Southern Community Laboratories Limited

Southern District Health Board

A Report by the

Health and Disability Commissioner

(Case 12HDC01574)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. This report is about the standard of care provided to Mrs X by Southern Community Laboratories Limited (SCL) and Southern District Health Board (SDHB) in 2012.

2. In January 2012 Mrs X found a lump in her right breast. She underwent a number of clinical examinations including biopsies of both breasts. The biopsy result from her right breast revealed sclerotic fibroadenoma, a benign lump. That result was considered to be inconsistent with Mrs X's clinical presentation and, following a multidisciplinary meeting, it was agreed that Mrs X should undergo another biopsy. On 2 February 2012 Mrs X underwent a further biopsy, which revealed invasive lobular carcinoma (invasive breast cancer). Mrs X subsequently elected to have a bilateral mastectomy.

3. In March 2012 concerns were raised that another patient (Patient Y) had had unnecessary surgery due to a biopsy swap. Internal investigations undertaken by the providers involved concluded that Mrs X's biopsy of 25 January 2012, and Patient Y's biopsy of the same day, had been swapped inadvertently at SCL. While SDHB informed Patient Y of the biopsy swap as soon as it came to light, Mrs X was not informed until three months later.

Findings

4. Although it appears that human error led to Mrs X's tissue sample being swapped with a sample from another consumer, SCL's processes for handling late-delivery breast biopsies such as Mrs X's included unsafe practices. Those practices directly contributed to Mrs X receiving biopsy results that did not belong to her. By failing to ensure that its processes were sufficiently robust, SCL failed to provide services with reasonable care and skill and, therefore, breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[1]

5. Open disclosure should occur where a consumer has been exposed to possible harm, irrespective of whether harm has occurred or is immediately apparent. In this case, a biopsy swap occurred, and both consumers involved should have been informed in a prompt and transparent manner. However, SDHB did not inform Mrs X of the error in a timely and appropriate manner. As a result, SDHB failed to provide Mrs X with information that a reasonable consumer in her position would expect to receive, and breached Right 6(1) of the Code.[2]

[1] Right 4(1) of the Code states: "Every consumer has the right to have services provided with reasonable care and skill."
[2] Right 6(1) of the Code states: "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive."

Complaint and investigation

6. The Commissioner received a complaint from Mrs X about the services provided to her by Southern District Health Board and Southern Community Laboratories Limited. The following issues were identified for investigation:

   - *The appropriateness of the care provided to Mrs X by Southern Community Laboratories Limited in 2012.*
   - *The appropriateness of the care provided to Mrs X by Southern District Health Board in 2012.*

7. An investigation was commenced on 2 April 2014.

8. The parties directly involved in the investigation were:

Mrs X	Consumer
Southern District Health Board	Provider
Southern Community Laboratories Limited	Medical testing laboratory/Provider

Also mentioned in this report:

Dr C	Consultant breast surgeon
RN D	Breast Care Nurse Specialist
Dr E	SCL Clinical Director
Dr F	Pathologist
Dr G	Breast surgeon
Dr H	Pathology registrar
Dr I	Chief Executive Officer
Ms J	Cut-up assistant

9. Independent expert advice was obtained from pathologist Dr Mee Ling Yeong (**Appendix A**).

Information gathered during investigation

Background

10. On 11 January 2012, Mrs X, then aged 54 years, saw her general practitioner (GP) due to a palpable lump in her right breast. Her GP referred her to the breast clinic at a public hospital.

First consultation — 23 January 2012

11. On 23 January 2012, Mrs X met with consultant breast surgeon Dr C and Breast Care Nurse Specialist RN D. Dr C recorded in the clinical notes that there was a suspicious mass in Mrs X's right breast and a large suspicious lymph node palpable in the right

axilla. Dr C requested a mammogram,[3] ultrasound,[4] and core biopsy of the mass in the right breast, and a fine needle aspiration (FNA)[5] of the right axillary lymph node.

Biopsies — 25 January 2012

12. On 25 January 2012, Mrs X provided written consent for a right breast core biopsy and an FNA of the right axillary lymph node.

13. On the same day, Mrs X underwent a bilateral mammogram and ultrasound, performed by a radiologist. Following these assessments, the radiologist considered that Mrs X's left breast should also be biopsied. The radiologist recorded:

> "It was decided to undertake a core biopsy of the main tumour within the right breast, but not to FNA the axillary nodes at this time due to the high number of biopsies required and the nodes being so grossly abnormal that axillary dissection will be required regardless of the FNA result. On the left [two] core biopsies … [have] been planned, with FNA of the left axillary nodes as these are more indeterminate."

14. RN D told HDC that the left breast biopsy was discussed fully with Mrs X, and that Mrs X gave verbal consent for her left breast to be biopsied.

15. Mrs X underwent one core biopsy of her right breast, and two of her left breast, as well as an FNA of the left axillary lymph node (as opposed to the right, as originally planned). The biopsies were sent to Southern Community Laboratories (owned and operated by Southern Community Laboratories Limited (SCL))[6] for processing.

16. The histology report for Mrs X's right breast revealed sclerotic fibroadenoma (a benign lump)[7] and associated microcalcification, with no evidence of malignancy. The histology report for her left breast revealed microcalcifications at both sites, with no evidence of malignancy.[8] Both histology reports were dated 25 January 2012 and signed off by three pathologists.

Biopsies — 2 February 2012

17. On 1 February 2012, Mrs X's case was discussed at a multidisciplinary meeting (MDM). The clinical records note that the benign histology results from Mrs X's right breast biopsy (sclerotic fibroadenoma) were inconsistent with her clinical

[3] A diagnostic and screening tool that uses low-energy X-rays to examine the breast.
[4] An imaging technique.
[5] A diagnostic procedure that uses a thin, hollow needle, inserted into a superficial lump, to extract cells for histological examination.
[6] SCL is a company that provides medical laboratory testing services directly and through a series of subsidiary companies throughout New Zealand. All laboratories within the SCL group are accredited by International Accreditation New Zealand (IANZ). The laboratories within the SCL group are also part of Healthscope NZ Limited, which provides a range of pathology services throughout New Zealand.
[7] A fibroadenoma is a benign breast lump composed of fibrous and glandular tissue. A sclerotic fibroadenoma is one that has stiffened, usually due to connective tissue.
[8] Microcalcifications associated with benign ducts and stroma (at 12 o'clock) and microcalcifications associated with fibrocystic change and adenosis (at 3 o'clock).

presentation, and so a repeat biopsy of the right breast was recommended. The result was considered to be a "false negative", which SDHB described to HDC as "not … a true representation of the abnormality of the breast". Dr C told HDC that "false negatives" are to be expected during breast cancer diagnosis. SDHB told HDC that the possibility that the biopsy results had been wrongly attributed to Mrs X due to an error at SCL was not considered.

18. The (benign) pathology result from the left side was considered consistent with the clinical and radiological findings.

19. At the same meeting, other breast patients were also discussed. One of those patients, Patient Y, had had a left breast biopsy taken (also on 25 January 2012), which had revealed pleomorphic invasive lobular carcinoma.[9] The MDM agreed that Patient Y would undergo further clinical investigation.

20. On 2 February 2012, two further biopsies were performed on Mrs X's right breast. The histology report, also dated 2 February 2012, revealed invasive lobular carcinoma (an invasive breast cancer).[10] This report was signed off by three pathologists, as well as pathologists Dr F and Dr E.

Bilateral mastectomy

21. On 10 February 2012, Dr C met with Mrs X and discussed the further imaging and treatment that were recommended. Among Dr C's recommendations was that Mrs X have magnetic resonance imaging (MRI)[11] of both breasts. Mrs X was later informed that the wait for an MRI in the public system would be five weeks and, consequently, Mrs X elected to have private treatment.

22. On 23 February 2012, Mrs X's care was taken over by breast surgeon Dr G in his capacity as a private surgeon. On the same day, Mrs X underwent an MRI of both breasts. The MRI showed extensive malignancy in the right breast and three areas in the left breast that were too small to characterise accurately on an MRI and needed further investigation. On 28 February 2012, Dr G recorded that he had discussed the MRI and options for treatment with Mrs X, and that she had decided to have a bilateral mastectomy. On 8 March 2012, Mrs X underwent a bilateral mastectomy (carried out privately by Dr G and Dr C).

Concerns raised

23. On Friday 9 March 2012, SCL consultant pathologist Dr F was reporting a mastectomy specimen for Patient Y. As part of that process, Dr F reviewed Patient Y's biopsy slides of 25 January 2012, which showed pleomorphic invasive lobular carcinoma, and her post-surgical biopsy slides, which showed no evidence of malignancy. This review confirmed that the biopsy slides had been correctly read and reported. Dr F told HDC that the differences between the samples nonetheless

[9] A rare and aggressive form of breast cancer, which starts in the cells of the lobules (milk-producing glands) that line the breast, and has spread to surrounding tissue.
[10] This is distinct from pleomorphic invasive lobular carcinoma.
[11] An imaging technique.

concerned her, as "… it seemed unlikely that we would not be able to identify a tumour [in the post-surgical histology] given the type and amount of tumour in the diagnostic biopsy".

24. Dr F investigated her concerns by initially "checking that all the laboratory form labelling and details, slide, and block numbering [for Patient Y] were correct", which was confirmed.

25. Dr F then reviewed the other breast biopsy samples submitted to SCL on 25 January 2012. She described her findings to HDC as follows:

> "Two other specimens were submitted that day from [Mrs X] … all of which were benign. I noted that [Mrs X] had had a subsequent biopsy … dated 02/02/12 which was diagnosed as invasive lobular carcinoma. On review this tumour looked remarkably similar to that seen in the initial tissue submitted on [Patient Y] …"

26. Based on her findings, Dr F became concerned that Mrs X's and Patient Y's biopsy specimens submitted on 25 January 2012 had been swapped. After informing SCL Clinical Director Dr E, Dr F alerted Dr C and Patient Y's surgeon to her concerns. On Monday 12 March 2012, Dr F, Dr E and Patient Y's surgeon met and arranged for SDHB and SCL to commence formal investigations, in order to ascertain whether a biopsy swap had occurred and, if so, when and where.

27. In March 2012, representatives from both SDHB and SCL met with Patient Y to discuss the suspected error and apologise. However, Mrs X was not informed of the error at this time. SDHB did not inform Mrs X of the biopsy swap until 13 June 2012, when Patient Y expressed a desire to speak with her (discussed further below).

28. On 30 March 2012, DNA testing confirmed that Mrs X's and Patient Y's biopsy results of 25 January 2012 had been swapped.

Subsequent communication with Mrs X

29. On 16 April 2012, SDHB wrote to Patient Y to inform her formally that it planned to review the mix-up in her biopsy sample. SDHB did not inform Mrs X of the biopsy swap or of the intended review at this time.

30. Mrs X told HDC that she had conversations with Dr G on 19 April and 21 May 2012, during which he suggested that she had been involved in a biopsy swap, and that SDHB would contact her about this.

31. From May 2012 onwards, the fact that a biopsy swap had occurred and resulted in unnecessary surgery for Patient Y drew media attention. Several online and print news articles in respect of the biopsy were published, with comment from SDHB. None of the articles named the patients involved.

32. On 13 June 2012, RN D contacted Mrs X to ask if she would be willing to meet with Patient Y, who had expressed a desire to meet with her. This was the first time that SDHB had contacted Mrs X about the biopsy swap. SDHB told HDC that RN D was

considered the best person to contact Mrs X, as they had a pre-existing relationship. Mrs X told RN D that she would be happy to meet with Patient Y, but expressed dissatisfaction with the lack of communication from SDHB generally.

33. Subsequently, representatives from SCL apologised to Mrs X for the biopsy mix-up, and SDHB also apologised for the failure to disclose the biopsy mix-up to her. Both made offers to meet with her.

34. Mrs X told HDC that the way SDHB communicated with her about the biopsy swap caused her to feel isolated, frustrated and hurt.

35. SDHB told HDC:

> "… Southern DHB apologises for not communicating with [Mrs X] sooner about her involvement in the Laboratory incident. The focus had initially been on the patient who had unnecessary surgery as a result of this incident. We acknowledge that [Mrs X] should have been informed of the incident and the investigation process earlier than she was, and it is recognised that early notification may have allowed [Mrs X] to raise any other concerns relating to her treatment, and to discuss those concerns with appropriate staff members."

SDHB's review

36. SDHB conducted an internal investigation into the incident and issued a Severity Assessment Classification (SAC) 1 Event Review Summary (the Review Summary).[12]

37. According to the Review Summary, both Mrs X's and Patient Y's biopsies were taken on 25 January 2012 in the Breast Care Unit at the hospital. The Review Summary states that the correct protocol for the collection of specimens was followed.

38. On 16 October 2012, SDHB sent Mrs X a redacted copy of the Review Summary, along with an invitation to discuss it.

SCL's review

39. SCL carried out its own internal review of the incident. As a result of its review, SCL found that the error was likely to have occurred when the biopsy samples were removed from their transport containers (the specimen containers) and placed into a plastic cassette used to hold the biopsy sample while in the processing machine (the histology cassette), during the "cut-up" process at the laboratory.

Cut-up process

40. "Cut-up" refers to the process where tissue samples from biopsies are prepared for final analysis. At SCL, "cut-up" is performed according to the guidelines specified in SCL's "Histology Cutup Assistants Procedures Manual" (the Manual). SCL provided

[12] SAC is a numerical rating that defines the severity of an adverse event (from 1, meaning severe, to 4, meaning minimal) and, as a consequence, the required level of reporting and investigation to be undertaken for the event.

HDC with a chart illustrating how the cut-up process is integrated into the histology process (ie, biopsy analysis) (**Appendix B**).

41. SCL advised that, at the time of these events, the standard cut-up process for each biopsy sample was as follows:

- The cut-up assistant scanned the biopsy specimen into the computer to confirm it had arrived in the cut-up room.
- The cut-up assistant checked that the patient details on the specimen container and specimen request form matched.
- The cut-up assistant labelled the specimen container with a unique number given to each biopsy specimen, called an accession number.
- The cut-up assistant handwrote the patient's name on the side of a histology cassette (the container in which the specimen is placed for analysis) and the accession number on the top.
- The pathology registrar checked that the two forms of identification on the histology cassette (ie, the patient's name and the accession number) matched the specimen request form and the specimen container.
- The pathology registrar opened the specimen container, removed the biopsy specimen in order to dictate its macro (ie, general) description, and then transferred the biopsy specimen to the histology cassette.

42. On 25 January 2012, the pathology registrar was Dr H, and the cut-up assistant was Ms J. SCL advised that Dr H was responsible for ensuring that the transfer of biopsy samples from specimen containers to histology cassettes was completed appropriately.

43. SCL found that, at some point during the cut-up process, Mrs X's right breast biopsy sample (which was given accession number XX-XXX4)[13] and Patient Y's left breast biopsy sample (which was given accession number XX-XXX5) were transposed. The sequential accession numbers indicate that the specimens were likely to have been positioned next to each other in the line of waiting specimen containers.

44. Dr H advised HDC:

> "In this case the nature of the process is such that I cannot know for certain what happened on the day of the error but I have no reason to doubt that I and the cut up assistant followed the standard practice of the cut up room. I have been over this in my mind many, many times and I do not know when in the process or how the error was made."

Pre-labelled histology cassettes

45. At the time of these events, the Manual did not specify exactly when the histology cassettes should be labelled.

[13] Mrs X's left breast biopsy, which was correctly assigned to her, was given the accession number XX-XXX6.

46. SCL advised HDC that, rather than labelling histology cassettes at the time they were needed, usual practice at the time of these events was for the cut-up assistant to pre-label the histology cassettes, "usually a whole batch of cassettes in advance". The histology cassettes were then placed on top of the matching specimen containers in preparation for transfer. When the pathology registrar came to dictate the specimen's macro description and transfer the specimen from the specimen container to the histology cassette, he or she would first move the paired specimen containers and histology cassettes from where they were placed, onto the cut-up bench, and then proceed with the rest of the procedure.

47. SCL told HDC:

> "While we cannot know for certain the reason for the error in this instance, it is likely that somehow the [histology] cassettes on adjacent [specimen containers] were mixed up, and this was not noticed by [Dr H]. Since these adjacent specimens were both breast core biopsies, the error was not found later in the histology process, as it would have been if the samples had been spaced appropriately, and the diagnoses were thereafter accurate but applied to the wrong patients."

Spacing and breast biopsies

48. SCL advised HDC that "spacing" refers to the practice of having different tissue types adjacent to one another during the cut-up process. Alternatively, it can mean placing two biopsies of the same tissue type next to one another, but ensuring that they are cut in a different way. For example, placing a skin sample cut with a scalpel and elliptical in shape next to a skin sample cut with a round biopsy tool (known as a punch biopsy), in order for them to be differentiated easily. SCL further advised HDC that spacing biopsy samples provides an additional safeguard against errors such as the one that occurred in this case because, if specimen containers or histology cassettes are inadvertently mixed up, the different tissue types or shapes will make the error more easily detectable later during the histology process.

49. The Manual at the time stated:

> "It is **ESSENTIAL** that specimens of a similar type are **NOT** serially accessioned, or processed sequentially at cut up i.e. always 'case-mix' breast cores / prostate biopsies with other types of specimens."

50. In this case, spacing did not occur. Mrs X's and Patient Y's biopsies, which (as stated above) were likely to have been next to one another in the cut-up room, were both breast biopsies.

51. SCL told HDC that, at the time of these events:

- the Manual required that breast core biopsies were treated as "urgent" because the Breast Screening Programme policy required that all breast core biopsy histology results be reported within 24 hours;

- the laboratory where this incident occurred was dealing with an increased workload because another SCL laboratory was not fully operational; and
- breast biopsies often arrived in the last delivery of specimens for the day at about 4.30pm.

52. SCL advised HDC that, in light of those factors, Mrs X's and Patient Y's breast biopsies would been have "batched" (ie, processed sequentially and without spacing) because "either all other specimens were already processed, or other non-urgent specimens were left for the following morning to be processed".

Changes to practice

53. SCL told HDC that it has taken the following steps as a result of this incident:

- All laboratory staff involved in the cut-up process have been reminded of the need to be vigilant with respect to checking all patient identifiers on histology specimens, and to ensure that only one specimen container is open at a time.
- It has stopped the practice of treating breast biopsies as routinely urgent because it considers that practice to be "potentially dangerous" because it disrupts the laboratory's usual practices and removes safety checks, as outlined above. SCL advised HDC: "Turn-around-times are not significantly altered by this change; it is our belief that any advantage gained by the urgent treatment of breast tissue analysis, is outweighed by the inherent risks of an incident such as this [case]."
- It has stopped the practice of pre-labelling histology cassettes. Histology cassettes are now labelled individually at the time the pathology registrar requires them.
- Spacing is now compulsory at all times. In the event that breast biopsies are received at the end of the day (and are therefore unable to be cut up alongside samples of a different tissue type or shape), they are not processed until the following day.
- It has commenced expansion and updating of the work area available for processing histology specimens.
- Pathologists and registrars are now authorised to view biopsy specimen X-rays through a digital radiology system, MammoPACS, which will provide a further opportunity for detection of error.
- It is in the process of introducing cassette and slide printers, which will operate in conjunction with a new tracking software system. SCL advised that this system "will track a sample through the complex pathway of the histology department. Integrated with the Laboratory Information System (LIS) and the cassette and slide writers, the tracking system scans barcodes at various stations to ensure that samples are not transposed. This software is relatively new and not totally proven as yet but appears to be of benefit."

54. Furthermore, SCL told HDC:

> "We have found this case to be unprecedented for our practice. This has been incredibly difficult at both a personal and professional level for all the staff involved. It has been a steep but valuable learning curve for SCL as an organisation. It is regrettable that this has come at a high personal cost to the two women involved.
>
> We are confident that the measures we have implemented, combined with those we plan to implement, will make it extremely unlikely for similar mistakes to occur. However, we will continue to review all our processes with the view to improving the standard of care we provide to all patients."

55. Dr H told HDC:

> "To both women involved in this grave error, please accept my sincere apology for the error which led to the harm caused to both of you. While it was completely accidental, I feel that you have been let down by the healthcare system and I hope you can find it in your hearts to forgive my involvement in this. I am devastated that this error has resulted in harm to patients and it goes against the reason why I chose to enter medicine which was, and still is, to help people."

New Zealand Society of Pathologists — response to errors with breast biopsies

56. In May 2012, the New Zealand Society of Pathologists (NZSP) published a press release in respect of breast biopsy errors. NZSP strongly advised that a review of guidelines for the handling of breast biopsy cases was needed, with changes made in favour of routine, non-urgent processing of these specimens. NZSP stated that this would allow laboratories to:

- avoid batching of similar biopsy material;
- perform ancillary studies like immunostains to enhance diagnostic accuracy; and
- include collegial opinion of difficult material.

Report of the National Panel

57. This biopsy swap was one of five anonymised cases reviewed by a National Panel convened by the Chief Medical Officer of the Ministry of Health in response to a number of unnecessary surgeries resulting from errors in laboratory diagnoses of biopsy specimens. The panel's report, entitled *Report of the National Panel to Review Breast Biopsy Errors: Findings and recommendations*, was published in September 2012 (the Report).

58. Referring to a literature review, the Report stated that although the prevalence of errors in histopathology specimen collection, processing, and reporting was relatively small, misidentification by incorrect or insufficient labelling constituted the major cause of errors.

59. In the five cases reviewed by the Report, four of the cases involved transposition errors in laboratories. The Report noted the lack of standardisation of processes and

systems in the laboratories, and commented critically "… how each laboratory seems to need to learn the same lessons for itself".[14]

60. The Report recommended the double checking of specimens and labels by staff at identified critical control points, and noted that the aim was for technological means, such as barcoding, to be introduced by all laboratories to reduce the risk of specimen handling errors. In February 2013, SCL's Chief Executive Officer, Dr I, responded to the Ministry of Health's recommendations on behalf of SCL and other laboratories within the Healthscope NZ Limited group. The full list of recommendations made by the Report relevant to laboratory services generally, and Dr I's response, is attached as **Appendix C**.

61. Regarding MDMs, the Report stated:

> "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."

62. The Report also recommended that providers examine their implementation of open disclosure in relation to affected patients and staff. It noted that support measures should include prompt and empathic communication, full disclosure of all information, options for further support, and an acknowledgement that trust has been damaged.

SDHB's Open Disclosure Policy

63. SDHB has an Open Disclosure Policy (the Policy), which states that staff are expected to ensure that open disclosure is provided whenever a patient in the care of SDHB has:

- suffered harm while receiving health care;
- been exposed to possible harm resulting from a system error that affected the patient's care but does not appear to have caused harm, or may not be immediately apparent;
- suffered harm as a result of a complication of his or her health care management; and/or
- had his or her privacy breached.

64. The Policy states that, when things go wrong, the patient and his or her support person(s) should be provided with information about what happened, in an open and

[14] *Report of the National Panel to Review Breast Biopsy Errors: Findings and recommendations*, published in September 2012, page iii.

honest manner at all times, and that the open disclosure process is fluid and may involve providing ongoing information. It also states that all incidents/adverse events should be acknowledged to the patient and/or his or her support person(s) as soon as practicable (ideally within 24 hours) along with a genuine apology. The Policy makes a number of references to external policy documents and guidelines, including HDC's *Guidance on Open Disclosure Policies*.[15]

Response to provisional report

65. SCL and SDHB accepted the findings and recommendations made in the provisional report in relation to the care they provided.

66. Having reviewed the "Information gathered during investigation" section of the provisional report, Mrs X made a number of comments, which have been taken into account in my consideration of this investigation.

Opinion: Southern Community Laboratories Limited

Introduction

67. As a health consumer, Mrs X had the right to have services provided to her with reasonable care and skill. In this case, it is clear that SCL's cut-up policy was not followed by the individuals present in the cut-up room and, as a result, Mrs X's biopsy sample was swapped with the biopsy sample belonging to another patient. It is also clear that, at the time of these events, SCL's processes regarding breast biopsies included a number of unsafe practices, which failed to ensure that the laboratory's services were provided with the expected level of care and skill. These issues are addressed below.

Unsafe practices — Breach

68. In its internal review, SCL identified the practice of pre-labelling histology cassettes, and of not spacing biopsy samples in accordance with policy, as factors that potentially played a role in Mrs X receiving incorrect biopsy results.

69. At the time of this incident it was standard practice for histology cassettes to be pre-labelled, rather than labelling them when they were needed. SCL did not have a policy in relation to how histology cassettes should be labelled.

70. My expert pathologist advisor, Dr Mee Ling Yeong, advised that the practice of pre-labelling histology cassettes increased the risk of a specimen container being inadvertently paired with the incorrect histology cassette. As noted by Dr Yeong, the specimen and accession numbers may be the only distinguishing features on the specimen containers and histology cassettes.

[15] Available at www.hdc.org.nz.

71. In relation to spacing, SCL's policy required biopsies of similar type to be separated or, where same-type biopsies were processed next to each other, the policy required that the samples could be easily differentiated from one another by, for example, the way they were cut up.

72. However, it was also SCL policy to process breast biopsies as "urgent", and breast biopsies often arrived at the laboratory in the last delivery for the day. SCL told HDC that, as a result, Mrs X's and Patient Y's biopsy samples would have been "batched", rather than processed following the spacing requirements.

73. Dr Yeong considered that the time pressure imposed on the cut-up room staff by the late delivery of the breast biopsies and the Breast Screen Programme's requirement that breast biopsies be processed and reported urgently carried a high risk of error. In Dr Yeong's opinion, the need for early diagnosis of breast cancer must be carefully balanced against the need for a correct and safe diagnosis. I agree. There is no doubt that the policy of processing breast biopsies urgently, without following the normal requirements for spacing, introduced an opportunity for error.

74. I am also mindful of Dr Yeong's comments about SCL's cut-up process at the time of these events being heavily reliant on individuals (as opposed to automated processes). While it is imperative that those individuals are vigilant in carrying out their roles, an individual-based process must also take into account the inherent possibility of human error by having appropriate policies and procedures in place. In this case, I consider that SCL's practices outlined above not only failed to mitigate the risk of human error occurring, but directly contributed to it.

75. In addition, I note Dr Yeong's comment that batching breast biopsies increased the risk that, if a small piece of tissue was inadvertently carried from one specimen container or histology cassette to another patient's histology cassette, the reporting pathologist would not be able to tell that the stray tissue was from another patient.

76. SCL advised HDC that, following this incident, it stopped the practice of pre-labelling histology cassettes, and that spacing is now compulsory at all times. In addition, breast biopsies are no longer treated as urgent at SCL. According to SCL, this does not delay turnaround times significantly, and the advantage of urgent processing is outweighed by the risk of errors such as this one. In addition, I note that, in May 2012, NZSP also advised in favour of the routine, non-urgent processing of breast biopsies.

77. In addition to stopping the practices of pre-labelling histology cassettes and batching late-delivery breast biopsies, SCL has implemented (or is in the process of implementing) a number of other changes, including changes that will lead to a cut-up process with increased automation (in the form of new tracking software).

78. I agree with Dr Yeong that these measures will increase the safety of the cut-up process. However, I consider that additional changes to SCL's cut-up policy may also be warranted. In particular, I note Dr Yeong's suggestion that requiring both cut-up staff to check patient details on the specimen containers and histology cassettes would

help ensure the safe transfer of tissue samples. Requiring a verbal cross-check of patient details between cut-up staff may also provide an additional safeguard.[16]

Conclusion

79. In my view, SCL's processes for handling late-delivery breast biopsies such as Mrs X's included unsafe practices that directly contributed to Mrs X receiving biopsy results that did not belong to her. By failing to ensure its processes were sufficiently robust, SCL failed to provide services to Mrs X with reasonable care and skill and therefore breached Right 4(1) of the Code.

Individual error — Adverse comment

80. It appears that human error during the cut-up process led to Mrs X's tissue sample being mixed up with a sample from another consumer. The staff member responsible for ensuring the appropriate process took place, pathology registrar Dr H, told HDC that he does not know when or how the error was made. While it is possible to speculate, it is difficult to identify conclusively at which point in the cut-up process the error occurred.

81. It is clear that the SCL policies for spacing were not adhered to in this case. However, as stated above, it is also clear that SCL's policy that breast biopsies be processed urgently meant that the requirement for spacing to occur was not always complied with. Furthermore, the accepted practice of pre-labelling the histology cassettes also introduced the opportunity for error.

82. Therefore, while the exact reason for the error cannot be known, there were a number of practices in place at the time that, as noted by Dr Yeong, contributed to the cut-up staff working in an environment that was "not … conducive to maximal safety". I consider that, while it appears that an individual error occurred, these factors directly contributed to Mrs X being mistakenly provided with another consumer's biopsy results. In my view, the error was a result of a number of unsafe policies and practices in place at the laboratory at the time. Accordingly, I consider that the ultimate responsibility for the error must fall on the laboratory itself.

83. Nonetheless, I agree with Dr Yeong's comments that it is imperative that the importance of individuals' vigilance is engrained in SCL's culture. I note that, following this incident, SCL has reminded all staff involved in its histology process to be diligent with regard to patient details and ensuring that only one biopsy is dealt with at a time.

[16] This measure was introduced by another laboratory following an HDC investigation into a similar biopsy swap incident — see Opinion 11HDC01318, www.hdc.org.nz.

Opinion: Southern District Health Board

Standard of clinical care — No breach

84. Overall, I consider that the clinical care provided to Mrs X by SDHB clinicians between 23 January and 23 February 2012 (before she elected to have private treatment) was appropriate. SDHB clinicians undertook appropriate diagnostic investigations in a timely manner, and recognised that the 25 January 2012 biopsy results were inconsistent with Mrs X's clinical presentation.

Open disclosure — Breach

85. As a health consumer, Mrs X had the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive. As stated in HDC's *Guidance on Open Disclosure Policies*, it is seldom reasonable to withhold information about a consumer from that consumer.

86. Mrs X received histology results that did not belong to her due to a biopsy swap. However, Mrs X was not informed of the biopsy swap until three months after SDHB became aware of the error. Mrs X told HDC that SDHB's communication with her about the biopsy swap caused her to feel isolated, frustrated and hurt.

87. SDHB acknowledged that Mrs X was contacted about the error only when Patient Y expressed a desire to speak with her. In explaining why Mrs X was not contacted at the same time as Patient Y, SDHB stated that "the focus had initially been on the patient who had unnecessary surgery as a result of this incident". SDHB acknowledged that Mrs X should have been informed of the biopsy swap earlier; however, I note that there is no evidence that SDHB intended to inform Mrs X of her involvement in the biopsy swap prior to Patient Y's request to meet with her.

88. In my view, this is unacceptable. As stated in SDHB's Open Disclosure Policy (which I consider is appropriate and comprehensive), open disclosure should occur whenever a consumer has been exposed to possible harm, irrespective of whether harm has occurred or is immediately apparent. In this case, both Mrs X and Patient Y received biopsy results that did not belong to them, and I consider that both consumers should have been communicated with in a prompt and transparent manner regarding what had occurred.[17]

89. However, SDHB did not follow its own policy, and did not inform Mrs X of the error in a timely and appropriate manner. As a result, SDHB failed to provide Mrs X with information that a reasonable consumer in her position would expect to receive, and breached Right 6(1) of the Code.

[17] For the avoidance of doubt, I note that I consider that SDHB assumed the responsibility to ensure the biopsy swap was disclosed to Mrs X in an appropriate manner when it disclosed the biopsy swap to Patient Y.

Recommendations

Southern Community Laboratories Limited

90. I recommend that Southern Community Laboratories Limited provide a written apology to Mrs X for its breach of the Code. The apology is to be sent to HDC for forwarding to Mrs X within one month of this report.

91. I also recommend that Southern Community Laboratories Limited:

a) Audit the laboratory's compliance with the amended cut-up process, in particular the requirements that histology cassettes are not pre-labelled and that spacing occurs at all times, and report the results of the audit to HDC.
b) Provide HDC with an update regarding the progress of its implementation of cassette printers, slide printers, and a tracking software system.
c) Consider whether a policy that both cut-up staff check patient details on specimen containers and histology cassettes and/or that verbal cross check of these details occurs between cut-up staff is required, and report back to HDC on the outcome of its consideration.

Southern District Health Board

92. I recommend that Southern District Health Board provide a written apology to Mrs X for its breach of the Code. The apology is to be sent to HDC for forwarding to Mrs X within one month of this report.

93. I also recommend that Southern District Health Board provide training to its staff about its Open Disclosure Policy in light of its breach of the Code in this case, and provide evidence of that training to HDC within three months of this report.

Follow-up actions

94.
- I note that recommendation 5(a)6 of the *Report of the National Panel to Review Breast Biopsy Errors* (attached as Appendix C) recommends that laboratories, using the National Laboratories Quality Managers Group with input from the appropriate professional bodies, 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. I have written to the Ministry of Health asking to be kept updated on the effective implementation of this recommendation.

- A copy of this report with details identifying the parties removed, except the expert who advised on this case, Southern Community Laboratories Limited, and Southern District Health Board, will be sent to the Health Quality and Safety Commission, International Accreditation New Zealand, and the Ministry of Health, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A — Independent expert advice to the Commissioner

The following expert advice was obtained from pathologist Dr Mee Ling Yeong:

"I have read, and agree to follow the Commissioner Guidelines for Independent Advisors.

My qualifications are:

Bachelor of Medicine, Bachelor of Surgery (MB,BS), Singapore, 1972

Fellow of the Royal College of Pathologists of Australasia (FRCPA), 1980

My present position, since 2000, is Clinical Director of histology and cytology, Diagnostic Medlab, Auckland. I have more than 30 years as a consultant pathologist and have been employed in various capacities, including senior lecturer and head of department, in Auckland and Wellington. As clinical director, I have overseen or established all of our quality and safety processes in both the histology and cytology departments.

General comments
In the field of surgical pathology (histology), where a piece of tissue is submitted by a surgeon/clinician for a diagnosis to be made by a pathologist, the tissue sample progresses through a series of steps [see Appendix B], which involves significant manual handling by a staff member, culminating in a diagnostic assessment which is undertaken by another human (pathologist) as opposed to a measurement by a machine.

Human error on occasion is unavoidable and the risk of human error is deeply embedded in every sphere of life. Laboratories are not exempt. For this reason, laboratory procedures for handling tissue samples are governed by a set of rules to ensure that the errors are kept to the minimum or, if an error does occur somewhere in the chain of events outlined in the Histology Process Flow, it is identified further downstream so that it is quickly corrected, before it can impact on a patient. The safety procedures for each laboratory are recorded in the laboratory's safety and procedure manuals, which are available for inspection and approval by the New Zealand laboratory accreditation body, IANZ (International Accreditation New Zealand).

I might also add that the multidisciplinary meeting should act as an additional guard against errors in the long chain of safety processes: for example, the caregivers at the MDM questioned the diagnosis of a sclerotic fibroadenoma for [Mrs X's] biopsy, in light of the radiologically malignant features. The reaction was to take another biopsy sample.

[Mrs X's] second biopsy was carried out soon after the first and had returned the correct diagnosis of a carcinoma. I do not know if the 2 radically differing biopsies were discussed at a subsequent MDM and whether this had raised some red flags that 2 biopsies from the same patient and the same tumor could be so radically different. If the discrepancy had been looked at more closely at the time, it may have prevented an unnecessary mastectomy on [Patient Y]. Her operation was carried out about a month following the biopsy result, giving ample time for a

transfer error to be identified and proven. The second biopsy did lead to a correct diagnosis for [Mrs X], but failed to prevent a mastectomy for [Patient Y].

Adequacy of the policies and procedures in place at SCL at the time of the events complained of as well as the subsequent changes SCL has made to its policies

The practice for processing Breast Screen biopsy samples that SCL had at the time of the error, of batching breast core biopsies for cut-up and the prelabelling of the cassettes carried a high risk of error for the following reasons:

- The samples arrived late in the day and staff may have had other distracting duties to complete before the close of the day.
- The breast cores were probably submitted in similar containers and breast core samples from different patients would look the same to the naked eye. The pre-labelled cassettes would also look the same for all patients.
- Tissue cassettes are very light plastic containers which have a tendency to slide across work surfaces and to move easily from one surface to another.
- There is a risk of carrying a small piece of tissue from patient A to the next patient's cassette through instruments or through being picked up from the cut-up table if meticulous cleaning after each transfer is not carried out. The reporting pathologist will not be able to tell that a stray piece of tissue is from someone else if both tissue pieces are from the breast.
- The prelabelling of cassettes in a batch from different cases presents a high risk of cassettes being placed on the wrong specimen container, leading to the wrong cassette being picked up for a particular patient's. The only distinguishing feature between patient samples cassettes is the specimen number on the cassette, which may not be distinct, compounded if numbers are similar or consecutive.

I believe that the Breast Screen program's requirements for breast cores to be processed and reported urgently increases the risk of error, both in the way tissues are processed and in the way pathologists assess the tissue samples, because of the pressure imposed by the turnaround times. Women are understandably anxious when a cancer is suspected and would naturally want an early result. That need must be carefully balanced against the imperative of a correct, safe diagnosis even if that takes a day or two longer to achieve.

The measures that were introduced by SCL include

- Seeding of breast biopsy samples among other types of tissue samples, so that no two consecutive samples are breast core biopsies.
- Prelabelling of cassettes to be stopped and cases to be dealt with individually.
- Availability of x-rays to be viewed by the pathologist for comparisons between the x-rays and microscopic material.
- Careful checking of patient and other details to ensure that the cassettes match the patient etc.

There are other measures planned, including automation, barcoding and a tracking system.

The above measures will significantly increase the safety of the SCL laboratory system but I cannot emphasise enough the importance of the vigilance of individuals engaged in the work. I note there were 2 people present at cut-up. I suggest that both individuals check the specimen details to ensure a safe transfer. It is imperative that it is ingrained in the culture of any laboratory that vigilance at all times is needed.

Having the x-ray images for a pathologist to view may help, but this would have been the normal process in a multidisciplinary meeting, which has the added advantage of opinions from the radiologists and surgeons being available. As I indicated in an earlier paragraph, an MDM is another portal for detection of discrepancies of any kind and a high level of vigilance should be maintained.

Individual/s responsible for the error

It does appear from the report of the sequence of events and [Dr E's] statement that [Dr H] had inadvertently placed the core biopsy samples in the wrong cassettes. In defense of [Dr H], however, the environment in which he worked had not been conducive to maximal safety for the reasons identified above, which is, batching of similar tissues, prelabelling of slides, end-of-day duties. The task he had can become a monotonous routine and it is conceivable that a moment's inattention or distraction could cause the error.

I note that [Dr H] was assisted by another person, [Ms J]. I strongly suggest that where 2 people are present at cut-up that BOTH staff members check that all details are correct before placement of tissues into cassettes, as a standard of practice.

[…] [Redacted as advice relevant to Patient Y only.]

[…] [Redacted – issue addressed independently of this report.]

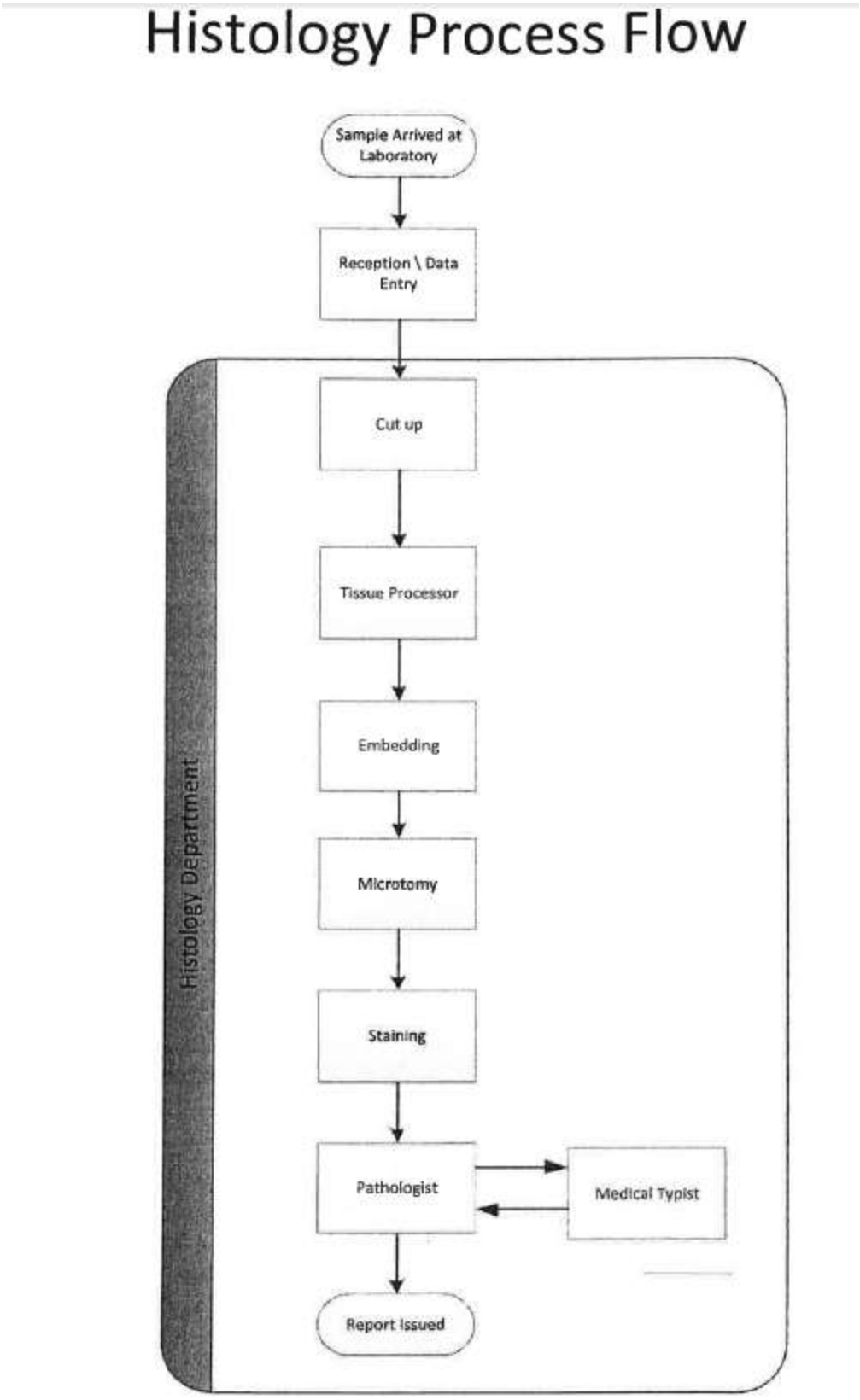
Severity of departure from an appropriate standard of care

Although the error appeared to be a small and innocent 'slip', it was likely made in circumstances and laboratory practice conditions that were not entirely conducive to safety of practice. Furthermore subsequent MDMs failed to note that both [Mrs X's] biopsy samples about one week apart were radically different when they were apparently taken from the same radiological tumor. When an error occurs that impacts on a patient, it is often not a single event but a series of events where the safety processes at more than one station had failed. This apparently small initial 'slip' led to devastating consequences for one patient and severe distress to both. I would view the conduct with severe disapproval.

Closing remarks

I hope I am not trivializing the error or making excuses for SCL by saying that the error that occurred could have occurred in any other laboratory anywhere in the world. SCL personnel had responded by extensively revising its practices, which I am satisfied, will markedly improve safety in the processing of their tissue samples. They had acted promptly and responsibly when the error was uncovered and I believe had been honest in dealing with both patients."

Appendix B — SCL's Histology Process Flow



Names have been removed (except Southern Community Laboratories Limited, Southern District Health Board and the expert who advised on this case) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

Appendix C — Recommendations: Report of the National Panel to Review Breast Biopsy Errors

The following recommendations are quoted from pages 19–20 of the Ministry of Health's *Report of the National Panel to Review Breast Biopsy Errors: Findings and recommendations* published in September 2012. The italicised text underneath each recommendation is SCL's response, as quoted from Dr I's letter to the Ministry of Health dated 14 February 2013.

"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. 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.

All our laboratories work within the terms of reference of the appropriate DHB Quality and Safety Committees as well as the appropriate governance groups to provide full disclosure of serious and sentinel events. We work within these groups as well as the referrer to provide appropriate support to the affected parties. Generally it would be the responsibility of a pathologist to discuss with the referrer what the appropriate response when communicating to the patient is.

Patients have the right to discuss any issues with the laboratory and/or HDC thus we have pamphlets advising this right in all our collection facilities. However, we do not control whether these pamphlets expressing patient rights to contact HDC are located in the referrer practices.

Our staff are supported by their managers and by our Employment Assistance Programme that is provided by EAP Services.

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

Our laboratories have an internal risk database (RISKMAN) whereby we report all serious and sentinel events. Sentinel events are reported back to our Australian Parent company (Healthscope) and a process is immediately instigated to perform a root cause analysis investigation. Outcomes of these investigations are fed back into our process improvement system with procedures updated regularly.

Those laboratories that are associated with public DHBs also report sentinel events to their DHB Quality and Risk Committee who are responsible to report to the Health Quality and Safety (HQS) Commission. The other laboratories that are not affiliated with a hospital currently do not report these to the HQS Commission. However we are in discussion with NZAPP [New Zealand Association of Pathology Practices] to arrange a mechanism to make this happen.

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.

The laboratory supports and provides advice to the clinicians and ongoing information to ACC as required.

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.

Automation will minimise the risk of specimen handling errors, especially in the larger laboratories. Bar-coding is already in place in the largest of our laboratories as well as the use of cassette and slide writers, this together with specialised features of our in-house LIS [Laboratory Information System] serve as specimen tracking devices to minimise and identify any specimen handling errors. Using this laboratory as a reference similar automation is being considered at our other sites as and when the opportunity arises.

We are actively investigating commercial tracking systems that are available currently. [SCL advised HDC on 17 April 2014 that it was introducing a tracking system at [its Laboratory.]

In the meantime, all our laboratories have reviewed all their processes to reduce the risk of specimen handling errors.

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

  This is already in place for all our laboratories.

- wherever possible specimens of the same tissue type should not be handled sequentially

  Wherever possible this is the instruction for staff accessioning and prosecting samples at all our laboratories, however there are situations when the majority of cases are biopsy specimens of skin or breast or prostate or GI tract. It is not always possible to separate the same tissue type. Therefore we also try to ensure that samples of the same biopsy technique are also not processed sequentially. For example, skin punch biopsies are interspersed with simple skin excisions and between multi-pot samples where possible.

- robust training and supervision of new staff should be a priority

  There is a defined training programme in place whereby staff are signed off by a pathologist at the end of each stage, eg at the completion of simple transfer training.

- double checking of specimens and labels by staff at identified critical control points

  All the laboratories have reviewed their procedures to enable double checking of specimens and labels at critical points. For example, all specimens are double checked after the sample has been accessioned and labelled. Sample details are checked by another staff before they are signed out to the pathologists. All slides are double checked with the paraffin blocks as another form of checking before being sent to the pathologists.

  Macro dictation and LIS are checked at time of transcription as well as against the sample on the slide, ie size and site matches that on the request form and all labelling matches. Pathologists recheck transcriptions before electronically validating case.

- all checks should be done in a standard way by all staff involved in the process.

  There are detailed protocols for all these steps which all staff are trained in and expected to follow as instructed.

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."