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.\(^1\) 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.\(^2,3\) 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.\(^4\)

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?
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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