

The WHO surgical safety checklist-part two: feasibility of the application in an operating theater in Basrah

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ABSTRACT

Background: This is a prospective two-stage interventional study carried out at one of the main operating theaters in Basrah General Hospital. The study lasted for 6 months (from May to October 2013).

Objectives: The study was designed to assess the adherence of staff in the operating theater to items of services covered by a World Health Organization Surgical Safety Checklist and to measure the effect of active reminding of them about such list. The study is in line with the vision of the Ministry of Health to provide high quality care.

Methods: A structured questionnaire form was prepared for the purpose of the study. It is an adapted list of the first edition of the World Health Organization Surgical Safety Checklist. The study consisted of two phases: Phase One, which involved the observation of procedures, instructions and labeling of patients before, during and after the surgical operation. This phase was completed without informing the involved staff about any specific requirement regarding adherence to safety measures and checklist. A total of 269 surgical operations (patients) were covered in this phase. In phase Two, full group instructions and explanation of the safety check list was made to operative theater staff. The same manner of observation on each patient was done for the rest of this phase and covered 109 surgical operations (patients).

Results: A substantial improvement in the adherence of staff was observed following the active intervention by the researchers to remind all parties of the importance of the World Health Organization Surgical Safety Checklist.

Conclusions: it is feasible to use Surgical Safety Checklist and its use must be continuously monitored to make the best of its application.

Key words: WHO, Safety checklist, Basrah, Performance

قائمة السلامة الجراحية لمنظمة الصحة العالمية- الجزء الثاني: إمكانية التطبيق في صالة العمليات في البصرة

الخلفية: الدراسة الحالية أجريت في إحدى صالات العمليات في مستشفى البصرة العام لمدة ستة أشهر امتدت من مايس إلى تشرين أول ٢٠١٣. *الأهداف:* قياس المدى الذي يلتزم به الكادر بمحتويات قائمة السلامة الجراحية لمنظمة الصحة الدولية ولقياس تأثير التذكير النشط بتلك القائمة على تحسن الأداء في صالات العمليات.

الطرائق: تم إعداد استبيان خاص مبني على قائمة السلامة الجراحية المعدة من قبل منظمة الصحة الدولية ومرت الدراسة بمرحلتين: في المرحلة الأولى

تم جمع البيانات بمتابعة ٢٦٩ عملية جراحية دون تنبيه الكوادر العاملة في صالة العمليات بأي متطلبات خاصة ذات صلة بالقائمة. في المرحلة

الثانية تم تبليغ الكوادر تفصيلاً بمتطلبات الالتزام بتلك القائمة وأيضاً متابعة ١٠٩ مرضى بنفس أسلوب العمل في المرحلة الأولى.

النتائج: أظهرت النتائج تحسناً كبيراً في تحسن الأداء في المرحلة الثانية مقارنة مع المرحلة الأولى في جميع المفردات وكان التحسن في بعض

المفردات كبيراً جداً.

الاستنتاج: من الممكن والمفيد جداً الالتزام بتطبيق قائمة السلامة الجراحية في صالات العمليات الجراحية ولا بد من المراقبة المستمرة للالتزام بها.

كلمات دالة: منظمة الصحة الدولية، قائمة السلامة الجراحية، البصرة، الأداء.

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INTRODUCTION

Surgical care is an integral part of health care throughout the world, with millions of surgical procedures being carried out annually.^[1] Surgery is performed in every community regardless of location, economic development or social setting to save life or to ameliorate pain. Surgical procedures however, are associated with a lot of pitfalls and errors and a peri-operative rate of death from inpatient surgery of 0.4 to 0.8% and a rate of major complications of 3 to 17% were reported.^[1] Thus, complications associated with surgery represent a substantial burden of disease worthy of attention from the public health community worldwide. Teamwork with effective communication and adherence to predefined rules are likely to result in reduced rates of adverse events.^[1] Medical errors occur mainly due to defective communication between members of the healthcare team.^[2-7] In the surgical domain, error rates are particularly high.^[8-9] Tension and non-adherence to regulations is associated with errors that are avoidable and approximately one third of the failures had observable negative outcomes including delay, inefficiency, and team tension.^[10] Preliminary assessment of surgical practice within the immediate boundaries of operating theaters is a pre-requisite to the implementation and evaluation of complex interventions, such as the team checklist proposed by the World Health Organization (WHO), which seeks to change team members behavior.^[2] Researchers have advocated a phased approach to such complex interventions to ensure their acceptability and feasibility before trial based testing.^[3] In 2009, the World Health Organization issued a worldwide recommendation for the use of **its Surgical Safety Checklist** in all operative procedures.^[5] The surgical safety checklist is simple, practicable, feasible and inexpensive tool to use in assessing patient care from admission for surgical operation to the recovery period. Given

the trend adopted by the Iraqi Ministry of Health to achieve high quality care in various components of the health care system in Iraq,^[11] it was thought useful to explore the quality of care in operating theaters in Basrah hospitals and to explore the effect of verbal and written instructions on the use of the WHO Surgical Safety Checklist. In previous paper we reported an overall account of surgical safety practice in Basrah.^[12]

In this paper we report the results related to the effectiveness of applying the WHO surgical Safety Checklist on quality of care in operating theaters.

PATIENTS AND METHODS

This was a prospective observational study carried out within one of the operating theaters of Basrah General Hospital. This hospital is one of the teaching hospitals in Basrah. It is a multispecialty secondary medical care institution, located almost in the centre of Basrah city and serving a large catchment population. The Data collection phase of the study extended for a period of 6 months from May to October 2013. Patients who were admitted to the operating theatre for elective surgery on specific days of the week were recruited in the study and completely followed up until two hours post-operatively. The study involved careful observation on patients subjected to surgical operations. The work plan consisted of full observation of patients enrolled and recording data on each using a special form modified from the original WHO safety Checklist. The observation started at the moment the patient was brought to the waiting room until two hours post-operatively. One of the investigators stayed with the staff of the operating theater for a full morning in selected days of the week. Patients were operated upon by a number of surgeons and not restricted to one particular surgeon or particular surgical

condition. However, the study did not involve emergency cases but was meant to be done on normal elective surgical operations. The study consisted of two phases:

Phase One: Observation of staff behavior regarding procedures, instructions and labeling of patients before, during and after the surgical operation. This phase was completed without informing the staff involved about any specific requirement regarding adherence to safety measures and checklist. A total of 269 surgical operations were covered in this phase of the study.

Phase Two: At the end of phase one, full group instructions and explanation of the safety check list was made to operative theater staff both verbally and in written documents. Then, the same manner of observation on each patient was done for the rest of this phase. A total of 109 surgical operations were covered in this phase. For each surgical operation(patient), the documentation of full name, age, sex, next of kin, mobile phone number, patient tag, informed consent, history of certain chronic diseases, last meal, drugs of surgical importance, preoperative investigations, operative site marking, allergy to anesthetic drugs, history of shortness of breath, possibility of significant blood loss, surgical team availability, need for prophylactic

antibiotics, operation explanation received by candidate to surgery, pack, cotton calculation and instrument checking after finishing the operation, operative notes documentation, post operative treatments and instructions, biopsy taking and marking, devices checking, patient recovery and immediate post operative complications documentations were all checked in both phases of the study. Data were fed on computer software (SPSS: Statistical Package for Social Science version 15). After thorough checking, data were analyzed in the form of tables. Chi-squared test/Fisher Exact test were used whenever indicated to test the association and differences in the magnitude of deficient items. A probability value (P) of < 0.05 was considered as significant in this study.

RESULTS

Documentation of selected patient attributes

Table-1, shows that almost all patients have their age and gender documented in both phases of the study. The next of kin was documented in 71.0% in phase one and in 85.3% in phase two. Mobile phone recoding increased from 66.9% to 83.5% and patient tag from only 11.2% to 70.6%. Informed consent was well written and signed in both phases (95.5 and 97.2% respectively).

Table 1. Documentation of selected patient attributes

Variable	Phase one		Phase two	
	No.	%	No.	%
Age^a				
Documented	269	100.0	108	99.1
Not documented	0	0.0	1	0.9
Gender^a				
Documented	267	99.3	109	100.0
Not documented	2	0.7	0	0.0
Next of kin^b				
Documented	191	71.0	93	85.3
Not documented	78	29.0	16	14.7
Mobile phone number^b				
Documented	180	66.9	91	83.5
Not documented	89	33.1	18	16.5
Patient tag^b				
Available	30	11.2	77	70.6
Not available	239	88.8	32	29.4
Informed consent^a				
Well written	257	95.5	106	97.2
Written but not signed, or not written	12	4.5	3	2.8

^a The difference in documentation between the two phases is insignificant (P > 0.05)

^b The difference in documentation between the two phases is significant (P<0.05)

Documentation of selected histories

Table-2, shows that significant improvement was noted in asking and documentation of medical histories in phase two compared to phase one of the study. The only non-significant

improvement is seen in asking about and documentation of the use of contraceptive pills by female patients.

Table 2. Documentation of selected medical histories.

Variable	Phase One		Phase Two	
	No.	%	No.	%
History of chronic disease^b (N=378)				
Asked	198	73.6	105	96.3
Not asked	71	26.3	4	3.7
Last meal^b (N=378)				
Asked	196	72.9	107	98.2
Not asked	73	27.1	2	1.8
Anti coagulant use^b (N=378)				
Asked	108	40.1	74	67.9
Not asked	142	52.8	32	29.4
Not applicable	19	7.1	3	2.8
Steroid use^b (N=378)				
Asked	114	42.4	74	67.9
Not asked	134	49.8	33	30.3
Not applicable	21	7.8	2	1.8
Contraceptive pills use for females^a (N=174)				
asked	75	64.1	41	71.9
Not asked	42	35.9	16	28.1
N.S.A.I.D Use^b (N=378)				
asked	133	49.4	77	70.6
Not asked	114	42.4	29	26.6
Not applicable	22	8.2	3	2.8

^a The difference in documentation between the two phases is insignificant (P>0.05)

^b The difference in documentation between the two phases is significant (P<0.05)

Documentation of selected preoperative tasks

A number of preoperative tasks are expected to be done and documented. These are shown in Table 3. The documentation showed substantial improvement in phase two as compared to phase one, except surgical site marking which remained low (53.2%) despite the significant

improvement also. In some tasks the improvement was not significant simply because the level of adherence was also high in phase one (e.g., asking about shortness of breath and the availability of surgical team).

Table 3. Documentation of selected preoperative tasks.

Task	Phase one		Phase two	
	No.	%	No.	%
Preoperative investigations^b (N=378)				
Done and available	156	58.0	92	84.4
Done not available	24	8.9	1	0.9
Partially done	58	21.6	3	2.8
Not adequately done	31	11.5	13	11.9
Surgical site^b (N=378)				
Marked	30	11.2	58	53.2
Not marked	239	88.8	51	46.8
Allergy to anaesthesia^b (N=378)				
Ascertained/ documented	228	84.8	105	96.3
Not ascertained	41	15.2	4	3.7
Shortness of breath^a (N=378)				
Ascertained	240	89.2	107	98.2
Not ascertained	29	10.8	2	1.8
Blood loss anticipation and preparation^b(N=378)				
Blood loss not anticipated	190	70.6	92	84.4
Blood prepared, matched and available	7	2.6	0	0.0
Blood, prepared, matched, not available.	33	12.3	8	7.3
Blood prepared but not well labeled or matching not documented.	39	14.5	9	8.3
Prophylactic antibiotics^b (N=145)				
Needed and given	65	67.0	46	95.5
Needed not given	32	33.0	2	4.5
Availability of surgical team^a (N=378)				
All team present	255	94.8	108	99.1
Not all team present	14	5.2	1	0.9
Operation explanation^b(N=378)				
Adequate	171	63.6	89	81.7
Not adequate	98	36.4	20	18.3

^a The difference in documentation between the two phases is insignificant ($P > 0.05$)

^b The difference in documentation between the two phases is significant ($P < 0.05$)

Documentation of postoperative tasks

Substantial improvement was observed after the intervention in most of the tasks studied, (Table-4). Significant improvement is seen in pack and instrument calculation, operative notes, postoperative instructions and surgical device checking. However the postoperative patient

instructions and the checking of surgical devices remained very low even in phase two of the study. The other tasks listed in the table did not show significant improvement because their documentation was very good in phase one also and the avenue for improvement was limited.

Table 4. Documentation of selected postoperative tasks.

Task	Phase one		Phase two	
	No.	%	No.	%
<u>Pack and instrument calculation</u>^b (N=378)				
Done	206	76.6	100	91.7
Not done	63	23.4	9	8.3
<u>Operative notes</u>^b (N=378)				
Written clearly	216	80.3	99	90.8
Written but not clear	53	19.7	10	9.2
<u>Postoperative instructions</u>^b (N=378)				
Adequate	95	35.3	47	43.1
Not adequate	174	64.7	62	56.9
<u>Biopsy taking</u>^a (N=227)				
Proper	135	87.1	68	94.4
Not proper	20	12.9	4	5.6
<u>Surgical device checking</u>^b (N=378)				
Done	47	17.5	36	33.0
Not done	222	82.5	73	67.0
<u>Patient recovery checking</u>^a (N=378)				
Done and documented	248	92.2	94	86.2
Inadequately done	21	7.8	15	13.8
<u>Intra operative complications</u>^a (N=378)				
occurred and not documented	9	3.3	3	2.8
Did not occur	260	96.7	106	97.2
<u>2 hour post operative complications</u>^a (N=378)				
occurred and not documented	6	2.2	0	0.0
Did not occur	263	97.8	109	100.0

^a The difference in documentation between the two phases is insignificant (P>0.05)

^b The difference in documentation between the two phases is significant (P<0.05)

DISCUSSION

Despite the new advances and technology in surgical practice in the last few decades, still minimal considerations have been given to the analysis of team dynamics and behavioral interactions in the operative theatre particularly in Iraq. Surgical safety checklist which was recommended by the World Health Organization was meant to be globally used wherever surgical procedures were done, as an easy and rapid way to review the patient health state and indirectly the competence of care providers. In the absence of regular auditing in Iraqi hospitals, it would be expected that the use of safety checklists including the WHO one is intermittent and sporadic for most items required to be covered. The present study is the first in Basrah to evaluate the use of safety checklist in operating theaters. The study is an

explorative in its first phase, interventional in the middle and explorative again in the second phase. The study should not be considered ideal in design, conduct and results but the researchers believe that it provides sufficient evidence about the quality of surgical care at one major operating theater in one of the major hospitals in Basrah. The results could be generalized to other theaters in Basrah but with some reservation. The situation in other theaters, though expected to be similar in the level of practice, but differences could be present due to the effect of doctors, management and other determinants. Before giving anesthesia, it is expected that the identity of the patient, the consent, the special related points in history, the investigations, the operative site marking, the allergy to anesthetic

drugs, the history of shortness of breath, the anticipation of significant blood loss, the need for prophylactic antibiotics, the presence of whole surgical team, and the clear explanation of detailed surgical procedure to the patient are all carried out and documented. Regarding patient identity, the documentation was excellent in both of the study phases and the avenue for improvement was very limited in documentation of age and gender. However, the documentation of next of kin and communication means (mobile phone) was not adequate in both phases despite the improvement in the second phase. The improvement was probably due to the instructions done by the researchers about the use of the checklist. The use of patient tag during the first phase of the study was remarkably poor and the result was surprisingly low. In the second phase a substantial increase has happened but still more than one fourth of the patients were without tags. In a study done in Sulaimanayah, Iraq, in 2009 in Hatwan hospital, similar improvement in patient identity identification after implementation of surgical checklist was reported, but both the base rate of use and the rate after implementation were much higher than the results in the current study.^[13] On the other hand, informed consent documentation was very high in both phases of the study, a result which is similar to the study carried out in Sulaimanayah.^[13] However, in this study in very few cases, the documentation was incomplete. The results are also similar to the results of a study carried out in Germany to monitor the sustainability of adherence to safety checklist, in which they found a high rate of initial adherence but significant attrition was observed with time.^[14] The high rate of adherence to documentation of consent is a reflection of the legal consequences of any undesired outcomes of surgery. When patients sign consent they share the responsibility with surgeons and other medical staff. With respect to medical history, statistically significant improvement in all selected items

documentation before and after reminding intervention was noticed. However, the degree of change did not raise the performance to an acceptable level in most of the variables studied. For example the inquiry about history of chronic disease and about last meal was high even in phase one (73.6% and 72.9% respectively) but increased to excellent level in phase two (96.3% and 98.2% respectively) whereas the performance in other items was very low in phase one and remained low in phase two also. Very good improvement in the preoperative investigations documentation from phase one to phase two was observed in this study, The percentage of the patients with ideal situation (all relevant investigations done and available increased significantly in phase two compared to phase one. These results are consistent in direction with the results of the German Study which showed positive and clear and statistically significant marking of the surgical site after checklist implementation.^[14] Surgical site marking which is important task to be done pre-operatively as it would eliminate the possibility of making surgery in the wrong sites was unfortunately inadequate in both phases. The level of adherence was still not up to the standard and mistakes cannot be ruled out in the future, a point which suggests the need for further enforcement of the safety checklist by respective authorities. Also good results were achieved in anesthetic drugs allergy documentation. The need for blood in surgical operations is one of the criteria of good medical care. The safety checklist emphasizes three points; the anticipation of blood loss, the preparation of blood and the correct labeling of prepared blood. The results showed only mild but significant improvement in adherence to the above mentioned criteria. The issue of communication in the operative theatre and during perioperative time with respect to blood being checked, matched and present at time of need in surgery was studied by Lingard et al^[15], who showed that communication failures were

commonplace, occurring in 30% of procedurally relevant information exchanges among operating team members and approximately one third of the failures had observable negative outcomes. They also noted that the checklist discussion improved efficiency and communication. The surgical team availability was excellent in both phases of the present study and the anticipation and use of antibiotic prophylaxis documentation was very good particularly in phase two with a significant improvement in comparison to phase one. These findings are similar in direction to those reported in Sulaimaneyah study^[13] but their results (increase from 85.7% to 100%) were better at both phases than our results. Another poor indicator was the operative details explanation documentation. Although good and statistically significant improvement in the proportion of procedures with adequate operative details explanation from 63.6% in phase one to 81.7% in phase two, a proportion of 18.3% remained with inadequate explanation of surgical procedures in phase two. A good response to checklist was also reported in the German study^[14] where they reported that orthopaedic surgeons have better informed the patients about the operative procedure expression, the planned operation and the assignment of tasks during surgery with progressively more positive adherence over the time and more use of surgical safety checklist. The post operative tasks were much better documented and good improvement was seen in pack, cotton, and surgical instrument counting documentation, together with a highly significant drop ($P < 0.001$) in none counting cases seen after implementation of checklist in phase two of study. However, still 1 in 12 (8.3%) of the procedures where no counting was done a fact which does not guarantee against faults that might result from forgetting some pieces inside the surgical fields. These results are consistent with the results of a comparative study carried out in the United States of America^[16] which showed that reduction in

overall adverse event (missed pack, or surgical instrument) rates from 23.60% for historical control cases and 15.90% in cases with only team training, to 8.20% in cases with complete checklist use. Thus any minor non-counting of these items after the completion of the operation carries a risk, regardless of its magnitude, of forgetting something inside the surgical wound. Also we noticed a fair adherence to and improvement in operative notes writing. The percentage of clear and adequate writing of notes increased from 80.3% in phase one to 90.8% in phase 2 but still unclear notes are written in about 9.2% of operations. The clear well organized hand writing of operative notes is a reflection of quality of care and helps to verify any complaints which may be raised later on for any reason. In the meantime, the quality of documentation of instructions and treatment details was poor in both phases of the study. Although improvement in response to introduction of the checklist reminding was significant, at least in 56.9% of the notes, there was deficiency in clarity and completeness. Compared to the results of the study carried out in the United States of America, the results in the present study are disappointing. They reported a proper documentation rate much higher and much better than the rate which we obtained in the present study. Only in 2.7% of their cases, documentation was considered inadequate.^[16] Good handling and documentation were seen in both phases in biopsy preparation and marking and noticeable improvement was seen in phase two also. The rate of proper handling increased from 87.2% to 94.4%. A tangible improvement in surgical device competency and well functioning checking was seen from phase one to phase two where the checklist used (17.5% checked in phase one to 33.0% in phase two). However this level of checking is poor and indicates a defect in the quality of care in operating theaters. Similar result was seen in the study done in Sulaimaneyah, Iraq,^[13] where good improvement

in theatre device checking (anesthesia related and surgery related devices and equipments like laryngoscopes, monitors, DC shock machine, pulse oximeter, screens, laparoscopy camera, cautery machine, ..etc) but their level of adherence was much higher than the level observed in the present study. The documentation rate of patient recovery was very good in both phases (before and after the use of checklist) and only in small percentage of cases the recovery was done in hurry and not documented. All complications that occurred during the period of the study were not documented on the patient data sheet, which means very poor adherence to checklist in phase two in spite of education about this item. We as researchers did, however, documented few complications observed during and immediately postoperatively. Because these complications were very few, it is difficult to conclude whether the introduction of the safety checklist could reduce complications or not. A larger study shared by more than one theater and monitored by a sufficient number of surgeons is needed to document this outcome at local setting.

In conclusion, it is clear that the introduction of the safety checklist in an active manner to both surgical and anesthesiology teams in daily surgical practice in local operative theatre was of value in decreasing the perioperative missing with subsequent improvement in quality of care at least in terms of proper adherence to required tasks. Patient safety and probably more cooperation between all teams and components in operative theatre must be better and in the correct direction of high quality care. This view is supported by the results of many studies on various components of the checklist.^[17-22] Evidence from a number of studies across Europe^[18-22] did support its use also to help improve quality of care. We, in the light of the present study, also recommend the use of such list and stress that adherence to assigned tasks before, during and immediately after surgical procedures must be mandatory and carried out

with high accountability and faith by all parties involved in patient care.

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