Report of the National Panel to Review Breast Biopsy Errors

2012

Findings and recommendations

I am not an outcome. I am a patient with feelings and emotions.
(Woman affected by biopsy error)

We do so many good things and have very high standards, but just one mistake can be devastating.
(Clinician affected by biopsy error)

Acknowledgements and disclaimer

This report was prepared by a Panel of experts convened by the Chief Medical Officer of the Ministry of Health. The Panel membership was:

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The report presents the consensus view of Panel members; it does not represent Ministry of Health Policy.

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MANATŪ HAUORA

Preface

This review was prompted by a number of events where people had unnecessary surgery as a result of an error in the laboratory diagnosis of a biopsy specimen. The review panel has considered two aspects of these events: the laboratory and subsequent processes and the support provided for the affected women. There are some significant and important conclusions.

Four of these errors involved specimen transposition and misidentification. Although there was human error, four similar errors in different locations meets James Reason's definition of a system problem.[1] There are many steps from a biopsy being taken, through the laboratory, to a decision about surgery. The process is complicated and at each step there is a possibility for error. Each laboratory involved has reviewed its processes. All of them identified and implemented changes to improve reliability and safety. I note how little standardisation of processes and systems there has been between laboratories and how each laboratory seems to need to learn the same lessons for itself. As a result the systematic protection for patients (and staff) is variable. One of the panel's recommendations is that the report be used to drive improved systems in all of New Zealand's laboratories. The responsibility for this lies with the professional and accrediting bodies and the leadership of each laboratory. Each and every laboratory should ask itself whether its systems are actually providing the best safety for its patients.

Good medical practice involves evaluating information from a wide variety of sources while continually being aware of the broader (clinical and social) context in which decisions are being made. With increasing specialisation and segmentation of service delivery comes the risk that aspects of the clinical picture will be viewed in isolation and, for instance, discordant results are not detected. In organisationally and clinically complex situations, systems and processes should be designed to mitigate the risk of fragmentation by supporting clinicians to critically evaluate and compare all data before them.

The panel interviewed some of the affected women. Their experiences are painful and make for difficult reading. It is noteworthy that the principles of open disclosure remain so inconsistently applied. 'In New Zealand, provider organisations have a legal duty to take steps to ensure that open disclosure is practised by staff and supported by management.'[2]

The women we spoke with described a lack of timely and effective communication which they felt demonstrated a lack of compassion. The New Zealand Medical Council's guidance is clear. 'If a patient under your care has suffered serious harm or distress act immediately to put matters right... express regret at the outcome, apologise if

[1] James Reason (1990) Human Error, Cambridge University Press, Cambridge, UK

[2] http://www.hdc.org.nz/decisions--case-notes/open-disclosure

appropriate, and explain fully and without delay...'.[3] The women described a sense that providers have moved on rapidly while they are left to deal with life-changing events. Although they were not responsible for the errors, surgeons were often the primary contacts. But in some cases it took a long time for the laboratory to contact the women, apologise and explain what was happening. New Zealand has a unique legislative system which separates questions of fault from redress. There should be no cause for delay in contacting, apologising and explaining events to patients who have been harmed. The laboratory has a duty to the patients and a duty to explain how they have come to harm. Some individuals have made notable efforts to support women. Organisational responses have been less satisfactory and inconsistent. Fronting up and staying in touch with the affected women while investigations were under way would go a long way to meeting that obligation. Engaging the women in the investigation would go even further. As it is, many of them were left feeling that nobody cared they were treated dismissively. There needs to be a more connected, systematised and respectful way of working to support patients through events like these. This requires clear leadership to ensure that everything is done with empathy and coordination.

The panel's recommendations focus on three areas:

- better systems to reduce the likelihood of error
- better systems to test laboratory findings against the clinical findings to look for discordance and make better decisions about subsequent surgery
- better and more effective support for people who are harmed by diagnostic errors.

Across all of these is the important issue of consistency of approach. The report discusses proven ways to improve safety. Best practice should be standard across laboratories. New Zealand has a number of laboratories – hospital and community, public and private, which have different approaches to each of the three areas mentioned above. Patients usually know little about which laboratory is examining their specimens. They have a legitimate expectation that they will be cared for consistently regardless of which laboratory is involved. This does not seem to be the case. It is time that the laboratory and wider sector addressed this issue. It is my expectation that, on receiving this report, all laboratories will review their own processes and start a collaborative approach to reducing the risks of errors.

I will be writing to the sector in November 2012 asking all laboratories to explain how they have assessed their own processes in light of this report, what they have found and what they have done as a consequence. I will also be seeking confirmation of progress on the recommendations and making this progress known publicly.

Dr Don Mackie
Chair, National Expert Advisory Panel
Chief Medical Officer, Ministry of Health

[3] http://www.mcnz.org.nz/assets/News-and-Publications/good-medical-practice.pdf

Glossary of terms

Axillary clearance	Surgical removal of all lymph nodes from the under the arm on the side affected by cancer to assess extent of spread of breast cancer to these nodes.
Benign	Not malignant, do not metastasize.
Concordant results	Where the clinical, pathological and radiological findings about a specific area under investigation are all consistent with the same diagnosis (whether benign or malignant). The opposite is discordance – where the findings from clinical, imaging and pathology tests of the lesion are not all aligned. Discordant results require further evaluation before definitive treatment is undertaken, in order to avoid an error or misdiagnosis.
Carcinoma	A cancer arising in the epithelial tissue of the skin or of the lining of the internal organs.
Core biopsy	A non surgical technique for removing slender cylinders of tissue from an area of concern in the breast, usually under imaging guidance, so histologic examination can be carried out in the laboratory. The examination of the biopsy sample allows diagnosis of the nature of the larger lesion.
Epithelial	The thin tissue forming the outer layer of a body's surface and lining the alimentary canal (the whole passage along which food passes through the body during digestion) and other hollow structures.
Fibroadenoma	A tumour formed of mixed fibrous and epithelial tissue, typically occurring as a benign growth in the breast.
Fibrosis parenchyma	Benign thickening of the non-glandular support tissues in the breast.
Invasive ductal carcinoma (IDC) of no special type	The most common form of invasive breast cancer.
Histology	The study of the microscopic structure of tissues.
Lesion	Any localized, abnormal, structural change in the body.
Malignancy (of a tumour)	Cells that are characterized by uncontrolled growth and the ability to spread to other sites in the body (metastasize); cancerous, invasive.
Mastectomy	Surgical removal of the breast.

Maxillectomy	Surgical excision of the upper jaw bone.
Microcalcification	Fine calcium deposits in breast tissue which show up in mammograms, as white specks. Depending on their specific shape and characteristics they may be a sign of a breast malignancy.
Multidisciplinary Meeting	Scheduled, formal meetings of medical and other health professionals, from a range of disciplines and relevant specialties to discuss and coordinate the diagnosis and further management of patients.
Multifocal (malignancy or breast cancer)	Having more than one focus.
Pleomorphic Lobular Carcinoma	Lobular carcinoma is the second most common form of invasive breast cancer. The pleomorphic variant is of higher grade than the classic subtype of this cancer.
Sentinel Node Biopsy	Surgical removal and examination of one or several lymph nodes, usually from under the arm, to which the lymphatic drainage from the breast is first directed. This is used to predict the likelihood of further nodal spread of breast cancer.
Squamous Cell Carcinoma	A cancer of epithelial cells which line various parts of the body, including the skin and mouth.
Stromal calcifications	Calcium deposits in the supportive tissue of an epithelial organ, tumour, gonad, etc., consisting of connective tissues and blood vessels.
Wide Local Excision	Surgical removal of a tumour in the breast together with a wide margin of normal tissue in the hope of taking out all cancerous cells but avoiding a mastectomy.

Contents

Executive summary

In June 2012 the Ministry of Health convened a Panel of experts to provide advice after the occurrence of five incidents of serious errors in reporting of anatomical pathology results.

The errors occurred over a two-year period.

- Four incidents involved breast biopsy tissue and the fifth involved oral tissue.
- The errors occurred in both hospital and community laboratories.
- Each of the errors resulted in the patient undergoing unnecessary surgery.

The Panel had the opportunity to consider reports of the investigations into each of the events and also spoke with several of the patients affected as well as their family members.

Four of the errors resulted from transposition of specimens with those of other patients during the laboratory process. The fifth error resulted from a misinterpretation of the specimen.

The Panel considers that overall quality processes in New Zealand laboratories are of a high standard. Nevertheless international evidence shows that the nature of processing anatomical pathology specimens is vulnerable to errors of the type seen here.

A longer term solution to reducing these errors is to introduce greater automation of the laboratory process. The Panel makes recommendations for how processes should be standardised in the meantime to minimise the risk of errors.

The Panel also makes a number of other recommendations including:

- improved reporting of serious and sentinel events
- improved collaboration between laboratories on quality initiatives
- improved and nationally consistent processes for supporting patients affected by serious errors.

After the Panel concluded its deliberations, further information on actions taken by affected laboratories in response to these events became available. This information is included in summary form as Appendix Three.

1 Introduction

As of early June 2012 the Ministry of Health was notified by several District Health Boards of a number of confirmed or possible cases in which anatomical pathology specimens had been transposed between patients, or where the initial report gave an incorrect diagnosis. The errors led to the wrong results being provided to the requesting clinicians and consequently patients had unnecessary medical procedures, including surgery.

Four of these errors involved specimens of breast tissue and one involved oral tissue. The breast specimens were derived from patients in both screening and diagnostic pathways for breast cancer and the incidents involved both hospital and community laboratories.

Investigations into each of these events by the relevant agencies are either under way or have been completed.

The Ministers of Health have asked for assurance that patients who have had biopsies can have confidence in the results they receive, and for recommendations for any quality improvement measures that may be required. The Ministry of Health's Chief Medical Officer convened a panel of independent experts (the Panel) to provide advice on quality and safety issues in anatomical pathology. The Panel's Terms of Reference are attached as Appendix One.

This paper provides the Panel's findings and recommendations. The report has four sections under the following headings:

- description of events as well as the experience of both patients and health staff
- description of laboratory processes and literature review findings
- discussion and findings
- recommendations.

Following preparatory teleconferences and briefings, the Panel convened for a two day meeting in June 2012 and afterwards met several times by teleconference to consider additional information and to finalise its report.

During its deliberations the Panel had the opportunity to hear how these events have affected the patients and health staff involved. The Panel recognises and acknowledges the distress and shock these errors have caused for the patients, their families and the health professionals involved. The Panel is grateful for the willingness of the people affected to support efforts to reduce the possibility of future errors.

2 Description of events and patients' experience

a) Description of events

Patient A had a wide local excision for breast cancer five years previously. On a routine follow-up surveillance mammogram in July 2010 she was found to have microcalcifications and so was referred for biopsy. The core biopsy took place in September 2010. Calcifications were documented in the core biopsies by specimen X-ray. The core biopsy specimens were reported as showing a moderately differentiated invasive ductal carcinoma (IDC). The clinical findings, imaging and pathology results were discussed at a Multidisciplinary Meeting[4] (MDM) and presumably were considered to be concordant (that is the clinical, pathological and radiological information all supported the same diagnosis). On the basis of these results, the patient underwent mastectomy and axillary clearance on 9 November 2010.

Examination of the surgical specimens showed no carcinoma. Subsequent investigation by the laboratory found that this patient's original core biopsy specimen had been transposed with that of a different woman (Patient M) who had also undergone core biopsies on the same day. These were sent for examination to the same laboratory as Patient A's samples and were coincidentally placed next to Patient A's specimen during processing in the laboratory.

The specimen transposition took place at the stage where the core biopsies were being transferred from the specimen container to the cassette used in processing (see section 3 below for a description of the laboratory process for handling and preparing specimens). Human error at the stage of specimen transfer was the cause of the error. The reporting pathologist reported correctly the slides prepared for them from these tissues, but unfortunately the tissues on the slides being examined belonged to the wrong patient.

[4] Multidisciplinary (Team) Meetings (MDM) are regular, formal meetings of the various health professionals involved, convened to ensure that all aspects of a patient's care are effectively coordinated. They are commonly used internationally and in New Zealand and especially for cancer care. The Ministry of Health's Cancer Control Group and Breast Screen Aotearoa both provide guidance on the composition, objectives and operation of MDMs.

Patient M is a 39-year-old woman whose biopsy result was reported as showing fibrosis with benign stromal calcifications. In the light of the imaging and clinical findings, this result was considered discordant at the MDM, and a repeat core biopsy was performed. The second core biopsy revealed an invasive ductal carcinoma, as expected. The patient underwent wide local excision and axillary clearance with subsequent chemotherapy and radiation therapy. Excepting the need for a second core biopsy, Patient M had appropriate investigation and early management of her breast cancer.

Patient B was a 46-year-old woman in the breast screening programme, who was found to have an indeterminate and probably benign mass lesion on mammography in November 2011. This lesion was assessed by core biopsy. On 12 December 2011 her biopsy result was reported as showing an invasive ductal carcinoma (IDC). In line with this laboratory's usual practice, the biopsy specimen was double-read by a second pathologist. It is noted that the second pathologist was made aware of the diagnosis of their more senior colleague, ie, this was not a 'blinded' second opinion. Further evaluation of the breast showed multiple further lesions, radiologically similar to the index lesion.

The case was discussed at a MDM on 14 December 2011 and subsequently was referred for treatment. A second biopsy was carried out on 22 December 2011 and was reported as showing normal tissue. At this stage a Magnetic Resonance Imaging (MRI) scan was considered for investigation of multifocal malignancy but was not carried out. It does not appear that a further MDM discussion was held subsequent to the second biopsy.

The patient went on to have a mastectomy, sentinel node biopsy and breast reconstruction on 17 January 2012. The mastectomy showed multiple fibroadenomas but no malignancy. In view of this discrepancy, the original slides were reviewed and on 8 February 2012 it was concluded that a diagnostic error in the classification of the original core biopsy sample as malignant rather than fibroadenoma was the proximal cause of the error. Since the index lesion was reported as malignant, the multiple other lesions found on imaging were also assumed to be malignant. She was treated with mastectomy for presumed multifocal breast cancer.

Patient C had a wide local excision for breast cancer 10 years previously. On a routine follow-up surveillance mammogram she was found to have indeterminate microcalcifications in the other breast and so was referred for biopsy. Core biopsy was performed on 25 January 2012. Microcalcifications were confirmed in the specimen radiology of the biopsy sample. The pathology of the core biopsy was reported as showing pleomorphic lobular carcinoma. A MRI scan was carried out but found no suspicious lesions. The case was discussed at a MDM. Since the pathology had diagnosed malignancy and MRI could not provide information regarding the extent of the lesion, it was decided appropriate and safest to recommended mastectomy. The patient thus underwent mastectomy and sentinel node biopsy on 2 March 2012.

Examination of the mastectomy specimen showed no tumour. Subsequent investigation by the laboratory found that Patient C's core biopsy specimen had been transposed with that of Patient N at the stage where the core biopsy was being transferred from its container to a pre-labelled cassette labelled with the identification details of another patient, Patient N. These two patients both had breast core biopsies which were processed sequentially in the laboratory. The error was confirmed on 9 March 2012 by the laboratory. Human error in mismatching the incorrect pre-labelled cassette and tissue was identified as the primary cause of the error.

Patient N had a palpable breast mass, clinically suspicious for cancer. She had undergone core biopsies, sent for examination to the same laboratory as those of Patient C, and coincidentally placed next to Patient C's specimen during processing in the laboratory. These biopsies were reported as benign. This result was unexpected and discordant with her clinical presentation. A second core biopsy was performed that confirmed the clinical suspicion for an invasive carcinoma. Excepting the need for a second core biopsy, Patient N appears to have had appropriate investigation and early management of her breast cancer.

Patient D[5] had an architectural distortion (abnormal mammographic appearance of the breast tissue) and increasing density of the right breast on her screening mammogram on 12 March 2012. She underwent core biopsy examination of this area. The core biopsy was reported as a high grade invasive ductal carcinoma. This case was discussed at MDM on 6 May 2012 and the results were considered concordant. The patient was informed of the diagnosis of cancer and she underwent wide local excision and sentinel node biopsy on 17 May 2012. The surgical specimen showed no malignancy. Preliminary investigation of this matter by the laboratory suggests that Patient D's core biopsy specimen was transposed with that of Patient O during the process of transferring the section of the specimen to pre-labelled glass slides.

Patient O had an abnormal mass on mammography. Her initial core biopsy was reported as benign fibrous parenchyma. This result was considered discordant with the imaging findings. The core biopsy procedure was repeated. This was found to show high grade invasive carcinoma, which was in keeping with the imaging features and she proceeded to surgery on this basis. Excepting the need for a second core biopsy, Patient O appears to have had appropriate investigation and early management of her breast cancer.

Patient E had experienced dental and sinus symptoms. She underwent a biopsy of oral tissue on 1 April 2011. The specimen was reported on 8 April 2011 as showing moderately differentiated squamous cell carcinoma. This was an unexpected finding for the ENT surgeon. After intensive clinical and radiological work up (including MRI scan) and MDM review, the diagnosis was acted upon and the patient underwent a right partial maxillectomy on 9 May 2011. The surgical specimen showed chronic inflammation but no evidence of malignancy was found.

[5] At the time that the Panel convened few details of this case were available and a full investigation had not been completed.

Upon investigation by the laboratory an error was confirmed on 30 May 2011. It is believed that Patient E's specimen was transposed with that of another patient, Patient X, who had also undergone biopsy for an oral lesion and whose specimen had been sent for examination to the same laboratory as that of Patient E. These specimens were coincidentally placed next to each other during processing at the laboratory. It appears that during the stage of description and specimen transfer, the person responsible inadvertently picked up the request form of Patient E with the specimen container of Patient X, thus transposing the samples. No interpretive errors were made by the reporting pathologist.

Patient X had a clinically suspicious oral lesion. The first set of biopsies was reported as showing chronic inflammation. Due to lack of correlation with the level of clinical concern for cancer, repeat biopsies were performed. These confirmed invasive squamous cell carcinoma. They proceeded to treatment on this basis. Excepting the need for a second biopsy, Patient X appears to have had appropriate investigation and early management of their cancer.

In summary:

- four out of the five events relate to breast biopsies while the fifth was a specimen of oral tissue
- of the four breast biopsy cases, two were taken as part of the national screening programme process
- one of the errors resulted from a misread while the other four resulted from transposition of specimens during the laboratory process.

b) Patients' experience

A Ministry representative and a member of the Panel visited four of the women who had been affected by errors and who were prepared to meet. The Panel believed it was important to gain a first-hand perspective of the experiences of these women (and their family/whānau some of whom were also in attendance). The Panel representatives also asked to hear about the support that was offered to them as a result of these errors and hear their views on how the sector should respond in such events. The women also had the opportunity to express any concerns they felt were unresolved which the representatives may have been able to help with.

The women were very welcoming of the opportunity to discuss their experiences and their concerns. One woman commented on the visit 'at least someone is taking a little more interest' to which her husband agreed. The Panel was grateful to the women for sharing their experiences and for their willingness to help the sector avoid future errors.

All women agreed to notes being taken and one provided a written summary. This material has been used in putting the patient experience together for this report.

The collective experiences are presented here as themes. This assists in protecting the identity of the women and enables different voices to be heard. While there were similar issues and experiences there were also differences.

Responsiveness of providers

This varied but generally was short in duration and largely unsatisfactory. One woman who initially had a false negative result reported the response from providers as being very unsympathetic because they believed her cancer had been caught in time and her treatment had not been delayed. They failed to appreciate or acknowledge the impact this had on her and her family/whānau or her decision making about further treatment.

Other women reported being told of the errors over the phone quite some time after surgery and all but one reported an apology in some form had been received. One woman waited three months for an apology from the laboratory; her surgeon had already apologised. Another woman was very happy with the response from one laboratory and their follow-up.

The follow up service once women were at home received varying comments. One woman described all the health staffs visiting were not what she really needed; it was home help that would have been more appropriate. Another told us the District Nurses 'were wonderful, they were amazing'.

Responsibility / accountability

Some of the women are confused, frustrated and upset as to why when it is clear that there has been a slide transposition error there isn't a connection between who takes responsibility and who then pays compensation. One woman felt that the accountability rested with 'those people who supervise the trainees' and that 'there should be consequences'. The same woman observed, 'If something happens it should be dealt with; if there's no consequence no one wants to do anything or take any responsibility.' Another woman reported of her surgeon, 'He was devastated'. So, while there is a need to identify and sort accountability alongside responsibility it is not clear what the 'collective consequences' are for those people who actually made the errors and the providers they work for.

Tunnel vision

Of the actual transposition errors themselves one woman made the point that trainees shouldn't be working alone and they should only have one thing in front of them at a time. 'You don't interview two patients at a time; it's not a group thing.' When reflecting on their experience and discussing their ordeal with different professionals and services most women felt there were 'warning bells' of which more notice should have been taken. At the time of assessment there were things that didn't quite match up, yet the treatment continued. In one case none of the scans showed any sign of cancer, 'Yet they still went ahead with it,' (based on the biopsy results). When two of the women queried aspects of their results they didn't understand (prior to surgery) they were told, 'It was just terminology and how they write things,' and, 'It was

explained'. One woman was told on physical examination that she definitely had breast cancer; then the biopsy came back negative. 'They could not understand how there could be a false diagnosis after I had told them in very direct fashion I had breast cancer.' As a result of these responses the women have lost faith in the health system summed up in this comment. 'Gone are the days when you believe everything your doctor tells you.' If the picture doesn't match up, the clinician needs to take a step back in the process and 'consider' a laboratory/pathology error.

Overall impact

'You want to know how I was affected – all I can say is it has been unpleasant and very difficult.'

Partners and family/whānau of the women observed depression, a loss of confidence, withdrawal and different levels of frustration in their loved ones. Some of the women themselves noted their partners had difficulty coping, getting time away from work to support them and were distressed. One husband described seeing his wife differently now that she had undergone surgery and he found it very difficult.

Often their first reaction on finding about the error had been, 'Well, what about the other person?' This included issues of time – 'What if I could have avoided the other woman having her breast being removed unnecessarily'. Some have been in touch with this person, others have not. Having surgery, scans, tests and appointments has had an impact on the lives of these women and their families/whānau. There were problems with on-going infections. 'It was eating away the flesh, but I thought I had cancer – you have to go through this'. On-going life with a disability as a result of the error is the reality for one of these women while others consider breast reconstruction options.

Financially things have been difficult for nearly all of the women. They have had time off work; one woman has lost her business and another unable to pursue employment. Support from the Accident Compensation Corporation (ACC) has been variable with one woman describing it as 'very good', while another said, 'ACC's treated me like, tough, this is the rules, a treatment injury.' Two women were disappointed that no one discussed options of compensation at all and both are now investigating this further. One woman is seeking legal advice for compensation.

Compensation

The women believe they are entitled to compensation, notwithstanding the money two of them have thus far received from ACC. This view is reflected in the following comment. 'Compensation should be when a mistake is made.' The three women who spoke about this believe they are entitled to monetary compensation to make up for the hardship and loss they have suffered. 'All I want to do is get back to where I was before this happened. It's not unfair to ask for that.' Even though things will never be the same, the women feel they should not be worse off for the ordeal. Adequate compensation would ensure they are at least not financially worse off for undergoing treatment they did not need in the first place.

The collective narratives paint a picture of emotions ranging from despair and anger to reconciliation and acceptance. The impact of these biopsy errors will remain with these women for the rest of their lives. Their disfigurement will be a constant reminder of their pain and anguish which will surface in their daily interactions with family/whānau, friends and partners as they struggle to come to terms with why this has happened and hope it never happens again to anyone else again.

c) Clinicians' experience

In addition to the patients' experiences, the Panel also wanted to understand the impact of biopsy errors on the clinicians involved. Interviews occurred with groups of doctors and laboratory staff involved with two of the incidents.

The key points that came out of these interviews included the following.

- Staff are very dedicated and when an error occurs they are utterly devastated.
- Staff involved in an error may experience loss of confidence which may be worsened by a tendency to work through perceived issues in isolation. The importance of collegiality in restoring confidence was stressed.
- Many of those involved welcomed an approach of immediate and open disclosure particularly with the affected patients but also for communication via the media. There were concerns in some instances of incorrect facts being reported in the media.
- Challenges also included:
  - repairing a health system while it is running and at full steam
  - putting things into perspective, having guidance and support in how to respond while being committed to open disclosure.
- Clinicians felt that it is important to have a central body of some kind that this type of incident can be reported to as soon as possible and that it is essential to have consistency across the country.
- Clinicians felt that it would be helpful to have national principles, a national approach and a support package for women and clinicians. This would support consistency of processes and communications.

These points are taken up further below in the discussion section and are reflected in several of the recommendations.

3 Description of laboratory processes and literature review findings

a) Specimen handling process

In respect to the accession, processing, analysis and reporting of anatomical pathology specimens all laboratories in New Zealand follow broadly similar processes, in line with accepted international practice. The following is a description of the process provided by the Surgical Pathology Unit of North Shore Hospital (Waitemata DHB).[6]

- **Collection**. Requesting doctor sends collected specimen with laboratory request form. A consignment/delivery note may also accompany specimen batches collected by the laboratory.
- **Specimen Reception**. Bags and bins are opened one at a time. Two persons check that labels on pots and forms are identical. Specimen pot and request forms matched against consignment or delivery list. Any missing, mislabelled or unlabelled specimens are immediately dealt with by referring back to the requester.
- **Accessioning and Registration**. Form time/date machine stamped and initialled. Accession numbers are stuck on the pots and the request forms. Pots are placed in order, forms copied and maintained in the same order as the pots. Pots and forms are paired and should not be separated. Urgent requests are considered and prioritised as appropriate. Pots and forms are distributed to designated Pathology Assistants (PA) to commence processing. Copies of accessioned forms sent to administrative staff for registration.
- **Specimen Check and Cassette Printing**. Assigned PA prints cassettes using the assigned accession number and the patient's surname.
- Prior to dissection of specimen, the PA checks that identifiers on request form, specimen pot and printed cassettes are all identical. The PA should work with only one specimen and its corresponding form at a given time. The PA dictates the patient's clinical details as written on the request form. The label on the pot is also recorded. Tissue samples described (and or dissected) then placed in the printed tissue cassettes for fixation prior to processing, according to standard process.
- **Processing and Embedding**. Following machine processing, the tissue pieces are removed from the cassettes and transferred to labelled mould and secured with paraffin wax. Paraffin embedded tissue is cut into thin sections and mounted onto glass slides. The slides must have identical identifiers to the block.

[6] Courtesy of Gomez R, Senior Pathology Assistant, Waitemata DHB.

- **Staining, Cover-slipping and Quality Check**. Specimen on the glass slide is stained and cover-slipped. Stained specimen on glass slide is matched to corresponding block as a further quality check. Technician in charge of quality matches the details on request form, block and glass slide. Glass slide is placed in folder with the request form and taken to the pathologist for microscopic examination.
- **Microscopy and Diagnosis**. Pathologist receives folder with request form, the macroscopic description of the samples received, the record of the number of cassettes prepared and the matching slides.
- **Final Diagnosis**. Pathologist examines the slides using a microscope and reports their histologic findings. A report is dictated, again using a system which matches patient details to the specimen number. Report is finalised, signed and exported via the laboratory information system (LIS) to the requesting medical practitioner.
- **Specimen Storage**. Slides, blocks and request forms are kept for 20 years. Remaining tissues are stored for eight weeks. Containers with no specimens are disposed of after four weeks.

b) Summarised findings from literature review

Three hundred and sixty-seven references were extracted relating to errors that may occur with pathology specimens during the pre-analytical, analytical, and post-analytical phases of processing and reporting. These were further filtered for surgical pathology/histology specimens. A representative selection of references is presented in Appendix Two describing the points of processing with potential risk of error along with statistical estimates for prevalence.

The outcomes mostly relate to all histology specimens and will apply to specific specimen types such as breast and also routine and special testing.

Analysis shows that the prevalence of errors in histopathology specimen collection, processing and reporting is relatively small compared to the volume of samples processed in a laboratory. One estimate[7] is that errors occur in about 0.1 percent of specimens handled and that, of these, 1 percent may adversely affect patient care (0.001 percent or 1 in 100,000 specimens). As there is no standard national reporting, either of anatomical pathology volumes or of errors, it is not easy to estimate the prevalence of errors in New Zealand laboratories.

Misidentification by incorrect or insufficient specimen labelling constitutes the major cause of error. The cut-up area and labelling of slides is cited as an area of concern where mislabelling may result in misdiagnosis. One reference reports that the largest number of processing errors occurs with breast samples. Significance of error also relates to specimen complexity (increase complexity relates to more error). There are

[7] Nahkley R, Idowu M, et al. 2011. Mislabelling of cases, specimens, blocks and slides: a College of American Pathologists study of 136 institutions. *Archives of Pathology and Laboratory Medicine* 135(8): 969–74.

also relationships to the time of day and week for processing as well as increased error by non-permanent staff.

Some of the references cited offer solutions to reduce/minimise/determine error such as inking of biopsy specimens, use of PCR identification techniques in cases of suspected transposition, and systems such as electronic ordering and bar-coding of all specimens.

4 Discussion and findings

The Panel considered a number of issues:

- the standard of accreditation, quality assurance and safety in New Zealand laboratories
- specific measures to reduce the likelihood of transposition or interpretation errors
- processes for identification, management and reporting of errors
- the role of MDMs in reducing the consequences of error
- measures to support affected patients
- contextual or environmental factors which may contribute to the risk of errors.

a) Safety and quality assurance in New Zealand laboratories

All publicly funded medical laboratories are required to be accredited with International Accreditation New Zealand (IANZ). IANZ Laboratory Accreditation for Medical Testing is in compliance with NZS ISO 15189 Medical Laboratories – Particular Requirements for Quality and Competence.

The requirement to adhere to quality standards and to participate in regular, formal external audit processes has long been established in New Zealand.

The first medical laboratory to be accredited in New Zealand was in 1977. Initially laboratories were accredited to NZ Code of Medical Laboratory Practice and then to ISO 15189 when it was first published in 2003. New Zealand was the first country to accredit medical laboratories to this international standard. IANZ also has Mutual Recognition Agreements for medical testing with ILAC (International Laboratory Accreditation Cooperation) and APLAC (Asia Pacific Laboratory Accreditation Cooperation), which means any test results from accredited medical laboratories can be accepted in other countries.

Under the standards laboratories must use suitably trained and professionally registered staff. In order to maintain vocational registration pathologists must be engaged in ongoing continuing professional development (CPD) activities. Professional development requirements are set by the Medical Council of New Zealand. The Royal College of Pathologists of Australasia (RCPA) offers an External Quality Assurance Programme with general as well as speciality modules (including breast) that meets the Medical Council requirements and in which most New Zealand pathologists participate. CPD activities include peer review, clinical audit and ongoing education.

Similarly Medical Laboratory Scientists and Technicians must be registered with the Medical Sciences Council of New Zealand and are required to participate in continuing professional development programmes.

The Panel considers that a culture of, and processes for, quality assurance and safety are well established in New Zealand laboratories and, in the view of Panel members, attitudes, systems and practices compare well with laboratories internationally.

The role of accreditation is to ensure that laboratories have adopted appropriate processes and are using technically valid procedures for carrying out the various aspects of their work. The validity and quality of these processes and procedures, along with the effectiveness of the overarching quality management system, is assessed during annual site visits. Accreditation is a formal recognition that a laboratory has adopted a professionally acceptable set of operating procedures and standards of practice and has a quality management system that provides assurance of the quality and validity of examination results. While the use of appropriate processes and effective quality systems should mitigate the risk of error, accreditation is no guarantee that episodic errors will not take place.

The panel notes that all these errors took place in accredited laboratories by appropriately qualified and credentialed practitioners.

b) Measures to reduce the risk of errors

There are specific points along the pathway for receiving, processing, analysing and reporting anatomical pathology specimens where there is risk of loss, transposition or interpretation errors. Laboratories have processes for identifying and managing these 'critical control points' but they are not standardised across laboratories. This results from differences between laboratories in terms of size, degree of sub-specialisation (and hence staff mix) and the degree of automation and information system capability.

The Panel notes that four of the five incidents relate to errors of transposition of specimens during the specimen preparation process (the remaining case involves an interpretation error by the pathologist). Of these four cases of transposition, three appear to have occurred during transfer of specimens from containers to tissue cassettes and one during sectioning with transposition to the wrong pre-labelled slide. The Panel notes that the errors in these cases appear to have occurred at the stages in the specimen preparation process reported in the literature as high risk.

There are current and emergent technologies which automate the specimen preparation process and reduce the risk of human error. These technologies, which include bar-coding and radio frequency identification (RFID), have been used by some institutions, to varying degrees, but are not universally used in New Zealand or Australia. To our knowledge, RFID is not used in New Zealand at present while estimates indicate bar-coding for histology processes is used in approximately a third of laboratories in New Zealand. No New Zealand laboratory is fully automated at the current time.

The Panel considers that as their implementation becomes more economic, such automated, individualised mechanisms for specimen labelling and handling should be the gold standard for reducing the risk of transposition errors.

In the absence of automation, laboratories have used other error reduction strategies.

The use of different indelible dyes for breast core biopsies of different patients has been found to be effective in uncovering transposition errors. This technique is not in wide usage, as it adds approximately 20 percent to the prosection time.

The preparation of core imprint cytology from the fresh (unfixed) cores biopsies and submission of these for examination with the histology sample, provides another safety net to guard against transposition errors. This technique is also in limited use, as cytology skills are required to interpret the core imprints.

The panel believes that, at a minimum, laboratories should utilise, document and be audited on the following process measures to reduce risk:

- where possible in the process only one specimen should be handled at a time, batching is error-prone and should be minimised as far as possible
- wherever possible specimens of the same tissue type should not be handled sequentially[8]
- robust training and supervision of new staff should be a priority
- double checking of specimens and labels by staff at identified critical control points, this includes the pathologists noting the clinical history and macroscopic description of the specimen in comparison to the histologic slides prepared for them
- all checks should be done by in a standard way by all staff involved in the process.

The Panel recognises that laboratories do use some or all of these measures and believes that their use would be strengthened by standardising these requirements and including them in future audits. The Panel notes that the quality managers of laboratories meet on a regular basis and that this would be the ideal group to be tasked with developing the specific criteria.

The Panel notes that correlation of the features of the specimen with the clinical information provided by the requesting clinician provides an opportunity for the examining pathologist and clinicians to identify a potential discrepancy. The more complete the information provided in the request form the greater the possibility that the examining pathologist will identify an error.

[8] The Panel notes that there may be some laboratories which are specialised and which handle a large volume of specimens of the same type. In these circumstances avoiding non-sequential handling may not be feasible and the laboratory should ensure that robust measures are in place to prevent and detect specimen transposition.

c) Management processes in the event of errors

There are no standardised processes across laboratories for identifying, managing and reporting critical incidents involving loss, transposition or misinterpretation of anatomical pathology specimens. Accordingly there is no way of measuring the prevalence of these events or of establishing whether the current cluster represents an emergent trend. The Panel is not aware of any systematic changes in staffing, process or case volume to account for this cluster.

The Panel notes that private laboratories are not required to report serious sentinel events to the Health Quality and Safety Commission.

Laboratories have internal processes for identifying, reporting and investigating critical incidents. However, from anecdotal experience, the Panel believes that more minor events or even 'near misses' also occur from time to time in laboratories and these events are dealt with variously by different laboratories. We have no assurance that systematic and standardised reporting, investigation and mitigation of risk factors occurs in all circumstances. The Panel considers that all laboratories should formally report sentinel level events to the Health Quality and Safety Commission and develop nationally consistent processes for internal reporting, investigating and monitoring of incidents below sentinel level events[9]. In view of the rarity of sentinel events within each laboratory, the Health Quality and Safety Commission may wish to consider pooling and reporting the anonymised experiences of these cases so that the significant opportunities for improvement may be shared with the wider pathology community.

The Panel also considers that compliance with standards for internal identification, reporting and monitoring of critical incidents should be audited by IANZ.

d) The role of multidisciplinary meetings

The Panel notes that in several cases MDMs detected discordance in false negative results and that, in some of the false positive cases, the opportunity may have existed for MDMs to have identified discordance between the clinical, radiological and pathological findings. MDMs do provide an important stage in the decision-making process where data can be reviewed and, if necessary, diagnoses and assumptions challenged. As such they provide an opportunity to mitigate the consequences of laboratory error.

The Ministry of Health's cancer programme provides guidance for implementing cancer multidisciplinary meetings.[10] The focus of the MDM discussions as described is around review and planning the management of cases.

[9] Note that this information should only be for internal reporting by laboratories in order to support quality assurance.

[10] Communication from the Ministry of Health Cancer Programme.

In Australia, particularly in the setting of BreastScreen Australia accredited services, MDMs are convened and charged specifically with correlating the clinical, imaging and pathology findings, ensuring any biopsies are representative and devising the next steps in patient management. Thus review of the diagnostic pathways takes place as formally described process, separate from treatment planning decisions that will follow.

The Breast Screen Aotearoa (BSA) National Policy and Quality Standards[11] (NPQS) do specify that MDMs have a role in reviewing results and establishing concordance of information (Standard 26.1). This is achieved by meetings at the BSA venue to establish concordance of information or as part of a larger breast cancer MDM.

The Panel considers that guidelines for MDMs, both within the auspices of BSA and outside, should clearly state one objective as being review and critical evaluation of the diagnosis, confirmation of concordance of clinical, imaging and pathology findings. Terms of reference based on these guidelines should provide a structured process for MDMs to function.

The Panel also notes that in false negative cases, where there are unusual findings or significant discordance between laboratory findings and other clinical and imaging data, MDMs should consider the possibility that a transposition error may have occurred and work with laboratory providers to identify a corresponding false positive result. In the cases under consideration, the false negative cases were identified and were rebiopsied, but this did not lead to the identification of the false positive cases.

e) Measures to support affected patients and clinicians

If a biopsy error happens again suggestions for better handling and support of such incidents should be followed.

- Acknowledgement and understanding of the full impact and implications of the mistake should be prompt.
- Mistakes should be dealt with promptly.
- Full disclosure of all information should be provided to the women and opportunities to discuss the information with appropriately qualified staff.
- Communication from people representing providers should convey empathy, understanding and a willingness to engage with the affected parties on their terms.
- Options for support should be provided and affected parties should be asked as to what support they prefer including establishing the nature of ongoing contact.
- Acknowledgement that trust has been damaged and that willingness, time and effort will be required to rebuild trust.

[11] BreastScreen Aotearoa: National Policy and Quality Standards. Ministry of Health, Wellington, July 2008.

These suggestions are covered in the Guidance on Open Disclosure Policies that has been produced by the Health and Disability Commissioner (HDC).[12] The Health Quality and Safety Commission is currently developing a web-based training package that will be released in October 2012 to support the health sector and providers to apply the HDC guidelines.

ACC provides cover for individuals of biopsy error as a treatment injury where the legislative criteria are met. This allows individuals access to a range of entitlements for treatment, rehabilitation or support for their day to day needs. Individuals injured through biopsy error are able to seek a lump sum payment by undergoing an impairment assessment which measures the permanent loss of function and any mental or cosmetic injury. Based on the known injures, they are likely to rate low impairment scores and receive limited payment only, if any.

The Accident Compensation Act 2001 (the Act) prevents civil proceedings being taken for damages arising directly or indirectly for personal injury (including Treatment injury) covered by the Act, therefore affected individuals are unable to take proceedings in New Zealand.

Three of the four women have sought lump sum compensation for treatment injury. Their experience to date is that the process for consideration and decision making has been difficult for them. This suggests there is an opportunity for ACC to review and improve its policies and processes in these circumstances.

The affected women's view is that the amount of compensation available for this sort of injury is not commensurate with the harm they experience. The Panel considers this is a policy issue for ACC to consider although it acknowledges this would take some time and would be unlikely to benefit the particular women affected by these current errors.

e) Other issues

There are a range of other systemic or contextual factors that have also been suggested to the Panel as possible contributors to an increased likelihood of specimen loss or transposition errors. These include tight reporting timeframes, workforce pressures in the face of increasing demand and a culture that does not support collaboration between laboratories.

The BSA reporting requirement is for 80 percent of core biopsy results to be reported within three working days. It has been suggested that in some circumstances, meeting these reporting timeframes creates pressure that increases the risk of errors. It is also reported that in some cases the next scheduled MDM occurs within the three working days, requiring even faster reporting to avoid delays in treatment decisions.

[12] Guidance on Open Disclosure Policies Health and Disability Commissioner, Revised December 2009: http://www.hdc.org.nz/decisions--case-notes/open-disclosure

Some observers believe that these reporting requirements are unduly onerous and are not justified on the grounds of clinical need even for the treatment of breast cancer. However there is also a contrary view that the timeframes in the BSA standards are reasonable especially in the context of a screening programme where it is considered most important that women have certainty at the earliest possible stage. The view of a national breast consumer group (Breast Cancer Aotearoa Coalition) is that the current NPQS standard is appropriate, unless it is clear that it compromises quality.

The Panel's view is that the BSA standard is appropriate but that MDMs need to be scheduled in a way that allows adequate time for laboratory reporting.

The Panel also considers that handling of specimens by routine processes helps to reduce the risk of errors. Increasing the urgency with which a specimen is handled – either at the request of a referrer or to meet a scheduled MDM – should be a rarity.

Another concern centres on overall workforce pressures in the face of increasing demand. The suggestion is that funding mechanisms fail to account for increasing volume and complexity of laboratory work; the result is a workforce spread too thinly with concomitant increase in errors. The Panel is not in a position to comment on these suggestions or concerns but does note a relative absence of systemically collected and internationally benchmarked data on laboratory staffing.

The Panel notes that policy makers, funders and providers of laboratory services are currently meeting as part of a Laboratory Roundtable process (reviewing the strategic direction of laboratory services in New Zealand). The Panel considers that defining workforce information requirements and benchmarking should be included in the Roundtable's workplan.

A final concern relates to the apparent barriers to laboratories collaborating on quality issues. As stated, the Panel considers that laboratories do promote a culture of safety and quality within their own organisation. Ideally laboratories would also work collectively to develop and share effective and efficient approaches to quality. However in the competitive New Zealand commercial environment, there may be some reluctance for laboratories to collaborate. The Panel recognises the reality of the commercial environment but believes that if the contracting framework is configured in ways that support greater collaboration on quality and systems, error rates may be reduced.

This issue should also be considered by the Laboratory Roundtable process.

5 Recommendations

a) For providers

1 DHBs and private health providers, including providers of laboratory services, should examine their implementation of open disclosure particularly in relation to support for patients and staff affected by errors[13]. Support measures should include:

- prompt acknowledgement and understanding of the full impact and implications of the mistake
- full disclosure of all information should be provided to the women and opportunities to discuss the information with appropriately qualified staff
- communication from people representing providers should convey empathy, understanding and a willingness to engage with the affected parties on their terms
- options for support should be provided and affected parties should be asked as to what support they prefer including establishing the nature of on-going contact
- acknowledgement that trust has been damaged and that willingness, time and effort will be required to rebuild trust.

2 All laboratories (public and private) should be required to report sentinel events to the Health Quality and Safety Commission.

3 Individuals involved in preventable serious and sentinel events resulting from biopsy errors should be advised of the scope of their entitlements. Clinicians should be aware of patient entitlements and proactively support individuals with entitlements as their clinical presentation and needs change over time.

4 Over time and as technical solutions become economic, automation should be pursued for steps involving specimen handling. The aim is for technological means, such as bar-coding, to be introduced by all laboratories to reduce the risk of specimen handling errors. Until technological measures are universal laboratories should collectively create a standard for process measures to reduce risk. The standard should form part of the IANZ audit process.

5 Process measures to reduce the risk of transposition errors should include:

- where possible in the process only one specimen should be handled at a time

[13] The Health Quality Safety Commission is developing an on line learning package on open disclosure due for release in October 2012, which may assist providers to refine their current policies and procedures, or help the development of policies and procedures where these are not currently in place.

- wherever possible specimens of the same tissue type should not be handled sequentially
- robust training and supervision of new staff should be a priority
- double checking of specimens and labels by staff at identified critical control points
- all checks should be done in a standard way by all staff involved in the process.

6 Using the National Laboratories Quality Managers Group and with input from the appropriate professional bodies, laboratories should develop and implement a standard process for identification, management, internal reporting and monitoring of critical incidents (or near misses) in histopathology, particularly those involving specimen loss or transposition.

b) For the Ministry of Health

7 The Ministry of Health should ensure that guidelines for MDM processes clearly specify their role in confirming diagnoses and establishing concordance between clinical, imaging and pathology data. Consideration should be given to a separate meeting to specifically achieve these aims, distinct from management and treatment planning MDMs.

8 These five critical events should be written up by the Ministry of Health as an educational package and used to support quality improvement among laboratories.

c) For the Laboratory Roundtable

9 The Laboratory Roundtable forum should consider and mitigate any contractual or funding barriers to collaboration between laboratories on improving quality and safety.

10 The Laboratory Roundtable forum should consider routine collection of:

- trends in demand and complexity in anatomical pathology
- workforce trends and requirements
- appropriate international benchmarks.

d) For ACC

11 ACC should note the experiences of the women in this report and consider its policies in regard to lump sum compensation for patients affected by biopsy errors as well as its processes for responding to such claims.

Appendix One: National Panel to Review Breast Biopsy Errors Terms of Reference

19/6/2012

Background

1 As of early June 2012 the Ministry of Health was aware of four confirmed or possible cases where pathology tests for breast cancer had been misinterpreted, or the results transposed between patients, resulting in false positive results being provided to the women. These biopsy errors have occurred in both screening and diagnostic pathways and in both public and private laboratories. Investigations into each of these events by the relevant agencies are either underway or have been completed.

2 The Ministers of Health have asked for assurance that women who have had biopsies can have confidence in the results they receive, and for recommendations for any quality improvement measures that may be required.

3 The Chief Medical Officer has been charged with providing this advice to the Ministers and has convened a panel of experts (the Panel) to assist him in this task.

Scope

4 The mandate of the Panel is to provide the Chief Medical Officer (who shall be its Chair) with expert advice on laboratory processes for the handling of breast cancer biopsy specimens and communication of results.

5 Specific issues for the Panel to advise on include, but are not limited to:

- what safeguards exist in laboratories to prevent transposition of either specimens or results
- what safeguards exist in laboratories to minimise the risk of biopsy interpretation error
- is there any external validation for these processes
- are these processes standardised across New Zealand
- do these processes reflect best practice

- assessment of the impact of errors on women and providers
- what, if anything, needs to be done to improve the quality or consistency of these processes.

Membership of the Panel

Panel members have been selected primarily to provide expert advice rather than to represent the views of their organisations. However it is expected that members will make use of their networks, associations and organisations in order to provide the best possible advice.

Panel membership

Name	Title	Organisation
Don Mackie (Chair)	Chief Medical Officer	Ministry of Health
Associate Professor Gelareh Farshid	Senior Consultant Pathologist, South Australian Pathology Clinical Director, BreastScreen SA	The Royal College of Pathologists of Australasia (RCPA)
Richard Steele	Vice-President for NZ and Chairman NZ Committee	The Royal College of Pathologists of Australasia (RCPA)
Chris Walsh (consumer representative)	Chair	National Cancer Consumer Representation Advisory Group
	Vice Chair	Breast Cancer Aotearoa Coalition
Gavin Harris	Anatomical Pathologist	Canterbury Health Laboratories
Karen Wood	CEO, Anatomical Pathologist	Aotea Pathology
Andy Simpson	National Clinical Director, Cancer Programme	Ministry of Health (from 4 July 2012)
	Executive Director (Clinical), Medicine Cancer & Community	Capital & Coast DHB
Gloria Crossley	Clinical Services Manager (Allied Health, Scientific and Technical)	Taranaki DHB
Shelli Turner	Programme Manager Medical Testing (and NSU National Cervical Screening Programme)	International Accreditation New Zealand (IANZ)
Stephen Allpress	Pathologist, BreastScreen Waitemata	National Screening Unit Unidisciplinary Group

Roles and process

6 The Panel Chair is responsible for the following:

- overseeing and chairing meetings
- coordinating the work of the Panel and delivery of a final report
- facilitating discussion among members
- right of decision on co-opted members or invited guests
- designated spokesperson for Ministers of Health, and the media if required.

7 Meetings of the Panel may be conducted face-to-face, by videoconference or teleconference. Panel members are expected to undertake work between, and in preparation for, the meetings to ensure the progress of the Panel's work.

8 Members have a responsibility to offer independent and balanced advice. Other responsibilities include:

- being available and prepared to participate in meetings of the panel
- considering information that is relevant to the Panel's mandate
- sourcing the information the Panel must or may use in reaching its conclusions, including the views of relevant stakeholders and specialist clinical or other advice.

9 Decision-making on the wording of a final report will be by consensus. If a consensus is not possible then a report reflecting the majority view will be prepared with a clear description of minority views.

10 Discussion will be conducted under principles of transparency and open disclosure although confidentiality will need to be maintained with some material such as information around specific cases. The Panel may hold discussions in committee with the approval of the Chair.

11 The Panel will have access to relevant material held by the Ministry of Health such as incident reports and literature reviews.

12 The Ministry of Health will provide secretariat, logistical, analytical and financial support for the Panel as required.

13 A register of interests will be maintained. Potential conflicts of interest should be identified as soon as they arise and will be managed by the Chair.

Appendix Two: Summary of literature review references pertaining to errors in processing for histology

Reference	Cases	Detail	Outcome	Data analysis
Bronner MP. 2006. *DNA Fingerprint Analysis for Specimen Identification*. Cleveland Clinic Clinical and Translational Pathology Research. Fall: 5–7.	Report from Cleveland Clinic	Histology processing steps where errors leading to diagnostic mistake	List of process points for risk	N/A
Nakhleh RE. 2006. What is quality in surgical pathology? *Journal of Clinical Pathology* 59(7): 669–72.	Quality in surgical pathology	Identifying points of error	List and descriptions of key points of error	N/A
Know Error. 2010. *Specimen Provenance Complications in the Biopsy Evaluation Process: Frequency of occurrence, detection methods, and prevention*. Know Error, Specimen Provenance Complications, November.	White paper. Specific case base outcomes	Specimen provenance complications in tissue biopsy processing	Review of histology errors with case based examples including prostate and breast with methods to reduce errors	1.02% complications due to specimen mix ups or contamination
RCPA. 2004. *Breast Fine Needle Aspiration Cytology and Core Biopsy: A guide for practice*. RCPA and National Breast Cancer Centre, 1st edition.	Best practice guidelines for breast FNA and core biopsy	Best practice including basic requirements for processing	Reiteration of need for good QA and preventing sampling errors	Standard for false negative rate of less than 6%
Nakhleh RE, Idowu MO, et al. 2011. Mislabelling of cases, specimens, blocks, and slides: a College of American Pathologists study of 136 institutions. *Archives of Pathology and Laboratory Medicine* 135(8): 969–74.	Study across 136 institutions	Investigation of mislabelling	Analysis and reinforcing quality checks	Mislabelling rates (0.11%), specimens (0.1%), blocks (0.17%), and slides (0.11%)

Reference	Cases	Detail	Outcome	Data analysis
Smith ML, Raab SS. 2011. Assessment of latent factors contributing to error: addressing surgical pathology error wisely. *Archives of Pathology and Laboratory Medicine* 135(11): 1436–40.	Observational check list method with root cause analysis over 5 days	Frequency and cause of near miss events during processing	Focus on near miss events to identify latent factors to target	2310 process-dependent and 266 operator-dependent near-miss events (frequency of 5.5 per specimen)
Layfield LJ, Anderson GM. 2010. Specimen labelling errors in surgical pathology: an 18-month experience. *American Journal of Clinical Pathology* 134(3): 466–70.	18-month study of mislabel errors from receipt to reporting	Calculation of error per case, block and slide	Mostly occurred during cut up, and related to slide labelling	75 labelling errors (0.25% of cases) detected. 73% involved patient name, 24% involved site
Renshaw AA, Kish R, et al. 2007. The value of inking breast cores to reduce specimen mix-up. *American Journal of Clinical Pathology* 127(2): 271–2.	Inking of 1000 consecutive breast core biopsies	Identify rate of switching (mix up) of **breast biopsy specimens**	3 case errors. Recommend inking to reduce	1 blocks being switch, 1 incorrect labelling, 1 typographical error
Hill PM, Mareiniss D, et al. 2010. Significant reduction of laboratory specimen labelling errors by implementation of an electronic ordering system paired with a bar-code specimen labelling process. *Annals of Emergency Medicine* 56(6): 630–6.	61-month study of specimens from ED department including histology	Comparative hand versus electronic bar code labelling	Majority of continued errors with hand labelling including histology biopsies	0.42% preintervention, errors versus 0.11 postintervention, a 74% relative and 0.31% absolute decrease
Rakha EA, Clark D, et al. 2012. Efficacy of an incident-reporting system in cellular pathology: a practical experience. *Journal of Clinical Pathology*.	Analysis of 584 biopsy incidents over 2 years	All phases of process analysed with root cause analysis for risk	Booking in and specimen labelling most significant. 14% posed a major risk to patients, such as specimen loss or mix-up	59% occurred pre-analytical, 23% analytical and 18% post-analytical phases. 56% were booking-in and specimen labelling-related incidents
Amin S, Freeman A, et al. 2011. PCR-based tissue identification: the UCLH experience. *Journal of Clinical Pathology* 64(10): 921–3.	PCR techniques to reduce specimen carry over since 2003	Emphasis on carry over with malignancy	Experience in effectiveness of technique to reduce carry over	Reported rates of carryover range from 0.6% to 2.9% of slides without intervention

Reference	Cases	Detail	Outcome	Data analysis
Sandbank S, Klein D, et al. 2010. The loss of pathological specimens: incidence and causes. *Dermatologic Surgery: Official Publication for American Society for Dermatologic Surgery* [et al] 36(7): 1084–6.	4400 outpatient plastic surgeon biopsy specimens	Measure of specimen loss	Critical point of specimen loss was noninsertion of the specimen into the container by medical staff	Incidence of specimen loss was 1 in 1466 (0.068%)
Dunn EJ, Moga PJ. 2010. Patient misidentification in laboratory medicine: a qualitative analysis of 227 root cause analysis reports in the Veterans Health Administration. *Archives of Pathology and Laboratory Medicine* 134(2): 244–55.	Quantitative analysis of 227 root cause analysis reports	Patient misidentification from sampling to reporting including histology	Detailed analysis of 132 pre-analytical, 37 analytical and 13 post-analytical events across pathway	Patient misidentification accounted for 182 (71.9%) of 253 adverse events
Makary MA, Epstein J, et al. 2007. Surgical specimen identification errors: a new measure of quality in surgical care. *Surgery* 141(4): 450–5.	21,351 in- and outpatient biopsies for a 6-month period	Analysis of the incidence and type of specimen labeling errors **and includes breast**	Procedures involving breast most common for ID error	Identification errors are common and occurred in 4.3 per 1000 surgical specimens. 0.512% originated from outpatients and 0.346% from inpatients
Schmidt RL, Messinger B, et al. 2012. Labelling errors in a surgical pathology gross room: a root cause analysis. *Laboratory Investigation* 92: 506A.	42,684 specimens over 22 months	Root cause analysis of errors throughout pathway	Errors increase with more complex specimens and times of day when processed	0.2% labelling errors, 10 times higher for non-regular staff
Casey M, Rosenblatt R, et al. 1997. Mastectomy without malignancy after carcinoma diagnosed by large-core stereotactic breast biopsy. *Modern Pathology* 10(12): 1209–13.	Case study of potential false positive **core breast biopsy** followed by definitive surgery	3 cases studied to determine reason for false positive	Reasons presented including misidentification	8% of cases not confirmed as malignant on mastectomy

Appendix Three: Immediate steps taken by laboratories

1 All laboratories reviewed their systems and processes following the serious and sentinel event occurring and have made immediate changes to minimise the risk in the future of the incident occurring again. Examples of changes made by laboratories include:

- a the matching of the correct pot to the individual request form by two people independently by a member of staff writing the number on the cassette and showing another member of staff
- b additional staining of certain specimen types to further assist a differential diagnosis to be made
- c a review of the protocol of performing and recording independent double reading of particular pathology specimen slides and the way in which discordance is resolved and recorded
- d a review of the incident notification process and to formalise the development of a sentinel event policy
- e to implement into practice a policy for the separation of core biopsy samples both during processing and reading
- f the separation of biopsies by other types of specimens and this to be added to the manual of the cut-up assistant and the cut-up procedure manual
- g review and revise the Standard Operation Procedure to specify the checks of patient identification before and after sectioning
- h reinforcing that slides are not to be pre-labelled
- i a review of the cut-up procedures in all areas was completed and the manual was updated
- j the process of independent review of staff practices at cut up benches has been defined
- k a requirement for all medical staff working in the cut-up room to read the manuals and record that they have done so
- l a copy of the specimen radiograph must now be attached to the request form for all screening and diagnostic breast biopsies. This requirement will provide a further safeguard with respect to lesion and patient identification
- m a review of histology laboratory process/work flow
- n the implementing of a quality monitoring and reporting system

o reviewing the options for technical and managerial leadership structures in Histology Laboratory to enhance dedicated technical advisory leadership

p the creation of a regional networking quality model (with a focus on learning/sharing of best practice) for histology laboratories.

2 In response to the incident being notified, a second (and broader) investigation was also undertaken by the organisations that were accountable for the laboratory services. The actions identified by the laboratory were considered by these reviews and included into their reports, where appropriate. Actions that were identified as being relevant for other participants in the health system were also included in these reports to enable the wider health system to improve from the incident and to prevent its re-occurrence.