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The effects of a surgical safety checklist on mortality, morbidity and cancellation

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Chapter 1 - Introduction and Literature review

Definition and Epidemiology

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]. An adverse event injury is one caused by medical management (rather than the underlying disease), and negligence refers to care that falls below the standard expected of surgeons in their community[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.

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, 23].

Classification

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 (Table 1)[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.

Table 1: Clavien-Dindo grading system for the classification of surgical complications

Grade	Definition	Examples
1	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions. Acceptable therapeutic regimens are: drugs such as antiemetics, antipyretics, analgesics, diuretics and physiotherapy. Wound infections opened at the bedside.	Transient confusion, Atelectasis.
2	Requiring pharmacological treatment with drugs other than those allowed for grade I complications. E.g. blood transfusions and total parenteral nutrition.	A-fibrillation, Confusion.
3	3 a Intervention not under general anesthesia 3 b Intervention under general anesthesia. Requiring surgical, endoscopic or radiological intervention	Heart failure, Anastomotic leak.
4	4a Single organ dysfunction (including dialysis) 4b Multi-organ dysfunction a Intervention not under general anesthesia	
5	Death	

(Modified from Dindo D. et al. Classification of Surgical Complications. A New Proposal with Evaluation in a Cohort of 6336 Patients and Results of a Survey. Annals of Surgery. Volume 240, Number 2, August 2004).

WHO Checklist

The main goal of the WHO guidelines for safe surgery (2009) was to improve patient safety policy and practice in every country in the world irrespective of the economic status, through development of an effective checklist that could be modified for an individual country[16]. The main objectives were to ensure that;

(1)The team will operate on the correct patient at the correct site.

(2) The team will use methods known to prevent harm from administration of anaesthetics, while protecting the patient from pain.

(3) The team will recognize and effectively prepare for life threatening loss of airway or respiratory function.

(4) The team will recognize and effectively prepare for risk of high blood loss.

(5) The team will avoid inducing an allergic or adverse drug reaction for which the patient is known to be at significant risk.

(6) The team will consistently use methods known to minimize the risk for surgical site infection.

(7) The team will prevent inadvertent retention of instruments and sponges in surgical wounds.

(8) The team will secure and accurately identify all surgical specimens.

(9) The team will effectively communicate and exchange critical information for the safe conduct of the operation.

(10) Hospitals and public health systems will establish routine surveillance of surgical capacity, volume and results.

A modified multidisciplinary World Health Organization safety checklist was introduced at our institution - Charlotte Maxeke Johannesburg Academic Hospital, Division of Orthopaedics on the 1st March 2011 (appendix 4). Prior to this there was no formal surgical safety checklist. Pre-operative work-up which included, inter alia, checking and acting on blood results, pre-operative optimizing of patients by consulting other relevant medical specialties, limb marking and informed consent was in most instances delegated to the most junior member of the team (intern/ medical officer or junior registrar). With the checklist, at least one of the surgeons checks all of the above and makes sure that the patient is ready before being booked.

The surgical safety checklist list consists of 3 components, namely the pre-operative, intra-operative and immediate post-operative section (appendix 4). The pre-operative section contains 14 items, including the American Society of Anaestheologists' (ASA) rating of patients. Subsequent items on the checklist ensure that an electrocardiogram and chest x-ray are completed and that routine bloods are taken, checked and documented

(appendix 4 page 1). The surgical site is marked and most importantly informed consent is documented. Pre-operative planning, including the ordering of implants, is done. This document must be checked by the registrar or the surgeon pre-operatively and any missing information rectified prior to the patient being booked by the team for surgery. Patients found to be unfit for surgery are cancelled immediately and replaced with other patients.

The intra-operative section, as with the original World Health Organization checklist, comprises 20 items divided into 3 parts (before induction, before skin incision and before leaving the theatre). The first section i.e. before induction consists of 7 items to be checked by the scrub sister once the patient is in theatre. This includes confirming the patient's identity. The marked site of operation is confirmed to be correct and any known allergies are noted. The anaesthetic equipment is also checked including making sure that all surgical sets are available and sterilized. Any discrepancies are identified and rectified before the patient is given any form of anaesthesia. A further check is completed before skin incision by any member of the theatre personnel (scrub sister/ surgeon or anaesthetist). This verifies all the details again, starting with the name of patient, the procedure, consent and implants availability. If any discrepancy is found it is rectified before skin incision. In addition, prior to leaving theatre, the scrub nurse, anaesthetist and the surgeon have to confirm that there were

no problems during the operation (appendix 4 page 3). Any anticipated immediate post-operative complications must be clearly identified, recorded and communicated to ward personnel. This intra-operative section also includes a section of theatre operation notes which details the date, ICD 10 code of procedure, surgeon and assistants, position of patient, duration of operation, tourniquet and theatre time. Lastly the details of the operation (surgical approach, implants used and post-operation instructions) are fully and clearly documented (appendix 4 page 4).

The post-operative section is completed by the orthopaedic registrar involved in the case to check, amongst other things, that the operated limb is perfusing well and that thromboprophylaxis and antibiotics are prescribed where indicated immediately after theatre in the ward (appendix 4 page 2).

The WHO safety checklist was validated by the multicenter World Health Organization "Safe Surgery Saves Lives" program[12]. This program was carried out at academic and district hospitals in 8 different countries with diverse populations and Gross Domestic Product. These countries included Canada, India, Jordan, New Zealand, Philippines, Tanzania, England and the USA. 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%[5].

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%. This was a comprehensive study in that it included patients who were followed up from admission to discharge (i.e. the entire surgical pathway). The SURPASS study was carried out in the Netherlands and involved academic, tertiary teaching and regional teaching hospitals where the standard of care is very high. 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.

Chapter 2: Research Question

Background:

Charlotte Maxeke Johannesburg Academic Hospital 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.

Prior to the introduction of a surgical safety checklist, surgical outcomes in the division of orthopaedics were evaluated by weekly morbidity and mortality meetings chaired by consultants. There was no formal pre-operative checklist. A checklist has now been introduced.

Hypothesis:

The introduction of a surgical safety checklist in our institution will lead to reduction in mortality, morbidity and cancellation.

Aim/Objectives:

The aim of the study was to assess whether there is any difference in health care before and after the introduction of safety checklist in terms of;

1. Mortality rate

2. Morbidity rate

3. Surgical cancellation rate

Secondary Objective:

To establish whether a surgical safety checklist should be implemented in orthopaedic departments of the University of the Witwatersrand.

Significance:

There is currently no published study about surgical safety checklists in South Africa, hence the need for this study in order to assess whether a safety checklist would be effective in our setting. With the ever spiralling costs of health care, reducing complications would help to decrease the cost of health care and save lives.

Chapter 3: Study design and methodology

Study Design

This was a retrospective observational study from stored database hence no consent was needed from patients.

Statistical analysis

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.

Intervention:

Data was collected from the saved orthopaedic department database of weekly morbidity and mortality (MM) reports presented by registrars to the department from the 1st January 2011 to 29th February 2011 (2 months) as the pre-implementation phase. These morbidity and mortality meetings were chaired by senior consultants of the division of orthopaedics. 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 morbidity and mortality data was analyzed and compared with the pre-implementation data.

Inclusion criteria

All elective patients admitted in all the units of the division (inclusive of emergency admitted patients who were subsequently operated on elective "list"). Prior to implementation, all involved personnel (consultants in orthopaedics and anaesthesia, registrars in departments, nursing staff in the wards and theatre and clerical staff) were familiarized with the checklist using lectures.

Exclusion criteria

All emergency patients sent directly for operation from the emergency department. These included polytrauma patients who had been treated using "Damage Control Surgery" principles.

Chapter 4: Results

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.

Table 2: Summary of the Division of Orthopaedics

	Total Admissions	Clinics (OPD)	Theatre cases	Cancellations	Morbidity	Mortality
Pre- implementation	461	2596	438	35	14	8
Post- implementation	461	2360	425	36	11	6
Total	922	4956	863	71	25	14

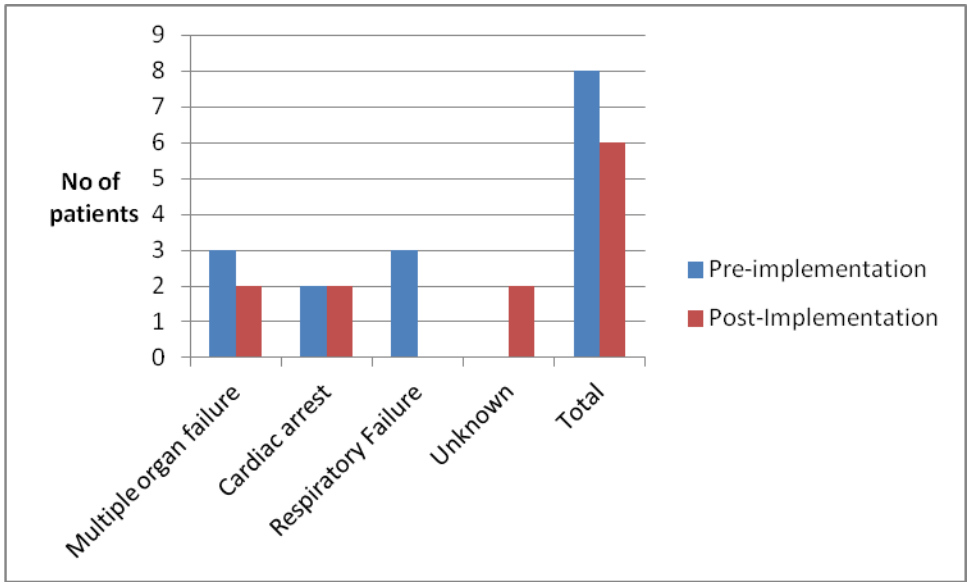
As shown in table 2 and table 3 we had similar total admissions, outpatient attendances and theatre cases in the pre-implementation and the post-implementation phase.

Table 3: 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

There was a significant increase in pediatric cancellations post-implementation (7) from pre-implementation period (3) (see table 3). The 3 pre-implementation patient cancellations were due to lack of time (1), gastro-enteritis (1) and general anaesthetic risk (1). 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.

Graph 1: Breakdown of mortality cases



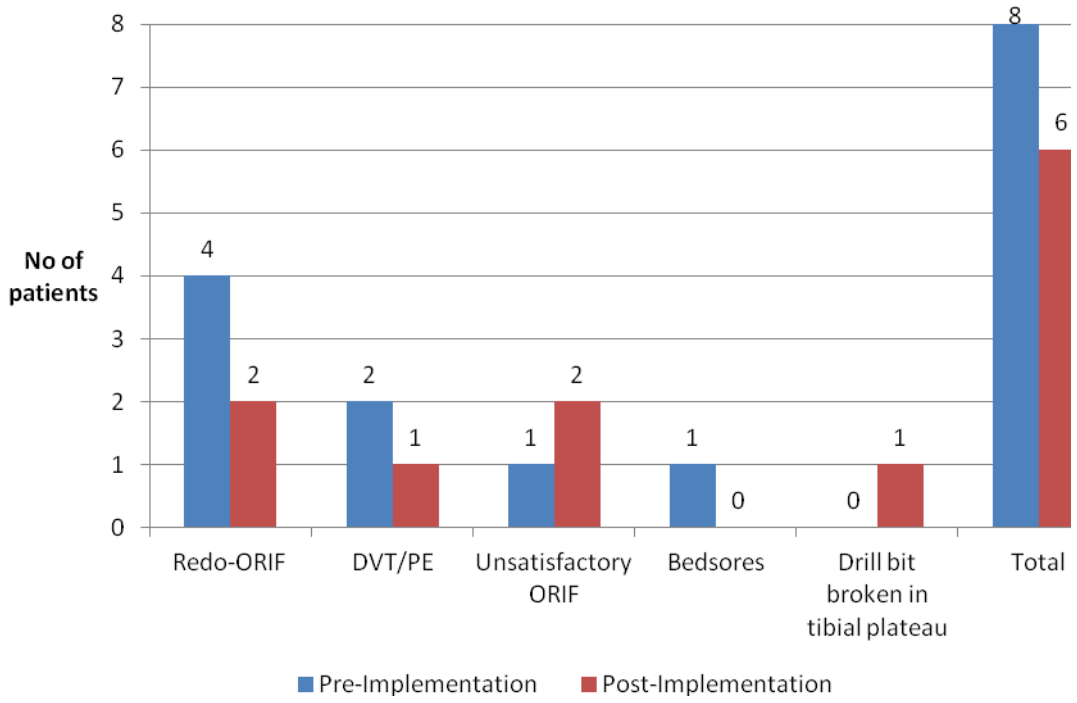
Graph 1 shows the causes of mortality in the pre-implementation and post–implementation periods. The mortality rate decreased by 0.42 %, from (8/438) 1.83% to (6/425) 1.41% at pre-implementation period compared to post-implementation period. Statistically there was no difference in the mortality rate between the pre-implementation period and post-implementation period ($p<0.789$).

Table 4: Breakdown of morbidity cases

Variable	Pre-Implementation	Post-Implementation
*Redo-ORIF	4	2
*DVT/PE	2	1
Post-operative seizures	1	0
Pneumonia	1	0
*Unsatisfactory ORIF	1	2
*Bedsores	1	0
Drill bit broken in tibial plateau	0	1
Post-operative Respiratory Distress	0	1
Unreducible DDH	1	0

*avoidable

Graph 2: Breakdown of avoidable morbidity cases

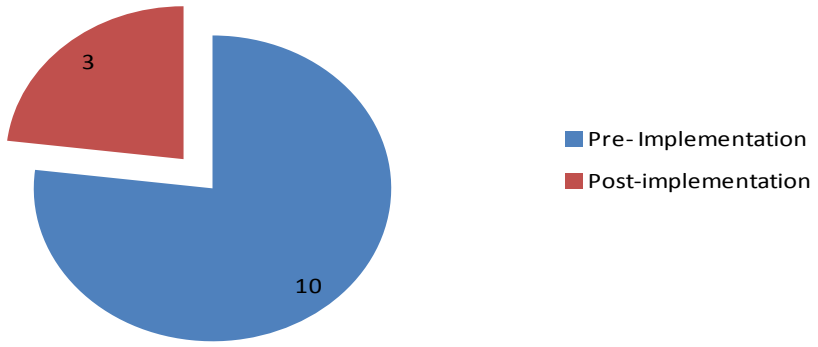


There was reduction of avoidable mortality of 0.66 % (from (8/438) 1.83% to (5/425) 1.17%) as shown in graph 2. There was no statistical significance between the pre-implementation and post-implementation phases ($p<0.579$).

Table 5: Summary of the causes of cancellation

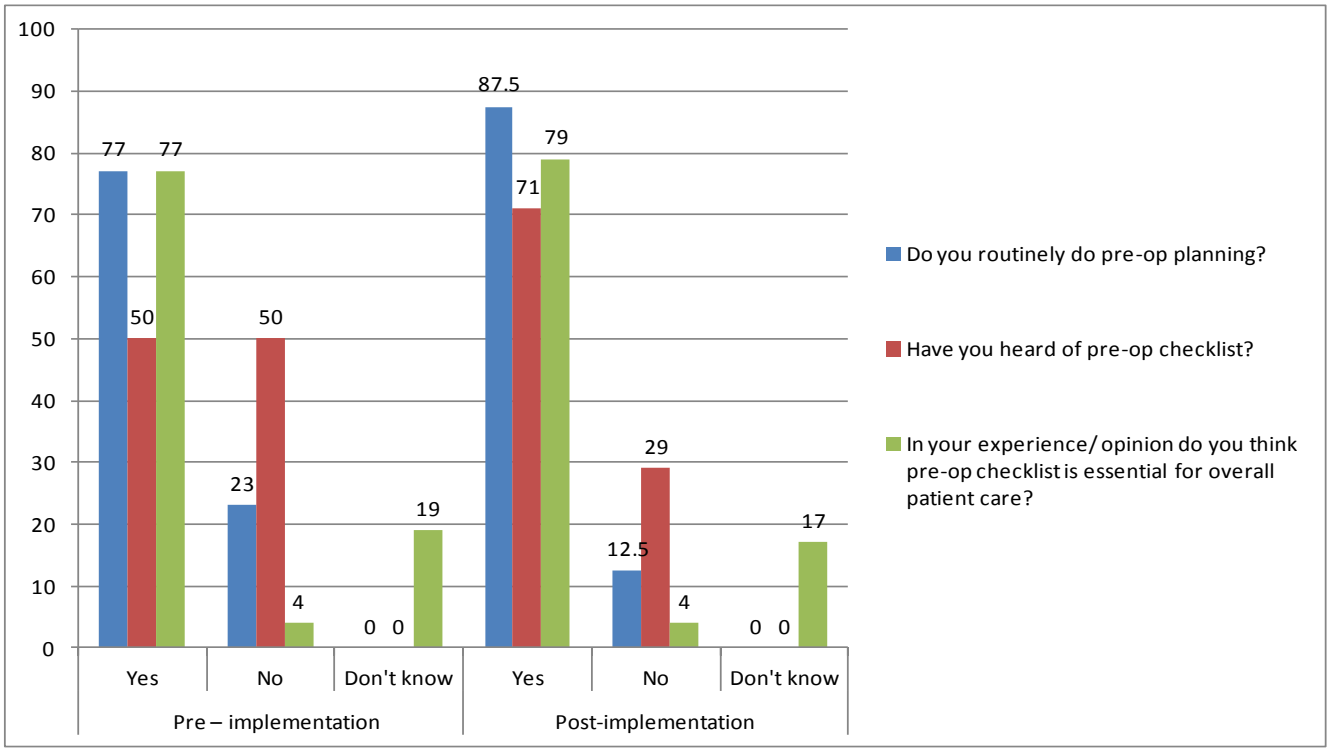
Variable	Pre-implementation	Post-implementation
Lack of theatre Time	11	19
No High Care Bed or ICU bed	4	5
No “Air Pressure” in theatre	8	0
Faulty Anaesthetic Machine	0	2
No appropriate implants	0	1
Upper respiratory tract infection	0	2
Gastroenteritis	1	0
Patient arrived late	1	2
No anaesthetist consultant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

Figure 1: Total of pre- implementation and post-implementation avoidable cancellations



There were 25 cancellations before and 33 after implementation (Table 5). Overall there was no difference between the 2 groups. 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% as shown in figure 1 above.

Graph 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 graph 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 ($p<0.0865$).

Chapter 5: 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].

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.

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. 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.

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 0.8% 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.

Our study also 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 very hard 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.

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.

Chapter 6: Conclusion and recommendation

Conclusion

The implementation of a surgical safety checklist was associated with a reduction in mortality, avoidable morbidity and cancellation.

Recommendation

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.

References

1. Sokol DK, Wilson J. What is a surgical complication? World J Surg. 2008; 62(2): 455–461

2. Dindo D, Clavien PA. What is a surgical complication? World J Surg 2008; 32:939–941

3. Brennan T. A., L. L. Leape, N. M. Laird, A. R. Localio, A. G. Lawthers, J. P. Newhouse, P. C. Weiler, and H. H. Hiatt. 1991. Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I. New England Journal of Medicine 324: 370-376

4. Tsai Thomas, Boussard Tinna, Welton, Mark, Morton, John. Does a surgical safety checklist improve patient safety culture and outcomes? [Abstract]. In: American College of Surgeons Annual Clinical Congress. 2010 October 3-7; Washington D.C. Journal of American College of Surgeons.

5. Andrews LB, StockingC, Krizek T, Gottlieb L, Krizek C, Vargish T, Siegler M. An alternative strategy for studying adverse events in medical care. Lancet. 1997 Feb 1; 349(9048):309–313.

6. Wanzel KR, Jamieson CG, Bohnen JM. Complications on a general surgery service: incidence and reporting.Can J Surg.2000 April; 43(2):113-7

7. De Vries E, Ramrattan MA, Smorenburg SM, Gouma DJ, Boermeester MA. The incidence and nature of in-hospital adverse events: a systematic review. Qual Saf Health Care2008; 17:216-23.

8. Wilson RM, Runciman WB, Gibberd RW, Harrison BT, Newby L, Hamilton JD. The Quality in Australian Health Care Study. Medical Journal of Australia, 1995, 163:458–471.

9. Leape LL, Brennan TA, Laird N, Lawthers AG, Localio AR, Barnes BA, Hebert L, Newhouse JP, Weiler PC, Hiatt H. The nature of adverse events in hospitalized patients—results of the Harvard Medical Practice Study II. New England Journal of Medicine, 1991, 324:377–84.

10. United Kingdom Department of Health. An organization with a memory. London, 2000

11. de Vries EN, Prins HA, Crolla RM, den Outer AJ, van Andel G, van Helden SH, Schlack WS, van Putten MA, Gouma DJ, Dijkgraaf MG, Smorenburg SM, Boermeester MA. Effect of a comprehensive surgical safety system on patient outcome. N Eng J Med. 2010; 363; 1928-1937

12. Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AH, Dellinger EP, Herbosa T, Joseph S, Kibatala PL, Lapitan MC, Merry AF, Moorthy K, Reznick RK, Taylor B, Gawande AA;. A surgical checklist to reduce mortality and morbidity in global population. N Eng J Med. 2009 Jan 29; 360 (5): 491-9

13. Greenberg CC, Regenbogen SE, Studdert DM, et al. Patterns of communication breakdowns resulting in injury to surgical patients.J Am Coll Surg 2007; 204:533-40

14. Griffen FD, Stephens LS, Alexander JB, Bailey HR, Maizel SE, Sutton BH, Posner KL. The American College of Surgeons closed claims study: new insights for improving care. JAm Coll Surg 2007; 204:56-9

15. WHO Guidelines for Safe Surgery 2009.

16. Neily J, Mills PD, Young-Xu Y, Carney BT, West P, Berger DH, Mazzia LM, Paull DE, Bagian JP.Association between implementation of a medical team training program and surgical mortality. JAMA Oct 2010; 304(15):1693-700

17. Dindo D, Demartines N, Clavien Pierre-Alain. Classification of Surgical Complications. A New Proposal with Evaluation in a Cohort of 6336 Patients and Results of a Survey. Annals of Surgery. Volume 240, Number 2, August 2004.

18. Clavien P, Sanabria J, Strasberg S. Proposed classification of complication of surgery with examples of utility in cholecystectomy. Surgery.1992; 111:518–526.

19. Gawande AA, Thomas EJ, Zinner MJ, Brennan TA. The incidence and nature of surgical adverse events in Colorado and Utah in 1992. Surgery, 1999, 126:66–75.

20. Kable AK, Gibberd RW, Spigelman AD. Adverse events in surgical patients in Australia. International Journal of Quality in Health Care, 2002, 14:269–76.

21. Bickler SW, Sanno-Duanda B. Epidemiology of paediatric surgical admissionsto a government referral hospital in the Gambia. Bulletin of the World HealthOrganization, 2000, 78:1330–6.

22. Yii MK, Ng KJ. Risk-adjusted surgical audit with the POSSUM scoring system in a developing country. British Journal of Surgery, 2002, 89:110–3.

23. McConkey SJ. Case series of acute abdominal surgery in rural Sierra Leone. World Journal of Surgery, 2002, 26:509–13.

Appendix 1

Ethics Approval

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Dr Laughter Lisenda

CLEARANCE CERTIFICATE **M120911**

PROJECT The Introduction of a Surgical Safety Check-list, Does it Improve Patient Outcome?

INVESTIGATORS Dr Laughter Lisenda.

DEPARTMENT Division of Orthopaedics

DATE CONSIDERED 28/09/2012

DECISION OF THE COMMITTEE* Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 28/09/2012 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Professor M Lukhele

DECLARATION OF INVESTIGATOR(S)
To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...

Appendix 2 Revised title document

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Dr Laughter Lisenda

CLEARANCE CERTIFICATE	**M120911**
PROJECT	The Effect of a Surgical Safety on Mortality, Morbidity and Cancellation (revised title)
INVESTIGATORS	Dr Laughter Lisenda.
DEPARTMENT	Division of Orthopaedics
DATE CONSIDERED	28/09/2012
DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 18/11/2013 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Professor M Lukhele

DECLARATION OF INVESTIGATOR(S)
To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...

Appendix 3 CEO permission



GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Enquiries:
Office of the Chief Executive Officer
Charlotte Maxeke Johannesburg Hospital
Tell: 011 488 3792
Fax: 011 488 3753
Email: lindiwe.mngomezulu@gauteng.gov.za
Date: 03rd September 2012

Dr. Laughter Lisenda
Registrar
Orthopaedics Department

Dear Dr. Lisenda

RE: "The introduction of a surgical safety checklist, does it improve patient outcome"

Please note that your above request is provisionally approved. Your study can only commence once ethics approval is obtained.

Yours sincerely

Dr. T.E. Selebano
Chief Executive Officer

Appendix 4 Page 1

WARD: PRE-OP CHECKLIST

By Intern, MO or Registrar:

1) ASA Rating: 1 (A normal healthy patient)
2 (A patient with mild systemic disease)
3 (A patient with severe systemic disease)
4 (A patient with severe systemic disease that is a constant threat to life)
5 (A moribund patient who is not expected to survive without the operation)

2)	Anaesthetic consult (if ASA ≥ 3):	YES	Not necessary
3)	Blood results in file:	YES	Not necessary
4)	ECG:	YES	Not necessary
5)	CXR:	YES	Not necessary
6)	ICU bed:	YES	Not necessary
7)	Recent X-rays:	YES	NO
8)	Other investigations:	YES	Not necessary
9)	Blood ordered:	YES	Not necessary
10)	Surgical site marked:	YES	NO

Signature: Date:

Appendix 4 Page 1 continued

By Surgeon:

11) Informed consent: YES

12) Pre-op x-ray planning: YES Not necessary

13) Instruments / implants ordered: YES Not necessary

14) Discussed with senior: YES

Signature: Date:

By Intern, MO or Registrar:

WARD: WARD POST-OP ROUND CHECKLIST

By Registrar:

1)	General:	Vital signs	
		CNS	
		Respiratory	
		CVS	
		Urine	
		Elevation	
		Bleeding	
3)	Analgesia:		
4)	DVT prophylaxis:		
5)	Antibiotics:		
6)	X-rays returned from theatre:		

Signature: Date:

PATIENT DETAILS / Hospital Sticker:

BEFORE INDUCTION OF ANAESTHESIA	BEFORE SKIN INCISION	BEFORE LEAVING OPERATING THEATRE
By nurse and anaesthetist:	***By nurse, anaesthetist and surgeon:***	***By nurse, anaesthetist and surgeon:***
1) Has the patient confirmed his / her identity, site, procedure, and consent? ☐ Yes	☐ **1) Confirm all team members have introduced themselves by name and role.**	**Nurse Verbally Confirms:** ☐ 1) The name of the procedure
2) Is the site marked? ☐ Yes	☐ **2) Confirm the patient's name, procedure, and where the incision will be made.**	☐ 2) Completion of instrument, sponge and needle counts
3) Is the anaesthesia machine and medication check complete? ☐ Yes	**3) Has antibiotic prophylaxis been given within the last 60 minutes?** ☐ Yes ☐ N/A	☐ 3) Specimen labelling (read specimen labels aloud, including patient name)
4) Is the pulse oximeter on the patient and functioning? ☐ Yes	**4) Surgical sets checked & complete?** ☐ Yes	☐ 4) Whether there are any equipment problems to be addressed
5) Does the patient have a: Known allergy? ☐ No ☐ Yes Difficult airway or aspiration risk? ☐ No ☐ Yes, and equipment available. Risk of >500ml blood loss (7ml/kg in children)? ☐ No ☐ Yes, and two Ivs / central access and fluids planned	**5) Anticipated Critical Events** **To Surgeon:** ☐ What are the critical or non-routine steps? ☐ How long will the case take? ☐ What is the anticipated blood loss? **To Anaesthetist:** ☐ Are there any patient specific concerns? **To Nursing Team:** ☐ Has sterility (including indicator results) been confirmed? ☐ Are there equipment issues or any concerns?	**5) To Surgeon:** ☐ What are key concerns for recovery and management of this patient? **6) To Anaesthetist:** ☐ What are key concerns for recovery and management of this patient? **7) To Nursing Team:** ☐ What are key concerns for recovery and management of this patient?
By surgeon: **6) Surgical site and procedure personally confirmed with patient?** ☐ Yes **7) All surgical sets confirmed to be sterilised and in theatre? Image intensifier?** ☐ Yes	**6) Is essential imaging displayed?** ☐ Yes ☐ N/A	PATIENT DETAILS / Hospital Sticker:

PATIENT DETAILS / Hospital Sticker:

Date:	ICD 10 code:
Surgeon:	Procedure:
	Assistant/s:
Anaesthetist:	
	Anaesthetic: GA:
Position: Supine Prone	Regional block:
Other:	Theatre time: In:
Operating time: Start:	Out:
Finish:	Tourniquet: On: Site:
Diathermy pad site:	Off: mmHg:
Antibiotic: Dose:	Estimated blood loss:

Incision / approach:

Details of procedure:

Closure & immobilisation:

Specimens:
Post op instructions:

Appendix 5

Ward pre-operative checklist: Registrars Survey

1. During your time in orthopaedics have you had the following:

	Yes	No	Preventable
1.1 Patient cancellation			
1.2 Intra-operation surgical errors			
1.3 Recovery room morbidity			
1.4 Immediate ward morbidity			
1.5 Post mortem morbidity			

2. Do you routinely do pre-op planning?
3. Have you heard pre-op checklist?
4. In your opinion /experience do you think pre-op checklist would lead to:

	Yes	No	Don't know
4.1 Decrease in cancellation			
4.2 Decrease in surgical errors			
4.3 Decrease in morbidity			
4.4 Decrease in mortality			
4.5 Decrease in workload			

5. In your opinion /experience do you think pre-op checklist is essential for overall patient care? Yes No Don't know
6. Should patient be sent to theatre without the checklist been filled?

Yes No

7. COMMENTS?

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