University of Otago

trading as MedLab Dental

A Report by the

Health and Disability Commissioner

(Case 11HDC01318)

Health and Disability Commissioner

Te Toihau Hauora, Hauātanga

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Executive summary

Background

1. In April 2011, Mrs A had a biopsy taken by an oral surgeon. The biopsy was sent to MedLab Dental, a medical testing laboratory owned and operated by the University of Otago. The biopsy was processed at MedLab Dental and the report indicated squamous cell carcinoma, a form of cancer.

2. Mrs A was subsequently diagnosed with cancer by clinicians at a District Health Board in a different area (the DHB) and underwent extensive surgery. Histology following surgery showed no sign of cancer. The possibility was therefore raised that the original biopsy results showing cancer did not in fact belong to Mrs A.

3. The DHB alerted MedLab Dental, which undertook an internal investigation. The investigation concluded that Mrs A's tissue sample had been wrongly labelled with another patient's name when the biopsies were being processed at the laboratory. Consequently, Mrs A was given the wrong biopsy result.

Findings

4. The Commissioner found that, while the cause of the mix-up appeared to be human error, the University of Otago (trading as MedLab Dental) was responsible for ensuring that its processes were sufficiently robust to prevent such errors from occurring. The Commissioner considered this to be particularly important for a specialised laboratory such as MedLab Dental. By giving Mrs A biopsy results that did not belong to her, the University of Otago (trading as MedLab Dental) 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]

Complaint and investigation

5. The Health and Disability Commissioner received a complaint from Mrs A about the services provided by medical testing laboratory MedLab Dental, which is owned and operated by the University of Otago. The following issue was identified for investigation:

- *The appropriateness of the care provided to Mrs A by the University of Otago (trading as Medlab Dental) in April 2011.*

6. The parties directly involved in the investigation were:

Mrs A	Complainant
University of Otago	Provider

[1] Right 4(1) of the Code states: "Every consumer has the right to have services provided with reasonable care and skill."

MedLab Dental	Medical testing laboratory
Also mentioned in this report:	
Dr B	Pathology registrar
Ms C	Medical scientist
Dr D	Consultant oral pathologist
Dr E	Doctor at the DHB

7. Independent expert advice was obtained from a pathologist, Dr Jonathan Allen, and is attached as **Appendix A**.

8. The Commissioner also reviewed the care provided by the DHB and considered that the care provided to Mrs A was appropriate and consistent with expected standards.

Information gathered during investigation

Mrs A

9. Mrs A, aged 62 years at the time of these events, had dental surgery in 2008 to replace a missing tooth with an implant. On 31 March 2011 Mrs A saw an oral surgeon, due to pain and swelling around the site of the dental surgery. The following day the oral surgeon took a biopsy from the affected area and sent it to MedLab Dental for analysis. The referral form stated that the oral surgeon's provisional diagnosis was peri-implantitis.[2]

10. The histology report of Mrs A's biopsy, dated 7 April 2011, revealed moderately differentiated squamous cell carcinoma (SCC).[3]

11. Mrs A was subsequently referred to a specialist at the DHB for treatment and diagnosed with cancer. She underwent extensive surgery as a result. Following surgery, the resected tissue was analysed by hospital pathologists. That resection specimen showed no sign of cancer. It then became apparent that Mrs A's initial biopsy results may have been incorrect. The DHB alerted MedLab Dental, which subsequently undertook an internal investigation in June 2011.

MedLab Dental

12. MedLab Dental is a medical testing laboratory that is part of the University of Otago's School of Dentistry. It operates as a teaching and research facility, as well as a diagnostic laboratory. Unlike many other medical testing laboratories that process a wide range of types of tissue samples, MedLab Dental is the only specialist oral pathology laboratory in New Zealand.

[2] Inflammation around the site of dental implants.
[3] SCC is a form of cancer. The degree of differentiation indicates how advanced the cancer is.

13. MedLab Dental was accredited by International Accreditation New Zealand (IANZ)[4] before and after the events complained of.

MedLab Dental's investigation

14. MedLab Dental undertook an internal investigation into the reasons for the incorrect report. This involved first reviewing the biopsy slides, which confirmed that those slides did show SCC, as stated on the histology report. The possibility that the slides had been wrongly read or reported was therefore excluded.

15. MedLab Dental then reviewed the other biopsies received on the same day as Mrs A's (6 April 2011). The reviewing clinicians noted that one of those biopsies, labelled Patient X, had shown "non-specific inflammation". Patient X's referring clinician had sent a further biopsy from Patient X to MedLab Dental approximately two weeks later. Patient X's second biopsy had shown SCC (the same diagnosis as Mrs A's biopsy).

16. Patient X's biopsy had been sent from a source different to Mrs A's. Therefore, there was no possibility that the biopsies were mixed up or swapped prior to arrival at MedLab Dental. Consequently, the possibility was raised that there had been an inappropriate transfer or assignment of tissue samples (between Mrs A and Patient X) during the processing of the biopsies at Medlab Dental on 6 April 2011.

17. MedLab Dental obtained an independent review from a consultant pathologist. His report stated that it was possible that an inappropriate transfer of tissue samples had occurred and, if this was the case, it was likely this would have happened during the "cut-up" process (see below).

18. On 21 June 2011 MedLab Dental sent a letter to the DHB stating that it wished to "proceed as rapidly as possible to undertake DNA testing at [MedLab Dental's] cost and with [Mrs A's] consent to end the uncertainty".[5] Mrs A signed a consent form for DNA testing dated 13 July 2013.

19. On 12 August 2011 the results from Mrs A's DNA test showed that the tissue sample used in the original biopsy did not belong to Mrs A. It was therefore confirmed that Mrs A's tissue sample had been wrongly labelled with Patient X's name, and vice versa.

20. MedLab Dental told HDC that it has expressed to Mrs A verbally and in writing "its deep sorrow and dismay at what [has] occurred".

The cut-up process

21. "Cut-up" refers to the process where tissue samples from biopsies are prepared for final analysis. At MedLab Dental, cut-up is performed according to the guidelines

[4] IANZ is a not for profit organisation that evaluates New Zealand laboratories against international standards for laboratory performance.

[5] In the course of my investigation and in response to my provisional opinion, Mrs A stated that the DNA testing was undertaken at her suggestion.

specified in MedLab Dental's "Cut Up Manual" (the Manual), which has been accredited by IANZ.

22. MedLab advised HDC that, at the time of these events, the cut-up process consisted of the following steps:

- The specimen jars and accompanying pathology request forms were placed in numerical order by a laboratory member on a bench to the right of the pathologist.
- The pathologist picked up one specimen jar and accompanying pathology request form at a time.
- The pathologist confirmed the correspondence between the biopsy number and patient name on the specimen jar and the same on the accompanying pathology request form.
- The pathologist dictated the biopsy number and patient name into a handheld tape recorder, followed by a general description of the specimen.
- The medical scientist labelled a histology cassette with the biopsy number and patient name, and checked that these details corresponded with the pathology request form.
- The pathologist opened the specimen jar, prepared the tissue sample and transferred it to the corresponding labelled histology cassette.
- The pathologist dictated a draft histology report for subsequent review and finalisation by one or more consultant oral pathologists.

23. On 6 April 2011 the pathologist registrar in the laboratory was Dr B. The medical scientist was Ms C.

24. Mrs A's biopsy results were reported by Dr B and consultant oral pathologist Dr D.[6] MedLab told HDC that, on 6 April 2011, 15 specimens were dealt with. These specimens were labelled 11/0463 through to 11/0477. At some point during the cut-up process, it seems the last two specimens, labelled 11/0476 (Mrs A's sample) and 11/0477 (Patient X's sample), were transposed.

25. Dr B advised HDC that

> "… the cut-up session was, as far as I can recollect, routine and unremarkable, I am unable to recount any peculiarities or specific events. I cannot postulate in which step the transposition may have occurred."

26. Similarly, Ms C stated that

[6] Dr D was not involved with the cut-up process.

> "[w]hen the laboratory was advised on 1 June 2011 that the subsequent surgical specimen from [Mrs A] showed no evidence of carcinoma the possibility of specimen mix-up was raised. I checked the technical side of the specimen registration and cut-up. I retrieved the two pots, request forms, cut-up day books, cassettes and the slides. There was no evidence of incorrect labelling or procedures.
>
> Nothing unusual happened on the morning of 6th April 2011 to interfere with the technical handling of these specimens."

27. MedLab Dental acknowledged that an error occurred within the cut-up process as prescribed by the Manual, leading to the incorrect transposition of biopsy numbers and patient details on two histology cassettes. MedLab Dental considered that the transposition of specimens in this case "appears to have occurred notwithstanding adherence to the accredited manual as it then stood". There was no requirement at the time for a verbal cross-check of patient details between the pathologist and medical scientist in the laboratory.

Report of the National Panel

28. Mrs A's case 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).

29. 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.

30. 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".[7]

31. 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. The full list of recommendations made by the Report relevant to laboratory services generally is attached as **Appendix B**.

32. Of particular relevance to MedLab Dental, the Report stated on page 14 that "… wherever possible specimens of the same tissue type should not be handled sequentially". The Panel noted that for some specialised laboratories that handle a

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

large volume of specimens of the same type, avoiding sequential handling may not be feasible, and that those laboratories "should ensure that robust measures are in place to prevent and detect specimen transposition".

Changes at MedLab Dental

33. On 14 June 2011 MedLab Dental issued an updated edition of the Manual, which included changes made as a result of Mrs A's biopsy error. Specifically, when correlating the patient details on the specimen container with the accompanying laboratory request form, the pathologist must now read the correlation out loud to the medical scientist. The medical scientist must then repeat the information back to the pathologist.

34. MedLab Dental also provided HDC with information regarding how it has responded to the Report recommendations, which is attached as **Appendix C**.

Response to provisional opinion

35. The University of Otago in accepting the findings in my provisional opinion stated:

> "[It considers] the overriding cause of the incident was a single incident of human error in following policy, rather than an overall failure of the University's policies themselves.
>
> That said [it accepts] that the University has been able to find ways of strengthening its practices and [it accepts] that the former policies were open to improvement to the extent that a further cross check would now enable the identification of an error if one arose through an initial failure to follow policy requirements."

Opinion: Breach — University of Otago (trading as Medlab Dental)

36. As a health consumer, Mrs A had the right to have services provided to her with reasonable care and skill. In this case, it is clear that Medlab Dental's policy for cut-up was not followed (if it had been, this error would not have occurred). However, I consider that MedLab Dental's policies and procedures were insufficiently robust to ensure that services were provided with the expected level of care and skill.

Policies not followed

37. As noted by my independent expert, Dr Jonathan Allen, Medlab Dental had procedures in place that should have prevented this event from happening. However, in this case, an error was made and Mrs A was mistakenly provided with biopsy results that did not belong to her. This should never occur. Anyone who is attributed with biopsy results that are not their own is at an increased risk of being misdiagnosed and given the wrong treatment.

38. It appears that during the cut-up process human error led to Mrs A's tissue sample being mixed up with a sample from another consumer. Although neither of the two staff members in the laboratory at the time recall anything that could explain how the mix-up occurred, it is clear that the policies and procedures MedLab Dental did have in place were not adhered to. While it is possible to speculate where exactly the error occurred, it is difficult to identify conclusively which step or steps of the cut-up process were not followed. In my view, the ultimate responsibility for providing accurate biopsy results to consumers must fall on the laboratory itself.

Policies not adequate

39. I note Dr Allen's advice that MedLab Dental's cut-up process was IANZ accredited and "[there is no evidence that] the laboratory service was organized or carried out in a careless manner". Dr Allen advised that MedLab Dental's cut-up process "appears similar to those used in many other histopathology laboratories".

40. However, Dr Allen also noted that, prior to the event, the cut-up manual did not specifically state that the patient ID and number on the request form, specimen pot and on the tissue processing cassette should be checked by both persons at the cut-up.

41. Dr Allen stated:

> "A single specialty laboratory is more vulnerable to swaps not being noted. In larger more general laboratories processing a variety of tissues the swap is more likely to be with a clearly incompatible tissue and would be therefore noticed at the microscopy reporting stage. This strategy of separating similar specimen by placing tissue from different sites between them at the cutup is used by a number of laboratories to help prevent this type of mix-up. Laboratories remote from the practises they are serving are less likely to be able to identify this problem as they are unlikely to attend subsequent multidisciplinary meetings."

42. I accept Dr Allen's advice that there is a higher risk of errors occurring at MedLab Dental than at pathology laboratories that deal with a wider range of tissue samples. Due to its speciality, MedLab Dental is less able to rely on commonly used strategies to mitigate the risk of error, such as separating similar types of specimen from one another. It therefore needed to devise alternative strategies to ensure its processes sufficiently mitigated the increased risk of error.

43. I note that this accords with the view of the Report panel that, where sequential handling of specimens of the same type is unavoidable, "the laboratory should ensure that robust measures are in place to prevent and detect specimen transposition".

44. MedLab Dental's systems were not robust enough in the circumstances of a specialist laboratory, and further checks and balances should have been in place. I note that since this incident, MedLab Dental has added an additional step to the cut-up process as prescribed by the Manual. The addition requires a verbal cross-check of patient details between the pathologist and medical scientist in the laboratory.

45. Dr Allen has suggested that a digital barcode tracking system may also help reduce the risk of errors such as in Mrs A's case. This was also recommended in the Report. I note from the document attached as Appendix B that MedLab Dental is in the process of purchasing the required equipment to implement such a system.

46. While I acknowledge Dr Allen's advice that MedLab Dental's processes at the time were similar to processes at other laboratories, I consider that MedLab Dental, when electing to operate as a specialist laboratory, needed to have additional measures in place to mitigate against the resulting increased risk of error.

Conclusions

47. In my view, MedLab Dental's processes should have prevented consumers from being given biopsy results that did not belong to them and, in this case, they did not. By giving Mrs A the wrong biopsy results, MedLab Dental failed to provide services with reasonable care and skill. I therefore find that the University of Otago (trading as MedLab Dental) breached Right 4(1) of the Code.

Recommendations

48. I recommend that the University of Otago (trading as Medlab Dental) provide a written apology to Mrs A. The apology is to be sent to HDC by **7 April 2014** for forwarding to Mrs A.

49. In addition, I recommend that the University of Otago:

- Identify any other instances between 2011 and the date of the final opinion where biopsies have been mislabelled, wrongly assigned, or otherwise mixed up at MedLab Dental (to include near misses), and send a report outlining incidents to this Office. This should include details of steps taken to inform consumers of any such events involving their biopsy samples.
- Audit compliance with the amended cut-up process at MedLab Dental and report on its effectiveness to this Office.
- Provide HDC with an update regarding the progress on the implementation of a foot operated dictation system at cut-up, and the purchase of equipment to barcode slides and cassettes (as referred to in **Appendix C**).

50. I recommend that the University of Otago report to HDC three months after the date of this report on the outcome of these recommendations.

Follow-up actions

51.
- I note that recommendation 5(a)6 of the Report (attached as Appendix B) 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 am writing 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, will be sent to the District Health Board, and it will be advised of the University of Otago's (trading as MedLab Dental) name.

- A copy of this report with details identifying the parties removed, except the expert who advised on this case and the University of Otago (trading as MedLab Dental), will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A — Independent advice to the Commissioner

The following expert advice was obtained from pathologist Dr Jonathan Allen:

> "I have been asked to provide expert advice on case number 11/01318. I have read and agree to follow the Commissioner's guidelines for independent advisors.
>
> I am a registered medical practitioner with vocational registration in Pathology, practising in the subspecialty of Anatomical Pathology. My qualifications are MBChB (Auckland), FRCPA. I commenced in specialist practise in 1988 and have been engaged full time in anatomical pathology practice in New Zealand since then. I have held positions as Clinical Director or Clinical Head in small and large anatomical pathology laboratories. I have no conflict of interest in providing advice in this case.
>
> I attach a copy of the referral instructions.
>
> The documents I have received are (in approximate chronological order) [these have been removed for brevity.]
>
> I have also referred to
>
> Edward J. Dunn, MD, ScD; Paul J. Mo. Patient Misidentification in Laboratory Medicine. A Qualitative Analysis of 227 Root Cause Analysis Reports in the Veterans Health Administration. Arch Pathol Lab Med. 2010;134:244–255
>
> Lester J. Layfield, MD; Gina M. Anderson, HT(ASCP). Specimen Labelling Errors in Surgical Pathology: An 18-month Experience. American Journal of Clinical Pathology. 2010;134(3):466–470
>
> National Panel to Review Breast Biopsy Errors. 2012. Report of the National Panel to Review Breast Biopsy Errors: Findings and recommendations. Ministry of Health, NZ. September 2012
>
> Raouf E. Nakhleh, MD; Michael O. Idowu, MD; Rhona J. Souers, MS; Frederick A. Meier, MD; Leonas G. Bekeris, MD. Mislabeling of Cases, Specimens, Blocks, and Slides. A College of American Pathologists Study of 136 Institutions. Arch Pathol Lab Med. 2011;135:969–974
>
> I understand the facts to be as follows.
>
> In 2008, [Mrs A] underwent dental implant surgery to her right upper jaw. In 2011, there was an abnormal area noted, clinically thought to be inflammatory, which was biopsied by [Dr E] and the biopsy was sent to Medlab Dental (MLD), University of Otago, Dunedin. The sections taken were diagnosed as containing invasive squamous cell carcinoma. The patient was referred to the [DHB]. They arranged for their pathologists to review the MLD histology who confirmed the

diagnosis of squamous cell carcinoma. Consequently [Mrs A] had a right partial maxillectomy (upper jaw resection) and fibula free flap repair which entailed considerable discomfort and disability. No squamous cell carcinoma was found in the resection specimen. The possibility of specimen misidentification was raised [at the DHB] and on further investigation, the original squamous cell carcinoma biopsy was found to have probably been from another patient (whose biopsy had been reported as non-neoplastic). The swap was confirmed by ESR DNA molecular studies. [Patient X] (the other patient) subsequently had a biopsy showing squamous cell carcinoma. As there was a tissue swap between two patients in one laboratory, it is accepted that the misidentification occurred in MLD and not from specimen mislabelling [by Dr E].

The points to be addressed are

1. Please comment generally on the care provided to [Mrs A]

I can only comment on the laboratory aspects of the care. Apart from the tissue swap, I can identify no significant deficiency. I have not reviewed the histological sections of either of the biopsies or of the final resection specimen but I understand that the histological interpretation is not in dispute. The sections were reviewed at a multidisciplinary meeting ([the] DHB) prior to definitive treatment and this was probably the last chance to pick up the swap. I believe it was the intention of Medlab Dental (MLD) laboratory to provide a high quality service and that the laboratory management believed it had taken all reasonable steps to provide a safe service. As soon as the issue of possible tissue swap was raised, MLD conducted an internal review and arranged an external review. They then arranged for DNA confirmation of the swap. All the involved services have acknowledged and offered apologies for the incident. Cutup procedure at MLD has been reviewed and amended to prevent recurrence.

2. What standards apply.

The standards that apply to medical laboratory practise are documented in the appropriate laboratory manuals and are certified as appropriate and sufficient by IANZ under standard NZS/ISO 15189 Medical Laboratories — Particular Requirements for Quality and Competence. MLD was assessed under this standard, both before and after this incident.

3. Were those standards complied with

From the IANZ reports both prior to and subsequent to the incident, and from the extracts from the cutup manual enclosed, the laboratory had appropriate procedures in place that should have prevented this event from happening. At some point, either steps of checking the identities on the containers and request form was omitted or the wrong number was written on the cassette. The same failure (or one of similar effect) took place in both [Mrs A's] and [Patient X's] specimens and the most likely cause of this would be either a specimen swap or a prelabelled cassette swap on the cutup bench. I note however that it was not

practice to prelabel cassettes which essentially narrows the problem to a specimen swap. I take it that the number of fragments in the macroscopic descriptions corresponds with the number of fragments in the slides, which would confirm the moment of the incident. In failing to check that the identity of the specimen pot corresponded to the request form at the moment of tissue transfer, MLD did not comply with its own procedures.

4. Was the cutup procedure at Medlab Dental on 6 April 2011 appropriate and consistent with professional standards?

Although according to the laboratory manual and the IANZ inspection adequate procedures were in place, the correct steps seem not to have been followed for both specimens. The laboratory cannot be faulted for failing to specify correct procedure as the cutup manual appears similar to those used in many other histopathology laboratories, but the evidence indicates that some aspect of this was not followed. I note that the cutup manual prior to the event did not specifically state that the patient ID and number on request form, specimen pot and on the tissue processing cassette should be checked by both persons at the cut up.

5. Are the subsequent changes to the 'cut up' procedure at Medlab Dental appropriate to prevent a recurrence of transposition of specimens? If not, what further changes do you suggest should be made.

The changes made specifically state that the patient ID and number on the request form, specimen pot and on the tissue processing cassette be checked by both persons at the cut up. This should be adequate to prevent a transposition recurrence if they are correctly followed. The only improvement I can suggest is a digital barcode tracking system to force checks at cutup and at other instances of tissue transfer (embedding, section to slide etc.), as in my experience the commonest cause of occasional near misses is failure to perform identity check at every instance of tissue transfer. However I accept that this would be difficult to justify in a laboratory with relatively modest work volumes when these systems have not been widely adopted in much larger laboratories in New Zealand. This also leaves the problem of specimen labelling outside the laboratory which is, if anything, a numerically greater issue, but which is usually corrected at specimen entry and registration.

I note the absence of an NHI number on all of the enclosed MLD histology reports. I am not sure why this is considered acceptable practise outside public hospitals, whereas inside hospitals it has been virtually mandatory for a decade or so.

6. Was it appropriate for [Dr B] to be processing specimens without the direct supervision of an oral pathologist on 6 April 2011.

Yes. [Dr B] had had three years post graduate training in oral pathology and it was entirely appropriate for him to be performing cutup. Pathology registrars of

similar length of training in medical anatomical pathology laboratories would certainly be taking a similar level of responsibility.

7. Was it reasonable for [Dr B] and [Dr D] to have not identified the possibility that there may have been a transposition of specimens when they reported [Mrs A's] histology on 7 April 2011.

Yes. The clinical features of early squamous cell carcinoma can be non-specific. Tissue swaps are quite unusual events and, as several of the correspondents have stated, they have not come across one before in their practise. They are certainly less common than atypical clinical presentations. In retrospect, the presence of skeletal muscle in an alveolar biopsy might have been a flag.

8. Was it reasonable for Medlab Dental to have not identified the possibility of a transposition of specimens when [the DHB clinician] requested [Mrs A's] histology slides prior to [Mrs A's] surgery.

Yes, as it is common practise for specialty centres to request review of histological material prior to definitive treatment and MLD (or any other laboratory) would not view the request as anything unusual.

9. Are there any aspects of the care provided by University of Otago that you consider warrant additional comment.

A single specialty laboratory is more vulnerable to swaps not being noted. In larger more general laboratories processing a variety of tissues the swap is more likely to be with a clearly incompatible tissue and would be therefore noticed at the microscopy reporting stage. This strategy of separating similar specimen by placing tissue from different sites between them at the cutup is used by a number of laboratories to help prevent this type of mix-up. Laboratories remote from the practises they are serving are less likely to be able to identify this problem as they are unlikely to attend subsequent multidisciplinary meetings.

[Mrs A] was entitled to expect that provision of pathology services would include accurate correspondence of sample and patient identity. The lack of this in this case is a breach of [Mrs A's] legitimate expectation. However I do not see evidence that the provider's laboratory service was organized or carried out in a careless manner. Although the action leading to the adverse outcome would have been a momentary distraction, the consequences have been very significant and distressing. From the literature, swaps of this type leading to severely adverse outcomes would number approximately 1 in 100,000 specimens, which would correspond, in New Zealand, to approximately 4 such events throughout the country each year. A pathologist might reasonably expect not to see one in his or her practicing lifetime and a clinician would be most unlikely to see one.

Concurrent with this incident, a number of other similar errors in handling of breast biopsies resulted in a ministerial review, which has recently reported back (copy enclosed). Many anatomical pathology laboratories in NZ have reviewed or

are in the process of reviewing their procedures to prevent recurrence of this type of incident."

Further advice

Dr Allen provided the following further advice on 1 December 2013:

"In reply to your question was it reasonable for MedLab Dental not to have identified the possibility of a transposition of specimens in light of:

1. [The DHB clinician's] request to review [Mrs A's] histology slides; and
2. The fact that Patient X (the other consumer involved in the biopsy mix-up) had a repeat biopsy two weeks after his initial biopsy, the results of which were quite different to his initial biopsy results (ie non-specific inflammation vs squamous cell carcinoma)?

Yes I believe it was reasonable for Medlab Dental not to have identified the tissue swap, either at the request to review [Mrs A's] histology or at the second biopsy from Patient X. [The DHB clinician's] request to review [Mrs A's] histology slides prior to surgery would have been considered a routine event as subspecialty units frequently request slides for review in these circumstances, and it would not be a sign that anything was amiss. The second biopsy from Patient X would have arrived 2 weeks later (after numerous intervening specimens had been received) and would not have been linked to [Mrs A's] biopsy. The fact that Patient X's first biopsy was negative for malignancy would have been interpreted as tissue not representative of the lesion (a quite frequent occurrence) rather than a specimen transposition."

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

The following is 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:

"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.

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
- 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."

Appendix C — Measures taken by the University of Otago (trading as MedLab Dental) to reduce risk of transposition error

Measures taken to reduce risk of transposition errors	Implementation
The cut-up area is a designated Quiet Area and staff and laboratory personnel are kept to a minimum during the cut-up. There is no chatter or interruptions and a "Do Not Disturb" sign is placed on the laboratory door.	Fully implemented
Cut-Up Pathologist and Medical Laboratory Scientist to verbally double check the name and specimen number of each case against details on the pottle and details on the request form. This QC step is recorded for each case.	Fully implemented
Cut-Up Pathologist and Medical Laboratory Scientist to verbally double check case number against details on the request form and on the processing cassette.	Fully implemented
Use of adhesive printed biopsy number labels for all slides.	Fully implemented
Cut-up process concentrates on one specimen at a time.	Fully implemented
Strict attention and supervision on trainee staff. All trainees are required to sign that they have read, and will abide by, the instructions in the cut-up manual.	Fully implemented
Use of foot operated dictation system at cut-up	In progress. Quotes have been obtained but there has been a delay while new digital dictating system is made compatible with the current taping system.
Purchase of equipment to barcode slides and cassettes	In progress. [MedLab Dental has] been granted funding to purchase a barcoding device and have a quote from InstrumeC Pty Ltd for a Primera Signature Slide Printer. However, [MedLab Dental has] been advised by the manufacturer that part of the technology is not yet complete. Therefore, [MedLab Dental is] waiting to purchase this.