

An Observational Study to Improve the Surgical Safety Checklist Viability

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Abstract: To improve safety, and to reduce the mortality and complication rates during surgeries, the World Health Organization developed the Surgical Safety Checklist (SSC). The SSC has been recently implemented in Portuguese hospitals and we have performed an observational study where several health professionals were observed during their normal surgical routine and interviewed. The objective of this study was to understand the current use of the SSC, and how it may be improved in terms of usability, taking advantage of current technological advancements. During two days, in a public health center in Portugal, a clinical team (surgeons, anesthesiologists and nurses) was observed in 14 surgeries. Some observations disclose that several health professionals are not familiarized with the SSC guidelines, which demonstrates that it is urgent to change the mindset of health professionals, and that the addition of some features in the SSC may be necessary. With the results of the observational study, we have designed and developed a web application for the SSC with new functionalities to improve and aid the health professionals in its use.

1 INTRODUCTION

The Surgical Safety Checklist (SSC) is a support of information that helps humans to reduce mistakes, compensating for the possible limits in his memory and attention. In other words, the checklist guarantees consistency and entirety in the realization of a task (Emerton et al., 2009). The use of checklists is broad in fields such as aviation, and more recently in clinical settings.

The concept of a checklist was first introduced by the administration and engineers of the Boeing Corporation, in sequence of the prototype B-17 accident (1935) in the field of Wright, in Dayton, Ohio, killing two pilots. The investigation showed that the plane did not present any mechanical problem, and that the accident was caused by human error. The Boeing Corporation confronted with this problem, developed and implemented a checklist, and the B-17 aeroplane flew more 1.8 million miles without further incidents (Downey, 2010),(Schamel, 2012). It is estimated that

surgeries on the wrong body part, and to the wrong patient take place in around 1 in each 50000 to 100000 proceedings in the United States of America (USA), representing 1500 to 2500 adverse events of this type yearly (Kwaan et al., 2006).

Between 2007 and 2008, inspired by the aviation, the World Health Organization (WHO), identifying a problem with surgical complications and errors, created the programme “Safe Surgery Saves Lives” to improve the surgical safety and to reduce the number of deaths and surgical complications. Within this programme the WHO developed the SSC, and it was tested between October 2007 to September 2008, in a multicentric study (8 hospitals in 8 different cities: Toronto, Nova Deli, Amman, Auckland, Manila, Ifakara, London and Seattle). After the introduction of the checklist, the incidence of patient complication lowered from 11.0% to 7.0% ($P < 0.001$), and the rate of death declined from 1.5% to 0.8% ($P = 0.003$) in all institutions (Haynes et al., 2009).

In a different study, it was observed that after

the SSC introduction the nurses recognized that patients identity was more often confirmed (81.6% to 94.2%, $P < 0.01$), and the anesthesiologists were better aware of available cross-matched blood and of due checking of anesthesia equipment. This study also stated that anesthesiologists discussed more often the possible critical events with surgeons (of 22.0% for 42.6%, $P < 0.001$) after the post-operative (Takala et al., 2011).

In June 2010, in Portugal, the “Direção-Geral da Saúde” (DGS) in the use of the technical or normative norms, determined the implementation of the “Safe Surgery Saves Lives”, in all the operation rooms (OR) of the National Health System until the end of the September 2010 (George, 2010). In 2011 the impact of the SSC in 5 Portuguese hospitals was studied. The authors observed, after interviewing 153 health professionals, that 41.6% did not know the SSC. Another interesting result is that before September 2010 (mandatory adhesion by all the OR to the SSC) just one hospital had implemented the SSC (Valido, 2011). In June 2013, a circular normative has been issued reinforcing the mandatory implementation of the project “Safe Surgery Saves Lives” in accordance with the “Implementation manual - Surgical Safety Checklist” (George, 2013).

Knowing this, there is a need to understand the workflow of the SSC in Portuguese hospitals and the difficulties felt by the users. All due to the importance of patient safety, since that surgical procedures are an integrant part of healthcare systems all over the world.

1.1 The Surgical Safety Checklist (SSC)

The Surgical Safety Checklist (SSC) divides the surgery in three phases, each one corresponding to a specific period in the normal flow of the surgery: the period before induction of anesthesia; the period after induction and before skin incision; and the period during or immediately after the wound close, but before patient leaves the room. To ensure the fulfilment of the SSC one person should be designated to verbally check all the steps and actions with the team, usually the circulating nurse but it may be any element of the team, by the checklist coordinator.

In the first phase (before induction of anesthesia), at least one nurse and one anesthesiologist must be present. In the second (before skin incision) and third (before patient leaves operating room) phases all the participants should be present, nurses, anesthesiologists and surgeons.

2 OBSERVATIONAL STUDY AND INTERVIEWS METHODOLOGY

This observational study was performed at public health center in Portugal, after institutional approval. During two days the clinical team in one of the hospital’s operating rooms (OR) was observed during their standard clinical practice. This observational study encompassed 14 surgeries, and the clinical team was not aware of the true intent of the observer. After the observational study a set of questions were made to the intervenients and other related professionals.

2.1 Observational Study

The observations aimed to understand the functioning of the SSC in the OR during the standard clinical routine, and observe how the different health professionals were involved in this task, surgeons, anesthesiologists and nurses. In this study, the observer degree of involvement and relation to the observed was considered to be passive. He was not directly involved in the situation that was observed, meaning, the observer did not interact, neither intentionally affected the object of observation (bystander). In addition, the participants did not knew the objective of this observational study. The observer focused on the same points of interest in all interventions:

- At what surgery stage is recorded each SSC phase;
- Which health professionals register each checklist phase;
- Are all items of the SSC read out loud;
- Are there items of the checklist said out loud that are not registered immediately after.

This information was registered throughout the surgical interventions.

2.2 Interviews

After the observational study, the researcher conducted the interviews to these professionals, using a semi-structured approach. One of the objectives of the semi-structured interviews was to know the opinion of health professionals on the use and utility of the SSC. The respondents were surgeons, anesthesiologists and nurses in the same OR of the observational study. The semi-structured interviews followed a previously prepared questionnaire that served as a guideline, with no strict order of questions, managing to adapt the development of the interview to the respondent, ensuring that participants responded to

these same questions outlined, but with a high degree of flexibility depending on the answers given. The guideline was as follows:

- What is your profession?
- Is the SSC used in the operating rooms of your hospital according to the rules explained in the WHO manual:
 - Each item of SSC is validated at the time that statement is read?
 - How is the validation performed (item by item, phase by phase, all at once)?
 - All questions are listed in the predetermined order?
- In your opinion, are all the questions correctly formulated?
- Did the checklist change the way you work?
- In your opinion, what are the benefits and disadvantages of implementing the checklist, defined by WHO / DGS in 2010?
- In your opinion, would it be advantageous to adapt the checklist to each type of surgery?
- In your opinion, would it be advantageous to use a Tablet / Smartphone for implementing the SSC?

In addition of the health professionals, the IT professionals of the hospital were also interviewed. The semi-structure guideline of the interviews followed the same rules of the script for the health professionals. The questions were as follows:

- In your opinion, would it be advantageous to adapt the SSC to each type of surgery?
- In your opinion, would it be advantageous to use a Tablet/Smartphone for implementing the SSC?
- Do external application may be added into the hospital software?

The answers to the questions made were not recorded by any kind of device, we just took notes during an interview, compiling them right after.

3 RESULTS

The clinical setting observed was one of the operation rooms (OR) of the 11 available at the hospital. Surgical interventions in this hospital cover several medical specialties such as General Surgery, Orthopedics and Traumatology, Gynecology, Urology, Pediatric Surgery, Otorhinolaryngology, Ophthalmology, Plastic Surgery and Maxillofacial Surgery.

Figure 1 presents an overview of the OR where the observational study took place. It is possible to see the

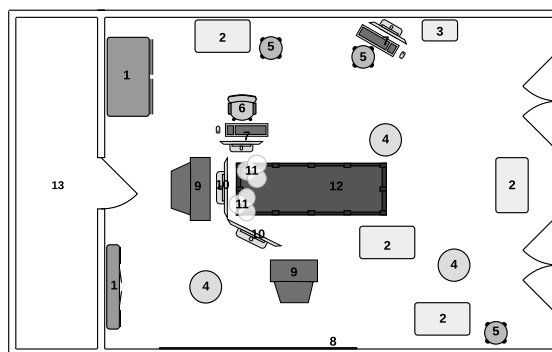


Figure 1: Operating Room (view from the top): 1. anesthesia material and equipment cabinet; 2. surgical and anaesthesia equipment/material trolleys; 3. refrigerator with material; 4. trash cans; 5. stools; 6. chair; 7. computers; 8. white board, and x-ray light; 9. surgical equipment; 10. ventilator and anaesthesia monitors; 11. surgery lights; 12. operating table; 13. sterilization room.

setting organization, and display of the material in the available space, including the material trays, anaesthesia monitors and ventilator, operating table and support tables.

Figure 2 presents the action zones for each actor inside the OR. This observation can help us to understand why and how each actor interacts with the SSC and if we can adjust the guidelines to their current methodology.

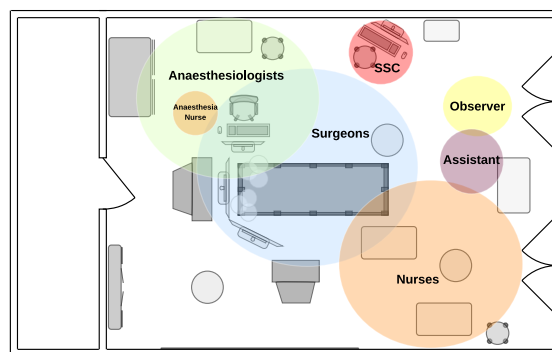


Figure 2: Zones of action inside the Operating Room (view from the top) for each actor.

3.1 Observation

On the first day, the study was performed during the morning period, from 10:30 am to 2:30 pm, and afternoon period, from 3:30 to 9:30 pm. The observer was present in 4 surgeries through the entire process of the Surgical Safety Checklist (SSC), and in 4 surgeries for some of the parts of the procedure. On the second day, during the afternoon period, from 04:00 pm to 8:30 pm, the observer was present in 6 surgeries

Table 1: Observations to the Surgical Safety Checklist usage in the operating room at a public health center. In this table we can see, for each surgery, what stages of the Surgical Safety Checklist were properly done and what was not done in accordance with the guidelines.

Surgery ID	Items with-out immediate registration	Sign In	Time Out	Sign Out	Actors	Read Aloud
1st and 8th	_____	During surgery	During surgery	Before patient leaves operating room	Circulant Nurse or Circulant and Instrumentalist Nurse	Only the items that were unknown to the user or no item
2nd	Sign In	Anaesthesia	When anaesthesia	Before patient leaves operating room	Circulant Nurse and Surgeon in Sign Out	Only Sign Out
3rd, 6th and 9th	Sign In	During surgery	During surgery	During surgery	Circulant Nurse	No item
4th, 5th, 7th, 10th and 11th	Sign In	Before patient leaves operating room	Before patient leaves operating room	Before patient leaves operating room	Circulant and Instrumentalist Nurse or Anaesthetist Nurse	No item or Anticipated blood loss and completion of instrument, sponge and needle counts
12th	Sign In, Time Out	During surgery	During surgery	Before patient leaves operating room	Circulant Nurse	Time Out and Sign Out
13th and 14th	_____	Before induction of anaesthesia	Before skin incision	Before patient leaves operating room	Circulant Nurse	All items

Table 2: Pros and cons retrieved from the interviews to the health professional (surgeons, anesthesiologists and nurses) about the Surgical Safety Checklist use.

Nurses	
Pros	"The use of the checklist is important and should be enforced properly" "If the checklist was a team work, this time would not be a waste, and its use would be improved" The adaptation of the checklist to the type of surgery would be a good solution
Cons	At the beginning of the implementation of the checklist, professionals complied with the rules of the user manual, but due to the attitudes of some surgeons they have stopped doing it The collaboration of surgeons is scarce The registration of the checklist in the hospital software is done by these professionals, their names can be held liable if an incident occurs The use of a mobile application would not improve the functioning of the checklist
Anesthesiologists	
Pros	"The use of the checklist is important and should be enforced properly" The adaptation of the checklist to the type of surgery would be a good solution
Cons	The use of a mobile application would not improve the functioning of the checklist The checklist is not used properly because no one is blamed if an incident occurs due to lack of data completion
Surgeons	
Pros	The adaptation of the checklist to the type of surgery would be a good solution "It is a memory aid, because we are human and we all fail" "The first questions should be asked before the patient is sent down to the operating room, and surgeons should have access to them"
Cons	It is difficult to apply the checklist when experienced health professionals do not set an example, especially to the younger ones It is necessary to change minds, they are aware that many colleagues do not collaborate with the nurses "If anyone who did not fill up the checklist, or did not cooperate in their fulfillment was punished, it was possible to work" Demotivation of health professionals with the health system at the moment (possible justification for not completing the checklist) "When there are new implementations, especially surgeons, are very reticent" "It would take several serious incidents to open the minds of these professionals" Many of the resident surgeons, do not know the function of the checklist "There is always a way to not comply with the rules of the checklist or other computerized program"

through the entire SSC process. Table 1 summarizes the observed procedures regarding the checklist use in the two days.

In the two days of the observation, and of the 14 observed surgeries, only 2 surgeries met the requirements for the three phases of the SSC, as defined by the WHO. Of the remaining 12 observed surgeries, 9 surgeries completed the last phase at the correct time. The SSC was always filled by any of the nurses that were available, except for a surgery in which a surgeon helped the nurses to fill one of the last phases.

It was also observed that only in 2 surgeries all the phases of the SSC were read aloud to the team. In the remaining surgeries, in 4 of them some of the phases were read aloud and in 8 of them none of the phases were read aloud to the team. We also observed that, in 7 surgeries, several items were read aloud and answered but no one was checking the SSC, only after the end of the phase.

3.2 Interviews

In the end of the two days, several health professionals and technicians (surgeons, circulating nurses, anesthesiologists and IT) were interviewed by the same observer. Their opinions are presented in Table 2.

In general, the circulating nurses have the opinion that the use of the SSC is very important, but reported that not all health professionals involved collaborate the same way. When the SSC became mandatory they tried to follow with all the rules of the World Health Organization (WHO), but due to lack of cooperation of the surgical team, they decided to stop asking a few items aloud, stating: “if the SSC was a team work, this time would not be a waste, and its use would be improved”. In their opinion, a mobile application would not help to improve the functioning of the SSC. They consider that the SSC could be adapted to each type of surgery, for example, they consider that the identification of all team members by name and role, in most of the Portuguese hospitals would be unnecessary, because usually the teams are known to each other. Other example is the different materials used, depending on the type of surgery that the SSC request to confirm in the last phase.

The anesthesiologists were also in favor of the SSC and in their opinion, the main reason for the low commitment to not follow the rules according to the WHO guidelines, is that nobody wants to be held responsible in case of a preventable complication: “it is filled according to some of the rules but I admit that not all of them, there is not a lot of rigour in its register”. The anesthesiologists also do not find the use of a mobile application a surplus value for the SSC, but

quite the opposite, stating that the adaptation of the SSC would be a good improvement.

All the surgeons that have participated in the surgeries (orthopedics, urology and plastic surgeons) were interviewed, and presented very divergent opinions. Some considered that the use of SSC is very important for the safety of the patient, mainly in the points of the laterality and identification, but recognize that many health professionals, mainly the surgeons, still have not adapted to its use. Also, they stated that if in the case of complications, if the SSC was used to find the reason of the problem, they would rapidly change their attitude towards it. Other surgeons state that the SSC may be important but they do not usually do it. Actually they consider that the years of experience are more important than a single SSC. Finally, one of the problems cited is the fact that “the register of the SSC or any register was easier when done in paper when compared to a computer program”. Regarding the mobile application, they consider it to be useful in the confirmation of the material and equipment necessary for the procedures, so the nurses could register that information in the place where the material is stored. The SSC adaptation to different surgery types, in their opinion, would be ideal, since they consider some items superfluous.

The IT staff of the hospital was surprised with the observations because they never thought that the professional were not complying with the WHO guidelines. Also, they explained that it is possible to adapt the SSC software available at the hospital to a new application (software that may for example adapt the SSC for each type of surgery), after approval from “Direção-Geral da Saúde” (DGS).

4 SURGICAL SAFETY CHECKLIST APPLICATION PROPOSAL

After an analysis of the results obtained in the observational study, and the opinions gathered in the interviews, the next step of this study was the development of a SSC application responding to the health professionals requests, that may be adapted to the type of surgery, and easily introduced in the hospital’s system. We have chosen an web approach due to all the advantages of this platform (Umbach, 2004; Manfreda et al., 2002).

In this application the user can chose between a SSC already created to a specific surgery or to create a new SSC, adding and adapting some questions from the World Health Organization (WHO) standard. In

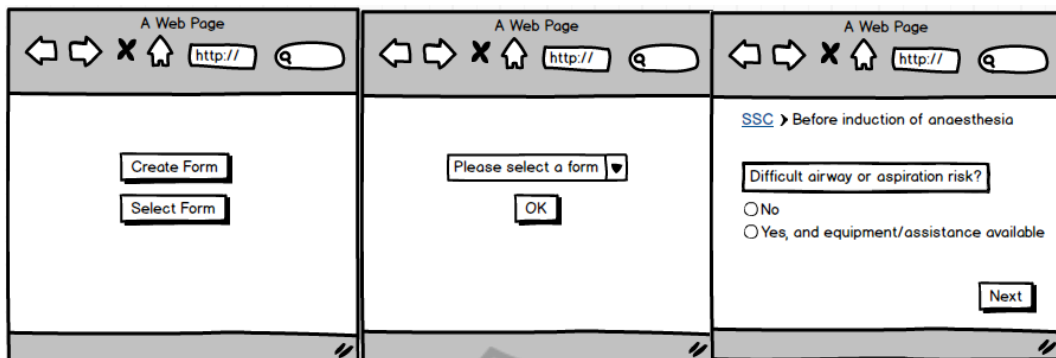


Figure 3: Mockup layouts of the web proposal. In this mockup it is possible to see some of the improvements proposed mainly in the third layout you can see the single question at a time, the progress bar and the no go back option.

this proposal the improvements are focused in forcing the user to focus in the workflow of the SSC and to save the input timestamps and any actions made by them. Therefore, we believe that the following features implemented will achieve that goal (see figure 3).

- Display one item of the SSC at a time. This feature will force the user to focus on the question at hand and will not allow the user to answer other questions out of order;
- Display the stage where the SSC is, so the user knows what he is doing and to help him, guiding him through the SSC;
- Do not allow going back to the previous step. This feature forces the user to be fully aware of his answers. In this feature we will implement some safeguards such as highlighting the answers and only allowing keeping forward some time after the answer is given. A go back button should be implemented anyhow, but the user will be informed that that action will be registered as a forced go back requested by the user;
- Do not allow going forward to the next item if the current is not filled;
- Do not allow going forward to the next item if the time it took to fill the item was too short. This feature tries to stop random inputs to just force the SSC to go further, or to prevent any by heart input;
- Log any action made by the user. This feature will allow to access if the SSC is being filled properly according to the WHO guidelines.

5 DISCUSSION AND CONCLUSIONS

The surgical treatment is an integrant part of health-care systems all over the world, with a respected value of 234 million fulfilled surgeries, annually (Haynes et al., 2009). Preventable surgical complications represent a large percentage of injuries and deaths worldwide. It is estimated that adverse events affect 3 to 16% of all hospitalized patients, 3% of those adverse events occurring during surgery and 0.5% ending in mortality, i.e. almost 7 million patients have significant surgical complications where each year 1 million will die during or immediately after surgery (Kable et al., 2002), (Gawande et al., 1999). It very important that all health professionals comply with the rules of the WHO manual because this numbers can be reduced with a simple gesture of teamwork.

The positive points of the observational study were the full collaboration of the healthcare professionals involved, and also from the IT team of the hospital. Also, observing the SSC use was of paramount importance in the understanding of the entire process at the operating room. It should be highlighted, that due to the study design and specificity, data volatility may be an issue, since everything was noted down and not recorded, and in the operating rooms several simultaneous events were happening at the same time which may have led to missed events.

The results of the observational study, indicate that the SSC is not properly filled, in the majority of times, according to the WHO guidelines. It is concluded that it is urgent to change the mindset of many health professionals, and that there is a need to raise awareness to the SSC impact, through, for example, interventions to various undergraduate courses related to healthcare, or lectures from aviation professionals as a parallel example of the checklists successful

used. We also believe that more hearings to the use of the SSC in the hospitals or a certification may incite its proper use. Reported incidents may serve as examples of the SSC impact, as it happens in the aviation (Downey, 2010).

The designed application may be integrated in the hospitals' systems, to control the use of the SSC, and the new proposed features may help the SSC to become more user-friendly, and reliable. This needs to be investigated in further studies and a collaboration with the WHO is required to validate modifications for each type of surgery.

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