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The Effect of a Surgical Safety Checklist on Mortality, Morbidity and Cancellation at a South African Tertiary Institute Orthopaedic Department.

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Background: ***Surgical complications are common and most of them are preventable, especially if one considers that 53% to 70% of surgical errors occur outside theatre. Recent studies have shown that pre-operative checklists are associated with improved patient outcome. We hypothesize that in our institution there will be an improvement in patient outcome if a safety checklist is introduced.***
Methods: ***A modified multidisciplinary WHO safety checklist was introduced at our institution on the 1st March 2011. The primary focus was on elective patients admitted in all the units of the division of orthopaedic surgery. We retrospectively collected data from the daily morbidity and mortality (MM) reports presented by the different units of the division of orthopaedic surgery from the 1st January to 31st May 2011. In addition a pre-induction and post-induction survey was completed by all registrars.***
Results: ***The mortality rate decreased by 0.42% (from 1.83% to 1.41%) after the introduction of a surgical safety checklist. There was also a 0.66% reduction in avoidable morbidity (from 1.83% to 1.17%) and a 1.6% reduction in avoidable cancellation (from 2.3% to 0.7%). Only 77% of registrars acknowledged undertaking pre-operative planning prior to implementation of the checklist compared with 87.5% post implementation.***
Conclusion: ***The implementation of the modified WHO safety check list was associated with some reduction in cancellations, avoidable morbidity and mortality. Surgical safety checklists should be regarded as a standard practice for all orthopaedic procedures in order to decrease complications, especially in high operation volume and training centers.***

Introduction

A surgical complication is described as any 'undesirable, unintended and direct result of an operation affecting the patient, which would not have occurred had the operation gone as well as could reasonably be hoped[1].' A more inclusive definition is 'any deviation from the ideal postoperative course that is not inherent in the procedure and does not comprise a failure to cure[2].' Surgical complication in this study includes both adverse events and negligence cases as defined by *Brennan et al* [3].

Surgical complications are common and most of them are preventable[4]. *Andrew et al's* [5] prospective observational study of 1997, carried out in three large teaching hospitals in the United States of America, showed that 17.7% of inhospital patients experienced at least one serious adverse event. *Wanzel et al* [6] showed an incidence of 39% of surgical complications in a prospective study of 192 patients carried out in Wellesly Central Hospital in Canada in 2000, of which 18% were due to error. *De Vries et al's*[7] systematic review revealed that 1 in 150 patients admitted in hospital have an adverse event, and that 2/3 of in-hospital events are associated with surgical care. Adverse events have been estimated to affect between 3% and 16% of all hospitalized patients, and more than half of such events are known to be preventable[3,8,9,10]. Several studies have shown that between 53% and 70% of surgical errors occur outside theatre before and after surgery[11,12,13,14]. The introduction of a safety checklist is necessary in order to decrease these errors.

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The incidence of surgical complications differs between developed and developing countries. The incidence of major complications in developed countries is quoted as between 3% and 22% of inpatient surgical procedures and deaths due to complications fall between 0.4% and 0.8%[19,20]. Nearly half of these adverse outcomes were determined to be preventable[19, 20]. In developing countries, deaths rates associated with major surgery were cited as between 5% and 10%[21,22, 23].

The WHO safety checklist was validated by the multicenter World Health Organization "Safe Surgery Saves Lives" program[12,15]. The study, conducted by *Haynes et al* [12] looked at peri-operative patients only and showed a reduction in the rate of major complications from 11.0% to 7.0% and also a decrease in mortality from 1.5% to 0.8%[12]. Subsequently, *de Vries et al* 's[11] Surgical Patient Safety System (SURPASS) collaborative study showed similar reduction in complications from 27.3% to 16.7 % and reduction in mortality from 1.5% to 0.8%. The reduction in mortality attributed to a safety checklist was further reinforced by *Neily et al's*[16] study which showed a reduction in complications of 18% in 74 institutions that introduced the safety checklist compared to a 7 % reduction in 34 institutions without a checklist.

The main aim of the study was to determine whether there is any difference in health care before and after the introduction of safety checklist in terms of the mortality rate, morbidity rate and surgical cancellation rate. The secondary objective was to establish whether a surgical safety checklist should be implemented in orthopaedic departments of the University of the Witwatersrand.

Patients and Method

This was a retrospective observational study from stored database from the division of orthopaedic surgery of Charlotte Maxeke Johannesburg Academic Hospital (CMJAH). CMJAH is a level 1 trauma centre and one of the two main teaching hospitals of the University of the Witwatersrand catering not only for inner centre of Johannesburg but also for the whole of South Gauteng, neighbouring provinces and countries. In 2010, the division of orthopaedics admitted a total of 2408 patients of which 2255 had operations and 21495 patients were seen in outpatients.

Before starting the study, ethics clearance was obtained from the University of the Witwatersrand ethics committee to conduct the study (MH120911). A modified multidisciplinary World Health Organization safety checklist was introduced at our institution on the 1st March 2011 (appendix 1)[15]. Prior to this there was no formal surgical safety checklist, surgical outcomes were evaluated by weekly units' morbidity and mortality (MM) reports presented by registrars, chaired by senior consultants. Data from the 1st January 2011 to 29th February 2011 (2 months) was used as the pre-implementation phase. The data from March 2011 was taken as familiarization month with the checklist. From the 1st April 2011 until 31st May 2011 (2 months) post-implementation MM data was analyzed and compared with the pre-implementation data.

All elective patients admitted in all the units of the division (inclusive of emergency admitted patients who were subsequently operated on elective "list") were included in the study while emergency patients sent directly for operation from the emergency department were excluded. Prior to implementation, all involved personnel (consultants and registrars in orthopaedic surgery and anaesthesia, nursing staff in the orthopaedic wards and theatres, clerical staff) were familiarized with the checklist using lectures. A survey of the University of the Witwatersrand orthopaedic registrars was also done at both the pre-implementation and

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post-implementation phase about their knowledge on surgical checklists (appendix 2).

We intended to enroll 500 consecutive patients as per *Haynes et al's*[12] study. The sample size was calculated to detect a 20% reduction in complications after implementation, with statistical power of 80% and alpha value of 0.05. Data was collected using ***Microsoft excel*** and ***stata version 11.1. Fisher's exact test*** was used to compare the difference pre-implementation and post-implementation.

Results

We had similar total admissions, outpatient attendances and theatre cases in the pre-implementation and the post- implementation phase as shown in table 1 and 2. Figure 1 below shows the causes of mortality in the pre-implementation and post–implementation periods. The mortality rate decreased by 0.42 %, from (8/438) 1.83% to (6/425) 1.41% at pre-implementation period compared to post-implementation period. Statistically there was no difference in the mortality rate between the pre-implementation period and post-implementation period ($p<0.789$).

There was reduction of avoidable morbidity of 0.66 % (from (8/438) 1.83% to (5/425) 1.17%) as shown in Figure 2. There was no statistical significance between the pre-implementation and post-implementation phases ($p<0.579$). There were 25 cancellations before and 33 after implementation (Table 3). Overall there was no difference between the 2 groups. There was significant increase in pediatric cancellations post-implementation (7) from pre-implementation period (3) (see table 2). The 3 pre-implementation patient cancellations were due to lack of time (1), gastro-enteritis (1) and general anaesthetic risk (1) as shown in table 3. Post-implementation cancellations were due to lack of time (3), upper respiratory infection (2) and faulty anaesthetic machine (2). The causes were unavoidable and in both cases beyond the surgeon's control. Similarly for trauma there was an increase in cancellations from 17 to 19 while in the other specialties there was a decrease in cancellation rates.

Table 1. Summary of the Division of Orthopaedics

	Total Admissions	Clinics (OPD)	Theatre cases	Cancellatio	Morbidit	Mortalit
Pre-Pre-imp	461	2596	438	35	14	8
Pos Post-impl	461	2360	425	36	11	6
Total	922	4956	863	71	25	14

Key: Pre-imp = Pre-implementation. Post-imp = Post-implementation

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Table 2. Summary of the Activities of Each Clinical Unit

	Trauma		Arthroplasty		Pediatrics		Spine		Sports		Tumour/Sepsis	
	Pre-	Post-	Pre-	Post-	Pre-	Post-	Pre-	Post-	Pre-	Post-	Pre-	Post-
Admissions	219	248	53	35	118	112	40	34	10	9	21	23
Clinics(OPD)	988	918	391	371	695	621	299	251	58	53	165	146
Theatre cases	257	249	38	36	96	96	23	21	10	10	14	13
Cancellations	17	19	8	7	3	7	2	0	0	0	6	3
Morbidity	11	5	3	1	1	3	0	1	0	0	0	0
Mortality	2	4	0	0	0	0	4	1	0	0	2	2

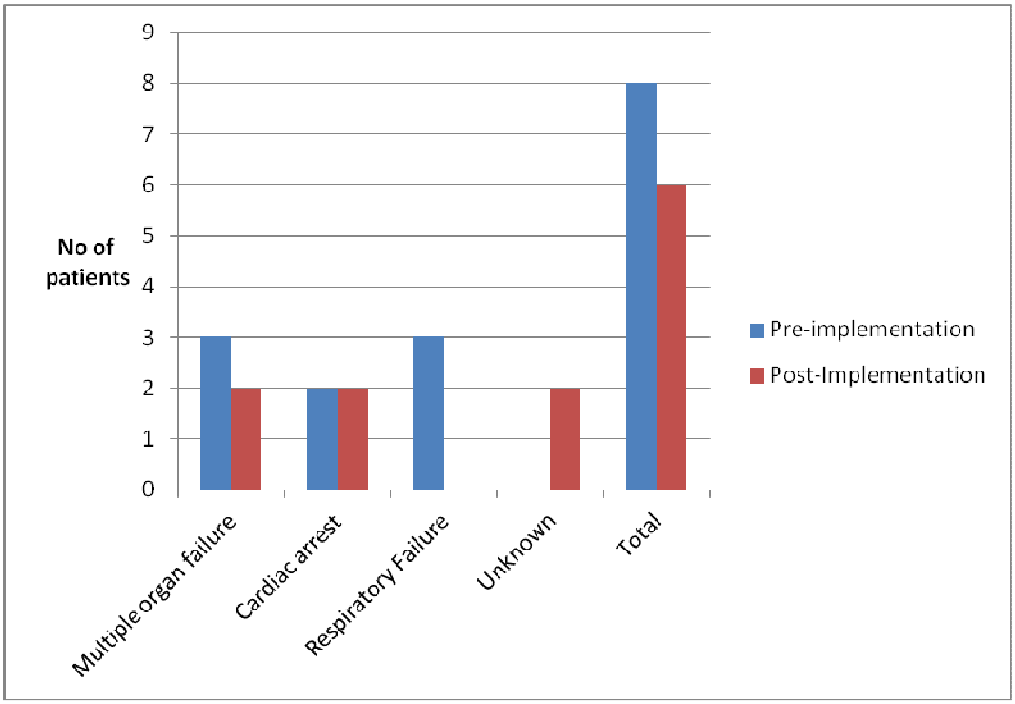

Figure 1. Breakdown of Mortality Cases

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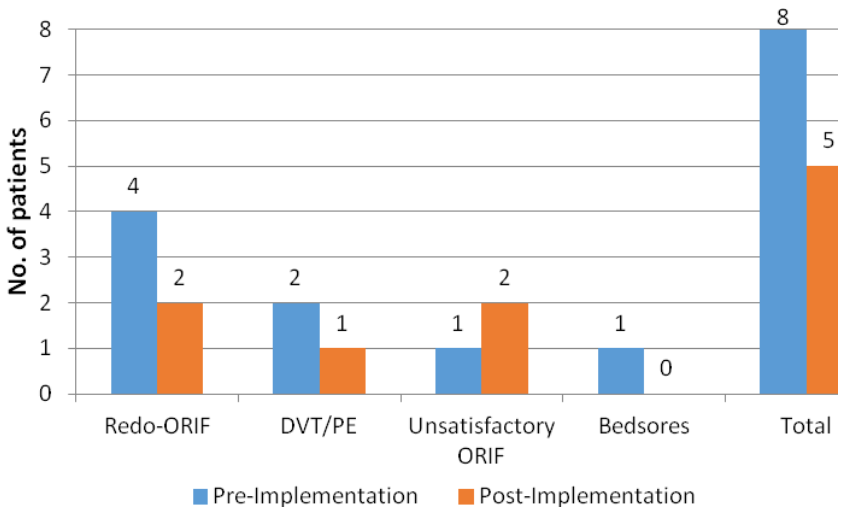

Figure 2. Breakdown of avoidable morbidity cases

Table 3. Causes of Cancellation

Variable	Pre-implementation	Post-implementation
Lack of theatre Time	11	19
No High Care Bed or ICU bed	4	5
No "Air Pressure" in theatre	8	0
Faulty Anaesthetic Machine	0	2
No appropriate implants	0	1
Upper respiratory tract infection	0	2
Gastroenteritis	1	0
Patient arrived late	1	2
No anaesthetist consultant cover	0	2
Total	25	33

However if one divides them into un-avoidable and avoidable groups, there was 1.57% reduction of avoidable cancellations (10/438) 2.28 % compared to (3/425) 0.71%.

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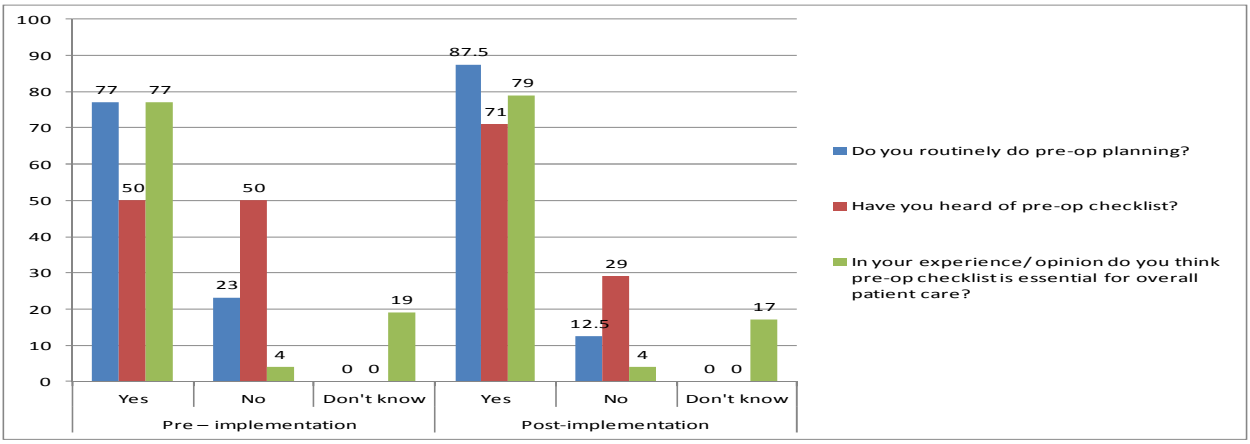

Figure 3. Survey of Orthopaedic Registrars at Witwatersrand Orthopaedic Circuit pre-implementation and post-implementation of surgical safety checklist

Only 77% of registrars acknowledged performing pre-operative planning prior to implementation compared to 87.5% post-implementation, as shown in Figure 3. This means that 12.5% of our registrars still do not practice pre-operative planning, post-implementation of the checklist, although this was not statistically significant ($p<0.062$). There was also an increase from 50% to 71% of those who have heard of a surgical safety checklist at pre-implementation compared to post-implementation, which was statistically significant ($p<0.004$). Despite the implementation there was an increase of only 2% (77% to 79%) of registrars who thought that the checklist was essential for overall patient care ($p<0.0865$).

Discussion

The introduction of a surgical safety checklist is associated with reduction of mortality, avoidable morbidity and cancellations. This is consistent with the published literature which indicates that the introduction of a surgical safety checklist was associated with reduction of surgical complications as per the original mandate of the "Safe Surgery Saves Lives" WHO initiative[4, 11, 12].

Our study showed a decrease in mortality rate of 0.42%, which is comparable to the published data of 0.7% (*de Vries et al* [11] and *Haynes et al* [12]). It is difficult to attribute the reduction of mortality in our studies to our checklist as the documented cases' cause of death was from unavoidable causes. These were fully discussed in our mortality and morbidity meetings and were found to be unavoidable. For example, all of the mortality cases from respiratory failure were from the spine unit with high cervical spine injuries. Regardless of the checklist the mortality rate from respiratory complications is approaching 100% within a few months of admission.

On comparing our study to the published data, we see that *Haynes et al* [12] showed a reduction of 3% in morbidity while *De Vries et al* [11] showed a decrease of 10.6% compared to a modest 0.66% decrease in avoidable morbidity in our study. The abovementioned published studies involved all patients in surgical disciplines including emergency patients where the risk of complications is high. Our study was limited to elective patients and emergency patients who were operated in elective list.

Regarding the total cancellations results, there was no difference between the two study groups but when only avoidable cancellations were scrutinized there was a 1.6% reduction.

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One would have expected a decreased overall number of cancellations post implementation but in our case this could be accounted for by intentional overbooking/ having patients on standby in case a surgery is cancelled and another patient may take the booking. Patients were informed that they were on standby and would subsequently be put on the next list if they were not operated on. Unfortunately we did not specify or indicate in our records whether the cancelled patient was a standby patient, therefore this affected our analysis of cancellations. One might argue that patients with cardiac problems should be included in the "unavoidable" section but we included them in the "avoidable" section because these are high risk patients who should be fully worked up by the treating orthopaedic team in conjunction with anaesthetists and cardiologists. This would lead to fewer cancellations and also lower morbidity and mortality. Routinely, other specialists are involved but the high cancellation rate could be explained by the pre-operative workup which is mostly done by junior members of the anesthetic team only to be cancelled by consultants in theatre the next day. To overcome this, back-up cases were added on lists to fully utilize the theatre time.

There was a significant increase in the percentage of registrars who were initially not routinely practicing pre-operative planning from 77% to 87.5 % and also of those who have heard of a checklist (50% to 71%) from pre-implementation to post- implementation. This could be explained by the fact that some registrars were not rotating at CMJAH during the study period but the survey included all registrars in the circuit. Despite this there was little difference regarding their opinions as to whether it is essential for overall patient care pre-implementation and post-implementation. Not all registrars in the circuit completed the survey as some would have been at outreach hospitals, attending to emergencies or on leave.

Compared to published studies our sample size was very small and the study period very short (total of 5 months) inclusive of 1 month for getting acquainted to the surgical safety checklist. We found that the pre-operative and intra-operative sections of the checklist were fully completed compared to the post-operative section as most doctors would revert back to the medical file for documentation rather than the checklist.

The limitations of this study include underreporting of morbidity and cancellation rates by the units of the division of orthopaedics. Also, only in-patient morbidities were recorded. Thus, patients who presented in outpatient with post-operative morbidities were not recorded. In addition, the Hawthorne effect might have played a role with more active documentation and reporting after implementation, as registrars knew their documentation was being closely scrutinized.

There is currently no universally accepted and widely used classification for surgical complications, but the Clavien-Dindo grading system which was introduced in 1992, and subsequently modified in 2004, is the most commonly used[17,18]. The difficulty with this classification system is underreporting. The unavailability of a universally accepted classification system makes it difficult to obtain data in a standardized manner, and for different centres to compare their outcome. In our study we did not use any classification system but compared like for like of complications before and after implementation of the surgical checklist.

Conclusion

The implementation of a surgical safety checklist was associated with a reduction in mortality, avoidable morbidity and cancellation. Surgical safety checklists should be regarded as a standard practice for all orthopaedic procedures to decrease complications especially in high operation volume and training centers.

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