Decision 24HDC01632
xx December 2025

HEALTH & DISABILITY COMMISSIONER
TE TOIHAU HAUORA, HAUĀTANGA

Failures in pathology reporting processes result in biopsy being incorrectly diagnosed as cancer

Introduction

1. In October 2023, pathologist Dr B at Awanui Labs incorrectly reported Mrs A's oesophageal[1] biopsy as adenocarcinoma.[2]

2. Mrs A subsequently underwent unnecessary neoadjuvant[3] chemoradiation therapy and oesophagogastrectomy[4] at a public hospital (Health New Zealand | Te Whatu Ora (Health NZ)).

3. Mrs A complained to the Health and Disability Commissioner (HDC) about the misdiagnosis of the oesophageal biopsy as well as the way in which the error was communicated to her. For the reasons below, I find Dr B in breach of Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code) for failing to take adequate care when reporting on Mrs A's oesophageal biopsy. I also find Awanui Labs in breach of Right 4(1) of the Code for failing to ensure that services were provided to Mrs A with adequate skill and care.

4. The parties to this complaint were given an opportunity to comment on the provisional decision. Comments have been incorporated into this report where appropriate.

Clinical background

5. On 19 October 2023, Mrs A had a CT scan of her abdomen[5] to investigate causes of a 10-day history of upper abdominal symptoms (pain, bloating, and vomiting). The CT report noted a moderate-sized hiatal hernia[6] with abnormal wall thickening of the lower thoracic oesophagus, which was thought to be suspicious for oesophageal adenocarcinoma. An alternative suggested diagnosis was oesophagitis.[7] While in hospital, Mrs A also reported difficulty swallowing in the previous 'few months.'

6. On 20 October 2023, Mrs A had a gastroscopy,[8] which identified a medium-sized ulcerating mass with no bleeding in the middle third of the oesophagus. A biopsy was taken and sent to Awanui Labs for review.

[1] The oesophagus is a muscular tube connecting the throat to the stomach.
[2] Adenocarcinoma is a type of cancer that starts in the glands that line the organs.
[3] Treatment given as a first step to shrink a tumour before the main treatment, usually surgery.
[4] Surgical removal of part of the oesophagus and part of the stomach.
[5] Performed at a public hospital.
[6] A hiatal hernia occurs when part of the stomach pushes up through the diaphragm into the chest cavity.
[7] Inflammation of the oesophagus.
[8] A procedure where a thin, flexible tube with a camera is inserted into the oesophagus, stomach, and duodenum to visualise the upper digestive tract.

Names have been removed (except Awanui Labs and Health New Zealand | Te Whatu Ora) to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

October 2023 biopsy misdiagnosis

7. Awanui Labs and Dr B confirmed to HDC that an error was made in the reporting of the biopsy specimen. The biopsy misdiagnosis was identified in March 2024, after the tissue that was surgically removed during Mrs A's oesophagogastrectomy (resection specimen) was reported as being negative for malignancy, which prompted a review of the biopsy specimen. I have discussed this in more detail in the next section of this report ('Investigation and disclosure of diagnostic error').

8. Awanui Labs said that contributing factors for the biopsy misdiagnosis were confirmation bias in the context of a high clinical suspicion of malignancy[9] and time pressure.

9. First, there was a strong clinical impression of cancer as the clinical history, CT radiological findings, and mass visualised on endoscopy were noted as fulfilling three of the four criteria for malignancy (histology showing the cancer is the fourth criteria). Further, review of the biopsy was rushed in response to pressure from Mrs A's clinical team, who wanted the biopsy results for discussion of Mrs A's case at the next gastrointestinal (GI) multidisciplinary meeting (MDM).

10. The biopsy specimen was viewed by Dr C at Awanui Labs the day before the MDM. Her impression was of an adenocarcinoma, and she requested cancer biomarkers,[10] but she did not complete her report and was on leave the following day. Despite the report not being finalised, Dr B presented the biopsy images at the MDM alongside the clinical, radiological, and endoscopic findings. Health NZ's Adverse Event Review (AER) report noted that Dr B assumed that Dr C had seen cancer cells because she had requested biomarkers.

11. Dr B said: 'Based on the urgency and high pre-test probability of a malignancy, I must have therefore agreed in the MDM, overcalling the [October 2023 biopsy] as "Adenocarcinoma".'

12. Dr B said that he should not have agreed to the 'urgent on-the-spot review at the MDM' and should instead have taken the appropriate time to complete the report for review at the following week's MDM. Awanui Labs said that the clinical information provided to the pathology team is vital to the biopsy assessment process and strongly influences the assessment, but in this case confirmation bias occurred.

13. A root cause analysis completed by Awanui Labs in August 2024 stated:

> 'The case had been added urgently for review to the MDM, despite the report not being complete, by the clinical team due to the strong clinical impression of a cancer and urgency to both plan and institute management. While the pathology team [tries] to accommodate requests for urgent additions to MDMs, there is a degree of risk associated with this as there is time pressure, which can result in error.'

[9] Confirmation bias is the tendency to give greater weight to information that confirms existing thinking while neglecting or downplaying contradictory evidence.

[10] Additional specialised tests for cancer cells assessing for genetic, protein, or immune changes. These tests are not usually requested unless cancer cells have been identified on histology.

Investigation and disclosure of diagnostic error

14. Unfortunately, Mrs A was told conflicting information about the misdiagnosis, which added to her distress. This happened because of deficiencies in the histology reporting of the resection specimen and review of the biopsy specimen as well as inadequate communication between Awanui Labs staff and Health NZ staff.

15. After Mrs A's oesophageal surgery on 28 February 2024, general pathologist Dr D at Awanui Labs reviewed the resection specimen on 4–5 March 2024 and considered that there was no residual malignancy or changes consistent with tumour eradication by chemoradiation. This prompted a 'blind audit' of the biopsy specimen, undertaken on 6 March 2024.[11]

Blind audit of biopsy specimen

16. The findings of the blind audit were completed on 7 March 2024. The consensus was that the biopsy specimen was negative for invasive carcinoma, with Barrett's oesophagus and low-grade dysplasia.[12]

17. The blind audit did not include senior GI pathologists (Dr B and Dr C) as they were on leave. Dr B said that this does not reflect 'everyday practice' at Awanui Labs because, owing to the difficulty in assessing dysplasia in Barrett's oesophagus, Awanui Labs's usual practice is for general pathologists to refer dysplasia cases to senior GI pathologists. Awanui Labs said that, in retrospect, the review should have waited until the senior GI pathologists had returned because they had reviewed and reported on the case originally, they have the most expertise in the team, and it would have been desirable to have more pathologists participate in the audit.[13]

Reporting of resection specimen

18. The resection specimen was initially reported on 7 March 2024 by Dr D at Awanui Labs as being negative for invasive carcinoma, with Barrett's oesophagus and low-grade dysplasia (resection specimen report #1). Dr D discussed this finding at the GI MDM on 14 March 2024 (at which Dr E (Mrs A's surgeon) was also present), including that there was no evidence of fibrosis to indicate chemoradiation changes. The MDM concluded that the pathology results were discordant, with no cancer identified in the specimens. The plan included recommending a Safety1st notification,[14] but this was not recorded as an action item and

[11] The biopsy slides were 'mixed in' among other pathology samples for review by pathologists at Awanui Labs without knowledge of the case history.
[12] Dysplasia refers to abnormal growth or development of cells and tissues. Low-grade dysplasia is considered the early stage of precancerous changes. High-grade dysplasia means that severely abnormal cells are present and there is a high risk of progression to cancer.
[13] Only five of the 10-member pathology team were available to take part in the blind audit.
[14] Safety1st is an incident and feedback reporting system.

was not submitted at that time.[15] Dr D authorised a supplementary report[16] on 15 March 2024 (resection specimen report #2).[17]

19. Awanui Labs told HDC that, after returning from leave on 19 March 2024, Dr B viewed the resection specimen. Dr B agreed that there was no invasive carcinoma, but he identified focal high-grade dysplasia in addition to the low-grade dysplasia. Dr B also considered that there *was* 'tumour bed,'[18] represented by a 'loose form of fibrosis,' indicating that there had previously been a tumour. This was not recognised at the initial assessment (which involved review by a general pathologist only (Dr D), not by a senior GI pathologist).

20. On 21 March 2024, Awanui Labs issued an amended report[19] for the resection specimen – resection specimen report #3. The reason for this report was 'full review of slides, including previous [biopsy specimen],' and the report was prepared and authorised by Dr G (pathologist and Medical Director at Awanui Labs), with slides also reviewed by Dr B and Dr D. The report findings included that the resection specimen showed focal high-grade dysplasia among extensive low-grade dysplasia. The report also noted that the biopsy specimen had been reviewed and the findings were of Barrett's oesophagus with low-grade dysplasia and no evidence of invasive malignancy. Resection specimen report #3 does not mention tumour bed or fibrosis, but it does include a 'modified Ryan'[20] score to indicate the response to neoadjuvant therapy to reflect the presence of a tumour bed not previously identified. The modified Ryan score was: '0 (complete response; no viable cancer cells).' Dr B explained that 'not all malignancies elicit a fibrotic response,' and the modified Ryan grading system takes this into account.

Communication between pathologists and Dr E

21. Accounts differ as to when Awanui Labs communicated the concerns about misdiagnosis to Mrs A's surgeon, Dr E.

22. Awanui Labs said that its pathologists told Dr E of the biopsy specimen misdiagnosis on three occasions — first by Dr D on 7 March 2024, then again by Dr D in the GI MDM on 14 March 2024, and lastly by Dr B on 19 March 2024 (after he had returned from leave and reviewed the biopsy slides again).

23. Awanui Labs said that Dr D verbally communicated his concerns about the biopsy misdiagnosis with Dr E on 7 March 2024, after the results of the blind audit had been collated. On the other hand, Dr E told HDC that he was first told of the potential misdiagnosis

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[15] An incident report was first submitted on 22 April 2024 when Mrs A made a formal complaint to Health NZ. This was six weeks after the resection specimen was reported as being negative for any signs of malignancy and three and a half weeks after open disclosure.

[16] Supplementary reports are issued when additional information is added by pathologists or there is a change in grading but the diagnosis is unchanged.

[17] Resection specimen report #2 was issued to add supplementary information about whether the surgical margin (the border of the tissue removed in surgery) was free of cancer cells. The report stated: 'There is Barrett metaplasia at the proximal margin without dysplasia.'

[18] An area of the body where a tumour was located before it was removed by surgery or treated with chemotherapy, radiation therapy, or hormone therapy.

[19] Amended reports are issued when there has been a change to the diagnosis.

[20] The modified Ryan grading system is a tool used to evaluate the tumour regression grade after neoadjuvant therapy.

by Dr D on 8 March 2024 and that he was told at that stage that the blind audit was still to be undertaken. Dr E provided HDC with a copy of a text message between himself and Mrs A's second operating surgeon on 8 March at 3.54pm, in which the second surgeon wrote: 'Let me know if you hear from path[ology]. I'm anxious to hear the outcome of that further review.' Dr E said that he was not advised of the outcome of the blind audit until he telephoned Dr D on 28 March 2024 to ask for the results, prior to Dr E's clinic appointment with Mrs A that day. Health NZ's AER report said that the pathologists informed Dr E on 7 March 2024 but made no comment about whether the blind audit results had been collated at that point.

24. Dr E agreed that the resection specimen was discussed at the GI MDM on 14 March 2024 but said that, at that stage '[t]his was still reported by only one pathologist who was not our usual upper GI pathologist,' and the findings of Dr D remained in contrast to the conclusions of the two senior pathologists. Dr E said that the first formal pathology report of the resection specimen was not available on the hospital's electronic clinical record until 15 March 2024 (resection specimen report #2).

25. Regarding Dr B's conversation with Dr E on 19 March 2024, Dr E said that this was a 'very brief call' during which Dr B apologised for his error but that 'this was not a formal discussion of his error.'

26. Dr E said that it was not until 21 March 2024 that a formal review and report of the initial biopsy and the surgical specimen by two pathologists took place (resection specimen report #3). Dr E said that he did not see this report until 22 March 2024. This is supported by an electronic audit report provided to HDC.

27. Awanui Labs said that, after resection specimen report #3 was issued on 21 March 2024, Dr B contacted Dr E to discuss the amended findings. Neither Dr B's nor Dr E's summary of events mention this conversation, nor is there any other evidence that this occurred.

28. Health NZ's AER report noted that, at the time, there was no process in place to guide communication and actions for cross-organisation adverse events management involving a private provider (Awanui Labs) and multiple hospital specialties. Further, the AER report identified that early notification of this incident into Health NZ's Safety1st reporting system would have initiated a review process at the outset, which would have identified the need for a process to allow Mrs A and her family to work through this with the clinical and pathology teams.

Health NZ open disclosure policy

29. Health NZ's open disclosure[21] policy and guidelines (March 2023) outline when and how open disclosure should occur, including when a patient has suffered harm because of a known complication of their healthcare management. The policy states that key principles of open disclosure include openness and timeliness of communication and that all incidents should be acknowledged to the patient as soon as practicable and ideally within 24 hours. The policy notes that open disclosure is important because the physical harm from an

[21] Open disclosure is the timely and transparent approach to communicating with a patient and their families/whānau about incident(s) that result in harm while they were receiving health care.

adverse event can be compounded by emotional or psychological harm when consumers discover that relevant information has been withheld from them.

30. The open disclosure guidelines state that open disclosure is the responsibility of the consultant in charge of the patient. The level of response is dependent on the severity of the incident, with incidents of higher severity requiring a 'high-level response' where patients are provided with an explanation of what occurred, the immediate effects, and the prognosis and are informed that the incident will be reported and investigated. The guidelines acknowledge that disclosure may be delayed if the patient is too unwell to understand or comprehend the disclosure.

Decision to wait to disclose to Mrs A

31. When Dr D initially told Dr E about the concerns of a misdiagnosis, Dr E decided to wait to tell Mrs A the news at her postoperative clinic appointment on 28 March 2024. Dr E's reasons for waiting were that, at that stage, the diagnosis was still uncertain, not yet reported in writing, and contradictory to the previous reported pathology diagnosis. Dr E said:

> 'It was [Dr D's] opinion that the two senior Upper GI Pathologists who had double read the initial biopsy were incorrect. Which left me as the treating clinician not knowing who to believe. I had to err on the side of the original pathology report, as that was in writing and had been reviewed at our MDM, with the pathologist pointing out the reasons why the patient had invasive adenocarcinoma.'

32. Dr E considered that further tests and written confirmation were required before bringing this 'life-changing information' to Mrs A. Additionally, at this time, Mrs A was recovering from surgery, and waiting would allow the team to first discuss the findings at the GI MDM on 14 March 2024.

33. Dr E said:

> 'For [clinicians] to accept a biopsy result, it must be concordant with the clinical picture and supported by a second pathologist. This is the standard practice. Therefore, I could not share Dr D's apparently rushed provisional verbal report with a patient due [to] the significant risk that such report may change again.
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> Waiting for the MDM was to allow Dr D and Awanui Laboratories time to follow the standard process for getting the biopsy specimen and the resection specimen reviewed by a second pathologist. This [is] an international standard, to avoid any incorrect reporting.'

34. As outlined in paragraph 26, Dr E said that it was not until 21 March 2024 that a formal review of the initial biopsy and the surgical specimen was undertaken by two pathologists. The formal report (resection specimen report #3) was released that day and accessed by Dr E on 22 March 2024 (a Friday). The following Monday was a public holiday, so the next opportunity that Dr E had to discuss the results with Mrs A was Tuesday 26 March 2024. As this was two days before Dr E's scheduled clinic appointment with Mrs A, he decided to wait until then to discuss the results in person.

Disclosure to Mrs A

35. On 28 March 2024, Mrs A met with Dr E for postoperative review. Dr E told Mrs A that there had been an 'over grade' in the diagnosis of the biopsy specimen, that she had not had adenocarcinoma of her oesophagus, and that chemoradiation and surgery had been unnecessary. This was, understandably, a significant shock to Mrs A. Following the meeting, Mrs A queried why she had not been informed earlier. She said:

> '[As] we were still in [the area] [on 14 March 2024] we [cannot] understand why we had [to] wait for two weeks until [28] March to be told … We were totally unprepared for this appointment and as you would imagine we have more questions requiring answers.'

Biopsy specimen supplementary report

36. Dr C returned from leave on 2 April 2024 and reviewed the biopsy specimen. She agreed that the biopsy was negative for invasive carcinoma but identified an area of high-grade dysplasia in addition to low-grade dysplasia. Following further review by Dr B, Dr D, and Dr G, on 10 April 2024 an amended report for the biopsy specimen was issued with the findings of Barrett's oesophagus and oesophagitis with low-grade and high-grade dysplasia (biopsy specimen report #2).

37. Biopsy specimen report #2 was automatically sent to Mrs A's surgeon, who had requested the original biopsy. The amended report and findings were not sent or communicated to Dr E.

Further communication with Mrs A

38. On 23 April 2024, Mrs A met with pathologists Dr C and Dr G. Mrs A had expected Dr B to attend this meeting to achieve 'closure,' but he was absent as he was ill, so Dr G attended instead. Awanui Labs said that the pathologists apologised[22] for the biopsy misdiagnosis and confirmed that the biopsy was negative for invasive carcinoma. They also told Mrs A that, because the endoscopic and radiological findings were strongly suggestive of invasive carcinoma and that in their view the resection specimen showed evidence of cancer that had responded to treatment (tumour bed), they were 'highly suspicious' that Mrs A *did* have cancer in her oesophagus 'but this was not captured in the original biopsy sample … due to sample error.'[23] As such, the pathologists told Mrs A that it was possible that 'surgery was not necessarily needless.'

39. The pathologists also explained that 'the absence of carcinoma in a resection specimen does not necessarily imply that there was no carcinoma in the diagnostic biopsy,' because a 'significant percentage' of carcinomas respond completely to chemoradiation. The implication was that the neoadjuvant chemoradiation treatment Mrs A had had may have eradicated the cancer before the surgery.

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[22] Mrs A said that the pathologists did not apologise at this meeting. She said that she only received an apology two weeks later, when a written apology was sent from Dr G apologising to Mrs A on behalf of the pathologists at Awanui Labs.

[23] In pathology, sample error is a mistake in the process of obtaining or handling a tissue sample for analysis. This can include taking insufficient, inadequate, or non-representative tissue samples.

40. During this appointment, the pathologists also gave Mrs A a copy of biopsy specimen report #2 (which noted the finding of high-grade dysplasia). Dr G told Mrs A that chemoradiation treatment may have been required because the high-grade dysplasia may have developed into cancer cells, if some were not already present.

41. Later that day, Mrs A met with Dr E. She told Dr E about the information she had been told by the pathologists. Dr E told Mrs A that, although chemoradiation treatment does sometimes completely eradicate cancer, in her case the pathologists had made 'an error of judgement.' Dr E reiterated the findings discussed at the 14 March 2024 GI MDM – that there were no fibrotic changes in the resection specimen – and that review of the biopsy specimen had found only low-grade dysplasia. Dr E also told Mrs A that treatment for a patient with low-grade or high-grade dysplasia would be continued monitoring. He noted that biopsy specimen report #2 had been issued without consultation between himself, the pathologists, and the GI MDM and had not been forwarded to him.

42. Mrs A said that she felt traumatised by the conflicting information.

43. Health NZ's AER report notes that, after the meetings on 23 April 2024, a clinical nurse specialist (CNS) emailed Mrs A's wider healthcare team to request that all specialists involved with Mrs A's care meet with Mrs A and her family. However, for reasons unknown, it appears that this meeting did not happen.

44. Awanui Labs said that, before the meetings on 23 April 2024, its pathologists had tried to contact Dr E to discuss matters and set up a combined meeting with all parties involved. Awanui Labs said that Dr E did not respond to these requests, which 'had a significant negative impact,' and the pathologists decided to meet Mrs A without Dr E as they wished to apologise and answer her questions.

45. On the other hand, Dr E said Awanui Labs did not contact him before 23 April 2024 to organise a meeting. Dr E provided a copy of an email chain showing that, on 19 April 2024, Mrs A emailed a CNS with a list of questions she wished to have answered at her upcoming clinic appointment with Dr E (on 23 April 2024). Dr E had responded to the CNS explaining that the upcoming clinic appointment was not the appropriate environment for a long discussion about the misdiagnosis, and he suggested that, if Mrs A wished to have all her questions answered, it would be better to reschedule the clinic appointment and arrange a family meeting together with all of the involved specialists. Dr E copied the email chain to Dr B. Dr B responded that the pathologists still intended to meet with Mrs A and her family on 23 April 2024 as scheduled and that they would also be able to attend a group meeting if arranged.

Written apology from Awanui Labs

46. Following the meeting between Awanui Labs pathologists and Mrs A and her family on 23 April 2024, Awanui Labs sent Mrs A a written apology. The letter did not identify Mrs A as the patient, and it was not dated, signed, or on letterhead. The letter also contained an offer for Mrs A to submit invoices to Awanui Labs for any costs incurred because of ongoing

treatment, and Awanui Labs would ensure that these were paid.[24] Mrs A felt that this was inappropriate and indicative of a 'cover up,' and this added to her distress.

Other comments

47. Regarding the reporting of the biopsy and resection specimens, Awanui Labs said:

> 'We made an error [in the] diagnosis of [the biopsy specimen] and an under call of both tumour response and high-grade dysplasia in the original assessment of the [resection] specimen, for which we sincerely apologise. In retrospect this case should not have been rushed to be presented at both GI MDMs and due consideration given to both biopsy and the [resection] specimen features without time pressure.'

48. Awanui Labs said that, in retrospect, the biopsy specimen should have been reported as 'extensive Barrett intestinal metaplasia present in all the biopsy fragments with low- and high-grade dysplasia. This biopsy may not be representative of the mass lesion, and repeat biopsy should be considered.'

49. Regarding the communication with Mrs A, Awanui Labs noted that 'clinicians are responsible for relaying information provided in the pathology reports for their patients.' It told HDC that 'there is fibrosis present in the [resection] specimen, which likely represents tumour bed' and that although there is no histological confirmation that Mrs A had invasive carcinoma, the presence of dysplasia on a background of extensive Barrett's oesophagus in the clinical context of a mass lesion raises suspicion that the oesophageal biopsy was 'not representative of the mass visualised and sampled.' Awanui Labs noted that this possibility 'does not appear to have been considered by the clinical team,' and 'this scenario should have been considered and discussed by the clinical team on the 28th of March 2024.'

50. Dr B told HDC that he 'apologise[s] unreservedly for the error that occurred in the interpretation and reporting of both specimens, and for the upset and distress Mrs A and her family have experienced as a result and by the communication processes in conveying this information.'

51. Dr E said that if the original biopsy had demonstrated high-grade dysplasia in the presence of an ulcer or a lesion, the next step would have been to organise a repeat gastroscopy to confirm the presence of an underlying malignancy or lesion.

External pathology review commissioned by Health NZ

52. As part of its AER, Health NZ arranged an external pathology review of Mrs A's biopsy and resection histology slides. This was not a 'blind review,' as the external pathologist was given a deidentified case summary outlining the sequence of events, clinical and histological opinions, and reports.

53. The findings of the external pathology review were consistent with the findings of the Awanui blind audit of the oesophagus biopsy showing low-grade dysplasia and Barrett

[24] Awanui Labs said this offer was made to 'help mitigate the emotional and financial costs consequent on [its] diagnostic error.'

mucosa. Review of the surgical specimen showed Barrett mucosa with low-grade dysplasia, and no high-grade dysplasia, malignancy, or features of a tumour bed (scar).

54. Dr B, Dr C, and Dr D disagreed with the external pathology review findings. They noted their concern that the external pathology reviewer may have missed the presence of a tumour bed, just like Dr D first did.[25] The Awanui Labs pathologists raised this because they want to ensure that Mrs A and her clinical teams have all the available information to ensure she has the correct follow-up and care if in fact she has had a treated cancer, rather than be discharged from further follow-up because no cancer was identified.

Opinion: Awanui Labs — breach

55. Under Right 4(1) of the Code, Awanui Labs had a duty to ensure that services provided to Mrs A were provided with reasonable care and skill. In this regard, Awanui Labs failed Mrs A on several occasions.

56. Mrs A's diagnostic biopsy was rushed to presentation at the October 2023 MDM before the report had been finalised. This meant that the biopsy diagnosis was made in a setting that increased the risk of confirmation bias and with additional pressures that would not be present in a pathologist's usual work environment.

57. While I acknowledge that the pathology team was responding to pressure from the hospital clinical team, ultimately Awanui Labs was responsible for ensuring that its pathologists reported on the biopsy specimen with appropriate time and care. I am critical that Awanui Labs did not have processes in place to prevent the unsafe practice of pathology specimens being presented at MDMs before final sign-off of the report. I consider this directly contributed to Mrs A's biopsy specimen being misdiagnosed. I acknowledge the distressing and ongoing consequences of this for Mrs A and her family.

58. The blind audit of the biopsy specimen and initial review of the resection specimen were undertaken before appropriate input from senior GI pathologists could be obtained. This resulted in conflicting reports. This time, the biopsy specimen was 'underreported'; it was not identified that there was high-grade dysplasia in addition to low-grade dysplasia. In addition, initial reviews of the resection specimen failed to identify that there *was* evidence of 'tumour response' to chemoradiation and that there was high-grade dysplasia in addition to low-grade dysplasia. Consequently, Dr E had an incomplete understanding of the pathology when he communicated the diagnostic error to Mrs A on 28 March 2024, which caused her further harm.

59. I am also critical of Awanui Labs's communication of these matters with Mrs A's surgeon, Dr E. Awanui Labs told HDC that Mrs A's clinical team should have considered the possibility that the biopsy was not representative of the mass that had been seen on endoscopy and CT. However, in my view, it was the responsibility of the reporting pathologist to alert the clinical team to this possibility. I note that Awanui Labs has acknowledged that the biopsy specimen report should have stated this and recommended repeat biopsy. Failing this, I

[25] Health NZ's AER report notes that, on subsequent review after reviews by Dr B and Dr C, Dr D 'saw unmistakable evidence of a tumour bed' on the resection specimen.

consider it was the responsibility of the pathology team to discuss this with the clinical team during the subsequent investigation of the misdiagnosis.

60. In addition, it appears that the findings of tumour bed or fibrosis in resection specimen report #3 were not discussed with Dr E. Awanui Labs said that Dr B discussed these findings with Dr E. However, there is no supporting evidence that this occurred. The statements from Dr B and Dr E do not mention this. Further, it appears that Dr E was not aware that there was evidence of chemoradiation changes in the resection specimen because he told Mrs A on 23 April 2024 that there was no evidence of this. On this basis, I find it more likely than not that Awanui Labs did not discuss the amended finding of resection specimen report #3 with Dr E.

61. Further, I consider that it was inappropriate for the pathologists to tell Mrs A during their meeting with her on 23 April 2024 that chemoradiation and surgery *may* have been required because high-grade dysplasia identified in the biopsy specimen may have developed into cancer cells and the biopsy may not have been representative of the lesion. It appears that this information was intended to alleviate the devastation Mrs A felt about having had cancer treatment for a cancer diagnosis she did not have. However, I consider that stating that treatment *may* have been required in any case was presumptive and caused Mrs A further distress and confusion. It is agreed that if the biopsy specimen had been reported accurately, the recommendation would have been for further investigations to be undertaken. The pathology team should have explained this to Mrs A without further speculation about what the results of the investigations may have shown or what treatment may have been indicated.

62. In summary, I consider that the adverse event process undertaken by Awanui Labs was inadequate, resulting in fragmented review, confusion among clinicians, and a well-meaning but inappropriate apology, all of which compounded trauma for Mrs A and her family. For the above reasons, I find that Awanui Labs failed to provide Mrs A with services with reasonable care and skill and, accordingly, breached Right 4(1) of the Code.

63. Lastly, I note that the findings of the external pathology review highlight the significant diagnostic challenges in this case. These findings have added further uncertainty about whether the resection specimen showed evidence of tumour bed, thereby resurfacing questions about whether Mrs A had oesophageal cancer or not. While I do not underestimate the impact of this uncertainty on Mrs A and her family, given the multiple reviews already undertaken, I consider that the question of which analysis of the resection specimen was accurate is, unfortunately, unlikely to be resolved with further investigation by this Office.

Opinion: Dr B — breach

64. I acknowledge that in agreeing to present the biopsy images at the GI MDM in October 2023 despite the report not being finalised, Dr B's intentions were only to assist Mrs A's clinical team, who wished to review her case urgently because of a strong clinical indication of cancer. Unfortunately, this decision resulted in inadequate care being taken in the reporting of the biopsy specimen.

65. As the senior GI pathologist who reviewed and authorised the biopsy specimen report, Dr B is responsible for the misdiagnosis of the biopsy specimen. I am critical that he presented Mrs A's case at the GI MDM despite the report not being complete. I consider that, by authorising the report in this setting, Dr B impaired his ability to assess the biopsy with appropriate care and to resist confirmation bias. This resulted in a misdiagnosis that caused significant harm to Mrs A. I find that Dr B failed to provide Mrs A with services with reasonable care and skill and, accordingly, breached Right 4(1) of the Code.

Opinion: Dr E— educative comment

66. Health NZ's open disclosure policy required that disclosure of an event be made as soon as practicable and ideally within 24 hours. I note that HDC's Guidance on Open Disclosure Policies[26] states that open disclosure is not a single conversation but a process of ongoing communication. In circumstances where providers are still searching for answers about how an event occurred, patients should be told of the error with an acknowledgement of the limits of what is known and a commitment to sharing further information as it becomes available. While it may be beneficial for the care team to meet prior to the disclosure taking place, this will not always be possible and should not delay disclosure to the patient.

67. In this case, the fragmented adverse event process meant there was significant uncertainty about when, exactly, it was known that an error had in fact occurred. Awanui Labs pathologists appear to have accepted that an error occurred once the results of the blind audit were collated on 7 March 2024, and it said that these results were communicated to Dr E that day. However, a text message between Dr E and the second operating surgeon indicates that, on 8 March 2024, they were still awaiting the audit results, and Dr E's account is that he was not advised of these results until he followed up with Dr D on 28 March 2024. Based on the text message of 8 March 2024, I accept that Dr E had not been advised of the audit results at that point; however, because of the conflicting accounts, I am unable to determine precisely when these were communicated.

68. In any case, given that the results of the blind audit and resection report #1 of 7 March 2024 were discordant with the initial biopsy specimen results and the clinical and radiological findings, and that there had at that point been no involvement of senior GI pathologists, I accept that Dr E reasonably felt that there was insufficient diagnostic certainty at that point to confidently tell Mrs A about a misdiagnosis. In this context, I consider it was not unreasonable for Dr E to decide to wait until there had been a formal review and report of the biopsy and resection specimens by a senior GI pathologist. This occurred on 21 March 2024, with Dr E accessing the formal report on 22 March 2024. Dr E's next working day was 26 March 2024, two days before his scheduled clinic appointment with Mrs A on 28 March 2024.

69. Mrs A expressed that she felt unprepared when Dr E told her about the misdiagnosis on 28 March 2024, and she queried why she had not been told earlier. Given the enormity of the news, it is understandable that Dr E wanted to tell Mrs A in person, especially as their meeting was imminent. Having said this, I must stress that timeliness of disclosure must be prioritised, and Mrs A's case highlights how the physical harm from an adverse event can be

[26] Guidance on open disclosure policies — Health & Disability Commissioner

compounded by emotional or psychological harm when consumers feel that relevant information has been withheld from them.

70. Lastly, I note that this case serves as a stark reminder of the importance of ongoing open communication between providers to ensure that patients are provided with clear and accurate information following an error in their health care.

Opinion: Health NZ — no breach

71. I am satisfied that Health NZ had adequate policies and guidelines in place to support staff to follow appropriate open disclosure processes. I find that Health NZ did not breach the Code.

72. I acknowledge the findings in Health NZ's AER report that the incident reporting, investigation and disclosure was adversely impacted by a delayed Safety1st notification and lack of a formal cross-system process for managing multi-organisation adverse events. I note that the AER team recommended changes (outlined below) to address these deficiencies with the aim of ensuring a cohesive reporting and disclosure process, which I consider appropriate.

Changes made

73. Awanui Labs has made the following changes since the events:

a) Only completed pathology reports are submitted to an MDM. Awanui Labs has told the hospital clinicians that 'pre-loading of incomplete histology/cytology puts undue pressure on pathologists and may compromise patient safety.'

b) To utilise the pathology resource efficiently, pathologists will contribute to MDMs only where the pathology report is discordant with the clinical impression. Awanui Labs said that confirming and reading out concordant reports is inefficient and takes the pathologist away from reporting on other patients' cases.

c) It has been discussed in Awanui Labs's intra-departmental meetings that the histology team is to 'resist confirmation bias in the setting of discordant biopsies in the clinical context of a suspected tumour.'

74. Health NZ's AER report included the following recommendations:

a) Awanui Laboratories and Health NZ surgical team to review, agree, and document criteria and process for requesting, reporting, and management of an urgent result.

b) Awanui Labs to undertake a review of pathologist workload and leave management with a quality lens acknowledging the workforce shortage.

c) Awanui Labs to review its process for ensuring that amended reports are sent to the treating team as well as the referring team where amendments have significant clinical impact, such as in this case. There is to be an additional clinician-to-clinician discussion where the report is manifestly different to the original.

d) Awanui Labs to undertake a review of its current adverse event process, including recommendations for changes to align with the Te Tāhū Hauora Health Quality & Safety

Commission National Adverse Events Reporting Policy.[27] Awanui Labs pathologists are to undertake training of the adverse event process.

e) Interdisciplinary review of MDM meetings to explore explicit criteria for including a case in MDMs by Health NZ in response to the increased burden on pathology. A review of GI and other HNZ MDM protocols and Terms of Reference for the functioning of the meetings to ensure signing of reports and processes are understood, and followed, and align with the 'Standards for high-quality cancer Multidisciplinary Meetings (MDMs) in Aotearoa New Zealand 2024.'[28]

f) Health NZ to develop a guideline for the management of discordant pathology results. This case is also to be discussed as a case study in management of discordant results.

g) Health NZ surgical services to review processes for identifying and submitting adverse events. Health NZ GI MDM to review their actions and closing of the loop post-MDM. Discussion at the Clinical/Medical Directors forum with the emphasis on the importance of submitting Safety1st incidents to allow system review.

Recommendations

75. Taking account of the changes made, I recommend that Awanui Labs:

a) Provide a written apology to Mrs A for the care deficiencies identified in this report. The apology is to be sent to HDC within 15 working days of this report for forwarding to Mrs A.

b) Use this case as a basis for developing education/training on confirmation bias for staff. Evidence confirming the content of the education/training (eg, training material) and delivery (eg, attendance records) is to be provided to HDC within three months of this report.

c) Confirm that the process for presenting only authorised pathology reports at MDMs has been formally documented and implemented and conduct a review of the effectiveness of this policy/process (eg, audit of compliance to this policy/process). Evidence of implementation (eg, a copy of the new policy, communication/education delivered to staff) and the outcome of the review of effectiveness (eg, audit results) is to be provided to HDC within three months of this report.

76. As recommended, Dr B provided a written apology to Mrs A for the care deficiencies identified in this report. The apology has been forwarded to Mrs A.

77. Health NZ has been asked to provide an update on the recommendations made in its AER report by 30 April 2026.

[27] National Adverse Events Reporting Policy | Health Quality & Safety Commission Te Tāhū Hauora.
[28] Final_Standards_for_high-quality_cancer_Multidisciplinary_Meetings_MDMs_in_Aotearoa_New_Zealand_Te_Aho_o_Te_Kahu_April_2024.pdf

Follow-up actions

78. A copy of the sections of this report that relate to Dr B will be sent to the Medical Council of New Zealand.

79. A copy of this report with details identifying the parties removed, except Awanui Labs and Health New Zealand, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Dr Vanessa Caldwell
Deputy Health and Disability Commissioner