General Practitioner, Dr B
Medical Centre

A Report by the
Deputy Health and Disability Commissioner

(Case 22HDC00760)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. On 26 March 2019, a woman in her sixties attended a consultation with her general practitioner (GP). The woman said that she reported to the GP that she had been experiencing post-menopausal bleeding 'on and off' for a few years. The GP documented that the woman had experienced some bleeding over the past few days that was not associated with any pain. The GP provided the woman with a voucher for an ultrasound scan with a radiology provider of her choosing and documented that he would see the woman 'before long' to attend to other screening matters. However, following the consultation the woman did not undergo the ultrasound scan as she had the impression from the consultation that the bleeding was nothing to be concerned about and that the scan was optional. Approximately one year later, the woman developed accompanying abdominal pain, and, sadly, she was diagnosed with stage 4 endometrial cancer.

Findings

2. The Deputy Commissioner accepted that at the time of the appointment on 26 March 2019, the GP believed that the post-menopausal bleeding that the woman was experiencing was not recurrent. Accordingly, it was found that the GP followed the appropriate Community Health Pathway by referring the woman for an ultrasound prior to undertaking any further investigation of the bleeding. However, in light of the significant risk of endometrial cancer, the Deputy Commissioner was critical that the GP did not follow up with the woman to ensure that she had undergone the scan. The Deputy Commissioner was concerned about aspects of the GP's communication with the woman, particularly that the woman left the consultation on 26 March 2019 with the impression that the scan was optional and that the bleeding was nothing to be concerned about. The Deputy Commissioner found the GP in breach of Right 4(1) of the Code for failing to provide services to the woman with reasonable care and skill.

3. The Deputy Commissioner also made adverse comment about the medical centre for minor deficiencies in its policies for tracking referrals.

Recommendations

4. The Deputy Commissioner recommended that the GP provide an apology to the woman, and that he undergo training in therapeutic communication with patients should he return to practice.

5. The Deputy Commissioner recommended that the medical centre update HDC on the outcome of its discussion with the PHO/MedTech about introducing a system in the future that allows for an automatic task reminder to be set every time a voucher is generated; that it undertake an audit of all practice voucher referrals to ensure that task reminders have been made by clinicians to follow up on the scans being completed; that it update HDC on the outcome of its preliminary learnings that have been shared with staff as a result of the events; and that it develop an education session for staff using an anonymised version of the HDC report.

Complaint and investigation

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

- *Whether Dr B provided Mrs A with an appropriate standard of care between 26 March 2019 and 8 June 2020 (inclusive).*
- *Whether the medical centre provided Mrs A with an appropriate standard of care between 26 March 2019 and 8 June 2020 (inclusive).*

7. This report is the opinion of Deborah James, Deputy Health and Disability Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

8. The parties directly involved in the investigation were:

Mrs A	Consumer/complainant
Dr B	GP/provider
Medical centre/group provider	

9. Further information was received from:

Te Whatu Ora	Provider
Dr C	GP/ACC clinical advisor
Accident Compensation Corporation (ACC)	

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

Information gathered during investigation

Introduction

11. Mrs A, aged in her sixties at the time of the events, consulted her GP, Dr B,[1] after experiencing post-menopausal vaginal bleeding (PMB). Dr B provided Mrs A with a voucher for an ultrasound scan (USS) with a radiology provider of her choosing. However, following the consultation Mrs A did not obtain a scan, as her understanding was that there was nothing of concern regarding her symptoms. Approximately one year later, Mrs A developed abdominal pain and, sadly, she was diagnosed with stage 4 endometrial[2] cancer. Mrs A is now receiving palliative care. I extend my sympathies to Mrs A for this distressing outcome.

[1] Dr B had been Mrs A's GP for approximately 35 years.
[2] The lining of the uterus.

Post-menopausal bleeding

12. PMB refers to any vaginal bleeding in a patient who has completed menopause.[3] It can be caused by many benign and malignant conditions but is the presenting sign in more than 90% of postmenopausal women with endometrial cancer.[4]

Consultation 26 March 2019

13. On 26 March 2019, Mrs A attended a consultation with Dr B as she had experienced some recent PMB. Dr B documented that Mrs A was approximately seven or eight years' post menopause, and noted: '[S]he has had a little fresh blood … over past few days painless and not post-coital,[5] otherwise well but wanting to do the right thing about it.'

14. As part of a claim to ACC, Mrs A sought clinical advice from another GP.[6] Mrs A told the GP that contrary to what Dr B had recorded in his clinical notes, she had been bleeding for a few years, for a few days at a time. In response to the provisional opinion, Mrs A advised that it is incorrect that she said during the appointment that she had only had slight bleeding in the last couple of days. She stated: '[Dr B's] notes are incorrect. I said I had been having it on and off for a few years.' In addition, Mrs A said that she has now learned that even one instance of PMB is sufficient to generate 'serious concern and immediate action via a scan or further testing'. She said that it is her view that Dr B is justifying his failure to communicate risk by relying on his incorrect view that she said that she had been bleeding only for a couple of days.

15. Dr B told HDC that he undertook a physical examination, including updating Mrs A's height and weight, which indicated a body mass index (BMI) within the healthy range.[7] Dr B examined Mrs A's cervix and uterus and concluded that the cervix had a healthy appearance and the uterus was of a normal size, and no abnormalities were noted.

16. Mrs A said that during the consultation, Dr B told her that her cervix 'looked fine', and she responded that this did not explain whether something was 'going on' in her uterus that was causing the bleeding. Mrs A said that Dr B did not express any concern about the bleeding, and he told her that she could book a scan privately if she was concerned. In response to the provisional opinion, she said that Dr B gave her no accompanying comments or instructions. She stated:

[3] Twelve months without menstruation.
[4] ACOG Committee Opinion No. 734: 'The Role of Transvaginal Ultrasonography in Evaluating the Endometrium of Women With Postmenopausal Bleeding'. Obstet Gynecol. 2018 May;131(5):e124–e129.
[5] Occuring after sexual intercourse.
[6] As part of a complaint to ACC regarding her original treatment injury claim, Mrs A obtained her own clinical advice to provide comment in response to the advice obtained by ACC's expert advisor. The GP also provided advice to Mrs A on the care provided by Dr B.
[7] The lifetime risk of endometrial cancer in females in 3% but with every five unit increase in a person's body mass index (BMI), the relative risk increases by more than 50%. https://bpac.org.nz/2023/endometrial-cancer.aspx#:~:text=Obesity.,increases%20by%20more%20than%2050%25.

> 'As a consequence I felt that I had nothing to be concerned about as I trusted his judgement which I believe is a reasonable thing to have done as he had been my GP for over 35 years.'

17. In response to the provisional opinion, Mrs A reiterated that there was 'zero communication' from Dr B that PMB is not normal and needs to be investigated. She said: 'I only needed to be told this and I would have booked the scan immediately.'

18. A smear test[8] was also undertaken during the consultation, which Dr B said was part of the standard cervical screening programme and 'not as an investigation of the postmenopausal bleeding'. However, Dr B documented that there was blood present when taking the smear. The smear test subsequently returned normal results, and a repeat smear was recommended for 12 months' time.

19. Dr B documented that he generated a voucher for a USS of the pelvis. The voucher stated that the USS was 'routine' and that Dr B had conducted a pelvic examination, visualised the cervix and undertaken a smear test. Dr B told HDC that this was in keeping with local postmenopausal bleeding guidelines (see Appendix D). He said that the local district health board did not have the capacity to provide any USS services for general practices, but it had a scheme whereby it would pay for a scan to be performed in a private radiology service 'provided certain criteria are met'. Dr B told HDC:

> '[Mrs A's] symptoms and my clinical examination fulfilled these criteria so I was able to generate a voucher which I gave to [Mrs A], enabling her to make an appointment with a local radiology provider and get a scan at no cost to her.'

20. Dr B documented that he would contact Mrs A if any results were abnormal, and that she was to return if the bleeding continued. He also documented that Mrs A had mentioned bladder issues since having children, and that there were 'other screening matters to attend to'[9], so he invited her to return about these matters 'before long'. Dr B told HDC that he was expecting to have the opportunity to follow up with Mrs A at that stage. However, in response to the provisional opinion Mrs A told HDC that she was not aware of any other 'screening matters' and that she was not invited to return about these matters.

21. Mrs A told HDC that she left the consultation with the impression that she would have to pay for the USS, and she had felt reassured that the PMB was nothing to be concerned about. She said that Dr B did not mention the potential risk of endometrial cancer. She stated that she was 'handed a piece of paper' and told to get a scan if she wanted to, with no sense of urgency and no effort made by Dr B to complete a formal referral. Consequently, Mrs A did not undergo the USS. Mrs A told HDC that she did not return after

[8] A method of cervical screening used to detect potentially precancerous and cancerous processes in the cervix. Abnormal findings are usually followed up by more sensitive diagnostic procedures and, if warranted, interventions that aim to prevent progression to cervical cancer.

[9] Dr B said that these included that Mrs A had also mentioned bladder issues, which were not explored at the time, but he invited her to return before long to pursue this. He also advised that there were other outstanding screening investigations to be undertaken, including updating her cardiovascular risk assessment and mammography screening.

the 26 March 2019 appointment because the bleeding had stopped, and she was reassured by Dr B that she had no reason to be concerned.

22. Dr B told HDC that he regrets that Mrs A was left with the impression that the USS was optional and for 'reassurance only'. He said that he cannot recall the wording he used during the consultation (owing to the time that has lapsed), but it is likely that he did say that the normal clinical findings from the physical examination were 'reassuring'. Dr B told HDC:

> 'It is clear to me from my records that I intended [Mrs A] to have an ultrasound scan and that I wanted her to return if bleeding continued. However, as above, [Mrs A] took more reassurance from the consultation than I intended, and I regret that.'

23. Dr B said that regrettably he omitted to set himself a 'task' reminder to ensure that Mrs A underwent the USS. He said that although the medical centre had a policy regarding the tracking of referrals,[10] private radiology referrals using the voucher system do not generate a task reminder. Dr B said that it was up to him to set a reminder manually to look out for the results of the USS, which he accepts he did not do in this case. He told HDC:

> '[W]hile my safety netting advice to [Mrs A] within the consultation was clearly documented, there was a regrettable weakness in my own safety netting task-setting system, and therefore I did not send her a reminder to get the scan. I would like to apologise to [Mrs A] for this omission.'

24. The medical centre told HDC that it was the practice's procedure for clinicians to set task reminders manually to follow up on ultrasound scans, X-rays, CT scans and MRI scans. It provided HDC with a copy of its 'Managing Test results Policy' that was in place at the time of the events. The policy states that the clinic uses a function of its practice management software, which automatically creates a task for a clinician who writes a referral or requests a laboratory test or imaging. The policy also states:

> 'When there is concern that a result may be of priority importance individual clinicians have the responsibility of creating a memo to themselves to ensure that these are chased up with appropriate urgency.'

25. It is noted that the policy did not state that if using the voucher system, the clinician would need to set a task reminder manually. However, as noted above, Dr B was aware that it was up to him to set a reminder manually to look out for the results of the USS.

26. In relation to the management of PMB, the medical centre told HDC that it did not have a specific policy or protocol for the management of PMB, but it follows the Community Health Pathway guideline for Postmenopausal Bleeding.

[10] Including that tasks for tracking referrals are automatically set when referrals are sent for laboratory tests, and when referrals to secondary care services through Health Link are made.

27. Dr B told HDC that he followed the Community Health Pathway for Postmenopausal Bleeding, in that he performed a physical examination including visualisation of the cervix, and then organised an ultrasound scan of the pelvis[11] (via the voucher system) having met the criteria that the patient must have had a pelvic examination and a cervical smear (if not done within the previous three months).

28. Dr B said that Mrs A did not meet the criteria[12] for referral to the district health board gynaecology service, including that she had not been experiencing recurrent PMB (he documented that the bleeding had been present for only a few days).

Consultation 8 June 2020

29. On 8 June 2020, Dr B had a telephone consultation with Mrs A during COVID-19 Alert Level Two restrictions.[13] During these restrictions, general practices were advised to manage most of their patient consultations remotely rather than face-to-face.

30. Dr B said that Mrs A reported that she was continuing to get light vaginal bleeding 'on and off' and that (in contrast to the first appointment) she had been experiencing this for 'years'. Dr B documented that Mrs A 'never went for the USS last [year] but continued to get light … bleeding on and off which she has had for years'. Dr B also documented that Mrs A had now reported an accompanying pelvic ache, which was 'generally manageable' but could disturb her sleep. Mrs A told Dr B that the ache felt like premenstrual pain. Dr B documented that he advised Mrs A to get a pelvic USS, which she advised she would get 'asap', and that she would then require a face-to-face appointment with him.

31. In response to the provisional opinion, Mrs A told HDC that after experiencing four days of abdominal discomfort, she called Dr B to 'ask for the name of a place where [she] could go for a scan'. She stated: 'He may have rung them, but it was me who rang and made the appointment.' Mrs A said that Dr B did not advise her to get a pelvic USS, rather she specified that she needed one and just wanted to know where to go.

32. Dr B told HDC that he expressed concern that Mrs A did not complete the USS the previous year, and that she had never returned for follow-up despite the ongoing PMB. He said that he advised Mrs A that it was important to get the scan done as soon as possible and to see him for a follow-up face-to-face consultation 'as [Mrs A's] situation was too concerning to continue managing by phone'. In contrast, Mrs A told HDC that there was no discussion about a face-to-face consultation and no discussion about her care being too serious to manage by phone. She said that she has not had an appointment with Dr B since 26 March

[11] The guideline recommends that a USS referral is made within two weeks.

[12] '2. Request non-acute gynaecology assessment, irrespective of ultrasound results if: the patient is on tamoxifen, as endometrial cancer risk is increased; the patient has recurring PMB. 3. If any other cervical or vaginal abnormality (apart from atrophic vaginitis), request non-acute gynaecology assessment.'

[13] COVID-19 Alert Level Two 'Health and Disability Care Services' restrictions stipulated: 'Health and disability care services operate normally as far as possible … Primary and community health providers will operate in line with the Community Response Framework. Physical distance and infection control guidelines should be followed. Remote consultations should be used wherever possible.'
See: https://covid19.govt.nz/assets/resources/tables/COVID-19-Alert-Levels-detailed-table.pdf.

2019 and that he did not ask her to make one until after she was advised of her terminal diagnosis on 29 July 2020.

33. Dr B said that he immediately sent an electronic referral to get the scan done at a named radiology provider near where Mrs A lived. He told HDC that he does not recall any discussion about the cost of getting the scan without another voucher for district health board funding, but that in order to qualify for another voucher, Mrs A would have required another smear (or to at least state that one had been completed within the previous three months), which was not appropriate as he regarded the situation as 'urgent'. In response to the provisional opinion, Mrs A also advised that there was no discussion about the cost associated with getting a scan.

USS 10 June 2020

34. Mrs A underwent a USS two days later, on 10 June 2020. The radiology report stated that the indication for the scan was that Mrs A had been experiencing '[l]ight intermittent PMB for several years'. The report showed the following:

> '1. Two vascularized nodular filling defects within the endometrial cavity are consistent with endometrial polyps.[14] A specialist gynaecological opinion is recommended, particularly in view of postmenopausal bleeding.
>
> 2. Bulky uterus with asymmetric myometrial thickening and heterogeneity, consistent with adenomyosis.[15]'

Telephone consultation 11 June 2020

35. Dr B said that he received the USS report the following day, on 11 June, and he telephoned Mrs A to discuss the results with her. He said that there were two abnormal features mentioned in the scan report, and he explained these to Mrs A 'as well as [he] could over the phone, noting that there was no mention of possible malignancy'. Dr B told HDC that he advised Mrs A that the best course of action would be to see a gynaecologist to have curettage[16] for histology, and to have the suspected polyps removed, which would 'hopefully stop the ongoing bleeding'.

36. Dr B documented that he explained the polyps and adenomyosis and advised that there was 'nothing to suggest malignancy', and that Mrs A was 'relieved to have that news'. In response to the provisional opinion, Mrs A said that the technician who had performed the scan had given her 'preliminary view' and that she was therefore not overly concerned and believed that based on what the technician said, she may require some minor surgery. She said that she was not 'relieved' to have that news, because at that stage it was what she expected. Mrs A said that Dr B showed 'very little leadership on what to do with the scan results'. She said that Dr B asked her if she had a gynaecologist to whom he could send the

[14] A projecting growth of tissue from a surface in the body.
[15] A condition that causes endometrial tissue in the lining of the uterus to grow into the muscular wall of the uterus.
[16] The scraping or removal of tissue lining the uterine cavity (endometrium) with a surgical instrument called a curette.

results, and, because she did not, she suggested that the results be sent to the local district health board. Mrs A said that she expected that Dr B would be able to provide advice.

37. That day, Dr B made a referral to the Gynaecology Clinic at the local hospital.

38. Dr B told HDC that again he followed the Community Health Pathways for Postmenopausal Bleeding guideline in deciding the next steps for Mrs A. He said that in contrast to the consultation on 26 March 2019, at the consultation on 8 June 2020 it was clear that Mrs A was now experiencing recurrent PMB, which according to point 2 of the above-mentioned Community Health Pathway for Postmenopausal Bleeding guideline (Appendix D) required non-acute gynaecology assessment. Dr B said that accordingly (on 11 June 2020), he arranged an urgent USS followed by an immediate referral to the Gynaecology Clinic, in line with the guidelines.

39. In contrast, Mrs A told HDC (in response to the provisional opinion) that the referral to the local district health board was not made 'urgently', rather that it was made in due course after the results came through from the radiologist and after speaking with Mrs A.

Subsequent events

40. Mrs A had an initial gynaecology specialist appointment on 18 June 2020. The clinical notes from this appointment record that Mrs A had been experiencing PMB, which had started '1 year ago', and that it was irregular and light in volume with accompanying 'crampy abdo[minal] pains'. A pipelle biopsy showed endometrioid adenocarcinoma Grade 1[17] (endometrial cancer). However, a pelvic MRI on 23 July 2020 showed '[a]ppearances … concerning for advanced endometrial carcinoma'. Sadly, Mrs A was diagnosed with metastatic endometrial cancer (cancer that has spread to other parts of the body).

41. On 10 August 2020, Mrs A underwent a palliative laparoscopic hysterectomy.

Further information

Mrs A

42. Mrs A told HDC that she is concerned that Dr B did not exercise sufficient leadership in her referral process during and following her initial consultation with him when she first presented with her symptoms. She also raised concerns that there is a general lack of public awareness about endometrial cancer.

Dr B

43. Dr B noted that there is a different version of events relating to the history of Mrs A's PMB in the clinical notes of 26 March 2019 and 8 June 2020. He told HDC:

> 'Having reviewed the records since, I have become aware that there is a discrepancy between the recorded medical history in these two consultations [26 March 2019 and 8 June 2020]. In the earlier consultation I recorded that I was told there had been a

[17] Most Grade 1 endometrial cancers are confined to the uterus at the time of diagnosis and have not spread to other parts of the body.

> little bleeding over the *past few days.* The following year I wrote that [Mrs A] said she *continues to get light PV bleeding on and off which she has had for years.* If that was the case on 26 March 2019, it would amount to recurrent PMB and would have required immediate referral at that time.'

44. Dr B said that he has worked on a '20 minute appointment system for many years', whereas most GPs undertake 15-minute consultations. He said that this enables him to take more care over details and to give more time to careful communication, 'both of which are important to [his] ethos of medical practice'. Dr B also stated that he 'believe[s] on each occasion [he] recorded what [he] understood [he] was told on the day'.

45. Dr B offered to have a mediated meeting with Mrs A to discuss her concerns further and to have the opportunity to apologise to her in person for 'aspects of [his] care which [he] regret[s] could have been better managed'. HDC was advised that Dr B retired in 2022.

Medical centre

46. The medical centre told HDC:

> 'We are very sorry that [Mrs A] was diagnosed with Stage 4 endometrial cancer and for the distress such a diagnosis brings with it. We regret [Mrs A] is upset and feels let down by the standard of care provided to her. At [the medical centre] we strive to provide our patients with the best possible care and have no hesitation in apologising for any deficiencies identified in the care provided to [Mrs A].'

ACC

GP Dr C

47. Dr C provided clinical advice to ACC (Appendix C) for the purpose of deciding whether to accept a treatment injury claim from Mrs A. The ACC report states: 'The base of the claim is failure to treat in a timely manner/failure to refer … leading to delayed diagnosis of endometrial cancer stage 4.' In summary, Dr C advised:

> 'I believe that taking the clinical information available in March 2019 into account, a clear "red flag" was present, and the GP did not adequately follow the recommended clinical pathways to investigate this patient's post-menopausal bleeding as outlined in the BPAC and NZ Health Pathways guidelines … I can find no evidence that the nature and duration of the bleeding was sufficiently explored nor relevant personal and family history of associated cancers … Although a pelvic exam and cervical smear were appropriately carried out and an ultrasound scan was ordered, the importance and relevance of this imaging does not appear to have been explained to the patient at the time … Although the patient does have personal responsibility in their own health care, the GP has the responsibility to provide the patient with sufficient information to make an informed decision … I believe the GP should have been more proactive in following-up the scan at the time considering this patient would have very likely needed a biopsy to complete the diagnostic pathways for post-menopausal bleeding as per the New Zealand Health Pathways guidelines for general practice.'

Responses to provisional opinion

Mrs A

48. Mrs A told HDC:

> '[My purpose in complaining to HDC was to] receive acknowledgement that I was let down by inadequate care and that as a consequence my life has been shortened and my family and I have experienced a lot of grief, loss and stress[;] ensure that there is greater awareness of endometrial cancer which is not the current situation in New Zealand[;] establish far broader awareness of processes that a patient should expect when presenting with PMB … [I am] alarmed to see how inaccurate his notes are, how poor his processes were and how that impacted his care decisions.'

49. Mrs A told HDC that Dr B had a duty to explain that there was some risk 'not necessarily cancer', but just to explain that investigation was needed.

Dr B

50. Dr B told HDC:

> 'I have carefully considered your opinion, taken on board the findings, the shortcomings identified and recommendations. As set out previously, I reflected at length on what I should have done differently and before my retirement, I was more diligent in setting tasks for myself to ensure that patients were followed up and even more aware of the fine balance to be achieved between being alarmist in the absence of most risk factors and ensuring that sufficient concern is conveyed to the patient.'

51. In relation to the risk of endometrial cancer at the time of Mrs A's presentation on 26 March 2019, Dr B submitted that the risk was significantly lower than 10% as Mrs A did not have any of the seven risk factors for endometrial cancer and he understood that the bleeding had been occurring only for the past few days at that stage.

52. Dr B accepted the proposed recommendations and stated that he has no intention of returning to clinical practice.

Medical centre

53. The medical centre told HDC:

> 'As previously stated, the Practice strives to provide our patients with the best possible care, and we are committed to continuously reviewing and improving our practice systems and policies. As noted in your decision, we have used [Mrs A's] complaint and investigation process and findings as a means of improving our policies and systems and have made some changes to the services provided as a result … We would like to take this opportunity to again express our regret [Mrs A] was let down by the care provided to her.'

54. In response to the proposed recommendation that it consider introducing a system that allows for an automatic task reminder to be set every time a voucher is generated, the medical centre told HDC that this would require the software to be changed and that 'this

can only happen at DHB and [the PHO] level and in consultation with Medtech vendors themselves'. The medical centre advised that it has raised this with MedTech and the PHO and suggested that they consider this as an upgrade to the software in the future.

55. In response to the recommendation that it undertake an audit of all practice USS voucher referrals (from 2019 to current), the medical centre told HDC that to extract and audit data of all USS voucher referrals from 2019 to date would be very labour-intensive and would require auditing over 400 patient records. The medical centre suggested an amendment to the audit recommendation.

56. The medical centre agreed with the other recommendations.

Opinion: Dr B — breach

Introduction

57. This report relates to the standard of care provided to Mrs A by Dr B in relation to the management and investigation of her PMB and eventual diagnosis with endometrial cancer. As part of my assessment of this case, I sought in-house clinical advice from GP Dr David Maplesden.

58. ACC obtained clinical advice from GP Dr C as part of its assessment of the treatment injury claim.

Management of PMB

Recurrence of PMB

59. On 26 March 2019, Mrs A attended a consultation with Dr B for a routine smear test and to discuss PMB. Dr B documented that Mrs A 'had had a little fresh blood … over past few days' but that there was no pain associated with the bleeding. Dr B told HDC that his understanding at the time of this appointment was that the bleeding was not recurrent (ie, that it had not occurred previously).

60. The initial gynaecology specialist appointment on 18 June 2020 notes: 'Over the last year, [Mrs A] has been having irregular light PV bleeding.' This is consistent with Dr B's documentation from the consultation on 26 March 2019.

61. Conversely, Mrs A said that she told Dr B that the PMB had been occurring for the past few years, for a few days at a time. In addition, during the appointment on 8 June 2020, Dr B documented that Mrs A reported that she had been experiencing light bleeding, which she 'has had for years'.

62. Dr Maplesden advised that if Mrs A gave a history of recurrent PMB over several years and this was ignored or documented by Dr B incorrectly, then this would represent a moderate departure from accepted standards of clinical documentation.

63. It is clear that the accounts from Mrs A and Dr B differ as to whether the bleeding had been recurrent prior to 26 March 2019, and further, whether Dr B was aware that the bleeding had been recurrent at that stage. I note, however, that the documentation made by Dr B on 26 March is consistent with the notes made at the gynaecology specialist appointment on 18 June 2020, which reflects that the bleeding had been occurring over the last year.

64. Accordingly, while I note that the bleeding may have been occurring for longer, I accept that Dr B was not aware of this on 26 March 2019, and reasonably believed that it had not been recurrent. I am therefore not critical of Dr B for proceeding on the basis that the PMB was not recurrent on 26 March 2019.

USS referral

65. Following Dr B's physical examination of Mrs A on 26 March 2019, he generated a voucher for a USS of the pelvis. The voucher stated that the scan was 'routine' and that Dr B had conducted a pelvic examination, visualised the cervix and taken a smear. Under the title 'summary', it stated: 'Funding Stream: Community/Private Radiology (DHB Funded) Funding Location: Community Radiology Provider.' Dr B told HDC that this was in keeping with the Community Health Pathway for Postmenopausal Bleeding guidelines. Dr B also said that the local district health board did not have the capacity to provide any USS services for general practices, but it had a scheme that allowed the patient to undergo a funded scan in a private radiology service. Dr B told HDC that this enabled Mrs A to make an appointment with a private radiology provider and to have a scan at no cost to her.

66. Conversely, Mrs A told HDC that she left the consultation with the impression that she would have to pay for the ultrasound herself, and she felt reassured that the PMB was nothing to be concerned about. Consequently, she did not book or undergo a USS.

67. Dr Maplesden advised that Dr B's assessment of Mrs A was consistent with accepted practice. He said that there were no features of the assessment or documented history that required acute or direct gynaecology review, and that it was appropriate for Dr B to order a pelvic USS as the first step. Dr Maplesden advised:

> 'Had there been a clear history of recurrent PMB, ultrasound was still required but once the result was received gynaecology referral was indicated irrespective of result (per the cited Health Pathway).'

68. The Community Health Pathways for Postmenopausal Bleeding guidelines state that the clinician should first perform a physical examination, and then arrange a USS, provided the patient meets the criteria for referral for USS — including that a physical examination with visualisation of the cervix has been undertaken, and that a cervical smear has been undertaken if not done within the previous three months. The guidelines state that non-acute gynaecology assessment (irrespective of ultrasound results) should occur only if the patient is on tamoxifen[18] (as endometrial cancer risk is increased) or if the patient has recurrent PMB. As I have established above, it is my opinion that at the time of the

[18] A side effect of tamoxifen is to increase the risk of endometrial cancer.

consultation on 26 March, Dr B was of the view that the bleeding was not recurrent. Dr B undertook both a physical examination (including visualisation of the cervix) and a smear test, and then generated a voucher for Mrs A to undergo a USS scan.

69. Accordingly, I accept Dr Maplesden's advice that Dr B followed the appropriate Community Health Pathway for Postmenopausal Bleeding guidelines in this regard, by referring Mrs A for a USS and awaiting the results before undertaking further investigations.

Management of USS referral

70. Following the generation of the USS voucher, Dr B documented that he would contact Mrs A if any results were abnormal, and that she should return if the bleeding continued. He also documented that Mrs A had mentioned bladder issues since having children, and that there were 'other screening matters to attend to', so he invited her to return about these matters 'before long'.

71. However, Mrs A told HDC that she did not undergo the scan as she left the consultation with the impression that the PMB was nothing to be concerned about. Mrs A also told HDC that Dr B did not advise her that there were other screening matters to attend to. However, I note that Dr B documented those as relating to ongoing bladder issues, cardiovascular assessment, and mammogram screening.

72. Dr Maplesden advised that given the significant risk (around 10%) of Mrs A's symptoms being associated with endometrial malignancy, he believes it was important to track the result as per the Royal New Zealand College of General Practitioners (RNZCGP) guidance, with enquiry being made if the USS was not completed within the recommended two- to four-week timeframe. However, he also noted:

> '[I]t must be acknowledged the responsibility for completing a recommended procedure involved a well-informed partnership between the patient and clinician rather than being the sole responsibility of either party.'

73. In any event, Dr Maplesden considered that the failure by Dr B to track the USS referral in this situation would constitute a moderate departure from accepted standards. I agree.

74. Dr C also noted that the diagnostic pathway was left incomplete when the USS was not completed.

75. Dr B has accepted that he omitted to set himself a task reminder to ensure that the USS was completed. He explained that the IT system at the medical centre at that time did not have the capacity to track referrals through the voucher system by generating a task reminder (as it did for laboratory tests and secondary care services referrals). Therefore, it was up to the individual GP to set a task manually to look out for the USS results, which in this case, he accepts that he did not do. Dr B told HDC:

> 'I am not sure why I didn't do this at this time. So, while my safety netting advice to [Mrs A] within the consultation was clearly documented, there was a regrettable

weakness in my own safety netting task-setting system, and therefore I did not send her a reminder to get the scan. I would like to apologise to [Mrs A] for this omission.'

76. I accept that at the time, Dr B was of the view that he would see Mrs A again soon for other matters, and that he could discuss the PMB further with her at that time (when he had received the results of the USS). I also note that Dr B documented that he advised Mrs A to return should she experience any further episodes of bleeding (at which point the PMB would be considered recurrent). However, I am critical that Dr B failed to track the scan results, which meant that he was unaware that Mrs A had not undergone the scan in 2019.

Conclusion

77. Overall, as detailed above, I have accepted that at the time of the events on 26 March, Dr B was of the view that the PMB that Mrs A was experiencing was not recurrent. Accordingly, I have accepted Dr Maplesden's advice that Dr B followed the Community Health Pathway for Postmenopausal Bleeding guidelines appropriately by referring Mrs A for a USS prior to undertaking any further investigation of the bleeding.

78. However, I am concerned that in light of the significant risk of endometrial cancer (around 10%), Dr B did not follow up with Mrs A and ensure that she had undergone the scan. This meant that Dr B was unaware that Mrs A had not completed the scan until she contacted him approximately one year later with accompanying pain.

79. I note Dr B's comments in response to the provisional opinion that at the presentation on 26 March 2019, Mrs A's risk of endometrial cancer was 'significantly lower than 10%', as she did not have any of the seven risk factors for endometrial cancer. However, I accept Dr Maplesden's advice that as post-menopausal bleeding was present, Mrs A's risk of endometrial cancer was 10%.

80. The effect of this omission was significant, and I accept Dr Maplesden's advice that it was a moderate departure from accepted standards. In my view, this omission represents a failure by Dr B to provide services to Mrs A with reasonable care and skill. Accordingly, I find that Dr B breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code). [19]

Communication — adverse comment

81. Mrs A told HDC that she left the consultation of 26 March with the impression that the PMB was nothing to be concerned about. She said that Dr B did not mention the potential risk of endometrial cancer, and there was no sense of urgency and no effort made by Dr B to complete a formal referral.

82. Dr B told HDC that he regrets that Mrs A was left with the impression that the ultrasound was optional and for reassurance only. He said that he cannot recall the wording he used during the consultation (owing to the time that has lapsed), but it is likely that he did say

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

that the normal clinical findings from the physical examination were 'reassuring', and his notes at the time regarding the USS report 'imply that there was an expectation that it would be completed'. Dr B stated:

> 'It is clear to me from my records that I intended [Mrs A] to have an ultrasound scan and that I wanted her to return if bleeding continued. However, as above, [Mrs A] took more reassurance from the consultation than I intended, and I regret that.'

83. Dr Maplesden advised:

> '[I]t must be acknowledged the responsibility for completing a recommended procedure involves a well-informed partnership between the patient and clinician rather than being the sole responsibility of either party.'

84. I agree. Good communication is imperative in every therapeutic relationship. It is clear that in this case there was a miscommunication between Dr B and Mrs A during the consultation of 26 March 2019, which unfortunately led to Mrs A's understanding that the USS was for 'reassurance only' and not an important investigation into her PMB.

85. Dr Maplesden advised that there is a careful balance to be maintained between overly alarming a patient about a potential risk of serious disease, while ensuring that sufficient concern is maintained 'to facilitate [the] completion of requested investigations'.

86. Dr C considered that it was insufficient to ask Mrs A to return only if the bleeding continued, and that there is no evidence that the relevance or necessity of the USS was explained or what further investigations might need to be completed on receipt of the USS results.

87. There are two possible scenarios before me. The first is that Dr B reassured Mrs A that it was unlikely that there was a serious cause for the PMB but that it was important to undergo a USS to confirm this. Dr Maplesden advised that if this first scenario is correct, this would meet an appropriate standard of care. The second possible scenario is that Dr B reassured Mrs A that it was unlikely that there was a serious underlying cause for the PMB, but he would provide Mrs A with a USS voucher to use if she felt that she required further reassurance. Dr Maplesden advised that the second scenario would represent at least a moderate departure from accepted standards.

88. On the information available to me, I accept that Dr B did have an expectation that Mrs A would complete the USS. This is evidenced by his clinical documentation, which notes:

> '[S]mear sent and voucher generated for USS of uterus we will contact her if anything abnormal and she will return if bleeding continues … [T]here are other screening matters to attend to, so invited to return about outstanding matters before long.'

89. In my view, this documentation shows that Dr B was expecting that Mrs A would complete the USS, and that he would be in contact with her again shortly. However, I do have concerns about Dr B's communication with Mrs A about the PMB she was experiencing,

particularly in the context of the potential risk of Mrs A's symptoms being associated with endometrial malignancy.

90. Mrs A left the consultation on 26 March 2019 with the impression that the PMB was nothing to be too concerned about and that the USS was optional. Although I have established that Dr B appropriately advised Mrs A that the USS should be completed (and that he had the expectation that it would be), I am concerned that there is no documented discussion about the purpose of completing the USS or that further investigations would likely need to be conducted should the bleeding continue or should the USS results not be reassuring. I encourage Dr B to reflect on this.

Opinion: Medical centre — adverse comment

91. As a healthcare provider, the medical centre is responsible for providing services in accordance with the Code. Dr B was working at the medical centre at the time of these events, and I have found Dr B in breach of the Code for failing to follow up on Mrs A's ultrasound scan results. In my view, this was predominantly a clinical error for which Dr B holds individual responsibility, but I have a minor concern with the medical centre's policy for tracking referrals.

92. The medical centre provided HDC with a copy of its relevant policies in place at the time of these events, including its 'Managing Test Results Policy'.

93. The policy stipulates that the clinic uses a function of the patient management software that automatically creates a task for a clinician who requests a laboratory test or imaging, or writes a referral. However, the policy does not advise that if using the voucher system, the clinician needs to set a task reminder manually to follow up on the test results. However, the policy does state:

> 'When there is concern that a result may be of priority importance individual clinicians have the responsibility of creating a memo to themselves to ensure that these are chased up with appropriate urgency.'

94. As outlined above, Dr B has acknowledged that it was his responsibility to set a manual task reminder to follow up on the results of an ultrasound scan ordered through the voucher system, and that he failed to do so on this occasion. Dr B was an experienced clinician and was aware of his responsibilities in this regard. Accordingly, I accept that Dr B's omission was an individual failing and does not indicate broader systems issues at the medical centre. However, I note that the policy in place at the time of these events did not distinguish between the usual process for referrals (in that a task would be generated automatically when a clinician requested a laboratory test or imaging) and the process for following up on referrals through the voucher system. In my view, this should have been made clear, but I do not consider that it amounts to a breach of the Code.

95. I acknowledge that the medical centre has since updated its policy to include the process for using the voucher system.

Changes made

Dr B

96. Dr B told HDC that he made the following changes because of these events:

- He reflected at length on what he could have done differently, including omitting to follow up on the USS referral and his communication with Mrs A.
- He resolved to be more diligent in setting tasks for himself to ensure that patients were followed up if they had not completed important investigations for which he had referred them (prior to his retirement from clinical work at the end of 2022).

97. Dr B stated:

> 'I became even more aware of the fine balance to be achieved between being alarmist in the absence of most risk factors and ensuring that sufficient concern is conveyed to the patient that they follow through on recommended procedures and follow up advice.'

Medical centre

98. The medical centre told HDC that it made the following changes because of these events:

- It updated its process for using funding for the voucher system, including a reminder that a manual task reminder must be set every time a clinician refers a patient for an ultrasound scan. The policy also states that an online referral can be sent directly to the radiology provider, and that this online referral allows for a task to be generated in the clinician's task box. The medical centre provided HDC with a copy of its updated policy.
- Its Clinical Team reviewed and updated its policy (see paragraph 95).
- It scheduled a full practice team meeting on 30 May 2023 to discuss this case (on an anonymous basis) and to share its preliminary learnings with all staff.
- It reminded all staff of the importance of setting up their own tasks to follow up test results and scans so that there is appropriate safety-netting when referring patients for further testing/investigations.

Recommendations

99. In my provisional opinion, I recommended that Dr B provide a written apology to HDC for forwarding to Mrs A. Dr B provided this apology to HDC, and it has been forwarded to Mrs A.

100. In addition, I recommend that should Dr B return to practice, he undergo training in therapeutic communication with patients.

101. I recommend that the medical centre:

a) Advise HDC of the outcome of its discussion with the PHO/MedTech about the possibility of updating the software in the future to include a system that allows for an automatic task reminder to be set every time a voucher is generated. The medical centre is to advise HDC of the outcome of its discussion within three months of the date of this report.

b) Undertake an audit of all practice USS voucher referrals from May to December 2023 to ensure that task reminders have been made by clinicians within the practice to follow up on the scans being completed. If the audit identifies any shortcomings, the practice is to report back to HDC on the remedial actions it has taken as a result. The results of the audit and any remedial actions is to be sent to HDC within six months of the date of this report.

c) Update HDC on the outcome of its meeting of 30 May 2023, including the preliminary learnings that have been shared with staff as a result of these events. The medical centre is to provide this information to HDC within two months of the date of this report.

d) Develop an education session for staff using an anonymised version of this report, to discuss the following:

   i. Management of postmenopausal bleeding;

   ii. Risk factors for endometrial cancer; and

   iii. Follow-up of referrals and test results.

Follow-up actions

102. A copy of this report with details identifying the parties removed, except the in-house clinical advisor on this case, will be sent to the Medical Council of New Zealand, and it will be advised of Dr B's name in the covering correspondence.

103. A copy of this report with details identifying the parties removed, except the in-house clinical advisor on this case, will be sent to the Royal New Zealand College of General Practitioners and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: In-house clinical advice

The following in-house advice was obtained from GP Dr David Maplesden on 8 November 2022:

> '1. My name is David Maplesden. I am a graduate of Auckland University Medical School and I am a practising general practitioner. My qualifications are: MB ChB 1983, Dip Obs 1984, Certif Hyperbaric Med 1995, FRNZCGP 2003. Thank you for the request that I provide clinical advice in relation to the complaint from [Mrs A] about the care provided to her 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.
>
> 2. I have reviewed the following information:
>
> - Complaint from [Mrs A]
> - Response from [Dr B]
> - GP notes [medical centre]
> - Clinical notes [DHB]
>
> 3. [Mrs A] ([in her sixties]) complains about the delayed diagnosis of her endometrial cancer. She states that in March 2019 she presented to [Dr B] with concerns about post-menopausal bleeding (PMB). A cervical smear was performed and [Dr B] reassured [Mrs A] that her cervix appeared normal. [Mrs A] states: *I responded by saying that surely that didn't explain if something was going on in my uterus. He didn't express any concern about the bleeding but did say I could book a scan privately if I was concerned. [Mrs A] felt reassured that there was no particular need for further investigation.* However, in May 2020 she developed abdominal pain and contacted [Dr B] to arrange a private trans-vaginal scan as she understood from the previous conversation with [Dr B] that that was the only option available to her. The scan results were abnormal and [Mrs A] received follow-up though [the DHB] and in July 2020 received a diagnosis of Stage 4B (terminal) endometrial cancer. She underwent a palliative hysterectomy on 10 August 2020. [Mrs A] is concerned that her DHB providers indicated she should have been referred for urgent pelvic ultrasound and gynaecology referral as soon as she presented with PMB and this is available in the public system.
>
> 4. Expected management of women with PMB is summarised in a 2019 BPAC article[1] with further local advice included in the relevant … Regional Community Health Pathway[2]. The BPAC article includes the following points with reference to PMB:
>
> (i) Post-menopausal bleeding is defined as any bleeding that occurs after 12 months or more of menopausal amenorrhoea. Post-menopausal bleeding is a red flag for

[1] BPAC. Investigating and managing abnormal vaginal bleeding: an overview. 2019. https://bpac.org.nz/2019/bleeding.aspx Accessed 8 November 2022

[2] Section 'Postmenopausal Bleeding'

endometrial cancer and this must be excluded as the cause of post-menopausal bleeding with high priority.

(ii) Diagnostic and imaging tests that may be indicated when investigating post-menopausal bleeding include:

- Cervical smear test — if the last cervical smear test was more than 6–12 months ago*
- STI testing as indicated by risk
- Pipelle biopsy — to sample the endometrium to rule out hyperplasia or malignancy
- Pelvic ultrasound — an exception may be those who have recently initiated MHT
- Hysteroscopy — for women with post-menopausal bleeding who are taking tamoxifen

(iii) The most common cause of post-menopausal bleeding is endometrial or vaginal atrophy (60–80%), followed by menopausal hormone therapy (MHT) (15–25%), endometrial or cervical polyps (2–12%), endometrial hyperplasia (10%), endometrial cancer (10%), cervical cancer (< 1%).

(iv) **All women who present with post-menopausal bleeding who have not recently initiated MHT should be referred for pelvic ultrasound with high priority (i.e. within two to four weeks**). If the woman is taking tamoxifen, refer for hysteroscopy and pelvic ultrasound.

(v) Bleeding after six months of continuous MHT or unscheduled bleeding in women taking cyclical MHT should be investigated with pelvic ultrasound.

(vi) If there is a high suspicion of endometrial cancer, arrange a pipelle biopsy while awaiting the ultrasound results.

(vii) Post-menopausal bleeding caused by atrophic vaginitis can be managed with vaginal moisturisers, lubricants or topical vaginal oestrogens. If the woman has had breast cancer, discuss with a relevant specialist in secondary care.

5. The cited Health Pathway refers to the importance of establishing the pattern of vaginal bleeding and assessing risk factors for endometrial cancer. Abdominal and pelvic (bimanual plus speculum) examination is recommended with cervical smear performed if the most recent result was more than three months ago. Following examination: Arrange ultrasound scan of the pelvis within 2 weeks once criteria are met. Clearly state that the patient is postmenopausal on the ultrasound request form. Criteria for pelvis ultrasound in postmenopausal bleeding (PMB) — The patient must have had: a pelvic examination, including visualisation of the cervix; a cervical smear (if not done within the previous 3 months). The process for accessing ultrasound varies between DHBs with some outsourced to private providers but at no cost to eligible patients. This was the case in [the DHB] area in 2019. The cited Health

Pathway includes the following more recent statement regarding referrals in the former [the DHB] area: From 20 June 2021, referrals to [the DHB] for non-acute gynaecology assessment for abnormal uterine bleeding and postmenopausal bleeding will require an attached pelvic ultrasound scan and pipelle biopsy result. A documented attempt at pipelle biopsy is sufficient if there were technical difficulties in obtaining an adequate sample. Investigations should be performed within 2 weeks of the decision that the bleeding is not responding to medical management, or suggests a risk of cancer. Subsequent management recommendations are based largely on the ultrasound result but referral for non-acute gynaecology assessment is recommended irrespective of the ultrasound result if there is recurrent PMB.

6. [Dr B's] notes for the consultation of 26 March 2019 read as follows:

7 or 8 yrs after menopause she has had a little fresh red blood PV over past few days, painless and not post-coital, otherwise well but wanting to do the right thing about it. \wt 69\ht 167 chaperone offered and declined vulva and vagina NAD, cx looked very healthy but there was a little bleeding on taking smear with cervibroom, bimanual indicated normal uterine size smear sent and voucher generated for USS of uterus — we will contact her if anything abnormal and she will return if bleeding continues I mentioned Ovestin and she mentioned bladder issues since having kids, and there are other screening matters to attend to, so invited to return about outstanding matters before long.

7. An electronic template (ProExtra Diagnostic Service Request) was completed on 26 March 2019 stating request for routine pelvic ultrasound with criteria: Post-menopausal bleeding after 1 year of amenorrhoea. I have carried out a pelvic examination, visualised the cervix and taken a smear. [Height and weight recorded — BMI in healthy weight range in this case] … PMB 7 yrs after menopause, clinically cx and uterus nad. [Dr B] states the process enables generation of a voucher (valid for three months) which is given to the patient to make an appointment with a private ultrasound provider at no cost. The voucher was provided to [Mrs A]. [Dr B] notes in his response that he omitted to put in place any tracking of the ultrasound referral. The practice has a policy recommending tracking of important tests and referrals and such tracking is automatically activated for tests and referrals generated through HealthLink (a majority of such correspondence). However, the ProExtra referral required tracking to be initiated manually by the requesting clinician and [Dr B] regrets his oversight in not initiating tracking on this occasion. The cervical smear result was normal with repeat recommended in 12 months.

8. In his response, [Dr B] notes he refers in subsequent correspondence to [Mrs A] having a history of PMB over several years. However, he believes the documentation of 26 March 2019 accurately reflects his understanding of [Mrs A's] symptoms at that time. He has reflected on [Mrs A's] perception that he was not concerned about her PMB symptom but states he was concerned which was why the ultrasound was ordered and [Mrs A] was invited to return if her symptoms recurred or persisted.

However, he acknowledges there may have been some miscommunication if [Mrs A] felt reassured that there was no pressing need to have the ultrasound completed.

9. Comments

(i) I believe the clinical documentation of 26 March 2019 is adequate assuming it accurately represents the history provided by [Mrs A]. Best practice would be to document exploration of endometrial cancer risk factors but I have rarely seen this completed in the many notes I have reviewed over time. If [Mrs A] gave a history of recurrent PMB over several years and this was ignored or incorrectly documented by [Dr B], this would represent a **moderate** departure from expected standards of clinical documentation.

(ii) The documented assessment was consistent with accepted practice. There were no features in the assessment or documented history that required acute or direct gynaecology review, and it was appropriate to order a pelvic ultrasound as the first step. Had there been a clear history of recurrent PMB, ultrasound was still required but once the result was received gynaecology referral was indicated irrespective of the result (per the cited Health Pathway). Given the significant risk (around 10%) of [Mrs A's] symptoms being associated with endometrial malignancy I believe it was important to track the result (as per RNZCGP guidance)[3] with enquiry being made if the procedure was not completed within the recommended two to four week time frame. I believe the failure by [Dr B] to track the ultrasound referral in the clinical scenario described would be met with **moderate** disapproval by my peers. However, it must be acknowledged the responsibility for completing a recommended procedure involves a well-informed partnership between the patient and clinician rather than being the sole responsibility of either party.

(iii) It appears [Mrs A] gained the impression from [Dr B] that the ultrasound would be at her expense and that it was optional "for reassurance only" rather than it being a critical part of the management of her PMB. While it is not clear how these misperceptions occurred, it is appropriate [Dr B] has reflected on his communication with [Mrs A] on this occasion. There is sometimes a careful balance to be maintained between overly alarming a patient about a potential risk of serious disease while ensuring sufficient concern is maintained to facilitate completion of requested investigations. There are two scenarios to consider here: [Dr B] reassured [Mrs A] that it was unlikely there was serious underlying pathology but it was important ultrasound was undertaken to confirm this — consistent with accepted practice; [Dr B] reassured [Mrs A] that it was unlikely there was serious underlying pathology but he would provide her with an ultrasound voucher for her to use if she felt she required further reassurance — at least **moderate** departure from accepted practice. However, I note reference in the notes to an intention to contact [Mrs A] regarding the ultrasound result (implying there was an expectation it would be completed) and there is appropriate safety-netting advice documented with [Mrs A] being invited to return for

[3] https://www.rnzcgp.org.nz/gpdocs/New-website/Advocacy/PB6-2016-Apr-Managing-patient-test-results.pdf Accessed 8 November 2022

review if her bleeding persisted and to address some additional health (screening) issues.

(iv) Referral for gynaecology review was (per the cited Health Pathway) dependent on the ultrasound result if [Mrs A] had presented a single episode of PMB. Therefore, it was appropriate for [Dr B] to arrange the ultrasound and await the result before determining appropriate further management (including gynaecology referral). I believe for this reason it was vital the referral was tracked (as previously discussed) and that safety netting advice was provided regarding importance of attending promptly if there was further bleeding (documented as being provided).

10. There was no further contact between [Mrs A] and [Dr B] until June 2020. On 26 February 2020 it appears a smear recall letter was generated but there is no reference to [Mrs A] responding to the recall assuming she received the letter. On 8 June 2019 [Dr B] undertook a telephone consultation with [Mrs A] (Covid level 2 precautions) documented as:

phone consult during level 2, she never went for the USS last yr but continues to get light PV bleeding on and off which she has had for years, however in the past week she has also had a pelvic ache which is generally manageable but can disturb sleep, feels like premenstrual pain, urinary frequency longstanding, tendency to constipation longstanding too advised important to get a pelvic USS which she will get … asap and then needs F2F appt with me afterwards

11. An electronic referral was made to a named local provider (referral viewed and of adequate standard) and was undertaken on 10 June 2020, two days after the telephone consultation. [Dr B] does not recall discussing the cost of the scan but felt there was a degree of urgency to get the scan completed and to qualify for a voucher would have required completion of a cervical smear. The scan result was suggestive of adenomyosis and endometrial polyps with no reference to suspected malignancy but a specialist gynaecological opinion is recommended, particularly in view of postmenopausal bleeding. On 11 June 2020 [Dr B] discussed the result per phone with [Mrs A], documented as:

phone consult to discuss result of her USS, explained the polyps and adenomyosis, nothing to suggest malignancy but the wisest course would be to see a gynaecologist to consider curettage to obtain histology, as well as hopefully stopping the PMB, refer […], she is relieved to have that news.

[Dr B] generated an e-referral to the DHB gynaecology service which was acknowledged on 15 June 2021 as being graded priority 1 (high suspicion of cancer). The referral included a copy of the three consultation notes referred to previously and the ultrasound report. I believe it was of adequate quality to enable appropriate prioritisation.

12. I believe [Dr B's] management of [Mrs A] on 8 and 11 June was reasonable and would be met with general approval by my peers. It may be that communication regarding the scan arrangements could have been improved with the option provided of public referral via the voucher system with the proviso that a face to face consultation and repeat smear was required before that option could be completed. However, I agree with [Dr B] that completion of the scan was urgent and using the method undertaken was likely to give the timeliest result. Referral to the gynaecology service was required irrespective of the scan result and this was undertaken by [Dr B] in a timely manner. The standard of clinical documentation was adequate. It might be worth clarifying the steps taken to recall [Mrs A] for her follow-up cervical smear and the practice policy in this regard. Had she responded to recall attempts in February/March 2020 this might have led to an earlier diagnosis of her malignancy although still a year later than the first opportunity to have made the diagnosis.

13. [Mrs A] was seen by the DHB gynaecology service on 18 June 2020. Clinic note refers to the PMB history as: Over the last year [Mrs A] has been having irregular light PV bleeding. [Mrs A] became more concerned this month as this has been associated with some cramping abdominal pain. I note this history varies from that recorded latterly by [Dr B] which referred to 'years' of intermittent symptoms. Bulky retroverted uterus was noted on bimanual examination and pipelle endometrial biopsy was performed. At next review on 8 July 2020 the histology result was discussed (Grade 1 endometroid adenocarcinoma) and [Mrs A] was referred for further staging investigations. Sadly MRI and CT scans revealed advanced endometrial cancer with an enlarged para-aortic node and pulmonary metastases (Stage IV disease). Management plan was for palliative hysterectomy (undertaken on 10 August 2020) and palliative hormone blocker.'

Appendix B: Advice provided to ACC by Dr C

ACC provided HDC with the following advice it received from GP Dr C:

> 'Question 1. Given the clinical presentation of the claimant at the time of initial GP consult on 26/03/2019, taking into consideration clinical knowledge at the time and without the benefit of hindsight, should an alternative treatment path have been chosen? If so, please explain what should have been done, when this should have occurred and why.
>
> I believe that the presentation on 26-3-2019 is critical in the evaluation of this claim. The then [in her sixties] patient presented to the GP reporting post-menopausal bleeding. She reported being 7–8 years after menopause at this time. The bleeding was painless and not post-coital. Internal exam revealed a uterus of normal size, and a cervical smear was taken. Despite a normal cervical aspect, contact bleeding from the brush was reported at that time. The smear was sent, and the patient advised that she would be contacted if the results were abnormal. She was also asked to get a pelvic ultrasound and to return for review if the bleeding continued. The cervical smear was later reported to be normal.
>
> The key to this claim is the fact that a woman well in the post-menopausal phase came to the GP reporting post-menopausal bleeding. This should always be seen as a red flag and investigated. In most cases, benign causes such as endometrial polyps or atrophic vaginitis are often the cause; however approximately 10% of women will have endometrial cancer. When a patient presents with post-menopausal bleeding, the GP should enquire about the onset and nature of the bleeding and the presence of (infective) discharge or pain, use of any menopausal hormonal therapy as well as other medications and/or supplements (especially relevant if a patient seeks advice from integrative medical practitioners who often give herbal or dietary supplements) and personal and family history of breast, bowel or endometrial cancer. Physical examination should be carried out including a cervical smear. It should be noted that a cervical smear is intended to assist in diagnosing cervical cancer, therefore a normal smear does not rule out endometrial cancer. A pelvic ultrasound should be carried out which can reveal the presence of uterine abnormalities such as polyps and endometrial thickening, results which will guide further management decisions. A pipelle biopsy is also recommended and absolutely indicated in a post-menopausal patient if the endometrial thickness on a scan is 5 mm or greater. If a GP does not carry out pipelle biopsies (not all will), the patient can be referred to the gynaecology service for this procedure.
>
> In this case, the GP has not adequately documented the relevant history as I have described above, only noting vaginal bleeding over the previous few days which was not post-coital. He notes that the patient is 7–8 years after menopause but has not recorded when the onset of bleeding was, nor has he recorded any personal or family history of relevant cancers or medication use (including herbal treatments or supplements). If this information is not documented, it is difficult to determine what was and wasn't discussed during a consultation. A bimanual exam was carried out and

a cervical smear taken, which were appropriate in this case. An ultrasound was ordered for the patient; however, I can find no documentation that the relevance or necessity of this was explained or that a pipelle biopsy or gynaecology referral may later have been required based on the results of this scan. I believe it was insufficient to only ask the patient to return if the bleeding continued. In my opinion, the GP should have asked the patient specifically to follow-up after the scan had been carried out to discuss a further management plan. The smear results were normal; however, in this case, this would not have been reassuring as post-menopausal bleeding is more frequently associated with endometrial cancer than cervical cancer. I have found no record that the GP was proactive in following-up with this patient, and it appears that she unfortunately did not attend the recommended pelvic ultrasound.

She sought contact more than a year later reporting ongoing light vaginal bleeding. This time she reported this had been occurring for "years", and recently she experienced pelvic pain which disturbed her sleep. She was now advised of the importance of getting a pelvic ultrasound and specifically asked to book a face-to-face follow up with the GP after the scan.

The scan showed endometrial polyps and a thickness of 7 mm. Both of these findings were indications for gynaecology referral, and this appears to have been communicated to the patient at this time. Histology would certainly have been desirable at this point, either pipelle or curettage, and the patient was appropriately referred for semi-urgent gynaecology review. Unfortunately, pipelle biopsy carried out by the specialist showed endometrial adenocarcinoma.

In summary, I believe that taking the clinical information available in March 2019 into account, a clear "red flag" was present, and the GP did not adequately follow the recommended clinical pathway to investigate this patient's post-menopausal bleeding as outlined in the BPAC and NZ Health Pathways guidelines. If a GP feels there is a reason not to adhere to the guidelines, the reason for this should be clearly documented in the notes. A patient presenting with post-menopausal bleeding without a reasonable explanation should be investigated for the possibility of uterine cancer. It is impossible to know what questions were asked during a consultation if these are not adequately documented; however, I can find no evidence that the nature and duration of the bleeding was sufficiently explored nor relevant personal and family history of associated cancers. Medication use, especially if the patient may be consulting various practitioners, would have also been an essential piece of information in this case. These are not recorded in the clinical documentation. Although a pelvic exam and cervical smear were appropriately carried out and an ultrasound scan was ordered, the importance and relevance of this imaging does not appear to have been explained to the patient at the time. The scan would have informed the need for further investigation (i.e. pipelle biopsy/histology) and/or referral to the gynaecologist. Although the patient does have personal responsibility in their own health care, the GP has the responsibility to provide the patient with sufficient information to make an informed decision, i.e. to ensure the patient understands the reason, necessity and importance of the tests being ordered. I believe the GP should have been more proactive in following-up the scan at the time

considering this patient would have very likely needed a biopsy to complete the diagnostic pathway for post-menopausal bleeding as per the New Zealand Health Pathways guidelines for general practice.

As discussed above, I believe the GP failed to follow-up with regard to the pelvic ultrasound scan ordered in March 2019 leaving the diagnostic pathway incomplete. The scan in 2020 showed endometrial polyps, adenomyosis and a thickened endometrium of 7 mm. Although it is difficult to say what the imaging would have revealed if it had been done in 2019, it is likely that one or more of these abnormalities (which can cause abnormal uterine bleeding) would have been visible and would have led the GP to refer this patient for gynaecological review in 2019. Taking into account the age of the patient and the presence of postmenopausal bleeding, I think it is likely that the specialist would have taken a biopsy as part of their work-up, although it is beyond my scope of practice to comment on this further. It is very possible that the malignancy could have been discovered up to a year earlier. Although it is difficult to comment with certainty, it is possible that the cancer may not have spread to the extent that it had by the time the cancer was identified in 2020.

Question 3. If a failure to treat/refer on in a timely manner, in accordance with local DHB protocols, has occurred please indicate at which point this failure/departure from a reasonable standard of care occurred.

I do not believe that the guidelines for assessment and the recommended clinical pathway of postmenopausal bleeding are much different at the current moment compared to 2019, nor do I believe that these guidelines would in essence have differed between regions. Differences may occur in the number of GPs performing pipelle biopsies in their practice versus referral to the gynaecologist to request this procedure; however, the relevance of a histological diagnosis would not have been different in 2019 from the present regardless of the manner of obtaining these results. Referral guidelines would not have been essentially different from today.

As I have previously discussed, I believe the recommended diagnostic pathway was left incomplete in 2019. The patient did not have the recommended pelvic ultrasound which I believe led to specialist review/biopsy not occurring in a timely manner. In my opinion, the GP should have proactively followed-up with this patient with regard to the scan which had been ordered. The guidelines recommend a scan with some urgency (within approximately two weeks if possible), therefore I believe that follow-up in some form should have been planned by the end of April at the latest. If the GP had actively followed-up with the patient, he may have discovered in a much earlier stage that the patient had for whatever reason not gone for the scan and would have had an opportunity to discuss the need for this or clarify any questions or doubts she had. By not following up, this opportunity was missed and the necessary diagnostics were only carried out more than a year later.

Please provide any other comment if required

No further comment at this time. I am happy to provide any additional comment as required.'

Appendix C: Community Health Pathway — Postmenopausal bleeding guideline

Assessment

1. History:
   - Take a history of all postmenopausal vaginal bleeding (PMB), including recurrent PMB .
   - Assess:
     - pattern of bleeding.
     - risk factors for endometrial cancer .

> **Risk factors for endometrial cancer**
>
> - BMI > 30
> - History of chronic anovulation, including associated polycystic ovarian syndrome (PCOS)
> - Exposure to unopposed estrogen
> - Familial disposition fulfilling the Amsterdam criteria , diagnostic of hereditary nonpolyposis colorectal cancer (HNPCC) or Lynch syndrome
> - Nulliparity
> - Māori or Pacific ethnicity
> - Diabetes

     - use of menopause hormone therapy (MHT) and tamoxifen .
2. Perform examinations:
   - Abdominal examination
   - Speculum:
     - Inspect vulva, vagina, and cervix – if cervical polyps present, also see Cervical Polyps pathway.
     - Take cervical smear if last smear was > 3 months ago.
     - Offer swabs if appropriate.
   - Bimanual examination
3. Arrange ultrasound scan of the pelvis within 2 weeks once criteria are met. Clearly state that the patient is postmenopausal on the ultrasound request form.

> **Criteria for pelvis ultrasound in postmenopausal bleeding (PMB)**
>
> The patient must have had:
>
> - a pelvic examination, including visualisation of the cervix.
> - a cervical smear (if not done within the previous 3 months).

Management

1. If severe bleeding with requires immediate intervention, seek gynaecology advice.
2. Request non-acute gynaecology assessment, irrespective of ultrasound results if:
   - the patient is on tamoxifen, as endometrial cancer risk is increased.
   - the patient has recurrent PMB.
3. If any other cervical or vaginal abnormality (apart from atrophic vaginitis), request non-acute gynaecology assessment.
4. Manage according to ultrasound scan results:
   - If endometrial polyps are present on scan, request non-acute gynaecology assessment.
   - If the scan reports fluid within endometrial cavity, or cystic spaces within the endometrium, arrange a pipelle biopsy , regardless of the endometrial thickness.
   - If endometrium < 5 mm treat atrophic vaginitis .
     - Review in 2 months.
     - Consider practice recall, and if further bleeding occurs, request non-acute gynaecology assessment.
   - If endometrium 5 to 8 mm, arrange a pipelle biopsy .
   - If endometrium > 8 mm:
     - arrange a pipelle biopsy .
     - request non-acute gynaecology assessment irrespective of pipelle results, as these patients have a higher risk of endometrial cancer or a polyp.
   - If any other ultrasound abnormality, request non-acute gynaecology assessment.

Appendix D: Best Practice Advocacy Centre (bpac^{NZ}) 'Investigating and managing abnormal vaginal bleeding' 2019

(i) *Post-menopausal bleeding is defined as any bleeding that occurs after 12 months or more of menopausal amenorrhoea. Post-menopausal bleeding is a red flag for endometrial cancer and this must be excluded as the cause of post-menopausal bleeding with high priority.*

(ii) *Diagnostic and imaging tests that may be indicated when investigating post-menopausal bleeding include:*

- *Cervical smear test — if the last cervical smear test was more than 6–12 months ago**
- *STI testing as indicated by risk*
- *Pipelle biopsy — to sample the endometrium to rule out hyperplasia or malignancy*
- *Pelvic ultrasound — an exception may be those who have recently initiated MHT*
- *Hysteroscopy — for women with post-menopausal bleeding who are taking tamoxifen*

(iii) *The most common cause of post-menopausal bleeding is endometrial or vaginal atrophy (60–80%), followed by menopausal hormone therapy (MHT) (15–25%), endometrial or cervical polyps (2–12%), endometrial hyperplasia (10%), endometrial cancer (10%), cervical cancer (< 1%)*

(iv) ***All women who present with post-menopausal bleeding who have not recently initiated MHT should be referred for pelvic ultrasound with high priority (i.e. within two to four weeks).*** *If the woman is taking tamoxifen, refer for hysteroscopy and pelvic ultrasound.*

(v) *Bleeding after six months of continuous MHT or unscheduled bleeding in women taking cyclical MHT should be investigated with pelvic ultrasound*

(vi) *If there is a high suspicion of endometrial cancer, arrange a pipelle biopsy while awaiting the ultrasound results*

(vii) *Post-menopausal bleeding caused by atrophic vaginitis can be managed with vaginal moisturisers, lubricants or topical vaginal oestrogens. If the woman has had breast cancer, discuss with a relevant specialist in secondary care.*