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ORIGINAL ARTICLE

Evaluation and Customization of WHO Safety Checklist for Patient Safety in Otorhinolaryngology

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Abstract The WHO has designed a safe surgery checklist to enhance communication and awareness of patient safety during surgery and to minimise complications. WHO recommends that the check-list be evaluated and customised by end users as a tool to promote safe surgery. The aim of present study was to evaluate the impact of WHO safety checklist on patient safety awareness in otorhinolaryngology and to customise it for the speciality. A prospective structured questionnaire based study was done in ENT operating room for duration of 1 month each for cases, before and after implementation of safe surgery checklist. The feedback from respondents (surgeons, nurses and anaesthetists) was used to arrive at a customised checklist for otolaryngology as per WHO guidelines. The checklist significantly improved team member's awareness of patient's identity (from 17 to 86%) and each other's identity and roles (from 46 to 94%) and improved team communication (from 73 to 92%) in operation theatre. There was a significant improvement in preoperative check of equipment and critical events were discussed more frequently. The checklist could be effectively customised to suit otolaryngology needs as per WHO guidelines. The modified checklist needs to be validated by otolaryngology associations. We conclude from our study that the WHO Surgical safety check-list has a favourable impact on patient safety awareness, team-work and communication of operating team and can be customised for otolaryngology setting.

Keywords Safe surgery · WHO checklist · Customised checklist · Otolaryngology

Introduction

An estimated 234 million operations are performed yearly [1]. Surgical complications are common and often preventable. Peri-operative mortality rate of 0.4–0.8% and major complications rate of 3–17% [2, 3] have been reported in inpatient surgery. These rates may be much higher in developing countries [4–6].

Most otolaryngology procedures are day-care requiring minimal access. They are susceptible to complications related to wrong procedure, wrong side and wrong patient (WSPE), as often side involved is evident only on imaging. Adverse events in any surgery usually result from simple human error which can thereby be prevented by reducing chance of such mistakes [7–11]. These errors can be reduced significantly by following a checklist which validates all steps of on-going procedure.

WHO has developed a surgical safety checklist to improve patient safety during surgery in 2009, as an add-on security tool. In an international multicentre study, the implementation of this checklist brought about significant reduction of complications and mortality. This reduction was observed, regardless of the healthcare system or economical setting [12]. This checklist has been effective in reducing complications in urgent surgery significantly.

The checklist consists of an oral confirmation by surgical teams of the completion of basic steps for ensuring safe delivery of anaesthesia, prophylaxis against infection,

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effective teamwork, and other essential practices in surgery. It is used at three critical junctures in care: before anaesthesia is administered, immediately before incision, and before patient is taken out of operating room.

A thorough literature search on this topic revealed only one study which explored application of the checklist in otorhinolaryngology. This was conducted in Helsinki as a part of multicentre study which showed promising results [13]. Surgical care in India, is characterised by high volumes and, sometimes an absence of standard safety checks which are the norm in other countries. This prompted us to undertake a study, in our ORL-HNS setup, to assess the benefits of a checklist.

A prospective, non-randomised and comparative survey was done before and after implementation of WHO surgical checklist. The design involved a comparison of pre-intervention and post-intervention data and the consecutive recruitment of two groups of patients. This design was chosen because it was not possible to randomly assign the use of the check-list to different operations concomitantly without significant cross-contamination in the same period. ENT operation theatre was identified as the study room. Patients, who were undergoing surgery, were consecutively enrolled for the study. The participants of the study were the operating personnel present in the operating theatre. The checklist was tested for its effectiveness in improving team-work and communication.

The checklist had a favourable impact on issues related to patient safety in the ORL-HNS setup.

The Finnish study expressed a need to modify the checklist to suit ORL-HNS setup [13]. The check list can be customised in order to meet the need of different surgical specialties and institutions [14–16]. In fact, WHO in its website encourages modification of the checklist to suit each speciality and setup to bring an ownership to it, which will ensure its successful implementation.

Aim of the current study was to evaluate the impact of WHO safety checklist on patient safety awareness in the Otorhinolaryngology setup and to customize the WHO checklist as per otorhinolaryngology requirements.

Materials and Methods

Institutional ethical clearance was obtained from local ethical committee.

Sample Size

Responses were collected for a total of 126 consecutive surgeries, 63 cases in 1 month before implementation of the checklist and 63 cases in the first month after implementation with a response rate of 100%. The sample size was limited to 126 consecutive surgeries as it was done for a limited time span in a single otolaryngology setup. Participants in this study were operating personnel, surgeons, anaesthesiologists and nurses present for each case. The respondents were a total of 15 surgeons, 14 anaesthetists and 8 nurses. Some (one-third) of the participants were experienced surgeons and anaesthetists while others were newer entrants in the field.

Intervention

The study model involved a two step data collection in the pre and post intervention periods. The intervention consisted of WHO checklist implementation program. After collecting baseline data using a questionnaire, the 19-item WHO safe-surgery checklist was implemented. The questionnaire was prepared by the primary investigator. Data was collected by observer who was not part of surgical team, to minimise assumptions or bias. The study team introduced the checklist to operating-room staff, using power point presentations, written materials and direct guidance. The primary investigator also participated in training by distributing a recorded video. The checklist was introduced to the operation theatre. Data collection resumed after orientation on the checklist use.

Time Period

This study was completed over a 2 month period. A time period of 1 week was allotted before data collection for pilot testing of the questionnaire. 50 days were used for data collection of which 25 days each were allotted for each phase of data collection before and after implementation of the check-list. 1 week was allotted for implementation of the checklist where operating personnel were oriented on WHO Surgical Safety check-list.

Procedure

An observer based questionnaire was addressed to operating room team for consecutive operations for a period of 25 days before and after implementation of WHO surgical safety checklist. Observer was a medical student conducting this research and not a member of operating personnel to eliminate bias.

The questionnaire had 11 questions regarding patient safety awareness concerns. These were selected after a period of 1 week of pilot testing. Responses were recorded as follows(1 = know, 0 = don't know; 0 = none, 1 = present; 1 = yes, 0 = no; 1 = done, 0 = not done; 1 = good, 0 = bad)which can be summarised as 1 for positive response and 0 for negative response which applies differently for each question in the questionnaire. Only if

all members of operating personnel gave a positive response the question was graded a 1 or else 0. Some fields were recorded based on responses to directly asked questions like "What is the name of patient?" or What is the name of scrub nurse?", while other fields like team-communication, confirming adequate starvation, etc. were all observed and recorded accordingly.

After collecting responses in phase-1, a training and orientation of operating personnel to WHO Surgical safety check-list was undertaken before implementation of the check-list, as per WHO guidelines.

A presentation was made in operating room and doubts and queries regarding the check-list implementation were addressed. WHO check-list coordinator was operating theatre nurse. Oral confirmations of steps were done.

Statistical Analysis

Data was presented in numerical form as proportion of 'yes' answers (%), unless otherwise indicated. Comparisons between before and after checklist groups were calculated by Chi square test. P values of < 0.05 (95% confidence interval)were considered significant.

Statistical analysis was carried out with GRAPHPAD INSTAT software version 3.1.

Results

A total of 126 operations were recorded on operation database, 63 before and 63 after checklist implementation. Operations covered all subgroups of ORL-HNS and are depicted in Fig. 1.

The check-list improved the score on various patient safety parameters after implementation. The pre and post implementation data expressed as proportion (%) are depicted in Fig. 2.

Identity of Patient

The checklist improved verification of patient's identity by all operating room-team members. The two-sided P value was < 0.0001, considered extremely significant.

Otolaryngologists' and anaesthesiologists' awareness of procedure and side of operation, before and after check-list implementation, was equally good and marginal improvement seen with the check-list was not statistically significant.

Operating Personnel Awareness of Each Other's Role and Identity

The checklist significantly improved otolaryngologists' and anaesthesiologists' awareness of other operating room-team members' names and roles. The two-sided P value was < 0.0001, which is considered extremely significant.

Imaging Study Displayed

The checklist significantly improved the practice of displaying relevant radiological investigation during surgery. The two-sided P value was < 0.0001, considered extremely significant.

Equipment Issues

Pre check of equipment increased significantly after check list implementation ($P < 0.0001$). Also any problems in equipment/instruments were better addressed and resolved, in post-surgery check, after check list implementation.

Communication

Checklist significantly improved communication among all team members. The two-sided P value was 0.0087, considered very significant. In addition, they discussed possible critical events in the operation more frequently. Postoperative instructions and prescriptions were better recorded with the checklist. These results are depicted in Table 1.

There was no significant difference in anaesthesiologists' awareness of patient's medical history, medication and allergies or their assessment of difficult airway. Likewise, anaesthesiologists were found to exercise due care in patient specific concerns, like prevention of aspiration and protection of eyes even without the checklist. Nursing team also kept correct count of gauze and instruments both before and after checklist implementation. The patient safety parameters that didn't display significant change with the introduction of the check-list are depicted in Table 2.

Taking into account views and feedback of our operating team about the checklist after using it first hand, we modified WHO checklist for needs of our ORL-HNS setup. All collected data and suggestions in the free text comments were analyzed and modifications were made so as to customize the checklist for Otorhinolaryngology. The modified checklist is depicted in Table 3 and can be used post-validation.

Discussion

The checklist improved awareness of patient's identity, team's communication and awareness of each other's role. There was a significant improvement in preoperative check

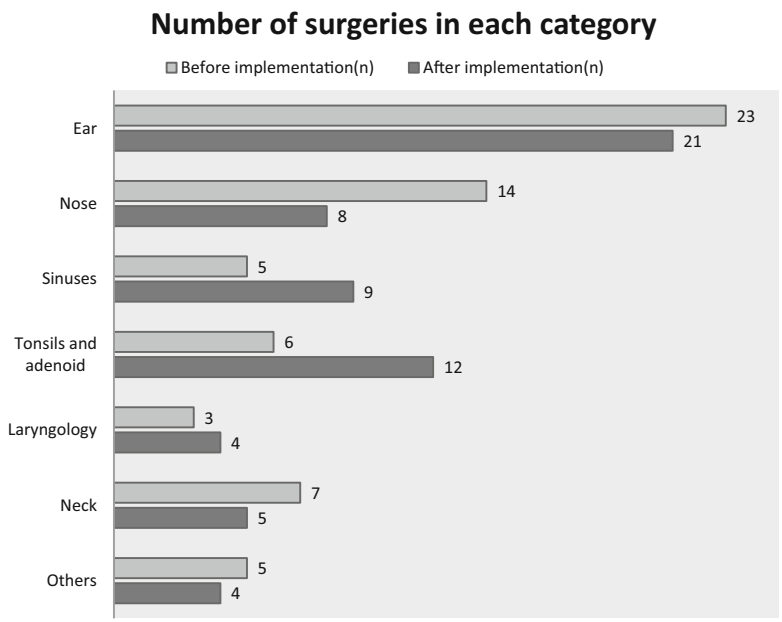

Fig. 1 Number of surgeries in each sub-speciality performed during the study period before and after implementation of the checklist. n = number of cases performed in the time period in that subspecialty

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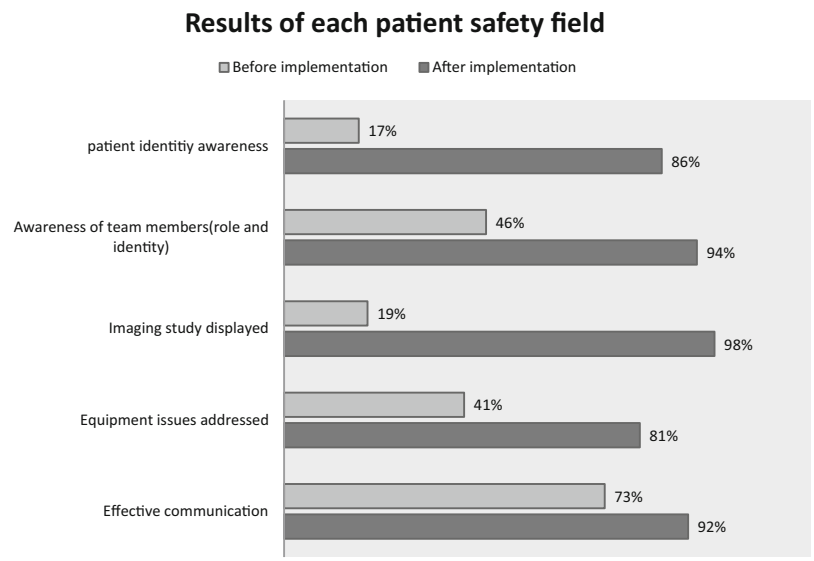

Fig. 2 Results of each parameter that was assessed in the two periods of data collection compared. The values are expressed as proportion (%) of positive responses from all team members: surgeon anaesthetists and nurses for questions related to patient identity and awareness identity and role of other team members and as proportion (%) of positive observations recorded by the investigator for the other parameters

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of equipment. Critical events were discussed more frequently between anaesthesiologists and otolaryngologists.

As anaesthesiologists were already using a check-list of their own, there was no significant difference in anaesthesiologists' awareness of patient's history, medication, allergies or difficult airway assessment.

The debriefing in 'sign out' phase of the checklist improved recording of patient's postoperative prescriptions and instructions. It also improved feedback about dysfunctional instruments to CSSD ensuring that such instruments were changed for next surgery.

All these factors are crucial in not only avoiding adverse events, but also in dealing with them if they arise. Use of checklist improves information transfer process, and reduces communication failures with better clinical outcome [17]. Benefits of the checklist in improved team

Table 1 Results of the identity of the patient on responses collected from all three team members

Sr no.	Patient safety parameters	Before implementation n (%)[a]	After implementation n (%)	*P* values	Significance[b]
1.	Patient identity awareness	11 (17)	54 (86)	< 0.0001	S
2.	Awareness of team members (identity and roles of team members)	29 (46)	59 (94)	< 0.0001	S
3.	Imaging study displayed	12 (19)	62 (98)	< 0.0001	S
4.	Equipment issues addressed	26 (41)	51 (81)	< 0.0001	S
5.	Effective communication	46 (73)	58 (92)	0.0087	S

[a]Number (n) and proportion (%) of positive responses from all team members: surgeon anaesthetists and nurses for questions related to patient identity and awareness identity and role of other team members and as proportion (%) of positive observations recorded by the investigator for the other parameters

[b]Statistical significance for difference, calculated by the Chi square test. The values were considered significant at 95% confidence interval $P < 0.05$) denoted by S

Table 2 Results of parameters that weren't statistically significant

Sr no.	Patient safety parameters	Before implementation n[a]	After implementation n
1.	Awareness of the procedure and side to be operated (1 = know, 0 = don't know)	62	63
2.	Confirmed adequate starvation. (1 = done, 0 = not done)	62	63
3.	Difficult airway assessed and uneventful intubation (yes = 1, no = 0)	62	63
4.	Eyes protected (yes = 1, no = 0)	60	63
5.	Endotracheal cuff inflated and throat packed (yes = 1, no = 0)	61	63
6.	Gauze and instrument counted and correct (yes = 1, no = 0)	62	63

[a]Number (n) of positive responses from all team members: surgeon anaesthetists and nurses

communication have also been seen in paediatric, trauma and orthopaedic series [14, 18].

Throughout the study there was excellent awareness of side of operation and this may be due to Hawthorne effect, an improvement in performance due to subjects' knowledge of being observed [19]. Contribution of Hawthorne effect is difficult to disentangle from an observer based study model.

In our setting the check-list implementation was neither lengthy nor costly. The checklist has also been found to be a cost-effective tool as it significantly reduces serious complications in surgery neutralising cost of its implementation [20].

The WHO safe surgery checklist template is not intended to be comprehensive. The WHO checklist needs to be modified to the end user as per the 'One size doesn't fit all' WHO philosophy of customizing the checklist to meet specialty needs. The checklist modification also creates buy-in from staff and ownership of the project. Additionally, the process of modifying the checklist is considered to be a key step in implementation process. Modification process brings people together from all relevant disciplines and fosters teamwork that will enhance use of the checklist.

Taking into account views and feedback of our operating team about the checklist after using it first hand, we modified WHO checklist for the needs of ORL-HNS setup. In its manual for implementation of safe surgery checklist, WHO encourages modification of the checklist to account for differences among facilities with respect to their processes, culture of their operating rooms and degree of familiarity each team member has with each other. However, removing safety steps because they cannot be accomplished in the existing environment or circumstances is strongly discouraged. Safety steps should inspire effective change that will bring an operating team to comply with each and every element of the checklist. As the checklist is designed primarily to promote team-work and communication, team-work/communication items should not be removed while modifying the checklist. These WHO guidelines for modifying the checklist were followed to arrive at a customized checklist for ORL-HNS. The essential spirit of WHO checklist was retained in the modified checklist.

As per the process laid down by WHO, entire operating team collaborated to modify the checklist by following WHO checklist modification questionnaire and testing the

Table 3 Customised WHO surgical safety checklist for ORL-HNS set-up

Before induction of anaesthesia Sign in	Before procedure Time out	Before patient leaves operating room Sign out
Patient has confirmed	**Confirm all team members have introduced themselves by name and role**	**Confirm**
Identity	**Surgeon, anaesthesia professional and nurse verbally confirm**	Hemostasis
Procedure	Patient	Aspiration risk
Site	Site	Missing teeth/dentures
Adequate starvation	Procedure	**Nurse verbally confirms with the team:**
Consent	**Anticipated critical events**	**The name of the procedure recorded**
Site marked/not applicable	**Surgeon reviews:**	**That instrument, sponge and needle counts are correct** (or not applicable)
Anaesthesia safety check completed?	What are the critical or unexpected steps, operative duration, anticipated blood loss?	**How the specimen is labelled** (including patient name)
Pulse oximeter on patient and functioning	**Anaesthesia team reviews:** are there any patient-specific concerns?eye protection? Patient positioned correctly?	**Whether there are any equipment problems to be addressed**
Does patient have a:	**Nursing team reviews:** has sterility (including indicator results) been confirmed? are there equipment issues or any concerns? Special equipment/devices/implants available	**Surgeon, anaesthesia professional and nurse review the key concerns for recovery and management of this patient**
Known allergy?	**Has antibiotic prophylaxis been given within the last 60 minutes?**	
No	Yes	
Yes	Not applicable	
Difficult airway/ aspiration risk?	**Is essential imaging/audiogram displayed?**	
No	Yes	
Yes, and equipment/ assisistance available	Not applicable	
Risk of > 500ml blood loss		
(7 ml/kg in children)?		
No		
Yes, and adequate intravenous access and fluids planned		
Confirm		
No respiratory tract infection		
No anticoagulants given		
No lignocaine sensitivity		
Adrenaline concentration checked		
Dental check completed		

modified checklist on table-top simulation before using it in OR. In our series, in pre-intervention phase, there was an isolated incident of ingestion of loose tooth during tonsillectomy, which was subsequently retrieved by rigid endoscopy. As WHO checklist doesn't address this issue, we recommend inclusion of dental assessment both in sign-in and sign-out phases of all otolaryngology procedures under general anesthesia.

The checklist did not make any significant difference in issues related to patient safety like endotracheal cuff inflation and throat packing in cases under general anesthesia or protection of eyes in endoscopic sinus surgery. Nevertheless, as they are very important from otolaryngology point of view, they were also included in the modified checklist. We also included an additional column 'before extubation', for general anesthesia as this is a critical time in surgery from ORL-HNS point of view, as far as patient safety is concerned.

Thus our study supports the Helsinki study findings that WHO surgical checklist fits well into Otolaryngology. We also confirm that the checklist can be customized for Otolaryngology needs which can be used post-validation.

Conclusion

Our study further confirms that WHO Safe surgery check-list has a favourable impact on patient safety awareness, exchange of medical information and communication among operating personnel in ORL-HNS setup.

The customised check-list developed as a result of our exercise can be adopted as an ORL-HNS specific check-list once validated and ratified by otolaryngology associations.

Suggestions and Future Directions

Specific check-list for each sub-specialty in ORL-HNS can also be developed and put to use. To further ease implementation of the check-list we recommend an electronic format which is already available for the WHO safe surgery checklist. It will save paper and time.

Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. For this type of study formal consent is not required. This article does not contain any studies with animals performed by any of the authors.

Informed Consent Informed consent was obtained from all individual participants included in the study. Additional informed consent was obtained from all individual participants for whom identifying information is included in this article.

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