

Lessons Learned from Wrong Site Surgery

Introduction:

Surgical intervention is an essential and life saving component of health care and has made significant strides in terms of outcomes over the past 50 years. However procedural intervention continues to carry a significant and serious risk of complications not associated with the primary disease itself but notably due to preventable human error or wrong site surgery (WSS). Various papers have highlighted an often previously ignored aspect of clinical practice that error can and does occur with serious negative consequences for both the patient and the clinicians involved. Human error and problems with communication are the main cause of such error often compounded by complex clinical environments that can exceed normal individual human performance (1).

While awareness and moreover an acceptance that any individual or practice may be at risk of error has gained slow and sometimes reluctant acceptance, the reported estimates of risk in surgery remain unacceptably high (2). At present it is estimated that 5-10 incorrect procedures are performed daily in the USA (3). Between 2006 and 2007 one report detailed over 128,000 episodes of patient safety issues with more than 15 WSS for neurosurgical procedures alone (4,5). In 2010 one source reported over 25 wrong patient and over 107 wrong site procedures (1). Apart from the attendant morbidity, WSS is estimated to be associated with a 1% risk of overall mortality (6). When considered against the background of nearly 234 million operations performed annually worldwide this is clearly an unacceptable risk. Overall the incidence of major complications during surgery, including WSS, appears to vary between 3 and 22% but in the absence of universal mandatory reporting structures this may be an underestimate. (1).

Aims

The specific aims of this report are to present a document detailing lessons learned from a tragic wrong site experience that may prove of benefit to colleagues and help spread greater awareness of the perils of WSS and in so doing prevent or minimise such negative outcomes in the future.

Case Report

Most surgeons would not expect that a serious adverse event such as WSS could ever happen in their own practice but as indicated above it can and does happen with too great a frequency. My own experience in

this was when a 5 year old boy was admitted for an elective nephrectomy in 2008. His estimated differential renal function was 9% and 91% on a recent DMSA renal scan. His previous history was significant for a major congenital anorectal anomaly for which he had undergone surgery and numerous interventions. Several previous entries in the chart and in official X-ray reports had indicated left sided vesico-ureteric reflux which is known to be associated with congenital anorectal anomalies. These reports were shown much later to have been incorrect in that the impaired kidney was in fact the right kidney and not the left. This error was never noted or corrected as evident from 11 previous entries in the chart indicating the wrong side. When subsequently referred to my service at the age of 5 years he gave a history of recurrent serious urinary infection (fever, vomiting) requiring antibiotics and indicating significant renal parenchymal infection. The most recent DMSA scan showed 9 and 99% differential kidney function and he was erroneously booked for a left nephrectomy when in fact a right nephrectomy would have been the correct procedure. It is not certain how this occurred and to what extent this erroneous booking was influenced by the previously incorrect entries, simple human error or was influenced by the content of an unofficial X ray report. No official x ray report of the recent DMSA scan was available in the chart or Xray folder even at the time of surgery. Unofficial x ray reports are provisional reports and do not have laterality confirmed as in a final x ray report. Sadly at that time it was common practice to rely on unofficial reports while waiting for the definitive report. However review of the images themselves at that time would have alerted the surgeon to the incorrect report dating back to infancy and the recent DMSA scan. Unfortunately the X-rays were not available on that day in the OPD and rather than the booking being deferred he was given a date for surgery with the expectation that the imaging would always be reviewed at admission and prior to surgery. Irrespective of contributing factors the patient was booked for an elective procedure on the incorrect side which was sadly wrong.

The error could have been further prevented if a team briefing was part of the surgical framework but like the majority of Irish Hospitals at that time, it was not standard practice and did not occur. In addition the surgical list and team was divided between two theatres which was also standard practice at that time. Although the parents raised concerns many times before surgery these were not passed on and reliance was made on the consent which stated left nephrectomy, the booking form and previous, albeit incorrect, correspondence. The X-rays themselves were not reviewed and no report (official or unofficial) even, at that stage, was available in the chart.

On the day of surgery the booking error was not noted and the parents queries and concerns were allayed on the basis of incorrect documentation. There was no official hand over process in place and the Senior Registrar relied on prior documentation which was ultimately shown to be inaccurate. The imaging was not reviewed at this stage and the child tragically underwent removal of the more normal left kidney.

Efforts to auto-transplant the kidney failed and the child was left with one scarred kidney. To this date the child has thankfully not required dialysis.

The tragic event was the subject of an Internal Review, an External Expert Review (Great Ormond St) published on the hospital website (7) and also a public inquiry (Irish Medical Council, 2010) (8).

Lessons Learned from this Incident.

In presenting this case and the tragic events that led to WSS I propose to deal with the most significant areas as follows:

1. Risks of unofficial X ray reports;
2. The Importance of Time Out and addressing parental queries and concerns.
3. The Importance of holding a team briefing;
4. The risks associated with running parallel surgery lists;
5. The requirement for an official hand over;
6. The necessity for a pre-surgical review of all relevant imaging.

The Risks of Unofficial X Ray Reports;

Historically clinical teams had placed reliance on X reports that had not been signed off and were still "Unofficial". These reports were available on the hospital system and could be accessed from any area. This practice was to allow clinicians have an X ray report earlier than the signed off process would normally allow. However it may have contributed to the initial error in this child and following this incident they are no longer available. The potential for inaccurate reporting was significant in this system as laterality in unofficial reports was not confirmed until a subsequent review and check of the accuracy of the report. In many instances the unofficial report can be changed significantly when the final report is issued.

The Importance of Time Out and Addressing Parental Concerns and Queries;

The JCI and WHO in 2003 and 2007 (9,10). respectively instituted safety checks that are aimed at improving the safety of patients undergoing

surgery mostly to confirm the essential aspect of correct laterality. This process of "Time Out" is a series of objective checks to confirm that the patient is the correct patient having the correct procedure on the correct side. It's other important function is to empower all staff members who for one reason or another may feel unable to voice concerns over the planned procedure. While "Time Out" was not universally accepted in Ireland prior to this sentinel event it is still possible that the process may not of itself, have prevented the tragic outcome for this 6 year old boy. This is largely because parents are typically excluded, as in this case, from the Time Out process and therefore not every member of the theatre team would have been aware of the concern raised by the parents over laterality. Findings from a subsequent prospective study looking at the value and acceptance of parents and team members over parental involvement suggest that every Time Out must involve the parent as an essential member of the team. In my mind this acts as a absolute failsafe in elective Paediatric Surgery where parental concerns are aired in the presence of the entire surgical team before the patient is anaesthetised. Concerns that parental involvement at this stage may prove distressing to both parent and staff have been not been upheld and our findings indicate that 100% of staff and parents consider that it should be a mandatory part of Time Out (11). Site marking and consent must be performed and taken by a surgeon who understands the procedure planned but who ideally must also participate in the procedure itself. This also provides an additional safeguard against communication problems that may have gone unanswered. Many of these safeguards are part of standard taught post graduate courses but are not so in most Medical Schools Undergraduate Curriculum. Risk management education should no longer be confined to a post graduate role and inclusion in undergraduate medical education should serve to embed risk avoidance in clinical practice.

The Importance of Team Briefing;

Team briefing and review of the imaging would have offered greater protection for this patient and is a clear measure to allow the busy surgical team take stock of the days planned activities and address any concerns. Improving communication in this way is beneficial and team briefing is now a standard part of the daily surgical activity. It also facilitates the development of team co-operation and heralds a worthy departure from more traditional autocratic systems.

The implementation of a multidisciplinary team meeting as also recommended, is now a standard part of any planned major intervention whose most useful function is to facilitate discussion and review of surgical plans and imaging. A pre-admission clinic was part of the GOS recommendations and the dept of Surgery continues to advocate strongly to have such a clinic implemented. Hospital financial constraints appear to be the only obstacle delaying this important aspect of safety. These vital aspects of patient safety must not be postponed or whittled away due to financial constraints and hospital management must work to provide safe working environments for patients and staff.

The Potential Problems of Parallel Operating Lists;

The GOS report referred to the problem of Parallel Operating Lists and while historically such arrangements were common practice in all Irish Hospitals it is now, I hope the exception rather than the rule. Surgeons and hospitals faced with increased referrals and inadequate consultant numbers have viewed such practices as a way to deal with large waiting lists. This is clearly no longer acceptable and hospitals must place patient safety before all else. Parallel lists are no longer practiced and consultant expansion has occurred although is not yet at its optimal level.

The Importance of Hand Over;

American researchers have suggested that incorrect surgical procedures are not only an operating room challenge but are also a challenge for events occurring outside the operating room (3) as in this patient. The chain of events that began years before this tragedy with reports of incorrect laterality, undue reliance on unofficial X-ray reports, unavailable imaging, and failure to communicate valid parental concerns combined to overcome the usual barriers against WSS. The end result was that the patient came to theatre with many staff aware of residual concerns voiced by the parents but no effective action resulted. Appropriate handover at this stage may have prevented WSS but this was not standard procedure at this time. All surgical lists now have formal team briefings and hand over.

It is well recognised that doctors and pilots in stressful environments often fall back to actions that they know and are familiar with and continue on a negative course. This "plan-continue-fail" action is viewed as contributing to adverse events in clinical and airline disasters and could explain why the operating surgeon continued with the procedure despite the operative findings being out of sync with the indications for nephrectomy (6,12). The airline industry recognises this potential and has installed effective barriers to this action so that any member of cockpit staff may call attention to their concern. In surgery this concept needs greater development since the issues of ultimate responsibility and clinical autonomy are less separate than in the airline industry. It does however suggest that an additional safety layer be introduced in the WHO check list to ensure that in operative situations of extirpative surgery, a final "on table Time Out " must be performed where the operating surgeon corroborates the pre operative diagnosis with the on table operative findings (13). In the event of any mismatch the operating surgeon must halt the procedure and confirm the planned procedure by collegiate consultation. If necessary the procedure can be halted and imaging reviewed again repeated as required.

The Importance of Pre-Operative Review of All Imaging;

The root cause analysis reported in the GOS review detailed these issues in depth highlighting the need for adequate hospital systems to provide for better filing of X-rays and reports. The report also highlighted difficulties with X ray availability during a patients hospital journey. Since this error all patients must have their x rays with them during their entire hospital journey. The recent availability of a PACS (Patient Archiving and Retrieval System) now makes it virtually impossible for any patient to transit through the hospital system without the medical teams having full and comprehensive access to both reports and images at every point of their journey. It is official hospital policy that all X rays are not only in the operating room but are clearly displayed and reviewed prior to surgery. Imaging must be displayed during extirpative surgery and referred to again in any situation of laterality concern.

Discussion

To err is human and it is clear that when humans interact in complex environments such as hospitals that there will always be a potential for risk or error. This should not detract from our efforts to recognise the potential for error in clinical systems and to insert obstacles and measures that effectively prevent them. Much of what we know today about clinical error has been derived from work done by the Joint Commission on Accreditation of Healthcare Organisations (now called the Joint Commission International-JCI) and the Worldts Health Organisation (WHO). Both organisations recognised that irrespective of advances in science and technology that patients were still at significant risk from largely preventable human factors (9,10). Recognition of these factors also stressed that the solution to these problems was not punitive but rather should be based on an analysis of events and implementation of more robust safeguards to prevent re-occurrence. Much important insight into human error has also been provided by the airline industry who for long have recognised and valued the critical importance of human error in Airline disasters. However there has been a slow uptake of the basic concepts of these costly lessons in surgical practice and the incidence of medical error as reported above may in fact be an underestimate. While voluntary systems may allow meaningful reporting, modern systems utilise mandatory reporting structures that report each and every incident to an in house risk manager and to a National database, e.g. Starsweb / NAPSA (4,5). Post graduate courses in risk management and risk avoidance are increasingly being taken by doctors and nurses providing insight into how the professions increasingly view the importance of risk avoidance.

Conclusion

It is clear that clinical error will continue to occur wherever humans interact with each other in complex and stressful environments such as the operating theatre. We have learned through the tragic outcome of this child's wrong sided nephrectomy that systems we trusted to deliver safe care were proven to be grossly inadequate. Traditional barriers considered previously to be robust failed to halt progression to a tragic outcome. Most major errors are a series of small ones where deficits in communication combine with assumptions that problems or concerns will be dealt with by the system or by some other team member. Acceptance and implementation of team based responsibilities with team briefings, Time Out (including parental involvement) improve communication and help prevent recurrence of such problems. In addition surgeons must be encouraged to confirm to the entire team that the operative findings (after the organ has been surgically exposed) are in keeping with the planned surgical procedure. If there is any concern operating surgeons must halt the procedure and obtain collegiate advice. Hospital managers and their Boards must also bear responsibility for ensuring proper implementation of risk avoidance measures and ensure safety not only for patients but also for medical staff employed by them.

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