Surgical patient safety: analysis and interventions

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A safer surgical pathway: monitoring in the operating room alone is insufficient

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ABSTRACT

Surgical adverse events remain a considerable problem: over 50% of in-hospital adverse events are related to a surgical procedure. The WHO, in its ‘Safe Surgery Saves Lives’ campaign, propose what is essentially an expanded time out procedure, including a debriefing. In recent years, this type of procedure has been widely advocated and implemented. While it is valuable, it has one major drawback: it is limited to the operating room. We recently observed 170 patients undergoing surgery. Over 50% of the incidents observed occurred outside the operating room, before and/or after surgery. Many near misses can be intercepted before entering the operating room. We therefore developed and validated a multidisciplinary checklist that covers the entire surgical patient pathway, instead of just the operative phase. The implementation of the so-called Surgical Patient Safety System (SURPASS) checklist is currently underway. The effectiveness of the checklist in reducing adverse events and improving patient safety is being studied.
INTRODUCTION

Both national and international literature show that a large proportion of in-hospital preventable adverse events can be attributed to surgical disciplines: more than half of adverse events are related to a surgical procedure. In 2007, the Health Care Inspectorate (IGZ) investigated the preoperative pathway in 23 Dutch hospitals. The results of this investigation were alarming: there was little standardization in the provision of information and the quality of medical record keeping was extremely varied. In addition, there was clear room for improvement in the areas of information transfer and interdisciplinary cooperation. In view of these findings, the per- and postoperative pathways were investigated as well. In 2008, the IGZ published its report on the peroperative pathway, entitled: ‘Standardization is essential to achieve risk reduction in the surgical pathway’. This part of the pathway also shows significant shortcomings: there is no central structure, communication in the operating room is insufficiently standardized and infection prevention must be improved. The report was recently commented upon in this journal.

It seems probable that something can be gained in the surgical disciplines. In recent years, several initiatives have been launched to improve surgical patient safety. A much-discussed intervention is the so-called ‘time out procedure’; the Inspectorate mentions adoption of this procedure as one of the key measures in its report on the peroperative pathway. Although undoubtedly valuable, in our opinion, the time out procedure is too limited and is executed too late in the surgical patient pathway (‘five-to-twelve’ check). There is a considerable chance that it will lead to an illusion of safety and inefficient use of space and resources.

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 comprehensive surgical safety system requires a multidisciplinary approach covering the entire surgical pathway. In this comment, we would like to plead for a more comprehensive approach in improving surgical patient safety.

WHO CHECKLIST IS EXPANDED TIME OUT PROCEDURE

In June 2008, the World Health Organization (WHO) launched its campaign Safe Surgery Saves Lives. They presented a checklist to be used in the operating room to improve safety in surgical procedures. This ‘Surgical Safety Checklist’ is essentially an
expanded version of the time out procedure mentioned before\textsuperscript{8, 9}. The time out procedure or briefing consists of a short discussion in the operating room, just before the start of the procedure, between surgeon, anaesthesiologist and operating assistant. During this discussion, the right patient, side and procedure are confirmed, the administration of preoperative antibiotics is checked and the presence of all equipment, instruments and material is confirmed. Some versions of the time out are executed just before the incision; others prior to the induction of anesthesia. In this last version, the patient takes part in the time out procedure. In the WHO’s version, the checks have been split up into a part before the induction of anesthesia and a part before the incision. In addition, a postoperative debriefing has been added to check whether all sponges and instruments have been counted. The use of this checklist in eight hospitals across the world was associated with a reduction in major complications and mortality\textsuperscript{10}. However, when looking in detail at baseline data, it becomes clear that this effect is likely to be based to a large extent on the introduction of basic surgical safety policies such as antibiotic prophylaxis, sponge count protocols and pulse oximetry into low- or middle-income settings with relatively low baseline standards of care. In three out of the four hospitals in high-income countries, outcomes did not improve significantly. In the Netherlands, the Eye Hospital Rotterdam was the first centre to introduce a time out procedure. The involved doctors reported no more wrong-site surgeries after implementation. Meanwhile, the time out procedure has been implemented by a large number of hospitals.

**PROCESS DEVIATIONS OUTSIDE OF THE OPERATING ROOM**

The surgical patient follows a pathway with several locations: from the ward, the patient is taken to the operating room. After surgery, the patient temporarily stays in the recovery room or the intensive care, after which the patient is transferred back to the ward. Observations of the surgical pathway of 170 patients showed that 58% of all process deviations takes place outside of the operating room, before and after surgery\textsuperscript{11}. Many of these deviations can and should be corrected at an earlier stage than just before starting surgery. If the essentials are not checked until the patient is literally lying under the operating lights, this can lead to risky situations, as was illustrated in an example given at the launch of the WHO campaign\textsuperscript{7}. A patient had already been anesthetized when it was
revealed during the time out procedure that her knee prosthesis was not available in the right size. The patient was woken up and the surgery was postponed until later that day.

The WHO presented this case as an example of the beneficial effect of the time out. Indeed, the problem was discovered before the incision had been made. However, the case could also be judged a preventable error, leading to unnecessary anesthesia and postponement of surgery. This postponement led to extra costs and a considerable psychological burden for the patient. In addition, there was the risk of the alternative: because the first step had been taken, the surgeons might have decided to continue the procedure, using another size prosthesis and possibly leading to a suboptimal result. These risks can be prevented by intervening earlier, for example by confirming the presence of all required material on the day before surgery.

Even after the patient has left the operating room, he or she is not risk-free yet: many adverse events originate in the postoperative phase. For example, the observational study mentioned earlier showed that in 22% of patients, postoperative instructions were not complete\(^\text{11}\). In addition, 11% of patients were discharged without prescriptions for their home medication.

**CHECKLIST FOR THE ENTIRE PATHWAY**

In many hospitals, checklists are used for parts of the surgical pathway, for example for anesthesia equipment or to prepare the patient for discharge. A checklist that combines the safety checks in the entire surgical patient pathway has not been described before. The awareness that surgical safety risks do not exist in the operating room alone, motivated the development in 2003 of the SURgical PAtient Safety System (SURPASS) checklist at the department of Surgery of the Academic Medical Centre in Amsterdam. The validation of this checklist was completed in 2007. The list was designed in analogy to take-off checks in the aviation industry and was based on literature about surgical complications, errors and adverse events\(^\text{12-15}\). It was subsequently validated by real-time observation of the surgical pathway and comparison of all observed process deviations to the concept checklist. The result is a multidisciplinary checklist that covers the entire surgical patient pathway from admission until discharge (table 1)\(^\text{11,16}\).

A preoperative time out procedure is included in the checklist. In addition, there are several checking moments: preoperatively on the ward, postoperatively in the operating room, at handover from recovery to ward and at discharge. Surgeon,
anaesthesiologist, ward doctor, ward nurse and operating assistant are all involved in completing the list. The SURPASS checklist defines and monitors the responsibilities of all involved caregivers in the surgical pathway and guards information transfer moments. The checklist has now been expanded to include a pre-admission part, in rapport with the concept guideline ‘Preoperative process’ from the Quality Institute for Healthcare (CBO). SURPASS can be downloaded at www.surpass-checklist.nl.

EFFECTIVENESS STUDIES REQUIRED

Before instruments like a time out procedure or the SURPASS checklist can be implemented on a large scale, their effectiveness in actually improving patient safety should be demonstrated. Several studies have shown that seemingly obvious solutions for unsafe situations do not always have the desired effect when practically applied\textsuperscript{17, 18}. A study into the causes of wrong-site surgery found that in 18% of wrong-site surgeries, a time out procedure had been correctly executed; thus, the time out procedure did not prevent all wrong-site surgeries\textsuperscript{19}.

At the moment, the SURPASS checklist is being implemented in six Dutch hospitals: the Academic Medical Centre and the Onze Lieve Vrouwe Gasthuis in Amsterdam, the Jeroen Bosch Hospital in Den Bosch, the Amphia Hospital in Breda, the Maastricht University Medical Centre in Maastricht and the Rijnland Hospital in Leiderdorp. During this implementation process, effectiveness is researched; both the effect of the checklist on process deviations and complications and the factors determining an effective implementation are studied.

<table>
<thead>
<tr>
<th>Location</th>
<th>WHO’s checklist</th>
<th>SURPASS checklist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timing</td>
<td>Operating room</td>
<td>Ward, holding, operating room, recovery/ICU</td>
</tr>
<tr>
<td>Involved disciplines</td>
<td>Surgeon, anaesthesiologist, operating assistant</td>
<td>Ward doctor, ward nurse, surgeon, anaesthesiologist, operating assistant</td>
</tr>
<tr>
<td>Implementation</td>
<td>Relatively easy</td>
<td>Relatively elaborate</td>
</tr>
<tr>
<td>Range</td>
<td>Limited</td>
<td>Extensive</td>
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</tbody>
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CONCLUSION

The surgical patient runs an above-average risk of preventable harm. In its recent report about the peroperative pathway, the IGZ is justified in demanding improvements in patient safety in the operating room. In this light, the WHO’s initiative for a checklist is commendable, in particular because of the worldwide attention it raises for surgical patient safety. However, a time out procedure does not suffice and is executed too late in the surgical pathway. After all, the risks for the surgical patient are spread out along all stages and locations of the surgical pathway. Too much focus on a time out procedure completely ignores the fact that many risks for the surgical patient occur outside of the operating room.

A comprehensive surgical safety system requires a multidisciplinary approach, in which the contribution of ward doctor and nurse is indispensable. For this reason, we plead for a broader approach to substantially improve surgical patient safety. The SURPASS checklist is a validated instrument covering the entire surgical pathway. Of course, the resources and efforts required to implement such an instrument cannot be justified until its effectiveness has been demonstrated.
REFERENCES

LETTER TO THE EDITOR:

In your editorial of July 5th, you describe the launch of the Safe Surgery Saves Lives campaign by WHO’s World Alliance for Patient Safety. The Alliance has developed a surgical safety checklist that is essentially an expanded time out procedure, including a debriefing. In recent years, this type of procedure has been widely advocated and implemented. Although it is unquestionably valuable, it has one major drawback: its timing.

In an observation of 170 surgical procedures, more than 50% of all deviations in surgical processes occurred before or after surgery. Many of these omissions and incidents can and should be corrected at an earlier stage than just before starting surgery, when it could be too late. Not checking the essentials until inside the operating room might lead to compromised safety or postponement of surgery, resulting in substantial psychological burden for the patient. Additionally, the patient is not safely home after surgery: many adverse events originate in the postoperative phase.

Therefore, we would like to plead for a checklist that covers the entire surgical patient pathway from admission to discharge, instead of just the perioperative phase. The surgical patient is at risk; and no less so on the ward or in the recovery room than in the operating theatre. With attitudes starting to change and a safety culture slowly emerging, we now have the opportunity to really improve patients’ safety. Let’s not be too easily satisfied.

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