klimaat van openheid en veiligheid, het geven van feedback, een breed draagvlak voor de implementatie, teamtraining, steun van het (hoger) management en het aanhoudend onder de aandacht brengen van de patiëntveiligheid. Andere factoren hadden een vertragende werking op de ontwikkeling van het systeem, zoals vooral de traagheid van de cultuurverandering en onderrapportage.

Beschouwing

Het project 'Safety First' ging van start als een systeem voor het vrijwillig melden van incidenten. Door dit te integreren met het evalueren van protocollair werken, de door ons gevalideerde complicatieregistratie en met de bewustwording van groepsprocessen door TRM-training, is het uitgegroeid tot een volledig patiëntveiligheidsmanagementsysteem overeenkomstig de norm zoals die is geformuleerd in de Nederlandse Technische Afspraak 8009:2007.

Chapter 15

Het vrijwillig melden van (bijna-) incidenten is goed ontvangen en blijkt inmiddels verankerd te zijn in de cultuur van de afdeling. De meldingen worden daadwerkelijk gebruikt om verbeteringen te bewerkstelligen, maar het aantal meldingen blijft constant. We vermoeden dat er overrapportage is van onschuldige incidenten en onderrapportage van ernstige incidenten. Capuzzo et al. beschreven al dat er een verschil bestaat tussen het aantal en het soort incidenten dat door medewerkers gemeld wordt en het aantal en het soort incidenten dat door onafhankelijke waarnemers worden gesignaleerd. [12] Er is gelukkig een toename van het aantal meldingen door artsen, waarschijnlijk door de aanhoudende aandacht voor patiëntveiligheid en door het voorbeeldgedrag van stafleden. Analyse van gerapporteerde incidenten (PRISMA- danwel SIRE-analyse) blijkt een tijdrovende, maar zeer waardevolle bezigheid. Het verdient de voorkeur een PRISMA-analyse kort na de melding te verrichten, zodat de betrokkenen zich nog zoveel mogelijk details kunnen herinneren. Zij en hun collega's zien dat er actie wordt ondernomen en dat de bedoeling nadrukkelijk is om te leren van de voorgevallen incidenten. Ook bij het registreren van complicaties is er onderrapportage. In de praktijk blijkt het aantal gemelde complicaties nauw samen te hangen met de aandacht die de superviserende intensivist of fellow aan het melden besteedt. Er blijkt een neiging om alleen de ernstigste complicaties te melden, alsmede die waarbij er een fout in het zorgproces is opgetreden. Daarnaast werd door artsen 'registratiemoeheid' als reden voor niet registreren genoemd. Het niet melden van incidenten en complicaties hangt samen met het ontbreken van feedback en van een 'veilige' cultuur, en met angst voor repercussies. Een eenvoudig en toegankelijk meldinstrument en doeltreffende educatie over de zin van het melden van incidenten en complicaties maakt de meldingsbereidheid groter. [1,13] Zoals te verwachten, blijkt het doorvoeren van technische en organisatorische verbeteringen minder moeilijk dan het aanpakken van menselijke factoren. Onze overtuiging is dat juist hier teamtraining een belangrijke rol kan spelen, omdat daarin aspecten zoals communicatie, groepsdynamiek en stressmanagement aan de orde komen. Ook een systeem voor het melden van (bijna-)incidenten kan een belangrijke bijdrage leveren aan cultuurverandering. Hierbij hoort uiteraard een analyse naar oorzakelijke factoren. In een functionerend veiligheidsmanagementsysteem hoort een meetinstrument voor de uitkomst van de zorg, zoals complicatieregistratie of een andere prestatie-indicator, zodat gecontroleerd kan worden of de verbeteringen ook werkelijk effectief zijn. Gezien de relatief korte looptijd van het 'Safety First'-project, konden we echter nog niet aantonen of het veiligheidsmanagementsysteem leidt tot een betere kwaliteit van zorg.

Conclusie

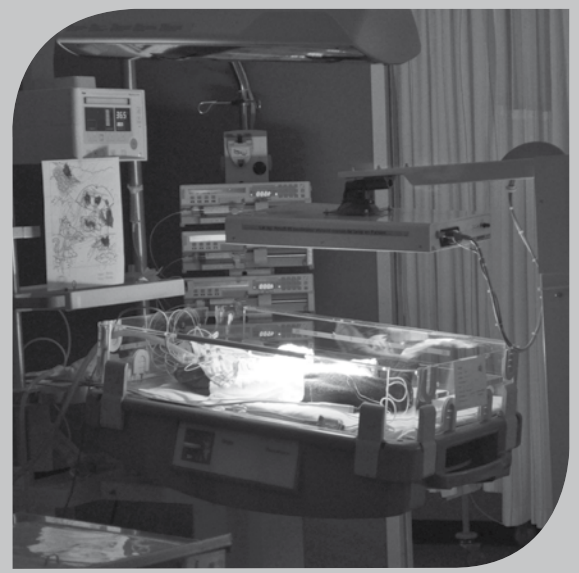
Het blijkt goed mogelijk een veiligheidsmanagementsysteem te implementeren en de professionele verantwoordelijkheid hiervoor te dragen. [14] De basiselementen van de Nederlandse Technische Afspraak 8009:2007 blijken goed kwantificeerbaar, zodat ook gerichte maatregelen en de resultaten hiervan in maat en getal kunnen worden uitgedrukt. Cultuurverandering, dat wil zeggen een klimaat van openheid en veiligheid creëren, is een belangrijke voorwaarde voor het slagen van de implementatie. Hierbij dient de klinische staf, samen met het hogere management – tot aan de raad van bestuur –, een voorbeeldfunctie te vervullen in het omgaan met incidenten, fouten en complicaties.

Referenties

1. Wagner C, de Bruijne M. Onbedoelde schade in Nederlandse ziekenhuizen: EMGO Instituut en NIVEL; 2007 Contract No.: Document Number|.
2. Nederlandse Technische Afspraak 8009. Veiligheidsmanagementsysteem voor ziekenhuizen en instellingen die zorg verlenen.: NEN; 2007 Contract No.: Document Number|.
3. Hanekamp MN, Mazer P, van der Cammen-van Zijp MH, et al. [Neurological defects and developmental disorders following neonatal extracorporeal membrane oxygenation: results of a follow-up study after 5 years]. Ned Tijdschr Geneeskd. 2008;152(4):207-212
4. Billings CE, Reynard WD. Human factors in aircraft incidents: results of a 7-year study. Aviat Space Environ Med. 1984;55(10):960-965
5. Harris CB, Krauss MJ, Coopersmith CM, et al. Patient safety event reporting in critical care: a study of three intensive care units. Crit Care Med. 2007;35(4):1068-1076
6. Pronovost PJ, Thompson DA, Holzmueller CG, et al. Toward learning from patient safety reporting systems. J Crit Care. 2006;21(4):305-315
7. Binnekade JM, de Mol BA, Kesecioglu J, et al. The Critical Nursing Situation Index for safety assessment in intensive care. Intensive Care Med. 2001;27(6):1022-1028
8. van den Beuken MGA, Schulpen TWJ, Te Pas E, et al. Complicatieregistratie in de kindergeneeskundige praktijk. Tijdschr Kindergeneeskd. 2006;74(3):106-113
9. Marang-van de Mheen PJ, Kievit J. [Automated registration of adverse events in surgical patients in the Netherlands: the current status]
   Geautomatiseerde registratie van complicaties door heelkundige afdelingen in Nederland: huidige stand van zaken. Ned Tijdschr Geneeskd. 2003;147(26):1273-1277
10. Kaplan HS, Battles JB, Van der Schaaf TW, et al. Identification and classification of the causes of events in transfusion medicine. Transfusion. 1998;38(11-12):1071-1081
11. Leistikow IP, den Ridder K. Patientveiligheid; systematische incident reconstructie en evaluatie. Maarssen: Elsevier gezondheidszorg; 2005.
12. Capuzzo M, Nawfal I, Campi M, et al. Reporting of unintended events in an intensive care unit: comparison between staff and observer. BMC Emerg Med. 2005;5(1):3
13. Leape LL. Reporting of adverse events. N Engl J Med. 2002;347(20):1633-1638
14. Stephenson T. Improving patient safety in paediatrics and child health. Arch Dis Child. 2008;93(8):650-653

Part 6

Appendices



CHAPTER 16

Ervaringen met simulatietraining op een Kinder-IC

Van den Bos-Boon A, van der Starre C, Houmes RJ, Gischler S, Tibboel D, van Dijk M. Ervaringen met simulatie-training op een Kinder-IC. Tijdschrift Kinderverpleegkunde. 2010; 16(2):22-25

SIMULATIETRAINING OP EEN KINDER-IC: LEREN VAN DE LUCHTVAART

Eén van de belangrijkste aspecten van een veiligheidscultuur, is teams te leren samenwerken. In de luchtvaart is hiervoor de Crew Resource Management (CRM) Training ontwikkeld. Op de IC Kinderen van het Erasmus MC-Sophia is deze training in grote lijnen overgenomen. De principes die men leert, worden daarna in een simulatiesetting praktisch getraind door middel van teamscenario's.

Een van de voorvechters van patiëntveiligheid, Lucian Leape, beschrijft dat een veiligheidscultuur ontstaat door zes belangrijke veranderingen:
- Bewustwording dat menselijke fouten gemaakt worden omdat het systeem het toelaat.
- Menselijke fouten niet bestraffen maar ervan leren.
- Fouten zichtbaar maken, zodat men kan zorgen dat deze niet weer gebeuren en dat anderen ervan kunnen leren.
- De patiënt centraal stellen, niet de hulpverlener.
- Teams creëren die geleerd hebben hoe men met elkaar samenwerkt.
- En ten slotte: alle niveaus verantwoordelijk maken voor veiligheid.

Effectief teamwerk is echter een essentiële voorwaarde om dit te bereiken, en daarvoor is Crew Resource Management (CRM) zeer geschikt. Tevens is het al bewezen dat volwassenen beter leren van ervaring en oefening dan van leerboeken of hoorcolleges. CRM komt voort uit de luchtvaart, waar slechte communicatie de oorzaak bleek van zeventig procent van de ongevallen. CRM training richt zich op het verbeteren van de communicatie en het teamwerk. In ziekenhuizen wordt ook nauw samengewerkt in teams, bijvoorbeeld op afdelingen Spoedeisende hulp en Intensive Care. De risico's hier zijn vergelijkbaar met die in de luchtvaart. Een manier om de CRM basisprincipes praktisch te trainen, is simulatietraining met gebruikmaking van een pop of een computermodel . Als de setting zeer realistisch is spreekt men van 'high fidelity' simulatietraining. Deze vorm is kostbaarder dan de 'low fidelity' variant. Een simulatietraining kan in een speciaal simulatiecentrum (bijvoorbeeld Veldhoven en Groningen) uitgevoerd worden. Een nadeel hiervan is dat dit het team veel reistijd kost en de setting anders is dan in de praktijk. De laatste jaren is er een trend om de simulatietraining dicht bij de afdeling uit te voeren. Dat is goedkoper en praktischer. Daarnaast benadert dit de echte setting zoveel mogelijk.

Functioneren als team

Sinds 2005 past de IC Kinderen van het Erasmus MC-Sophia een vorm van CRM toe voor de verpleegkundigen en artsen. De CRM training en simulatietraining zijn onderdelen van het Patiënt Veiligheid Management Systeem op de IC Kinderen. De tweedaagse CRM training behandelt een zevental onderwerpen:
1. Informatiemanagement: de focus ligt op het creëren van situational awareness van het team. Situational awareness houdt in dat alle betrokkenen een bepaalde situatie op dezelfde manier bekijken en interpreteren. Voor het optimaal functioneren als team is het dus belangrijk kennis te hebben van informatieverwerking.
2. Communicatie: wat kan er misgaan in de communicatie en wat is effectieve communicatie in teamverband?
3. Stressmanagement: gaat in op de (positieve en negatieve) invloeden van stress op het functioneren en hoe hiermee om te gaan.
4. Groepsprocessen: met nadruk op groepscohesie en groepsdenken, evenals de gevaren van groepsdenken en hoe dit te voorkomen.
5. Effectief leiderschap en volgerschap: Wat heb je nodig om een effectieve leider te zijn en wat zorgt ervoor dat er goed volgerschap is?
6. Besluitvorming: gaat in op het nemen van besluiten onder stress en het belang van het vasthouden aan genomen besluiten.
7. Risicomanagement: betreft het monitoren van de risico's waarmee de afdeling te maken heeft.

Deze onderwerpen worden vervolgens in teamverband getraind binnen een simulatiesetting aan de hand van zogenaamde teamscenario's.

Methoden

Setting

De IC Kinderen bestaat uit vier units met in totaal 28 bedden. Gemiddeld worden per jaar ongeveer 1300 kinderen tussen de nul en achttien jaar opgenomen, inclusief pasgeborenen met ernstige aangeboren afwijkingen. Er werken elf kinderartsen/intensivisten, vijf fellows, veertien arts-assistenten, 120 verpleegkundigen en twintig zorgassistenten. Speciale aandachtsgebieden zijn: neonatale chirurgie, extracorporele membraanoxygenatie (ECMO), cardiologische patiënten, patiënten met noodzaak tot neuromonitoring, en algemene IC patiënten.

Patiëntveiligheidsmanagementsysteem

Het melden van incidenten was een van de eerste onderdelen van ons patiëntveiligheids-managementsysteem.Vanaf 2003 zijn maandelijks ongeveer 150 (bijna-) incidenten gemeld. Deze worden vervolgens geanalyseerd met als doel zowel ad hoc als structurele verbeteringen in te kunnen zetten. Daarna zijn er een aantal onderdelen toegevoegd om de risico's van de afdeling nog beter in kaart te brengen (zie figuur 1).

Simulatietraining

Een groep van zeven verpleegkundigen en drie artsen heeft in 2007 een train-the-trainer-cursus gevolgd bij het Center of Advanced Pediatric Education aan de Stanford University in Los Angeles (www.cape.lpch.org). Hier hebben zij geleerd om teamscenario's te schrijven voor kindergeneeskundige intensive care casuïstiek. Het streven was om iedereen op de IC Kinderen twee keer per jaar een eendaagse simulatietraining te laten volgen. Aan een simulatietrainingsdag nemen negen tot twaalf medewerkers deel, verdeeld in drie groepen, elk onder leiding van twee trainers. In elke groep zijn minimaal drie verpleegkundigen ingedeeld; indien een scenario de aanwezigheid van een dokter vereist, kan men deze oproepen. Tevens wordt op een simulatietrainingsdag onderwijs gegeven in twee andere onderwerpen; de groepen rouleren gedurende de dag en zo volgt elke groep.
ook de simulatietraining. Deze andere onderwerpen staan los van de simulatietrainingen. Tijdens de twee uur durende simulatietraining worden drie teamscenario's gespeeld. Als introductie wordt uitgelegd wat er wel en niet kan in de trainingsruimte, hoe de simulatiepoppen werken, en wat

de regels en afspraken over het scenario zijn. De huidskleur (grauw, bleek of rood) of de lichaamstemperatuur van de pop zijn niet te simuleren en daar moet men desgewenst naar vragen. Vervolgens ontvangt de verpleegkundige die geacht wordt voor 'de patiënt' te zorgen een briefing over de gesimuleerde patiënt. De rest van het team wacht dan in een andere ruimte. Het scenario begint met de verpleegkundige die 'de dienst' start zoals gebruikelijk op de werkvloer. Afspraken controleren over beademing of infusen, controle van materiaal rondom de patiënt, etc. Intussen simuleren de trainers een incident, bijvoorbeeld huilen vanwege pijn, een snelle hartactie of een lager wordende bloeddruk bij shock na een bloeding. De verpleegkundige kan een arts bellen (die op afdeling werkzaam is, maar wel naar de training toe kan komen) of een andere verpleegkundige vragen mee te helpen en te denken. Een bepaald scenario wordt gestopt na vijftien à twintig minuten, als de van tevoren bepaalde leerpunten (vaardigheden, kennis en teamwerk) zijn gehaald. Elk scenario wordt gefilmd en teruggekeken. Dit maakt het gemakkelijk de leerpunten te bespreken tijdens de afsluitende debriefing. Hierin evalueren de deelnemers onder begeleiding van de trainers wat er goed of fout ging, welke inzichten men heeft gekregen en wat men de volgende keer anders zou doen.

Evaluatie en analyse

Om de training te kunnen beoordelen en te verbeteren, is een vragenlijst ontwikkeld. Afgezien van achtergrondgegevens zoals beroepsgroep, leeftijdscategorie en aantal jaren ervaring, worden acht vragen gesteld over de inhoud van het scenario. Voorts wordt gevraagd te reageren op acht stellingen over de simulatietraining, op een 5-punts Likert schaal van 'geheel mee eens' tot 'geheel niet mee eens'. Daarnaast wordt een rapportcijfer gevraagd over de kwaliteit van de communicatie tijdens de simulatietraining. Gegevens die normaal verdeeld zijn, worden weergegeven als gemiddelde en standaarddeviatie, niet normaal verdeelde variabelen als mediaan en interkwartiel range. Verschillen in frequenties tussen artsen en verpleegkundigen werden getoetst met de Chi-kwadraat toets.

Resultaten

Er zijn 272 enquêtes ingevuld over tien scenariodagen in de periode november 2008 tot en met mei 2009. Bijna driekwart (72,4 procent) werd door verpleegkundigen ingevuld en ruim een kwart (27,6 procent) door artsen. Binnen de verpleegkundige groep was 29 procent High Care verpleegkundige en 71 procent IC verpleegkundige. Bijna de helft van de artsen was man tegenover tien procent van de verpleegkundigen. 29 procent van de artsen was dertig jaar of jonger tegenover negen procent van de verpleegkundigen. Het merendeel van de verpleegkundigen (83 procent) was tussen de 31 en 50 jaar, het merendeel van de artsen (93.5procent) tussen de 20 en 40 jaar. De gemiddelde ervaring in
de gezondheidszorg van de verpleegkundigen was twintig jaar (SD 8) en van de artsen zeven jaar (SD 4). In totaal werden elf verschillende scenario's gespeeld, met onder andere de onderwerpen ventrikel fibrilleren, gastroschisis, necrotiserende enterocolitis, stomp buiktrauma, near drowning en supraventriculaire tachycardie.

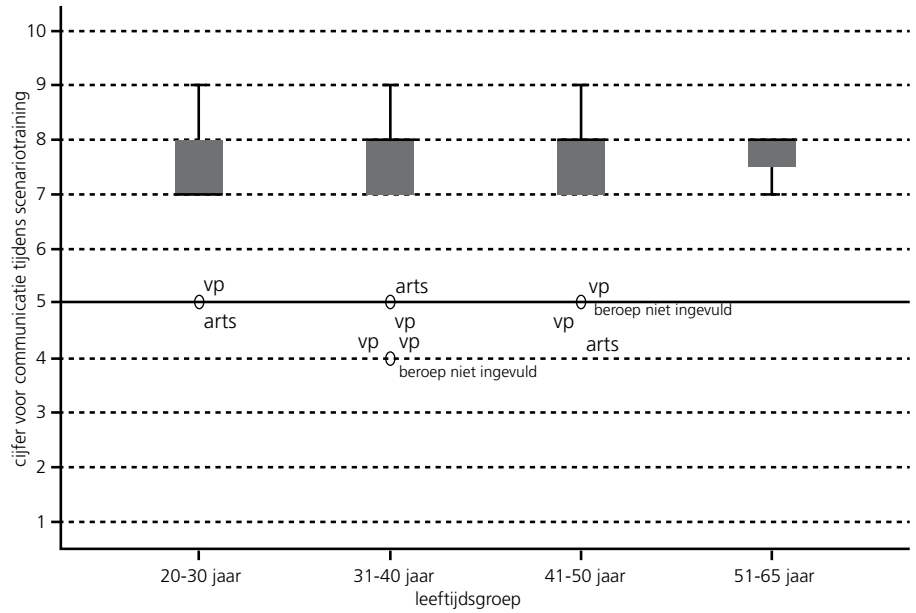
De respondenten moesten aangeven of ze:

1. de informatie over de training van tevoren per email voldoende vonden;
2. of ze voldoende tijd hadden om de scenarioruimte te bekijken;

3. of de briefing over de patiënt voldoende was.

Het bleek dat 63 procent van de artsen een of meer van deze aspecten onvoldoende vond tegenover vijftien procent van de verpleegkundigen. Dit verschil was statistisch significant (Chi-kwadraat toets, p< 0.001). Dit verschil is te verklaren omdat de artsen niet tijdens de briefing aanwezig waren, maar tijdens het scenario konden worden opgeroepen. Het merendeel van de respondenten vond de scenariosetting overeenkomen met de praktijk (85 procent). Respondenten werd gevraagd een rapportcijfer te geven voor de communicatie tijdens de scenariotraining. 43 respondenten vulden deze vraag niet in. Dertien van de overige 229 respondenten (7,4 procent), vonden de communicatie onvoldoende. Figuur 1 laat zien dat het rapportcijfer niet significant verschillend is voor de verschillende leeftijdsgroepen (p=0,50).

Figuur 1



Tijdens het spelen van het scenario voelde 98 procent van de respondenten zich veilig, en 83 procent van de respondenten voelde zich niet geremd. Op de stelling 'Ik voelde me zeker in mijn handelen' tijdens het scenario reageerde 55 procent van de respondenten positief, 28 procent neutraal, en 17 procent negatief. Zes respondenten (2 procent) voelden zich niet veilig, maar geremd en onzeker. Bij twee was dit het geval in het scenario over gastroschisis, bij twee in het scenario over stomp buiktrauma, bij een ritmestoornis en bij een in het necrotiserende enterocolitisscenario. Deze zes respondenten waren op vier verschillende dagen aanwezig en vier van hen hadden hun achtergrondgegevens niet ingevuld. 94 procent van de respondenten vond dat er tijdens de debriefing voldoende aandacht was voor de punten die goed gingen, vier procent regeerde neutraal op de betreffende stelling, en twee procent van de respondenten was het oneens. 93 van de respondenten was het niet eens met de stelling: Ik kon tijdens de debriefing NIET alles zeggen wat

ik zou willen. Slechts drie procent van de respondenten was het eens met deze stelling. De overigen reageerden neutraal. Slechts twee procent van de respondenten was het eens met de stelling: Ik vond het moeilijk om feedback te geven, negen procent reageerde neutraal, en 89 procent vond het niet moeilijk om feedback te geven. Ook werd gevraagd of de simulatietraining effect had op de kwaliteit van zorg door 1) het oefenen in communicatie; 2) het opdoen van nieuwe kennis; en 3) door meer zekerheid in de praktijk als men in de situatie van het scenario zou terechtkomen. Dit werd beaamd door respectievelijk 85 procent, 84 procent en 79 procent van de respondenten. Tabel 1 geeft een overzicht van de percentages artsen en verpleegkundigen die het helemaal eens of eens waren met de stellingen. Dit betreft ongeveer tachtig procent van de respondenten, aangezien 47 respondenten geen beroep hebben ingevuld en in een enkel geval items niet werden ingevuld. De tabel onderschrijft dat artsen minder goed voorbereid waren op de scenariotraining.

Tabel 1 Samenvatting van de resultaten uitgesplitst voor artsen en verpleegkundigen

	Artsen[1]	VP[1]
	%	%
Genoeg tijd om scenarioruimte te verkennen	**45**	**95**
De informatie over de training via de email was voldoende	**24**	**77**
De briefing van de patiënt was voldoende	**76**	**91**
De scenariosetting kwam overeen met de praktijk	93	84
Ik voelde me geremd tijdens het scenario omdat ik het gevoel had bekeken of beoordeeld te worden	16	17
Ik kon tijdens de debriefing NIET alles zeggen wat ik zou willen	5	2
tijdens de debriefing was er voldoende aandacht voor de punten die goed gingen	92	93
Ik vond het moeilijk om feedback te geven	-	3
Dit scenario heeft invloed op kwaliteit van zorg omdat:		
Ik kon oefenen in communicatie	86	85
Nieuwe kennis heb opgedaan	80	86
Zekerder ben wanneer ik in de praktijk in deze situatie terechtkom	91	81

[1]percentages van resp. artsen en verpleegkundigen die het met de stelling helemaal eens of eens waren.

Discussie

Uit de vragenlijst blijkt dat het merendeel van de respondenten zich veilig genoeg voelt om door middel van teamscenario training ervaring op te doen in onder andere teamvaardigheden. Deze bevindingen zijn vergelijkbaar met die van buitenlandse studies. Het lijkt erop dat meer High Care verpleegkundigen zich zeker voelen in deze scenariosetting dan Intensive Care verpleegkundigen. Een mogelijke verklaring hiervoor is dat de High Care verpleegkundige altijd eerst nog om hulp kan vragen bij de IC-verpleegkundigen. Het is lastig om het effect van teamscenario training te meten. Een review uit 2008 beschreef slechts één gerandomiseerde studie waarin artsen zonder en met simulatie training om chirurgische ingrepen te oefenen werden vergeleken.
De deelnemers die simulatietraining hadden gekregen functioneerden inderdaad beter. Het is echter

de vraag of simulatietraining ook voor andere, niet-chirurgische vaardigheden de meest effectieve training is. In een editorial uit 2009 noemt Ventre ook de grote verschillen tussen simulatietrainingen op het gebied van feedback geven, mogelijkheden tot herhaaldelijk oefenen en integratie in het gehele curriculum. Omdat simulatietraining meer en meer wordt toegepast, is het belangrijk om de effectiviteit te meten volgens een gestandaardiseerde methode. Twee procent van de deelnemers voelde zich niet veilig tijdens de training. Bij de artsen trad dit voornamelijk op indien men opgeroepen was om mee te draaien in het teamscenario en ze niet wisten dat het gefilmd en nabesproken werd. Voor de artsen was het daarnaast soms lastig dat ze onvoorbereid de simulatietraining ingingen. Zij kregen tevoren namelijk geen informatie over deze dag.

Dit punt is verbeterd. 's Morgens tijdens de overdracht worden de simulatiepatiënten ook overgedragen zodat een ieder weet dat het mogelijk is hiervoor gebeld te worden. Verpleegkundigen die aangaven moeite te hebben met deze vorm van trainen, werden gecoacht door een maatschappelijk werker of psycholoog. Op deze manier kunnen we achterhalen waarom men zich niet veilig voelde en wat daaraan gedaan zou kunnen worden. Een beperking van onze studie is dat er gekeken is naar ervaringen van deelnemers, maar effecten op dagelijkse zorg zijn vooralsnog moeilijk of niet te meten.

Conclusie

Simulatietraining is een goede manier om teams te leren samenwerken, te oefenen in communicatie en kennis te delen. Daarbij is het filmen van de teamscenario's een onmisbaar onderwijsmiddel. Men leert ervan door de situatie met eigen ogen terug te zien.

Met dank aan de leden van het Sophia Simulatie Training Team voor hun enorme inzet.

LIST OF ABBREVIATIONS

abd/surg	abdominal/surgical
AE	adverse event
AER	Adverse event registration
AHRQ	Agency for Healthcare Research and Quality
BD	brain death
card	cardiac/circulatory
CDH	Congenital diaphragmatic hernia
CIA	Critical incident analysis
CNSI	Critical Nursing Situation Index
CPAP	continuous positive airway pressure
CPOE	Computerized physician order entry
CPR	cardiopulmonary resuscitation
CRM	Crew Resource Management
CT	computer tomography
DNR	do not resuscitate
ECLS	Extracorporeal life support
ECMO	Extracorporealmembrane oxygenation
ED	emergency department
ET	endotracheal tube
FDA	Food and Drug Administration
FONA	faults or near accidents
GA	gestational age
Hb	Hemoglobin
HC	high care
HFMEA	Healthcare Failure Mode and Effect Analysis
ICU	intensive care unit
ICUSRS	Intensive Care Unit Safety Reporting System
IHI	Institute for Healthcare Improvement
IOM	Institute of Medicine
IQR	interquartile range
IV	Intravenous
LST	life sustaining treatment
M&M	Mortality and Morbidity
MAS	meconium aspiration syndrome
MCA	major congenital anomalies
MMS	Mortality, morbidity and safety
MRI	magnetic resonance imaging
N/A	not available
neur	Neurological
NICU	neonatal intensive care unit
PDMS	Patient Data Management System
PICU	pediatric intensive care unit
PRISM	Pediatric Risk of Mortality
PRISMA	Prevention and Recovery Information System for Monitoring and Analysis
PSICU	pediatric surgical intensive care unit
PSMS	Patient Safety Management System
PVMS	Patient Veiligheid Management Systeem
RCTs	randomized controlled trials
RES	failed resuscitation
resp	respiratory insufficiency
resusc	Resuscitation
Rx	Therapy
SAQ	safety Attitudes Questionnaire
SD	standard deviation
SSTT	Sophia Simulation Team Training
SWR	Safety Walk Rounds
TRM	Team Resource Management
TT	Trigger tool
VAS	Visual Analogue Scale
VLBW	very low birthweight

LIST OF PUBLICATIONS

International

Van der Starre C, Van der Tuijn Y, Tibboel D. Patient Safety Management System in Pediatric ICUs. In: Vincent JL, editor. Yearbook of Intensive Care and Emergency Medicine: Springer; 2006. p. 745-754.

Naghib S, **van der Starre C**, Gischler SJ, Joosten KF, Tibboel D. Mortality in very long-stay pediatric intensive care unit patients and incidence of withdrawal of treatment. Intensive Care Med. 2010 Jan;36(1):131-136.

Ceelie I, **van der Starre C**, Tibboel D, Stol K, Koren G, de Wildt SN. Evaluation of drug formularies for pediatric intensive care. Pediatr Crit Care Med. 2011 Jan;12(1):e14-19.

Poley MJ, **van der Starre C**, van den Bos A, van Dijk M, Tibboel D. Patient safety culture in a Dutch pediatric surgical intensive care unit: An evaluation using the Safety Attitudes Questionnaire. Pediatr Crit Care Med. 2011 May 12.

National

Van der Starre C, van den Bos-Boon A, van der Tuijn Y, Maas I, Molendijk AH, Offringa M, et al. Multidisciplinaire aanpak van patientveiligheid op de kinder-IC. Ned Tijdschr Geneeskd. 2009 Feb 21;153(8):334-339.

Van den Bos, van Dijk, **van der Starre**, Tibboel. Patiëntveiligheid op een Intensive care Kinderchirurgie. Best Practices Zorg – praktijkcases voor de manager in de zorg. 2008; 1(2): 8-13.

Van den Bos, **van der Starre**. Veilige zorg op de Kinder-IC. In: Karien den Ridder, Yvonne Tuitert, Yvonne van der Tuijn, Annelies van Bon. Patiëntveiligheid voor verpleegkundigen: Elsevier; 2010. p. 197-201.

Van den Bos-Boon A, **van der Starre C**, Houmes RJ, Gischler S, Tibboel D, van Dijk M. Ervaringen met simulatie-training op een Kinder-IC. Tijdschrift Kinderverpleegkunde. 2010; 16(2):22-25

As participants of the NEOSAFE study Group:

Snijders C, Kollen BJ, van Lingen RA, Fetter WP, Molendijk H, et al. Which aspects of safety culture predict incident reporting behavior in neonatal intensive care units? A multilevel analysis. Crit Care Med. 2009 Jan;37(1):61-67.

Snijders C, van der Schaaf TW, Klip H, van Lingen RA, Fetter WP, Molendijk A, et al. Feasibility and reliability of PRISMA-medical for specialty-based incident analysis. Qual Saf Health Care. 2009 Dec;18(6):486-491.

Snijders C, van Lingen RA, Klip H, Fetter WP, van der Schaaf TW, Molendijk HA, et al. Specialty-based, voluntary incident reporting in neonatal intensive care: description of 4846 incident reports. Arch Dis Child Fetal Neonatal Ed. 2009 May;94(3):F210-215.

Snijders C, van Lingen RA, van der Schaaf TW, Fetter WP, Molendijk HA, NEOSAFE Group. Incidents associated with mechanical ventilation and intravascular catheters in neonatal intensive care: exploration of the causes, severity and methods for prevention. Arch Dis Child Fetal Neonatal Ed. 2011 Mar;96(2):F121-126.

CURRICULUM VITAE

Cynthia van der Starre was born in Spijkenisse on September 29th, 1969. In 1987 she graduated from secondary school at the "Blaise Pascal" in Spijkenisse. She started her medical training in that same year at the Medical Faculty of the Erasmus University Rotterdam and in 1994 she received her medical degree. After working as a public health physician in Dordrecht and Gorinchem for one year, she started as a resident in 1995 at the Department of Pediatric Surgery of the Erasmus MC Sophia Children's Hospital in Rotterdam. In 1996 she transferred to the Department of Pediatrics in the same hospital and in 1998 started her traineeship at the Erasmus MC Sophia Children's Hospital (Prof. dr. B. van der Heijden) and the Zuiderziekenhuis in Rotterdam (Prof dr. R. Sukhai). After becoming a pediatrician in 2003, she started her fellowship (Prof dr. J. B. van Goudoever and dr. B. J. Smit) and became a neonatologist in 2005. Next she started working on the pediatric surgical ICU (Prof. dr. D. Tibboel) and the neonatal ICU in the Erasmus MC Sophia. In 2005 the work on patient safety and this thesis started. She completed the Patient Safety Officer Executive Development Program at the Institute for Healthcare Improvement (Boston, USA) in 2009 and since then is working as patient safety officer for the pediatric ICU.

PHD PORTFOLIO

Summary of PhD training and teaching

Name PhD student: Cynthia van der Starre Erasmus MC Department: IC Kinderen Research School:	PhD period: 2006-2011 Promotor(s): Prof. dr. D. Tibboel Supervisor: dr. M. van Dijk	
1. PhD training		
	Year	Workload (Hours/ECTS)
Specific courses (e.g. Research school, Medical Training) - Patient Safety Officer-executive development program, Institute for Healthcare Improvement, Boston, USA	2009	56 hours
Presentations - Kennis Beter Delen, Nieuwegein - Veiligheid in veelkleurigheid, Utrecht - Nederlandse Intensivisten dagen, Ede - 2e kwaliteitsforum CBO, Nieuwegein - Venticare, Utrecht - Een vak apart IV, Rotterdam - Leiderschap en professionaliteit, Rotterdam - Van ziekenhuis naar zorg, NIAZ conferentie, Utrecht - Jaarcongres NVK, Veldhoven - Neonatologie aan de Maas, Tegelen	 2006 2006 2007 2007 2008 2008 2009 2009 2010 2010	 12 hrs 8 hrs 8 hrs 8 hrs 8 hrs 8 hrs 8 hrs 8 hrs 8 hrs 12 ECTS
(Inter)national conferences - Patient Safety 2006 conference, Birmingham - European Academy of Paediatrics Congress, Barcelona - Jaarcongres NVK, Veldhoven - Symposium Patiëntveiligheid IGZ, Rotterdam - Zuigelingen met kanker en bloedziekten, Rotterdam - Pediatrische Farmacotherapie, Rotterdam - Hot topics in neonatology, Washington - Neonatologendag, Zwolle - Quality and Safety in Healthcare, Paris - 2008 PAS Annual Meeting, Honolulu - Risky Business conference, London - 25th International ISQUA conference, Kopenhagen - 2010 PAS Annual Meeting, Vancouver - Extreme prematuur, Rotterdam - 27th International ISQUA Conference, Parijs - Grote mensen huilen niet, Utrecht - Patiëveiligheid, hoe doen we dat? Rotterdam - International Forum Quality and Safety Healthcare, Amsterdam	 2006 2006 2006 2007 2007 2007 2007 2008 2008 2008 2008 2008 2010 2010 2010 2010 2010 2011	 12 hrs 32 hrs 8 hrs 8 hrs 5 ECTS 5 ECTS 24 hrs 5 ECTS 18 ECTS 20 ECTS 8 hrs 18 ECTS 20 ECTS 8 hrs 18 ECTS 8 hrs 8 hrs 20 hrs
2. Teaching		
	Year	Workload (Hours/ECTS)
Lecturing - PAOK Patiëntveiligheid, Rotterdam - Masterclass Patiëntveiligheid NVK, 5 x, Zeist - Team Resource Management basistraining, 10 x, Rotterdam - Team Resource Management vervolgtraining, 10 x, Rotterdam - Grand Round Patient Safety, Rotterdam - VMS conferentie Veilige zorg voor zieke kinderen, Utrecht - Medicatieveiligheid PAO Farmacie, Utrecht	 2006 2009-2011 2008-2011 2009-2010 2009 2011 2011	 10 hrs 44 hrs 180 hrs 90 hrs 8 hrs 10 hrs 8 hrs

DANKWOORD

Het is er! Het boekje met daarin de uitkomsten van jaren hard werken aan patiëntveiligheid en het resultaat van maanden keihard werken om het allemaal op te schrijven. Dit was nooit gelukt zonder de hulp van een heleboel mensen, waarvan ik er een aantal in het bijzonder wil bedanken.

Mijn promotor, Prof. dr. D. Tibboel.
Beste Dick, ik had nooit gedacht dat er ook maar iemand bestond die mij aan het promotie-onderzoek zou krijgen, maar jou is het gelukt. Ik weet nog goed dat je na het overleggen over een ECMO-kandidaat op de neonatologie vroeg of ik al besloten had wat mijn keuze zou worden: "Cynthia, met die patiëntveiligheid zit het zo: je bent gewoon de juiste vrouw op de juiste plek op de juiste tijd hiervoor!" En je had gelijk. Patiëntveiligheid is helemaal "mijn ding". Dank voor de kans die je me hiermee geboden hebt, voor je steun bij de ontwikkeling ervan, en vooral ook voor je vertrouwen. En niet te vergeten dank voor het hoge tempo waarin we de laatste fase afgerond hebben!

Mijn copromotor, dr. M. van Dijk.
Beste Monique, zonder jou was dit echt niet geworden wat het nu is, en zeker niet zo snel! Dank voor je onmisbare hulp met mijn digitale nachtmerries SPSS, Endnote, Word enzovoort. Maar vooral ook voor het meedenken over wat we nou eigenlijk gedaan hebben de laatste jaren en wat daar nou eigenlijk uit gekomen is, en wat we daar nou eigenlijk van vinden….

De leden van de kleine promotiecommissie: Prof. dr. J. Klein, Prof. dr. W.P.F. Fetter,
Prof. dr. J.B. van Goudoever.
Heren, hartelijk dank voor het snelle beoordelen van het manuscript en het zitting nemen in de kleine commissie. Beste Hans, wie had dat ooit gedacht? Volgens mij wij allebei niet…

De overige leden van de grote promotiecommissie: Prof. dr. A.J. van der Heijden, Prof. dr. R.M.H. Wijnen, dr. I. Leistikow. Hartelijk dank voor uw bereidheid zitting te nemen in de commissie.

Mijn maatje en mede Patient Safety Officer Ada van den Bos-Boon.
Lieve Ada, wat een klus hebben we op ons genomen! En hoe hebben we ons daarin ontwikkeld! Het is super om met je samen te werken en ik kijk ontzettend uit naar wat we nog allemaal gaan aanpakken en verbeteren. "Patients, there's no need to feel down… We've found safety! It's the new kid in town! There are methods – waiting just to be found…That will make your care less lethal……"

Jan Dekker en Marjan de Jong, als meest recente mede-veiligheidsmensen toegetreden tot ons "team" heb ik nu al gemerkt dat jullie onmisbaar zijn! Dank voor al jullie hulp!

Saskia Gischler en Robert Jan Houmes: de eerste stafleden die zich ook met patiëntveiligheid zijn gaan bezig houden; super zoveel als ik van jullie geleerd heb en hoe we daar nu mee verder gaan. Ben er trots op met jullie samen te werken!

Inge van 't Wout: in mijn optiek het beste unithoofd dat er rond loopt, en zeker niet alleen omdat je patiëntveiligheid hoog in je prioriteiten hebt staan! Dank voor je luisterend oor, vele adviezen, shoppen in Boston….

Corinne Buysse, Janet Bogert, Helma den Boer, Olga Stoffels, Ramona Sebes, Angelique Hoogenboom, Irma Radder: zonder al het werk dat ons Safety Action Team verricht heeft, was het nooit gelukt om dit boekje te kunnen schrijven. Jullie hebben me even moeten missen, maar we gaan weer in volle vaart verder.

Iedereen die ooit in de CRM werkgroep en/of de brainstorm-groep en/of de klankbordgroep en/of het SSTT team en/of de CNSI ploeg heeft gezeten of nog zit: ben trots op wat er inmiddels staat aan patiëntveiligheid en dat komt mede door jullie!

De overige staf van de IC Kinderen: Matthijs, Linda, Ulrike, Sara, Koen, Jan, Saskia, Natasja, Annemieke, Sascha, Muriël, Suzan, Berber, Enno (zullen we ooit ophouden over SF te kletsen, hoop van niet…), Kim (wij kunnen niet eens ophouden met kletsen…): zonder jullie als collega's was dit nooit op deze manier gelukt, bedankt!

Irwin Reiss: nu van de IC Neonatologie, maar toen ik hieraan begon nog van de IC Kinderen; dank voor je steun en vertrouwen en wijze adviezen, echt waar! En succes natuurlijk …

De staf van de IC Neonatologie: Monique, René, Ronny, Marijn, Renate, Nynke,
Sandra, Jeroen, Femke, Ellen, Willemijn, Jeanine: onmisbaar zoals jullie vooral in de laatste fase telkens weer bereid waren te helpen en mij vrij te plannen voor die laatste loodjes, super!

Liesbeth: de fijnste kamergenote die ik kon wensen! Dankjewel voor het meehelpen met de focus en concentratie die zo hard nodig waren. Succes met de cyclaam…

Marlou en Annemarie: heel goed dat jullie me af en toe achter m'n bureau vandaan sleurden om een Doppio te scoren, heel veel succes met jullie boekjes, je hebt gezien hoe het niet moet als je het verstandig wil doen…

Het moge inmiddels wel duidelijk zijn dat al dit werken aan patiëntveiligheid dus niet iets is dat je in je eentje doet. Zonder de inzet van de verpleegkundige teams, de ventilation practitioners, de nurse practitioners, de secretaresses, de zorgassistenten en de afdelingsassistenten van de beide IC's waar ik werk, waren we nooit zover gekomen. Dames, en de enkele heren, het blijft ontzettend fijn met jullie samen te werken, zowel aan het bed als aan de patiëntveiligheid! Henrike, mijn allereerste sparring partner bij het analyseren van de eerste incidenten, we zijn een heel eind op weg, nu de rest nog!

Ko Hagoort: wat een eindspurt! Door jouw kritische vragen, verbeteringen en commentaren zijn de artikelen stukken duidelijker en beter geworden. Op naar de volgende ….

Marten Poleij: dank voor je hulp met het opzetten van de databases en met het opstarten van onze onderzoeken.

Annemarie Illsley, Chantal Strik, Karen Suvaal en Judith Visser: wat moet ik zonder jullie hulp bij deze toestanden?

Mijn collega's van het Sophia Patiëntveiligheidsoverleg, in het bijzonder Diane van Felius: dank voor het meedenken, meewerken, mee voorbereiden en meedoen met alle patiëntveiligheid activiteiten, samen maken we het Sophia een stuk veiliger!

Jeanette en Monique: bedankt voor het mij in eigenlijk heel korte tijd een stuk gezonder en sportiever krijgen en houden! (voor zover ik dat toelaat dan….)

Daniella, George en André: lieve vrienden, jullie steun en vriendschap waren onmisbaar, niet alleen nu maar alle jaren dat we elkaar al kennen, zowel binnen het Sophia als vooral ook (en gelukkig) daarbuiten.

Lieve Nikk: telkens weer verrast het me hoeveel we voor elkaar betekenen. Ik kan me niet voorstellen hoe het nu met me zou zijn zonder de vele dingen die we samen al beleefd hebben. Zoals ik al eerder heb gezegd: jij hebt mijn blik op de wereld verruimd: Namaste!

Lieve Oma: je oudste kleinkind heeft weer een grote stap gedaan, zoals ik er als klein kind al zovelen aan jouw hand heb gedaan. Ben superblij dat je erbij bent vandaag!

Lieve Liesbeth: mede door jouw onvoorwaardelijke liefde en steun ben ik zo ver gekomen als ik nu ben en ik prijs me zeer gelukkig met jou als collega, buurvrouw en tante maar bovenal ben je de beste vriendin die ik me kan wensen. Mijn bewondering voor jou is enorm en ik hoop dat we samen nog vele reisavonturen en wandeltochten enzo zullen maken.

Lieve Ma: eigenlijk heb ik geen woorden voor jou, want er zijn er toch niet genoeg!
Ik ben zo ongelooflijk trots op jou en op mij en op dat we deze klus ook weer geklaard hebben. We blijven samen de wereld ingaan met open blik, (en natuurlijk met de juiste witbalans, de beste sluitertijd, de ideale diafragma-instelling, de goede scherpte-diepte, de juiste ISO-waarde en de beste camera's), en we blijven genieten van al die dingen die we delen. Ik hou van je. xxx C.

STELLINGEN

Stellingen behorende bij het proefschrift "Patient safety in pediatrics: a developing discipline".

Vermijdbare sterfte is niet geschikt als uitkomstmaat voor kwaliteit en veiligheid van zorg voor patiënten op een kinder intensive care.
(dit proefschrift)

Er is geen "gouden standaard" voor het opsporen van complicaties; daarom moet de beste combinatie van methodes gebruikt worden om zoveel mogelijk schade aan patienten op te sporen: de trigger tool methode gecombineerd met incident meldingen en registratie door artsen.
(dit proefschrift)

Aanbevelingen uit incident analyses, M&M besprekingen, Safety Walk rounds en dergelijke moeten opgepakt worden door daarvoor aangewezen medewerkers in een vooraf bepaald tijdspad. Hun vooruitgang dient bijgehouden te worden en een onderdeel zijn van functioneringsgesprekken.
(dit proefschrift)

De toepassing van human factors engineering en ICT technologieën is cruciaal om de medicatieveiligheid te verbeteren.
(dit proefschrift)

De beste manier om de veilgheidscultuur te meten? Slechts 1 vraag: "zou u zich helemaal veilig voelen als u hier behandeld werd?"
(dit proefschrift)

"Geneeskunde is een gebrekkige wetenschap, een bedrijf met constant veranderende kennis, feilbare individuen, en tegelijkertijd levens die op het spel staan. Er zit wetenschap in wat we doen, ja, maar ook gewoonte, intuïtie en soms gewoonweg gokken."
Atul Gawande; Complications: A Surgeon's Notes on an Imperfect Science. 2002, New York, USA.

"Alhoewel het gebrek aan verbetering op grote schaal een redden voor bezorgdheid is, is het geen bewijs dat de huidige inspanningen om de veiligheid te verbeteren vergeefs zijn"
Landrigan CP, Parry GJ, Bones CB, Hackbarth AD, Goldmann DA, Sharek PJ. Temporal trends in rates of patient harm resulting from medical care. N Engl J Med. 2010 Nov 25;363(22):2124-2134.

"Medische opleidingen moeten geherstructureerd worden, om te verminderen dat de focus bijna volledig ligt op het vergaren van wetenschappelijke en klinische feiten en om de nadruk te leggen op het ontwikkelen van vaardigheden, gedrag en attitudes die artsen nodig hebben".
Leape L, Berwick D, Clancy C, Conway J, Gluck P, Guest J, et al. Transforming healthcare: a safety imperative. Qual Saf Health Care. 2009 Dec;18(6):424-428.

"Langdurige yoga training vermindert de mate van geestelijke onrust, angst, boosheid en vermoeidheid niet alleen op de korte en middellange termijn, maar ook op de lange termijn."
Yoshihara K, Hiramoto T, Sudo N, Kubo C. Profile of mood states and stress-related biochemical indices in long-term yoga practitioners. Biopsychosoc Med. 2011;5(1):6.

"We moeten een einde maken aan traditionele 24-uurs diensten, de effectiviteit bestuderen van verschillende manieren om dit te bereiken en de beste manieren verspreiden zodat we betere en veiligere zorg kunnen leveren in alle intensive care units en ziekenhuizen van het land."
Landrigan CP. Resident sleep deprivation and critical care: the unintended consequences of inaction. Crit Care Med. 2010 Mar;38(3):980-981.

Alle mensen worden vrij en gelijk in waardigheid en rechten geboren. Zij zijn begiftigd met verstand en geweten, en behoren zich jegens elkander in een geest van broederschap te gedragen.
Artikel 1 van de Universele verklaring van de rechten van de mens.

PROPOSITIONS

Preventable mortality fails to be an adequate outcome of quality and safety of care in pediatric ICU patients.
(this thesis)

There is no "gold standard" for detecting adverse events; therefore the best combination of detection methods should be used to capture as many injuries as possible: the trigger tool methodology combined with incident reporting and physician registration.
(this thesis)

Recommendations from incident analysis, M&M conferences, Safety Walk rounds etc should be adopted by appointed employees with a set time frame. Their progress should be monitored and be a topic in their performance reviews.
(this thesis)

The application of human factors engineering and ICT technologies is pivotal to successfully improve medication safety.
(this thesis)

The best way to assess safety culture? Just one question: "Would you feel perfectly safe being treated here?"
(this thesis)

"Medicine is an imperfect science, an enterprise of constantly changing knowledge, uncertain information, fallible individuals, and at the same time lives on the line. There is science in what we do, yes, but also habit, intuition, and sometimes plain old guessing."
Atul Gawande; Complications: A Surgeon's Notes on an Imperfect Science. 2002, New York, USA.

"Although the absence of large-scale improvement is a cause for concern, it is not evidence that current efforts to improve safety are futile."
Landrigan CP, Parry GJ, Bones CB, Hackbarth AD, Goldmann DA, Sharek PJ. Temporal trends in rates of patient harm resulting from medical care. N Engl J Med. 2010 Nov 25;363(22):2124-2134.

"Medical education needs to be restructured to reduce its almost exclusive focus on the acquisition of scientific and clinical facts and to emphasize the development of skills, behaviours and attitudes needed by practising physicians".
Leape L, Berwick D, Clancy C, Conway J, Gluck P, Guest J, et al. Transforming healthcare: a safety imperative. Qual Saf Health Care. 2009 Dec;18(6):424-428.

"Ongoing yoga training reduces the level of mental disturbance,anxiety, anger, and fatigue not only over the short- or intermediate-term, but also over a long term".
Yoshihara K, Hiramoto T, Sudo N, Kubo C. Profile of mood states and stress-related biochemical indices in long-term yoga practitioners. Biopsychosoc Med. 2011;5(1):6.

"We must eliminate traditional 24-hr shifts, study the effectiveness of diverse approaches to doing so, and disseminate best practices so that we can achieve better, safer care in our critical care units and hospitals nationwide."
Landrigan CP. Resident sleep deprivation and critical care: the unintended consequences of inaction. Crit Care Med. 2010 Mar;38(3):980-981.

"All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood."
Article 1 of the United Nations Universal Declaration of Human Rights