



11-1-2015

Wrong site surgery & surgical time out

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Citation

Khan MF. Wrong site surgery & surgical time out [Masters dissertation]. Dublin: Royal College of Surgeons in Ireland; 2015.

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“Wrong-site surgery & surgical time-out”

by

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Health Care Ethics & Law

MSc Dissertation - RCSI

August 2015

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Chapter 1

Introduction

“In 1935, the US Army Air Corps held a flight competition for airplane manufacturers vying to build its next generation long range bomber. In early evaluations, the Boeing plane had surpassed designs. The flight competition, was regarded as a mere formality. With the most technically gifted test pilot in the army on board, the plane roared down the tarmac, lifted off smoothly, and climbed sharply to three hundred feet. Then it stalled, turned on one wing, and crashed in a fiery explosion. Two of the five crew members died, including the pilot. An investigation revealed that nothing mechanical had gone wrong. The pilot had forgotten to release the new locking mechanism on the elevator and rudder controls. A few months later army pilots were convinced the plane could fly and invented something that would be used on the few planes that had been purchased....A checklist, with step by step checks for takeoff, flight, landing and taxiing. With the checklist in hand the pilots went on to fly the model (B-17) a total of 1.8 million miles through several conflicts without one accident”. (Gawande A. 2007)

This episode has been heralded as the key milestone in the birth of the checklist.

The delivery of healthcare is complex and hence riddled with the potential for errors due to human factors, system failures, and more

commonly, a combination of the two. Fortunately, many of the errors do not result in harm, but some do, often as a result of a multiplicity of minor errors co-aligning and resulting in a more serious event that results in patient harm. The proliferation of epidemiological and qualitative research into medical errors has contributed to improvements in our understanding of the root causes of many of these errors. Clinical outcomes, morbidity and mortality are the product of both technical and non technical skill. Indeed analysis of error and morbidity suggest that technical failures account for only a small proportion of these. Healthcare systems are now recognised to be a series of complex interrelated Microsystems where clinicians, patients and patterns of practice interact to determine the outcome. It is clear that substantial aspects of clinical practice are now too complex for groups of healthcare professionals to carry out reliably from memory alone. Surgery is one such example where clinicians are faced with high levels of uncertainty in their daily work, which may impact on the quality and safety of care patients receive. This understanding means that it is important for professionals (and their respective bodies) to identify and implement strategies that reduce the risk of iatrogenic harm while at the same time ensuring that optimum outcomes are most likely.

Surgical care has become an integral part of healthcare throughout the world, with an estimated 234 million operations performed annually. This yearly volume now exceeds that of child birth (Alex B et al, 2009). Surgery is performed in every community: wealthy and poor, rural and urban, and in all regions. The World Bank reported that in 2002, an estimated 164 million disability-adjusted life years, representing 11% of the entire disease burden, were attributable to surgically treatable

conditions. Although surgical care can prevent loss of limb or life, it is also associated with a considerable risk of complications and death. The risk of complications is poorly characterized in many parts of the world, but studies in industrialized countries have shown a perioperative rate of death from inpatient surgery 0.4% to 0.8% and a rate of major complications of 3 to 17% (Alex B et al, 2009). These rates are likely to be a lot higher in developing nations.

In the UK most people will have surgery at some point in their life. Approximately 4.2 million surgical operations are carried out every year in England alone. That equates to one operation for every twelve people per year. Surgery has been categorized as a very unsafe undertaking with a rate of fatal adverse events (catastrophic events per exposure) of 1 per 10000 surgical procedures. In industrial countries, major complications occur in 3-16% of inpatient surgical procedures and permanent disability or death rates are 0.4-0.8%. In trauma surgery, the rate of serious complications is substantially higher at an estimated 1 per 100 surgical exposures. By contrast, in civil aviation, railway transport and nuclear power the rate of death is less than one per million exposures. (Amalberti et al. 2005)

“While surgical training and practice has focussed on technical skills and technological advances there has been little recognition of the benefits of non-technical skills (human factors)” (Panesar et al, 2007). Most of the errors that occur during surgery can be attributed to failures in these non-technical skills such as situation awareness, decision making, communication and teamwork and leadership. Other high risk industries such as aviation and petroleum have made great progress in managing these challenges and have reduced harmful events by several orders of

magnitude. They have achieved this by accepting that humans working in complex systems inevitably make errors and have provided opportunities to learn and improve performance. This insight has led to a focus on building systems that reliably deliver what is required and that identify errors causing harm. Central to the success of such initiatives has been an increased appreciation of the role of human factors, the value of teamwork and the principles of reliable system design. Specifically they have built formal mechanisms of communication, trained in non-technical skills and developed checklists.

In January 2007, the World Health Organization (WHO) began a programme aimed at improving the safety of surgical care globally. This initiative – Safe Surgery Saves Lives – identified minimum standards of surgical care that can be universally applied across countries and settings. A core set of safety checks was developed in the form of a WHO Surgical Safety Checklist that can be used in any surgical setting and operating theatre environment. Each step in the checklist is simple, widely applicable, measurable, and has been shown to be associated with a reduced risk of death and major complications in a range of clinical settings. The instrument suggests three phases: Sign – in, Time – out and Sign –out. The “Sign-in” is done prior to induction of anaesthesia and includes confirmation of patient identification, consent and site-marking as well as checks for allergies, assessment of difficult airways and anticipated blood loss. “Time-out” occurs just prior to the skin incision and serves to confirm the patient, site, procedure and position, the application of the surgical site infection bundle, the use of venous thromboembolism prophylaxis, the presence of the correct imaging, equipment sterility and the anticipation of any critical steps.

Prior to removal of the drapes, the “Sign – out” confirms the procedure performed and the instrument and swab counts as well as plans for post-operative management. These questions are a final check. They are intended to be usually a redundant step in the process identifying the few occasions when all other processes have failed to ensure the patient receives everything intended. This and the simple effect of knowing they are to be asked significantly improve the reliability of the clinical processes and may reduce complications by up to 50%. (Haynes et al. 2009)

Overview of the Elements of the Surgical Safety Checklist

Sign in

Before induction of anaesthesia, members of the team (at least the nurse and an anaesthetic professional) orally confirm that:

- The patient has verified his or her identity, the surgical site and procedure, and consent
- The surgical site is marked or site marking is not applicable
- The pulse oximeter is on the patient and is functioning
- All members of the team are aware of whether the patient has a known allergy
- The patient’s risk airway and risk of aspiration have been evaluated and appropriate equipment and assistance are available.
- If there is risk of blood loss of at least 500ml (or 7ml/kg of body weight, in children), appropriate access and fluids are available

Surgical Time Out

Before skin incision, the entire team (nurses, surgeons, anaesthesia professionals, and any others participating in the care of the patient) orally:

- Confirms that all team members have been introduced by name and role
- Confirms the patient's identity, surgical site and procedure
- Reviews the anticipated critical events
 - Surgeons reviews critical and unexpected steps, operative duration, and anticipated blood loss
 - Anaesthesia staff review concerns specific to the patient
 - Nursing staff review confirmation of sterility, equipment availability, and other concerns
- Confirms the prophylactic antibiotics have been administered at least 60 minutes or less before incision is made or that antibiotics are not indicated
- Confirms that all essential imaging results for the correct patient are displayed in the operating room

Sign Out

Before the patient leaves the operating room:

- Nurse reviews items aloud with the team

- Name of the procedure as recorded
- That the needle, sponge, and instrument counts are complete (or not applicable)
- That the specimen (if any) is correctly labelled, including with the patient's name
- Whether there are any issues with equipment to be addressed

The surgeon, nurse, anaesthetist professionally review aloud the key concerns for the recovery and care of the patient.

(The checklist is based on the first edition of the WHO Guidelines for Safe Surgery)

Wrong Site Surgery

Despite the various protocols and simplification of the checklist, an article in The Washington Post, 2011 suggested, as certain researchers and patient safety experts said; that the problem of wrong-site surgery had not improved considerably and may be getting worse, but no clear cut or strong evidence behind some of the assumptions. A Joint Commission on Accreditation of Healthcare Organizations (JCHAO) estimated that wrong-site surgery occurs 40 times a week in U.S hospitals and clinics. What seemed pretty straightforward in 2004, when the safety checklist was being rolled out in terms of implementation, now seems more complicated. Preventing wrong site surgery is a complicated procedure as it involves changing the culture of hospitals and getting surgeons, who typically would have prized their autonomy, resist checklists and underestimate their propensity for error – to follow standardized procedures and work in teams.

While some wrong-site errors inflict little or no injury, either because they are corrected early or did not involve major surgery, others are devastating. One example cited involved a jury returning \$20 million negligence verdict against Arkansas Children's Hospital for surgery on the wrong side of the brain of a 15 year old boy who was left psychotic and severely brain damaged. Testimony showed that the error was not disclosed to his parents for more than a year.

The scale of complication and/or frequency of same, vary within the different surgical specialties. Data from the National Health Service Litigation Authority (NHSLA) in 2006 revealed that the cost of settling wrong site surgery claims was over £1 million pounds in England alone (House of Commons Health Committee, 2009). NHSLA data also revealed that trauma and orthopaedics had the highest number of claims with 29.8% of the total compared with next speciality, dentistry at 16.8% (Cowel HR, 1998).

It is very important and researchers have shown that the way a surgical timeout is done and hence how it is performed makes a difference. All the participants, surgeons and rest of theatre staff need to be fully involved, and enthusiastic about the protocol, details that the protocol initially did not specify. Doctors who verify the site and procedure with patients prior to them being wheeled into theatre for surgery are less likely to make a mistake of wrong site surgery. In this day and age time pressures are always an issue and all the pressures are on the side of production, at times the increased pressure to turn over operating rooms quickly has been the main goal as opposed to patient safety, increasing the chance of error.

Morally and ethically it is imperative that surgical teams in charge of the patients care, pre, intra and post operatively commit themselves to this

simple and effective protocol. Patient consent forms a very important safety step, and which member of the team, timing and manner can help prevent a lot of error strewn cases. There are numerous litigation cases, such as negligence and malpractice suits, as expected after such adverse events.

Aim

The Question being raised for the purpose of this thesis and this topic is as follows:

“Has there been a significant reduction in the incidence of wrong-site surgery after the introduction of the surgical time-out?”

Chapter 2

Methodology

Key areas being looked at for this dissertation project:

- 1) Wrong site surgery, its implications and assessment of World Health Organisation's surgical timeout policy. To see whether significant changes have been obtained as far as reduction in wrong site surgery is concerned.
- 2) Consent – overview. The role of informed consent and its symbiosis with the entire surgical intervention, and link with wrong site surgery. To enhance a better understanding for the patient population involved.
- 3) A detailed review of an actual case report. To draw out various salient features, and highlight importance of consent, surgical time out and avoidance wrong site surgery.

Research methods used here are a mixture of a traditional qualitative review with some precise systematic review type approach to the data being gathered and analysed.

Literature review as a research methodology

Literature review is a summary of a subject field that supports the identification of specific research questions. A literature review needs to draw on and evaluate a range of different types of sources including

academic and professional journal articles, books, web-based resources.

“The search and review of the literature is a critical evaluation, analysis and synthesis of existing knowledge relevant to the research problem. It is an analysis in that you are required to extract different kinds of information from what you read. It is a synthesis to show the relationships that exist between different studies and show how these relate to research. Aiming of a literature review is used to assess critically what definitions of the topic or problem have been offered and how they have been used and to evaluate the methodological approaches employed and to identify gaps in empirical work and assumptions. A literature review is therefore not a summary, synopsis or series of annotations or a description of other people’s work” (Hart et al, 2005)

General Concept

As a researcher, one must become familiar with the topic at hand, adequate search strategies need to be devised, obtaining and reading as much material as possible, before being able to extract the relevant data and hence form an opinion for interpretation purposes. “A good literature search demonstrates the ability to search, identify and select materials relevant to the topic and which needs to be reviewed at an appropriate level. The key to a successful search are: planning, acquiring, retrieving, maintaining accurate records, selecting potentially useful items, including argument, data, theories, concepts and definitions. (Hart et al, 2001)

Search Phase

A number of papers, articles, were read through, of which 6 were chosen as being the main papers, which helped in coming to some form of conclusion in relation to wrong site surgery, surgical timeout and importance of informed consent.

The case report and its analysis was based on the actual review of the incident itself, personal choice of case, as it occurred just prior to surgical time out introduction as a mandatory step prior to operations. Plus it as a “local” case, in the city I currently work and practice in.

Search Method

Books, articles, internet and intranet analysis. World Health Organisation database, Cochrane review PubMed and Medline were used. National Patient Safety Goals and The Joint Commission Board of Commissioners reports were looked at as well. Medline – is a database of indices and abstracts from the National Library of Medicine (U.S), covering biomedical journal articles from approximately 4000+ journals. 75% of the citations are published in English, and database is updated weekly.

Key Words

Wrong site surgery, surgical time out, informed consent, surgical intervention, WHO time out proposal

Inclusion and exclusion criteria

Inclusion criteria are characteristics that the prospective subjects must have if they are to be included in the study, while exclusion criteria are those characteristics that disqualify prospective subjects from inclusion in the study.

Items looked at for criteria allocation were:

- 1) Language
- 2) Publication type
- 3) Date of publication
- 4) Content relevance
- 5) Study category and measure

Inclusion criteria:

- 1) Language – English
- 2) Full text / PDF publication
- 3) Date, time frame – within 20 years in relation to wrong site surgery and surgical timeout.
- 4) Content – related to keywords
- 5) Wrong site surgery and time out policy were the study group category and measure.

Exclusion criteria:

- 1) Language – any other than English
- 2) Publication type – abstract or unpublished
- 3) Date – more than 20 years
- 4) Content – no identifiable keywords.

Understanding and critiquing research papers

When it comes to critiquing research, various frameworks can be used as an aid. Some of these frameworks have been designed to assist in critiquing both qualitative and quantitative research data, which may raise the question of whether such frameworks can truly evaluate either when the background beliefs (philosophies) of the two worldviews (paradigms) are so different. Either way, personally, interpretative skills and certain bias will always play a role when collating such data especially from a qualitative background. Hence it is important to be able to articulate one's own viewpoints and simplify analysis as much as possible in order to obtain a broad spectrum answer.

Bray and Rees (1995) framework stated that the first task when evaluating and critiquing is to establish the general area the article covers which is the focus or theme. The focus allows the author to establish some expectations about the research and its content (Bray and Rees, 1995).

Bray and Rees (1995) – Critiquing framework

- 1) Focus – what is the topic or theme of the articles?
- 2) Background – What justification is given for choosing this topic, is there a reference to previous reports, studies and is there a trigger which explains why they did the study?
- 3) Terms of reference – Is there a hypothesis? What was the particular question they wanted to answer?
- 4) Study design – is it an experimental design where the author was looking for cause and effect relationship? Is it descriptive where the purpose to describe a particular situation? Or is it an

action based prospective research, where something new has been introduced into the provision of the services and then evaluated?

- 5) Tool of data collection – which method of data collection has been used and was it tested on a pilot study?
- 6) Ethical considerations – has confidentiality, informed consent, and harm versus benefit been considered? Was an ethics committee involved?
- 7) Sample – Is there and inclusion and exclusion criteria? Numbers involved, how were they chosen?
- 8) Data presentation – how does the researcher present the results, form factor, tables, figures, percentages?
- 9) Main findings – what are the results which relate to the terms of reference?
- 10) Conclusion and recommendations – Is the hypothesis accepted or rejected? What is the author's answer to the terms of reference? What recommendations are made?
- 11) Readability – simplicity, easy to understand and follow?
- 12) Implications for practice.

Methodology Conclusion

A strong case report has been selected, to use as an example of wrong site surgery, and detailed review discussed, followed by the various search criteria used to try and obtain adequate to the point papers, text, data to clarify an overall stance of the link between surgical time out and wrong site surgery rates, with an overview of surgical informed consent procedure, its importance and medical legal implications.

Chapter 3

Case Report

A case of wrong site surgery that happened here in Dublin, Ireland not too long ago will be used as an example to highlight the intricate culmination of events that can lead to such an unexpected, unintentional end point. Obviously for the patient, family and those healthcare providers who were doing their utmost to perform and make life better for their patient, such an event is a life changing episode and can impact hugely on both parties involved.

The actual case report for the events that unfolded will be used, the layout and transparency of it, and salient points shall be discussed. The concept of surgical timeout, and safe site surgery protocols and their relevance shall become clear, and the potential for avoiding such events.

Independent review report

“Investigation into the removal of the wrong kidney from patient XY at Our Lady’s Children Hospital Crumlin – this report details the review commissioned by the hospital, to mainly investigate the circumstances that lead to a wrong site nephrectomy being carried out on patient XY in the Spring of 200x.

The authors for this report were Mrs P Tallents (Acting Assistant Director / Patient Safety & Complaints Manager) and Mr. I Mushtaq (Consultant Paediatric Urologist) of Great Ormond Street Hospital for Children NHS Trust, London (GOS).

Summary of events

Following an outpatient clinic review, a patient, aged 9 was mistakenly listed for an elective left sided nephrectomy, when main disease pathology involved the poorly functioning right kidney. The patient was admitted onto the wards day prior to surgery and consent was taken from the parents for left sided nephrectomy. The operation was carried out the following day by an SpR (Specialist Registrar) in paediatric surgery who had not seen the patient previously. They had realised immediately the error of their surgery after the healthy left kidney had been removed, but it was not possible to revascularise it, and hence it was an irreversible problematic outcome.

Background

Patient XY had been under the care of a general surgical team at OLCHC (Our Lady's Children's Hospital Crumlin), which happens to be one of the three paediatric units providing surgical service to the patient population not only in Dublin but also surrounding counties. The general surgical department consisted of four consultant general surgeons (of which two worked in OLCHC on a full time basis), four Specialist Registrars (SpRs) and six Senior House Officers (SHOs).

Terms of Reference

The report was commissioned by L Bristhistle, Chief Executive Officer of OLCHC, on behalf of the hospital's Board of Management, in April 2008. An independent review team was established at Great Ormond Street Hospital in London, aided by a mixture of risk management and clinical expertise.

The formal terms of reference of the review were as follows:

1. Examination of events, circumstances current and historic at OLCHC pertaining to the wrong site surgical removal of the left, healthy kidney from the patient.
2. Verification to their satisfaction that the internal preliminary review report was a comprehensive record of the various factors and circumstances which resulted in the error.
3. Examination of set protocol and procedures in place at OLCHC for carrying out this particular type of surgery taking into consideration prevailing standards of best practice.
4. Root cause analysis to be undertaken of the incident.
5. To be able to make positive recommendations post root cause analysis and review of reports to the hospital, with the main aim being the avoidance of any repetition of such an event in the future.
6. Report was to be completed by 1st September 2008 (within a 5month time frame from initial commencement).

The external review group was given access to all documentation which they had considered necessary and important to complete their task at hand and were entitled to interview all personnel as they deemed appropriate.

OLCHC's Clinical Risk Manager provided extensive support to the review, by coordinating interviews, providing documentation and facilitating contact with the family. The review team was chaired by Ms Tallents and administrative support was provided through Great Ormond Street Hospital's Patient & Staff and Urology departments.

Investigation type & evidence

Documentary evidence was provided in advance by the hospital in response to certain requests by the review team. These included clinical information about patient XY, formal statements from staff, relevant policies and procedures, and data about the general surgical service.

The review team conducted interviews over four dates in May and June 2008 with staff who were directly involved, to obtain factual information about their involvement and to understand the clinical environment and practices relating to the incident. Visits were made to a selection of clinical areas. Comments were also obtained from a number of clinicians and managers who were not directly involved, to obtain their feedback and views on the incident.

Involvement and support of the family

Ms Tallents and Mr Mushtaq met with Patient XY's parents in June 2008. Prior to this meeting the review team had received information

about a previous meeting between the family and OLCHC staff. This included a summary of the questions and concerns raised by the family about XY's care. The present report aims to answer those points which relate to the circumstances of the wrong – side operation.

The review team had acknowledged that OLCHC will continue liaising with the family following the report to provide assurance to them that the hospital has learned and taken action as a result of this incidence involving their child, and to answer any additional questions about XY's care that may ensue.

Involvement and support provided for staff involved

The staff principally involved were interviewed on at least one occasion. Support was primarily provided to them by OLCHC, from their immediate colleagues and senior members of staff. The review team endeavoured to make the investigation process a clear and transparent one, emphasising the systems focus of the review, and asking staff for their constructive suggestions about the system changes that the hospital should consider.

The review team acknowledge that OLCHC will distribute this report to the staff involved and may find it helpful to arrange debriefing sessions. There will be ongoing contact and support from hospital management for the specialty teams involved, during the action planning, implementation and audit phases that will follow these recommendations.

Chronology of events

A detailed chronology of events was prepared by the review team, based on the documentary evidence and interviews. The chronology is not included in this report as the level of detail it necessarily contains would conflict with the family's request to keep the details of their child's care confidential.

The chronology incorporates a list of Care and Service Delivery Problems, which can be defined as follows:

Care Delivery Problems are usually actions or omissions by members of staff in the process of providing care, where care has deviated beyond generally accepted safe limits of practice. Service Delivery Problems are usually failures associated with the way that a service is delivered, and the underlying procedures and systems in that service.

Notable practice

Before discussing these problems, the review team would like to acknowledge the good practice which staff demonstrated at specific points in XY's care:

1: The consultant attempted to arrange a multidisciplinary discussion of the plan for XY, including a review of bladder function, in the window between the outpatient review and admission date.

2: On transfer to theatre, the ward nurse handed over to the receiving nurse a concern expressed by the parents about the side of surgery. The receiving nurse immediately contacted her manager and obtained help from the SpR, who came to talk with the parents.

3: The multidisciplinary team in theatre responded rapidly and proactively to the incident as soon as it was realised. Help was sought from appropriate experts within the hospital and from a specialist transplant team based elsewhere in the city. Consultants, SpRs and SHOs in the general surgical team became involved to support the team in theatre and to complete the operating list to ensure that other patients' care was not affected. The actions to try and rescue the situation were prompt and appropriate, but unsuccessful.

4: There was a prompt discussion with the family in which the consultant was open about the error, giving an immediate apology and taking responsibility for what had happened.

5: Patient XY's parents commented that care in the hospital since the incident had been "second to none".

Contributory factors

The chronology and Care / Service Delivery Problems were analysed to indicate the Contributory Factors to this incident occurring.

Contributory Factors are systemic practices or circumstances which affect the performance of members of staff, thereby having a negative effect on the delivery of safe and effective care, and the likelihood of problems occurring.

The review team identified ten principal Contributory Factors which are discussed below.

1. An incorrect imaging report from six years earlier had not been identified and corrected.

2. Delays in filing hard copy x-ray reports in the medical records, and lack of reference to an electronic copy.
3. There was no failsafe system to ensure that a patient undergoing removal of a major organ was discussed in a multidisciplinary setting, as the consultant had intended.
4. Patients are regularly admitted outside normal working hours.
5. Radiology is not normally sent to the ward or to theatre.
6. Formal consent is generally taken by surgeons who are not competent to perform the procedure.
7. The person taking consent for a procedure will not normally review imaging.
8. SpR hours and workload, and concomitant lack of planning for cross-cover.
9. The hospital has no site marking policy, or common practice.
10. The operation and planning of the parallel theatre list.

1: An incorrect imaging report from six years earlier had not been identified and corrected

Patient XY had had an MCUG (micturating cysto-urethrogram) six years previously, which had shown minimal reflux in the right ureter. The formal radiology report stated that the reflux was on the left side.

This report appears to have formed the basis for the error in the medical records that there was a left sided abnormality, although the true right sided problem was also documented (see below). The radiology

department commented that it would not be possible for all reports that indicate laterality to be double checked.

There were subsequent radiology studies which all showed that the patient had a right sided kidney abnormality - for example, two ultrasounds in 2005 and a further ultrasound in 2007 were all reported to show a scarred right kidney. The discrepancy was not noted or corrected within radiology or by one of the clinicians who saw the patient over the following years.

2: Delays in filing hard copy x-ray reports in the medical records, and lack of reference to an electronic copy

In Patient XY's case, several months had passed since the ultrasound and DMSA scan which confirmed that there was an abnormal right-sided kidney, but the formal reports for those studies were not in the medical records.

The usual process is that once a formal report is issued by the radiology department, one copy is filed in the x-ray packet and a second is sent to the requesting consultant. The consultant signs the report, takes any necessary action, and passes it to his secretary for filing.

The review team were not able to establish exactly where in this process Patient XY's report had been 'lost' for six months (the period between the studies and admission for surgery). Medical Records staff commented that it can be difficult for administrative staff to access the records library. The Clinical Risk Group acknowledged that the hospital does not yet have a robust process for formal x-ray reports being reviewed, signed off, actioned and filed in a timely way.

To mitigate against this, radiology reports can in the interim be viewed on a computer, although this was not done in Patient XY's case when they were listed for surgery (in outpatients), or clerked and consented on admission to the ward.

It was not clear from the investigation whether Patient XY's x-ray packet was present in clinic when they were listed for surgery, although staff did not generally express concerns about non-availability of x-ray packets in clinic. However the consultant would not have had a computer in the clinic room to look up the radiology report. There is one computer at the nurses' station in outpatients, shared between five clinic rooms.

3: There was no failsafe system to ensure that a patient undergoing removal of a major organ was discussed in a multidisciplinary setting, as the consultant had intended.

After clinic the consultant planned to initiate a multidisciplinary discussion around XY's radiology, and wrote to a consultant radiologist to ask for a comment about the bladder, but a reply was not received and a discussion did not take place before XY was admitted for the operation.

If these discussions had taken place, they may have led to further radiology review, an opinion from a kidney specialist, and a view on the extent to which XY's bladder function may have been contributing to the problems. This would have helped to confirm the indication for the procedure and also given an opportunity to list the patient for the correct sided procedure. The consultant felt that the reason the discussion did not happen was partly due to the operation date being brought forward by approximately 3 months. However there was no system in place to

ensure that this triggered an earlier discussion, or to defer listing the patient until after the discussion had taken place and the indication for surgery was re-confirmed.

4: Patients are regularly admitted outside normal working hours

Patient XY arrived at the Admissions Department at around 16:00 and was admitted to the ward at around 16:30. The ward attempted to bleep the daytime SHO but without success, and instead contacted the SHO who was on-call for the evening. He attended the ward at around 16:45 to clerk and consent Patient XY.

This means that XY was in fact admitted within normal working hours, but seen by an on-call SHO. The surgical team raised concerns about the high proportion of patients admitted outside working hours, which the review team felt would be helpful to include in the report.

General surgical patients are not pre-admitted or pre-clerked. Elsewhere in OLCCHC, the cardiac team offer a pre-admission service, although the Clinical Risk Group commented that this presents logistical difficulties given the national catchment area, as patients and families may have very long distances to travel.

A number of staff stated that as many as half of elective general surgical patients are admitted after normal working hours (definitive data was not seen by the review team). This would mean that they are not seen by a member of their consultant's team, but by another general surgical SHO, or possibly an SHO from a different specialty altogether who is cross-covering.

The Admissions Department confirmed that it is normally only possible to confirm a patient's bed on the day of admission, once the wards have confirmed their bed occupancy. This was reportedly influenced by the admissions of non-elective patients coming through A&E, or emergency transfers from other hospitals. The Clinical Nurse Manager of the ward where Patient XY was admitted quoted a bed occupancy rate of 88%. Late notice of which ward a patient will go to was also a factor in the radiology department's decision not to release x-rays for inpatients.

The effect of this system is that a patient admitted after hours is unlikely to be reviewed by a member of his / her consultant's team until the morning of surgery, or to be seen by a surgeon who is competent to perform the operation. There is a theoretical thirty-minute window the following morning for a more senior member of the team to review the day's patients, and address any discrepancies in the admission or consent process, before the morning theatre list starts. This makes it impractical for a doctor who has not previously seen the patient to familiarise him- / herself in depth with the history and planned procedure.

5: Radiology is not normally sent to the ward or to theatre

Patient XY was clerked and consented for a left nephrectomy without access to the imaging, and it was not available on the pre-operative morning ward round. It was brought to theatre after Patient XY had arrived at the reception, by a second SpR who knew from experience that it would not be there already.

The radiology department ceased sending inpatient x-rays to the Admissions Department (and thence to the ward with the patient) around three years earlier, as an attempted solution to difficulties in the tracking

and reporting of films. X-rays are stored instead in a trolley in the radiology department and are not delivered to any wards. They are delivered to theatre for one of the four consultant general surgeons (not Patient XY's consultant), who had stipulated that his patients would not be allowed into theatre unless the imaging was there. The radiology department accommodated this, but the same service was not requested by the remaining three consultants. If one of these other teams required x-rays in theatre then one of the junior surgeons would go to fetch them. The patient may have been anaesthetised by this point.

There was general agreement amongst the junior surgeons that this works reasonably well in that if they go to radiology they can find the x-rays that they need; and clinic staff reported excellent availability of xrays in outpatients. The onus is on medical staff to collect imaging if they feel it is needed for an individual patient, and in practice this seemed to happen infrequently. It should be noted that patients are generally clerked and consented by SHOs who would not be expected to review x-rays.

6: Formal consent is generally taken by surgeons who are not competent to perform the procedure

Patient XY, who was having a major procedure, was clerked and consented by an SHO who was not competent to perform the operation, and who obtained consent on the basis of what was written in the notes. This would be normal practice within the department, although the majority of surgeons indicated that the formal radiology report should also be reviewed at this point.

The Clinical Risk Group (CRG) advised that there had been discussions over a period of some years with the HSE and CIS regarding responsibility for consent. One outcome was that it is acceptable for consent to be obtained by someone who is competent to take consent (presumably trained in the general principles of consent in paediatrics and able to conduct an adequate discussion of the procedure), but does not have to be personally competent to do the procedure.

In practice this appears to fall to SHOs in the majority of cases. The review team did not explore what in-house training is offered to SHOs (and SpRs) in how to obtain formal consent for specific procedures. The hospital's consent guidelines for staff indicate that the person obtaining consent must understand the treatment and its risks, and be able to answer any questions that the parent has.

SHOs would not be expected to review imaging at the point of taking consent, as it is felt that they lack the experience to interpret it.

The review team acknowledge that the volume of work, the numbers of junior surgeons, and difficulties in admitting patients within working hours may make this a reasonable and pragmatic approach at the present time. It must also be stated however that this approach falls short of accepted best practice in consent.

In XY's case there had also been discussions between the family and the consultant surgeon (in outpatients), the anaesthetic SpR, and the surgical SpR. These would all contribute to a formal consent process, although they were not documented as such, for example by use of a consent form, and did not include a review of imaging.

The CRG also alluded to a change in practice within the hospital that formal consent for the procedure would be initiated in outpatients, and

the admitting junior doctor would only need to take consent 'for admission'. As indicated above, the consultant had had some discussion with XY's parents in clinic, but formal consent was not sought. The review team noted a perception amongst the team that the consent form 'expires' after an amount of time - quoted as two weeks by one surgeon, and two months by another.

The hospital's consent guidelines confirm that there is no legal guidance on the length of time that consent is valid for. The guidelines state that if formal consent has been obtained in outpatients, and the patient's condition has not changed so as to affect the nature, purpose and risks of the procedure, then a confirmatory discussion should be held when the patient is admitted.

If the formal consent process were to be genuinely started in outpatients, this would accord well with the good availability of imaging in clinic, although the significant workload of clinics (25-35, rising to 40, patients in a half-day clinic) may make it difficult for the consultant or SpR to allow time for an in-depth discussion with the parents.

From the interviews with surgical staff there were different interpretations of the in-house rules. It was commonly felt that an admitting SHO would take consent for the procedure if they were confident about what to discuss, but if not they would take 'consent for admission'. 'Consent for admission' was thought to be rare amongst the general surgical SHOs, but more likely if a non-general surgeon was covering the general surgical patients. The junior surgeons did not appear to check whether someone more senior had already initiated the consent process in clinic, which may be because this is not common practice at the moment.

If the admitting SHO was not able to obtain consent for the procedure, they may either contact the oncall SpR, or defer it for the ward team to complete the next morning.

7: The person taking consent for a procedure will not normally review imaging

In patient XY's case the imaging was not reviewed at any stage:

In clinic at the point of listing for surgery; At the point of clerking and taking consent; On the pre-operative morning ward round; In response to the parents' queries about the operation side.

In addition the imaging was not reviewed in theatre prior to positioning XY for the procedure or making the incision, and intra-operatively when the kidney was noted to have a healthy appearance.

This relates closely to the above discussion about who obtains consent. As discussed, the way in which the hospital's consent process is structured makes it unlikely that the person obtaining formal consent will be competent to review x-rays, and neither are the films readily available on the ward. Discussions in clinic are not universally treated as part of the formal consent process and it is not stipulated that radiology should be examined at that point. The surgical team were all in agreement that the imaging should have been reviewed at the start of the procedure which is standard surgical practice. It appears that responsibility for this was not taken partly as a consequence of the late handover of the case.

Interestingly though, comments were also noted from some members of the team about reaching a certain level of confidence or seniority as a surgeon, when it is less likely that you will need to check the imaging; or

that it may only be checked if there are any doubts or 'alarm bells' about the operation. Some surgeons indicated that it was only essential to look at the imaging for procedures where the abnormality cannot be seen from outside the body (eg pyeloplasty, nephrectomy). The investigation revealed that it not uncommon practice to rely on radiology reports as a substitute for the images.

8: SpR hours and workload, and concomitant lack of planning for cross-cover

Patient XY was under the care of a consultant general surgeon whose usual SpR was on planned leave for a week. It was agreed amongst the remaining three SpRs on the morning of XY's surgery that one of them would 'cross-cover' the consultant's theatre list for that day. The SpR had been out of the hospital the previous afternoon, and had not reviewed the list (it would not be normal practice for the SpRs to review a theatre list that they are cross-covering, as they generally would with their own consultant).

There are four general surgical SpRs, each attached to one of the four consultants. Some of these jobs are acknowledged to be busier than others, as only two of the consultants are based full-time at OLCCHC.

It was noted by several clinicians that once annual and study leave is factored in, the SpR rota is closer to a '1 in 3' than a '1 in 4' rota. The SpRs record the hours that they work, and reviewing their diaries for January-April 2008, the average working week where an SpR was not on-call was approximately 73 hours; an on-call week was approximately 107 hours. An on-call weekend would usually run from Saturday morning

to Monday evening (approximately 56 consecutive hours of live-in on call), including elective operating lists on Monday.

When one of the SpRs is on leave, it falls to the remaining SpRs to arrange cross-cover for the four consultant teams. There did not appear to be a universal process whereby the consultants reduce their clinical workload on days that SpR numbers are reduced.

It is usual for the SpRs to negotiate cross-cover between themselves, at short notice – sometimes negotiating throughout the day to ensure that all commitments are covered. It was generally agreed that it is usually possible to anticipate which SpR will cover which clinics / theatre lists, as the team are familiar with each consultant's day-to-day commitments, and each other's workload. This makes it feasible for an SpR to know in advance that s/he will be covering for another team's patients on the following day. However this does not appear to be explicitly agreed until the day in question and there is no time allotted to work up these patients.

The team are accustomed to helping each other out in this way and it is important to acknowledge the positive aspect of close team working, with the flexibility and personal commitment to the service that it implies. Some surgeons also noted that the pressurised nature of the role has a positive aspect in terms of the amount of operating experience that the SpRs get.

The weakness in this approach for the cross-covering SpR is that it does not allow time for planning, communication and preparation. Consultants would lack assurance that they are working with an SpR who has had an opportunity to familiarise him / herself with the patients.

The consultants may not be aware of which SpR will be working with them on a given clinic / operating list if their usual SpR is away. The patient 'work-up' (review of casenotes) and conversations about an operating list which would normally take place at least the day beforehand between a consultant and his SpR, do not appear to take place when the usual consultant + SpR team is changed. If an SpR is away for more than one day there may be no continuity between the different SpRs who step in to cover that team's patients, day by day. An SpR cross-covering another consultant's theatre list - as in this case - may not have any knowledge of individual patients before the day of surgery.

9: The hospital had no site marking policy, or common practice

Patient XY was marked in the theatres reception by the SpR, in the presence of the parents, on the basis of a review of the medical records (but not imaging).

At the time of the incident, OLCHC had no formal or universal process to confirm the pre-operative checks that should be made to confirm that the correct patient was having the correct procedure, and on the correct side. It was essentially at the discretion of the general surgeons to formulate their own practice, based on internationally accepted standards.

There was a general consensus amongst the surgeons that site marking should take place, although feedback from clinical staff suggested variable practice.

It was noted by more than one consultant that they would expect site marking to be done when the patient was clerked and consented, ie on

admission to the ward, normally by an SHO. This would mean that site marking could not be done with reference to radiological imaging, as SHOs are not felt to have the experience and competence to review imaging, and it would not usually be present on the ward.

Between SHOs, practice appeared variable. One SHO said that he would mark the patient on the basis of x-ray reports and correspondence that confirmed the side. Another said that he would not mark for any procedure that requires a review of x-ray images to confirm site / laterality.

Ward and theatre staff commented that in their experience patients may not be marked until arrival in theatre. It would not be unheard-of for a patient to be marked after they have been anaesthetised and positioned for the procedure.

10: The operation and planning of the parallel theatre list

Patient XY was on a 'parallel' morning list, running simultaneously in Theatre 5 and Theatre 7. The SpR was working in Theatre 7 and the consultant in Theatre 5. After the first few patients there was a pause in between patients coming to Theatre 7, and the SpR went to Theatre 5 to see how he could assist. He helped to prepare and position Patient XY, now anaesthetised, for the operation. The consultant asked him if he would like to do the case. A nephrectomy was within the competence of the SpR, although he had never performed one completely unsupervised, and was handed the case at short notice.

This weekly 'parallel' list in Theatres 5 and 7 is supervised by a single consultant general surgeon who will operate on some patients himself, and provide varying levels of supervision to the SpR and SHOs who are

assisting him and / or undertaking their own cases (depending on their competencies). The two theatres are physically distant from each other in the theatre complex. The list contains a mix of privately- and publicly-funded patients, and must also accommodate recent emergency admissions - there is no separate emergency theatre.

Both theatres will normally begin with day cases. The list order is generally coordinated by senior theatres staff who have significant autonomy to decide which patient should go to which theatre, in discussion with the wards. The consultant will become personally involved in deciding when to call for the major cases on the list (like XY), who would tend to come to Theatre 5 where he is based. Overall the decisions about patient order coming into both theatres are made on an ongoing basis throughout the list.

This means that the surgeons may have no advance knowledge of which patients they will personally be operating on. There is no formal briefing at the outset of the list (or the day before, as had been the practice with one consultant, since retired), or at the start of each case. It is possible to see the approximate shape of a list at least the week beforehand from the theatre diary, but it is not universal practice for the consultant / SpR teams to brief themselves this far in advance. The consultants would not always allocate specific patients to an SpR beforehand; the comment was made by more than one SpR that it would not be unusual for them not to know in advance which patients they would be taking on a particular list.

The list in question had 15 elective cases booked, which would appear to be on the upper side of normal for this consultant. Completed lists for the previous four weeks were reviewed to indicate the usual numbers of patients (case complexity not reviewed): 11 booked (9 completed + 2

emergencies = 11); 10 booked (9 completed + 1 emergency = 10); 16 booked (11 completed + 1 emergency = 12); 13 booked (13 completed + 4 emergencies = 17). The review team were provided by data from theatres, looking at the same parallel list but over a different four week period (September 2007). This data indicated that collectively Theatre 5 and Theatre 7 over-ran their allotted time with 8 elective and 2 emergency patients over the course of the month. Several clinicians felt that these lists are particularly demanding.

The review team found significant disagreement between staff about whether the parallel lists are valuable for their flexibility and efficiency, or unsafe for their lack of consultant supervision.

The head of department felt that without parallel lists the department would not be able to keep pace with its service commitments. Theatre staff reported that theatre usage was at 95% and the average turnaround time between patients was two minutes. In terms of safety, the consultants give cases to individual juniors based on what they knew of their competencies and experience; none of the juniors indicated that they were given cases they felt personally unable to complete.

The case of Patient XY illustrates the risks of this working practice, in that it did not seem unusual for a major case to be handed to an SpR with little advance warning, the patient anaesthetised, no assistant, and no subsequent supervision.

Root causes

Based on the above ten Contributory Factors, the team felt that eight of these could be considered as Root Causes of the incident.

A Root Cause can be defined as the initiating cause in a causal chain which led to the incident being studied. It is commonly used to describe the point at which an intervention can reasonably be implemented to prevent a recurrence of the incident.

1. Delays in filing hard copy x-ray reports in the medical records, and lack of reference to an electronic copy.
2. Patients are regularly admitted outside normal working hours.
3. Radiology is not normally sent to the ward or to theatre.
4. Formal consent is generally taken by surgeons who are not competent to perform the procedure.
5. The person taking consent for a procedure will not normally review imaging.
6. SpR hours and workload, and concomitant lack of planning for cross-cover.
7. The hospital has no site marking policy, or common practice.
8. The operation and planning of the parallel theatre list.

Recommendations are included later in this report for system changes that would help in resolving each of these Root Causes.

The review team felt that two of the Contributory Factors would require further analysis to reach the associated Root Causes, although OLCHC may feel that changes in practice can be implemented at this stage, based on existing knowledge of the service:

1. An incorrect imaging report from six years earlier had not been identified and corrected.
2. There was no failsafe system to ensure that a patient having a major procedure was discussed in a multidisciplinary setting.

The review team acknowledge that many of the clinicians who were interviewed felt that the heavy caseload for the general surgery team, considered against the number of paediatric surgeons in the hospital, was a Root Cause to this incident. The review team understand that there have been discussions with the HSE over a period of several years about consultant numbers in the service. Data was provided which indicated an increase in the number of paediatric surgery referrals to the hospital over the last three years, and an increase in the quantity of surgery to be performed, within the same staffing resource.

It was outside the remit of this review to analyse the relationship between referral patterns, work practices and staffing levels in the department, not least as this has a city-wide and a national dimension, but the team wished to acknowledge the prevalence of this view amongst the clinical staff.

Review of a previous 'near-miss' event

The Terms of Reference (point 1) required the review team to examine 'all the circumstances current and historic' that related to the incident. This was achieved through the interviews and documentary evidence, which elicited detailed information of the working practices and systemic challenges that contributed to the incident.

On the review team's second visit to the hospital, the Chief Executive drew a previous near-miss event to our attention. Seven years earlier a patient booked to have a left-sided procedure had had a rightsided incision made. The error was noted at an early point in the procedure and the correct procedure was performed.

A limited review of this case was undertaken, consisting of: examination of the medical records; and written questions to three of the staff members who were involved. A summary of the clinical features of the case has been provided to the hospital separately to this report to preserve patient confidentiality.

The rationale for not undertaking a full review was in consideration of the passage of time with its effect on individual memories, and intervening changes in hospital systems; and the limited additional learning to be gained for those reasons. The review team felt that the Root Cause Analysis of the incident involving Patient XY would provide sufficient and relevant learning to the hospital. It should also be noted that it is usually considered discretionary to undertake a Root Cause Analysis for an event like this which could be considered a 'near miss'.

It can be noted that Patient Z was admitted and consent was obtained for the correct procedure. The error occurred in theatre after the patient was placed in a prone rather than supine position. The case was performed by a consultant surgeon, not an SpR or SHO.

In terms of Root Causes which are common between the two incidents, one member of staff recalled that Patient Z was site-marked shortly before the incision was made, but another member of staff recalled that they were not site-marked at all. In either case, they had not been site-marked on the ward at the point of clerking and obtaining consent.

It is not known whether the patient's imaging was available on the ward when they were admitted; this incident occurred before the radiology department stopped sending imaging to the wards. It was not clear from the statements obtained whether the radiology was available in theatre, and whether it was reviewed before the patient was positioned and marked.

The incident was discussed at the general surgical team's Audit (Morbidity & Mortality) meeting, where the importance of site marking was emphasised and it was agreed that the site of surgery should be marked. It is not clear whether any supporting practices were put in place. The incident does not appear to have been formally reported. Incident reporting using an incident form was actively in existence in 2001. Incidents requiring action were reported to the Senior Hospital manager and all incident reports were reviewed by the hospital insurers. However formal structures such as a Clinical Risk Manager, or incident database were not available.

The review team have therefore made a further recommendation that the hospital examines its incident reporting systems to ensure that there is clearer communication and accountability for following up clinical incidents within specialty teams, including 'near misses' which illustrate significant threats to patient safety. The culture and structure of risk management in the hospital have no doubt evolved, but by current standards it would not be adequate for an incident of this nature, with systemic implications, not to be reported and discussed more widely.

Recommendations

The review team made eight recommendations for areas of practice that the hospital should consider changing, to counter the Root Causes that led to the wrong kidney being removed from XY.

1: The hospital should review its radiology systems with a view to introducing PACS (Picture Archiving & Communications System). PACS enables radiological images to be stored electronically and viewed on screens, creating a near filmless process. If this is not achievable, or in the intervening time before it is introduced, the review team recommend that imaging should be physically present at all points in the patient's journey where a clinician is expected to take formal responsibility for site marking (see recommendation 4), and in theatres. Regardless of the system that is introduced, there should be ongoing and consistent leadership from all consultants that it is not acceptable to rely on imaging reports or the content of medical records as a substitute for images. Consultant staff should model best practice for their junior colleagues in order to achieve a cultural change in the team.

2: The hospital should give consideration to extending the system of pre-admitting patients into general surgery.

3: The hospital should implement a process for initiating formal consent in outpatients, when patients are seen by a clinician who is personally competent to do the procedure and review the imaging, which is more likely (under the present system) to be available at that point. The process should also include a clear standard for the follow-up discussions to be held by the more junior staff who will admit the patient, from any specialty, and describe the circumstances in which the SpR on-call should be contacted, rather than deferring discussions until the following morning where there are significant time pressures. The hospital should consider stipulating that patients who are being admitted

for major cases the night before must be re-consented by someone who is competent to perform the procedure and review the imaging.

4: The hospital should introduce a correct site surgery policy, to establish best practice at all the relevant points in the patient's journey, from outpatient review to the point of making the incision in theatre. This policy should take account of recommendations 1 and 3 above. The review team acknowledge that patients are generally admitted to the ward by surgeons who are not considered competent to review imaging. If review of imaging is required in order to safely complete consent and site marking procedures, the hospital should consider stipulating that a more senior surgeon is called to the ward. If this is not achievable then the hospital should ensure that all of the other stages in the site marking procedure are robust enough to counter the risk of an inexperienced surgeon marking the incorrect side - or failing to mark the side - when the patient is admitted.

5: The hospital should introduce formal diary monitoring of junior surgical hours in accordance with the requirements of the European Working Time Directive, and in liaison with the appropriate external agencies ensure that the results are factored into ongoing workforce planning.

6: The general surgeons should introduce team briefings at the outset of each theatre list where the day's patients are reviewed, and the list order is indicated per theatre (for parallel lists), and conduct a 'surgical pause' at the beginning of each case.

7: The general surgeons should introduce weekly SpR planning meetings to agree cross-cover and plan elective work. These plans should take into account the time that will be needed to work-up patients with whom the SpR would not otherwise be familiar until the day of

surgery. The consultants should be informed of the arrangements and ensure that they discuss their elective lists with cross-covering SpRs, in the same way as they would discuss the lists with their usual SpR.

8: The hospital should ensure that risk management processes are embedded within clinical teams, for example by establishing a clear link between specialty Morbidity & Mortality meetings and central risk management systems. The hospital has consultant sessions dedicated to risk management which is excellent practice and this role could be used to create and promote such links.

Implementation of the recommendations All of these recommendations will require a detailed implementation plan, including an audit program which can deliver sensitive measures of progress and also any barriers to change. The review team have not proposed implementation plans as it will be important for the senior clinical and managerial staff at OLCHC to review these recommendations within the hospital. Some elements of the report may require wider discussion with external agencies.

It is the responsibility of OLCHC and their stakeholders to bring a risk assessed approach to bear. If it can be objectively demonstrated that a recommendation can not be implemented, it is at the discretion of OLCHC Board to agree a reasonable alternative course of action.

If a decision is made to restrict implementation of any of these recommendations to individual specialties in the first instance, a plan should be created for roll-out to other areas at an appropriate interval.

Sharing arrangements

This report and its appendices will be issued to OLCHC. The review team anticipate that it will be shared in full with Patient XY's family, and recommend that it is also shared with all the staff who were involved in the incident, and contributed to the investigation. Further sharing and circulation of the report will be at the discretion of the OLCHC Board, and to fulfil the hospital's accountability to the wider health community.

Acknowledgements

The review team acknowledged that the hospital has been extremely supportive of the review at the most senior level, and has proactively shared information and analysis of the events. It was clear from the outset that the hospital was keen to learn from this incident and had begun work immediately to identify system changes. All staff were open and responsive to the review team's questions, and must be thanked and commended for this." (Case Report - OLCHC, 2008)

At the time of the case and the report, the concept of surgical timeout and implementation had not occurred in Ireland as of yet, that does not mean such an event should be accepted or taken lightly, but it highlights the importance of a surgical timeout prior to any significant or small case being undertaken. With current set ups in surgical units, consent is taken by a senior member of the team, someone who has the appropriate knowledge about the procedure and who would ideally be performing the operation. Imaging as mentioned in the report, is of utmost importance, and would be reviewed, re-reviewed numerous times prior to such surgery in common practice. Multidisciplinary team meetings are held prior to such elective cases, where surgeons, not only those directly

involved but the entire unit would be present, including radiologists, oncologists and pathologists. Case data is talked through and imaging reviewed, with planned operation discussed and agreed upon by those present in the room, this has become the “Gold Standard” of approaching such cases and is part and parcel for the set ups at this point in time.

It was interesting and necessary to see the working hours being mentioned, and although European Working Time Directive (EWTD) has been attempted in relation to its implementation here in Ireland, it still is not being delivered upon, even to this day at all levels of the surgical team. For example to ensure you can accommodate the limited hours (a 48 hour week for instance), you need to have enough doctors to fill those roles, at a more senior level, senior registrar or specialist registrar levels, 100 hour weeks are still quite a normal accepted thing, especially in the surgical practice. Fatigue may not have been an issue as far as the SpR involved was concerned for this case, but it is clear the lack of extra numbers of colleagues, being handed over a case at the last minute and at the time lack of surgical time out intervention, such a mistake was allowed to occur.

The surgical time out would not have guaranteed a safe and error free operation, but would have ensured, particularly in this type of a scenario, the right procedure, to correct operation to be carried out. It is morally an obligation nowadays and an ethically right decision to participate in a timeout procedure to ensure patient / parent satisfaction, safety and also covering the healthcare teams from devastating repercussions and medicolegal litigations.

Chapter 4

Consent

“Informed consent is a legal term supported by jurisdiction and international laws and is described as a “voluntary authorization, by a patient or research subject, with full comprehension of the risks involved, for diagnostic or investigative procedures, and for medical and surgical treatment” (year introduced : 1973).

Daily surgical practice involves increased complexity of operative procedures, while time pressure on the staff / team involved continues to increase. Moreover, a patient today tends to demand more extensive information from his / her doctors. Relaying these complicated processes must be legally sound. One way to cope with these developments is to optimize patient education to surgical informed consent.

Background History of Surgical Informed Consent

In medieval times doctors asked for a “hold harmless document” aimed at releasing them from any future responsibility to the patient or family in the event anything adverse happened following therapy. This *pro corpore mortuoto* can be found in Italian, French, and Middle East archives as early as the 14th century and is considered an early precursor of informed consent, although its purpose was to protect the doctor and not the patient.

Some bizarre landmark cases may be identified and are worth mentioning in the present overview. In the 18th century, a patient sued

his doctor for refracturing his leg and experimenting with a novel external fixating mechanism without informing the patient or obtaining approval. This 1767 Slater vs. Baker and Stapleton trial was the first example of an informed consent case. The concept of informed consent was used in an 1845 novel by Edgar Allen Poe. A patient was asked for permission for an experimental therapy just before his death (Altschuler et al. 2003)

The fundamentals of today's practice of surgical informed consent gained more structure at the beginning of 20th century, especially after the development of anaesthesia and more invasive surgery. In Mohr vs. Williams in 1905, a woman agreed to an operation on her right ear. However, during the operation the surgeon found her left ear in the need of a repair. He was subsequently sued and convicted because he had not proceeded according to the preoperative agreement. The judge called this agreement a contract that authorizes the physician to operate only to the extent of the consent given. In Schoendorff vs. Society of New York Hospital in 1914, Justice Benjamin Cardozo became famous for his judgment in the following case. A woman had consented to an abdominal examination under anaesthesia but not to an operation. Nevertheless, the surgeon removed a tumour that eventually led the patient to file a law suit. Cardozo's opinion has become one of the most basic elements in the concept of consent development: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body, and a surgeon who performs an operation without the patient's consent commits an assault for which he is liable in damages" (Armstrong et al, 1997). A patient should be as a person who has the right of bodily self-determination viewed.

After the Second World War, there was an intense public reaction to the brutalities carried out by Nazi concentration camp "doctors" who performed repulsive tests on "patients" without former information or regard. A code was composed as an immediate aftereffect of the Nuremberg trials (U.S.A. versus Karl Brandt et al.). This "Nuremberg Code" was a critical stride in the advancement of the informed consent inclusion in trials. It comprised ten preconditions any human research study needed to complete. Interestingly, the first legislative direction for informed consent trials began in Germany and was composed in 1900. Later on in 1964, The World Health Organization devised the Declaration of Helsinki with 22 preconditions for human examination. The 1957 case Salgo versus Leland Stanford, Jr. College Board of Trustees presented the term "informed consent" and this term was acknowledged in Natanson versus Kline in 1960.

At the same time, a development occurred in the domain of "information." The 1957 UK case Bolam vs. Friern Hospital Management Committee focused on which risks should be discussed with a surgical patient. This doctor-centered view resulted in a reasonable standard: Any surgeon should tell what other surgeons also tell their patients, a principle known as the Bolam principle (Armstrong et al, 1997). However, the 1972 Canterbury vs. Spence case determined that all risks and alternatives of a procedure have to be explained. This trial clearly demonstrated a shift from the doctors' point of view toward the patients' point of view as the standard of informed consent: the "reasonable patient standard". Subsequently, the Australian High Court overruled the Bolam principle in the 1992 Roger vs. Whittaker case of a woman losing sight in her good eye after being operated on her diseased eye (Skene L et al, 2002). Although the risk of this happening

was a mere 1:14,000, the court ruled that the surgeon should have informed the woman of the risk as she had apparently asked for this information. On the other hand, the doctor had considered this low risk not relevant. Although not totally abandoned, the “reasonable doctor standard” has become a secondary standard next to the “reasonable patient standard” in most countries (Kastelein et al, 1998). Since the 1980 Truman vs. Thomas case, information provided in an informed consent process must also include the risks of “not acting or postponing”. In this case, a Pap smear was refused by a woman who claimed not to know the associated risks, i.e., not detecting cancer in time for curative treatment. Dutch legislators as well as governments from various other Western countries have realized that their legislation was out of date. Based on cases such as those mentioned above, several adjustments have led to the 1995 Dutch Medical Treatment Contract Act in which all elements of IC are present, including preconditions, information, and consent. Although legislation differs widely between countries, these “basic elements” are consistent in the Western world.

Present practice of surgical informed consent

Current elements

Based on historical cases and legislation, informed consent is supported by three cornerstones: “preconditions,” “information,” and “consent”. Preconditions include competence and voluntariness. A patient is a person who has a right of self-determination. He/she must be able to

make decisions about his/her own body and must be able to decide freely without being influenced by others. The second cornerstone is information. According to the 1995 WHO declaration on the promotion of patient's rights, patients have the right to be fully informed about their health status, including the medical facts about their condition; about the proposed medical procedures, together with the potential risks and benefits of each procedure; about alternatives to the proposed procedures, including the effect of non treatment; and about the diagnosis, prognosis and progress of treatment. All this information must be disclosed by the surgeon to enable the patient his/ her right of self-determination. A well-defined care plan incorporating the surgeon's advice should be discussed and it must be verified that the patient understands this information.

The Elements of Informed Consent

Preconditions: Competence Voluntariness

Informational elements: Disclosure of information Recommendation of a care plan

Understanding of this information by the patient

Consent Elements: Decision by patient Authorization by the patient to proceed

The third cornerstone is consent: registration of the patient's decision and (written) consent. Informed consent is often given by the patient during a preoperative consult with a consultant, a resident, or a

specialized nurse. The information associated with a surgical procedure can be exchanged verbally, in writing, by video, or by computer technology. In this respect, large differences exist between countries. The US demands a patient signature, whereas a note in the patient chart is sufficient in the UK. In the Netherlands, doctors are not strictly required to obtain written consent.

Preconditions

As a routine, the patient's competence is only "checked" in a general sense and deemed appropriate if communication with a patient is "normal". Only if the patient is officially "incompetent" will a legally appointed surrogate decision maker or another representative in accordance with the law be allowed to decide for the patient. However, a normal intelligence per se does not necessarily mean that a patient is really competent.

Recently, Appelbaum reviewed the literature on patient competence. A group of patients with known cognitive disease and patients with cancer demonstrated variable outcomes on competence tests. Lower scores were found in people of older age and limited education. The number of "incompetent" patients was higher than expected. Surprisingly, the doctor's ability to differentiate between competent and incompetent was not better than throwing a dice. On the other hand, even patients who are objectively deemed competent may be ignorant. They frequently do not know the process of surgical informed consent and do not know their rights, which results in wrong beliefs. Only 40% of the patients think that the informed consent paper confirms their wishes (Akkad et al, 2006). Interestingly, they usually do not feel the need for more information and

their actual knowledge of the benefits and risks involved remains poor. In contrast, when asked what information they would like to have, they indicate that they would like more information than they actually receive. Several misconceptions also exist with respect to voluntariness. One study reveals that 46% of patients in the study were under the impression that the major goal of an informed consent is to protect the hospital from litigation. In addition, 68% of the patients were convinced that the informed consent process gives the doctor control of what is going to happen. (Ghulam et al, 2006).

Information elements

Literature on patient education is extensive and is usually focuses on informing patients in a general sense. On the other hand, studies on information in relation to the informed consent process are scarce. Results consistently demonstrate that neither doctors nor patients are well prepared for all elements of the informed consent. Residents are frequently “in charge” of the process but do not know what to tell a patient and do not perform well in tests on consent and medical law (McGaughey I, 2004). In contrast, they are more capable in informing the patient of benefits of the surgical procedure than they are giving information about risks or alternatives. Interestingly, 21% of patients in one study reported that they received most information from sources outside the hospital (Lavelle et al, 1993).

The way information is presented greatly influences what a patient remembers. Oral information is retained very poorly, and patients tend to forget crucial parts of information such as alternative treatment options. This will lead to false-negative feelings, particularly in patients with an IQ

below average, age over 60, a tendency to somatization, or a poor perceived control. On the other hand, better informed patients will have more realistic expectations, higher satisfaction, and demonstrate more treatment cooperation. A recent study reveals that a great difference exists between the points of view of surgeons and patients regarding relevance of information and what should be told or not told. Another study demonstrates that patients are not interested in the consent form that is used, and two thirds of the patients do not read it carefully. Studies on the patient's comprehension of information are rare. Analyses of tapes of informed consent indicate that various elements of the surgical procedure are discussed in 71% of the cases. The assessment of whether the patients actually understand this information is performed in only 1.5% of the cases (Brezis M et al, 2008).

Consent elements

Studies focusing on the consent element indicate that consent forms are not composed very well. Readability is poor, and only a minority are written on a 12-year-old reading level, which is best practice. More than half of all IC forms are filled out incorrectly. One retrospective study shows that the consent forms cannot be retrieved in 7.7% of the cases (Issa et al, 2006)

Future improvements of surgical informed consent

Substantial weaknesses and omissions of surgical informed consent are evident and the current elements of the consent process are largely neglected in daily practice. Preconditions are ignored, information is incomplete, and the consent itself is not an accurate reflection of the patient's authorization. Surgical informed consent apparently is not a popular part of the doctor–patient relationship, and presumably both parties are guilty. In the media surgeons are blamed for making mistakes and people are encouraged to “sue for every fault their surgeons make,” leading to an increase in medical legal claims (Shamsian et al, 2005). However, it should be realized that most legal cases are not due to failures in treatment but due to failure in communication. Discrepancies between expected and achieved results (55%) and faulty information (30%) are the main reasons for patients to file claims. In contrast to what one would expect, most complaints are generated after minor elective operations (70%). Articles analyzing the quality of the consent forms and their performances in court were not identified in the present overview. Circumstantial evidence, however, supports the view that ample opportunities are available to improve not only these forms but the whole process. An informed consent form is inadequate if it deals only with the form itself while omitting the incorporation of the information process or the quality of the total process. Several cases based on faulty forms resulted in successful claims: no documented alternatives, risks, or consent form at all (Baum et al, 2006). Hence, a non-standardized way of informing a patient of the risks of complications inherently results in a vulnerable position for the surgeon. Both surgeons and their patients must realize that an improved and standardized process leads to more realistic expectations.

Better-informed patients are more satisfied, have a higher commitment to their treatment, and demonstrate less tendency toward filing legal claims. Both groups obviously have a lot to gain from an optimized surgical informed consent process. Strengthening the surgeon's education might look like an easy way to optimize this. However, training doctors, or specialised nurses, aimed at improving their skills in the informed consent process is not very successful and this approach is very time consuming. A computer may aid the doctor help his patient receive high-quality surgical informed consent for elective procedures. It should be realized that computer programs do not undermine the doctor–patient relationship but are potentially valuable. The surgical informed consent should therefore ideally be performed using an integrated interactive computer program. As most surgeons prefer to spend their time on surgery itself, they must consider introducing computer technology as an aid in the consent process in daily surgical practice. A number of validated tests have been developed to check the patient's competence. Examples of such validated tests are the Mini-Mental State Examination, the MacArthur Competence Assessment Tool, the Decision Evaluation Scales (DES), and the MacCaT-T. All these tests are suitable for computer-based programs. An effective way of informing patients about their surgical procedure might be by using computer-based information. The more interactive information is provided, the more a patient remembers. Nonetheless, the amount of information that is transferred during a preoperative consultation in an outpatient environment can be overwhelming. If transfer of information is adjusted to the patient's own speed and wishes in an interactive setting, he/she tends to comprehend more and will have better recapitulation. Surprisingly, patients with limited computer experience, a low educational level, or of old age appear to benefit (Jimison et al, 1998).

Validated tests have been developed to check if the patient actually understands the information. Using this approach, doctors buy time that can be used for discussing specific procedural details, personal questions, or emotions. Recording the surgical informed consent process is of growing importance in medical legal cases. Computer-based interactive programs have the advantage of recording every step a patient takes in gaining information. In various empirical studies the consent form is replaced by a recorded patient authorization through a computer-based interface (Klima et al, 2005). This approach focuses on only the consent part of the process; it does not check whether a patient is competent or understands the information sufficiently. Basically, it is nothing more than a digitized consent form. More research is necessary to improve the surgical informed consent in daily practice.

Practice implication for an adequate informed consent process

General

1. Professionalize and structure your consent and do not rely on good intent.
2. Focus on all operations, not just on the major operations.
3. Make patients and doctors aware of the importance of an adequate consent.
4. Teach your patient what IC is.
5. Make sure the patient realizes he/she is in control and not the doctor.
6. Do not be afraid to use an interactive computer to help you, the doctor, and the patient.

Competence

Check your patient's competence and do not count on your clinical insight.

Information

1. Provide locally adapted information and try not to use general information.
2. Check if your patient understands your plan of operation, e.g., ask the patient to repeat the information.
3. Check if your patient understands the risks and the alternative.” (Wouter K et al, 2010)

Informed consent in general

Informed consent is a somewhat vague concept. It depends on a determination of whether a person has been given enough information in order to be able to base his consent on all the relevant facts. Although there has been some uncertainty in Irish Law for many years about the correct standard for the disclosure of risks of any treatment or intervention, recent jurisprudence indicates that in Irish Law the "patient-centred" test to disclosure is to be preferred. The patient-centred test involves disclosing all the information regarding risks that a reasonable patient in the position of the person undergoing the procedure in question would regard as "material" or significant. A clinician has a "therapeutic privilege" to withhold information where she feels the information would be harmful to the patient. This therapeutic privilege does not amount to a license to lie in response to a direct question. Where a patient claims that his consent to treatment was not informed,

he must prove that if he had been properly informed he would have not undergone treatment.

The Irish Approach to Informed Consent

"Informed consent" is a name given to the courts recognition that doctors have a duty to disclose information to patients. The extent of the duty to disclose information is generally measured according to one or two standards: 1) The "doctor – centred" standard: the doctor is obliged to disclose what the reasonable doctor would disclose. 2) The "patient-centred" standard: the doctor is obliged to disclose what the reasonable patient would wish to know. Irish law is at a crossroads in terms of the test to be adopted.

Broadly speaking a doctor is obliged to disclose the significant risks of any treatment to the patient, but may have some limited discretion to withhold information in certain limited circumstances.

The law in Ireland appears to mandate a greater degree of disclosure when: 1) a procedure is elective; it appears that more elective (in the sense of non –essential) a procedure or treatment is, the greater onus on the practitioner to disclose the risks of that procedure or treatment. 2) Where an elective procedure involves a risk of long lasting or severe pain, there is a substantial onus on the practitioner to disclose the risk of pain.

The Irish Supreme Court has adapted a doctor-centred approach to the duty to disclose, but there is some High Court jurisprudence to the effect

that the patient centred test is to be preferred. If the patient asks questions the clinician should answer them as truthfully as possible.

Any person alleging negligence as a result of a failure to obtain proper consent must show that the failure caused harm by causing the person to undergo the procedure and suffer injury in circumstances where he would not have undergone the procedure had he been properly warned. The assessment in Irish law of whether the patient would have taken a different course if properly informed is based on a mixture of a subjective and objective tests.

Withholding Consent

Any person who is competent to give consent is also free to withhold consent. It is not necessary that a person's reasons for refusing a treatment be rational, so long as the thought processes underlying the refusal are rational. A person is at liberty to refuse treatment even where that refusal exposes him to the risk of death or serious harm: the patient has a "right to be wrong". There are likely to be limitations on the minor's right to refuse medical treatment that would be in that minor's best interests, even where that minor would otherwise be competent to consent to treatment. (Mills, 2007)

Informed Consent to Medical Treatment.

The following information is taken from the Irish Medical Council's guide to professional conduct and ethics for registered medical practitioners:

Consent given by the patient is the exercise of a voluntary choice; it is the giving of permission for the intervention to be carried out by

competent professionals, where possible in an appropriate environment. It needs to be explained in such a way as to ensure that the patients do not feel that their consent is simply a formality or a signature on a page.

As part of the informed consent process, patients must receive sufficient information, in a way that they can understand, to enable them to exercise their right to make informed decisions about their care. This refers to the disclosure of all significant risks or substantial risks of grave adverse consequences.

Timing of consent process

Effective communication is the key to achieving informed consent. Obtaining informed consent cannot be an isolated event. It involves a continuing process of keeping patients up to date with any changes in their condition and the treatments or investigation proposed. Treatment options should be discussed at a time when the patient is best able to understand and retain information. Hence it is not recommended to seek consent when the patient may be in a stressed, sedated or in pain and therefore less likely to make a calm and reasoned decision.

Responsibility for seeking consent

Finally, the doctor providing treatment or undertaking an investigation or carrying out a surgical procedure, it is his / her responsibility to discuss it with the patient. As the treating doctor, they would have a full understanding of the procedure or treatment, how it is carried out and the risks attached with it. (Irish Medical Council Guide to Professional Conduct, 2009).

Chapter 5

Results

Chapter 3 and 4 are part of the “results” following various searches and research based approach. This chapter will look at particular papers of interest, and give a brief synopsis of each, in order to be able to answer the initial question set out, “Has there been a significant reduction in the incidence of wrong-site surgery after the introduction of the surgical time-out?”

The following papers were used as part of the review:

- 1) Devine, J et al (2010). Avoiding wrong site surgery: A systematic review. *Spine*, 35 (9 Suppl), S28-36.
- 2) Allard, J et al (2011). Pre-surgery briefings and safety climate in the operating theatre. *BMJ Quality & Safety*, 20(8), 711-717.
- 3) Conrady, J et al (2010). Determining the state of knowledge for implementing the universal protocol recommendations: An integrative review of the literature. *AORN Journal*, 92 (2), 194-207.
- 4) Neily, J et al (2010). Association between implementation of a medical team training program and surgical mortality. *JAMA*, 304 (15), 1693-1700.
- 5) Sax, H et al (2009). Can aviation-based team training elicit sustainable behavioural change? *Archives of Surgery*, 144 (12), 1133-1137.
- 6) Maher, P et al (2011). Intervention for reducing wrong-site surgery. *Cochrane Database of Systematic Reviews (protocol)*, Issue 11. Art. No: CD009404.

- 7) Van Klei et al (2012). Effects of the Introduction of the WHO “Surgical Safety Checklist” on In-Hospital Mortality. *Annals of Surgery*. Volume 255, Number 1, January 2012.
- 8) Walker, I et al (2012). Surgical safety checklists: do they improve outcomes? *British Journal of Anaesthesia*. 175, 1-8.
- 9) Panesar, S et al. (2011). Can the surgical checklist reduce the risk of wrong site surgery in orthopaedics? – can the checklist help? Supporting evidence from analysis of a national patient incident reporting system. *Journal of Orthopaedic Surgery and Research*. 6:18
- 10) Mary, R et al. (2006). Incidence, Patterns, and Prevention of Wrong-Site Surgery. *Arch Surg*. 141:353-358.

Paper Analysis

Brief abstract will follow for each paper to highlight salient features and an end note in regards to its conclusion; which was obtained after application the critiquing framework mentioned in the methodology section (Chapter 2).

Paper 1 - Devine, J et al (2010). Avoiding wrong site surgery: A systematic review. *Spine*, 35 (9 Suppl), S28-36.

Background: From 1995 to 2005, the Joint Commission (JC) sentinel event statistics database ranked wrong site surgery as the second most frequently reported event (12.8%). Although the event seems to be rare, the incidence of these complications has been difficult to measure and quantify. The implication of wrong site surgery go

beyond the effects to the patient. Such an event has profound medical, legal, social, and emotional implications.

Objective: To report (1) the incidence and (2) cause of wrong site surgery; and to (3) determine what preoperative measures are effective in preventing wrong site surgery.

Study Design: Systematic review

Population: Included patients undergoing spine surgery or other surgery

Methods: A systematic review of the English language literature was undertaken for articles published between 1990 and December 2008. Electronic databases searched included Medline, EMBASE, the Cochrane Library, the Food and Drug Administration database, Joint Commission database; also reference lists of key articles were systematically checked. Two independent reviewers assessed the level of evidence quality using criteria set by The Journal of Bone and Joint Surgery, American Volume.

Findings: From 65 identified papers, 11 met inclusion criteria. The estimated rate of wrong site surgery varies widely ranging from 0.09 to 4.5 per 10,000 surgeries performed. There is no literature to substantiate the effectiveness of the current JC Universal Protocol checklist, the North American Spine Surgery (NASS) checklist, or any other strategy in decreasing the rate of wrong site surgery.

Conclusion: Wrong site surgery may be preventable, but the checklists on their own are insufficient to minimise the complications.

Paper 2 - Allard, J et al (2011). Pre-surgery briefings and safety climate in the operating theatre. *BMJ Quality & Safety*, 20(8), 711-717.

Background: In 2008, the WHO produced a surgical safety checklist against a background of a poor patient safety record in operating theatres. Formal team briefings are now standard practice in high risk settings such as the aviation industry and improve safety, but are resisted in surgery. Research evidence is needed to persuade the surgical workforce to adapt safety procedures such as briefings.

Objective: To investigate whether exposure to pre-surgery briefings is related to perception of safety climate.

Study Design: Complex, longitudinal prospective collaborative inquiry.

Population: Contexts include operating room ad hoc teams, teams with more or less continuity, and with different kinds of surgical foci.

Methods: Three safety attitude questionnaires, completed by operating staff in 2003, 2004 and 2006, were used to evaluate the effects of an educational intervention introducing pre-surgery briefings.

Conclusion: The study reported a powerful link between briefing practices and attitudes towards safety. Although the use of checklists was a component of the intervention, it is not possible to isolate the effect of the checklist on reduction of wrong site surgery.

Paper 3 - Conrady, J et al (2010). Determining the state of knowledge for implementing the universal protocol recommendations: An integrative review of the literature. *AORN Journal*, 92 (2), 194-207.

Background: Despite the implementation of Joint Commission's (JC) Universal Protocol in 2004, wrong site, wrong procedure, wrong person surgery persists.

Objective: The purpose of this study was to determine the current state of knowledge concerning the implementation of the JC's Universal Protocol.

Study Design: Integrative review and synthesis guided by Reason's Vulnerable Systems Syndrome theory as theoretical underpinnings and Bibb and Wanzer's Identifying, Organizing, and Synthesizing (IOS) strategy as the conceptual framework.

Methods: Question guiding review, with literature search from January 1999 to October 2008.

Findings: Thirty – four included papers. Significant trends in current practice identified and categorized into 6 domains: universal protocol elements, communication, systems processes, team performance organizational / behaviour and patient assessment.

Conclusion: There is a lack of any scientific evidence on the usefulness of the Universal Protocol to prevent wrong site, wrong procedure, and wrong person surgery. The universal protocol has the following elements: a multidisciplinary team approach, active staff/patient participation, supportive hospital administration/leadership, and active communication that promotes a healthy work environment.

Paper 4 - Neily, J et al (2010). Association between implementation of a medical team training program and surgical mortality. *JAMA*, 304 (15), 1693-1700.

Background: There is insufficient information about the effectiveness of medical team training on surgical outcomes. The Veterans Health Administration (VHA) implemented a formalized medical team training program for operating room personnel on a national level.

Objective: to determine whether an association existed between the VHA Medical Team Training program and surgical outcomes.

Study Design: A retrospective health services cohort study with contemporaneous control group was conducted (n=182,409 sampled procedures from 108 VHA facilities)

Population: Data collected from VHA Surgical Quality Improvement Program (VASQIP) annual surgical morbidity rates from 108 facilities for 3 fiscal years (2006, 2007, and 2008) for major non cardiac operations.

Intervention: Medical Team Training (MTT) program based on crew resource management theory from aviation. MTT included checklist-guided preoperative briefings and postoperative briefings.

Methods: Outcome data were obtained from the VHA program and from structured follow up quarterly interviews.

Findings: The 74 facilities in the training program experienced an 18% reduction in annual mortality. 35 training facilities (42.7%) reported improved communication among operating theatre staff; 34

(46%) reported improved operating theatre awareness; 48 (64.9%) reported improved operating theatre teamwork.

Conclusion: This study demonstrates a multifaceted intervention was associated with improved teamwork and reduced surgical mortality. Although use of checklists was a component of the intervention, it is not possible to isolate the effect of the checklist on reduction of wrong site surgery.

Paper 5 - Sax, H et al (2009). Can aviation-based team training elicit sustainable behavioural change? *Archives of Surgery*, 144 (12), 1133-1137.

Background: Patient safety is a central theme in medicine and issues leading to unsafe healthcare environments was brought to light by IOM report, *To Err is Human*. Drawing on analogies between aviation and medicine, programs have been developed based on crew resource management (CRM) that focus on both human and systems issues to improve communication, error management and work culture. It is difficult to objectively quantify the effects of CRM.

Objective: To quantify effects of multidisciplinary aviation – based crew resource management training program on patient safety-related behaviours and perceived personal empowerment.

Study Design: Prospective observational study.

Population: There were 857 participants, the majority of whom were nurses (50%), followed by ancillary personnel (28%) and physicians (22%). Setting was in a 722 bed university hospital; 247 bed affiliated community hospital.

Outcome: checklist adoption and use, self-reporting of errors and unsafe conditions, and perceptions of personal and institutional empowerment to create a culture of safety.

Methods: Prospective observational study of checklist use, error self-reporting, and a 10 point safety empowerment survey. Checklist compliance was monitored by circulating nurse.

Findings: Since 2003, 10 courses trained 857 participants in multiple disciplines. Preoperative checklist use rose (75% in 2003, 86% in 2004, 94% in 2005, 98% in 2006 and 100% in 2007). Self-initiated reports increased from 709 per quarter in 2002 to 1481 per quarter in 2008. Perceived self-empowerment created a culture of safety. There was a trend toward a hierarchical effect with participants less comfortable confronting incompetence in a physician than in nurses or technicians.

Conclusion: Crew resource management programs can influence personal behaviours and empowerment. Effects may take years to be ingrained into the culture. Although use of checklists was a component of the intervention and checklist compliance increased overtime, it is not possible to isolate the effect of the checklist on reduction of wrong site surgery.

Paper 6 - Maher, P et al (2011). Intervention for reducing wrong-site surgery. *Cochrane Database of Systematic Reviews (protocol)*, Issue 11. Art. No: CD009404.

Background: Over the last decade, much work has been done to determine which specific, and potentially modifiable, risk factors may contribute to wrong-site surgery, or, if modified, prevent it.

Objective: The objectives of this systematic review as per the published protocol are to determine the effectiveness of organisational and professional interventions for reducing wrong site surgery.

Study Design: systematic review including randomized controlled trials (RCTs), well-designed quasi randomized controlled trials, controlled before and after studies (CBAs) that include at least two intervention and two control sites, and interrupted time series designs that meet the Cochrane Effective Practice and Organisation of Care (EPOC) Group inclusion criteria. The review includes studies involving healthcare professionals providing care to surgical patients; studies where patients are involved to avoid the incorrect procedures; or studies with interventions addressed to healthcare managers, administrators, stakeholders or health insurers.

Population: All patients undergoing any type of surgery; nurses or clinicians involved in delivering surgical care; operating room technicians, healthcare managers or administrators and health insurers involved in delivering surgical care.

Outcome: Primary outcomes will be the incidence of wrong site surgery, including wrong-site, wrong-side, wrong-procedure and wrong-patient surgery. Secondary outcomes include mortality, health service resource consumption healthcare professional behaviour and resource burden on healthcare providers in terms of additional time taken to undertake the intervention. Also included will be the process measures (completion rate of checklists) where available.

Methods: Related systematic reviews and primary studies to be identified by searching worldwide databases, with no language restrictions, as direct translation will be available.

Findings and conclusion: ongoing protocol driven reviews, with some data feedback, overall consensus still in keeping with the fact that checklists on their own are not sufficient to prevent wrong-site surgery.

Paper 7 - Van Klei et al (2012). Effects of the Introduction of the WHO “Surgical Safety Checklist” on In-Hospital Mortality. *Annals of Surgery*. Volume 255, Number 1, January 2012.

Objective: To evaluate the effect of implementation of the WHO’s Surgical Safety Checklist on mortality and to determine to what extent the potential effect was related to checklist compliance.

Background: Marked reductions in postoperative complications of a surgical checklist have been reported. As compliance to the checklists was reported to be incomplete, it remains unclear whether the benefits obtained were through actual completion of a checklist or from an increase in overall awareness of patient safety issues.

Methods: This retrospective cohort study included 25,513 adult patients undergoing non-day case surgery in a tertiary university hospital. Hospital administrative data and electronic patient records were used to obtain data. In-hospital mortality within 30 days after surgery was the main outcome and effect estimates were adjusted for patient characteristics, surgical specialty and comorbidity.

Results: After checklist implementation, crude mortality decreased from 3.13% to 2.85% ($p = 0.19$). After adjustment for baseline differences, mortality was significantly decreased after checklist implementation. The effect was strongly related to checklist compliance.

Conclusion: Implementation of the WHO Surgical Checklist reduced in hospital 30-day mortality. Although the impact on outcome was smaller than previously reported, the effect depended crucially on checklist compliance. Wrong-site surgery rates have not been targeted in this study as mortality was the final end point outcome that was being concentrated on, difficult to extrapolate without detailed figures to show that there was a significant or marked reduction in wrong site surgery as well after checklist usage.

Paper 8 - Walker, I et al (2012). Surgical safety checklists: do they improve outcomes? *British Journal of Anaesthesia*. 175, 1-8.

Summary: Concept of using a checklist in surgical and anaesthetic practice was energized by the publication of the WHO Surgical Safety Checklist in 2008. It was believed that by routinely checking common safety issues and hence better team communication became mandatory, this would lead to an improved morbidity and mortality rates. The magnitude of improvement demonstrated by the WHO pilot studies was surprising. These initial results have been confirmed further by detailed work demonstrating that when checklists implemented properly can make a substantial difference to patient safety. Once again, avoidance of wrong site surgery is part of an overall picture and a step in obtaining adequate patient safety and the

target goal, unable to isolate the effect of the checklist; in solely being responsible for reduction in wrong site surgery.

Paper 9 - Panesar, S et al. (2011). Can the surgical checklist reduce the risk of wrong site surgery in orthopaedics? – can the checklist help? Supporting evidence from analysis of a national patient incident reporting system. *Journal of Orthopaedic Surgery and Research*. 6:18

Background: Surgical procedures are now very common, with estimates ranging from 4% of the general population having an operation per annum in economically-developing countries; this rising to 8% in economically-developed countries. While these surgical procedures typically result in considerable improvements to health outcomes, it is increasingly appreciated that surgery is a high risk industry. Tools developed in the aviation industry are beginning to be used to minimise the risk of errors in surgery. One such tool is the WHO surgery checklist. The National Patient Safety Agency (NPSA) manages the largest database of patient safety incidents (PSIs) in the world, already having received over three million reports of episodes of care that could or did result in iatrogenic harm. The aim of this study chosen was to estimate how many incidents of wrong site surgery in orthopaedics that have been reported to the NPSA could have been prevented by the WHO checklist.

Methods: The National Reporting and Learning Service (NRLS) database was searched between 1st January 2008 – 31st December

2008, to identify all incidents classified as wrong site surgery in orthopaedics.

Results: 133/316 (42%) incidents satisfied the inclusion criteria. A large proportion of the cases, 183/316 were misclassified. Furthermore there were fewer cases of actual harm (9%) versus “near-misses” (91%). Subsequent analysis revealed a smaller proportion of “near-misses” being prevented by the checklist than the proportion of incidents that resulted in actual harm.

Conclusion: orthopaedic surgery is a high volume speciality with major technical complexity in terms of equipment demands and staff training and familiarity. There is therefore an increased propensity for errors to occur. Wrong-site surgery still occurs in this speciality and is a potentially devastating situation for both the patient and surgeon. Despite the limitations of inclusion and reporting bias, the study highlights the need to match technical precision with patient safety. Tools such as the WHO surgical checklist aid in achieving this goal.

Paper 10 - Mary, R et al. (2006). Incidence, Patterns, and Prevention of Wrong-Site Surgery. *Arch Surg.* 141:353-358.

Background: Hypothesized that wrong-site surgery is infrequent and that a substantial proportion of such incidents are not preventable by current site-verification protocols.

Study Design: Case series and survey of site-verification protocols.

Setting: Hospital and a malpractice liability insurer.

Population: All wrong-site surgery cases reported to a large malpractice insurer between 1985 and 2004.

Main outcome measures: Incidence, characteristics, and causes of wrong site surgery and characteristics of site-verification protocols.

Results: Among 2,826,367 operations at insured institutions during the study period, 25 non-spine wrong-site operations were identified, producing an incidence of 1 in 112,994 operations. Medical records were available for review in 13 cases. Among reviewed claims, patient injury was permanent-significant in 1, temporary major in 2, and temporary-minor or temporary insignificant in 10. Under optimal conditions, the Joint Commission on Accreditation of Healthcare Organizations Universal Protocol might have prevented 8 (62%) of 13 cases. Hospital protocol design varied significantly. The protocols mandated 2 to 4 personnel to perform 12 separate operative-site checks on average (range, 5-20). Five protocols required site marking in cases that involved non-midline organs or structures; 6 required it in all cases.

Conclusions: Wrong site surgery is unacceptable but exceedingly rare, and major injury from wrong-site surgery is even rarer. Current site-verification protocols could have prevented only two thirds of the examined cases. Many protocols involve considerable complexity without clear added benefit.

Summary of paper analysis

The surgical safety checklist has been implemented to ensure patient safety, and hence reduce the risk of accidental morbidity and mortality. Of the papers reviewed and analysed, overall consensus is that the introduction of the surgical checklist has clearly highlighted the need for set protocols and the potential problems that lie within

this field. But there has been no clear, isolated finding to suggest that the surgical checklist on its own, the “time-out” phase would be solely responsible for significant reduction of wrong-site surgery. At the same time the checklist is part of a number of overall steps, that aid in better communication, between operative staff and puts them on high alert to pick up on potential disasters. In that sense the checklist does definitely help in the attempted reduction in wrong site surgery, even if there are no clear quantitative or statistical data to suggest so. More prospective studies and unbiased data collection, in various fields is still needed.

Chapter 6

Discussion

The case report used as an example of wrong-site surgery, with its detrimental effect on the patient, patient family, surgical team and hospital involved highlights the major complexities of any surgical cases that take place in a given setting. The period when that incident took place, the World Health Organisation's surgical safety checklist had need been implemented, or added as part of a protocol.

“The root causes of wrong-site surgery are multifactorial. Featuring prominently in some of the analyses include breakdown in communication between surgical team members, theatre staff, absence of verification in the operating theatre and of a verification checklist, incorrect marking or consent, preparation of the wrong side, incorrect draping, patient answering to the wrong name and failure of a formally conducted surgical timeout procedure”. (Giles et al, 2006)

“WHO guidelines for safe surgery were published following a systematic review of evidence available, with formal recommendations linked to the strength of evidence” (WHO guidelines, 2009). Ten essential objectives for safe surgery were identified that were applicable in all WHO member states; these related to:

- (i) Correct site surgery
- (ii) Provision of safe anaesthesia
- (iii) Management of airway problems

- (iv) Avoiding known allergies
- (v) Minimizing the risk of surgical site infection
- (vi) Preventing the retention of swabs and instruments
- (vii) Accurate identification of specimens
- (viii) Effective communication within the surgical team
- (ix) Routine surveillance of surgical outcomes.

The Safe Surgery Saves Lives (SSSL) group investigated the impact of the WHO checklist in eight hospitals worldwide, four in high-income settings and four in low and middle income settings. “Data on in-hospital complications occurring within the first 30 days after surgery were collected prospectively from consecutively enrolled adult patients undergoing non cardiac surgery, 3733 before and 3955 after the implementation of the checklist. The overall death rate was reduced from 1.5% to 0.8% ($p=0.003$) and inpatient complications from 11.0% to 7% ($p < 0.001$)” (Haynes et al, 2009)

Wrong site surgery avoidance is part of the overall checklist, the surgical time out aids in highlighting its relevance, but all of the above mentioned steps are necessary to ensure patient safety. Hence a breakdown in communication can trigger a cascade of errors, that can lead to significant complications, opening the passage for litigation procedures and stress for all concerned. The checklist is an extremely effective tool at preventing both near misses and actual-harm in the following categories of wrong-site surgery: wrong side block, wrong side marked on patient, wrong side prosthesis and wrong side surgery. One must remember that the checklist is of limited use in ensuring correct filling and obtaining of a consent form. That’s why informed consent, especially surgical informed consent is the key moment and personally, I believe the start of “correct-site” surgery. The importance given to the

consent from is clearly evident during medical training, as a student and a practitioner. At times, it becomes clearly evident, in a rushed busy service and environment, consenting a patient is seen as a very quick step in the steps that eventually lead the patient up from an admissions bay to theatre. Consenting should also form a mainstay in the safety procedure protocol, instead of being taken for granted or as an arbitrary step. If proper consent is taken, by the experienced personnel, i.e. the surgeon who shall be performing the case itself, wrong-site surgery can be prevented, or stopped from occurring, and the surgical safety checklist or surgical timeout should be seen as the important adjunct, or safety measure in the final process before commencing the operation. Hence the importance and the inclusion as a separate chapter earlier on, in relation to consent. It cannot be taken lightly, it is not, and from a “surgical cultural” set up, the consent, surgical informed consent can be and should be seen as the first step to negating wrong site, wrong procedure operations.

“Communication errors are one of the most important cause of adverse events in healthcare, and in this setting can lead to wrong-site surgery type event taking place. For instance, information does not reach the right person, or is inaccurate, or issues remain unresolved until they become critical. In the operating theatre this leads to mistakes, inefficient use of resources, wasted equipment, frustration, poor morale, delays, and cancelled operations. Patterns of inter-professional communication in theatre follow complex hierarchies, and the communication style of senior members of the team acts as an important role model for trainees. A confrontational style maybe mimicked, or it may act as a barrier to a trainee speaking up” (Lingard et al, 2002).

“Despite the fact that a large proportion of incidents result in no harm to the patient, they all represent a major increase in the risk of an adverse event occurring and reveal systems with significantly degraded risk resilience. Degraded risk resilience represents a situation in which many of the barriers protecting against error have failed; there is an accident waiting to happen” (Annual CMO report, 2005). The capacity to defend against the potential for minor mishaps having a cumulative effect and escalating into more serious breakdowns is an essential characteristic of a reliable process. It requires a focus on the adequacy of the organisational defences that remain in reserve and provide “resilience” to the risk of an event escalating into a major untoward event. (Jefferies et al, 2009). It is imperative that the systems in place identify potential errors before they escalate and also have defensive capacity beyond this in case the events develop further, i.e. “to survive the unforeseen” (Macrae et al, 2011).

Finally, having worked and continuing to do so in the surgical field for over a decade, I strongly feel that along with the WHO patient safety checklist, the surgical informed consent should be given the utmost respect and time as the checklist in itself. Patients should also be made aware of the checklist that it is in place, to ensure that they are in good capable, safe hands and all necessary precautions are taken prior to their procedure, regardless of the complexity and whatever surgical subspeciality it belongs to.

Chapter 7

Conclusion

Like in any team sport, patient care is dependent on a team approach. One sole “superstar” cannot manage a sick patient on his/her own. They may be able to guide the rest in the necessary steps, in the end better teamwork and communication in operating theatres improves outcomes, reduces risk, improves staff well-being and mental health, reduces staff turnover and reduces delays in the surgical process. Teamwork is definable and measurable and can be improved through formal structured communication, such as checklists. Healthcare and surgery in particular rely on a team based service, yet at times we have ignored the experience of other high risk industries to our patients cost. Wrong site surgery can be prevented by taking appropriate steps as mentioned, the surgical time out from the WHO safety checklist is an integral part of these steps. Even if it has to be regimented, cultural differences, various hospital locations across the globe, the checklist has to be part and parcel of regular surgical hospital activity. The current state of knowledge in this field makes it professionally unacceptable to continue without using these simple yet effective tools to improve all aspects of perioperative care.

“For those who find the culture of using checklists difficult, the barriers are not the time taken, or that the checks are unnecessary, but lie within ourselves and our ability as clinicians to adapt our safety culture to perform checks in a prescribed manner. We can catch a plane, none of us object to our passport being checked and we expect that routine safety procedures will always be followed. Our patients should be guaranteed the same” (Walker et al, 2012).

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