

Safe Use of Medical Devices in Dutch Hospitals



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VRIJE UNIVERSITEIT

SAFE USE OF MEDICAL DEVICES IN DUTCH HOSPITALS

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CHAPTER 1

General introduction

TO ERR IS HUMAN

“The problem is not bad people in health care--it is that good people are working in bad systems that need to be made safer”.¹

The Harvard Medical Practice Study was the first study to estimate the number of adverse events (AEs) in hospitalised patients. It estimated that AEs occurred in 3.7% of hospitalisations, and that 27.6% of the AEs were due to negligence.² The Institute Of Medicine aimed to improve the safety of patients by designing processes of care to ensure that patients are safe from AEs. This led to growing international awareness of the fact that the hospital is not naturally a safe place for patients. Despite the growing interest in patient safety and the increasing number of safety regulations around medical devices, little is known about their safe use.

Several countries initiating research to improve patient safety often measure harm as a starting point. Even though a shift is going from safety-I thinking ensuring that ‘as few things as possible go wrong’ to safety-II thinking, ensuring that ‘as many things as possible go right’.³ Following the example of the Harvard Medical Practice Study, research groups from all over the world carried out similar studies in their own countries. These studies look into the incidence of AEs and whether these AEs could have been prevented. An AE is defined by three criteria: 1) an unintended injury, 2) resulting in prolongation of hospital stay, temporary or permanent disability or death, 3) caused by healthcare management rather than by the patients’ disease. A review from studies published until February 2007 showed AE rates between 2.9 and 16.6%, with a preventability between 37.1 and 51.2%.⁴ Also, more recent studies showed similar results.⁵⁻¹¹ The Netherlands performed multiple nationwide studies that showed a decrease of potentially preventable deaths from 4.1% of all hospital admissions in 2004 to 3.1% in 2015/2016.^{12-15w}

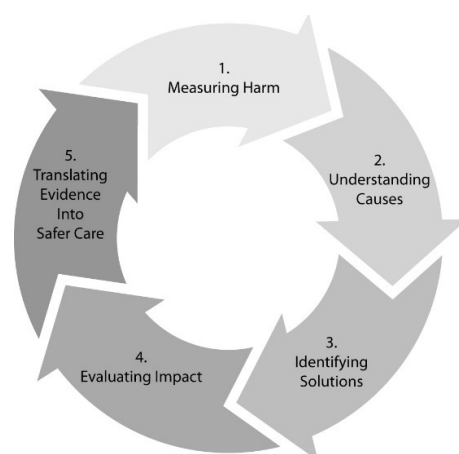


Figure 1. Patient safety cycle¹⁶

Measuring the incidence of AEs is a first important step in the improvement of patient safety, but will not automatically lead to the desired improvement. As can be seen in Figure 1, a cycle has to be followed to improve safety and to continue improving.¹⁶ In this cycle the measurement of harm (AEs) is the first of five steps: measuring harm, understanding causes, identifying solutions, evaluating impact, and translating evidence into safer care.¹⁷ In the Netherlands, several programmes were launched to improve patient safety since 2004.^{18, 19} The most extensive national safety programme, ‘Prevent harm, work safely’, ran from 2008 until 2012.¹⁹ In this programme all Dutch hospitals could participate, with the implementation of a safety management system as the main focus. Furthermore, interventions on ten specific themes, such as high-risk medication and the prevention of infections after surgery, were developed and could be used by all hospitals. Before and after this safety programme an AE measurement was performed to assess the effects.²⁰ This study showed some improvements in preventable adverse events in general. Moreover, improvement was found in the areas that were addressed during the comprehensive national safety programme, for example in the number of postoperative infections.²¹ Although a decrease in the number of AEs was found after the national safety programme, new focuses emerged from the research. One of these focal points was medical devices. Despite the overall decrease of AEs, the percentage of patients with an AE related to medical devices (AMDE) increased from 2.3% in 2008 to 2.9% in 2011/2012.^{12, 14}

Safety of medical devices

Medical devices have the potential to improve the quality and safety of healthcare. However, their introduction and use also carry risks for the safety of patients and staff.²² The UK National Health Services estimated 6,600 AMDEs in 1999 in the United Kingdom, including 87 deaths and 345 serious injuries.²³ Moreover, the US Food and Drug Administration (FDA) receives 80,000 to 120,000 AMDE reports every year, although it is not clear whether all of these events led to patient harm.²⁴ Most of these reports come from manufacturers; about 5,000 are received from medical facilities. It is estimated that this is a huge underreporting of AMDEs and that only 0.5% of all AMDEs are reported to the FDA.²⁵ Other studies also show the importance of improving the safety and safe use of medical devices in various settings. For example, a study of 44 tertiary care, paediatric hospitals in the USA showed that 3.3% of the admitted children suffered an AMDE on or during their admission.²⁶ Another study where operation room nurses reported equipment-related incidents during surgery procedures found 148 incidents in 1,580 surgeries.²⁷ Moreover, from 4,188 AMDEs in anaesthesia and intensive care that were reported to the French safety database in 2005 and 2006, 7% were severe and 2% were fatal.²⁸ Furthermore, qualitative studies show that the safety of medical devices can be improved. For example, a study by Sahlström et al. showed that patients experience device safety as the worst aspect of safety in hospitals compared to treatment and medication safety.²⁹ Another study among

119 radiologists found that 80% of the respondents had experienced an incident related to the failure of a medical device.³⁰

These AMDEs happen despite the regulations that are implemented for medical devices. Medical devices have to be approved before they are allowed to enter the market.³¹ Some countries like the USA, China and Japan have one regulatory system for both medication and medical devices.³² In contrast, medical devices in the EU are regulated in a similar way to any other customer product.³² These (inter)national regulations are mainly focused on the safety of medical devices and to a lesser extent on the local context and safe use of medical devices. Before medical devices are allowed to enter the market, there is a pre-market evaluation. This evaluation is similar in most countries and depends on the respective risk related to a medical device.³¹ The amount and type of research required before a device is approved depends on which risk class it belongs to. Next to the national tools there are risk assessment tools specifically developed for the use within hospitals. An example of such a tool is developed by the American Society for Healthcare Engineering.³⁴ These tools are not mandatory to use, but might assist hospitals in taking the necessary precautions for the safe use of medical devices. In the Netherlands, hospitals use prospective risk assessment tools as part of their safety management system to identify and minimise risks in health care processes, including the use of medical devices.³⁵ Although precautions are taken, medical devices that cause or contribute to AMDEs are still able to enter the market and hospitals.^{32, 36} Various countries have implemented a database that registers AMDEs. Depending on the country, only manufacturers or both manufacturers and user facilities (e.g. hospitals) are required to report AMDEs shortly after their occurrence.³¹ These AMDEs are registered in databases and are used to recall unsafe medical devices as well as for research purposes.³⁶

In addition to the European regulations, the Netherlands has its own laws and regulations concerning medical devices. The most important one is the law on medical devices, in which the European regulations are put into the Dutch context.³⁷ A more recent law that includes medical devices is the law on quality, complaints and disputes in healthcare.³⁸ This law is aimed at the safe use of medical devices by healthcare staff. The law stipulates that proficiency requirements should be available for all medical devices, and that staff that works with medical devices should meet the proficiency requirements. Next to the laws, there are national guidelines with which the hospitals must comply. In 2011, national guidelines were developed in the Netherlands to improve the safe application of medical devices in hospitals. The 'Covenant safe application of medical devices in hospitals'³⁹ (hereafter: covenant) was commissioned by representatives of all Dutch hospitals and supports the risk management and safe application of medical devices in patient care. The guidelines in the covenant facilitate the safe implementation, use and disposal of medical devices by providing support and interpretation with regard to the risk management

and safe use of medical devices in patient care. In this, the safe application of medical devices means a safe product, in the hands of a trained user in an environment that can guarantee safe use. These three aspects are of uttermost importance for the safety of medical devices and the prevention of AMDEs. In this thesis we focus on the safe use of medical devices by a trained user.

Origin of AMDEs

AMDEs are typically caused by several factors, organisational and structural defects as well as human errors.⁴⁰ A subdivision of five classes of AMDEs are: device error, user error, external factors, support system failures, and errors related to tampering and sabotage.⁴¹ Studies focused on the safety of medical devices often find human errors involved in a large proportion of AMDEs. Rates of human involvement were found in 70% up to 87% of AMDEs.⁴² Although the origins of AMDEs are often described as human factors, including users' inexperience, studies suggest that they are typically multifactorial in origin.^{40, 41, 43} For example, one study in operating theatres showed that AMDEs are related to equipment configuration and setting (43%), unavailability at the point of need (37%) and device malfunctioning (34%).²²

A method to better understand the origin of errors is the system approach, which suggests that humans are fallible and errors are to be expected, even in the best organisations. A commonly used method to explain the system approach is Reasons' Swiss cheese model, an example of which is presented in Figure 2.⁴⁴ This approach concentrates on the conditions under which people work, and tries to build defences to prevent errors.

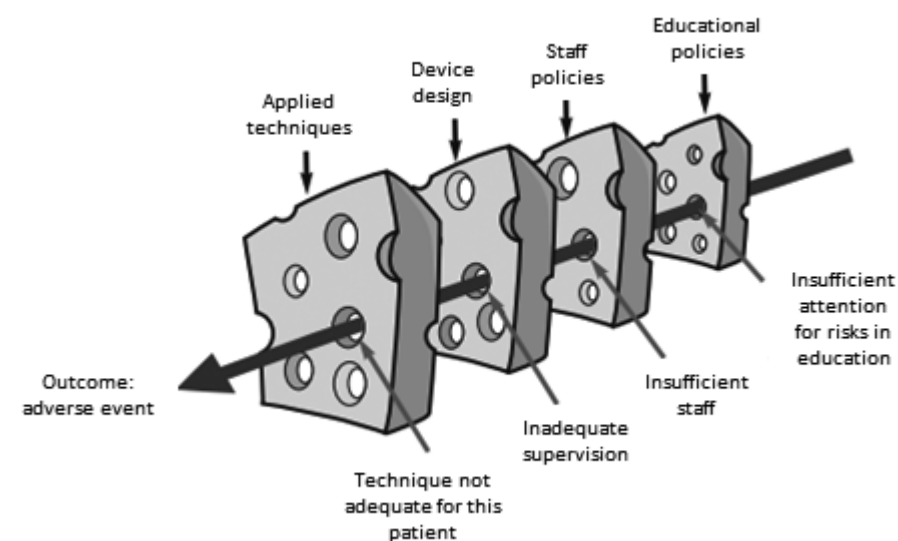


Figure 2. Swiss cheese model¹⁸

These defences are represented by the slices of cheese, where each of these barriers have unintended weaknesses or holes. These weaknesses are inconstant, i.e. the holes open and close at random. When by chance all holes are aligned, the hazard reaches the patient and causes harm.

The model includes two types of factors that could lead to errors, namely active and latent factors. Active failures are 'unsafe acts' committed by those who are in direct contact with the patient or system. They have a direct and usually short-lived impact on the integrity of the defence, for example slips, lapses, fumbles, mistakes, and procedural violations. Latent conditions develop over time and lie dormant before combining with other factors or active failures to breach a system's safety defences. These conditions arise from decisions made by designers, builders, procedure writers, and top-level management. The decision itself might be a correct one, but could be a hazard for the system in combination with other decisions. Latent conditions can lead to two kinds of unwanted effects. The first are error provoking conditions within the local workplace, for example time pressure, understaffing and inadequate equipment. The second can create long-lasting holes or weaknesses in the defences, for example untrustworthy alarms, or unworkable procedures and design.

The Swiss cheese model suggests that the conditions under which people work influence the occurrence of errors. For example, a lack of training, insufficient supervision or inadequate device design.^{45,46} In modern healthcare the time available for medical education is shortened, while the demand for education is increasing because of the growing number of medical devices.⁴⁷ To maintain the proficiency of users of medical devices, training should be adapted to the current, more demanding, environment.

Training for the safe use of medical devices

Training is an important aspect of improving the safe use of medical devices – not only for students, but also after graduation. This applies particularly to the fast-developing medical device field, where staff has to be trained continuously to be able to use devices in a safe way. Moreover, the need for continuous training is also recognised by governmental organisations. To demonstrate, current Dutch regulations demand that staff has to be trained to be proficient to use medical devices.³⁹ A proficient person has a deep understanding, sees actions holistically, and can achieve a high standard routinely.^{48,49} A model by Dreyfus and Dreyfus describes proficiency as one of the five developmental stages to acquire skills: novice, advanced beginner, competent, proficient and expert.⁴⁸ The difference between competent and proficient is mainly how the context is assessed. A competent person assesses the context analytically, while a proficient person does this holistically. The different aspects of competency in the medical field are described in the CanMEDS framework.⁵⁰ As can be seen in Figure 3, CanMEDS represent seven

roles for healthcare staff, with 'Medical Expert' as an integrating role. The other six roles are 'Professional', 'Communicator', 'Collaborator', 'Leader', 'Health Advocate' and 'Scholar'. The first step in becoming proficient is to acquire the necessary technical skills, which is part of the role of medical expert. This thesis focuses on the technical skill part of proficiency.

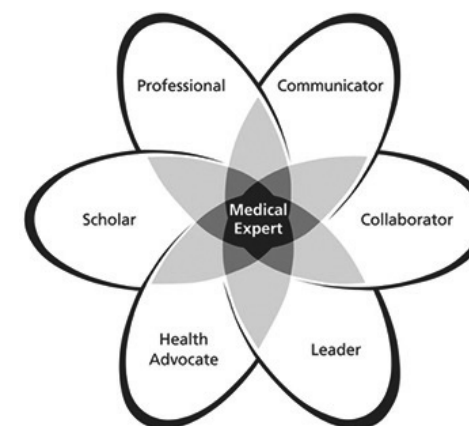


Figure 3. CanMEDS⁵⁰

Because of previous training and experience, it could be expected that staff is proficient. However, changes in working environment and developments of medical devices might require additional training. The amount of training depends on the person, as well as on someone's experience and ability to learn and adapt. Therefore, demotivating staff by unnecessary training could be prevented by competency-based training. In the past training used to be time-based and ended after a predefined time-span, but this is shifting to competency-based training that ends after a certain level of competency is reached. There is a growing interest in this type of training in the Netherlands, but also in other countries.⁵¹ Competency-based training has two possible advantages. The first is that some trainees will become proficient sooner, thus saving time and money.⁵² Second, the trainees who are not proficient within the previously required training time are trained until proficiency, and might therefore be less of a threat to patient safety.⁵³

With competency-based training, it is necessary to evaluate competencies on a regular basis. This is possible with summative and formative assessment methods. Summative assessment is the recording of the overall achievement in a systematic way. This assessment is seen as a final point of judgement, which has no influence on the process. Formative assessment is to recognise and discuss positive achievements, so that next steps can be planned. For an assessment to be formative, feedback is required, indicating the existence of a gap between the actual level of the

work being assessed and the required standard.^{54,55} Both summative and formative assessment can be used in competency-based training. Summative assessment can be used to assess whether someone has reached the desired competences and is able to use a medical device proficiently. Formative assessment can be used to evaluate which competences need further development and tailor training to these findings. Another advantage of assessment is the so-called testing effect or retrieval practice. This effect is described as the finding that retrieval of information from memory produces better retention than restudying the same information for an equivalent amount of time.⁵⁶ In other words, testing will help in learning and remembering knowledge and skills. Moreover, assessment can be used as a tool to support motivation to learn and improve.⁵⁷ For both the testing effect and the increase of motivation, formative assessment and in particular providing feedback is the best method.

RESEARCH QUESTIONS

In this thesis we look at the Dutch context, in which regulations became more extensive after implementation of the covenant on the safe application of medical devices in hospitals in 2011. We focus on two components of this covenant, which are the obligatory use of risk assessment tools and the obligatory continuous education of staff in the use of medical devices. It is expected that hospitals use these tools with the goal to improve patient safety, but little is known about how hospitals manage this. The aim of this thesis is to explore the safe use of medical devices in hospitals, and possible solutions to improve it. We formulated the following two research questions.

- 1) To what extent is the safety of patients in the Netherlands threatened by medical devices, and what are possible solutions to improve the safe use of medical devices?
- 2) How do Dutch hospitals apply proficiency testing to improve the safe use of medical devices, and what is the attitude of healthcare staff towards proficiency testing?

THESIS OUTLINE

The aim of this thesis is to gain more insight into the safe use of medical devices in Dutch hospitals. To achieve this aim, the research questions are answered with the help of the safety cycle of Figure 1.

To what extent is the safety of patients in the Netherlands threatened by medical devices, and what are possible solutions to improve the safe use of medical devices?

The answer to this question, and the first step of the safety cycle, measuring harm, is described in **Chapter 2**. In this chapter we describe the incidence, types and causes of AMDE in hospitals. This

information is extracted from patient records of 6894 admissions in 32 Dutch hospitals by trained nurses and medical specialists. The second and third step of the safety cycle is to understand the causes of the harm and to identify possible solutions. This is discussed in Chapters 2, 3 and 4. **Chapter 2** describes, next to the incidence of AMDEs, possible solutions to decrease the number of AMDEs. Two solutions are described in more detail in Chapter 3 and 4, respectively. **Chapter 3** describes the use of risk assessment tools in Dutch hospitals. We explore which risk assessment tools and criteria are used to assess the risk of medical devices in hospitals, and the link between the risk of a medical device and the training of staff. This information is collected within a questionnaire that was sent to all Dutch hospitals. In **Chapter 4**, the development of another solution, proficiency requirements and a proficiency test, is described. In this chapter we discuss how proficiency requirements can be developed using cognitive task analysis. Furthermore, we describe how a proficiency test can be developed based on proficiency requirements. This chapter focuses on a specific medical device, namely infusion devices as used by nurses within a hospital.

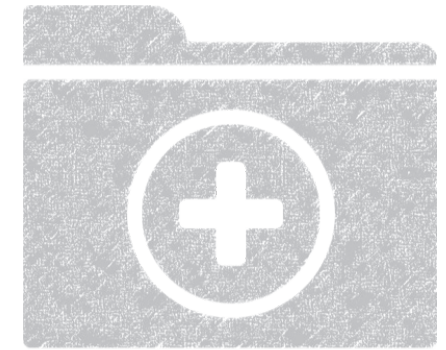
How do Dutch hospitals apply proficiency testing to improve the safe use of medical devices, and what is the attitude of healthcare staff towards proficiency testing?

The results and opinion of nurses about the proficiency test are described in **Chapter 4**. This is part of the fourth step of the safety cycle, evaluating impact. Furthermore, in **Chapter 5**, the perceptions of medical specialists towards proficiency and proficiency tests are explored. Based on the results of eleven interviews, we explore whether medical specialists wish to develop proficiency requirements and tests as a way to ensure proficiency. In **Chapter 6** we describe the current implementation of national guidelines on training, examination and registration of proficiencies for the safe use of medical devices, and explore the barriers faced by facilitators during the implementation of these national guidelines. This is the last step of the safety cycle, translating evidence into safer care. To collate this information a questionnaire was sent to all Dutch hospitals, and interviews were held in six hospitals. In this chapter the same questionnaire is used as described in Chapter 3. Finally, the general discussion is presented in **Chapter 7**. In this chapter we conclude with recommendations for practice and possibilities for further research.

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CHAPTER 2

The incidence and nature of adverse medical device events in Dutch hospitals, a retrospective patient record review study

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ABSTRACT

Objectives Despite widespread use of medical devices and their increasing complexity, their contribution to unintended injury caused by healthcare (adverse events, AEs) remains relatively understudied. The aim of this study is to gain insight in the incidence and types of AEs involving medical devices (AMDEs).

Methods Data from two patient record studies for the identification of AEs were used. Identification of AMDEs was part of these studies. Patient records of 6894 admissions of a random sample of 20 hospitals in 2011/2012 and 19 hospitals in 2015/2016 were reviewed for AMDEs by trained nurses and physicians.

Results In 98.7% of the admissions a medical device was used. AMDEs were present in 2.8% of the admissions, with 24% of the AMDEs being potentially preventable. Of all AEs, in 40% medical devices were involved. Of all potentially preventable AEs, in 44% medical devices were involved. Implants were most often involved in potentially preventable AMDEs.

Conclusions Medical devices are substantially involved in potentially preventable AEs in hospitals. Research into AMDEs is of great importance because of the increasing use and complexity of medical devices. Based on patient records, most improvements could be made for placement of implants and prevention of infections related to medical devices. Safety and safe use of medical devices should be a subject of attention and further research.

INTRODUCTION

In recent years, the availability and use of medical devices in healthcare have increased. At the same time, medical devices have become more complex.¹ Medical devices are defined as: 'The application of organized skills and knowledge in the form of devices that are developed to solve health problems and improve quality of life'.² The increased availability and use of medical devices has benefits for the patients as well as risks for patient safety. Medical devices facilitate diagnosis and treatment of diseases,³ but the increased use of medical devices could also increase the risk of adverse events (AEs).^{4,5} An AE is defined by three criteria: 1) an unintended injury, 2) resulting in prolongation of hospital stay, temporary or permanent disability or death, 3) caused by healthcare management rather than by the patients' disease. AEs happen in 3-17% of the hospital admissions and are potentially preventable in 37-51% of the AEs.⁶

It is unknown in how many AEs in hospitals a medical device is involved (AMDEs). One publication estimated over 6,600 incidents involving medical devices in the UK in 1999, including 87 deaths and 345 serious injuries.⁷ The total number of hospital admissions was around 8.5 million in that year. Several studies researched the number of incidents with medical devices, but did not look into the consequences for the patient.^{8,9} Other studies looked into AMDEs outside hospitals,¹⁰ AMDEs in specific settings^{5,11} and patient reported problems with medical devices.¹² Furthermore, one study showed that AMDEs are caused by several factors, particularly organizational and structural defects as well as use errors.¹³ As far as we know, no study identified the incidence of (potentially preventable) AMDEs in a representative sample of a hospital population.

One method to identify AMDEs is the use of registration databases in which healthcare staff report problems with medical devices.¹⁴ In some countries this reporting is voluntary, while in other countries mandatory.⁵ An example of such a database is the MAUDE registration system in the USA that contains medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as healthcare professionals, patients and consumers. It is estimated that there is a huge underreporting of AMDEs and that only 0.5% of all AMDEs are reported to the database.¹⁵ Europe and the Netherlands also have databases where manufacturers can report incidents (post-market surveillance) and Dutch hospitals have reporting systems for their staff. Those are not publicly available so little information is available about incidence and type of incidents. A registration database as a source is not ideal, because often only a part of AMDEs is reported. Even when reporting is mandatory, the reporting rates are lower than could be expected.^{16,17} Incident reporting rates could be low because AMDEs are not always recognized by hospital staff. This depends on the knowledge and professional experience of the staff, medical device performance and clinical manifestations of the patient.¹⁸ Furthermore, physicians may perceive AMDE

reporting as unnecessary, not possible or futile.¹⁹ Another source for identifying AMDEs are patient records, which are often used for identifying different types of AEs.^{14, 20, 21} Patient records provide information about the course of events during hospitalization, but may lack information about application of some types of medical devices. However, this method is currently recognized as the best method for identifying AEs and will give valuable insights in the incidence of AMDEs and types of medical devices involved.²²

The aim of this study is to gain insight in the incidence and types of medical devices involved in AMDEs in Dutch hospitals using patient records. These insights could be used as a starting point for further research and to develop new research strategies. Therefore, the research questions are: 1) What is the incidence of AMDEs in Dutch hospitals detected in patient records 2) Which types of medical devices are involved in AMDEs.

METHODS

Design and setting

The data used for this study were collected in two patient record review studies in the Netherlands with the aim to identify AEs in Dutch hospitals. The identification of AMDEs was part of these studies. These review studies are repeated every four years to monitor patient safety in Dutch hospitals. To achieve a confidence level of 99% with an expected incidence of 2.0% and a total width of the confidence interval of 1.0% a sample size of 5409 is needed.²³ Therefore, data from two consecutive periods were used for this paper. Patients records from 1 April 2011 until 31 March 2012 and from 1 April 2015 until 31 March 2016 were used.^{24, 25} The review of the records took place in 2012/2013 and 2016/2017 respectively. In 2011/2012, 20 randomly sampled Dutch hospitals participated, a representation of Dutch hospitals (20% of all hospitals). To be eligible, hospitals had to have at least 200 beds. The sample was stratified for hospital type (university(n=4), tertiary teaching (n=6) and general (n=10)) and verified for a representation of urban and rural settings. In each hospital, 200 patient admissions were randomly selected for review. Half of the sample were patients who deceased in the hospital, the other half of the sample concerned patients who were discharged alive. Patients admitted to the psychiatry department, obstetrics and children under one year of age were excluded, because the trigger tool used is not developed for these patient populations.²⁶ In 2015/2016, a new random sample of 19 Dutch hospitals was taken (four university, seven tertiary teaching and eight general hospitals). Of these hospitals six also participated in 2011/2012, this were two university and four tertiary teaching hospitals. In each hospital 150 patient admissions of patients who deceased in the hospital were randomly selected. Detailed information on the design of the study is published elsewhere.^{26, 27} To enhance accurate and complete reporting of

this study, the STROBE guideline was used.²⁸ The study protocol was reviewed and approved by the ethical review board of the VU University Medical Center.

Review procedure

All reviewed records for the study were screened for the use of medical devices and for AMDEs. First, we describe the general review process of patient records. Next, we describe the screening for the use of medical devices and the use of medical devices involved in AEs. The method of determining AEs was comparable to those of other international studies.^{21, 29} For every admission, the patients' nursing and medical records were reviewed by trained nurses and physicians. Nurses screened all records using screening criteria (triggers) indicating potential AEs, a description of the triggers can be found in appendix 1.²⁶ When one or more criteria were met, the record was reviewed by a physician. The nurse indicated which type of physician should review the record. Physicians were encouraged to discuss the record with (more specialized) colleagues when necessary. The physicians reviewed the records using a standardized procedure to determine presence and preventability of AEs following a questionnaire developed for this research. Physicians judged all events triggered by nurses using a six-point Likert scale to score the likelihood of cause by healthcare management as well as preventability. An AE was marked as caused by healthcare or as potentially preventable when physicians scored the AE a 4, 5 or 6 on the six-point Likert scale, indicating more likely(4), strong evidence(5) or certain evidence(6) of the AE being caused by healthcare or being potentially preventable. When an AE was marked as caused by healthcare management other questions about involved specialism(s), procedures, involvement of medication and medical devices and causes were asked. To ascertain reliability of the identification of adverse events and the perception of their preventability, 10% of the records were reviewed by two reviewers for both records that were screened by nurses and by physicians. There was moderate agreement among nurses for triggers, with a kappa statistic of 0.49 (95% CI 0.42 to 0.56) in 2011/2012 and a kappa statistic 0.60 (95% CI 0.55 to 0.66) in 2015/2016. The agreement between physicians' assessment for the presence of an AE was fair with a kappa of 0.40 (95% CI 0.33 to 0.46) in 2011/2012, and a kappa of 0.35 (95% CI 0.28 to 0.42) in 2015/2016.

During the review of the patient records by nurses, the nurses documented which medical devices were used during the admission. To simplify this documentation nurses filled in a predefined list of eight categories of medical devices that are often used or have high risks for the patients. There was an additional category 'other devices' in which nurses could write down all the other devices that were used. The eight categories were; infusion devices, ventilation, catheters, drains, surgical instruments and devices, implants, scopes and radiotherapy devices. The categories had different subcategories, to simplify the assessment whether a device from a category was applied. When the physician found an AE during the review of the records,

experienced physicians assessed whether a medical device was involved in the AE. A medical device was involved in the AE (AMDE) when the use of a medical device was perceived to have contributed to the occurrence of the AE. This focuses on the device itself, but also the application, the quality control and the organization around the use of the device. When it was unclear whether a medical device was involved in an AE, it was not scored as an AMDE.

Analysis

Descriptive characteristics of the samples were calculated with Stata 14 (StataCorp, 2015). Calculated characteristics were the frequency of the use of medical devices, AEs, AMDEs, potentially preventable AEs, potentially preventable AMDEs, potentially preventable deaths and causes of AMDEs. Because of the small, absolute number of AMDEs of both individual studies, we only present combined results. Characteristics were weighted for the sampling frame to make the total study sample representative for the total population of Dutch hospitalized patients. The outcomes were corrected for the oversampling of deceased patients, the difference in year and the distribution of the type of hospitals. The sample weight was the inverse of the probability of being included in the sample due to the sample design. The sample consists of all patients included in the analysis from both 2011/2012 and 2015/2016. The weighted percentages presented in this article are a percentage of the whole hospitalized population of both inclusion periods.

RESULTS

In total 6894 patient records were reviewed: 4871 inpatient deaths and 2023 discharged alive. In 6832 of the 6894 admissions (weighted 98.7%) a medical device was used. An AMDE occurred in 244 patients, in 10 patients 2 AMDEs occurred and in 1 patient 3 AMDEs occurred, making the total number of events 255. Figure 1 provides an overview of all admissions, the occurrence of AMDEs, potentially preventable AMDEs and potentially preventable deaths related to AMDEs. Of all patients, 2.8% suffered from an AMDE. AMDEs were not always preventable, but in 0.7% of the admissions there was a potentially preventable AMDE. In 0.05% of all patient records, the death of the patient was potentially preventable and the use of a medical device was perceived to have contributed to the occurrence of the AE. When examining all AEs, AMDEs accounted for 40% of all AEs. For potentially preventable AEs, the percentage in which medical devices were perceived to have contributed was 44%.

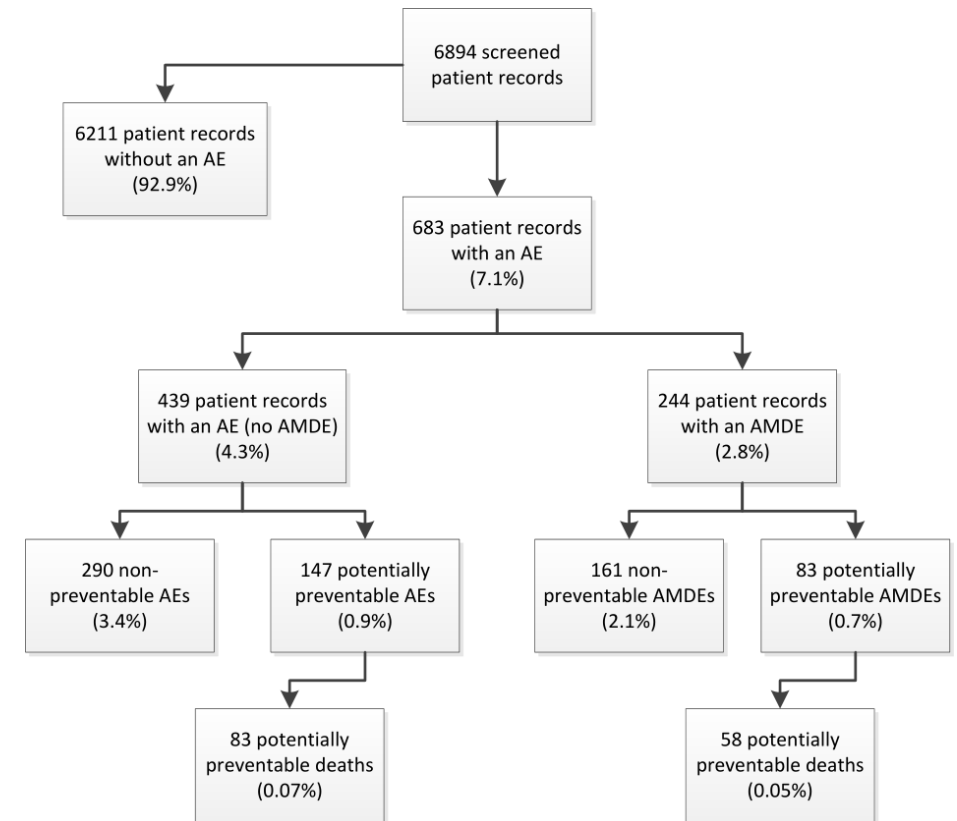


Figure 1. Incidence of (potentially preventable) AMDEs, AEs and deaths. Percentages are weighted as a percentage of the whole hospitalized population.

The percentage of AMDEs and potentially preventable AMDEs for different types of medical devices is shown in Figure 2. Relatively, most AMDEs (6.6%) were related to the placement of an implant or the care around this placement. The medical devices that were most often involved in potentially preventable AMDEs were also implants (1.2%). Percentages and 95% confidence intervals can be found in appendix 2. AMDEs that were not related to the use of one of the predefined categories of devices were placed in the category other. Examples of these AMDEs were rectum perforation after an enema, internal bleeding after tight fixation, empty oxygen tanks and bleeding during extracorporeal membrane oxygenation.

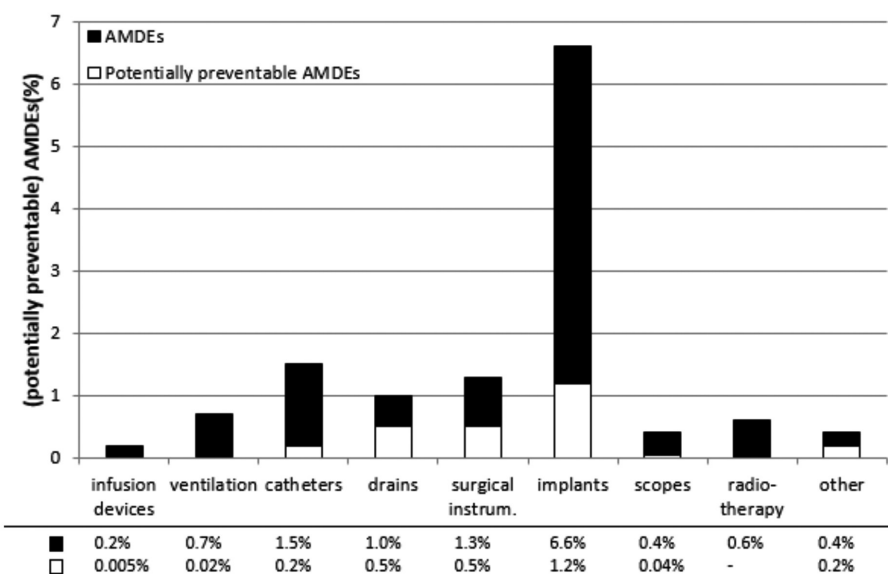


Figure 2. AMDEs and potentially preventable AMDEs for different types of medical devices in hospitals as weighted percentage of all the patients in which this medical device was used. The AMDEs are presented as a percentage of the hospitalized patients in which the medical device was used.

AMDEs were most common related to infection, sepsis and incorrect placements and procedures. About 24% of the AMDEs were potentially preventable. Most of those potentially preventable AMDEs were because of late or inadequate diagnoses, treatments and procedures and because of procedures performed without a clear indication. Examples of AMDEs including the causes are shown in Table 1.

Table 1. Examples of AMDEs with the involved medical devices and causes.

Description AMDE	Involved medical device
Non-preventable AMDEs	
Infection of a PEG tube causing a delay of a thorascopy	PEG (Percutaneous endoscopic gastrostomy) tube
Pneumothorax during the placement of a pacemaker	Implant (pacemaker)
Double-sided tension pneumothorax during PEEP (positive end-expiratory pressure) ventilation due to double-sided pneumonia	Ventilation
Dissection of a coronary artery during a percutaneous coronary intervention	PCI (percutaneous coronary intervention)
Potentially preventable AMDE	
Late diagnosis of a perforation of the colon during a colonoscopy	Scopes (colonoscopy)
Faulty laparoscopic equipment causing an unnecessary lengthening of the procedure	Laparoscopy
Inadequate procedure of fixation of the ankle for which reoperation of the ankle was necessary	Implant (osteosynthesis)
Extensive injuries of bladder and urethra caused with a urinary catheter after removing of the catheter by the patient. The patient had 5 urinary catheters with insufficient fixation and preventive care	Urinary catheter
Potentially preventable death related to an AMDE	
87-year-old patient with aortic valve disease who was admitted with bacterial endocarditis after a phlebitis not treated with antibiotics.	Peripheral infusion
Perforation of the bladder when inserting a suprapubic catheter followed by urosepsis, acute heart failure, reoperation and death	Suprapubic catheter
Difficult start of a laparoscopic procedure of an incisional hernia after which was converted to an open procedure. A colon perforation and that the small intestine was stitched to the colon were not recognized	Robotic surgery
Infection of the hip prosthesis for which no diagnostics and treatment was done	Implant (hip prosthesis)

DISCUSSION

In 2.8% of all admissions in Dutch hospitals an AMDE occurred. These AMDEs were potentially preventable in a quarter of the cases, in 0.7% of all admissions. Most AMDEs were related to the use of implants, mostly joint implants and implants around or in the heart. Most potentially preventable AMDEs also were implants. Other categories with a high amount of potentially preventable AMDEs were drains and surgical instruments and devices. Potentially preventable

AMDEs with surgical instruments and devices were often inadequate laparoscopic procedures, for example a not recognized perforation.

Our finding that AEs occur in 7.1% of the admissions fits in with other studies with AEs in 3.2-16.6% of the hospital admissions.⁶ Compared to these findings the number of AEs is in the lower range in comparison with other countries. However, these studies did not examine the number of AEs in which a medical device is involved. Our finding of the involvement of medical devices in 40% of the AEs shows that medical devices substantially contribute to AEs in hospitals. Two common medical devices involved in AMDEs, implants and laparoscopes, are both related to surgery. Other studies also showed that AEs related to surgery are more prevalent than non-surgical AEs.^{6,30} There are several possible explanations. Besides a higher risk for patients, it could be that a better registration of surgical events or the presence of many medical devices in an operating room are reasons for the difference.³⁰ Moreover, AEs related to surgery, for example infections and bleedings, are often more visible and have more serious consequences for the patient.^{31,32} Medical devices could also lead to less visible events. For example, delayed treatment because of incorrect settings of an infusion pump,³³ indirect harm of longer anaesthesia because of faulty devices during surgery⁹ and a longer recovery time because of increased blood loss during surgery.³⁴ This kind of AMDEs might be hard to recognize in patient records and could therefore be underreported with the current study method.

Despite the best available method to identify AEs is used,²² the current method of reviewing might give a underestimation of medical devices in relation to AE. Moreover, the method is known to have a low reliability.⁶ Preferably, a method for record reviewing focused on AMDEs should be developed. A first step could be to develop a new trigger tool that uses data of medical devices and technology to register abnormalities, for example in physical parameters, surgery lasting longer than expected or automatic detection of infections in patient records.¹² Also, techniques like big data and pattern recognition could help in identifying abnormalities. A study showed that it is possible to develop automatic detection tools to detect rare AMDEs.³⁵ Another study showed the use of machine learning and a national implant database to detect AMDEs.³⁶ Although these methods are not yet developed to detect AMDEs in general, it might be possible to alter or expand these methods to make this possible. Furthermore, qualitative methods like observations and interviews with staff could help in getting more insight in AMDEs and might increase the awareness of staff.³⁷ This makes it possible to study possible AMDEs with other sources than only patient records and eventually could be used to improve patient safety. For example, these methods could be used to get more insight in the role of medical devices in AMDEs and the possible preventability measures.

Even though it is plausible that not all AMDEs were recognized, this study has found a considerable number of AMDEs. Medical devices make diagnosis and treatment of diseases possible and could possibly prevent AEs, but are also causing AMDEs.³⁸ Other studies have found that AMDEs are often caused by human-technology interaction.^{38,39} These kind of interactions might be difficult to detect in patient records. For example, when a laparoscopic procedure went wrong, it might not be clear from the record whether it was because someone chose wrong settings (human), because the device did not work correctly (technical) or because someone pushed the wrong function because of illogical design (human-technology interaction). More knowledge into system interaction and human factors is needed to gain a more reliable insight in the causes of AMDEs. Medical devices are increasingly designed to be user-friendly and to prevent AEs. However, medical devices are not designed to prevent all unpredictable use errors.^{40,41} Post-market surveillance might be helpful to learn from unexpected use error by using a medical device. Post-market surveillance is a combination of activities that the manufacturer must perform to monitor the safety and performance of the product. In most countries this results in a database with AMDEs that can be used to improve patient safety.¹⁵ Moreover, design of devices and the suitability for healthcare staff to work with them should be taken more into account. By investigating the variables that affect user performance, proper design of a device could assist users to accomplish their tasks efficiently, effectively and safely.⁴²

Moreover, a high percentage of the AMDEs are judged to be not preventable. Compared to AEs, which show a preventability of 37.1-51.2%,⁶ our finding of a potential preventability of 24% is low. This could be caused by the introduction of new risks with new devices, that might not be preventable right away.⁴³ Developments should also focus on the identification of these risks and finding ways to prevent these risks. In this study, laparoscopic surgery is a frequent cause of AMDEs. Laparoscopy is used instead of open surgery and has benefits for the patient, like shorter recovery time and smaller scars.⁴⁴ Even though it causes a considerable number of AMDEs, several studies show lower AMDE rates compared to open surgery.^{45,46} However, it brings other risks that surgeons have to take into account and should be aware of.⁴⁷ For example, damaging of internal structures without noticing.

To prevent the hazards that emerge with new technologies training of staff is important. AMDEs can be caused by the interaction between human and medical devices. This could, for example, be caused by new functions of the device or a change in interface. A simulation centre could support learning outside the real patient situation, and therefore without harm to patients.⁴⁸ Simulation based medical education enables knowledge, skills and attitudes in a safe and efficient manner.⁴⁹ Furthermore, new settings and unexpected events could be trained in a safe way. New devices even require more training and giving professionals the chance to pursue a learning curve.⁴⁹ An example is robotic surgery, which brings considerable changes to the operating room.

Visible contact with the surgeon is not possible when a surgeon is engaged with a robot, which has a huge impact on communication and teamwork.⁵⁰ Suboptimal teamwork and communication are known threats for patient safety and should be important subjects in training.⁵¹

One of the strengths of the study is that many patient records were reviewed by qualified nurses and physicians in a structured manner. The records were reviewed retrospectively following international guidelines that are currently recognized as the best method for identifying AEs.²² However, the retrospective review of records is a limitation of the study and could lead to hindsight bias. Hindsight bias is the influence of the knowledge of the outcome and severity on the judgement. This might overestimate the incidence of AMDEs. Another limitation of the study is that the reviewing depends on the information in the patient record that is sometimes limited, especially about the use of medical devices. This could make it difficult to find the relation between AEs and medical devices. However, the reviewers only classified the AE as an AMDE when they were certain there was a relation between the AE and a medical device. Moreover, the assessment of the contribution of medical devices to AEs was done by one reviewer, which makes it impossible to show the agreement between reviewers for AMDEs. However, the agreement between reviewer for AEs in general are sufficient to show the reliability of the used method.⁵²

CONCLUSION

This study is the first study that gives an overview of AMDEs in hospitals. AMDEs occur in 2.8% of all Dutch hospital admissions, a quarter of these AMDEs potentially could have been prevented. All kinds of medical devices are involved in AMDEs, but implants are most prevalent. Implants cause most AMDEs and most potentially preventable AMDEs. Other research methods should be used to analyse the root causes of AMDEs and to get more insight in the interaction between humans and medical devices. Research into AMDEs is of great importance because of the increasing use of medical devices, their increasing complexity and the changes in healthcare because of the introduction of new medical devices. This study shows that safety and safe use of medical devices should be a subject of attention and further research.

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APPENDIX 1

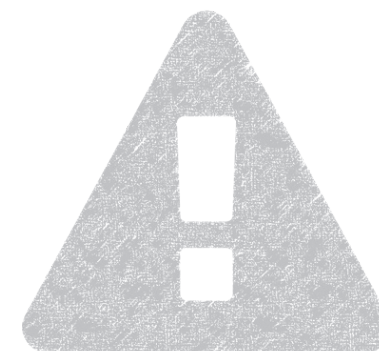
Screening criteria for potential adverse events

1. Unplanned readmission within 12 months after discharge from index admission
2. Hospital-incurred patient injury (Permanent or temporary injury obtained (acquired) during index admission)
3. Adverse drug reaction
4. Unplanned transfer from general care to (an) intensive care (unit)
5. Unplanned transfer to another acute care hospital (after unexpected deterioration of the patient)
6. Unplanned return to the operating room
7. Unplanned removal, injury or repair of organ during surgery
8. Hospital-acquired infection or sepsis
9. Other patient complication
10. Development of neurological deficit not present on admission
11. Unexpected death
12. Cardiac or respiratory arrest
13. Dissatisfaction with care documented in the medical record and/or documentation or correspondence indicating litigation
14. Any other undesirable outcome not covered above

APPENDIX 2

AMDEs and potentially preventable AMDEs for different types of medical devices as weighted percentage and 95% confidence interval of all hospitalized patients in which this medical device was used.

Medical device	AMDEs (%[95%CI])	Potentially preventable AMDEs (%[95%CI])
Infusion devices	0.2 [0.1-0.5]	0.005 [0.002-0.01]
Ventilation	0.7 [0.1-4.2]	0.02 [0.002-0.1]
Catheters	1.5 [0.8-2.6]	0.2 [0.03-0.8]
Drains	1.0 [0.4-2.5]	0.5 [0.1-1.9]
Surgical instruments and devices	1.3 [0.7-2.2]	0.5 [0.2-1.2]
Implants	6.6 [4.5-9.6]	1.2 [0.5-3.0]
Scopes	0.4 [0.1-2.3]	0.04 [0.02-0.08]
Radiotherapy	0.6 [0.2-2.1]	-
Other	0.4 [0.2-1.0]	0.2 [0.1-0.7]



CHAPTER 3

Exploring medical devices: The use of risk assessment tools and their link with training in hospitals

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ABSTRACT

Objectives The aim of this study was to explore the risk assessment tools and criteria used to assess the risk of medical devices in hospitals, and to explore the link between the risk of a medical device and how those risks impact or alter the training of staff.

Methods Within a broader questionnaire on implementation of a national guideline, we collected quantitative data regarding the types of risk assessment tools used in hospitals and the training of healthcare staff.

Results The response rate for the questionnaire was 81 percent; a total of sixty-five of eighty Dutch hospitals. All hospitals use a risk assessment tool and the biggest cluster (40 percent) use a tool developed internally. The criteria used to assess risk most often are: the function of the device (92 percent), the severity of adverse events (88 percent) and the frequency of use (77 percent). Forty-seven of fifty-six hospitals (84 percent) base their training on the risk associated with a medical device. For medium- and high-risk devices, the main method is practical training. As risk increases, the amount and type of training and examination increases.

Conclusions Dutch hospitals use a wide range of tools to assess the risk of medical devices. These tools are often based on the same criteria: the function of the device, the potential severity of adverse events, and the frequency of use. Furthermore, these tools are used to determine the amount and type of training required for staff. If the risk of a device is higher, then the training and examination is more extensive.

INTRODUCTION

Although patient safety is a priority within healthcare across the globe, medical errors still cause a considerable number of deaths. Factors contributing to medical errors are rapid changes in healthcare systems, increased use of medical devices, the quickening pace of work and the increased complexity of medical devices.¹ For example, in the USA, there are an estimated 454,383 adverse device-related events per year.² The more complex a medical device is, the more difficult it is to recognise and control the hazards associated with its use.³

There is a great variety between different medical devices and their associated risks. For example, bandages are low risk for the patient, while medical ventilators are high risk for the patient. The risk associated with a medical device is a combination of the hazards, the probability and the consequences of potential adverse events. Different risks can be evaluated to determine their acceptability. If a risk is judged as too high, adequate measures for risk reduction should be implemented.⁴ One of these possible measures is to train the users of the associated medical device.^{5,6} However, training of staff is resource-intensive.⁴ The amount and type of training deemed adequate depends, among other things, on the risk of the medical device.⁷ The risk of a medical device can be evaluated using a risk assessment tool developed for this purpose.⁵

There are several assessment tools available to evaluate the risk of individual medical devices. The risk can be assessed at a national level, which is often the case before a medical device enters the market. The classification tools used to evaluate these risks vary from country to country.⁸ In addition to those at a national level, there are risk assessment tools specifically developed for use within hospitals. An example of such a tool has been developed by the American Society for Healthcare Engineering.⁹ This risk classification tool is based on: function of the device, risk for the patient and maintenance of the device.¹⁰ Other criteria on which risk assessment tools can be based are: the degree of the invasiveness, the severity of adverse events and the body system affected.⁸

Although it is unknown whether used risk assessment tools are adequate, it is likely that hospitals use the risk assessment tools to ensure and improve patient safety. For example, hospitals could use the risk associated with a certain medical device to determine the amount and type of training. As it is unknown if and how risk assessment tools are used to determine the amount and type of training, this paper aims to explore this subject in Dutch hospitals. The goal of this study is to explore the risk assessment tools and criteria used to assess the risk of medical devices in hospitals, and to explore the link between the risk of a medical device and how those risks impact or alter the training of staff.

METHODS

A questionnaire was sent to all Dutch hospitals to collect quantitative data about the implementation of a national guideline.¹¹ This guideline was developed to support the risk management and safe application of medical devices in hospitals. The guideline facilitates the safe implementation, use and disposal of medical devices by providing support and interpretation regarding risk management and safe use of medical devices in patient care.

Development of the Questionnaire

The questionnaire was developed based on literature and expert opinions, then discussed with researchers in the research group. To achieve face and content validity, the questionnaire was piloted in the taskforce Medical Devices of the Dutch Hospital Association. The Dutch Ministry of Health, Welfare and Sport, the Dutch Hospital Association and the Netherlands Federation of University Medical Centers were asked to comment on the questionnaire. The final questionnaire contained thirty-seven questions, of which three were focused on risk assessment tools and their link with training (table 1). Hospitals were asked to send documentation about their risk assessment tools and the training systems developed based on the risk assessment.

Table 1. Questions on risk assessment tools in the questionnaire sent to all Dutch hospitals

No.	Question
1	Which risk assessment tool is used in your hospital? Please write the features of the tool or add relevant documentation to the questionnaire. (FDA; MDD; own system; otherwise, namely...; not applicable)
2	Which criteria are considered in the risk assessment tool? (Number of users; function of the device; frequency of use; severity of adverse events; otherwise, namely...)
3	Are there differences between risk classes, with regard to the organisation of training and the examination of proficiencies? Please write the differences or add relevant documentation to the questionnaire.

Participants

The paper-based questionnaire was sent to all eighty Dutch hospitals, both university and general, in December 2015. The list of hospitals was obtained from the Dutch National Atlas of Public Health 2014.¹² In the case of hospitals with multiple locations, the main site was selected. When there was no clear main location, the questionnaire was sent to all. Questionnaires were addressed to the board of directors. The cover letter requested that the questionnaire be delivered to the person responsible for implementation of the national guideline in their hospital, as well as explaining the goal of the research and stating that results were to be treated confidentially. Three and, if necessary, 4 weeks after the first questionnaire was sent,

two reminders were sent to the nonresponsive hospitals. Following these reminders, an e-mail was sent to the board of directors of the hospitals that had not responded. In this e-mail, permission was asked to contact the person responsible for the implementation of the national guidelines by telephone. Finally, all hospitals that did not respond were telephoned to request their participation in the study.

Analysis

Following manual entry of the data, 10 percent of the data were checked for accuracy. An error rate of less than 1 percent was considered acceptable. The responses to the questionnaires were analyzed using descriptive statistics in Stata 14 (Stata-Corp, 2015).

RESULTS

Of the eighty hospitals, sixty-five returned the questionnaire (81 percent response rate). Nine hospitals were not able to participate in the study due to time constraints, and three did not provide a reason for nonparticipation. The responsible employees in the remaining three hospitals could not be reached. Approximately one-third of the respondents (26 of 62) were medical physicists, while nine were the head of their hospitals' medical devices department. In total, thirty-three hospitals provided additional documentation regarding their risk assessment tools or training systems. Eight hospitals sent their risk assessment tools, six sent their training systems and six sent both. The remaining thirteen hospitals provided additional information on the questionnaire.

Risk Assessment Tools

Every hospital that returned the questionnaire uses a risk assessment tool. The majority of hospitals use a tool developed internally (40 percent), while the next most common tools in use were developed by the American Society of Healthcare Engineering (ASHE) (19 percent),⁹ the Medical Device Directive (11 percent)¹³ and the US Food and Drug Administration (5 percent).¹⁴ Furthermore, there were 16 hospitals (25 percent) that use another tool. Tools developed by hospitals or other tools often use the ASHE tool as a base for their risk assessment method. The tools are based on different criteria designed to assess the risk of a medical device. Commonly used criteria for assessing the risk of a medical device are: the function of the device (92 percent), the severity of adverse events (88 percent) and the frequency of use (77 percent). The different criteria and the percentage of risk assessment tools in which the different criteria are applied can be seen in Figure 1.

Criteria for risk classification system

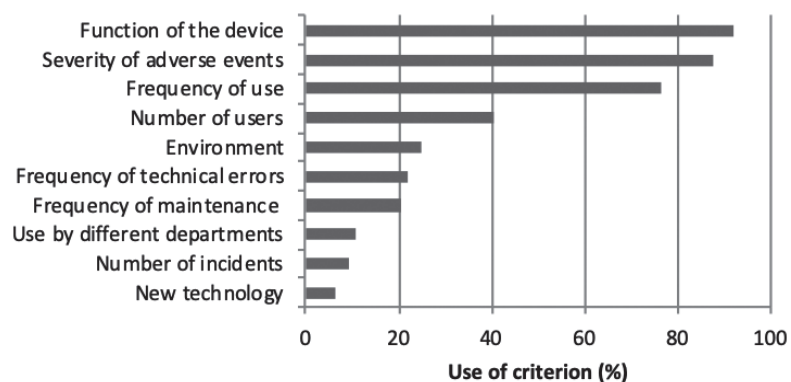


Figure 1. Percentage of risk assessment tools in which the different criteria are used (n=62)

In most assessment tools, the medical device is awarded points for every criterion, with the total number of points determining the risk category of the device. The number of criteria used to assess a tool ranges from one to nine. Criteria differ between tools, but also among the same tools used in different hospitals. Two examples of risk classification criteria, function of the device and severity of adverse events, can be found in table 2.

Table 2. Examples of criteria for the risk classification of medical devices.

	Points
Function of the device	
Life support	10
Surgical or intensive/critical care unit treatment	9
Critical monitoring	8
Diagnostics or physiological treatment	7
Therapeutic or treatment	6
Analytical	5
Not patient-related	1
Severity of adverse events	
Potential risk of patient death	8
Potential risk of patient injury	6
Potential risk of wrong therapy/diagnosis	4
No influence	1

Training and Examination

Fifty-six hospitals responded to the question as to whether they organize their training systems based on the risk assessment of their medical devices. Of these hospitals, forty-seven base their training on the risk of medical devices, while nine hospitals do not. Some training systems are not solely based on the risk of medical devices, but also on the frequency of use.

Hospitals provided additional information about their training system and the type of training, but not all hospitals were able to provide information on all risk levels. Twenty-six hospitals provided additional information on training for low- and high-risk devices, while twenty-five hospitals did so for medium-risk devices. The additional information was collected from the open field in the questionnaire or from the documentation added by hospitals. For a certain level of risk, it was possible for a hospital to require multiple types of training. For high- ($n = 18$) and medium-risk devices ($n = 17$), most hospitals provide training followed by education. In this context, “education” is defined as information-delivery education focused on theoretical knowledge, while “training” is defined as practical training focused on the skills of the user. For low-risk devices, most hospitals only require staff read the relevant user manual ($n = 15$). The training provided for the different risk levels can be seen in Figure 2.

Some hospitals provided additional information about staff examinations based on the risk assessment. Of the hospitals that provided information about low-risk devices ($n=15$), none conducted examinations for staff. For the medium-risk devices, thirteen hospitals provided additional information, with seven requiring no examination, three requiring a self-assessment and three holding an examination. Of the twenty-one hospitals that provided information about examinations for high-risk devices, all conduct examinations ($n = 19$) or self-assessment ($n = 2$).

The frequency of training and/or examinations is dependent on the level of risk of the device. Several hospitals provided additional information on the frequency of training and examinations. For low-risk devices, several hospitals (8/19) train their staff only once. This training occurs when the new device is introduced or when staff start working at the hospital. For medium-risk devices, the biggest group of hospitals train and/or examine staff once every 3 years (6/16), while two do this more often. For high-risk devices, the biggest group of hospitals train and/or examine staff once every 3 years (8/19), while five do so more frequently.

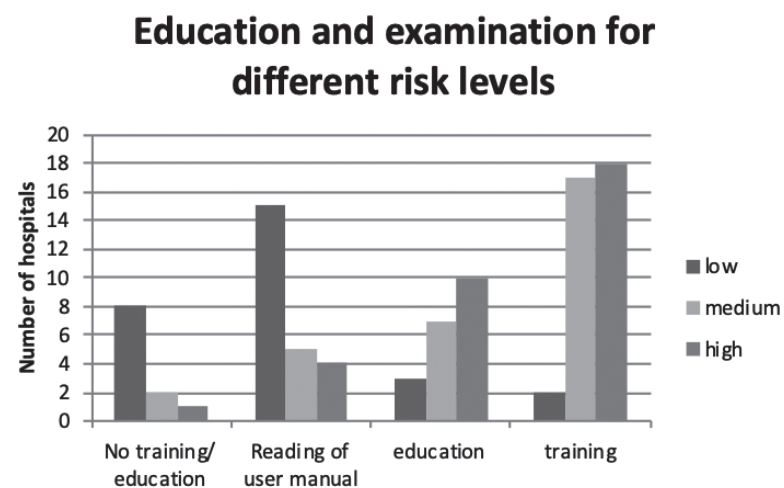


Figure 2. Type of training for healthcare personnel based on the risk of a medical device. The categories (high-risk (n=26), medium-risk (n=25) and low-risk (n=26)) were answered by a different number of hospitals. It was possible for hospitals to provide more than one answer for each category.

DISCUSSION

In general, Dutch hospitals base their training for medical devices on the risk of the medical device. With increased risk, the amount and type of training and examination also increases. This was found to be independent of the type of risk assessment tool used. The use of a risk assessment tool and a plan for the training of medical device use are mandatory for Dutch hospitals. However, it is not mandatory for the training to be linked to the risk associated with a medical device. The finding that most hospitals base their training on the risk of a medical device could indicate that risk assessment is a helpful tool in determining training needs.

Risk assessment tools used by hospitals consider several criteria. The most common criteria are: the function of the device, the severity of adverse events and the frequency of use. These criteria are more extensive than those used by the European union (EU) and United States. Risk assessment in the United States is mainly based on the potential harm for the patient,¹⁵ while in the EU it is focused on the invasiveness of the device.¹⁶ In the majority of tools, the invasiveness of the device is not considered as a criterion, although the potential harm for the patient is. Although hospitals use different tools, it is unknown whether this can lead to variances in classification for the same medical device. Such variances could lead to a difference in the perceived risk and might influence patient safety if the assessed risk is too low.¹⁷

Alongside the criteria, the number of variables considered could influence the risk classification.¹⁸

¹⁹ In Dutch hospitals, tools vary in number of criteria, from one to nine. When more criteria are considered, more potential influencers of risk are assessed. The drawback of considering too many criteria is that the most important will have less influence.^{20 21} A possible solution, which is already in use, is to prioritize and weigh the different criteria against each other.^{19 22} Further research could help to identify the key criteria, as well as the optimal number of criteria. To develop a tool, the multiple steps of risk assessment could be applied, namely: identification of the risks, assessment of the risks and identification of a solution.²³ Historical data are often used in safety research to identify possible improvements.²⁴ In the case of medical devices, it is possible to use past incidents and errors to identify those that are high-risk. However, this method will not predict the risks of future medical devices. A more evidence-based risk assessment tool should be developed for hospitals, where the necessary evidence could be collected through analysis of the different criteria and the degree of influence they have on risk assessment and safety.

Furthermore, criteria could be interpreted differently and therefore influence the assessed risk of a device. For example, frequency of use is considered in 77 percent of the risk assessment tools in Dutch hospitals, and many hospitals stated that the risk associated with a device increases with more use. In contrast, some hospitals stated that a device is riskier when used less often. Therefore, both frequent and infrequent use of a medical device could increase its risk. Frequent use of a device increases the chance that adverse events occur. Moreover, users could become unaware of the risks.²⁵ However, infrequent use could increase the risk of adverse events as users do not have a thorough understanding of the instructions for device operation,²⁶ or because they are unaware of the risks.²⁵ When a risk assessment tool is developed, it is not only the criteria that should be evaluated, but also the way criteria are applied.

The results of the questionnaire suggest that the risk of a medical device guides hospitals to determine which methods of training and examination are most suitable to improve safe use. However, the quality and results of training were not assessed as part of this research. To improve safety and decrease the risk of working with medical devices, it is necessary to use validated training programs.²⁷ Moreover, training should be tailored for staff, who may work with the medical devices in diverse ways. These differences were not found in the policies sent by Dutch hospitals however, it could be that these differences are present in practice. Further research should reveal whether differences in training occur. Moreover, research should examine the clinical effects and safety of risk assessment tools, as well as the combination of risk of a medical device and the training provided for its use.

To the knowledge of the authors, this research is the first to provide an overview of the risk assessment tools used in Dutch hospitals and their link with training and examination. For patient safety, it is recommended that hospitals use the optimum tool to assess the risk of medical devices. However, the most effective method of risk assessment and the link between risk classification and training is not known. Moreover, the differences between hospitals indicate that it is difficult to identify the optimum tool. Lack of knowledge as to which is the optimum tool can lead to difficulties in risk assessment and subsequent training.²⁸ Hospitals should receive support to determine which tool is best to use. A starting point could be to assess the number of incidents with a certain medical device, and the changes in number of incidents when risk assessment tools were implemented or altered. Furthermore, the assessed risk of medical devices could be compared with the perceived risk by staff and the amount of training they desire.

One strength of this study was the response rate of the hospitals. All Dutch hospitals were asked to complete the questionnaire and 81 percent did so. Of the hospitals that returned the questionnaire, fifty-six of the sixty-five (86 percent) completed the question about the link between risk classification and training, although only twenty-nine hospitals provided additional information on this subject. This might be because the question was not clear enough: It was an open-ended question that asked if there was a link, and what the link was, between the risk of a medical device and the training. When the questionnaire was developed, the researchers did not have base information that would enable the asking of more specific questions, for example, about registration of training. By suggesting that attachments could be added and using an open-ended question, the researchers received information from hospitals on a broad range of subjects. This provided an abundance of additional information about how training and examination take place. A limitation of the study was that the questionnaire was completed by staff who were involved with the implementation of risk assessment tools, leading to a risk of socially desirable answers. However, this is not expected to be the case due to the nature of the questions and the risk assessment and training policies that were sent. Moreover, the questionnaire was sent to Dutch hospitals and therefore, only provides insight on the situation in the Netherlands. However, the results indicate which risk assessment tools are used in hospitals and in which way training can be linked to the risk of a medical device. This knowledge can be applied in hospitals outside the Netherlands.

In conclusion, all Dutch hospitals use tools to assess risks associated with the use of medical devices. There is wide variety in the form and content of these tools. The most common criteria in risk assessment tools were found to be: the function of the device, the severity of adverse events and the frequency of use. The different tools could lead to varying classifications for the same medical device. The risk associated with a medical device is often used to determine the

amount and type of training and examination. When the risk of a medical device is higher, the training and examination are more intensive and compulsory. Understanding the link between the risk of a device and the amount and type of training could improve the proficiency of users and, therefore, might influence patient safety.

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CHAPTER 4

**Improving the proficiency of nurses:
Validation of a proficiency test for infusion
pumps**

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C.P.M. van der Vleuten, C. Wagner

Submitted for publication

ABSTRACT

Objectives Training is used to ensure proficiency of nurses with medical devices. Proficiency tests could be an alternative to training and reduce training time when training is tailored on the proficiency level of the nurse. The aims of this study were to develop minimum proficiency requirements for infusion pumps and to develop and validate an infusion pump proficiency test for nurses based on these proficiency requirements.

Design An infusion pump proficiency test was developed based on proficiency requirements developed by a group of infusion pump experts. Analysis of the results was done with classical test theory and item response theory.

Participants The test was validated among three groups of nurses with different knowledge levels; experienced nurses, less experienced nurses and nursing students.

Results A total of 64 proficiency requirements were developed from which 23 were used in the proficiency test. A total of 226 nurses completed the test consisting of 40 questions from which 20 questions were used in the final analysis. Significant differences were found between the test results of the three groups of nurses in which those with more experience had higher scores ($p < 0.001$). Both nurses and nursing students agreed that healthcare will become safer if a nurse has to pass this exam before working with an infusion pump.

Conclusions Proficiency testing is a promising method to assess the proficiency of nurses with medical devices. Using proficiency requirements to develop a proficiency test gives the possibility to tailor training needs and reduce training time. The acceptability among nurses for proficiency testing shows that more research should be done in the usability of proficiency testing and the consequences for patient safety.

INTRODUCTION

Medication in hospitals is often administered by an infusion pump. Estimations suggest that about 85-90% of all patients admitted to a hospital receive intravenous therapy by means of an infusion pump [1, 2]. Because infusion pumps are frequently used to administer critical fluids, infusion pump related adverse events can have significant consequences for patient safety. From 2005 through 2009, the US Food and Drug Administration received approximately 56,000 reports of adverse events associated with infusion pump usage, including numerous injuries and 710 deaths [3]. A study showed that in the Netherlands about 13% of adverse medical device events are caused by infusion pumps [2, 4]. Additionally, a study of Taxis et al. showed that at least one error occurred in 49% of intravenous drug doses [5]. Although exact numbers are unknown, adverse events with infusion pumps are most likely a combination of device failure and human factors [6, 7]. One study identified human factors contributed in 95% of the medication related errors, the most common being "Negligence, forgetfulness or lack of attentiveness", "Proper protocol not followed" and "Lack of knowledge" [6]. For medical devices, like infusion pumps, errors are often caused by human-technology interaction [8, 9].

To decrease the number of errors with medical devices, training of all healthcare staff is often initiated [10]. Training could also help improve proficiency of nurses to work with an infusion pump. Reviews of the literature show that training improves knowledge and skills of nurses [11, 12] and influences clinical outcomes, like infection rates [13]. Although training could reduce the numbers of errors, training is very resource-intensive in an environment with a growing number of medical devices, while less time is available for training [14, 15]. Moreover, mandatory training programs may lack relevance to the specific needs of nurses and might not result in improved practice [16]. Whether a training is relevant depends on the proficiency of the individual nurse. To assess proficiency and to tailor training needs, a proficiency test could be used if the tool is valid and reliable [17]. Furthermore, a proficiency test has the advantages of the testing effect, which is a better long-term retention of knowledge after taking a test [18]. A proficiency test is currently not available for infusion pumps.

Proficiency is defined as a complex combination of knowledge, performance, skills, values and attitudes [19, 20]. According to the Millers' pyramid of proficiency the first step in proficiency is 'knows', followed by 'knows how', 'shows how' and 'does' [21]. The evaluation of knowledge is particularly done by objective, reliable test methods, while the assessment of skills is done with less objective methods [21]. This study focuses on assessing knowledge, the first and second step of the Millers' pyramid. To be able to assess the infusion pump knowledge of nurses, the proficiency requirements of working with infusion pumps should be known [22]. The aims of this study were to develop minimum proficiency requirements for infusion pumps and to develop

and validate a proficiency test for infusion pumps based on these proficiency requirements. The research question is: what is the acceptability and the ability to differentiate proficiency of an infusion pump proficiency test for nurses?

METHODS

Proficiency requirements

The minimum proficiency requirements were developed based on literature and expert opinion of infusion pump experts.

Participants expert group

The infusion pump expert group consisted of five experts; three nurses, one clinical physicist and one training and testing expert. Two nurses worked in a general hospital and one nurse worked in a specialized home-care infusion pump nursing team. The clinical physicist worked in an academic hospital with a focus on the safe use of infusion pumps. The meetings were led by two researchers (PP and LV).

Development proficiency requirements

The development of proficiency requirements was based on cognitive task analysis [23]. Cognitive task analysis has five common steps, namely (1) collect primary knowledge, (2) identify knowledge representations, (3) apply focused knowledge elicitation methods, (4) analyze and verify data acquired and (5) format results for the intended application [23].

In the first step, (inter)national literature and guidelines were collected to identify existing proficiency requirements, procedures and areas of risk. An overview of necessary knowledge and skills for the safe application of infusion pumps was made by one researcher (PP). Next, there was an expert meeting with the expert group for additional input. In the second step the expert group discussed and identified minimum knowledge and skills requirements for safe application of infusion pumps. In the third step, one researcher (PP) drafted a concept version of the levels of complexity of the proficiency requirements based on Bloom's taxonomy [24]. Only the first three levels of complexity (remembering, understanding and applying) were used for the proficiency requirements. Action words such as 'name', 'explain' and 'demonstrate' corresponding to the level of complexity were used in the description of the proficiency requirements. In the fourth step, a second expert group meeting was held for verification, refinement and revision of the concept proficiency requirements. Additionally, the proficiency requirements were sent to the scientific associations of nurses and clinical physicists for feedback and approval. One researcher (PP) adjusted the concept version. The final proficiency requirements were sent to all experts

for approval. In the fifth and last step, the knowledge proficiency requirements were used to develop the proficiency test.

Proficiency test

Development

The proficiency test was an online test provided by a Dutch, commercial publisher specialized in the development of e-learning and online tests. The proficiency requirements were used as a base for the test. Members of the expert group were asked to prioritize the proficiency requirements as low, middle or high priority. The average priority of the different experts was taken as the priority of the proficiency requirement. Requirements with the highest priority were represented in three questions, for the middle priority in two questions and for the lowest priority in one question. Proficiency requirements from the third level of complexity (applying) were excluded for use in the proficiency test, because these requirements can only be examined in a practical examination. Also, proficiency requirements which were only applicable for specific hospitals or types of infusion pumps, were excluded for use in the proficiency test. Questions were based on (inter)national literature and protocols. When possible, existing questions from the publisher were used, if not possible new questions were developed. Exam questions were developed by an educational measurement specialist and a text editor. Questions were multiple choice, true/false, matching or pointing questions. All questions were reviewed by the expert group per e-mail and when necessary discussed and adapted.

Participants

Three groups of nurses were invited to test the proficiency test: experienced nurses (with more than ten years of experience), less experienced nurses (with less than five years of experience) and nursing students with no experience. Nurses were asked to participate through hospitals, social media (LinkedIn, Facebook and Twitter) and a magazine for nurses. A flyer was spread with information about the research and the inclusion criteria. Inclusion criteria were: nurses working in a hospital with infusion pumps, with less than 5 or more than 10 years of experience. Nurses could send an email to one of the researchers (PP) to participate. Included nurses received an email with login credentials and a link to the online test. Nursing students were second year students from one university of applied science. Students were asked via email to participate in a lecture about patient safety including the proficiency test.

All participants answered the same questions, but in a random order to prevent that (answers of) questions influenced the answer of other questions. Before the test started, the characteristics of the participants were asked. Also, participants were asked the extent to which they agreed to the statement: 'I am proficient to work with an infusion pump'. Moreover, two statements were given after the nurses completed the proficiency test. The first statement was: 'A nurse should pass

this exam before he/she is allowed to work with an infusion pump'. The second statement was: 'Healthcare will become safer if a nurse has to pass this exam before he/she is allowed to work with an infusion pump'. All statements could be answered on a five-point Likert scale (strongly disagree to strongly agree) and were used to examine the acceptability of the proficiency test.

Psychometric characteristics and validation

Classical test theory (CTT) and item response theory (IRT) were used to determine the psychometric characteristics of the questions and to validate the proficiency test. CTT was used to describe features of all questions and to select the best questions for further analysis with IRT. CTT is based on the idea that a person's score is the sum of the correct answered questions. IRT takes into account the difficulty of items when calculating test scores and might therefore be more valid and give more information to test takers and institutions. Analysis was done with SPSS 22 (descriptives and CTT), R 3.4.2 and R studio 3.4.2 (IRT). The R-packages mirt, ltm, psych, lavaan, qgraph, igraph and ega were used during analysis.

Classical test theory

With CTT we calculated different parameters for the questionnaire and individual questions. Chronbach's alpha is calculated as an estimate of the reliability of the test as a whole. For the individual questions, p- and Rit-values were calculated. The p-value represents the share of candidates that answered the question correctly. The Rit-value reflects the performance of the item versus the test as a whole. It tells us to what extent an item contributes to the discrimination of the level of performance. P- and Rit-values were used to select the most informative questions of the exam for further analysis. This was necessary because of the large number of questions compared to the number of participants. To contain content validity for each proficiency requirement the best question was selected, except for proficiency requirements with the lowest priority. For this category only questions with a p-value between 0.3 and 0.8 and a Rit-value above 0.3 were selected. For the high and middle priority proficiency requirements, the questions with the highest Rit-value and a p-value between 0.3 and 0.8 were selected. When such a question was not available, a question with p- and Rit-values closest to these values was selected.

Model assessment item response theory

Before IRT was done, data was explored with principal component analysis and the Kaiser-Meyer-Olkin measure was calculated to ensure sample adequacy. Several parameters can be assessed in IRT. The θ -parameter is a parameter for item discrimination. This parameter indicates how well the item is able to discriminate between knowledgeable and less-knowledgeable participants. The β -parameter is known as the difficulty parameter. It corresponds to the knowledge level at which the probability of answer the item correct is the same as the probability of answer the item

incorrect. The c-parameter, or guessing factor, describes the probability that a respondent with no knowledge will answer the item correctly [25]. Parameters can be estimated, depending on the chosen model. Three models were compared; a one-parameter (Rasch model, only θ -parameter), a two-parameter (2-PL model, θ - and β -parameters) and a three-parameter (3-PL model, θ -, β - and c-parameters) model. The three models were compared applying a likelihood-ratio test and comparing the differences in the Akaike information criterion (AIC). The AIC estimates the quality of each model, relative to each of the other models. Lower AIC-values indicate a better-fitting model. We calculated the root mean square error of approximation (RMSEA) and the comparative fit index (CFI) to examine whether the model had a good fit. Literature has shown that for adequate fit, the criteria for RMSEA is <0.05 and for CFI ≥ 0.95 [26].

Validation

The scores of participants in IRT are represented by the θ -parameter. This reflects the difficulty of the questions (θ) which a participant is able to answer correctly. After assessment of the normal distribution of the group scores, the mean and standard deviation for each group were calculated. One way ANOVA tests were used to see whether groups of participants had different knowledge levels.

RESULTS

Proficiency requirements

The development of proficiency requirements for infusion pump resulted in a list of 64 requirements [27]. The requirements were distributed between three categories of priority: high, medium and low. From this list, 23 requirements were used to develop the knowledge test. 41 requirements were not included in the knowledge test because these requirements represented a skill or were hospital or infusion pump specific (appendix 1). One requirement (2.4) was excluded after the test started because the question was not clear.

Proficiency test

Participants

From the 316 nurses and nursing students who indicated they wanted to participate, 226 (70.8%) completed the proficiency test. The proficiency test was completed by: 75 nursing students, 62 nurses with 0-5 years of experience and 89 nurses with more than 10 years of experience. Characteristics of the participants can be found in Table 1. Most participants were female (89.4%), were under 25 years of age (43.4%) and worked in a general hospital (36.7%). Participants could indicate whether they think they are proficient to work with an infusion pump on a 5-point Likert scale. Students were less proficient than nurses with 0-5 years of experience ($p<.001$) and nurses with more than 10 years of experience ($p=.002$). There was no difference between the

self-declared proficiency of nurses with less than 5 or more than 10 years of experience ($p=.51$). Most nurses and nursing students agreed that a nurse should pass this exam before working with an infusion pump and that healthcare will become safer if a nurse has to pass this exam before he/she is allowed to work with an infusion pump. There were no significant differences for these statements between groups.

Table 1. Characteristics and mean scores and agreement to statements about proficiency and the proficiency exam ($n=228$). *All nursing students were included, also those who follow dual education (combining work and study).

	Student	0-5 years of experience	10+ years of experience	Total
Number of participants	75	62	89	226
Female (n(%))	73 (97)	51 (82)	78 (88)	202 (89)
Age (n(%))				
Under 25	67 (89)	31 (50)	0	98 (43)
25-34	4 (5.3)	30 (48)	7 (8)	41 (18)
35-44	3 (4.0)	1 (2)	27 (30)	31 (14)
45-54	1 (1.3)	0	33 (37)	34 (15)
55 or older	0	0	22 (25)	22 (10)
Years of experience (n(%))				
0-1 years	42 (56)	7 (11)	-	49 (22)
1-2 years	26 (35)*	13 (21)	-	39 (17)
2-5 years	7 (9)*	42 (68)	-	49 (212)
10-20 years	-	-	30 (34)	30 (13)
20-30 years	-	-	30 (34)	30 (13)
30+ years	-	-	29 (33)	29 (123)
Workplace (n(%))				
General hospital	-	32 (52)	51 (57)	83 (37)
Tertiary teaching hospital	-	16 (26)	22 (25)	38 (17)
University hospital	-	14 (23)	16 (18)	30 (13)
Agreement to statement on 1-5 scale (mean (sd))				
I am proficient to work with an infusion pump	1.47 (0.70)	4.45 (0.53)	4.39 (0.54)	3.47 (1.47)
A nurse should pass this exam before he/she is allowed to work with an infusion pump	4.35 (0.80)	3.61 (0.98)	3.74 (0.91)	3.91 (0.95)
Healthcare will become safer if a nurse has to pass this exam before he/she is allowed to work with an infusion pump	4.21 (0.70)	3.82 (0.84)	3.83 (0.83)	3.96 (0.81)

Psychometric characteristics and validation

P-values varied between 0.19 and 0.99, Rit-values between 0.03 and 0.66 (appendix 2). P- and Rit-values were used to select the most informative questions of the exam for further analysis. For high- and middle-priority questions one question for each proficiency requirement was selected, based on the highest Rit-value and a p-value between 0.3 and 0.8. For low priority questions only questions with a p-value between 0.3 and 0.8 and a Rit-value above 0.3 were selected. This resulted in a total of 20 items for IRT analysis. The Chronbach's alpha for the whole proficiency test was 0.692 (95% CI 0.632-0.747), which indicates a questionable internal consistency. The Chronbach's alpha of the 20 selected questions was 0.755 (95% CI 0.706-0.799) which represents an acceptable internal consistency. The principal component analysis on the 20 items in the sample of 226 participants showed one principal component. The Kaiser-Meyer-Olkin measure was 0.79 which demonstrated sample adequacy for the analysis. After the exploration of the data, the best-fitting model for the data was assessed. The 2PL model demonstrated a significantly better fit ($P < .001$) than the Rasch model. The 3-PL model demonstrated no significantly better fit than the 2-PL model ($P = .34$) and had a higher AIC, so the 2-PL model was selected. For the 2-PL model the RMSEA was 0.034 (95% CI 0.017-0.047) and the CFI was 0.954 which indicated a good fit of the model.

Test results

Table 2 shows the mean scores of different groups when using two different methods of calculation test scores; CTT (20 selected questions) and IRT (20 selected questions). The p-values, Rit-values, θ -parameters and β -parameters for the different questions are shown in appendix 2. The CTT scores were significant different between the different groups ($P < .001$). Moreover, the IRT scores were significant different between the groups ($P < .001$).

Table 2. Exam scores of candidates following the classical test theory and item response theory

	Student	0-5 years of experience	10+ years of experience	Total
Exam score CTT 20 selected questions (mean (sd))	8.52 (2.28)	13.98 (2.38)	14.99 (2.34)	12.57 (3.70)
Exam score IRT 20 selected questions (mean (sd))	-0.97 (0.45)	0.27 (0.53)	0.55 (0.52)	0.33 (0.84)

Figure 1 represents with which precision (information) and standard error the ability of a person can be estimated. The ability is estimated with most precision on the lower side of the centre of the ability scale.

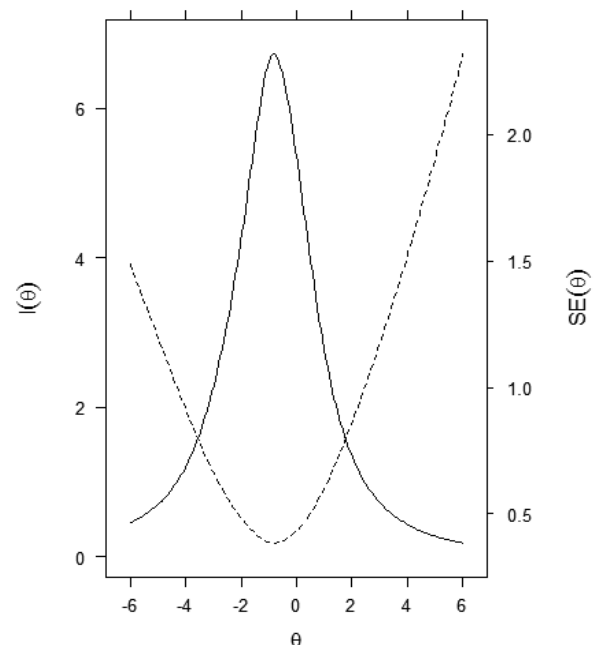


Figure 1. Information curve (solid line) and standard error curve (dashed line) for the complete test as a function of the abilities.

DISCUSSION

The results of the test show that different levels of knowledge can be distinguished with the developed infusion pump proficiency test. More questions of the test were answered correctly by nurses with more experience. Moreover, when the difficulty of questions is taken into account with item response theory, experienced nurses score significantly higher than less experienced nurses who score significantly higher than nursing students. The test results do not show the same pattern as the self-declared proficiency. Nurses with less experience state they are as proficient as nurses with more experience. The test results however show a significant difference in the knowledge level of both groups. Regardless of their experience, nurses would accept this proficiency test as part of their education. Participants agree that a nurse should pass this exam before he or she is allowed to work with an infusion pump and that healthcare will become safer if a nurse has to pass this exam before working with an infusion pump.

Although both nurses and nursing students agree that a proficiency test should be passed before working with a device, nursing students agree much stronger. A possible explanation could be that nursing students feel more ensured after passing a test. A positive test result indicates that a nurse has reached a professional standard [17]. Moreover, it could give students and novice

nurses an easier method to say that they are not yet proficient. Speaking up is important to improve patient safety, but is negatively influenced by factors like 'fear of conflicts' or 'concerns of appearing incompetent' [28]. The obligation to pass a proficiency test could therefore improve the confidence of nurses and the safety of patients.

Another influence on the acceptability of the proficiency test could be that nurses think the test needs to be improved before a proficiency decision is taken. Although the test distinguishes between experience levels, it might not be able to give a reliable pass-fail decision yet. In order to reach a reliable pass-fail decision, further research should compare this test with other methods like skill assessment to ensure the proficiency is assessed in different ways. At this moment there are few valid and reliable measuring tools available to assess medical device proficiency of nurses [29]. This makes it difficult to compare this test with a golden standard. However, the aim of the proficiency test is to assess whether nurses achieve professional standards [17]. Therefore, the results of the proficiency test should be compared with the professional standards and skills of nurses to obtain more information about the correlation. Furthermore, a multi-method approach of determining proficiency gives a better overall estimate of proficiency [30]. When knowledge is compared or combined with skills, a pass-fail norm for future use could be determined.

Next to a pass-fail decision, the proficiency test could be used for feedback. Effective feedback is important in learning and helps learners in achieving educational goals [31]. In this test each question is linked to a proficiency requirement, which makes it possible to link deficiencies in knowledge to these requirements. To provide nurses with tailored feedback, it would be beneficial if the test could take into account possible incorrect evaluation. For example, by providing more questions for areas in which proficiency is assessed as insufficient. One possibility to achieve this is to develop a computerized adaptive test (CAT). A CAT more precisely estimates the ability of the test-taker after each question and selects a next question based on this estimate [32]. However, this would require the development of more questions and sophisticated analysis [33]. Therefore, CAT might be more suitable for larger tests and groups, for example a national proficiency test before a nurse is allowed to work in practice. The proficiency requirements and test developed for this study could be a starting point for developing a nationwide test of proficiency of nurses.

Although the proficiency test is able to distinguish between experience of nurses, this study did not look into the influence on patient safety. There is evidence that training has an impact on patient safety, but no studies are known about the impact of proficiency tests on safety [13]. Further research with the proficiency requirements and test is needed to get an idea of possible influence on patient safety. General opinion indicates that the development of this kind of proficiency test is desired for the safety of patients. For example, the importance of continuing

education has been increasingly emphasized in the literature [34]. Moreover, a study indicated that 89% of the public believes there is a need for nurses to show competence periodically [35].

A limitation of this study is the low number of participants which restricts the possibility to take more questions into account with IRT. However, the combination of CTT and IRT made it possible to select and test the best questions which led to a reliable IRT model. This gives a reason to continue and extend research with these proficiency requirements and test. Another limitation of the study was that the link to the online test was sent to nurses by email. Although we emphasized that the test had no consequences and was for research purpose only, it could have been that nurses discussed questions with colleagues or looked them up. Nevertheless, nurses participated voluntarily and individually to this test, decreasing the chance of discussing questions with colleagues.

CONCLUSIONS

The infusion pump proficiency test is able to distinguish nursing students, nurses with 0-5 years of experience and nurses with more than 10 years of experience. This indicates that the proficiency test could be used to assess proficiency in practice. Moreover, the proficiency test is well accepted by both nursing students and nurses. They agree that healthcare will become safer if this test has to be passed before working with an infusion pump is allowed. Both findings indicate that proficiency testing could be used in daily practice. Tests based on proficiency requirements make it possible to tailor feedback and training to healthcare staff and therefore to save time. Further development and research of proficiency tests could save time to ensure proficiency of nurses and could improve patient safety and increase the time available for patient care.

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APPENDIX 1

Appendix 1: proficiency requirements [27] with the corresponding priority within in the exam or the reason of exclusion for the exam. Priority 1 is the highest priority, priority 3 the lowest.

Basis		
1.1	The nurse can name what the indications are for the use of an infusion pump	Priority 3
1.2	The nurse can name where information about the infusion pump can be found or where this can be retrieved	Priority 3
1.3	The nurse can name which infusion pump is suitable for which application (for example for the administration of medication / blood)	Priority 3
1.4	The nurse can name what the risks are of different administration routes	Priority 1
1.5	The nurse can name globally what is in the various protocols	Hospital dependent
1.6	The nurse can calculate the correct concentration and administration speed for a drug / fluid	Already examined in Dutch hospitals
1.7	The nurse can explain what the functionalities of the infusion pump are	Pump dependent
Preparation		
2.1	The nurse can explain the instructions of the doctor	Skill
2.2	The nurse can based on the instructions of the doctor reason what the correct treatment is	Priority 2
2.3	The nurse can explain how medication has to be made and checked	Priority 1
2.4	The nurse can name how it can be checked whether medicines may be administered together via one infusion line	Priority 3
2.5	The nurse can explain how to work in an aseptic manner	Priority 2
2.6	The nurse can name which equipment belongs with which infusion pump	Pump dependent
2.7	The nurse can name which equipment is suitable for which medication/ fluids	Pump/hospital dependent
2.8	The nurse can name which equipment is required in order to be able to connect an infusion pump correctly	Pump dependent
2.9	The nurse can name whether non-return valves have to be used	Priority 2
2.10	The nurse can demonstrate how the infusion pump has to be attached	Pump dependent /skill
2.11	The nurse can demonstrate how the infusion system has to be filled	Pump dependent /skill
Usage		
3.1	The nurse can demonstrate how one must work following the protocol	Hospital dependent/ skill

3.2	The nurse can name when it has to be checked whether the needle and system are still in a good position	Priority 2
3.3	The nurse can demonstrate how it has to be checked whether the needle and system are still in a good position	Skill
3.4	The nurse can explain which the correct program is in order to set the infusion pump	Pump dependent
3.5	The nurse can name what the different buttons on the infusion pump are for	Pump dependent
3.6	The nurse can demonstrate how the infusion pump has to be set	Pump dependent /skill
3.7	The nurse can demonstrate how adjustments have to be made to the infusion pump	Pump dependent /skill
3.8	The nurse can name why the infusion pump settings have to be double-checked	Priority 1
3.9	The nurse can demonstrate how an extra drug has to be connected	Pump dependent /skill
3.10	The nurse can name what the effects can be when several fluids are administered via one infusion line (multi-infusion)	No priority (high similarity to 3.12, 3.13 and 3.14)
3.11	The nurse can demonstrate which line / infusion pump belongs with which medication / fluid and how this can be checked	Skill
3.12	The nurse can explain that, when several drugs are running through one infusion line, the concentration ratio of the drugs in the line is the result of the settings from the infusion pumps which are connected to the same line	Priority 2
3.13	The nurse can explain that, when several drugs are running through one infusion line, in the case that an infusion pump setting changes it will take some time before the right concentration ratio of medication is given to the patient	Priority 2
3.14	The nurse can explain that when several drugs run through one infusion line a temporary dosing error can occur at infusion pumps which are not modified.	Priority 1
3.15	The nurse can explain what the consequences of rinsing or not rinsing the infusion line can be	Priority 2
3.16	The nurse can demonstrate how free-flow can be prevented	Priority 2
Alarms		
4.1	The nurse can explain what all the alarms mean	
4.2	The nurse can demonstrate how to handle the situation when there is an alarm	Priority 1
4.3	The nurse can demonstrate what has to be done in the case of an occlusion	Priority 1
4.4	The nurse can name what the dangers of occlusion are	
4.5	The nurse can name which alarm settings the health professional can or cannot modify themselves	Pump/hospital dependent

4.6	The nurse can name when the alarm settings may be adjusted	Pump/hospital dependent
4.7	The nurse can demonstrate how the alarm settings can be adjusted	Pump dependent
4.8	The nurse can demonstrate how the alarm settings can be checked	Pump dependent
4.9	The nurse can explain what the alarm settings are and why these are the settings	Hospital dependent
4.10	The nurse can name that there are different types of alarm settings and that these settings vary between departments	Priority 3
4.11	The nurse can name what the consequences are when the alarm settings are adjusted	Priority 1
After use		
5.1	The nurse can demonstrate how the infusion has to be rinsed through	Pump dependent /skill
5.2	The nurse can demonstrate how the infusion pump has to be disconnected	Pump dependent /skill
5.3	The nurse can demonstrate how the infusion pump has to be cleaned	Pump dependent /skill
5.4	The nurse can demonstrate how the infusion pump has to be stored	Pump/hospital dependent /skill
Transport/transfer/mobility		
6.1	The nurse can demonstrate how one should handle a patient who has come from outside the hospital and who has an infusion pump	Hospital dependent/ skill
6.2	The nurse can demonstrate how a patient with an infusion pump can be transported safely	Skill
6.3	The nurse can demonstrate how a patient with an infusion pump has to be prepared for diagnostic tests	Priority 3
6.4	The nurse can demonstrate how a patient with an infusion pump must be transferred when being moved to another department / another hospital	Hospital dependent / skill
6.5	The nurse can explain to the patient how he can be mobile with an infusion pump.	Pump dependent
Power supply		
7.1	The nurse can explain how the infusion pump is provided with power	Priority 3
7.2	The nurse can demonstrate how to handle the battery of an infusion pump	Pump dependent /skill
7.3	The nurse can demonstrate how the infusion pump has to be charged	Pump dependent /skill
7.4	The nurse can demonstrate which wall socket has to be used	Hospital dependent/ skill
7.5	The nurse can explain how to recognise when the infusion pump battery is about to run down	Pump dependent
7.6	The nurse can name what has to be done in the event of a power failure	Pump/hospital dependent

7.7	The nurse can discuss why the plug has to be disconnected on the side of the wall socket and not on the side of the infusion pump	No scientific proof
Malfunction		
8.1	The nurse can demonstrate how it must be checked whether an infusion pump is functioning well	Pump dependent /skill
8.2	The nurse can recognise when there is a problem with the pump	Pump dependent
8.3	The nurse can name what must be done if the infusion pump is not functioning well or if there is doubt concerning this	Pump/hospital dependent

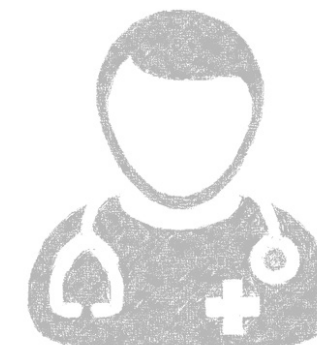
APPENDIX 2

Item characteristics of the proficiency test. The items are categorized following the priority and proficiency requirements. For the different proficiency requirements the values and parameters of 3 questions (high priority), 2 questions (middle priority) or 1 question (low priority) are given.

Item	Proficiency requirement	Classical test theory		Item response theory	
		p-value	Rit-value	θ-parameter	β-parameter
Priority 1 (high)					
1.4	The nurse can name what the risks are of different administration routes	0.52	0.58	2.07	-0.68
		0.45	0.32	x	x
		0.54	0.49	x	x
2.3	The nurse can explain how medication has to be made and checked	0.99	0.03	x	x
		0.19	0.26	x	x
		0.86	0.55	1.47	2.45
3.8	The nurse can name why the infusion pump settings have to be double-checked	0.64	0.05	x	x
		0.85	0.12	x	x
		0.82	0.59	1.54	2.12
3.14	The nurse can explain that when several drugs run through one infusion line a temporary dosing error can occur at infusion pumps which are not modified.	0.77	0.10	x	x
		0.82	0.33	0.42	1.56
		0.46	0.22	x	x
4.2	The nurse can demonstrate how to handle the situation when there is an alarm	0.65	0.45	0.88	0.75
		0.21	0.15	x	x
		0.68	0.28	x	x
4.3	The nurse can demonstrate what has to be done in the case of an occlusion	0.79	0.50	0.74	1.49
		0.64	0.11	x	x
		0.41	0.15	x	x

4.11	The nurse can name what the consequences are when the alarm settings are adjusted	0.82	0.30	x	x
		0.27	0.22	x	x
		0.52	0.39	0.84	0.10
Priority 2 (medium)					
2.2	The nurse can based on the instructions of the doctor reason what the correct treatment is	0.66	0.36	0.65	0.72
		0.94	0.32	x	x
2.5	The nurse can explain how to work in an aseptic manner	0.90	0.54	1.22	2.70
		0.69	0.24	-	X
2.9	The nurse can name whether non-return valves have to be used	0.24	0.39	0.89	-1.32
		0.42	0.11	x	x
3.2	The nurse can name when it has to be checked whether the needle and system are still in a good position	0.78	0.57	1.84	2.01
		0.31	0.05	x	x
3.12	The nurse can explain that, when several drugs are running through one infusion line, the concentration ratio of the drugs in the line is the result of the settings from the infusion pumps which are connected to the same line	0.36	0.28	0.32	-0.60
		0.92	0.38	x	x
3.13	The nurse can explain that, when several drugs are running through one infusion line, in the case that an infusion pump setting changes it will take some time before the right concentration ratio of medication is given to the patient	0.19	0.10	x	x
		0.31	0.32	0.59	-0.86
3.15	The nurse can explain what the consequences of rinsing or not rinsing the infusion line can be	0.88	0.24	0.54	2.06
		0.47	0.13	x	x
3.16	The nurse can demonstrate how free-flow can be prevented	0.39	0.15	x	x
		0.75	0.66	2.64	2.18
Priority 3 (low)					
1.1	The nurse can name what the indications are for the use of an infusion pump	0.38	0.51	1.43	-0.68
1.2	The nurse can name where information about the infusion pump can be found or where this can be retrieved	0.91	0.44	x	x
1.3	The nurse can name which infusion pump is suitable for which application (for example for the administration of medication / blood)	0.60	0.40	1.02	0.50

2.4	The nurse can name how it can be checked whether medicines may be administered together via one infusion line	x	x	x	x
4.10	The nurse can name that there are different types of alarm settings and that these settings vary between departments	0.39	0.35	0.45	-0.45
6.3	The nurse can demonstrate how a patient with an infusion pump has to be prepared for diagnostic tests	0.53	0.04	x	x
7.1	The nurse can explain how the infusion pump is provided with power	0.58	0.43	1.02	0.39
7.7	The nurse can discuss why the plug has to be disconnected on the side of the wall socket and not on the side of the infusion pump	0.75	0.32	0.75	1.22



CHAPTER 5

**Proficient until proven unproficient?
Exploring attitudes and perceptions
of medical specialists on proficiency,
proficiency requirements and proficiency
tests for the safe use of electrosurgery: a
qualitative study**

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Submitted for publication

ABSTRACT

Background The correct and safe use of electrosurgery requires medical specialists to be proficient. Minimum proficiency requirements and proficiency tests are a manner to structurally assure proficiency. The objective of this study is to explore attitudes and perceptions of medical specialists on proficiency, proficiency requirements and proficiency tests for the safe use of electrosurgery.

Methods A qualitative study among medical specialists using semi-structured interviews.

Results The participants recognized that the use of electrosurgery poses risks to the safety of patients and perioperative staff. According to some participants, increased awareness on the risks of electrosurgery is required. Most medical specialists however thought that proficiency of users of electrosurgery is sufficiently assured. Medical specialists stated to support proficiency requirements when they are endorsed by their scientific association. Proficiency tests encountered much resistance. Medical specialists argued that electrosurgery should not be tested as a single device but should be embedded in a larger entity, for example in a broader course or proficiency test.

Conclusions When assuring proficiency of users of electrosurgery, the positive attitude towards proficiency requirements and the more negative attitude towards proficiency tests should be taken into account.

BACKGROUND

Electrosurgical devices have become one of the most commonly used medical devices across all surgical disciplines.¹ Electrosurgery is used in more than 80% of all surgical procedures and is described as the application of high frequency electrical current to raise intracellular temperature and thereby obtain surgical effects.^{1,2} Electrosurgery reduces operation time,² minimizes bleeding and reduces post-operative complications such as pain.³ Despite these advantages, the use of electrosurgery carries high risks for injuries to patients and perioperative staff.⁴ Damage to the insulation of the device, capacitive coupling and direct coupling could cause unintentional energy transference and can thereby cause burns to both patient and surgeon.^{4,5} High temperatures or sparks produced in the proximity of combustible materials can cause surgical fires.⁶

For medical devices in general, risks arise from different causes including technical, organisational, human and patient-related causes.⁷ Human factors are largely responsible for healthcare-associated adverse events involving medical devices.^{7,8} These adverse events are partially caused by insufficient knowledge of and attention to safety among users.⁷⁻¹⁰ For electrosurgery, two studies among obstetricians and gynaecologists indeed demonstrated poor knowledge on both surgical safety and hazard prevention.^{10,11} Another study showed that general surgeons and surgical trainees at all levels have knowledge gaps in the safe and effective use of electrosurgery, regardless of years of experience.¹² In addition, the electrosurgical concepts taught during residency are often seen as inadequate and structural training for medical specialists is often lacking.^{11,13} In order to minimize the risks associated with electrosurgery, increased awareness of these risks and of the safe use of electrosurgical devices is required.

Safe use of medical devices such as electrosurgery requires medical specialists to be proficient.¹⁴ Proficiency implies that medical specialists possess specific knowledge, user skills and experience.¹⁴ A study by the Dutch Health Care Inspectorate in Dutch hospitals, however, shows insufficient attention to proficiency assurance in the use of medical devices in general.¹⁵ The study illustrates that most training in medical devices is aimed at nurses, while medical specialists often have limited training.

A proposed manner to improve the safe use of electrosurgery and to structurally assure proficiency is to develop proficiency requirements and proficiency tests (hereafter requirements and tests) for users of electrosurgery, based on knowledge and skills needed to safely use electrosurgery.¹⁶ These requirements and tests provide a more objective way of determining proficiency of medical specialists, contrary to the current methods, like a periodic self-declaration.^{14,17}

It is not known to what extent medical specialists view electrosurgery as a technique that poses problems to patient and perioperative staff safety, and whether they experience a need to assure proficiency of users of electrosurgery. Therefore, the aim of the present paper is to explore the attitudes and perceptions of medical specialists on proficiency, proficiency requirements and proficiency testing in the use of electrosurgery. Based on the results of this study it can be determined whether it is desired by medical specialists to develop these requirements and tests as a manner to assure proficiency.

METHODS

An exploratory qualitative study using face-to-face semi-structured in-depth interviews was conducted to elicit participants' attitudes and perceptions on proficiency, requirements and testing in the use of electrosurgery. The interviews were held in March, April and May 2016 by one researcher (LM). A topic list for the interviews was developed based on sensitizing concepts derived from literature, expert inputs and intuition (appendix 1). Prior to the interviews, a pilot interview was conducted to test the topic list. The main concepts stated in the topic list were the problem perception, experiences with incidents, the current situation concerning education and testing in the use of electrosurgery, continuous learning, proficiency requirements and proficiency tests. Before the start of each interview, the aim of the study was described and oral informed consent was obtained. The interviews were held in a private room at a convenient location for the medical specialist. The study has an iterative approach in which preliminary analysis is performed to provide additional input for the interviews.

Population and procedures

Medical specialists were eligible for the study if they (a) were employed in a hospital (b) as gynaecologist, urologist or surgeon and (c) used electrosurgery. The sampling was purposive to explore possible differences within perceptions and attitudes of medical specialists. We sampled based on the hospital size and type and specialisation and experience of the specialists. Initially, the gynaecology, urology and surgery departments of six Dutch hospitals were addressed based on the hospital type and size (two academic medical centres, two tertiary teaching hospitals and two general hospitals). Participants were recruited through an e-mail invitation sent to either the secretariat or the chairman of the departments requesting novice and advanced medical specialists using electrosurgery in a hospital setting. After the first recruitment round, the departments of eleven additional hospitals (six academic medical centres, four tertiary teaching hospitals and one general hospital) were addressed following the same procedure as the first recruitment.

Data analysis

The interviews were recorded using a digital audio recorder and transcribed, coded and analysed using MAXQDA (MAXQDA 11; VERBI Software GmbH, Berlin, Germany). For quality assurance, each participant received a written transcript of the interview and was given the opportunity to provide additional information. In order to systematically analyse the interviews, a thematic content analysis approach was used following multiple coding steps.¹⁸ First, open coding was conducted by one researcher (LM), which consisted of reading the transcripts and grouping texts into segments. Provisional codes were assigned to text segments and a code list was developed. One novice and one advanced researcher (PP and LV) independently checked the open coding and discussed codes until consensus was reached. Subsequently, axial coding was used through which overlapping codes were merged and comprehensive codes were split into more specific codes. Hereafter, selective coding was used to establish connections between themes and to identify the essence of each theme in relation to the attitudes and perceptions of medical specialists. Finally, the researchers (LM, PP and LV) discussed the themes that emerged from the analysis and discussed possible explanations for these findings.

RESULTS

Medical specialists from eight gynaecology departments, fifteen urology departments and ten surgery departments (n=33) from seventeen different hospitals were invited. A total of 22 medical specialists agreed to participate in this study. The main reasons for declining participation were time constraints and a lack of interest to participate. Due to busy schedules and due to unforeseen schedule changes of medical specialists, nine of the 22 medical specialists were not able to participate. Therefore in total 13 medical specialists participated in this study.

Table 1 presents information on the characteristics of the participants. The medical specialists were mostly male (n=10) and were employed in eleven different hospitals (four academic medical centres, four tertiary teaching hospitals and three general hospitals). The self-reported number of surgeries performed per year ranged from 150 to 500. The mean interview duration was 31 minutes (21-50). During and after the eleventh interview, no new information emerged which implied that data saturation had been reached. Therefore active recruitment of participants was stopped.

Table 1. Participant characteristics by specialty

Specialty	Participant	Hospital type	Medical specialist since (years)
Gynaecology	G1	Tertiary teaching hospital	8
	G2	Tertiary teaching hospital	32
	G3	Tertiary teaching hospital	14
	G4	Academic medical centre	14
	G5	General hospital	>20
Urology	U1	Academic medical centre	30
	U2	Academic medical centre	3
	U3	Academic medical centre	30
	U4	General hospital	3
Surgery	S1	General hospital	14
	S2	Academic medical centre	12
	S3	Tertiary teaching hospital	35
	S4	Tertiary teaching hospital	19

No differences emerged on participant characteristics. The results are therefore presented without distinction for these characteristics. The five main themes that were identified are risk perception, proficiency, problem perception, awareness and resistance. These themes are described to more extent.

Risk perception

Medical specialists recognized that the use of electrosurgery poses risks to the safety of both patients and perioperative staff. However, participants indicated that they do not perceive their use of electrosurgery as hazardous. Medical specialists said that due to the high frequency of use and the perceived low degree of difficulty they do not always dwell on these risks.

“It is our daily routine. (...) No it is definitely not harmless. But is it something we use every day. So it is very normal for us, nobody sees it as a high-risk instrument.” (S4)

Most medical specialists compared the required knowledge and the level of difficulty of electrosurgery to driving a car: it is not difficult but one needs to be able to drive, not cause accidents, respond to unexpected changes, recognize alarms and know how to respond to these alarms.

“It is not that terribly complicated. Just like driving. Driving is not that complicated but you have to learn it.” (G1)

Proficiency

All medical specialists endorsed the importance of being proficient in the use of electrosurgery. They all agreed that the definition of proficient in the use of electrosurgery comprised at least that a medical specialist could operate the device in such a way that the operation can be performed correctly. However, medical specialists' opinions varied on the degree of knowledge that is required to be proficient in the use of electrosurgery. Some found it sufficient to know what tissue effects are caused by the different settings of the device, while others commented that profound understanding of electrical theory is required.

“I think that you ... need to understand what the background is. And how it works. I think that at least secondary school knowledge on physics in this area can be expected to be present. You do not have to know the physics background of it but you must know what happens when you do this and what happens when you do that etcetera.” (G2)

The medical specialists illustrated that proficiency in the use of electrosurgery is achieved during residency through theoretical courses and the master-apprentice training, in which medical specialists train resident trainees on the job.

“Nobody can declare themselves to be proficient, the trainer does that. Those who train residents in urology eventually declare residents proficient to perform ... procedures.” (U3)

Medical specialists stated that after residency training, it is assumed that proficiency in the use of electrosurgery is maintained and therefore repetitive assessment during work life is not applied. They mentioned that lifelong learning was of great importance to medical specialists, however they said this was not applicable to electrosurgery as the technique has not changed significantly during their working life. One participant, however, indicated that when s/he got employed at another hospital, an electrosurgery course and test were mandatory prior to working with electrosurgery. S/he mentioned that this course had increased awareness on the risks associated with the use of electrosurgery and provided insights into things s/he did not know.

“I have previously worked in [hospital X] and over there I had to pass an exam before I was allowed to work with electrosurgery. But that was the first hospital I have experienced that. (...) The funny thing is, when you are not aware, you do not miss it. (...) When it is not asked for deliberately, you assume that everything is well. And when you're not corrected, or even get the possibility to use it, you get the feeling that it is going well. But when I got at [hospital X], while I had worked with electrosurgery for years, (...) I suddenly had to go through some sort of skillslab with a theoretical course on what electrosurgery comprised and what it does

to people and which settings the device had and how long and how high certain things are and what the consequences were. I did not know that. I never knew.” (S2)

Problem perception

The perceptions of medical specialists varied on the extent to which proficiency of medical specialists in the use of electrosurgery is assured. Most medical specialists thought that current knowledge on the risks of electrosurgery and measures taken to minimize these risks are sufficient to assure patient and perioperative staff safety. They commented that proficiency of users of electrosurgery was therefore sufficiently assured.

“When I look around, I think that the people using electrosurgery are absolutely proficient. It is so essential for our profession that one cannot function properly without understanding how the technology works and what can be done with it.” (U2)

“We are all proficient because we’ve done it since day one.” (S4)

Medical specialists said that they have never experienced major incidents personally or among colleagues. Participants considered the knowledge that is necessary to safely use electrosurgery as only a small part of the total knowledge required to conduct an operation. They said that therefore attention should be paid to assuring proficiency of a broader subject and not only electrosurgery.

Some participants had the impression that there is a lack of knowledge among medical specialists to be able to safely use electrosurgery. They commented that in the past too little attention has been paid to the safe use of electrosurgery and that no structural initiatives have eliminated this deficit.

“In my opinion, there is a substantial lack of knowledge among most people working with electrosurgery. (...) That has to do with the fact that for a long time little attention has been paid to that [the safe use of electrosurgery].” (G2)

In addition, they thought that the knowledge of some masters in the master-apprentice training is insufficient to transfer the required knowledge and skills to assure patient and perioperative staff safety.

“I think that a lot of masters who are supposed to train the apprentices do not fully understand the ins and outs of electrosurgery.” (G4)

Awareness

Although most medical specialists made positive comments about the current state of knowledge of medical specialists on electrosurgery, some medical specialists said that increased awareness on the technique and the risks for injuries caused by the use of electrosurgery is required. Most medical specialists thought it is more important to raise awareness amongst users than to determine proficiency.

“I think that there can be a better understanding of what you are doing and what it means.” (G4)

“So I think that testing should mainly be about creating awareness.” (S2)

Medical specialists were positive towards establishing minimum quality standards for users of electrosurgery, presented as minimum proficiency requirements, as they considered it important to possess certain knowledge and user skills.

“I think that for some parts it is very good to have a minimum safety threshold, so that people cannot do too dumb things. One should do that themselves but, well, that is just not the way it is.” (G2)

Resistance

Some medical specialists expressed a strong resistance against testing to ensure this minimum proficiency, while others thought education and testing are inseparable. Different reasons for resistance against proficiency testing for the safe use of electrosurgery were mentioned. First, participants generally perceived the expected benefits as low. A few medical specialists perceived that incidents are mainly caused by carelessness, which they thought is not prevented by testing.

“[Incidents are caused by] careless use. (...) We know it but when you are busy you have actually already forgotten that it [the electrosurgical device] is hot because you do not touch it with your hands.” (G4)

Second, the development of proficiency tests by entities other than scientific associations was seen as undesired external interference by many participants. However, some medical specialists said that external interference such as governmental interference has in the past led to improvements in patient safety.

“Well, over the years, more and more people who have nothing to do with our profession have become involved in our profession and think they know something and need to say something about it.” (S4)

Third, medical specialists commented that they are not used to being tested and are not always open for this although some medical specialists found testing a logical continuation of education. Fourth, participants expressed resistance against the by them perceived tendency to increase regulation on performance and tests to prove proficiency to external entities.

“I think that we are currently in a culture in which much is tested, much is asked for. So I am a bit cynical about it [proficiency testing].” (U3)

Finally, some participants perceived testing, and especially testing through an on-site assessment, as a sign of mistrust on the professional behaviour of medical specialists.

“I see it as a symptom of too little confidence in the profession. That there is someone who comes over to what, no, I think that is a sign of mistrust.” (U3)

DISCUSSION

In this study, the attitudes and perceptions of medical specialists on proficiency, proficiency requirements and proficiency tests for the safe use of electrosurgery were explored. Medical specialists recognized that the use of electrosurgery poses risks to the safety of patients and perioperative staff. Some participants argued that increased awareness among medical specialists on the risks associated with the use of electrosurgery is desired. They perceived the knowledge of a part of the users as insufficient and thought that the technique is sometimes used carelessly. In contrast, most participants did not perceive that the technique poses risks in practice to patient and perioperative staff safety. They do not experience careless use of the technique and they say that medical specialists are aware of how the technique should be used.

All medical specialists endorsed the importance of being proficient, however medical specialists understood proficiency differently; opinions varied on the degree of knowledge required to be proficient. Moreover, not all participants thought that the technical background of medical devices was part of their professional role. Proficiency testing on the other hand encountered much resistance, especially by some participants who saw this as unwanted external interference and as a sign of mistrust. In addition, medical specialists did not see how proficiency tests could prevent incidents. Medical specialists argued that if proficiency requirements and tests will be

developed, this should be embedded in a larger entity. This could be, for example, a broader course or proficiency test involving multiple medical devices used during one procedure.

In light of the current focus of healthcare on good quality care and reducing, preventing, reporting and analysing incidents,^{19,20} medical specialists saw it as a logical step to set minimum requirements on knowledge and skills for medical specialists to be allowed to apply the technique. These minimum proficiency requirements can additionally provide clarity on what proficiency in the use of electrosurgery comprises, as currently opinions of medical specialists differ.

The opinions of some participants indicating that knowledge among medical specialists on electrosurgery is insufficient, is consistent with the literature. Previous survey studies in Western countries have shown that despite the widespread use, there is indeed a lack of knowledge among medical specialists of basic electrosurgery concepts.^{11,21} In addition, these studies have shown that medical specialists are not aware of these deficits. One participant in this study confirmed that s/he was not aware of this deficit until a mandatory electrosurgery course was taken.

In contrast, the majority of medical specialists experienced a low sense of urgency. According to them, knowledge among medical specialists to prevent, recognize and react to complications is sufficient. Their remarks showed that due to the frequent use of the technique and the perceived low level of difficulty, the risks of electrosurgery are not always dwelled on. When viewing these remarks in the context of the four stages of acquiring proficiency from unconscious unproficient to unconscious proficient, it seems that participants consider themselves and other medical specialists to be unconscious proficient.²² This implies that medical specialists master electrosurgery skills in such that during an operation the application of the technique is no longer deliberately dwelled on and medical specialists are able to correctly and adequately respond to difficult and unexpected situations. In addition, the remarks of most medical suggest that the use of electrosurgery has become automatic and routine behaviour, which is known to decrease awareness.²³ In practice, however, it remains unclear whether medical specialists in the Netherlands are indeed unconscious proficient, as after completion of the residency programme no further assessment of proficiency in the use of electrosurgery is performed.

The absence of figures on incidents with electrosurgery and the low problem perception caused resistance to proficiency testing. Resistance was also caused by the low expected benefits of proficiency requirements. It was perceived that incidents are mainly caused by carelessness, which will not be prevented by proficiency tests. Previous studies have indeed shown a higher resistance to change when the perceived problem and the perceived benefits of change are low.²⁴

²⁵ Resistance of most medical specialists against proficiency testing was caused by a negative attitude towards external interference. Previous studies have shown that resistance to change is mainly high in professions characterized by high professional autonomy, a characteristic feature of medical specialists.^{26,27} Therefore, in order to minimize this resistance, as referred to by participants, it is desirable that initiatives to assure and demonstrate proficiency are endorsed by the scientific associations.

Participants indicated that it is not desirable to test electrosurgery as a single device. Participants perceived other energy devices as more hazardous to patient safety compared to electrosurgery. Attention should be aimed at those devices and electrosurgery concepts could be incorporated.

This study has some strengths and limitations. The study only focused on electrosurgery instead of proficiency testing in general. It is, however, expected the results are transferable to other basic techniques with solid foundation in surgical procedures. This study was conducted among gynaecologists, urologists and surgeons, who constitute the vast majority of users of electrosurgery. It is unknown whether these results are transferable to other specialism using electrosurgery. The study was conducted in a country in which assuring proficiency of medical specialists is a topic of current interest. Therefore, it is a topic that specialists are aware of and have presumably formed an opinion on. The results of this study may provide insights for other countries in which assuring proficiency of medical specialists is a topic of interest.

CONCLUSIONS

This study shows that the development of proficiency requirements for the safe use of electrosurgery is desired by medical specialists. Proficiency testing however encountered much resistance, mostly because medical specialists do not see that electrosurgery poses risks in practice to patients and perioperative staff. When assuring proficiency of users of electrosurgery, the generally negative attitudes and perceptions of medical specialists on proficiency testing have to be taken into account. Incorporating proficiency assurance of electrosurgery into a larger entity and endorsement of the requirements and tests by scientific associations are expected to increase support from medical specialists on testing as a way to determine proficiency.

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APPENDIX 1

Topic list

Participant characteristics

- Years in function
- Years working with electrosurgery
- Procedures a year using electrosurgery

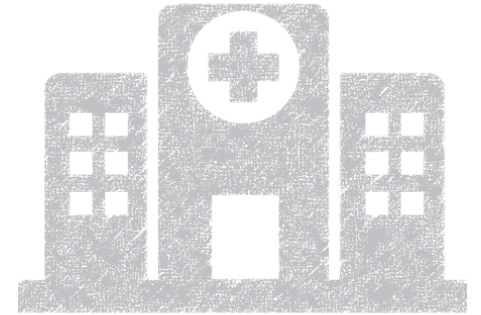
Problem perception

- Problem perception
- Own experience / experience of colleagues with incidents
- Currently taken risk reducing measures
- When considered proficient?
- Necessities becoming and remaining proficient
- Current situation education and testing electrosurgery
- Needs to achieve and remain proficiency

Continuous learning, proficiency requirements and testing

- Perspective on continuous learning
- Perspective on development proficiency requirements
- Perspective on development proficiency tests

Additional information



CHAPTER 6

**Hospitals need more guidance on
implementing guidelines for the safe use
of medical devices**

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ABSTRACT

Objectives To gain insight into the current implementation of national guidelines on training, examination and registration of proficiencies for the safe use of medical devices and to explore the barriers and facilitators faced during the implementation of these national guidelines.

Methods A questionnaire was sent to all Dutch hospitals and interviews were held with staff at six hospitals.

Results There are differences between hospitals in the implementation stage, but also within hospitals. The questionnaire showed differences between training and examination for devices used by nurses and those used by medical specialists. The interviews showed that most barriers and facilitators for implementation of the national guidelines can be found in organizational factors.

Conclusions According to the hospitals, implementation of national guidelines for the safe use of medical devices is a complex process that involves all departments. Furthermore, the staff do not always feel a sense of urgency to improve the safe use of medical devices. To facilitate implementation, more national guidance could be helpful.

INTRODUCTION

Medical devices have become increasingly important for the diagnosis, monitoring and treatment of patients.¹ In the USA, there are an estimated 454,383 device-related adverse events a year that result in emergency department visits.² In the UK, the National Health Service estimates that 400 people a year die or are seriously injured in adverse events involving medical devices.³ Given the growing numbers of medical devices coupled with the high incidence of device-related adverse events, the safe use of medical devices has become increasingly important for patient safety.⁴

To improve safety, the World Health Organization (WHO) and the International Organization for Standardization (ISO) developed regulations for the safe use of medical devices.^{5,6} The WHO developed a guide based on the regulatory systems of countries with advanced medical device regulations, including the United States, Canada, European countries, Australia and Japan. The ISO standard has been developed to assess an organization's ability to meet consumer and regulatory requirements. The regulations of both the WHO and ISO are based on the life cycle of the medical device. This life cycle consists of the conception and development, manufacture, packaging and labelling, advertising, sale, use and disposal of the medical device³. Because of their focus on the full life cycle of the medical device, they lack a detailed description of appropriate use of medical devices in specific settings, such as the hospital.

In 2011, national guidelines were developed in the Netherlands to improve the safe application of medical devices in hospitals. The 'Covenant for the safe application of medical devices in hospitals'⁷ was commissioned by representatives of all Dutch hospitals and aims to improve the risk management and safe application of medical devices in patient care. The covenant defines the safe application of medical devices as: 'A safe device in the hands of a trained user in a setting that can ensure safe use'⁷. These national guidelines cover three stages of the life cycle of medical devices in hospitals, namely implementation, use and disposal.

The phase in the life cycle where device-related adverse events occur is in the use of the device.⁸ The UK National Patient Safety Agency reported that device-related incidents are caused by device failure (43.8%), inappropriate use (29.3%), lack of training (12.3%) and poor maintenance (1.5%).⁹ Both the WHO regulations and the ISO standard state that staff should have the necessary knowledge, skills and experience before they work with a device. In accordance with this, the Dutch national guidelines state: 'The hospital must have a procedure that ensures that a user who applies a medical device for the first time is proficient in the application of the medical device'.⁷

The importance of making sure that users of medical devices are proficient in using that medical device is also reported in the literature. Thomas et al. reported that a meaningful proportion

of device-related adverse events are caused by human error.⁹ Although there are many factors that affect the likelihood of human error, some of these adverse events could be prevented by having proficient staff. Ensuring that staff are proficient in the use of medical devices is an extensive and time-consuming process.¹⁰ Furthermore, staff members experience barriers to becoming proficient, for example in terms of time constraints, lack of support and working commitments.¹¹ National guidelines could help in ensuring the proficiency of staff, but little is known about the factors which could hamper (barriers) or enhance (facilitators) implementation of these guidelines.

The objective of this study was to gain insight into the current implementation of training and examination for the safe use of medical devices and to explore the barriers and facilitators faced during the implementation of the national guidelines for the safe application of medical devices. Therefore, a national survey was conducted among hospitals and interviews were held with hospital staff.

METHODS

This study is a cross-sectional study with a mixed-methods design. Quantitative data were collected using a questionnaire. Interviews with hospital staff were held to study perceived barriers and facilitators during implementation.

Questionnaire

The questionnaire included questions on the extent of implementation of the national guidelines. The majority of questions addressed the proficiency of users by asking about the organization of training and examination. The questionnaire was developed based on literature and expert opinions and was discussed with researchers. The questionnaire was then tested with six members of the Medical Devices taskforce of the Dutch Hospital Association in order to achieve face and content validity. This showed that general questions concerning training, examination and registration of proficiencies were difficult to answer because of the differences between technologies and users. These questions were changed to device-specific questions for electrosurgery and infusion technology. These technologies were chosen because they are widely used, are seen as high-risk medical devices and have different main users. Infusion pumps are used to deliver fluids into a patient's body and are often operated by nurses. Because they are regularly used for critical fluids and high-risk medication, failures can have significant implications for patient safety.¹² Electrosurgery is used by surgeons to cut, coagulate, desiccate and fulgurate tissue. High-frequency current is passed through tissue to generate heat. If not properly used, this high current can injure both patient and operator.¹³

Finally, the Dutch Ministry of Health, Welfare and Sport, the Dutch Hospital Association and the Netherlands Federation of University Medical Centres were consulted about the questionnaire. The questionnaire (Appendix A) started with general questions about the hospitals, followed by questions about the extent and organization of implementation. Next, questions were asked about the organization of training and examination for the use of electrosurgery and infusion technology. Finally, the questionnaire asked about the registration of proficiency among staff.

Participants

The paper-based questionnaire was sent to all 86 Dutch hospitals, both university and general hospitals, in December 2015.¹⁴ If a hospital had multiple locations, we selected the main location. If the main location was not clear, the questionnaire was sent to all locations. We addressed the board of directors, who were asked to send the questionnaires to the person responsible for implementation of the national guidelines in their hospital. Two reminders were sent to the non-respondents, three and four weeks after the first questionnaire. After these reminders, we phoned all non-responding hospitals to ask them to participate.

Analysis

After data was entered manually, 10% of the data were checked for accurate entry. An error rate of less than 1% incorrect data entry was considered acceptable. Data analysis was done and checked by two researchers (JM and PP). The responses to the questionnaires were analysed using descriptive statistics in Stata 14 (Stata-Corp, 2015). A chi-square test was used to test for significant differences between the organizations for users of infusion technology and electrosurgery. A p-value below 0.05 was considered statistically significant.

Interviews

In addition to the questionnaire, staff at six hospitals were invited for an interview. These interviews focused on implementing procedures regarding the proficiency of the staff. A semi-structured topic guide with open questions was developed based on items in the national guidelines (Appendix B). The topic guide elaborated on their experiences in general during implementation and on facilitators, barriers and how they overcame barriers.

Participants

For the interviews, we purposively selected hospitals that had been implementing the national guidelines for more than one year. These hospitals were selected to ensure they had already encountered barriers and facilitators during implementation. Hospitals were selected and approached if reports by the Healthcare Inspectorate or presentations at national congresses showed they had been implementing parts of the guidelines focusing on the proficiency of users for more than one year. Between December 2015 and January 2016, we interviewed the

employees who were responsible for implementation of the national guidelines. We tried to ensure a general view instead of a device- or professional-specific view by asking the respondents to answer the questions while keeping all types of medical devices and different professionals in mind. All interviews were conducted by a single interviewer (JM) in a private room at the workplace of the respondent.

Analysis

The interviews were recorded using a digital audio recorder and transcribed, coded and analysed using MAXQDA (MAXQDA11; VERBI Software GmbH, Germany). For quality assurance, each participant received a written transcript of the interview. Coding was conducted by two researchers (JM and LV) using codes taken from the domains of the PRISM Framework.¹⁵ This framework was chosen because it considers implementation in non-research settings. The framework focuses on implementation in healthcare and consists of 39 elements in four domains. These domains are: 1) elements of the programme (organizational and patient perspective), 2) characteristics of recipients of the programme (organizational and patient characteristics), 3) influences of the external environment and 4) implementation and sustainability infrastructure. Because the implementation has an influence on professionals, we chose to use the professional perspective and characteristics instead of the patient perspective and characteristics. The coding by the two researchers was discussed until consensus was reached. Hereafter, the coding was used to establish connections between themes and to identify the essence of each theme. Finally, two researchers (PP and LV) discussed the themes that emerged from the analysis and possible explanations for these findings.

RESULTS

Questionnaire

Participants

The questionnaire was sent to all 86 general and university hospitals in the Netherlands. Six hospitals had recently merged. Of the 80 remaining hospitals, 65 hospitals returned the questionnaire (81% response rate). Nine hospitals were not able to participate in this study due to time constraints, three hospitals did not provide a reason for non-participation and in three hospitals the responsible employee could not be reached. 26 out of 65 respondents were medical physicists and nine respondents were heads of the medical devices department. The median number of beds in the hospitals was 497 (interquartile range 300-750). The number of responses to a question can deviate from the total number of respondents because hospitals were asked to skip questions if professionals did not receive regular training.

General implementation of the national guidelines

Almost all hospitals (95%) have a multidisciplinary taskforce that is responsible for the implementation of the proficiency part of the national guidelines. The group generally includes the head of the medical devices department, a medical specialist, a medical physicist, a policy officer and an educational expert. The biggest cluster of hospitals (30%) started the implementation of the national guidelines after a letter from the Healthcare Inspectorate in June 2015, which announced the inspectorate would start auditing the implementation in January 2016. The hospitals are at different stages in the implementation of the national guidelines, ranging between adoption (28%), implementation (40%) and evaluation and maintenance (32%). Hospitals that are in the adoption stage have an action plan or protocols that are in line with the national guidelines. If hospitals are in the implementation stage, this means these protocols are being followed. In the evaluation and maintenance stage, the protocols are being adapted based on evaluation of the implementation.

Proficiency of users

Questions about examination and the registration of the proficiency of users were asked separately for two technologies: infusion technology and electrosurgery. Users of infusion technology were more likely to have been trained ($p < 0.001$) and examined ($p < 0.001$) and the proficiencies were also more likely to be monitored ($p < 0.001$). Lack of proficiency is more likely to be revealed during an annual assessment interview in the case of infusion technology ($p < 0.001$) and because of a mistake or complication in the case of electrosurgery ($p = 0.024$).

The main results for the questions about proficiency are presented in Figure 1. Training in infusion technology was more often a combination of knowledge and skills (67% of the training programmes) in comparison with training in electrosurgery, which mostly involves training in skills only (48% of the training programmes). In 69% of hospitals, the type of training and examination medical specialists receive for other high-risk medical devices is similar to a high or very high degree to the training and examination in electrosurgery. In 75% of hospitals, the training and examination nurses receive for other high-risk medical devices is similar to a high or very high degree to the training and examination in infusion technology.

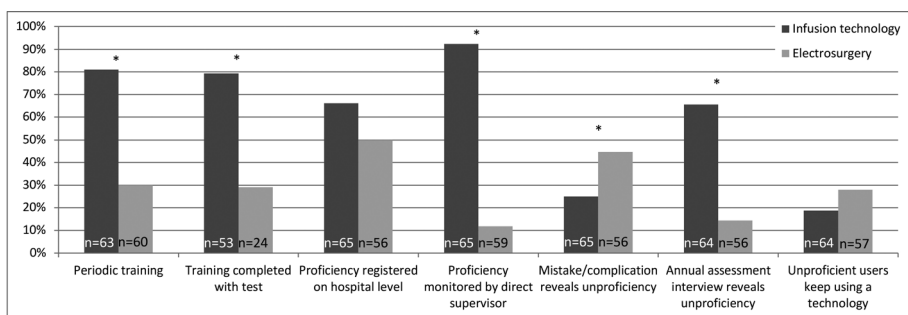


Figure 1. Results of training and examination of staff and the registration of proficiency, for users of infusion technology and electro-surgery. The number of hospitals who answered the question differ between the questions and are indicated within the bars. (* indicates significant difference between infusion technology and electro-surgery (P<0.05))

Interviews

Participants

The interviews were performed with nine employees in total, at six hospitals, who were responsible for implementation of the parts of the national guidelines that concerned the proficiency of staff. No new information emerged in the fifth and sixth interviews, which implied that data saturation had been reached. Four of the interviewees were medical physicists, four worked in the educational department and one was the head of the medical device department. The interviews ended when all information had been collected and took between 27 and 89 minutes (mean length 59 minutes). Most interviewees were male (6 out of 9). The interviews were held in hospitals of different sizes and types (two university and four general hospitals). The stage of implementation in the hospitals where interviews were held varied between adoption and evaluation and maintenance. All six hospitals had developed a programme for the training of staff, although sometimes this plan indicated that no training was needed for medical specialists. The main results of the interviews are displayed in Figure 2 and explained below.

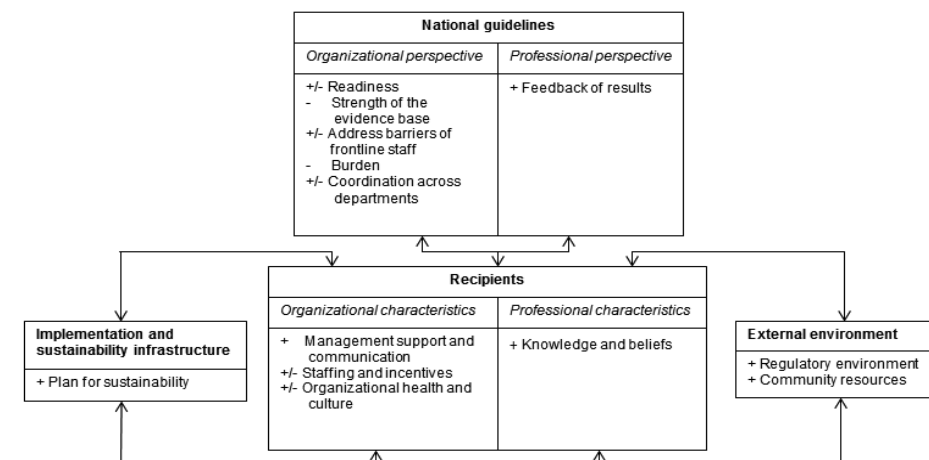


Figure 2. Implementation of the national guidelines, figure adapted from the PRISM framework(13). + means the element is a facilitator, - means the element is a barrier and +/- means the element is both a barrier and facilitator for implementation.

Organizational perspective

Respondents perceived “readiness”, “addressing the barriers facing frontline staff” and “coordination across departments” as both barriers and facilitators. “Strength of the evidence” in relation to patient safety and “burden” were seen as barriers for implementation of the national guidelines. Respondents remarked in particular on the reasons that medical specialists gave for the implementation being a burden.

One reason the medical specialists mentioned was the amount of additional work in combination with their already high workload. Another reason according to medical specialists was that the national guidelines reduced their autonomy. However, the readiness for implementation can be triggered by an incident or by external pressure such as an audit by the Healthcare Inspectorate, which is a governmental healthcare supervisory authority.

“I think that the problem is that you ask things from people who are close to being overloaded. The drawback is that you encounter autonomy questions.”(Respondent 3)

“But people are only going to really do things when there is pressure. And that pressure comes from a major incident or if the inspectorate breathes down your neck.”(Respondent 6)

For this reason, respondents stated that the barriers faced by frontline staff should be addressed. A perceived barrier is that departments spend as little time as possible on the development of training. These barriers could be reduced by respecting and helping the frontline staff and

by adjusting the level of training to the level of the employee. Another facilitator is tempting employees into training by making it an enjoyable activity.

“It is about tempting professionals to get trained. That sounds a bit odd, but professionals are rather afraid of training and exams. But it can be made enjoyable if an appealing speaker is invited, if food is provided or if professionals can earn accreditation points.” (Respondent 4)

Moreover, respondents perceive the strength of the evidence as a weak point. There is no evidence that implementation of the national guidelines will improve safety, and similar programmes did not prove to be effective.

“Hospitals often cover their bases because the Healthcare Inspectorate wants it. So we can measure everything objectively, all very formal, yet the effect has been shown to be small.” (Respondent 3)

The burden is seen as an important barrier by the respondents. Elements that are named as barriers are the large amount of time it takes to implement the national guidelines, the complexity of the implementation and the amount of money needed for the development of training.

Another factor is the hospital-wide nature of the national guidelines, which makes coordination across departments necessary, according to respondents. The respondents see the involvement of different departments as a barrier. A positive aspect in the experience of the respondents is the formation of connections between the different departments.

“The hospital has to deal with the covenant [national guidelines] and that affects everyone. They looked at why some hospitals manage it and others don’t. You need someone who can connect people.” (Respondent 4)

Organizational characteristics

“Management support” and “communication” are facilitators according to the respondents, while “staffing and incentives” and “organizational health and culture” are seen as both barriers and facilitators.

Respondents say implementation is facilitated if the management makes implementation a priority, actively promotes implementation and has a strict policy.

“Can you name a facilitator in this hospital?” (interviewer) “Initially, the strict policy of the board of directors. No longer accepting that people are not proficient.” (Respondent 5)

Management also has an influence on the organizational health and culture. The organization is both a barrier and a facilitator. Respondents named giving feedback and a culture in which staff can give each other criticism as a facilitator. However, high turnover in staff is seen as a barrier that might influence the existing culture and knowledge.

“We must make people aware of how to work with devices and teach them that you need to work safely with people. It is much more about creating a culture within the organization in which learning is normal.” (Respondent 2)

Furthermore, respondents mentioned the personal responsibility of staff for their own proficiency as both a barrier and a facilitator. Staff appreciate it when they are trusted to judge their own level of proficiency. A barrier is that staff are not always motivated to work on their proficiency.

Professional perspective and characteristics

“Feedback of results” from training and examination is seen as a facilitator. Feedback encourages staff to attend training. Staff are also encouraged if there is a positive incentive, for example accreditation points when they complete a training programme.

Moreover, respondents perceive the knowledge and beliefs of staff as a facilitator for implementation. It helps if staff have an intrinsic motivation to be proficient and to attend training.

Implementation and sustainability infrastructure

A facilitator for the implementation of the national guidelines is the “existence of a plan for sustainability”. Respondents mentioned a continuous cycle of improvement and recurrent audits or evaluations as facilitators.

“I see that it is a project in many hospitals. We do it and then it’s finished, whereas it is actually a permanent notion. It is also not a question of getting it right in one go, because next year we have another cycle and we have new people etc. You have to continuously keep doing that [updating risk analysis and quality documents].” (Respondent 4)

External environment

The “external environment” can have a facilitating effect on the implementation of the national guidelines. Facilitators are having the process steered at the national level and determining nationally which technologies cause a large number of adverse events.

“What also plays a role is that we had very few really testable standards. For electrosurgery there is a list from the association with standards for knowledge requirements. That harmonizes what people need to know, and that was what was missing. We see that it is starting to take off now.” (Respondent 3)

DISCUSSION

The objective of this study was to gain insight into the current implementation of national guidelines on training and examination for the safe use of medical technologies and the barriers and facilitators during implementation of the guidelines. The stage that hospitals had reached in the implementation of the national guidelines varied between adoption (28%), implementation (40%) and maintenance (32%). Furthermore, the questionnaire data showed differences in training and examination between two different devices with different main users. The interviews showed that most barriers and facilitators of implementation of the national guidelines can be found in the organizational factors, like readiness, strength of the evidence base and addressing barriers experienced by frontline staff. Facilitators for implementation are the knowledge and beliefs of staff, giving staff feedback, a plan for sustainability and external resources.

Differences between medical devices in procedures

Procedures regarding the examination and registration of the proficiency of users are more likely to be applied for users of infusion technology in comparison with users of electrosurgery. A likely explanation is the difference in the main users: infusion technology is used by nurses while electrosurgery is used by medical specialists. More barriers are perceived by respondents when training and examining medical specialists in comparison with nurses. Respondents mention that the autonomy and workload of medical specialists could explain why implementation is more difficult. Previous studies have shown that resistance to change is mainly high in professions characterized by professional autonomy.^{16 17} Moreover, resistance to change is also known to increase when the workload is higher.¹⁸ The increase in resistance is caused by the fear or knowledge that change requires an investment of time. Another explanation could be that nurses are more used to being examined. Implementation of new processes is easier when changes are smaller and new procedures are in line with old procedures.¹⁹ However, it is unclear whether hospitals do not try to implement training and examination or whether they try but do not manage to implement it. The interviews indicated that more barriers were perceived with the

training and examination of medical specialists. Moreover, the questionnaire data showed there were different policies for nurses and medical specialists. This could indicate that hospitals do not try to implement training and examination for certain types of users.

Barriers and facilitators for implementation

The interviews gave insight into the barriers and facilitators for implementation. We found that the implementation of the national guidelines is a complex process with barriers and facilitators from several different origins. Most barriers and facilitators can be found in the organizational perspective and characteristics. This project involves all the different departments and layers of the organization. The costs and time the implementation takes are seen as an important barrier. There are not enough staff and money available to facilitate the implementation. This problem is often seen in hospitals as a barrier to implementation.^{18 20} National support from experts or frameworks to guide implementation could help hospitals with the implementation. Moreover, a factor that increases the burden is that people do not see the importance and extent of the problem.²⁰ Most staff within the hospital see the implementation of the national guidelines as a problem, while the real problem is the unsafe use of medical devices and the effects this has on patient safety. Although this subject is receiving increased attention, the interviews suggest that hospitals still need an incident or visit from the Healthcare Inspectorate to make the safe use of medical devices a priority.

Accordingly, respondents say the management has important facilitating effects. The first facilitator is the promotion of the national guidelines. Promotion makes staff aware of the existence and importance of the implementation.²⁰ In addition, it is helpful if the management has a strict policy. If management clearly considers implementation to have a high priority, staff are motivated to implement the national guidelines. Moreover, creating a culture in which training, examination and registration of proficiency is normal could facilitate implementation, although it is important not to demotivate staff by giving them an increased workload. However, staff also have to perceive the importance of being proficient and should no longer think it is acceptable to use medical devices in which they are not proficient. The current organizational culture regarding the proficiency of staff can be both a barrier and a facilitator. Some facilitators for involving staff in training are to tempt them with enjoyable activities and rewards. It can also help to create a culture in which giving and receiving feedback is normal. Giving and receiving feedback improves the quality of work and makes feedback in other forms, like an examination, less threatening.²¹ These necessary changes in culture take time and the implementation of the national guidelines should be in line with the change in the culture.

In addition to the change in culture, a cyclical implementation of the national guidelines facilitates the sustainability and ensures a more solid implementation because the changes in the

organization and environment are taken into account.²² To ensure support among staff, it is also necessary to have proof of the positive effects of the national guidelines.^{17,22} These advantages could be made visible by evaluation and improvement of the procedures. Another way to facilitate implementation is to make national frameworks available for implementation. These frameworks could describe in more detail which steps should be taken for a solid implementation and could for example give expert opinions about the organization of training and examination of proficiencies. These frameworks should not be forced upon hospitals but could help them determine the right procedures.

Strengths and limitations

The strengths of this study are the high response rate of 81% and the mixed methods design. The content and face validity of the questionnaire was assured by consulting several experts. A general limitation in survey research is the risk of social desirable answers of respondents. In this case, respondents involved in the implementation of the guidelines could have given more positive answers than other respondents. This potential bias is minimized by collecting data in a confidential way and assuring that all results are treated confidentially. The hospital respondents answered most questions, including the confidential ones, minimizing the chance that respondents deliberately did not answer questions. Another limitation of this study is that it was conducted in the Netherlands, which might influence the generalizability of the findings. Although there are few countries with guidelines for the safe use of medical devices, this is a subject of growing importance and interest. Countries that decide to implement similar guidelines could use this study to facilitate the implementation. Furthermore, the questionnaire focused on two types of medical devices, which might also influence generalizability. On the other hand, staff indicated in the questionnaire that training and examination are similar for other high-risk medical devices.

CONCLUSIONS

This study shows that the implementation of a national guideline for the safe application of medical devices is a complex process in which all the different departments in a hospital are involved. An instigator such as an incident or external pressure facilitates implementation. This could indicate that staff do not always experience a sense of urgency for the proficient use of medical devices amongst other priorities. Moreover, differences were found between the training and examination of nurses and that of medical specialists. A better understanding of the reasons for this difference could reveal other barriers and facilitators of implementation. Another barrier is the lack of staff, time and money. For this, national guidance, for example through frameworks or expert opinions, could be helpful to facilitate the implementation of national guidelines.

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APPENDIX A

Questionnaire

Questions
General
What is your position within the hospital?
What is your link with the Covenant [national guidelines]?
Does the hospital have multiple locations? (Yes; No)
Do these locations have the same policy concerning proficiency? (Yes; No; Not applicable)
What is the number of beds in the hospital?
What is the amount of fulltime-equivalent (FTE)?
Implementation of proficiency requirements
What is the stage of implementation of the Covenant [national guidelines]? (Stage 1: Plan of implementation is present; Stage 2: Protocols are present and conform the national guidelines.; Stage 3: Protocols are followed and responsibilities are assigned; Stage 4: Implementation of proficiency requirements is being evaluated; Stage 5: Protocols are adapted based on the evaluation)
Who plays the leading role in implementation of proficiency requirements? Also indicate who has the leading role or who are represented in the multidisciplinary group. (individual; multidisciplinary group (medical specialist; quality employee; nurse; certified nursing assistant; medical physicist; head of the department; educationalist; coordinator medical technology; otherwise, namely ...))
When was implementation of the Covenant [national guidelines] started? (After publication of the Covenant [national guidelines] in November 2013; After a letter of the inspectorate which announced audit (23 May 2013); After audit of the inspectorate between June and November 2013; after the report of the inspectorate of June 2014; After audit of the inspectorate between the end of 2014 and begin of 2015; After a letter of the inspectorate about the inspection of implementation (15 June 2015); Otherwise, namely ...)
Does the staff notice changes on the organization of proficiencies? More than one answer possible. (Changes in their work methods; changes in proficiency exams; changes in registration of proficiency; few or no changes; otherwise, namely ...)
Training and testing for electrosurgery and infusion technology
Are professionals periodically trained for infusion technology/electrosurgery? (yes, no)
Is training mandatory? (always/mostly; sometimes; rarely/never)
Is training concluded with a test? (always/mostly; sometimes; rarely/never)

What is usually trained and tested?

(knowledge; skills; both)

Who determines how proficiency requirements are being trained or tested?

(Education committee/human resources; device committee/medical technology/medical physics; teamleader/direct manager; medical department head; division board; board of directors; otherwise, namely ...)

Who develops training and testing for infusion technology/electrosurgery which are being used in your hospital?

(A department of the hospital; federation of medical specialists; manufacturers of medical technologies; external organizations specialized in development of training; otherwise, namely ...)

How do you assess the quality of training offered by the manufacturer?

(Excellent; sufficient; moderate; insufficient; not applicable)

Who is responsible for the actual provision of training for infusion technology/electrosurgery to professionals in your hospital?

(Education committee/human resources; device committee/medical technology/medical physics; teamleader/direct manager; medical department head; division board; board of directors; medical board; otherwise, namely ...)

Registration of proficiency

At which level is proficiency for infusion technology/electrosurgery registered?

(hospital level; department level; individual level)

Who monitors if compulsory training for professionals on infusion technology/electrosurgery is completed and registered?

(Device committee/medical technology/medical physics; teamleader/direct manager; medical department head; division board; board of directors; medical board; otherwise, namely ...)

When is usually discovered that staff is not proficient to use infusion technology/electrosurgery?

(During a check of proficiency before the use of a device; when an adverse event happen during the use of a device; at a periodic check; during annual assessment interview; otherwise, namely ...)

What action is usually taken when a professional is not proficient to use infusion technology/electrosurgery?

(The use of the medical device is taken over by a proficient colleague; the use of the medical device is postponed; de medical device is used anyway; otherwise, namely ...)

To what extent is the organization (ie training and registration) of proficiencies for the use of infusion technology/electrosurgery in line with the organization of other high-risk technologies used by professionals?

(To a very high degree; to a high degree; to a reasonable degree; hardly; not at all; I don't know)

Finally

Additional comments

APPENDIX B

Topic guide for interviews

Introductory

What is your position within the hospital and how are you involved in implementation of proficiency requirements of the National guidelines?

How did the hospital approach implementation?

What is the state of implementation?

Can you tell us briefly what the hospital has implemented?

Barriers and Facilitators

How did the hospital come to this system of training and registration of proficiencies?

Why has the hospital made these choices?

What were barriers during implementation?

Was it hard to implement proficiency requirements?

How did the hospital deal with these barriers?

(How) could these barriers be prevented?

What were facilitators during implementation?

What went well and why?

Concluding

Do you think this hospital is a forerunner hospital?

Which advice would you give to other hospitals?



CHAPTER 7

General discussion

This thesis focused on the safe use of medical devices in Dutch hospitals. To get more insight into the safety of medical devices and possible improvement measures we followed the patient safety cycle, which consists of five steps: measuring harm, understanding causes, identifying solutions, evaluating impact, and translating evidence into safer care. We did this by answering two research questions: *'To what extent is the safety of patients in the Netherlands threatened by medical devices, and what are possible solutions to improve the safe use of medical devices?'* and *'How do Dutch hospitals apply proficiency testing to improve the safe use of medical devices, and what is the attitude of healthcare staff towards proficiency testing?'* We discuss the findings of this thesis in light of the literature.

To what extent is the safety of patients in the Netherlands threatened by medical devices, and what are possible solutions to improve the safe use of medical devices?

The first research question reflects the first three steps of the safety cycle which are measurement of harm, understanding causes and identifying solutions. Our research showed that medical devices contribute substantially to AEs in Dutch hospitals. Chapter 2 showed that the use of a medical devices led to an AMDE of 2.8% in all hospital admissions. In the Netherlands this means that about 40% of the AEs are related to medical devices. When compared to other types of AEs in the Dutch context, AMDEs are more prevalent than for example medication-related AEs, which are already seen as an important priority for patient safety.^{1,2} The biggest group of AMDEs was related to the placement of an implant or the care around this placement. The medical devices that were most often related to potentially preventable AMDEs were scopes and implants. The most common natures of AMDEs were related to infection, sepsis, and incorrect placements and procedures. Infections are often found in AEs; they represent for example 40% of the surgical AEs.³

These results show that medical devices are a threat for patient safety, but one should realise that they are also inevitable for the best possible treatment of patients. For example, endoscopes make it possible to internally examine the patient without an incision, increasing the possibilities and ease for a diagnosis. Other medical devices, such as smart infusion pumps, increase safety by reducing medication error rates, and ultrasound-guided catheterisation reduces the number of adverse events such as arterial punctures.^{4,5} However, it is possible that medical devices introduce new risks, or do not eliminate all existing risks for patient safety. The exact impact of the combination of positive and negative effects of medical devices on patient safety is unknown. Next to this research, there is little research on the risks of medical device use for patients in general, and on the risks of specific medical devices. This lack of knowledge may be caused by difficulties in identifying the benefits and harm of medical devices. For individual healthcare staff, safety overviews of specific medical devices are more helpful than general overviews. It is

useful to compare medical devices with each other and with other procedures.⁶ This could help staff to choose a safer medical device, and enhance their awareness of risks of certain devices.

The second and third step of the safety cycle, understanding causes and identifying solutions are important steps in the design of preventive measures. In Chapter 2 we found that 24% of the AMDEs was potentially preventable. Human error is named as a common cause in an AMDE study⁷, but other studies show that AMDEs are caused by human-technology interaction.^{8,9} Human-technology interaction is not solely a human error, because the device, for example the design, plays an important role in the origin of the AMDE. In the Netherlands the 'Covenant safe application of medical devices in hospitals' was developed to reduce the number of AMDEs. Safe use is one of the three main requirements, next to a safe product and a safe environment. These components are also taken into account in the Systems Engineering Initiative for Patient Safety (SEIPS) model (Figure 1).¹⁰ The SEIPS model is in line with the Swiss cheese model described in the introduction, and indicates that errors are caused by a combination of faults and incidents occurring at the same time and leading to an event. The Swiss cheese model focuses on causes and contributing factors of AEs, giving the possibility to identify the root causes of AEs. The Swiss cheese model is less suitable however to describe the interactions between human and device which could lead to AMDEs. To describe these interactions the SEIPS model could be used, which focuses on system design and its impact on processes and outcomes. The SEIPS model shows us that even though a case is marked as having a single cause, several other factors and interactions probably played a role. The combination of the causes, contributions and interactions from both the Swiss cheese and SEIPS model could help to identify improvement measurements to prevent AMDEs in the future.

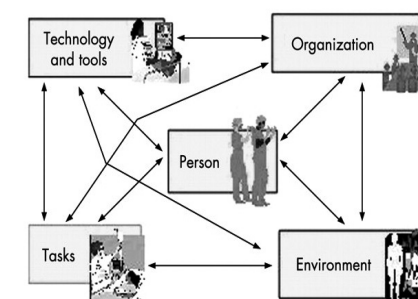


Figure 1. part of the SEIPS model that influences processes and therefore patient outcomes and employee and organisational outcomes.¹⁰

The SEIPS model is commonly used in patient safety to describe the influences on the person (healthcare provider, other staff members, patients etc.) in the centre of the model. According to

the work system model, a person performs a range of tasks using various tools and technologies. The performance of these tasks occurs within a certain physical environment and under specific organisational conditions. All these components interact with each other and influence each other, leading to a specific outcome. The components are all influenced by several factors. The person component for example is influenced by knowledge, motivation and characteristics. Examples of organisational elements are teamwork, communication, work schedules and relationships. Technologies are characterised by information technology, medical devices, and human factor characteristics of technologies. The task component is e.g. influenced by variety, content and autonomy. For the environmental factors, noise, lighting and work station design could be of influence.

The covenant focuses on three of the components, namely safe use (person), a safe product (technology and tools) and a safe environment (environment). Although the other components of the SEIPS model are not named, they influence the person, technology and tools and environment in several ways. In the covenant different aspects are named to ensure safety next to proficiency of users. For example, the possibility for staff to check the technical state of the device, preventive maintenance and procedures for when an incident happens.¹¹ Many of the aspects that could influence safety are also taken into account by hospitals in risk assessment tools for medical devices.

Chapter 3 shows that the 'function of the device', 'severity of AEs' and 'frequency of use' are most often used when assessing the risk of a medical device. The risks assessed by these tools are used to determine the necessary amount of training. This helps in prioritising training, but will not automatically lead to a reduction in the number of AMDEs. One of the reasons is that training focuses on the human component in AMDEs. However, some studies already suggested that human error is often multifactorial in origin.^{3,12} This is in line with the SEIPS model, which indicates that several interacting factors underlie unsafe situations in the use of medical devices. The interaction between humans and medical devices is of great importance in AMDEs.¹³ This interaction might not always emerge from the patient records, which are studied in Chapter 2, and is therefore difficult to find. For example, when the wrong dose of a medication is administered it might not be clear from the patient record whether this is a calculation mistake (human error), wrongly programmed into the infusion pump (human-technology interaction) or an internal error of the infusion device (technical error). Staff perform a range of tasks using tools and technology within an environment under specific conditions, and all these elements influence the performance. However, for the identification of solutions as next step of the safety cycle we chose to focus on the human factors (knowledge). Currently, hospitals are trying to minimise AMDEs caused by human errors with training.¹⁴ In Chapter 4 we discuss the possibility of using proficiency testing as a possible solution to improve the safe use of medical devices.

With proficiency testing it might be possible to save time by tailoring training when necessary and possible. Moreover, the test enhances learning by providing a better long-term retention of knowledge.¹⁵

How do Dutch hospitals apply proficiency testing to improve the safe use of medical devices, and what is the attitude of healthcare staff towards proficiency testing?

The fourth step of the safety cycle is to evaluate the impact of measures, in our research an infusion pump proficiency test for nurses which is described in Chapter 4. This test showed that it is possible to significantly divide nurses by knowledge level ($p < 0.001$), which might be useful to identify nurses who need additional training. Because the test was developed based on proficiency training, it could be used for tailored training in the future. Moreover, nurses think that a proficiency test can be used to improve patient safety by making it obligatory for nurses to pass a test before they are allowed to use the medical device. As described in Chapter 5, physicians are more hesitant towards proficiency testing. Although we did not implement proficiency tests in hospitals as the fifth step of the safety cycle, we asked hospitals about barriers and facilitators for the implementation of training and examination. To arrive at a competence-based training for healthcare staff the added value has to be shown, such as less training, training tailored to the risks and the level and interests of staff, and eventually an improvement in patient care.

Healthcare staff has an important role in the safe use of medical devices and is represented in the centre of the SEIPS model. Although healthcare staff is influenced by several factors, it is important that they are proficient in using a device. This thesis focused on training as one of the possible solutions, which is already used by hospitals to achieve and maintain proficiency of medical device use. However, the use of proficiency tests could further support in differentiating proficiency and training needs.

Chapter 3 shows that the risk of a medical device already plays an important role in the training; 47 of 65 hospitals base their type and amount of training on the risk of the medical device. The shift of time-based training towards competency-based training is also visible in the medical device training of professionals. At least 21 of the 65 hospitals examine their staff for the use of medical devices and base the type and frequency of testing on the risk of the device. Moreover, Chapter 6 shows that about 80% of the hospitals complete the training of high-risk medical devices for nurses with a test, about 30% of the hospitals will also do this for physicians. As explained in the introduction, competency-based training ends after a certain level of competency is reached. Even though the use of a test does not mean that hospitals have competency-based training, it gives the opportunity to tailor the training needs to the abilities of the staff. For competence-based training there is an increasing need for summative

and formative assessment methods, which are not always available for medical devices. The finding that hospitals complete training of their staff with a test does not necessarily mean that this training is tailored to the test results.

In Chapter 4 we describe the development and validation of a proficiency test for infusion technology. To obtain a valid and reliable proficiency test the development has to be thorough, for example by using cognitive task analysis.¹⁶ The cognitive task analysis method analyses and represents the cognitive activities needed to perform a task proficiently. The product of the analysis can be used to design training and tests. The proficiency test we developed shows that when following the different steps of cognitive task analysis, it is possible to develop a test that can be used in clinical practice. A drawback of this method to develop a proficiency test is the effort and resources required. Moreover, it might be difficult to implement proficiency testing within the hospital. In Chapter 6 we describe the barriers and facilitators of implementing the 'Covenant safe application of medical devices in hospitals' and especially the training, examination and registration of proficiency of staff. We found that most barriers and facilitators were organisational factors, such as readiness, strength of the evidence base, and addressing barriers experienced by frontline staff. Furthermore, staff do not always feel a sense of urgency to improve the safe use of medical devices. We also found differences between training and examination for devices used by nurses and those used by medical specialists. More barriers are perceived by respondents regarding training and examining medical specialists as compared to nurses. However, it is unclear whether hospitals do not try to implement training and examination, or whether they try but fail.

In implementing proficiency tests the perception of healthcare staff is important. Chapter 4 and Chapter 5 show the difference in beliefs between nurses and physicians. Nurses would accept medical device proficiency tests as part of their education. Moreover, they agree that nurses should pass a proficiency test before being allowed to work with a medical device. Among physicians, proficiency tests encountered much resistance as they believe that proficiency is already sufficiently ensured. When proficiency tests are developed, physicians think that medical devices should not be tested individually, but be embedded in a larger entity. This thought is in line with CanMEDS framework, which represents seven roles for proficient healthcare staff, emphasising that different aspects are important to be proficient.¹⁷ However, for the safe use of medical devices it is important to be proficient in the use of the device, especially because of the fast development and changes of such devices. Proficiency testing makes it possible to tailor the training needs to ensure proficiency in a more efficient way than with regular training.

This switch from time-based training towards proficiency-based training could encounter several barriers when implemented. These barriers are expected to be similar to those encountered

when implementing the covenant (training and examination), e.g. burden and strength of the evidence. Facilitators like readiness, management support and feedback of results should be used to more easily implement proficiency testing in hospitals. It is possible that more resistance is encountered from physicians, because their attitude towards proficiency testing is more negative, and more changes are necessary to implement proficiency tests for them. Next to proficiency testing, other effective methods could be used for continuing medical education, such as interactive education, feedback, academic detailing and reminders.¹⁸ Hospitals should invest in new methods of ensuring proficiency of staff to motivate them to learn and stay proficient. When proficiency for medical devices is fully ensured and embedded within hospitals the safety cycle continues with the first step: the measurement of harm done by medical devices.

METHODOLOGICAL CONSIDERATIONS

This thesis described several studies that contributed to improving the safe use of medical devices. A strength of this thesis is that we followed the full patient safety cycle as a structured approach.¹⁹ Moreover, the different studies have a good response rate and provide an overview of the perspectives of different stakeholders with different study methods. A limitation of this thesis is that we focused only on the Netherlands. The 'Covenant safe application of medical devices in hospitals' makes the Dutch legal environment different to those of other countries. This makes it difficult to project our results on other countries. However, some findings, such as improvement measures and implementation strategies, might be useful for other countries. For the safety in Dutch hospitals it is an advantage that the study focused on the Dutch context. This facilitates the application of the findings almost directly in hospitals, with some adjustments for the local context.

For an overview of the number of AMDEs we used a patient record review study. Patient record review is used for detection of specific types of AEs, like medication or surgery related adverse events, and for general overviews. This method however is not necessarily the best suitable for the detection of AMDEs, although it is the best known and most common method to detect specific types of AEs. Moreover, the method is not suitable to determine the causes of AMDEs in a reliable way, which did not allow for us to determine the causes based on our own research. For example, when medical devices are involved in AEs, it might be difficult to determine the role of the medical device based on only the patient record. General overviews are helpful for policy makers and to monitor effects of safety programmes.²⁰

Another limitation of this thesis is the way we looked at proficiency. As explained in the introduction with the CanMEDS framework, proficiency of health care staff is represented by several roles. In this thesis we focused on the technical side of proficiency. However, other skills

are also important for the safe use of medical devices, for example the communication with colleagues. Focusing on different types of skills might further improve the safety of patients. Moreover, our study followed the steps of the patient safety cycle once. Therefore, we did not look into the change of patients' safety regarding medical device use. Before harm is measured again, proficiency testing and tailored training should be implemented in all hospitals. A new evaluation of AMDEs could show the effects of this intervention, and which points should be targeted in future.

RECOMMENDATIONS

This thesis is a first step to gaining more insight into the safe use of medical devices in general. We hope the importance of this subject will be noticed and further research will be carried out. Therefore, we provide the following recommendations.

Enhance the visibility of the risks of medical devices

Medical devices are used in almost all admissions in Dutch hospitals, which makes them an important component of healthcare. The SEIPS model shows the importance of technology, as it is one of the five main components for safe care. Although medical devices are important in healthcare, staff has little knowledge about the risks of medical devices in general and the consequences for patient safety. To make healthcare staff more aware, they should be provided with continuous and local evidence of safety and risks of medical devices. In this study we used the common method of patient record review to detect AMDEs. However, it might not be the most suitable method for the detection of AMDEs and their causes. For example, a mistake in the admission of medication with an infusion pump (e.g. too fast or too slow admission) might not be noticed because no direct effects are visible, but could lengthen a patient's duration of stay. New trigger tools for the identification of medical devices could be developed by linking information from medical devices to patient records. For the example of an incorrect infusion rate this would mean that the infusion rate of the electronic prescription is linked to the real infusion rate to detect inconsistencies. Moreover, technology to register abnormalities, for example in physical parameters or surgery lasting longer than expected, could be used to find potential AMDEs.²¹ To gain more insight into the occurrence of AMDEs, a first step would be to compare prospective research (e.g. observations) with the retrospective research as we did. This would give insight into which incidents occur with medical devices, what the (long-term) consequences are for patients, and what can be detected from the patient records afterwards. Moreover, the link between the different components of the SEIPS model can be considered, to see the interactions that lead to AMDEs. The first link on which to focus is the link between person and technology. Other studies attributed AMDEs to human-technology interaction. Observations could be used to find how the device and the human play a role in the origin of AMDEs.

Next to general overviews, healthcare staff could be made more aware of safety by means of a safety indication on individual medical devices. An upcoming method to compare medical devices is comparative effectiveness research.²² This is a method to identify best practices in clinical settings, making the research more relevant for clinical practice. Different research methods, such as randomised controlled trials, observational research and literature reviews can be combined to provide safety and effectivity evidence for well informed decisions in clinical practice.²² Two or more medical devices or procedures can be compared to provide information about for example effectiveness, clinical outcomes and safety. This information can be used to help healthcare staff make decisions to use specific medical devices, and highlight the risks related to specific medical devices. An example is an observational study that followed patients with two different methods of pacemaker lead placement. The choice of treatment was made without interference of the researchers. To get comparable groups, researchers matched patients using eleven pre-implant baseline characteristics. Their comparative effectiveness assessment showed that one method had lower revision rates and a lower cost burden. This could support physicians in their choice of treatment.²³ Other strategies that are already used to improve patient safety could also be applied to improve the safe use of medical devices. For example, improving the safety culture and teamwork with leadership walk rounds, structured educational programmes, team-based strategies and simulation-based training programmes.²⁴ Moreover, reports of incidents currently collected in hospitals could be stored in national databases where central monitoring is possible and hospitals could learn from each other. This is already done in the USA, where the MAUDE database is used. The Manufacturer and User Facility Device Experience (MAUDE) data base, maintained by the FDA, stores reports on adverse medical device events submitted by both mandatory and voluntary reporters. Researchers use this database to investigate device-related complications and the types and frequencies of complications reported over the years.²⁵ It should be monitored whether these, or other, initiatives are effective in generating more awareness of medical device safety and the safety of patients.

Gain more insight into the root causes of adverse medical devices events

Knowledge of the causes of AMDEs could provide valuable information for the development of tailored strategies to decrease the likelihood of similar adverse events occurring in the future. There are several possibilities to gain different types of information and insights. Root-cause analysis (RCA) and health failure mode and effect analysis (HFMEA) are commonly used methods. RCA is a retrospective approach used to ascertain the "root cause" of a problem that has already occurred, whereas HFMEA is a prospective risk assessment tool whose aim is to recognise risks to patient safety.²⁶ Prospective risk assessment, like HFMEA, is already applied in Dutch hospitals when new devices are implemented. With HFMEA, high-risk processes are analysed and possible hazards are identified. The parts of the processes that have the highest risks for the safety of the patient are altered before failure can occur. HFMEA is very useful in proactively recognising

and preventing potential problems, but is very costly and time consuming. HFMEA could be helpful in identifying potential hazards with the use of medical devices and minimising them, especially when a new device is introduced. In RCA a team of skilled staff analyses a problem, which includes defining the event, verifying the root cause(s), and creating solutions. The quality of RCA is dependent on the available data of the event and the skills of the team members. RCA could be used in hospitals to identify incorrect application of, or problems with devices after implementation and should be used in larger studies to identify root causes of AMDEs in general.

In our study a retrospective method is used, but a combination of different methods is necessary to understand the context and underlying interactions of AMDEs. This could for example be a combination of observations, interviews and extended incident reports in which (near) misses are analysed with root-cause analysis methods. Moreover, the safety-II approach should be used to gain more insight in the safe use of medical devices.²⁷ The first steps would be to consider cases of success and to look into the differences between work-as-imagined and work-as-done to get more insight in the resilience of the system.²⁸ The combination of research methods could provide more information than patient records in which incidents are described less extensively or not at all. The SEIPS model can be used as a reference for exploration of the different interactions in AMDEs that might not be possible to extract from patient records, for example the interaction between humans and technology. When the technology works flawlessly and the staff is well trained, the use of devices could still lead to AMDEs. For example, a design that is not user-friendly can make it difficult to find the right settings (delay) or easy to press a wrong button (error). Another example is the interaction between environment and healthcare staff.

Medical devices produce an overload of alarms, which are not clinically relevant and can lead to alarm fatigue. Alarm fatigue may occur when staff is exposed to an excessive number of alarms. This can result in desensitisation to and missed alarms and is a common threat to patient safety.²⁹ When causes and the interaction between them are known, appropriate measures can be taken. In the two examples given above, the design of devices plays an important role. When this information is obtained from root-cause analysis, a solution can be found that suits this cause. For example, human factor engineering, which researches the variables that affect user performance. This is considered when designing a device in accordance with the needs of staff, as they interact with the device. In this approach end users can be involved in the development or improvement of a device.⁷ Moreover, hospitals could take user-friendly design of a device into account and organise possibilities for users to experience and evaluate new devices. These examples show that when the cause of AMDEs is known, it is possible to come up with solutions that are tailored to the cause. This might have more effect on patient safety than introducing general solutions. Furthermore, when explained to healthcare staff, this increases the support

for measures, making it easier to introduce and follow the measures to further improve the safety of patients.

Find new, time efficient ways to ensure proficiency of users of medical devices

Hospitals use training to maintain the proficiency of their staff in working with medical devices. The drawback of training is that it takes time, which is an increasing problem as the number of medical devices grow. Basing the amount of training on the risk of the medical device, proficiency testing and tailored training might decrease the burden of ensuring proficiency. However, other methods could be used or developed to further decrease this burden. A possibility is to implement the use of entrustable professional activities (EPAs), a concept that is used in competency-based medical education. An EPA can be defined as 'a unit of professional practice that can be fully entrusted to a trainee/staff member, as soon as he or she has demonstrated the necessary competence to execute this activity unsupervised'.³⁰ EPAs describe what staff must demonstrate before they are trusted, how staff should be prepared, and how the staff readiness is assessed. EPAs can also be applied to medical device use, both for trainees and staff. EPAs also have to be evaluated regularly to ensure proficiency, which is time-intensive. However, EPAs could be used to concentrate medical device use. Medical devices are becoming increasingly more complex and specific for certain conditions or treatments. Similar to treatments that only can be carried out by selected hospitals or staff members, the use of certain medical devices can be limited too. Staff members can be linked to EPAs to only train and certify the staff members for the EPAs to which they are linked. This approach reduces training and testing time because staff members use fewer medical devices. The use of EPAs and the corresponding assessment of readiness can be used to ensure proficiency. Other methods known for continuing education could also be tested for usability in ensuring proficiency. For example, regular feedback of peers or trainers, academic detailing by an expert to provide staff with the latest information, or reminders that give staff an short update of the medical device that they are going to use.¹⁸ The different methods should be tested, for example on ensuring proficiency, usability and acceptance among staff.

Use medical devices to improve patient safety

The use of medical devices is an interaction between humans and technology. As can be seen in the SEIPS model other factors also play a role, but the interaction between the human and the device is of utmost importance. Training and increasing the awareness of staff are steps towards the safe use of medical devices. However, humans are fallible and these measures will not prevent all AMDEs from happening. To further reduce the number of AMDEs, medical devices could be used to improve safety. Techniques for the improvement of safety should not be limited to those already in place, such as human centred design and alarm warning systems. New techniques such as artificial intelligence might be the next step towards safer medical

devices. Artificial intelligence is intelligence demonstrated by machines and is for example used in self-driving cars. This technique could also be developed for use in medical devices. Self-thinking medical devices will not take over the treatment of patients right away, but could be used to assist staff in the beginning, for example, by proposing device setting based on patient characteristics and circumstances. A recent study already showed that it is possible to use artificial intelligence for an adequate diagnosis in retinal disease.³¹ Other possibilities could be to adjust alarms to (personal) circumstances, recognising emergency situations and giving feedback to the users. The future should show what is possible with new techniques in healthcare. New developments in healthcare will show what is possible in the field of medical devices, and how this will influence patient safety.

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Summary

Awareness of the importance of patient safety started to increase in the nineties, after revolutionary research emphasised the importance of the safety of patients in hospitals.^{1,2} The emphasis on patient safety is also increasing in the medical device field, a fast-developing and changing environment. This growing attention is especially visible in the increased number of medical device regulations at the European and national level.³⁻⁵ The Dutch regulations, defined in more detail as the 'Covenant safe application of medical devices', describe guidelines that hospitals must comply with in the field of the safe use of medical devices. The guidelines in this covenant facilitate the safe implantation, use and disposal of medical devices. One of these guidelines is the obligation that all staff should be proficient to use medical devices, as 'human involvement' causes from 70% to 87% of adverse medical device events (AMDEs), although studies suggest they are typically multifactorial in origin.⁶⁻⁹

In this thesis we focus on the Dutch context, in which regulations became more extensive after implementation of the 'Covenant safe application of medical devices in hospitals' in 2011. The aim of this thesis is to explore the current safe use of medical devices and possible solutions to improve it by answering the following two research questions.

- 1) *To what extent is the safety of patients in the Netherlands threatened by medical devices, and what are possible solutions to improve the safe use of medical devices?*
- 2) *How do Dutch hospitals apply proficiency testing to improve the safe use of medical devices, and what is the attitude of healthcare staff towards proficiency testing?*

In **Chapter 2** we measured the patient harm related to medical devices in Dutch hospitals. Furthermore, we looked into the causes of harm. We studied data from two patient record studies in which a total of 6,894 patient records from 32 Dutch hospitals were included in 2011/2012 and 2015/2016. The patient records were reviewed for AMDEs by trained nurses and medical specialists. In total, 2.8% of the hospital admissions led to an AMDE, from which 24% was potentially preventable. The most common nature of AMDEs was related to infection, sepsis and incorrect placements and procedures. The biggest group of AMDEs were related to the placement of an implant or the care around this placement. The medical devices most frequently related to potentially preventable AMDEs were scopes and implants. The increasing complexity and use of medical devices will continuously influence healthcare. We recommended that safety and safe use of medical devices is a subject of attention and further research.

Chapter 3 explored the use of risk assessment tools for medical devices and their link with training in hospitals. Within a broader questionnaire on implementation of a national guideline we collected quantitative data on the training of staff in the use of medical devices and the link between training and the risk of a medical device. All hospitals that responded to the questionnaire (65/80) use a risk assessment tool. The criteria mostly used to assess risks are

the function of the device (92%), the severity of AEs (88%) and the frequency of use (77%). Risk assessment tools are used to determine the volume and type of training for staff. Forty-seven out of 56 hospitals (84%) base their training on the risk of a medical device. For low-risk devices the required training is often reading the user manual, whereas practical training is mostly used for medium and high-risk devices. About twenty hospitals provided additional information about examinations for the different medical devices. None of the hospitals examined staff for low-risk devices, about half of the hospitals had an examination for medium-risk devices, and all hospitals carried out some form of examination for high-risk devices. Understanding the link between the risk of a device and the volume and type of training could improve the proficiency of users and might therefore influence patient safety.

Chapter 4 described the development and validation of an infusion pump proficiency test for nurses. First, proficiency requirements were developed by infusion pump experts using cognitive task analysis. With these requirements a proficiency test for nurses was developed. This test was validated among three groups of nurses with different knowledge levels (nursing students, less than five years of experience and more than 10 years of experience) using classical test and item response theories. For the proficiency test of 40 questions, 23 of the 64 proficiency requirements were used. The test was completed by 226 nurses, who agreed that healthcare will become safer if a nurse has to pass this exam before working with an infusion pump. Significant differences were found between the test results of the three groups of nurses, in which those with more experience had higher scores ($p < 0.001$). This shows that proficiency testing is a promising method to assess the proficiency of nurses with medical devices and could be used to tailor training needs.

The interview study described in **Chapter 5** explored the attitudes and perceptions of medical specialists on proficiency, proficiency requirements and proficiency tests for the safe use of electrosurgery. The participants recognised that the use of electrosurgery poses risks to the safety of patients and perioperative staff. According to some participants, increased awareness on the risks of electrosurgery is required. Most medical specialists however thought that the proficiency of users of electrosurgery is sufficiently ensured. Medical specialists stated to support proficiency requirements when they are endorsed by their scientific association. Proficiency tests encountered much resistance. One of the main reasons for the resistance was the small contribution of electrosurgery to the whole procedure. Electrosurgery could be one of many subjects in a course or proficiency test. If proficiency for electrosurgery is ensured in the future, the positive attitude towards proficiency requirements and the more negative attitude towards proficiency tests should be considered.

In **Chapter 6** the barriers and facilitators of the implementation of the 'Covenant safe application of medical devices' in Dutch hospitals were described. To gain insight into the implementation and explore the barriers and facilitators, a questionnaire was sent to all 80 Dutch hospitals (response rate 81%) and an additional six interviews with hospital staff were held. The questionnaire showed that not all hospitals implemented the covenant, even though the health care inspectorate demanded this. Furthermore, the questionnaire showed implementation differences within the hospital. For example, the policies for training and examination for medical devices differ according to the main users. Nurses were significantly more trained and examined and the proficiencies were also monitored more often. Training for infusion pumps (nurses) was more often a combination of knowledge and skills (67% of the training) compared with training for electrosurgery (medical specialists), in which skills are mostly trained (48% of the training). The interviews showed that implementation of national guidelines for the safe use of medical devices is a complex process that involves all departments. Most barriers and facilitators of implementation of the national guidelines can be found in organisational factors, like readiness, strength of the evidence base and the addressing of barriers of the frontline staff. Facilitators for implementation were the knowledge and beliefs of staff, feedback to staff, a plan for sustainability, and external resources.

Chapter 7 is the general discussion of this thesis. We describe our findings in light of the literature and give recommendations. We aimed to answer two research questions focused on the safe use of medical devices in Dutch hospitals.

To what extent is the safety of patients in the Netherlands threatened by medical devices, and what are possible solutions to improve the safe use of medical devices?

Medical devices can pose a threat to patient safety. However, the positive effects of medical devices probably outweigh this threat. Without medical devices patients could be helped less adequately or not at all. Nevertheless, the number of AMDEs should be reduced as much as possible. This could be done for example by working with the medical devices that prove to be the safest in clinical practice. Moreover, insight into the causes of AMDEs could assist in selecting preventive measures to improve patient safety. A recommendation for practice is to make the risks of medical device use more visible. The increase in awareness might improve the safe use of medical devices. The results we found in the literature suggest that AMDEs are mostly caused by human factors or human-technology interaction. The exact role of the device was not described in our record reviews and therefore remains unclear. For now, solutions to improve the safe use of medical devices should focus on the proficiency of users. A first step could be to develop proficiency tests for medical devices on which training can be tailored. Ensuring proficiency always remains important, also when future research more clearly describes

the role of medical devices and other factors in the emergence of AMDEs. Tools that assess risk could help in prioritising training or examination, but also in other important aspects like ensuring safe devices and environments. In the future more insight should be gained into the root causes of AMDEs. Knowledge of the causes of AMDEs could provide valuable information for the development of strategies to decrease the number of AMDEs.

How do Dutch hospitals apply proficiency testing to improve the safe use of medical devices, and what is the attitude of healthcare staff towards proficiency testing?

Hospitals apply testing in combination with training, especially for high-risk medical devices. The use of tests does not automatically make the training proficiency-based, this requires that training is adapted based on the test results. For medical devices more valid and reliable tests should be developed to adapt training based on test results. Implementation of competency-based training could encounter several barriers, such as resistance from healthcare staff. It is likely that more resistance will come from physicians than from nurses. At this moment physicians are tested less, so they would face more changes. Moreover, physicians have a more negative opinion of proficiency testing. Physicians believe that proficiency is sufficiently ensured, while nurses think that passing a proficiency test before working with a medical device will make healthcare safer. We recommend to find new ways to ensure the proficiency of users, such as entrustable professional activities or reducing the number of medical devices used by a staff member. Moreover, medical devices should be used more to improve patient safety. New techniques, for example artificial intelligence, might be the next step towards safer medical devices. Other possibilities could be to adjust alarms to (personal) circumstances, recognising emergency situations and giving feedback to the users. New developments in healthcare will show what is possible in the field of medical devices, and how this will influence patient safety.

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Samenvatting

Het bewustzijn voor patiëntveiligheid is sinds de jaren negentig toegenomen, nadat onderzoek het belang hiervan in ziekenhuizen benadrukte.^{1,2} De aandacht voor patiëntveiligheid neemt ook toe in relatie tot medische hulpmiddelen, een gebied dat snel ontwikkelt en verandert. Deze groeiende aandacht is zowel zichtbaar op Europees als op nationaal niveau.³⁻⁵ De Nederlandse regelgeving, die is uitgewerkt in het 'Convenant Veilige toepassing van medische technologie' beschrijft de richtlijnen waaraan ziekenhuizen moeten voldoen. De richtlijnen in dit convenant beschrijven de veilige implementatie, het gebruik en het afvoeren van medische hulpmiddelen. Eén van deze richtlijnen is de verplichting dat alle medewerkers bekwaam moeten zijn voordat ze een medische technologie mogen toepassen. Deze richtlijn bestaat omdat de oorzaak van AMDE's (Adverse Medical Device Events, zorggerelateerde schade gerelateerd aan medische hulpmiddelen) in 70 tot 87% wordt geclassificeerd als menselijke fout. Uit onderzoek blijkt echter dat AMDE's vaak meerdere oorzaken hebben.⁶⁻⁹

In dit proefschrift richten we ons op de Nederlandse context waarin regelgeving rondom medische technologie in 2011 werd uitgebreid met de implementatie van de 'Convenant Veilige toepassing van medische technologie'. Het doel van dit proefschrift is om het veilig gebruik van medische hulpmiddelen te onderzoeken en te kijken welke verbetermaatregelen mogelijk zijn voor het veilig gebruik van medische hulpmiddelen. Dit wordt gedaan door de volgende twee onderzoeksvragen te beantwoorden.

- 1) *In hoeverre wordt de veiligheid van patiënten in Nederland op dit moment bedreigd door medische hulpmiddelen en wat zijn mogelijke oplossingen om het veilige gebruik van medische hulpmiddelen te verbeteren?*
- 2) *Hoe passen Nederlandse ziekenhuizen bekwaamheidstoetsen toe om het veilig gebruik van medische hulpmiddelen te verbeteren en hoe staat het gezondheidszorgpersoneel tegenover bekwaamheidstoetsen?*

In **Hoofdstuk 2** hebben we de schade aan patiënten gerelateerd aan medische hulpmiddelen in Nederlandse ziekenhuizen gemeten. We bestudeerden gegevens uit twee patiëntendossierstudies uit 2011/2012 en 2015/2016 waarin in totaal 6894 patiëntendossiers van 32 Nederlandse ziekenhuizen zijn onderzocht. De patiëntendossiers werden op AMDE's gecontroleerd door getrainde verpleegkundigen en medisch specialisten. In totaal leidde 2,8% van de ziekenhuisopnamen tot een AMDE, waarvan 24% mogelijk te voorkomen was. De meest voorkomende aard van AMDE's was gerelateerd aan infecties, sepsis en incorrecte plaatsingen en procedures. De grootste groep AMDE's had te maken met de plaatsing van een implantaat of de zorg rondom deze plaatsing. De medische apparaten die het vaakst geassocieerd werden met mogelijk te voorkomen AMDE's waren scopen en implantaten. De toename in complexiteit en gebruik van medische hulpmiddelen zal een continue invloed hebben op de gezondheidszorg.

Wij raden aan dat veiligheid en veilig gebruik van medische hulpmiddelen een onderwerp van aandacht en toekomstig onderzoek is.

Hoofdstuk 3 gaat in op het gebruik van risicobeoordeling van medische hulpmiddelen en hun verband met training in ziekenhuizen. In een bredere vragenlijst over de implementatie van het convenant verzamelden we kwantitatieve gegevens over de opleiding van personeel in het gebruik van medische hulpmiddelen en het verband tussen training en het risico van een medisch hulpmiddel. Alle ziekenhuizen die op de vragenlijst hebben gereageerd (65/80) gebruiken een methode om het risico van medische hulpmiddelen te beoordelen. De criteria die gebruikt worden om het risico in te schatten zijn de functie van het hulpmiddel (92%), de ernst van complicaties (88%) en de frequentie van het gebruik (77%). Het risico van medische hulpmiddel wordt als criterium gebruikt om de hoeveelheid en het soort training voor het personeel te bepalen door 47 van de 56 ziekenhuizen (84%). Voor apparaten met een laag risico is de vereiste training vaak het lezen van de gebruiksaanwijzing. Voor apparaten met een gemiddeld en hoog risico wordt meestal praktijktraining gegeven. Ongeveer twintig ziekenhuizen hebben aanvullende informatie gegeven over toetsing van de verschillende medische hulpmiddelen. Geen enkel ziekenhuis toetste personeel voor apparaten met een laag risico, voor apparaten met een gemiddeld risico had ongeveer de helft van de ziekenhuizen een toets en voor apparaten met een hoog risico hadden alle ziekenhuizen een vorm van toetsing. Inzicht in het verband tussen het risico en het type training kan de bekwaamheid van gebruikers verbeteren en daarmee de patiëntveiligheid beïnvloeden.

Hoofdstuk 4 beschrijft de ontwikkeling en validatie van een bekwaamheidstoets over infuuspompen voor verpleegkundigen. Als eerste werden bekwaamheids-eisen ontwikkeld door infuuspompexperts met behulp van cognitieve taakanalyse. Met deze eisen werd een bekwaamheidstoets voor verpleegkundigen ontwikkeld. Deze toets werd gevalideerd met klassieke testtheorie en itemresponstheorie onder drie groepen verpleegkundigen met verschillende kennisniveaus (verpleegkundestudenten, verpleegkundigen met minder dan 5 jaar ervaring en verpleegkundigen met meer dan 10 jaar ervaring). Voor de vaardigheidstoets van 40 vragen werden 23 van de 64 bekwaamheids-eisen gebruikt. De toets werd voltooid door 226 verpleegkundigen, die het erover eens waren dat de gezondheidszorg veiliger wordt als een verpleegkundige voor deze toets moet slagen voordat hij/zij met een infuuspomp mag werken. Significante verschillen werden gevonden tussen de toetsresultaten van de drie groepen verpleegkundigen waarbij degenen met meer ervaring hogere scores hadden ($p < 0,001$). Dit toont aan dat bekwaamheidstoetsen een veelbelovende methode is om de bekwaamheid van verpleegkundigen met medische hulpmiddelen te beoordelen en dat deze toetsen gebruikt kunnen worden om te bepalen welke en hoeveel training iemand nodig heeft.

De interviewstudie beschreven in **Hoofdstuk 5** onderzocht de attitudes en percepties van medisch specialisten over bekwaamheid, bekwaamheids-eisen en bekwaamheidstoetsen voor het veilige gebruik van elektrochirurgie. De specialisten erkenden dat het gebruik van elektrochirurgie risico's meebrengt voor de veiligheid van patiënten en personeel. Volgens sommige specialisten is een groter bewustzijn van de risico's van elektrochirurgie nodig. De meeste medische specialisten waren echter van mening dat de vaardigheid van gebruikers van elektrochirurgie voldoende is. Medische specialisten gaven aan bekwaamheids-eisen te ondersteunen wanneer deze ondersteund worden door hun wetenschappelijke vereniging. Bekwaamheidstoetsen zorgen voor veel weerstand. Eén van de belangrijkste redenen voor deze weerstand in het geval van elektrochirurgie is de geringe bijdrage van elektrochirurgie aan de gehele operatieprocedure. Elektrochirurgie zou één van meerdere onderwerpen kunnen zijn in een cursus of bekwaamheidstoets. Als de bekwaamheid voor elektrochirurgie in de toekomst geborgd wordt, moet rekening worden gehouden met de positieve houding ten opzichte van bekwaamheids-eisen en de meer negatieve houding ten opzichte van bekwaamheidstoetsen.

In **Hoofdstuk 6** worden de bevorderende en belemmerende factoren van de implementatie van het 'Convenant Veilige toepassing van medische technologie' in Nederlandse ziekenhuizen beschreven. Om inzicht te krijgen in de implementatie en de bevorderende en belemmerende factoren, werd een vragenlijst gestuurd naar alle 80 Nederlandse ziekenhuizen (responspercentage 81%) en werden er nog eens zes interviews met ziekenhuismedewerkers gehouden. Uit de vragenlijst bleek dat niet alle ziekenhuizen het convenant geïmplementeerd hadden, ondanks dat de inspectie voor de gezondheidszorg dit van ziekenhuizen eiste. Bovendien toonde de vragenlijst verschillen in implementatie binnen de ziekenhuizen. Het beleid voor training en toetsing voor medische hulpmiddelen met verschillende hoofdgebruikers is bijvoorbeeld anders. Verpleegkundigen werden significant vaker getraind en getoetst en de bekwaamheden werden ook vaker gecontroleerd. Training voor infuuspompen (verpleegkundigen) was vaker een combinatie van kennis en vaardigheden (67% van de trainingen) in vergelijking met training voor elektrochirurgie (medisch specialisten) waarbij meestal alleen vaardigheden worden getraind (48% van de trainingen). Uit de interviews bleek dat de implementatie van het convenant een complex proces is waarbij alle afdelingen betrokken zijn. De meeste bevorderende en belemmerende factoren van de implementatie van het convenant zijn te vinden in de organisatorische factoren, zoals gereedheid, sterkte van het bewijsmateriaal en het aanpakken van de barrières van het personeel. Bevorderende factoren voor implementatie waren de kennis en overtuigingen van het personeel, het geven van feedback aan personeel, een plan voor duurzaamheid en externe middelen.

Hoofdstuk 7 is de algemene discussie van dit proefschrift. We beschrijven onze bevindingen reflecterend op de literatuur en geven aanbevelingen. We hebben drie onderzoeksvragen

beantwoord die gericht waren op het veilige gebruik van medische hulpmiddelen in Nederlandse ziekenhuizen

In hoeverre wordt de veiligheid van patiënten in Nederland op dit moment bedreigd door medische hulpmiddelen en wat zijn mogelijke oplossingen om het veilige gebruik van medische hulpmiddelen te verbeteren?

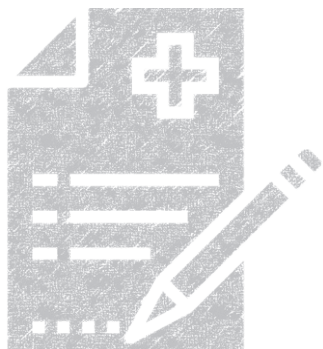
Medische hulpmiddelen kunnen een bedreiging vormen voor de veiligheid van de patiënt. De positieve effecten van medische hulpmiddelen wegen echter zwaarder dan deze gevaren. Zonder medische hulpmiddelen zouden patiënten minder adequaat of helemaal niet geholpen kunnen worden. Niettemin moet het aantal AMDE's zo veel mogelijk worden beperkt. Dit kan bijvoorbeeld worden gedaan door te werken met medische hulpmiddelen die in de klinische praktijk het veiligst blijken te zijn. Daarnaast kan inzicht in de oorzaken van AMDE's helpen bij het selecteren van preventieve maatregelen om de veiligheid van patiënten te verbeteren. Een aanbeveling voor de praktijk is om de risico's van het gebruik van medische hulpmiddelen beter inzichtelijk te maken. De toename van het bewustzijn zou het veilige gebruik van medische hulpmiddelen kunnen verbeteren. De resultaten die we vonden in de literatuur suggereren dat AMDE's meestal worden veroorzaakt door menselijke factoren of de interactie tussen mens en hulpmiddel. De exacte rol van het hulpmiddel werd niet beschreven in onze dossier studie en blijft daarom onduidelijk. Op dit moment moeten oplossingen om het veilig gebruik van medische hulpmiddelen te verbeteren zich richten op de bekwaamheid van gebruikers. Een eerste stap zou kunnen zijn om vaardigheidstoetsen voor medische hulpmiddelen te ontwikkelen waarmee de soort en hoeveelheid benodigde training kan worden bepaald. Het aantonen van bekwaamheid blijft altijd belangrijk, ook wanneer toekomstig onderzoek duidelijker de rol van medische hulpmiddelen en andere factoren bij het ontstaan van AMDE's beschrijft. Instrumenten die het risico inschatten kunnen helpen bij het prioriteren van training of onderzoek, maar ook bij andere belangrijke aspecten, zoals het waarborgen van veilige apparaten en omgevingen. In de toekomst zou er meer inzicht moeten worden verkregen in de hoofdoorzaken van AMDE's. Kennis van de oorzaken van AMDE's kan waardevolle informatie opleveren voor de ontwikkeling van methodes om het aantal AMDE's te verminderen.

Hoe passen Nederlandse ziekenhuizen bekwaamheidstoetsen toe om het veilig gebruik van medische hulpmiddelen te verbeteren en hoe staat het gezondheidszorgpersoneel tegenover bekwaamheidstoetsen?

Ziekenhuizen passen toetsen toe in combinatie met training, vooral voor medische hulpmiddelen met een hoog risico. Het gebruik van toetsen betekent niet automatisch dat het niveau van de training gebaseerd is op iemands kennis en vaardigheden, hiervoor moet de training worden aangepast aan de toetsresultaten. Voor medische hulpmiddelen moeten meer valide en betrouwbare toetsen worden ontwikkeld om de training aan te kunnen passen op basis van toetsresultaten. Bij implementatie van competentiegerichte training kan men verschillende belemmerende factoren tegenkomen, zoals weerstand van medisch personeel. Het is waarschijnlijk dat er meer weerstand zal zijn van artsen in vergelijking met verpleegkundigen. Op dit moment worden artsen minder getoetst, waardoor er voor deze groep meer zal veranderen. Bovendien hebben artsen een negatiever oordeel ten opzichte van bekwaamheidstoetsen. Artsen zijn van mening dat de bekwaamheid voldoende is geborgd, terwijl verpleegkundigen denken dat het verplicht halen van een bekwaamheidstoets voor een medisch hulpmiddel de gezondheidszorg veiliger zal maken. We raden aan om nieuwe manieren te vinden om bekwaamheid van gebruikers te garanderen, zoals bijvoorbeeld 'entrusted professional activities' of het verminderen van het aantal hulpmiddel dat personeel gebruikt. Bovendien moeten medische hulpmiddelen meer worden gebruikt om de veiligheid voor de patiënt te verbeteren. Nieuwe technieken, zoals bijvoorbeeld kunstmatige intelligentie, kunnen een volgende stap zijn naar veiligere medische hulpmiddelen. Andere mogelijkheden zijn om alarmen aan te passen aan (persoonlijke) omstandigheden, herkenning van noodsituaties en het geven van feedback aan gebruikers. Nieuwe ontwikkelingen in de gezondheidszorg zullen uitwijzen wat mogelijk is in het veld van medische hulpmiddelen en hoe dit de patiëntveiligheid beïnvloedt.

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About the author

Petra Porte was born on 29 March 1991 in Voorschoten, the Netherlands. After graduation from Atheneum at Veurs Lyceum Leidschendam in 2009, she studied technical medicine at Twente University in Enschede. She finished her Bachelor in 2012, after which she pursued with the technical medicine master medical sensing and stimulation. She did several clinical research internships at university hospitals and an expertise center for epilepsy. In 2015 she obtained her Masters degree, after which she started her PhD project on the safe use of medical devices. The PhD project was a collaboration between NIVEL (Netherlands Institute for Healthcare Research) in Utrecht and the VU University in Amsterdam. She worked at NIVEL from 2015 till 2017 and at the VU University from 2017 till 2018 to finish her PhD project. Currently, Petra is working as a clinical informatics trainee at the Albert Schweitzer Ziekenhuis in Dordrecht and is attending the post-Master programme of clinical informatics at the Eindhoven University of Technology.

PhD education

Petra followed several courses during her PhD research. She trained her research skills with the courses research integrity (VUmc Academy), English writing and presenting (Babel) and qualitative research (NIVEL). She learned more about the training and examination in clinical setting at the courses "Assessment and evaluation" (Maastricht University) and "Psychometrics applied to healthcare professions education" (European Board of Medical Assessors). Next to that she followed several workshops to obtain skills like networking, communication with infographics and LinkedIn.

Petra attended several congresses and scientific meetings. She attended the Mobile Healthcare Congress and the Learning Summit congress. Next to that she participated in scientific meetings (NIVEL), research group scientific meetings (NIVEL, VUmc) and PhD intervision (NIVEL). She also followed several colloquia (NIVEL) like 'participatory action research', 'do's and don'ts researchers' and 'capacity theory'.

Petra supervised education for Bachelor and Master students of the medicine study of VUmc in several subjects like patient safety and confidentiality. She did several lectures for medical interns and the midwifery academy in patient safety. Next to that, she mentored two internship students during their research Masters internship of the studies health science and biomedical sciences.

