Health New Zealand |Te Whatu Ora

A Report by the
Health and Disability Commissioner

(Case 23HDC00079)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Complaint and investigation

1. The Health and Disability Commissioner (HDC) received a complaint from Mrs A about the services provided by Auckland District Health Board (now Health New Zealand|Te Whatu Ora Te Toka Tumai Auckland (Health NZ))[1] and the Ministry of Health National Screening Unit.[2]

2. The following issue was identified for investigation:

- *Whether Health New Zealand|Te Whatu Ora provided Mrs A with an appropriate standard of care between March 2017 and March 2023 (inclusive).*

3. The parties directly involved in the investigation were:

Mrs A	Consumer
Laboratory service	Provider
National Screening Unit (NSU)	Provider
Health NZ	Provider
Dr B	Radiation oncologist/provider
Dr C	Gynaecologist/provider

4. Also mentioned in this report:

Mrs D	Medical laboratory technician
Mrs E	Medical laboratory scientist
Dr F	General practitioner
Dr G	Medical oncologist
Dr H	Pathologist
Dr I	Gynaecological oncologist

5. Further information was received from a medical centre (a non-subject provider/primary care practice) and ACC.

[1] On 1 July 2022, the Pae Ora (Healthy Futures) Act 2022 came into force, which disestablished all district health boards. Their functions and liabilities were merged into Health New Zealand|Te Whatu Ora). All references in this report to Auckland District Health Board now refer to Health NZ Te Toka Tumai Auckland.
[2] Previously, the National Cervical Screening Programme (NCSP) was led out of the National Screening Unit (NSU), Ministry of Health. The NSU was disestablished in November 2023 and the functions of the NSU transitioned to the Prevention Directorate, National Public Health Service (NPHS) (Health NZ).

Information gathered during investigation

Introduction

6. Mrs A is a Māori woman in her forties, who, in 2017 and 2020, underwent routine cervical cytology screening[3] (a smear test) — the results of which were both reported as normal. Following tests in 2021–2022 to investigate the cause of heavy menstrual bleeding, sadly, Mrs A was diagnosed with stage III cervical cancer[4] in March 2022. Despite radical chemoradiotherapy,[5] the cancer progressed, and Mrs A was diagnosed with stage IV metastatic cervical cancer[6] in September 2022.

7. Following her stage III diagnosis, Mrs A requested a retrospective smear review, which was completed in May 2022 and showed that both her previous smears had been interpreted incorrectly and were in fact abnormal. However, Mrs A was not informed of this until December 2022. The incident was not reported until she contacted the National Cervical Screening Programme (NCSP) in March 2023, which in turn prompted Health NZ to undertake an adverse event review (AER).

8. This report concerns the misinterpretation of Mrs A's cervical smear tests, resulting in a delayed diagnosis of cervical cancer, open disclosure, and incident review.

9. At the outset, I offer my sincere sympathies to Mrs A, her whānau, and her communities for her diagnosis, and I acknowledge the severe impact this has had on them. Furthermore, I take this opportunity to express my gratitude to Mrs A for her instrumental role in this investigation. Mrs A has advocated strongly for her own health and wellbeing throughout these events, and by bringing her complaint to this Office during such difficult circumstances, I recognise her dedication to ensuring the health and wellbeing of all wāhine, for which she is to be commended. Me aro koe ki te hā o Hine-ahu-one.[7]

Cervical smear tests

10. Health NZ's AER states that cells taken during cervical screening are pre-screened with a computer imaging system (ThinPrep Imager), which identifies 22 fields of view (FOV) where abnormal cells are possibly located. A cytoscientist or technician then examines the FOV to interpret the sample. If no abnormalities are identified, and in the absence of any concerning clinical information or abnormal screening history, the sample is reported as normal. If the sample is considered abnormal, it will be assigned to another cytoscientist for further interpretation and sent to a pathologist for final reporting.

[3] Cervical screening involves the microscopic analysis of cells taken from the cervix during a speculum examination to determine whether there are pre-cancerous cell changes in the cervix or vagina. Regular cervical screening is recommended at three-yearly intervals for women aged between 20 and 69 years to increase the chance of early detection.
[4] Stage III cervical cancer means that the cancer has spread from the cervix and into the pelvic area.
[5] Chemoradiotherapy is the combination of chemotherapy and radiotherapy to treat cancer.
[6] Stage IV cervical cancer means that the cancer has grown into other organs or has metastasised (spread). Stage IV cervical cancer is not curable in many cases.
[7] 'Pay heed to the dignity and power of women!'

11. Clinical notes from the medical centre show that Mrs A had routine cervical smear tests in 2007, 2008, 2011, and 2013, all of which were reported as normal.

12. On 22 March 2017, Mrs A underwent another routine cervical smear test at the medical centre. The sample was interpreted by medical laboratory technician Mrs D at a medical laboratory[8] and reported as '[n]egative for intraepithelial lesion[9] or malignancy'.

13. On 19 February 2020, Mrs A presented to an ADHB contraception clinic for the insertion of a Mirena®[10] as a method of contraception and underwent a further routine cervical smear. The sample was interpreted by medical laboratory scientist Mrs E, and again it was reported as negative for SILs or malignancy.

14. Mrs A stated that following both the 2017 and 2020 smear tests, she was advised that the results were normal and that no further action was required.

False negative and sensitivity rates in cervical cytology

15. It is noted that on both the 2017 and 2020 reports, the advice that '[a] cervical smear has a significant false negative rate[11] for high grade lesions'[12] was documented. Health NZ told HDC that cervical screening has an 'inherent irreducible false negative rate' (estimated to be 25%) and the risk of false results (positive or negative) is related to the prevalence of the disease being screened for, and the sensitivity[13] and specificity of the screening process.

16. Health NZ's AER states that the sensitivity rate for detecting high-grade lesions in cervical screening is thought to be around 70–75% for a single test and notes that 93% of all cytology samples are reported as normal, with around 0.5% reported as high-grade abnormalities (including both HSIL and ASC-H[14]).

Presentations to GP — November–December 2021

17. On 23 November 2021, Mrs A presented to the medical centre with a 10-day history of abnormal uterine bleeding (AUB). Prior to this, Mrs A had no medical history of note and was not taking any regular medications. Dr F (GP) performed a pelvic examination and noted

[8] The medical laboratory provides cervical cytology services for the NCSP and is overseen by Health New Zealand|Te Whatu Ora Te Toka Tumai Auckland. The medical laboratory must comply with the policies and standards as set out by the NCSP.

[9] Squamous intraepithelial lesion (SIL) is the abnormal growth of squamous cells on the surface of the cervix.

[10] A hormone-releasing intra-uterine device (IUD) that is used to treat unexplained heavy menstrual bleeding.

[11] Where the cytology result incorrectly indicates the absence of an abnormality when there is actually an abnormality present.

[12] High-grade squamous intraepithelial lesion (HSIL) is a squamous cell abnormality associated with human papillomavirus (HPV). Without treatment, these types of cells have an increased likelihood of progressing to cancer.

[13] Sensitivity of a test describes the true positive rate and is the ability to correctly detect 'disease'.

[14] Atypical squamous cells (ASC-H) represent cellular abnormalities more marked than simple reactive changes. The presence of ASC-H indicates the possibility of high-grade change but cannot be diagnosed definitively as HSILs. Patients with ASC-H are therefore at higher risk of developing a precancerous lesion.

'lots of blood' and clots in the vagina, although the cervix appeared normal. Mrs A was referred for an ultrasound and prescribed Provera.[15]

18. On 23 November 2021, an ultrasound showed mild thickening of the anterior myometrium[16] and a 'bulky' uterus, suggestive of 'focal adenomyosis[17]'. Dr F informed Mrs A that adenomyosis was likely the cause of her AUB, but this was 'very common' and able to be treated by the Mirena.

19. On 16 December 2021, Mrs A re-presented to the medical centre as the bleeding had not stopped. Dr F changed Provera to Primolut[18] and requested specialist advice from ADHB's gynaecology service 'about [the] next step in management'. The advice, provided to Dr F on 22 December, was to increase the prescription of Provera and to '[r]e-refer if fails to settle'.

20. On 29 December 2021, Dr F received an email from Mrs A, who described being 'miserable' with 'massive haemorrhage each day', despite taking the medication. Dr F increased the Provera dose (as directed by the specialist advice) and referred Mrs A to ADHB's gynaecology service on 5 January 2022.

Gynecology clinic — February 2022

21. On 4 February 2022, Mrs A was seen at ADHB's gynaecology clinic, and a pelvic examination was undertaken, which showed 'some friability in the cervix[19] … with contact bleeding'. A pipelle biopsy[20] was taken and sent for histology, as there was 'concern for malignancy or pre-malignancy'.

22. On 22 February 2022, the histology was reported as 'high grade squamous intraepithelial lesion, invasion cannot be excluded'. Mrs A was informed of these results and referred to the gynae-oncology unit urgently on 23 February 2022 for a colposcopy.[21]

Gynae-oncology assessments — March 2022

23. On 8 March 2022, Mrs A was seen by a gynaecologist, Dr C, who examined Mrs A's cervix and noted 'a 4.5 cm suspicious irregular appearing lesion'. Dr C suspected 'at least a Stage 1B3 cervix cancer'.[22] A further biopsy was taken, which confirmed 'squamous cell carcinoma,[23] HPV associated'.

[15] A hormonal medication used to treat abnormal uterine bleeding.
[16] The middle layer of the uterus (the muscle wall).
[17] Adenomyosis occurs when tissue similar to the uterine lining (endometrium) grows within the myometrium.
[18] Medication used to treat heavy menstrual bleeding, endometriosis, and irregular periods.
[19] When the cervix is friable, the cervical tissue is more sensitive than usual, which can cause it to tear and bleed easily when touched.
[20] A procedure that takes a small sample of cells from the uterine lining.
[21] A diagnostic procedure to examine the cervix, vagina, and vulva visually using a magnifying instrument called a colposcope.
[22] Stage IB3 cervical cancer means that the tumor is 4cm or more in width but remains confined to the cervix.
[23] Squamous cell carcinoma (SCC) is a common type of cervical cancer that develops from cells in the ectocervix (the outer part of the cervix that opens into the vagina).

24. On 22 March 2022, an MRI and PET CT scan were performed. The MRI showed a 5cm cervical tumour and the PET CT scan reported 'pelvic and para-aortic FDG avid lymph nodes[24]'. The following day, a gynae-oncology multidisciplinary meeting (MDM) was held to discuss the findings of the assessments, and a preliminary diagnosis of stage III cervical cancer was made.

25. Dr C noted in his clinical letter, dated 24 March 2022, that in addition to the reported para-aortic nodal involvement, the PET CT scan reported 'a potentially suspicious cervical and left axillary lymph node' (a lymph node in the armpit); however, this was not discussed at the MDM. Dr C recorded that he would consult a radiologist and re-discuss at the next MDM, as the prognosis and treatment would differ depending on the assessment of the axillary lymph node.

26. On 24 March 2022 Dr C informed Mrs A that she had either stage III or stage IV squamous cell carcinoma of the cervix and noted: 'The news has come hard for [Mrs A] and her husband, and obviously they are in shock from this news.' Subsequently, Mrs A was referred to both the radiation and medical oncology teams on 25 March 2020.

27. On 30 March 2022, a further MDM was held to review the PET CT scan findings. It was confirmed that 'the PET scan has only got suspicious nodes up to the low para-aortic (at the level of bifurcation)'. The MDM noted: 'The cervical and axillary lymph nodes are deemed to be physiological and not due to metastatic disease.' The diagnosis as documented on the MDM summary was therefore stage III, and the recommendation for treatment was '[c]hemo-radiation as planned'.[25]

Stage III diagnosis and retrospective smear review

28. On 31 March 2022, Mrs A met with Dr C, who confirmed a diagnosis of stage III squamous cell carcinoma of the cervix. Dr C recorded in his clinic letter from this appointment: '[Mrs A] and her husband are obviously struggling with the diagnosis especially due to her last pap smear in 2020 which was normal.' Health NZ's AER states that '[t]he request for a retrospective slide review was initiated by [Mrs A]'.

29. Mrs A told HDC that she was advised by Dr C 'that he would request a "human" review of [her] previous smears, as they are typically read by a machine and only 60% effective at interpreting the results'. Dr C noted that he would start the process of reviewing her previous smears from 2008 onwards.

30. Health NZ's AER states that on 8 April 2022, Dr C emailed a pathologist at the medical laboratory asking who the most appropriate person would be to contact to organise a retrospective review of Mrs A's slides, 'as the process for this was unclear'. The AER states that the pathologist indicated that the reporting laboratory would undertake the review but suggested contacting Radiation Oncology for advice as 'they thought the Radiation Oncology

[24] Para-aortic lymph nodes lie between the renal veins and bifurcation of the aorta into the common iliac arteries. Fluorodeoxyglucose (FDG) avid lymph nodes are not specific for malignancy.
[25] Mrs A began radical chemoradiotherapy on 3 May 2022 under the care of Dr B, a radiation oncologist, and the ADHB medical oncology team. The course of treatment was completed on 9 June 2022.

Service may have had some previous experience in requesting slide reviews'. The AER states that Dr C then contacted the laboratory service on 12 April 2022 requesting a retrospective review of Mrs A's smears taken in 2017 and 2022.

Findings of retrospective smear review

31. Health NZ's AER states that on 6 May 2022, the results of the retrospective smear review were confirmed to Dr C by email, and the results showed that both Mrs A's smear samples from 2017 and 2020 had been interpreted incorrectly, with abnormal cells found on review. The email stated the following:

- The 2017 sample showed the presence of a low-grade squamous intraepithelial lesion (LSIL)[26] and ASC-H and was interpreted as not being able to exclude an HSIL.
- The 2020 sample showed the presence of an HSIL with some features raising the possibility of invasive SCC.[27]

32. Health NZ stated:

> 'It is important to recognise that there is a powerful bias that exists during slide review, where missed abnormalities are more easily found retrospectively as they [are] specifically known to be present in one or more of the slides presented for review.'

Further gynae-oncology assessments and stage IV diagnosis — August–September 2022

33. On 4 August 2022, a month following her radical chemoradiotherapy treatment, Mrs A presented to the medical centre with symptoms of discomfort. On examination, the GP found 'a new nodular vs cystic lesion' in the lower vagina and referred Mrs A back to ADHB Oncology on 9 August 2022.

34. On 17 August 2022, Mrs A was examined by Dr B, who thought the 'new lower vaginal painful lump' to be a 'probable [tumour] recurrence'. A biopsy, taken the following day, confirmed 'invasive HPV-associated SCC'. A further MRI and PET CT scan undertaken on 30 August 2022 found that the cancer was 'unusual and aggressive' and had metastasised to the lungs, lower vagina, lymph nodes, and deltoid.[28]

35. The findings of the assessments were reviewed at a further MDM on 7 September 2022 and a diagnosis of '[r]ecurrent metastatic squamous cell carcinoma of the cervix — vaginal, nodal, lung, deltoid' was made. Dr B told HDC that she 'had the difficult task of informing [Mrs A] she unfortunately had incurable cancer' that afternoon. Dr B noted in her clinical letter:

> '[Mrs A] was traumatised and most distressed and tearful at this news … [Mrs A] was overwhelmed with the implications for her family and that she will not see her kids grow

[26] An LSIL is an area of abnormal cell growth in the cervical tissue. Some of these lesions return to normal without treatment.
[27] The cancerous lesion has become invasive, meaning it has spread and developed into surrounding tissue/areas.
[28] The muscle forming the rounded contour of the shoulder.

> up … It was all too much today to go through any more in terms of what the future may hold.'

36. Dr B recommended two weeks of palliative radiotherapy[29] and sent a referral to Medical Oncology for further treatment.

Discussion around disclosure of retrospective smear review results

37. Health NZ's AER states that on 9 September 2022, Dr C emailed Dr B the results of the retrospective smear review and asked her to inform Mrs A of the findings. Dr B told HDC that she had been made aware of the retrospective smear review and its findings only two days prior, on 7 September 2022. Dr B stated: 'The delay of [four] months before Oncology became aware of the review's outcome was unfortunate.'

38. Dr B told HDC:

> 'As I had just informed [Mrs A] of the devastating news that she had incurable cancer two days earlier, which understandably caused her immense stress and anxiety, I was very concerned that the impact of this information would cause her more distress and may overwhelm her. There is advice on the Medical Council website that delay in giving information may be acceptable if it is in the patient's best interests.'

39. Dr B stated that she balanced Mrs A's right to know her health information against the likely adverse impact this news would have, and discussed this with Dr C, as well as her Medical Oncology colleagues, before 'reach[ing] the view that this was not the appropriate time [to] inform [Mrs A] of the smear test review results'.

40. Mrs A told HDC that she understands that the delay in disclosing the outcome of her retrospective smear review was due to a 'paternalistic approach', but she does not want this to happen to anyone else.

41. Furthermore, Dr B told HDC that there was a lack of clarity as to who had primary responsibility to inform Mrs A of the retrospective smear review results. Dr B stated that she had 'little knowledge and no oversight of the smear test review process' and therefore it did not seem appropriate for her to inform Mrs A of this outcome when she was not involved with the review itself. Dr B stated:

> 'I did not have sufficient knowledge to answer any important questions regarding the smear review process which [would] have understandably arisen … I would have needed to meet with colleagues in the women's health service who are involved with the smear review process in order to impart the news in an appropriate way and to provide correct information for [Mrs A].'

Oncology treatment — October–November 2022

42. On 12 October 2022, Mrs A was seen by a medical oncologist, who (at Mrs A's request) gave her an estimated life expectancy of 12–18 months. Palliative chemotherapy 'with an

[29] Mrs A completed her two-week course of palliative radiotherapy on 30 September 2022.

expected response rate of approximately 50%' was agreed to[30] and immunotherapy treatment (pembrolizumab[31]) was also discussed.

43. A chest, abdomen, and pelvis CT scan performed on 21 October 2022 showed evidence of mild disease progression, with enlargement of Mrs A's pelvic nodes and pulmonary metastases.

44. On 25 October 2022, Mrs A attended an appointment with Dr G,[32] a medical oncologist at a private clinic, to discuss the option of self-funded immunotherapy.[33] Dr G noted that immunotherapy could improve Mrs A's prognosis of 12–18 months' life expectancy and that Mrs A was 'tackling' this 'challenging time' 'bravely'. Mrs A began her first cycle of pembrolizumab[34] together with cycle two of palliative chemotherapy on 16 November 2022.

Disclosure of retrospective smear review results — December 2022

45. Dr B told HDC that as Mrs A's care had been transferred to Medical Oncology, 'regrettably there was further confusion around the responsibility of who was to inform [Mrs A] regarding the results from her smear test review'. Dr B stated that she discussed Mrs A's case with Dr G, and they 'both felt that [they] were not the appropriate people to inform her of the detail of the review process and its outcome, as [they] were not involved in it'.

46. On 16 December 2022, when Dr B realised that Mrs A still had not been informed of the retrospective smear review results, she forwarded the email from Dr C (regarding the retrospective slide review findings) to Dr G, asking her to raise this issue with him and to meet with Mrs A.

47. On 29 December 2022, Mrs A met with Dr C and Dr G to discuss the findings of the retrospective smear review. Mrs A told HDC that she was informed that 'the results of the review indicate that BOTH previous smears in 2017 and 2020 were in fact "ABNORMAL", and read/interpreted incorrectly'. Mrs A said that she was 'further advised that had they been read/interpreted correctly, [she] may have been looking at a pre-malignancy or an earlier stage malignancy'.

48. Dr G recorded the following in her clinical letter, dated 29 December 2022:

> "[I]f these smears had been read appropriately … [i]t is likely in 2017 [Mrs A] would have a colposcopy and potentially this would have picked [up] pre-malignant changes. This would have changed the frequency of her smears and follow up. We would anticipate

[30] Mrs A began her first cycle of palliative chemotherapy on 26 October 2022.
[31] Pembrolizumab (Keytruda®) is used to treat certain cancers by working with the body's immune system to detect and destroy cancer cells (called immunotherapy).
[32] Dr G also worked as a consultant medical oncologist for ADHB.
[33] Immunotherapy was not funded in the public system at the time of these events. As of 1 April 2023, pembrolizumab is funded, but only for people who meet the Special Authority Criteria set by Pharmac: https://pharmac.govt.nz/news-and-resources/consultations-and-decisions/2023-03-07-decision-to-fund-two-new-treatments-for-people-with-advanced-non-small-cell-lung-cancer (Accessed 13 March 2024).
[34] Currently Mrs A is still undergoing immunotherapy treatment.

> if there was cancer present then, it would have been detected at an earlier stage than when she developed symptoms at the end of 2021 … This is a difficult situation for [Mrs A] and her family and understandably devastating to think that this could have been picked up at an earlier stage.'

49. Dr G submitted an ACC treatment injury claim on behalf of Mrs A on 29 December 2022 and recorded that Mrs A 'asked what can be done to improve this for others moving forward'. A discussion was had about the change in screening to HPV testing,[35] planned for 2023, but Dr G noted that '[u]nfortunately, this does not change the situation for [Mrs A]' and discussed the possibility of submitting a complaint to HDC as Mrs A was 'keen to improve the process moving forward'.

HDC complaint — January 2023

50. On 10 January 2023, HDC received a complaint from Mrs A regarding 'the failure of systems that [led] to the incorrect reading of [her] smear tests on 2 occasions … [which] subsequently allowed this cancer to progress when it could have been prevented, to the point of incurable treatment'.

51. Mrs A considers it unsatisfactory that smear testing is only 60% effective and is 'outraged that the same error has and will possibly happen for more women'. Mrs A told HDC:

> 'How the health system has failed me but also how it may be (and likely is) failing other women keeps me awake at night. I would not wish my experience on my worst enemy. Before I die I need to know that I have done everything I can to make sure this does not happen to anyone else. I will have no peace unless I do.'

52. Furthermore, Mrs A considers it unsatisfactory that an oncologist had to request the retrospective smear review at the time of her diagnosis, rather than it being reviewed automatically, and stated that the 'length of time of review was unsatisfactory'.

Adverse event review

53. On 6 March 2023, Mrs A contacted the NCSP requesting a review of what had happened regarding her smear reporting. On 22 March 2023, the adverse event was reported in Datix[36] and an adverse event review was undertaken by Health NZ. The AER, dated June 2023, found the following:

The false negatives were a result of the interpretation of the smear tests

54. Health NZ's AER found that in Mrs A's case, 'the false negative cervical smear tests were both a result of the interpretation of the slides'. The AER notes that misinterpretation of slides accounts for the minority of false negative results, and the probability of consecutive

[35] On 12 September 2023, NCSP changed the primary screening modality for cervical cancer from cervical cytology screening to an automated test for the presence of human papillomavirus (HPV), the cause of over 95% of cervical cancers.

[36] Health NZ's Incident Management System used for the reporting and management of incidents.

false negative results, due to misinterpretation of slides, 'is very low given the relatively low prevalence of cervical cancer in NZ'.

55. Health NZ's AER found that no system or process issues contributed to this outcome. The AER states that the NCSP has comprehensive quality assurance processes that the laboratory service met at the time of the previous smears 'and continues to meet now'. Furthermore, the AER found that there were no difficult or unusual work constraints on the laboratory service in both 2017 and 2020, and no reporting competency issues were identified in relation to the technician and/or cytoscientist who interpreted the slides.

56. Health NZ's AER states that Mrs A did not have any symptoms at the time of her smear tests in both 2017 and 2020, which did not prompt the need for a second review (in reference to the process outlined in paragraph 10), reflecting the limitations of cervical cytology. This 'is one of the key drivers' for the change to HPV testing (described below) as the primary screening modality for cervical cancer. HPV testing was introduced as the primary screening modality in September 2023.

57. Health NZ's AER states that under HPV testing, every smear will be reviewed by two different screeners as standard process, and although missed cases will still occur, HPV testing is expected to 'significantly reduce the false negative rate', as it is more sensitive (95%) than cervical cytology screening. Furthermore, the AER states that HPV testing 'is expected to reduce inequity and improve access to screening for participants who are currently unscreened and under-screened'.

The process to initiate the retrospective slide review was unclear

58. Health NZ's AER found that Dr C did not know whom to contact to initiate the retrospective smear review as, at the time of these events, there was no routine system that allowed for a clinician to initiate a review of previous cervical smears at the time of diagnosis of cervical cancer.

59. Furthermore, Health NZ's AER states that although Mrs A's previous smears would have been reviewed by the laboratory service, as part of the NCSP's quality assurance processes,[37] this would have occurred some months after her diagnosis, and there is no current system that involves notifying the patient or the managing clinician of this review and/or the outcome.[38]

There was a significant delay in open communication regarding the result of the retrospective smear review

60. Health NZ's AER states that it is important to find the right time to communicate distressing information to a patient, and Dr B felt that it was not the appropriate time to disclose the

[37] Laboratories are sent a report, at six-monthly intervals, of all patients diagnosed with either HSIL or cervical cancer and are required (under Standard 522 of the NCSP's 'Providing a Laboratory Service' policy) to review all smears performed in the 42 months prior to diagnosis. The proportion of reviewed cases that are upgraded on review are monitored by the NCSP against a target threshold for maximum upgrade rate to determine whether the laboratory is under- or over-reporting abnormalities.

[38] Under the NCSP Standards, laboratories are not required to notify the patient and/or managing clinician of this review and/or amended cytology results upon review (under Standard 534).

retrospective smear review results. The AER also states that Dr B considered that she had insufficient knowledge of the 'diagnostic and staging pathway' to be able to answer Mrs A's questions appropriately, which 'compounded the delay'.

61. Health NZ's AER found that the delay in communicating the results of the retrospective smear review contributed to a delay in submitting an ACC treatment injury claim, and that Mrs A 'has suffered emotionally, physically, and financially as a result of both the cervical cancer diagnosis, and the delay to an ACC decision'.

62. Health NZ's AER also found that if the incident had been reported into Datix on 6 May 2022, when the results of the retrospective review were known, this 'would have presented an opportunity to review at an earlier stage with escalation to the Director of Clinical Support (the director responsible for the laboratory service) and open communication with [Mrs A]'.

Recommendations

63. Health NZ's AER recommended the following:

- The Director of Clinical Support to write to NCSP and use Mrs A's case as an example of the issues that require consideration in the design of the proposed invasive cancer audit being developed by the NCSP.
- Review the system in place within the laboratory service and Gynaecology Oncology for reporting of events using the existing Datix system, including the use of the 'huddle proforma[39]', which includes sections on open disclosure and communication with the patient.
- Review the process of open disclosure in the laboratory service, specifically as it pertains to Health NZ's policy for ensuring a 'joined-up approach' with the treating clinical teams.

Information provided by ACC

64. Following Mrs A's cancer diagnosis, a treatment injury claim was lodged with ACC for 'Progression of Cervical intraepithelial neoplasia[40] to stage four cervical cancer'. ACC accepted the treatment injury claim and, as part of its assessment, sought external advice from an anatomical pathologist, Dr H, and a gynaecological oncologist, Dr I. A copy of these reports was provided to HDC by ACC.

65. Dr H conducted blind reviews of Mrs A's 2017 and 2020 smears by three cytology-trained scientists and technologists. All three screeners detected abnormality (although not necessarily identifying the correct diagnostic category in both smears), which would have required a referral of the smear to a pathologist for review. However, Dr H advised ACC that '[t]he complete elimination of bias in a blind review is impossible', as screeners from a different institution will know from the outset that abnormal cells are present.

[39] A discussion about the incident by those undertaking open disclosure.
[40] Neoplasia is the uncontrolled, abnormal growth of cells or tissues in the body.

66. Dr H's treatment injury advice states that cervical smears are a screening test and not necessarily a diagnostic one. He advised ACC that false negative rates of up to 20% are considered acceptable practice in community-based cytology screening, and '[t]he causes of false negative results are complex and often multiple'.

67. Dr I's treatment injury advice states that if the smears had been interpreted correctly at the time, it is likely the cancer staging would have been different and curative treatment offered. However, he advised ACC that normal smears being upgraded on review are rare, but inevitable in any large cytology-based screening programme, and although the consequences are very severe, the likelihood of a missed cervical cancer diagnosis for any individual taking part in a screening programme is extremely low.

Further information

Mrs A

68. A hui ā-whānau [41] was held on 1 December 2023 to discuss Mrs A's concerns and expectations of the outcome of her complaint with HDC. Mrs A stated that she wants the support and assurance of HDC to make sure that someone is going to 'fight the beast' if she is no longer here; she wants to leave a legacy to ensure that no other women go through her experiences and that systems faults are brought to attention.

69. Mrs A told HDC that Health NZ has been very responsive in engaging with her concerns, for which she is appreciative, and she acknowledges the proposed recommendations for change. However, she is aware that 'these things could be forgotten or delayed like her results being lost in a doctor's inbox'. Furthermore, Mrs A would like to see accountability bolstered and wants to ensure that long-lasting change occurs, which she hopes to see in her lifetime.

Dr B

70. Dr B maintains that it was the correct decision not to inform Mrs A of the retrospective smear review results at the same time as delivering the 'devastating news' of her early recurrence of cancer but stated that it was not appropriate for Mrs A to be given this information as late as December 2022.

71. Furthermore, Dr B said that it was not clear at the time (and it remains unclear) that the responsibility for disclosing the results of the retrospective smear review had been handed over to Radiation Oncology by the screening service. She stated that '[t]his highlights an area that needs to be improved' and that 'as part of such a review there should be clarity at that time as to who will provide relevant information regarding the review to the patient concerned'.

72. However, Dr B accepts that she could have followed up earlier to ensure that the appropriate people had provided the results of the review to Mrs A and apologised for her part in this delay.

[41] A support meeting facilitated using Māori methods of engagement and protocols (tikanga).

National Screening Unit (NSU)

73. NSU acknowledged 'how devastating it is for [Mrs A] to have developed invasive cervical cancer despite participating in cervical screening', as well as the distress and clinical impact as a result of Mrs A's slides being under-reported, and NSU apologised that this occurred.

74. NSU stated that laboratory performance is monitored regularly by the NCSP by way of reports and quality assurance programmes (such as the process described in paragraph 59) and there is no evidence of systemic under-reporting at the laboratory service. NSU told HDC that in New Zealand, there is a rate of slides with HSIL abnormality that is expected to be reported by laboratories annually,[42] and it has no outstanding concerns regarding the high-grade reporting rate at the laboratory service.

75. NSU acknowledged that the NCSP does not prevent all cases of cervical cancer, even for those who do participate, and NSU is 'continually working hard to improve the programme'.

Health NZ

76. Health NZ emphasised that smear testing is a screening test, not a definitive diagnostic test for cervical cancer, and false negative results are unavoidable in screening programmes. Health NZ stated:

> '[This] issue represents a problem with the screening programme (specifically, a limitation of cervical cytology as a screening test) and it is our view that it is not due to a problem with the screeners.'

77. Health NZ said that at the time the cervical screening tests were read, no concerns had been raised about the performance of either Mrs D or Mrs E, and no concerns have been raised at any time, and '[b]oth employees have continued to meet expected professional standards throughout their employment'. Health NZ stated that no issues with their reporting competency have been identified, and the 'individual screener monitoring records' show that they were both within the accepted sensitivity range for reporting high-grade cervical cytology at the time these events occurred. Health NZ said that both Mrs D and Mrs E have been deeply affected by this event and express their sincere regret about what occurred.

78. Health NZ acknowledged that 'due to a lack of reliable process, there was a considerable delay in communication of the results of the slide review to Mrs A'. Health NZ expressed its sincere apologies and regret that this occurred and acknowledged the emotional and financial distress this has had on her.

79. Health NZ told HDC that upon review of the smears, Mrs A's cytology report was not amended on the NCSP Register as there was a confirmed cancer diagnosis, and therefore only Dr C, who requested the retrospective smear review, was informed of the smear review outcome, which 'created uncertainty regarding responsibility for adverse event incident reporting in this case'. Health NZ further stated that when the results of the retrospective smear review were communicated to Dr C, no incident report was submitted as the adverse event occurred in the laboratory service, not ADHB, and '[t]he quality control and audit

[42] Health NZ told HDC that the expected sensitivity average for cervical cytology is set by the NCSP at 0.5%.

mechanisms that exist within [the laboratory service] and the NCSP operate separately to the Te Toka Tumai incident monitoring system'.

Responses to provisional opinion

Mrs A

80. Mrs A was given an opportunity to respond to the information gathered during this investigation but had nothing further to add.

Dr C

81. Dr C was given the opportunity to respond to the provisional opinion. Dr C accepted the findings made in the report and regrets his inadequate communication with Mrs A and her whānau. He stated that the recommendations will be taken seriously, and he will use this case as a guide towards his current and future professional conduct.

82. In addition, Dr C stated that he is 'hopeful that [Mrs A's] complaint will evolve into a legacy and NCSP improvements'.

Dr B

83. Dr B was given the opportunity to respond to the provisional opinion, and her comments have been incorporated into the report where relevant and appropriate.

84. Dr B reflected on Mrs A's case and, while she appreciated the findings made in the report, Dr B reiterated that she 'had a very difficult judgement call', knowing how confronting disclosure of the retrospective smear results would have been for Mrs A in addition to the significant distress she was already under at the time, and genuinely believed it was not appropriate or in Mrs A's best interests to have disclosed the results.

National Screening Unit (NSU)

85. The NSU was given the opportunity to respond to the provisional opinion. The NSU acknowledged how devastating the sequence of events are for Mrs A and her whānau and continues to be extremely apologetic that this has occurred.

Health NZ

86. Health NZ was given the opportunity to respond to the provisional opinion, and its comments have been incorporated into the report where relevant and appropriate.

87. In response to the provisional opinion, Health NZ stated that where harm occurs during a hospital admission, under the care of one clinician, it is accepted that the responsible clinician should provide timely open disclosure. However, it stated that in circumstances where an adverse event occurred years previously, related to the NCSP (such as in Mrs A's situation), open communication is more complex and only likely to be possible over a long period with the involvement of several people. Health NZ referenced the proposed invasive cancer audit (discussed in paragraph 150), which outlines that the clinical service involved in the patient's care will take responsibility for communication with the patient regarding smear reviews, and stated that open communication should be a shared responsibility between the NCSP and clinical team, as both services have detailed knowledge of distinct

but different aspects of the processes, and such detailed knowledge from both is necessary to allow a patient to be fully informed.

Relevant policies and standards

88. The NCSP 'Section 5: Providing a Laboratory Service' policy (2021) provides the following:

- Standard 521: 'Laboratories must correlate all histology results with any cytology slides taken in the previous six months. If there is discrepancy and slides are reviewed, laboratories must document the review outcome and evidence of notification of amended results to colposcopists,[43] sample takers, the NCSP Register and NZCR (when required) for audit purposes.'
- Standard 522: 'Laboratories must review and document the review outcome of all cytology slides reported as negative, benign/reactive or unsatisfactory in the 42 months before a high-grade or invasive diagnosis on histology.

  …

  The laboratory must document any confirmed slides reviewed as upgraded to definite or possible high-grade abnormalities. The laboratories must forward cumulative data to the NCSP every six months, no later than three months after the end of the six-month period.'
- Standard 534: 'All amended cytology or histology results must be notified within five working days from the date of the slide review to:
  - the sample taker
  - anyone else who was issued with the original report
  - the colposcopist managing the case, if appropriate
  - the NCSP Register
  - The NZCR, if appropriate.'

89. Health NZ's 'Open Disclosure[44] Following an Adverse Event'[45] policy (2022) provides the following:

[43] A trained specialist who examines the cervix, vagina, and vulva for the presence of suspicious areas of tissue that may indicate cancer.
[44] Open disclosure is defined in the policy as '[t]he timely and transparent approach to openly and honestly communicating with, engaging with and supporting consumers, their families and whānau when an adverse event occurs. Open disclosure is not a single conversation, but a process of ongoing communication. Communication should continue until the consumer (and/or the consumer's representative or the suitable person who has been informed) has all the information and support needed.'
[45] An adverse event is defined in the policy as '[a]n incident that results in harm to a consumer'.

- 'When things go wrong, the consumer and their support person/family must be provided with information about what has happened, in an open and honest manner at all times. This may involve provision of initial information and subsequent information as the review progresses.'
- 'Those undertaking open disclosure should meet to confirm the facts known to date, and to discuss the incident or harm before speaking with the consumer and family/whānau. This discussion provides an opportunity to … ensure the incident has been logged in Datix, the online Safety Management System.'
- 'It is expected that the senior health care professional responsible for the care of the consumer discloses the adverse event and does so in an open, honest and empathetic manner.'
- 'There must be contact with the consumer and their family/whānau as soon as possible after the event, within 24 hours of the event becoming known where possible.'

90. The Medical Council of New Zealand's publication 'Good Medical Practice' (2021) provides the following:

- 'Work collaboratively with colleagues to improve care, or maintain good care for patients, and to ensure continuity of care wherever possible.'
- 'Transfer of care involves transferring some or all of the responsibility for the patient's ongoing care … You should also provide your colleague with appropriate information about the patient and their care, and must ensure that the chain of responsibility is clear throughout the transfer.'
- 'Be honest and open when working with patients; act ethically and with integrity by … acting without delay to prevent risk to patients.'

91. The Medical Council of New Zealand's publication 'Disclosure of Harm following an Adverse Event' (2010)[46] provides the following:

- 'It is important that you make a disclosure in a timely manner. Therefore it is appropriate to make the initial disclosure as soon as practical, with a more detailed discussion with the patient to follow once the team has had an opportunity to meet and assess the circumstances that led to the patient being harmed. This will also give time for the patient to think about the situation and provide an opportunity to ask for more information.'
- 'While it may be more appropriate to disclose the harm in stages so the patient understands and processes the information without being overwhelmed, ongoing delay in giving full information is only acceptable if this is in the patient's best interests.'

[46] The 2010 statement was applicable at the time of the events but was superseded by the 2024 statement.

Opinion: Health NZ — breach

Introduction

92. In New Zealand, approximately 180 people are diagnosed with cervical cancer and 60 people die from cervical cancer every year. Furthermore, approximately 85% of those diagnosed with cervical cancer have either never been screened or have been screened infrequently.[47] This was not the case for Mrs A, who underwent regular cervical smear testing from 2007.

93. Mrs A has endured an extremely unfortunate set of circumstances. She was a healthy woman with less than five months' relevant medical history when first diagnosed with stage III cervical cancer in March 2022. Despite cervical cancer being a slow-growing malignancy,[48] and despite undergoing radical chemoradiotherapy, Mrs A's cancer was unusually aggressive and quickly progressed to stage IV by end-August 2022. It is recognised that cervical screening has an inherent false negative rate, although the probability of consecutive false negative results due to misinterpretation of slides is very low. On review, Mrs A's smears were found to have been misread consecutively.

94. Health NZ is responsible for the operation of the clinical services it provides and carries responsibility for service failures. Health NZ had a duty to ensure that the services Mrs A received were provided with reasonable care and skill. In assessing whether Health NZ acted appropriately and in accordance with an acceptable standard of care, I have taken into account the irreducible false negative rate associated with the cervical cytology screening programme.

Retrospective smear review process

95. Following Mrs A's stage III cervical cancer diagnosis on 31 March 2022, Dr C told Mrs A that he would initiate a retrospective review of her previous smears, which was requested from the laboratory service on 12 April 2022 after Dr C confirmed who would undertake the review.

96. It is clear from the information gathered, and in the findings of Health NZ's AER, that the process to initiate the retrospective slide review was unclear. It is understandable that Mrs A was 'struggling with the diagnosis', especially as her last smears had been reported as normal (as per paragraph 28), and therefore it was reasonable that she (or any person in her position) would want a review of her previous smears. However, the AER found that Dr C was unsure of whom to contact to organise the review, as there was no system in place at the time of events that allowed for a clinician to initiate a review of previous cervical smears at the time of diagnosis of cervical cancer.

97. Furthermore, Health NZ's AER found that although Mrs A's previous smears would have been reviewed by the laboratory service in the next reporting cycle, as part of NCSP's quality

[47] https://www.tewhatuora.govt.nz/whats-happening/news-and-updates/older-news-items/new-cervical-cancer-screening-tests-a-game-changer-for-reducing-cervical-cancer-rates/ (Accessed 13 March 2024).
[48] Cervical cancer has a long latency period, taking on average 10–20 years to develop. https://bpac.org.nz/bpj/2009/september/csmears.aspx (Accessed 13 March 2024).

assurance programme, there was no process in place to notify patients and/or managing clinicians of cases where cytology results have been amended on review.

98. Health NZ's AER has identified that the proposed invasive cancer audit will alleviate the risk of this happening in future for other women. This is because it will prompt an earlier review of previously reported 'normal' slides, without requiring a clinician's request, shortly after a cervical cancer diagnosis is confirmed, and the relevant clinician will be notified of the results (as discussed in the 'changes made' section below).

99. However, like Mrs A, I consider it unacceptable that in this instance, Dr C was left to request a review of slides (at Mrs A's instigation) once there had been a diagnosis, and that the process to initiate this review was unclear, thereby delaying the review by 13 days. In my view, Health NZ's lack of processes in this respect put further undue stress on Mrs A and her whānau in an already difficult and unfortunate set of circumstances.

Disclosure of retrospective smear results

100. The results of Mrs A's retrospective smear review were emailed to Dr C on 6 May 2022 and showed that her smear samples from 2017 and 2020 had been interpreted incorrectly. Mrs A was under the care of Dr B at this time and therefore Dr C forwarded the results of the retrospective slide review to Dr B on 9 September 2022, requesting that she inform Mrs A of the findings.

101. Dr B told HDC that she was made aware of the review and its findings only on 7 September 2022 — the day on which she informed Mrs A that her cervical cancer had progressed to stage IV and therefore was incurable. Given this, Dr B felt that it was not an appropriate time to inform Mrs A of the retrospective review outcome and that she was not the appropriate person to relay this information, as she had 'little knowledge and no oversight' of the smear review process and it was unclear at the time that she had this responsibility.

102. Subsequently Mrs A's care was transferred to Medical Oncology in October 2022 for further treatment, which Dr B stated caused further confusion regarding the responsibility of informing Mrs A of the retrospective smear review outcome. By mid-December 2022, Mrs A was still unaware of the review findings, and therefore Dr B told HDC that she asked Dr G, as the private clinician managing Mrs A's care at the time, to collaborate with Dr C on meeting with Mrs A to discuss the review findings. This meeting was undertaken on 29 December 2022 and an ACC treatment injury claim lodged.[49]

103. As stated in Health NZ's Open Disclosure policy, open disclosure should occur in a timely manner whenever there is an incident that results in harm to a consumer (an adverse event). In this case, the adverse event was the misinterpretation of Mrs A's smear results in 2017 and 2020, which was not disclosed to her for seven and a half months. In addition, HDC's 'Guidance on Open Disclosure Policies' states that a consumer should be informed about any adverse event, usually within 24 hours of the event occurring, or of the harm or error

[49] Prior to the ACC claim being accepted, Mrs A was having to self-fund her treatment.

being recognised, and it is seldom reasonable to withhold information about a consumer from that consumer.

104. Health NZ acknowledged that a lack of reliable process led to a considerable delay in communicating the results of the slide review to Mrs A. Furthermore, Health NZ's AER found that the delay in communicating the review findings contributed to a delay in submitting an ACC treatment injury claim, and that Mrs A suffered emotionally, physically, and financially as a result. I accept the findings of the AER and acknowledge Health NZ's apology for the 'considerable delay' in disclosing the results to Mrs A.

105. It is clear from the information gathered, particularly the comments from Dr B, that the lack of clear processes caused confusion as to who had primary responsibility for disclosing the smear review findings. Although the Open Disclosure policy outlined that the senior healthcare professional responsible for the care of the consumer was to disclose the adverse event, it appears that there was confusion as to who this healthcare professional was and/or should be, given the overlap in services between the laboratory service (where the adverse event occurred) and ADHB's Gynae-Oncology, Radiation Oncology, and Medical Oncology teams, and the lack of guidance regarding responsibility in this instance.

106. I note that Dr C was the clinician who requested the review, and that Mrs A was under the care of Dr B at the time the results of the retrospective smear review became available. They both, therefore, had a responsibility towards Mrs A, which I will address further below. However, I consider that the lack of processes regarding primary responsibility for disclosing the results of the retrospective review was a systems issue that primarily resulted in the delay of the results being communicated to Mrs A.

107. Although I acknowledge the changes made by Health NZ, in particular the amendments to the Open Disclosure Policy and the proposed invasive cancer audit, which outlines who has primary responsibility for communicating with the patient, I am critical that in this case, the results of the retrospective review were not disclosed to Mrs A for seven and a half months, resulting in the delay of an ACC claim being lodged, and emotional and financial distress to her.

108. I acknowledge the separation of roles and responsibilities between Health NZ and NCSP and the comments made by Health NZ about this in response to the provisional opinion. I agree that should these circumstances arise again, there should be shared responsibility between the NCSP and the clinical team in disclosing smear review results (adverse events) to ensure that patients are fully informed, noting Dr B's comments that she 'did not have sufficient knowledge to answer any important questions regarding the smear review process which [would] have understandably arisen' (as per paragraph 41). I will therefore make a recommendation for Health NZ to liaise with the NCSP on how this shared responsibility will occur.

Adverse event reporting

109. As stated above, the results of Mrs A's retrospective smear review were emailed to Dr C on 6 May 2022 and showed that her smear samples from 2017 and 2020 had been interpreted

incorrectly. Mrs A was made aware of the review findings on 29 December 2022, and on 6 March 2023 she contacted the NCSP requesting a review of what happened regarding her smear reporting. The adverse event was reported in Datix on 22 March 2023 and an adverse event review was completed by Health NZ in July 2023.

110. Health NZ told HDC that upon review of the smears, Mrs A's cytology report was not amended on the NCSP Register, and therefore only Dr C, who requested the retrospective smear review, was informed of the smear review outcome, which 'created uncertainty regarding responsibility for adverse event incident reporting in this case'. Health NZ further stated that as the adverse event occurred in the laboratory service, not ADHB, the incident was not reported as the quality control and audit mechanisms that exist within the laboratory service operate separately to Health NZ Te Toka Tumai Auckland's incident monitoring system.

111. Health NZ's AER found that if the incident had been reported in Datix on 6 May 2022, when the results of the retrospective review were known, this would have prompted earlier review and open communication with Mrs A.

112. I accept the findings in Health NZ's AER and acknowledge the changes made to the Datix Incident Reporting Guidelines for Staff and the laboratory service's Pathologists Manual, which outline an appropriate process in place where incidents will be reported in Datix, when triggered. It is imperative to good patient care that when an incident arises, all appropriate people are notified so that timely and transparent investigation and assessment occurs (with a view to timely systems quality improvement) as well as disclosure to the consumer and/or their whānau.

113. I am concerned that in this instance, there was uncertainty regarding responsibility for adverse event reporting, which ultimately delayed investigation, potential quality improvement measures, and therefore open disclosure with Mrs A about this incident.

Conclusion

114. Under Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code), Mrs A had the right to services of an appropriate standard. As concluded above, at the time of events Health NZ did not have in place a system that allowed for a clinician to initiate a review of previous cervical smears at the time of a cervical cancer diagnosis. Furthermore, there was no clear guidance and system regarding primary responsibility for open disclosure of the results of the retrospective review, or clear responsibility and processes for initiating an adverse event incident report. For these reasons, I find that Health NZ breached Right 4(1) of the Code.

115. Under Right 6(1) of the Code, consumers have the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive. In my view, the lack of clear systems and processes resulted in an unreasonable delay of seven and a half months in disclosing the results of the retrospective slide review to Mrs A, resulting in emotional and financial distress to her. This was information to which she was entitled under Right 6(1)

of the Code, and for failing to disclose the results of the retrospective smear review in a timely manner, I find that Health NZ breached that right.

Misinterpretation of cervical smears — no breach

116. Mrs A underwent routine cervical smear testing in 2017 and 2020, and both tests reported the result as 'normal'. The 2017 sample was interpreted by medical laboratory technician Mrs D, and the 2020 sample was interpreted by medical laboratory scientist Mrs E.

117. After a series of tests in 2021–2022 to investigate the cause of heavy menstrual bleeding, Mrs A was diagnosed with stage III cervical cancer in March 2022. A review of her previous smears was undertaken and showed that both samples had been interpreted incorrectly, with abnormal cells found on review. Subsequently Mrs A was diagnosed with stage IV cervical cancer in September 2022.

118. Mrs A was informed of the retrospective smear review findings on 29 December 2022 and told that if the smears had been interpreted correctly at the time, it is likely that she would have undergone further investigations that potentially could have detected pre-malignancy changes and/or the cancer (if it was present then) at an earlier stage. This is reflected in Dr I's ACC treatment injury advice, which states that if the smears had been interpreted correctly at the time, it is likely the cancer staging would have been different and curative treatment offered. However, he advised ACC that the likelihood of a missed cervical cancer diagnosis is extremely low for any individual taking part in a screening programme.

119. Both Health NZ and ACC advisor Dr H emphasised that smear testing is a screening test, not a definitive diagnostic test for cervical cancer. Health NZ told HDC that cervical cytology has an 'inherent irreducible false negative rate' and therefore false negative results are unavoidable in screening programmes, which was also advised by Dr I in his ACC treatment injury advice.

120. Dr H's treatment injury advice states that '[t]he causes of false negative results are complex and often multiple'. Health NZ's AER found that in Mrs A's case, both the false negative smear tests were a result of the interpretation of the slides, which accounts for the minority of false negative results, and the probability of consecutive false negative results due to misinterpretation of slides is very low.

121. Health NZ stated that the issue of false negatives represents a problem (limitation) with the screening programme, not with the screeners. Health NZ's AER found no issues with either Mrs D's or Mrs E's reporting competency. Furthermore, Health NZ stated that they were both within the accepted sensitivity range for reporting high-grade cervical cytology at the time these events occurred, and '[b]oth employees have continued to meet expected professional standards throughout their employment'. In addition, the AER found that no system or process issues contributed to this outcome.

122. It is apparent from the findings in Health NZ's AER, as well as the ACC treatment injury advice and my own research into this matter, that cervical cytology screening has an inherent false negative rate that cannot be avoided. Furthermore, I acknowledge the bias that exists in

retrospective slide reviews, as outlined in Dr H's ACC treatment injury advice and by Health NZ. I therefore accept the findings in the AER that Mrs A's false negative smear tests were the result of a misinterpretation of slides, for which no one can be held accountable.

123. In making this finding, I acknowledge how very unfortunate this situation is for Mrs A — that in conjunction with the recognised false negative rate of cervical screening, Mrs A's slides were misinterpreted consecutively, which accounts for the minority of false negative results.

124. On 12 September 2023, the NCSP changed the primary screening modality for cervical cancer from cervical cytology screening to HPV testing. The NSU website states:[50]

> 'By adopting HPV primary screening, the goal is to enhance the accuracy and sensitivity of screening, enabling early detection and intervention for improved health outcomes. HPV testing is a better primary screening test and will prevent more cervical cancers.'

125. Health NZ's AER explains that HPV testing is more effective than cervical cytology as it is more sensitive than cervical cytology (95% as opposed to 70–75%) and is therefore expected to 'significantly' reduce the false negative rate. Furthermore, the AER states that as Mrs A did not have any symptoms at the time of her previous smears, it did not prompt the need for a second review, whereas, under HPV testing, every smear will be reviewed by two different screeners as standard process.

126. In addition, Health NZ's AER states that HPV testing is expected to reduce inequity and improve access to screening for participants who are currently unscreened and under-screened.

127. Wāhine/Māori women are currently under-screened, with only around 60% of wāhine accessing cervical screening. They also have higher rates of incidence and death from cervical cancer than non-Māori women.[51] Cost, as well as the invasive nature of the cervical sample test, have been barriers to access. As such, HPV testing has a particular emphasis on Māori participants and increasing screening rates, which will be achieved through the establishment of new clinical pathways and a new NCSP Register: [52]

- The new clinical pathways embed more choice and flexibility into screening by including the option to self-test at home, as well as a clinician-taken sample. Free screening is available to all wāhine, regardless of age.
- Screening records and individual schedules will be integrated into the new NCSP Register, which will lead to better identification of the eligible population for HPV screening and improve screening participation. The NCSP Register will also allow for improved communication between primary care, laboratories, and participants.

[50] Introduction to HPV primary screening | National Screening Unit (nsu.govt.nz) (Accessed 13 March 2024).
[51] https://www.tewhatuora.govt.nz/whats-happening/news-and-updates/older-news-items/new-cervical-cancer-screening-tests-a-game-changer-for-reducing-cervical-cancer-rates/ (Accessed 13 March 2024).
[52] PowerPoint Presentation (nsu.govt.nz) (Accessed 13 March 2024).

128. It is encouraging to read that the implementation of HPV testing will significantly reduce false negative rates, require each smear to undergo a double review, improve communication, reduce inequities for Māori, and improve access to screening. Although I appreciate that this does not change the outcome for Mrs A, I hope she takes comfort in the fact that this programme appears robust and accountable and will minimise the risk of her unfortunate situation happening to other women in New Zealand.

129. I take this opportunity to encourage all women, especially wāhine, to get tested under the new HPV screening method and for all healthcare providers to tautoko (support) and manaaki (take care of) their participation in the improved screening programme.

Opinion: Dr C — adverse comment

130. Mrs A was under the care of Dr C from 8 March 2022, until her care was handed over to Dr B on 3 May 2022.

131. During this time, on 31 March 2022 Dr C confirmed a stage III cervical cancer diagnosis to Mrs A and requested a retrospective smear review from the laboratory service on 12 April 2022, noting her previously reported 'normal' smear results. The results of the retrospective review were emailed to Dr C on 6 May 2022 and showed that Mrs A's smear samples from 2017 and 2020 had been misinterpreted.

132. Following Mrs A's stage IV diagnosis, on 9 September 2022 Dr C forwarded the results of the retrospective slide review to Dr B (who stated that she had been made aware of the review and its findings only two days prior) and asked Dr B to inform Mrs A of the findings. The results of the retrospective smear review were not disclosed to Mrs A until 29 December 2022, when Dr C, alongside Dr G, met with Mrs A to discuss the findings.

133. As stated in Health NZ's Open Disclosure policy, open disclosure by the senior healthcare professional responsible for the care of the consumer should occur in a timely manner whenever there is an incident that results in harm to the consumer (an adverse event). In this case, the adverse event was the misinterpretation of Mrs A's smear results in 2017 and 2020, which was not disclosed to her for seven and a half months. I acknowledge that Mrs A's care had been handed over to Dr B at the time the results of the retrospective smear were confirmed to Dr C, and therefore he was not the senior healthcare professional responsible for the care of Mrs A at the time of the adverse event becoming known.

134. Furthermore, I have already determined that the delay in the results being communicated to Mrs A was largely due to a lack of clear processes regarding primary responsibility for disclosure. However, I consider that Dr C contributed to this delay by taking four months to inform Dr B of the retrospective smear review and its findings.

135. As noted by Dr B in paragraph 37, the delay of four months before Oncology became aware of the retrospective review's findings was 'unfortunate'. I am concerned that Dr C allowed

four months to pass before asking Dr B to disclose the results of the retrospective smear review to Mrs A, especially given his obligations under the Medical Council of New Zealand's 'Good Medical Practice' standard. In particular, Dr C had an obligation to '[act] without delay to prevent risk to patients' and, while I acknowledge that Mrs A was no longer under his care at this time, Dr C also had the obligation to '[w]ork collaboratively with colleagues to … maintain good care for patients, and to ensure continuity of care whenever possible', which includes providing colleagues with appropriate information about the patient and their care.

136. In my opinion, Dr C should have sent the results of the retrospective review and his request to Dr B to inform Mrs A of the findings much earlier. Even though he did not have primary responsibility for the disclosure at that time, he had requested the retrospective review, and he should have been aware of the Open Disclosure policy's directive to disclose adverse events in a timely manner and should have worked collaboratively with Dr B to ensure that timely disclosure occurred for Mrs A.

Opinion: Dr B — adverse comment

137. Mrs A's care was handed over to Dr B from Dr C on 3 May 2022 for radical chemoradiotherapy treatment. Mrs A was under the care of Dr B from this date until her care was transferred to Medical Oncology on 12 October 2022 for further treatment.

138. The results of Mrs A's retrospective smear review were emailed to Dr C on 6 May 2022 and showed that her smear samples from 2017 and 2020 had been interpreted incorrectly. Dr C forwarded the results of the retrospective slide review to Dr B on 9 September 2022 and asked her to inform Mrs A of the findings.

139. Dr B told HDC that she was made aware of the review and its findings on 7 September 2022 — the day on which she informed Mrs A that her cervical cancer had progressed to stage IV and was therefore incurable. Given this, Dr B felt that it was not an appropriate time to inform Mrs A of the retrospective review outcome and that she was not the appropriate person to relay this information, as she had 'little knowledge and no oversight' of the smear review process and it was unclear at the time that she had this responsibility.

140. Subsequently Mrs A's care was transferred to Medical Oncology in October 2022 for further treatment, which Dr B stated caused further confusion regarding the responsibility of informing Mrs A of the retrospective smear review outcome. By mid-December 2022, Mrs A was still unaware of the review findings, and Dr B told HDC that therefore she asked Dr G, as the private clinician managing Mrs A's care at the time, to collaborate with Dr C on meeting with Mrs A to discuss the review findings. This meeting took place on 29 December 2022, a total of seven and a half months after the retrospective review results were known.

141. I acknowledge Dr B's comments that 'as part of such a [retrospective smear] review there should be clarity at that time as to who will provide relevant information regarding the review to the patient concerned'. As noted above, I have determined that the lack of clear

processes for disclosing the results of the retrospective review was a systems issue that primarily resulted in the delay of the results being disclosed to Mrs A.

142. I also acknowledge Dr B's apology for her part in this delay and her admission that she could have followed up earlier to ensure that the appropriate people had provided the results of the review to Mrs A. Although I agree that Dr B could have followed up earlier on whether Mrs A had been informed of the retrospective smear review findings following her transfer of care to Medical Oncology, I am concerned that Dr B could have disclosed the results to Mrs A herself at a time during which Mrs A was under her care.

143. I do not take lightly the difficult situation Dr B faced balancing Mrs A's right to know her health information against the likely adverse impact this news would have had, and I acknowledge the importance of finding the appropriate time to communicate distressing information to a patient. As Dr B has identified, the Medical Council of New Zealand's Disclosure of Harm standard stated that ongoing delay in giving full information may be acceptable if it is in the patient's best interests.

144. While I appreciate that disclosing the results of the retrospective smear review to Mrs A at the same time as informing her of her stage IV diagnosis may not have been in her best interests, especially given Dr B's note from 7 September 2022 that 'it was all too much today [for Mrs A] to go through any more' (as per paragraph 35), the results of the review could have been disclosed later in stages 'so the patient understands and processes the information without being overwhelmed', as suggested by the Medical Council's Disclosure of Harm standard. Mrs A was under Dr B's care for a further month after being informed of the stage IV diagnosis. In my opinion, there was an opportunity for Dr B to disclose the results of the retrospective smear review in stages over this time.

145. I acknowledge that Dr B felt that she was not the appropriate person to disclose this information, given that she had little knowledge of the review process and would have needed to meet with colleagues who were involved with the smear review process to provide the correct information to Mrs A. It is noted in Health NZ's AER that this 'compounded' the delay.

146. I accept this finding in Health NZ's AER and note that by staging the disclosure, this would have allowed for initial disclosure to have been made, with a more detailed discussion with Mrs A to follow once Dr B had an opportunity to meet with the appropriate people and assess the circumstances that led to the patient being harmed, as outlined in the Medical Council's Disclosure of Harm standard.

147. Furthermore, by staging the disclosure, this would have allowed Mrs A to determine the level of disclosure she was comfortable with. I draw reference to the Ngā Paerewa Health and Disability Services Standards, which require Dr B to recognise Mrs A's tino rangatiratanga and Māori mana motuhake.[53] Given that Mrs A initiated the retrospective

[53] Outcome 1.3.5 of the Ngā Paerewa Health and Disability Services Standards (NZS 8134:2021) states: 'My service provider shall recognise Māori mana motuhake.' Mana motuhake is defined in the standard as

slide review (as outlined in paragraph 28), it would have been appropriate to initially disclose that the results had been confirmed and allow her the opportunity to determine when the appropriate time would be to discuss the findings.

148. In response to the provisional opinion, Dr B stated that while she acted only with Mrs A's best interests in mind, she acknowledged that a staged disclosure of the review results, while Mrs A remained in her care, may have been appropriate in the circumstances.

149. While I again acknowledge that the delay in the results being communicated to Mrs A was largely due to a lack of clear processes regarding primary responsibility for disclosure, I am concerned that Dr B contributed to this delay. Dr B had a duty of care to Mrs A and could have taken further steps to ensure that timely disclosure occurred for her. By disclosing the adverse event in stages while Mrs A was under her care, this would have allowed for collaboration with other colleagues and for Mrs A to exercise her Māori mana motuhake over her own health care.

Changes made since events

150. NSU told HDC that the NCSP is planning to introduce a formal audit of all cases of invasive cervical cancer in 2024, which is proposed to address many of the issues encountered as a part of Mrs A's experience of the screening programme and the subsequent events. In particular, the audit will:

- Include a review of clinical records and screening histories and a review of any slides reported as less than high-grade change in the previous screening round.
- Operate in real time, meaning the NCSP will be directly and rapidly informed about each case of invasive cancer shortly after the diagnosis is confirmed (in particular, those who develop cervical cancer despite undergoing cervical smears) and will proceed to investigate the circumstances under which it has occurred.
- Link the screening programme and the laboratory service with the clinicians providing care to patients, and prompt earlier review and notification (without requiring a clinician's request). The clinical service involved in the patient's care will take responsibility for communication with the patient.
- Give those with cervical cancer an opportunity to discuss the audit findings of their individual case.

151. Health NZ told HDC that it has been active in implementing the new HPV screening programme at a local level.

'[s]eparate identity, autonomy, self-government, self-determination, independence, sovereignty, authority — mana through self-determination and control over one's own destiny'.

152. Health NZ stated that all the recommendations set out in the serious event report have been actioned as follows:

- A copy of the letter sent by the Director of Clinical Support to NSU (dated 7 December 2023) was provided to HDC, which expressed support for the proposed invasive cancer audit with a request to use Mrs A's case as an example of issues that need to be considered.
- Additional references have been included in Health NZ's 'Datix Incident Reporting Guidelines for Staff' policy, which outline when to report an incident in Datix and open disclosure/communication following an adverse event.
- Updates have been made to the laboratory service's Pathologists Manual, which include:
    - Any substantial change in diagnosis that may have substantial implications for patient management must be notified to the Clinical Lead and a Datix incident must be submitted.
    - An added section on 'reporting changes to cervical/vaginal cytology or histology following MDM case review or clinician-requested case review'. This includes when to amend cytology reports and requirements to notify (within five working days) the sample taker, all other people who were issued with the original report, the clinician managing the case (if appropriate), the NCSP Register, and the New Zealand Cancer Registry (if appropriate).
    - A link to the current NCSP Policies and Standards Section 5: 'Providing a Laboratory Service'.
- Health NZ Te Toka Tumai Auckland is in the final stage of developing new guidance for staff in open communication, which has taken into the account the recently updated New Zealand Medical Council advice and the recent Australian Clinical Excellence publication and included video tutorials as supporting material. In response to the provisional opinion, Health NZ told HDC that the new guidance on open communication will aid in complex circumstances of open disclosure, where multiple parties are involved, by ensuring that staff have access to appropriate supporting materials at the appropriate time that they need to use them, such as during the open communication process.

153. In response to my recommendation made in the provisional opinion, Dr B provided a written apology to Mrs A for the deficiencies identified in this report.

Recommendations

154. I recommend that Health NZ provide a written apology to Mrs A for the deficiencies in care identified in this report. The apology should be sent to HDC within three weeks of the date of this report, for forwarding.

155. I recommend that Health NZ Te Toka Tumai Auckland, in light of the changes made:

a) Provide a copy of the updated 'Datix Incident reporting Guidelines for Staff' policy and the [Laboratory Service] Pathologists Manual' to HDC within six weeks of the date of this report.

b) Evaluate the effectiveness of the changes made to incident reporting by conducting an audit of compliance and provide HDC with the outcome report with any corrective actions to be implemented, within six months of the date of this report.

c) Evaluate the effectiveness of the changes made to cytology report amendments and notification requirements by conducting an audit of compliance and provide HDC with the outcome report with any corrective actions to be implemented, within 12 months of the date of this report.

d) Provide an update on, or copy of (if applicable), the new guidance for staff in open communication, within six weeks of the date of this report.

e) Develop an implementation plan for the new guidance in open communication including role-specific needs, and an outline of how it will be introduced and adopted across the organisation. As part of the training material developed, consider using this case as an example of a clinical situation where significant preparation and planning are required prior to an open communication process. The implementation plan and evidence of the education/training in the form of material is to be provided to HDC within six months following its introduction.

f) Conduct an evaluation of the effectiveness of the new guidance in open communication 12 months following its introduction via a survey of clinical leaders and provide HDC with the outcome report with any corrective actions to be implemented, within 15 months following its introduction.

g) Provide an update on the actions taken to implement the new HPV screening programme at a local level (as per paragraph 151). Please explain how Health NZ has been active in implementing the new HPV screening programme, including any testing of patients, advertisement, and/or information provided to patients. This update is to be provided to HDC within six weeks of the date of this report.

h) Liaise with the NCSP on the proposed invasive cervical cancer audit regarding how shared responsibility in open disclosure (where adverse events arise) will occur. An update on the decisions reached between Health NZ and NSU is to be provided to HDC within three months following this liaison.

156. I recommend that the NCSP, Prevention Directorate, NPHS, Health NZ (formally NSU, Ministry of Health):

a) Provide an update on the proposed invasive cervical cancer audit, including the results of the audit if this has been undertaken. This update is to be provided to HDC within three months of the date of this report.

b) Provide an update on phases one and two of the 'HPV Primary Screening Road to Rollout'. In particular, please comment on the effectiveness of the HPV rollout to date, including the implementation of the new NCSP Register, self-tests in relation to screening rates, screening rates in relation to Māori, and training on the new HPV primary screening process. This update is to be provided to HDC within 12 months of the date of this report.

157. I recommend that Dr C:

a) Provide a written apology to Mrs A for the deficiencies in care identified in this report. The apology should be sent to HDC within three weeks of the date of this report, for forwarding.

b) Attend the education/training outlined in paragraph 155(e). Evidence of attendance, in the form of attendance records, is to be provided to HDC within one month following the education/training session.

158. I recommend that Dr B attend the education/training outlined in paragraph 155(e). Evidence of attendance, in the form of attendance records, is to be provided to HDC within one month following the education/training session.

Follow-up actions

159. A copy of this report with details identifying the parties removed, except Health New Zealand|Te Whatu Ora Te Toka Tumai Auckland and the Ministry of Health National Screening Unit, will be sent to Te Aho o Te Kahu|Cancer Control Agency, Te Tāhū Hauora|Health Quality & Safety Commission and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.