REVIEW ARTICLE

The Effect of the WHO Surgical Safety Checklist on Complication Rate and Communication

Axel Fudickar, Kim Hörle, Jörg Wiltfang, Berthold Bein

SUMMARY

Background: In 2009, the World Health Organisation issued a worldwide recommendation for the use of its Surgical Safety Checklist in all operative procedures. In this review, we present the available data on the implementation of this checklist and its effect on perioperative morbidity and mortality and on operating-room safety culture. We also survey the experience with the checklist to date and give some recommendations for its practical implementation.

Methods: We reviewed pertinent original publications retrieved by a selective search in the PubMed and Medline databases on the search term "Surgical Safety Checklist". All papers published before February 2012 were analyzed.

Results: The 20 studies that we analyzed included a single prospective randomized trial concerning the effect of the WHO checklist on safety-related behavior in the operating room. The two surgical outcome studies documented a relative improvement of perioperative mortality by 47% in one study (from 56 in 3733 cases [1.5%] to 32 in 3955 cases [0.8%]) and by 62% in the other (from 31 in 842 cases [3.7%] to 13 in 908 cases [1.4%]), as well as a relative improvement of perioperative morbidity by 36% in one study (from 411 in 3733 cases [11.0%] to 288 in 3,955 cases [7.3%]) and by 37% in the other (from 151 in 842 cases [17.9%] to 102 in 908 cases [11.2%]). Improved interdisciplinary communication was also found. Factors that aided effective use of the checklist included exemplary implementation by team leaders and structured training.

<u>Conclusion:</u> These results support the WHO's recommendation to use the Surgical Safety Checklist in all operative procedures. The checklist should be understood not merely as a list of items to be checked off, but as an instrument for the improvement of communication, teamwork, and safety culture in the operating room, and it should be implemented accordingly.

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ost errors in areas where safety is a concern are attributable to inadequate communication and poor teamwork (e1). Strategies for reducing errors take this into account: This is why, for example, briefings are carried out before airline flights (e2). A briefing is a team meeting in which all of the information needed for the joint performance of a task is exchanged and checked (e3, e4). Briefings in the operating room improve team cooperation, motivation, discipline, and outcomes (e5, e8).

The concept of safety culture encompasses all of the activities and behaviors in a hospital that are relevant to patient safety. A longitudinal study involving 597 hospital workers revealed that briefings improve safety culture, as quantified by the Safety Attitude Questionnaire, by about 7%, and that the frequency of briefings in the operating room is correlated with the improvement in safety (r = 0.4) (e9). Moreover, a multicenter study revealed that the improvement of safety culture owing to the introduction of perioperative briefings was associated with a reduction of complication rates by amounts ranging from 4% to 75%, depending on the center (r = 0.7)(1). General communication training in the operating room also has a beneficial effect on technique and outcomes (e10). Despite these findings, structured briefings have not yet been introduced in operating rooms, except in a small number of centers (2, e5).

The World Health Organization's Surgical Safety Checklist

In 2007, the World Health Organization (WHO) drafted a Surgical Safety Checklist for briefings in the operating room (3, 4, e7). The three-part checklist and instructions for its use were published on the WHO website (4). The performance of briefings requires that the course of anesthesia and surgery be interrupted at three specific times, so that important information can be checked and communicated to all team members: These three times are immediately before the induction of anesthesia ("sign-in"), immediately before the skin incision ("time-out"), and right after skin closure ("sign-out"). The sign-in, carried out by the anesthesiologist, the anesthesia nurse, and the patient, consists of a check on the

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TABLE 1

Original publications on the implementation of the WHO's Surgical Safety Checklist and its effect on morbidity, mortality, and safety culture

Target criterion	Study	Study design	Sample size	Findings
Efficacy	Haynes 2009 (5)	Prospective longitudinal study	842(908) ^{*1} /8 ^{*2} 3733(3955)/8	Reduction of mortality from 1.5% to 0.8% and of complication rate from 11% to 7%
	Weiser 2010 (7)	Prospective longitudinal study	1750/8	Reduction of mortality from 3.7% to 1.4% and of complication rate from 18.4% to 11.7%
	Van Klei 2012 (8)	Retrospective cohort study	25513/1	Reduction of mortality, correlation with correct implementation
	Panesar 2011 (9)	Retrospective chart review	133	Potential prevention of 21.1% of all wrong-side errors
	Truran 2011 (10)	Prospective longitudinal study	370/1	Reduction of errors in thrombosis prophylaxis (6.9% to 2.1%)
Safety culture	Haynes 2011 (1)	Retrospective data analysis	281/1	Reduction of complication rate is correlated with improvement in safety culture (r = 0.71)
	Nilsson 2010 (11)	Staff questionnaire	331/2	93% of persons surveyed thought that the time- out increases patient safety in the OR
	Helmio 2011 (12)	Longitudinal staff questionnaire	288(412)	Communication in the OR rated more frequently as effective, both by anesthesiologists (79.2% vs. 86.9%) and by OR nurses (64.9% vs. 90.8%)
	Takala 2011 (13)	Longitudinal staff questionnaire	901(847)/4	Improved communication and awareness of safety-related information
	Calland 2011 (14)	Prospective randomized study	20/1	Behavior showing more consciousness of safety issues after introduction of the WHO checklist
Practical implementation	Sivathasan 2010 (15)	Cross-sectional study, survey	138/138	Acquaintance with the WHO checklist in 99% of all hospitals surveyed, introduction in 66%
	Conley 2011 (16)	Structured interviews	10/5	Implementation depends on the example set by leading physicians and their leadership style
	Paull 2009 (17)	Longitudinal observational study	64/64	Implementation depends on the example set by leading physicians (R = 0.34, p = 0.03)
	Gueguen 2011 (18)	Retrospective chart review and qualitative staff survey	34(36)/2	Hôpital Belle-Isle, Metz: 100% implementation, 70% complete University Hospital, Nancy: 50% implementation 20% complete Items raising concern in 15.2% and 32.4% of list
	Paugham-Burtz 2011 (19)	Retrospective chart review Observation of implementation	25/1	Sign-in and time-out both 90% complete, sign-out 75% complete Adequate communication in only 4% of cases, no communication at all in 27%
	Vogts 2011 (20)	Observational study	100/1	Implementation rates: sign-in 99%, time-out 94% sign-out 2%
	Fourcade 2011 (21)	Retrospective longitudinal chart review	303(1299)/17	Implementation (70% to 100%), completeness (20% bis 100%), and changes in these two value over one year (–21.25% to 17.5%, and –37.5% t 22.5%, respectively) vary widely among hospital items raising concern in 1.5% to 1.9%
	Rateau 2011 (22)	Retrospective analysis of electronic patient data	40000/1	Performance of operation despite presence of items raising concern in 2.1% of cases.
Training	Sewell 2011 (23)	Prospective longitudi- nal chart review	480(485)/1	Training raises the frequency of implementation (from 7.9% to 96.9%).
Costs	Semel 2010 (24)	Cost calculation	-	Prevention of 5 serious complications neutralize the cost of implementation of the WHO checklist at a complication rate of 3%
Acceptance among patients	Kearn 2011 (25)	Postoperative patient survey	58/1	Preoperative check does not make patients mor worried (100%), but rather reassures them (97%)

^{*1}The numbers in parentheses indicate the sample size of the second group in longitudinal studies ^{*2}The number after the slash indicates the number of participating centers

patient's identity, the procedure to be performed and the side it is to be performed on, and other points relating to the anesthesia. In the time-out, the patient's identity is checked again, the name and roles of all team members are stated, and all important aspects of the operation itself, including its expected duration and the expected blood loss, are communicated. Finally, in the sign-out, major concluding points are checked, e.g., the correctness of final sponge count and the completion of the postoperative orders.

The WHO checklist was evaluated in a study in eight hospitals in different parts of the world; some of these hospitals provided primary care, others complete (tertiary) care. 3733 patients were studied longitudinally and prospectively before the WHO checklist was introduced, and 3955 patients afterwards. The perioperative morbidity and mortality up to the time of discharge or within 30 days of surgery were assessed with standardized questionnaires.

The introduction of the checklist was found to have the following effects, independently of the socioeconomic characteristics of the hospitals (5):

- a statistically significant relative reduction of mortality in major surgery by 47%, from 56 in 3733 cases (1.5%) to 32 in 3955 cases (0.8%)
- a statistically significant relative reduction of major morbidity by 36%, from 411 in 3733 cases (11%) to 288 in 3955 cases (7%).

The WHO therefore recommended that the checklist be used in all operations (e11) and integrated into surgical training (e12). This recommendation has been taken up by many surgical specialty societies (Box).

Individual adaptation of the content, form, and mode of use of the checklist to local conditions is allowed, as long as the purpose remains the structured communication among team members about important information relating to the procedure.

In Germany, the WHO checklist was first presented and debated in 2008 in publications in Deutsches Ärzteblatt (6) and Deutsches Ärzteblatt International (e13–e15).

In this article, we present data on the implementation of the WHO checklist and its effects on operative morbidity, mortality, and safety culture that have been published in original articles that appeared after the initial evaluative study. We also provide an overview of our own experience with the checklist to date and give recommendations for its practical use.

Methods

We selectively searched the PubMed and Medline databases for articles containing the term "Surgical Safety Checklist." All such articles published before February 2012 were considered in the evaluation.

Results

A literature search on evaluations of the WHO checklist yielded 187 potentially relevant articles

that appeared in the last five years and contained the search term "Surgical Safety Checklist."

Original articles

Among the retrieved publications were 20 original articles about studies that evaluated the process of implementation of the WHO's surgical safety checklist and its effect on operative morbidity, mortality, and safety culture (*Table 1*).

The effect of the WHO checklist on safety-related behavior in the operating room was the subject of a single randomized controlled study.

The benefit that was demonstrated in the longitudinal studies on morbidity and mortality was not necessarily due to the use of the WHO checklist alone, as the outcomes may have been positively influenced by an intervention-independent secular trend toward lower morbidity and mortality.

Effects on perioperative morbidity and mortality

In the aftermath of the initial evaluative study, the effectiveness of the WHO checklist for emergency procedures was also demonstrated.

The complication rates of 842 patients who underwent emergency surgery before the WHO checklist was introduced were compared with those of 908 patients who underwent emergency surgery afterward. A significant improvement was found—a 36% relative reduction of the complication rate, from 151 in 842 cases (18.4%) to 102 in 908 cases (11.7%). Likewise, there was a statistically significant 62% relative reduction in mortality, from 31 in 842 cases (3.7%) to 13 in 908 cases (1.4%) (7). These findings were confirmed in a retrospective cohort study on 25 513 patients: The efficacy of the checklist was found to be correlated with correct performance of the briefing (8).

A retrospective study revealed that the use of the WHO checklist could have prevented 14.9% of all wrong-side errors (such as marking the wrong side) that did not lead to surgery being performed on the wrong side and 85.3% of all wrong-side errors that actually did lead to surgery being performed on the wrong side (9).

A further study documented a beneficial effect of the checklist on the correct implementation of guidelines for thrombosis prevention (10).

Effects on safety culture

The initial validation study of the WHO checklist was accompanied by a questionnaire, in which roughly 80% of the persons that used the checklist in the study stated that they considered the checklist to be simple and thought that it would prevent errors. Roughly 90% said they would want the checklist used if they were to undergo surgery themselves (1).

A year after the WHO checklist was implemented in two Swedish hospitals, 93% of the treating staff stated that they thought it increased patient safety.

Sign-in	Time-out	Sign-out
Before the induction of anesthesia (anesthesiologist, anesthesia nurse, patient)	Before skin incision (surgeon, entire team)	After skin closure (OR nurses, entire team)
 patient identity procedure side of body consent form signed blood products for transfusion and adequate IV access pulse oximeter functional anesthesia apparatus checked allergies aspiration risk airway problem 	- names and functions of all team members - patient identity - procedure - side of body - expected length of operation - expected blood loss - patient position checked - antibiotics - imaging studies present - instruments complete - concurrent illnesses	operation performed sponge, needle, and instrument counts complete specimens correctly labeled technical problems to be solved? postoperative orders criticism and suggestions for improvement

¹¹ The three parts of the checklist are implemented at defined time-points by the team acting together under the responsibility of the persons named under each part. The sign-in is initiated by the anesthesiologist immediately before injecting the anesthetic, the time-out by the surgeon immediately before skin incision. The sign-out is carried out under the responsibility of the OR nurses after skin closure. The staff members responsible for each part of the checklist confirm implementation with their signatures. All information that has been exchanged is relayed to any team members that go on shift during the procedure. Once it has been completed, the checklist is inserted in the patient's chart.

68% thought the use of the checklist provided an opportunity to identify and solve problems (11).

In a Finnish study, treating staff were polled by questionnaire before and after the WHO checklist was introduced (288 and 412 respondents, respectively). Significant improvement was found in their knowledge of the names and tasks of team members and of the patient's identity, history, medications, and allergies. Moreover, the surgeons and anesthesiologists discussed critical incidents more often (12).

These findings were confirmed in a further study by the same research group (13). A randomized controlled study also revealed greater safety consciousness after the WHO checklist was introduced (14).

Practical implementation

In the United Kingdom, where universal implementation of the WHO checklist is officially required, only two-thirds of all National Health Service (NHS) hospitals have adopted it to date for compulsory use in all operations (15). In Washington, D.C., structured interviews with five physician team leaders revealed that the quality of implementation depends on these physicians' ability to explain and demonstrate the use of the checklist (16, 17).

In France, at the Hôpital Belle-Isle in Metz, the checklist was found to be present in all patient charts one month after its introduction, but only 70% of the individual items were filled out. At the university hospital in Nancy, the checklist was found in only 14 of 28 patient charts, and only 20% of the checklists

were filled out completely. Gaps were found particularly in the third (sign-out) portion of the checklist. Items raising concern were found in 25% of the lists, particularly with respect to material defects and the administration of antibiotics (18).

In a retrospective study, the frequency of implementation of the WHO checklist was found to have dropped from 88% to 76% in its first year of use. The first two parts of the checklist were found to have been filled out with about 90% completeness, and the third part with 75% completeness. Only 18% of all items on the WHO checklist were also communicated in the operating room (19). A study in New Zealand revealed that the third part of the checklist was complete in only 2% of cases (20), and a multicenter retrospective study in France confirmed this finding. The frequency of items raising concern ranged from 1.5% to 1.9%, with common ones including forgotten administration of antibiotics, unexpectedly high risk of bleeding, incomplete preparation, and incomplete orders (21). A further study showed that 2.1% of operations were begun despite the known presence of items raising concern in the WHO checklist (22).

Training in the implementation of the WHO checklist in an orthopedic department was found to raise the frequency of its use (23). The cost-effectiveness of the checklist has also been studied: The prevention of five serious complications per year has been found to neutralize the cost of its implementation (24). A British study showed that the sign-in does not make patients more anxious, despite fears that it might do so (25).

^{*2} The checklist was modified from (e31) to take account of local conditions and divergent content

Practical experience and recommendations

Practical experience and recommendations on the implementation of the WHO checklist

The checklist will meet with acceptance only if the physician team leaders

- integrate it in their safety concept,
- take it seriously, and
- serve as an example to others by using it themselves.

Ideally, the WHO checklist should become a part of a comprehensive perioperative safety plan already incorporating other checklists that were previously in use, e.g., the four-column Surgical Patient Safety System (SURPASS) (e16, e17).

One checklist coordinator per department is helpful in the implementation of the checklist (17, e18).

Education and training (including in an operatingroom simulator) are needed to assure proper implementation. It is recommended that a pilot phase should begin in a single operating room and then be extended to all other operating rooms in the hospital.

Interdisciplinary communication helps prevent conflicts in the operating room about proper implementation (e19). Written instructions should be made available.

Training videos demonstrating the implementation of the checklist are also helpful (e20, e21). Every surgical department can evaluate the effect of the checklist by keeping track of complication rates before and after its implementation, e.g., with the Global Trigger Tool (e22). From the medicolegal point of view, the checklist does not alter the division of labor or the distribution of responsibility in the operating room in any way. The person who signs the checklist thereby confirms only that it was implemented, not that the content is necessarily correct (e23). It is true, however, that the documentation of correct implementation can be relevant in malpractice cases, where nonperformance of a briefing might be construed as negligence. This might be more likely to happen under the Patients' Rights Law that is currently being planned in Germany, which will require, among other things, that an error-avoidance culture be actively promoted (e24).

Acceptance in the operating room

Although 90% of physicians would want the WHO checklist to be used if they were to undergo surgery themselves, physicians still harbor some reservations about the checklist (2).

A common objection is that some of the same items are checked even when the list is not used. Many types of information, however, are not communicated systematically, and repeated checking does increase safety (e3). Underlying this objection is a narrow conception of the WHO checklist as an instrument solely for the purpose of checking a list of items, overlooking its benefits with respect to orderly communication and improved teamwork.

BOX

Medical bodies that recommend the use of the WHO's Surgical Safety Checklist in all surgical procedures

- International Task Force on Anaesthesia Safety of the World Health Organization
- World Federation of Societies of Anaesthesiologists
- European Society of Anaesthesiology
- Joint Commission on Accreditation of Healthcare Organizations International (USA)
- National Health Service Trust (United Kingdom)
- Haute Autorité de Santé (France)
- German Society of Surgery (Deutsche Gesellschaft für Chirurgie) (Germany)
- Action League for Patient Safety (Aktionsbündnis Patientensicherheit) (Germany)

Problems can also arise if physicians consider themselves infallible. Those who are in the grip of such a notion may feel slighted by the search for potential error that is inherent to the WHO checklist (e25). Furthermore, a culture of minimal communication in the operating room can be an impediment. Minimal communication may reflect the team's ability to work together effectively while exchanging only a few words, but it can also heighten the risk that important information will be lost, particularly when team members go on and off shift during the procedure or when an unexpected situation arises.

The introduction of the WHO checklist calls for a level of discipline in the team's communication culture going well beyond what was usual before (14).

Relaying information out loud and introducing oneself by name before the start of surgery can at first seem odd and, for some team members, even embarrassing (e25).

Reading the checklist can turn into a problem of hierarchy-versus-autonomy if the operating surgeon begins to feel that he or she has suffered a loss of authority by falling under the control of the operating room nurses. Moreover, the interruption of workflow by the briefing can be bothersome. There may also be economic objections, as it may be feared that operations will be prolonged and costs will go up, even though the studies cited above actually showed the contrary (24, e7).

A team that has had some practice in the use of the checklist can complete all three parts of it in about two minutes.

Errors in implementation

When adapting the checklist to local conditions, one must bear in mind that it contains only the most essential items and is designed to be implemented in under two minutes so that it will meet with acceptance among its intended users (2).

Typical errors in implementation are lack of completeness and processing in the absence of team members. It is also wrong for a single person to go through all of the items on the list without communicating their content to others or providing any opportunity for an exchange of information.

Simply checking off one item after another is less useful than benefiting from the opportunity the checklist provides for collegial discussion of the critical aspects of the operation.

The list must be read aloud in its entirety and should not be implemented from memory. A particularly severe problem arises when the briefing is not taken seriously by staff members in leadership positions, who then fail to serve as a model to help others improve their communication practices (1, 2).

Faulty implementation can foster a dangerous false sense of security and thus convert the positive effect of the checklist into its opposite. The measurable benefit of checklists has been found to depend on a parallel improvement of safety culture and communication, but this cannot take place if the items on the list are simply checked off by rote (e18).

The directly observable effects of the WHO checklist are improved checking of important information and better communication of such information to the entire team. The checklist also helps dismantle hierarchical barriers to communication, enabling more frequent information transfer (e7). Team cooperation is measurably improved (e16).

Briefing with the aid of checklists helps bring about an open workplace culture in which training is improved through information exchange, dialogue, and the chance to express one's own opinion (e26). The public, too, has become aware of the WHO checklist. The exemplary function of leading physicians and their responsibility for good communication and team-building have been highlighted

in the media just as much as the checking of important information before surgery (e27–e30).

The checklist at the University Medical Center Schleswig-Holstein, Campus Kiel

A modified version of the WHO checklist was developed at the University Medical Center Schleswig-Holstein, Campus Kiel, to take account of local conditions and divergent content. An item entitled "Criticism and Suggestions for Improvement" was added at the end of the list to provide a defined time at which comments can be made about the course of the operation.

Beneath the title of each section of the checklist, the team members that are responsible for processing that section of the list are named, followed by the rest of the participating team members.

The descriptions of the individual checklist items that follow have been considerably shortened, in order to shorten the reading time. The boxes to be ticked off have been omitted. Under each section of the list, a signature field has been added, so that the responsible team member can confirm that the section has been processed (*Table 2*). Training films on the implementation of the list were produced for internal use, an informational brochure was created, and standardized training sessions were held.

Our checklist was introduced in a pilot project that began in August 2010 in the Department of Oral and Maxillofacial Surgery at the University Medical Center Schleswig-Holstein, Campus Kiel. After successful implementation there, the checklist was put into use in the institution's remaining clinical departments.

The effect of the WHO checklist on safety culture is the subject of a longitudinal study currently in progress in the Department of Neurosurgery of the University Medical Center Schleswig-Holstein, Campus Kiel.

Conclusion

The positive study findings to date, the reported positive experiences in clinical practice, and the recommendations of the surgical specialty societies and

KEY MESSAGES

- The World Health Organization's Surgical Safety Checklist enables the interdisciplinary perioperative checking and communication of essential information before the induction of anesthesia, before skin incision, and after skin closure.
- In two studies, the implementation of the WHO checklist was followed by a relative reduction of perioperative mortality by 47% and 62%, and by a relative reduction of perioperative morbiditiy by 36% in both studies.
- The introduction of the WHO checklist improved interdisciplinary communication and safety culture (i.e., activities and behaviors related to patient safety) in the operating room.
- The correct implementation of the WHO checklist depends on the setting of a proper example by leading staff members as well as on structured training sessions.
- The beneficial effect of the WHO checklist on perioperative complication rates indicates that communication with the aid of checklists might improve outcomes in other medical fields as well.

patients' associations ought to provide sufficient motivation for the WHO checklist to be implemented in all surgical procedures. The checklist should be understood not merely as a list of items to be checked off, but as an instrument for the improvement of communication and safety culture in the operating room, and it should be implemented accordingly.

Moreover, the beneficial effect of the WHO checklist on operative complication rates indicates that more intensive communication with the aid of checklists might improve outcomes in other medical fields as well.

Conflict of interest statement

Prof. Bein is a member of the Advisory Board of Pulsion Medical Systems. He has received reimbursement of participation fees and travel and accommodation expenses for scientific meetings and has been paid for the preparation of scientific continuing education events by Abbott, CSL Behring, Pulsion, GE Healthcare, and Merck. He has been paid for the performance of scientific studies on behalf of Organon, Air Liquide, Pulsion, BMEye, and GE Healthcare. He has also received funding from Pulsion, Air Liquide, BMEye and GE Healthcare for a research project that he initiated.

Kim Hörle, Dr. Axel Fudickar, and Prof. Wiltfang state that no conflict of interest exists

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