A surgical checklist increases patient safety

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Background

In 2007, WHO launched a worldwide Safe Surgery Saves Lives campaign to decrease the risk of surgical complications. An international group of experts developed a surgical checklist that was piloted in eight different centers around the world. The aim of the present MUMM (Managed Uptake of Medical Methods) review was to evaluate the effectiveness of checklists in the prevention of surgical complications.

Methods

A systematic literature review of electronic databases (Medline, HTA) was conducted. The GRADE system was used for the evaluation of quality and evidence. In addition, vital statistics about surgery in Finland were assessed.

Results

Use of the WHO checklist had been examined in one multinational prospective comparative study. The checklist was found to reduce the rate of postoperative complications by more than one third. In countries with a high gross national product (GNP), the rate of surgical complications decreased from 10.3% to 7.1% and mortality from 0.9% to 0.6%. Converted to NNT (number-needed-to-treat), if the list were used 31 times, one complication would be prevented, and if it were used 333 times, one death would be prevented. No checklist-related adverse events have been reported.

Conclusions

The surgical checklist is a simple method, and there is evidence for its effectiveness in reducing complications in clinical use. WHO recommends use of the checklist in all surgical operations and encourages clinicians to modify the list for different specialties and hospitals.

The estimated annual number of surgical operations worldwide is 234 million, i.e., one operation for every 25 people (1). Growth in the number of accidents and in cases of cancer and cardiovascular disease will increase the number of surgical procedures further.

Surgical procedures are performed to improve the patient's quality of life or to save his/her life, but surgery may also cause significant damage. In the United States, for example, 1,500-2,500 wrong-side operations are performed each year (2). In industrialized countries, significant complications have been reported in 3-22% of all cases of surgery and the risk of permanent damage or death is 0.4-0.8%, meaning 7 million complications causing long-term disadvantage and 1 million deaths from surgery per year (3,4). One half of all the adverse events patients suffer in hospital conditions are related to surgery.

In 2007, the WHO World Alliance for Patient Safety (WAPS) launched a worldwide campaign to reduce adverse events related to surgery. Multinational groups of specialists in various fields concentrated on four primary areas of surgery: reduction of surgical infections; safe anesthesia; team work in the operating room; and follow-up of the results of surgery. The Safe Surgery Saves Lives guideline is based on the literature and on clinical experience. One of the main tools included in the guideline is the WHO Surgical Safety Checklist. Aviation specialists participated in the production of the one-page checklist including 19 items. Similar checklists have been successfully used in anesthesia and intensive care (5). By September 2009, the WHO checklist had been adopted by as many as 1,841 hospitals in 74 countries.

The advanced and successful aviation and airline safety culture offers information and practices that can be utilized in the operating room. Most aircraft accidents are due to hu-

PEER-REVIEWED

Literature
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man error made by the flight crew, not technical error. Such human errors are not associated with flying skills or technical capability but are caused by faulty communication or poor team work, decision-making, or leadership. This realization led to the development of multi-disciplinary Crew Resource Management (CRM) training. The flight crew and all aviation professionals involved in securing aviation safety receive such one-day training.

In the field of medicine, the aims of CRM training have been adapted, for instance, to improving attitudes and working methods in surgical teams. Other than technical skills required can be divided as follows:
1) safety, situation awareness, and error management;
2) awareness of one's own action, and communication;
3) decision-making and reporting.

In a recently published study, teams were assessed by observing their work before and after CRM training. Attitudes related to safety improved ($p = 0.007$), as did skills related to communication within the team ($p = 0.021$), and technical errors decreased (1.73 vs. 0.98/operation, $p = 0.009$) without extending the time required for surgery (6).

CRM training is given to make the team work so as to reduce errors and mistakes. It is essential to share observations and suggested measures, to communicate and to maintain a general situation awareness constantly. Safety risks in aviation are managed not only by CRM but also by systematic work to control organizational factors affecting the work of the crew and to ensure the preconditions for safe work. The current high level of aviation safety can be considered an outcome of this work.

The surgical checklist produced by WHO includes issues that are essential for anesthetic and surgical safety, which the surgical team checks item by item before starting the procedure. There are items such as a possibly difficult airway or risk of heavy bleeding, double-checking the side to be operated on, timely administration of antibiotic prophylaxis, and accurate labeling of specimens (7). Each item on the list is read out loud to make sure that the whole team knows that the essential items have been taken into account and implemented. Checking the three sections on the list (sign in, time out, sign out) takes a total of 2-3 minutes.

Use of the checklist in Finland

The catchment areas of each Finnish university hospital district were represented in the European launch meeting of the WHO checklist in London in January 2009. Two hospitals started using the checklist in their operating rooms almost immediately after the meeting (Pertti Aarnio and Kalevi Karjalainen, personal communication).

In spring 2009, four university and central hospitals together carried out a structured survey among surgical team members concerning the adoption of the checklist. The results showed that use of the checklist improved performance for several items (8). Three hospitals started using the list routinely after the survey. The checklist with instructions has been translated into Finnish, and the material posted on the website of the Ministry of Social Affairs and Health, where it is available to every hospital district (9).

Aim

The aim of the present MUMM review is to assess the advantages of using the checklist in the operation room and its effect on patient safety outcome. The following PICO (Patient, Intervention, Comparator, Outcome) framework was used for planning the study questions:

- **Patient:** All patients undergoing a surgical procedure in operating room conditions
- **Intervention:** Use of the checklist in connection with the procedure
- **Comparator intervention:** No checklist
- **Primary outcome variables:** Patient safety indicators: mortality, complications, adverse events, 'near misses'
- **Secondary outcome variables:** Surgical process variables.

The trial setup has to be comparative because, owing to the nature of the study question, a randomized setup was considered impossible.

Methods

Literature search

A literature search for this review was performed in Medline, Medline in Process and

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Financial ties:
The members of the HALO group have no financial ties pertinent to this subject.

HTA databases in February 2009. The basic search statement was ((General Surgery/ or Surgical Procedures, Operative/) and (Safety/ or Safety Management/)), supplemented with free text terms describing the subject. In addition, a separate search was performed in the Finnish Medic database in order to review the literature in Finnish. The exact search words are listed in Attachment Table 1 in the PDF version of this article (www.laakarilehti.fi > Sisällysluettelot > 49/2009).

Selection of articles

Of the literature references, we chose articles studying the use of the checklist or examining the scientific background of checklist items. Two researchers (AM and SLP) reviewed the results of the original literature search and chose the articles for inclusion. Only one article dealt with the effectiveness of a surgical checklist; the main articles included in the literature references for that article, and dealing with the same subject, were retrieved (10). In addition, the literature references for two WHO publications, The WHO Guidelines for Safe Surgery (1st edition 2008) and Implementation Manual Surgical Safety Checklist (1st edition), were reviewed (TSI); some of the main studies from these were also selected.

TABLE 1.

Changes in complications in pooled results for all hospitals.

	Baseline %	When using the checklist %	p value
Mortality	1.5	0.8	0.003
All complications	11.0	7.0	<0.001
Wound infections	6.2	3.4	<0.001
Repeat operations	2.4	1.8	0.047

TABLE 2.

Changes due to the use of the checklist in industrialized countries compared to countries with low or medium high gross national product (GNP).

	All complications	Mortality
High GNP	10.3% → 7.1%*	0.9% → 0.6%
Medium high or low GNP	11.7% → 6.8%*	2.1% → 1.0%*

*p < 0,05

Data extraction

One researcher (IS) reviewed the article of Haynes et al. reporting on the effectiveness of using a surgical checklist and extracted the main results into tabular form. Another researcher (SLP) checked the accuracy of the tables. A total of 32 full-text articles were reviewed.

Quality review

Two independent reviewers (TSI and AM) assessed the quality and the degree of evidence by means of the GRADE method. The method considers observational as well as randomized studies (11). It assesses the scientific quality of research as well as the conformity of results, the direct connection between evidence and the study question, the accuracy of the results, any publication bias, the strength of the effect, dose-response dependence, and the credibility of efficacy. The degree of evidence is classified as strong (A), moderate (B), scanty (C) or very scanty (D). This classification resembles that used in the Current Care Guidelines of the Finnish health system.

Vital statistics about surgery in Finland

Numbers of elective, emergency and day-case surgical operations were examined from data included in the HILMO Care Register for Social Welfare and Health Care. The HILMO Register was also gone through for data on fatalities and complications related to surgical operations. Statistics kept by the Association of Finnish Local and Regional Authorities, Valvira National Supervisory Authority for Welfare and Health, and Provincial Governments gone through for information on the number of operating rooms in use and surgical specialists in Finland.

Results

Effectiveness of the checklist

One comparative observational study on the use of a surgical checklist was published in January 2009 (10). It included eight hospitals

from countries with a high, intermediate, or low national product. Before the study, work in each hospital was assessed, and a control group was studied in each before launching the checklist. The numbers of patients in the groups were 3,733 and 3,955, and the groups had comparable background variables. Follow-up was continued as long as the patient stayed in hospital but no longer than 30 days. The variables that were followed were the 19 most common and most significant adverse events associated with operative treatment. The study period was one year.

In the pooled results, use of the checklist resulted in a clear reduction in the number of complications in most hospitals (Table 1). Changes in individual complications were not always statistically significant in every hospital, but all hospitals showed a consistent and notable reduction of several complications. Mortality was nearly halved, and the total number of complications decreased by more than one third.

In industrialized countries, the baseline situation was better for most variables. Nevertheless, all adverse events decreased significantly in these countries as well (Table 2). Mortality decreased by a third, but the decrease did not reach statistical significance.

The study also followed changes in operating room work after the checklist was introduced. Significant improvement was noted in these as well ($p < 0.001$). No checklist-related adverse events were reported.

The study quality was assessed using the GRADE system applied by the Cochrane network. The quality assessment criteria and the results are given in Table 3 (for complete data, see Attachment Table 2, www.laakarilehti.fi > Sisällysluettelot > 49/2009). When assessing

TABLE 3.

Methodological quality of the studies (only one controlled study with historical controls).

Study	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	Sum	Study quality
Haynes 2009	yes	yes	unclear	yes	yes	no	yes	unclear	unclear	5/9	high

Quality assessment criteria:
(1) Groups and prognostic factors specified
(2) Groups collected at the same stage of disease
(3) Implementation of the intervention confirmed
(4) Groups comparative for confounding factors
(5) Sufficient control of confounding factors
(6) Evaluation of results blinded for treatment
(7) Sufficiently long follow-up to show effects
(8) Loss percentage below 20
(9) Rates of and reasons for losses similar in intervention and control groups

TABLE 4.

Effectiveness of the surgical checklist. Summary of main outcome variables (mortality, complications) and degree of evidence assessed by the GRADE method.

Study and variable	Surgical checklist n/N (%)	Control group n/N (%)	Effect (95% CI) RR or OR	NNT	Study quality	Importance of result	Degree of evidence (GRADE)
Haynes 2009							
Mortality	32/3955 (0.8)	56/3733 (1.5)	Not given	143	High	Critical	C
Complications	277/3955 (7)	410/3733 (11)	Not given	25	High	Critical/important	C

the degree of evidence, mortality was considered to be a critical variable and complications as either critical or important variables. Detailed assessment of the degree of evidence is presented in electronic form in Attachment Table 3 (www.laakarilehti.fi > Sisällysluettelot > 49/2009). According to the GRADE classification, as the evidence was based on one non-randomized comparative study, it was of degree C (Table 4). The NNT (Number-Needed-to-Treat) for mortality was 150, i.e., when the checklist was used for 150 surgical patients, one death was prevented, and the NNT for preventing complications was 25. The NNT for mortality calculated for countries with high GNP was 333, i.e., when the list was used for one thousand surgical patients, three deaths were prevented, and one complication was prevented when the list was used 31 times.

Data on surgery in Finland

There was no information available on the number of operating rooms in use in Finland.

According to the HILMO Register, 346,000 elective surgeries and 72,000 emergency operations were performed in Finland in 2007. In addition, about 188,000 day-case operations were performed in that year (12). These numbers also cover private hospital practice reported to the HILMO Register.

No pooled, published statistics are available for total surgical mortality or for surgical complications.

According to Finnish Medical Association statistics (1.1.2009), the numbers of working-aged specialists in surgical specialties in Finland were as follows: 329 otologists; 435 ophthalmologists; 640 gynecologists; 749 anesthesiologists; and 1,600 surgeons (in total, 928 were specialized in general surgery). The statistics do not state how many of these were actually working.

Discussion

A systematic literature review was made to examine the effectiveness of a surgical checklist on complications and mortality, and clinically measurable benefits were observed. The cost effects of the checklist were not estimated. However, use of the checklist presents a simple intervention with costs arising only from a few minutes of work input per surgical operation. The price of the extra time in the operating room can be compared, for example, against the costs of treating complications.

As the data on effectiveness are based on only one high-class comparative observational study, the evidence assessed by the GRADE method is of level C (scanty). The high quality of that study increases the credibility of the results, as does the fact that effectiveness was largely similar in hospitals studied in various countries. It is unlikely that the effectiveness of the checklist would even later be assessed by using a randomized trial setup, but further data and evidence may accumulate from comparative observational setups. Research on how the checklist affects the work process in the operating room would also be needed.

The checklist concentrates on deviations in the therapeutic process that have been found to be problematic, and on critical stages in the process. Good experiences have previously been obtained of systematic improvement of the safety of anesthesia. Thirty years ago, the risk of fatal complications arising from anesthesia for a healthy person undergoing general anesthesia was estimated at 1:5,000 (13). In an extensive review carried out in Australia in the early 2000s, anesthesia mortality was estimated at 1:56,000 (14). In addition to more systematic use and further development of the anesthesiological procedure, extensive use of pulse oximetry during surgery is considered to be one of the factors behind reduced mortality (15).

On this basis of research results, other items on the checklist have also been considered crucial for safety. Checking the labeling of specimens, for example, is based on results showing that one half of laboratory errors are due to faulty labeling (16) and that one in 18 labeling errors leads to an adverse event (17). The checklist items are strongly recommended in WHO Safe Surgery Saves Lives guidelines (18).

There are extensive recorded data available on the numbers of elective, emergency and day-case surgical operations in Finland. However, data on surgical mortality within 30 days of operation or data on complications have not been collected systematically. It was also surprising to find that there were no data on operating rooms in use in Finland. Data on individual patient groups are available, for instance,

from the Perfect project, where the surgical indications included balloon angioplasty and bypass operations of coronary arteries, hip fractures, and hip and knee replacement surgery (19,20,21).

The Finnish Patient Safety Strategy 2009-2013 by the Ministry of Social Affairs and Health emphasizes that clinical leaders must visibly bear the responsibility for promoting patient safety and that they cannot delegate this responsibility. This involves the assessment of all – including economic – decisions also from the point of view of patient safety. Management should facilitate and ensure working conditions that make safe treatment possible in the organization. Quality and risk management must also be considered (22). According to recently published studies (23,24), hospitals striving in a goal-oriented manner to provide high-quality treatment can prevent as many as one half of all surgical complications. Further improvement of good results usually requires a high input in relation to the benefits achieved, but the checklist is a cheap tool and easy to use. Adverse events should preferably be reported to the HILMO register. This could improve quality within the unit and could provide information at the national level.

Conclusions

There is research-based evidence of a positive effect of the surgical checklist on risk management and the prevention of adverse events among surgical patients. Systematic use of the checklist decreased the number of surgical complications even in industrialized countries with high technology. The checklist can be used to reduce suffering and costs related to human errors and mistakes. It is a cheap tool and easy to use. It has not been found to have any adverse effects.

WHO encourages units and hospitals to modify the checklist, as necessary, to conform to their needs. Commitment by the management is the primary prerequisite for successful launch of the checklist. ■

ENGLISH SUMMARY

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Background About 234 million operations are done globally each year. A rate of 0.4-0.8% deaths and 3-16% complications means that at least 1 million deaths and 7 million disabling complications occur each year worldwide. In 2007 WHO launched an international campaign to decrease the surgical complication risk. An international group of experts developed a checklist that was piloted in 8 different centres worldwide.

Study question Our aim was to evaluate the effectiveness of checklists in the prevention of surgical complications.

Methods A systematic literature review was undertaken from databases (Medline, HTA) to collect relevant publications. GRADE system was used for the evaluation of quality and evidence. Vital statistics about surgery in Finland were assessed.

Effectiveness In a recent international prospective comparative study (1) the surgical checklist was found to reduce the rate of postoperative complications and death by more than one third. NNT numbers (number-needed-to-treat) in high-income countries were one prevented complication for 31 and one prevented death for 333 lists used. No checklist-related harms were reported. In Finland 346 000 elective operations, 72 000 emergency operations and 188 000 day surgery procedures were performed in 2007.

Conclusions The surgical checklist is a simple method, and there is evidence for it's effectiveness in clinical use. Clinics are encouraged to customize it to local setting and needs.

ATTACHMENT TABLE 1.

Search strategy.

Ovid MEDLINE(R) <1950 to February Week 2 2009>

#	Search
1	checklist*.ti,ab. (10869)
2	General surgery/ (27935)
3	exp Surgical Procedures, Operative/ (1796736)
4	Safety/ (26216)
5	Safety management/ (9961)
6	2 or 3 (1820220)
7	4 or 5 (36039)
8	1 and 6 and 7 (19)
9	((surger* or surgic* or operating room or theatre or theater) adj5 checklist*).ti,ab. (46)
10	(safe or safety).ti,ab. (260800)
11	9 and 10 (12)
12	(safe surgery and checklist*).ab. (3)
13	8 or 11 or 12 (27)
14	(news or letter or comment or editorial).pt. (1035364)
15	13 not 14 (21)
16	limit 15 to yr=”2000 - 2009” (16)
17	Intensive Care/ (10455)
18	exp Anesthesia/ (136349)
19	18 or 17 (146379)
20	1 and 19 (85)
21	20 not 14 (79)

EBM Reviews - Health Technology Assessment <1st Quarter 2009>

#	Search
1	(surger* or surgic*).af. (1219)
2	checklist*.af. (32)
3	1 and 2 (5)
4	Safety Management/ (12)
5	exp Surgical Procedures, Operative/st [Standards] (10)
6	4 and 5 (1)
7	exp Surgical Procedures, Operative/ (1357)
8	exp Postoperative Complications/ (47)
9	8 and 7 (16)

Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <February 24, 2009>

#	Search
1	checklist*.ti,ab. (842)
2	(surger* or surgic*).ti,ab. (45296)
3	2 and 1 (54)
4	(safe* or complication*).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (41386)
5	4 and 3 (19)
6	(anesthe* or anaesthe* or intensive care).ti,ab. (11696)
7	1 and 6 (23)
8	(comment or letter or editorial or news).pt. (60224)
9	7 not 8 (22)

Medic

Search	Hits
treatment team treatment work group “cooperative behavior” “relations between various professional groups” AND operating rooms “surgical ward nursing” surgical operations	16
risk factors safety management risk management “medical errors” AND operating rooms “surgical ward nursing” surgical operations “intraoperative treatment”	18

ATTACHMENT TABLE 2.

Methodological quality of the studies (only one controlled study with historical controls).

Study	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	Sum	Study quality
Haynes 2009	Yes	yes	unclear*	yes	yes	no	yes	unclear**	unclear**	5/9	high

Quality assessment criteria:
(1) Groups and prognostic factors specified
(2) Groups collected at the same stage of disease
(3) Implementation of the intervention confirmed
(4) Groups comparative for confounding factors
(5) Sufficient control of confounding factors
(6) Evaluation of results blinded for treatment
(7) Sufficiently long follow-up to show effects
(8) Loss percentage below 20
(9) Rates of and reasons for losses similar in intervention and control groups

*Did the observer make sure that the checklist was always filled in? If so, this was part of the intervention. The article does not show how completely the checklist was used. Or did they include only those patients, for whom the checklist was completed? If so, there are no data of the number of patients for whom the list was not filled.

**Losses were probably clearly less than 20%, and there is no difference between the groups in the rate or type of losses. However, this has not been reported.

Were the patients not checked at 30 days after operation?

ATTACHMENT TABLE 3.

Use of the surgical checklist. Summary of main outcome variables (mortality, complications during hospital stay up to 30 days) and degree of evidence assessed by the GRADE method. Mortality was assessed as a critical outcome variable and complications as critical/important outcome variables.

Study and variable	Setup	Methodological inadequacies	Non-uniformity of results	Indirectness of evidence	Inaccuracy of results	Suspected publication bias	Strength of effect	Dose-response ratio of effect	Credibility of effect	Degree of evidence (GRADE)
Haynes 2009										
Mortality	observational, controlled	No	no	no	no	no	-	-	-	C
Compli-cations	observational, controlled	No	no	no	no	no	-	-	-	C