District Health Board
Breast and General Surgeon, Dr B

A Report by the
Health and Disability Commissioner

(Case 19HDC01517)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report concerns the care provided to a woman who had been diagnosed and treated for breast cancer in 2013. During a routine check in 2018, she was found to have a breast lump. A breast and general surgeon performed a fine needle aspiration (FNA) biopsy on the lump, but did not order a mammogram or an ultrasound.

2. The Commissioner emphasises the importance of complying with district health board (DHB) protocol and accepted practice with respect to investigating breast lumps, and highlights her concerns about the efficacy of FNA biopsies to determine malignancy, given the availability of other methods such as mammograms, ultrasounds, and image-guided core biopsies.

Findings

3. The Commissioner found the surgeon in breach of Right 4(1) of the Code for failing to request an ultrasound or a mammogram of the woman's breast lump.

4. The Commissioner considered that the omission was an individual error and did not indicate broader systems or organisational issues at the DHB. Accordingly, the Commissioner found that the DHB did not breach the Code.

Recommendations

5. The Commissioner recommended that the surgeon conduct an audit of her last 20 assessments of patients where there was suspicion for a breast lump and report back to HDC on the results, and provide a written apology to the woman.

6. The Commissioner recommended that the DHB report to HDC on the updates made to its Breast Clinic Management Protocol; use this report as a basis for staff training; and consider whether any further changes to its Breast Clinic Management Protocol are required to address any differences of approach to investigation between new and other referrals to its Breast Clinic.

Complaint and investigation

7. The Health and Disability Commissioner (HDC) received a complaint from Ms A about the services provided by Dr B and the DHB. The following issues were identified for investigation:

- *Whether the DHB provided Ms A with an appropriate standard of care in September 2018.*
- *Whether Dr B provided Ms A with an appropriate standard of care in September 2018.*

8. This report is the opinion of Health and Disability Commissioner Morag McDowell.

9. The parties directly involved in the investigation were:

Ms A	Consumer/complainant
Dr B	Provider/breast and general surgeon
District health board	Provider/DHB

10. Also mentioned in this report:

Dr C	General surgery registrar

11. Further information was received from a medical centre.

12. Independent expert advice was obtained from consultant general surgeon Dr Bernard Collins (Appendix A).

Information gathered during investigation

13. This report concerns the services that Dr B provided to Ms A (in her forties at the time of events) at a public hospital on 26 September 2018.

Background

14. In 2013, Ms A was diagnosed with breast cancer. Her treatment included a left skin-sparing mastectomy,[1] TRAM flat reconstruction,[2] chemotherapy, and Herceptin[3] treatment.

15. As part of her post-treatment follow-up, Ms A underwent a mammogram[4] on 18 May 2017, a bone scan on 28 July 2017, and another mammogram on 22 May 2018. None of the examinations revealed anything of concern.

Breast Clinic (26 September 2018)

16. On 26 September 2018, Ms A presented to Dr C (a General Surgery registrar) at the public hospital for a routine breast check. While examining Ms A, Dr C discovered what he described as "an area of thickening at the 12 o'clock position"[5] on Ms A's right breast, and documented that it felt "like fibrocystic change[6]". An "area of thickening" is also referred to as a "lump", which is the term I will use in my report for ease of description.

17. The DHB's Breast Clinic Management Protocol at that time stated that when a patient over the age of 35 years is clinically assessed as having a "breast lump", the patient should

[1] Removal of the left breast with preservation of most of the breast skin.
[2] A method of breast reconstruction surgery.
[3] An antibody used in the treatment of breast cancer and stomach cancer.
[4] An X-ray of the breasts.
[5] The top of the breast.
[6] Fibrocystic breast changes are lumpy textures that can appear in the breast; they are usually benign and do not require treatment.

undergo a mammogram, an ultrasound, and a palpation-guided biopsy,[7] followed by an image-guided biopsy if still indicated. In outlining these steps, the protocol does not make reference to any consideration of whether the patient has had a recent mammogram or not.

18. Dr C asked Dr B, a breast and general surgeon, to examine Ms A's lump, given Ms A's history of breast cancer. Dr C documented that Dr B said that the lump felt "just fibrocystic in nature". Dr B decided to test the lump by performing a fine needle aspiration (FNA) biopsy; she told HDC that she did this because there was "an abnormal clinical finding".

19. An FNA biopsy involves inserting a thin hollow needle into the skin to draw out a small quantity of fluid or tissue for testing. Usually, an FNA biopsy does not require an incision or anaesthetic. FNA biopsies are different to core biopsies, which remove more tissue and require anaesthetic.

20. Dr B sent the sample extracted from Ms A's breast to pathology for testing. The same day, a pathologist completed the test and documented:

> "The slides show occasional groups of ductal epithelial cells[8] with myoepithelial cells.[9] Fragments of adipose[10] tissue are present. No malignant cells are seen."

21. The pathologist reported the results of the test back to Dr B while Ms A was still at the hospital. Dr B told HDC that the benign result of the FNA biopsy "supported the clinical impression of the changes being a benign non-cancerous thickening". Dr B did not order a mammogram or an ultrasound, contrary to the DHB's protocol for the investigation of breast lumps. She advised Ms A that she was not concerned about the lump, and discharged her. Ms A told HDC that she was advised that the lump was a fibroadenoma.[11]

22. In the clinic letter to Ms A's GP (a copy of which was sent to Ms A), it was noted that Ms A had been advised to have yearly mammograms and to self-examine her breasts. It was also noted that if Ms A detected any masses, the Breast Clinic would "happily see her at any stage".

Subsequent events

23. Ms A told HDC that during the next five months she felt the lump grow rapidly. On 27 February 2019, she showed the lump to her GP. On 28 February, her GP referred her back to the public hospital. On 13 March 2019, a consultant radiologist examined Ms A and documented:

[7] A biopsy performed without the aid of imaging.
[8] Cells from the surfaces of the body (i.e., skin and blood vessels).
[9] A category of cell associated with excretions from the body (in this case, the mammary glands).
[10] Fat.
[11] A type of benign breast tumour.

> "[There is a] very firm mass about 5cm by about 4cm in size, not tethered to skin, felt at the 1–2 o'clock position and extending to under the areola.[12] The nipple is slightly displaced by it."

24. With Ms A's consent, the radiologist performed a series of ultrasound-guided core biopsies on Ms A's breast and sent the samples to pathology for testing. On 18 March 2019, a pathologist reported her findings from microscopic examination:

> "The needle core biopsies contain infiltrating lobular carcinoma.[13] The tumour is composed of small to intermediate sized malignant cells arranged in cords and single files. The tumour cells infiltrate fibrous and adipose stroma."[14]

25. This finding led to Ms A receiving treatment for breast cancer, including a mastectomy and chemotherapy. Her treatment is ongoing.

Further information

Ms A

26. Ms A told HDC that she would like to see a better system in place for the assessment of breast lumps. She stated:

> "I feel that considering my previous history any lump found should have warranted an ultrasound and biopsy. After experiencing both a fine needle aspiration and an ultrasound guided biopsy, I feel strongly that a FNA is blindly poking around — a biopsy can see exactly where to take tissue from."

DHB

27. The DHB told HDC:

> "We are truly very sorry about [Ms A's] delayed diagnosis of breast cancer, and the impact that this has had on her and her family."

Dr B

<u>Omission to perform an ultrasound</u>

28. Dr B told HDC:

> "I confirm at the time I believed the mobile thickening I could feel, was benign. Additionally, it was in the contralateral [opposite] breast from the original cancer, which is why I proceeded with an FNA. I was reassured by the recent normal mammogram and the benign feeling of the lump and therefore thought that an FNA was sufficient to exclude a malignancy. Had the thickening been more nodular or had it had other concerning features, then I would have proceeded with a focused ultrasound."

[12] The ring of pigmented skin surrounding the nipple.
[13] A breast cancer that begins in the lobules (the milk-producing glands) and spreads to other parts of the breasts or body.
[14] Fibrous and fatty tissues.

29. Dr B submitted that her decision-making may have been influenced by the fact that Ms A presented in the context of a five-year follow-up clinic rather than that of a new referral. In response to the provisional opinion, Dr B also noted that Ms A had undergone a mammogram on 22 May 2018, only four months prior to the clinic appointment with her. Dr B stated:

> "The shortest time interval between mammograms is 6 months (usual interval being 1–2 years), thus a repeat mammogram at the time [Ms A] was seen in clinic was not indicated."

30. Dr B also noted that Ms A's previous breast reconstruction may have complicated her assessment, as it meant that she "did not have a 'normal' side to compare with".

31. Dr B told HDC: "I agree that a focused ultrasound, and guided core biopsy if a lesion was seen on ultrasound would have been appropriate when I saw [Ms A]."

Apology

32. Dr B apologised for the care she provided to Ms A. Dr B stated:

> "I remain deeply sorry that my failure to further investigate the area of thickening on [Ms A's] right breast after the FNA findings were reported negative, contributed to a delayed diagnosis. I apologise unreservedly for the additional distress this has caused [Ms A]. As previously advised, I was reassured by the findings of the FNA, which supported my clinical impression that the changes were fibrocystic changes only. With the benefit of hindsight, I should have given further consideration as to whether an ultrasound was also indicated even though the FNA was reassuring."

Responses to provisional opinion

33. Ms A, Dr B, and the DHB were all given the opportunity to respond to the relevant sections of my provisional opinion. Where appropriate, their responses have been incorporated into this report.

34. In addition, Ms A stated, with respect to these events: "The emotional and financial strain on my family and I … has taken its toll without a doubt."

35. Dr B told HDC: "[Ms A's] case has had a profound effect on me, which has caused me to reflect on my practice." She said that she accepts the criticisms of the care she provided and has amended her practice accordingly, and has no hesitation in accepting the proposed recommendations. Dr B added that she is also appreciative of the advice from HDC's clinical advisor, Dr Bernard Collins, about being more specific with follow-up advice to patients. She said that she has taken steps to add an adapted version of Dr Collins' suggested follow-up advice (as set out in paragraph 49 below) into the DHB's Breast Clinic letters.

36. Dr B also told HDC:

> "Of note since this time a new technology called tomosynthesis is now available. This is also known as a 3 dimensional mammogram. It is now the standard investigation

> performed at [the DHB] for new patients and follow up patients, since the addition of our state of the art second mammogram machine in January 2021. It has an increased detection of cancers especially in young, denser breasts (up to 40% in some studies), a reduced false positive rate, and therefore reduced recall rates for further views by about 40%."

37. Dr B said that she would amend the DHB's Breast Clinic Management Protocol to include reference to the time since a prior mammogram, and to add tomosynthesis.

38. The DHB had nothing further to add.

Opinion: Dr B — breach

39. It is not in dispute that on 26 September 2018, Ms A underwent a routine breast check that detected an area of thickening near the top of her right breast. Having examined the lump and obtained pathology results from an FNA, Dr B formed the impression that the lump was a benign fibrocystic change rather than a malignant tumour. Ms A was later discharged with the advice described in paragraph 22 above.

40. At that time, the Breast Clinic Management Protocol specified that if a patient aged over 35 years was clinically assessed as having a breast lump, the patient should undergo a mammogram, an ultrasound, and a palpation-guided biopsy, followed by an image-guided biopsy if still indicated.

41. I sought expert advice from an independent surgical advisor, Dr Bernard Collins, regarding the examination and investigations undertaken for Ms A at this consultation. He commented that if a thickening is felt and there is sufficient concern, then an ultrasound is warranted; if the ultrasound is abnormal, then an ultrasound-guided core biopsy is required; and if the ultrasound is normal but there is still uncertainty, then the patient should either be reassessed or considered for a clinically guided core biopsy. Dr Collins further advised: "In [Ms A's] case the accepted standard of care would have been a focused ultrasound scan and guided core biopsy."

42. Dr Collins considered that Dr B's departure from the accepted standard of care was "moderate to severe".

43. I accept this advice. I also note that Dr B has accepted that it would have been appropriate for her to request an ultrasound for Ms A when she saw her on 26 September 2018.

44. I acknowledge that Dr B is an experienced surgeon, and that on this occasion her assessment, which included a tactile examination and an FNA biopsy, led her to conclude that Ms A's breast lump was benign and required no further assessment or treatment. Nevertheless, both Dr Collins' advice and the DHB's protocol are clear that the accepted standard of care would have been for Dr B to request an ultrasound of Ms A's breast.

45. Additionally, the DHB's protocol also required Dr B to request a mammogram for Ms A. I acknowledge Dr B's comment that Ms A had had a mammogram (which did not reveal any concerning information) only four months previously, and therefore, in her view a mammogram was not clinically indicated. I also accept that the protocol stated more generally that normally patients would have mammograms every one to two years. However, the protocol did not reference the age of the patient's most recent mammogram as a factor to consider; the protocol is clear that a mammogram should be performed for patients over the age of 35 who present with a breast lump. Dr B has advised that the protocol will be updated to include a reference to time since mammogram. It is for the DHB to consider whether and what proposed timeframe is appropriate as a factor for deciding what diagnostic techniques should then be used for breast lumps.

46. Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code) states that "[e]very consumer has the right to have services provided with reasonable care and skill". In my opinion, Dr B's decision to discharge Ms A without requesting an ultrasound was a departure from the accepted standard of care. It meant that an opportunity was missed to potentially diagnose and treat Ms A's breast cancer several months earlier than occurred. Undoubtedly this delay has been distressing for Ms A. Accordingly, I find that Dr B breached Right 4(1) of the Code.

47. I acknowledge that since these events, Dr B has committed to investigating all breast lumps with ultrasound.

Other comment — follow-up advice

48. The clinic letter following Dr B's examination and FNA of Ms A's breast lump noted that Ms A was advised to have yearly mammograms and to self-examine, and to see her GP if any masses were detected.

49. Dr Collins advised that a consumer being discharged from a breast clinic should be told to see their GP if they have any outstanding concerns after the consultation at the DHB. Specifically, Dr Collins expected the following follow-up advice to be given:

> "1. If the symptom is still persistent then the patient should see the GP who should examine the patient, confirm that finding & re-refer to the Surgical/Breast clinic.
>
> 2. If a new symptom has arisen, see the GP & re-refer to the Surgical/Breast clinic."

50. The advice to Ms A could have been more specific as to the need to see her GP if she had new concerns or if the symptom (the lump) persisted. I suggest that Dr B consider Dr Collins' comments in this respect.

Opinion: District Health Board — no breach

51. As a healthcare provider, the DHB is responsible for providing services in accordance with the Code. In this case, I consider that the error that occurred was an individual error and did not indicate broader systems or organisational issues at the DHB. Therefore, I consider that the DHB did not breach the Code directly.

52. In addition to any direct liability for a breach of the Code, section 72(2) of the Health and Disability Commissioner Act 1994 (the Act) states that an employing authority may also be found vicariously liable for any acts or omissions of its employees. A defence is available to the employing authority under section 72(5) if it can prove that it had taken such steps as were reasonably practicable to prevent the acts or omissions.

53. In September 2018, Dr B was an employee of the DHB. As set out above, I have found that Dr B breached Right 4(1) of the Code by deciding to discharge Ms A on 26 September 2018 without requesting an ultrasound and a mammogram of her right breast.

54. I note that Dr B is a senior surgeon with considerable experience.

55. I further note that the DHB's "Breast Clinic Management Protocol" specified that if a patient aged over 35 years was clinically assessed as having a breast lump, they were to undergo a mammogram, an ultrasound, and a palpation-guided biopsy, followed by an image-guided biopsy if still indicated. Dr B's omission to request an ultrasound and mammogram was inconsistent this protocol.

56. In my view, the DHB was entitled to rely on Dr B as a senior and experienced surgeon to provide an appropriate standard of care, and the breach that occurred was the result of Dr B's individual clinical decision-making. I do not consider that the DHB could have reasonably done anything more as Dr B's employer to prevent these events from occurring. Accordingly, I find that the DHB is not vicariously liable for Dr B's breach of the Code.

Opinion: FNA biopsy — other comment

57. Ms A underwent an FNA biopsy while she was at the public hospital on 26 September 2018. The biopsy returned a benign result. Dr B told HDC that this result supported her "clinical impression of the [lump] being a benign non-cancerous thickening". She also told HDC that at the time, given the "recent normal mammogram and the benign feeling of the lump", she thought that "an FNA was sufficient to exclude a malignancy".

58. Dr Collins advised that "some surgeons may do a free hand FNA bearing in mind that there are false negatives and false positives". He stated:

> "Free hand FNA is still used from time to time and is not inappropriate. However, I would only rarely use it in a situation if I expect a benign result (mainly to reassure the patient) rather than one where I am differentiating benign vs malignant."

59. I note further that in 2017 BreastScreen Australia provided guidance to its screening programme seeking to reduce reliance on FNA as a screening tool, owing to the inherent limitations of the technique (including a higher risk of false positives). It recommended that FNA in the screening setting be limited to cysts, lymph nodes, and the rare situations where core biopsy is not possible. Where possible, core biopsy should be the procedure of choice.[15]

60. Noting Dr Collins' advice, the position of BreastScreen Australia, and the circumstances of this case, I am concerned about the efficacy of FNA biopsies to determine malignancy, given the availability of other methods such as mammograms, ultrasounds, and image-guided core biopsies. I am also concerned about the risk to patients undergoing FNA biopsies in substitution for other, more preferable, methods of investigation.[16]

61. However, I am cognisant of Dr Collins' advice that FNA biopsies are "not inappropriate".

62. I will therefore be writing to the Royal Australasian College of Surgeons to suggest that it consider the appropriateness of FNA biopsies as a method of investigating the malignancy of breast lumps, and whether guidance for its surgeons on this issue may be warranted. I will also be writing to the Ministry of Health to highlight my concerns about FNA biopsies, and will ask it to report back on any action taken by it in response to this matter.

Changes made

63. Dr B told HDC that she has spent much time reflecting on Ms A's case. She stated:

> "I now make sure any lump or thickening is investigated with an ultrasound scan. If I am still not completely reassured then I will order an MRI scan, even if I believe it to be benign.
>
> If all imaging is normal but there is still a palpable lump, only then will I do a free hand FNA."

64. Dr B further stated that the DHB's Breast Clinic Management Protocol is a living document that is reviewed regularly "at least annually to keep up with evolving practice".

65. Since these events, the DHB has updated its Breast Clinic Management Protocol. The protocol now states that when a patient over the age of 35 years is triaged as having a "breast lump", the patient should undergo a mammogram and an ultrasound, and if a lesion is seen on the ultrasound, an ultrasound-guided biopsy should then be performed. The guidance to perform a biopsy by palpation was removed from the protocol. Dr B told HDC

[15] https://www.health.gov.au/sites/default/files/documents/2020/03/use-of-fine-needle-aspiration-in-breastscreen-australia-services_0.pdf.
[16] This issue has already been brought to the attention of the Ministry of Health by letter dated 31 July 2020, from Deputy Commissioner Rose Wall.

that the change in protocol reflects the fact that image-guided biopsy is preferred and more accurate than a palpation-guided biopsy, "so should be the first line investigation".

Recommendations

66. In accordance with a proposed recommendation in my provisional opinion, Dr B has provided a written apology to Ms A, which has been forwarded to Ms A.

67. Bearing in mind the above changes made by Dr B, I recommend that Dr B conduct an audit of her last 20 assessments of patients where there was suspicion for a breast lump. Dr B is to report back to HDC, within three months of the date of this report, on whether the audit showed that the appropriate steps as mandated by the Breast Clinic Management Protocol were taken in those cases. Where the audit finds that appropriate assessment was lacking, the report should outline why, and the steps taken to remedy such issues.

68. Bearing in mind the above changes made by the DHB, I recommend that the DHB:

a) Provide HDC with the updated copy of the Breast Clinic Management Protocol within three months of the date of this report.

b) Use this report as a basis for staff training at the DHB, focusing particularly on lessons gained from the breach of the Code identified, and provide evidence of that training to HDC within three months of the date of this report.

69. Additionally, in her responses to this complaint, Dr B commented that had Ms A been referred through to the Breast Clinic as a new referral (rather than as a five-year follow-up), with her history, a mammogram and ultrasound scan would have been arranged, performed, and reported prior to her clinic appointment. This suggests that there is a difference of approach to investigation between new and other referrals. I therefore suggest that the DHB consider whether further changes to its Breast Clinic Management Protocol are required, to address this difference (and its potential impact on clinical decision-making).

Follow-up actions

70. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Medical Council of New Zealand and to the Royal Australasian College of Surgeons (RACS), and they will be advised of Dr B's name.

71. I will write to RACS to suggest that it consider, in light of this case (including the expert advice provided, and the guidance of BreastScreen Australia), the appropriateness of FNA biopsies as a method of investigating the malignancy of breast lumps, and whether or not further guidance should be provided to surgeons.

72. I will also write to Te Aho o Te Kahu (the Cancer Control Agency) to highlight my concerns about FNA biopsies, and will ask it to report back on any action taken by it in response to this matter.

73. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Health Quality & Safety Commission and Te Aho o Te Kahu, and will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent clinical advice to the Commissioner

The following expert advice was obtained from consultant general surgeon Dr Bernard Collins:

> "I am writing in response to your letter providing expert advice to the HDC on the care provided by [Dr B] at [the public hospital] to the above patient in September 2018.
>
> I do not have a personal or professional conflict in the case. I have read the letter of complaint dated 15 August 2019, [the DHB's] response dated 05 November 2019 and also the clinical records from [the DHB].
>
> I will outline the time frame of the management of this patient in the first instance.
>
> [Ms A] was [in her thirties] when she presented to a Private Breast Surgeon in [city] and had a skin sparing mastectomy and an immediate TRAM FLAP Breast Reconstruction done on 28 June 2013. The pathology of the tumour was 6mm Grade 3 infiltrating ductal cancer with LVI positive, ER negative, PR negative and HER-2 positive with one sentinel lymph node which showed 0.9mm micromet. She also had a 60mm High Grade DCIS in that breast. By way of adjuvant treatment she was offered Chemotherapy and Herceptin. Following this she has had a regular follow up in private.
>
> [Ms A] was referred to [the DHB] and was seen in the Breast Clinic on 27 September 2017 having had a Mammogram on 18 May 2017 which was normal. She has had a Bone scan done on 28 July 2017 for sacral pain which was normal. She was advised to come back in a year's time and a mammogram was ordered.
>
> [Ms A] was seen in the [DHB] Breast Clinic on the 26 September 2018 by the Surgical Registrar [Dr C] who had noted an area of thickening at the 12 o'clock position of the opposite (right) breast which was mobile and was of the opinion that it was probably a fibrocystic change (benign). [Dr C] sought the advice of his Consultant [Dr B] given [Ms A's] past history.
>
> [Dr B] assessed the patient and was of the opinion that this was probably fibrocystic change and decided to do a free hand FNA because of an abnormal clinical finding. [Ms A's] most recent mammogram was 22 May 2018 ([four] months prior). This mammogram was reported as normal. The FNA was reported as benign (B2) and the patient was discharged from the Breast Clinic back to the care of the GP because [Ms A] was five years post mastectomy with the advice that she needed annual mammography up to the age of 45 and then two yearly with BSA Programme. She was also advised self-examination of her breasts and if there was any concern to refer her back to the Breast Clinic.
>
> [Ms A] in her letter of complaint indicates that this lump in her right breast was growing over 5–6 months and went to see her GP who referred her to [the public hospital] where [a radiologist] performed an ultrasound of her right breast and an ultrasound guided core biopsy 13 March 2019. This lump was now 4.5cm and [the radiologist] had noticed

a slight distortion of the nipple. The histology was reported as lobular cancer Grade 2, ER positive and PR positive, HER-2 negative.

[Ms A] had apparently seen a private surgeon with this histology report and now an obvious lump in the 12 o'clock position of the right breast. She underwent a mastectomy with an implant reconstruction (Tissue expander) sometime in the first week of April 2019. Unfortunately [Ms A] was admitted with septic shock from an infected breast implant which needed her admitted to the ICU in [the public hospital], washout of the breast and removal of the tissue expander and supportive treatment with appropriate antibiotics.

I have outlined the time line of events which has been unfortunate for [Ms A] in two ways. Firstly the delay in diagnosing right sided breast cancer and secondly the post op complication of septic shock from an infected breast implant.

In general lobular cancers of the breast are harder to palpate, they tend to be soft and ill-defined and mammograms often miss lobular cancers particularly in younger patients (like [Ms A]) who tend to have dense breast parenychia.

Some Breast Surgeons would still do a free hand FNA if the clinical suspicion is benign as was thought in [Ms A's] case (thickening which was mobile). If that was more nodular one could argue then a focused ultrasound or a repeat mammogram would have been prudent.

In [Ms A's] case the accepted standard of care would have been a focused ultrasound scan and guided core biopsy. If a thickening was felt in the 12 o'clock position of the right breast in September 2018, depending on the index of suspicion, if it's a low index of suspicion (to something sinister) some surgeons may do a free hand FNA bearing in mind that there are false negatives and false positives. If it is felt that there is sufficient concern to warrant a further test then an ultrasound in the first instance (in preference to a FNA). If the ultrasound is abnormal, then an ultrasound guided core biopsy. If the ultrasound is normal then either reassess the patient or consider a clinically guided core biopsy if still concerned.

Free hand FNA is still used from time to time and is not inappropriate. However, I would only rarely use it in a situation if I expect a benign result (mainly to reassure the patient) rather than one where I am differentiating benign vs malignant.

The delay in [Ms A's] case of getting an ultrasound guided core biopsy was six months and my peers would consider this to be moderately significant.

I trust I have covered all the issues you asked me to comment on."

Further advice was sought from Dr Collins about the severity of [Dr B's] departure from the accepted standard of care. He advised that her departure from the accepted standard of care was "moderate to severe".

Dr Collins reviewed [the DHB's] and [Dr B's] responses to his advice. He advised:

> "I have nothing to add as [the DHB] has changed their protocol to image guided biopsy & have added MRI if the Mam & US normal & one has clinical suspicion."

Dr Collins provided the following further comments in respect of the expected safety-netting advice and follow-up advice in this case:

> "The safety netting advice would be to do ultrasound guided biopsies of breast lumps/thickenings & NOT doing free hand Fine Needle biopsies for clinically suspicious findings.
>
> Follow up instructions to the patients once they are discharged from the breast clinic is to see the GP if the patient has reservations of the consultation at [the DHB]. The GP could contact [the DHB] of the respective service & ask for another review.
>
> …
>
> **Follow up advice**
>
> 1. If the symptom is still persistent then the patient should see the GP who should examine the patient confirm that finding & re-refer to the Surgical/Breast clinic.
>
> 2. If a new symptom has arisen, see the GP & re-refer to the Surgical/Breast clinic."