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Modified surgical safety checklist (mSSC)- a must to avoid disaster in neurosurgical procedures!

The World Health Organization (WHO) introduced surgical safety checklist (SSC) as a part of Second Global Patient Safety Challenge: Safe Surgery Saves Lives to address the safety of surgical care. Although found to be beneficial for general surgical patient, we introduced certain modification to suit neurosurgical patients and hereby present our experience with the modified checklist.

We introduced the modified SSC in July 2012 for neurosurgical purpose after we identified minor but common errors in carefully audited 100 patients in our operating theatre. Modification included checklists in pre procedure room, during sign in enquiring for pulse oximeter (for local anesthetic procedures) and lastly during sign out an elaborated list of items to guarantee safe transfer of the patients. Nurses and doctors were trained and SSC was methodically administered. Outcome as number of complications was evaluated and graded according to no harm, low harm, moderated harm, severe harm and death.

During last 5 years (July 2012 to June 2017), 1310 patients undergoing surgical procedures in neurosurgical theatre at KMCTH were studied. Modified SSC was used in both routine (50.5%) and emergency cases (49.5%), of which compliance was 80% and 55% respectively. Poor compliance was due to ignorance of its use, emergency nature of procedure, change of staff. Completeness of mSSC was found in 70% cases with most left out part of mSSC was during signing out (i.e during transfer of patients). Use of mSSC identified many common but minor negligent acts on part of doctors, nurses and OR technicians which could be rectified in time and hence avoided any major mishaps. Age of the patients ranged from newborn to 98 year old. There were no major mishaps including death on table events. Despite confirming during mSSC checklist, machine failure occurred in 10 cases (0.8%) which were of low harm category. The total time taken for performing and filling the checklist took roughly 7 minutes.

Of over 250 million surgical procedures performed annually worldwide, major complications have been reported in 3%-17% of which many were avoidable.¹ Surgical and medical errors are being reported result from failures in communication and handoffs as well as lack of standardization in clinical protocols and safety practices.

Recently WHO have published a surgical safety checklist (SSC). SSC has not only been found to improve closed loop communication but also flatten vertical authority gradients, and decrease procedural errors.²

SSC is being used increasingly around the world, but in developing countries like ours it is limited to verbal confirmation without any documentation. Hospitals who have made this mandatory have found its use and recommend them for patient safety.^{1,2,3,4,5}

Loco regional variation in conceptual approach, set up, instrumentation and operative procedure create lot of confusion in using a universal SSC.⁶ Besides lack of technical knowledge and use of not-for-purpose instruments during surgery demand good communication between team members. Hence we designed a modified version of WHO SSC which suits our demands and is easy to administer.

Materials And Methods

At Kathmandu Medical College Teaching Hospital (KMCTH), we designed a modified version of WHO Surgical Safety Checklist (mSSC) considering the need of the team members and frequently encountered problems(See table 1). We audited 100 patients comprehensively to identify common mistakes during transfer and surgery. Preventive measures were identified and incorporated into mSSC (See table 2).

We conducted this prospective study enrolling all patients who underwent surgical procedures in neurosurgical theatre at KMCTH since July 2012 till June 2017.

We modified WHO surgical safety checklist to include post operative transfer out to recovery room and used it in both routine and emergency procedures. This has helped us to avoid major mishaps during and after the neurosurgical procedures. We recommend stringent use of SSC in all neurosurgical centre and advise suitable local modifications according to prevailing conditions for special procedures or locations.

Keywords: Checklist; Neurosurgery; Patient safety; Quality improvement

We administered mSSC in 4 places during patient transfer to operating room where index events of likely errors is very high (See figure 1): before shifting to pre-op room (Ward), before shifting to OR (in Pre-op room), At the time of incision (Sign-out in OR) and finally shifting the patient to ward (in Recovery room). Either a floor nurse or surgical team member were required to fill the checkboxes and sign it with his name and time. All the checklists were maintained by OR staff and audited by OR in-charge.

Critical events were recorded and reviewed for improvement. Cohort analysis was done for compliance and completeness of the mSSC. Outcome as number of complications was evaluated and graded according to no harm, low harm, moderated harm, severe harm and death.

Results

Over the 5 year period of its existence over 1500 patients got operated in neurosurgical theatre at KMCTH. During the initial set up, WHO standard surgical checklist was introduced. However day to day management of patients revealed few problems which could have invited major disaster and hence careful audit of 100 patients was conducted to identify these missed points. Subsequently, since July 2012 we introduced mSSC incorporating these modifications. A total of 1310 patients underwent surgical procedures in neurosurgical theatre at KMCTH during this period, of which 49.5% were done as emergency procedures. Age of the patients ranged from newborn to 98 year old.

Of the routine surgeries, 80% had mSSC filled as compared to 55% of emergency procedures. Poor compliance was due to ignorance of its use, emergency nature of procedure and change of staff. Overall completeness of mSSC was found in 70% cases with most left out part of mSSC was during signing out (i.e during transfer of patients out of OR).

Modified surgical safety checklist for neurosurgical procedures

Use of mSSC identified many common but minor negligent acts on part of doctors, nurses and OR technicians which could be rectified in time and hence avoided any major mishap. Common errors like failure to give pre operative antibiotics, putting up pre operative scans, equipment check up and team verification were seen.

There were no major mishaps including death on table events. Despite confirming during mSSC checklist, machine failure occurred in 10 cases (0.8%) which were of low harm category.

The sheet were filled by floor nurse or doctor, and none had reported any difficulty in filling the form. The total time taken for performing and filling the checklist took roughly 7 minutes.

Discussions

Adverse event (AE) is a collective term including complications, failures, mistakes, errors and violations. AEs are estimated to occur in 9.2% of surgeries with 0.1% fatalities worldwide.⁷

6 categories of contributory factors in neurosurgical adverse events have been identified in past. These are issues affecting surgical technique, perioperative medical management, use of and adherence to protocols, preoperative optimization, technology, and communication. Wong et al in their study have identified 5 priority recommendations for improving outcomes for neurosurgical patients at a population level: 1) development and implementation of a national registry for outcome data and monitoring; 2) full integration of the WHO Surgical Safety Checklist into the operating room workflow, which improves fundamental aspects of surgical care such as adherence to antibiotic protocols and communication within surgical teams; and 3) activity by neurosurgical societies to drive increased standardization for the safety of specialized equipment used by neurosurgeons; 4) more widespread regionalization and/or sub-specialization; and 5) establishment of data-driven guidelines and protocols. The fraction of adverse events that might be avoided if proposed strategies to improve practice and decrease variability are fully adopted remains to be determined.⁸

We all wish to have a zero error system in our workplace.⁹ Various checklist not limited to WHO checklist, the Surgical Patient Safety System (SURPASS) checklist, a wrong-site surgery checklist or an anesthesia equipment checklist are in vogue.¹⁰ Using such a checklist is a proven method of avoiding surgical complication, a major cause of death and disability worldwide.^{6,10,11,12,13}

However in neurosurgical OR such SSC are still lacking and almost none in developing countries like ours.¹⁴

Use Modified surgical safety checklist
systematically in both routine as well as emergency procedures
in four phases of point wise verification and record
with clear verbal confirmation and affirmation
to be Signed by the enumerator
start it as a study protocol and periodically review
routinely conduct table top discussion with team to discuss results and difficulties

Table 1: Key points for use of Modified surgical safety checklist (mSSC)

to be administered in all neurosurgical procedures including emergency surgeries
waiting hall assessments included
to check pulse oximetry
to check for availability of equipment assistance
during SIGN IN: check for adequate intravenous access and fluids
during SIGN OUT (itemized): check for returned Blood products, Imaging studies, Patient chart, Artificial teeth, Recovery, Blood pressure, Pulse, Doctor's counseling, Activity sheet completed and Transfer notes

Table 2: Modifications introduced in WHO surgical checklist

Written specifications with regard to procedures performed, equipment used, and training of the involved personnel are widely used in the industry and aviation to guarantee constant quality. Similar systems are progressively being introduced to medicine.^{5,7,9} In an attempt to reduce these in June 2008, the WHO has proposed a series of measures applicable to medical and surgical patients. Within these last ones is the surgical safety checklist (SSC), a brief questionnaire that does not increase healthcare costs, is accessible to all surgical centre and can be adapted to each specific environment.^{1,8,11,15,16}

It is a human nature to be emotional and consider past experiences in future actions and planning. If a problem has not occurred recently or is rare, we tend to overlook the factors for the same. Besides error usually occur if process is left solely as a responsibility of one individual and his memory. Hence a flow checklist administered by the team at every one of these high risk points, is must to avoid to overlook such occurrences.^{9,17,18,19} This is more pertinent during emergency procedures where due to level of stress and fatigue, certain seemingly small details are easily overlooked to doom the outcome. Hence it is vital to follow a systematic review of details in such conditions.²⁰

AT WAITING HALL	BEFORE INDUCTION OF ANESTHESIA	BEFORE SKIN INCISION	BEFORE LEAVING OPERATING ROOM																						
PRE PROCEDURE	SIGN IN	TIME OUT	SIGN OUT																						
Patient's representative activity confirms with registered nurse <ul style="list-style-type: none"> Identify <ul style="list-style-type: none"> Yes Procedure and procedure site <ul style="list-style-type: none"> Yes Consent <ul style="list-style-type: none"> Yes Site marked by person performing the procedure <ul style="list-style-type: none"> Yes n/a Registered nurse confirms presence of <ul style="list-style-type: none"> History and physical exam <ul style="list-style-type: none"> Yes Pre-anesthesia assessment <ul style="list-style-type: none"> Yes Diagnostic and radiologic test results <ul style="list-style-type: none"> Yes n/a Blood products <ul style="list-style-type: none"> Yes Units n/a Any special equipment, devices, implants <ul style="list-style-type: none"> Yes n/a Recorded by: Time:	Patient has confirmed <ul style="list-style-type: none"> Identify <ul style="list-style-type: none"> Site Procedure Consent Site marked/not applicable? <ul style="list-style-type: none"> Yes Anesthesia safety check completed? <ul style="list-style-type: none"> Yes Pulse oximeter functioning? <ul style="list-style-type: none"> Yes Does patient have a known allergy? <ul style="list-style-type: none"> No Yes Difficult airway/airway risk? <ul style="list-style-type: none"> Yes Equipment/assistance Available <ul style="list-style-type: none"> Yes Risk of $\geq 500\text{ml}$ blood loss (7ml/kg in Children)? <ul style="list-style-type: none"> No Yes Adequate intravenous access and fluids planned?	Confirm all team members have introduced themselves by name and role <ul style="list-style-type: none"> Surgeon, anesthesia, professional and nurse verbally confirm <ul style="list-style-type: none"> Patient Site Procedure Anticipated critical events surgeon reviews: <ul style="list-style-type: none"> What are the critical or unexpected steps? Operative duration, anticipated blood loss? Anesthesia team reviews: <ul style="list-style-type: none"> Are there any patient-specific concerns? Nursing team reviews: <ul style="list-style-type: none"> Has sterility (including indicator results) been confirmed? Are there equipment losses or any concerns? Has antibiotic prophylaxis been given within the last 60 Minutes? <ul style="list-style-type: none"> Yes Not applicable Is essential imaging displayed? <ul style="list-style-type: none"> Yes Not applicable Recorded by: Time:	Nurse verbally confirms with the Team: <ul style="list-style-type: none"> The name of the procedure recorded That instrument, sponge and needle counts are correct (if not applicable) How the specimen is labeled (including patient name) Whether there are any equipment problems to be addressed Surgeon, anesthesiologist and nurse review the key concerns for recovery and management of this patient <table border="1"> <thead> <tr> <th>Checklist</th> <th>Yes/No</th> </tr> </thead> <tbody> <tr> <td>Blood X match (Returned)</td> <td></td> </tr> <tr> <td>Imaging studies</td> <td></td> </tr> <tr> <td>Patient chart</td> <td></td> </tr> <tr> <td>Artificial teeth</td> <td></td> </tr> <tr> <td>Recovery</td> <td></td> </tr> <tr> <td>Blood pressure</td> <td></td> </tr> <tr> <td>Pulse</td> <td></td> </tr> <tr> <td>Doctor's counselling</td> <td></td> </tr> <tr> <td>Activity sheet completed</td> <td></td> </tr> <tr> <td>Transfer</td> <td></td> </tr> </tbody> </table> Handed Over by (OT nurse): Received by (ICU/Ward nurse): Recorded by: Time:	Checklist	Yes/No	Blood X match (Returned)		Imaging studies		Patient chart		Artificial teeth		Recovery		Blood pressure		Pulse		Doctor's counselling		Activity sheet completed		Transfer	
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Figure 1: Modified WHO surgical checklist (modification has been highlighted)

We did not wish the mSSC protocol to be rigid and is planned to be reviewed every 5 years. We find its use not only in routine planned surgeries but also should be followed in emergency scenarios or unplanned surgeries. Frequent complaint of wastage of time in administrating mSSC had been shown to be vague as in our study it takes on an average 7 minutes.

Due to pressure of work occasionally it was seen on part of staff to try skip the protocol, however on persistent motivation and perseverance mSSC can become mandatory.

Wrong level exposure is documented in 0.32% to 15% of cases.²¹ In a web based survey of 1045 American spine surgeons, almost 50% of 569 responders reported to have performed wrong level lumbar spine surgery at least once and over 10% a wrong side lumbar spine surgery at least once. 40% surgeons believe that the site marking or time out protocol of the joint commission on the accreditation of Healthcare Organization has led to reduction in these errors.²²

Da Silva-Freitas R et al have shown that routine use of SSC could correct 88.23% of mistakes and prevented appearance of peri-operative events in 1 out of 13 procedures.¹¹ Bliss LA et al in a comparison of 30-day morbidity demonstrated a statistically significant ($p = 0.000$) reduction in overall adverse event rates from 23.60% for historical control cases and 15.90% in cases with only team training, to 8.20% in cases with checklist use.²³

In a survey done at UCLA, 98.9% of surgical team members felt that time out helped ensure all team members to voice safety concerns. The checklist process

favorably impacts team's safety attitude and perception as well overall safety climate in neurosurgical OR.²⁴ This and many such studies have amply mitigated the concerns of the surgeons or OR manager regarding compliance and increase in workload by adopting such protocols.^{24,25}

Need of improvisation or specificity

As new gadgets are being frequently introduced in neurosurgery like endoscope and MRI inside Operative room (OR), improvised safety checklist to ensure patient safety in OR is mandatory.^{6,26,27}

Procedure specific or technology tailored SSC have been designed incorporating specific steps of surgery to ensure safety of patient.^{6,24,25}

Successful implementation requires peri-operative stakeholders to understand the nature of errors, recognize the complex dynamic between systems and individuals, and create a just culture that encourages a shared vision of patient safety.²⁸

Limitations

Compliance!

In neurosurgical set up, compliance with various stages of SSC was found to be average 92%, with worst compliance seen during Sign-in (82%). Besides emergent nature of a surgery was statistically associated with reduction in compliance with SSC.¹⁴ However such high adherence with the protocol in not seen uniformly with other centers.²⁹

The difference in compliance vastly depends upon the motivation and strictness with which the protocol is

administered and monitored. Hence compliance in centers with checklist under a research protocol may differ from centers where SSC is introduced independently.³⁰

Not all causes of medical errors are covered!

Even though mSSC takes care of majority of causative factors for wrong level like poor communication, but technical issues (like failure to visualize known reference points, recognize unconventional spinal anatomy, relocalize after exposure and adequately visualize the level because of large body habitus) need to be addressed by the surgeon to re-ascertain on case to case basis.²¹ Besides using fluoroscopy or real time navigation methods, use of Intra-operative neurophysiological monitoring (IONM) improves the safety of spine surgery.³¹ The surgical skills can be improved by individual surgeons participation in frequent training programs, audits and review of data as well as by accrediting authorities monitoring the outcomes.³²

However one must not forget that all complications during surgical interventional are not avoidable and such need to be discussed with the patients and their families prior to surgery.

2 of the other three surgical patient safety events beside wrong site surgery, like retained surgical items (RSI) and surgical fires even though rare are not covered with this mSSC and needs separate protocol.³³

Besides the above limitation, training and motivation which can change attitudes adds further to patient safety but are difficult to measure.⁷

Our study shows the feasibility of administering mSSC in neurosurgical procedures not limited to routine surgeries. With this study we have stressed on modification in WHO SSC like the need of waiting hall assessments (PRE PROCEDURE), need of checking pulse oximetry, availability of equipment assistance and adequate intravenous access and fluids during SIGN IN and check for returned Blood products, Imaging studies, Patient chart, Artificial teeth, Recovery, Blood pressure, Pulse, Doctor's counseling, Activity sheet completed and Transfer notes during SIGN OUT.

Conclusion:

We have developed and tested a modified version of WHO surgical Safety checklist (mSSC) which is quick and provides for patients' safety and improves communication in our loco-regional scenario without increasing health care costs or operative time. However use of such protocol needs commitment of the team and hence requires stringent monitoring and attitude build up.

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