General Practitioner, Dr B
Medical Centre

A Report by the
Deputy Health and Disability Commissioner

(Case 20HDC00511)

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), in particular an endometrial pipelle biopsy (which involves taking a sample of cells from the lining of the uterus for testing) taken without the woman's consent. In the report, the Deputy Commissioner reaffirms the fundamental importance of informed consent under the Code of Health and Disability Services Consumers' Rights.

2. The woman presented to her GP at a medical centre for insertion of a contraceptive intrauterine device (IUD). During insertion of the IUD, the GP also performed a pipelle biopsy without informing the woman that she was going to do so.

Findings

3. The Deputy Commissioner considered that the intention to take a pipelle biopsy was information that a reasonable consumer in the woman's circumstances needed in order to make an informed choice and give informed consent. As the GP did not provide the woman with information about the biopsy, the Deputy Commissioner found the GP in breach of Right 6(2) of the Code. The GP was also found to have breached Right 7(1) of the Code, because without that information, the woman was not in a position to make an informed choice and give informed consent for the treatment provided.

4. The Deputy Commissioner considered that the pipelle biopsy was not clinically indicated, and that the performance of this invasive procedure amounted to a failure to provide care with reasonable care and skill. Accordingly, the GP was found to have breached Right 4(1) of the Code.

5. The Deputy Commissioner was critical that the GP did not document the woman's consent to the IUD insertion, and criticised the timing of the GP's discussion with the woman about the woman's positive bacterial vaginosis result (a bacterial infection of the vagina).

6. The Deputy Commissioner was also critical of the way in which the medical centre responded when the woman first raised concerns about the GP having performed the pipelle biopsy.

Recommendations

7. The Deputy Commissioner recommended that the GP undertake training on communication and informed consent; arrange for an external audit of a random sample of documentation for 10 pipelle biopsy procedures she has performed; review the local guidance on IUD insertions and pipelle biopsies; and apologise to the woman. The Deputy Commissioner also recommended that the Medical Council consider whether a review of the GP's competence and/or conduct is warranted.

8. The Deputy Commissioner recommended that the medical centre review and amend its complaints policy; provide training to staff on the amended complaints policy; and consider creating a new general informed consent policy.

Complaint and investigation

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

- *Whether Dr B provided Ms A with an appropriate standard of care in December 2019.*
- *Whether the medical centre provided Ms A with an appropriate standard of care in December 2019.*

10. This report is the opinion of Deputy Health and Disability Commissioner Vanessa Caldwell, and is made in accordance with the power delegated to her by the Commissioner.

11. The parties directly involved in the investigation were:

Ms A	Consumer
Dr B	Provider/GP
Registered Nurse (RN) C	Registered nurse
Dr D	GP/director of the medical centre
Dr E	GP
Medical centre	Provider/medical centre

12. Further information was received from:

Primary Health Network
Accident Compensation Corporation
Medical Council of New Zealand

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

Information gathered during investigation

Introduction

14. This report discusses the care provided to Ms A (aged in her twenties at the time of events) by GP Dr B when Dr B performed a pipelle biopsy during a procedure to insert a Mirena intrauterine device (IUD). Ms A complained to HDC that the pipelle biopsy was performed without her knowledge or understanding, and that she did not give her consent to the procedure.

15. A pipelle biopsy involves taking a sample of cells from the lining of the uterus for testing. The Mirena IUD releases the hormone progestogen. Usually, a Mirena IUD is used for long-term contraception, but can also be used to treat heavy menstrual bleeding (menorrhagia).

Background

Dr B and the medical centre

16. Dr B works as a GP at the medical centre. She is not vocationally registered as a GP.[1] She is also a director and shareholder of the medical centre. Dr B immigrated to New Zealand and began working at the medical centre. Prior to that, she had been working as a GP overseas.

17. The medical centre told HDC that at the time of events there was no employment or contractor agreement in place between the medical centre and Dr B, although there was a shareholders' agreement.

4 December 2019 — initial consultation

18. On 4 December 2019, Ms A saw Dr B at the medical centre. During the consultation, Ms A discussed contraceptive options with Dr B.

19. Dr B wrote in the notes that Ms A was "upset by" Depo Provera (a contraceptive injection containing progestogen), and that the combined oral contraceptive pill caused "mood changes" for Ms A. Dr B documented that they "discussed coils" (coils is another term for IUDs). In addition, she documented that Ms A was not pregnant at the time, as well as other information about Ms A's sexual health history.

20. Dr B also wrote that Ms A had "just had a smear in [town] — [some] abnormal [cells] — needs another smear in 1 year ([Family Planning Clinic] in [town])". HDC obtained a copy of the smear results (from August 2019), which showed the presence of low-grade abnormalities (specifically, the presence of "abnormal squamous [a type of skin cell] cells consistent with a low grade squamous intraepithelial lesion"[2]). The results recommended a repeat cervical smear in 12 months' time.[3]

21. Dr B told HDC that Ms A also presented with low ferritin levels (a deficiency of iron in red blood cells) and tiredness. Dr B added that she was mindful that she was unable to determine Ms A's normal menstrual cycle because she had been taking the combined oral contraceptive pill and had been receiving Depo Provera for some time.

22. Dr B also told HDC that during this consultation they discussed more details about the Mirena IUD. Dr B stated:

> "I discussed the method used for insertion, explaining the following: we use a disposable speculum, locate the cervix, sometimes we need to clamp the cervical wall to steady it … I explained that I first need to assess the length of the uterus. For this I would use a sound/pipelle. I would have shown her a Mirena device (in a packet) …"

[1] Dr B was awarded the general scope of practice in 2015.

[2] Abnormal growth of squamous cells on the surface of the cervix.

[3] In the Ministry of Health's Guidelines for Cervical Screening in New Zealand (August 2008), LSIL (low-grade squamous intraepithelial lesion) and ASC-US (atypical squamous cells of undetermined significance) results are grouped together as "Low grade Squamous Abnormalities".

23. Dr B documented in the clinical notes that she "discussed [the Family Planning Association] [web]site". She explained that she advised Ms A to look at several websites, including the Family Planning Association website from her home country, for more information on the Mirena IUD.

24. Dr B cannot recall whether she discussed taking a pipelle biopsy at this stage.

25. Ms A told HDC that Dr B did explain the tools she would use for the Mirena insertion. Ms A also stated that she told Dr B that she was due to have another cervical smear in 12 months' time, only because it sounded like a similar procedure, not because Ms A had any concerns about her smear result. With respect to the pipelle biopsy, Ms A stated that Dr B did not mention this during this consultation.

26. Dr B also documented taking vaginal swabs and urine samples for testing for sexually transmitted infections (STIs) and bacterial vaginosis (BV) (a bacterial infection of the vagina). Ms A told HDC that she asked to have these tests done because she wanted the results before the insertion of the Mirena IUD.

27. On 5 December 2019, Dr B added to the clinical notes the results from the BV test (positive) and STI tests.[4]

6 December 2019

BV result

28. On 6 December 2019, Ms A returned to the medical centre for insertion of the Mirena IUD.

29. A registered nurse, RN C, told HDC that she was called in to be a chaperone for the procedure, and recalled entering the room as Ms A was getting onto the bed. RN C said that she checked Ms A's clinical notes on the computer and noted a positive BV result, and she informed Dr B of this. RN C stated: "It appeared that neither [Dr B] nor [Ms A] had been aware of the positive [BV] result until that point."

30. Ms A also told HDC that RN C was the person who checked the computer and saw the BV result. Ms A said that she asked Dr B if they could still proceed with the IUD insertion in light of the positive BV result, and Dr B said "yes", so Ms A agreed to continue. Dr B told HDC: "BV is not a contraindication to having a Mirena so long as it is treated at the time." Dr B prescribed Ms A medication[5] to treat the BV.

Pipelle biopsy performed during IUD insertion

31. During the insertion of the Mirena IUD, Dr B also performed a pipelle biopsy. Ms A told HDC that the pipelle procedure was performed without her knowledge or understanding. No consent form was signed prior to the procedures.

[4] Negative for chlamydia and gonorrhoea.
[5] Ornidazole.

32. Dr B stated:

> "Although [Ms A's] symptomology did not indicate that a pipelle biopsy was necessarily required, I decided to perform the biopsy in any event as I wanted to be safe and thorough and [Ms A] was very anxious and concerned about her symptoms."

33. Dr B told HDC that she was trained to insert IUDs in a country "where it is routine practice to use a pipelle to sound the uterus [determine the depth and position of the space inside the uterus] and we take a uterine sample at the same time". She stated that because it is routine to take a uterine sample when inserting the IUD, it is not routine practice to obtain separate consent for this.

34. Dr B documented the following notes about the procedures:

> "[N]eeded to dilate [cervix] and clip anterior [cervix]/pipelle taken although not sure if a great sample/mirena inserted — did get a good fundal insertion and string left a little long/analgesia etc advice ++++."

35. Dr B told HDC that although her usual practice would be to have a clear discussion about what the procedure involved, she is unable to recall whether she obtained Ms A's consent to the pipelle biopsy procedure. Dr B said that she told Ms A that she was sounding the uterus with the pipelle and was attempting to get a sample of cells. Dr B stated that because Ms A was uncomfortable, she told Ms A that she would abandon trying to get the sample, as she had no clinical concerns.

36. RN C also documented notes about the procedure. She wrote: "Assisted [Dr B] with Mirena insertion — Noted BV result not seen. Oral [prescription] given. Pipelle taken for precaution?/Mirena inserted."

37. RN C told HDC that she was not present for the informed consent process between Dr B and Ms A; however, RN C recalled being aware that the procedure to be undertaken was insertion of a Mirena. RN C further stated that the first time she was aware that Dr B would be performing a pipelle procedure was when she saw the pipelle equipment on the trolley. She said that she asked Dr B if she would be performing a pipelle biopsy, and Dr B confirmed that she would be.

38. Ms A also recalled RN C questioning Dr B. However, Ms A recalls RN C simply asking, "Are we doing that?" during the procedure, and that Dr B told RN C something along the lines that her gynaecologist friend does it when inserting a Mirena, because that is best practice. Ms A said that the words "pipelle biopsy" were not mentioned.

39. RN C documented that Ms A had a sore back immediately following the procedure, and noted that Ms A's mother (who works in the same building as the medical centre) was called in to provide support.

PHO claim

40. Later that day, Dr B submitted to the Primary Health Network (PHO) an electronic claim for reimbursement for the pipelle biopsy procedure. In the claim, under the field "Indication for Pipelle Biopsy", Dr B selected the option "Heavy Menstrual Bleeding" (the other options were "Post-menopausal Bleeding", "Intermenstrual Bleeding", and "Endometrial Cells on Cervical Smears"). Dr B also ticked a box to confirm "Informed Consent Obtained".

41. The PHO told HDC that claims for reimbursement are submitted through its online portal, and the portal also makes available to clinicians agreed clinical pathways/criteria for services. The PHO provided HDC with an excerpt from the pathway for pipelle biopsies, which stated that pipelle biopsies are indicated "only as part of a full clinical assessment", and referenced the pathways for abnormal uterine bleeding, post-menopausal bleeding, and endometrial (glandular) cells on cervical smears.

7 December 2019 — follow-up contact by Dr B

42. Dr B told HDC that she tried to call Ms A to see how she was doing. However, Ms A did not answer, so Dr B sent her a text message which said: "Hi [Ms A] Just left a msg on your phone — hope all okay after yesterday — you did really great — well done. Call me if you need to. BW [Dr B, the medical centre]."

43. Dr B said that she then went overseas for three weeks, during which time her patients were seen by her colleagues, Dr E (a medical centre director and shareholder at the time) and Dr D (a medical centre director and shareholder at the time, and currently).

11 December 2019 — follow-up consultation with Dr E

44. On 11 December 2019, Ms A returned to the medical centre for a review and was seen by Dr E. Ms A told HDC that at this appointment Dr E told her that the pipelle procedure had taken place during the insertion of the Mirena. Ms A said: "[Dr E] and [RN C] then found out that I had neither any prior knowledge or had given consent to have the Pipelle done."

45. Dr E documented: "[Ms A] not aware of pipelle before mirena insertion. No clear medical indication for pipelle as well as patient is not aware [of] this invasive procedure." Dr E also recorded that Ms A was not aware of the positive BV result, and that she said she would have deferred the Mirena insertion until after she had completed her BV treatment (although Dr E noted that a Mirena can be inserted even where it is unknown whether the consumer has such an infection).

46. Dr E also wrote in the notes that Ms A wanted Dr E to inform her mother (who was unavailable at the time of Dr E's consultation with Ms A) on Ms A's behalf about the fact that the pipelle biopsy had been performed without her consent.

47. Dr E told HDC that he had never met Ms A before this consultation. He said that his initial understanding was that Ms A required a consultation in order to find out the results of the endometrial biopsy; however, he recalls "feeling quite shocked … as it became clear that [Ms A] had not consented to the endometrial sampling undertaken by [Dr B]". Dr E recalled that both Dr D and Dr B were on leave at the time.

48. Ms A told HDC that although the details are a little hazy for her, she remembers expressing to Dr E that she wanted to make a formal complaint, and that Dr E directed her to HDC. She does not recall laying a formal complaint with the medical centre, and changed to a new medical practice shortly after the events. Ms A also recalled that she ended up crying during her appointment, and telling Dr E and RN C (who was also present) that she felt very uncomfortable and upset about what had happened. She said that Dr E was very helpful to her in the aftermath.

49. Later on 11 December 2019, Dr B remotely accessed (while overseas) the medical centre's patient management system. She explained that she did this because she did not want to get behind on administrative tasks while on leave, and she also wanted to check whether there were any urgent requests for any of her patients, and to help alleviate any additional workload her absence created for her colleagues. Dr B said that she accessed Ms A's record specifically because she wanted to see if Ms A had responded to her text message (referred to in paragraph 42 above) or contacted the medical centre. Dr B then saw Dr E's entry in Ms A's clinical notes and decided to "enter a note in response to provide further information to try to alleviate [Dr E's] concerns and explain [her] clinical rationale for taking the pipelle biopsy".

50. In an entry into Ms A's notes dated 11 December 2019 (with the heading "above note — remote access"), Dr B wrote that she had discussed the vaginal swab and BV results prior to insertion, and that Ms A was "keen to have the coil inserted". Dr B also documented:

> "[T]aking a pipelle sample prior to insertion is good practice again as per guidelines and widely practiced by gynaecologists in NZ. Did explain this to [Ms A] this was good practice and just for reassurance although clinically there were no concerns."

Histology results and apology

51. On 17 December 2019, RN C documented Ms A's histology results as "Insufficient Endometrial Tissue for Diagnosis". This information was passed on to Ms A.

52. On 29 December 2019, Dr B recorded in the notes that she had spoken to Ms A on the phone. Dr B wrote: "[Explained] re pipelle — apologised for not explaining my thinking at the time to [Ms A]."

Subsequent events

53. Dr E stated that at the start of 2020, he approached Dr D informally and spoke about Ms A's case. Dr D does not recall Dr E discussing Ms A with him in early 2020; however, Dr D told HDC that after becoming aware of Ms A's concerns, he advised Ms A's parent to complain to HDC about the treatment that Ms A received.

54. Dr E said that he, Dr B, and Dr D met on 24 February 2020 to discuss a number of Dr E's concerns, including about Ms A's treatment. Dr B told HDC that she did attempt to discuss Dr E's concerns with him at a meeting.[6] Dr D cannot recall discussing Ms A's case at any

[6] However, Dr B believes that this meeting took place in January 2020, not February.

formal meeting he attended with Dr B and Dr E. There are no records or minutes of any such meeting.

55. All three doctors told HDC varyingly that there were communication issues and that relationships had deteriorated, and that around that time it had become acrimonious between Dr E and the two other doctors at the medical centre.

56. In March 2020, following the meeting that Dr E said took place in February, Dr E wrote to the Medical Council of New Zealand about his concerns. In the letter, he commented that the pipelle biopsy had been performed on Ms A "with no obvious clinical indication", and that Ms A had not been informed about (and therefore had not consented to) the procedure. He also referred to the February 2020 meeting with Dr B and Dr E, describing it as becoming "acrimonious".

57. Ms A told HDC that she did not receive anything in writing from the medical centre in response to her concerns.

Further information

Ms A

58. Ms A told HDC:

> "I am immensely upset and angered by what has happened and wish for [Dr B] to be held accountable for her actions …
>
> It has been explained to me that there is a small but potential risk of future fertility complications as a result of trauma caused by this procedure. This was most upsetting to be told as I had no control over anything."

Medical centre

Policies

59. The medical centre provided HDC with copies of its "Informed Consent for Mirena IUD Insert" form (the IUD Consent Form) and "Informed Consent for Endometrial — Pipelle Biopsy" form (the Pipelle Biopsy Consent Form) in place at the time of events. The IUD Consent Form sets out in detail the benefits and risks of the procedure, and includes a space for the patient to sign to confirm that they have discussed information regarding the IUD with the doctor, that they have received a written information brochure about the IUD, and that they consent to the insertion of the IUD. The consenting doctor or a witness is also to sign the form.

60. The Pipelle Biopsy Consent Form sets out the indications for performing the procedure: abnormal vaginal bleeding; heavy or prolonged periods; bleeding in between periods; post-menopausal bleeding; and if further investigation is required after an ultrasound scan has showed thickened lining of the uterus. The Pipelle Consent Form includes a space for the patient to sign to confirm their consent to the pipelle biopsy, and also a space for the doctor to sign.

61. The medical centre told HDC that aside from these two forms it did not have a separate informed consent policy.

62. The medical centre also told HDC that in respect of the steps to be taken when a practitioner becomes aware of concerns regarding the competence or care provided by another medical centre practitioner, it follows the Medical Council of New Zealand (MCNZ) statement, "What to do when you have concerns about a colleague".[7]

63. The medical centre also provided HDC with a copy of its Complaints Policy.[8] Broadly, the Complaints Policy requires the following:

- Complaints are to be made in writing (and patients who wish to make a complaint are to be provided with the appropriate form).
- Patients' complaints and actions taken by medical centre staff are to be documented.
- Within five working days of receipt of a patient complaint, the complaint is to be acknowledged in writing.
- Within ten working days (unless the complaint will take longer to resolve, in which case the patient is to be informed), the medical centre is to decide whether the complaint is accepted or not, and advise the patient:
  - The reason for the decision;
  - Any actions the medical centre proposes to take;
  - Any appeals procedure the medical centre has in place; and
  - The patient's right to complain to HDC or the Privacy Commissioner, if they feel the matter remains unresolved.

Responses to provisional opinion

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

65. Ms A told HDC that she had no further comments to make.

66. Dr B also did not wish to make any further substantive comments about the findings.

67. The medical centre told HDC that it is happy to amend its complaints policy (in accordance with the recommendation in paragraph 104 below). It noted (as referred to in paragraph 59 above) that the medical centre has protocols in place for consent in the context of pipelle biopsies, and that Dr B "quite simply did not follow them".

[7] Relevant extracts of this statement are set out in Appendix B.
[8] Relevant extracts of this policy are set out in Appendix C.

68. Dr D (a director and shareholder at the time, and currently) also reiterated that he told Ms A's family members to make a complaint when they asked him whether or not to do so, and that he fully supported the complaint being made.

Opinion: Dr B — breach

Introduction

69. This opinion is primarily about informed consent and, in particular, whether Ms A was informed about, and gave her consent to, the pipelle biopsy being performed during the insertion of a Mirena IUD.

70. The principle of informed consent is at the heart of the Code of Health and Disability Services Consumers' Rights (the Code). Right 7(1) of the Code provides that apart from exceptional situations,[9] health services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent. Right 6(2) of the Code states that before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, needs to make an informed choice or give informed consent.

Pipelle biopsy

Informed consent

71. Ms A stated that she had no knowledge of, and did not consent to, Dr B performing the pipelle biopsy during the Mirena IUD insertion on 6 December 2019. Dr B stated that although her usual practice would be to have a clear discussion about what the procedure involved, she is unable to recall whether she obtained Ms A's consent to the pipelle biopsy procedure. No consent form was signed, despite the medical centre having a specific consent form for pipelle biopsies. In addition, Dr B did not document anything about a discussion of pipelle biopsies, either during the initial consultation on 4 December, or when the procedure was performed on 6 December. I also note that Dr E documented, on 11 December: "[Ms A] not aware of pipelle before mirena insertion."

72. I note that Dr B, when submitting the PHO claim on 6 December, confirmed that she had obtained Ms A's consent to the procedure. Dr B also documented retrospectively (on 11 December) that she did explain to Ms A that performing the pipelle biopsy was "good practice" and "just for reassurance".

73. However, on the evidence before me, I find that Dr B did not inform Ms A what a pipelle biopsy involved, or that she was going to perform a pipelle biopsy while inserting the Mirena

[9] Specifically, Right 7(1) states that services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.

IUD. Plainly, this is information that a reasonable consumer, in Ms A's circumstances, needed to make an informed choice and give her informed consent to the pipelle biopsy.

Clinical indication for pipelle biopsy

74. At Ms A's initial consultation with Dr B on 4 December, they discussed contraceptive options. It was recorded in the notes that Ms A was unhappy with Depo Provera, and that oral contraceptives had caused mood changes. It was also noted that she had had a recent cervical smear that had shown some low-grade abnormal cells.

75. My clinical advisor, GP Dr David Maplesden, commented that Ms A did not appear to have any clinical indication for performing a pipelle endometrial biopsy. Dr Maplesden explained that the result from the smear in August 2019 was not a clinical indication to perform the pipelle biopsy. Dr Maplesden further advised:

> "I could not find any reference in the relevant [overseas guidance or patient information] to pipelle biopsy being a routine part of IUD insertion and I am not aware of any NZ guidance which makes this recommendation ... I am not aware of any recommendation or evidence for routine screening for endometrial cancer by way of pipelle endometrial biopsy of young asymptomatic women with no risk factors for endometrial cancer. In summary, I do not believe there was any clinical indication for [Dr B] to perform an endometrial biopsy on [Ms A] on 6 December 2019."

76. I note Dr B's submission that she was trained in a country where it is routine practice to use a pipelle to sound the uterus and take a uterine sample at the same time. However, as Dr Maplesden noted, Dr B did not provide "any information from New Zealand or [her home country] that supports performing pipelle endometrial biopsy on young asymptomatic women with no risk factors for endometrial cancer as a routine process during Mirena or other IUCD insertion". I therefore accept Dr Maplesden's advice and find that there was no clinical indication for Dr B to perform the pipelle biopsy. This is very concerning.

Conclusion

77. Overall, Dr Maplesden advised:

> "[Dr B's] management of [Ms A] in relation to performing a pipelle biopsy on 6 December 2019 was at least a moderate departure from accepted practice. My reasons for this opinion include: the absence of a clinical indication for the procedure; the failure to discuss and gain consent for the procedure, or at least to establish [Ms A] had a clear understanding of the procedure and the reasons for undertaking it; the failure to comply with the medical centre policy regarding gaining written consent for the procedure."

78. Given that Dr B did not provide Ms A with information about the pipelle biopsy that a reasonable consumer, in Ms A's circumstances, needed to make an informed choice or give her informed consent, I consider that Dr B breached Right 6(2) of the Code. It follows that Ms A was not in a position to make an informed choice and give informed consent for the treatment provided. Consequently, Dr B also breached Right 7(1) of the Code.

79. In addition, in my opinion, performing an invasive procedure such as a pipelle biopsy when the procedure is not clinically indicated amounts to a failure to provide care with reasonable care and skill. Accordingly, I find that Dr B also breached Right 4(1) of the Code.

Mirena IUD insertion

Informed consent — adverse comment

80. When Dr B discussed contraceptive options with Ms A on 4 December, she recorded in the notes "discussed coils". Dr B stated that she described the insertion process and showed Ms A the equipment to be used. Ms A confirmed that Dr B did discuss the equipment to be used. Dr B also said that she told Ms A to review certain websites, including that of Family Planning, for more information about the Mirena IUD. The medical centre has a specific consent form for IUD insertions; however, no such form was signed prior to the insertion of the Mirena IUD.

81. Dr Maplesden said that he is mildly critical that Dr B neither documented Ms A's verbal consent for the Mirena IUD insertion, nor obtained a signed IUD Consent Form prior to performing the IUD insertion procedure. I accept that Dr B did discuss and provide some information to Ms A about Mirena IUDs, although aside from a reference to the overseas family planning website, details of this discussion were not documented. I also accept that Ms A did consent to the Mirena IUD insertion.

82. However, I agree with Dr Maplesden that Dr B should have ensured that this consent was documented. I also note that the MCNZ Statement on informed consent (relevant excerpts are set out in Appendix B) requires doctors to keep clear and accurate records of the information that was discussed, any specific risks that were highlighted, any request or concerns expressed, and any decisions made and the reasons for them. Dr B should have documented the discussion and recorded Ms A's consent in one form or another.

Undertaking insertion with positive BV result — adverse comment

83. Prior to the Mirena IUD insertion being performed, the positive BV result was noted by RN C. Dr B prescribed medication to treat the BV, and proceeded with the insertion. Dr Maplesden advised: "[T]he presence of BV is not a contraindication to Mirena insertion. It was reasonable to provide BV treatment following insertion of the device." I accept Dr Maplesden's advice and am therefore not critical that Dr B proceeded with the Mirena IUD insertion in these circumstances.

84. However, for completeness, I note that it was not until Ms A was getting onto the bed in preparation for the Mirena IUD insertion, and only after RN C checked the computer, that Dr B discussed the BV result with Ms A. In my opinion, the timing of this discussion was less than ideal. It would have been more appropriate for Dr B to have discussed the BV result, and any implications that it may have had on the Mirena IUD insertion, and obtained Ms A's written consent for the procedure before Ms A physically began to prepare for the procedure.

Opinion: Medical centre — adverse comment

85. As a healthcare provider, the medical centre is responsible for providing services in accordance with the Code. Dr B worked at the medical centre at the time of these events, although there was no formal employment or contractor agreement in place.

86. As noted above, I have found that Dr B breached the Code. I also note the following advice from Dr Maplesden:

> "[The medical centre] has provided policies [the consent forms] regarding Mirena insertion and Pipelle biopsy which were in force at the time of the events in question. These each contain information sheets for the patient and a consent form to be signed prior to the procedure. It is apparent [Dr B] did not make use of these resources and did not follow the practice policy regarding gaining of written informed consent."

87. Individual providers are responsible for obtaining informed consent for procedures that they perform. In my opinion, the errors identified with respect to informed consent and the pipelle biopsy were individual failings. Therefore, I consider that the medical centre did not breach the Code. However, in my view there may be some benefit in the medical centre adopting a general informed consent policy to complement the IUD Consent and Pipelle Biopsy Consent Forms, and I recommend that the medical centre consider this.

88. I also have some concerns about the way in which the medical centre handled the situation after Ms A told Dr E that she was not aware of, and did not consent to, the pipelle biopsy on 7 December 2019.

89. After Dr E's consultation with Ms A, during which Ms A told Dr E that she was upset and uncomfortable about what had happened with the pipelle biopsy, it appears that a meeting was held at some stage in early 2020 between Dr B, Dr D, and Dr E. However, there are no records or minutes of any such meeting. I note Dr Maplesden's comment that best practice is to record minutes of any such meeting for later reference. I agree. If a consumer's concerns as significant as Ms A's are discussed during a meeting, there should be a written record of such discussions and any actions to be taken. I suggest that the medical centre reflect on Dr Maplesden's comments.

90. In March 2020, shortly after the meeting that Dr E said occurred, he wrote to the Medical Council about his concerns. Dr Maplesden advised that he considered Dr E's actions to have been reasonable, and I accept this advice.

91. I also note that the medical centre did not acknowledge or respond in writing to Ms A's concerns that she did not consent to the pipelle biopsy.

92. As evidenced by the information from Dr B, Dr E, and Dr D, it is apparent that the relationship between the three doctors had become or was becoming strained at the time that Ms A's concerns were raised with Dr E. As Dr Maplesden commented: "[I]t appears the collegial relationship was dysfunctional and constructive communication was difficult …"

93. Right 10 of the Code requires that providers' complaints procedures ensure that a complaint is acknowledged in writing within five working days of receipt, and that the consumer is informed of the outcome of their complaint[10] within ten working days of acknowledging the complaint. The timeframes as set out in the medical centre's Complaints Policy for acknowledging complaints and advising consumers of the outcome of their complaint align with Right 10, including the timeframes.

94. I acknowledge that Ms A did not formally lay a complaint with the medical centre. However, it was clear from her appointment with Dr E that she was upset and concerned about what had happened, and that the medical centre was aware of the nature of those concerns. In my view, it would have been appropriate for the medical centre to have responded formally to her concerns. I also acknowledge that there were informal conversations with Ms A, including Dr B calling Ms A and apologising on 29 December 2019. I also acknowledge Dr D's submission that he told Ms A's parents that he fully supported the complaint about Dr B, and that ultimately Ms A decided to make her complaint to HDC.

95. However, the medical centre did not acknowledge or respond to Ms A's concerns in writing, which is inconsistent with the requirements of Right 10 and the medical centre's Complaints Policy. Given the significance of the concerns Ms A was reporting (a procedure being performed without her knowledge or consent), this is concerning. It seems that the dysfunction and interpersonal difficulties at the medical centre discussed above may have distracted the medical centre from providing a formal response to Ms A about her concerns. Nonetheless, I expect all providers to comply with the requirements of Right 10, and it is not acceptable for interpersonal issues to affect a provider fulfilling its obligations to a consumer under the Code. The consumer's experience and concerns must remain the focus.

96. I also note that the Complaints Policy requires patient complaints to be made in writing. As this Office has stated previously,[11] the Code does not require complaints to be made in writing; instead, Right 10 states that consumers have the right to complain about a provider in any form. I recommend that the medical centre amend its Complaints Policy immediately to ensure that it is consistent with Right 10.

Changes made

Dr B

97. Dr B told HDC that in accordance with a suggestion made by Dr Maplesden in his advice, she has completed an audit of ten patients on whom she performed a Mirena insertion and/or pipelle biopsy (both prior to and after the events). She provided HDC with evidence of the

[10] Including whether the complaint is justified or not, or whether the provider needs more time to investigate the complaint.
[11] See Opinion 17HDC00974.

audit, which showed that the relevant consent forms were signed. Dr B also stated that all ten patients had clinical indications for the Mirena IUD and/or pipelle biopsy.

98. In addition, Dr B told HDC that since these events:

- She takes more time when having consenting discussions with patients, reads out consent forms, answers patients' questions, and gives patients additional time to read over the forms, and is more mindful of documenting consenting discussions.
- She has undertaken cultural competency training.
- She held an in-house training session on informed consent with other practitioners at the medical centre, with a particular focus on Māori health.

Medical centre

99. Since these events, the medical centre has updated its Pipelle Biopsy Consent Form to require that two doctors sign: first, the doctor who is performing the procedure; and secondly, a doctor who has checked the indications for performing the procedure and who agrees that the procedure is reasonably and necessarily indicated.

Recommendations

100. Bearing in mind the changes made by the parties since these events, I make the following recommendations.

101. I recommend that Dr B:

a) Undertake training on communication and informed consent, and provide HDC with evidence that the training has been completed, within three months of the date of this report.

b) Arrange for an external audit of a random sample of documentation for having performed 10 pipelle biopsy procedures in the year 2019 to confirm that:

   i. the procedure was clinically indicated; and

   ii. the consumer's informed consent was obtained and documented appropriately.

   The results of the audit are to be provided to HDC within three months of the date of this report. If the audit does not identify 100% compliance, then Dr B is also to report back on what actions have been taken to address these issues.

c) In response to a recommendation proposed in the provisional opinion, Dr B told HDC that she has reviewed the local HealthPathways guidance on Mirena insertion and pipelle biopsy, particularly in relation to patient information and informed consent. With this in mind, I recommend that Dr B consider using the written patient information and written consent forms referred to in the HealthPathways guidance, and report back

to HDC on any further changes made to her practice following her consideration, within three months of the date of this report.

102. In accordance with the proposed recommendation in my provisional report, Dr B provided a written apology to Ms A. The apology has been forwarded to Ms A.

103. I recommend that the Medical Council of New Zealand consider whether a review of Dr B's competence and/or conduct is warranted, based on the information contained in this report.

104. I recommend that the medical centre:

a) Review and amend its Complaints Policy to ensure that it is consistent with Right 10 of the Code, and in particular to acknowledge that consumers may make complaints in any form and are not required to make complaints in writing. A copy of the amended Complaints Policy is to be provided to HDC within one month of the date of this report.

b) Provide training to its staff on the amended Complaints Policy. Evidence of this training is to be provided to HDC within three months of the date of this report.

c) Consider creating and adopting a new general informed consent policy. The medical centre is to report back to HDC on the results of its consideration, and provide a copy of the new policy it has adopted (if any), within three months of the date of this report.

Follow-up actions

105. A copy of this report will be sent to the PHO.

106. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Medical Council of New Zealand, and it will be advised of Dr B's name.

107. A copy of this report with details identifying the parties removed, except the expert who advised 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 to Commissioner

The following expert advice was obtained from Dr David Maplesden:

"1. Thank you for the request that I provide clinical advice in relation to the complaint from [Ms 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. I have reviewed the information on file: complaint from [Ms A]; response from [Dr B]; GP notes [medical centre].

2. [Ms A] ([aged in her twenties]) complains that on 6 December 2019, during a scheduled appointment for insertion of a Mirena intra-uterine device (IUD), [Dr B] performed a pipelle endometrial biopsy on [Ms A] without her knowledge or consent. At an appointment with another provider, [Dr E], on 11 December 2019 [Ms A] was made aware the procedure had been performed. [Ms A] is concerned that the invasive procedure was performed without her knowledge and without any clinical indication.

3. [Dr B] includes the following information in her response to the complaint:

(i) [Dr B] saw [Ms A] on 4 December 2019 to discuss contraception. [Ms A] had a recent abnormal cervical smear taken at [a] Family Planning Clinic and this was to be repeated in a year. I have not been provided with a copy of the cervical smear result but assume it was an ASCUS result. The possibility of a Mirena IUD was discussed and [Dr B] described the insertion process. She states she discussed the process for sounding the uterus and *I cannot recall now if I discussed taking a pipelle sample at this stage*. [Ms A] expressed an interest in having the Mirena inserted. Routine vaginal swabs were taken but [Ms A] had no concerning symptoms. [Dr B] advised [Ms A] to review some named websites to gain further information on the Mirena device.

Addendum 26 April 2021: Smear result dated 21 August 2019 has been sighted and states: *There are abnormal squamous cells present consistent with a low-grade squamous intra-epithelial lesion (LSIL; CIN 1/HPV).* Recall was recommended for 12 months and SMS text reminders were sent to [Ms A] on 17 August and 17 September 2020.

(ii) [Ms A] presented for Mirena insertion on 6 December 2019. Swabs had revealed bacterial vaginosis (BV) and a prescription for ornidazole was provided. [Dr B] states that during the procedure for insertion of the *Mirena I inserted the pipelle to sound the uterus and tried to obtain cells but got very little. I talked to [Ms A] throughout the procedure which is common practice for me. I always explain each step as I go along and explained that I was trying to take some cells from the inside of her uterus for reassurance only*. The Mirena was inserted with no apparent complications.

(iii) [Dr B] states she was trained in [a country] *where it is routine practice to use a pipelle to sound the uterus and we take a uterine sample at the same time … as it is routine*

practice [there] to sample the uterus, it is not routine practice to obtain separate consent for this … I realise now that even though I explained what I was doing as I was performing the procedure, best practice would be to explain this prior to starting the procedure at the time I demonstrate the device.

4. Review of GP notes

(i) Notes dated 4 December 2019 include: *Upset by depot provera, COC caused mood changes. Discussed coils — discussed [overseas family planning website]* … sexual health history discussed together with recent cervical smear history. Swabs and urine taken with results showing BV only.

(ii) Notes dated 6 December 2019 include: *has needed rx for BV before — soaps etc advice. Needed to dilate cx and clip anterior cx, pipelle taken although not sure if a great sample, mirena inserted — did get good fundal insertion and string left a little long, analgaesia etc advice ++++ … see when I am back from holiday re strings okay*. Practice nurse has noted assisting [Dr B] and *Noted BV result not seen. Oral Rx given. Pipelle taken for precaution?/Mirena inserted. Analgesic advice. Sore back post-insertion — mum called in for support. Monitored for 20 minutes post-insertion. Review PRN.* Prescriptions were provided for codeine, ibuprofen, paracetamol and ornidazole.

(iii) [Dr B] has made notes dated 11 December 2019 which refer to the relationship between IUD insertion and BV and also: *Taking a pipelle sample prior to [IUD] insertion is good practice again as per guidelines widely practiced by gynaecologists in NZ* … On 17 December 2019 practice nurse notes are: *Given histo results to [her] (mum) for [Ms A]. To review PRN.* [Unclear if [Ms A] had formally consented to her mother being provided with her personal health information]. Histology result showed insufficient tissue for diagnosis. On 29 December 2019 [Dr B] has recorded: *spoke with [Ms A] at 2139 — explained re pipelle — apologised for not explaining my thinking at the time to [Ms A], PV bleeding nil, nil discharge, back pain apparent later in the day when hungry, otherwise nil changes*. [Ms A] subsequently had ongoing issues with symptomatic BV which is not the subject of this report.

(iv) I have not been provided with any written consent forms in relation to the procedures performed on [Ms A] on 6 December 2019 (Mirena IUD insertion, pipelle endometrial biopsy).

5. Comments

(i) It is difficult to determine from the clinical notes the extent of discussion undertaken with [Ms A] regarding the risks and benefits of Mirena insertion and other contraceptive options. Local guidance [1] suggests provision of written information regarding the insertion process. Neither the cited written information recommended nor the websites named by [Dr B] which [Ms A] was referred to discuss pipelle endometrial

[1] Community HealthPathways section 'Intrauterine Device (IUD) Insertion'

biopsy as part of the IUD insertion process. However, the websites, if accessed by [Ms A], contain a reasonable amount of information regarding Mirena use.

Addendum: [The medical centre] has provided policies regarding Mirena insertion and Pipelle biopsy which were in force at the time of the events in question. These each contain information sheets for the patient and a consent form to be signed prior to the procedure. It is apparent [Dr B] did not make use of these resources and did not follow the practice policy regarding gaining of written informed consent. Since becoming aware of [Ms A's] concerns, the practice has amended the consent form for Pipelle biopsy to require co-signing by two GPs.

(ii) Appropriate STI screening was undertaken prior to Mirena insertion and the presence of BV is not a contraindication to Mirena insertion. It was reasonable to provide BV treatment following insertion of the device. Local advice[2] includes: *A STI check, and testing if necessary, should be undertaken prior to inserting an IUD. If the patient is asymptomatic, an IUD can be inserted prior to swab results being available, provided they can be promptly contacted if they have a positive result. STIs can usually be treated without the need for removal of the IUD.*

(iii) [Ms A] did not appear to have any clinical indication for performing a pipelle endometrial biopsy. I have assumed her cervical smear result did not refer to abnormal endometrial (glandular) cells on the smear which might be an indication for endometrial biopsy. However, an ASCUS result would not be an indication. **Addendum 26 April 2021: see smear result s 3(i). There was no clinical indication to perform an endometrial biopsy on the basis of the smear result.** I could not find any reference in the relevant [guidance or patient information from Dr B's home country] to pipelle biopsy being a routine part of IUD insertion and I am not aware of any NZ guidance which makes this recommendation, but I would be happy for [Dr B] to supply me with the references she discusses for such formal guidance. I am not aware of any recommendation or evidence for routine screening for endometrial cancer by way of pipelle endometrial biopsy of young asymptomatic women with no risk factors for endometrial cancer. In summary, I do not believe there was any clinical indication for [Dr B] to perform an endometrial biopsy on [Ms A] on 6 December 2019.

Addendum: [Dr B] has not provided any additional information which alters my opinion that there was no clinical indication for [Ms A] to undergo a pipelle biopsy. She has not provided any information from NZ or [her home country] that supports performing pipelle endometrial biopsy on young asymptomatic women with no risk factors for endometrial cancer as a routine process during Mirena or other IUCD insertion and I remain of the view this is not standard or accepted practice.

(iv) I believe there is no expectation by patients undergoing Mirena insertion in New Zealand that a pipelle endometrial biopsy is undertaken routinely as part of the procedure and that if pipelle biopsy is to be performed as part of the procedure, this

[2] https://bpac.org.nz/2019/contraception/long-acting.aspx Accessed 3 August 2020

would require separate discussion and consent. I acknowledge Mirena insertion is often undertaken as treatment for menorrhagia or hormone-related dysfunctional uterine bleeding when endometrial biopsy might be indicated, but this does not mean it can be regarded as routine and not requiring separate discussion or consent. Endometrial biopsy requires removal of tissue which may have significant cultural significance for Māori patients[3]. Potential procedure complications of bleeding, pelvic infection and uterine perforation are similar to those associated with IUD insertion but I believe these should also be discussed separately to the IUD insertion process, particularly if there is no clinical indication for the biopsy.

(v) The cited HealthPathways guidance notes: *Informed consent is required for all procedures and treatments. Cornerstone Accreditation suggests written consent for minor surgery, ear syringing, IUCD and Mirena, and pipelle biopsies.* I believe best practice is to document verbal informed consent as a minimum, with written consent preferred for Mirena insertion and pipelle biopsy. Some PHOs provide templates for such consent[4]. If the consent form refers only to Mirena insertion and pipelle biopsy is to be performed, this should be listed on the Mirena consent form or a separate form provided for the biopsy.

(vi) The use of a pipelle sampling cannula for sounding the uterus is a reasonable strategy[5] although dedicated flexible sounds are readily commercially available. Using the pipelle cannula as a sounding device only would not require additional discussion or consent provided sounding the uterus has been discussed as part of the insertion process. However, as discussed above, if endometrial biopsy is to be performed I believe this requires separate discussion and consent.

6. In summary, I believe [Dr B's] actions in performing an endometrial biopsy on [Ms A] when there was no clinical indication, no discussion of the reason for the procedure prior to the procedure being commenced, and no consent for the procedure obtained, represents at least a moderate departure from accepted practice. I believe that my peers in NZ would obtain separate informed consent to perform an endometrial biopsy in addition to that obtained for inserting a Mirena IUCD if the two procedures were to be performed concurrently. If the pipelle cannula was to be used just as a sounding device without any intent to biopsy, I do not believe separate informed consent would be required, but that is not the case presented here. I am mildly critical there is no specific reference to verbal consent being provided for the Mirena insertion, or no copy of a signed written consent document, but acknowledge the discussion and information

[3] https://www.ccdhb.org.nz/our-services/a-to-z-of-our-services/maori-health/tikangamaoriaguideforhealthcareworkersbooklet.pdf Accessed 3 August 2020
[4] E.g. https://practicespinnacle.co.nz/uploads/mirena-or-jaydess-consent.pdf and: https://www.poac.co.nz/site_files/359/upload_files/LARC-IUCDConsentformdocx(002).pdf?dl=1 Accessed 3 August 2020
[5] Eg. See: http://thischangedmypractice.com/endometrial-aspirators-for-iud-insertion/ Accessed 3 August 2020

provided regarding the device and insertion procedure. I make the following recommendations:

- [Dr B] review her local HealthPathways guidance on Mirena insertion and pipelle biopsy, particularly in relation to patient information and informed consent, and she consider using the written patient information and written consent forms referred to in the pathways
- [Dr B] perform an audit of 10 patients on whom she has performed Mirena insertion and/or pipelle biopsy to determine if informed consent has been obtained and appropriately documented and to notify the Commissioner of the results.
- [Dr B] confirm whether or not a claim was lodged with her PHO for the pipelle biopsy procedure and if a claim was lodged the PHO should be notified of concerns regarding the consenting process.

Addendum: Having considered the additional information provided by [Dr B] I remain of the view that her management of [Ms A] in relation to performing a pipelle biopsy on 6 December 2019 was at least a moderate departure from accepted practice. My reasons for this opinion include: the absence of a clinical indication for the procedure; the failure to discuss and gain consent for the procedure, or at least to establish [Ms A] had a clear understanding of the procedure and the reasons for undertaking it; the failure to comply with [medical centre] policy regarding gaining written consent for the procedure. I am mildly critical that [Dr B] did not follow [medical centre] policy regarding gaining written informed consent prior to insertion of the Mirena.

My recommendations above remain. I note [Dr B] has undertaken some cultural training which is appropriate. I remain of the view that [Dr B] and/or the practice should undertake an audit of patients who have undergone pipelle biopsy performed by [Dr B] to determine if practice policy was followed with respect to gaining written informed consent prior to the procedure being performed (as opposed to discussion about the procedure while it was being undertaken)."

The following further advice was obtained from Dr Maplesden:

"I have reviewed the following information:

- Further information from [the medical centre] received 29 May 2021
- Further comments (email) from [the medical centre] received 27 June 2021
- Letter to HDC from [Dr E's] solicitor dated 2 June 2021 (and attachment)
- Letter to HDC from [Dr B's] solicitor dated 15 June 2021

Listed below are comments in relation to the questions you have posed:

1. *The appropriateness of [Dr E's] actions after he became aware of [Ms A's] concerns about the pipelle biopsy (when [Dr E] saw [Ms A] on 11 December 2019).*

(i) [Dr E] saw [Ms A] in [Dr B's] absence on 11 December 2019, five days following the Mirena insertion and pipelle biopsy. He established [Ms A] was unaware of the pipelle

procedure and was upset it had been undertaken without her knowledge or consent. [Dr E] could not establish any clinical indication for the procedure. These concerns were documented and [Ms A] requested [Dr E] discuss the issues with her mother. It is unclear when/if this discussion took place. [Dr B] and [Dr D] (other partners of [the medical centre]) were on leave at this time. [Dr E] states he approached [Dr D] early in the New Year (when [Dr D] returned from leave) to informally discuss his concerns at [Ms A's] management and general concerns that [Dr B] was performing other procedures that weren't clinically indicated. [Dr E] states he proposed a formal meeting between the three partners to discuss these concerns but [Dr D] offered a counter-proposal of reassuring [Ms A] that pipelle biopsy *was simply a free service provided in advance of Mirena insertion*. [Dr E] states he was uncomfortable with this approach and discussed this further with a senior locum colleague at [the medical centre] who supported his concerns. A formal meeting was held between the three partners on 24 February 2020 to discuss some of [Dr E's] concerns, primarily an [incident] not related to this report. [Dr E] reported the meeting to be dysfunctional and distressing for him. [Dr B] justified her management of [Ms A] by stating routine pipelle biopsy prior to IUCD insertion was recommended by a local gynaecology colleague [who] has apparently since denied making such a recommendation. Given the unsatisfactory outcome of the 24 February 2020 meeting, and [Dr E's] unresolved concerns at various aspects of [Dr B's] practice ([Ms A's] management being only one of multiple concerns) [Dr E] proceeded to make a formal written complaint to the Medical Council of NZ (MCNZ) on 20 March 2020 (viewed).

(ii) There was no specific process or policy in place at [the medical centre] regarding management of collegial complaints or competency concerns. [Dr D] states in his response that the practice follows the relevant MCNZ guidance in this regard.

(iii) The relevant MCNZ guidance is the statement 'What to do when you have concerns about a colleague (Dec 2010)'[6]. This is supported by a section on the MCNZ website titled 'Conduct and competence concerns'[7]. The latter includes the comments:

As an employer, colleague or health practitioner, you may become concerned about a doctor's competence or conduct. Before referring the matter to the Council, it is worth considering the following:

Have you discussed your concerns with the doctor?

Was it a one-off incident, or is a pattern emerging? For example, has the doctor failed to prescribe properly on multiple separate occasions over the last 3 months?

[6] https://www.mcnz.org.nz/assets/standards/ecb7db60c9/Concerns-about-a-colleague.pdf Accessed 2 August 2021
[7] https://www.mcnz.org.nz/our-standards/fitness-to-practise/conduct-and-competence-concerns/ Accessed 2 August 2021

Was it a minor incident or a serious departure from accepted medical practice? If it was a departure, did the doctor have an acceptable explanation?

Has there been a recent change in the doctor's behaviour or ability? If so, a health issue could be affecting their performance.

... You may choose to tell the doctor that you are considering telling the Council about your concerns. If you refer the matter to us, as long as you act in good faith and with reasonable care, you will not be legally liable for your statements.

On review of the cited MCNZ statement I believe [Dr E's] actions on becoming aware of [Ms A's] concerns were consistent with accepted practice as represented by the statement, in particular the need to refer the issue externally *if you have raised your concern through local channels but are not satisfied that the responsible person or body has taken adequate action.* I note [Ms A's] management was one of several issues causing collegial concern, and noted in [Dr E's] report to MCNZ, and I am unable to comment on the additional issues raised. [Dr E's] report to HDC appears professional and objective.

2. The comments above are based on [Dr E's] response. You have asked me to comment on an alternative scenario: *That [Dr E] did not report concerns to [Dr D] and no meeting was held, and that [Dr E] instead reported his concerns directly to the Medical Council without first raising them internally at [the medical centre].*

(i) [Dr D] reports that he does not recall discussing [Ms A's] case with [Dr E] at any meeting when all three partners ([Dr E], [Dr D] and [Dr B]) were present. He does not comment on the issue being raised informally between himself and [Dr E] as reported by [Dr E].

(ii) [Dr B] reports there was a meeting in January 2020 when she had returned from overseas and states: *I did attempt to discuss [Dr E's] concerns with him … though [Dr E] did not engage with the discussion, became confrontational and walked away stating 'I have reported you'.*

(iii) Based on the reports from all three partners, it appears the collegial relationship was dysfunctional and constructive communication was difficult. Noting the multiple and varied issues raised by [Dr E] in his complaint to MCNZ (apparently made some weeks after the meeting with [Dr B]) I believe his concerns justified referral to MCNZ because of risk of harm (as defined in the MCNZ statement). I believe the reference in the statement to external referral being indicated *if you cannot raise the issue with the responsible person or body locally because you believe that they are part of the problem* may also be relevant in this case. In summary, in either scenario presented, I believe [Dr E's] actions were reasonable (with reference to his referral of [Dr B] to MCNZ).

3. *The appropriateness of [the medical centre's] response to [Dr E] reporting [Ms A's] concerns about the pipelle biopsy.*

(i) I would be concerned if [Dr D's] response to discussion of [Dr E's] concerns about [Ms A's] management, as reported by [Dr E], was accurate. I would regard the recommendation to reassure [Ms A] that the pipelle biopsy was simply *a free service provided in advance of Mirena insertion* as unprofessional and an inappropriate response to the concerns raised (at least moderate criticism).

(ii) I note [Dr B's] response as to why she accessed the PMS remotely on 11 and 12 December 2019 while overseas to complete additional notes in [Ms A's] file, essentially seeking to explain her management on 6 December 2019 (see Appendix 1). This may have been a useful action to assist [Dr E] in managing [Ms A's] concerns in [Dr B's] absence but, as discussed in my original advice, [Dr B's] justification for performing the pipelle biopsy (*taking a pipelle sample prior to insertion is good practice again as per guidelines and widely practiced by gynaecologists in NZ*) does not appear to have any basis in fact and [Dr B] has not provided any information to support this view although she was given the opportunity to do so. [Dr E] had already concluded, correctly in my view, that there was no clinical indication for the procedure.

(iii) I would be concerned if [Dr E] requested a formal meeting of partners to discuss the various concerns he had about aspects of [Dr B's] practice and he was denied this opportunity by the other partners. I believe best practice is to record minutes of such a meeting for later reference. I would be surprised if a formal serious event review was not undertaken in relation to the immunisation incident, and there should be documentation of such a review.

(iv) Conversely, I would be critical if [Dr E] was invited to a formal collegial meeting to discuss his concerns regarding [Dr B's] practice and he refused to engage in this process, unless he had ground to believe there was sufficient dysfunction between the partners to prevent any objective discussion of the concerns.

Appendix 1: Copy of notes completed by [Dr B] (NB [Dr B] was overseas and time completed represents NZ time)

- Original note completed Wednesday 11 December 2019 8.50 pm
- Addition Wednesday 11 December 2019 10.34 pm in bold italics.
- Addition Thursday 12 December 2019 7.56 pm in bold plain text

'above note — remote access Mirena and pipelle procedure in PN room with [RN C] as chaperone — discussed HVS result before insertion and [Ms A] was keen to have the coil inserted before the weekend — hence inserted — also BV results not a CI to insertion as long as treated as per FP — John Guilland guidelines ***indeed depoprovera and mirena coils are indicated for recurrent BV infections as they alter the local pH [Ms A] has a hx of recurrent BV infections*** taking a pipelle sample prior to insertion is good practice again as per guidelines and widely practiced by gynaecologists in NZ. Did explain to [Ms A] this was good practice and just for reassurance although clinically

there were no concerns (again [RN C] present for the whole consult and procedure) I did check all was well over the weekend with [Ms A] and on the Monday — before I left for holiday If there are any concerns regarding the coil then can arrange an US — message sent to [Dr E] **\worth doing a clinical examination to check the strings.**'"

Appendix B: Relevant standards

The Medical Council of New Zealand's statement on "Informed Consent: Helping patients make informed decisions about their care" (September 2019) provides:

> "You must keep clear and accurate patient records that note: a) the information that was discussed b) any specific risks that were highlighted c) any request or concerns expressed d) any decisions made and the reasons for them."
>
> "1 Trust is essential in the doctor–patient relationship. One way to build trust is to provide information openly and honestly to your patient.
>
> …
>
> 3 You must give your patient the information they need to help them make a fully-informed decision."

The MCNZ statement on "What to do when you have concerns about a colleague" (December 2010) provides:

> "**Raising a concern**
>
> *Raising concerns directly with your colleague*
>
> …
>
> 7. If a colleague:
>
> …
>
> - behaves in any other manner which is inappropriate or unprofessional
>
> then you should speak to them and raise your concerns in a constructive manner.
>
> 8. If the colleague does not respond to your concerns and continues to act inappropriately or unprofessionally, raise your concerns with a manager, appropriate senior colleague or external agency as described in paragraphs 9–12.
>
> *Raising concerns locally*
>
> 9. If you have reasonable grounds to believe that patients are, or may be, at risk of harm for any reason, do your best to find out the facts. Then you should follow your employer's procedures or policies, or tell an appropriate person or organisation straight away. Do not delay taking action because you yourself are not in a position to put the matter right.
>
> 10. In the first instance, wherever possible, raise your concerns with your manager, human resources staff or an appropriate senior colleague — such as the consultant in charge of the team, the Chief Medical Advisor or a practice partner. Make them aware of any relevant evidence. If you are an intern or newly registered doctor it may be appropriate to raise your concern with your supervisor. You should follow any workplace procedure or policy for reporting adverse incidents and concerns.

11. Be clear, honest and objective about the reason for your concern. Acknowledge any personal criticism that may arise from the situation, but focus on the issue of patient safety.

12. Keep a record of your concerns and any steps taken to resolve them.

Raising concerns externally

13. You should contact an external body with authority to investigate the issue in the following circumstances:

- if there is no responsible person or body locally that you can report to
- if you cannot raise the issue with the responsible person or body locally because you believe that they are part of the problem
- if there is an immediate risk to patients from a colleague and an external body needs to be alerted straight away (though in such cases you should also, at the same time or as soon as possible afterwards, make the appropriate local person or body aware of your concerns and the action you have taken)
- if you have raised your concern through local channels but are not satisfied that the responsible person or body has taken adequate action

…

Concerns about a doctor's competence

20. Although it is not mandatory, you are encouraged to report any concerns about a colleague's competence to Council.

…

22. The Council has developed the following criteria for 'risk of harm' and 'risk of serious harm' to help outline where the thresholds for acting on concerns about competence lie. The Council recommends that you take action to raise concerns locally and also consider notifying the Council if a 'risk of harm' exists, and that you always notify the Council if there is a 'risk of serious harm'.

Risk of harm may be indicated by:

- a pattern of practice over a period of time that suggests the doctor's practice of medicine may not meet the required standard of competence; or
- a single incident that demonstrates a significant departure from accepted standards of medical practice …"

Appendix C: Relevant policies

Complaints Policy

The medical centre provided HDC with a copy of its Complaints Policy.[1] This policy states that all complaints must be made in writing, and that patients who wish to make a complaint should be given a copy of the medical centre's complaint form. The policy further states:

"**Minimum standards for management of complaints**

- Acknowledge patients' complaints in writing within five working days of receipt, unless the patient's complaint has been resolved to their satisfaction in that time
- Inform the patients of our practice's complaints procedure and the fact that they can make complaints to the Health and Disability Commissioner (if the complaint relates to services) or the Privacy Commissioner (if the complaint relates to a breach of privacy)
- Clearly and unambiguously advise the patient that their complaint needs to be in writing; remain transparent in our explanation of this process
- Document patients' complaints and the actions that our staff have taken in relation to those complaints
- Where a complaint is taking some time to resolve, advise patients about the progress of their complaint each month.

…

- Within 10 working days we must decide whether or not we accept that the patient's complaint is justified
- If more than 20 working days is needed to investigate a complaint, be transparent in advising the patient that we need more time to make a decision and explaining the reasons as to why this is the case.
- After we decide whether we accept the complaint, we shall advise the patient of:
    - The reasons for our decision;
    - Any actions we propose to take;
    - Any appeal procedure that our practice has in place; and
    - The patient's right to complain to the Health and Disability Commissioner or the Privacy Commissioner if they feel the matter remains unresolved."

[1] The copy of the policy provided to HDC was undated; however, the medical centre told HDC that it was the same as that in place at the time of events (December 2019).