Prospective methods for identifying perioperative risk-assessment methods for patient safety over 20 years: a systematic review

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Background: Serious preventable surgical events still occur despite considerable efforts to improve patient safety. In addition to learning from retrospective analyses, prospective risk-assessment methods may help to decrease preventable events further by targeting perioperative hazards. The aim of this systematic review was to assess the methods used to identify perioperative patient safety risks prospectively, and to describe the risk areas targeted, the quality characteristics and feasibility of methods.

Methods: MEDLINE, Embase, CINAHL and Cochrane databases were searched, adhering to PRISMA guidelines. All studies describing the development and results of prospective methods to identify perioperative patient safety risks were included and assessed on methodological quality. Exclusion criteria were interventional studies, studies targeting one specific issue, studies reporting on structural factors relating to fundamental hospital items, and non-original or case studies.

Results: The electronic search resulted in 16,708 publications, but only 20 were included for final analysis, describing five prospective risk-assessment methods. Direct observation was used in most studies, often in combination. Direct (16 studies) and indirect (4 studies) observations identified (potential) adverse events (P)AEs, process flow disruptions, poor protocol compliance and poor practice performance. (Modified) Healthcare Failure Mode and Effect Analysis (HFMEA™) (5 studies) targeted potential process flow disruption failures, and direct (P)AE surveillance (3 studies) identified (P)AEs prospectively. Questionnaires (3 studies) identified poor protocol compliance, surgical flow disturbances and patients’ willingness to ask questions about their care. Overall, quality characteristics and feasibility of the methods were poorly reported.

Conclusion: The direct (in-person) observation appears to be the primary prospective risk-assessment method that currently may best help to target perioperative hazards. This is a reliable method and covers a broad spectrum of perioperative risk areas.

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Introduction

The surgical volume worldwide has been estimated at 312·9 million operations in 2012, an increase of 33·6 per cent over 8 years¹. The surgical care pathway is complex, and serious adverse events (AEs) remain common². An AE is usually defined as an unintended injury or complication resulting in prolonged hospital stay, disability at the time of discharge or death, caused by healthcare management rather than by the patient’s underlying disease process³—⁵. Major studies³—¹¹ have reported AE rates of 3–16 per cent and progress towards reduction seems lacking¹². In addition, serious, potentially devastating, preventable surgical events, named ‘never events’, continue to occur despite considerable efforts to improve patient safety², and are considered to be unacceptable¹³.

The incidence and estimates of wrong-site surgery and retained surgical items in the US setting vary considerably
by data source and procedure, with median estimates of one event per 100,000 and one per 10,000 surgical procedures respectively\textsuperscript{14}. Wrong-site surgery refers to surgery on the wrong side or at the wrong site, the wrong procedure, the wrong implant, or the wrong patient. Retained surgical items refers to items left unintentionally in a patient after surgery, some being clinically asymptomatic and even discovered a long time after the surgical procedure.

The AEs can also lead to severe consequences for clinicians and institutions, including the psychological effect on involved healthcare professionals, the financial burden of medicolegal action, and negative effects on a professional reputation. Further, patient harm generates a considerable strain on health system finances. Treating AEs might even contribute to about 15 per cent of hospital activity\textsuperscript{15}. From an economic perspective, patient harm may cost trillions of dollars each year through loss of capacity and productivity of patients and their caregivers. In a political sense, the costs of safety failure include loss of trust in the health systems, governments, and social institutions\textsuperscript{15}.

To apply the most efficient and effective interventions to decrease the AE rate in healthcare, assessments of safety risks must capture reliable information in dynamic and complex care situations. As a large proportion of AEs are related to the surgery, it has been advised\textsuperscript{5} that funds and efforts be concentrated on interventions aimed at reducing these types of event in this field.

Risk analysis is gaining significance to help organizations minimize risks of patient harm, and there is a growing need for better and systematic insight into methods available to perform such a prospective risk assessment. Prospective methods to measure patient risks have advantages over retrospective ones, as they do not have to rely on an AE having occurred and been reported, and allow for the identification of latent factors that may lead to hazards. In contrast to retrospective risk assessment\textsuperscript{16}, little is known about the availability of prospective procedures. This study aimed to perform a systematic review of the literature on the prospective methods used to identify perioperative patient safety risks. This included the full perioperative path, from preoperative surgical and anaesthesia risk assessment to patient admission, surgical procedure and discharge from hospital. A secondary aim was to describe the kinds of risk area targeted per method and, if studied, to assess the quality characteristics and feasibility of each method.

**Methods**

The methodology and reporting of this study was performed according to the PRISMA guidelines\textsuperscript{17}. The types of included study and quality characteristics were categorized according to UK National Institute for Health and Care Excellence (NICE) public health guidelines\textsuperscript{18}.

**Inclusion and exclusion criteria**

All published literature in the English and Dutch language between 1 November 1999 and 23 May 2019, reporting primarily on methods assessing patient risks prospectively in a perioperative setting, was searched for inclusion. Original research papers were included if: they provided a clear description of methodology, population of interest, and results; and more than one surgical subspecialty was involved in the studies (unless there was no doubt that the used method was applicable to other surgical specialties). Scientific publications were excluded if they met at least one of the following criteria: studies that described interventions on improvement of patient safety, such as implementation of the WHO Surgical Safety Checklist, or interventions on surgical team performance; studies in which only one specific patient safety issue was targeted, such as surgical-site infection or medication safety; and studies reporting on structural factors relating to fundamental hospital items, such as staff qualifications and equipment skills. Narrative reviews, editorials, opinions, personal views, response letters, and case reports or case studies were also excluded.

**Information sources and searches**

In May 2019, a search was performed using the following databases: MEDLINE (PubMed), Embase, the Cumulative Index to Nursing and Allied Health Literature (CINAHL) and the Cochrane Library. A full electronic search strategy for the MEDLINE database is presented in Appendix S1 (supporting information). The studies were screened independently for eligibility on the basis of title and abstract; the full text was screened when the abstract was not available. Discrepancies resulting from article screening were discussed further to reach consensus; however, in cases of doubt, studies were still included. The full-text content of selected publications was then screened for final inclusion or exclusion. Finally, all references of the included studies were searched manually to identify additional relevant studies.

**Study characteristics**

For each selected study, the following key characteristics were extracted: period of study and country, aim of the study, study design (based on the NICE Appendix D
Glossary of study designs\textsuperscript{18}, perioperative phase, target group or sample size, and type of prospective measurement method.

**Study quality**

The methodological quality was investigated using the NICE Appendix G Quality appraisal checklist\textsuperscript{18}. Studies were excluded when graded a minus for overall internal or external validity.

**Risk-assessment methods**

For each reported method, the following data were extracted: a description of the method, the way of performing, identified risks and risk areas, and key conclusions. Feasibility and quality characteristics, such as measurability, applicability, discriminatory capacity and improvement potential, as well as validity characteristics were also extracted from publications if reported, using the grading or wording of the authors. Finally, an overview of employed methods and targeted risks was presented, and results were grouped and summarized.

**Results**

From 16708 papers identified in the four databases, 14708 studies remained after removal of duplicates. Some 100 publications were considered eligible for full-text screening, and 82 were excluded after further examination. Three additional studies were included, identified by hand-searching, resulting in the inclusion of 21 studies for data analysis (Fig. 1).

**Study characteristics**

The key features of the 21 studies are outlined in Table S1 (supporting information). Most studies were conducted

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**Fig. 1 PRISMA diagram for the systematic review**

Records identified through database searching $n = 16708$

Records after duplicates removed $n = 14708$

Records screened $n = 3083$

Full-text articles assessed for eligibility $n = 100$

Full-text articles excluded $n = 82$
- Duplicate $n = 1$
- Editorial/narrative review $n = 17$
- Hospital programme $n = 1$
- Intervention/Implementation $n = 12$
- Overlap with key publication $n = 1$
- Retrospective study $n = 5$
- Specific safety domain/specialty $n = 18$
- Team performance assessment $n = 3$
- WHO SSC measurement $n = 24$

Studies included $n = 18$

Additional studies included from other sources $n = 3$

Total studies included $n = 21$

SSC, Surgical Safety Checklist.
in the UK (8 studies) and USA (6). Remaining studies were performed in Austria (1), Belgium (1), Egypt (1), the Netherlands (3) and Switzerland (1). There were 19 cross-sectional and two prospective cohort studies. Various surgical procedures and perioperative phases were studied, such as patient admissions to surgery wards, operating room and recovery area, and postoperative surgery ward area.

**Study quality**

One study was excluded from further analysis because of low outcome and analysis scores (Appendix S2, supporting information). Thus, 20 studies showing good internal and external validity remained, and were used for in-depth analysis.

**Risk-assessment methods**

An overview of the included studies on prospective risk-assessment methods for identifying perioperative patient safety risks, targeted risk areas, characteristics and feasibility is shown in Table 1. Five categories of prospective risk-assessment methods included: direct AE surveillance (3 studies), direct (in-person) observation (16), (modified) Healthcare Failure Mode and Effect Analysis (m-HFMEA™, Department of Veterans Affairs, National Center for Patient Safety, Ann Arbor, Michigan, USA) (5), indirect observation (4) and use of questionnaires (3). In 11 studies a combination of methods was described (Table 1). m-HFMEA™ methods and direct AE surveillance methods were always combined with direct observations. Furthermore, seven studies described the use of one or more additional prospective assessment tools: contextual inquiries (3 studies), interviews (4), photographs (1) and protocol assessment (1) (Table 1). Risk assessments were conducted by various professionals, such as surgeons, medical students and independent consultants (Appendix S3, supporting information).

### Table 1 Overview of prospective perioperative risk-assessment methods (20 studies)

<table>
<thead>
<tr>
<th>Reference</th>
<th>Risk-assessment method</th>
<th>Study quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anderson et al.</td>
<td>Direct AE surveillance, Direct observation</td>
<td>Yes</td>
</tr>
<tr>
<td>Bentz et al.</td>
<td>Direct observation, (Modified) HFMEA™</td>
<td>Yes</td>
</tr>
<tr>
<td>Blikkendaal et al.</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Borns et al.</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Catchpole et al.</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Christian et al.</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Davis et al.</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Gurses et al.</td>
<td>Yes</td>
<td>Contextual inquiries, photographs</td>
</tr>
<tr>
<td>Hamilton et al.</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Heideveld-Chevalking et al.</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Heideveld-Chevalking et al.</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Hu et al.</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Johnston et al.</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Kaul and McCulloch</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Kreckler et al.</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Marquet et al.</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Nagpal et al.</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Parker et al.</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Smith et al.</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Thompson et al.</td>
<td>Yes</td>
<td>Contextual inquiries</td>
</tr>
<tr>
<td>Total</td>
<td>3</td>
<td>16</td>
</tr>
</tbody>
</table>

AE, adverse event; HFMEA, Healthcare Failure Mode and Effect Analysis.

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and interviews with perioperative staff members. Recently, direct AE observation was correlated with two retrospective AE reporting systems in 211 surgical cases. Overall, the rate of variance reported by safety observers was 65 per 100 cases, compared with seven per 100 cases for handwritten reporting cards and one per 100 cases using the electronic reporting system. However, the preventability of (potential) AEs was not reported22.

**Direct (in-person) observation**

In total, 16 of the 20 studies used direct observations to identify and analyse disruptions that may lead to AEs in surgical care. Ten of these studies combined direct observations with other methods (Table 1). Problems in communication and information flow, and workload with competing tasks were found to have a measurable negative impact on team performance and patient safety23. In addition, length of stay was significantly associated with (potential) AEs in emergency general surgery admissions24. A surgical flow disruption tool to classify flow disruptions in cardiovascular operations has been also proposed25, with strong interrater reliability.

Other methods included the combination of direct observation, contextual inquiries and photographs to identify and categorize hazards in cardiac surgery26. Hazards were related to care providers (such as practice variations), tasks (such as high workload), tools and technologies (such as poor usability), physical environment (such as cluttered workspace), organization (such as hierarchical culture) and processes (such as non-compliance with guidelines). A peer-to-peer assessment model in cardiovascular operating rooms identified six priority hazard themes including: safety culture, teamwork and communication, prevention of infection, transitions of care, failure to adhere to practices or policies, and operating room layout and equipment27. Finally, a Surgical Patient Safety Observation Tool (SPOT) was developed and tested to measure and benchmark perioperative patient safety performance28. SPOT showed good measurability, applicability and improvement potential for compliance to (inter)national patient safety guidelines. The tool showed good discriminatory capacity, with a range of 72.5–100 per cent in compliance performance between hospitals and departments.

**(Modified) Healthcare Failure Mode and Effect Analysis (m-HFMEA™)**

Five studies used a m-HFMEA™ method combined with direct observations to identify and prioritize hazards. The m-HFMEA™ method incorporates a multistage approach that utilizes the expertise of an interprofessional team. This includes the development of process flow charts, hazard scores and decision trees to define areas of potential failure where the patient is most susceptible to avoidable harm. Using this methodology, hazardous failures identified included hand hygiene, infection, vital signs, medication delivery and handover29, as well as communication problems, understaffing and hierarchical barriers30. Studies also reported that most failures were identified before surgery31. One study32 used a structured what-if technique (SWIFT) to identify non-operative risks in group sessions. A total of 102 risks were identified, and the top 20 recommendations were judged to encompass about 75 per cent of the total estimated risk attributable to the processes considered32.

**Indirect observations by video recordings**

Four studies used indirect observations to assess performances and disruptions in surgical procedures, to identify perioperative risk. In one study33, a correlation was found between the occurrence of minor problems, intraoperative performance and duration of surgery. Minor problems were defined as those negative events that were seemingly innocuous, and intraoperative performance as the proportion of key operating tasks that were disrupted. In addition, eight major problems – events that compromised directly the safety of the patient or the quality of the treatment – were observed. Interestingly, using a method of audio-video recording, transcribing ten highly complex operations and then identifying deviations by majority consensus of a multidisciplinary team, a mean of one deviation every 79 min during complex procedures has been reported34. Similarly, using videos, a statistically significant correlation between accurate handover and adherence to guidelines was found in an advanced trauma paediatric resuscitation bay35.

**Questionnaires**

Three studies used questionnaires as a prospective risk assessment method. One paper36 reported that women, educated patients and those in employment were more willing to ask questions, whereas men, less educated or unemployed people were less willing to challenge healthcare staff regarding their care than to ask healthcare staff factual questions. However, doctor's instructions to the patient increased patient willingness to challenge doctors and nurses. Some 10 years later, a Self-assessment Instrument for Perioperative Patient Safety (SIPPS) was developed and validated by perioperative healthcare staff37. SIPPS showed good measurability (99.8 per cent) and applicability (99.9 per cent), although mean compliance was 76 per cent among five institutions, and mixed results.
Table 2 Overview of prospective perioperative risk-assessment methods with their targeted risk areas, and reported quality and feasibility characteristics

<table>
<thead>
<tr>
<th>Study characteristics</th>
<th>Targeted risk areas</th>
<th>Risk assessment method</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Direct AE surveillance</td>
</tr>
<tr>
<td></td>
<td>(Potential) AEs</td>
<td>x</td>
</tr>
<tr>
<td></td>
<td>Perioperative process flow disruptions</td>
<td>x</td>
</tr>
<tr>
<td></td>
<td>Adherence to standard operating procedures</td>
<td>x</td>
</tr>
<tr>
<td></td>
<td>Individual or team performance</td>
<td>x</td>
</tr>
<tr>
<td>Quality characteristics</td>
<td>(Face) validity</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>Interrater reliability</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>Measurability, applicability, improvement potential, discriminatory capacity</td>
<td>+</td>
</tr>
<tr>
<td>Feasibility</td>
<td>Easy to use</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>Clear formulation, relevant, good answering possibility, acceptable time effort</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Requiring considerable personnel</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Time-consuming</td>
<td>-</td>
</tr>
</tbody>
</table>

x, Targeted risk area; +, advantage; −, disadvantage. AE, adverse event; HFMEA, Healthcare Failure Mode and Effect Analysis.

were shown in discriminatory capacity. In 2018, a Surgical Safety Questionnaire was developed to be completed after gynaecological procedures, by surgeons, scrub nurses and anaesthetists. The validity of the questionnaire was confirmed by comparison with video analysis. Potential safety concerns were reported, related to surgical flow disturbances consuming time and to using a new instrument or device.

Quality characteristics and feasibility of included studies

Various quality characteristics were reported in five of the included studies: three direct observation studies, and two questionnaires (Appendix S3, supporting information). The direct observation method was reported with a strong interrater reliability. In addition, good measurability, good applicability, good improvement potential and good/mixed results in the discriminatory capacity were reported for direct observation and questionnaire methods.

The Surgical Safety Questionnaire validation resulted in reliable quantitative results, allowing this questionnaire to be considered a validated tool to evaluate and maintain surgical safety, which may help prevent potential safety hazards during minimally invasive procedures.

Feasibility of the studied methods was reported in ten included studies, with quantified results in three studies. Whereas (in)direct observation methods and direct AE surveillance methods were described as simple, clear, practical and easy to use, the (modified) HFMEA method was considered time-consuming, requiring considerable personnel resources.

An overview of prospective perioperative risk-assessment methods and key characteristics is presented in Table 2. Methods were found to detect four risk areas: (potential) AEs and risk factors, problems and errors; perioperative process flow disruptions and hazardous failures within these processes; adherence to evidence-based guidelines; and individual or team practice performance (disruptions of operational key tasks).

Discussion

Literature review identified five categories of prospective perioperative risk-assessment method. Overall, about half of the studies addressed more than one methodology, and m-HFMEA™ and direct AE surveillance were always combined with direct observations.

At present, the primary prospective risk-assessment method that may best help to target perioperative hazards is direct (in-person) observation. This method covers a broad spectrum of perioperative risk areas and is relatively straightforward to perform. Direct observation was used across different phases in the perioperative care process and for various procedures and operation types, especially in high-risk surgery (such as cardiovascular surgery and gastrointestinal oncology).

In contrast, the method of indirect observation was studied less frequently, although it targeted the same risk areas.
as direct observation. Indirect observation by video record-
ing allowed accurate and detailed assessment, and provided
the opportunity to analyse data more efficiently. Participa-
tion in video recordings, however, was sometimes limited,
reflecting a prevailing culture of unease about personal
video observation. Both types of observation (direct and
indirect) are limited by observer variation, and a potential
Hawthorne effect (the type of reactivity in which individ-
uals modify an aspect of their behavior in response to
their awareness of being observed) might be stronger dur-
ing in-person observations owing to the visibility of the
observers.

(Modified) HFMEA™ was found to be helpful in under-
standing processes and identifying potential hazardous
failures in the perioperative process. In all m-HFMEA™
studies, additional real-time clinical observation was used,
both to help map the process and to confirm assessed fail-
ure modes. In addition, direct (real-time) AE surveillance
was always combined with observation methods, and this
combination detected tenfold more AEs than common
(retrospective) AE reporting systems.

Finally, three different questionnaire studies gave
insight into the views and perspectives of caregivers and
patients. A disadvantage of this method is results being
based on just a sample of the study population.

Validity and feasibility of included methods were studied
poorly and need further research, although it seems
that validation methods were applied more frequently in
more recent studies. Various quality characteristics
were studied in three studies on direct observation
and in two questionnaire studies, showing satisfac-
tory results. Whereas (in)direct observation methods
and direct AE surveillance methods were described as
feasible, the (modified) HFMEA™ method was
considered time-consuming, requiring considerable
personnel resources. Irrespective of the risk-assessment
method used, involved personnel must be trained in eval-
uation and analysis to give consistent and meaningful
results.

This review offers a comprehensive overview of the avail-
ability of prospective methods used for identification and
monitoring of perioperative patient safety risks that may
lead to AEs, and their advantages and disadvantages.

Intraoperative safety interventions, such as a time-out
procedure, are intended to reduce patient safety risks such
as wrong-site operations. The character of such an inter-
vention is to target directly possible risks and prevent
AEs on a single-patient level. However, the intervention
itself is not designed for prospective assessment of perfor-
ance variability (how a time-out procedure is performed).
More specifically, an AE such as wrong-site surgery can
be detected primarily and thus prevented by a time-out
procedure. However, a retrospective analysis can be used
to detect why wrong-site surgery occurred in a specific
or multiple cases, although factors that possibly lead to
wrong-site surgery should be identified with a prospective
risk assessment.

The choice of risk-assessment method can affect the
detection rate of AEs up to 50-fold. Nevertheless, a
prospective risk assessment may be performed at each
chosen moment, and specific perioperative target areas
can also monitor perioperative patient safety intervention
effects over time, and enable benchmarking prospectively.

This review has some limitations. First, the terms com-
pliance or adherence were not included in the literature
search. However, terms such as guidelines and extensive
hand-searching of the references were used in order not to
miss relevant studies. Second, the literature before 1999,
when the paper ‘To err is human’ was published by the
US Institute of Medicine, was not covered. Third, stud-
ies that involved more than one surgical subspecialty and
those that targeted specific patient safety issues (such as
surgical-site infection or medication safety) could have
been missed. Finally, the designs of included studies were
heterogeneous and no single checklist fitted well, such as
the COnsolidated criteria for Reporting Qualitative
research (COREQ) checklist for qualitative studies or the
checklist for clinimetric criteria for the development and
validation of measurement instruments.

The complexity of surgical care, combined with heavy
workloads, fatigue and production pressure, makes the sur-
geical care process particularly vulnerable to AEs. At the
same time, despite this vulnerability, most surgical pro-
cedures are performed proficiently and safely, highlight-
ning the resilience of individuals and surgical teams to the
potential adversity of the setting. This suggests that, in
addition to studying AEs and errors, it seems crucial also
to study the achievements of teams and how threats to safety
are managed successfully. Risk assessments should move
forward by combining two complementary views of think-
ing of safety: learning from both how things went wrong,
and how things go right.

According to the present findings, a direct observa-
tion method is required, ideally in combination with at
least one of the following methods: indirect observation;
direct AE surveillance; m-HFMEA™; questionnaires;
and supplementary tools such as interviews, contextual
inquiries, photographs and protocol assessment. These
methods can be used in a complementary manner to one
another, each targeting a different aspect of perioper-
ative care. Furthermore, if similar methods are used,
benchmarking in hospitals and departments is possible,
enabling learning from both low- and high-practice performances.

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References

Identification of perioperative patient safety risks


Supporting information

Additional supporting information can be found online in the Supporting Information section at the end of the article.