A Literature Supported Conceptual Framework to Develop an Operation Room Audio-Visual Electronic Assistant (ORAVEA) as a Tool for Performing Surgical Safety Checklist

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Abstract

Background: *The literature discusses the use of Surgical Safety Checklist (SSC) to enhance patient safety in the operation rooms (ORs). However, a limited number of studies address an e-SSC process, particularly with a focus on patient identification method. This paper aims to examine the existing literature on e-SSC-frameworks to propose a potential framework that can address patient identification as an important aspect of e-SSC process to enhance patient safety.*

Methods: *A literature search was conducted on NCBI PubMed, AUT Library and Google Scholar, using inclusion and exclusion criteria that helped selecting six frameworks used for Electronic Surgical Safety Checklist (e-SSC). The selected frameworks are examined to identify each framework's strengths and barriers to propose a potential framework that could overcome practical difficulties that may have encountered by OR personnel when performing SSC.*

Results: *The literature analysis identified that the existing frameworks lacked the electronic patient identification methods in the e-SSC process. The paper conceptualised a potential framework imbedded with RFID technologies, which is imbedded with patient identification method. The proposed framework was then compared with the existing frameworks to seek its relevance and usability for performing SSC in ORs.*

Conclusion: *The paper proposes a potential framework, which may provide safer surgeries for patients with its emerging idea of Operation Room Audio-Visual Electronic Assistant (ORAVEA), as an automated hands-free method to perform SSC in ORs. However, since the proposed framework is an emergent conceptualisation based on a literature review, it requires further examination and interventions to seek its reliability and feasibility in ORs.*

Key Words: Surgical safety checklist, electronic, digital checklist for surgery, RFID in patient safety, Auto-identification in SSC.

Introduction

World Health Organisation (WHO) reported that more than seven million surgical patients face debilitating complications and more than one million patients die due to their peri-operative adverse events (WHO, 2018). Weiser et al. (2016) estimated that a global volume of surgeries per year, with more than 234.2 million with majority (138.0 million) surgeries are performed globally in a year and 13% of these surgical procedures led their patients to disability-adjusted life years (DALY). WHO introduced "safe surgery saves lives" guidelines and called for implementation of WHO Surgical Safety Checklist (SSC) in 2008 (WHO, 2018). Haynes et al. (2009) investigated the situation after the introduction of SSC, reported that the death rate from surgical procedures reduced from 1.5% to 0.8% and in hospital complications related to surgical procedures reduced from 11.0% to 7.0% after the implementation of SSC.

Bergs et al. (2014) stated that the development of SSC is similar to checklists used by aviation pilots and space programme product engineering process. WHO-SSC consists of three main events, as briefly explained and illustrated in Figure 1.

1) **Sign in**: it is before the induction of anaesthesia, patient identification, site, procedure and consent for that procedure;
2) **Time out:** it is before the skin incision, team members are introduced by names, their role in the surgery and once again surgeon confirms the identification of patient, procedure and site of the procedure;
3) **Sign out**: it is before the patient leaves the operation room, where confirmation about name of the procedure and sponge, instruments are counted and if there were any specimens, labels are checked and identified with patient identification on it (WHO, 2018).

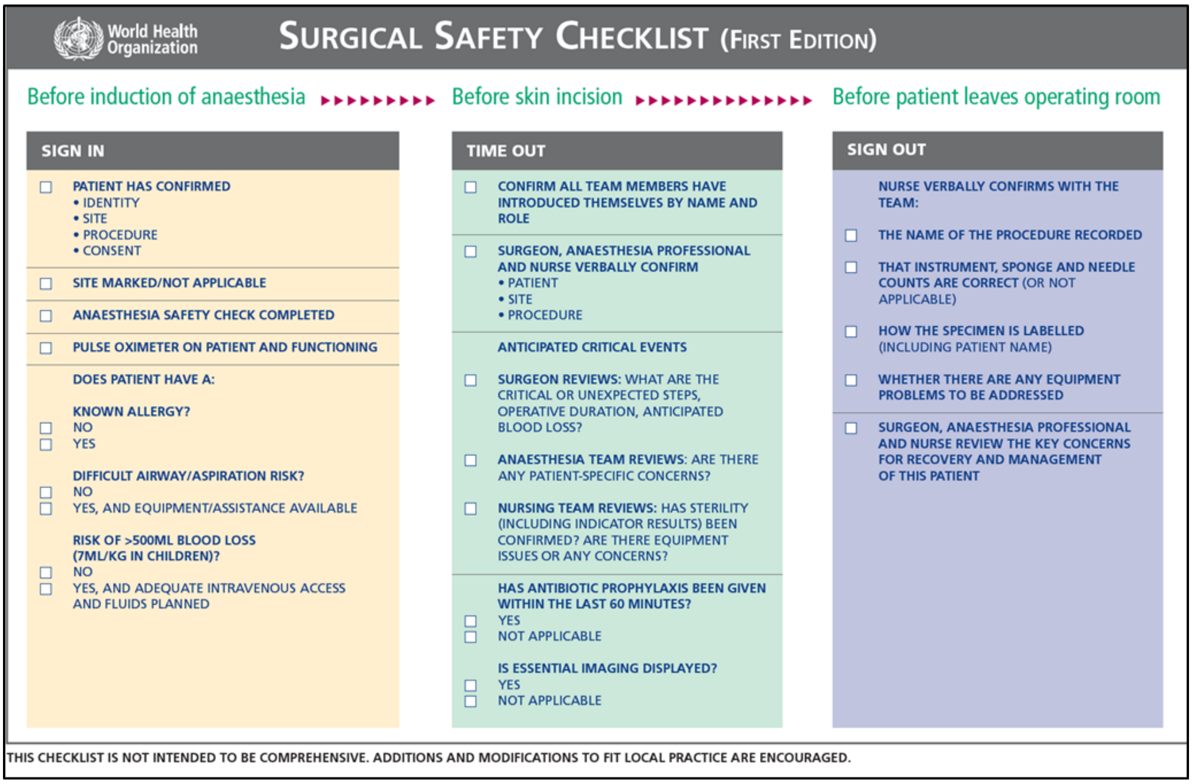

Figure 1.WHO Surgical Safety Checklist (WHO, 2018)

Despite the positive results of performing SSC, which showed a remarkable reduction in the rate of surgery-related complications and morbidity and mortality rates, several barriers in the implementation of SSC are discussed in the literature. Fourcade, Blache, Grenier, Bourgain, and Minvielle (2011) reported eleven barriers to effective adaption of SSC that includes duplication of items in the checklist, poor communication between surgeon and anaesthetist, time spent to complete the checklist without any benefit and lack of understanding and timing of item checks. Similarly, Dixon et al. (2016) described that the inconsistency in compliance of health care workers to SSC and their reason behind this inconsistency is believed to be a process of completing the SSC, which is time consuming, routine-based daily work and merely “ticking off the box”.

The lack of effective implementation of SSC with its manual format led some institutions to introduce innovative, interactive digital ways to perform the SSC (Norton, 2012; Reed, Ganyani, King, & Pandit, 2016), namely, an electronic system of SSC. Several experimental studies discussed the implementation of Electronic Surgical Safety Checklist (e-SSC) (Kiefel et al., 2018; Rothman et al., 2016) identifying the advantages of using Radio Frequency Identification (RFID) identifying its strengths and positive outcomes of tracking the retained surgical instruments (RSIs). RFID methods plays an important role in managing an accurate counting of RSIs, which also have ability to tag or barcode patients and surgical instruments to be identified and recognised in the operation theatre (Huang et al., 2016).

Previous literature discussed the benefits and effectiveness of using RFID to detect RSIs in ORs. This includes 100% accuracy level RFID for detecting RSIs(Fabian, 2005; Macario, Morris, & Morris, 2006; Steelman, 2011), performing sponge counts by using tags in items/supplies (Kranzfelder et al., 2013; Kranzfelder et al., 2012; Lazzaro et al., 2017) specificity and sensitivity of RFID in detecting RSIs (Lazzaro et al., 2017; Steelman, 2011), use of different types of scanning devices such as wand (Macario et al., 2006), tracking tags in supplies and arrangement of the surgical trays (Kusuda et al., 2016) Detecting tags at different conditions such as that were affixed in dummies with submerged in water(Rogers, Jones, & Oleynikov, 2007) Detecting tags at different places in ORs (Kranzfelder et al., 2012) and tracking items that were hidden in different parts of the dummy bodies (Lazzaro et al., 2017; Steelman, 2011).

Regardless of a wide range of literature discussed on accurate process of performing SSC including the use of RFID for tracking RSIs, the patient identification process is scarcely addressed as part of the SSC process. This paper examines the literature on e-SSC performing methods aiming to propose a potential framework, to use as a tool for performing an e-SSC process imbedded with patient identification method to enhance surgical patient safety in ORs.

Methods

A Literature search was conducted from NCBI PubMed, AUT Library, Google Scholar websites focusing on the period between 2008 to 2018. The process of literature search and selection of articles is shown in Figure 2. Table 1 illustrates the keywords used for the literature search outlining the inclusion and exclusion criteria.

Table 1 Search Terms and Inclusion Criteria

Categories	Inclusion criteria
Search Keywords	electronic AND surgical safety checklist, digital-automated AND surgical safety checklist
Main headings	Automated or electronic or non-paper dependant surgical safety checklist. This excluded modification of WHO-surgical safety checklist. All paper related to surgical safety checklist and other electronic checklists those are not related to surgical safety
Study design	Original study evaluates electronic or automated ways of performing surgical safety checklist, specifically designed to improve safety of surgical patients.
Language	Only articles written in English are included.
Time-period	Articles published last 10 years are included (2008 to 2018).

The number of articles retrieved ranged 209 using the keywords "electronic surgical safety checklist", as shown in Table 1. The following three-step criteria were then followed to select the most relevant articles for the literature examination:

1) From 209, 65 articles were excluded as they did not have clear abstracts and details in the papers.
2) From the remaining 144 articles, 138 were excluded after a careful read-through and examination seeking useful ideas for a potential framework, which could improve the existing e-SSC method.
3) The remained six articles were based on studies related to e-SSC frameworks and also proposed an e-SSC automated method, which were carefully examined using a grid (Table 2) to seek ideas that are useful for a potential framework to increase surgical patient safety.

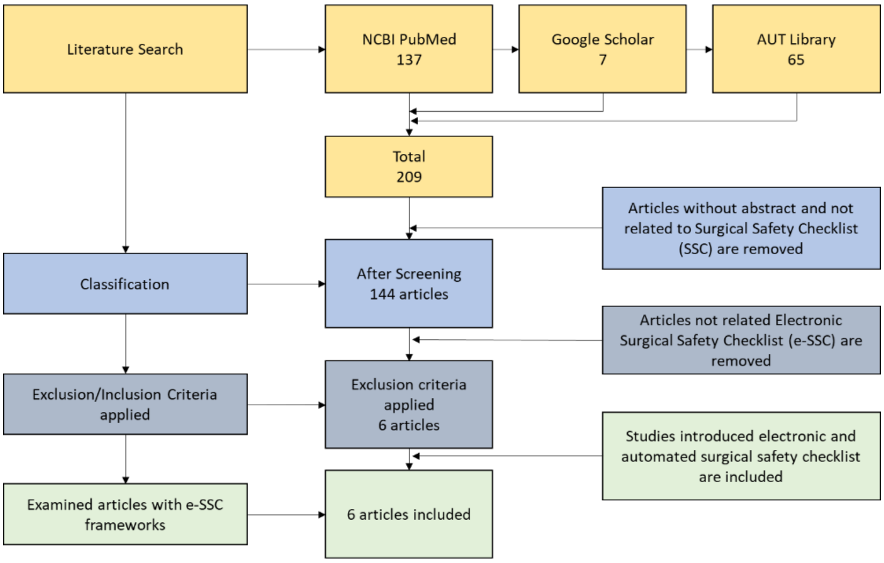

Figure 2.Literature search and selection process

Results

The features of the six e-SSC frameworks are summarised in Table 2, identifying strengths and barriers of each. The content of the Table is arranged in a chronological order from old to recent (2012 to 2018). The primary aim of all studies examined was to introduce advanced and interactive method of performing WHO's SSC to enhance surgical patients' safety. The main results are briefly described below.

Types of the studies: The studies were comprised of three observational studies, two feasibility studies and one comparative study.

Outcomes of these studies: Five out of six studies proposed an automated OR related information system using the hospital-based Electronic Health Record (EHR).

Data used in the studies: Three studies investigated auto-recorded patient data including laboratory investigation results, allergy and medication history in to information visualisation point in the operation theatres (Kiefel et al., 2018; Mainthia et al., 2012; Rothman et al., 2016). The other study used audio of pre-recorded SSC components to initialise the proceeding of SSC (Reed et al., 2016).

Use of technology in the proposed e-SSC system: The basic technology adopted to develop the electronic version of surgical safety checklist was very similar in all studies, except two studies that used mobile gadget (tablet/smart phone) in the OR with the installed application that can perform patient identification data for the hospital EHR system. In these studies, when the patient data displayed the OR-staff can interact with those inputs and perform identification of the patient and proceed with safety checklist (Kiefel et al., 2018; Uppot et al., 2017). Three studies used electronic whiteboard in the OR which connected to hospital EHR system. The whiteboard retrieves patient information including laboratory investigation results, allergy, medication history, planed surgical procedure. The imbedded software will allow to perform SSC electronically with minimal interference of any staff (Mainthia et al., 2012; Rothman et al., 2016; Shear et al., 2015).

Strengths recognised: One (Kiefel et al., 2018) out of six studies selected for this review implemented RFID technologies to identify patients and included barcode scanning techniques imbedded in the e-SSC system. The remaining five studies did not discuss the patient identification techniques. All six studies showed some promising outcomes such as an automated-electronic SSC method, an improved compliance, communication among staff members and the high level of accuracy in SSC process.

Barriers identified: Regardless of successful outcomes of these studies, there are some barriers identified in the reviewed studies. These include lack of patient identification techniques. Primarily, the surgical safety process involves three main aspects related to the performance of surgery (right surgery, right patient, and right site). More precisely, doing the right surgery for the right patient and at the right site. Apart from that avoiding complications such as leaving surgical instruments inside a patient's body and sending wrongly labelled specimen to the laboratory are important areas that required attention. Finally, the literature examination also identified that a staff member has to always occupy during the e-SSC process to physically check SSC by ticking off the electronically displayed list so to accurately complete the check-list. Based on the examination, this paper proposes a conceptual framework to implement a fully-automated-method imbedded with the e-SSC process, as described in the following section.

Table 2 Selected articles analysed

Criteria	Study 1	Study 2	Study 3	Study 4	Study 5	Study 6
Author	(Mainthia et al., 2012)	(Shear et al., 2015)	(Rothman et al., 2016)	(Reed et al., 2016)	(Uppot et al., 2017)	(Kiefel et al., 2018)
Type of study	Observational study	Prospective Observational trial	Feasibility study	Comparison study	Observational study	Literature review and feasibility study for designed UI for e-SSC
SSC framework/procedure	Electronic whiteboard visualises patient data and supports SSC.	Electronic Flight Board with connection EHR system and clinical decision support system	Electronic white board that displays components of e-SSC.	Pre-recorded audio delivery of SSC	Clinical Assist Decision Interface (CADI) a mobile application connected to EHR system and provide voice to the e-SSC.	User interference (UI) on Tablet which can be connected to OR displays, and layout supports a process-oriented use of SSC.
Technology used or required	Electronic whiteboard, EHR system, computers, WIFI connection	Surgical Flight-board, monitors, Computers, WIFI connection	Electronic whiteboard, WIFI, EHR system, Computers	Audio player with speakers and assigned person to play pre-recorded SSC steps	Mobile gadget, WIFI, EHR system	Tablets that can scan Barcodes, WIFI, Wall mounted displays, computers, barcode scanners, EHR system
Patient identification method / RFID used	Through EHR system, No RFID used	Through EHR system, No RFID used	Through EHR system, No RFID used	Through traditional methods, no RFID technology used	Through EHR system no RFID technology used	Barcodes or chip readers and through EHR system RFID used
Electronic Health Record system required	Yes	Yes	Yes	No	Yes	Yes
Findings	e-SSC dramatically increased compliance with procedural timeouts in the OR	Checklist performance improved	Overall performance improved. The implementation of the e-SSC is cost-effective	Checklist completion improved to 100%	CADI statistically improved SSC.	Digital SSC in the form of a tablet and /or a computer in the OR connected to EHR was favoured by the

						majority of the people
Strengths	Improved compliance with SCC and improved staff communication	Increased patient safety and compliance and communication	Electronic whiteboard saved time and compliance and increased safety	No extra cost for technology Simple technique for improvement od SSC	-CADI can be modified according to procedure -it checks for accountability	User friendly application with automated system with RFID technology for patient identification No extra cost will require
Barriers	Need physical Human interference to complete the checklist Identification method not described	Only checks intraoperative phase of surgery checklist Patient identification methods not described	Human interference needed to start the checklist and complete it. Patient identification was not described	No active Automation of SSC. Patient identification not used	Software could not recognise values given in Lab reports Patient identifications methods were not described	An Application on tablet may have risk of breakdown Documentation and saving patient related logfiles in hospital information system are important

Proposed Conceptual Framework

The reviewed literature identified strengths and barriers that may influence OR staff-work during their performance of SSC, which suggests important elements to include in the design of a proposed framework:

1) Automated identification of the surgical patient (once a patient is posted for surgical procedure starting from surgical outpatient's clinic);
2) Fully electronic a hands-free method: Surgical safety checklist is performed fully electronically without occupying manpower of OR personnel; and
3) An electronic patient log in the EHR: A log files of e-SSC is saved in the hospital EHR system and can be retrieved using unique identification process.

The Components of ORAVEA

The proposed framework encompasses with three components: EHR system, health database, Operation Room Audio-Visual Electronic Assistant (ORAVEA), as described below.

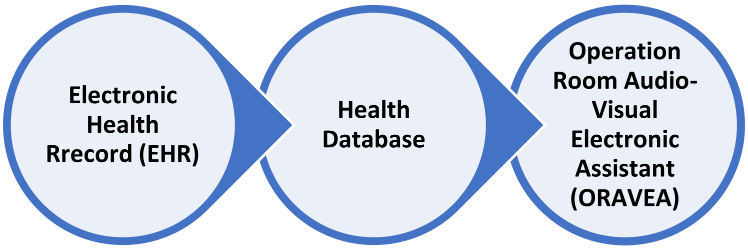

Figure 3.The components of ORAVEA

Electronic Health Record System: EHR is the backbone of hospital-based information system, as it provides well-structured and necessary information required to support the development of an information system (Katz, Andres, & Scanlon, 2018). The reviewed literature points out that five out of six e-SSC systems selected for this paper developed SSC process using a hospital based EHR systems (Kiefel et al., 2018; Shear et al., 2015). The EHR included details about patient demographic data, clinical diagnosis, medication history, allergies and other relevant information for e-SSC. It also contained up-to-date and real time laboratory reports, radiology imaging-results and pathology reports, which can play an important role in the patient safety.

Hospital Database: Patient related data are sensitive information that required to be secured with a limited access to only authorised personnel. EHR system is connected to the hospital data system, which transfers/exchanges information from different platforms such as consultation rooms, ORs, ICUs, laboratories, nursing sites, administrations. e-SSC requires retrieving information/clinical data or any relevant information from the hospital database to identify patients. In addition, the hospital database can generate an automated file after completion of any procedures that also contains information about safety checklist, operative notes, and incidents occurred during a specific procedure. These files can be extracted for the purpose of knowledge exploration, clinical research or any medico-legal purposes.

Operation Room Audio-Visual Electronic Assistant (ORAVEA): Contolini, Applebaum, and Panchapagesan (2017) invented wireless command microphone management for voice-controlled surgical system aiming to have voice-controlled assistance in OR. Voice recognition intelligent technology is a growing field of information technology including smart houses, mobile phones, and transportations. Some examples of these systems include, Amazon’s Alexa and Apples-Siri (Maddox, Smith, & Graylin, 2017). In this project, the suggested ORAVEA is an intelligent system, which can recognise voice commands from OR personnel and perform several tasks including e-SSC. ORAVEA can consist of intelligent software applications that are connected to the EHR and hospital database through an internet secured network. For the purpose of clear communication between and across OR personnel, the e-SSC system can be in-built with microphones, speakers and video cameras, audio-visual and motion sensors in specific areas of ORs. With the in-built-voice command capabilities, the proposed e-SSC system can have patient identification technologies including different types of barcodes and microchips that have reading abilities using RFID technologies. Following section describes the proposed ORAVEA framework.

Description of ORAVEA Framework

Figure 3 portrays a conceptualisation of the designed ORAVEA e-SSC framework including the main components and its process of how it can work with an intelligent software connected with several networks with ORs. The framework describes the procedure of an integrated ORAVEA system, which starts from the admission desk of the hospital when patient is first admitted for a planned surgical procedure in which a unique identification barcode will be created via the RFID technologies. The information in the barcode would contain patient demographic details, diagnosis, details of the planned surgical procedure and other relevant information such as lab-reports, allergies etc. The data will be stored and shared with EHR system, hospital data repository and ORAVEA. Other benefits of this step could include, without any further notifications of OR, based on the available patient data, such as medications and allergies, the system can automatically calculate the expected blood-loss and will generate notifications for the concerned staff members of the blood-banks to take required precautions.

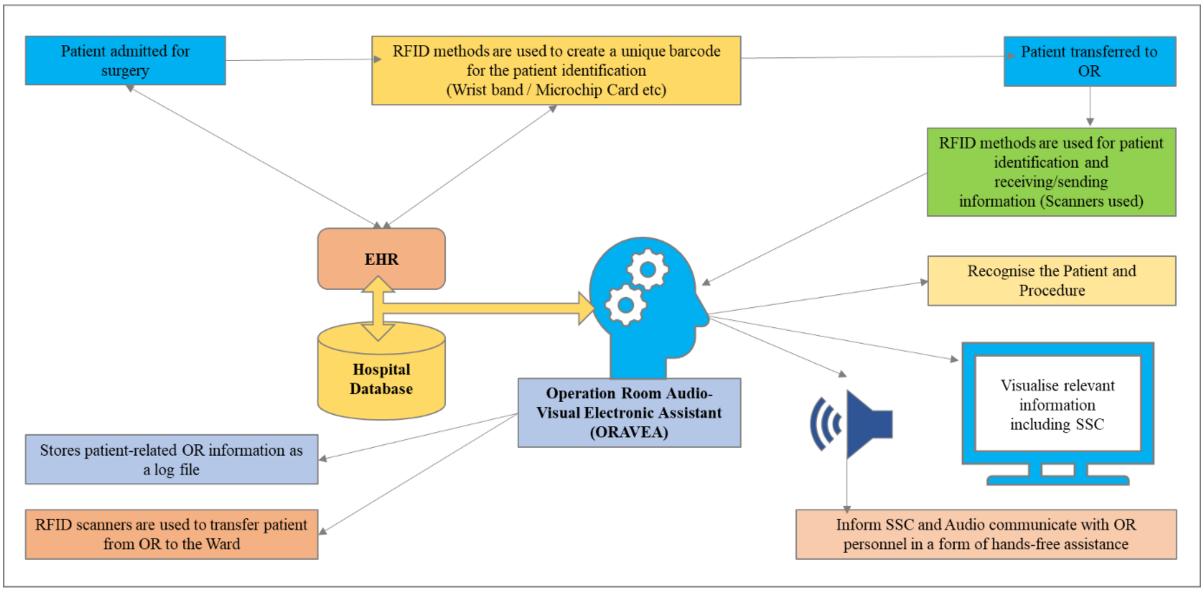

Figure 4. Diagram of Proposed Electronic Surgical Safety Checklist

Initially, when patient is received to the OR, using an auto-identification technology the system will record and register the patient to ORAVEA. Subsequently, it will have the ability to display patient-related information using machine learning process, analyse records, highlight any relevant concerns and produce alerts that can increase patient safety. The ORAVEA model can assist via the audio-visual techniques by recognising OR personnel who are involved, including clinicians/surgeons, anaesthetists and nursing team who will have any form of interaction with the patient's surgical procedure. Once the patient is prepared, OR staff can give verbal commands to perform SSC on audio-visual forms with audio commands to ORAVEA, which can perform the SSC using the information received from the EHR system, hospital database and by reading the barcodes and tags attached to the patient without any physical interference from OR personnel. Similarly, it can count instruments, surgical sponges suture materials and needles accurately adding layer of safety in the procedure. At the completion of surgical procedure, before transferring the patient to the ward, scanning will be required with RFID methods to sign off the patient and procedure from the ORAVEA system. Subsequently, the system will be ready for the next patient.

In addition, the system can store the specimen labels and identification methods using the specimen handling instructions. After the sign-off, a log file will be created, which can contain the details of procedure and patient-related information stored in the hospital data repository, which also can be re-visited if required for various purposes including research and medicolegal requirements. Table 3 summarises the results of comparison between ORAVEA and other e-SSC system selected from the literature and are discussed below.

Table 3. Comparison of ORAVEA with other e-SSCs

Criteria	Study 1	Study 2	Study 3	Study4	Study 5	Study 6	ORAVEA
SSC procedure	Display in the OR projects SSC and nurse at OR computer performs SSC	Surgical flight board displays SSC with real time clinical decision support	Electronic system to present a time-out checklist on large display	Pre-recorded audio delivery of the SSC	Mobile application verbalises the hard-stop checklist	Mobile application connected to OR monitor	ORAVEA performs SSC with voice command
Technology required	OR computer with software	OR computer with user interference application	OR computer with special software	Audio player with sound system in OR	Software in OR computer with network connection	Tablet connected to OR computer Barcode reading	OR computer with intelligent software with voice command recognition, audio-visual equipment. RFID readers
RFID used	No	No	No	No	No	Used in patient identification	Used in patient and instrument identification
EHR required	Yes	Yes	Yes	No	Yes	Yes	Yes
Form of OR electronic manager used	Software connected to EHR displays information	Software designed to manage OR	Software connected to EHR displays information	No OR electronic manager	Software based Clinical Decision Support system	Software connected to EHR retrieve patient related information	Intelligent software with audio command manage OR

Discussion and Conclusion

The examined literature identified six studies proposed an electronic method of performing SSC to enhance patient safety, outlining a critical gap related to the integration of patient identification method in the SSC. Previous literature discussed the benefits and effectiveness of using RFID to detect RSIs in ORs. (Fabian, 2005; Kranzfelder et al., 2013; Kranzfelder et al., 2012; Macario et al., 2006; Steelman, 2011). However, patient identification is given little attention regardless of it is being considered as a vital component of WHO-SSC (WHO, 2018). This paper argues that any modification or digitalisation or integration to SSC should encompass with the patient identification in its methods. In a recent study, Paaske, Bauer, Moser, and Seckman (2017) recognised several benefits of RFID technology of using tags to reduce misidentification issues and human errors when it is integrated in ORs. Ku, Wang, Su, Liu, and Hwang (2011) studied application of RFID in perioperative care, reported that it increases in-patient identification from 75% to 100%.

In the proposed e-SSC framework, a considerable attention is given to patient identification process, as it is an important component of the WHO-SSC (WHO, 2018). Patient identification techniques are used in the proposed model from the very start of the patient 'sign in' stage to the hospital with a purpose of surgery until the patient's 'sign-off' of stage from the OR. The paper proposes implementing a e-SSC hand-free automated-method, using RFID technology, for patient identification, namely, ORAVEA. The ORAVEA model aims to reduce complications and human errors in pre- and post-surgical procedure to enhance surgical patient safety.

Previous studies report that traditional way of doing surgical safety checklist is proven to be ineffective and less accurate, which can lead to occurrence of several adverse events (Buzink, van Lier, de Hingh, & Jakimowicz, 2010; Dixon et al., 2016). Nan et al. (2017) studied benefits of dynamic checklists instead of static-check lists and found that dynamic checklist can improve healthcare- work-load than a static checklist.

With the intervention of information technologies (IT) in the healthcare, a variety of applications and digital equipment are used during surgeries. e-SSC is one of the applications that provides such advantages and considered a hands-free method, utilising less man-power to complete the SSC. The emerging model proposed in this paper, namely ORAVEA, could follow voice commands to perform SSC, more specifically embodied with patient identification method in its process.

Operation rooms are one of the busiest places of hospitals working on schedules of a 24/7 basis managing critical emergency surgeries, planned routine surgeries and minor procedures. Possibility of human errors is a likelihood scenario unless certain standard protocols and guidelines are strictly followed. To assist in such protocols, IT provides a form of software applications that have features of artificial intelligence, machine learning ability and knowledge exploring capabilities. The reviewed literature identified that studies introduced methods of using software with the e-SSC OR system (Mainthia et al., 2012; Rothman et al., 2016; Shear et al., 2015). The three studies introduced an automated-electronic whiteboard as a tool that can display patient-related information including real time laboratory investigation results and radiology images. This information can have a positive impact on outcomes of the procedure, which could play an important role in enhancing patient safety in ORs. The ORAVEA model proposed in this paper has suggested an advanced feature than merely an electronic whiteboard. The ORAVEA can retrieve information about patient and procedure that are stored at different network (EHR and hospital database) through a secured network, communicate verbally with OR personnel and perform e-SSC as a hand-free method. This emerging model is anticipated to provide cost effectiveness to the system (time and cost) by reducing human interference in managing routines and technical work that inherent to every day OR- protocols. In the meantime, it could enhance patient safety, with an increase of SSC accuracy level by providing accurate identification of patients and specimens.

The primary type of technologies utilised to develop the proposed e-SSC models imbedded with an automated method was varied in the reviewed studies. In three studies, electronic whiteboard with LCD monitor mounted inside OR, which was also connected with the hospital based EHR was used, as illustrated in Table 3. Other studies (2 studies) used mobile applications that had capability of scanning barcodes to identify patient, can project patient and procedure related information on wall mounted large monitor. These systems are also connected with EHR system and hospital database. The proposed ORAVEA model will use intelligent software connected to the hospital EHR with audio-visual capabilities imbedded with verbal command interference that can assist to a hands-free method to complete the SSC.

One of the limitations in the proposed framework includes the challenge of developing intelligent software that has advanced features of learning from hospital database and provide decision support for surgical teams. Furthermore, creating an intelligent system which can follow verbal commands form the surgical team can be a challenging task, particularly with a focus on sending/receiving clear commands and clarifying vague and unclear commands when and where necessary. These are important aspects to be considered when designing a tool as ORAVEA. Unquestionably, this model requires further investigations and reviews in order to seek its practicality when working with OR personnel. Since the proposed framework is an emergent conceptualisation based on a literature review, it requires further examination and interventions to seek its reliability and feasibility in ORs to enhance surgical patient safety.

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