

Independent Review Report

Investigation into the removal of the wrong kidney from patient XY Our Lady's Children's Hospital, Crumlin

Introduction

This is the report of an Independent Review commissioned by Our Lady's Children's Hospital, Crumlin (OLCHC), into the circumstances in which a healthy kidney was removed from Patient XY in Spring 2008.

The authors of the report are Ms Penny Tallents (Acting Assistant Director / Patient Safety & Complaints Manager) and Mr Imran Mushtaq (Consultant Paediatric Urologist) of Great Ormond Street Hospital for Children NHS Trust, London (GOS).

Summary incident description & consequences

A patient with a poorly functioning right kidney was incorrectly listed by a consultant general surgeon for a left sided nephrectomy, following attendance in outpatients. The patient was admitted the day before surgery and consent was obtained from the parents for a left sided nephrectomy. The procedure was carried out the following day by an SpR in paediatric surgery who had not seen the patient previously. The error was realised immediately after the healthy left kidney had been removed, but it was not possible to revascularise it.

Background and context

Patient XY was under the care of the general surgical team at OLCHC which is one of three children's hospitals in Dublin providing a paediatric surgical service. The general surgical department consists of four Consultant General Surgeons (two of whom work at OLCHC on a full-time basis), four Specialist Registrars (SpRs) and six Senior House Officers (SHOs).

Terms of reference

The report was commissioned by Lorcan Birthistle, 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, incorporating a mixture of clinical and risk management expertise.

The formal Terms of Reference of the review were as follows:

- 1. To examine all the circumstances current and historic pertaining to the incorrect surgical removal of the left kidney of the patient.*
- 2. To verify to their satisfaction that the internal preliminary review report is a comprehensive record of the facts and circumstances which resulted in the error.*
- 3. To examine the protocols and procedures in place in Our Lady's Children's Hospital for the conduct of this type of surgery taking into account prevailing standards of best practice.*
- 4. To undertake a root cause analysis of the incident.*

5. *Arising out of the review and root cause analysis to make recommendations to the hospital with a view to avoiding the recurrence of such an incident.*
6. *To report to the hospital by 1st September 2008.*

The External Review Group shall be provided with access to all documentation which they consider necessary to complete this review and shall also be entitled to interview such personnel as they consider 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 Safety and Urology departments.

Investigation type and evidence collected

A Root Cause Analysis of the incident was undertaken, in accordance with point 4 of the Terms of Reference.

Documentary evidence was provided in advance by OLCHC, and in response to the specific requests of the review team. This consisted of clinical information about Patient XY, formal statements from staff, relevant policies and procedures, and data about the general surgical service.

The review team were provided with OLCHC's internal preliminary review report, and confirmed that this was an accurate summary of XY's clinical history and the incident.

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.

A full list of the documentary evidence seen is appended to this report. A record of staff interviews and statements has also been completed but is not incorporated in this report, in order to protect the confidentiality of staff.

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 acknowledge that OLCHC will continue liaising with the family following this report, to

provide assurance to them that the hospital has learned and taken action as a result of this incident 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 OLCHC, 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 x-rays 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 on-call 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 OLCHC.

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 has 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, OLCCH 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 daycases. 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 OLCCH 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 right-sided 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 has 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 acknowledge 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.

The review team would particularly like to thank Patient XY's parents for their involvement in the review, the time which they spent discussing the events, and for their clear expectation that the hospital will respond positively to these events by making definitive changes for the benefit of future patients.

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