General Practitioner, Dr B
Medical Centre

A Report by the
Health and Disability Commissioner

(Case 19HDC00988)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report concerns the care provided to a woman by a general practitioner (GP) and a medical centre in 2015 when the woman presented with left breast concerns and unilateral blood-stained nipple discharge (a "red flag" symptom). It highlights the importance of GPs thoroughly investigating red flag symptoms, including referring to specialists as required, to ensure that opportunities for early diagnosis and treatment of breast cancer are not missed. Three weeks after the woman's initial presentation, she had an ultrasound scan for further investigation of her symptoms. A practice nurse told the woman that the scan results were "fine" with no follow-up required. Irrespective of the scan outcome, the woman should have been referred to a breast specialist because of the red flag symptom, but this did not occur. About nine months after receiving the scan result, a biopsy of the woman's left breast confirmed a diagnosis of breast cancer. Sadly, despite active treatment, the woman passed away in 2019.

2. Following these events, the medical centre instituted a system of notifying patients directly of investigation results by electronic messages on their patient portal, rather than via the practice nurse team. The GP anticipates that when patients receive health messages in writing via their portal, they will have more opportunity to re-read and take in the messages. The medical centre further stated that as a result of this incident, it will be ensuring a more robust safety-netting and follow-up process for high-risk patients.

Findings

3. The Commissioner found that the GP failed to provide services with reasonable care and skill, and breached Right 4(1) of the Code. The Commissioner was critical that the GP did not refer the woman to a breast surgeon after her ultrasound scan, as required for a red flag symptom of unilateral blood-stained nipple discharge. The Commissioner considered that the omission was a missed opportunity to diagnose and treat the woman's cancer at an earlier stage.

4. The medical centre was not found in breach of the Code.

Recommendations

5. The Commissioner recommended that the medical centre conduct an audit of 10 randomly selected patients with a coded diagnosis of a breast symptom in the past year to ensure that the care undertaken is consistent with current guidance, and provide evidence of the steps it has taken to ensure a more robust safety-netting and follow-up process for high-risk patients. The Commissioner also recommended that the GP provide a written apology to the woman's husband.

Complaint and investigation

6. The Health and Disability Commissioner (HDC) received a complaint from Mr A about the services provided to his wife, Mrs A, by Dr B at the medical centre. The following issues were identified for investigation:

- *Whether Dr B provided Mrs A with an appropriate standard of care in Month1[1] and Month2 2015 (inclusive).*
- *Whether the medical centre provided Mrs A with an appropriate standard of care in Month1 and Month2 2015 (inclusive).*

7. The parties directly involved in the investigation were:

Mr A	Husband of consumer
Medical centre	Group provider
Dr B	Provider/general practitioner (GP)

8. Also mentioned in this report:

RN C	Registered nurse

9. In-house clinical advice was obtained from GP Dr David Maplesden (Appendix A).

Information gathered during investigation

Introduction

10. This report discusses the care provided to Mrs A (in her twenties at the time of events) after she presented to GP Dr B at the medical centre about left breast concerns in Month1. Mrs A did not have a family history of breast cancer. About nine months after the medical centre told Mrs A that an initial ultrasound scan of the breast was normal, Mrs A was diagnosed with breast cancer. Sadly, she died in 2019.

11. At the time of these events, Dr B was a director of the medical centre.

12. Mrs A had been a patient at the medical centre since 2012, and her first consultation with Dr B was on 16 Month1.

Consultation — 16 Month1

13. On 16 Month1, Mrs A presented to the medical centre with concerns about her left breast, and was seen by Dr B. Mr A (Mrs A's husband) told HDC that Mrs A had finished breastfeeding their first child six months prior to the consultation, and that her left breast symptoms at that stage included:

[1] Relevant months are referred to as Months 1–2 to protect privacy.

"1) blood coming from the nipple of the breast on a daily basis (she had to put folded up toilet paper in her bra as to not get blood on her shirts).

2) a change in size of the breast, a full cup size

3) a firming or thickening of the breast."

14. Dr B told HDC that this was the first time Mrs A had presented with breast symptoms. Dr B stated that Mrs A had experienced occasional milk leakage from the right breast and "some watery or blood stained fluid from the left breast" since she had stopped breastfeeding six months previously. Dr B said that Mrs A was otherwise well and did not have a fever or "other constitutional symptoms".

15. Dr B documented in the clinical notes:

"History: Stopped feeding 6/12 ago

some milk occasionally from [right]

[Left] side — larger after [breast] feeding (a whole cup size) leaks serous[2] or haemoserous[3] fluid daily — small amount — 4 weeks

no [family history]

no changes in texture + well"

16. On examination, Dr B noted "nil" concerns with Mrs A's right breast but that the left breast was "larger, firmer and lobes individually far firmer in texture". Dr B further noted that Mrs A's nipples were healthy and she did not have enlarged lymph nodes in the armpits or any evidence of mastitis.[4]

17. Dr B recorded a plan to order a test to check Mrs A's prolactin[5] level, and an ultrasound diagnostic breast image (DBI) at the public hospital to check for any other pathology. Both tests were requested the same day.

18. Mrs A's prolactin result came back that day and was within the normal range.[6] Dr B stated that this result helped to exclude a hormonal cause for the breast discharge. Mrs A was informed of the prolactin result on 31 Month1.

DBI ultrasound

19. Mrs A's clinical notes record that on 28 Month1 Mrs A messaged the medical centre to say that she would like to pay privately for an earlier ultrasound investigation at a radiology

[2] Relating to or resembling serum (the clear yellowish fluid that remains from blood plasma after the blood has clotted).
[3] Thin, watery, pink-coloured or blood-stained fluid composed of blood and serum.
[4] Inflammation of the breast.
[5] In relation to prolactin, Dr B stated that it is "a hormone which if abnormally high is linked to lactation (discharge of milk from the breast) in the absence of breast feeding".
[6] The result was 102. The normal range is 50–550.

service, and that she was aware of the cost this would involve. Dr B told HDC that as a result of this, Mrs A's DBI request at the public hospital was then cancelled.

20. The following day, the radiology service informed the medical centre that Mrs A had changed her mind about the private DBI and wanted to go back to the public waiting list. The medical centre re-sent the DBI request to the public hospital the same day.

21. On 7 Month2, a radiologist performed Mrs A's DBI ultrasound scan at the public hospital, and reported it the same day. The report stated that the indication for the scan was "intermittent spontaneous blood stained nipple discharge" since the cessation of breastfeeding six months previously. The radiologist recorded his findings as follows:

> "FINDINGS: Ultrasound of the left breast centrally demonstrated mildly prominent central ducts consistent with post lactational state. No ductal abnormality seen.
>
> No abnormal mass lesion apparent.
>
> The left upper inner quadrant was also scanned as [Mrs A] mentioned fullness in this region.
>
> Mildly prominent generalised fibroglandular tissue[7] is apparent. No discrete mass lesion seen.
>
> COMMENT: Post lactational changes left breast. No other abnormality seen. Management on clinical ground suggested."

22. Dr B told HDC that the radiologist's report "appeared highly reassuring", and that in accordance with the medical centre's standard process,[8] she sent a task via the computer practice management system (CPMS)[9] to Registered Nurse (RN) C, to telephone Mrs A and inform her of the image results, which appeared satisfactory.

23. Dr B stated:

> "In this setting where a breast image result is very satisfactory but contains the statement 'manage on clinical grounds' my usual practice is to inform the patient this is a very reassuring result but to add a safety net to be reviewed in the context of any further concern around symptoms from the breast, and in particular new symptoms or further changes."

24. Dr B further stated that some of the factors that led her to "weight [Mrs A's] presentation more favourably and seeking to review her clinically with persistent symptoms in due course" were:

[7] Non-fatty tissue in the breast. Dense breasts have a higher proportion of fibroglandular tissue to fatty tissue, and dense breast tissue is linked to an increased risk of breast cancer.
[8] The medical centre's policy for "Managing patients test results and correspondence" stated: "As a means of tracking results of significant concern, the Doctors send themselves tasks about patients of concern so that they can complete an action once the correspondence is in. A task can be sent to the nurse to chase a patient that may not have completed an investigation or to assist in tracking an investigation."
[9] At the time of these events, the CPMS in use at the medical centre was "Houston VIP".

a) Mrs A's nipple leakage was "from both breasts, as opposed to true unilateral leakage". Dr B told HDC that this bilateral activity reduces the chances of a malignancy finding and increases the chance of a physiological cause.

b) Mrs A's presentation could not be classified as "true spontaneous discharge" from the nipples because the bilateral breast leakage had been ongoing since Mrs A stopped breastfeeding.

c) Mrs A did not have a lump in her breast, which pregnancy-related breast cancers usually present with.

d) The DBI report was "overwhelmingly clear and reassuring, showing marked post-lactational changes, even after some months of cessation of breast feeding".

e) The blood-staining had been occurring for a "far shorter period", and her management plan allowed for a review and re-evaluation in the setting of ongoing symptoms or concerns.

f) There would have been a likelihood of any referral to the DHB being declined following Mrs A's negative DBI result. Dr B stated: "A DBI check is a usually reliable 'sieve' as to whether further investigation is warranted for the majority of breast issues, in particular in lower risk cases."

25. The clinical notes record that on 12 Month2, RN C telephoned Mrs A and informed her that — "as per [Dr B's] notes" — her DBI ultrasound was "fine", and RN C advised Mrs A to see the GP for review in two months' time if she had any concerns. Mr A told HDC that the nurse told Mrs A that "everything was fine with the left breast, no cancer or anything else to worry about".

26. Although the task Dr B sent to RN C is not documented on the CPMS, Dr B told HDC that the "as per notes" wording recorded by RN C would refer to the task she sent. Dr B stated that she may have written other guidance for RN C within that task, but is unable to say for certain what, if any, additional guidance may have been included. Dr B said that she is reasonably sure that the practice nurse followed the instructions noted in the task for informing Mrs A of her scan result, and that the nurse stated a "time limited interval to re-consider if matters remained unsatisfactory". The medical centre told HDC that RN C now has no recollection of the wording of Dr B's task or of her discussion with Mrs A that day.

Subsequent events

27. On 26 Month2, the medical centre's clinical record shows that Mrs A was about six weeks pregnant with her second child. Dr B said that Mrs A did not attend the medical centre throughout the pregnancy, but that the medical centre did receive copies of some of Mrs A's antenatal tests and letters.

28. Dr B next saw Mrs A at the medical centre two days after Mrs A had given birth. Dr B documented that an area of Mrs A's breast was "rock hard, tender and starting to flush". Dr B told HDC that although these symptoms usually indicate mastitis, "there was no fever so it was not absolutely classic". Dr B prescribed Mrs A antibiotics for possible mastitis, and

recorded that a scan should be considered if the antibiotics showed no signs of resolving the symptoms.

29. A few days later, a practice nurse at the medical centre documented that Mrs A's mother called and advised that the mass in Mrs A's breast was still present, and that Mrs A had not taken the antibiotics because there was no evidence of mastitis. Mrs A's mother requested another appointment for Mrs A to have a breast examination.

30. On the same day, Dr B reviewed Mrs A and, following examination, sent an urgent request for an ultrasound scan of Mrs A's breast. The scan was performed, followed by an MRI the next day. A biopsy of Mrs A's left breast confirmed a diagnosis of breast cancer.

31. Sadly, despite active treatment, Mrs A passed away in 2019.

Further information

Complainant

32. Mr A told HDC that his main complaint was how the medical centre informed Mrs A of the ultrasound scan results. He stated:

> "Whether or not the [medical centre staff member] said to come back and see the GP if there were any more concerns or not is really irrelevant. … These conversations need to be run differently. Either the patient needs to come in and have a face to face conversation or the phone conversation needs to be a lot more thorough."

33. Mr A stated that Mrs A needed to be told that "the scan had come back as clear at this point but that the symptoms were not normal" and that she needed to remain vigilant regarding any further changes.

34. Mr A told HDC that after Mrs A became pregnant with her second child, many of the breast changes from that point on were seen as being related to her pregnancy.

Dr B

35. Dr B told HDC that Mr A raised "some very pertinent issues in his letter about how much patients take in when they are hearing messages from health professionals". Dr B stated:

> "I do take on board the feedback resulting from [Mrs A's] case, that important safety netting advice in the context of a reassuring test could be strengthened or emphasised more."

36. Dr B told HDC that her usual practice in relation to breast care is to assure patients that it is good to get checked for any breast symptoms, and to advise that all symptoms are taken seriously until there is enough information to be reassured adequately.

37. Dr B told HDC: "I do fully appreciate the 'red flag' nature of blood-stained nipple discharge, and in any case of *spontaneous, unilateral* blood-stained nipple discharge I would discuss the case with the local breast surgeon as a minimum." Dr B stated that her actions, which

included arranging an urgent diagnostic breast image, illustrated her appreciation of the "red flag" nature of Mrs A's presentation.

38. Dr B said that while at the time she felt that there were a number of mitigating factors that led her to take a more "watchful approach", in hindsight the weighting she gave to Mrs A's presentation was misjudged. Dr B stated that her practice has changed since this case, and told HDC: "I find it hard to imagine any scenario in the future in which I would feel comfortable to reassure any case of nipple discharge, let alone blood-stained discharge."

39. In relation to her personal response to Mrs A's case, Dr B told HDC:

> "[I]t would be inadequate of any further response from me not to express my emotional view. In fact, this dominates my mind far more than anything cognitive, as like other GP's I came to medicine to do a good job looking after others. … I feel desperately saddened for [Mr A], her [children], her mum and her wider family, for their grief. … But I can learn from my mistakes, and I have, and what's more I endeavour to pass my learnings on to the younger doctors I supervise."

Medical centre

40. The medical centre told HDC that it has considered these events carefully and taken care to see whether there are lessons it can learn or policies that need to change as a result of what occurred. The medical centre stated:

> "After taking into consideration all of the facts within the complaint as well as the feedback from [Mr A] it is difficult to see how, with current best practice anyone could have ensured a more positive outcome with the particular convergence of circumstances in this case. Having carefully studied this case & given the same situation arising at that time we may not have done anything differently to the actions taken by [Dr B]."

Changes to practice since these events

41. Dr B stated:

> "At the time of this case, I had [a] responsibility for teaching, mentoring and coaching doctors coming into the GP profession. … With this responsibility, many aspects of my practice have been re-scrutinised through this teaching lens, including tightening up safety netting strategies, and ensuring the young doctors I mentor have a very clear appreciation of the importance of this aspect to GP consultations. I teach them to be very specific — both in the 'what' and in the 'when' of the safety netting advice they give, and in so doing I seek to model this myself. It is a source of much regret to me that this was not done more effectively by me for [Mrs A]."

42. Since these events, the medical centre has transitioned to the new "My Practice" CPMS. Dr B noted that the old CPMS did not automatically stamp the record with the wording of tasks, and that the new CPMS captures all comments in tasks. In addition, Dr B told HDC:

> "We also now notify patients directly of results and other information by electronic messages on their portal, when the patient is subscribed to that system, rather than via our practice nurse team."

43. Dr B said that she hopes that when patients receive health messages via their portal and those messages are written down, "they might have more opportunity to re-read and take in such messages", and also be able to review the practice notes from their consultations and other entries in the record.

44. The medical centre told HDC that it will now discuss all medical incidents and significant events at director level, in addition to the discussions that take place between clinicians. It further stated that as a result of this incident, it will be ensuring a more robust safety-netting process and planned follow-up for high-risk patients.

Responses to provisional opinion

45. Mr A, the medical centre, and Dr B were given the opportunity to respond to relevant sections of my provisional opinion.

46. The medical centre and Dr B told HDC that they accept the recommendations in this report, and that they had no further comments to make.

47. In response to my provisional opinion, Mr A told HDC:

> "The family and I appreciate the ownership that [Dr B] seems to now have taken in regards to this case. We appreciate her self-reflection and that she has learned from these events and become a better doctor. We hope, more than anything, that this does not happen again to someone else. Doctors are people too and oversights can be made and that's just life."

Opinion: Dr B — breach

48. As discussed above, Mrs A presented to Dr B in Month1 with occasional milk leakage in the right breast for the last six months and some "blood stained fluid from the left breast" in the four weeks prior to the consultation. Dr B obtained a prolactin result, which was normal, and also ordered a DBI ultrasound scan to check for pathology in Mrs A's left breast.

49. Dr B told HDC that she understood the "red flag" nature of blood-stained nipple discharge, and that if such discharge was spontaneous and unilateral she would discuss the case with a breast surgeon at a minimum. However, Dr B stated that in her view, Mrs A's nipple leakage was not "true unilateral leakage" because there was leakage from both breasts, and also that Mrs A's presentation could not be classified as "true spontaneous discharge" from the nipples because the bilateral breast leakage had been ongoing since Mrs A had stopped breastfeeding.

50. Dr B told HDC that she believes that the district health board would have declined a referral of Mrs A to the breast service immediately following the negative breast imaging results. Dr B said that as the results of the DBI scan were reassuring, and because Mrs A did not have a lump in her breast, she sent a task to the practice nurse, who then told Mrs A that the scan results were "fine" and to see Dr B for review in two months' time if she had any concerns.

51. My in-house clinical advisor, GP Dr David Maplesden, said that when considering this case, he took into consideration the potential mitigating factors of Mrs A's young age, reassuring clinical examination/imaging results, and the safety-netting advice provided.

52. Dr Maplesden advised that although the history of left nipple discharge provided by Mr A in his complaint "emphasises somewhat more the bloody nature of the discharge than the history recorded by [Dr B]", there is no dispute that Mrs A had developed unilateral serosanguinous[10] nipple discharge of the left breast, even if this was "superimposed on possible bilateral physiological discharge". Dr Maplesden advised that blood-stained nipple discharge, particularly if unilateral, is a "red flag" for possible malignancy. He said that all of the guidance he reviewed on breast symptom management supported this view.[11]

53. I note that on one hand Dr B has said that she recognised the potential red flag nature of blood-stained nipple discharge, but she has also submitted that the discharge was not "true" unilateral or spontaneous leakage. There is no in-between ground in such a matter — either the red flag of bloody and unilateral nipple discharge was present, or it was not. It is clear from Mr A's complaint, the clinical records, and Dr B's responses that in Mrs A's case, only the left breast had blood-stained nipple discharge. Therefore I do not accept Dr B's submission that because Mrs A also had a history of milk leakage from her right breast, the bloody discharge from her left nipple was not "true unilateral leakage". I accept my expert's advice that the unilateral blood-stained nipple discharge was a red flag and should have been treated as such.

54. Dr Maplesden advised that given Mrs A had a history of spontaneous serosanguinous discharge from her left nipple only, accepted management would have been to examine her breast, refer her for diagnostic imaging, then refer for surgical review irrespective of the results of the breast examination and imaging results.

55. Dr Maplesden further advised that in this case, Mrs A's DBI ultrasound was reassuringly normal, and that given her young age and absence of any breast cancer risk factors, the chances of Mrs A having an underlying malignancy were low. Dr Maplesden said that to

[10] See footnote 2 regarding "haemoserous" (haemoserous is synonymous with serosanguinous).

[11] Dr Maplesden cited various sources to support this advice (see Appendix A), including the literature review "Nipple discharge" (Goshan M, June 2019). This states: "Referral for surgical evaluation and biopsy is warranted for evaluation and management of bloody nipple discharge … Bloody nipple discharge, and abnormal mammogram or breast ultrasound, or the presence of a breast mass on physical examination requires evaluation by a surgeon." Dr Maplesden further cited the "New Zealand Guidelines Group" (2009) publication regarding guidelines for investigation and referral in the setting of suspected cancer in primary care. This states: "A person presenting with spontaneous unilateral bloody nipple discharge should be referred urgently to a specialist."

the point of receipt of the ultrasound results, Dr B's management of Mrs A was consistent with accepted practice.

56. However, Dr Maplesden noted that notwithstanding the reassuringly normal DBI ultrasound, accepted practice would have been to refer Mrs A promptly for review by a breast surgeon in light of her unexplained unilateral bloody nipple discharge. Dr Maplesden considered that Dr B departed from accepted practice by not doing so. In relation to Dr B's submission that any referral to the DHB's breast service immediately following the negative breast imaging results would likely have been declined, Dr Maplesden advised:

> "I challenge this statement and note that unilateral serosanguinous nipple discharge is listed as a red flag for malignancy in the relevant [regional] DHB Health Pathway[12] with [high suspicion of cancer] referral recommended if any red flag is present."

57. In relation to Dr B's decision to reassure Mrs A and suggest that she return for review only if she had concerns, and the telephone call in which Mrs A was informed of her examination results, Dr Maplesden advised:

> "It is evident in hindsight that [Mrs A] perceived the information provided by the practice nurse as meaning she did not need to be concerned about ongoing bleeding from the nipple or further change in the shape of her breast. I think this emphasizes the importance of providing explicit information about what might or might not be a clinical concern in the context described."

58. Although a number of factors may have reduced Mrs A's risk of malignancy, the inescapable fact is that Dr B should have referred Mrs A to a breast surgeon after her DBI scan regardless of the scan results, because of the unilateral blood-stained nipple discharge, yet she did not. The failure to do so led to Mrs A being informed that her results were fine and that no scheduled follow-up was required, and placed the onus on Mrs A to follow up if she had further concerns, which was inadequate advice in the circumstances. I do not accept Dr B's view that any referral to the local breast service in these circumstances would likely have been declined, nor does such a view justify not carrying out her obligation to attempt such a referral in light of the red flag concerns. I am critical of Dr B for not referring Mrs A to a breast specialist following receipt of her DBI results. As a consequence, opportunities were lost to diagnose and treat Mrs A's breast cancer at an earlier stage.

59. Accordingly, I find that Dr B failed to provide services to Mrs A with reasonable care and skill, and breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[13]

[12] Dr Maplesden noted that even though this guidance may not have been available to Dr B at the time of these events, the identification of unilateral serosanguinous nipple discharge as a red flag for potential breast malignancy was not a new concept, and he would regard it as a basic part of GP knowledge.
[13] Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."

60. I acknowledge Dr B's comment that, in hindsight, her management of Mrs A's presentation was misjudged, and that she has reflected considerably on these events and on the importance of providing clear and effective safety-netting advice. I further note Dr B's comment that she now notifies patients of their results directly by electronic message on their patient portal, rather than via a practice nurse, and that she hopes that as a result, patients will have more opportunity to read and understand such messages.

Opinion: Medical centre — other comment

61. As a healthcare provider, the medical centre is responsible for providing services in accordance with the Code. Dr B was employed by the medical centre at the time of these events, as well as being a director of the company.

62. My in-house clinical advisor, GP Dr David Maplesden, advised that at the time of these events the medical centre had accepted processes in place in relation to the handling of investigation results and clinical correspondence. He noted that as relevant pathways were available to staff and there were no competency issues identified with Dr B before (or after) these events, there was little more the medical centre could have done as an organisation to alter what occurred.

63. I accept this advice. While I have found that Dr B breached the Code, in this case I consider that the errors that occurred did not indicate broader systems or organisational issues at the medical centre. Therefore, I consider that the medical centre did not breach the Code directly.

64. 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.

65. The medical centre employed Dr B at the time of these events. As noted above, I have already found that the medical centre had appropriate systems in place for the management of investigation results and clinical correspondence at the time of these events. In addition, as the medical centre had not previously identified any competency issues with Dr B's practice, I do not consider that it could have reasonably done anything more as an employing authority to prevent these events from occurring. Accordingly, I do not find the medical centre vicariously liable for Dr B's breach of the Code.

Further comment

66. I note the medical centre's comment that "given the same situation arising at that time", it may not have done anything differently to the actions taken by Dr B. This is of some concern, as I consider that it is undeniable that Mrs A's red flag symptom required prompt

referral to a breast specialist for further evaluation without unnecessary delay. It is important that the medical centre learn the necessary lessons from this case, and that process begins with acknowledging where things went wrong.

67. I acknowledge the steps the medical centre has taken since these events, including discussion of all significant events at director level, and ensuring a more robust safety-netting process and planned follow-up for high-risk patients. I consider these steps appropriate.

Recommendations

68. In my provisional opinion it was recommended that Dr B provide a written apology to Mr A for her breach of the Code. In her response to my provisional opinion, Dr B sent the apology to HDC, and this has been forwarded to Mr A.

69. I recommend that the medical centre:

a) Conduct an audit of 10 randomly selected patients with a coded diagnosis of a breast symptom (such as a breast lump, breast pain, or nipple discharge) in the past 12 months to ensure that the management undertaken is consistent with current guidance. The medical centre is to report the audit results to HDC within three months of the date of this report.

b) Provide evidence, within three months of the date of this report, of any discussions at director level in relation to significant events that have occurred in the last six months, and the outcome of any such discussions.

c) Provide evidence, within three months of the date of this report, of the steps it has taken to ensure a more robust safety-netting process and appropriate follow-up for high-risk patients.

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 the Royal NZ College of General Practitioners, and they will be advised of Dr B's name.

71. 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 placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: In-house advice to the Commissioner

The following expert advice was obtained from GP Dr David Maplesden:

"1. Thank you for the request that I provide clinical advice in relation to the complaint from [Mr A] about the care provided to his late wife, [Mrs A], by [Dr B] of [the medical centre]. In preparing the advice on this case to the best of my knowledge I have no personal or professional conflict of interest. I agree to follow the Commissioner's Guidelines for Independent Advisors. I have reviewed the information on file: complaint from [Mr A]; response from [Dr B]; GP notes [the medical centre] which include specialist reports from [three district health boards].

2. [Mr A] states his wife [Mrs A] attended [Dr B] at [the medical centre] on 16 [Month1] with left breast symptoms. At the time [Mrs A] had completed breast feeding her first child about six months previously and was planning to get pregnant again. [Mr A] lists [Mrs A's] symptoms as: *blood coming from the nipple of the breast on a daily basis (she had to put folded up toilet paper in her bra so as not to get blood on her shirts); a change in size of the breast — a full cup size; a firming or thickening of the breast.* After an assessment by [Dr B], [Mrs A] was referred for breast ultrasound (performed privately). This was performed in the next couple of weeks and on 12 [Month2] [Mrs A] was notified by a staff member at [the medical centre] that *everything was fine with the left breast, no cancer or anything else to worry about.* [Mrs A] did not recall any additional information provided although [Mr A] acknowledges the clinical notes record advice to re-attend if there were ongoing breast issues. [Mr A] is concerned this information was given over the phone rather than face-to-face, and [Mrs A] had limited opportunity to question the expected course of her symptoms or seek additional information. He also expresses concern at the delay in her eventual diagnosis. [Mrs A] became pregnant with her second child soon after and although she had ongoing breast symptoms, these were attributed by her to the pregnancy. About three weeks after delivery [Mrs A] was referred for further imaging because of persisting left breast symptoms and she was diagnosed with metastatic breast cancer. Despite active treatment (breast and brain surgery, chemo-radiotherapy) [Mrs A] sadly succumbed to her disease [in 2019] leaving behind two [children].

3. …

4. [Dr B] states in her response she saw [Mrs A] on 16 [Month1]. [Mrs A] had stopped breast feeding six months prior and *had experienced occasional milk leakage from the right breast and some watery or blood-stained fluid from the left breast together with an awareness her left breast had increased in size since breast feeding*. There was no family history of breast cancer and the breast had not changed in texture. [Mrs A] was otherwise well and breast examination revealed a normal right breast *but a firmer overall (all breast lobes) left breast, normal nipples and no sign of enlarged lymph nodes in the armpits.* [Dr B] determined it was necessary to check [Mrs A's] prolactin levels and to organize breast imaging. Prolactin level result was received the same day

and was normal. Ultrasound request was sent to [the DHB] initially (no copy on file) but on 28 [Month1] [Mrs A] requested private referral and this was arranged. GP notes are consistent with the response. In particular there is the comment that the left breast *leaks serous or haemoserous fluid daily — small amount — 4 weeks.* Normal prolactin level was conveyed to [Mrs A] on 31 [Month1] after she rang for the result (notes document instructions on 16 [Month1] that the result would be notified if abnormal but [Mrs A] could ring to check in any case if she wished). There is an entry on 29 [Month1] suggesting [Mrs A] changed her mind about the private ultrasound referral and requested referral back to the DHB but it appears she eventually proceeded with the private ultrasound.

Comments:

(i) [Mrs A] presented with symptoms of left breast enlargement and spontaneous serosanguinous left nipple discharge with what sounds like occasional milk or physiological right breast discharge. The history of left nipple discharge provided by [Mr A] in his complaint emphasizes somewhat more the bloody nature of the discharge than the history recorded by [Dr B], but there was clearly a degree of bloodstaining of the left sided discharge and this was conveyed to [Dr B]. This is a critical aspect of history as blood-stained nipple discharge, particularly if unilateral, is a 'red flag' for possible malignancy.

(ii) A respected reference source[1] states: *Grossly bloody or sanguineous nipple discharge simply means that a lesion in the duct is bleeding. The bleeding can be caused by an intraductal carcinoma (in-situ or invasive), a bleeding papilloma, or benign fibrocystic changes with an active intraductal component (eg, plasma cell mastitis, ductal ectasia, intraductal hyperplasia, or papillomatosis). Bloody nipple discharge can also be seen in approximately 20 percent of women during pregnancy and lactation. The cause is usually hypervascularity of developing breast tissue, which is benign and requires no treatment. However, the evaluation of breast complaints in pregnancy and lactation can be complicated by the changing breast examination.* ***Referral for surgical evaluation and biopsy is warranted for evaluation and management of bloody nipple discharge … Bloody nipple discharge, an abnormal mammogram or breast ultrasound, or the presence of a breast mass on physical examination requires evaluation by a surgeon*** [my emphasis].

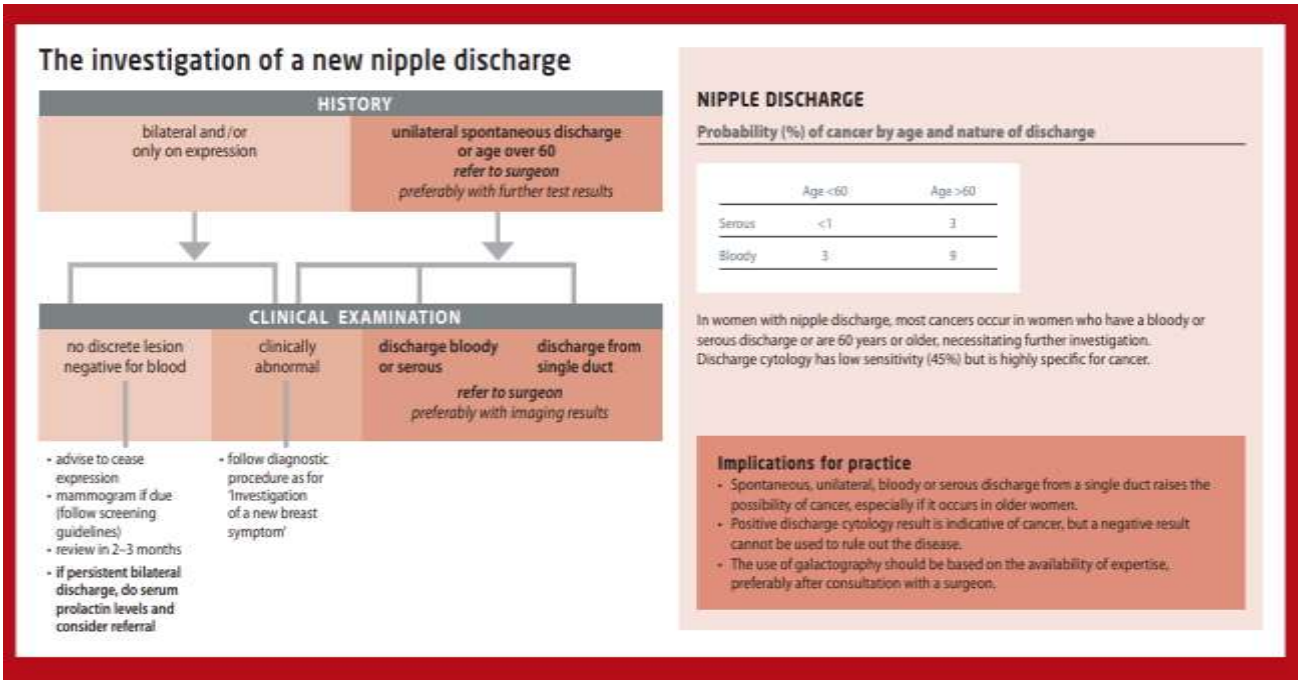
(ii) There is current local guidance[2] available on management of breast symptoms which includes: *Bloody or serous unilateral nipple discharge* as a red flag, with management advice for patients with *any one or more of the* [listed] *red flags present* being to arrange diagnostic imaging in the first instance (generally ultrasound only for women aged < 35 years). Given this guidance was not available in 2015, I have

[1] Golshan M. Nipple discharge. Uptodate. Literature review current through June 2019. www.uptodate.com Accessed 29 July 2019

[2] [Regional] Health Pathways section on 'Breast Symptoms'. [Website reference] By subscription. Accessed 29 July 2019

referred to 2009 guidance[3] which includes the recommendation: *A person presenting with spontaneous unilateral bloody nipple discharge should be referred urgently to a specialist.*

(iii) Recommendations provided to Australian GPs in 2006[4] regarding management of nipple discharge is similar (see below) with recommendation for surgical referral, preferably with imaging results, for patients with blood or serous discharge although the absolute risk of malignancy as a cause of the symptom remains low in a pre-menopausal woman. This guidance was updated in 2017[5] and gives the same recommendations.



(iv) Similarly, another respected reference source (MSD manual on-line)[6] summarises the key point of nipple discharge management as:

- Nipple discharge is most often benign.
- Bilateral, multiductal, guaiac-negative discharge is usually benign and has an endocrine etiology.

[3] New Zealand Guidelines Group. Suspected cancer in primary care: guidelines for investigation, referral and reducing ethnic disparities. Wellington: New Zealand Guidelines Group; 2009. https://www.health.govt.nz/system/files/documents/publications/suspected-cancer-guideline-sep09.pdf Accessed 29 July 2019

[4] https://canceraustralia.gov.au/sites/default/files/publications/ibs-investigation-of-new-breast-symptoms_50ac43dbc9a16.pdf Accessed 29 July 2019

[5] https://canceraustralia.gov.au/system/tdf/publications/investigation-new-breast-symptom-guide-general-practitioners/pdf/2017_inbs_gp_card.pdf?file=1&type=node&id=3439 Accessed 29 July 2019

[6] https://www.msdmanuals.com/en-nz/professional/gynecology-and-obstetrics/breast-disorders/nipple-discharge Accessed 29 July 2019

- Spontaneous, unilateral discharge requires diagnostic testing; this type of discharge may be cancer, particularly if it is bloody (or guaiac-positive).
- Presence of a breast mass, a bloody (or guaiac-positive) discharge, or history of an abnormality on a mammogram or an ultrasound scan requires follow-up with a surgeon who is experienced with breast disorders.

(v) Based on the cited references, and noting [Mrs A] had a history of spontaneous serosanguinous discharge from the left nipple only, I believe accepted management was to examine her breast, refer for diagnostic imaging (initially ultrasound given [Mrs A's] age) then refer for surgical review irrespective of the results of the breast examination (which was not particularly concerning) and imaging results (which were similarly reassuring — see below). To the point of receipt of the ultrasound results (see below), I would regard [Dr B's] management of [Mrs A] as being consistent with accepted practice.

5. Ultrasound results were received on 7 [Month2] and were as follows:

INDICATION: Finished breast feeding six months ago. Intermittent spontaneous blood stained nipple discharge.

FINDINGS: Ultrasound of the left breast centrally demonstrated mildly prominent central ducts consistent with post-lactational state. No ductal abnormality is seen.

No abnormal mass lesion apparent.

The left upper inner quadrant was also scanned as [Mrs A] mentioned fullness in this region. Mildly prominent generalised fibroglandular tissue is apparent. No discrete mass lesion seen.

COMMENT: Post-lactational changes left breast. No other abnormality seen. Management on clinical ground suggested.

[Dr B] states she found the radiology report (which had been double read) as reassuring and followed her usual practice when receiving a normal result in this context which was to have the result conveyed to the patient along with safety netting advice that the situation should be reviewed if there were any ongoing concerns. Nurse notes dated 12 [Month2] are: *advised USS fine — if any concerns to see GP for review 2 mths as per notes …*

Comment: I agree the ultrasound was reassuringly normal, and given [Mrs A's] young age and absence of any factors increasing her risk of breast cancer, the chances of her having an underlying malignancy were low. Nevertheless, she had unexplained unilateral bloody nipple discharge and as discussed previously, I believe accepted practice in this situation is to refer the patient promptly for review by a breast surgeon, preferably with imaging results. If the bleeding symptom had resolved completely, formal re-evaluation in one or two months (as opposed to 'come back only if there are concerns') might have been a possible option but assuming her symptoms were ongoing (and there is nothing to suggest they had resolved) I am of the opinion that [Dr B's] decision to reassure and see only 'if concerned' was a

moderate departure from accepted practice (mitigating factors being [Mrs A's] young age, the reassuring clinical examination and imaging result, and some degree of safety netting advice provided). It is evident in hindsight that [Mrs A] perceived the information provided by the practice nurse as meaning she did not need to be concerned about ongoing bleeding from the nipple or further change in the shape of her breast. I think this emphasizes the importance of providing explicit information about what might or might not be a clinical concern in the context described. I am unable to predict whether surgical referral at this stage would necessarily have resulted in a confirmed diagnosis of breast cancer.

6. [Dr B] states there was no further contact from [Mrs A] regarding breast symptoms in 2015, with results forwarded from [Mrs A's] LMC indicating [Mrs A] had rapidly fallen pregnant and went on to deliver her second [child]. … [T]he LMC requested an urgent GP review for [Mrs A] who was two days post partum and had developed breast pain with engorgement. [Dr B] recorded in her response: *the area of fibroglandular tissue noted on the previous ultrasound had become rock hard, tender, and was starting to flush. She was not having any fevers nor was she systemically unwell. [Mrs A's] mum (present) had concerns that some of the symptoms had started antenatally, which seemed somewhat odd. [Mrs A's] mum is [a health professional].* Treatment was provided for suspected mastitis (flucloxacillin and analgesia) and [Dr B] recalls asking [Mrs A] *to get back in touch in the next week or so if matters were not settling with treatment, and sooner if any worsening occurred.* A repeat ultrasound scan was to be considered if the swelling did not resolve completely. [Dr B's] practice nurse was informed by [Mrs A's] mother that the breast engorgement had settled without antibiotics but the left breast mass remained. [Dr B] assessed [Mrs A] the same day noting persistence of the left breast mass and querying possible blocked duct, abscess or other pathology. Urgent breast ultrasound was arranged (initially DHB referral, changed to private [referral]) and was undertaken [a few days later]. This was reported as:

CLINICAL

Postpartum. Enlarged, hardened left breast.

FINDINGS

Breast skin perhaps mildly thickened. Underlying breast tissue increased in echogenicity and is difficult to penetrate with normal frequency ultrasound. Diffuse alteration in parenchymal texture. No definite collection or focal mass seen but limited visualisation and difficult interpretation. There are abnormal appearing lymph nodes in the axilla with cortices measuring up to 5mm diameter.

IMPRESSION

Sonographic appearances are not specific. Changes of extensive probable oedema/ abnormal tissue. Both infection and neoplasia are possibilities. MRI would give more specific information.

> [Dr B] contacted [a breast surgeon] on receipt of the report ([date]) to find [the surgeon] had already reviewed [Mrs A], MRI performed (inconclusive) and biopsy arranged.
>
> Comment: The response is consistent with the clinical documentation. Management on this occasion was consistent with accepted practice with prompt organising of appropriate diagnostic imaging and prompt follow-up/referral (intended but pre-empted by [the breast surgeon]).
>
> 7. Histology of the biopsy revealed at least stage 2 infiltrating ductal carcinoma with staging CT and bone scans suspicious for a left iliac bony metastasis. [Mrs A] underwent neoadjuvant chemotherapy with left mastectomy and axillary node clearance … followed by radiotherapy to the left ilac lesion and chest wall. Sadly, [Mrs A] developed cerebral metastases and despite further radiotherapy, chemotherapy, immunotherapy and neurosurgery [overseas] her disease progressed and she died [in] 2019. My condolences go to [Mrs A's] family on suffering such a tragic loss.
>
> 8. I feel the issue of delayed consideration of an ACC Treatment Injury claim has been adequately addressed by [Dr B] with the educational approach she has taken in this regard being most appropriate. ACC has only recently (2019) released a treatment injury lodgement guide for health professionals[7]."

Dr Maplesden provided the following further expert advice on 9 October 2019:

> "Thank you for providing additional correspondence relating to this advice.
>
> 1. I have reviewed [Dr B's] response to my original advice. She feels I have taken an overly 'black and white approach' based on guidelines, and I have taken inadequate account of potential mitigating factors, in my conclusion that any blood-stained nipple discharge requires surgical referral. I make no apology for this approach as I feel it is clinically appropriate and evidence-based. There is no dispute that [Mrs A] had developed unilateral serosanguinous nipple discharge even if this was superimposed on possible bilateral physiological discharge. This symptom is regarded as a red flag for malignancy in all the guidance on breast symptom management I reviewed (and which is cited in my original advice) with advice in this situation to seek prompt surgical review preferably with prior breast imaging but the decision to review not dependent on the result of that imaging. [Dr B] states that there was a likelihood referral of [Mrs A] to the DHB breast service immediately following the negative breast imaging results would be declined. I challenge this statement and note that unilateral serosanguinous nipple discharge is listed as a red flag for malignancy in the relevant DHB Health Pathway with HSCAN referral recommended if any red flag is present. I acknowledge (as I did in detail in my original advice) that there were a number of mitigating factors in this case including [Mrs A's] young age, peri-lactation status, apparently normal breast examination and normal imaging result. These factors were taken into account when quantifying the degree of departure from accepted practice in this case and I

[7] https://www.acc.co.nz/assets/provider/405074f420/treatment-injury-claim-lodgement-guide.pdf

see no reason to alter my original advice in this regard. I do acknowledge [Dr B's] reflective comments and feel she has taken appropriate remedial measures relating to this case, and her experience will be valuable in her role as a teacher and supervisor of GP trainees. I acknowledge [Dr B] did not seek to harm [Mrs A], and that no practitioner, myself included, is immune from making clinical decisions which appear reasonable at the time but in hindsight were misjudged.

2. The information from [the medical centre] I think indicates there were accepted processes in place at the facility at the time of the events in question in relation to handling of investigation results and clinical correspondence. I agree with the respondent that there is little more [the medical centre] could have done as an organization to alter the events. Relevant health pathways were available to staff and there were no competency issues identified with [Dr B] either before or following the events. The issue of the precise nature of clinical advice provided to [Mrs A] following receipt of her normal ultrasound result remains somewhat unresolved but this factor does not influence my original advice which took into account the scenario of specific safety netting advice being provided."

Dr Maplesden provided the following further expert advice on 19 March 2020:

"I was referring to the [regional] HealthPathways in my memo. Even though the pathway may not have been available to [Dr B] at the time of the events in question, the identification of unilateral serosanguinous nipple discharge as a red flag for potential breast malignancy was not a new concept and I would regard it as a basic part of GP knowledge. I have attached a copy of the first part of the pathway as requested (freely available to all GPs in the DHB area although password required).

Regarding the moderate departure, the failure to refer to a surgeon and the reassuring of [Mrs A] her result was normal and didn't require any scheduled followup are closely linked and I think don't require separate quantification of departures. If [Dr B] had appropriately identified [Mrs A's] unilateral nipple discharge as being a malignancy red flag requiring surgical referral even though the imaging was reassuring, she would not have given the advice that no further scheduled follow-up was required.

Dr David Maplesden
Medical Advisor
Health and Disability Commissioner"