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The Incidence and Nature of Adverse Medical Device Events in Dutch Hospitals: A Retrospective Patient Record Review Study

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P.P., M.d.B., C.v.d.V., and C.W. did the paper concept and design. P.P. did the acquisition of data. P.P. and M.S. did the analysis and interpretation of data. P.P. drafted the manuscript. M.S., L.V., M.d.B., C.v.d.V., and C.W. did the critical revision of the manuscript for important intellectual content.
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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 was 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 2015/2016were reviewed for AMDEs by trained nurses and physicians.
Results: In 98.7%of the admissions, a medical device was used. Adverse events involving medical devices 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 ofmedical 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.

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 have 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: (a) an unintended injury, (b) resulting in prolongation of hospital stay, temporary or permanent disability or death, and (c) caused by healthcare management rather than by the patients' disease. Adverse events happen in 3% to 17% of the hospital admissions and are potentially preventable in 37% to 51% of the AEs.[6]

It is unknown in howmany AEs in hospitals amedical device is involved (AMDEs). One publication estimated more than 6600 incidents involving medical devices in the UK in 1999, including 87 deaths and 345 serious injuries.[7] The total number of hospital admissions was approximately 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] Adverse events involved medical devices in specific settings[5,11] and patientreported 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 Manufacturer andUser Facility Device Experience registration system in the United States that contains medical device reports submitted to the US Food and Drug Administration 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 AMDEs reporting as unnecessary, not possible or futile.[19] Another source for identifying AMDEs is 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 ofAMDEs 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: (a) What is the incidence of AMDEs in Dutch hospitals detected in patient records? And (b) Which types of medical devices are involved in AMDEs?

Methods

Design and Setting

The data used for this studywere 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 reviewstudies are repeated every 4 years tomonitor 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 (CI) of 1.0%, a sample size of 5409 is needed.[23] Therefore, data from two consecutive periodswere used for this article. Patient records from April 1, 2011, to March 31, 2012, and from April 1, 2015, to March 31, 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 samplewere 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 younger than 1 year were excluded, because the trigger tool used is not developed for these patient populations.[26] In 2015/2016, a new randomsample 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 protocolwas 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 with 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 (http://links.lww.com/JPS/A240).[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 after 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 AEs 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 κ statistic of 0.49 (95% CI = 0.42–0.56) in 2011/2012 and a κ statistic of 0.60 (95% CI = 0.55–0.66) in 2015/2016. The agreement between physicians' assessment for the presence of an AE was fair with a κ statistic of 0.40 (95% CI = 0.33–0.46) in 2011/2012, and a κ statistic of 0.35 (95% CI = 0.28–0.42) 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 ofmedical 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 as follows: 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 categorywas 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 not only 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 characteristicswere 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 because of 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.

[Figure 1], [Figure 2], [Table 1],

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% experienced an AMDE. Adverse events involving medical device 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%.

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% CIs can be found in Appendix 2 (http://links.lww.com/JPS/A241). Adverse events involving medical device 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. Adverse events involving medical device were most common related to infection, sepsis, and incorrect placements and procedures. Approximately 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.

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% to 16.6% of the hospital admissions. [6] Compared with 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 nonsurgical 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 anesthesia because of faulty devices during surgery,[9] 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 that 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] In addition, techniques such as big data and pattern recognition could help in identifying abnormalities. A study showed that it is possible to develop automatic detection tools to detect rareAMDEs.[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 such as 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.

Although 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 kinds 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 with AEs, which show a preventability of 37.1% to 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, such as shorter recovery time and smaller scars.[44] Although it causes a considerable number of AMDEs, several studies show lower AMDE rates compared with 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. Adverse events involving medical device 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 center 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 after 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 judgment. 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 that 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]

Conclusions

This study is the first study that gives an overview of AMDEs in hospitals. Adverse events involving medical device 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 analyze 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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Tables and Figures

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

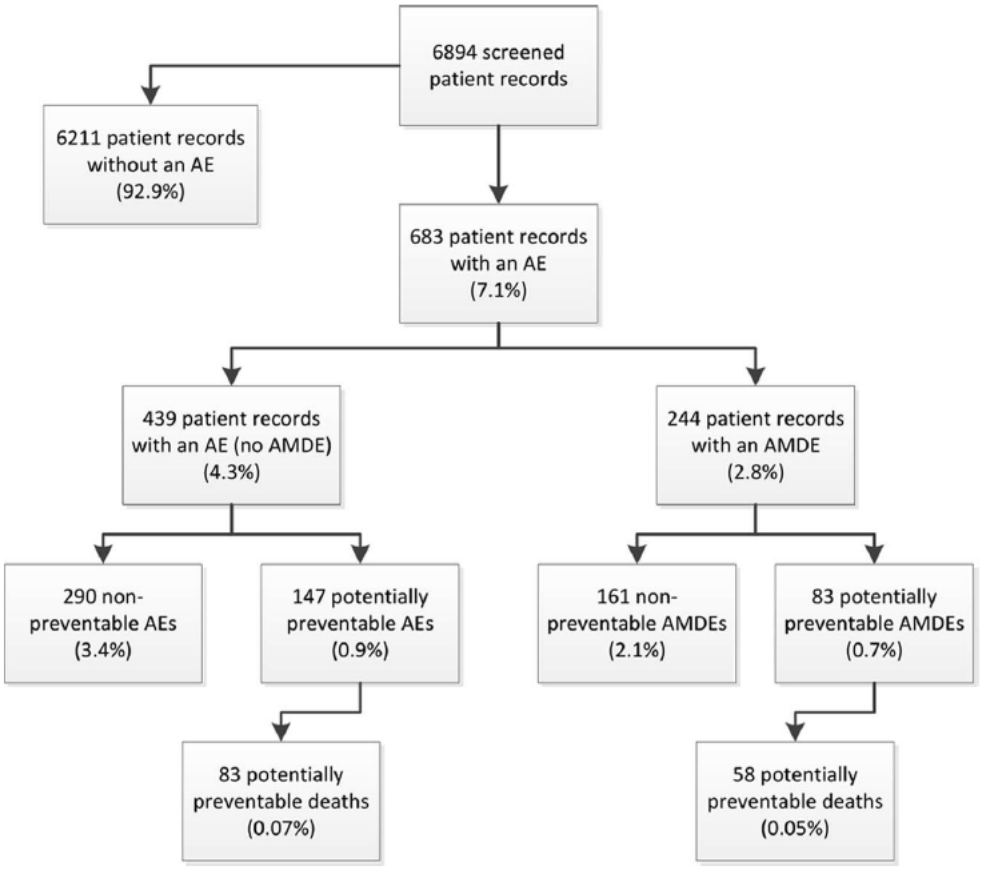

Figure 2. Adverse events involving medical devices and potentially preventable AMDEs for different types of medical devices in hospitals as weighted percentage of all the patients in which this medical device was used. The AMDEs are presented as a percentage of the hospitalized patients in which the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

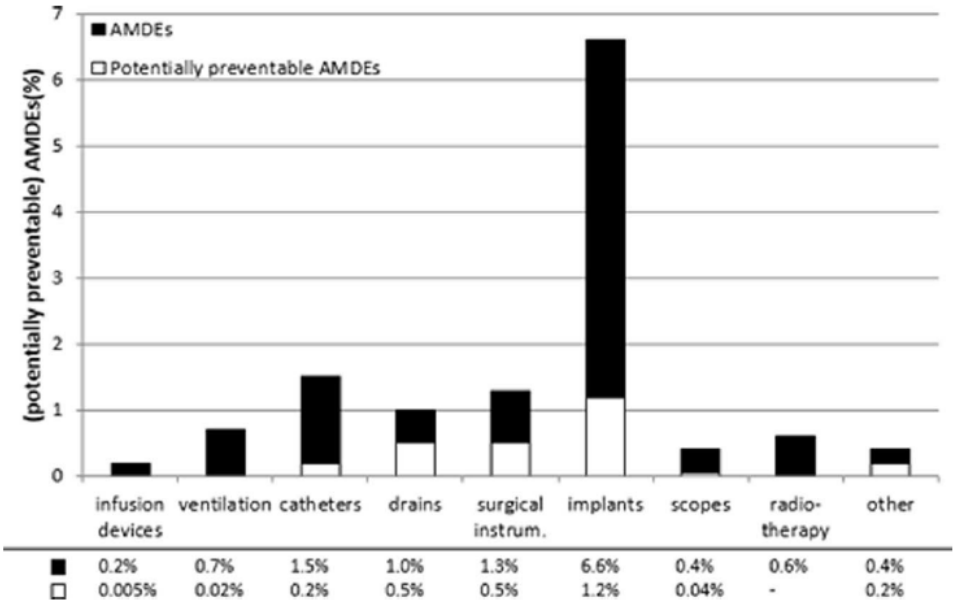

Table 1. Examples of AMDEs With the Involved Medical Devices

Description AMDE	Involved Medical Device
Nonpreventable 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	
A 87-y-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)