Surgical patient safety: analysis and interventions

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Summary
&
future directions
SUMMARY OF THE CHAPTERS

In this thesis, the various studies that were conducted surrounding the development and evaluation of the SURgical PAatient Safety System (SURPASS) checklist, are described.

Adverse events lead to substantial physical, emotional and financial damage. An attempt is made to provide an overview of the severity of the problem and the distribution of adverse events over different disciplines. Since more than half of adverse events can be attributed to a surgical discipline, surgical patient safety interventions are needed.

A comprehensive safety checklist was developed to standardize the surgical patient pathway and increase safety. As the surgical patient is at risk during the entire pathway, a plea is made for a comprehensive approach covering the pathway from admission to discharge, rather than settling for a checklist that is confined to the operating room.

The SURPASS checklist was subsequently evaluated in various ways. Complication and mortality rates were studied in a controlled multicentre setting before and after implementation of the checklist. To assess the mechanism behind the effect of the checklist and the contribution of each part of the checklist, the incidents intercepted by the use of the checklist were analysed. Furthermore, surgical malpractice claims were studied to learn which proportion of claims might have been prevented by using the checklist. Finally, the effect of the checklist on the timing of antibiotic prophylaxis was assessed in two retrospective cohorts of surgical patients.

In addition, the RADiological PAatient Safety System (RADPASS) checklist was developed and its effect on process deviations was studied. While the design of RADPASS is analogous to SURPASS, the content of this checklist was specifically selected for radiological interventions.

In chapter 1, a systematic review on in-hospital adverse events (AEs) is presented. Primary endpoints were incidence of in-hospital AEs and percentage of preventability. Secondary endpoints were AE outcome and subdivision by provider of care, location and type of event. Eight studies from the USA, Canada, the UK, Australia and New Zealand, including a total of 74,485 patient records, were included. All studies used a two-stage retrospective record review technique.

The median overall incidence of in-hospital AEs was 9.2% (interquartile range (IQR) 4.6-12.4%), which amounts to nearly one out of every ten patients admitted to a hospital. A median of 43.5% (IQR 39.4-49.6%) of these events was judged preventable. The median percentage of AEs that led to no or minor disability was 56.3% (IQR 51.4-62.8%). Permanent disability was found in 7.0% (IQR 6.1-11.0%)
of patients experiencing an AE, while 7.4% (IQR 4.7-14.2%) of AEs caused the death of the patient. Operation- (39.6%) and medication-related (15.1%) events constituted the majority. Since almost half of these events were preventable, we conclude that funds and efforts should be concentrated on interventions aimed at reducing operation- and medication-related events.

One example of an intervention aimed at reducing surgical adverse events is the use of checklists. In chapter 2, the development and validation of the SURPASS checklist are described. A prototype checklist was constructed based on literature on surgical errors and adverse events, and on human factors literature. The checklist accompanies the patient during each step of the surgical pathway. It is split up into different phases of admission (pre-operative ward, operating room, recovery or intensive care unit, post-operative ward) and focuses on the patient transfer moments in between stages (including admission and discharge). The list is multidisciplinary: ward doctor, surgeon, anaesthesiologist, operating assistant and nursing staff are all responsible for completion of parts of the checklist. The items on the prototype checklist were validated by comparison with process deviations (safety risk events) during real-time observation of the surgical pathway. Process deviations were defined as situations where an aspect of care had not been executed correctly (e.g., ‘right side not marked’ or ‘equipment not checked’). A process deviation did not necessarily correspond to an adverse outcome. During 171 high-risk surgical procedures, 593 process deviations were observed, more than half of which occurred in the pre- and postoperative stages of the pathway. Of the deviations suitable for coverage by a checklist, 96% corresponded to an item on the SURPASS checklist. Subsequently, the checklist was evaluated in daily clinical practice. Users were generally positive about the checklist, but a number of logistic improvements were suggested. The SURPASS checklist is the first validated patient safety checklist for the surgical pathway from admission to discharge. However, before widespread implementation of this instrument can be advised, effectiveness needs to be demonstrated to ensure that the checklist is not merely an extra layer of administration, but actually contributes to patient safety.

In 2008, the World Health Organization launched a worldwide campaign called Safe Surgery Saves Lives and presented a ‘Surgical Safety Checklist’. In chapter 3, some critical remarks are issued concerning this checklist, which is focused solely on
the operating room. While the WHO’s initiative for a checklist is commendable, in particular because of the worldwide attention it raises for surgical patient safety, it is too limited. Although undoubtedly valuable, a checklist for the operating room alone does not suffice and is executed too late in the surgical patient pathway (‘five-to-twelve’ check). There is a considerable chance that it will miss a substantial proportion of surgical errors and lead to an illusion of safety and inefficient use of space and resources.

Since several studies have shown that the safety risks in the surgical patient pathway are spread out along all stages and locations of this pathway, from pre-admission to discharge, a more comprehensive approach in improving surgical patient safety is argued for. However, it is also concluded that the resources and efforts required to implement such an approach cannot be justified until its effectiveness has been demonstrated.

In chapter 4, the effect of implementation of the SURPASS checklist on patient outcomes is studied in a controlled multicentre setting. The checklist was implemented in two academic hospitals and four regional teaching hospitals with high standards of care. All complications occurring during admission were prospectively registered in these hospitals and in five hospitals with comparable characteristics where the checklist was not implemented.

Two three-month periods were compared: a baseline cohort of 3,760 patients pre-implementation was compared to 3,820 patients after implementation of the checklist, while accounting for potential confounders (sex, age, ASA score, hospital, type of surgical procedure, urgency category).

The total number of complications per 100 patients decreased from 27.3 (95% CI 25.9-28.7) to 16.7 (95% CI 15.6-17.9), an absolute risk reduction (ARR) of 10.6 (95% CI 8.7-12.4). The proportion of patients with one or more complications was 15.4% in the pre-implementation period versus 10.6% in the post-implementation period (p<0.001). In-hospital mortality decreased from 1.5% (95% CI 1.2-2.0) to 0.8% (95% CI 0.6-1.1), an ARR of 0.7% (95% CI 0.2-1.2). The proportion of patients experiencing temporary disability, as well as the proportion of patients that required a reoperation to resolve a complication, also decreased significantly by 2.7% (95% CI 1.5-4.0) and 1.1% (95% CI 0.4-1.9), respectively.

The effect of the checklist remained significant after controlling for potential confounding factors by zero-inflated negative binomial regression analysis. In contrast, in the five control hospitals, complication and outcome rates did not change significantly over the same study periods. The number of complications per
100 patients was 30.4 in the first period and 31.2 in the second period (ARR -0.8 (95% CI -3.2-1.7). The proportions of patients with one or more complications were 17.6% and 17.9%, respectively (p = 0.95).

The improvements in outcome that were found confirm the results that were achieved by the WHO's surgical safety checklist, to be used only in the operating room. However, in the present study, only hospitals with a high baseline standard of care were included, whereas the hospitals included in the WHO study were much more diverse.

Improved outcomes after implementation of SURPASS may be explained by a number of mechanisms. Specific items on the checklist may directly prevent adverse events. In addition, the implementation of the checklist triggers improvements in the entire surgical pathway. Finally, the checklist may lead to improved outcomes by improving teamwork, communication and attitudes towards quality and safety.

To shed more light on one of the mechanisms of the beneficial effect of the SURPASS checklist on surgical patient outcomes and to assess the contribution of each part of the checklist, the number, nature and timing of incidents intercepted by use of the checklist is assessed in chapter 5.

Data were collected in the six hospitals that participated in the SURPASS Implementation Group. Users of the checklist (ward doctors, surgeons, anaesthesiologists, operating assistants and nurses) had three options for each item that was checked: 'not applicable,' 'yes, executed' and 'intercepted by checklist.' All checklists were collected after discharge of the patient and the first 1,000 completed checklists per hospital were entered into an online central database.

In the six participating hospitals, 6,313 checklists were collected. Per checklist, the mean percentage of items that had been completed was 72.2%. One or more incidents were intercepted in 2,562 checklists (40.6%). Incidents that were intercepted most often included the preoperative absence of instruments, preoperative omissions in medication prescriptions, lack of postoperative instructions by the anaesthesiologist, and missing medication prescriptions at discharge.

In total, 6,312 incidents were intercepted, of which 54.8% occurred preoperatively, 14.2% peroperatively, and 31.0% postoperatively. After correction for the number of items in each part of the checklist and the percentage of completion, the number of intercepted incidents was highest in the pre- and postoperative stages. In most checklists with intercepted incidents, the incidents were intercepted at only one of the stages of the surgical pathway. There was a small minority of checklists (4.8%) in which incidents were intercepted both in the pre- and peroperative stages.

Since more incidents were intercepted outside than inside the operating room, the
SURPASS checklist may have a larger impact than a checklist for the operating room alone.

Malpractice claims constitute an interesting supplement to other information sources on adverse events. In chapter 6, the proportion of surgical malpractice claims that might be prevented by the use of SURPASS, is assessed. A retrospective claim record review was performed using the database of the largest Dutch insurance company for medical liability. All accepted or settled closed surgical malpractice claims filed as a consequence of an incident in a two-year period between Jan 1st 2004 and Dec 31st 2005 were included.

We included 294 claims. The majority of claims were filed against general surgery (33%) and orthopaedic surgery (15%). A failure in diagnosis (26%) or treatment (13%), peroperative damage (20%), and wrong side (2%), wrong site (7%), wrong procedure (6%) or wrong patient (1%) constituted the majority of incidents. Cognitive factors were present in two thirds of all claims. ‘Error in judgment’, ‘failure of vigilance/memory’ and ‘failure in communication between care providers’ were the most frequent contributing factors (29%, 16% and 16%, respectively). Of a total of 412 contributing factors, 29% might have been intercepted by the SURPASS checklist. Most or all incidents that were the consequence of a failure to adhere to protocols, failure to register informed consent, failure in communication between care providers, or the preoperative absence of information or material, might have been prevented by using SURPASS. When looking at the outcome of the incidents, 31% led to temporary disability without reoperation. More than a third of incidents (37%) required a reoperation to be resolved and 29% led to permanent disability, whereas 3% was fatal. The checklist might have prevented 40% of deaths and 29% of incidents leading to permanent damage.

One of the items on the SURPASS checklist is the timely administration of antibiotic prophylaxis before induction of anaesthesia. The aim of the study described in chapter 7 was to determine the effect of SURPASS implementation on timing of antibiotic prophylaxis.

A retrospective analysis was performed on two cohorts of patients: one cohort of surgical patients that underwent surgery before implementation of the checklist and a comparable cohort after implementation.

A total of 772 surgical procedures were included. After implementation, the checklist was used in 81.4% of procedures. Data on timing of antibiotic prophylaxis were available in 590 procedures. The mean interval between administration of AP and incision increased from 23.9 minutes (standard deviation 37.1) before
implementation of the checklist to 29.9 minutes (standard deviation 31.9) after implementation ($p=0.047$). The proportion of patients that received antibiotics after instead of before the incision decreased from 12.1% to 7.1% ($p=0.04$). When looking only at procedures where the checklist was actually used, the interval between AP administration and incision increased to 32.2 minutes ($p=0.006$). In this subgroup, the proportion of patients that received antibiotics after the incision decreased to 6.0% ($p=0.015$).

This study shows that implementation of a comprehensive surgical safety checklist (SURPASS) significantly improved compliance with hospital standards for timing of antibiotic prophylaxis administration.

Interventional radiology (IR) encompasses a wide range of procedures which can pose safety challenges similar to those in the operating room. The need for more standardization to improve patient safety and quality of care is increasingly being recognized in IR. In chapter 8, a RADiological PAtient Safety System (RADPASS) checklist is developed and tested. A prototype checklist was developed based on available literature and expert opinion. The checklist was adapted based on observation of daily practice in a tertiary referral centre and evaluation by users. The RADPASS checklist is split up into two parts: A (Planning and Preparation) and B (Procedure). The latter is separated in checks just before starting a procedure (B1) and in items concerning the post-procedural care immediately after completion of the procedure (B2).

To assess the effect of RADPASS, a series of radiological interventions was observed before and after implementation of the checklist; all deviations from optimal care were registered. Process deviations were defined as situations where an aspect of care had not been executed correctly (e.g., ‘right side not marked’ or ‘monitoring equipment not checked’). A process deviation did not necessarily correspond to an adverse outcome.

Two cohorts of respectively 94 and 101 radiological interventions were observed; the mean number of process deviations per intervention decreased from 24% pre-implementation to 5% post-implementation ($p<0.001$). Postponements and cancellations decreased from 10% pre-implementation to 0% post-implementation. In addition, the checklist was evaluated by interviewing all users. The majority of users agreed the checklist was user-friendly and increased patient safety and efficiency. The RADPASS checklist is the first validated safety checklist developed specifically for interventional radiology.
FUTURE DIRECTIONS

Patient safety is a relatively new subject in medical research. While the subject is highly topical and contains great opportunities for research and improvements in patient care, there are some factors that may complicate the design and interpretation of patient safety studies.

One complicating factor is the multifactorial nature of adverse events. Since most adverse outcomes are dependent on a diversity of factors, improvements in patient outcomes cannot always be easily attributed to specific changes in processes. This hampers the accurate study of the effect of changes in processes and the demonstration of a clear correlation between a particular process and a clinical outcome.

Another factor that complicates the design of effectiveness studies in patient safety interventions is the contamination of study arms. Most patient safety interventions, and certainly checklists, involve human behavioural changes. This means that in a randomized controlled trial, there will always be an undesirable and uncertain amount of contamination: the care that is provided to control patients will be influenced, whether consciously or not, by use of the intervention in the intervention arm. This factor renders it difficult if not impossible to acquire reliable results on the effect of the intervention from a randomized controlled trial.

A parallel design comparing different hospitals or departments is hampered by uncertainties related to inter-hospital differences and differences in case mix. However, this does not mean that patient safety interventions should not be studied in more detail and become evidence-based. It is not impossible to pronounce on the effect of these interventions with certainty. Pre-/post-intervention studies, observational studies and retrospective studies provide valuable data. Possible confounding factors associated with the lack of control data can be corrected for statistically. ‘Triangulation’, or the accumulation and integration of different types of data that from different viewpoints all suggest the same effect, is recommended in quality improvement research.

The studies presented in this thesis showed that it is feasible to develop and implement a comprehensive surgical safety checklist both in academic and regional hospitals. In addition, it was demonstrated that the use of this checklist leads to a considerable reduction in complication and mortality rates in hospitals with high baseline standards of care.

A number of subjects remain to be studied. First, the effect of SURPASS has been
proven in general surgery. Although the checklist has already been successfully implemented in other surgical disciplines, the effect on patient outcomes in these disciplines has not been studied yet. Moreover, the exact mechanisms through which implementation of the checklist leads to improved outcomes have not yet been fully elucidated. We hypothesized that the effect of the checklist was due to three mechanisms: direct prevention of errors by completing the checklist, optimization of processes in the surgical pathway triggered by implementation of the checklist, and improvements in teamwork and communication inspired by the checklist. Which of these separate mechanisms contributed most to the beneficial effect of SURPASS remains to be studied.

There were considerable differences in the effect of SURPASS on complication rates between the six hospitals that were studied. These differences could be due to several reasons: among others, different baseline situations, different implementation strategies and different safety cultures and attitudes. Another future study could aim to assess which of these factors most influenced the effect of SURPASS.

A comparison between the comprehensive SURPASS checklist and the more concise WHO checklist, to be used only in the operating room, would also be an interesting subject for further study. The effect of the two checklists on patient outcomes was more or less comparable, although the SURPASS checklist achieved this effect in high income hospitals only, whereas the effect of the WHO checklist was most apparent in hospitals in developing countries. Finally, it would be informative to study cost-effectiveness of the SURPASS checklist. One argument that is often used against implementing the checklist is the amount of time that is spent completing it; however, it would be interesting to see whether using the checklist can actually save time and increase efficiency. In addition, the costs of implementation and usage could be measured against costs saved by prevented adverse outcomes.

The advance of checklists in surgery seems inevitable. Strict application of stopping rules (i.e., if the checklist has not been completed, the patient does not continue to the next phase of the surgical pathway) will increase compliance to these checklists, possibly leading to a larger effect on patient outcomes. Eventually, checklists will be integrated in digital patient information systems, facilitating the development of more intelligent checklists that can provide prompts and links to other information sources. The most important factor that will be of influence in the eventual success of checklists and the effect they will or will not have on patient safety, is the development of a safety culture. The potential effect of the use of checklists and protocols is optimal in an environment where all care providers are aware of their own fallibility
and acknowledge the value of checklists and protocols as a way of standardizing procedures.

With the increased attention for patient safety, both in the media, in scientific journals and in hospitals themselves, this culture change is gradually starting to set in. The changed culture will need to be consolidated by integration of patient safety training and interventions into standard procedures. In addition, with the integration of the subject of patient safety in the medical curriculum, a new generation of doctors will be trained for whom attention for safety will be self-evident.

In the past decade, there has been a torrent of patient safety and quality improvement interventions. In an effort to contribute towards safer and higher-quality healthcare, many organizations have come up with sets of rules and regulations, guidelines, checklists and quality indicators. The risk of this multitude of initiatives is that healthcare organizations will be overwhelmed by the abundance of interventions that are being enforced, often at their own expense. If so many different interventions must be implemented at the same time, motivation in healthcare organizations will decrease, interventions will be implemented half-heartedly and perfunctorily, and patient safety will ultimately not improve.

In this time of increased pressure by governments and inspectorates, we would like to plead for evidence-based patient safety. In the multitude of interventions currently available, prioritization based on proven effectiveness should be made possible.