PATIENT SAFETY AND MEDICAL DEVICES
Interacting contributing factors leading to unintended patient harm

Mees Casper Baartmans

NIVEL
Kennis voor betere zorg

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Interacting contributing factors leading to unintended patient harm

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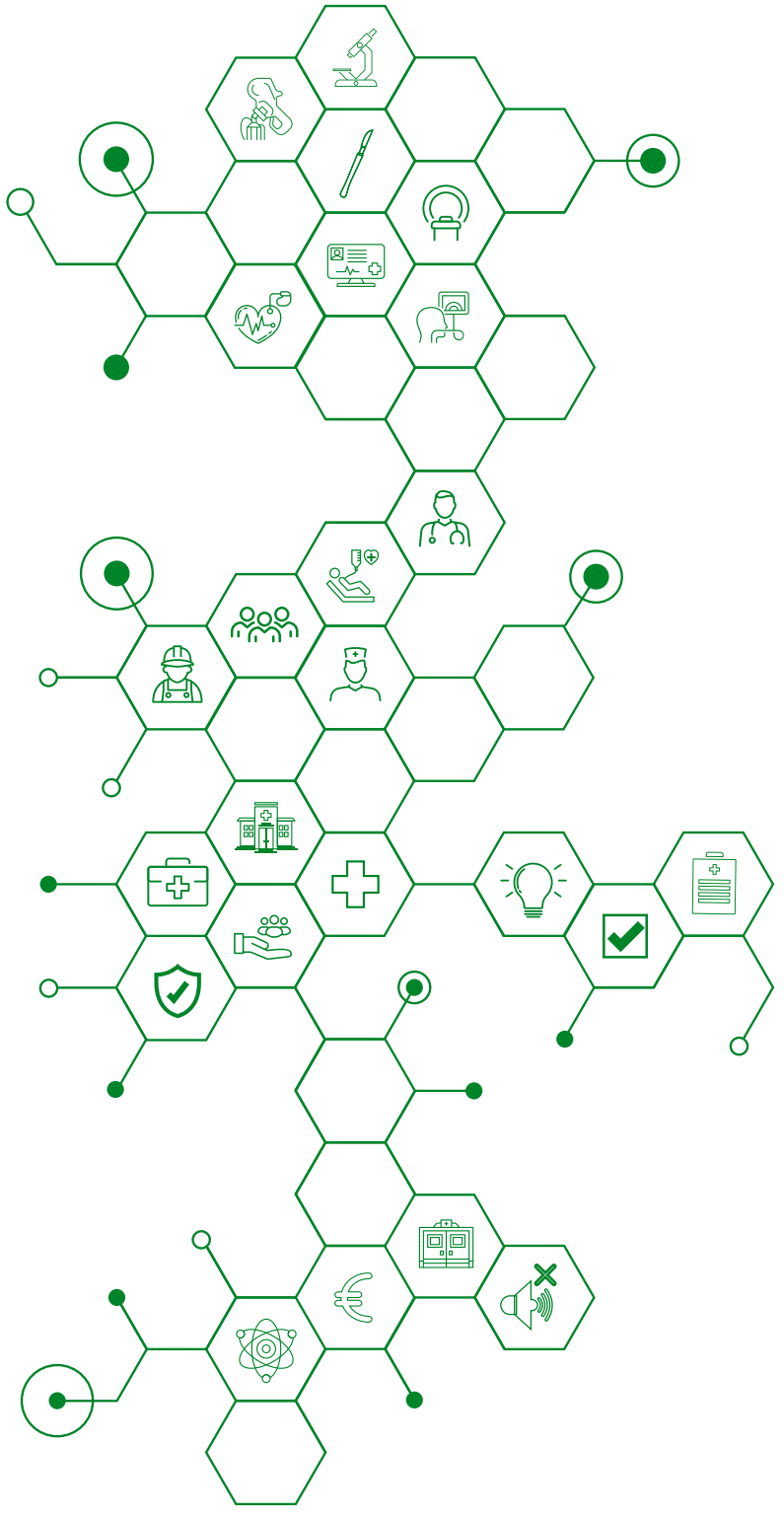
“Human error in medicine, and the adverse events that may follow, are problems of psychology and engineering, not of medicine.”

John W. Senders [1]



Chapter 1

General introduction

Medical devices are essential for providing hospital care, as they are applied to nearly all patients admitted to hospitals[2]. Without the use of medical devices, most medical procedures – simple and complex - could not be performed. According to the World Health Organization[3], nowadays about 2 million different kinds of medical devices are on the world market, varying from simple suture material to complicated robotic surgical systems. Most of the times application of medical devices is safe and effective, but occasionally devices are involved in unintended patient harm, as illustrated in the following case.

> *A heating mattress is placed around an infant patient to prevent hypothermia during surgery. The mattress is set to maximum (44 degrees Celsius). During the procedure the patient feels remarkably warm, and the mattress is set to 40 degrees Celsius. When after several minutes this has no effect, the mattress is turned to the lowest setting. This does not help either. A body temperature of 39.5 degrees Celsius is then measured. The mattress is turned off immediately. Redness is observed on both legs of the patient, which indicate serious 1st and 2nd degree burns on an estimated 13% of the body surface. Subsequently it is determined that the heating mattress was improperly connected to the heating unit, which meant the temperature of the heated air was not fed back to the unit. As a result, the heating unit continued to heat the air, and the mattress could reach a temperature of 66 degrees Celsius, while the device indicated a temperature of 44 degrees Celsius.*
>
> *(Centraal Tuchtcollege voor de Gezondheidszorg Den Haag, ECLI:NL:TGZ-CTG:2013:108[4])*

This case exemplifies how a medical device can cause serious unintended patient harm. At the same time, it raises questions about the underlying causes of the event. Some may argue this was a simple misapplication by the user; improperly connecting the mattress to the heating unit. Others might wonder why the device design allowed for this improper connection, or why the device did not provide an alarm. What the case certainly illustrates, is that such events have severe impact on patients, their family and involved healthcare professionals. Therefore learning from these events to prevent recurrence is of vital importance.

Accordingly, the role of medical devices in adverse events and its causes must carefully be investigated to seek leads to further improve patient safety. This aligns with the “primum non nocere” (or “first, do no harm”) obligation of medical professionals, which makes the medical profession strive for the absence of unintended patient harm. Though, zero unintended patient harm is often considered inconceivable. In particular with all other urgent challenges healthcare faces nowadays, e.g. personnel and supply-chain shortages, financial restrictions, and an aging population with expanding complexity and care needs[5-7]. Nevertheless, working on minimizing unintended patient harm is worth striving for, in particular considering the suffering inflicted at the individual level.

In this thesis we study the role of medical devices in events that result in unintended patient harm, and focus on Dutch hospital care. The aim of this thesis is to increase knowledge and provide deeper understanding on how medical devices are involved in unintended patient harm in hospitals, and identify leads to further improve patient safety.

MEDICAL DEVICES

Hospitals nowadays are high-technical environments, where medical devices are essential for providing patient care. Medical devices include a wide range of products, such as drips, surgical endoscopes, dialysis machines, medical software, consumables and implants. Medical devices can be defined as “any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used for human beings for one or more specific medical purposes (e.g. diagnosis, prevention, monitoring, treatment, etc.)”[8].

Since 2007, the Emergency Care Research Institute each year formulates a top ten health technology hazards list, with the aim to raise awareness for medical device related hazards for patient safety[9]. Some examples of presumed risks in past years lists were: misconceptions among electrosurgery unit users that can lead to serious burns[10], drug entry fields that populate after only a few letters which could induce fatal medication errors[11], or failure to adequately reprocess contaminated duodenoscopes that could lead to infections[12]. These examples indicate that risks can relate to the user, the device itself, and the organization in which devices are used. If such risks are not adequately considered or mitigated, an event leading to unintended patient harm may result.

The United States Food and Drug Administration receives about a hundred thousand reports each year of adverse events involving medical devices[13]. Of all incidents reported in England to the National Health Services’ Reporting and Learning System, medical device related incidents account for 2%[14]. A study by Beydon et al[15] showed that for patients in anesthesiology and critical care 4,188 adverse events involving medical devices were reported in 2005-2006 to the French national healthcare safety agency. Of these events, 7% had severe consequences and 2% were fatal. Another study among hospitalized children in 44 pediatric hospitals between 2004 and 2011 in the United States found that in 3.3% of all admissions at least one adverse event involving a medical device was found[16]. A 2013

systematic review showed that equipment and technology failure accounted for 23% of all errors in the operating room[17]. For the Dutch context, Porte et al.[18] studied the incidence of adverse events involving medical devices in hospitals in 2011/2012 and 2015/2016. They found adverse events involving medical devices were present in 2.8% of all admissions. Medical devices were involved in 40% of all adverse events, and in 44% of all potentially preventable adverse events. These numbers prove that medical devices are involved in adverse events, and can contribute to serious unintended patient harm. To minimize the occurrence of such events various efforts are made.

Worldwide numerous countries have national policies on medical devices[19], generally to ensure access to safe, effective, and high-quality devices. For example, by developing guidelines, norms and standards. Over recent years, in many countries (extra) legislation came into force on premarket approval and post market surveillance, often aligned with the level of risk the device potentially poses to patients[20-22]. Before entering the market, manufacturers must demonstrate their device is safe and effective. After market approval, devices must be followed and adverse events associated with devices must be reported to competent authorities[20]. National registries on adverse events involving medical devices were setup, such as in 1993 the United States' Food and Drugs Administration Manufacturer and User Facility Device Experience[13]. Such registries aim to provide continuous feedback about medical devices that are on the market, by gathering adverse event reports submitted by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters (health care professionals, patients and consumers)[13].

In Europe, one of the key aspects of the in 2017 endorsed new regulations on medical devices (MDR) and in vitro diagnostic medical devices (IVDR) was the creation of the European database on medical devices (EUDAMED). This database intends to improve overall openness, by enhancing information access for the general public and medical professionals[23]. Among other modules, EUDAMED will provide an European Union wide system for vigilance and market surveillance. But not all parts of EUDAMED are yet ready for use. By the course of 2023, EUDAMED is anticipated to be completely accessible[24]. The MDR and IVDR further aim to assure the safety of medical devices and ensure medical devices remain available for patients, by setting stricter rules for the market entering of devices and through stricter monitoring of manufacturers and their products when available on the market[25]. Since the MDR and IVDR came into force, products must comply with the new legislation and must thus have new certificates. Certification under this new legislation has been slow, inducing fear of supply-chain shortages[26], which may bear serious risks for quality and safety of care[6].

To implement the European legislation and set additional rules on specific topics, national legislation has been endorsed in the Netherlands. The Medical Devices Act (in Dutch: Wet Medische Hulpmiddelen) was accepted in 2019 and translates the MDR and IVDR to the national level[27]. Other legislation that was already in place, also relates to the safe use of medical devices. For example, the law on quality, complaints and disputes in healthcare (In Dutch: Wet kwaliteit, klachten en geschillen zorg) states that safe application of medical technology by healthcare providers is part of providing good care[28]. The Individual Healthcare Professions Act (in Dutch: Wet op de beroepen in de individuele gezondheidszorg) emphasizes that individual professionals are obliged to consider his/her competence to perform any reserved action. Although the competency to work with medical devices is not explicitly defined by this act, the use of devices is inseparable from the performance of most reserved actions.

In addition to these European and national legislation, in the Netherlands more practical regulations exist, aiming to ensure the safe application of medical devices. Various stakeholders formulated a national guideline on the safe application of devices in medical specialist care in 2011; the 'Covenant safe application of medical devices'. This guideline focuses on risk management and safe application of medical technology with the aim to facilitate safe implementation, use and disposal of medical devices[29 30]. The covenant includes articles to establish the implementation for the safe use of medical technology within healthcare facilities. Advocated procedures include e.g. establishing a record prior to the procurement of a device, which documents procurement requirements, prospective risks analyses, and competence requirements of future users. Furthermore, the covenant places the responsibility regarding quality assurance of medical technology with the board of directors. Implementation of the guideline among hospitals has been difficult[31 32]. Hospital boards did not directly gave the covenant sufficient priority, risk awareness regarding medical devices was lacking, and the assurance of user proficiencies was insufficiently developed[29 33]. To better support the implementation and application of the guideline, it was updated in 2016 resulting in a second edition[30]. The Dutch Health and Youth Care Inspectorate (In Dutch: Inspectie Gezondheidszorg en Jeugd, IGJ) considers the guideline as an important field standard[29].

Furthermore, all Dutch hospitals have a safety management system, for which a technical standard was developed (NEN 8009)[34]. Such a safety management system aims to embed patient safety and risk management within hospitals, and for example facilitates external audits and incident reporting[28 35]. Incident reporting systems allow healthcare workers to report incidents and near-misses, which are then analyzed to identify patterns in causes and find opportunities for improvement. If an incident results in serious patient harm or death, it is considered a sentinel event. Hospitals are obliged to file a report to the national healthcare inspectorate and thoroughly investigate such sentinel events[36]. For investigation, hospitals combine data from patient records, interviews with those involved and reviewing additional documentation (e.g. ward protocols, or professional standards). In case a medical

device is involved in a sentinel event, additional information can be gathered, such as user manuals, malfunctioning history, or maintenance data. Because of combining these variety of data, reports often entail great detail on what happened.

HOW MEDICAL DEVICES ARE INVOLVED IN UNINTENDED PATIENT HARM

To further improve the safe application of medical devices, it is important to understand how devices are involved in unintended patient harm, and how such events could potentially be prevented.

Case studies and case series[37-40] exemplify how medical devices are involved in causing patient harm. But these studies are by definition anecdotal. Reports filed to national databases such as the Manufacturer and User Facility Device Experience database are also used for scientific studies on adverse events involving medical devices. These studies often focus on specific (types of) devices[41-43], procedures[44], or departments[15 45]. Based on solely the minimal information in the registry reports of such databases, establishing if a device actually caused a specific event is difficult[13]. Inherently, determining various types of causes and assessing potential preventability is then virtually impossible. Porte et al.[18] reported from a patient record review study which devices were often involved in adverse events involving medical devices (e.g. implants), what type of harm was found (e.g. infection, sepsis, and incorrect placement), and reported on the potential preventability of events. The study, however, did not provide information on the causes of events. The authors advocate to use other strategies, methods and data sources to provide more insights in the differentiated causes and contributing factors of events[18]. Although scarce, there are some studies that did report on the causes of events involving medical devices. These argue that while events are usually attributed to either human error or device failure[15 46], causes are in fact often multidimensional[47 48].

Still, there seems to exist a knowledge gap on the nature of events involving medical devices, in particular on the role of the device and the multidimensional causes and underlying contributing factors. A deeper understanding on the causes and contributing factors and how these interact could help to better understand how devices are involved in unintended patient harm, and aid in identifying leads to further improve patient safety. For example, a better understanding is needed of the more deeply engrained technical issues (e.g. device design and usability) and system issues (e.g. workload and coordination of care), that could lead to unsafe application by the operator (e.g. user error, or misapplication), and eventually result in patient harm. These factors and mechanisms typically remain unseen in existing literature. For studying such multidimensional interacting contributing factors, a broad perspective that captures various domains of a work system and addresses complexity of the healthcare system is necessary.

SYSTEMS THINKING AND HUMAN FACTORS

Systems thinking attempts to understand complex work systems[49]. In healthcare, such a system can be composed by e.g. patients, healthcare professionals, technology and the environment where care takes place. Understanding how these various elements interact with each other to achieve a specific goal, is the practice of systems thinking[50]. Systems thinking further aims to structure those work systems in more effective and efficient manners[51]. Within systems thinking, human factors principles are often applied to optimize the design of complex systems and enhance safety.

Human factors is a multidisciplinary scientific field that aims to adapt complex work systems to the -centrally positioned- person involved. It specifically accounts for human abilities and limitations[52], and is dedicated to optimize all aspects of a work system to support human performance and safety[53]. Related to patient safety, human factors may address various aspects, such as human error, healthcare worker performance, and system resilience[54]. For medical devices, human factors is considered an important manner to improve user friendliness and efficient operation, to eventually reduce errors during device use[48].

Adopting a perspective that incorporates systems thinking and human factors to patient safety event analysis, may enhance our understanding of the interactions between different components of a work system and the people involved[55]. One model that addresses issues from a systems perspective and is rooted in human factors, is the Systems Engineering Initiative for Patient Safety (SEIPS) model[56 57] (Figure 1). It approaches patient safety by studying influences from various sociotechnical domains (i.e. persons, tools and technology, tasks, organization, internal environment and external environment). The model specifically focusses on interactions between domains, and is therefore particularly helpful to study multidimensional contributing factors of events and understand how patient safety events emerge. The model has evolved over time[56-58] and is widely applied for patient safety research[59-61], including preliminary work on the analysis of patient safety events[62 63]. This SEIPS model may for these reasons be an appropriate tool to better reveal the role of medical devices in the emergence of unintended patient harm. Therefore this model has a prominent place in this thesis.

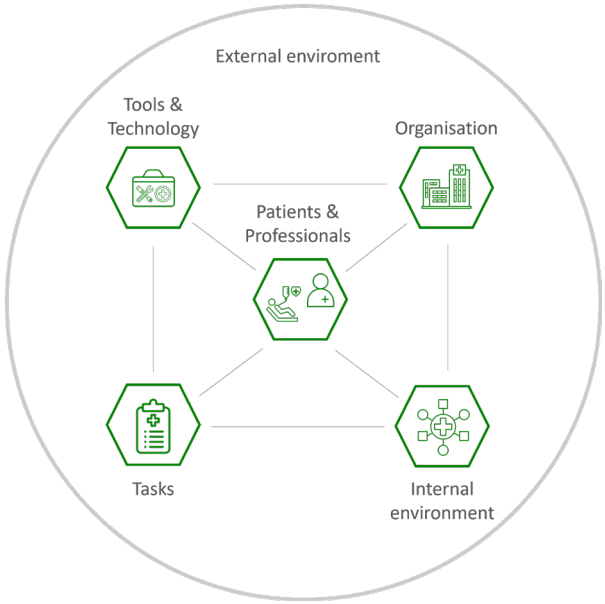


Figure 1. The Systems Engineering Initiative for Patient Safety model, adopted from Holden et al.[57]

RESEARCH QUESTIONS AND METHODS

This thesis aims to increase knowledge and provide deeper understanding on how medical devices are involved in unintended patient harm in hospital care, and identify leads to further improve patient safety. Therefore, the following research questions will be answered:

- What is the incidence and nature of events involving medical devices leading to unintended patient harm?
- How are the causes of events leading to unintended patient harm currently studied, and how can this be improved?
- What are the causes and interacting contributing factors of sentinel events in general, and specifically for events involving diagnostic errors and events where medical devices are involved?

To answer these questions and, hence, gain a deeper understanding on how medical devices are involved in unintended patient harm, a mixed methods approach was used (see overview in Table 1). For reporting the incidence and nature of adverse events involving medical devices, data from a patient record review study on adverse events in Dutch hospitals in 2019 were used. From this data the incidence of potentially preventable adverse events involving medical devices was reported, and specific common topics among these events were identified. Then, one of the methods Dutch hospitals commonly use for studying patient safety events and analysis of causes, was thoroughly studied with a systematic literature review. Scientific literature was reviewed to study the application in healthcare facilities worldwide of the Prevention and Recovery Information System for Monitoring and Analysis (PRISMA) method. This helped to understand how hospitals typically study events and its causes. Subsequently, a structured multi-stepped approach was followed for developing a novel generic analysis method to perform a cross-hospital aggregated analysis of sentinel events, using a systems thinking and human factors perspective. The new method aims to improve studying events and analysis of its underlying causes and contributing factors. The developed method was applied to perform a retrospective aggregated cross-hospital analysis of sentinel event reports from Dutch general hospitals. The analysis focused on identifying contributing factors and interactions underlying events. Apart from this overall aggregated analysis, two additional subanalysis were performed, using extra tools and classification systems to elucidate on human errors in the diagnostic process, and differentiate on the role of medical devices in sentinel events. From these studies, we could derive how events and its underlying causes and contributing factors could best be studied, and shed light on the nature of causes and contributing factors of events.

Table 1. Overview of the studies and research methods applied for this thesis

Chapter	Objective	Method	Data
2	To report the incidence of potentially preventable adverse events involving medical devices, and provide an overview of specific topics on how devices were involved in patient harm.	Cross-sectional nationwide retrospective patient record review study	2,998 patient records of patients deceased during admission in 20 Dutch hospitals
3	To map the use of the PRISMA method in healthcare facilities worldwide, assess the insights that the method offers, and propose recommendations to increase its usability in healthcare facilities.	Systematic literature review	2,773 references, of which 25 articles met inclusion criteria
4	To develop a novel Generic Analysis Method (GAM) to facilitate a holistic event analysis using a human factors perspective and ease aggregate analysis of sentinel events across hospitals.	Stepwise development of a novel analysis method	Expert panel consultation, and user test sessions
5	To examine if performing cross-hospital aggregate analysis of sentinel events applying the GAM, can enhance learning from sentinel events.	Cross-sectional retrospective aggregated cross-hospital sentinel event analysis	69 sentinel event reports, from 28 Dutch general hospitals
6	To determine whether an in-depth analysis of the human errors involved in diagnostic errors in the emergency department, using information-rich sentinel event reports, will increase our understanding of diagnostic errors and will provide leads to improve analysis of diagnostic events and specify recommendations for improving diagnostic safety.	Cross-sectional retrospective aggregated cross-hospital sentinel event analysis	23 sentinel event reports on diagnostic errors from Dutch general hospitals
7	To identify the contributing factors of sentinel events involving medical devices, and the interactions between factors that jointly lead to unintended patient harm.	Cross-sectional retrospective aggregated cross-hospital sentinel event analysis	20 sentinel event reports on medical devices from Dutch general hospitals

THESIS OUTLINE

Results of the patient record review study on the incidence and nature of adverse events involving medical devices are described in Chapter 2. Chapter 3 describes the results of the literature review on the PRISMA method. The studies on the development and application of the generic method for sentinel event analysis are elaborated on in Chapter 4 and 5 of this thesis. The extra subanalysis on sentinel events related to human errors during the diagnostic process is described in Chapter 6, and Chapter 7 elaborates on the differentiated contributing factors of sentinel events involving medical devices.

Chapter 8 concludes with a general discussion in which we highlight the most important results, place these in a broader context, address important methodological considerations and formulate recommendations for practice, policy and future research.

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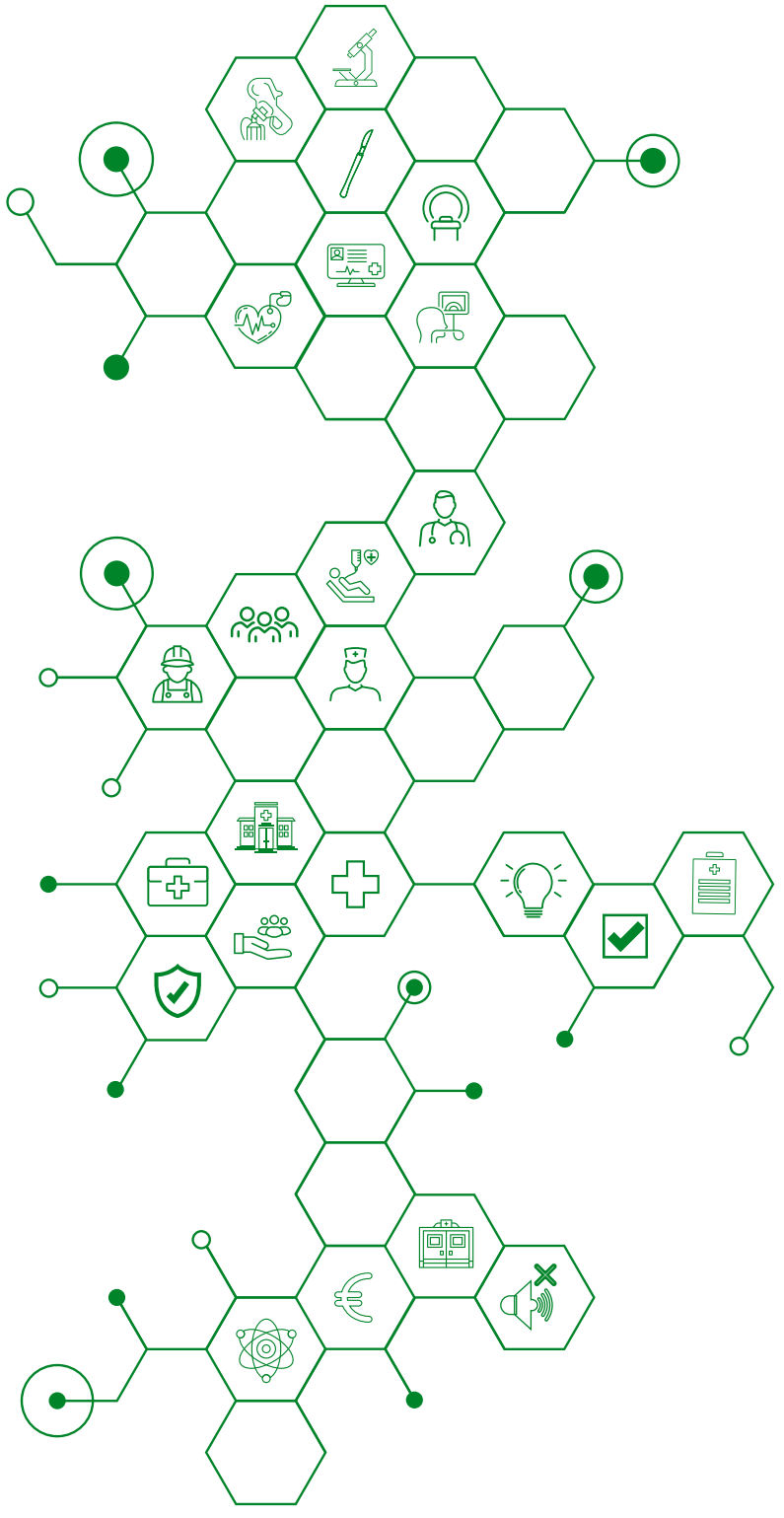

Chapter 2

Adverse Events involving Medical Devices in Dutch Hospitals: A patient record review study

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ABSTRACT

OBJECTIVES

To report the incidence of potentially preventable Adverse Events involving a Medical Device (AEMD) and provide an overview of specific topics on how devices were involved in causing patient harm.

METHODS

A retrospective nationwide patient record review study using randomly selected records of 2,998 patients deceased during their admission in 20 Dutch hospitals in 2019.

RESULTS

63 potentially preventable AEMDs were identified, corresponding to a weighted incidence of 1.9% (95CI 1.5%-2.5%). Medical devices were involved in about half of all potentially preventable adverse events. Consequences for patients were often severe. Themes in how medical devices were involved in causing patient harm were: invasive (endo) scopic procedures causing perforations and hemorrhages, bleedings and infections after placement of heart- and vascular implants, and respiratory harm related to naso- and orogastric tube application. In most cases, the role of the device in causing adverse events was that of prompting a known complication. Preventability in these cases often lied in the subsequent management of the bleeding, perforation or infection.

CONCLUSIONS

AEMDs occur in a small percentage of patients admitted and deceased in Dutch hospitals, but do represent a substantial part of all potentially preventable adverse events identified amongst the old and severely comorbid patient group in this study. An additional analysis of the data, provided a more thorough understanding of how the use of medical devices contributes to patient harm. Other study designs are necessary to learn more about technical and organizational issues that might trigger AEMDs.

PUBLIC INTEREST SUMMARY

Most medical device applications are safe and effective. Though in a small number of cases an Adverse Event involving a Medical Device (AEMD) occurs. This study found that in 1.9% (95CI 1.5%-2.5%) of patients deceased during their admission in 20 Dutch hospitals in 2019 a potentially preventable AEMD occurred. Identified topics in these AEMDs were perforations, bleedings, and infections after invasive (endo)scopic procedures, heart- and vascular implants, and tubes for enteral feeding or drainage. The role of the devices in these AEMDs was often that of prompting a known complication and considered non-preventable. Preventability in most cases lied in the subsequent management of the perforation, bleeding or infection.

INTRODUCTION

Preventable patient harm is an important cause of morbidity and mortality in healthcare[1]. Patient harm is often prevalent in advanced specialties[2] and frequently relates to medical intervention or surgery settings[3]. Medical devices are an essential element of patient care in these settings, and are used in order to sustain life and improve health. Medical devices include a wide range of products (e.g., surgical stapler, infusion pump, or dialysis machine) and can be defined as “any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more specific medical purposes (e.g. diagnosis, prevention, monitoring, treatment, etc.)”[4]. Although essential for patient care, medical devices can also cause unintended patient harm.

Medical device adverse event databases, such as the United States Food and Drugs Administrations’ Manufacturer and User Facility Device Experience, show that annually several hundred thousand reports are filed of adverse events involving medical devices[5]. A study on Adverse Events (AEs) in the Netherlands found that in 40% of all AEs a medical device was involved. A quarter of these AEs involving medical devices was considered to be preventable[6]. Causes of such adverse events can relate to the device itself (e.g. device malfunctioning, faulty design, or device failure), to suboptimal application of properly functioning devices (i.e. user errors)[7], but also to inadequate patient management after device application. In most events, causes are in fact multidimensional[8].

To enhance safety, regulations, directives and frameworks have been setup to mitigate hazards related to medical devices. Regulatory bodies across the world use premarket approval and post market surveillance[9]. In Europe, new Medical Device and In Vitro Diagnostic Regulations came into force in May 2017, which strives to standardize high quality and safety standards for medical devices[4]. For example by imposing stricter requirements on manufacturers, importers, and notified bodies. But also by improving vigilance and post market surveillance across Europe, by establishing the European Databank on Medical Devices (EUDAMED). In some countries, field parties came up with standards to improve the safe application of medical devices. In the Netherlands, a national guideline was developed and implemented, aiming to facilitate the safe implementation, application and disposal of medical devices[10]. Despite such efforts, difficulties remain to enhance the safe application of medical devices.

Improving safety might be hindered because existing literature on this topic often does not combine representative data on the occurrence of Adverse Events involving Medical Devices(AEMDs) with information on *how* medical devices are involved in causing patient harm. It lacks the combination of data on which type of medical devices are involved,

causing which type of patient harm, during which procedures, what went wrong and what role the device played. For example, Porte et al.[6] provide a representative overview on the incidence of AEMDs in hospitals. They showed which device categories were most often involved in AEs (implants, surgical instruments, and drains), and what the nature of the adverse events was (e.g., infections and sepsis). However, although also giving short examples of AEs, the study provided only limited information on *what exactly went wrong and how the devices were involved*. Case studies do provide insights in how devices are involved in causing patient harm[11 12], but are by definition anecdotal. Observational studies on medical device related AEs often focus on specific devices (e.g., ventilators[13], duodenoscopes[14], endoscopes[15]) or study particular settings (e.g., intensive care unit[7]). Such studies on specific devices or departments tell a more broad story, but still focus on one or a few devices. Moreover, studies using reports filed to for example the Manufacturer and User Facility Device Experience to study AEMDs, might not be able to describe how devices are involved in causing patient harm. The information in these reports is often too limited to determine if a device caused the AE[16 17].

These limitations in various types of scientific literature on medical device related adverse events, makes it hard for stakeholders (i.e. policy makers, competent authorities, individual healthcare professionals or facilities, and healthcare professions) to set more broad topics to further improve medical device safety. This necessitates for combining quantitative data on the incidence of adverse events involving medical devices, with additional analysis to understand *how* medical devices were involved in causing patient harm.

Therefore, in this study, the incidence of potentially preventable Adverse Events involving Medical Devices is reported based on a patient record review study representative for all patients died during hospitalization in Dutch hospitals in 2019. An additional analysis provides insights in important themes, looking at *how* medical devices are involved in causing patient harm. Helping to signal specific topics on which relevant stakeholders could devise recommendations and preventive strategies to further improve patient safety.

METHODS

A retrospective patient record review study of patients who died during their admission in Dutch hospitals in 2019 was performed. A detailed description of the overall study design has previously been published[18 19]. In this methods section we highlight the most important elements of the overall patient record review study and focus on the additional steps to study potentially preventable Adverse Events involving Medical Devices (AEMDs).

RECORD REVIEW

Records from a stratified sample of 20 Dutch hospitals were included for the patient record review study. Included hospitals represented urban and rural settings, and were stratified for university, tertiary teaching and general hospitals. From each hospital 150 medical records from deceased patients were randomly selected for review. Patients admitted to the psychiatry department, obstetrics and children under 1 year of age were excluded. After data-cleaning 2,998 records were included from four academic, six tertiary teaching, and ten general hospitals. University hospitals were overrepresented, therefore percentages were weighted in the analyses. The sample was compared to other reference values of all inpatient deaths in the Netherlands in 2019, and concluded as representative.

Reviewers & interrater reliability

A two-stage review of the electronic patient record systems was conducted. First, experienced nurses (n=17) screened the nursing and medical records, using an internationally recognized trigger list[20]. They searched for triggers indicating potential patient harm. Whenever a trigger was identified by the nurse, the record was further reviewed by one of the experienced physicians (n=8, specialized in internal medicine, neurology or surgery). A standardized protocol was used to systematically review the record to determine the presence and preventability of adverse events. An AE was determined based on three criteria: the event must 1) have resulted in an unintended injury of the patient, 2) have resulted in prolonged hospital stay, disability or death, and 3) have been caused by healthcare management, rather than the disease for which the patient was treated. Preventability was assessed based on whether the provided care was below the level of standard care as could be expected from healthcare professionals and organisations. Clinical guidelines were taken into account. Physicians also assessed to what extent the AE contributed to the patient's death.

Reviewers were extensively trained in reviewing records. Most reviewers had previous experience with patient record review studies. If not, thorough peer coaching was provided. Additionally, multiple peer-to-peer sessions were planned during the study to enhance inter-rater reliability. In both stages of the study, about 10.0% of the patient records was reviewed double blind to calculate the positive and negative agreement between reviewers. The positive agreement for finding a trigger (i.e. the first stage) was 97.4% (n=297 records double reviewed). The negative agreement was 75.0%. For the second stage, positive agreement for finding an AE was 63.0% (n=248 records double reviewed) and negative agreement 75.4%.

Record selection for Adverse Events involving Medical Devices

After the standard two-stage patient record review, all adverse events were additionally assessed by a physician reviewer [HA] on whether a medical device was involved in the occurrence or development of the event. The reviewer studied the open text fields of adverse events and clinical context descriptions. If the reviewer was convinced a medical device was

involved, the adverse event was classified as an AEMD. Involved did not merely imply that a device was applied during hospital admission, but also that the device played a role in the occurrence or development of the adverse event. For this study we focused on potentially preventable AEMDs, since these may provide the most learning potential. The study was limited to hardware (i.e. instruments, apparatus, appliances, and implants) as part of the more broad concept of medical devices. Software was not included for methodological reasons.

DATA ANALYSIS

General data such as patient and admission characteristics (e.g., age, gender, type of admission, admission department, and treating specialty) were collected. Incidences of adverse events, adverse events involving medical devices, and potentially preventable adverse events involving medical devices were calculated. To make the sample representative of the population of patients died in Dutch hospitals in 2019, percentages were weighted.

Analysis of the role of medical devices in potentially preventable adverse events

For all potentially preventable AEMDs, researchers [MB & SVS] independently analysed the description of AEMDs. The stepwise thematic analysis approach of Braun & Clark[21] was used for searching across open text fields of the AEMDs to identify specific patterns or topics. These steps include: familiarizing with the data, generating initial codes, searching for themes, reviewing themes, defining and naming themes, and producing a report. Thematic analysis was chosen because it is a flexible and systematic method to identify themes within more qualitative data (i.e. the open text field descriptions of AEMDs). Elements we were particularly interested in related to our research aim, were openly coded, and involved; the type of involved device, type of patient harm, the procedure during which the event occurred, what went wrong and what role the device played. We then searched for overarching themes or patterns in our codes. These themes were discussed with the core research team [MB, SVS, and CW]. We conducted a final check and defined three themes.

For each theme we studied the type of device involved, type of patient harm, type of procedure, identified root causes, and preventive strategies as formulated by the reviewer that could have prevented the AEMD. We subtracted from these data what went wrong and what role the device played. Conclusions were submitted to one of the physician reviewers for verification [HA].

RESULTS

A total of 2,998 records from patients deceased during their admission in Dutch hospitals in 2019 were reviewed. The median age of the total sample was 78, and most patients had a high comorbidity score (median Charlson index 7, with 83.3% score >5). A majority of the patients was admitted acutely (88.6%) and over one third (33.1%) stayed at the ICU or MCU during their hospitalization.

Table 1. Descriptive statistics study population

Characteristic	Patient records (total, n=2,998)
Age, median [IQR]	78 [69-85]
Female, n [%]	1,357 [45.3%]
Admission time (in days), median [IQR]	4 [2-10]
Hospital type, n [%]	
General	1,494 [49.8%]
Tertiary teaching	894 [29.8%]
University hospital	610 [20.4%]
Acute admission, n [%]	2,657 [88.6%]
Intensive/Medium care stay during admission, n [%][a]	1,004 [33.1%]
Admission department, n [%]	
Cardiology	178 [5.9%]
Surgery	265 [8.8%]
Geriatrics	127 [4.2%]
Internal medicine	975 [32.5%]
Intensive Care	500 [16.7%]
Pulmonary diseases	359 [12.0%]
Cardiac monitoring	139 [4.6%]
Neurosurgery	18 [0.6%]
Neurology	311 [10.4%]
Orthopaedics	41 [1.4%]
Urology	22 [0.7%]
Other, surgical	11 [0.4%]
Other, not surgical	52 [1.7%]
Charlson Comorbidity Index, n [%][a, b]	
Score 0 (12% 1 yr mortality)	24 [0.8%]
Score 1-2 (26% 1 yr mortality)	103 [3.4%]
Score 3-4 (52% 1 yr mortality)	396 [12.6%]
Score ≥5 (85% 1 yr mortality)	2,475 [83.3%]

a Percentages are weighted for overrepresentation of university hospitals
b Charlson score calculated based on age and selected comorbidities

Of the 2,998 screened patient records, in 435 patient records one or more AEs were identified. For 127 patients one or more AEs were considered potentially preventable, resulting in a total of 133 potentially preventable AEs. Of the 133 potentially preventable AEs, in 63 a medical device was involved, and were therefore considered as potentially preventable AEMDs (Figure 1). These 63 AEMDs occurred amongst 60 patients. The weighted incidence of potentially preventable AEMDs was 1.9% [CI 1.5%-2.5%]. In 49 of the 63 potentially preventable AEMDs, the event substantially contributed to, or caused the patients' death.

The 63 cases of potentially preventable AEMDs were further analysed. Although cases varied widely, three themes could be identified; Perforations and hemorrhages after applying (endo)scopes for invasive procedures, bleedings and infections after placement of heart implants and vascular implants, and respiratory harm related to nasogastric and orogastric tubes. Other cases involved, among other things, suboptimal hip arthroplasty, pressure ulcers due to the application of medical devices, or patient harm after intubation. Brief descriptions of all events are included in Appendix I.

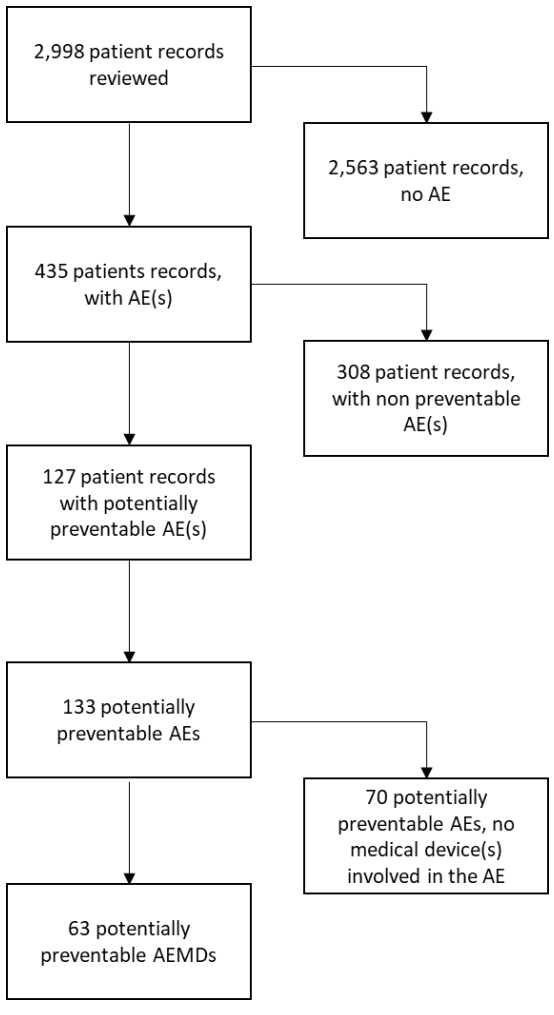

Figure 1. Flowchart of AEMD selection. Some patients experienced multiple potentially preventable AEs during their admission. Therefore the number of potentially preventable AEs is higher than the number of patient records in which a potentially preventable AE was identified.

PERFORATIONS AND HEMORRHAGES IN INVASIVE PROCEDURES APPLYING (ENDO) SCOPES

One theme identified in the potentially preventable AEMDs was related to hemorrhages and perforations after application of (endo)scopes for invasive surgical procedures. In particular laparoscopes were involved, but also other types of scopes such as: gastroscopes, thoracoscopes, a bronchoscope, colonscope and cystoscope. Procedures for which the scopes were used varied widely and included i.a. laparoscopic inguinal hernia repair or pancreas-milt surgery, thoracoscopic lobectomy, or colon resection. The main type of patient harm were internal bleedings and perforations of parts of the intestinal tract, infections, and abdominal- or urosepsis.

In most adverse events, the scopes perforated vessels or parts of the intestinal tract during the procedure. Other cases related to anastomotic leakage after laparoscopy and coloscopy. Preventability of these events did not necessarily focused on the technical procedure, e.g. mishandling of the scopes resulting in a perforation, but rather on the subsequent management of the harm. Perforations, bleedings and anastomotic leakages often remained unnoticed or inadequately treated, and subsequent infections emerged.

> *Case: A 50-60 year old patient undergoes a laparoscopic nephrectomy. Two days postoperative a colon perforation is diagnosed and treated with suturing and a diverting colostoma. Abdominal sepsis is treated with antibiotics. Eventually the patient is stable with a final ascend stoma. Although damage to internal structures (such as perforation of the colon) is considered a known complication, retrospectively it was concluded that the colon was insufficiently monitored during and after the laparoscopic procedure.*

Better postoperative monitoring of patients and quicker response to deviating check-results, were indicated by the physician reviewers as most important way to prevent AEMDs related to this theme. Better examination of the patient and the surgery site, during and after the procedure, were mentioned as an important aspect for preventability as well.

BLEEDINGS AND INFECTIONS AFTER PLACEMENT OF HEART IMPLANTS AND VASCULAR IMPLANTS

Bleedings and infections after placing heart implants and vascular implants involved devices such as surgical treatment material (e.g. catheters, gripper lines, and suture material) and implants themselves (e.g. pacemakers, stents, aorta protheses, and aortic valves). Procedures included amongst others, trans aortic valve implantation, removal of an infected aorta prothesis, or a percutaneous coronary intervention. Patient harm often concerned bleedings and infections per- and postoperative.

Devices were involved in adverse events in various ways, e.g. implants (aorta protheses, pacemaker lead) got infected, application of surgical materials (catheter, gripperline, suture material) caused perforations of blood vessels, or a stent was placed despite contra-indications. Preventability of most events focused on the late diagnosis or inadequate treatment of the infections and bleedings.

> *Case: A 70-80 year old patient undergoes transaortic valve implantation. Direct postoperative hemorrhagic shock due to aorta perforation occurs for which an emergency laparotomy is conducted, but kidney failure with tubular necrosis and atrioventricular block remains. Ultimately, the patient dies in the ICU shortly after the initial surgery. Given the nature of the aorta lesion, a forcefully inserted catheter seems to be the most likely cause of the damage to the aortic vessel wall.*

Patient harm for this topic could have been prevented by adhering to contra-indications, better monitoring of the patient and patient data, and more thoroughly checking the surgical site per-/postoperative. More caution when placing sutures could have prevented harm to surrounding vessels or bowel structures.

RESPIRATORY HARM RELATED TO NASOGASTRIC AND OROGASTRIC TUBES

A third topic that emerged from the data, were problems with tubes used for enteral feeding and gastric drainage. Involved devices were naso- and orogastric tubes. Patient harm occurred during or as a result of placing or removal of tubes, and related in most cases to harm to the respiratory system after aspiration and aspiration acquired pneumonia.

Tubes were incorrectly inserted or removed, or removed too early or too late. This way the devices were involved in causing aspiration and aspiration acquired pneumonia. In one case incorrect placement of the tube resulted in a perforation of the trachea. Incorrect placement, incorrect positioning checking, or decisions about placing or removing the tubes too late/early, determined these events to be considered preventable.

> *Case: A feeding tube is inserted into a 60-70-year-old ventilated patient. The tube is apparently placed in the pleura, causing empyema. Pleural drainage and surgical interventions are to no avail. Patient died of respiratory insufficiency. Harm could have been prevented if more attention was paid when inserting the feeding tube for this ventilated patient.*

More caution when placing tubes to prevent complications was considered the most important preventive strategy. Better communication and consideration about the necessity of nasogastric tubes, and more checks and monitoring of patients once the tube was placed

were also reported. Other enteral feeding or drainage techniques also caused issues in two other cases. Such as leakage and peritonitis after a Percutaneous Endoscopic Jejunostomy (PEJ), and small intestine perforation and abdominal sepsis after a Percutaneous Endoscopic Gastrostomy (PEG).

DISCUSSION

Although most medical device applications are safe and effective, in a small number of cases adverse events occur causing serious patient harm. In this study we reported the incidence of potentially preventable Adverse Events involving Medical Devices (AEMDs) based on a patient record review study. Subsequently, we signaled specific topics in these AEMDs and explain how medical devices were involved in causing patient harm.

We found 63 potentially preventable AEMDs in 60 records, of the total of 2,998 screened patient records of patients admitted and deceased in Dutch hospitals in 2019. This corresponds with an incidence of 1.9% (CI 1.5%-2.5%). These AEMDs represent about half of all potentially preventable adverse events. In 49 of the 63 events the AEMD substantially contributed to, or caused the death of the patient. Langelaan et al.[22] found that for screened records of patients that died during hospitalization in 2015/2016, in 1.7% (CI 1.3-2.22) of the patients one or more potentially preventable AEMD occurred. Porte et al.[6] reported over the combined period of 2011/2012 and 2015/2016 for all potentially preventable AEs, medical devices were involved in 44%. The outcomes found in the current study using 2019 data are thus generally in line with these previous studies on adverse events in Dutch hospitals, and seem stable over time. An incidence of 1.9% might be interpreted as a generally spoken, acceptable level– especially when taken into account the widespread use of devices. Though when potentially preventable adverse events occur, medical devices are involved in a substantial part of the events, and the consequences for the patient are frequently severe.

Besides the incidence of potentially preventable AEMDs, this study provides some insights into how specific medical devices caused patient harm. However, this study does not calculate a risk measure for specific devices or procedures, because we cannot compare the events to numbers on device application. We did signal three themes in our data, and described how devices were involved. For all topics holds that the patient group was complex. Risks are particularly high for older patients with severe comorbidity and complex care needs. Nonetheless, in the assessment of potential adverse events and preventability, clinical guidelines and patient characteristics were taken into account.

The first topic we identified was invasive (endo)scopic procedures that resulted in perforations and bleedings. Here, the application of (endo)scopic devices caused

perforations of intestinal tissue or blood vessels. Such vascular damage and intestinal injury are known complications in various types of minimal invasive surgery[23-25]. Yet, complications in laparoscopic surgery can vary between hospitals[26] and surgeons[27]. Keswani et al.[28] showed that, for a specific endoscopic procedure (i.e. ERCP), increasing endoscopist volume is associated with lower AE rates (including bowel perforations and bleedings). Another example of strategies that may help to decrease AE rates are specific registries and auditing programs. Nationwide auditing was implemented among Dutch hospitals for colectoral cancer care. While guideline compliance for diagnostics, preoperative multidisciplinary meetings and standardized reporting improved, complication-, reintervention- and postoperative mortality rates decreased[29]. This indicates that it may be possible to reduce complication rates, and suggests that for example experience, volume effects, or dedicated auditing programs may influence outcomes.

Second, we identified placement of heart implants and vascular implants caused bleedings and infections. These are known complications. For example, major bleedings related to trans cathetric aortic valve implantation is a known but rare risk[30]. A well-known device-related complication after endovascular aneurysm repair of the thoracic and abdominal aorta is graft infection[31].

Again, complication rates may not be set in stone. For example, after transaortic valve replacement evolved over time and next generation devices became available (e.g. smaller delivery sheets), outcomes improved impressively. Also strategic case selection (treatment of patients with less high risk characteristics), improved procedural techniques and increased site experience seem important drivers of these improvements[32 33]. This indicates that improvement is possible and complications during placement of implants that are now considered non-preventable, may become preventable over time. Analogue to registries for endoscopic procedures, for procedures like TAVI also quality registries are available[34]. These may have the potential to improve safe care.

Third, AEMDs stood out in which aspiration and aspiration pneumonia occurred that related to the application of naso- and orogastric tubes for enteral feeding and drainage. Nasogastric and orogastric tubes were placed incorrectly or too late. In some cases tubes were removed too early. Respiratory harm due to application of nasogastric/nasoenteric tubes is relatively common[35]. Complications related to mispositioned tubes are usually considered preventable[36]. By carefully studying and following clinical guidelines, complications associated with tubes for enteral feeding may be reduced[37].

Preventability of most of these cases, in particular for the first two themes, did not relate to for example the bleeding, infection or perforation itself, but rather to the subsequent care. Elements of care that determined events to be preventable were: suboptimal monitoring of the patient, insufficient checking the surgical site per- and postoperative, and intervening late when a patient deteriorates. There might be strategies to mitigate such preventable events. For example, improved situational awareness of nurses[38], or improving speaking-up behavior of healthcare professionals[39].

LIMITATIONS

Although we used a method that is considered the golden standard for studying AEs, using patient records to study the role of medical devices has limitations. Technical issues, such as malfunctioning, breakdowns, or suboptimal device design, might not always be reported in patient records. Sometimes such issues remain unnoticed, are not documented, or are only registered in the medical device management or maintenance systems. For example, when due to malfunctioning during a procedure, a device must be switched and retracting the malfunctioning device causes a perforation. Or when suboptimal usability of a device triggers a perforation. In such cases, the perforation will be reported in the patient record, while the malfunctioning or suboptimal usability of the device might not always be recognized, or not explicitly reported in the patient record. For the current study, this might have caused that our reviewers were not or limitedly able to identify such technical issues. The same problem -to a lesser extent- holds for system and organizational issues that prompt events. For example, when weak organization of care encourages inexperienced clinicians to place tubes for enteral feeding without supervision and under time pressure, or when an operating schedule was very busy contributing to a surgeon not thoroughly checking the surgery site postoperative. In these examples the organizational factors triggering events might not be reported in the patient record. Even though such factors are important to understand and prevent patient harm. It can thus be expected that the incidence of AEMDs might be underestimated and underlying device related and organizational/system issues remained unseen.

Another limitation is that we only focused on hardware. While in contemporary healthcare, software and health-IT related issues can also cause adverse events[40-42]. Software was excluded as it might even be harder to study these software and health-IT issues via patient record review.

RECOMMENDATIONS

As the identified topics reveal, the role of devices in most AEMDs is that the application of the device causes a known complication and care to adequately manage this complication falls short. Although in these cases the complications were often not considered preventable, it might still be possible to mitigate these. For example, specific bench marking[43 44] using clinical quality registries and auditing[45-48] and learning from excellence[49] have the potential to improve outcomes. In this manner it might be possible to identify best practices. Joint reflections between hospitals could then result in learning from such best practices, also related to medical devices. For example by exchanging; how to train clinicians, devices that

have great usability, or how care can be organized in such a manner that it improves safe application. Moreover, systematically registering AEMDs and mutually exchanging these with other healthcare professionals, analogue to for example the Netherlands' Pharmacovigilance Center Lareb, might help in preventing AEMDs. This is preferably organized on an aggregate (inter)national level, which requires an infrastructure for standardized registration of AEMDs. Over time the European database on medical devices EUDAMED might provide an outcome for this matter. Still, underreporting of AEMDs is a known limitation of such systems, and causes for not reporting are diverse and persistent[50 51].

The fact that some themes stood out, also raises other questions. If there are adverse events due to perforations of scopes, is it then very hard to use such devices? Do clinicians need better training? Could the usability of the device be improved? Or are there any other shortcomings in the design or environment that hinder safe application? Based on the current study, we can only signal AEMDs and not properly answer such questions. Partially because of the previously mentioned limitations of patient record review studies. To better explore the role of technology, and user-device and user-context interactions in adverse events, data from patient records, interviews with healthcare professionals and technical research should be combined. A compelling example is the study of Rauwers et al.[15], who after extensive root cause analysis and technical research, identified design issues in duodenoscopes threatening patient safety. Sentinel event or incident reports including root cause analysis descriptions might therefore be a useful source to further study the role of medical devices in patient safety events. Such data types and methods may also be more effective to study software and health-IT related adverse events. For such in-depth technical investigations, it is important to secure devices and any consumables after an event for further retrospective inspection.

CONCLUSION

Potentially preventable Adverse Events involving Medical Devices (AEMDs) occur in 1.9% of all patients deceased during their admission in Dutch hospitals in 2019. Most AEMDs contribute to, or cause the death of the patient. Medical Devices are involved in about half of all preventable adverse events. Themes in preventable AEMDs are: 1) application of (endo)scopes in which bleedings and perforations occur, 2) placement of heart implants and vascular implants after which infections and bleedings are lately diagnosed or inadequately treated, and 3) nasogastric and orogastric tubes that are incorrect positioned, or placed too early or too late. The role of the device in causing patient harm frequently related to provoking a known complication. This was often considered non-preventable. Preventability of most events lies in the subsequent management of bleedings, perforations, or infections.

Combining numbers on the incidence of AEMDs with additional analysis of the role of medical devices in these events, improves our insights on how medical devices are involved in adverse events. Though, for studying technical issues, observe interactions between device, user and environment, as well as software and health-IT related adverse events, further research -exploiting other types of data and methods- is needed.

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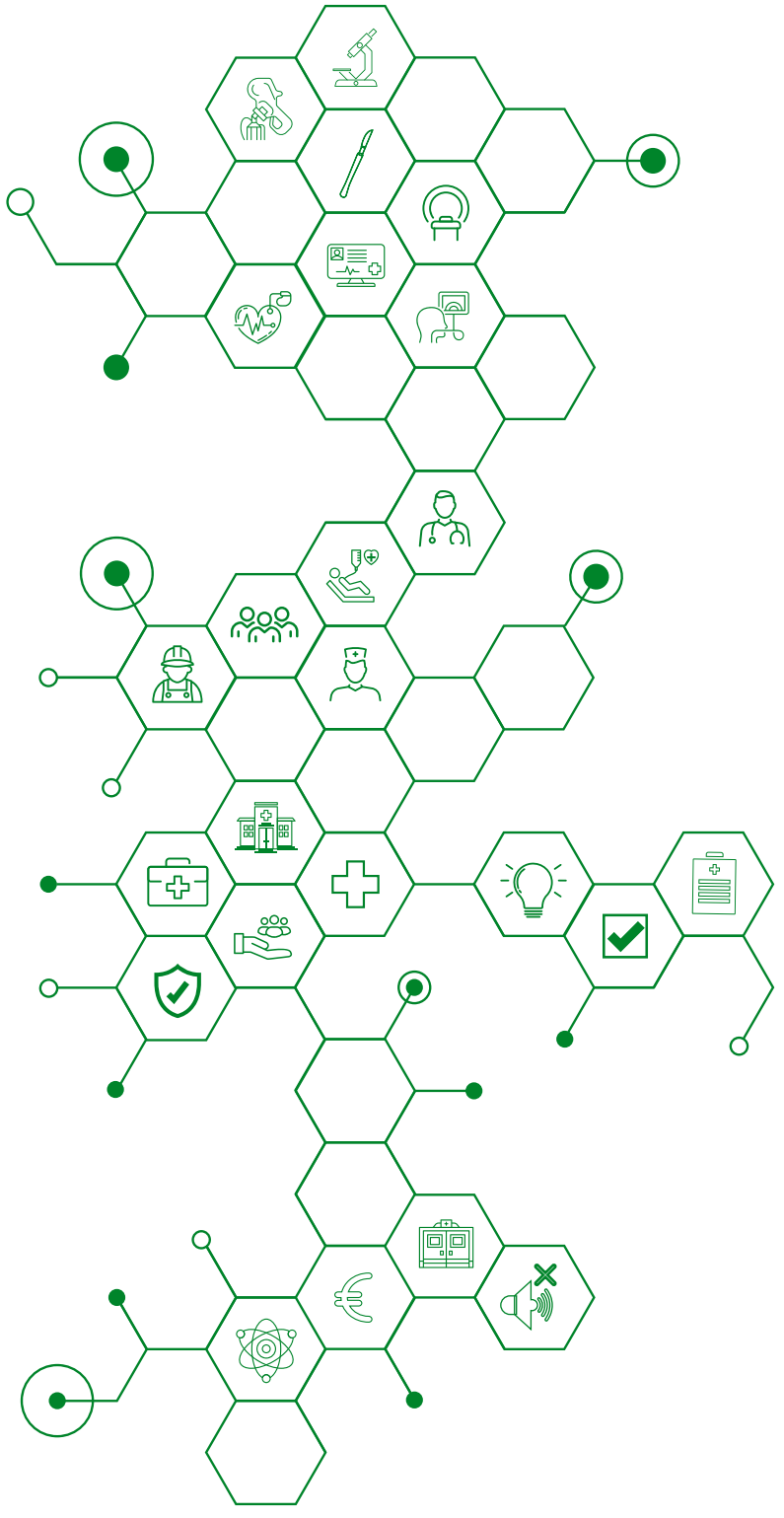
APPENDIX I.

ADVERSE EVENT SUMMARIES

Summaries of all potentially preventable adverse events involving medical devices
Died from abdominal sepsis as complication of ischemic perforation of the colon after implantation of an aortic bifurcation endoprothesis
Died in the aftermath of aspiration pneumonia after cystectomy and urinary (evacuation) deviation according to Bricker due to missed diagnosis of paralytic ileus
Died from abdominal sepsis after perforation of small intestine during PEG tube placement
Died due to complications (bleeding) after thoracoscopic lobectomy for carcinoma
Died of abdominal sepsis after peroperative undetected perforation of small intestine during laparoscopic pancreatic and spleen surgery
Non indicated gastroscopy in terminal esophageal carcinoma
Died due to intracranial hemorrhage after thrombectomy and late thrombolysis for stroke with concomitant hypertension
Died from complications of inadequate vascular reconstruction iliac vessel after damage during pelvic osteosynthesis
Died due to bleeding including retroperitoneal after non indicated thrombolysis after failed thrombectomy for cerebral vascular accident
Pneumothorax after too deep intubation (without control) for which a pleural drain was inserted
Multiple abdominal procedures and finally a colostoma after laparoscopic nephrectomy
Died due to sepsis after apical TAVI
Died after aortic arch surgery with multiple complications; intestinal ischaemia, renal insufficiency, and cerebral entrapment
Died after aortic valve surgery which caused a narrowed left coronary artery with cascade of complications
Died due to empyema (multiple drains) after aspiration pneumonia due to improper placement of feeding tube
Died after endovascular surgical procedures involving post-bleeding in ICU with resuscitation. At re-thoracotomy bleeding problems (on heparin) from rib fractures and thoracic wound
Died as a result of aspiration in postoperative highly productive gastroparesis wrongly treat with only duodenum feeding tube
Late diagnosis of infected aortic prosthesis
Died due to bleeding after inadequate explantation of an infected aortic prosthesis and insertion of new aorto-iliac system
Died after inadequate treatment of collapses and severe anaemia (no observation) in severe aortic stenosis
Died of endocarditis after inadequate follow-up of infected pacemaker
Died after inadequate surgery with bowel injury, causing enterocutaneous fistula after extensive colon surgery
Died after application of extracorporeal membrane oxygenation (ECMO), with a missed perforation of the iliacal artery
Died as a result of cardiac complications after very severe abdominal bleeding during inadequate percutaneous valve implantation
Died due to complications after laparotomy, including peritonitis due to perforation
Bleeding after ischemic stroke under anticoagulants, which were started too soon
Decubitus occiput and heels in a comatose patient
Died after non indicated carotid stenting in preparation for TAVI, resulting in ischemic colitis and ischemic cerebral vascular accident, and eventually respiratory insufficiency
Died as a result of a perforation of the heart by a subcutaneously cut and left behind wire of a mitraclip delivery system
Hematuria after application of a Foley catheter under high International Normalized Ratio

Continued.

Summaries of all potentially preventable adverse events involving medical devices
Died after inadequately treated septic complications of severe peripheral mixed atherosclerotic vascular disease and pressure ulcers
Died as a result of infected hemiarthroplasty with inadequate treatment and late diagnosis
Died due to sepsis staph aureus from peripheral infusion during admission and acute coronary syndrome
Died after inadequate surgery with complications after laparoscopic cholecystectomy with bile leakage (requiring ERCP), and pancreatitis
Died of intracerebral hematoma after late thrombolysis
Died as a result of aspiration after anesthesia/laparotomy
Died due to multiple complications of infected arthroplasty and very complex comorbidity involving insufficient care management
Intracerebral hemorrhage after contraindicated thrombolysis for pulmonary embolism
Died of peritonitis from PEJ catheter leakage
Died after inadequate surgery with septic complications after colon resection for recurrent volvulus
Died after inadequate surgery for bilateral inguinal hernia repair with complications, strangulation small intestine
Died as a result of pulmonary hemorrhage after a bronchoscopy for lung carcinoma under anticoagulation
Died due to late diagnosis of infected hematoma after total hip replacement
Died after suboptimal treatment, management and support of cholecytisis
Died due to acute renal failure after ascites drainage without albumin supplementation and lab monitoring
Died as a result of aspiration after a too early removed tube for enteral feeding
Died after inadequate laparoscopic surgery with bleeding complications and ischemic cerebral vascular accident after hemicolectomy
Died as a result of an untreated hemorrhage after endovascular treatment of severe central and peripheral obstructive vascular disease
Death after complicated course of a surgical treatment of a perforated diverticulitis
Died after a nephrectomy for urosepsis and untreatable hematuria due to kidney stones and infection
Inadequate diagnosis, patient was declared dead based on the monitor while in fact the patient was still alive
Died due to abdominal sepsis after perforation and/or anastomotic leakages of the duodenum after laparoscopic nephro-ureterectomy
Died as a result of aspiration pneumonia after faulty placement of enteral tube feeding
Contra-indicated surgery for urothelial carcinoma
Inadequate pain management in palliative management due to miscommunication about the rate of the IV-morphine pump
Died after inadequate reconstructive vascular surgery for aneurysm due to occlusion arterial vascular bed with ischemia in distal area
Died due to bleeding in surgical area of hemiarthroplasty
Died from complications (bleeding, urosepsis) after inadequate transurethral treatment in urothelial cell carcinoma
Died from complications (compartment syndrome and distal embolism) after attempted thrombolysis of already four-week-old occluded peripheral arterial bypass
Died as a result of a cardiac event after anemia caused by postoperative blood loss/hematoma under a suboptimal dose of Low-molecular-weight heparin (LMWH) for which no transfusion was given after a laparoscopic inguinal hernia repair
Late diagnosis anemia after mechanical heart valve implantation under anticoagulation
Trachea perforation and pneumothorax after enteral feeding tube placement
Died of cardiac complications after inadequate laparoscopic surgery for bladder colonic fistula



Chapter 3

Root cause analysis using the PRISMA-method in healthcare facilities: A systematic literature review

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ABSTRACT

OBJECTIVES

Unintended events (UEs) are prevalent in healthcare facilities and learning from them is key to improve patient safety. The Prevention and Recovery Information System for Monitoring and Analysis (PRISMA)-method is a root cause analysis (RCA) method used in healthcare facilities. The aim of this systematic review is to map the use of the PRISMA-method in healthcare facilities worldwide, to assess the insights that the PRISMA-method offers and to propose recommendations to increase its usability in healthcare facilities.

METHODS

Pubmed, EMBASE.com, Cinahl and the Cochrane library were systematically searched from inception to February 26th 2020. Studies were included if the PRISMA-method for analysing UEs was applied in healthcare facilities. A quality appraisal was performed and relevant data based on an appraisal checklist were extracted.

RESULTS

The search provided 2773 references, of which 25 articles met our inclusion criteria reporting 10816 UEs. The most frequently identified root causes were human-related, followed by organisational factors. The majority of studies took place in the Netherlands (n=20) and the sample size ranged from 1-2028 UEs. The study setting and collected data used for PRISMA varied widely. PRISMA performed by multiple persons resulted in more root causes per event.

CONCLUSION

To better understand UEs in healthcare facilities and formulate optimal countermeasures, our recommendations to further improve the PRISMA-method mainly focus on combining information from patient files and reports with interviews, including multiple PRISMA-trained researchers in an analysis, and modify the Eindhoven Classification Model if needed.

INTRODUCTION

One of the key elements to improve patient safety is learning from adverse events.[1] Especially unintended events (UEs) can be a valuable source of information to improve patient safety. Unintended events are a broad group of events, including near misses, that might but do not necessarily result in patient harm.[2,3] They can be both preventable and unexpected. In clinical practice, there is an increasing interest in the development of systems to systematically evaluate UEs, because several large studies showed that medical errors result in patient harm, leading to temporary or permanent disability or death.[4–6] To gain insight into the quality of care, it is necessary to know more about the types of UEs and their root causes, which will simultaneously give insight into possibilities for prevention of UEs. However, there is no standard method to systematically collect, analyze, and compare data related to UEs and their causes among healthcare facilities.[7]

A frequently used approach to improve patient safety is to thoroughly study and analyze a UE to find contributing factors and root causes, and formulate corrective measures.[8] A number of analysis tools are brought together under the term root cause analysis (RCA), for example, fishbone diagrams, cause-effect charts, and “five whys.”[8] A comprehensive RCA-method that is frequently used in Dutch healthcare facilities is the Prevention and Recovery System for Monitoring and Analysis (PRISMA)-method.[9,10] This method examines the relative contributions of latent factors (technical and organizational root causes), active failures (human behavior–related root causes), and other factors (patient-related and other root causes). The main goal of the PRISMA-method is to build a quantitative database of UEs and process deviations, to facilitate the development and evaluation of system-based preventive strategies.

The PRISMA-method consists of 3 important pillars: incident description, root cause classification, and the translation to structural measures. First, the incident is described using a causal tree that provides a visual interpretation of the chronological chain of critical activities and decisions leading to an UE. At the top of the tree, the top event, a brief description of the event, is formulated, which is the start of the analysis. By continuously asking “why” the event occurred, all direct causes are identified. When no further objective causes can be identified, the last indirect cause is considered as the root cause. All root causes are logically related to each other and incorporated into the tree (Appendix 1, and Fig. 1). After compiling the causal tree, the root causes, which form the bottom layer of the causal tree, are classified using the Eindhoven Classification Model (ECM; Appendix 2). The ECM distinguishes 4 main categories, namely, technical, organizational, human, and other factors, including patient-related factors and unclassifiable factors. These main categories can be subdivided into 20 subcategories. After root cause classification, information on the event and the identified root causes are placed in a database. Prevention strategies can then be directed at these most frequently occurring (combinations of) root causes.

Although this method is accepted in healthcare facilities and adopted by the World Health Organization[11,12], little is known about the application (type of event, study setting) and implementation (data collection, study size, execution of analysis) of the PRISMA-method for analyzing UEs in healthcare facilities. This knowledge gap hinders our ability to learn from insights the PRISMA-method has already provided, and makes it difficult to further improve the application of PRISMA to prevent UEs in healthcare facilities worldwide.

The aims of this study are therefore to give a systematic literature overview of the use of the PRISMA-method in healthcare facilities and to assess the overall insights the PRISMA-method offers to better understand the causes of the UEs. We are particularly interested in the application and implementation of the PRISMA-method and the most common root causes contributing to UEs in healthcare facilities. Moreover, we intend to provide recommendations for further improvement of the method.

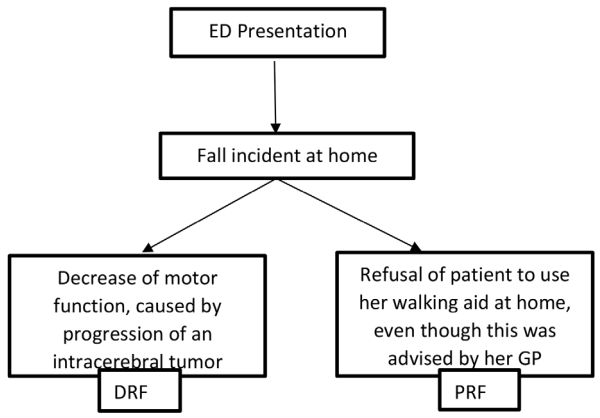

Figure 1. Example of root causal tree.

METHODS

To achieve this aim, we performed a systematic literature review. Two researchers (B.E.J.M.D., R.O.) used the structure and recommendations from the Preferred Reporting Items for Systematic Review and Meta-Analysis checklist (PRISMA statement, www. prismastatement. org) as a guideline to conduct the literature search.[13] We performed systematic searches to find all relevant publications about the "Prevention and Recovery Information System for Monitoring and Analysis" (PRISMA) in the analysis of medical incidents and events searching the bibliographic databases PubMed, EMBASE.com, CINAHL (via EBSCO), and The Cochrane Library (via Wiley) from inception to February 26, 2020. Search terms included controlled terms (e.g., MeSH in PubMed and Emtree in Embase) as well as free-text terms. We used free text terms only in The Cochrane Library. Search terms expressing "PRISMA" were used in combination with terms comprising "medical events." In the search, all languages were accepted. The references of the identified articles were searched for relevant publications. The full search strategies for all databases can be found in Appendix 3.

Subsequently, all search results were uploaded to Endnote, to facilitate organizational and removal of duplicates. Second, results (duplicates excluded) were imported in Rayyan, an Internet-based software program that facilitates collaboration among reviewers during the study selection process. Two reviewers (B.E.J.M.D., M.B.) independently screened titles and abstracts and assessed these for eligibility. Ineligible records were excluded (reasons were recorded), and full texts of the remaining studies were assessed independently for eligibility. Results of these assessments were compared, and in case of uncertainty about inclusion, the articles were discussed with a third researcher (H.M.). English- or Dutch written articles were included in the study if they (1) published original findings using PRISMA analysis in healthcare facilities, (2) classified the root causes using the ECM, and/or (3) used an observational study design, which included prospective and retrospective cohort studies, case-control studies, cross-sectional studies, case series, and case reports. Studies that applied PRISMA outside of healthcare facilities, articles only focusing on elaborating PRISMA, and articles using the ECM in combination with an unknown RCA or RCA other than PRISMA were excluded. When there was no full text available, articles were excluded. There were no restrictions by publication year, type of setting within healthcare facilities, or follow-up.

QUALITY APPRAISAL AND DATA SYNTHESIS

Two authors (B.E.J.M.D., M.B.) independently assessed the quality of included studies using the National Heart, Lung, and Blood Institute Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies[11] to ensure an objective evaluation process. This tool includes 14 questions assessing the internal validity of the studies resulting in an overall quality rating of "good," "fair," or "poor." The tool considers information such as specification of study population, participation rate, measurement of exposure(s) of interest, time frame, and blinding of outcome assessors.

DATA EXTRACTION

The following data were extracted from each included study; title, first author, journal, publication year, language, aim, design, study period, study population, hospital setting, department setting, data collection, PRISMA analysis, intervention, type of ECM used, follow-up, outcomes, limitations, future research, and implications. In addition, specific data regarding characteristics and application of the PRISMA-method were extracted, such as number of researchers conducting the PRISMA, training/experience in PRISMA of

researchers, ECM-classification profiles, and types of suggested measures for improvement. During the whole process, uncertainties were resolved through team discussions (B.E.J.M.D., M.B., and H.M.) and consensus.

RESULTS

STUDY SELECTION

A total of 3926 studies including duplicates were retrieved from all databases after the initial search. After removal of 1153 duplicates, 2773 unique studies remained for the title and abstract review. Next, 2150 studies were excluded after screening titles and abstracts. Main reasons for exclusion were “Descriptive,” “Use of causal tree, no PRISMA,” “Not in Healthcare facility,” “No RCA,” and “Other type of RCA.” From the resulting 623 articles, there was no access to a full-text version of 72 of the studies, and 17 articles were poster or congress abstracts. Another 509 studies were excluded after full-text evaluation because the study applied a different type of analysis from the PRISMA-method. Eventually, 25 studies were included in the final review. Figure 2 outlines the article selection process.

QUALITY ASSESSMENT

Overall, 3 studies were rated as “poor,” 8 studies as “fair,” and 14 studies as “good” quality (Table 1). The articles with a “poor” quality rating lacked information concerning research question, study design, study population, and description of implication of the PRISMA-method. Because of the aim of the study was to give a comprehensive overview of the application of PRISMA, we also included these “poor”-rated studies in our sample. Overall agreement on methodological quality score between researchers was 88%.

STUDY CHARACTERISTICS

The characteristics of the included articles are presented in Table 2. The publication year of the 25 articles ranged from 1998 to 2019, and most of the studies (n = 20) took place in the Netherlands. The sample size ranged from a single case study[21] to a multicenter study analyzing 2028 UEs.[27] All studies were presented as observational cohort studies, with a retrospective (n = 23) and prospective (n = 1) design. Van Dulmen et al[16] combined a retrospective patient record review with prospective event reporting. The design was not clearly mentioned in 5 studies but interpreted as observational by the researchers.

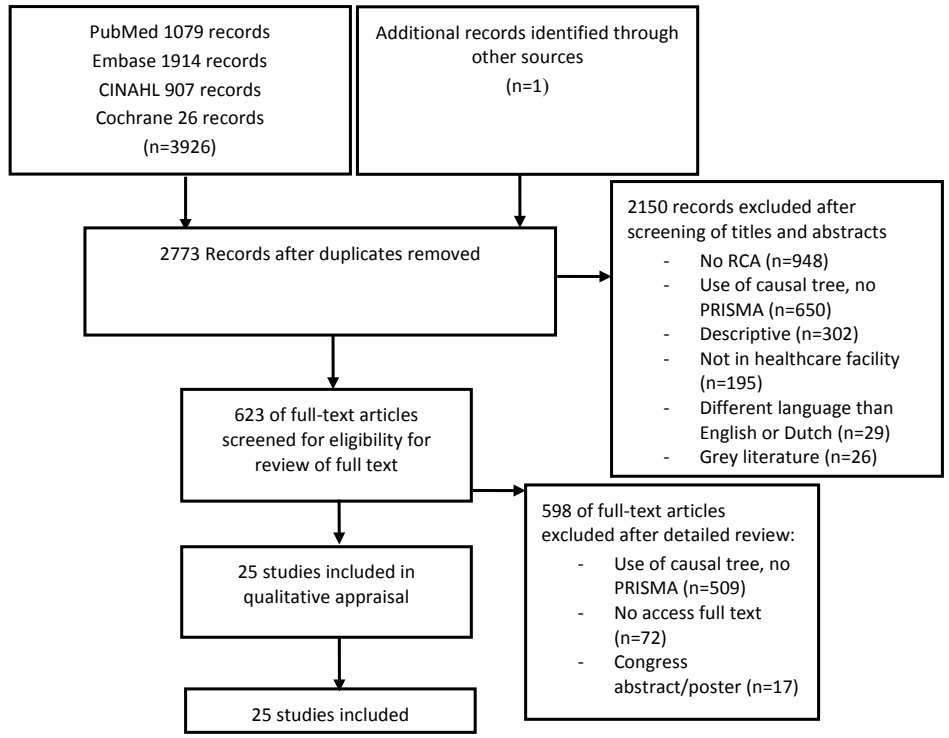

Figure 2. PRISMA Flow diagram of article selection.

Table 1. NHLBI, NIH: National Heart, Lung, and Blood Institute Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies [11].

Reference	Author	Score	Missing information in description of:
12	Battles et al. 2001	Fair	Study population Exposure measures and assessment
14	Cooksley et al. 2015	Fair	Study population Exposure measures and assessment
15	Driesen et al. 2018	Good	
16	Van Dulmet et al. 2011	Fair	Sample size justification Exposure measures and assessment
17	Fluitman et al. 2016	Good	
18	Van Galen et al. 2016	Good	
19	Van Galen et al. 2018	Good	

Table 1. Continued.

Reference	Author	Score	Missing information in description of:
20	Kaplan et al. 1998	Poor	Research question, Study population Participation rate Time frame
21	Klemt-Kropp et al. 2011	Poor	Research question Exposure measures and assessment Outcome measures
22	Lubberding et al. 2011	Good	
23	Merten et al. 2013	Good	
24	Van Noord et al. 2010	Good	
25	Rodriques et al. 2011	Poor	Research question Study population Exposure measures and assessment Outcome measures
26	Sasaki et al. 2018	Fair	Study population Blinding of outcome assessors
27	Smits et al. 2009	Good	
28	Smits et al. 2009	Good	
29	Smits et al. 2019	Fair	Study population Groups recruited from the same population
30	Snijders et al. 2008	Good	
31	Snijders et al. 2010	Fair	Study population
32	Thomas et al. 2007	Good	
33	De Vries et al. 2015	Fair	Sample size Blinding of outcome assessors
34	Wagner et al. 2016	Good	
35	Van Wagtendonk et al. 2010	Good	
36	Wubben et al. 2010	Fair	Sample size justification Time frame
37	Zegers et al. 2011	Good	

Table 2. Descriptive characteristics of included studies.

Reference	Author	Country Year of publication	Type of event	Setting Depart-ment	Data collection	Nr of Root causes	Root cause per event	ECM modification	Most reported ECM classification
12	Battles et al.	USA, The Netherlands 2001	Error (n=3)	ED and IC	NR	19	6.3	Original	Organisational n= 11 (59%)
14	Cooksley et al.	UK 2015	Readmissions (event) (n=50)	Oncology	Patientfile	NR	NR	Original	Patient N=50 (100%) disease related
15	Driesen et al.	The Netherlands 2018	Increased ED-LOS (event) (n=74)	ED	Patientfile	276	3.3	Modified Disease related factor added	Organisational n=216 (78%)
16	Van Dulmen et al.	The Netherlands 2011	Incidents (n=18)	Physiotherapy, occupational therapy and cesar-mensendieck therapy	Patientfile	55	3.1	Original	Human n=40 (73%)
17	Fluitman et al.	The Netherlands 2016	Readmissions (event) (n=50)	Internal medicine	Patientfile	100	2	Modified Disease related factor added	Disease related n=46 (46%)
18	Van Galen et al.	The Netherlands 2016	Unplanned ad missions (event) (n=49)	IC	Patientfile	155	3.2	Modified Disease related factor added	Human N=71 (46%)
19	Van Galen et al.	The Netherlands 2018	Readmissions (event) (n=237)	Surgery	Reportform Interview	271	1.1	Modified Disease related factor added	Disease related n=218 (87%)
20	Kaplan et al.	USA 1998	Events/process (n=506)	Blood center Transfusion center	Reportform	1238	2.9	Modified Content adopted for MERS-TM, no change in (sub) categories	Human n=569 (46%)
21	Klemt-Kropp et al.	The Netherlands 2011	Error (n=1)	MDL	NR	8	8	Original	Organisational n=5 (63%)

Table 2. Continued.

Reference	Author	Country Year of publication	Type of event	Setting Depart-ment	Data collection	Nr of Root causes	Root cause per event	ECM modification	Most reported ECM classification
22	Lubberding et al.	The Netherlands 2011	Unintended events (n=625)	Internal medicine	Reportform Interview	920	1.5	Original	Human n=706, 77%
23	Merten et al.	The Netherlands 2013	Adverse events (n=663)	All departments, excluding psychiatry, obstetrics, children<1year	Patienfile	1278	1.9	Modified • Human-violation added Human-other added	Human n=808 (63%)
24	Van Noord et al.	The Netherlands 2010	Malpractice claims (Incident) (n=50)	ED	Patientfile	114	2.3	Modified • Organisational X-ray results (OR) added Organisational no contact with supervisor (OS) added	Human n=76 (67%)
25	Rodriques et al.	Portugal 2011	Error (n=79)	Radiology	NR	NR	NR	Modified Content adopted for medical imaging field, no change in (sub)categories	NR
26	Sasaki et al.	Japan 2018	Incidents (n=95)	Allergology	Reportform	220	2.3	Modified Home/facility category instead of Organisational	Organisational-home facility n=74 (34%)
27	Smits et al.	The Netherlands 2009	Unintended events (n=2028)	ED, Internal medicine, Surgery	Reportform Interview	3015	1.4	Original	NR
28	Smits et al.	The Netherlands 2009	Unintended events (n=522)	ED	Reportform Interview	845	1.6	Original	Human N=507 (60%)
29	Smits et al.	The Netherlands 2019	Adverse events (n=571)	All departments, excluding psychiatry, obstetrics, children<1year	Patienfile	588	1.0	Modified • Violation added • Human skills added Other added	Patient related n= (47.4%)

Table 2. Continued.

Reference	Author	Country Year of publication	Type of event	Setting Depart-ment	Data collection	Nr of Root causes	Root cause per event	ECM modification	Most reported ECM classification
30	Snijders et al.	The Netherlands 2008	Incidents (n=981)	NICU and PICU	Reportform	2313	2.4	Original	Human n=1480 (64%)
31	Snijders et al.	The Netherlands 2010	Incidents (n=533)	NICU and PICU	Reportform	1233	2.3	Original	Human n=293 (55%)
32	Thomas et al.	UK 2007	Incidents (n=349)	ED	Reportform, Patienfile, Interview	852	2.4	Modified • Technical-other instead of Technical-material • Human-execution instead of Human-intervention Multiple-patients added	Organisational n=295(35%)
33	De Vries et al.	The Netherlands 2015	Unintended event (n=41)	Urology	Reportform.	NR	NR	Original	Human, estimated 65%
34	Wagner et al.	The Netherlands 2016	Incidents (n=2028)	ED, Internal medicine, Surgery	Reportform Interview	3015	1.5	Modified Patient related and other combined in one category	Human n=2117 (70%)
35	Van Wagtendonk et al.	The Netherlands 2010	Unintended events (n=881)	Surgery	Reportform Interview	1250	1.4	Original	Human n=904 (73%)
36	Wubben et al.	The Netherlands 2010	Incidents (n=15)	Operation room	Reportform, Patientfile, Interview	40	2.7	Original	Human n=16 (40%)
37	Zegers et al.	The Netherlands 2011	Adverse Events (n=367)	Surgery	Patientfile	653	1.8	Original	Human n=426 (65%)

NR: not reported
ED: emergency department; GLD: Gastroenterology and liver disorders; IC: intensive care department; PICU: pediatric intensive care unit; NICU: neonatal intensive care unit; MERS-TM: medical event reporting system for transfusion medicine

STUDY POPULATION

Variations in definitions, type of event, and measurement of the study population were evident. In 6 studies, events without deviations were analyzed.[14,15,17–20] The study objects in these articles were event reports in transfusion medicine,[20] readmissions,[14,17,19] unplanned intensive care department admissions,[18] and an emergency department (ED) length of stay >6 hours.[15]

In 19 studies, events with deviations were analyzed, including incidents,[16,24,26,30–32,34,36] UEs,[22,27,28,33,35] errors,[12,21,25] and adverse events.[23,29,37] In almost all (n = 7) of the studies analyzing incidents, a clear definition of "an incident" was mentioned. For example: "A critical incident was defined as an event that had actual or potential harmful effects on the outcome of the management of a patient or group." [33] Unintended events were defined as "a broader group of events—including near misses—that do not necessarily result in patient harm."[22,27,28,32,35] The adverse events in the study by Zegers et al[37] and Merten et al[23] were defined as "unintended injuries among patients that results in disability, death or prolonged hospital stay, and is caused by health care management."

STUDY SETTING

The majority of the studies (n = 23) were conducted in a hospital setting. In the 2 other studies, patients were included from 3 allied healthcare disciplines (physical therapy, occupational therapy, and Cesar Mensendieck exercise therapy)[16] and from a blood and transfusion center.[20] The majority of studies (n = 16) limited the study population to one department or specialty,[14,15,17–19,21,22,24–26,28,29,32,33,35,36] whereas others included cases from various hospital departments.[19,29,33,36–39]

DATA COLLECTION AND IMPLEMENTATION OF PRISMA

The collected data used for the PRISMA analysis were gathered using different sources. In 9 studies, the information for the PRISMA analysis was based on patient files,[14–18,23,24,29,37] and in 5 studies, the data were collected from a report form.[20,26,30,31,33] In 3 studies, the report form was based on voluntary, nonpunitive reporting.[26,30,31] In some studies, the data were collected from a combination of sources; 6 studies used a combination of a report form and an interview,[19,22,27,28,34,35] and 2 studies used a combination of a report form, an interview, and a patient record.[32,36] In 3 studies, the sources underlying the data used for analysis are unknown.[12,21,25]

Researchers received a PRISMA-training in almost half (n = 12) of the included studies.[15,17,18,20,22,24,27,30,31,34,35] This training ranged from a 3-hour workshop[20] to a 2-day course.[30,31] In the majority of studies (n = 14), the PRISMA analysis was performed by 2 persons or a team (independent from each other). This team could consist of "analysts,"[33] "researchers,"[15,17,18,22,34] a multidisciplinary safety commission consisting of at least 1 physician and 3 nurses,[36,37] multiple doctors,[12,23,26,33,37] or physical therapists.[16] The mean root causes per event were 2.5 in the articles where the analysis was performed by multiple persons (range, 1.4–6.3). In 8 studies, the PRISMA analysis was conducted by a single person[19,20,24,28,29,32,35,36]; here the mean root causes per event were 1.8 (range, 1.0–2.9). In 3 articles, it is unknown who performed the PRISMA.[14,20,25] Furthermore, interobserver agreement on root causes and ECM classification was studied in 10 of the studies,[16,24,27–33,37] with scores ranging from "moderate" to "good."

ROOT CAUSES AND ECM

Human-healthcare worker–related root causes were the most frequently found ECM-classified root causes in the majority of the studies (n = 14).[16,18,20,22–24,28,30,31,33–37] In other studies, the main category of root causes was organizational factors (n = 5),[12,15,21,26,32] disease-related factors (DRF; n = 2),[16,19] and patient-related factors (n = 2).[14,30] The distribution of root causes was not mentioned in 2 studies.[25,27] The most frequently reported human-healthcare worker–related root causes were as follows: knowledge-based behavior (n = 3),[16,23,24] intervention (n = 2),[22,36] verification (n = 1),[33] monitoring (n = 1),[18] external (n = 1),[6] and rule-based behavior (n = 1).[31] In 5 studies, the further subdivision of the human/healthcare worker– related root causes was not reported.[12,30,34–36]

In the 14 studies where human-healthcare–related root causes were most prominent, the majority of the studies analyzed incidents.[16,24,30,34,36] Furthermore, the analysis was limited to one department,[18,20,22,24,28,33,35–37] and the PRISMA was done by multiple persons[16,18,22,23,30–32,34,37] in most of the cases. Six studies[22,28,30,34–36] used a combination of data sources for the PRISMA-method. Patient interviews were used in 5 studies.[28,30,34–36] The number of root causes per event ranged from 1.4[35] to 3.2.[18]

In 13 studies, the original ECM was used, and in 12 studies, the ECM was modified because the current ECM did not sufficiently cover the observed types of failures (Table 2). In 4 studies, a new DRF category was added.[17–19,29] The disease-related root cause was first described by Fluitman et al[17] in 2016 and defined as "failures related to the natural progress of disease which are beyond control of patients, their carers and staff." In these 4 studies, the DRF refers to readmissions and unplanned admissions of patients. The authors assumed that progression of disease would be identified as root cause in many readmissions without other factors contributing. Other modifications included adaptation of the content of categories to the study population[20,25] and addition of new subcategories, for example, human violation[23,29] and organizational x-ray results.[24]

DISCUSSION

This systematic review identified 25 original studies using the PRISMA-method for RCA. The results show that the PRISMA-method is applicable in a wide variety of healthcare settings. Most studies analyzed UEs, predominantly incidents. Furthermore, most studies were limited to one department or specialty and used patient files or report forms for data collection, and the analysis was done by multiple persons. Overall, human-healthcare worker– related root causes were the most common root causes, followed by organizational factor–related root causes.

Based on descriptions of various RCA methods in the literature[10,38–42] and their limitations,[43–46] and the results of this review, we believe that PRISMA has some important features that make it one of the most valuable RCA methods. First, PRISMA is suitable for events varying in seriousness and complexity, whereas other methods are designed to investigate more serious adverse events. Another advantage of PRISMA medical is that it intends to build a database of multiple events to find reoccurring patterns of root causes.[9,10] Based on these patterns, it might be possible to formulate more effective corrective measures. Because both active failures (human failures) and latent failures (technical and organizational failures) are discovered through PRISMA, the total profile of root causes provides a more realistic view of how the system is actually working. The standardized root cause classification improves the comparability of investigated events between healthcare facilities as well as in the identification of common problems and concerns that exist throughout the medical field.

Most studies reported events where the reporting system and analysis was limited to a single department or service within the hospital. Local, department-based reporting systems can help to get faster and more detailed insight into unit-specific safety issues. The assumption is that incidents differ between departments and that incidents reported and analyzed by the department where the incident happened will create a greater sense of urgency and willingness to change practice. Wagner et al[34] found significant differences in incident types and especially in root causes between emergency, surgery, and internal medicine departments, therefore recommending department-based reporting. A limitation of department-based analysis is that causes occurred in other departments are classified as external. It is possible that an external factor in fact had more underlying root causes, and they remain hidden because of the choice to examine just one department. In 4 studies, events from the ED were collected and analyzed.[15,24,28,32] Many of the root causes in the studies restricted to the ED were classified external. Driesen et al[15] found 76% of the ED length of stay of more than 6 hours was due to organizational causes, of which 94% was outside the influence of the ED.[15] This indicates that a large number of events occurred in collaboration with departments outside of the ED, and the healthcare for patients depend on good collaboration between departments.

The patient file method for data collections was the most used, but this may not be the most accurate method. Technical and organizational causal factors are less often reported in patient files and may therefore be underestimated. An organizational factor could, for example, be a shortage of hospital staff. However, such causes are not typically written down in patient files and therefore remain invisible to the researchers. This is in line with our results; in the studies where the patient file was the only data source, the majority of the articles had a human factor as most common root cause[16,18,23,24,37] in contrast to other data sources. Multiple studies[14,17,18,23,29,37] suggested that besides the patient file or a report, an interview with those involved at a local level can lead to a deeper understanding. The interview depends on the recall of the reporters, and UEs should be discussed within a few days. This is in line with our results showing that when the data were based on interviews only, organizational root causes were most prominent.

On average, there were more root causes per event in the studies where the PRISMA analysis was done by multiple persons (2.5 versus 1.8). An explanation could be that multiple persons have different perspectives, especially when there is a multidisciplinary team including different healthcare workers, for example, doctors and nurses, or people without direct patient healthcare experience or contact, for example, experts in the field of human factors/ ergonomics, clinical technologists, or PhD researchers. This could also contribute to finding more technical and organizational root causes. Furthermore, based on our practical experience, we believe it is important for the reliability of the PRISMA-method that the researchers are trained in PRISMA and that they have knowledge of the department and its processes. In this study, almost half of the articles mentioned that the researchers received training. Only in a small part of the studies the content and the duration of the training were mentioned, and therefore, it was difficult to substantiate this hypothesis. Overall, human-healthcare worker– related root causes were most prominent in the included studies. These root causes can be defined as “errors and violations committed by those in direct contact with the human–system interface.” [47] Our finding that the root causes were mainly human-related is in line with other studies investigating (adverse) events that also found that causes related to the people involved, such as human behavior, cognitive biases, and poor communication, were frequently or dominantly reported.[38,48–51] However, as mentioned before, the type of root cause can be dependent on the source of the data collection used and PRISMA team composition. To get an overall view, a report form should be combined with patient file and an interview, and various disciplines should be represented in the team.

STRENGTHS

This is the first systematic literature review giving an overview of the use of the PRISMA-method in healthcare facilities. An experienced librarian (R.O.) assisted in the literature search, and the screening of the articles, the data collection, and the quality assessment

were independently done by 2 researchers (B.E.J.M.D. and M.B.).

LIMITATIONS

First, 3 studies were rated "poor quality" because information on several study characteristics was not reported. However, we included these studies because the aim of our study is to provide an overview, and therefore, the lacking information does not bias our results or discussion. Second, 20 of the 25 included studies were concerned with Dutch healthcare facilities. This may be the result of the popularity of the PRISMA analysis in the Netherlands, which in turn could be explained by the Dutch origin of the method and its founders.

RECOMMENDATIONS

To get a complete view of all contributing root causes of UEs, we recommend combining patient files and reports with interviews when conducting a PRISMA analysis, thereby striving for a small time lag between the occurrence and the assessment of the UE to decrease the likelihood of memory failure.[35] In that case, involved healthcare providers can be interviewed to provide more information on organizational and technical factors that might have contributed to the UE.

Preferably, the PRISMA should be performed by multiple researchers representing various disciplines, who should get training in making causal trees and classifying root causes, as training of researchers increases reliability.[52] When using department-based analyzing, it is advisable to modify the ECM to gain more insight into the causes outside of the department, for example, the addition of the DRF.

CONCLUSIONS

This study outlines the current variety of the use of the PRISMA-method in healthcare facilities worldwide. Human-healthcare worker–related root causes were found to be the most commonly reported root causes, followed by organizational factor–related root causes. The selected studies showed that the PRISMA-method is a useful tool with added value for analyzing UEs in healthcare facilities. To improve the usability of PRISMA, we suggest combining information from patient files and reports with interviews, including multiple PRISMA-trained researchers representing various disciplines in an analysis, and modify the ECM if needed, to make care safer and more efficient by learning from UEs in healthcare processes.

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APPENDIX 1.

SUPPLEMENTARY TEXT PRISMA.

A frequently used approach to improve patient safety by determining contributing factors and developing recommendations, is root cause analysis (RCA). A number of analysis tools is brought together under the term RCA, for example fishbone diagrams, cause-effect charts and “five why’s”. A comprehensive RCA method that is frequently used in Dutch health care facilities is the Prevention and Recovery System for Monitoring and Analysis (PRISMA)-method. The PRISMA-method served as a basis for the World Health Organisation (WHO) to develop a conceptual framework for the international classification for patient safety. The PRISMA-method was originally developed to manage human error in the chemical process industry, but in the last decade, it was also applied in the transportation sector, as well as in healthcare (PRISMA-Medical). The method is based on the theory of system approach of Reason and the skill–rules–knowledge-based behavior model of Rasmussen and examines the relative contributions of latent factors (technical and organizational), active failures (human) and other factors (patient related and other) in order to facilitate the development and evaluation of system-based preventive strategies. The main goal of the PRISMA-method is to build a quantitative database of (unintended) events and process deviations, from which conclusions may be drawn to suggest optimal countermeasures.

The PRISMA-method consists of three main steps; incident description, cause classification and the translation to structural measures. In step one an incident or event description is carried out through the creation of a root causal tree. To construct a causal tree, the information from the interviews and EPR was used. At the top of each tree the presentation at the ED was placed. Just below the top event, all direct causes that can be identified are mentioned. They were retrieved by posing the question why the incident has happened. These direct causes often have their own causes, the indirect causes. By constantly asking “why” an event had taken place, relevant indirect causes were systematically exposed. When no further objective causes could be identified, the last indirect cause was considered as the root cause. Root causes are classified using the Eindhoven Classification Model (ECM, see Appendix 2) as technical-, organisational-, human-, and patient-related factors. The main categories can be subdivided into 20 subcategories. In the final step, the PRISMA profile is made and prevention recommendations can be directed at the most frequently occurring root causes. An example of a root causal tree is displayed in Figure 1.

APPENDIX 2.

DESCRIPTION OF CATEGORIES OF THE EINDHOVEN CLASSIFICATION MODEL: PRISMA MEDICAL VERSION [9,10]

Main category	Subcategory	Code	Description
Technical	External	T-ex	Technical failures beyond the control of the organization.
	Design	TD	Failures to poor design of equipment etc.
	Construction	TC	Correct design inappropriately constructed or placed.
	Materials	TM	Material defects not classified under TD or TC.
Organisational	External	O-ex	Failures at an organizational level beyond the control and responsibility of the investigating team.
	Transfer of knowledge	OK	Failure resulting from inadequate measures to train or supervise new or inexperienced staff.
	Protocols	OP	Failures relating to the quality or availability of appropriate protocols.
	Management priorities	OM	Internal management decisions which reduce focus on patient safety when faced with conflicting priorities.
	Culture	OC	Failure due to attitude and approach of the treating organization.
Human	External	H-ex	Human failures beyond the control of the organization/department
	Knowledge-based behavior	HKK	Failure of an individual to apply their knowledge to a new clinical situation
	Qualifications	HRQ	An inappropriately trained individual performing the clinical task
	Co-ordination	HRC	A lack of task co-ordination within the healthcare team.
	Verification	HRV	Failure to correctly check and assess the situation before performing interventions
	Intervention	HRI	Failure resulting from faulty task planning or performance
	Monitoring	HRM	Failure to monitor the patient’s progress or condition
	Skills-based	HSS	Failure in performance of highly developed skills
Patient	Patient-related	PRF	Failures related to patient characteristics or conditions, which are beyond the control of staff and influence clinical progress
X	Unclassifiable	X	

APPENDIX 3.

SEARCH STRATEGIES

Search strategy in PubMed (2020 February 26 th)

#	Query	Results
#9	#5 OR #6 OR #7 OR #8	**1079**
#8	#2 AND #3	**18**
#7	#1 AND #4	**32**
#6	#1 AND #2	**1020**
#5	"Medical Errors/classification"[Mesh] AND (cause*[ti] OR failure*[ti])	**33**
#4	prisma[tiab] AND (cause*[tiab] OR causal[tiab]) NOT systematic[sb]	**264**
#3	prisma[tiab]	**10431**
#2	"Root Cause Analysis"[Mesh] OR root cause*[tiab] OR (causal[tiab] AND tree[tiab]) OR Prevention and Recovery Information System for Monitoring and Analysis[tiab] OR eindhoven classification model[tiab] OR causal classification model[tiab] OR medical event reporting system[tiab]	**4771**
#1	"Medical Errors"[Mesh] OR medical event*[tiab] OR adverse event*[tiab] OR safety event*[tiab] OR error*[tiab] OR incident[tiab] OR incidents[tiab]	**625967**

Search strategy in Embase.com (2020 February 26th)

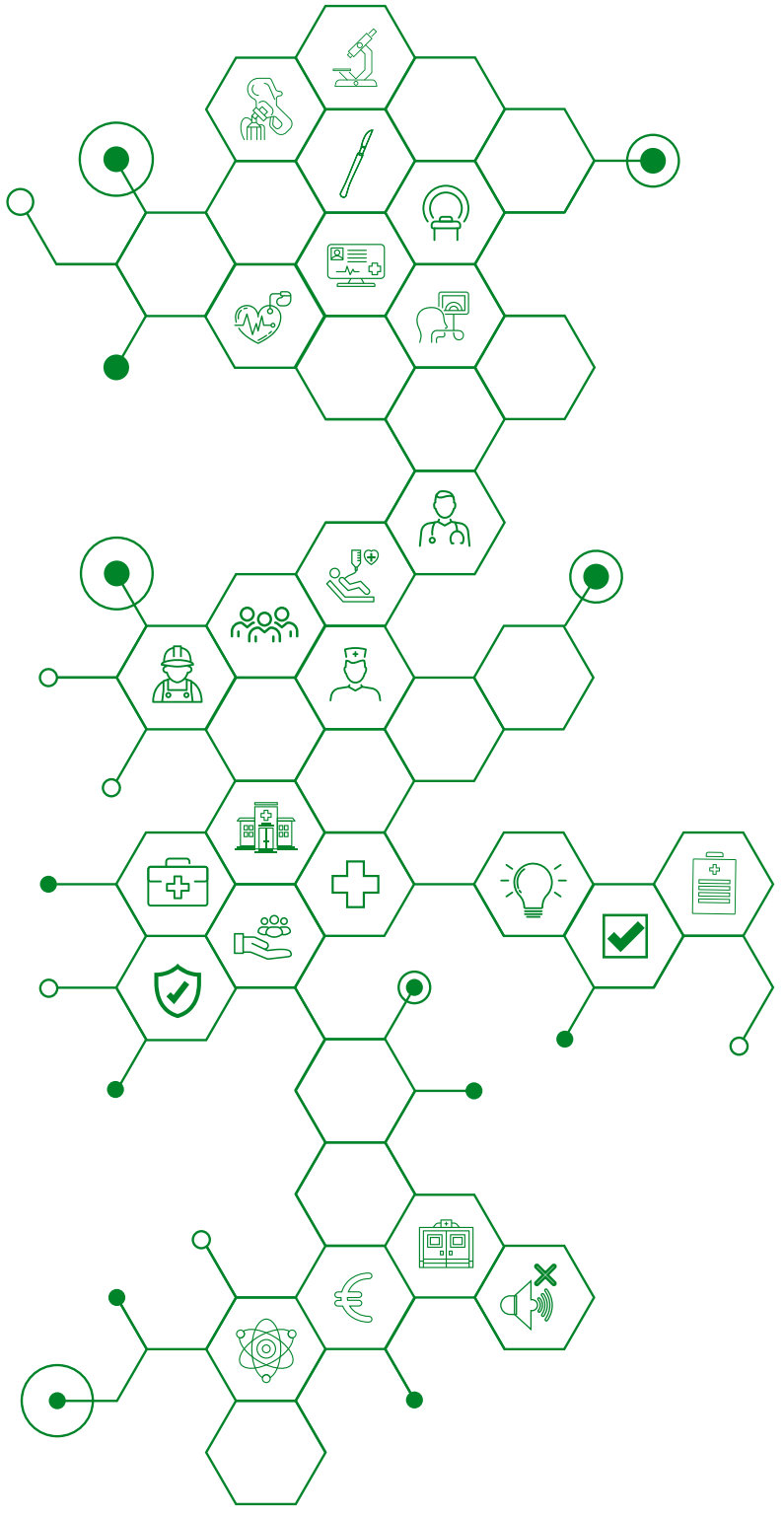
#	Query	Results
#8	#5 OR #6 OR #7	**1914**
#7	#2 AND #3	**25**
#6	#1 AND #4	**39**
#5	#1 AND #2	**1881**
#4	prisma:ti,ab,kw AND (cause*:ti,ab,kw OR causal:ti,ab,kw) NOT ([systematic review]/lim OR 'systematic review':ti,ab,kw)	**218**
#3	prisma:ti,ab,kw	**13624**
#2	'root cause analysis'/exp OR 'root cause*':ti,ab,kw OR (causal:ti,ab,kw AND tree:ti,ab,kw) OR 'prevention and recovery information system for monitoring and analysis':ti,ab,kw OR 'eindhoven classification model':ti,ab,kw OR 'causal classification model':ti,ab,kw OR 'medical event reporting system':ti,ab,kw	**7480**
#1	'medical error'/exp OR 'medical event*':ti,ab,kw OR 'adverse event*':ti,ab,kw OR 'safety event*':ti,ab,kw OR error*:ti,ab,kw OR incident:ti,ab,kw OR incidents:ti,ab,kw	**869396**

Search strategy in CINAHL (via EBSCO ; 2020 February 26 th)

#	Query	Results
S13	S9 OR S12	907
S12	S10 NOT S11	220
S11	((TI ("Prisma") OR AB ("Prisma")) AND (TI (cause* OR causal) OR AB (cause* OR causal))) Limiters - Publication Type: Systematic Review	117
S10	((TI ("Prisma") OR AB ("Prisma")) AND (TI (cause* OR causal) OR AB (cause* OR causal)))	337
S9	S5 OR S6 OR S7 OR S8	695
S8	S2 AND S3	6
S7	S1 AND S4	6
S6	S1 AND S2	682
S5	(MH "Treatment Errors+/CL") AND TI ((cause* OR failure*))	10
S4	((TI ("Prisma") OR AB ("Prisma")) AND (TI (cause* OR causal) OR AB (cause* OR causal))) NOT ((MH "Systematic Review") OR (TI "systematic review*") OR AB ("systematic review*"))	34
S3	TI ("Prisma") OR AB ("Prisma")	4,263
S2	(MH "Root Cause Analysis") OR TI ("root cause*" OR "Prevention and Recovery Information System for Monitoring and Analysis" OR "eindhoven classification model" OR "causal classification model" OR "medical event reporting system") OR AB ("root cause*" OR "Prevention and Recovery Information System for Monitoring and Analysis" OR "eindhoven classification model" OR "causal classification model" OR "medical event reporting system") OR ((TI "causal" OR AB "causal") AND (TI "tree" OR AB "tree"))	2,503
S1	(MH "Adverse Health Care Event") OR (MH "Incident Reports") OR TI ("medical event*" OR "adverse event*" OR "safety event*" OR "error*" OR "incident" OR "incidents") OR AB ("medical event*" OR "adverse event*" OR "safety event*" OR "error*" OR "incident" OR "incidents")	138,402

Search strategy in The Cochrane Library (via Wiley 2020 February 26 th)

#	Query	Results
#8	#5 or #6 or #7	**26**
#7	#2 and #3	**0**
#6	#1 and #4	**7**
#5	#1 and #2	**19**
#4	prisma:ti,ab,kw and (cause*:ti,ab,kw or causal:ti,ab,kw) not "systematic review":ti,ab,kw	**50**
#3	prisma:ti,ab,kw	**349**
#2	"root cause*":ti,ab,kw or (causal:ti,ab,kw and tree:ti,ab,kw) or "Prevention and Recovery Information System for Monitoring and Analysis":ti,ab,kw or "eindhoven classification model":ti,ab,kw or "causal classification model":ti,ab,kw or "medical event reporting system":ti,ab,kw	**103**
#1	"medical event*":ti,ab,kw or "adverse event*":ti,ab,kw or "safety event*":ti,ab,kw or error*:ti,ab,kw or incident:ti,ab,kw or incidents:ti,ab,kw	**48087**



Chapter 4

Generic Analysis Method to Learn from Serious Adverse Events in Dutch Hospitals: A human factors perspective

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ABSTRACT

BACKGROUND

Hospitals in various countries such as the Netherlands investigate and analyse Serious Adverse Events (SAEs) to learn from previous events and attempt to prevent recurrence. However, current methods for SAE analysis do not address the complexity of healthcare and investigations typically focus on single events on the hospital level. This hampers hospitals in their ambition to learn from SAEs. Integrating human factors thinking and using a holistic and more consistent method could improve learning from SAEs.

AIM

This study aims to develop a novel Generic Analysis Method (GAM) to: (1) facilitate a holistic event analysis using a human factors perspective, and (2) ease aggregate analysis of events across hospitals.

METHODS

Multiple steps of carefully evaluating, testing, and continuously refining prototypes of the method were performed. Various Dutch stakeholders in the field of patient safety were involved in each step. Theoretical experts were consulted, and the prototype was pretested using information-rich SAE reports from Dutch hospitals. Expert panels, engaging quality and safety experts and medical specialists from various hospitals were consulted for face and content validity evaluation. User test sessions concluded the development of the method.

RESULTS

The final version of the GAM consists of a framework and affiliated questionnaire. GAM combines elements of three methods for SAE analysis currently practised by Dutch hospitals. It is structured according to the Systems Engineering Initiative for Patient Safety model, which incorporates a human factors perspective into the analysis. These eases aggregated analysis of SAEs across hospitals and helps to consider the complexity of healthcare work systems.

CONCLUSION

The GAM is a valuable new tool for hospitals to learn from SAEs. The method can facilitate a holistic aggregate analysis of SAEs across hospitals using a human factors perspective, and is now ready for further extensive testing.

INTRODUCTION

Adverse events in healthcare represent a major source of morbidity and mortality and result in substantial societal costs.[1-4] Hospitals in numerous countries, such as the Netherlands, the USA, Canada, Australia and the UK, aim to learn from previous events by thoroughly investigating these. In particular, hospitals invest in studying the events that have caused temporary or permanent disability, death, or prolonged hospital stay, also known as sentinel events or Serious Adverse events (SAEs).[5-10] After hospitals investigate a SAE, they write a detailed report. This report starts with a comprehensive reconstruction of the event and concludes with a Root Cause Analysis (RCA), in which hospitals search for root causes and formulate recommendations to prevent recurrence.[11] SAE investigations and the associated reports offer great potential for hospitals to learn from each other and improve patient safety. However, SAE investigations and analyses are being criticized for oversimplification,[12] resulting in weak solutions,[10 11 13] and overall ineffectiveness.[11 13-15] Two important shortcomings impede hospitals in particular in their ambition to learn from SAEs.

First, SAE-investigations often neglect the complexity of healthcare.[13 15] Current methods applied for SAE analysis, focus on finding one linear root cause, even though SAEs are more likely to arise from interactions and combinations of causes and contributing factors in the complex healthcare system.[10 13 14] SAE analysis thus needs a shift from focusing on finding the 'one' linear root cause towards searching for the combination of interrelated contributing factors and causes. The incorporation of human factors thinking in SAE analysis is assumed to induce this shift.[16-20] Human factors is concerned with the understanding of interactions and interdependencies between humans and other elements of a work system.[21-23] It searches for opportunities to design healthcare systems that have a greater tolerance of faults and thus might improve the resilience of the system.[24-26] One model that integrated principles of human factors into the healthcare domain is the Systems Engineering Initiative for Patient Safety (SEIPS) [27-32] This theoretical model is used to study patient safety hazards and adverse events in various healthcare settings.[16 30-35] SEIPS is based on the well-known structure-process-outcome model for healthcare quality.[36] It therefore is assumed to be familiar to audiences working in healthcare quality and patient safety.[31] Although the potential of SEIPS to improve patient safety is proven,[31] adoption of the model in retrospective SAE analysis is still limited and should be refined and accelerated.[16 30]

A second shortcoming of current SAE investigations is that hospitals typically focus on single events within their own organisation,[13 14] even though attempts to learn from aggregate analysis of multiple events across hospitals, as already performed in Australia[37] and the USA,[38 39] are believed to improve learning.[38-41] It helps to discover combinations of recurring, underlying, patterns of causes and contributing factors[42] and may improve the formulation of more effective, system-aimed recommendations.[14 38] However, methods for analysing

4

SAEs vary substantially,[10] which complicates aggregate cross-hospitals analysis of SAEs. For example, in the Netherlands, where aggregate analysis of SAEs is scarce, hospitals use three differing methods for analysing SAEs[41 43 44]: Prevention and Recovery Information System for Monitoring and Analysis (PRISMA-medical),[45] Tripod Beta,[46] and Systemic Incident Reconstruction and Evaluation (SIRE).[47] These methods are useful for a structured analysis of SAEs, yet based on their description in scientific articles,[41 44 48 49] anecdotal evidence,[43 46 47] and experience, each method has its own approach, focus and limitations. PRISMA-medical, for example, is highly analytical and categorises latent (technical and organisational) as well as active (human) failures.[45] However, the absence of organisational or technical barriers that could prevent SAEs are not considered a root cause in this method.[50] Tripod Beta, however, thoroughly investigates system failures and organisational barriers that could prevent SAEs. However, human errors are also explained as organisational or system failures,[46 49] even though evidence indicates that flaws in the system and cognitive factors both play an important role in the emergence of human error.[51-53] SIRE, in turn, emphasises particularly on the primary process and provides a comprehensive narrative description of the event.[47 54] To ease aggregate cross-hospital analysis of SAEs, Smits et al.[43] made a primary attempt to integrate the structures and foci of PRISMA-medical, SIRE, and Tripod Beta into a generic framework. Anecdotal evidence of the benefits of this framework to perform an aggregate cross-hospital analysis was presented, but the study emphasised the importance of further development and evaluation.[43]

Addressing the complexity of healthcare[13] and using a consistent method[10 41] could thus improve learning from SAEs. This could help to formulate more effective recommendations to enhance patient safety. An alternative approach to study SAEs is therefore necessary. This study aims to develop a novel generic analysis method (GAM) that integrates the SEIPS model[31 32] and the PRISMA-medical, SIRE and Tripod Beta framework[43] to: (1) facilitate a more holistic analysis using a human factors perspective and (2) ease aggregate analysis across hospitals.

METHODS

We followed a structured process (Figure 1) of developing, evaluating, testing and refining prototypes of a GAM.

DESCRIPTION OF THE PROTOTYPE

A first prototype of the GAM was developed based on the theoretical SEIPS model[31 32] and the framework[43] combining PRISMA-medical, SIRE and Tripod Beta. This prototype included three main pillars. The first pillar addresses the gathering of basic SAE information. Second, each sociotechnical domain of the SEIPS-model is evaluated. All relevant characteristics should be collected about the: (1) persons involved, (2) tasks performed, (3) technologies used, (4) organisational factors affecting the work, (5) the physical environment, and (6) the external environment. In this evaluation, we also adopted some important elements of PRISMA-medical, SIRE and Tripod Beta as accumulated by Smits et al.[43] related to these six domains. The third pillar focusses on the outcomes of the SAE for the involved patients and/or their family, healthcare professionals, and the organisation. This part also includes the evaluation of the recommendations formulated in response to the event.

EVALUATING AND TESTING THE PROTOTYPE

We started with consulting two theoretical experts (A), both academics in the field of patient safety, to evaluate the first version of the prototype and ask for potential additional theoretical concepts that should be embedded.

We then used the prototype for a pretest session (B), in which the author (MCB) analysed six SAE reports covering the variation of RCA methods used by Dutch hospitals (PRISMA-medical, SIRE, and Tripod Beta). These reports were based on thorough SAE investigations performed by independent committees of various hospitals in 2018 or 2019. The multidisciplinary hospital committees investigating the event, typically consisted of a combination of clinicians and quality and safety officers. Committees combined multiple sources for studying the event. The most important source being in-depth interviews with involved healthcare personnel, and patients and/or family. Additionally, the committees reviewed all relevant information such as patient records, test results (eg, medical images, laboratory findings, etc), and documentation (eg, guidelines, work instructions, etc). The combination of interviews with the persons involved and reviewing all relevant documentation resulted in an extensive and detailed reconstruction of the event. After the event description, the hospital committees performed an RCA and formulated recommendations to prevent recurrence. The comprehensive data in the SAE reports was suited for a retrospective (re)analysis of the event and, hence, a first test of the prototype's content and face validity. By including a sample covering all three RCA methods, we could test whether our prototype was applicable irrespective of the initial RCA method used. This step contributed to improving the usability of the prototype, for example, the prototype could be aligned with the working methods of the hospitals.

Next a panel with experts from practice (C) was consulted for a thorough evaluation of the face and content validity of the prototype during a face-to-face meeting. This panel consisted of a mix of quality and safety officers (n=8) and medical specialists with direct experience in patient safety (n=5). All of them were currently practicing in various Dutch general hospitals (n=12). Minutes were taken during the meeting and the transcribed notes were sent for verification to the participants afterwards.

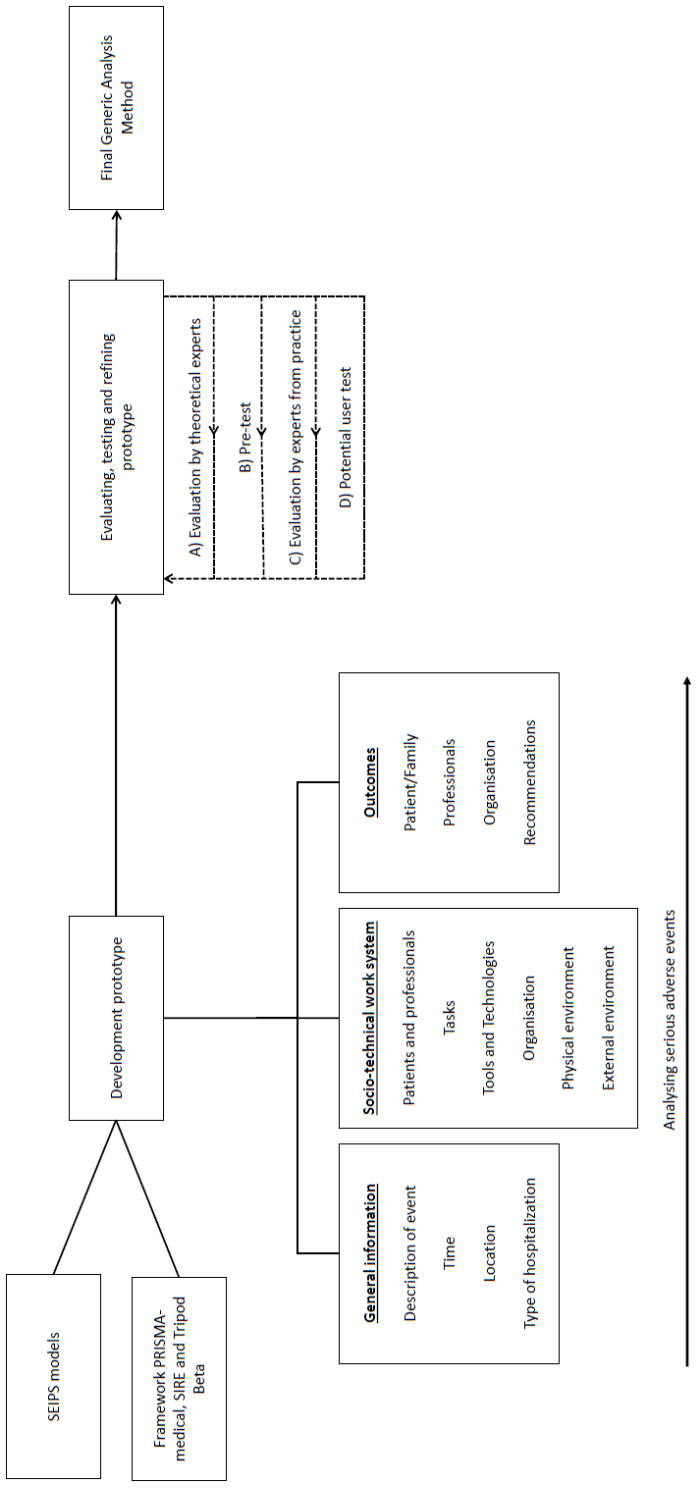

Figure 1. Overview of the steps taken in developing the Generic Analysis Method. PRISMA, Prevention and Recovery Information System for Monitoring and Analysis; SIRE, Systemic Incident Reconstruction and Evaluation; SEIPS, Systems Engineering Initiative for Patient Safety.

Subsequently, two potential users, both quality and safety officers, tested the prototype (D). Just as in the pretest session, information-rich SAE reports were used. The users analysed two distinct reports, written by two general hospitals in 2018. This test session was meant to further evaluate content validity of the method as experienced by potential users. It also helped to find flaws and practical barriers and provided the possibility to observe users' interactions with the prototype. Commentaries from the respondents were used to refine the usability. In addition, the author (MB) analysed the same two reports. This allowed a rough assessment of the agreement in analyses between the potential users and the researcher. As the most important questions were open ended, a qualitative approach on assessing the agreement between raters was performed. Overall agreement on all questions was reviewed by eye assessment, and differences between the interpretation of raters for the important questions were reflected upon (eg, by considering: did raters give different answers? Why did raters not answer that question the same way? Were these random outliers, or did it show a systematic difference in interpretation?).

PATIENT AND PUBLIC INVOLVEMENT

Since the method is specifically intended for use by healthcare professionals to learn from SAEs across hospitals, professionals (potential users) were consulted at multiple stages during the study. Patients were not involved in developing the method as they currently have no formal role in performing (aggregate) analysis of SAEs. Nevertheless, it is important to involve patients and their family in the SAE investigation by including their vision on the event through interviews and giving them insight into the findings.

RESULTS

EVALUATION AND TEST RESULTS

In the first step of evaluation, theoretical experts (A) stressed the importance to assess the element of human error in SAEs and therefore referred to the model of unsafe acts.[52] This model helps to differentiate between various types of human errors (eg, violations, mistakes, slips and lapses). This could provide a more in-depth understanding of these errors. Another concept the experts recommended to include were the efficiency-thoroughness trade-off principles. Evaluation of the trade-offs between working efficiently and working thoroughly, in this context safely, might enhance our understanding of safety critical decisions being made in complex healthcare situations.[55] As these trade-offs reflect situations in which there is a conflict between, for example, production pressure and providing safe and high quality care, they may raise awareness to more system related issues.

After pretesting the prototype (B), questions and answer categories were reconsidered and rewritten in order to make it more compatible with the information gathered in SAE

investigations. Test cases also gave a useful overview of the SAEs and helped to identify relevant characteristics, contributing factors, and root causes related to each of the sociotechnical work system domains. Examples of these findings are listed in table 1.

The discussion with experts from practice (C) resulted in a few additional topics that were particularly relevant and therefore needed to be explicitly adopted (eg, the identification and classification of fragility amongst elderly patients). Also, more practical issues were put forward such as the description and categorisation of clinical areas and age groups. The boundaries of external factors, such as financial restrictions or labour shortages, were argued and established as well.

The final test phase by potential users (D) brought up some important modifications of the questionnaire (eg, textual revision of questions, adjustment or addition of answer categories, and merging some of the questions). This test session also presented important misinterpretations of a few questions and answer categories. Overall agreement between the potential users and researcher was acceptable, with exemption of the misinterpreted questions. We decided better instructions were needed and composed an explanation file and example case in which the ambiguities were explained to help future users in interpreting the questions and answer categories as intended.

Analysis of the event reconstructions using the prototype helped in systematically considering all aspects of the sociotechnical work system. This resulted in a holistic analysis of the event. Mapping contributing factors and causes according to the prototype assisted in evaluating interactions and interdependencies between factors of various domains, addressing the complexity.

DESCRIPTION OF THE FINAL GAM

The described process of developing, evaluating, testing and refining prototypes resulted in a final version of the GAM, consisting of a framework (Figure 2) and an affiliated questionnaire (Appendix I). Both follow a basic structure for analysing SAEs.

The first step of the model only intents to gather basic information on what happened. A suggestion of the most important elements that could be included is presented in the upper part of Figure 2.

The method then evaluates the six domains of the work systems according to the SEIPS model. Each domain includes a description of relevant characteristics and potential contributory factors. Interactions and interdependencies between domains and factors can be mapped to address and visualise complexity. Appendix 2 provides an example of a case for which the work system was analysed using the GAM. In the tasks element, we included a question to get insight in unsafe human acts[52] contributing to the event. For the tasks and organisational elements, trade-offs are evaluated between efficiency and thoroughness. Table 1 specifies the six domains of the work system with a more detailed description and provides some examples, based on the test sessions and previous case studies.

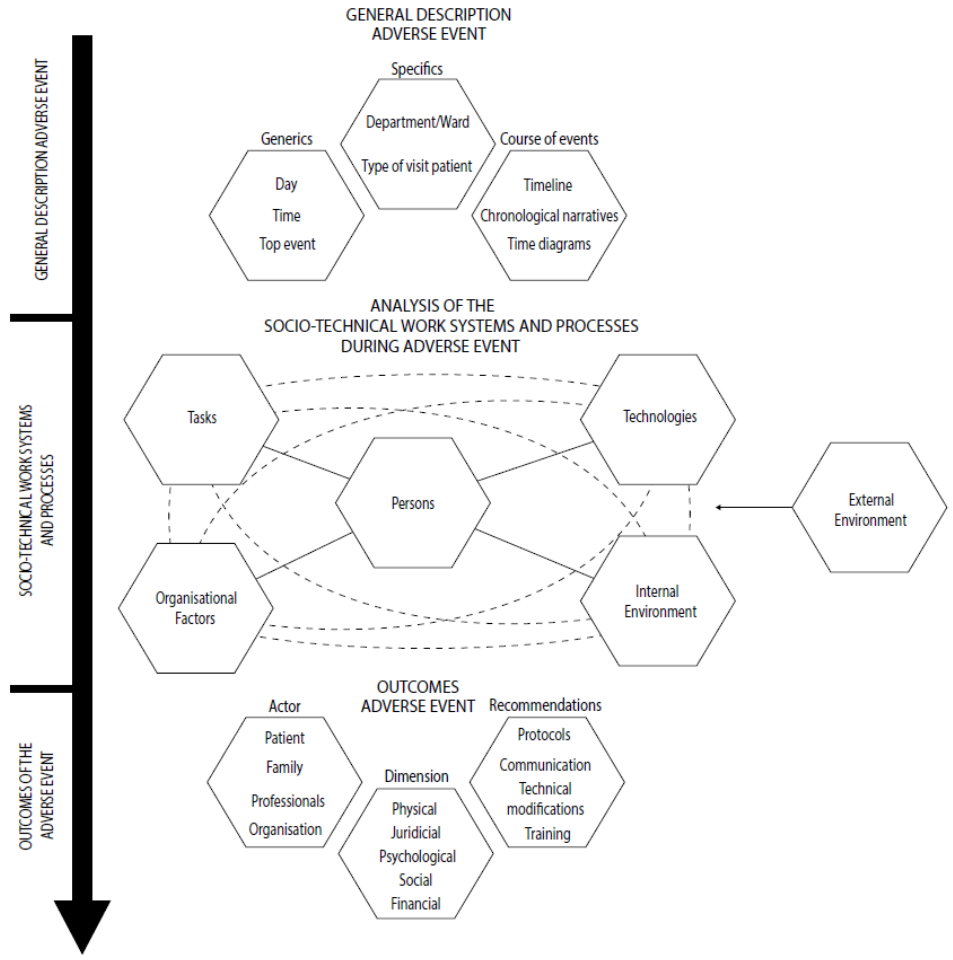

Figure 2. GAM framework, based on the work of Smits, Langelaan, and De Groot[43] and the SEIPS models[31 32]

After analysing the work systems and processes, the consequences of the SAE must be considered. It is important to assess the effects on patients and family, as well as caregivers, other professionals, and the healthcare facility. Outcomes of SAEs can be multidimensional and may affect the physical, psychological, juridical, social, and financial situation of all

those involved. When evaluating the impact of SAEs, both immediate as well as distant outcomes must be considered. Formulated recommendations are incorporated in this part as well, so evaluation of the type(s) of recommendations as suggested by the hospital in response to the SAE is possible.

Table 1. Description of the six interacting domains of sociotechnical work system, adopted from Holden et al.[31] and Carayon et al.[32] * The efficiency-thoroughness trade-off descriptions are adopted from Hollnagel.[55]

Sociotechnical element	Description	Example of influence on SAE
Person(s)	The central component of the work systems are the persons involved. This component is not limited to the healthcare professional(s), but also considers the patient and their family, and professionals of supporting services. The characteristics of the professionals and teams can be analysed, focusing on the level of knowledge, level of experience, and the perceived workload. Additionally, the teamwork and collaborations are considered. Various patient characteristics (e.g. physical, psychological, or social) can contribute to a SAE and are therefore be included in the analysis.	Patient/Family - A patient indicates atypical complaints when suffering from a ruptured aneurysm of the abdominal aorta. - The family of a patient disputes the treatment chosen and frustrates the care provided. Healthcare professional(s) - A healthcare professional chooses to work after two nights of bad sleep due to personal problems, makes a slip and incorrect medication is being prescribed. - An interim surgeon uses an instrument (s)he is unfamiliar with, which results in misapplication. Other professionals - A technician turns off the alarm modus of a patient monitoring system during maintenance by mistake, as a result of insufficient product knowledge
Tasks	The tasks element evaluates characteristics of the tasks of the persons involved. These can be considered by looking at the complexity, variety, and ambiguity of the tasks, and observing if they coincide with other tasks. Furthermore, eventual efficiency-thoroughness trade-offs made while performing these tasks must be evaluated.	Tasks - A radiologist swaps two patients with similar names and conditions and fills in his assessment of a MRI in the record for the wrong patient. Tasks related efficiency-thoroughness trade-offs - It will be checked/done by someone else* - A patient is transferred from a busy emergency department to another ward without performing an ECG, because time is scarce and the personnel expect the nursing ward receiving the patient will take care of this. - This way it is much quicker* - Instead of following a procedure in which medicine is allocated on the patient ward, accompanied by the patient, a nurse prepares the medicines of all patients together at the nurses' station bearing a greater risk of making mistakes in swapping medicines.

Table 1. Continued.

Sociotechnical element	Description	Example of influence on SAE
Technologies	Technologies used by the person(s) involved must be evaluated. Important features of the technologies are, for example, how easy they are to use, their accessibility, level of automation, functionality, and how easily the technologies can be transported, and adopted to other settings. This evaluation is performed preferably by both healthcare professionals and technical experts.	- A monitor in the operating theatre crashes during surgery resulting in limited visual information for the surgeon. - A ventilator on the intensive care unit does not provide an alarm when the ventilated air was not heated and moisturised because the apparatus had become loose.
Organisation	Organisational factors that contribute to the SAE and/or may influence other elements. This includes an evaluation of material factors, such as financial incentives and the accessibility and availability of resources (e.g. time, money, goods, and services) as well as social factors (e.g. management style, culture, hierarchy, social norms and values). Since the availability of resources and social factors are analysed in this component, an assessment of the eventual efficiency-thoroughness trade-offs related to social factors and resources is incorporated.	- The staffing of nurses is so low that during the holiday season the minimum level of experience is not guaranteed. - A hierarchical relationship between a resident and his supervisor forms a barrier to call during a night shift. Instead, the resident saves all his questions until the next day. Efficiency-thoroughness trade-offs related to the organisation - We always do it in this way here* An efficient, but unsafe, workaround – a way of temporarily addressing workflow problems- is taught to new nurses. - It is not my/our responsibility* After transferring a cardiac patient from the cardiology ward to the intensive care unit, the cardiologist does not feel responsible for this patient anymore, while the patient is, among other things, still suffering from cardiac instability.
Physical environment	Factors that define the physical environment such as lighting, noise, vibrations, temperature, the physical arrangement of the room(s), and the available space and air quality.	- Noise on an emergency department disturbs the communication between a nurse and a physician leading to a miscommunication about the volume of medicine. - The physical arrangement of a door, bed and other furniture in an emergency department room impedes the crashcar from being positioned inside the room, which hinders the rapid response team in their interventions.
External environment	Factors on a macro level that might affect decisions on a micro level in the sociotechnical work systems and procedures.	- Shortages in the labour market may lead to a deficiency of qualified nurses. - A budget cut and sustainability policy, aimed at reducing water waste, might lead to a faulty legionella bacteria prevention protocol.

DISCUSSION

Previous studies highlighted issues that hamper hospitals in their ambition to learn from SAEs. Methods used for analysing events, for example, have a strong focus on finding a linear root cause, thereby neglecting the complexity of healthcare.[13 14] Hospitals also often study single events within their organisation, instead of analysing multiple events across organisations.[13] Substantial variety in methods applied might complicate attempts to perform such aggregate cross-hospital analysis. Although potential solutions such as integrating human factors thinking in SAE analysis and using a more consistent analysis method have been proposed,[10 18 20 41] there remains a need for methods embracing these possible improvements. This study aims to develop a novel Generic Analysis Method (GAM) that stimulates a holistic analysis using a human factors perspective, and eases aggregate analysis across hospitals.

A GAM-prototype was developed based on a human factors model and integrating important elements of three currently practised methods for analysing SAEs. The paper describes the multiple steps of carefully evaluating, testing and refining prototypes. Suggestions of theoretical experts to complement the prototype were incorporated. Pretesting, evaluation by experts from practice and user test sessions, helped to improve the usability and face and content validity. User test sessions also allowed us to roughly assess inter-rater agreement and think of manners to improve future reliability. These steps resulted in a final version of the GAM, consisting of a framework and affiliated questionnaire. These assist in gathering structured information about the event, evaluate all domains of the sociotechnical work system, map interactions between factors from various domains, and assess outcomes of the SAE.

The SEIPS model on which the GAM is based helps to focus beyond hierarchical, linear and causal relations, and stimulates evaluation of complexity. To successfully unravel the complexity of healthcare work systems it is essential to understand the interactions and interdependencies between the persons involved and the other domains of the sociotechnical work system (eg, technology, tasks, organisation, and environment). As described by Holden et al.[31] any analysis of the work systems should, therefore, include three important concepts: (1) the sociotechnical work systems must be viewed as dynamic, hierarchical and interactive, (2) all individuals engaged in a process or work system should be mapped systematically to reveal social structures, and (3) analysis must depict how dynamic systems evolve over time in intended and unintended ways. As exemplified in Appendix 2, the GAM helps to evaluate the dynamics and interactions within a work system. By mapping all domains of the work system including the persons involved in a structured manner, it might be possible to depict the complex properties of SAEs. Whenever more SAEs are systematically mapped this way, underlying patterns of recurring interactions and structures might emerge. The inclusion of the trade-offs between efficiency and thoroughness,[55] as adopted in the organisational and task elements of the GAM, could provide an opening to compare actual (work as done) and expected work practices (work as imagined). This could help to understand how work systems have evolved over time in intended, and unintended ways.

In addition to incorporating human factors thinking, GAM combines the narrative approach of SIRE[47] with the more analytical approach of PRISMA-medical[45] and Tripod Beta[46] on both organisational barriers and human-related issues. Integrating important elements of these methods helps to perform a holistic analysis. At the same time, the combination of existing methods in one generic method might ease aggregate analysis of SAEs across hospitals.

As GAM is structured according to the widely used SEIPS model[30 31 56] and built on methods that are currently applied by hospitals, we believe GAM may be easily adopted. Other promising methods that aim to improve learning from root cause analysis such as the Human Factors Analysis and Classification System,[57] AcciMap,[58] and Functional Resonance Analysis Method,[59] were not specifically build on the well-known SEIPS model and existing methods. Other methods may also need a specific practice to investigate SAEs or tend to focus specifically on a small and delineated process. This might make them less easy to adopt for SAE analysis. Existing initiatives for aggregate analysis, such as those performed in the USA and Australia[37-39] and the preliminary attempts in the Netherlands,[41 43] lack the important human factors perspective to guide analysis. Aggregate analysis using the GAM might therefore lead to better understanding of SAEs and could result in more effective system-aimed solutions. Besides retrospective analysis of patient safety events, methods such as the Health Care Failure Mode and Effect Analysis[60 61] and Tripod Delta HC[62] intent to prospectively identify (latent) risks for patient safety. These methods remain important and can be used complementary to retrospective aggregate analysis of SAEs using the GAM. Outcomes of retrospective GAM-analysis might help to identify risks for such prospective analysis.

In its most basic application, GAM can help to perform a structured, holistic analysis of SAE reports from various hospitals, irrespective of the initial RCA method used. The method is thus suited to study the existing ‘treasure’ of SAE reports that is stored in the archives of hospitals and unleash its potential to jointly learn from SAEs. Considering GAM was developed in the Netherlands and integrates methods Dutch hospitals use for SAE analysis, the generic method is particularly suited for application in the Dutch context. However, PRISMA-medical, SIRE and Tripod are not solely used by Dutch hospitals. In particular PRISMA-medical is applied by hospitals in various other countries as it has been accepted by the World Alliance for Patient Safety of the World Health Organization.[63-65] At the same time, we believe GAM is also appropriate to stimulate and improve aggregate analysis of SAEs for hospitals currently using other methods, such as cause and effect diagrams, five whys and fishbone diagrams. These methods are after all also based on the principle of

investigating single SAEs and a search for a root cause. Application of the GAM might in this case be more time consuming though.

LIMITATIONS

A limitation of the study was the modest user test session, as it was limited to two cases. The process of testing was highly time consuming for potential users. Although we performed other testing and evaluation steps, including a pilot phase in which six more reports were analysed by the author, the number of cases in the user test session can be considered as a weakness. More extensive testing is therefore needed to further assess reliability and validity. Further testing might also provide leads to lean the method and improve its usability.

Another issue we should address is that we tested the GAM by applying it to reanalyse information gathered in SAE reports. Although the reports provided a thorough description of the event, the investigation did not specifically study the event according to the GAM. This might have made it difficult to subtract new or other relevant factors from the reports than those already found in the initial root cause analysis. The test sessions, however, indicated that adopting the GAM perspective to reanalyse information as included in the event reconstruction of the SAE reports can still lead to new insights. Directly studying an event using the GAM enables investigators to ask specific additional questions during the interviews with those involved on subjects that are only limitedly covered in traditional SAE investigations and analyses. Based on this study, we cannot draw strong conclusions on the usability of GAM for directly studying a SAE, but given its value in the analysis of SAE reports, the method seems promising for this purpose as well.

CONCLUSION

A novel Generic Analysis Method (GAM) was carefully developed. On balance, the method is a promising tool for taking a next step in learning from SAEs. It facilitates a holistic analysis of the SAE and addresses the complex sociotechnical work system in which SAEs in healthcare originate. GAM could also ease aggregate analysis of SAEs across hospitals. Using GAM might empower hospitals in their ambition to learn from SAEs, and could help to formulate more effective system-aimed recommendations to prevent recurrence of events. The method can now be used to analyse a large sample of events to further explore its potential to improve patient safety.

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4

APPENDIX 1.

QUESTIONNAIRE

A. General information about Adverse Events

1. Which method was used for the adverse event(AE) investigation?
    - PRISMA
    - SIRE
    - TRIPOD-bèta
    - Combination of the methods mentioned above (e.g. SIRE and PRISMA)
    - Other, please specify [Open text]

3. Give a brief summary of the AE. Focus on the most important elements of the AE, e.g. the occasion, the substandard actions taken and the outcomes (strive to use 200 words or less). [Open text]

4. At which department did the AE mainly take place: [Open text]

5. What was the reason for the initial hospital visit of the patient?
    - Inpatient care
    - Outpatient care
    - Planned test/research
    - Emergency care
    - Other, please specify [open text]

6. Describe the top event. Give a description of the AE in a few words. In SIRE and Prisma this is most often called the top event. In TRIPOD-bèta this is called an event. [Open text]

7. On which day did the top event occur?
    - Monday
    - Tuesday
    - Wednesday
    - Thursday
    - Friday
    - Saturday
    - Sunday

8. During which shift did the top event take place?
    - Day shift
    - Evening shift
    - Night shift

B. Socio-technical work systems & Processes

Persons- Patient

9. Gender of the patient
    - Female
    - Male

10. Age category of the patient:
    - 0 – 1 year
    - 2 – 4 years
    - 5 – 18 years
    - 19 – 65 years
    - 66 – 80 Years
    - Older than 80 years

11. Can the patient be categorised as fragile elderly? If yes, give a brief description of the frailty: [Open text]

12. Did medication play a role in the origin/development of the AE? If yes or possibly, give a description of the medication and the way in which it contributed: [Open text]

13.a Are one or more patient-related root causes found in the AE report?
    - Yes
    - No

13.b If yes, please give a description for each root cause: [Open text]

Persons – Healthcare professional(s)

14. What was the responsible medical specialism?
    - Anaesthesiology
    - Cardiology
    - Surgery
    - Dermatology
    - Geriatrics
    - Gynaecology/Obstetrics
    - Internal Medicine
    - Ear, Nose, Throat
    - Paediatrics
    - Pulmonology
    - Gastroenterology & Hepatology
    - Medical oncology

- Nephrology
- Neuro surgery
- Neurology
- Ophthalmology
- Orthopaedics
- Plastic surgery
- Psychiatry
- Radiology
- Rehabilitation medicine
- Rheumatology
- Emergency Medicine
- Trauma surgery
- Urology
- Other, please specify [open text]

15. Which healthcare professionals were involved in the AE? Describe, for each healthcare professional, particularities/specifics that might have contributed to the origin/development of the AE: [Open text]

16. Which professionals of medical supporting services were involved in the AE? Describe for each professional particularities/specifics that might have contributed to the origin/development of the AE: [Open text]

17. If the reports describe any details about the collaboration between professionals/departments, please provide a brief description: [Open text]

18.a Were any human-related root causes revealed?
- Yes
- No

18.b If yes, which type:
- Human - External (H-EX)
- Human – Knowledge-based behaviour (HKK)
- Human – Qualifications (HRQ)
- Human – Coordination (HRC)
- Human – Verification (HRV)
- Human – Intervention (HRI)
- Human – Monitoring (HRM)
- Human - Slips (HSS)
- Human - Tripping (HST)
- Communication

18.c Give a short description of the chosen human-related root cause: [Open text]

Tasks

19. Was the manner in which the top event proceeded an intended or an unintended action?
- Intended
- Unintended

20. Did the persons involved act according to their professional standard? If not, please give an explanation: [Open text]

21. Is there a trade-off being made between efficiency and thoroughness/safety when performing the care and other tasks? If yes, give a brief description: [Open text]

Technology

22. Are there any details reported about medical technology/did medical technology play a role in the origin/development of the AE? If yes, please give a description of this role: [Open text]

23.a Were any technical root causes revealed?
- yes
- No

23.b If yes, which type(s):
- Technical – Design (TD)
- Technical – Construction (TC)
- Technical – Materials (TM)
- Technical – External (TEX)
- Resources
- Maintenance

23.c Brief description of the technical root cause(s): [Open text]

24. Was a technical expert consulted during the AE investigation? If yes, explain which role this expert had in the investigation: [Open text]

Organisation

25. What were the most important organisational characteristics that contributed, even potentially, to the AE? [Open text]

26. Was a trade-off being made between efficiency and thoroughness/safety concerning organisational factors? If yes, give a description of this trade-off: [Open text]

27. Did the transfer of a patient between the healthcare providers contribute to the AE? If yes, please give a short description: [Open text]

28.a Were any root causes related to the organisation revealed?

- Yes
- No

28.b If yes, which type(s):

- Organisational – Transfer of knowledge (OK)
- Organisational – Protocols (OP)
- Organisational - Management priorities (OM)
- Organisational – Culture (OC)
- Organisational – External (OEX)
- Competing objectives
- Training and Education
- Orderliness and Neatness
- Protective equipment/-methods
- Failing barriers

28.c Give a short description of the chosen organisational-related root cause(s): [Open text]

Physical environment

29. Did the physical environment contribute, or possibly contribute to the AE? If yes, give a brief description: [Open text]

30.a Were any root causes found which related to the environment?

- Yes
- No

30.b If yes, which type(s):

- Environmental factors
- Protective equipment/-methods
- Orderliness & Neatness
- Other

30.c Give a brief description of the environmental root cause(s) chosen: [Open text]

External environment

31. Did external policy influence the origin/development of the AE? If yes, give a short description: [Open text]

C. Consequences of the adverse event

32. What were the consequences of the AE for the patient/family? [Open text]

33. What were the consequences of the AE for the healthcare and other professional(s)? [Open text]

34. What were the consequences of the AE for the healthcare organisation? [Open text]

35. Were any claims filed in response to the AE?

- Yes
- No

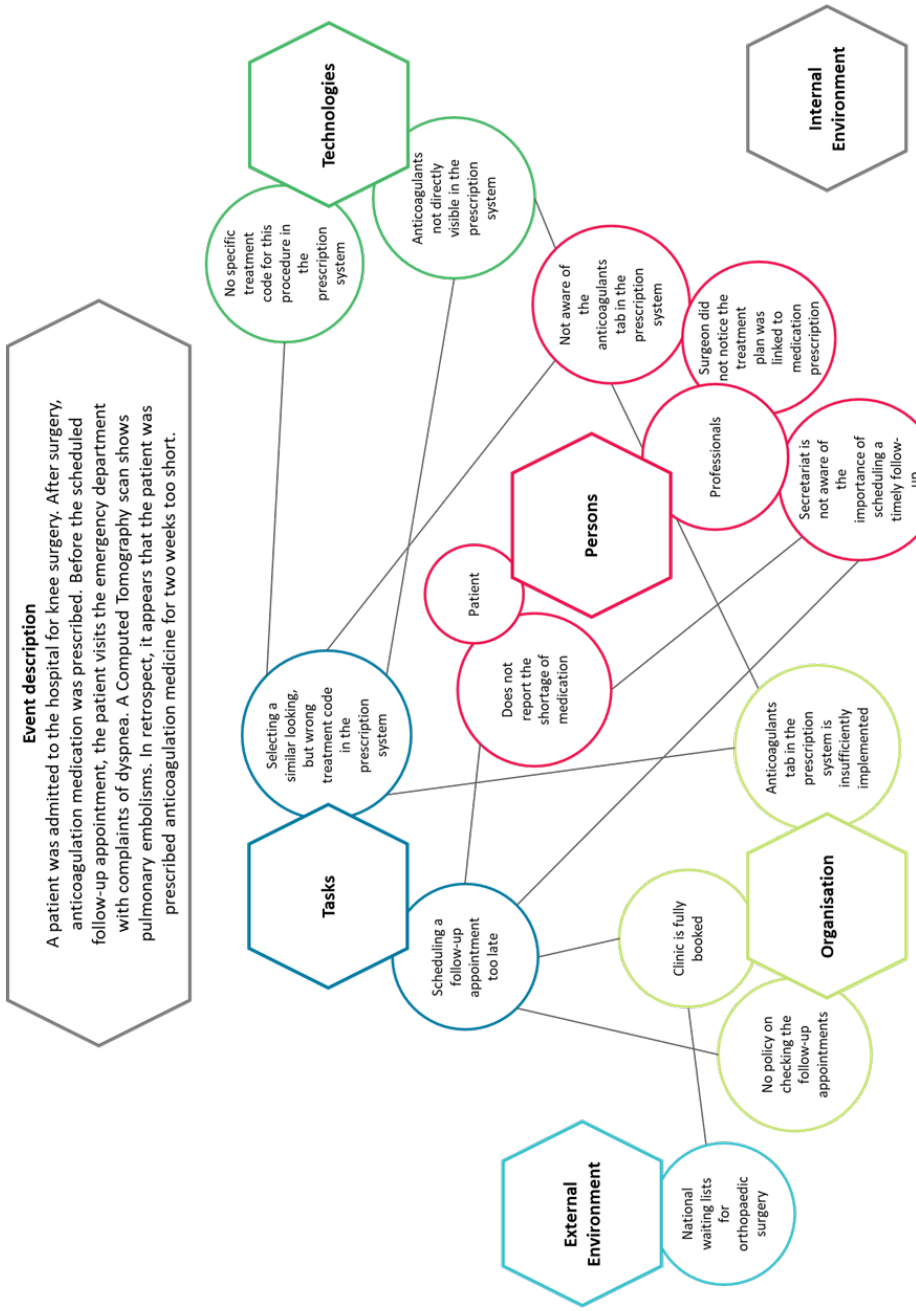
36.a Which type(s) of measure for improvements were formulated in response to the AE?

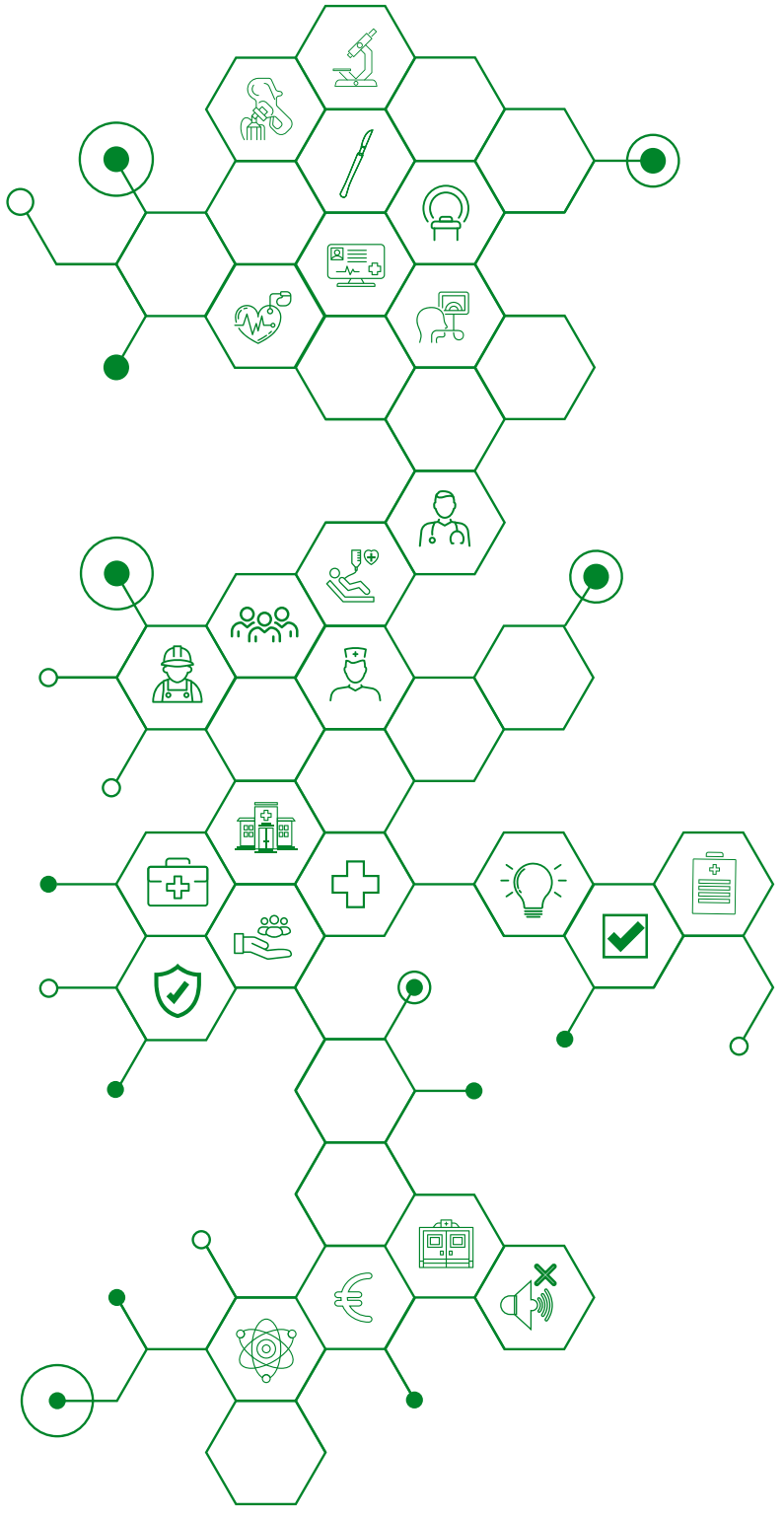
- Collaboration
- Communication
- Revise protocol(s)
- Adjustments in technology/ICT
- Training & Education
- Other, please specify: [Open text]

36.b Give a short description(s) of the measure(s) chosen in order to achieve an improvement: [Open text]

APPENDIX 2.

EXAMPLE OF AN ANALYSIS OF THE SOCIOTECHNICAL WORK SYSTEM USING THE GENERIC ANALYSIS METHOD





Chapter 5

Using the Generic Analysis Method to Analyze Sentinel Event Reports Across Hospitals: A retrospective cross-sectional study

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ABSTRACT

OBJECTIVES

Improving patient safety by investigating sentinel events (SEs) is hampered by the focus on isolated events within hospitals and a narrow scope of traditional root cause analysis methods. We aim to examine if performing cross-hospital aggregate analysis of SEs applying a novel generic analysis method (GAM) bearing a human factors perspective can enhance learning from SEs.

METHODS

A retrospective cross-sectional review of SE reports from 28 Dutch general hospitals using the GAM to reanalyse events was performed. A qualitative approach was used to identify contributing factors and system issues. Findings were discussed with a patient safety expert panel. Descriptive statistics and measures of associations between domains were calculated.

RESULTS

Sixty-nine SE reports were reviewed. Applying the GAM provided a more holistic SE analysis than a traditional method. Of the 405 identified contributing factors in all SEs, the majority related to the persons involved (patients and professionals, n=146, [36.2%]) and the organisation (n=121, [30%]). The most frequently recurring pattern was the combination of factors related to the persons involved, the technology used, the tasks of professionals, and organisational factors influencing the event. Cross-hospital aggregate GAM analysis of SEs helped to identify system issues and propose more system-oriented overarching recommendations.

CONCLUSIONS

This study found that applying the GAM to analyse SEs across hospitals can help to improve learning from SEs and may result in proposing stronger recommendations. The method can support hospitals, working together in a network of hospitals, to jointly learn from SEs.

INTRODUCTION

In-hospital adverse events threaten patient safety[1 2] and result in substantial societal costs.[3] Learning from these events is vital to continuously improve patient safety. Hospitals therefore thoroughly monitor and investigate events. In particular, sentinel events (SEs)[4 5] which can be defined as unintended and unexpected events, are related to the quality of care and having caused death or serious patient harm.[6] In SE investigations, hospitals aim to reconstruct what happened by combining multiple sources of data. After gathering a precise description of the event, they perform a root cause analysis and formulate possible recommendations to prevent event recurrence. These SE investigations and analyses are documented in a detailed report that bear great learning opportunities. Although the SE investigations and analyses have great potential to improve patient safety, important barriers exist to exploit its full potential.

One important constraint is that hospitals focus on singular events within their own organisation,[4 7] instead of pursuing to learn from multiple SEs across hospitals. This leads to recurring events with similar causes and contributing factors that remain hidden.[4] Hospital-level analysis is ineffective in identifying patterns and trends in causes and contributing factors on a system level, and hinders hospitals to jointly learn from SEs. Aggregate cross-hospital analyses of SEs might help to overcome these concerns, addressing more deeply engrained systemic and organisational issues.[4,5,8] Although in some countries (e.g., the United States [9 10]) hospitals made attempts to jointly learn from aggregate analysis, other countries are still lagging behind. In the Netherlands, clustering SEs for cross-hospital analysis is hindered by amongst other issues the application of differing methods for analysing SEs.[8] Dutch hospitals often use Prevention and Recovery Information System for Monitoring and Analysis (PRISMA-medical),[11] Systematic Incident Reconstruction and Evaluation (SIRE),[12] or Tripod-bèta[13] to perform root cause analyses,[14] all with their own approach and focus, making it difficult to perform an aggregate analysis of SEs across hospitals.

A second constraint is that traditional SE-analysis methods typically focus on finding ‘the one linear’ root cause, whereas SEs are more likely to result from interactions of multiple contributing factors.[4 7 15] This narrow scope of traditional analysis underestimates the complexity of healthcare. According to the emergent human factors scholarship, understanding of interactions between people (e.g., healthcare professionals and patients) and other sociotechnical elements (e.g., technology, organisation, or the environment) within the complex work systems of health care might enlighten root cause analysis.[16 17] Traditional methods for SE-analysis however, are not based on such human factors thinking.

The disaggregated hospital-level approach and the lack of a human factors perspective in traditional SE-analysis methods may support the formulation of weak and ad hoc

recommendations after SE investigations, instead of -more effective- system-level recommendations.[18] This frustrates hospitals in their ambition to learn from SEs and prevent recurrence. Therefore, a novel generic analysis method (GAM) was developed.[19] The GAM is an operationalisation of the human factors based Systems Engineering Initiative for Patient Safety (SEIPS) models.[20 21] It consists of a framework and affiliated questionnaire to analyse SEs, in which the foci and some important elements of 3 root cause analysis methods used by Dutch hospitals are integrated. The GAM could ease aggregate SE analysis across hospitals, irrespective of the initial root cause analysis method used, and enhance SE analysis.[19] This could result in stronger recommendations.

In this article we describe the results of an aggregate cross-hospital analysis of SEs applying the GAM. Using the rich data of SE reports we aim to (1) exemplify what the GAM approach yields as opposed to an initial root cause analysis, (2) explore which contributing factors and eventual patterns emerge after aggregate cross-hospital GAM analysis, and, most importantly (3) propose how these findings can help strengthen recommendations.

METHODS

A retrospective cross-sectional review of SE reports of Dutch general hospitals was performed. In the Netherlands, hospitals are obliged to report and investigate possible SEs and share a detailed report on the findings with the Dutch Health and Youth Care Inspectorate. The inspectorate assesses the reports on the quality of the investigation and appropriateness of recommendations.[6] For investigating SEs, each hospital has an independent multidisciplinary committee involving quality and safety officers, and clinicians. These committees use multiple sources to elicit the course of events. The most important source being in-depth interviews with involved (health care) personnel, and patients and/or family, which forms the foundation for a detailed description of the event. Information gathered through interviews is then combined with a review of documentation such as medical records, test results (laboratory results, medical images, etc.), and guidelines and work instructions. This completes an information-rich, comprehensive reconstruction of the event, which forms the first part of the SE report. The committee of each hospital is trained in performing a method to identify root causes (PRISMA-medical,[11] SIRE,[12] or Tripod-bèta[13]) and formulate possible recommendations. Description of identified causes and formulated recommendations forms the second part of the report.

DATA COLLECTION

The SE reports used for this study were shared by 28 Dutch general hospitals which cooperate in a network aiming to improve patient safety. All associated hospitals were asked to share reports of closed investigations of SEs between 2017 and 2019.

Four safety critical themes were formulated to structure the selection of reports and collect a sufficient amount of, somewhat, similar events. This could increase the chances in finding eventual patterns and trends in causes and contributing factors, and at the same time help to include events relating to various care settings. The four safety critical themes were as follows: (1) diagnostic process in the emergency department, (2) medical technology, (3) anticoagulation, and (4) critically ill patients (of whom 1 or more vital functions, such as breathing, circulation and consciousness, were disturbed and in danger of failure). These themes were based on their incidence in former Dutch adverse event studies[22-24] and inclusion in patient safety programs.[25] The processes underlying these themes cover a large part of care provided by hospitals; making a diagnosis, applying medical devices, prescribing and administering medication, and providing care to vulnerable patient groups.

Hospitals were asked to provide 1 or 2 anonymised SE reports per theme for analysis. After the hospital association checked the reports for anonymity, they were securely sent to the researcher (MCB) for analysis.

INSTRUMENT: GENERIC ANALYSIS METHOD

The reports were analysed using the GAM which is explained in detail in a former study.[19] GAM consists of three main pillars (figure 1).

First, the method gathers some general information of the event (e.g., day, time, location, summary of the event). Second, sociotechnical domains in the work system are evaluated. Interactions and interdependencies between persons involved and factors related to other domains of the sociotechnical system (tasks, technologies, organisation, and the physical and external environment) are mapped. This focus on interactions and interdependencies between centrally positioned persons and other domains of the work system reflects the human factors foundation of this method. Third, the method assesses the consequences of SEs for patients, their families, health care professionals and the organisation, as well as possible recommendations formulated by the hospital committee. The GAM was operationalised in an online survey environment that followed the GAM framework and included all the questions of the affiliated questionnaire (Supplemental Appendix I).

DATA-ANALYSIS

Analysis of SE reports was a 4-step process. First, the researcher (MCB), as GAM developer and expert, studied the event descriptions and reanalysed these following the GAM. Second, a representative of each of the participating hospitals also reanalysed SE reports using the GAM, to assess whether the general findings of the researcher aligned with what the hospital representative found. Agreement was qualitatively assessed by comparing a selection of answers of the most important open-ended questions. Third, findings were presented to and discussed with a panel of experts from the patient safety network,

5

consisting of quality and safety officers and clinicians from 13 of the 28 participating hospitals, to check and verify our findings. Eventual differences in the interpretation between both analysts (hospital representative and researcher) were reflected upon. In case of uncertainties or irregularities in the data, initial SE reports were reassessed. The panel also made suggestions for recommendations based on the aggregated cross-hospital GAM analysis. Minutes were taken during meetings, and transcribed notes were sent to the participants afterwards for verification. As a last step and double check, the data and general findings of the first theme (diagnostics at emergency departments) were verified by a second researcher (SVS). There was a large overall agreement in findings between both analysts, and the second researcher.

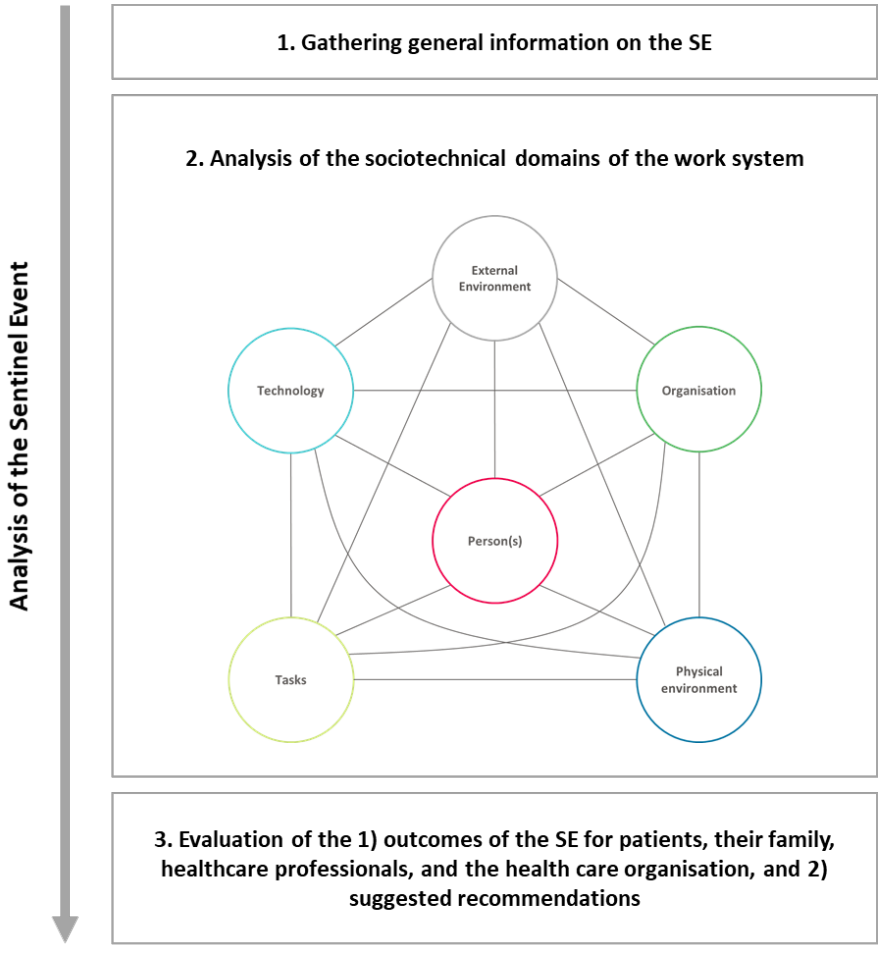


Figure 1. Overview of the generic analysis method, operationalization of the SEIPS-models[20 21] and elements of PRISMA[11], SIRE[12] and Tripod[13] are adopted.

Collected data was then qualitatively analysed to find relevant characteristics from the various sociotechnical domains in the set of open-ended questions. A sociotechnical characteristic was identified as a contributing factor whenever it (1) was explicitly described in the comprehensive event reconstruction in the SE report and (2) might have contributed in any matter to the event (as interpreted by the researcher). The factor did not necessarily have to be labelled as a root cause or basic risk factor. This aligns with the human factors philosophy, which proposes that we should evaluate interactions and interdependencies between all factors of the sociotechnical system and not merely focus on the final, hierarchal and linearly identified cause(s). We specifically tried to identify system issues, by evaluating all contributing factors. Factors that interacted with many other factors and those that recurred across events and hospitals and were related to the system were signalled as possible system issues.

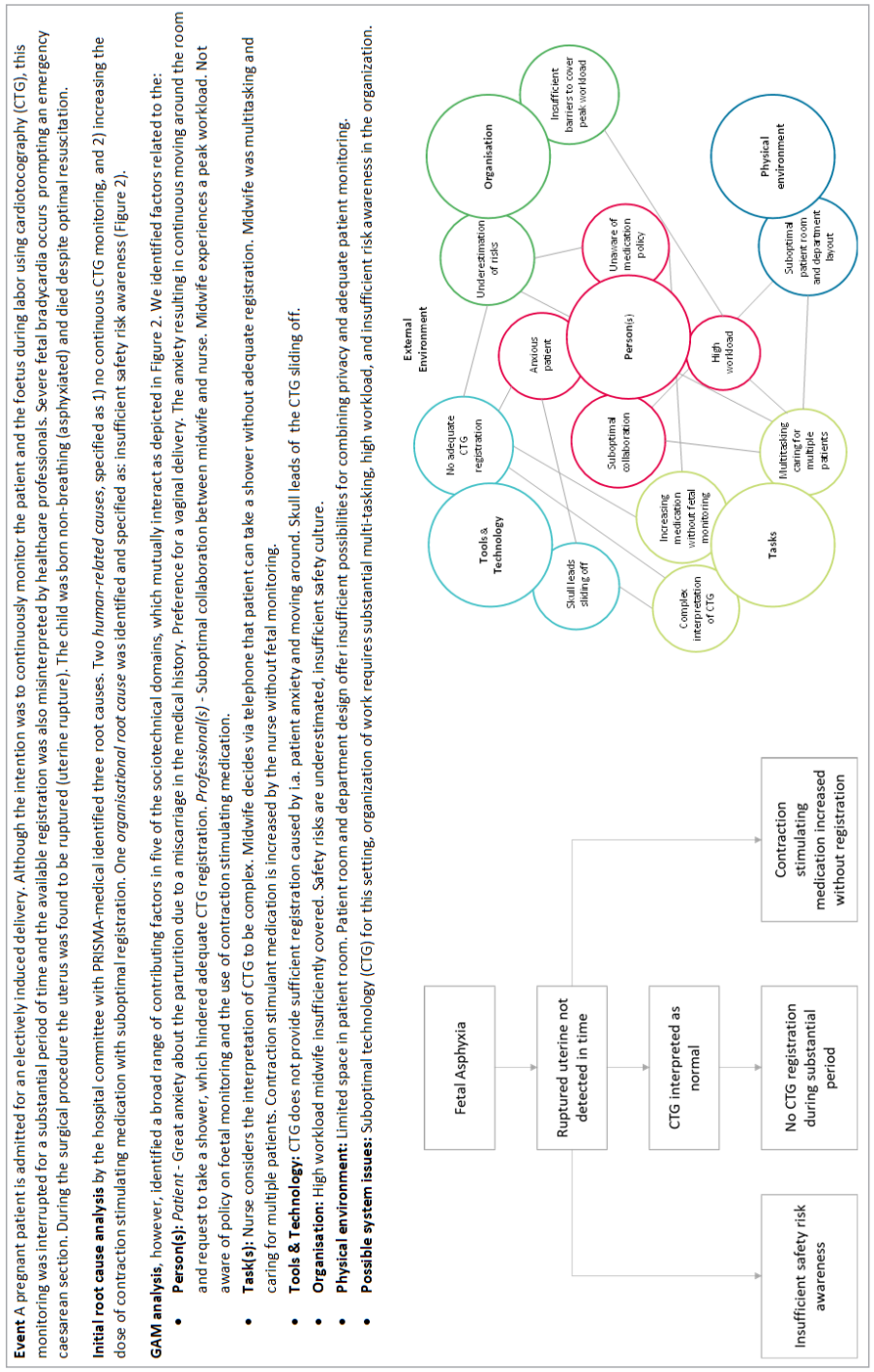
After identifying the (system) factors that contributed to the events, we calculated descriptive statistics. Associations between the sociotechnical domains were measured using nonparametric tests to identify to what extent the various domains simultaneously occurred within one SE and which domains were associated. Descriptive statistics and correlations measures were calculated using Stata 15 software (StataCorp LLC, College Station, Texas).

RESULTS

Sixty-nine SE reports were studied. The majority were filed under the theme diagnostic process in the emergency department (n=23). Twenty of the reports related to medical technology, 14 to anticoagulation, and 12 to critically ill patients. Of the patients involved, more than half was female (n=35), and most patients were in the adult, working age class of 18 to 65 years (n=36). Other patients were between 66 and 79 (n=18), and 80 years and older (n=12), and 3 cases involved minors. Event characteristics varied across themes (Supplemental Appendix 2).

A HUMAN FACTORS PERSPECTIVE

Figure 2 presents an example of how an event was analysed by the hospital using a traditional root cause analysis method (PRISMA-medical), and shows the results of analysis of the event description in the SE report using the GAM. PRISMA-analysis identified 3 independent root causes, whereas using the GAM to study the same event resulted in a total of 12 identified contributing factors and the evaluation of interactions between factors. Based on mapping the factors in this example and the identified interactions, possible system issues arose.



Box 1 [including figure 2]. Example of a SE, analysed using traditional root cause analysis; PRISMA-medical (left) and the GAM (right)

AGGREGATE ANALYSIS: CONTRIBUTING FACTORS & SYSTEM ISSUES

Cross-hospital aggregate GAM analysis of SEs resulted in 405 identified contributing factors (mean per report, 6) from various sociotechnical domains. Table 1 shows that most factors were identified for the domains organisation (n=121; e.g., resources, culture, scheduling, or training policies), and person(s); the professionals (n=103; e.g., knowledge, experience, tiredness, or cooperation) and patients (n=45; e.g., frailty, or cooperativeness). Factors related to the technology used (n=62; e.g., limited user-friendliness, technical failures, or misapplication) and tasks performed (n=48; e.g., complexity of the task or coinciding tasks) also frequently contributed. The domains of the physical environment (n=11; e.g., arrangement of the room or noise) and the external environment (n=15; e.g., legislation or budget cuts) provided for less factors. The distribution of factors per domain differed only slightly between the 4 safety critical themes, with medical technology as most divergent (figure 3).

Table 2. Sociotechnical factors identified in the SE-reports (N=69) and distribution of contributing factors (N=405)

Sociotechnical domain	Events* (n=69) n (%)	Factors** (n=405) n (%)	Examples of contributing factors
Person(s)	**38 (55.1)**	**45 (11.1)**	**Patient** Does not speak the language, which hampers the physical exam and medical history taking
			Stops taking medicine earlier than planned
	63 (91.3)	**103 (25.4)**	**(Healthcare) Personnel** Minimal experience in specific treatment leading to misapplication of a surgical instrument
			Suboptimal cooperation and communication between staff of different departments, which results in the omission of performing tests of vital parameters
Tools & Technology	**42 (60.9)**	**62 (15.3)**	Not user-friendly electronic medication prescription system hinders correct medication prescription
			The tip of an electrosurgical instrument breaks off during surgery
Tasks	**38 (55.1)**	**48 (11.9)**	Complexities in the diagnostic reasoning process (i.a. tunnel vision) leads to missing a high-risk diagnosis
			(Related to high workload) vital parameters are not measured and registered, contributing to missing the deterioration of a critically ill patient
Organisation	**59 (85.5)**	**121 (29.9)**	Anticoagulation work instructions are not up-to-date inducing a wrong medication policy
			Insufficient patient safety culture leads to taking high risks
Physical environment	**10 (13)**	**11 (2.7)**	Patient room is too small so caregivers get in each other's way during resuscitation
			Positioning of monitors and alarm screens hampers accessible patient monitoring information (e.g., cardiac activity, blood pressure and oxygen saturation) for caregivers

Table 2. Continued.

Sociotechnical domain	Events* (n=69) n (%)	Factors** (n=405) n (%)	Examples of contributing factors
External environment	**13 (19.1)**	**15 (3,7)**	Closure of wards in a nearby hospital causes extra bed pressure, contributing to the decision to not admit a patient Shortage of emergency doctors hinders sufficient staffing during weekends

*Number of SEs in which one or more factors of this domain contributed and corresponding percentage.
**Number of identified factors in all SEs and corresponding percentage.

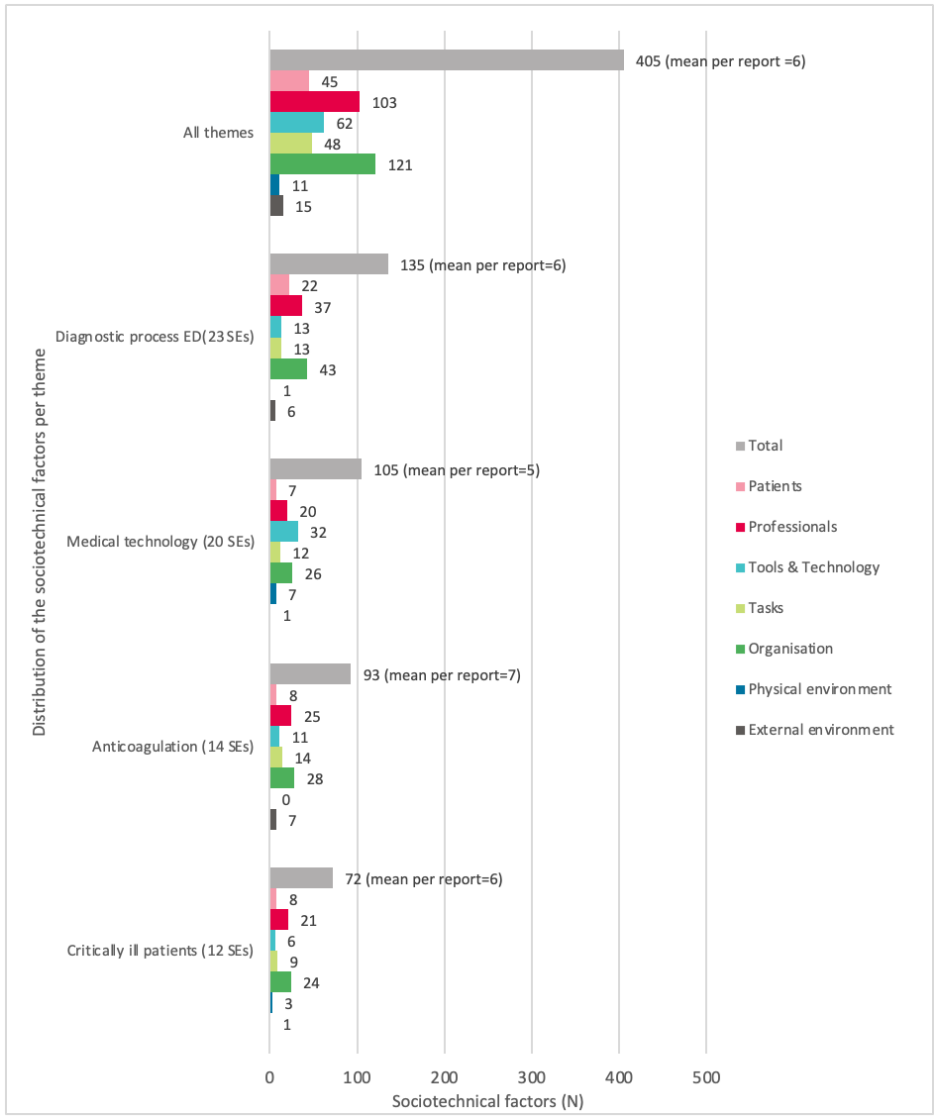


Figure 3. Distribution of the sociotechnical factors for the SEs for each theme and all SEs together

Identified system issues related, for example, to suboptimal cooperation (e.g., poor communication between hospital departments and information transfer between chain partners), limited user- and patient-friendliness of medical technology (e.g., usability problems related to electronic health records and prescription systems, or suboptimal technology design for clinical practice), and poor work structures (e.g., high workload, scheduling, staffing, high staff turnover or multitasking).

PATTERNS OF INTERACTIONS

Figure 4 shows commonly identified interactions between domains, based on domains that mutually contributed within one event. Characteristics of the person(s) involved contributed to nearly all SEs and therefore interacts with most other domains such as organisation (n=57), technology (n=39), and tasks (n=37). The domains of technology and organisation (n=36), tasks and organisation (n=35) and technology and tasks (n=24) also often contributed simultaneously. At the same time, it shows the rather small relation between the physical and external environment and other domains. None of the relations between domains were statistically significant associated (Supplemental Appendix 3). The most frequently observed combination of -more than 2- sociotechnical domains contributing to an event was the combination of the persons involved, the technology used, the tasks of (health care) professionals, and organisational factors influencing the event (n=14 [20.3%]).

IMPROVING PATIENT SAFETY

In the studied reports, hospital committees formulated 211 possible recommendations (mean per report, 3). A majority of the formulated recommendations were related to writing, adapting or raising awareness to protocols and work instructions (n=102). Recommendations regarding technology and ICT systems (n=24), improving staff training (n=23), and communication (n=17) were also regularly suggested. Measures aimed at improving collaboration (n=7) were proposed less frequently and changes in the organisation of care were rarely suggested. Other types of recommendations (n=38) focused on, for example, case discussion in department meetings or with chain partners. Most hospital committees formulated possible recommendations narrowly directed towards the identified root causes, as were identified with traditional root cause analysis methods.

Findings from the cross-hospital aggregated GAM analysis were used by the expert panel of the patient safety network to formulate possible recommendations on identified recurring patterns of factors and unruly organisation or system-level issues. Examples were to consider appointing a case manager for anticoagulation who can be easily approached by all units for questions regarding the anticoagulation policy, or evaluate and adapt the predefined lists of medication options in administrative systems, making it more intuitive and less prone to mistakes.

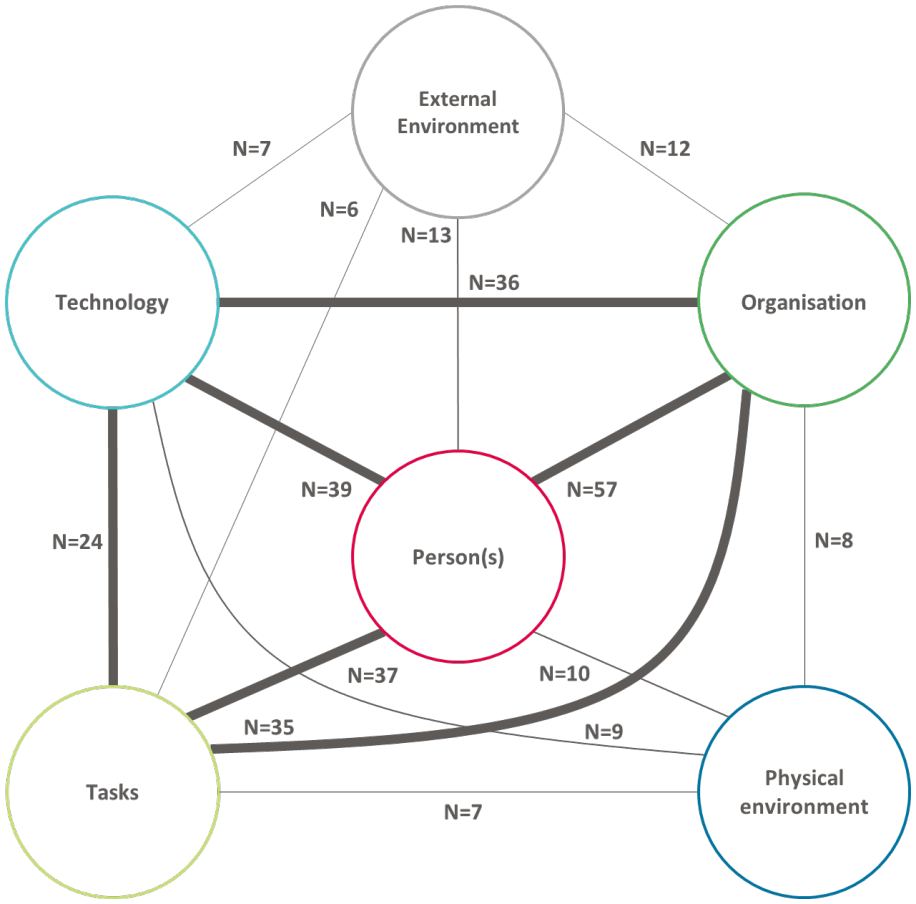


Figure 4. Interactions between sociotechnical domains over all reports.
Thick lines indicate the most frequently observed combination of -more than two- contributing domains.

DISCUSSION

Sixty-nine SE reports from 28 Dutch general hospitals were retrospectively analysed using the generic analysis method (GAM). We exemplified what the method yields opposed to traditional root cause analysis methods, provided insights in the contributing (system) factors of SEs and patterns herein across SEs, and illustrated how these findings can be used to improve possible recommendations.

Studying an event applying the GAM provided a richer and more holistic analysis than a traditional root cause analysis method. This finding aligns with previous studies that showed how traditional methods are characterised by their focus on one or a few linear, independent and detached causal factor(s).[4 26] Alternative approaches using human factors principles to analyse events typically identify a variety of interdependent factors, such as methods guided by the Systems Engineering Initiative for Patient Safety model[27 28] or other models (e.g., Human Factors Analysis Classification System[29] and Systems Theoretic Accident Modelling and Processes[30]).

Aggregated cross-hospital SE analysis using the GAM indicates that a majority of contributed factors related to the persons and organisation domains. Human and organisational factors are known to be the most frequently identified causes in SE or adverse event studies.[8 31 32] Not many contributing factors were identified that related to the physical and external environment. A possible explanation could lie in the fact that traditional root cause analysis methods do not or only limitedly address these domains and thus may be underreported in the SE reports. At the same time the more system-related issues (e.g., the external environment)[4 33] are often less explicit and thus more difficult to identify in SE investigations. Nevertheless, we found some important system issues by looking at interacting factors that were recurring across events and hospitals. In line with the identification of contributing factors, factors related to the persons and organisations domain most frequently coincided within one event. Although no domains were statistically significantly associated, systematically mapping factors of the various domains provided a valuable insight in the complexity and combinations of factors underlying SEs. The most frequently observed pattern (i.e. more than 2 coinciding factors) was the combination of factors related to the persons, organisation, technology, and tasks. This confirms the complex multidimensional nature of SEs, as also found in other SE studies.[8 34]

Recommendations in the studied SE reports were often narrowly directed towards the identified root causes, and the majority was related to improving work instructions and guidelines. These are considered common pitfalls. As discussed by Trbovich and Shojania,[33] root cause analysis teams tend to align their recommendations closely to identified causal factor(s) and resort to actions that are based on the specific individual case rather than on system issues. Other studies evaluating recommendations as reported by root cause analysis teams also found recommendations are mainly aimed at, for example, policy changes and administrative actions.[18 35] These type of recommendations are considered to be weak. Bos et al.[36] confirmed this finding of generally weak recommendations, as they concluded that the majority of recommendations in 115 Dutch SE-reports did not meet quality criteria and thus may have limited effect in improving patient safety. On the other hand, aggregate cross-hospital GAM analysis helped to formulate more system-oriented recommendations aimed at solving recurring issues across events and organisations. The examples provided, about adaptations in technology and institutional-level changes are considered more effective and sustainable.[18] Such system-level recommendations, however, may require substantial (financial) resources. Literature suggests SE investigators typically avoid these type of interventions.[33 36] Because the aggregated cross-hospital GAM analysis

recommendations are based on multiple SEs from various hospitals, they may provide more relevance and urgency than case-specific recommendations. In turn, this could help to mobilise the appropriate resources to implement and follow-up on recommendations.

There are several study limitations which should be considered when interpreting our findings. Our practice sample was purposefully selected and restricted to Dutch general hospitals. Therefore, caution is required when drawing generalisable conclusions. We think our findings regarding the core of the identified patterns in contributing factors and trends in possible recommendations, may be theoretically generalisable to other event types and settings, as they merely differed among the 4 investigated themes. However, results could differ when SEs would be included randomly. Likewise, if we would have included SEs from other types of hospitals, the substantive results might have been different because of, for example, a more complex patient population in academic hospitals. As a result of the study design, the numbers of SEs per theme do not reflect their true incidence. For example, numbers per theme may rather be affected by the timing of data collection (e.g., data on the latter 2 themes were collected during the COVID-pandemic) than by their occurrence in practice. In addition, although 69 SE reports is not a particularly small sample, examining a greater number of reports would enable us to perform more extensive statistical analysis. Applying a new analysis method to existing SE-reports in itself also holds some limitations. Researchers were not able to ask specific additional questions to those involved in the SE but were bound to the (comprehensive) event descriptions in the report. This may have resulted in an underestimation of factors related to the domains that are only minimally covered in traditional SE investigations and analyses, such as the physical and external environment. Nonetheless, the event descriptions in most SE reports were written in such detail that we were able to determine additional contributing factors, also for the domains that are less embedded in the traditional approaches.

Our study has some important implications. Hospitals can use the substantive insights into recurring and system-level issues as identified in the current study. More importantly, we recommend hospitals to use existing networks and its infrastructures to periodically perform a cross-hospital analysis of SEs, to identify patterns and trends in contributing (system) factors and put urgency on suggested recommendations. The GAM can assist to perform such retrospective aggregate cross-hospital analysis of SE reports, irrespective of the variety in underlying root cause analysis methods. Variation in root cause analysis methods has proven to be a major limitation in learning from SEs; it is therefore important to strive for more standardisation.[8 37 38] Ideally, the issue of unstandardized SE analysis is solved upfront, for example, by hospitals including the GAM as an alternative method for directly investigating and analysing SEs. This will ease analysis of SEs across hospitals and embeds a human factors perspective in future SE investigations. Further validation and evaluation of the usability of the method is recommended though.

We also propose that hospitals should train SE investigators in human factors principles and GAM analysis. Training of SE investigators could help them to set the focus during SE investigations on interlinked human factors domains and ask the right questions during interviews with those involved. Embedding human factors expertise in the SE investigation team could enlighten the SE analysis and may improve the quality of possible recommendations.[16] For specific cases, hospitals could also consider to consult other types of independent experts, for example, clinical technicians, health-IT specialists, or organisational or behavioural psychologists.

CONCLUSION

In conclusion, this study underlines the value of the GAM to learn from SEs. It provides a richer analysis than traditional root cause analysis methods, as it combines the foci of 3 existing methods. The human factors approach of the method stimulates to evaluate the complex nature of SEs. Applying the method for aggregate analysis of SEs across hospitals helps to identify trends and patterns, and may assist in formulating system-oriented recommendations. Wider application of the GAM has the potential to further improve patient safety.

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APPENDIX I.

QUESTIONNAIRE

A. General information about Adverse Events

1. Which method was used for the adverse event(AE) investigation?
    - PRISMA
    - SIRE
    - TRIPOD-bèta
    - Combination of the methods mentioned above (e.g. SIRE and PRISMA)
    - Other, please specify [Open text]

3. Give a brief summary of the AE. Focus on the most important elements of the AE, e.g. the occasion, the substandard actions taken and the outcomes (strive to use 200 words or less). [Open text]

4. At which department did the AE mainly take place: [Open text]

5. What was the reason for the initial hospital visit of the patient?
    - Inpatient care
    - Outpatient care
    - Planned test/research
    - Emergency care
    - Other, please specify [open text]

6. Describe the top event. Give a description of the AE in a few words. In SIRE and Prisma this is most often called the top event. In TRIPOD-bèta this is called an event. [Open text]

7. On which day did the top event occur?
    - Monday
    - Tuesday
    - Wednesday
    - Thursday
    - Friday
    - Saturday
    - Sunday

8. During which shift did the top event take place?
    - Day shift
    - Evening shift
    - Night shift

B. Socio-technical work systems & Processes

Persons- Patient

9. Gender of the patient
    - Female
    - Male

10. Age category of the patient:
    - 0 – 1 year
    - 2 – 4 years
    - 5 – 18 years
    - 19 – 65 years
    - 66 – 80 Years
    - Older than 80 years

11. Can the patient be categorised as fragile elderly? If yes, give a brief description of the frailty: [Open text]

12. Did medication play a role in the origin/development of the AE? If yes or possibly, give a description of the medication and the way in which it contributed: [Open text]

13.a Are one or more patient-related root causes found in the AE report?
    - Yes
    - No

13.b If yes, please give a description for each root cause: [Open text]

Persons – Healthcare professional(s)

14. What was the responsible medical specialism?
    - Anaesthesiology
    - Cardiology
    - Surgery
    - Dermatology
    - Geriatrics
    - Gynaecology/Obstetrics
    - Internal Medicine
    - Ear, Nose, Throat
    - Paediatrics
    - Pulmonology
    - Gastroenterology & Hepatology
    - Medical oncology

5

- Nephrology
- Neuro surgery
- Neurology
- Ophthalmology
- Orthopaedics
- Plastic surgery
- Psychiatry
- Radiology
- Rehabilitation medicine
- Rheumatology
- Emergency Medicine
- Trauma surgery
- Urology
- Other, please specify [open text]

15. Which healthcare professionals were involved in the AE? Describe, for each healthcare professional, particularities/specifics that might have contributed to the origin/development of the AE: [Open text]

16. Which professionals of medical supporting services were involved in the AE? Describe for each professional particularities/specifics that might have contributed to the origin/development of the AE: [Open text]

17. If the reports describe any details about the collaboration between professionals/departments, please provide a brief description: [Open text]

18.a Were any human-related root causes revealed?

- Yes
- No

18.b If yes, which type:

- Human - External (H-EX)
- Human – Knowledge-based behaviour (HKK)
- Human – Qualifications (HRQ)
- Human – Coordination (HRC)
- Human – Verification (HRV)
- Human – Intervention (HRI)
- Human – Monitoring (HRM)
- Human - Slips (HSS)
- Human - Tripping (HST)
- Communication

18.c Give a short description of the chosen human-related root cause: [Open text]

Tasks

19. Was the manner in which the top event proceeded an intended or an unintended action?

- Intended
- Unintended

20. Did the persons involved act according to their professional standard? If not, please give an explanation: [Open text]

21. Is there a trade-off being made between efficiency and thoroughness/safety when performing the care and other tasks? If yes, give a brief description: [Open text]
Technology

22. Are there any details reported about medical technology/did medical technology play a role in the origin/development of the AE? If yes, please give a description of this role: [Open text]

23.a Were any technical root causes revealed?

- yes
- No

23.b If yes, which type(s):

- Technical – Design (TD)
- Technical – Construction (TC)
- Technical – Materials (TM)
- Technical – External (TEX)
- Resources
- Maintenance

23.c Brief description of the technical root cause(s): [Open text]

24. Was a technical expert consulted during the AE investigation? If yes, explain which role this expert had in the investigation: [Open text]

Organisation

25. What were the most important organisational characteristics that contributed, even potentially, to the AE? [Open text]

26. Was a trade-off being made between efficiency and thoroughness/safety concerning organisational factors? If yes, give a description of this trade-off: [Open text]

27. Did the transfer of a patient between the healthcare providers contribute to the AE? If yes, please give a short description: [Open text]

28.a Were any root causes related to the organisation revealed?

- Yes
- No

28.b If yes, which type(s):

- Organisational – Transfer of knowledge (OK)
- Organisational – Protocols (OP)
- Organisational - Management priorities (OM)
- Organisational – Culture (OC)
- Organisational – External (OEX)
- Competing objectives
- Training and Education
- Orderliness and Neatness
- Protective equipment/-methods
- Failing barriers

28.c Give a short description of the chosen organisational-related root cause(s): [Open text]

Physical environment

29. Did the physical environment contribute, or possibly contribute to the AE? If yes, give a brief description: [Open text]

30.a Were any root causes found which related to the environment?

- Yes
- No

30.b If yes, which type(s):

- Environmental factors
- Protective equipment/-methods
- Orderliness & Neatness
- Other

30.c Give a brief description of the environmental root cause(s) chosen: [Open text]

External environment

31. Did external policy influence the origin/development of the AE? If yes, give a short description: [Open text]

C. Consequences of the adverse event

32. What were the consequences of the AE for the patient/family? [Open text]

33. What were the consequences of the AE for the healthcare and other professional(s)? [Open text]

34. What were the consequences of the AE for the healthcare organisation? [Open text]

35. Were any claims filed in response to the AE?

- Yes
- No

36.a Which type(s) of measure for improvements were formulated in response to the AE?

- Collaboration
- Communication
- Revise protocol(s)
- Adjustments in technology/ICT
- Training & Education
- Other, please specify: [Open text]

36.b Give a short description(s) of the measure(s) chosen in order to achieve an improvement: [Open text]

APPENDIX II.

SE CHARACTERISTICS PER THEME

Characteristics of the serious adverse events	Overall (N=69)	Diagnostic process ED (N=23)	Medical Technology (N=20)	Anticoagulation (N=14)	Critically ill patients (N=12)
Patient gender					
• Male	34	14	8	7	5
• Female	35	9	12	7	7
Age category patient					
• 0-17	3	1	1	-	1
• 18-65	36	13	13	6	4
• 66-79	18	3	5	5	5
• 80 and older	12	6	1	3	2
Shift type					
• Day	42	9	17	11	5
• Evening	9	6	1	0	2
• Night	18	8	2	3	5
Event location					
• Emergency department	29	23	1	3	2
• Operating room	12	-	9	2	2
• Floor units	24	-	9	7	8
• Other	4	-	1	2	1
Type of root cause analysis method used					
• PRISMA	29				
• SIRE	25				
• Tripod	5				
• Combination	10				

Sociotechnical domain	Example of contributing factors	Events* N (%)	Factors** N (%)	Diagnostic process ED, factors N	Medical technology, factors N	Anticoagulation, factors N	Critically ill patients, factors N
Person(s)	**Patient**	**38 (55.1)**	**45 (10.7)**	**22**	**7**	**8**	**8**
	Does not speak the language, which hampers the physical exam and medical history taking						
	Stops taking medicine earlier than planned	**63 (91.3)**	**103 (25.6)**	**37**	**20**	**25**	**21**
	(Healthcare) Personnel	**42 (60.9)**	**62 (15.4)**	**13**	**32**	**11**	**6**
	Minimal experience in specific treatment leading to misapplication of a surgical instrument						
	Suboptimal cooperation and communication between care staff of different departments, which results in the omission of performing tests of vital parameters						
Tools & Technology	Not user friendly electronic medication prescription system hinders correct medication prescription	**38 (55.1)**	**48 (11.9)**	**13**	**12**	**14**	**9**
	The tip of an electrosurgical instruments breaks off during surgery						
Tasks	Due to high workload vital parameters are not measured and registered, contributing to missing the deterioration of a critically ill patient	**59 (85.5)**	**121 (30)**	**43**	**26**	**28**	**24**
	Complexities in the diagnostic reasoning process (i.a. tunnel vision) leads to missing a high-risk diagnosis						
Organisation	Anticoagulation work instructions are not up-to-date inducing a wrong medication policy	**10 (13)**	**11 (2.8)**	**1**	**7**	**0**	**3**
	Insufficient patient safety culture leads to taking high risks						
Physical environment	Patient room is too small so caregivers get in each other's way during resuscitation						
	Positioning of monitors and alarm screens hampers accessible patient monitoring information (e.g., cardiac activity, blood pressure and oxygen saturation) for caregivers						

Continued.

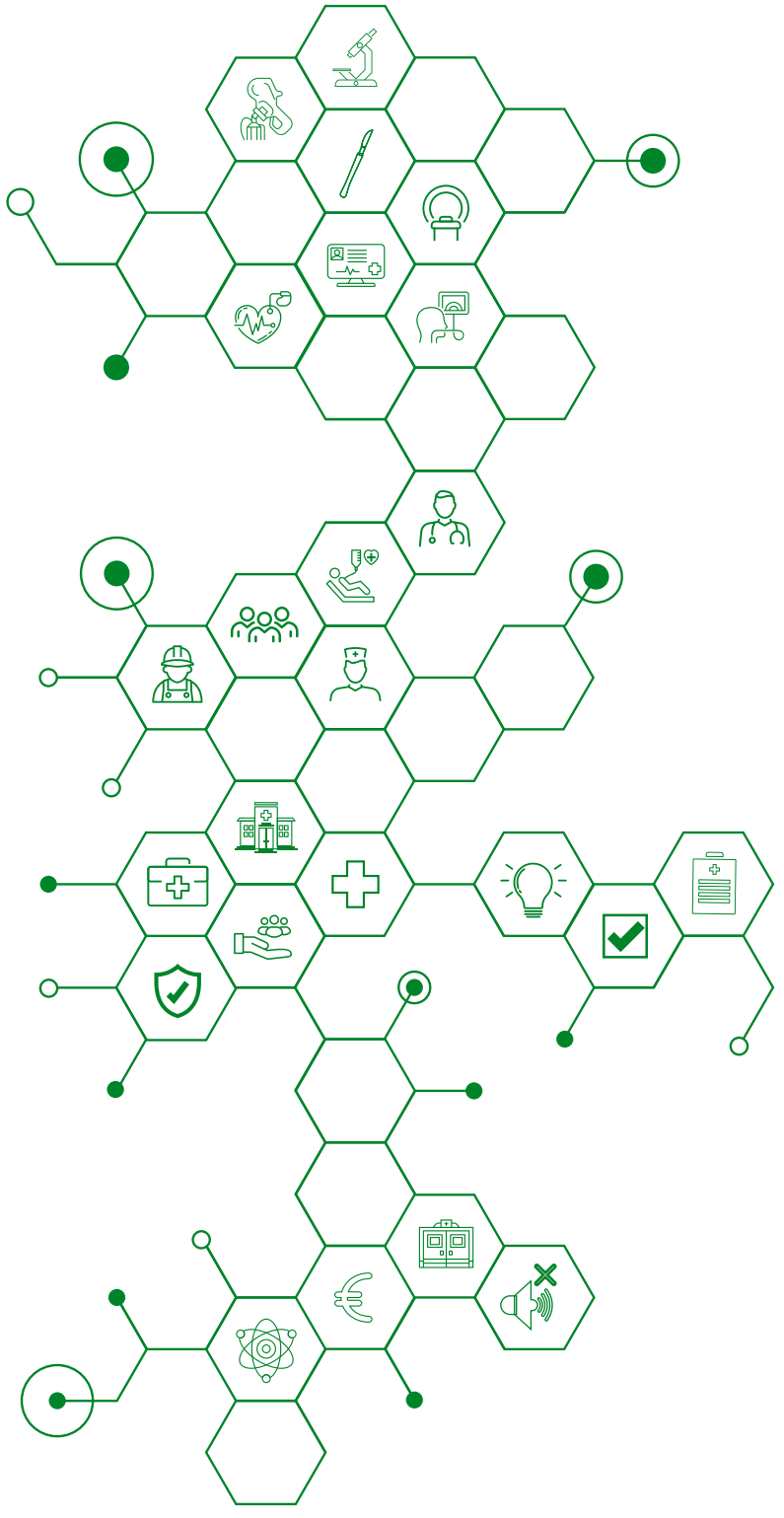
Sociotechnical domain	Example of contributing factors	Events* N (%)	Factors** N (%)	Diagnostic process ED, factors N	Medical technology, factors N	Anticoagulation, factors N	Critically ill patients, factors N
External environment	Closure of wards in a nearby hospital causes extra bed pressure, contributing to the decision to not admit a patient	**13 (19.1)**	**15 (3.7)**	**6**	**1**	**7**	**1**
	Shortage of emergency doctors on the labour market hinders sufficient staffing during weekends						
Total			**405 (mean per report 6)**	**135 (mean per report 6)**	**105 (mean per report 5)**	**93 (mean per report 7)**	**72 (mean per report 6)**

APPENDIX III.

OUTCOMES NON-PARAMETRIC TESTS FOR ASSOCIATION

Domains	Events N (%)*	Φ (p, Fisher's exact test)**	
Person(s)-Technology	39 (56.5)	-0.1709	(0.275)
Person(s)-Tasks	37 (53.6)	0.0932	(0.584)
Person(s)-Organisation	57 (82.6)	0.1141	(0.38)
Person(s)-Physical environment	10 (14.5)	0.0878	(1.0)
Person(s)-External environment	13 (18.8)	0.1027	(1.0)
Technology-Tasks	24 (34.8)	0.0519	(0.805)
Technology-Organisation	36 (52.2)	0.0073	(1.0)
Technology-Physical environment	9 (13)	0.2457	(0.076)
Technology-External environment	7 (10.1)	-0.0693	(0.753)
Tasks-Organisation	35 (50.7)	0.2075	(0.1)
Tasks-Physical environment	7 (10.1)	0.1235	(0.494)
Tasks-External environment	6 (8.7)	-0.0864	(0.545)
Organisation-Physical environment	8 (11.6)	-0.0644	(0.630)
Organisation-External environment	12 (17.4)	0.0931	(0.674)
Physical environment-External environment	0 (0)	-0.1984	(0.189)

*Number of SEs in which the combination of domains contributed to the event and corresponding percentage.
**Phi-coefficient for associations between the occurrence of the domains and outcomes of the fishers exact test (two-sided).



Chapter 6

What Can We Learn From In-Depth Analysis of Human Errors Resulting in Diagnostic Errors in the Emergency Department: An analysis of serious adverse event reports

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ABSTRACT

INTRODUCTION

Human error plays a vital role in diagnostic errors in the emergency department. A thorough analysis of these human errors, using information-rich reports of serious adverse events (SAEs), could help to better study and understand the causes of these errors and formulate more specific recommendations.

METHODS

We studied 23 SAE reports of diagnostic events in emergency departments of Dutch general hospitals and identified human errors. Two researchers independently applied the Safer Dx Instrument, Diagnostic Error Evaluation and Research Taxonomy, and the Model of Unsafe acts to analyse reports.

RESULTS

Twenty-one reports contained a diagnostic error, in which we identified 73 human errors, which were mainly based on intended actions (n=69) and could be classified as mistakes (n=56) or violations (n=13). Most human errors occurred during the assessment and testing phase of the diagnostic process.

DISCUSSION

The combination of different instruments and information-rich SAE reports allowed for a deeper understanding of the mechanisms underlying diagnostic error. Results indicated that errors occurred most often during the assessment and the testing phase of the diagnostic process. Most often, the errors could be classified as mistakes and violations, both intended actions. These types of errors are in need of different recommendations for improvement, as mistakes are often knowledge based, whereas violations often happen because of work and time pressure. These analyses provided valuable insights for more overarching recommendations to improve diagnostic safety and would be recommended to use in future research and analysis of (serious) adverse events.

INTRODUCTION

Research on diagnostic error has gained interest since the report 'Improving diagnosis in health care' of the National Academies of Science, Engineering, and Medicine was published in 2015[1]. The increase in attention for these errors is not without reason. Diagnostic errors imply a great risk for patient safety[2]; it is estimated that most people will experience a diagnostic error in their lifetime[1]. Diagnostic errors are defined by Graber et al. [3] as a diagnosis that was unintentionally delayed, wrong, or missed, as judged from the eventual appreciation of more definitive information. Consequences of diagnostic errors are often more severe (i.e., higher mortality rates) and more often considered preventable than other types of errors[4,5]. Studies in the Netherlands show that diagnostic errors are causative for a large proportion of adverse events in healthcare[5,6].

The emergency department (ED) is especially prone to diagnostic errors. It is a decision-dense department where many diagnostic decisions have to be made, often under time pressure and with high levels of uncertainty[7–9]. A study into the causes of diagnostic errors in the ED, using closed malpractice claims, identified multiple different factors that contributed[10]. In almost all cases (96%), at least one cognitive factor was present, such as mistakes in judgment, lack of knowledge, and lapses in vigilance or memory. Given this large contribution of cognitive factors, it is important to gain more knowledge about their nature.

Most studies that are focused on diagnostic error make use of retrospective data from patient records. Although these records can be useful for finding diagnostic errors, they lack information on the thought processes of the clinician. Interpretation of the cognitive processes based on the available information in patient records is difficult[11]. For example, a situation in which a physician decides not to order a certain laboratory test because they thought it was irrelevant, is very different from a situation in which the laboratory test was not ordered because the physician forgot to do so and calls for a different improvement measure. These types of nuances are difficult to extract from patient record review. To gain insight in those cognitive processes and thus reasons for certain diagnostic decisions or diagnostic errors, more detailed information from the physicians themselves should be gathered, for example, through interviews. A combination of clinical data and interviews with involved physicians has proven to be useful to gather more information on clinical thought processes [12]. These insights could help with suggesting recommendations for improvement.

In the current study, we have used data from serious adverse event (SAE) reports, which are based on extensive event investigation and include details of decisions made by the involved clinicians gathered through interviews. These reports are supposed to be a rich source of information and more suitable for subtracting information on the cognitive thought processes. For the current study, we focused on human errors—in which cognitive factors

play an essential role—because these have a large contribution in diagnostic errors[10], although we do recognize that these errors are commonly facilitated by other factors (e.g., system factors).

We have used 3 well-known and established methods for analysing the reports. For identification of reports that contained diagnostic error(s), we used the Safer Dx Instrument[13]. We used the Diagnostic Error Evaluation and Research Taxonomy (DEER taxonomy) to gain insight into where human errors occur in the diagnostic process[14,15]. Lastly, we used the Model of Unsafe Acts to determine the types of human errors. This last model is based on a well-known theory on human errors described by Reason[16,17]. It differentiates between decisions that were made intentionally and unintentionally. The addition of this model could provide a more in-depth understanding of human errors. Although these methods are well known, their combination has not yet been used in diagnostic error research nor for analysis of SAEs.

Applying these instruments, we aim to determine whether an in-depth analysis of the human errors involved in diagnostic errors in the ED, using information-rich SAE reports, will increase our understanding of diagnostic errors and will provide leads to improve analysis of diagnostic SAEs and specify recommendations for improving diagnostic safety.

METHODS

SERIOUS ADVERSE EVENT REPORTS

The current study was part of a bigger project including an aggregate analysis of SAEs. For this project, a group of cooperating Dutch general hospitals (n=28) were asked to share recent SAE reports (2017-2019) related to specific safety critical themes[18]. One of these themes was the diagnostic process in the ED. In the current study, we used the reports that were submitted under this theme (n=23). Because the reports were anonymized it is unknown how many of the participating hospitals are included in this sample.

These reports are based on a thorough investigation performed by a multidisciplinary independent hospital committee including physicians with various specialties (e.g., emergency physicians, radiologists, cardiologists), other clinicians (e.g., nurses, pharmacists, surgery assistants), and quality and safety officers [19]. These teams are trained in performing root cause analyses. The committee interviewed clinicians involved in the SAE, studied patient records, and analysed relevant documentation and test results. If necessary, they consulted an external expert. The investigation ended with an analysis of root causes and formulation of measures for improvement. Tools for the analyses of root causes that hospitals used varied per hospital but was either one or a combination of the following 3 conventional tools: Prevention and Recovery Information System for Monitoring and Analysis[20], Systemic Incident Reconstruction and Evaluation[21] and Tripod Beta[22]. Although hospitals used various methods for root cause analysis, all reports included: general patient information (gender, age, relevant medical history), information about the SAE (date, time, healthcare professionals involved, description of provided care, contributing socio-technical factors, and relevant events), a description of root causes (including a classification of identified root causes or failing barriers), and formulated measures for improvement. Reports were written according to the standards of the Dutch Health and Youth Care Inspectorate, which evaluates the content and quality of the reports.[19,23]

REVIEW PROCESS

We further analysed the reports as provided by the hospitals using established methods for analysing diagnostic (specifically, Safer Dx Instrument and DEER taxonomy) and human errors (Model of Unsafe Acts). The review process consisted of 4 steps as illustrated in Figure 1.

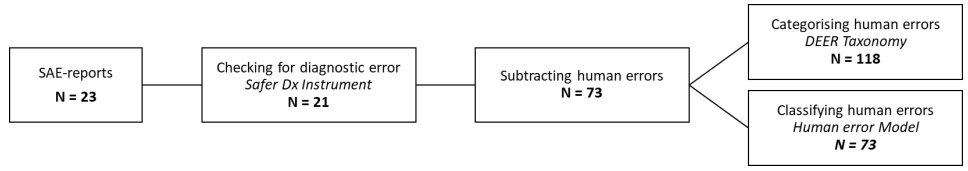

Figure 1. Flowchart of the review process. Resulting numbers are represented at each step.

Safer Dx Instrument

First, all reports were checked for the presence of a diagnostic error as operationalized by the Safer Dx Instrument[13]. This screening tool was developed to improve the accuracy of assessing diagnostic errors based on objective criteria. The instrument has been validated in the primary care setting and the paediatric intensive care unit[24] but has recently been revised to be used in other settings as well[13]. The revised instrument can be used by either researchers, safety professionals or clinicians[13]. It consists of 12 items (see Appendix 1), each targeting different aspects of the diagnostic process. The items are judged on a 7-point scale (1 = strongly disagree, 4 = neutral, 7 = strongly agree). A final 13th item addresses whether there was a 'missed opportunity to make a correct and timely diagnosis'. Only SAE reports that were judged 4 and greater on the overall score were considered diagnostic errors and were further analysed. The purpose of using the Safer Dx Instrument was to filter out any reports that were not diagnosis related. Researchers (MCB and JH) independently reviewed the reports and scored the thirteen items. The researchers agreed on all cases on whether the report related to diagnostic error and should be included.

Identifying human errors

The SAE reports that involved a diagnostic error were further analysed for human errors. For identifying these human errors, we focused in particular on the descriptions of root causes. We searched these descriptions for 'errors' mainly induced by the actions (or reluctance to act) of a person. When a human error including the underlying actions was already specified in the description of root causes, we adopted this description for our analysis. In some cases, we needed to go back to the detailed description of the event to specify the human error and find the corresponding acts. An example of an identified human error is: 'a resident fails in reading the Electrocardiogram (ECG) correctly and misses a heart failure diagnosis'. Missing the diagnosis is caused by the failure of the resident to accurately assess the ECG. The report specified that the resident evaluated the ECG but interpreted it incorrectly.

Diagnostic Error Evaluation and Research taxonomy

The identified human errors (n=73) were then categorised using the DEER taxonomy (see Appendix 2)[14,15]. This taxonomy helps to systematically aggregate diagnostic error cases and reveal patterns of diagnostic failures and areas for improvement. We used the DEER taxonomy to study in which part of the diagnostic process (access to care, history taking, physical exam, diagnostic testing, assessment, consultation/referral, or follow-up) the human errors occurred and specify what exactly went wrong. The DEER taxonomy-based categorisation of the human errors was independently executed by two of the researchers (MCB and JH). They indicated for all 73 identified human errors at which step in the diagnostic process the error occurred and what exactly went wrong (e.g., failure/delay in eliciting a critical piece of history data, error in clinical interpretation of test). Because some categories of the DEER taxonomy overlap or are closely related (e.g., too little weight given to the diagnosis and too much weight on competing diagnosis), a single human error could apply to multiple (sub)categories of the DEER. A third reviewer (LZ) was available when consensus could not be met. This was needed for categorising 9 of the human errors.

Model of Unsafe Acts

Lastly, the identified human errors were classified using the Model of Unsafe Acts by Reason[16]. This model has been occasionally used in health care settings [25], as well as in studies on the diagnostic reasoning process[12]. The model classifies acts leading to human errors as either intentional or unintentional actions (see Figure 2). It is important to emphasize this model classifies acts, not the outcomes of acts. The SAE-related outcomes are generally unintended, but the actions causing these outcomes can still be intended. For example, when a nurse decides to not adhere to an infection prevention protocol because compliance takes too much time and the work pressure is high, then, the action of not disinfecting hands is intended, while the outcome (e.g., infecting a fragile patient) is unintended.

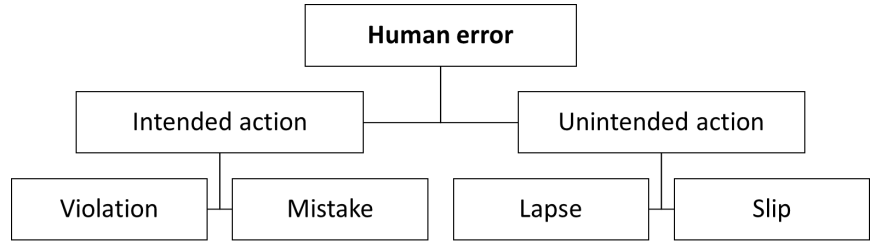

Figure 2. Model of Unsafe Acts[16]

Intended actions can be subdivided into mistakes and violations. A mistake occurs if a plan is performed as intended, but the plan was not adequate to reach the outcome that was intended (rule-based mistakes: e.g., misapplication of good rule, application of bad rule, and knowledge-based mistakes). A violation in this context does not imply malicious intentions but is an action that is not in line with the protocols, guidelines, or rules (e.g., routine violations, exceptional violations, efficiency-thoroughness trade-off). An example of a violation is a trade-off between doing your job fast (using erroneous shortcuts) and doing it thoroughly, also known as 'efficiency-thoroughness trade-offs'[26].

Unintended actions can be subdivided into lapses and slips, which are related to errors in execution. Slips occur when the correct action is executed poorly (attentional failures: e.g., intrusion, omission, reversal, misordering, mistiming). Lapses occur when the execution involves a failure in memory (e.g., omitting planned items, place-losing, forgetting intentions) [16,27].

All identified human errors (N=73) were classified by two researchers (MCB and JH) using this model. Whenever the researchers disagreed on the most appropriate class, a third researcher (LZ) was asked to assess the error (n=18). Furthermore, a 20% sample of the other errors was assessed by the third researcher (n=12). In case of a discrepancy between the assessments (N=3), we discussed motivations to reach consensus.

RESULTS

After screening all 23 reports with the Safer Dx Instrument, 2 reports were excluded because the researchers agreed that there was no missed opportunity for a correct and timely diagnosis (judgement on the overall question below a score of 4). The remaining 21 reports (a Safer Dx Instrument's 13th-item mean score of 6.19) were included in the further analysis.

SERIOUS ADVERSE EVENTS CHARACTERISTICS

Most prevalent missed or delayed final diagnoses were cardiovascular (n=11) or neurological

(n=5) conditions, such as aorta dissection, ruptured abdominal aortic aneurysm, subarachnoid haemorrhage, and spinal cord injury. Initial diagnosis varied widely. An overview of all initial and final diagnoses is presented in Table 1. This table further presents the sociotechnical factors that were identified by the hospitals in the SAE reports, which shows that organisational and patient-related factors contributed alongside the human errors. In our further analysis, we have focused on human errors.

HUMAN ERRORS IN THE DIAGNOSTIC PROCESS

From the SAE reports we subtracted 73 human errors. The DEER taxonomy tool was used to specify the errors further. One human error was not suitable for categorisation with the DEER taxonomy as it involved forgetting to administer medication after diagnosis was already established and thus was not part of the diagnostic process. A single human error could relate to multiple DEER subcategories. A total of 120 DEER categorisations were made, which is an average of 1.7 categories per error (min=1, max=4). These occurred most often in the assessment (n=49) and testing domain (n=36). Other human errors occurred during referral or consultation (n=13), history taking (n=7), the physical exam (n=8), follow-up (n=5), and at access to care or presentation (n=2).

Most human errors involved a failure or delay in recognising the urgency of the situation (n=14; e.g., the supervising physician is not contacted after a patient collapses in the middle of the night) or putting too much weight on a competing or coexisting diagnosis (n=14; e.g., the working diagnosis of a migraine disrupted the search for other causes of the symptoms of a patient with a subarachnoid haemorrhage). Other recurring themes are the failure or delay to consider a diagnosis (n=12), failed or delayed follow-up of (abnormal) test results (N=8), failure or delay in ordering needed tests (N=7), wrong test orders (N=6), and failure or delayed communication or follow-up of a consultation (N=6). Specified results on all subcategories are summarized in Appendix 2.

HUMAN ERROR CLASSIFICATION

The 73 identified human errors were also classified according to the Model of Unsafe Acts. Most human errors were based on intended actions and therefore classified as 'intended' (n=69). Fifty six of the intended actions were classified as mistakes and 13 as violations. Six violations seemed to be efficiency-thoroughness trade-offs (e.g., the physician only read a summary, not the full patient history file, because it is a busy night), one was related to routine-based violations (the intensivist does not immediately react to a rapid response team call made by a nurse, because they usually get those calls from physicians), the others were not further distinguishable. Unintended actions occurred less often (n=4) and were most frequently classified as action-based errors (slips). A summary of the results, including examples of each of the human error types, are provided in Table 2.

Table 1. Overview of the initial and final diagnoses of included cases with the number of identified DEER classifications, the number of mistakes and violations, and the presence of socio-technical factors.

Initial diagnosis	Final diagnosis	SOCIO TECHNICAL FACTORS*			DEER T AXONOMY							HUMAN ERROR			
		Technical	Organisational	Patient-related	Access	History	Physical Exam	Tests	Assessment	Referral	Follow-up	Mistakes	Violations	Lapses	Slips
Urinary tract infection	Ruptured abdominal aortic aneurysm		X				1	5	1			3	2	1	
Diverticulitis	Ruptured abdominal aortic aneurysm		X	X					5			4			
Pneumonia, delirium	Brain injury		X	X		1	1		1			1	1		
Migraine	Subarachnoid haemorrhage			X	1			1	4		1	4			
Pulmonary embolism	Aorta dissection	X	X	X			1	4	2	2		2	3		
Pulmonary embolism	Aorta dissection, pericardial tamponade			X				5	3	2		4			
Tendomyogene pain	Aorta dissection		X	X		2			7			5			
Retention bladder	Cardiogenic shock		X					4	1	1		1	2		
Neurological injury	Cardiac infarction					1		1	3	1		2	1		1
Muscle strain	Heart and lung perforation, pacemaker lead		X	X				1	2	1		3			
Ileus	Heart attack		X	X				1	1			1			
Tietze syndrome	Heart attack		X	X				4	2			4			
Fall, confusion	Myocardial infarction		X	X				1	2			2			
Pneumonia (suspected)	Unknown suspected cardiac/combination pneumonia and sleep apnea		X	X		1	1	1	1		1	2	1		1
Hip contusion	Fractured lumbar vertebra, incomplete spinal cord dwarslaesie		X				1		2			2			
Kidney stone	Rib fractures, lung contusion		X	X				1	2			2			
Mild brain damage	Spinal cord injury		X	X		1	1	2	1	1		3			
Myelopathy	Spinal fractures		X		1		1	2	1	2		4	1		

Table 1. Continued.

Initial diagnosis	Final diagnosis	SOCIO TECHNICAL FACTORS*			DEER T AXONOMY								HUMAN ERROR			
		Technical	Organisational	Patient-related	Access	History	Physical Exam	Tests	Assessment	Referral	Follow-up	Mistakes	Violations	Lapses	Slips
Rent bladder, urinary tract infection	Fournier gangrene			X				1	3	2	1	3	1		
Pneumonia	Airway obstruction, pneumonia in combination with myasthenia gravis		X	X		1	1		5	1		4			
Pericarditis	Lung carcinoma			X				2			2		1		1
					2	**7**	**8**	**36**	**49**	**13**	**5**	**56**	**13**	**1**	**3**

* An 'X' means that hospitals identified at least one socio-technical factor of that type during that case.

CLASSIFIED HUMAN ERRORS IN THE PHASES OF DIAGNOSTIC PROCESS

When we combine the results of the DEER-taxonomy and the human error classification, we can provide an overview of the DEER categories that were found per type of human error (as presented in Table 2). For example, of the DEER categories found in mistakes (n=99), approximately half (n=48) were related to the assessment phase of the diagnostic process**.** Human errors classified as mistakes were on average related to a higher number of DEER (sub)categories (1.9 category per mistake) than human errors classified as violations (1.3 category per violation). These insights in the specific types of human error combined with information on where in the diagnostic process they occur may provide important leads to more specifically aim recommendations to prevent recurrence.

Table 2. Human error classifications, including an example of each type of error and how the errors are related to the DEER taxonomy categories.

Human error	N=73	Example	DEER categories N*							
			Presentation	History	Physical Exam	Tests	Assessment	Referral	Follow-up	**Total**
Intended actions	*69*									
Violations	13	"It is busy in the ED, the physician arrives at the patient and likely makes an efficiency-thoroughness trade-off by not reading the triage report. Because of this, they miss information about fainting and high body temperature."	-	2	2	7	1	4	1	**17**
Mistakes	56	"The physicians focused on finding a neurological cause of the patients' symptoms. They failed to consider cardiac causes."	2	5	5	27	48	9	3	**99**
Unintended actions	*4*									
Lapses	1	"In the hectic situation after the diagnosis of a ruptured aneurysm, clinicians forget to administer vitamin K."	-	-	-	-	-	-	-	-**
Slips	3	"A nurse notes down a body temperature of 36.8 °C. Later, it turns out that the temperature was 38.6. The numbers got switched accidentally."	-	-	1	2	-	-	1	**4**
			2	**7**	**8**	**36**	**49**	**13**	**5**	***120***

* A single human error could be categorised in multiple DEER sub-categories, which resulted in a higher number of DEER categories than number of human errors.
** The lapse was not suitable for categorization with the DEER taxonomy.

DISCUSSION

We studied 21 diagnostic error-related SAE reports that occurred in the ED of several Dutch general hospitals to determine whether an in-depth analysis of human errors could help to improve the analysis of SAEs and help to aim specific recommendations for improvement.

We found that human errors in our study occurred most frequently within the assessment phase of the diagnostic process. This is congruent with earlier studies[15,28]. More specifically, they occurred because of a failure to consider the correct diagnosis, overweighing of a competing diagnosis, or a failure to recognize urgency. Apart from errors that were categorised in the assessment phase, we also identified a substantial number of errors in the testing phase, particularly in (wrongfully) ordering the needed tests, and the interpretation of test results.

Most of the human errors could be classified as intended actions (i.e., violations and mistakes). The overwhelming number of intended actions shows that actions that contributed to the diagnostic errors were deliberate decisions, such as the decision to skip reading a triage report, or focussing on a specific cause for a patients' symptoms (see examples in Table 2). Situations in which an action was unintended (i.e., lapses or slips), such as a laboratory result that was overlooked, were rare. These findings can in part be explained by the focus on diagnostic events and the nature of errors in the ED, which is a department where complex tasks are performed and many decisions are made[9]. Unintended actions (i.e., slips and lapses) are more action- and memory-based and are more often found in, for example, medication errors[29].

Although mistakes and violations are both intended actions, their underlying nature is very different. Mistakes are often based on a lack of specific knowledge (e.g., a physician who mistakes symptoms of a rare neurological disease with pneumonia), or pursuing the wrong diagnosis (e.g., focussing on neurological symptoms when in fact there was something cardiac going on), whereas violations are more often related to organisational and contextual factors (e.g., work and time pressure, which leads to making efficiency-thoroughness trade-offs). This is important, because recommendations for improvement aimed at mistakes will likely not be effective for violations and vice versa. Mistakes could benefit from knowledge-based interventions such as specific training and education to fill in knowledge gaps, feedback and reflection on diagnostic discrepancies, or implementation of diagnostic decision support systems. Violations, on the other hand, need a more system-based approach, such as lowering work pressure and crowding in the ED, improving patient safety culture, and improving teamwork.

A thorough analysis of human errors contributing to diagnostic errors in the ED based on SAE reports for which involved clinicians were interviewed has provided important insights that help to understand the role they play in diagnostic error. We would therefore recommend to perform an in-depth analysis of human errors using the DEER taxonomy and Model of Unsafe Acts whenever a SAE occurs. This can assist in further improving recommendations after SAEs occur by specifying what these should focus on to prevent recurrence of similar events. For example, in the cases we studied, most human errors were classified as mistakes and these mainly occurred in the assessment phase and during the interpretation of tests. Recommendations should then thus be aimed at these specific types of errors (i.e., knowledge-based interventions) and moments in the diagnostic process on the ED (e.g., interventions that directly support clinicians in their diagnostic reasoning process, such as a quick-response differential diagnosis generator). These may be more effective recommendations to prevent recurrence of events than those that are generally suggested after root cause analysis.

Hospitals currently typically focus their recommendations on the isolated event (i.e., generic education on the missed disease), and these are often of administrative nature (e.g., reviewing and adjusting ward specific protocols) [30–32], which are considered to be weak. Based on our experience from reading all SAE reports, we noticed hospitals seldomly propose overarching interventions to support the diagnostic process, for example, evidence-based strategies to improve specific knowledge, reforming training methods, structural feedback and reflection on diagnostic discrepancies, implementation of diagnostic decision support systems to improve diagnostic calibration, or implementing team based diagnosis. System-aimed interventions (e.g., lowering work pressure and crowding in the ED, improving patient safety culture, teamwork interventions and cultural aspects) are rarely proposed, while these types of recommendations may have a better chance of being effective in preventing similar cases and to improve diagnostic safety.

STRENGTHS & LIMITATIONS

The available information about SAEs in this study was particularly rich, which allowed for an in-depth analysis of the considerations and decisions of clinicians during the diagnostic process resulting in a diagnostic error. Moreover, we have shown that the combination of multiple established methods (the Safer Dx Instrument, DEER taxonomy and Model of Unsafe Acts) can help to gain insight into human errors. These methods could also be applied in future SAE investigations, which may help hospitals to formulate more specifically aimed recommendations to prevent recurrence. This makes our study a valuable addition to the existing literature, as it shows how these methods help to analyse human errors in SAEs and provide more specific recommendations.

Limitations of the study include limited generalizability due to a fairly small sample (n=21) and a focus on general hospitals only. This limits drawing generalizable conclusions about the causes of diagnostic SAEs. Furthermore, although the reports were created with great care and professionalism, they were not created for this study specifically. It was not possible to revisit the involved clinicians with eventual additional questions on the decision making process.

Despite these limitations, the SAE reports have proven themselves suitable for the purposes of this study. For future research, we would recommend using a larger and wider sample to represent and compare different types of hospitals.

CONCLUSION

An in-depth analysis of human errors contributing to diagnostic errors in the ED provides important insights in *where* in the diagnostic process *what* types of human errors occur. This can help us to aim recommendations more specifically to the types of human errors and the phase of the diagnostic process these errors occur to further improve patient safety. The current study suggests that recommendations should be specifically aimed at preventing mistakes in the assessment phase.

Serious adverse event reports have proven to be a useful source to study human errors. Ideally, the human error analysis is adopted into the initial SAE-investigation and included in a broader analysis of the event also focussing on other sociotechnical factors.

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APPENDIX 1.

THE SAFER DX INSTRUMENT AND OUTCOME CATEGORIES

The Revised Safer Dx Instrument

Item		Score*
1.	The documented history was suggestive of an alternate diagnosis, which was not considered in the diagnostic process.	
2.	The documented physical exam (including vital signs) was suggestive of an alternate diagnosis, which was not considered in the diagnostic process.	
3.	Data gathering through history, physical exam, and review of prior documentation (including prior laboratory, radiology, pathology or other results) was incomplete, given the patient's medical history and clinical presentation.	
4.	Alarm symptoms or "Red Flags" (i.e. features in the clinical presentation that are considered to predict serious disease) were not acted upon.	
5.	The diagnostic process was affected by incomplete or incorrect clinical information given to the care team by the patient or their primary caregiver.	
6.	The clinical information (i.e. history, physical exam or diagnostic data) should have prompted additional diagnostic evaluation through tests or consults.	
7.	The diagnostic reasoning was not appropriate, given the patient's medical history and clinical presentation.	
8.	Diagnostic data (laboratory, radiology, pathology or other results) available or documented were misinterpreted in relation to the subsequent final diagnosis.	
9.	There was missed follow-up of available or documented diagnostic data (laboratory, radiology, pathology or other results) in relation to the subsequent final diagnosis.	
10.	The differential diagnosis was not documented OR The documented differential diagnosis did not include the subsequent final diagnosis.	
11.	The final diagnosis was not an evolution of the care team's initial presumed diagnosis (or working diagnosis).	
12.	The clinical presentation at the initial or subsequent presentation was mostly typical of the final diagnosis.	
13.	In conclusion, based on all the above questions, the episode of care under review has a missed opportunity to make a correct and timely diagnosis.	

Note: * Score on a 7-point Likert scale; 1 = Strongly disagree, 7 = Strongly agree.

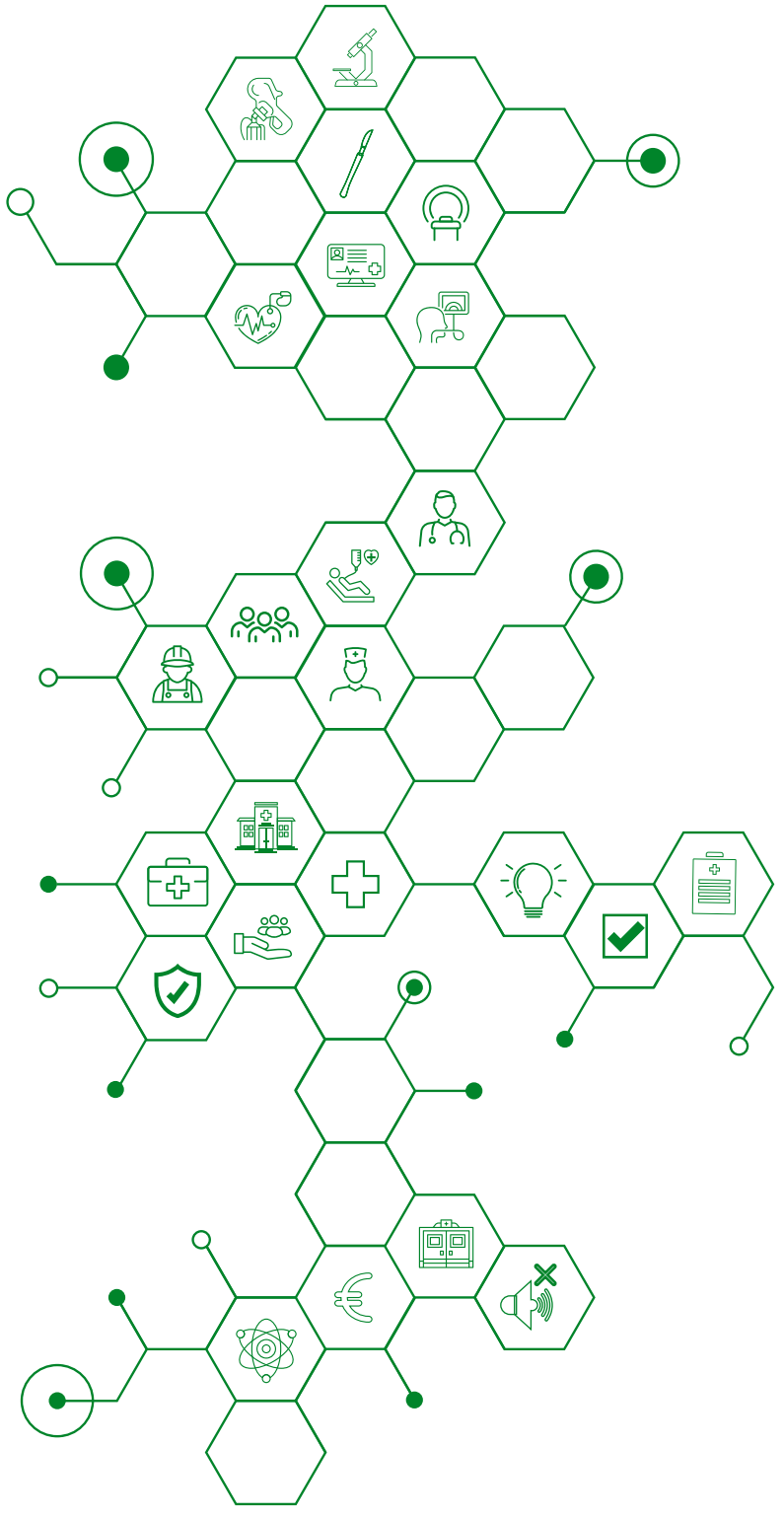
APPENDIX 2.

DEER TAXONOMY CLASSIFICATION RESULTS.

Where in the diagnostic process?		What went wrong?	Number of classifications per DEER category
1. Access/Presentation	A	Failure/delay in presentation	1
	B	Failure/denied care access	1
2. History	A	Failure/delay in eliciting a critical piece of history data	3
	B	Inaccurate/misinterpreted critical piece of history data	1
	C	Suboptimal weighing of a critical piece of history data	2
	D	Failure/delay to follow-up on a critical piece of history data	1
3. Physical Examination	A	Failure/delay in eliciting a critical physical exam finding	2
	B	Inaccurate/misinterpreted critical physical exam finding	6
	C	Suboptimal weighing of a critical physical exam finding	0
	D	Failure/delay in following up on a critical physical exam finding	0
4. Tests	*Ordering*		
(Laboratory/Radiology)	A	Failure/delay in ordering needed test(s)	7
	B	Failure/delay in performing ordered test(s)	4
	C	Error in test sequencing	1
	D	Ordering of wrong test(s)	0
	E	Test ordered wrong way	6
	Performance		
	F	Sample mix-up/mislabeled (e.g., wrong patient/test)	0
	G	Technical errors/poor processing of specimen/test	0
	H	Erroneous lab/radiology reading of test	3
	I	Failed/delayed reporting of result to clinician	2
	Clinician Processing		
	J	Failed/delayed follow-up of (abnormal) test result	8
	K	Error in clinician interpretation of test	5

Continued.

Where in the diagnostic process?		What went wrong?	Number of classifications per DEER category
5. Assessment	*Hypothesis Generation*		
	A	Failure/delay in considering the diagnosis	12
	Suboptimal Weighing/Prioritizing		
	B	Too little consideration/weight given to the diagnosis	5
	C	Too much weight on competing/coexisting diagnosis	14
	Recognizing Urgency/Complications		
	D	Failure/delay to recognize/weigh urgency	14
	E	Failure/delay to recognize/weigh complication(s)	4
6. Referral/Consultation	A	Failure/delay in ordering referral	4
	B	Failure/delay obtaining/scheduling ordered referral	1
	C	Error in diagnostic consultation performance	2
	D	Failure/delayed communication/follow-up of consultation	6
7. Follow-up	A	Failure to refer patient to close/safe setting/monitoring	2
	B	Failure/delay in timely follow-up/rechecking of patient	3



Chapter 7

Contributing Factors of Sentinel Events Involving Medical Devices: A cross-sectional retrospective human factors analysis

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ABSTRACT

BACKGROUND AND OBJECTIVE

Although most medical device applications in hospitals are safe and effective, in a small number of cases devices are involved in events causing serious unintended patient harm. These so called sentinel events are thoroughly investigated by hospitals, and detailed event descriptions are filed in a report. Studying these reports may help to fill the knowledge gap on the multifactorial and latent contributing factors of sentinel events involving medical devices. This study aims to identify the contributing factors of sentinel events involving medical devices, and the interactions between factors that jointly lead to unintended patient harm. Additionally we reflect on the suitability of sentinel event reports as data source for this purpose.

DESIGN

A cross-sectional retrospective analysis of 20 sentinel event reports involving medical devices from Dutch general hospitals, using a human factors perspective and specific classification system for medical device related events.

RESULTS

Sentinel event reports proved to be a useful source for in-depth analysis of multifactorial and latent contributing factors of events involving medical devices, as they entailed great detail on the event emergence and the role of the device. A total of 105 contributing factors were identified in 20 reports. For most events, factors relating to the operator (e.g. flaws in setting up and checking devices before use), device (e.g. design issues), infrastructure (e.g. poor environmental ergonomics) and patient (e.g. complicating anatomy) mutually contributed and interacted. Jointly these factors triggered events causing unintended patient harm.

CONCLUSIONS

Studying reports of sentinel events involving medical devices helps to better understand how medical devices are involved in unintended patient harm. Insights from this study in the underlying contributing factors and its interactions might help to further improve patient safety.

PUBLIC INTEREST SUMMARY

Medical devices can be involved in events leading to unintended patient harm in hospitals. We know little about the underlying factors contributing to such events. Therefore, 20 reports of events involving a medical device that leaded to serious patient harm, were in-depth analysed. In most events, factors contributed that related to the operator of the device, the device itself, the organisation and environment in which the device was applied, and the patient to which the device the was applied. Jointly these factors prompted the events and leaded to patient harm. The insights from this study can be used to further improve the safe application of medical devices in hospitals.

INTRODUCTION

Medical devices are essential for providing care, as they are indispensable for i.a. performing surgical interventions, treating diseases, diagnosing illnesses, and monitoring treatment. Medical devices include a wide range of products and can be defined as “any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used for human beings for one or more specific medical purposes (diagnosis, prevention, monitoring, treatment, etc.)”[1]. Although in most cases application of medical devices in healthcare is safe and effective, sometimes it poses risks for patient safety.

The Emergency Care Research Institute(ECRI) annually publishes a top-10 list of potential risks for patient safety related to health technology – including medical devices[2 3]. Examples of identified risks over the past few years were: flaws in medication prescription systems and failure of infusion pumps that may cause severe medication errors[2 4], and suboptimal reprocessing of endoscopes increasing patient infection risks[4 5]. These risks may result in adverse events with consequences for patients. National databases such as the U.S. Food and Drug Administration Manufacturer And User Facility Device Experience (MAUDE), annually receives several hundred thousand reports of adverse events involving medical devices[6]. A patient record review study among patients admitted to Dutch hospitals in 2011/2012 and 2015/2016, indicated that adverse events involving medical devices were present in 2.8% of the admissions[7]. This may seem a small percentage given the widespread use of medical devices. Yet, the same study reported that of all adverse events identified in the study, medical devices were involved in 40%, and in 44% of the potentially preventable adverse events[7]. Moreover, adverse events with medical devices can have severe or even fatal consequences for the patients involved[8]. Understanding how these events occur and insight in the underlying causes is therefore important to prevent recurrence and improve safety.

Amoore[9] investigated the causes of adverse events involving medical devices and concludes that, while events are often attributed to either user error or device failure, in fact, the causes are often multifactorial. Interactions between devices and other elements of the socio-technical system (i.a. the user, patient, organisation and environment) may mutually trigger events. For example, the chances of an adverse event will probably be greater when a professional has never used a complicated device before, and operates a complex patient under high work pressure. Current literature often does not provide insight on these multifactorial factors contributing to events involving medical devices, and how interactions between devices and other elements of the socio-technical system trigger events.

Studies using data from adverse event databases such as MAUDE may not succeed in identifying contributing factors. Indeed, it is not always possible to even confirm whether a device did cause the reported event based on merely the data filed to the database[6 10].

Patient record review studies on adverse events also suffer from data limitations. Organisational or system issues are often not documented in the medical records and thus such factors cannot be identified[7]. Also more latent technical factors (e.g. device design or usability issues) frequently remain unseen or are not registered in medical records. Questions that for these reasons stay unanswered are: What was the role of the medical device in causing patient harm, and how did other factors interact with the device? Were there any organisational or system issues that triggered the event, or was the event prompted by latent technical factors, such as design or usability issues?

There is another source of data that could help to further elucidate the multifactorial causes and underlying contributing factors of adverse events involving medical devices. Whenever an adverse event causes serious patient harm, hospitals thoroughly investigate these so called sentinel events. After investigation, hospitals in i.a. the Netherlands file a comprehensive report to the national Health and Youth Care Inspectorate[11]. These reports include a detailed event reconstruction, based on an extensive investigation in which interviews with involved healthcare personnel and patients are combined with reviewing relevant documentation (e.g. medical records, device instructions, maintenance data, protocols, guidelines, test results, etc.). This provides for detailed information on what exactly happened. Analysis of such sentinel event reconstructions, may enable us to learn more about the role of medical devices in unintended patient harm.

Learning from sentinel events is complicated though. Events are typically characterised by their complex nature in which a simple cause-effect relationship often does not hold[12 13]. To get a grip on this complexity it can be helpful to embed a human factors perspective in the event analysis[14-16]. Human factors emphasizes on the interactions between people and their environment -including the devices they use- and how these interactions contribute to performance[17]. A human factors perspective to analyse sentinel events involving medical devices can help to holistically analyse interactions between devices and other elements of the socio-technical system (e.g. the user, patient and environment). This may assist in identifying combinations of user errors, design or usability issues, and organisational or contextual flaws that jointly lead to patient harm.

In this study, reports of sentinel events involving medical devices are used to study the role of medical devices in events leading to unintended patient harm. A human factors perspective is embedded in the analysis. The aim of the study is to provide insight into deeply engrained contributing factors and user-device-context interactions that may trigger patient harm. Subsequently, this study briefly reflects on the suitability of sentinel event reports as a data source to study the role of medical devices in unintended patient harm.

METHODS

For this cross-sectional study we retrospectively analysed reports of Sentinel Events involving Medical Devices (SEMD) from Dutch general hospitals.

DATA COLLECTION

A group of Dutch general hospitals (n=28) cooperating in a patient safety network shared a sample of their reports on sentinel events occurred in 2017-2019 for aggregate cross-hospital analysis. Results of this aggregate study are published elsewhere[18]. Included reports related to four specific safety critical themes. One of them being medical devices, which was used for this study. Hospitals intended to share a report on each theme, but not all hospitals did. This might be due to a lack of a suitable event for this theme, but could also be a result of characteristics of the data collection set up (e.g. medical devices being not the first, but second in time theme for which the hospitals could file a report for). The sample of reports is because of these specific selection criteria not representative for the occurrence of sentinel events involving medical devices in the participating hospitals.

The reports were all based on a thorough investigation performed by a multidisciplinary independent hospital committee including clinicians and quality and safety officers. The committee interviewed those involved in the event; (healthcare) professionals, and patients or family. Patient records were reviewed, as well as relevant documentation (e.g. clinical guidelines, and ward protocols). Based on these sources the hospital committees reconstructed what happened in a comprehensive event description.

Participating hospitals were instructed to anonymise the information in sentinel event reports before sharing them for analysis. After a check for anonymity by the involved hospital association, the reports were securely shared for further analysis.

DATA-ANALYSIS

20 SEMD reports were shared and underwent a multi-step analysis. First, event reconstructions were reanalysed using a human factors perspective and contributing factors were identified. Then all contributing factors were classified using a structured approach, that was specifically developed for events involving medical devices. These steps are now elaborated upon.

Human Factors analysis

The comprehensive event descriptions in the SEMD reports were reanalysed applying the Generic Analysis Method (GAM)[19]. GAM is an operationalisation of the Systems Engineering Initiative for Patient Safety (SEIPS) model[20 21], which is rooted in the human factors discipline. GAM therefore explicitly focusses on the interactions between the technology, the

professionals and patients involved, and the organisation and environment in which the technology is used. GAM is described[19], and applied[18] in previous studies.

Both a representative of the hospitals and the researcher [MB] analysed the reports using the GAM. To determine whether the researcher's overall conclusions and those of the representatives of the participating hospitals were consistent, the open-ended questions were qualitatively assessed on interrater reliability. The researcher reverted to the original SEMD report whenever there were any ambiguities or irregularities. Also all findings were presented to a panel of experts, the patient safety network of the hospital association, in which quality and safety officers and medical specialists from thirteen of the associated hospitals participated. Notes were taken during the meeting, which were sent for member check to the attendees afterwards.

From the GAM-analysis data, contributing factors were identified. Contributing factors were determined by two criteria, the factor: 1) was reported in the event description of the SEMD report, and 2) played a part in the origin or development of the event, or increased the risk of the event occurring.

Classification of contributing factors

A structured approach was then used to zoom in on the role of the medical devices in the event. This approach was developed by Amoore[9], based on the ECRI classification of medical device incidents[22] and Shepherd's classification of medical device incidents[23]. The approach helps to classify the causes of medical device related events. It consists of a classification scheme including the main classes; Operator, Device, and Infrastructure. Subclasses differentiate on these various dimensions of the device (e.g. device failure, and issues related to the technical or human factors design), operator (e.g. user error, problems with setting up devices, and lack of training/education), and infrastructure (e.g. inappropriate procurement and commissioning, and poor environmental ergonomics). Tampering, Clinical and Patient factors, Unknown and No problem found complete the classification scheme.

Two researchers [MB & SVS] independently classified all identified contributing factors (n=105). After classifying the contributing factors from the first seven events, results were compared, discussed and further classification strategy was aligned. Thereafter, the contributing factors of the other 13 events were classified. Overall interrater agreement was assessed. Researchers agreed on the exact (sub)class for 76 factors (72.4%). For 14 factors (13.3%) researchers agreed on the main class, but differed in subclass. Researchers disagreed on the main class for 15 factors (14.3%). Those factors that were not consistently classified were discussed and consensus was reached.

RESULTS

We studied 20 Sentinel Events involving Medical Devices (SEMDs). Descriptive statistics are presented in table 1. Most cases related to medical apparatus (n=15, e.g. surgical endoscope or defibrillator). Other cases related to medical information technology (n=2, e.g. electronic health record), consumables (n=2, e.g. surgical consumables), and in-vitro diagnostics (hematology analyzer).

SENTINEL EVENT REPORTS: THE ROLE OF THE DEVICE

In thirteen event investigations internal and/or external technical expertise was consulted. Internal expertise included for example medical instrument departments, (bio)medical technicians or clinical physicists, while external expertise comprised manufacturers and suppliers. For some investigations, involved devices were additionally tested and examined, procurement documentation was reviewed, prospective risk analyses were considered, or maintenance history and log data of the devices were inspected. In some cases, technical investigation of the device did not show any deviations, or no technical inspection was possible, for example because consumables were disposed directly after an intervention.

Table 1. Characteristics of the sentinel events involving medical devices

Characteristics of the events (n=20)	n
Patients involved:	
Female	12
Age	
0-18	1
19-65	13
65-80	5
81 and older	1
Location of the event:	
Operating room	9
Floor unit	9
Emergency department	1
Medical laboratory	1
Treating medical specialty:	
Gynecology/Obstetrics	5
Surgery	4
Pulmonology	3
Cardiology	2
Urology	2
Internal medicine	1
Ophthalmology	1
Orthopedics	1
Unclear	1

Table 1. Continued.

Characteristics of the events (n=20)	n
Type of device involved in sentinel event:	
Medical apparatus	15
Medical information technology	2
Medical consumables	2
In-vitro diagnostics	1
Additional technical expertise consulted in the sentinel event investigation:	
Internal experts	5
External experts	5
Internal and external experts	3
No additional technical experts consulted	7

CLASSIFICATION OF CONTRIBUTING FACTORS

For all 20 cases, 105 contributing factors were identified. In most cases, factors from various domains mutually contributed. Figure 1 presents an overview of the contributing factors divided over the classes of the Amoore[9] classification. Most factors related to the operator (n=33) and device (n=27). A substantial number of factors fell under the infrastructure class (n=18). Another considerable number of factors could not be classified over the predefined classes, and were therefore classified as 'Other' (n=19). These related in most cases to organization related issues, such as high workload or insufficient risk awareness related to medical devices. Clinical and patient related factors were also identified (n=8, e.g. abnormal anatomy, or substantial comorbidity that hindered adequate device application). For none of the cases, factors related to tampering or remained unknown due to limited data or no investigation. In one case no contributing factors could be found, even after thorough investigation of the event.

Operator

Related to the operator, an important subclass was training. Factors included a lack of periodic education/training for operators for the use of a specific device, or an operator that did not know what the self-test of a surgical device entailed. Also factors related to setting up and user errors were identified. For setting up, factors included default settings that were manually adopted for some devices, corrosion in a surgical device due to wear and tear that was not noticed during the routine preuse check, incorrect settings set to a defibrillator, or critical values for alarms that were set incorrectly. User errors related to for example failure to operate a surgical device correctly or switching a device to an incorrect setting. Whenever a user error was identified, there was at least one device, context, patient or other factor that also contributed. User errors might thus be triggered by e.g. device design or usability issues, complicating patient factors, or other factors such as high workload. Communication problems and failure to follow protocols were mentioned in some cases.

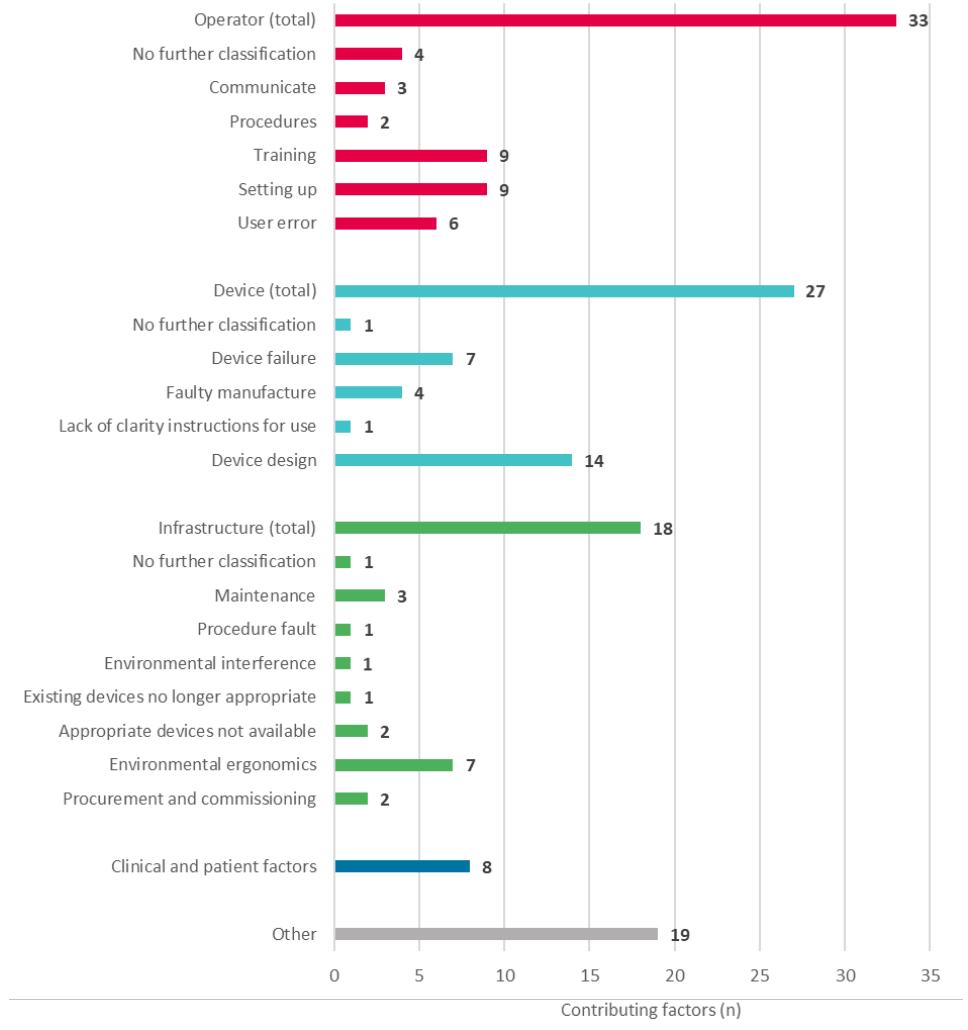

Figure 1. Classification of the contributing factors over the main and subclasses of the classification of Amoore[9]. The main classes 'unknown due to limited data or no investigation' and 'tampering' were not chosen and therefore excluded from this figure. Subclasses that were not chosen were also left out for readability. For one case no contributing factors were found, as the investigation found no problems/faults.

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Device

Most of the factors that were classified under device related to the device design. Both for the subsubclasses technical design and human factors design. Technical design issues related to faults in the device design. Examples were: an electronic health record that automatically overwrites the open text field after a predefined treatment code was chosen, losing important details about the intended treatment and resulting in a wrong-side surgery. Or a time-unit that was missing in the predefined codes of an automated medication prescription system, contributing to prescribing the correctly calculated dose of medication per hour instead of per day. Human factors design issues were not necessarily 'faults' in the technical design, but rather related to flaws in the way that a device design was tailored to potential users and specific settings in which the device was applied. An example of flaws related to the human factors device design were: The coding of medical gas bottles that looked similar according to nurses, inducing a nurse to choose the wrong bottle and connect it to a patient. Device failure also contributed to some events, e.g. a device that did not work or gave an error and therefore had to be replaced during care tasks. Or an electrosurgical device in which a voltage breakdown occurred during a procedure. Faulty manufacturing contributed as well and one factor related to a lack of clarity in the instructions for use.

Infrastructure

Subclasses that were found for infrastructure often included environmental ergonomics. Such as poor workplace ergonomics and flawed department layout (e.g. screens that could not be seen from the workplace of the employees, or audio alarms that could not be heard when healthcare professionals were doing patient work). A small number of factors related to devices that were not available, flaws in procurement and commissioning, maintenance, operating procedures, and environmental interference.

INTERACTIONS TRIGGERING EVENTS

The human factors perspective used for reanalyzing event descriptions helped to identify interactions between factors from various domains, mutually leading to the sentinel event. In Figure 2, for each case the identified contributing factors are divided over the domains of the Amoore classification. In almost all cases (n=17), factors relating to multiple domains mutually contributed.

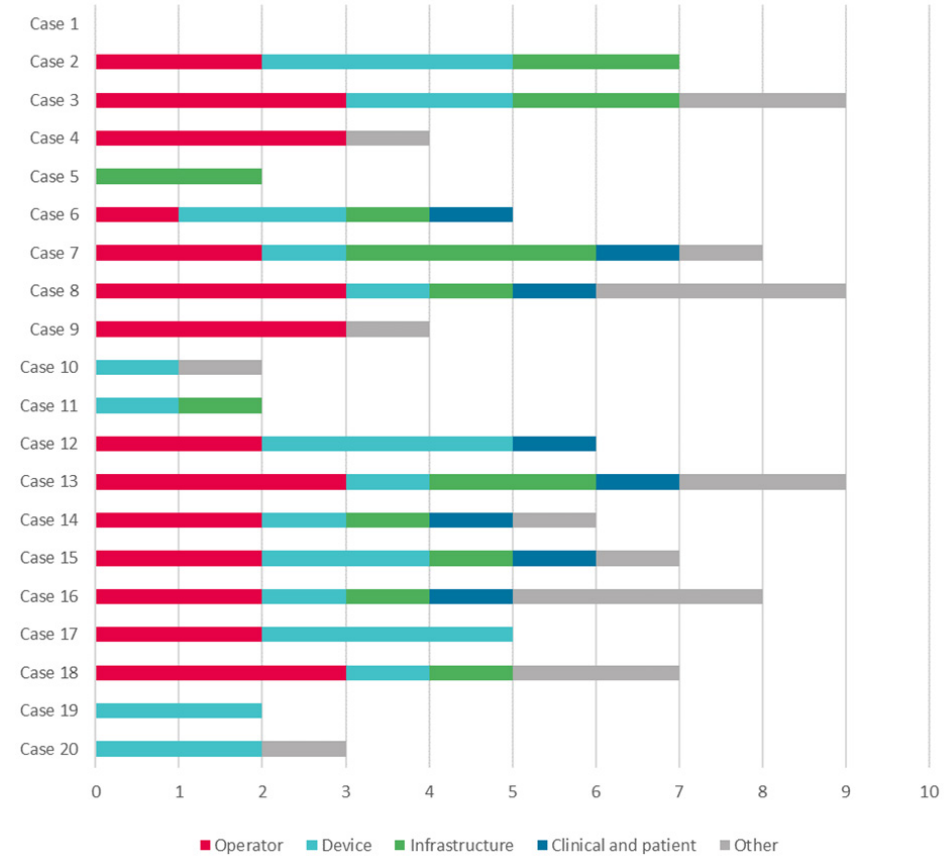

Figure 2. Contributing factors (n) per case deviated over the main categories.
*For Case 1 no contributing factors could be identified.

One example of a case with contributing factors relating to multiple domains, was an event in which a patient suffered harm due to a failure to operate an electrosurgical device correctly. While handling the device, the hot tip of the device stroke bowel structures, resulting in patient harm. Contributing factors were:

> *Device* – The design allowed the tip of the device to stay hot after use for a substantial manner of time, while other devices cool down after use quickly.
>
> *Operator* – The professional handling the device was an observing physician and unfamiliar with the device and the surgery team. Communication between the operating assistants and professional that handled the device was considered suboptimal; warnings of the operating team about the tip staying hot were not acted upon.

Infrastructure – Supervision by an experienced physician during the surgery was canceled due to a last minute change in the operating program.

Clinical and patient factors – The patient was complex, with high comorbidity and complicating anatomy, and many adhesions in the operating site.

Other – Before surgery the risks of applying the device were underestimated. As the operator estimated that (s)he would know how the device worked more or less, as (s)he had experience with similar devices in another hospital.

This case emphasizes how contributing factors from multiple socio-technical domains jointly lead to patient harm. Figure 3 visualizes for this case how operator, device, infrastructure, patient and other factors interacted, which can be seen as exemplary for other cases in this study.

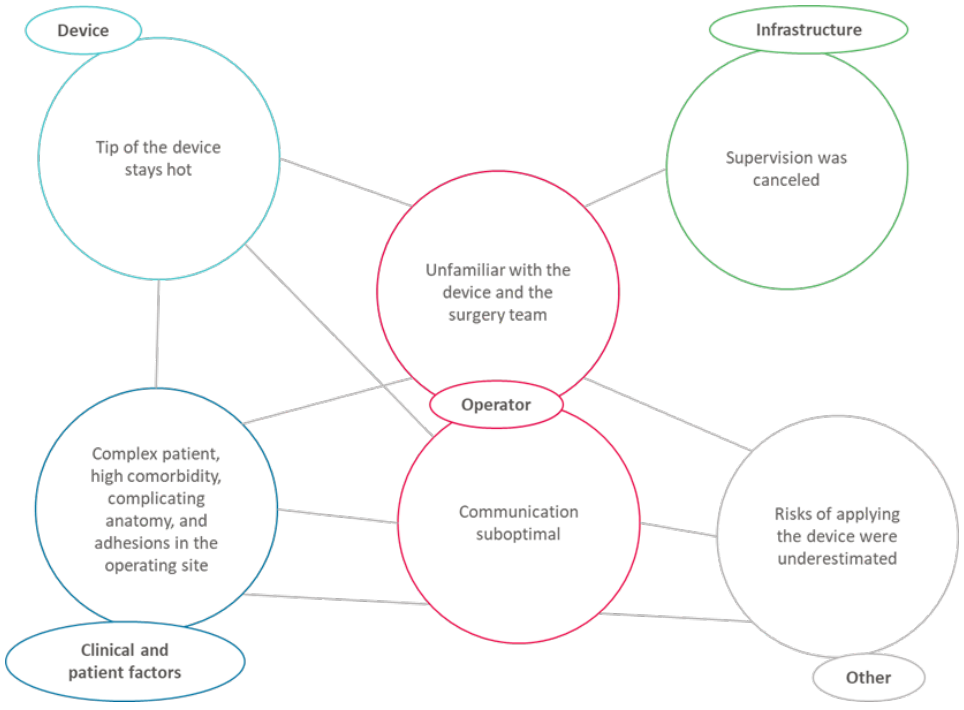

Figure 3. Overview of the interactions between contributing factors

DISCUSSION

While medical device application is often safe, sometimes devices are involved in events resulting in serious unintended patient harm. A knowledge gap exists on the multifactorial and latent contributing factors of such events, and how interactions between factors jointly trigger events. This study aimed to fill this gap by studying Sentinel Events involving Medical Devices (SEMDs) using a human factors perspective and a specific classification for causes of medical device related events. An additional aim was to briefly reflect on the suitability of sentinel event reports as data source to study this role of medical devices in unintended patient harm.

STATEMENT OF PRINCIPAL FINDINGS

The study showed SEMDs reports are a useful data source to study contributing factors of events involving medical devices. For most events, internal and/or external technical expertise was consulted during the event investigation, and often additional technical data was examined. Most reports therefore entailed great detail on the role of the devices in events, enabling a retrospective in-depth analysis using the Generic Analysis Method (GAM) and application of the Amoore classification – with substantial interrater agreement. Though, the initial event investigations were not performed from the perspective of these two instruments, and some domains may not be strongly embedded in the current investigation perspective of the hospital investigation teams. This might have resulted in an underestimation of some of the GAM and Amoore classification elements (e.g. environment related factors).

The in-depth analysis provided differentiated insights on the multifactorial and latent contributing factors. Classification of factors provided a nuanced sight on the emergence of events. Factors often related to device design issues, device failure, a lack of specific training and education of operators, operator errors in setting up and checking devices before use, and poor ergonomics of the infrastructure. But also patient factors and factors related to culture and workload contributed. The human factors perspective assisted in studying interactions between factors. In most events combinations of factors mutually interacted and hence jointly triggered events that leaded to unintended patient harm.

Strengths and limitations

An important strength of this study is that detailed information of sentinel event reports was used. This enabled an in-depth analysis and provided valuable insights that typically remain unnoticed in other studies on patient safety events involving medical devices. For example those that use data from mandatory registry databases or patient records reviews[7 10].

Limitations of this study include the lack of generalisability. The SEMDs used in this study are because of specific selection criteria and small numbers not representative for the occurrence of sentinel events involving medical devices in the participating hospitals nor for hospital care in general. Nevertheless, for the purpose of this study, the sample did provide the opportunity to analyse events and elucidate the role of the device in events resulting in patient harm. It should be seen as a first step for in-depth studying the multidimensional contributing factors of SEMDs, rather than an attempt to draw generalisable conclusions related to SEMDs.

Furthermore, since this study contained a retrospective analysis of reports, researchers lacked the opportunity to enquire more deeply into events. Although we were able to apply the GAM and classification of Amoore, it sometimes was difficult to for example differentiate whether a contributing factor related to e.g. operator failure or poor human-factors design. More extensive questioning of the professional involved and scrutinizing the device would then have made classification more easy. In addition, some contributing factors could not be classified and thus were gathered under 'other'. These often related to factors that are not typically seen as direct or linear causes of events (e.g. insufficient risk awareness and a high workload), and were therefore difficult to classify in this 'cause' classification system. Amoore[9] advises to add categories to the classification system if necessary. Based on the contributing factors found in this study and consistent with the human factors perspective, an additional class that relates to organisational and more cultural aspects should be considered.

Interpretation within the context of the wider literature

Applying the GAM with its human factors perspective, made it possible to identify latent and system related issues and study interactions between device, operator and context factors that jointly triggered events. Other studies using a human factors perspective to analyse patient safety events also found more latent and system related issues and interactions[15 24]. Also human factors aggregated analysis of events may lead to proposing stronger recommendations to improve safety[18].

Our study found the majority of identified contributing factors related to the operator and device, and a substantial number of factors related to the infrastructure domain. Another study[9] applying the classification found a fairly even distribution of causes among these three categories, but a small predominance for the infrastructure category. Yet, for separate specific types of devices, operator and device related causes were in the majority, aligning with the results of this study. Beydon et al.[8] assessed the causes of events involving medical devices, but only differentiated between device and human errors[8]. This traditional view on events as either caused by human error or device failure seems flawed, as the current study showed more nuance by the detailed differentiation on the subtypes of device failure (e.g. human factors design issues) or operator error (e.g. user errors related to setting up the devices properly). Also the current study showed substantial number of factors related to the infrastructure, patient and organisation. These outcomes underpin the claim that simply blaming users or devices for events involving medical devices is inconclusive[9 25].

As this study demonstrated how factors interact and jointly result in patient harm, recommendations to prevent recurrence focused on a singular element might not be effective. Instead, insights from this study plead for preventive strategies that address the combination of interacting multifactorial factors and latent issues. However, as explained by Trbovic and Shojania[26] investigators of sentinel events typically complete their analysis after identifying a human error and align their recommendations closely to this identified root cause. Missing the opportunity to dig deeper and address the multifactorial and latent issues. More system related or device design problems might therefore only seldomly be fixed. It should be noted though, that the type of recommendations that do address these issues often require substantial changes, necessitating significant effort and (financial) resources.

Implications for practice, policy, and research

For preventing SEMDs an integral approach focused on addressing the operator, device and infrastructure is needed. With regard to the operator examples of strategies could be: providing comprehensive training for all staff that use medical devices, in particular when new staff comes in or when new devices are commissioned, establishing and promulgating clear protocols and competence requirements for the use of (high-risk) devices, regularly reviewing and updating protocols and training materials, conducting audits to ensure devices are used safely and properly, encouraging staff to report incidents and near misses and investigate these. Here, also a cultural aspect with regard to underestimating the risks of device application and potential unconscious incompetence among operators should be addressed. Therefore organisations should foster a patient safety culture, and raise awareness to the risks of devices among users. Devices in their turn should be easy to use. Technical and human factors design issues and suboptimal usability as experienced by operators should therefore be taken seriously. It would for example make sense to make usability and human factors design a leading aspect for procurement, and be wise to deploy the same devices rather than similar devices that work just slightly differently. In line with an easy in use device, the infrastructure should support safe and easy device application. Hospitals should be mindful during commissioning of the workplace ergonomics where devices are applied.

With regard to studying sentinel events, there are some leads for improvement. After a sentinel event where a device was involved, a thorough technical investigation should be performed. To enable and strengthen such investigations, devices and consumables should

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be secured after an event. Moreover, we recommend hospitals to consider structurally expanding their multidisciplinary sentinel event investigation team with technical and human factors expertise. Technical expertise is now often organised ad hoc, and human factors expertise in an investigation team is scarce. Expanding the investigation team could be important because, in addition to healthcare professionals that bring in the user perspective, technical and human factors expertise could be key for finding more latent technical and system issues.
It may also be wise to structurally embed a human factors perspective in the sentinel event investigation, visualize interactions between contributing factors, and use classification schemes for technical causes more often. This way, trends in latent technical contributing factors (e.g. flaws in usability and design) and system issues could be discovered. Outcomes could then be discussed with manufacturers, higher level managers or policy makers to address persistent problems for safe device application. Over time, this could result in safer use of medical devices.

Future research could study a greater and more representative sample of events involving medical devices. Also it is important to study which types of recommendations after sentinel events are most effective to improve safe use of medical devices.

CONCLUSION

Using SEMD reports as data source provided the opportunity to apply a human factors perspective for in-depth analysis of events and differentiate on contributing factors. These SEMD reports therefore have proven to be an important source of data.

Studying event descriptions using a human factors perspective and zooming in on the medical device related contributing factors, helped to reveal deeply engrained multifactorial technical factors and system issues, and interactions that primed the events' trigger. Exposed issues could be addressed to improve patient safety.

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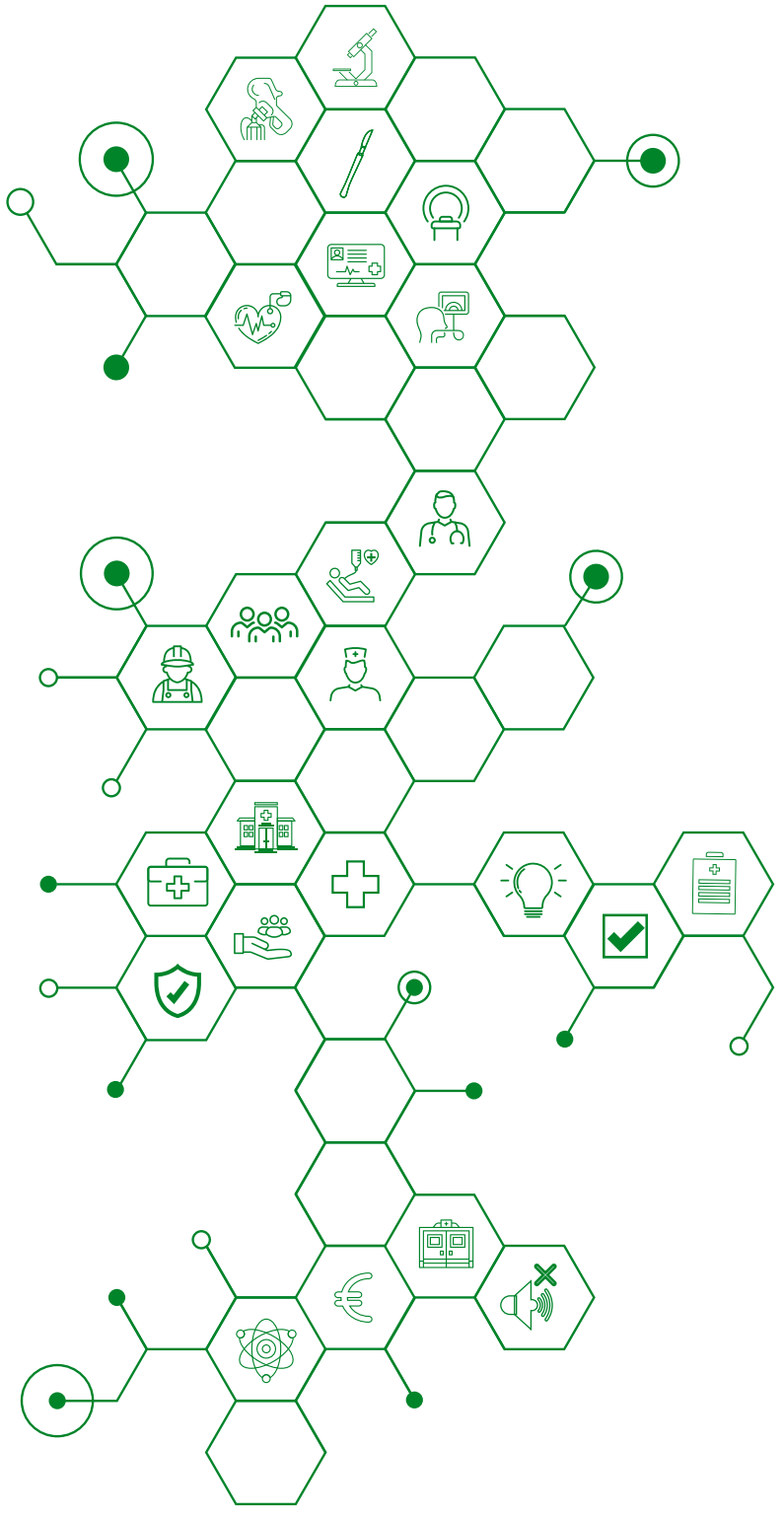

Chapter 8

General discussion

The aim of this thesis is to increase knowledge and provide deeper understanding on how medical devices are involved in unintended patient harm in hospital care, and identify leads to further improve patient safety. Therefore, the following research questions will be answered:

- What is the incidence and nature of events involving medical devices leading to unintended patient harm?
- How are the causes of events leading to unintended patient harm currently studied, and how can this be improved?
- What are the causes and interacting contributing factors of sentinel events in general, and specifically for events involving a diagnostic error and events where medical devices are involved?

Multiple studies were conducted to answer these questions; a patient record review study, systematic literature review, stepwise development of a novel sentinel event analysis method, and retrospective aggregated analysis of sentinel event reports. The main findings are outlined and interpreted in this chapter, thereby answering the research questions. Subsequently, methodological considerations are discussed as well as implications for practice, policy and future research.

MAIN FINDINGS AND INTERPRETATION

WHAT IS THE INCIDENCE AND NATURE OF EVENTS INVOLVING MEDICAL DEVICES LEADING TO UNINTENDED PATIENT HARM?

In Chapter 2 we reported on the incidence of potentially preventable Adverse Events involving Medical Devices (AEMDs) based on a patient record review study. 2,998 records of patients deceased during their admission in Dutch hospitals in 2019 were reviewed. A potentially preventable AEMD occurred in 1.9% (95CI 1.5%-2.5%) of the patients. In 78% of these potentially preventable AEMDs, the event substantially contributed to or caused the patients' death. Of all identified potentially preventable adverse events, devices were involved in 47%.

An additional analysis of the patient record review dataset provided further insights on the nature of events involving medical devices. The nature varied widely, but three topics that recurred were identified: Application of (endo)scopes resulting in perforations and hemorrhages, bleedings and infections after placement of heart- and vascular implants, and respiratory harm related to naso- and orogastric tube application. The analysis also provided increased understanding on how these medical devices were involved in patient harm.

'Involved in' may presume an important role of the devices in the causal pathway to unintended patient harm. However, involved in does not imply causal involvement. Only in 0.5 % (95CI 0,3%-0,9%) of all patients a potentially preventable adverse event was identified where a device was considered as the main or secondary cause of the event[27]. In most of the AEMDs the role of the device was that it prompted a known complication (e.g. perforation, bleeding or infection), which was considered non-preventable. Preventability of these events often lay in the late diagnosis and subsequent management of complications. This preventable part thus not primarily relates to the device, but more to clinical and organizational factors such as suboptimal clinical reasoning, inaccurate situational awareness, or flawed coordination of care.

To our knowledge, international scientific literature lacks other recent generic overview studies on the incidence and nature of (potentially preventable) AEMDs. This makes comparison and interpretation of the incidence of 1.9% difficult. Work done in Dutch hospitals in previous years, suggests a stabilization of the incidence of potentially preventable AEMDs since 2015/2016. Among patients died during their admission in 2015/2016, the incidence of potentially preventable AEMDs was 1.7% (95CI 1.3%-2.2%)[28]. For 2011/2012 an incidence of 0.7% potentially preventable AEMDs was reported[29], suggesting an upward flattening trend over the years.

This rise in incidence could be an important signal that the safe application of medical devices has deteriorated. For example, because devices are applied to more complex patients, which are at higher risk of adverse events[30]. Or because high workloads force professionals to make trade-offs between working efficient and thorough while applying devices. This would be consistent with the general believe that increased complexity in the hospital patient population and the changing healthcare work environment can affect patient safety[31 32]. However, it is also plausible that methodological differences are responsible for the rise in incidence over time. The 2011/2012 sample included not only patients that died during their admission (as in 2015/2016 and 2019), but also patients discharged from the hospital alive. Typically, (preventable) adverse events rates are higher among patients deceased during admission[33], which could explain the sharp rise between 2011/2012 and 2015/2016. Additionally, an increased awareness of device related risks could be part of the explanation. In 2016 the second version of the Covenant was endorsed in Dutch hospitals[34], which strongly emphasizes the potential risks related to the application of medical technology[35 36]. This could have improved reporting on device-related issues in patient records by healthcare professionals and increased alertness for medical devices among record reviewers, which may have resulted in a higher incidence.

It can be debated if an incidence of potentially preventable AEMDs of 1.9% is an acceptable risk, and if a stabilization of the incidence since 2015/2016 is a problem. Medical device application is widespread in hospital care, and risks are inevitable when medical devices

are applied. Technical innovations and novel devices enable new treatment possibilities, also for older and more complex patients. These new treatments however may also come with patient safety hazards. Though, previous treatment possibilities (including no treatment option) may have caused risks for the patient as well. Zero unintended harm is often assumed not feasible[37], and it can be questioned what is viable in the current situation where various goals strive for priority[38]. In times of staff and supply-chain shortages, and a growing aging population with increasing care needs, one might argue that a stabilization of potentially preventable AEMDs is acceptable and further reduction is not a priority. Or at least has to compete with other pressingly urgent matters. On the other hand, device use is widespread and devices are involved in a substantial part of all potentially preventable adverse events. Improving the safe application of medical devices could therefore be seen an important area to prioritize on when aiming to improve overall patient safety.

The identified topics on the nature of AEMDs align with findings of previous patient record review studies in Dutch hospitals[28 29], studies on complications of these types of interventions[39-43], and came up in patient safety alerts over the past few years[44 45]. The nature of these adverse events can thus not be considered new, but these persistent problems may therefore be even more interesting to reflect on and think of strategies to address them. As there seem to be no 'quick fixes' for these issues, a deeper understanding on their underlying causes may be needed to come up with appropriate solutions.

HOW ARE THE CAUSES OF EVENTS LEADING TO UNINTENDED PATIENT HARM CURRENTLY STUDIED, AND HOW CAN THIS BE IMPROVED?

Hospitals often conduct a root cause analysis to study unintended events leading to (serious) patient harm aiming to identify causes and prevent recurrence. One method that is often used for such analysis is the Prevention and Recovery Information System for Monitoring and Analysis (PRISMA) method[46]. Reviewing literature about the application of the PRISMA method in healthcare facilities worldwide (Chapter 3) showed PRISMA application predominantly results in finding human-related root causes. Technical causes are typically less frequently identified. Other literature[47-49] on root cause analysis aligns with these findings, as it stresses the analysis often focuses on finding one human error, rather than digging deeper into system issues, latent causes and contributing factors. This not only holds for PRISMA, but for root cause analysis methods in general.

Dutch hospitals commonly use either PRISMA or one of two other methods to conduct root cause analysis[50 51]; Systemic Incident Reconstruction and Evaluation (SIRE)[52] or Tripod Beta[53]. While these methods all have their own strengths and weaknesses and are based on varying causation models, they have in common that they are strongly focused on identifying one or a few linear root causes. This reductionists view does not match the complexity of health care, where many factors of various socio-technical domains are interrelated and mutually trigger patient safety events[48]. The multiple interacting contributing factors and more latent and system related issues typically remain unseen in root cause analysis. Even though addressing complexity and signaling system issues may be particularly relevant to improve patient safety[48].

From our findings of the PRISMA literature review we advocate that to gain a deeper understanding of unintended events in healthcare facilities and develop more effective recommendations, a key approach is to combine various sources of data, such as patient records and input from the professionals involved in the event. This aligns with other studies[54 55] that recommend that for studying the causes of events, research designs with the possibility to interview those involved are necessary. Also a multidisciplinary investigation team that is well-versed in the PRISMA method and inclusion of specific expertise (e.g. human factors or technical experts) could further improve analysis and aid in finding more latent organizational and technical causes.

Improving event analysis: addressing complexity and a cross-hospital aggregated approach

Event descriptions in sentinel event reports typically entail a great amount of detailed information, as these are based on data from patient records, interviews with those involved, and additional documentation. We hypothesized that reanalysis of such event descriptions using another approach may help to address underlying causes and interacting contributing factors. Moreover, aggregated cross-hospital analysis could reveal patterns in these interacting contributing factors and may assist in finding more system-related issues. Therefore a novel Generic Analysis Method (GAM) to perform a cross-hospital analysis of sentinel event reports was developed, as elaborated on in Chapter 4.

The GAM comprises of a framework and corresponding questionnaire. GAM is an operationalization of the Systems Engineering Initiative for Patient Safety (SEIPS) model, which incorporates a systems thinking approach and human factors perspective. Furthermore, GAM combines important elements of PRISMA, SIRE, and Tripod. Bringing together the differing angles of these methods intended to make GAM applicable to study reports from hospitals irrespective of the initial method applied for root cause analysis. At the same time, the combination of methods provides for a holistic perspective. In addition, elements of Safety-II were incorporated by asking about efficiency-thoroughness trade-offs[56]. These trade-offs between working efficient and working thoroughly (in this context safe) can help to reflect on safety-critical decisions made by healthcare professionals in daily practice.

Test sessions indicated the method was applicable to study sentinel event reports irrespective of the initial root cause analysis method (i.e. PRISMA, SIRE or Tripod) used. It also showed that GAM was successful in identifying latent causes and contributing factors,

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and mapping the interactions between factors from various sociotechnical domains. However, some new elements of the method (e.g. the efficiency-thoroughness trade-offs) were difficult to subtract from the sentinel event reports. These are usually not covered in the event investigations and analysis, and therefore were lacking in event descriptions of the sentinel event reports.

After development and test sessions, the GAM was used for cross-hospital analysis of 69 sentinel event reports from a group of 28 Dutch general hospitals (Chapter 5). Analysis of event descriptions in the reports using the novel approach, showed GAM embraced complexity of healthcare, and helped to reliably identify underlying causes and map contributing factors. The study exemplified that applying the GAM could provide a more holistic analysis than a traditional PRISMA-analysis. GAM also helped to interpret the interactions between contributing factors, and the patterns herein. We also found individual hospitals often formulated recommendations narrowly directed towards a single (human) root cause, instead of addressing multiple interacting contributing factors and underlying system issues. The substantive results on the identified causes and contributing factors are elaborated on further on in this discussion section when answering the third research question.

A benefit of GAM lies in the fact that it may be relatively easy to adopt and apply the method for retrospective aggregated analysis of existing sentinel event reports from various Dutch hospitals, because it combines elements of methods that are already utilized by hospitals. Other methods rooted in human factors, such as the Human Factors Analysis and Classification System[57 58] and AcciMap[59], have been applied amongst the gamut of healthcare and in other industries and were considered advantageous[59-63]. These methods, however, do not combine existing methods and therefore may be more difficult to use for a retrospective cross-hospital analysis of existing sentinel event reports. Also these analysis methods often require specific and extensive expertise (e.g. on human factors) to be applied, while such expertise is lacking in most Dutch hospitals. GAM could be seen as a first step towards incorporating a human factors and systems thinking approach to studying sentinel events.

Over time, the GAM could be considered as a method to not only study existing sentinel event reports, but rather as a method to directly investigate events that occurred in hospitals. This would incorporate the human factors perspective in the event investigations from the beginning, and could help to focus on e.g. potential trade-offs between efficiency and thoroughness underlying events. Further evaluation and validation of the GAM for this purpose is needed though, and other methods (e.g. Human Factors Analysis and Classification System, Systems-Theoretic Accident Model and Processes, and AcciMap) could be considered as well. A thorough evaluation and comparison of the strengths and weaknesses of various methods is then necessary. For example similar to the comparison by Igene and Johnson[64], who compared some methods incorporating a human factors and a systems thinking approach. GAM however has not been adopted in such comparisons yet.

Aggregated analysis of events is seen as one important strategy to improve learning from events[65-67], as it may be more relevant to identify (system) issues that recur in multiple events across hospitals. The results of our study performing aggregate cross-hospital analysis underline this assumption. GAM can help to ease such analysis. The combination of a group of hospitals that collectively reflect on multiple events and focusing on system issues and interacting contributing factors, made that cross-hospital aggregate GAM analysis helped to propose more system-oriented overarching recommendations. These may be more effective in improving patient safety[48 68]. Hence, our analysis of sentinel event reports revealed individual hospitals often narrowly focus their recommendations on singular root causes from isolated events, rather than aiming to formulate recommendations that address the interplay of factors and system-related issues that trigger multiple events. Also about half of all recommendations formulated by the hospitals was administrative of nature and related to e.g. writing, adapting, or raising awareness to protocols and work instructions (n = 102, 48%). This habit of formulating administrative measures is consistent with other studies reviewing recommendations after root cause analysis[69 70]. Cross-hospital GAM analysis helped to formulate more system-oriented recommendations, e.g. evaluating and adapting predefined lists of medication options in administrative systems, making the descriptions more intuitive and less prone to mistakes.

In-depth analysis of safety-critical themes

Our work showed in-depth analysis of specific topics within the aggregated cross-hospital sentinel event data, can help to further differentiate on the contributing factors and formulate tailored recommendations to improve. In particular when additional tools and classification systems are used, this can enhance understanding.

For example, Chapter 6 elaborates on human errors in the diagnostic process by studying 23 sentinel event reports containing a diagnostic error in the emergency department. Using the SaferDx tool[71], Diagnostic Error Evaluation and Research instrument[72], and the Model of Unsafe Acts[73] reports were revisited. This allowed for a deeper understanding of the mechanisms underlying diagnostic error, and showed in which phases of the diagnostic process which types of human errors occurred. We further elaborate on these findings later on in this chapter. Eventually this deeper understanding facilitated formulating more specific recommendations. The in-depth analysis of sentinel events involving medical devices, as described in Chapter 7, shows how classification of contributing factors using a device specific classification system[9] helps to increase our understanding of how devices are involved in events resulting in unintended patient harm. The human factors perspective helped to map the interactions between the device and other elements in the work system. This differentiated insight on the contributing factors of sentinel events involving medical devices, provided for a deeper

understanding and helped to tailor recommendations.

WHAT ARE THE CAUSES AND INTERACTING CONTRIBUTING FACTORS OF SENTINEL EVENTS IN GENERAL, AND SPECIFICALLY FOR SENTINEL EVENTS INVOLVING A DIAGNOSTIC ERROR AND EVENTS WHERE MEDICAL DEVICES ARE INVOLVED?

In the fourth study (Chapter 5), 405 contributing factors were identified in the cross-hospital aggregated analysis of 69 sentinel events. A majority of the factors related to the patients (e.g. frailty, or complicating anatomy), professionals (e.g. suboptimal communication), and organization domain (e.g. inappropriate work protocols). Also, a substantial part pertained to tools and technology (n=62, 15.3%). These factors exposed many characteristics of the medical devices applied during the event (e.g. limited user-friendliness of devices, or device parts that broke off during application). Contributing factors relating to the internal and external environment were infrequently identified. Further, analysis revealed the most frequently recurring pattern of factors underlying events was the combination of factors related to the persons involved, the technology used, the tasks of professionals, and organizational factors influencing the event.

There have been done other studies on the causes of sentinel and adverse events. Similar to our findings, these studies found that a vast majority of the causes or contributing factors related to the patients, professionals, and organization[65 74 75]. Our study, however, also found many factors related to the tasks and technology domain contributed. We furthermore expanded on existing literature by mapping out the interactions among different factors. This emphasized the multifactorial nature of sentinel events.

The internal and external environment were not often found to be contributive in our study. These domains are typically not strongly embedded in traditional root cause analysis methods, and therefore may also be not or only limitedly described in the event descriptions of sentinel event reports. Hence, the investigation of events by hospitals is conducted with the traditional method in mind. This is one of the reasons the authors of another study[57] stated they thought it was not possible to retrospectively study existing reports to apply a new analysis method. We think that utilizing the comprehensive event descriptions in existing reports is a viable option to reanalyze events to come to new insights. However, one must be aware that using existing reports could have resulted in some bias. At the same time, the more latent system-related issues (such as those related to the external environment) are by its nature less prominent and therefore more challenging to (retrospectively) notice in event investigations either way[48 76]. Our approach in reanalyzing existing reports can be seen as a first step. Applying a new method to analyze sentinel event reports helped to identify lacunes in current event investigations. These insights could be used to use a different approach in future investigations, and perform a more holistic and human factors based investigation and analysis.

Diagnostic errors and medical device related errors

Chapter 6 studied the human error in sentinel events where a diagnostic error in the emergency department occurred, applying multiple tools and classification systems for specific analysis. A total of 73 human errors were identified in 21 sentinel events. While alongside these human errors often factors relating to other sociotechnical domains contributed (i.e. organizational, patient-related and technical factors), this study focused solely on the human error.

The assessment and testing phase of the diagnostic process appeared to be the most critical stages of the diagnostic process, as here most human errors occurred. These are also phases where devices play an important role. In particular in the testing phase, where diagnostic tests are ordered and performed. For example when operating and setting up diagnostic devices (e.g. ultrasound, MRI, and hematology analyzers) or interpreting the output of diagnostic instruments (e.g. scans, x-rays and specimen test results). Also issues related to the electronic health record are a known driver of suboptimal diagnostics[77 78].

Classifying the type of identified human errors showed the majority of human errors were based on intended actions (n=69) and could be classified as mistakes (n=56) or violations (n=13). Given that violations frequently occur under the pressure of work and time constraints, whereas mistakes are frequently knowledge-based, these sorts of errors require different type of recommendations.

Hospitals commonly formulated non-specific administrative recommendations, e.g. adopting information about the missed disease in the ward protocol. These non-specific and administrative measures are often recommended after root cause analysis, but are considered weak[69 70]. The insights from this in-depth and specific analysis of human errors during the diagnostic process, could lead to formulating more specific and evidence based recommendations (e.g. structural feedback and reflection on diagnostic discrepancies, implementation of diagnostic decision support systems to improve diagnostic calibration, or implementing team based diagnosis) and more system-oriented recommendations (e.g. lowering work pressure and crowding in the emergency department, improving patient safety culture, or teamwork interventions).

A subset of sentinel event reports (n=20) that related to medical devices was also further analyzed (Chapter 7). The Amoore cause classification system[9] differentiated on the identified contributing factors underlying events, and the human factors perspective helped to study the interactions with factors of other elements of the system (i.e. the operator, patient, infrastructure and organization). This showed how medical devices were involved in events. Recurring contributing factors were a lack of specific device training and education of operators, operator errors in setting up and checking devices before use, faulty manufacturing, device

design issues, device failure, and poor ergonomics of the infrastructure. Jointly these factors relating to the operator, device, infrastructure and patient and organization related factors, triggered events leading to unintended patient harm.

The multifactorial view as emerged from this study corresponds to other studies on the causes of sentinel events in general[65 79], and events involving medical devices specifically[9]. Mapping these multifactorial causes using the human factors perspective helped to increase knowledge on the emergence of events involving medical devices, and helped to better understand how devices were involved.

METHODOLOGICAL CONSIDERATIONS

In this thesis several studies were described with regard to patient safety and medical devices. The mixed methods approach and variety of data sources used (i.e. patient record review data, literature review, and sentinel event reports analysis) is a strength of this thesis. Also the substantial numbers included in the study (2,998 patient records, and 69 sentinel event reports), can be considered an important strength. It allowed us to provide a generic overview of the incidence of potentially preventable adverse events involving medical devices, but also to in-depth study latent causes, and interacting contributing factors underlying events involving medical devices. This contributes to filling the knowledge gap on how medical devices are involved in events leading to unintended patient harm. In addition to these substantive insights on patient safety risks related to medical devices, also a new method, the Generic Analysis Method (GAM) was developed and tested to study sentinel event reports and elucidate the role of medical devices in unintended patient harm. This method is based on pre-existing methods and draws upon existing knowledge from international literature. Therefore, this thesis not only contributes to the medical debate on patient safety, but also contributed to a methodological issue. In all studies measures were taken to ensure quality, reliability and validity of the findings (e.g. double-review processes, assessment of interrater reliability, consulting expert groups, and carrying out member checks).

When interpreting the findings of this thesis, one should consider some limitations. We only performed retrospective research, which induces hindsight bias. This holds for the patient record review study, as well as for the investigations of sentinel events and analysis of subsequent sentinel event reports. Reanalyzing existing sentinel event reports using a new generic analysis method holds some implications too. For example, the inability of researchers to themselves enquire more deeply into the events, resulting in some domains remaining understudied. Further research and directly applying the generic method for event investigation is necessary to assess its potential, and evaluate the reliability and validity for this purpose.

In addition, we only studied events where something went wrong, while studying successful events and everyday practice might also offer important insights to learn from[80]. Also, sentinel events as studied in a substantial part of this thesis, are considered outliers, and often do not reflect normal course of events. Though, learning from sentinel events is considered important, as these have severe consequences for patients, their family, healthcare professionals and healthcare organizations. Preventing recurrence of such events is therefore of upmost important.

Furthermore we only studied the Dutch hospital context, and so not all results may be generalizable to the worldwide healthcare sector or to other care domains. Though, the medical device market is a global market, which means the same or similar devices are used across the world. Identified device related issues might therefore also appear in other countries. In addition, although system issues sometimes are country and health system specific, some issues could also be relevant for hospital care in other (high-income) countries. The devices that emerged in the studied events in this thesis are predominantly restricted to hospital application only. Therefore, the findings will indeed be difficult to be translated to domains of e.g. home and long-term care. Some findings that relate to system issues, however, are compatible to the wider healthcare system (e.g. specific personnel shortages, insufficient risk awareness related to medical device application) and thus may also be relevant for other care domains. Moreover, the methodological aspects for studying sentinel events discussed in this thesis will be relevant to other countries and other care settings.

RECOMMENDATIONS

The case as described in the introduction – in which an infant patient suffered serious burns after improper connecting a heating mattress – demonstrated such events have serious implications for patients their relatives, professionals, and healthcare institutions. The findings of this thesis helped to increase our understanding on the emergence of such events. We found events often are a result of multiple interacting contributing factors. For example for the specific case of the heating mattress, it might be that factors related to the device (e.g. shortcomings in the design of device connections and absent alarm systems), narrowly interacted with contributing factors of other domains of the socio-technical system (e.g. no work instructions on strict pre-use checks and not intervening promptly when something seems not right). Jointly these factors can trigger patient harm. To improve patient safety related to medical device application in a complex healthcare system, an integrative multipronged approach addressing factors from multiple socio-technical domains is needed. On multiple levels and from multiple stakeholders efforts must be made.

PRACTICE AND POLICY

Hospitals should continue to investigate sentinel events aiming to learn and prevent recurrence. From the findings of this thesis there are some strategies that could help improve this process. One important strategy is to embed a human factors and systems thinking perspective into event investigations and analysis, to address the complexity of contemporary healthcare. Underlying system issues and more latent (technical) contributing factors could then be recognized and addressed. The novel Generic Analysis Method (GAM) could embed such a perspective in sentinel event investigation and analysis.

To accelerate learning from sentinel events, hospitals could work together in networks to jointly learn from events. Aggregated cross-hospital analysis of events can help to identify trends and reveal system issues. Joint reflection on such underlying patterns of events can help to better understand emergence and aid sharing successful strategies to improve. Moreover, reusing the existing sentinel event reports that are typically not used for broader cross-hospital learning, is a sustainable way of using this valuable data to improve patient safety. However, barriers related to sharing information (e.g. lack of an infrastructure for sharing data, and strict privacy regulations) and the diversity of methods used by hospitals to study sentinel events can complicate aggregated cross-hospital analysis. The GAM could ease the latter issue, but the infrastructural and privacy related barriers remain a problem. Policymakers and umbrella organizations could help to develop structures for sharing data and facilitate in legal advice on privacy issues.

Additional tools as used in this thesis (i.e. SaferDx[71], Diagnostic Error Evaluation and Research taxonomy[72], Model of Unsafe acts[73], and Amoore classification system[9]) could be used more systematically to dig deeper into specific topics. This can help to better understand events and formulate more specific improvement measures.

Efficiency-thoroughness trade-offs[56] could also be used as an additional tool. These could help to reflect on decisions that are made by healthcare professionals due to scarcity. Healthcare demands are ever-increasing while resources are limited, necessitating for trade-offs in daily practice, which could pose risks to patient safety. The efficiency-thoroughness trade-offs as described by Hollnagel[56] could be helpful in identifying such trade-offs. Joint multidisciplinary reflection on these moments could contribute to better designing work processes, taking into account situations where scarcity of materials and human resources are pressing.

Another recommendation to improve sentinel event investigation and analysis, is to incorporate specific technical and human factors expertise. In-depth technical investigation by experts could help to find latent device related issues. One compelling example of thorough technical investigation, was provided by Rauwers et al.[81]. Among other issues, they demonstrated after dismantling duodenoscopes some important design abnormalities, which contributed to scope-associated infections. For such technical investigation, it is necessary to secure devices and consumables after a potential sentinel event occurs. Human factors expertise could help to incorporate the right perspective in event investigations and set the right emphases for analysis of interacting contributing factors. These experts could also help with formulating stronger recommendations that take into account the strengths and limitations of the individual professional working in a complex system.

Well-formulated (e.g. specific, concrete, measurable, and time-bonded) and strong substantive recommendations are important to improve after sentinel events[69 70]. Hence, recommendations can inform practice or process improvements, and eventually enhance patient safety. However, formulating recommendations after event analysis is considered difficult[47 69 76 82]. From evaluating the sentinel event reports, we learned that individual hospitals often tend to focus on solving singular root causes of isolated events with administrative measures, instead addressing multiple interacting factors and underlying issues from multiple events. Cross-hospital aggregate GAM analysis may help to formulate more system-oriented recommendations. Tools for evaluating the quality of formulated recommendations[83] could also be valuable to rethink and reformulate recommendations and may therefore be important to use in future sentinel event analysis. Moreover, it is important to develop a strategy on how to implement recommendations in order to achieve actual adjustments in daily practice. Embedding expertise from implementation science is therefore recommended.

To minimize adverse events involving medical devices, individual care professionals, hospitals, policymakers, and device industry could take various steps. With regard to preventing complications where devices play a role, as those highlighted in the patient record review (i.e. bleedings perforations and infections after application of scopes and placement of heart and vascular implants), policymakers and hospitals could stimulate learning from excellence and facilitate dedicated clinical auditing and registries. Such initiatives may provide leads to further improve care[84-87]. This aligns with the emerging Safety-II movement, that focuses on learning from daily practice and sharing best practices[88-90]. In addition, for preventing other types of adverse events, hospitals should promulgate adherence to evidence-based guidelines. For example with regard to adverse events related to nasogastric tube application, strict adherence to protocols is seen as an important strategy to reduce adverse events related to tube misplacement[43]. This is a typical example of traditional safety management (Safety-I), indicating how Safety-I and Safety-II complement and strengthen each other.

Another strategy that might reduce complications related to medical device application, is to carefully consider the risks of device application on a patient-by-patient basis.

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Additional prudence for specific patients and refined case selection could help to prevent complications. Over time, development of novel devices with important technical advantages (e.g. multibending endoscopes[91] or smaller delivery sheets for TAVI-procedures[92]) and implementing and endorsing technological possibilities for improving patient care (e.g. ultrasound guided placement of nasogastric feeding tubes[93]) may reduce complication rates as well. For stimulating such innovation, medical device industry should work closely together with end-users, to develop devices addressing the needs of end users. Human factors and ergonomics should be a key principle in device design processes (e.g. enhancing user-friendliness of device interfaces, and ensuring well-integrated software systems). Human factors principles could reduce mismatches between device design and the capabilities of operators that interact with the device, and help to tailor devices into the existing workflow where they will be implemented. This requires the acceleration of the fields of medicine, cognitive science, informatics, human factors and engineering to jointly work on device design and implementation. Hospitals could also make usability and human factors design a top priority in procurement and commissioning of medical devices.

Registration of adverse events remains of unchanged importance. But underreporting seems to be a persistent problem, in particular for AEMDs[94 95]. Follow-up on reported events is one important strategy to improve reporting, as well as raising overall awareness to the risks of devices[95 96]. Another important issue lies in the registration of events itself. Adverse event reporting should be easy and asks for a standardized registration platform[97]. Analogue to what in the pharmaceutical sector is common practice, providers and users of devices should be able to easily report and look up adverse events and reported side effects related to devices. In the Netherlands, Lareb provides such a platform for the pharmaceutical sector, but for medical devices an easily accessible and standardized platform is lacking. EUDAMED may over time become an appropriate platform for this purpose. But it is still unknown how this will turn out, and if it is suited for this specific ambition.

Some of the outlined recommendations align with existing standards for safety management systems in hospitals, and systems for integral quality assurance for medical technology[98 99]. The insights and recommendations from this thesis can complement such systems. This would, at the same time, help to embed the findings into existing hospital procedures, which may contribute to further improving the safe use of medical devices.

FUTURE RESEARCH

From the insights of this thesis several directions for future research follow. One important next step is to directly study events using the novel Generic Analysis Method. This could help to assess its potential for direct event investigation and further refine, evaluate, and validate the method.

Also, for this thesis only retrospective studies were conducted. It would be worth establishing prospective research methods as well. Using techniques as observations and interviews with professionals and patients, investigators could enquire more deeply into the safe use of devices in daily practice. This can provide the opportunity to study factors that contribute to patient safety events that are not documented in patient records, or cannot be retrospectively retrieved. Outcomes of these studies could be discussed in peer-meetings aiming to evaluate and reflect on the application of medical devices, to keep improving on technical skills and maybe identify leads for better device design.

This thesis focused on hospital care only, but growing interest should be on devices used in home care and long term care facilities. Here, increasingly complex and high risks devices are being introduced as a result of the increasing shift from hospital care to care provided in other settings. In these settings, safety policies with regard to medical device application may still be in its infancy[100]. This, in spite of signals that point towards serious risks, e.g. the number one patient safety hazard for 2023 as identified by the Emergency Care Research Institute concerns medical devices in the home setting[94]. Another issue that is becoming increasingly relevant towards the future, is safety related to medical information technology and software. Medical information technology and software, including artificial intelligence and machine learning principles, are increasingly adopted in clinical practice. They provide important solutions for the future healthcare landscape and have the ability to foster patient safety[101]. However, these technologies may also come with risks for patients, on which an increasingly amount of literature is being published[102-105]. Future research should focus on supporting the safe entry and application of these type of technologies.

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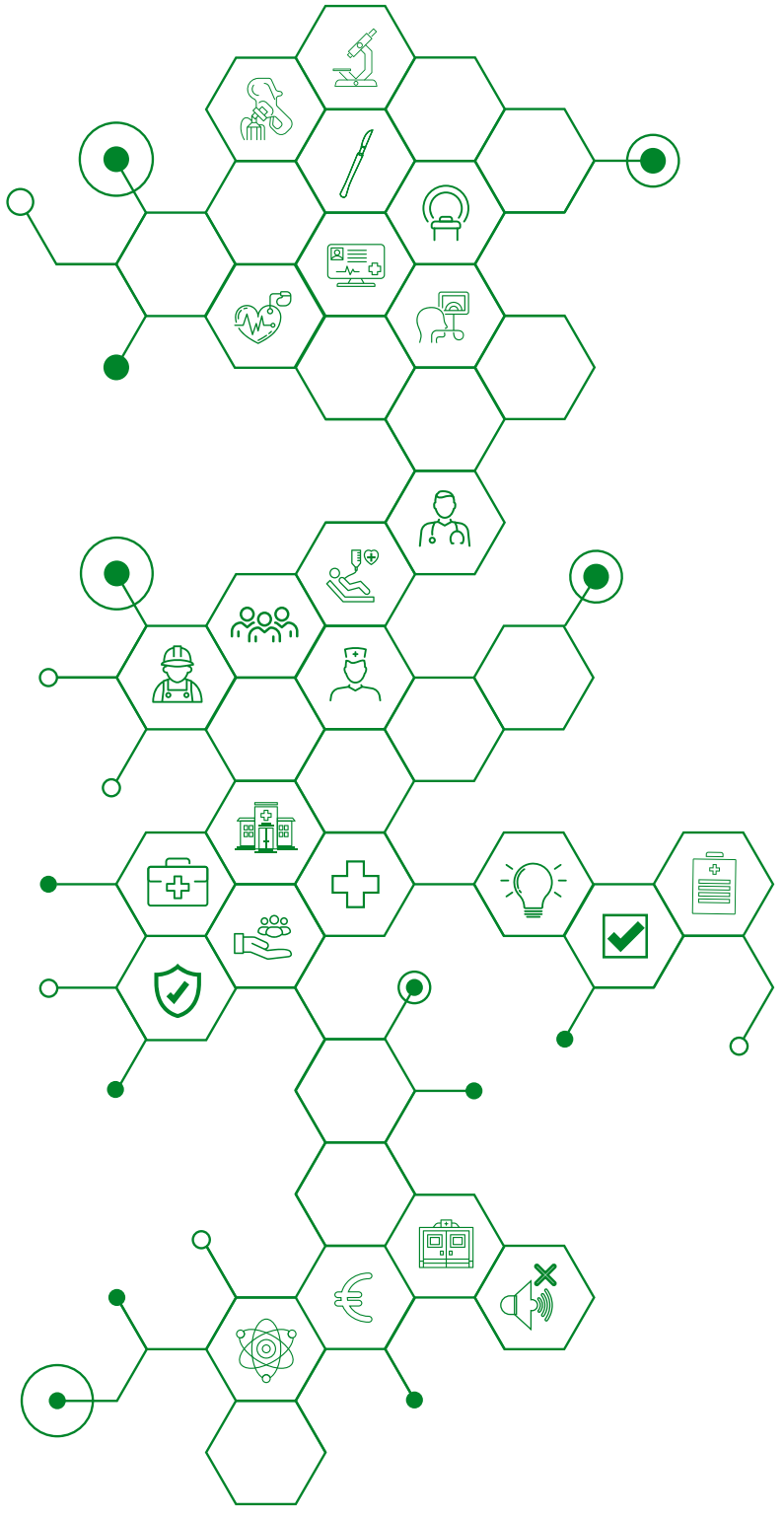

Chapter 9

Summary
Nederlandse samenvatting

SUMMARY

Hospitals are high-technical environments where medical devices are essential for providing patient care. Often the application of medical devices is safe, but occasionally devices are involved in events resulting in unintended patient harm. In some cases this patient harm could potentially have been prevented. However, much is unknown about how events leading to potentially preventable patient harm emerge and what role the device plays. This thesis aims to increase knowledge and provide deeper understanding on how medical devices are involved in unintended patient harm in Dutch hospital care, and identify leads to further improve patient safety.

To fulfill this aim various studies were conducted, namely I) a patient record review study on the incidence and nature of patient harm where medical devices are involved, II) a systematic literature review on one method currently applied to study the causes patient harm, III) the stepwise development of a new sentinel event analysis method, and IV) a retrospective aggregated cross-hospital analysis of sentinel event reports identifying contributing factors including those factors that relate to devices.

Chapter 2 presents the incidence and nature of potentially preventable Adverse Events involving Medical Devices (AEMD), based on data from reviewing 2,998 patient records from 20 Dutch hospitals. A potentially preventable AEMD occurred in 1.9% (95CI 1.5%-2.5%) of patients who died during their admission in Dutch hospitals in 2019. Perforations, bleedings, and infections after invasive (endo)scopic procedures, heart- and vascular implants, and tubes for enteral feeding or drainage were recurring topics identified in these AEMDs. The contribution of the device often laid in provoking a known complication, which in most cases was considered non-preventable. Preventability often not necessarily related directly to device application, but rather laid in the subsequent management of the perforation, bleeding or infection. However, a limitation of reviewing patient records is that it only provides limited insights in the more latent causes of events. In particular technical factors may often remain unnoticed. Therefore other methods were explored to study the underlying contributing factors of events.

The Prevention and Recovery Information System for Monitoring and Analysis (PRISMA) method is one of the methods used for investigating and analyzing causes of unintended events in healthcare. In **Chapter 3** the results of a systematic literature review are described on the worldwide application of PRISMA in healthcare facilities. Twenty-five references were included in this literature review, reporting on 10,816 unintended events. The references mainly identified human- and organization related causes, such as knowledge based failures or hospital staff shortages. Technical causes were less commonly observed. From the literature review we concluded that an important strategy to better understand unintended events and formulate stronger recommendations, was to combine multiple data-sources (e.g. interviews with those involved and reviewing patient records) and forming a strong multidisciplinary investigation team that is trained in the PRISMA method. Incorporating technical expertise in this investigation team (e.g. clinical technologists, clinical physicists or medical engineers) may help to identify more technical causes.

To better understand how events leading to patient harm emerge, the novel Generic Analysis Method (GAM) was developed to perform an aggregated cross-hospital analysis of sentinel events (**Chapter 4**). Sentinel events are those quality of care related unintended events that have caused death or serious patient harm. Hospitals carefully investigate such events using interviews with those involved (i.e. healthcare professionals and patients or their relatives) and data from patient records. Analysis of the causes of sentinel events is typically done using a root cause analysis method, e.g. PRISMA, Systemic Incident Reconstruction and Evaluation (SIRE) or Tripod-beta. Such methods have important limitations, e.g. they often tend to focus on finding one or a few linear root causes instead of addressing the complex interactions between a multitude of contributing factors. Also the analysis is generally aimed at independent isolated events instead of learning across events and organizations.

In a stepwise process, prototypes of the GAM were carefully evaluated, tested and refined. Stakeholders and experts in the field of patient safety (hospital quality and safety managers, medical specialists, and patient safety experts) were involved in the developing process. Face and content validity were evaluated and user test sessions were performed. The development process resulted in a framework and affiliated questionnaire, that are structured according to the Systems Engineering Initiative for Patient Safety (SEIPS) model. This model incorporates a systems approach and human factors principles into the GAM, which helps to address the influence of factors from various socio-technical domains. Also some important elements of three methods currently practiced by Dutch hospitals to study sentinel events were integrated, i.e. PRISMA, SIRE and Tripod-beta. The GAM can therefore ease an aggregated cross-hospital analysis of sentinel events. It may also help to perform a more holistic analysis, and provide deeper understanding on the emergence of events and the potential role of devices.

The GAM was then applied to perform a retrospective cross-hospital aggregated analysis of sentinel event reports. **Chapter 5** elaborates on the findings of this analysis of 69 events from 28 Dutch general hospitals. We exemplified that applying the GAM provided a more holistic sentinel event analysis than a PRISMA analysis. The focus shifted from identifying one or a few linear root causes to mapping complex interactions among contributing factors from various socio-technical domains. The majority of all identified contributing factors (n=405) related to the patients and professionals involved (n=148 [36.5%]) and the organization (n=121 [29.9%]). Tools and technology related factors, which include

characteristics of medical devices, were involved in 42 of the 69 events, and constituted a substantial number of factors (n=62 [15.3%]). Examples of such factors were: suboptimal usability of a medication prescription system or an electrosurgical device that broke off during surgery. Factors related to the tasks performed (n=48 [11.9%]) and the external (n=15 [3.7%]) and physical (n=11 [2.7%]) environment, were less commonly observed.

Cross-hospital aggregated GAM-analysis was found to more holistically analyze events and address complexity. It provided more insights in the system related issues underlying events and the potential role of devices. Moreover, this cross-hospital aggregate GAM approach helped to identify system issues and propose other, more system-oriented overarching recommendations. For example, rearranging responsibilities for consultation during crowding in the emergency department which helped to lower the workload for residents, or evaluating and adapting a predefined lists of medication options in a hospital wide administrative system, making it more intuitive and less prone to mistakes. Such recommendations are believed to be more successful in improving patient safety. Overall, the GAM method supports hospitals to jointly learn more from sentinel events.

A further in-depth analysis was conducted of a subset of sentinel event reports relating to diagnostic errors in the emergency department (n=23) (**Chapter 6**). Although the focus of this study was on human errors, it provided also some insights on devices as these are often essential for a timely and correct diagnosis. Using the detailed event descriptions in the sentinel event reports, human errors were thoroughly studied to better understand how diagnostic errors occur, and to formulate more specific recommendations. Various instruments were applied, i.e. the SaferDx instrument, the Diagnostic Error Evaluation and Research Taxonomy, and the Model of Unsafe Acts.

Seventy-three human errors were identified, and most of them were classified as mistakes (n=56) or violations (n=13). These errors mainly emerged during the assessment and testing phase of the diagnostic process. In these phases, various medical devices play an important role. For example medical information technology (e.g. ordering tests via the electronic health record), and diagnostic devices (e.g. setting up and performing X-rays and interpreting results). The insights from identifying and classifying human errors could be used to tailor recommendations. For example, violations often occur under the pressure of work and time constraints, whereas mistakes are frequently knowledge-based. These sorts of errors require different types of recommendations. Mistakes for example could benefit from knowledge-based interventions such as specific training and education, feedback and reflection on diagnostic discrepancies, or implementation of diagnostic decision support systems. Violations, on the other hand, are in need of a more system-based approach, such as lowering work pressure and crowding in the ED, or improving patient safety culture and teamwork.

The last study, as described in **Chapter 7**, zoomed in on sentinel events involving medical devices, aiming to identify and classify contributing factors. In 20 sentinel event reports, 105 contributing factors were identified. These were classified according to a specific classification system for medical device related events. The GAM was used to map the interactions between factors. Identified factors related to the operator (n=33, e.g. flaws in setting up and checking devices before use), the device (n=27, e.g. product design issues), the infrastructure (n=18, e.g. poor environmental ergonomics), the patient (n=8, e.g. complicating anatomy), or were categorized as 'Other' (n=19, e.g. insufficient organizational risk awareness related to medical devices). These identified factors often interacted and jointly triggered events that led to patient harm. Such in-depth analysis of sentinel events involving medical devices using specific classification systems helped to increase our understanding on how medical devices are involved in unintended patient harm. The differentiated insight on the contributing factors and interactions between factors, could help to further improve patient safety.

Chapter 8 constitutes the overall discussion of this thesis, wherein we present our findings in relation to the existing literature, discuss some important methodological considerations, and offer recommendations.

In short, this thesis found devices are involved in potentially preventable events leading to unintended patient harm. Current methods for studying such events not always successfully clarify the role of medical devices. Therefore the novel GAM was developed, in which a human factors perspective and systems thinking approach are embedded. Aggregate cross-hospital GAM-analysis of events indicates that characteristics of the device itself often interact with contributing factors related to other socio-technical domains such as the organization, patient, and professional. Jointly these factors trigger patient harm. Additional in-depth analysis on specific topics using specialized instruments can help to further increase our understanding and assist in formulating more specific measures for improvement. From these findings some important recommendations for practice and policy follow, including guidance on future sentinel event investigations and strategies to reduce adverse events involving medical devices. Future research should I) include prospective methods to study the safe application of medical devices, II) also focus on safety of devices in non-hospital settings, and III) study potential patient safety risks related to medical software and information technology in health care, including the emerging application artificial intelligence.

NEDERLANDSE SAMENVATTING

Medische technologie is tegenwoordig essentieel voor het verlenen van zorg aan patiënten in het ziekenhuis. Vaak verloopt de toepassing van medische technologie veilig, maar af en toe is de technologie betrokken bij gebeurtenissen die leiden tot onbedoelde schade aan de patiënt. In sommige gevallen was deze schade mogelijk te voorkomen. Kennis over het ontstaan van deze potentieel vermijdbare schade ontbreekt vaak nog, evenals inzicht in de rol van technologie hierin. Dit proefschrift heeft als doel onze kennis te vergroten en meer inzicht te bieden in de wijze waarop medische technologie betrokken is bij onbedoelde schade aan patiënten in de Nederlandse ziekenhuiszorg. Daarmee kunnen we aanknopingspunten formuleren om de patiëntveiligheid verder te verbeteren.

Om dit doel te bereiken zijn verschillende studies uitgevoerd, namelijk I) een landelijke dossierstudie naar de incidentie en aard van onbedoelde schades aan patiënten waarbij medische technologie een rol speelde, II) een systematisch literatuuronderzoek naar één van de methoden die momenteel wordt toegepast om de oorzaken van schades aan patiënten te onderzoeken, III) een stapsgewijze ontwikkeling van een nieuwe analysemethode voor calamiteiten, en IV) een retrospectieve ziekenhuisoverstijgende geaggregeerde analyse van calamiteitenrapportages gericht op het identificeren van meespelende factoren inclusief factoren gerelateerd aan de technologie.

Hoofdstuk 2 beschrijft de aard en incidentie van potentieel vermijdbare schade waarbij medische technologie een rol heeft gespeeld. De resultaten zijn gebaseerd op een studie waarin 2.998 patiëntendossiers uit 20 Nederlandse ziekenhuizen zijn onderzocht. De dossiers betroffen patiënten die zijn overleden tijdens hun opname in 2019. Potentieel vermijdbare schade waarbij medische technologie een rol speelde, werd gevonden bij 1,9% (95CI 1,5%-2,5%) van de patiënten. Perforaties, bloedingen en infecties na invasieve (endo)scopische procedures, het plaatsen van hart- en vaatimplantaten en het gebruik van neus-maagsondes voor voeding of drainage waren terugkerende thema's. De bijdrage van de technologie lag in de meeste gevallen in het veroorzaken van een bekende complicatie, wat vaak als niet-vermijdbaar werd bestempeld. Vermijdbaarheid lag veelal dus niet direct in de toepassing van de technologie, maar eerder in bijvoorbeeld een suboptimale opvolging en behandeling van de veroorzaakte perforatie, bloeding of infectie. Dossieronderzoek biedt echter slechts beperkt inzicht in de latente oorzaken van de gevonden schades. Met name technische factoren blijven vaak onopgemerkt. Daarom verkenden we andere methoden voor het onderzoeken van meespelende factoren.

De Prevention and Recovery Information System for Monitoring and Analysis (PRISMA) methode is één van de methoden die wordt gebruikt voor onderzoek naar oorzaken van onbedoelde gebeurtenissen. In **hoofdstuk 3** wordt een systematisch literatuuronderzoek beschreven naar de wereldwijde toepassing van de PRISMA methode in de gezondheidszorg. Vijfentwintig artikelen werden geïncludeerd die rapporteerden over 10.816 onbedoelde gebeurtenissen. Oorzaken van de gebeurtenissen waren veelal gerelateerd aan menselijk gedrag en de organisatie, zoals een kennisgebrek of personeelstekorten. Technische oorzaken werden minder vaak gevonden. Uit het literatuuronderzoek concludeerden we dat het, om onbedoelde gebeurtenissen in zorginstellingen beter te begrijpen en sterkere aanbevelingen te formuleren, belangrijk is om I) verschillende gegevensbronnen te combineren, zoals interviews met betrokkenen en patiëntendossiers, en II) een multidisciplinair onderzoeksteam te vormen dat is getraind in de PRISMA-methode. Het opnemen van technische expertise (bijvoorbeeld klinisch technologen, klinisch fysici of biomedisch ingenieurs) in het onderzoeksteam kan mogelijk helpen om meer technische oorzaken te identificeren.

Om beter te begrijpen hoe onbedoelde schade aan patiënten ontstaat, werd een nieuwe Generieke Analyse Methode (GAM) ontwikkeld voor het ziekenhuisoverstijgend analyseren van calamiteiten (**Hoofdstuk 4**). Calamiteiten zijn onbedoelde gebeurtenissen gerelateerd aan de kwaliteit van zorg die leiden tot ernstige schade aan de patiënt of zelfs tot overlijden. Ziekenhuizen onderzoeken calamiteiten zorgvuldig door onder andere interviews af te nemen met betrokkenen (zoals zorgprofessionals en patiënten en diens naasten) en patiëntendossiers te bekijken. Het onderzoek naar calamiteiten volgt veelal een standaard methode voor (basis)oorzakenanalyse, zoals PRISMA, Systematische Incident Reconstructie en Evalautie (SIRE) of Tripod-beta. Dergelijke methoden hebben enkele belangrijke tekortkomingen. Zo ligt de focus vaak op het identificeren van één of enkele basisoorzaken in plaats van te kijken naar de complexiteit en de interacties tussen meerdere meespelende factoren. Ook worden de methoden veelal ingezet voor de analyse van afzonderlijke calamiteiten binnen de eigen instelling, in plaats van te leren van meerdere calamiteiten uit verschillende organisaties.

In een stapsgewijs proces werden prototypes van de nieuwe GAM zorgvuldig geëvalueerd, getest en verfijnd. Deskundigen op het gebied van patiëntveiligheid (kwaliteits- en veiligheidsmanagers uit ziekenhuizen, medisch specialisten, en patiëntveiligheid experts) werden betrokken in het ontwikkelingsproces. De indruks- en inhoudsvaliditeit werden geëvalueerd en er werden gebruikerstestsessies georganiseerd. Het ontwikkelingsproces resulteerde in een raamwerk en bijbehorende vragenlijst. Beide zijn gestructureerd volgens het Systems Engineering Initiative for Patient Safety (SEIPS) model, waarmee de invloed van factoren uit verschillende socio-technische domeinen wordt bestudeerd. De methode is gebaseerd op het systeemdenken en omvat principes uit de veiligheidsergonomie. Ook zijn enkele belangrijke elementen geïntegreerd van drie methoden die momenteel door Nederlandse ziekenhuizen worden gebruikt om calamiteiten te onderzoeken en analyseren (PRISMA, SIRE en Tripod-beta). De GAM kan daarom een geaggregeerde

ziekenhuisoverstijgende analyse van calamiteiten vergemakkelijken. Ook leidt toepassing van de GAM mogelijk tot een meer holistische analyse en vergroot het ons inzicht in het ontstaan van de schade aan de patiënt en de rol die technologie daar eventueel in speelt.

De GAM werd vervolgens ingezet voor een retrospectieve ziekenhuisoverstijgende geaggregeerde analyse van calamiteitenrapportages. **Hoofdstuk 5** gaat dieper in op de bevindingen van deze analyse van 69 calamiteiten uit 28 Nederlandse algemene ziekenhuizen. Een uitgewerkt voorbeeld laat zien dat toepassing van de GAM een meer holistische calamiteitenanalyse oplevert dan een PRISMA-analyse. De focus werd verlegd van het identificeren van één of enkele lineaire basisoorzaken, naar het in kaart brengen van complexe interacties tussen meespelende factoren uit verschillende socio-technische domeinen. De meerderheid van alle geïdentificeerde meespelende factoren (n=405) had betrekking op de patiënten en professionals (n=148 [36,5%]) en de organisatie (n=121 [29.9%]). Factoren gerelateerd aan technologie waren betrokken bij 42 van de 69 calamiteiten, waarin een aanzienlijk aantal factoren werd geïdentificeerd (n=62 [15,3%]). Voorbeelden van zulke factoren waren: een suboptimale gebruiksvriendelijkheid van een medicatievoorschrijfsysteem en een elektrochirurgisch apparaat dat afbreekt tijdens een operatie. Factoren met betrekking op de taken (n=48, [11.9%]) en de externe (n=15, [3.7%]) en fysieke omgeving (n=11 [2.7%]) werden minder vaak teruggevonden in de rapportages.

De ziekenhuisoverstijgende geaggregeerde GAM-analyse hielp om meer holistisch te kijken naar meespelende factoren uit verschillende socio-technische domeinen, en interacties tussen factoren in kaart te brengen. Ook bood het meer inzicht in de rol van technologie en systeemproblemen. Deze inzichten leidde tot meer systeemgerichte overkoepelende aanbevelingen. Voorbeelden hiervan waren I) het herverdelen van verantwoordelijkheden rondom het inschakelen van supervisie tijdens drukte op de spoedeisende hulp waardoor een deel van de werkdruk voor arts-assistenten werd weggenomen, of II) het evalueren en aanpassen van een medicatielijst in een ziekenhuisbreed automatisch voorschrijfsysteem zodat deze intuïtiever werd en daardoor minder vatbaar voor fouten. De studie liet zien dat de GAM ziekenhuizen kan ondersteunen om gezamenlijk meer te leren van calamiteiten.

Vervolgens werd een deel van de calamiteiten dat betrekking had op diagnostische fouten op de spoedeisende hulp (n=23) verder geanalyseerd (**Hoofdstuk 6**). Al lag de focus in deze studie vooral op het menselijke aspect, de resultaten boden ook relevante inzichten over medische technologie. Technologie is immers vaak essentieel voor het stellen van een tijdige juiste diagnose. Aan de hand van de gedetailleerde gebeurtenisbeschrijvingen in calamiteitenrapportages werden ‘menselijke fouten’ grondig geanalyseerd om zo meer inzicht te krijgen in hoe diagnostische fouten ontstaan en om meer specifieke aanbevelingen te formuleren. Verschillende instrumenten werden toegepast; de SaferDx, Diagnostic Error Evaluation and Research Taxonomy en het Model of Unsafe Acts.

Drieënzeventig menselijke fouten werden geïdentificeerd, waarvan de meeste geclassificeerd konden worden als vergissingen (n=56) of overtredingen (n=13). Deze fouten kwamen voornamelijk naar voren tijdens de beoordelings- en testfase van het diagnostische proces. In deze fasen spelen verschillende medische technologieën een belangrijke rol, zoals medische informatietechnologie (bijv. het aanvragen van tests via het elektronisch patiëntendossier) en diagnostische apparatuur (bijv. het instellen en bedienen van röntgenapparatuur en het interpreteren van de resultaten hiervan). De inzichten ten aanzien van de menselijke fouten kunnen worden gebruikt om meer specifieke aanbevelingen te formuleren. Zo ontstaan overtredingen vaak onder werk- en tijdsdruk, terwijl vergissingen vaak kennis-gerelateerd zijn. Voor deze typen fouten zijn verschillende soorten aanbevelingen nodig. Voor het voorkomen van vergissingen is het bijvoorbeeld wenselijk kennisgerichte interventies in te zetten, zoals specifieke training en opleiding, feedback en reflectie op diagnostische discrepanties, of implementatie van beslissingsondersteunende systemen. Overtredingen vragen om meer systeemgerichte interventies, zoals het verlagen van de werkdruk op de spoedeisende hulp, of het verbeteren van de patiëntveiligheidscultuur en (mutlidisciplinaire) samenwerking.

In het laatste onderzoek, zoals wordt beschreven in **Hoofdstuk 7**, keken we specifiek naar calamiteiten gerelateerd aan medische technologie, met als doel het identificeren en classificeren van meespelende factoren. In 20 calamiteitenrapportages werden 105 meespelende factoren gevonden. Factoren hadden betrekking op de gebruiker (n=33, bijv. fouten bij het instellen en controleren van apparatuur vóór gebruik), de technologie zelf (n=27, bijv. ontwerpfouten), de infrastructuur (n=18, bijv. een indeling van een ruimte die het gebruik bemoeilijkt), de patiënt (n=8, bijv. een complicerende anatomie), of werden als ‘Anders’ gecategoriseerd (n=18, bijv. een gebrek aan risicobewustzijn ten aanzien van technologie op afdelingsniveau). De gevonden factoren interacteerden met elkaar en leidde zo gezamenlijk tot schade aan de patiënt. Een dergelijke diepgaande analyse van calamiteiten met medische technologie, waarbij de factoren en interacties die meespeelden nader werden bestudeerd, leverde meer inzicht op in de manier waarop medische technologie betrokken is bij onbedoelde schade aan patiënten. Dit inzicht kan helpen om de patiëntveiligheid op dit vlak verder te verbeteren.

Hoofdstuk 8 vormt de algemene discussie van dit proefschrift, waarin we onze bevindingen presenteren in relatie tot bestaande literatuur, enkele belangrijke methodologische overwegingen beschrijven en aanbevelingen doen. Samengevat laat dit proefschrift zien dat medische technologie op verschillende manieren betrokken is bij gebeurtenissen die leiden tot onbedoelde potentieel vermijdbare schade aan patiënten. Bestaande methoden voor het onderzoeken en analyseren van dergelijke gebeurtenissen brengen de rol van de technologie onvoldoende aan het licht. Daarom werd de GAM ontwikkeld, waarin het systeemdenken en een veiligheidsergonomisch perspectief zijn ingebed.

Een ziekenhuisoverstijgende GAM-analyse van calamiteiten toonde aan dat kenmerken van de technologie vaak interacteren met factoren uit andere socio-technische domeinen zoals de organisatie, de patiënt en de professional. Gezamenlijk leiden deze factoren tot schade aan de patiënt. Aanvullende diepgaande analyses op specifieke onderwerpen waarbij gespecialiseerde instrumenten werden ingezet hielpen om onze inzichten nog verder te vergroten en meer specifieke verbetermaatregelen te formuleren. Uit deze bevindingen volgen enkele aanbevelingen voor praktijk en beleid, waaronder adviezen voor het inrichten van toekomstige calamiteitenanalyses en strategieën om het aantal schades aan patiënten waarbij medische technologie een rol speelde te verminderen. Toekomstig onderzoek zou I) prospectieve methoden moeten omvatten om de veilige toepassing van medische technologie te onderzoeken, II) zich moeten richten op de veiligheid van de inzet van technologie buiten de muren van het ziekenhuis, en III) potentiële patiëntveiligheidsrisico's moeten bestuderen die verband houden met medische software en informatietechnologie in de gezondheidszorg, waaronder de opkomende toepassing van kunstmatige intelligentie.

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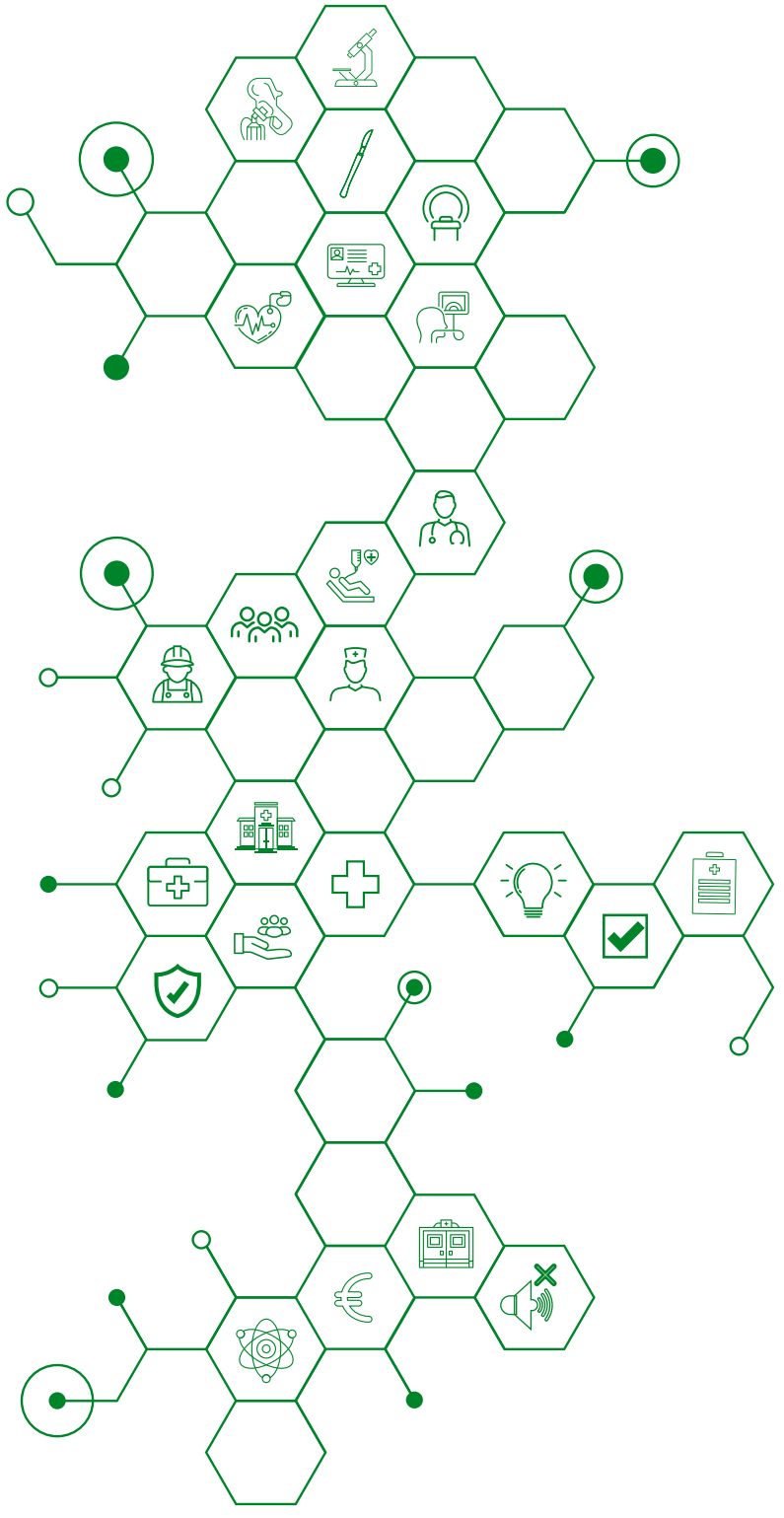

Addendum

Definitions and abbreviations
List of publications
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DEFINITIONS AND ABBREVIATIONS

KEY DEFINITIONS

Adverse event	An unintended injury, resulting in prolongation of hospital stay, temporary or permanent disability or death, and is caused by healthcare management rather than by the patients' disease.
Human Factors/Ergonomics	The scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance. Ergonomists contribute to the design and evaluation of tasks, jobs, products, environments and systems in order to make them compatible with the needs, abilities and limitations of people[1].
Medical device	Any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more specific medical purposes (e.g. diagnosis, prevention, monitoring, treatment, etc.)[2].
Sentinel event/Serious adverse event	An unintended and unexpected event related to the quality of care and having caused death or serious patient harm[3].

ABBREVIATIONS

AE	Adverse Event
AEMD	Adverse Event(s) involving a Medical Device
DEER	Diagnostic Error Evaluation and Research Taxonomy
ECM	Eindhoven Classification Model
ECRI	Emergency Care Research Institute
ED	Emergency Department
EUDAMED	EUropean DAtabase on MEdical Devices
GAM	Generic Analysis Method
IVDR	(The European Union) In Vitro Diagnostics Regulation
MAUDE	Manufacturer And User facility Device Experience
MDR	(The European Union) Medical Device Regulation
PRISMA	Prevention and Recovery Information System for Monitoring and Analysis
RCA	Root Cause Analysis
SAE	Serious Adverse Event
SE	Sentinel Event
SEIPS	Systems Engineering Initiative for Patient Safety
SEMD	Sentinel Event(s) involving a Medical Device
SIRE	Systemic Incident Reconstruction and Evaluation

1 As defined by the International Ergonomics Association
2 Derived from the definition in the European Medical Device Regulation
3 As defined in the Dutch law on quality, complaints and disputes in healthcare (In Dutch: Wet kwaliteit, klachten en geschillen zorg)

LIST OF PUBLICATIONS

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OTHER PUBLICATIONS

Baartmans, M., Schoten, S. van, Wagner, C. Ziekenhuisoverstijgende analyse van calamiteiten: een retrospectieve analyse van calamiteitenrapportages uit 28 algemene Nederlandse ziekenhuizen. Utrecht: Nivel, 2020. 59 p.

Baartmans, M., Keuper, J., Schoten, S. van, Bosmans, M., Wagner, C., Batenburg, R. Personele bezetting en patiëntveiligheid in de medisch specialistische ziekenhuiszorg: een verkenning van de wetenschappelijke literatuur en synthese van openbare cijfers in Nederland. Utrecht: Nivel, 2021. 94 p.

Schoten, S. van, Eikenhorst, L. van, Schouten, B., Baartmans, M., Bruijne, M. de, Jong, L. de, Waals, M., Asscheman, H., Wagner, C. Monitor Zorggerelateerde Schade 2019: dossieronderzoek bij overleden patiënten in Nederlandse ziekenhuizen. Utrecht: Nivel, 2022. 126 p.

Baartmans, M., Tuyl, L. van, Wagner, C. Samen leren van calamiteiten: ziekenhuisoverstijgende analyse van calamiteiten rond diagnostiek. Dordrecht/Utrecht: mProve/Nivel, 2023. 16 p.

Baartmans, M., Friele, R. Inducement in the medical device industry: an exploratory literature study. Utrecht: Nivel, 2023. 55 p.

PORTFOLIO

Activity & institute	Year	ECTS
Courses		
STATA voor beginners, *Nivel*	2019	0.5
Academic writing, *Babel*	2020	1.00
Persoonlijke effectiviteit, *Boertien Vergouwen Overduin*	2020	0.5
Research integrity, *VUmc Academie*	2021	2.00
Aansluiten bij stakeholders, *Boertien Vergouwen Overduin*	2021	0.40
Principes van epidemiologische data-analyse, *EpidM – Amsterdam UMC*	2021	1.30
De kunst van het netwerken, *GoodHabitz*	2022	0.10
Epidemiologisch onderzoek: basisprincipes, *EpidM – Amsterdam UMC*	2022	4.00
Human Factors Short Course, *Monash University – Department of Anesthesiology and Perioperative Medicine*	2022	1.29
Helder communiceren over je onderzoek, *Nivel*	2022	0.39
Talents in PhD, *Amsterdam UMC Doctoral School*	2022	0.20
Didactical skills, *Amsterdam UMC Doctoral School*	2022	0.40
Doelmatigheidsonderzoek: methoden en principes, *EpidM – Amsterdam UMC*	2023	1.30
Webinars		
Human Factors in Health and Social Care, *ISQua*	2020	0.04
The Importance of Human Factors in Preventing Harm and Protecting Workers, *ISQua*	2020	0.04
Critical Crisis Thinking Learning Journey, *ISQua*	2020	0.04

Continued.

Activity & institute	Year	ECTS
Teaching and student supervision		
Tutorial supervisor 'practica medische missers', *Amsterdam UMC*	2019, 2022 & 2023	1.50*
Thesis supervisor BSc student Health Sciences, *Vrije Universiteit*	2021	1.00
Symposium Team Resource Management, *Amsterdam UMC*	2023	0.43
Other activities		
Academic meeting – OKPV, *Amsterdam UMC & Nivel*	2019-2023	2.00
Academic meeting – WO, *Nivel*	2019-2023	3.00
Intervision junior researchers/PhDs *Nivel*	2019-2023	1.50
Nivel Representative PhD-Education Commission, *CaRe Research School*	2019-2023	2.00
Internal auditing, *Nivel*	2020	0.5
Invited speaker, Webinar 'Ziekenhuisoverstijgende analyse van calamiteiten', *Samenwerkende Algemene Ziekenhuizen & Nivel*	2020	0.5
Invited speaker, Master class 'Ziekenhuisoverstijgende analyse van calamiteiten', *General hospital 1*	2021	0.25
Invited speaker, Master class 'Ziekenhuisoverstijgende analyse van calamiteiten', *General hospital 2*	2022	0.25
Peer reviewing *Journal of Patient Safety*	2022 & 2023	0.5*
(Inter)national conferences		
Wetenschapsdagen, including oral presentations, *Nivel*	2020 & 2022	0,5
Annual CaRe days, *CaRe Netherlands School of Public Health and Care Research*	2021 & 2022	2.00
International Forum on Quality and Safety in Healthcare, including oral presentation, *Institute for Healthcare Improvement & British Medical Journal*	2022	2.00
International conference Healthcare Systems Ergonomics and Patient Safety, including oral presentation, *International Ergonomics Association*	2022	2.00

Continued.

Activity & institute	Year	ECTS
Ronde tafel conferentie SLIM 2030, *TU Delft Centrum voor Veiligheid in de Gezondheidszorg*	2022	0.29
APH's Annual Meeting, *Amsterdam Public Health Research Institute*	2022	0.30
Other activities		
Organisation publication day 'Monitor zorggerelateerde schade', *Amsterdam UMC & Nivel*	2021	1.00
Advisor taskforce risk profile diagnostic processes, *Kennisinstituut Federatie Medisch Specialisten*	2021	0.10
		32.82 in total *
Awarded grants and research applications		
Research proposal for mProve, Gezamenlijk leren van calamiteiten – Een ziekenhuisoverstijgende analyse van aan diagnostiek gerelateerde calamiteiten *Nivel*	2021	
ZonMw call Safety-II en veiligheidsergonomie, co-applicant *Nivel*	2022	
Research proposal for the Dutch health and youth care inspectorate, Gunstbetoon in de Medische Hulpmiddelen Sector – Een verkennend literatuuronderzoek *Nivel*	2023	
Nivel Travel Grant *Nivel*	2023	

*Only those activities approved by the APH Education committee are accounted for in the ECTS total

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Mees

ABOUT THE AUTHOR

Mees Baartmans was born in Schiedam, the Netherlands, on the 28th of February 1995. He completed secondary school (Atheneum) at S.G. Spieringshoek Schiedam in 2013, following which he commenced his bachelor's degree in Healthcare Technology at the University of Applied Sciences in Rotterdam in 2014. During his studies, Mees undertook internships at the Clinical Physics and Technology department of Maasstad Hospital in Rotterdam, and at the Safety and Risk Management department of RPS Consulting and Engineering Services in Delft. Mees graduated in 2017 and enrolled in the premaster program Health Sciences at Erasmus University Rotterdam, and pursued with the Master Health Economics, Policy and Law from which he graduated with a Master of Science degree in 2019. In July that same year he started the PhD project on patient safety and medical devices as outlined in this thesis at the Netherlands Institute for Health Services Research (Nivel) in Utrecht and Amsterdam Public Health Research Institute, Amsterdam UMC, Amsterdam. Presently, Mees is employed at Nivel as a health services researcher, actively engaged in various research projects within the domain of healthcare organization and quality, with particular emphasis on medical devices and patient safety.