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Feasibility and Design of an Electronic Surgical Safety Checklist in a Teaching Hospital: A User-Based Approach

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Abstract. *Background:* The Surgical Safety Checklist (SSC) is routinely used in operating rooms (OR) but its acceptance is low. One promising way to improve acceptance of the SSC and thus quality of patient care is digitalization. *Objective:* To investigate how a digitalization of the SSC could be implemented in a teaching hospital. Based on the identified user requirements we designed a first user interface (UI). *Method:* We performed a literature review, identified user perceptions and requirements during 12 interviews including a standardized questionnaire in surgical departments at the University Hospital Graz (Austria). Subsequently a first prototype of a UI was designed. *Results:* Seven different approaches for digital SSC were identified in literature. Our interviews showed that 90% of the participants had a positive attitude towards a digitalization of SSC. The most favoured version of a digitalized SSC was a tablet-based client-server system with integration in the EHR and projection on an OR monitor. *Conclusion:* Digitalization of the SSC is requested by medical and nursing personnel. Based on the identified user requirements we designed a process oriented UI of a digital SSC.

Keywords. eHealth, computer aided surgery, patient safety, surgical procedures, checklist

1. Introduction

The rate of surgery associated complications lies between 3% and 16% in developed countries, with a worldwide mortality of 1 million deaths per year [1]. Surgery associated complications are mostly wrong patient, wrong side, wrong procedure or even retained surgical items. Studies have also shown that poor teamwork and insufficient communication during surgery cause around 43% of all surgical failures. In addition, the risk of complications in operating rooms (OR) is increased by inadequate pre-surgical preparation like antibiotic prophylaxes. Nearly half of all complications are avoidable [1-3].

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In order to prevent surgical complications, the WHO published the "Surgical Safety Checklist" in 2007 [4] which should act as a supporting tool for the surgical staff to maintain patient safety and promote a reduction of errors such as wrong patient, , wrong side, surgical infections, perioperative complications and deaths [5].

Numerous studies have already proven that the use of this Surgical Safety Checklist (SSC) has positive effects on safety during surgery [6-9]; decreased mortality by 47% and complication rate by 36%. Communication and team cooperation is also positively influenced by the SSC [10].

In 2011 a modified paper-based WHO SSC was implemented within the University Hospital of Graz (UHG). Since then it became a mandatory tool in all surgical departments, but overall acceptance is still not reached yet. The use of the SSC has changed positively over the past years with nearly 90% now using the SSC. Nevertheless, the satisfaction with the SSC is comparatively low (only 55% of the nurses are satisfied or very satisfied) and completion rates drop down over the time (from 81.7% to 57.2%) [11,12]. In addition to that, the opening of the new central surgery at the UHG in October 2017 has a great impact on coordination and safety of patients, which add additional value to the use of a SSC. One promising way to improve acceptance of the SSC and thus quality of patient care and its safety is digitalization [13,14].

This article deals with the question if and how a digitalization of the SSC could be implemented in a teaching hospital. Literature was reviewed and user perceptions and requirements were identified and were used to design a digitalized SSC.

2. Methods

We performed a systematic literature review and qualitative (interviews) and quantitative (questionnaires) analyses to identify user perceptions and requirements. Based on the results we designed a first prototype of an UI.

2.1. Systematic literature review

We conducted a PubMed search (October 2017) focusing on the phrases "*surgical*", *(*or *"surgery", "surgical procedures", "perioperative")* in conjunction with *"checklist" (*e.g. *"safety checklist", "surgical checklist")*, "*patient safety*" and "*electronic checklist*" (or "*digital system*", "*digital assistance*", "*computerized*"). We additionally applied the snowball principle and categorized the identified literature by relevance.

2.2. Qualitative analysis of interviews

For qualitative analysis, we conducted 12 interviews. One half of the questions related to the current use of the paper-based SSC (satisfaction, problems and weaknesses of the SSC) and the other half dealt with possible improvements of the SCC and implementation conceptions towards digitalization. The participants have been selected by the Quality and Risk Management of UHG and came from different professional groups and departments to cover a wide range of SSC user groups (Table 1). During the interviews answers were documented in writing and audio recording. Afterwards, we analyzed all interviews by summarizing and categorizing the information.

Table 1. Interview participants (MF=managerial function)

Professional Group	Department	Position
Surgeon	Otolaryngology	Expert with MF
	Traumatology / Orthopedics	Expert with MF
	Plastic Surgery	Expert with MF
	Transplant Surgery	Expert without MF
	Thoracic and hyperbaric surgery	Expert with MF
	Special anesthesiology	Expert with MF
Assistant of surgeon	Cardiac-, thorax-, vascular surgery, anesthesiology and intensive care medicine	Expert without MF
Nurse	Otolaryngology	Expert without MF
	General surgery	Expert without MF
Anesthesia nurse	Special anesthesiology	Expert with MF
Surgery manager	Executive department of surgery management	Expert without MF
	Executive department of surgery management	Expert with MF

2.3. Quantitative analysis of questionnaires

For quantitative analysis, a standardized questionnaire with 16 questions was filled out by each participant after the interview (participants listed in Table 1). Opinions towards the currently used SSC and a digitalized checklist implementation, system requirements and suggestions for a possible digitalized SSC were inquired. The full list of questions can be requested. The participants had to pick the matching scale boxes of an ordinal 5 point Likert Scale, a nominal form ("*yes*" / "*no*" boxes) as well as pre-formulated selection options.

2.4. Iterative design of the user interface

Based on results from the literature review and focusing on specific user requirements which were gained from the interviews and the questionnaire, a first prototype UI of a new digital SSC was iteratively developed. This intends to pass a cyclic process of 4 main phases (Inception, Elaboration, Construction and Transition) with continual quality and functionality improvements after each of the iterations. The UI was then further refined according to improvement suggestions from users in the University Hospital of Graz and project members of JOANNEUM RESEARCH.

3. Results

3.1. Literature review

Thirteen out of 189 articles remained after exclusion of not relevant results. Reasons for exclusion were no relation to digitalized checklists, no relation to use in the surgery, duplicates or language other than German and English.

We used the included articles to compare evidence about electronic/digitalized SSC. Three publications showed the same checklist or a modified version of the checklist. One was a literature review about electronic checklists [15] and in one article development of an individual digital compilation of electronic checklists was described and a possible implementation in hospitals was suggested [16]. Seven different types of digital SSC exist and were summarized in Table 2. Main findings concerning features and benefits were: six out of 9 identified approaches of digital SSC were using monitors in OR during

team time out (TTO) with additional access to EHR (4 with interactive functionality). Furthermore, some of them support functions like critical information messages (auto-populations), process stops when items were not completed and process oriented workflow visualization. The most frequently achieved benefit was increased user compliance (6 of 9) and increased patient safety (6 of 9).

3.2. Qualitative analysis

Qualitative analysis based on 12 interviews revealed that nearly all interviewed persons confirmed that the currently used SSC is essential for patient safety. Seven participants said that the checklist is finally accepted but it took a long time, the remaining five participants added that the importance, meaningfulness, efficiency and responsibility are often not seen by the medical staff. A main aspect for poor user acceptance was the redundancy of items to be checked. The interview partners suggested that the SSC has to be redesigned or reduced, that a clear definition of responsibilities has to be implemented and that trainings have to be organized to achieve a better understanding of checklist items.

Reported problems of the SSC were: not all team members were present at TTO, the "moment of rest" was not enforced (attention is low) and additional time effort is produced if processes are not familiarized. To avoid these problems, the participants emphasize following points: the SSC should be short, augment the culture of safety (elucidate benefits and consequences, conduct trainings), the design should be process oriented (procedural, seamless handover, information gathering and communication flow).

Table 2. Results of the literature review: features and benefits of electronic checklists.

SSC type	Features	Benefit
Electronic flight board with clinical decision support (CDS) [14]/[17]*	Real-time patient data (EHR), critical information (auto-populating), process stop when item incomplete, access and projection of data (EHR), procedural, client-server-system (CSS)	Increased compliance, increased patient safety and staff acceptance
Pre-recorded audio checklist [18]	Audio delivery of items	Increased compliance, consistency of questions and staff attention
Pre-recorded audio checklist (mobile device connected to EHR [13])	Interactive screen, procedural, Real-time patient data (EHR), CSS	Increased compliance, staff acceptance and improved workflow efficiency
Video-based checklist [19]	Access and projection of data (EHR), audio delivery of items, CSS	Increased compliance, increased patient safety, staff acceptance and improved workflow efficiency
Interactive screens (LCDs linked to EHR) [19]/[20] **	Real-time patient data (EHR), access and projection of data (EHR), process stop when item incomplete, procedural, progress is visualized, CSS	Increased compliance, increased patient safety, improved workflow efficiency, cost saving
Integrated in OR connected with interactive screen (and EHR) [21]/[22]*	Real-time patient data (EHR) and critical information (auto-populating)	Increased compliance, increased patient safety, improved communication, improved workflow efficiency, cost saving
Integrated in OR connected with interactive screen [23,24]	Access and projection of data (EHR), procedural, progress is visualized	Increased patient safety, improved staff acceptance and communication, time saving

** same checklist different paper/method; ** same checklist but modified*

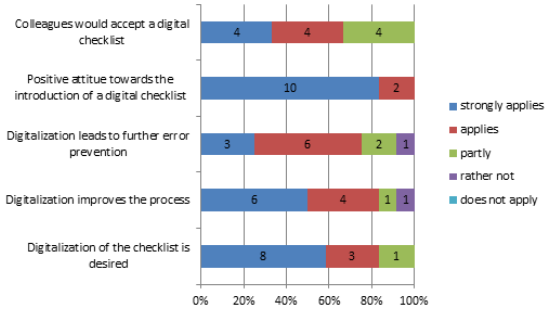

Figure 1. Results from the standardized questionnaire (excerpt).

Further requirements to an electronic SSC with strong agreement were: improved hard-stop culture (prohibit further steps), improved "moment of rest" (audio signal during TTO), prevent incompleteness (required fields), improved quality of data (no loss of data, better archiving and traceability), time saving (more efficient, has fewer redundancies, complete documentation), increase safety (warnings, no loss of device, less manipulation) and improves the workflow (less paperwork, better archiving, documentation, comprehensibility and evaluation).

The participants had a positive attitude towards a mobile solution in form of a tablet connected with a computer or monitor. Emphasis has to be placed on a user-friendly design. Eight out of 12 interview partners favored the idea to have the checklist information projected on a monitor in the OR. A connection to EHR is required from the majority (9 out of 12). A new digital SSC has to focus on seamless workflow integration. Following functions supported by a new digital SSC should be considered in a future development according to the interview partners: automatically retrieve patient data by scanning a QR-code on the patient wristband; display relevant notes, display patient images, automatically include diagnosis and patient data, scan barcodes of consumed materials during the operation (for documentation), handle postoperative arrangements and notes (free text), implement warnings and reminders (for allergies, antibiotic prophylaxis, incompleteness of items).

3.3. Quantitative analysis

Quantitative analysis based on the evaluation of questionnaires revealed that 7 out of 12 of the participants were satisfied with the currently used SSC, but stated that a further development on the paper-based checklist is necessary. Reasons were that the use is not mandatory, the use is not uniform, a signature for accountability is missing, there are ambiguous formulations of checklist items, some items are not suitable, the process is not displayed adequately and the current design should be improved.

Only 33% agreed with the statement that the responsibilities were reasonably regulated with the SCC. Main reasons for the low favorable result were irresponsible completion of the SSC and the hierarchic culture in OR. The opinion towards that a consistent use of the SSC can prevent errors was agreed by all participants (67% voted "*strongly applies*", 33% voted "*applies*") but some commented "only if used properly". Only half of the participants reported that the communication and information access regarding the SSC worked seamlessly.

Nearly all participants agreed with the statement that complications can be avoided due to the use of a SSC. 'Operation location marked' and 'patient identification' were

Figure 2. Prototype of the UI (tablet) for the new digital SSC.

the two most important items on the current SSC according to interviewed participants. Nearly all of the participants had a positive attitude towards a digital SSC implementation and more than half of participants evaluated that a digitalization of the checklist is strongly desired with an overall agreement that a digitalized process could improve the workflow, see Figure 1. A new digital SSC in the form of a tablet and/or a computer in the OR connected to EHR was favored by the majority (9 of 12).

3.4. User interface design

Based on the requirements from the literature review and from qualitative and quantitative analyses, a prototype of a UI was designed (Figure 2). We focused on an easy and user-friendly layout and supported a process oriented use of the SSC. Patient information will be displayed during the whole checklist process.

We chose a rugged tablet device for the usage in OR (Samsung Galaxy Tab Active). The UI prototypically provides features like: scan patients wristband (assures correct patient identification), scan barcodes of materials (managing consumption of materials during operation) and login of different users.

Users will be guided through the entire process by procedural visualization (e.g. SIGN IN is divided in nursing and anesthesia personnel). Auto-populating warnings remind the users of allergies and barriers should block the user from proceeding if the process is incomplete (TTO is only available if SIGN IN is completed). The connection to the EHR and to computers in the OR is envisaged. Interview participants preferred a tablet-based solution instead of a standard computer because they have to check SSC items immediately at point-of-care. There will be no additional infrastructure required to implement the solution within hospital settings because the equipment is already available (WiFi, wall-mounted displays, computers, speakers and barcode scanners).

4. Discussion

Our findings revealed that an electronic SSC is desired by the majority of interview partners. Based on these promising results, we designed a prototype UI for a digitalized

SSC. The comment: “a fool with a tool is still a fool” emphasize the critical attitude of surgical team members towards an electronic application. Without an added value, there will not be any changes in active participation and checking the list properly. Therefore, many interviewed participants requested additional features such as patient identification over wristband (scanning QR code), including material documentation (scanning barcode) and free-text fields to add documentation. Functions like auto-populating messages, process oriented workflow, barriers to prohibit continuing in case of unfinished tasks and monitor projection during TTO were requested.

The integration into the hospital information system (HIS) is regarded as the best choice in order to raise compliance concerning SSC items [13]. However, the approach of a tablet-based digitalization together with a HIS integration is assumed to best support OR-team members in a ubiquitous way. With a CDS, e.g. automatically retrieving patient demographics, updated laboratory values, allergies, medications and audio signaling helps to increase attention in each of the complex steps (SIGN IN: entering the OR – SSC on tablet could be used at point-of-care, TTO: skin incision – SSC can be projected on monitor via HIS; SIGN OUT: before skin suture).

Main barriers for implementation of SSC are challenges regarding efficiency (double checks), lack of knowledge about the correct use and stringent hierarchical structures [2,11,25]. Design issues, lack of process integration and inefficient timing of checklist use is also problematic [26]. Today there are still problems with the overall acceptance and compliance with SSC [2,11,12]. Encouraging healthcare professionals with new tools is difficult as it is always associated with the change of habits and engagement [11,26]. New tools “requires the willingness of healthcare professionals" [11] and it is “an ongoing challenge towards the goal of gaining acceptance amongst healthcare professionals and raising compliance” [12]. However, recent developments that handle with an electronic version of a SSC reported an increase in compliance as well as improved patient safety [7,13,27-29]. We found no studies of SSC used on tablets-PCs in our literature search.

Problems regarding electronic systems mentioned in the interviews were the risk of a breakdown (due to damage), transmission-, operation- and documentation errors and slow systems. Additional challenges mentioned were: multidisciplinary documentation, coordination of trainings and acceptance issues.

In conclusion, we found that digitalization of the SSC is feasible and desired by the OR staff. Beside the general consensus regarding the usefulness of checklists in OR the majority of interviewed participants agreed that transferring the paper-based checklist into an electronic version could improve the whole surgical process. One design favored by the majority of interview participants was the implementation of an electronic SSC in a tablet-based CSS integrated in the EHR with projection to an OR monitor. We designed a first prototype UI which will be further expanded as functional demonstrator of the SSC application and then validated in future usability tests.

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