General Practitioner, Dr C
Medical Centre

A Report by the
Health and Disability Commissioner

(Case 18HDC00843)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. In February 2015, Mrs B underwent routine screening mammography, with follow-up focused mammography and ultrasound in March 2015. The results of the additional mammographic views showed "benign very faint calcification in the 10 o'clock position of the right breast", and the ultrasound was described as normal apart from some areas of fibrocystic change. The mammogram report indicated that there was no evidence of breast cancer.

2. In September 2015, Mrs B presented to Dr C at a medical centre. Mrs B had experienced pain and swelling in her right breast over the past two to three days, although the swelling had decreased by the time of the consultation. Dr C examined Mrs B and found a 3cm cyst palpable in the right upper quadrant of the right breast.

3. Dr C reviewed Mrs B's notes and saw the report of her March 2015 mammogram. He was reassured that the palpable lump on examination was the same as the lesion described in the mammogram, as he felt that it was in the same position and was of the same nature. As her symptoms were also subsiding, Dr C interpreted the symptoms as being due to a benign cyst with a degree of mastitis.

4. Dr C explained to Mrs B that the same area had been noted and deemed not to be cancerous. He asked her to return for review if her symptoms worsened again. He did not refer her to a specialist as he assumed that the lump was benign.

5. In February 2016, Mrs B was seen by Dr D at the medical centre, with similar symptoms and concerns about the lump. Dr D told HDC that when he examined Mrs B, he could see the outline of the lump at the top of her right breast through her shirt. The lump was now harder and larger, and Dr D made an urgent referral to a specialist.

6. In April 2016, Mrs B was diagnosed with Stage 3 triple negative cancer of the right breast. Subsequently, Mrs B died.

Findings

7. Dr C was found to have breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code) for failing to refer Mrs B for further imaging of her breast lesion in the circumstances in September 2015.

8. The medical centre was not found vicariously liable for Dr C's breach of Right 4(1) of the Code.

Recommendations

9. It was recommended that Dr C provide a written letter of apology to Mrs B's family for the breach of the Code identified in this report, and provide HDC with evidence of his learnings and reflections from the Continuous Medical Education he has undertaken, and the ongoing e-learning he is undertaking, as well as any changes made to his practice as a result of this case.

Complaint and investigation

10. The Health and Disability Commissioner (HDC) received a complaint from Ms A about the services provided to her late sister, Mrs B, by Dr C and the medical centre. The following issues were identified for investigation:

- *Whether Dr C provided Mrs B with an appropriate standard of care in September 2015.*
- *Whether the medical centre provided Mrs B with an appropriate standard of care in September 2015.*

11. The parties directly involved in the investigation were:

Ms A	Complainant/consumer's sister
Dr C	Provider/general practitioner
Medical centre	Provider/general practice

12. Further information was received from Dr D, a general practitioner.

13. Expert advice was obtained from HDC's in-house clinical advisor, general practitioner Dr David Maplesden, and is included as **Appendix A**.

Information gathered during investigation

Introduction

14. Mrs B (aged 49 years at the time of events) underwent routine screening mammography in February 2015, with follow-up focused mammography and ultrasound in March 2015. There is nothing in the recorded history to suggest that she had breast symptoms at this time. The results of the additional mammographic views showed "benign very faint calcification in the 10 o'clock position of the right breast", and the ultrasound was described as normal apart from some areas of fibrocystic[1] change. The mammogram report indicated that there was no evidence of breast cancer.

15. Given the limitations on the sensitivity of radiological screening in diagnosing breast cancer, there was a standard postscript on the report encouraging Mrs B to report any new breast symptoms to her doctor.

Appointment in September 2015

16. In September 2015, Mrs B had an appointment with Dr C. At the time of events, Dr C[2] was a long-term locum at the medical centre.

[1] Characterised by the presence or development of fibrous tissue and cysts.
[2] Dr C is a registered doctor with an annual practising certificate from the Medical Council of New Zealand. He is also a member of the Royal New Zealand College of General Practitioners.

17. Dr C told HDC that Mrs B presented with pain and swelling in her right breast that had occurred over the past two to three days, although the swelling had decreased by the time of the consultation.

18. Dr C told HDC that he asked Mrs B's permission to examine her, and examined both breasts and armpits. He found a 3cm cyst palpable in the right upper quadrant of the right breast, and noted that there was no nipple discharge.

19. Dr C said that he reviewed Mrs B's notes and saw the report of her March 2015 mammogram. He was reassured that the palpable lump on examination was the same as the lesion described in the mammogram, as he felt that it was in the same position and was of the same nature. He said that as her symptoms were also subsiding, he interpreted the symptoms as being due to a benign cyst with a degree of mastitis[3] that was beginning to resolve.

20. Dr C said that he explained to Mrs B that the same area had been noted on her mammogram and deemed not to be cancerous, but as a "safety net" he asked her to come back for review if her symptoms worsened again. He said that he did not refer her to a specialist as he had assumed that the lump was benign.

Subsequent events

21. In February 2016, Mrs B was seen by Dr D at the medical centre, with similar symptoms and concerns about the lump. Dr D told HDC that he asked Mrs B questions about her family history for breast cancer and about her menstrual cycle, and read Dr C's notes.

22. Dr D told HDC that when he examined Mrs B, he could see the outline of the lump at the top of her right breast through her shirt. He identified that the lump was harder and 6x4cm in size. He said that there was not much doubt that this could be some form of breast cancer, and therefore he referred her urgently to a specialist.

23. In April 2016, Mrs B was diagnosed with Stage 3 triple negative cancer[4] of the right breast. Subsequently, Mrs B died.

Further information

Dr C

24. Dr C apologised for his decision not to refer Mrs B for further investigation in September 2015, and reflected on the reasons why he did not do so.

25. Dr C told HDC that to improve the care he provides and prevent this from happening again, he has updated his knowledge in diagnosing breast cancer by completing the Breast Cancer Foundation's Continuous Medical Education on expected examination and management. In addition, he took the opportunity to register for ongoing e-learning about

[3] Inflammation of the breast, usually caused by infection.

[4] Triple negative breast cancer is cancer that tests negative for oestrogen receptors, progesterone receptors, and excess HER2 protein, which means that the growth of the cancer is not fuelled by these factors, and therefore does not respond to medicines that target these.

clinical risk management with the Medical Protection Society, and has also discussed the events at his monthly peer group meeting. Dr C reviewed the current guidelines for the management of breast lumps.

Medical centre

26. The medical centre provided a response to HDC. It stated that the medical centre does not have its own formal policies and protocols regarding clinical examinations, documentation of consultations or referrals, and it considers that the development of comprehensive investigative and diagnostic pathway algorithms is beyond the scope of individual practices, risking "ad hoc" and incomplete pathways. The medical centre said that the HealthPathways site is accessible to all GPs, and that increasingly clinical staff have been using this to guide management in situations such as that presented to Dr C in September 2015. The medical centre noted that doctors would have been using this site in 2015, although with less familiarity and less frequency than is the case in 2019.

27. The medical centre said that all its staff have access to the DHB intranet, which opens up a large library of other online reference resources. The medical centre stated that UpToDate and HealthPathways are the most frequently accessed resources used on a regular basis — often on a daily basis — to guide clinicians on appropriate management of the clinical problems they face.

28. The medical centre advised that in cases where there remains a degree of diagnostic uncertainty despite following the online algorithms and references, all clinicians in their practice have access to, and make use of, the online e-referral system to request advice from specialists — most use this every week, and sometimes several times a day, and the specialists are responsive to their requests for advice. In addition, often clinicians discuss cases with each other at the practice.

29. The medical centre also advised that in a clinical staff meeting, staff were unanimous in their view that in future, clinical practice in a situation such as Mrs B's would be to refer to the relevant service. The medical centre said that it will encourage future locums to use group discussion with the other doctors and nurses in the practice, in addition to the online resources mentioned above. It will also encourage colleagues to use clearly defined timeframes in asking patients to return for review, when relevant.

Responses to provisional decision

Dr C

30. Dr C was given an opportunity to comment on the provisional report. He advised that he has no objections to the findings made, and accepts the proposed recommendations.

Medical centre

31. The medical centre was given an opportunity to comment on the provisional report, and advised that it had no further comment to make.

Ms A

32. Ms A was given an opportunity to comment on the "information gathered" section of the provisional report and provided a response. She reiterated her concerns about the care provided to Mrs B, and stated:

> "Whilst we cannot change the outcome we sincerely hope that the medical professionals involved in [Mrs B's] delayed diagnosis will carry on in their respective profession and hopefully learn from this experience to be able to go on and help others in the future."

33. Ms A stated that Dr C has her family's respect for apologising and taking ownership. She is pleased to read of the actions Dr C has taken to upskill his knowledge and raise awareness within the medical community. She is also pleased with the actions the medical centre has taken to ensure that its staff has access to resources.

Opinion: Dr C — breach

34. In September 2015, Mrs B presented to Dr C with pain and swelling in her right breast. Dr C examined Mrs B and found a lump in her right breast. Based on an earlier mammogram report that had found no evidence of cancer, and because her symptoms were subsiding, he determined that her symptoms were due to a benign cyst with a degree of mastitis. He explained this to Mrs B, but asked her to come back for review if her symptoms worsened again.

35. My in-house clinical advisor, Dr Maplesden, advised:

> "There were no features of the lump particularly suggestive of malignancy such as associated skin or nipple changes, or axillary changes. The nature of the lump in terms of mobility and texture is not fully described. On reviewing the mammogram report, I am not sure that 'very faint calcification at the 10 o'clock position' and 'a few areas of fibrocystic change' (position of these changes not otherwise defined) could be used as a reliable indicator that the nature of the 3cm mass detected by [Dr C] had been detected, and regarded as benign, in the imaging of six months previously. On the other hand, cysts can develop quite rapidly and change cyclically on a background of known fibrocystic disease (although [Mrs B] was menopausal with no period in the previous 12 months).
>
> While there were features of [Mrs B's] history and examination that favoured a benign cyst as the most likely diagnosis of her breast symptom, I think it was apparent [Mrs B] was experiencing a new breast symptom with a new discrete mass detected, and she should therefore have been referred for repeat breast imaging in the first instance whether or not the mass was felt to be benign …

> It is apparent [Dr C] advised [Mrs B] to return for review if her symptoms worsened and this is a mitigating factor. However, he had also reassured [Mrs B] as to the most likely benign nature of her lump which, together with the fact [Mrs B's] lump might initially have partially resolved, might have contributed to her delayed re-presentation."

36. Dr Maplesden advised that while he was unable to exclude the possibility that the lump Dr C detected was a simple cyst and that the cancer became apparent sometime after the assessment, in his view there were clear indications to refer Mrs B for further imaging of her breast lesion in September 2015, and the failure by Dr C to do this represented a moderate departure from expected practice.

37. I accept Dr Maplesden's advice. I find that by failing to refer Mrs B for further imaging of her breast lesion in September 2015 in the circumstances, Dr C failed to provide services with reasonable care and skill. Accordingly, Dr C breached Right 4(1) of the Code.[5]

Opinion: Medical centre — no breach

38. As a healthcare provider, the medical centre is responsible for providing services in accordance with the Code. In this case, I consider that the care provided did not indicate broader systems or organisational issues. The medical centre did not have its own formal policies and protocols regarding clinical examinations or documentation of consultations or referrals, and considers that the development of comprehensive investigative and diagnostic pathway algorithms is beyond the scope of individual practices, risking "ad hoc" and incomplete pathways. The medical centre has also referred to the resources available to GPs at the practice to guide management of clinical matters. I accept that the orientation and induction process for locums included adequate exposure to clinical resources that promoted appropriate clinical management. I note that Dr C had been working at the medical centre for several years at the time of these events. Therefore, I consider that the medical centre did not breach the Code directly.

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

40. I consider that the medical centre is an employing authority for the purposes of the Act. The medical centre told HDC that it employed Dr C as a locum doctor, and that he was paid for the days he worked. As set out above, I have found that Dr C breached Right 4(1) of the Code for failing to refer Mrs B for further imaging of her breast lesion in September 2015.

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

41. As noted above, appropriate steps were taken to induct and oversee Dr C's practice.[6] Accordingly, I do not find the medical centre vicariously liable for Dr C's breach of the Code.

Recommendations

42. I recommend that Dr C:

a) Provide a written letter of apology to Mrs B's family for his breach of the Code. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding.

b) Report to HDC, within three months of the date of this report, his learnings and reflections from the Continuous Medical Education he undertook with the Breast Cancer Foundation, and the ongoing e-learning he is undertaking with the Medical Protection Society, as well as any changes made to his practice as a result of this case.

Follow-up actions

43. 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 it will be advised of Dr C's name.

44. 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 (HQSC) and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

[6] Dr C was under appropriate supervision with no competency issues identified by the supervisors.

Appendix A: Independent advice to the Commissioner

The following expert advice was obtained from HDC's in-house clinical advisor, Dr David Maplesden:

"1. Thank you for providing this file for advice. To the best of my knowledge I have no conflict of interest in providing this advice. I have reviewed the available information: complaint from [Ms A], sister of [Mrs B] (dec); response from [Dr C]; response from [Dr D]; GP notes [the medical centre].

2. [Ms A] complains on behalf of the [whānau] regarding delays in the diagnosis of breast cancer in her late sister, [Mrs B] ([Year of birth]). [Ms A] states that [Mrs B] underwent a screening mammogram in February 2015 and a possible right breast abnormality was detected. Further imaging procedures were performed in March 2015 with the conclusion that there was no evidence of breast cancer. Six months later (September 2015) [Mrs B] developed pain and swelling in her right breast and was seen by [Dr C] at [the medical centre]. [Dr C] examined [Mrs B's] breast and reassured her she had a benign cyst with possible infection. [Ms A] continued to experience breast symptoms and in February 2016 she saw [Dr D] at [the medical centre]. [Dr D] detected a large mass in [Mrs B's] right breast and referred her for urgent surgical review. [Mrs B] was diagnosed with stage 3 breast cancer and despite treatment she died from her disease. [Ms A] is concerned that [Dr C] inappropriately relied on breast screening results that were six months old, and that he should have referred [Mrs B] for further investigation in September 2015. [Ms A] feels that earlier diagnosis and treatment of her sister's breast cancer may have led to a better outcome.

3. [Dr C] responded to [Ms A's] concerns noting he was working as a locum [at the medical centre] when he consulted with [Mrs B] in September 2015. He states [Mrs B] presented a history of two or three days of pain and swelling of the breast which had begun to subside by the time of the presentation. There was no nipple discharge. There was no family history of early onset breast cancer in a first degree relative. After seeking consent and offering a chaperone (declined) [Dr C] states he examined both of [Mrs B's] breasts and axillae. He *found a cyst of about 3cm palpable in the right upper quadrant of the right breast.* [Dr C] reviewed the breast screening results from March 2015 (see below) and felt the lesion he had palpated was consistent in position and nature with the benign changes described in the report. He felt the symptom flare was related to infection which was beginning to resolve and reassured [Mrs B] but *tried to build in a 'safety net' by asking her to come back for a review if her symptoms would worsen again.* [Dr C] notes he has reflected on his decision not to further investigate [Mrs B] in September 2015 and has undergone further education in regard to diagnosis of breast cancer. He is confident that had [Mrs B's] symptoms and findings in September 2015 been the same as noted by [Dr D] in February 2016 he would have referred [Mrs B] immediately. [Dr D] notes that when he saw [Mrs B] in February 2016 she gave a history of a lump that had been present for several months and had grown over that time and was tender. The lump was very firm and measured 6 x 4cm. The

lump had apparently changed dramatically since the review by [Dr C] and was highly suggestive of a breast cancer, hence the urgent referral.

4. Clinical notes review

(i) Breastscreen Aotearoa report [from] March 2015 (copy to [the medical centre] and [Mrs B]) includes: [Mrs B] *was recalled to assessment for calcification in the upper outer quadrant of the right breast … At assessment additional mammographic views showed benign very faint calcification at the 10 o'clock position of the right breast and ultrasound was normal apart from a few areas of fibrocystic change. [Mrs B] was therefore assessed as having* ***no evidence of breast cancer****. This result has been reviewed and agreed by the assessment team. She will be recalled for a further screening mammogram in two years' time, if she is still eligible.* There is a standard postscript addressed to the patient which includes: *Mammography can miss cancers. It is therefore important to see your doctor promptly if you notice any changes in your breasts.*

(ii) [Dr C's] notes [from] September 2015 read:

S/ pain in R breast on the weekend, it was swollen too. Actually came down already. Wonders if this is worrysome.

0/ declined chaperone: L mamma nad. axilla nad.

R mamma cyst about 3cm palpable in RUQ, nipple nad. axilla nad. No redness or swelling h.t.

mammogram plus review in March: benign lesion on same spot.

P/ explained benign cyst, may have had a degree of mastitis. if worsens r/v for now exp.

(iii) [Dr D's] notes [from] February 2016 read:

Still has a lump in R breast, periods have stopped in 9/2015

FH grandmother had breast cancer late 60 age

Now ongoing discomfort and swelling is visible, tender under R armpit

02 sats 97 hr 71 good BP 110/80

R breast harder swelling 6x4 cm (tender) upper side R breast, visible from the outside

no retraction of skin/ nipple area NAD rest of breast N

L breast NAD

E: quite a big swelling upper part R breast

P: referred urgently and FU discussed with nurse.

needs urgent app

has no tel reception at home but goes into town for messages.

she will contact if she has not heard anything in 1 wk

(iv) [Dr D] sent an urgent referral to [the DHB's] surgical service (referral viewed and of good quality) and [Mrs B] was reviewed by a surgeon [in] April 2016. Clinic report includes: [Mrs B] *has been aware of a lump in the right breast for 6 months. The lump started fairly small and then seemed to disappear at one stage. Since then it has increased in size again and has become progressively more painful. She has not noticed any nipple discharge or puckering of the breast skin or any redness overlying the tumour … On examination there is a 6cm visible and palpable lump in the 12 o'clock position of the right breast above the nipple. No other masses are palpable in either breast. There is some thickening in the axilla on the right* … Subsequent imaging (ultrasound) the same day confirmed the mass to be suspicious, with a further possibly suspicious mass demonstrated in the axillary tail and abnormal right axillary lymph nodes. Core biopsies were performed. The report concluded: *I suspect she has an aggressive breast carcinoma and I have asked for her results to be discussed at our multidisciplinary meeting next week.*

(v) Biopsies revealed a poorly differentiated invasive ductal carcinoma which was negative for oestrogen, progesterone and HER-2 receptors. Additional imaging showed no confirmed distant metastatic disease. Neo-adjuvant chemotherapy was recommended and [Mrs B] commenced this on 27 April 2016. She also accessed complementary therapies concurrently. [Mrs B] did not tolerate chemotherapy well and chose to stop this after two cycles despite obvious reduction in the size of her breast and axillary masses. [Mrs B] continued with her complementary therapy and took some time to decide whether or not she wished to proceed with surgery. On 15 November 2016 she underwent right mastectomy and immediate implant reconstruction together with right axillary clearance. At surgery the tumour was noted to have progressed since cessation of chemotherapy and [Mrs B] was advised to consider post-operative chemoradiotherapy to reduce the high risk of relapse. She declined chemotherapy and was referred to [the public hospital] for radiotherapy. When reviewed in … 2017 prior to commencement of radiotherapy, [Mrs B] was noted to have skin changes suggestive of local recurrence of her cancer, subsequently confirmed on biopsies. She underwent further surgery to the breast … ([in the public hospital] — completion mastectomy and removal of implant) and extensive cancer recurrence was found throughout the breast. Further surgery (re-excision of surgical margins) was undertaken at [the public hospital] … [A] CT scan … revealed new metastatic disease in the lungs and liver. [Mrs B] elected to continue with complementary therapy only and sadly succumbed to her disease some months later.

5. As a reference for expected practice I have used the Cancer Australia publication 'The investigation of a new breast symptom: a guide for General Practitioners (February 2006)' presented in Appendix 1 as a management algorithm. I believe the algorithm accurately represents expected and familiar practice in New Zealand in 2015. The guidance was updated in 2017 …

6. Comments

(i) [Mrs B] underwent routine screening mammography in February 2015 with follow-up focused mammography and ultrasound in March 2015. There is nothing in the recorded history to suggest she had breast symptoms, or was aware of any breast lump, at this time. The conclusion in March 2015 was that imaging was consistent with benign breast disease (fibrocystic disease) and there was no radiological evidence of malignancy. Because there are limitations to the sensitivity of radiological screening in diagnosing breast cancer[1], [Mrs B] was encouraged to report any new breast symptom to her GP.

(ii) [Mrs B] reported a new symptom (recent onset breast pain and swelling) to [Dr C] in September 2015. The symptoms were apparently resolving but [Dr C] detected a discrete 3cm lump in [Mrs B's] right breast which was felt to be cystic in nature. He felt the lump corresponded in position to areas described in the ultrasound report as representing fibrocystic change. There were no features of the lump particularly suggestive of malignancy such as associated skin or nipple changes, or axillary changes. The nature of the lump in terms of mobility and texture is not fully described. On reviewing the mammogram report, I am not sure that 'very faint calcification at the 10 o'clock position' and 'a few areas of fibrocystic change' (position of these changes not otherwise defined) could be used as a reliable indicator that the nature of the 3cm mass detected by [Dr C] had been detected, and regarded as benign, in the imaging of six months previously. On the other hand, cysts can develop quite rapidly and change cyclically on a background of known fibrocystic disease (although [Mrs B] was menopausal with no period in the previous 12 months).

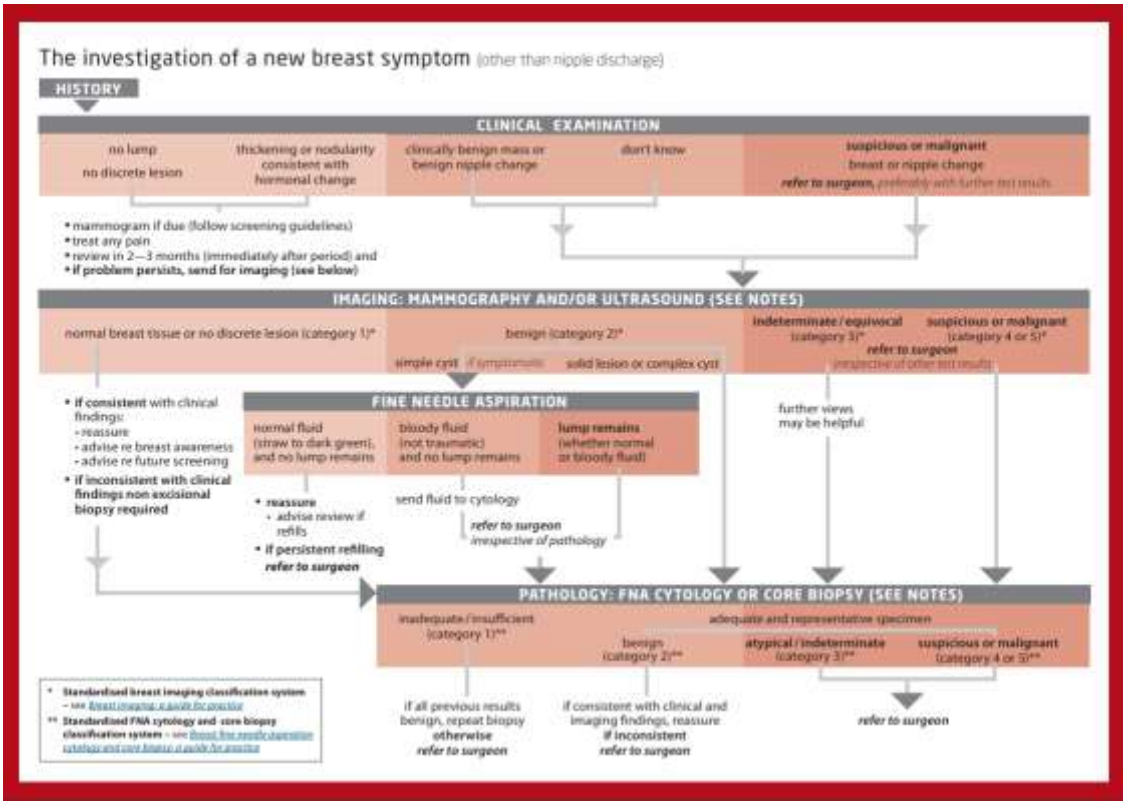
(iii) While there were features of [Mrs B's] history and examination that favoured a benign cyst as the most likely diagnosis of her breast symptom, I think it was apparent [Mrs B] was experiencing a new breast symptom with a new discrete mass detected, and she should therefore have been referred for repeat breast imaging in the first instance whether or not the mass was felt to be benign. I cannot predict whether such imaging would have confirmed the presence of a simple cyst (which it might have been reasonable to manage without further intervention if it had become asymptomatic, as per the cited guidance) or whether concerns would have been raised about the nature of the lesion making referral for biopsy (the third part of the 'triple test') mandatory. It is apparent [Dr C] advised [Mrs B] to return for review if her symptoms worsened and this is a mitigating factor. However, he had also reassured [Mrs B] as to the most likely benign nature of her lump which, together with the fact

[1] https://www.cancer.org/cancer/breast-cancer/screening-tests-and-early-detection/mammograms/limitations-of-mammograms.html Accessed 7 June 2018

[Mrs B's] lump might initially have partially resolved (see section 4(iv)), might have contributed to her delayed re-presentation.

(iv) The history presented to [Dr D] in February 2016, and his clinical findings, were somewhat different to [Mrs B's] presentation in September 2015 and were very suggestive of breast malignancy. [Dr D] managed [Mrs B] in accordance with expected practice. [Mrs B's] malignancy was particularly aggressive and noting the history that the lump detected by [Dr C] might have disappeared at some stage (section 4(iv)), I am unable to exclude the possibility that the lump he detected was a simple cyst and that the cancer became apparent some time after his assessment of [Mrs B]. Nevertheless, I believe there were clear indications to refer [Mrs B] for further imaging of her breast lesion in September 2015 and the failure by [Dr C] to do this represents a moderate departure from expected practice. The mitigating factors that have been considered are: the relatively recent breast imaging including focused mammography and ultrasound leading to a benign diagnosis; the nature of the breast lesion apparently being consistent with a simple cyst, possibly infected but resolving without treatment; the palpable lesion perceived as being in an area of known fibrocystic change (although this is debatable); safety-netting advice was provided."

Appendix 1. From: Cancer Australia — The investigation of a new breast symptom — a guide for General Practitioners (February 2006 version)[2]



[2] https://canceraustralia.gov.au/sites/default/files/publications/ibs-investigation-of-new-breast-symptoms_50ac43dbc9a16.pdf Accessed 7 June 2018