Surgical patient safety: analysis and interventions

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General introduction & outline of the thesis
GENERAL INTRODUCTION

The patient safety problem
In the past 20 years, it has become increasingly recognized that patient safety is not what it should be. Despite the Hippocratic oath of 'never do harm' that all physicians take, many patients are harmed during the very hospitalization that is meant to heal them. In-hospital adverse events (AEs) annually kill more people than breast cancer or motor vehicle accidents. An AE is usually defined as an unintended injury or complication resulting in prolonged hospital stay, disability at the time of discharge or death and caused by health care management rather than by the patient’s underlying disease process. An AE is not always the result of an error and vice versa: not every error leads to an AE (figure 1). Aside from the physical and emotional harm AEs inflict on patients, they are a considerable financial burden to health care. In 1999, it was estimated that total costs of preventable AEs in the USA lie between 17 billion and 29 billion dollars annually.

<table>
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<th>Figure 1. Errors versus adverse events</th>
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<td>Errors</td>
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Widespread attention and concern for the patient safety problem was generated by several landmark publications. In 1991, the Harvard Medical Practice Study was published. This study showed that AEs occurred in 3.7% of all hospitalizations in New York State and that 13.6% of these AEs led to death. A similar study conducted in Utah and Colorado in 1992 showed an AE rate of 2.9% with a mortality rate of 6.6%. Subsequent publications from around the world have reported similar or higher numbers. In 1999, the American Institute for Healthcare Improvement published its now well-known report ‘To err is human’. Extrapolating from the two studies mentioned earlier, it was estimated in this report that in the United States, 44,000 to 98,000 patients die each year as a consequence of an AE. The report issued a call for action and laid out a number of recommendations, among which were the encouragement of voluntary incident reporting systems and the standardization of work processes in health care organizations.

Patient safety publications in the Netherlands

In the Netherlands as well as in the rest of the world, ‘To err is human’ led to commotion. In the aftermath of this report, numerous studies and reports were published. In 2004, the Dutch Minister for Healthcare asked the President of Shell Nederland to analyse the safety situation in Dutch hospitals. In his report, Rein Willems estimated that the number of incidents could be reduced by 75% by following four recommendations, among which was the introduction of Safety Management Systems in all hospitals. In addition to the report by Shell, the Minister commissioned a report by the Advisory Council on Health Research on the need for further research into patient safety. The Council concluded that the existing patient safety research was being carried out in small projects and lacked continuity. It advocated a research program focusing on the issues of reporting and analysing adverse events, medication safety and complex care/communication. In a study commissioned by the Dutch Order of Medical Specialists, it was estimated that approximately 1,750 potentially preventable deaths occurred in Dutch hospitals yearly. The authors concluded that future patient safety efforts should focus on surgical procedures and older patients.

In 2007, the Dutch Health Care Inspectorate (IGZ) investigated the preoperative part of the surgical pathway in 23 hospitals. The Inspectorate found that there was little standardization in the provision of information and that the quality of medical record keeping was extremely varied. In its subsequent report on the peroperative pathway, the Inspectorate concluded that there was no central structure and that...
communication in the operating room was insufficiently standardized\textsuperscript{13}. The report on the postoperative part of the pathway is due this year.

**Culture change**

As the magnitude of the problem has slowly become clear, there has been a change in the way the medical community thinks about medical error. Only decades ago, the most prevalent culture in hospitals was a blaming culture: errors can be attributed to individuals and each individual responsible for an error should be held accountable and punished. This attitude has been found to be counterproductive and has gradually changed to a more open culture that is focused on systems. Care providers will make mistakes, no matter how large their dedication and effort, and the only way to increase safety is to design systems that can intercept the mistakes before they lead to adverse outcomes. In this ‘systems approach’, James Reason’s Swiss cheese theory is often used (figure 2)\textsuperscript{14}. The Swiss cheese theory models a system’s defenses against adverse outcomes as a series of barriers (layers of cheese), with weaknesses (holes) in each individual part of the system. The system as a whole produces adverse outcomes when all individual barrier weaknesses align, permitting “a trajectory of accident opportunity”, so that a hazard passes through the holes in all of the barriers, leading to an adverse outcome\textsuperscript{14}. Any patient safety solution should aim to fix the holes in as many barriers as possible.

The culture change towards more transparency and system thinking has cleared the way for thinking about interventions to improve patient safety. In 2001, an inventory of all available evidence on interventions to improve patient safety was published\textsuperscript{15}. The authors identified a wealth of safety practices with varying levels of evidence, but also concluded that many opportunities for research and improvement remained.

**Patient safety in surgery**

Almost two thirds of in-hospital adverse events are associated with a surgical provider\textsuperscript{2,3,16}. A number of reasons can be proposed for this disproportional contribution. Firstly, there is the inherent high risk associated with any intervention: the more invasive a treatment, the larger the risk that something will go awry. Secondly, the surgical patient is transported along a pathway that consists of a number of complex environments: the surgical ward, the operating theatre, the recovery room and sometimes the intensive care unit. Both the patient and all relevant information undergo multiple transfers, both between the different locations of the surgical pathway and between the professionals from various disciplines sharing responsibility...
for the patient. Lastly, the surgical patient pathway contains many man-machine interactions. During a surgical procedure, the patient is monitored by increasingly sophisticated anaesthesiological equipment. In addition, technology plays an increasingly important role in the surgical procedure itself, most notably in emerging minimally invasive surgical techniques.

Several interventions have been proposed to increase surgical patient safety. A number of these have focused on decreasing the risk of technical complications: among others, centralization of complex procedures to high-volume centres and virtual reality training programs for laparoscopic surgery. To improve inter- and intradisciplinary communication skills, there has been increased attention for teamwork and non-technical skills in the operating room.

Checklists in other risk industries

One of the recommendations to increase safety is the implementation of checklists into medicine. In high-risk petrochemical industries and aviation, the use of checklists...
has long been standard practice. No pilot would dream of taking off or landing a plane without running through extensive checklists. A review of 300 accident reports of the Aviation Safety Reporting System (ASRS) showed that checklists do indeed prevent accidents in aviation. Situations in which the crew failed to use the checklist or overlooked items, or situations in which checklist flow was interrupted by outside sources, were rated as causal or contributing in several major accidents. Accordingly, the introduction of safety systems, including checklists, in aviation has resulted in a fourfold reduction in the risk of dying in a domestic jet flight in a 15-year period. Occupational Health and Safety Administration programs have reduced workplace death rate by half in a similar period of time.

The extensive human factors research into checklists in these industries has led to a number of recommendations for the optimal design of safety checklists:

1. Checklists should not contain too many items because this will lead to checklist fatigue.
2. Items should be grouped corresponding to a system or process.
3. These groups should be graphically separated in the layout of the checklist.
4. Items should follow the operational sequence in such a way that the checklist sequence is parallel to flow patterns of a system or process and provides an association between location and sequence.
5. Critical items should be completed first and should be at the top of the checklist.
6. Critical items may be repeated to reduce the probability of skipping but overemphasis of many items can degrade overall checklist performance.
7. Completion of checklist items should not be tightly coupled with other tasks.
8. The use of terms and layout should be consistent and standardized.

Checklists in surgery
In the medical community, the systematic use of checklists is not widespread, although some studies have been published. The introduction of a checklist ensuring adherence with evidence-based guidelines virtually eliminated catheter-related bloodstream infections in the intensive care unit. In patients with myocardial infarction or stroke, the use of checklists and reminders in clinical pathways was shown to lead to better compliance with best practice treatments. In anaesthesia, the use of checklists was shown to be associated with lower perioperative mortality. Several similarities exist between aviation and surgery: both are complex, high-pressure environments where teams interact with technology and the cost of error is considerable. This has led to the hypothesis that checklists might work as well
to improve safety in surgery as they do in aviation. There have been a number of publications about surgical safety checklists. Makary et al introduced the concepts of ‘briefing’ and ‘debriefing’ and showed that preoperative briefings significantly reduced the perceived risk for wrong-site surgery. In 2008, Lingard et al demonstrated a reduction in communication failures in the operating room after the introduction of a short preoperative checklist containing patient information and operative issues. In 2009, a publication by the World Health Organization’s Safe Surgery Saves Lives working party presented improvements in complication and mortality rates after the implementation into diverse health care settings of a checklist to be used in the operating room.

The introduction of standardization and checklists into the surgical pathway was also pleaded for by the Dutch Inspectorate for Health Care in its critical reports on the pre- and peroperative parts of this pathway.

Entire surgical patient pathway

All of the checklists mentioned above are focused solely on the operating room; the pre- and postoperative parts of the surgical pathway are not considered. However, the surgical patient is at risk during each stage of the surgical pathway, including the stages outside of the operating room. This has been recognized by several health care associations. The 2002 Report by the National Confidential Enquiry into Perioperative Deaths ‘Functioning as a team?’ was based on a sample of 2,114 perioperative deaths from a larger sample of 21,654 records. Key findings were errors in preoperative drug treatment, patient transfer, pre-assessment, medical referral, drug prescribing, medical records and fluid balance. In 2003, the National Health Service Litigation Authority published a detailed list of safety recommendations consisting of a sequence of safety checks during the surgical patient pathway from admission to discharge.

Two separate malpractice claims studies confirm the necessity to cover the entire surgical pathway. In one study, 444 surgical malpractice claims were reviewed to identify causes of surgical error and opportunities for prevention. The authors found that in 60% of cases, errors occurred in pre- or postoperative care. In another study including 460 malpractice claims, surgeons identified deficiencies in care more often before and after operations than in the intraoperative period.

As the majority of surgical errors occur outside of the operating room, it seems
likely that a checklist covering the entire surgical pathway will have a larger impact on patient safety than an intervention to be used in the operating room alone. This insight motivated the development, validation and evaluation of a comprehensive safety system for the surgical patient: the subject of this thesis.
OUTLINE OF THE THESIS

This thesis describes the various studies that were conducted surrounding the development and evaluation of the SURgical PAtient Safety System (SURPASS) checklist.

To effectively target patient safety issues, it is necessary to gain a detailed understanding of the problem: where are the majority of safety risks concentrated and which risks are preventable? This information will enable identification of risk categories that are most susceptible to interventions to improve patient safety. In chapter 1, a systematic review is performed of all available literature on in-hospital adverse events. Information is presented on the overall incidence, preventability, outcome and subdivision by location, provider and type of in-hospital adverse events.

One of the interventions that are proposed to improve surgical patient safety is the introduction of checklists into daily practice. Chapter 2 describes the development and validation of the SURPASS checklist, a multidisciplinary safety checklist covering each step of the surgical patient pathway. The checklist is based on literature and validated and optimized by real-time observation of the surgical pathway in a cohort of high-risk surgical patients.

In 2008, the World Health Organization presented a ‘Surgical Safety Checklist’, a concise checklist to be used only in the operating room. Since the majority of surgical process deviations and errors occur outside of the operating room, a more comprehensive approach in improving surgical patient safety is argued for in chapter 3.

To justify widespread implementation of a comprehensive checklist, its effectiveness in decreasing adverse outcomes needs to be demonstrated. In chapter 4, the effect of implementation of the SURPASS checklist on patient outcomes is studied in a controlled pre-/post-intervention design. Postoperative complication and mortality rates are assessed before and after implementation of SURPASS in two academic and four regional teaching hospitals, as well as in five control hospitals where the checklist is not implemented.

In an attempt to elucidate the mechanism of the effect of the SURPASS checklist on surgical patient outcomes, the relative contribution of each part of the checklist is
described in chapter 5. Incidents intercepted by SURPASS have been self-registered by physicians on the checklist itself. All intercepted incidents in over 6,000 surgical patients are presented according to their timing and nature.

Malpractice claims represent an interesting addition to more traditional sources of information on adverse events. In chapter 6, surgical malpractice claims are evaluated in detail to assess the proportion and nature of claims that might have been prevented if the SURPASS checklist had been used, using the database of MediRisk, the largest insurance company for medical liability in the Netherlands.

One of the items that is discussed during the time out part of SURPASS is the timely administration of antibiotic prophylaxis. In chapter 7, the effect of implementation of the time out procedure on the timing of antibiotic prophylaxis (AP) is studied. The interval between AP administration and incision is compared between two cohorts; one cohort before implementation of the time out and one after implementation.

Although the majority of adverse events occur in surgical patients, patients are also at risk in other disciplines involving invasive procedures. Since interventional radiology (IR) shares several features with surgery, a checklist might be as useful in IR as it has proved in surgery. Chapter 8 describes the development and implementation of the specific RADiological PATient Safety System (RADPASS) checklist.
REFERENCES

1. Kohn LT. To err is human: building a safer health care system. Institute of Medicine, 1999.