

Delayed diagnosis of breast cancer

1. In 2022, the Health and Disability Commissioner (HDC) received a complaint from Ms B about the care provided to her by Dr A,¹ radiologist, and the national breast screening service, BreastScreen Coast to Coast (BreastScreen).² This report concerns a delayed diagnosis of breast cancer.

Information gathered

2017 ultrasound

2. On 29 June 2017, Ms B, aged 45 years, presented to her general practitioner (GP) at her local medical centre with a palpable lump in her right breast. She was referred for a bilateral breast ultrasound at a clinic operated by a local radiology service. Ms B said the sonographer mentioned that her breasts were very dense³ and difficult to assess and that there were a lot of lumps.
3. The ultrasound findings were reported remotely by Dr A on 24 August 2017. He recorded that Ms B had 'fibrocystic⁴ change[s],' and a 'macrocyt,'⁵ suggesting that there were no signs of malignancy. He advised (rather than recommended) that the GP consider a '[risk] assessment with mammography⁶ +/- tomosynthesis'.⁷ There was no recommendation to complete a biopsy, targeted ultrasound, or surgical review. A copy of the ultrasound report was sent to Ms B and her GP.

2017 mammogram

4. On 30 August 2017, Ms B self-enrolled with BreastScreen and had a routine screening mammogram on 7 September 2017. Ms B said that when asked, she disclosed she had undergone previous screening. The BreastScreen assessment form noted that Ms B had two breast lumps and discharge from the right nipple. The mammogram was reviewed by two radiologists: Dr C recommended that Ms B '[r]eturn to routine screening – [s]ymptom' and Dr D completed a second read and also recommended that she return to 'routine screening.' A third read⁸ of the mammogram led to a consensus that Ms B was to '[r]eturn to routine screening – [s]ymptom.' Health New Zealand | Te Whatu Ora Te Pae Hauora o Ruahine o

¹ At the time of the events, Dr A worked at the local radiology service MidCentral Medical Imaging (part of Health New Zealand | Te Whatu Ora Te Pae Hauora o Ruahine o Taranaki MidCentral), and BreastScreen Coast to Coast (part of BreastScreen Aotearoa).

² BreastScreen offers free breast screening every two years for eligible women aged 45–69 years with the aim of reducing breast cancer mortality. BreastScreen is now part of Health New Zealand | Te Whatu Ora.

³ Women with higher breast density have an increased risk of developing breast cancer and are more likely to have a diagnosis missed by mammography. However, discussions around the role of breast density reporting and whether additional screening should, or can, be offered to women are ongoing.

⁴ Characterised by benign alteration in the breast tissue that causes painful, lumpy breast tissue.

⁵ An aggregate of cells, which is painful and puts pressure on the adjoining breast tissue.

⁶ A low-energy X-ray used to examine the breast tissue.

⁷ A type of 3D mammography used to create images of the breast tissue slice by slice.

⁸ It is not known who completed the third read.

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Tararua MidCentral (Health NZ) said there were no specific policies at the time relating to the placement of patients in screening versus symptomatic programmes.

5. BreastScreen sent a letter to Ms B's GP on 13 September 2017. Although the letter stated there was 'no evidence of breast cancer,' it also stated that Ms B had mentioned a symptom/change in her breast at the time of her mammogram and '[y]our patient may require further mammography: ultrasound or surgical opinion ... BreastScreen Aotearoa has advised [Ms B] to consult you.' Unfortunately, both Ms B and her GP overlooked these letters.
6. Ms B is concerned that she was placed on a two-year recall for a 'routine screening' programme, despite being symptomatic. Health NZ told HDC that this was because BreastScreen does not have a pathway for redirecting women between services if they present with symptoms; however, staff will continue with the screening mammogram irrespective of any symptoms.
7. Ms B also said she is concerned that BreastScreen does not refer patients directly on to surgical specialists for further screening and that this process can lead to missed opportunities for quick and efficient action. In its response to the provisional opinion, Health NZ National Office acknowledged that the current process (requiring the community health provider to arrange clinical review or surgical opinion) can present access barriers for some people.

2018 ultrasound and mammogram

8. On 15 November 2018, Ms B presented to her GP with a new palpable lesion⁹ on the lower right breast, which she thought appeared to be very near, if not adjoining, the previously investigated lesion. The GP referred her for a further ultrasound of the right breast and a bilateral mammogram at MidCentral Medical Imaging, which is operated by Health NZ.¹⁰
9. The combined results of the ultrasound and mammogram were reported by Dr A on 12 December 2018, and a second read of the mammogram was completed by Dr D. Dr A noted that the breasts were extremely dense, which limited the sensitivity of the mammogram. Dr A told HDC that he was aware of the nipple discharge but that he could not elicit any discharge upon expression of the breast.
10. Dr A recorded that he compared the 2018 imaging with the mammogram of 7 September 2017, but he did not describe the outcome of the comparison, and he did not identify whether the lesion had increased in size. He also did not compare the imaging with the 2017 ultrasound. Dr A stated that this was because he was not aware of any previous ultrasound and that he did not have access to that ultrasound as he had completed it in a private capacity. He stated that the issue of separate archiving systems across private and public providers for diagnostic and screening examinations is well known. Dr D also supported this explanation.

⁹ An area of abnormal tissue.

¹⁰ This referral does not relate to the BreastScreen service.

11. In contrast, Health NZ said that the private 2017 ultrasound was stored in the MidCentral Picture Archiving and Communications System (PACS) and that the breast imaging service has had access to this digital imaging since 2013. It further confirmed that imaging from private facilities was accessible in 2017. However, clinicians must look ‘separately’ for these cases. In addition, Health NZ emphasised that all clinicians are aware they can ask at any time for images to be retrieved from other centres by contacting the breast imaging service or the PACS team. Health NZ acknowledges that it is an issue when the breast imaging service is not aware a patient has been imaged at a private facility and is therefore reliant on clinicians notifying the PACS team to retrieve this imaging.
12. Dr A concluded that the lesion was a ‘typical’ fibroadenoma¹¹ and that there were fibrocystic changes with multiple cysts.¹² Dr A reported that there was no specific cause for the right-sided nipple discharge and that there was ‘no evidence of malignancy.’ Dr A recorded that ‘[a]fter careful discussion with [Ms B], she had elected for conservative management.’ He also recorded that ‘If there is persistent clinical concern, surgical review should be *considered*’ [my emphasis].
13. The details of the conservative management options that were discussed were not documented. However, Dr A said he offered Ms B a biopsy and that, as per his usual practice, he explained the findings and outlined the procedure of a biopsy, including an explanation of its risks, benefits, and alternative options. Dr A said he discussed these options with Ms B, who then declined the biopsy and wished to monitor the lump (which was the alternative option). Although this discussion was not documented, Dr A said he has always advised all patients wishing to monitor a lump that if there are any changes and/or increase in the size of the lump, they should contact their GP and ask that consideration be given to a biopsy. He confirmed that this advice was given to Ms B.
14. Dr A provided slightly different statements with respect to the option of a biopsy in this case. Initially, Dr A told HDC that there were no guidelines regarding biopsy of a solid lesion but acknowledged that the practice of offering a biopsy was valid. Therefore, he offered the option of a biopsy to Ms B, as described above. However, in a further statement, Dr A told HDC that the usual and commonly recommended practice in 2018 did not involve a biopsy of fibroadenomas and that clinical follow-up was the norm. The medical imaging policies provided by Health NZ do not outline when biopsies are to be taken. In support of this position, Dr D told HDC that the protocol in 2018 following the detection of a new palpable mass was to ‘*consider* a biopsy’ and that biopsies are required in relation to all solid masses detected in women over the age of 25 under current protocols.
15. Ms B said that Dr A advised her that the lump was normal and benign and that the nipple discharge was not of concern; she said that Dr A provided this information with a degree of certainty. Ms B said that if there had been any uncertainty about the lump being normal and benign, she would have agreed to a biopsy. In her further response to the provisional opinion, Ms B said Dr A had framed the presence of a fibroadenoma as being definitive. In addition, he provided a pamphlet containing information about fibroadenomas. The pamphlet states that fibroadenomas ‘can vary in size from a few millimetres to five or more

¹¹ A solid breast lump that is benign and does not need treatment.

¹² A collection of cells.

centimetres in diameter,’ that ‘[m]ost get smaller, [s]ome remain the same size, and [a] few get bigger,’ and that she should continue to have normal interval screening. Ms B said that this information affected her decision-making. She said: ‘how [am I] supposed to know that the symptoms that I already presented with on multiple occasions are now deemed concerning enough to come forward with ... when a fibroadenoma can be 5cm or more and [when providers] are already aware of the discharge.’

16. As noted, Dr D completed a second read of the mammogram and confirmed that he did not make any changes or add any comments to Dr A’s report. Criterion 4.2.1 of the BreastScreen standards states that ‘[i]mages are [to be] read *independently* [my emphasis] by two radiologists.’ The medical imaging policies provided by Health NZ do not outline the second checking process. Dr D said the review was not blind, meaning he had access to Dr A’s report; however, Dr D also said that he does not usually discuss reports with the first reader. Dr D’s evidence also suggests that the 2017 mammogram was not available to him, which conflicts with the report by Dr A, which records that this image was available. I am satisfied that the 2017 mammogram was available to Dr D for comparison, but I cannot conclude with any degree of certainty whether he undertook a comparative analysis.
17. In relation to the second-read process, Dr D also said that different radiology information systems are used for screening and diagnostic imaging. In this case, the imaging undertaken by Dr D was diagnostic. Dr D said that diagnostic mammograms are stored within the MidCentral Health radiology information system called Carestream. In this system, the first read is blind, but when the second reader opens the case, the first reader’s report comes up automatically as a preliminary report and is visible to the second reader. In contrast, Dr D said the radiology information system used by BreastScreen allows a radiologist to read a screen with no knowledge of the other radiologist’s result.
18. The results of the 2018 imaging were sent to Ms B’s GP at her local medical centre. The GP said he filed the report on 17 December 2018, noting that the ‘new lesion [was] in keeping with fibroadenoma’ and that there was ‘NO evidence of malignancy.’ The GP told HDC that, despite Ms B’s nipple discharge, he was significantly reassured by the language of Dr A’s report that the lesion was ‘typical of a fibroadenoma’ and relied on this to form his judgement. Ms B also said her GP had relied on the reassurance conveyed in Dr A’s report.

2019 mammogram and 2020 ultrasound

19. In December 2019, Ms B was recalled for a mammogram by BreastScreen. Subsequently, she required a biopsy and ultrasound and, in February 2020, was diagnosed with grade 2 breast cancer with lymph node involvement. This required invasive surgery and treatment.

Responses to provisional decision

20. Ms B, Dr A, Dr D, Health NZ National Office, and Health New Zealand | Te Whatu Ora Te Pae Hauora o Ruahine o Taranaki MidCentral were given an opportunity to comment on the provisional decision in this matter, and their comments have been incorporated into the report where relevant.
21. Ms B appreciated the work undertaken by HDC and agreed with the provisional findings. She hopes her case has helped identify and rectify systemic issues and helped to streamline and clarify the process for other patients. In addition, she hoped Health NZ finds a way to

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address breast density for people being screened and hopes her case adds weight to the adoption of a clear symptomatic pathway for screening abnormalities. Although it is now five to six years since her cancer, Ms B continues to have little confidence in the breast screening system. She also emphasised that it is becoming more difficult to access GP care and harder to achieve continuity of care.

22. Health NZ National Office acknowledged the significant impact the delayed diagnosis has had on Ms B, supports HDC's recommendations, and is committed to strengthening the pathways within the BreastScreen programme.

Opinion

Issue to be determined

23. The critical issue for me to determine is whether an appropriate standard of care was met in relation to the reading and diagnostic reporting of imaging undertaken by Dr A and Dr D in 2017 and 2018 before Ms B's breast cancer diagnosis.

Clinical advice

24. To assist me in relation to the key issue, independent clinical advice was sought from Dr Melanie Rees, breast and oncology radiologist (see **Appendix A**). Dr Rees completed blind readings of the breast ultrasound of 24 August 2017 and the bilateral mammogram and right breast ultrasound of 12 December 2018. Dr Rees identified some departures from the standard of care in relation to both sets of images, which are discussed further below.
25. Dr E, radiologist, provided separate clinical advice to ACC. He had two radiologists complete a blind review of the imaging (although there is a lack of clarity in the report regarding the extent to which those reviewers had access to prior imaging). Dr E advised that there were two opportunities to either perform or recommend a biopsy of the right breast palpable abnormality following the 2017 and 2018 imaging.

Opinion

Dr A – breach

2017 imaging

26. In relation to the 2017 imaging, Dr Rees noted a 'subtle isoechoic¹³ mass.' On the other hand, the radiologists in Dr E's report considered the mass was a solid and significant finding, suspicious of a BI-RADS¹⁴ 4 lesion (a suspicious abnormality). I am mindful that the experts, although reporting 'blind' are not completely immune from the potential for bias that comes with the understanding that their advice is being sought in the context of a complaint or ACC claim (respectively).
27. Dr A's 2017 report suggests that the mass was a macrocyst and therefore benign.
28. Dr Rees stated that the accepted standard of care where there is a palpable abnormality is triple assessment, consisting of mammography, targeted ultrasound, and surgical clinical

¹³ Same echogenicity, or brightness, as adjacent normal tissue.

¹⁴ BI-RADS stands for Breast Imaging Reporting and Data System and was established by the American College of Radiology to categorise breast imaging findings. A BI-RADS 4 lesion is a suspicious abnormality. A lump is present but does **not** initially appear to have the morphological characteristics of breast cancer.

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review. Dr Rees was also of the view that Ms B required a biopsy. In that context, Dr Rees's advice was that, given the palpable abnormality, Dr A should have more strongly recommended a biopsy and surgical referral rather than suggesting that the GP give 'consideration' to a follow-up assessment and mammogram. She identified the failures to do so as a moderate departure from the standard of care. Likewise, Dr E commented that the standard of care would have been to do a biopsy of the 'palpable abnormality' where it was not clearly benign.

29. In response to Dr Rees's criticisms, Dr A has accepted that he could have worded the recommendation in his report differently to add strength to it. However, he strongly disagreed with Dr Rees's advice that the lesion was required to be biopsied or that that was the accepted standard of care. Dr A also pointed out in relation to the triple assessment that Ms B did have a screening mammogram after this ultrasound (as a result of her self-enrolment). The mammogram reported no evidence of breast cancer.

2018 imaging

30. Dr Rees was critical of Dr A's 2018 report as there was no described comparison to the 2017 mammogram and no comment on the 2017 ultrasound. She noted, having herself undertaken the ultrasound and mammography comparison, that the mass had increased in size and had new, albeit subtle, changes that were suspicious of malignancy and that required biopsy and surgical referral. Dr Rees's view was that the interpretation of the imaging and the standard of reporting and recommendations in the report represented a significant departure from the standard of care. She also stated that, independent of the misinterpretation as a fibroadenoma (Dr A's diagnosis), a palpable fibroadenoma in a 47-year-old woman required an ultrasound biopsy.
31. Later, when considering Dr A's response to her views, Dr Rees reiterated her opinion. Her concern was that the 2018 ultrasound images showed a palpable probably malignant hypoechoic¹⁵ mass that required biopsy but that was not biopsied. She reiterated her concern that there was no comparison to prior imaging, commenting that 'no breast imaging is reported in isolation without reference to priors ... in the absence of [a linking digital system] they would need to use an alternative method of obtaining prior imaging. Reporting breast imaging in isolation is not safe or standard practice.'
32. Dr E's report likewise identified, from comparison of the 2017 and 2018 ultrasounds, that the mass had grown and was characteristic of a malignancy requiring a biopsy.
33. In his response to the provisional opinion, Dr A said Ms B had multiple lumps and cysts and that no one can be certain that those imaged in 2017 and 2018 were indeed the same lump.
34. Dr A's report, while referencing the 2017 mammogram, does not describe any comparative characteristics from that mammogram relevant to the 2018 imaging. As discussed, Dr A said there were difficulties in accessing imaging undertaken in the private sector; therefore, he did not enquire about previous imaging and was not aware of the 2017 ultrasound, so no ultrasound comparison was made. He therefore concluded that the mass was a fibroadenoma and definitively stated in his report 'no mammographic ultrasonographic

¹⁵ A dark grey area in the ultrasound that indicates dense tissue.

evidence of malignancy.’ This report and the mammogram were independently reviewed (second read) at the time by Dr D. Dr D has stated that neither he nor Dr A had access to the 2017 mammogram or ultrasound. Although he did not ‘double read’ the most recent ultrasound, he had a quick view of it and ultimately endorsed Dr A’s report without changes. In response to this investigation, Dr D re-reviewed the 2018 mammogram and stated that he believed that most radiologists, without the benefit of hindsight, would classify the 2018 mammogram images as benign. Dr Rees has agreed that, without the benefit of previous imaging and the ultrasound not being double read, the mammography imaging of 2018 would be considered normal.

35. Dr A stated that, in 2018, there were no guidelines requiring a biopsy of a solid lesion and that it was not the standard for palpable fibroadenomas to require an ultrasound biopsy. Dr D agreed with this. Nevertheless, Dr A says he offered Ms B the option of a biopsy (including describing the procedure, with its risks, alternatives, and benefits), which she declined. He also advised the GP (via the report) to review Ms B’s nipple discharge with her and to make a referral to surgical services if warranted. Ms B agreed that she was offered the option of biopsy but declined on the understanding from Dr A that the lump was benign. She believed she had been cleared of anything suspicious.

Discussion

36. My role is to determine whether there has been a departure of the standard of care. In doing so, I must carefully weigh the evidence with reference to the standards that were operating at the time the images were read, and I must guard against the bias that comes with hindsight and knowing the outcome, including Ms B’s clinical journey. I must also be extremely mindful of such biases for the expert clinical advisors. I note further that the variance in the interpretation of the imaging in this matter clearly reflects the complexity and nuances inherent in breast imaging reporting, particularly of dense breasts.
37. I am satisfied that, in 2017 and 2018, the accepted standard of care for a palpable abnormality in the breast was triple assessment, consisting of mammography, targeted ultrasound, and surgical clinical review. However, I am also satisfied that, at least in the Mid-Central region, it was not standard practice to mandatorily biopsy palpable masses that were considered benign, and it was not standard practice to biopsy fibroadenomas – although this standard subsequently changed.
38. In relation to the interpretation of the 2017 ultrasound, I am not critical of Dr A. I have noted that all the radiologists (Dr Rees, those referenced by Dr E, and Dr A) characterised Ms B’s abnormality differently, and Dr Rees refers to the subtlety of the mass. Also, at the time of his interpretation, unlike the expert advisors to this matter, Dr A did not have access to the 2017 mammogram imaging (which was undertaken after his report). Noting that Dr A interpreted the mass as benign (unlike Dr E and Dr Rees), I am not critical that he did not recommend a biopsy.
39. However, I do agree with Dr Rees’s view that Dr A should have been stronger in his wording regarding follow-up mammography and surgical review, noting that these were the two further tenets of the triple standard for breast abnormality. Dr A has accepted this criticism.

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40. In relation to the 2018 imaging, I consider that Dr A made an incorrect interpretation of that imaging as benign, which led to the subsequent mismanagement of Ms B, which clearly had significant ramifications for her. In this respect, I note that Dr Rees and the two radiologists in the Dr E report characterised the mass as (at least) probably being malignant. Although Dr D, as an independent second reader, confirmed Dr A's diagnostic impression at the time (that the mass was characteristic of a fibroadenoma and therefore benign), he did not second read the ultrasound, which Dr Rees identified as showing the probable malignancy, as opposed to the mammogram, which did not. In reaching this conclusion, I have borne in mind the potential for Dr Rees to have hindsight bias. Nevertheless, her opinion is supported and therefore given weight by the radiologists referred to in the ACC advice.
41. I am also critical of Dr A's failure to ascertain whether Ms B had prior imaging undertaken (he stated he did not know that), and I accept Dr Rees's opinion that reporting breast imaging in isolation is not safe practice. At the very least, Dr A should have asked Ms B about any prior imaging so as to create an opportunity to retrieve that imaging before completing the report (especially noting that it was his private practice that undertook that reporting). Health NZ has said that access to the 2017 imaging was possible at this time and could have been requested. It is not necessary for me to reconcile the somewhat different accounts about access to the private 2017 ultrasound from the public system as, regardless, in my view it is concerning that Dr A was prepared to proceed with reporting the scans without inquiry about whether previous imaging had occurred. In my view, access to prior imaging is critical to supporting safe diagnosis and decision-making.
42. I have also considered whether Dr A should have been more direct in his recommendation for a biopsy, noting Dr Rees's advice that, even with a fibroadenoma, the standard required a biopsy. However, both Dr A and Dr D stated that this was not the standard at the time, although this standard was later changed, partly in response to Ms B's case. I accept their evidence in this respect. As it happened, Dr A did offer a biopsy, which Ms B declined, albeit on the basis that it was believed the mass was benign (which undoubtedly affected her decision).
43. I have carefully weighed the shortcomings in this matter and considered the factors that Dr A has put forward in mitigation. I have reached the conclusion that, collectively, Dr A's failure to more strongly word the recommendation for mammography and surgical review after the 2017 imaging, the misinterpretation of the 2018 imaging, and the failure to ascertain whether previous imaging had occurred and therefore the failure to retrieve the 2017 imaging before his 2018 report amounts to a breach of Right 4(1) of the Code of Health and Disability Services Consumers' Rights – that is, the right to have services provided with reasonable care and skill. In reaching this view, I have considered Dr Rees's view that the 2018 misinterpretation was a significant departure from the standard of care.

Dr D – no breach

44. As noted above, Dr D completed an independent second read of the 12 December 2018 mammogram, which was reported by Dr A. He agreed with Dr A's findings and did not make any changes to the report. However, I note that, during the second-read process, Dr A's report was displayed at the same time as the imaging through the digital system. Dr D also confirmed that this process was not blinded. Dr D said this was the acceptable standard at

the time and was unable to be avoided because of the radiology information system that was used.

45. Noting Dr D's explanation for why the review was not 'blind', which identifies how the digital system displayed the images and reports, I am not critical of Dr D's practice of second reading.

BreastScreen and Health NZ – adverse comment

46. Although, ultimately, the assessment decisions rested on individual clinicians at the time, I consider that several systems-level factors contributed to Ms B's delayed cancer diagnosis.
47. As noted, after the mammogram on 7 September 2017, letters were sent to Ms B and her GP referring to follow-up and a clinical review. Unfortunately, Ms B and her GP both overlooked these letters.
48. Ms B said she is concerned that BreastScreen does not refer patients directly onto surgical specialists for further screening and that this process can lead to missed opportunities for quick and efficient action. Dr Rees concurred with this view and noted that BreastScreen should be able to refer directly to the required services if a woman is symptomatic. I agree with this view and note that direct referrals for a mammogram after the ultrasound in 2017, and to surgical services after the imaging in 2018, may have reduced the risk of Ms B being lost to follow-up. Accordingly, I recommend that Health NZ review the feasibility of sub-specialist radiologists and BreastScreen being able to refer directly onto other specialists.
49. In addition, as identified in this report, views on the accessibility of imaging from the private and public sectors in the Mid-Central region differed. I have accepted Dr Rees's statement that the usual practice before reporting on any breast imaging is to seek prior imaging as part of safe and effective care and I agree; there needs to be an effective system in place to retrieve prior imaging. A system that relies on a clinician identifying that earlier imaging exists still poses clinical risk. To ensure safe and effective decision-making, a digital system enabling such access should seek to ease administrative burden and improve timely access to such images. Accordingly, a recommendation is made with this limitation in mind.

Changes made since events

50. My investigation has identified several changes in practice.
51. Any new palpable solid mass detected in women aged over 25 years now requires a biopsy.
52. All missed diagnoses and interval cancers¹⁶ are now reviewed by all breast radiologists and the lead BreastScreen surgeon.
53. Health New Zealand | Te Whatu Ora Te Pae Hauora o Ruahine o Tararua MidCentral has implemented the Royal Marsden Hospital protocol of early imaging to optimise the use of limited surgical resources.

¹⁶ Interval cancers in breast screening refer to breast cancers that are diagnosed between routine screening mammograms.

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54. Dr A, in his current leadership role, said there is now a weekly panel review of all biopsies, as well as negative benign findings to minimise the chance of future adverse outcomes. Dr A has given an undertaking to do the same for the wider Wellington region once his role extends to this region.
55. In 2025, Health NZ completed a technical review of breast density reporting in cancer screening. The role of breast density reporting and whether supplemental (additional) screening should or can be offered to women with dense breasts in the public system was considered. The report found that women with dense breasts may benefit from supplemental screening, such as risk-based screening protocols, but that this needed further assessment in the context of the current BreastScreen programme and whole-of-system capacity issues.
56. Health NZ is working to establish the benefits, costs, requirements, and timeframes for incorporating breast density measurement as part of BreastScreen. This is expected to take three years.
57. Health NZ developed a proposed research workplan based on the findings of breast density technical review, with three main workstreams: breast density/risk stratification, stakeholder and consumer perspectives, and the use of artificial intelligence in breast density measurement.
58. Health NZ has planned further work around assessing supplemental screening options. This includes evidence review, workforce and infrastructure capacity assessment, and modelling of the cost, health, and economic outcomes of various screening strategies to determine the best strategy for New Zealand's populations.
59. Health NZ is actively working to improve access to prior radiology imaging within symptomatic pathways for breast screening, which includes ongoing national work to ensure consistent access to prior imaging for all services.
60. HDC has previously raised concerns with Health NZ regarding the adequacy of digital radiology systems in the central region and continues to work with Health NZ to monitor its programme of work, including the ability of providers to access prior imaging.

Recommendations and follow-up actions

Dr A

61. I recommend that Dr A provides a written apology to Ms B for the deficiencies identified in this report. This apology is to be sent to HDC for forwarding to Ms B within three weeks of the date of this report.
62. I recommend that Dr A undertake an audit of his last 10 mammogram and ultrasound reports to determine whether the standard of reporting meets BreastScreen's standards. A summary of the audit findings along with any corrective actions is to be provided to HDC within 12 months of the date of this report.

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Health NZ (National Office)

- 63. I recommend that Health NZ National Office consider implementing a process whereby screening radiologists can refer a patient directly to a breast surgeon if there are any concerns about breast imaging or if patients present with significant symptoms. An update on this consideration is to be provided to HDC within six months of the date of this report.
- 64. I recommend that Health NZ National Office provide an update on the progress of the recommendations made in the technical review of breast density reporting (paragraphs 57–59) within 24 months of the date of this report.
- 65. I recommend that Health NZ National Office provide an update on implementing systems to improve access to previous radiology imaging across all districts and services, including the Central region. An update is to be provided to HDC within 6 months of the date of this report.

Health New Zealand | Te Whatu Ora Te Pae Hauora o Ruahine o Tararua MidCentral

- 66. If it has not already done so, I recommend that Health New Zealand | Te Whatu Ora Te Pae Hauora o Ruahine o Tararua MidCentral develop a formal protocol for undertaking biopsies of palpable abnormalities in the breast. A copy of this protocol is to be provided to HDC within 12 months of the date of this report.
- 67. A copy of the sections of this report that relate to Dr A will be sent to the Medical Council of New Zealand.
- 68. A copy of this report with details identifying the parties removed, except Dr Melanie Rees, Health NZ, and BreastScreen, will be sent to the Royal Australian and New Zealand College of Radiologists, Health NZ, the Ministry of Health | Manatū Hauora, and the Cancer Control Agency and placed on the HDC website, www.hdc.org.nz, for educational purposes.

Morag McDowell
Health and Disability Commissioner

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Appendix A: Independent clinical advice to the Commissioner

The following independent clinical advice was obtained from Dr Melanie Rees:

“Blind review of breast imaging 24 August 2017

The indication is ‘small palpable lump at 6 o’clock.’

This is an ultrasound of both breasts and axilla. This is a good-quality ultrasound that shows multiple simple and complex cysts.

The annotations indicate the right breast 6 o’clock axis as a region of interest. In this axis there are simple cysts. There is also a subtle isoechoic mass indicated as a region of interest and palpable and measured at 6 x 6 x 4mm. This is noted early in the scan, and the sonographer has returned to it at the end and taken further images. Measuring off the still images is 9 x 6 x 6mm, it has no capsule and interrupts tissue planes. This is a very subtle finding, possibly not identifiable without being palpable.

Blind review breast imaging 12 December 2018

This study is a bilateral mammogram and a right breast ultrasound performed by the reporting radiologist.

On the mammogram, a ‘bb’ indicates a palpable abnormality in the right breast at 6 o’clock, 57mm from the nipple. The breast parenchyma is markedly dense. Deep to the bb there are segmental micro-calcifications, 61mm in AP diameter. There are scattered micro-calcifications elsewhere.

It is usual practice when reporting breast imaging to seek any prior breast imaging. A PACSLink search identified an earlier BreastScreen mammogram from 7 September 2017. Comparison to this demonstrates that there were previous loose widespread micro-calcifications. The segmental calcifications are subtle but new.

Ultrasound of the right breast accompanies this mammogram. This demonstrates an unencapsulated hypoechoic mass measured at 13 x 8 x 8mm, which interrupts tissue planes. This is BI-RADS 4 suspicious for malignancy and amenable to ultrasound core biopsy.

Magnification views should have been performed of the micro-calcifications, and – if confirmed – a stereotactic biopsy of the anterior aspect remote from the mass would be recommended.

Surgical referral would be recommended.

Please review the enclosed documentation that relates to the care provided to Ms [B] by Dr [A] and provide your comments on the following points:

1. *Please comment on the standard of reporting of the breast ultrasound dated 24 August 2017*

I have commented on the interpretation of the imaging findings, the standard of reporting, and the recommendations of the report.

The radiologist describes the ultrasound as having been performed by a sonographer at a remote site, which means the radiologist has not scanned the patient and is reporting off

captured images and likely a worksheet or sonographer findings. This is not an uncommon scenario in New Zealand.

The radiologist describes a 'density' and findings of fibrocystic change and says that the area of concern is suggestive of a macrocyst.

The report does go on to say, 'consideration should be given to completion of wrist (sic) assessment with mammogram +/- tomosynthesis.' I am uncertain whether 'wrist' should read breast or risk; regardless, the wording should be stronger and the GP given more guidance than 'consideration.'

The radiologist in their report does not recognise the subtle hypoechoic mass as the palpable mass for which she presented and that requires a biopsy.

Triple assessment is standard practice when presenting with a palpable abnormality. Triple assessment consists of bilateral mammography (if 30 to 35 years or older; this varies between centres), targeted ultrasound, and surgical clinical review. Although mammography was suggested, it should have been recommended in view of the palpable abnormality. She should also have had an ultrasound-guided biopsy and a surgical referral.

This is a moderate departure from standard care; however, sonographic findings are subtle. This was, however, a missed opportunity to get a mammogram and a surgical referral to complete triple assessment given she was 45 years old and had a palpable abnormality.

2. *Please comment on the standard of reporting of the breast ultrasound dated 12 December 2018*

I have commented on the interpretation of the imaging findings, the standard of reporting, and recommendations of the report.

This was performed following referral from a family doctor with the indication 'new lesion in the inferior right breast.'

The reporting of the mammogram fails to recognise new segmental micro-calcifications at the site of the palpable abnormality. There is no described comparison to the prior BreastScreen mammogram of 7 September 2017.

The mass that is in the same location as in the previous ultrasound has increased in size. This is not commented on, and the prior ultrasound is not referred to.

The mass does not lie in the plane of breast parenchyma; it interrupts tissue planes and has no capsule. It should be categorised as BI-RADS 5 suspicious for malignancy and requires a biopsy and surgical referral.

This was not recognised as suspicious for malignancy.

It is described as 'typical of fibroadenoma.' The radiologist describes having a discussion with [Ms B] and that she elected for conservative management. There is no description or recommendation of what this conservative management might be.

The radiologist does go on to say that, if there is persistent clinical concern, surgical referral should be considered.

This is a severe departure from expected standard of care.

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3. ***Please comment on Dr [A]’s management of Ms [B] following the ultrasound of 12 December 2018, including the advice and information he states he provided to her (per provider response dated 16 April 2024)***

Dr [A] failed to recognise that the sonographic findings are not of a BI-RADS 2 benign fibroadenoma.

Dr [A] failed to recommend a biopsy and surgical referral.

Dr [A] failed to compare the current mammogram to priors and therefore did not have the opportunity to recognise new, albeit subtle, suspicious segmental micro-calcifications in the same segment.

Independent of not recognising this was not a fibroadenoma, a palpable fibroadenoma in a 47-year-old woman would have required ultrasound biopsy.

4. ***Please comment on the standard of clinical documentation with respect to the discussion Dr [A] states he had with Ms [B] on 12 December 2018 (please note that sole documentation appears to be the formal radiology report)***

It is usual practice for documentation of findings and of recommendations in an outpatient setting to be a radiology report only.

5. ***Any additional comments on Dr [A]’s role in Ms [B]’s management.***

No.

In relation to each of the questions above, please advise:

6. ***What is the standard of care/accepted practice?***

7. ***Has there been a departure from the standard of care or accepted practice? If so, please identify how the care departs from standards or accepted practice and the extent of that departure (mild departure, moderate departure, or severe departure) having regard to the scale in the table below:***

No departure	The care provided was consistent with standards and accepted practice in all respects.
Mild departure	While generally acceptable, the care provided did not meet some standards or accepted practice to a minor extent.
Moderate departure	The care provided did not meet a particular standard or accepted practice but there were relevant mitigating factors present and considered.
Severe departure	The care provided fell well below an acceptable standard in respect of an essential aspect of the consumer’s care, and there was an absence of relevant mitigating factors.

8. ***How would the care be viewed by your peers?***

This would not be accepted as the standard of care by a breast radiologist in New Zealand.

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Additional comments and also referring to [Ms B]’s summary

With regard to care from her family doctor. A family doctor has a breadth of knowledge to care for their community and should not be expected to be a breast specialist and should be able to rely on a breast radiologist for subspecialist breast management advice and guidance.

Her family doctor referred her for an ultrasound when she had a palpable lump and discharge. When reported as normal but suggested consideration of a mammogram, she was referred not unreasonably for a BreastScreen mammogram. This is a common mistake for GPs, not appreciating that BreastScreen imaging is set up for asymptomatic population-based screening.

[Ms B] did, however, declare nipple discharge at her screening mammogram with BreastScreen. When her mammogram was read as normal, she and her GP received a standard template letter designed for when a woman declares a symptom but the mammogram is normal. This letter goes to the woman and her family doctor saying that the mammogram is normal but she should have a clinical review. This was overlooked by both [Ms B] and the medical practice where it was filed. Mitigating factors were a change in doctor at this time.

Her new family doctor referred her to Midcentral [District Health Board] for investigation of a ‘new lesion in the inferior right breast.’ This was performed at [the local radiology service]. It was done 15 months after her BreastScreen mammogram, too early to be eligible for her next BreastScreen mammogram. There was no radiologist to perform the ultrasound, and she had a significant distance to drive to return later. I have given my opinion as to the interpretation and guidance of that imaging encounter.

Her next mammogram is the next routine BreastScreen mammogram on 7 January 2020 where there is a subtle mass and increasing segmental micro-calcifications. She was recalled for assessment. In the clinical notes for the BreastScreen assessment, the assessing radiologist has made a note that the sonographic finding has increased in size from 13mm on the previous ultrasound.

[Ms B] describes a desire to see the interface between BreastScreen and GPs be improved and that BreastScreen should be able to refer directly to the required services if a woman is symptomatic.

To clarify, this is my personal opinion, and I agree with [Ms B].

BreastScreen is a robust, longstanding, independently scrutinised national screening programme that offers two-yearly population-based screening to asymptomatic women between the ages of 45 and 69 years, to be increased to 74 years. It follows a set of mandated standards and pathways. Women who declare a symptom at booking a screen are redirected to the diagnostic service. Women who describe a symptom when they arrive get their mammogram as usual. If that mammogram is normal, it triggers a pathway of ‘return to routine screening with symptom,’ which generates letters to the woman and her family doctor prompting clinical review. This is to ensure that cancers that are not visible mammographically but present clinically are picked up. This clearly failed for [Ms B].

BreastScreen internally at a high level is investigating incorporating women who are symptomatic into screening and have already ceased turning away women who are

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symptomatic. There are many good reasons for this, including access, with mobile screening units getting to women who live far from screening sites, financial and physical barriers to women with symptoms seeing GPs, uncertainty navigating the system and being redirected when trying to book a mammogram, and being brave enough to finally seek investigation for a clinical concern. This is complex to consider introducing, including ensuring there is capacity, to not compromise existing screening, and that safeguards are in place to ensure women do not get lost between parallel symptomatic and asymptomatic pathways. This also involves change to the existing computer programs that provide the framework and safeguards for BreastScreen. This work is being done.

I would be happy to provide further clarification and advice on this case if required.

Sincerely yours,



Melanie Rees”

The following additional comments were provided by Dr Rees:

“I have read the response letters from Dr [A] and [Dr D]. My opinion dated 1 July 2024 remains unchanged.

I would make specific comments.

To summarise, my significant concern is the report on the imaging dated 12 December 2018, where there are multiple captured images on ultrasound of a palpable probably malignant hypoechoic mass, including measurements. This was not biopsied. This is a significant departure from the expected standard of care.

My further comments pertain to the availability of priors, specifically the absence of access to prior images with PACSLink referred to by Dr [A]. It is standard practice in all breast imaging to ask patients about prior imaging and retrieve the prior imaging for comparison prior to completing the report. No breast imaging is reported in isolation without reference to priors. This is the case in BreastScreen, in Diagnostic Breast Units in Health NZ, and in private breast imaging practices. Although many practices use PACSLink, in the absence of this they would need to use an alternate method of obtaining prior imaging. Reporting breast imaging in isolation is not safe or standard practice. The exception worth noting is BreastScreen, where only prior mammography is routinely retrieved. This is commented on by Dr [D], and I agree.

Kind Regards,

Melanie Rees”.

The following additional comments were provided by Dr Rees:

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“I agree with Dr [D] that the mammogram in isolation without reference to any priors and, in isolation, the ultrasound not being double read would have led to agreeing the mammography was normal and described the calcifications as benign.

Yours sincerely

Melanie.”