General Practitioner, Dr B

A Medical Centre

A Report by the

Health and Disability Commissioner

(Case 13HDC01212)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. Mrs A had a copper intrauterine contraceptive device (IUCD) inserted at a family planning clinic in May 2007. The IUCD was due to be removed five years later (May 2012).

2. On 16 January 2012, Mrs A presented to a medical centre with a history of vaginal discharge, which was confirmed as bacterial vaginosis (BV).[1] A general practitioner (GP) at the medical centre prescribed Mrs A antibiotics to treat this. Mrs A advised Registered Nurse (RN) RN E that she had a copper IUCD in situ, which was due to be removed in May that year. RN E recorded this information in Mrs A's clinical notes.

3. On 1 March 2012, Mrs A saw Dr B. There is no documentation of Dr B's assessment or the discussions that took place regarding heavy menstrual bleeding other than a prescription for Cyklokapron.[2] Mrs A specifically recalls telling Dr B at this consultation that she had an IUCD in place. Dr B said that she did not ask Mrs A about her contraceptive use and history, and was not aware that Mrs A had an IUCD in situ.

4. On 17 April 2012, RN E spoke to Mrs A over the telephone. RN E advised Mrs A to pick up a prescription from the medical centre for iron tablets (due to her low ferritin levels) and come for Mirena[3] insertion the next week. RN E's note of this conversation is the first reference to the Mirena device in Mrs A's clinical record.

5. Dr B and Mrs A recall discussing the risks and benefits of the Mirena, but it is not documented when this took place, or what was discussed.

6. On 1 June 2012, Mrs A attended an appointment with Dr B. Dr B told HDC that she performed pelvic and speculum examinations, and the results of these assessments were normal and there were no strings from an existing IUCD visible.

7. Dr B did not remove the existing IUCD that was in situ before she inserted the Mirena device.

8. On 13 June 2012, Dr B performed a follow-up vaginal examination and noted that the Mirena was in place and, on 11 October 2012, another GP at the medical centre performed a vaginal examination and noted that the thread was seen in place. Mrs A had recurring BV, which was treated with antibiotics.

[1] Bacterial vaginosis is a disease of the vagina caused by excessive bacteria. A common symptom is increased vaginal discharge, which is often odorous and usually white or grey in colour.
[2] Cyklokapron is used to stop or reduce unwanted bleeding.
[3] Mirena is an intrauterine device that is fitted into the uterus and contains a hormone but no copper. Mirena can be used for contraception and to treat heavy menstrual bleeding.

9. In July 2013, Mrs A fell and hurt her lower back. As part of the investigation of her back pain, an X-ray was taken, which revealed two contraceptive devices in her uterine cavity. On 2 September 2013, both devices were removed by Dr B, who recorded that strings from two contraceptive devices were seen.

Findings

10. Dr B did not assess Mrs A's contraceptive history adequately prior to inserting the Mirena on 1 June 2012. Dr B failed to read RN E's clinical notes, which set out that Mrs A did have an IUCD in place, and failed to consider alternative causes of Mrs A's heavy bleeding and BV. Dr B inserted a second contraceptive device while Mrs A already had an IUCD in situ. For these reasons, Dr B did not provide services to Mrs A with reasonable care and skill and breached Right 4(1)[4] of the Code of Health and Disability Services Consumers' Rights (the Code). Furthermore, Dr B did not keep adequate clinical records. Accordingly, she failed to comply with relevant professional standards and breached Right 4(2)[5] of the Code.

11. Adverse comment is made that Dr B did not discuss all clinically appropriate management options for heavy menstrual bleeding with Mrs A at the appointment of 1 March 2012.

12. Dr B's failures were matters of individual clinical judgement. No action or inaction of the medical centre was responsible for these failures. Therefore, the medical centre did not breach the Code.

Complaint and investigation

13. The Commissioner received a complaint from Mrs A about the services provided to her by general practitioner Dr B at the medical centre.

14. An investigation was commenced on 25 February 2014. The following issues were identified for investigation:

- *Whether Dr B provided appropriate care to Mrs A in 2012.*
- *Whether the medical centre provided appropriate care to Mrs A in 2012.*

15. The parties directly involved in the investigation were:

Mrs A	Consumer/Complainant
Dr B	General practitioner/Provider

[4] Right 4(1) of the Code states that every consumer has the right to have services provided with reasonable care and skill.
[5] Right 4(2) of the Code states that every consumer has the right to have services provided that comply with legal, professional, ethical and other relevant standards.

The medical centre	Provider

16. Information was reviewed from the above parties and from the Medical Council of New Zealand.

17. Other parties mentioned in this report:

Dr C	General practitioner
Dr D	General practitioner
RN E	Nurse
Dr F	General practitioner
RN G	Nurse
RN H	Nurse
Dr I	General practitioner

18. Independent expert advice was obtained from HDC's in-house advisor, general practitioner Dr David Maplesden (**Appendix A**).

Information gathered during investigation

Background

The medical centre

19. The medical centre offers a range of general practice services.

Mrs A

20. Mrs A had a copper intrauterine contraceptive device (IUCD) inserted at a family planning clinic in May 2007. The IUCD was due to be removed five years later in May 2012. Mrs A provided HDC with a copy of an IUCD information card provided to her at the time, which set out this information.

21. Mrs A became an enrolled patient at the medical centre in May 2008. Mrs A's previous general practitioner (GP), Dr C, transferred her medical records to the medical centre with a cover letter dated 30 May 2008, which recorded "Diane 35 Ed" (an oral contraceptive) under the heading "medications". The medical records show that the last time Mrs A was treated at Dr C's clinic was on 18 September 2001. Mrs A told HDC that she stopped taking oral contraception when she had her IUCD inserted. The cover letter does not refer to Mrs A having an IUCD in situ, and this was not recorded in her medical records from Dr C. Dr C confirmed that there was nothing to suggest that he or his clinic had been advised by any other provider that an IUCD had been inserted.

Dr B

22. Dr B is a vocationally registered GP and independent contractor at the medical centre.

Mrs A's medical history

23. Mrs A stated that she hardly ever went to the doctor because she was fit and healthy. However, on 16 January 2012, Mrs A (then aged 42 years) presented to the medical centre with a history of "smelly vaginal discharge for few days", and dizziness lasting a few seconds at a time. The medical centre said that she was seen by Dr D, who recorded a plan for vaginal and cervical swabs to be taken, issued a prescription for a seven-day course of metronidazole 400mg,[6] and ordered a blood test "for dizziness".

24. Mrs A advised RN E that she had a copper IUCD in situ, which was due to be removed in May that year. RN E noted this information in Mrs A's clinical record as: "Has iucd in situ and is due to come out in May."

25. On 18 January 2012, high vaginal swabs taken at the 16 January 2012 appointment confirmed the diagnosis of bacterial vaginosis (BV).[7] Mrs A was contacted that day, informed of the result, and advised to complete the prescribed course of metronidazole.

26. On 15 February 2012, Mrs A attended an appointment with Dr F at the medical centre for an ankle injury and irritated eyes.

1 March 2012 — Consultation with Dr B

27. On 24 February 2012, Mrs A had the blood test ordered by Dr D. The results of this showed low ferritin (17µg/L).[8] Therefore, Mrs A was recalled to attend a consultation at the medical centre. On 1 March 2012, Mrs A saw Dr B. Medical centre notes indicate that Mrs A attended one prior consultation with Dr B on 1 December 2009 regarding a knee injury.

28. Dr B recalls that at the appointment she and Mrs A:

> "… discussed her low ferritin laboratory results in the context of known menorrhagia.[9] She complained of dizziness. Her periods were regular and were heavy for the first two days. We discussed the oral contraceptive pill and Depo Provera as methods for reducing her menstrual losses, but [Mrs A] expressed her dislike of these options and preferred instead to continue on Cyklokapron.[10] Mirena[11] and other methods of contraception were not discussed at this consultation and instead the focus was on the management of her menorrhagia. She was an otherwise fit and healthy woman."

[6] Metronidazole is an antibiotic used to treat bacterial infections of the vagina.
[7] Bacterial vaginosis is a disease of the vagina caused by excessive bacteria. A common symptom is increased vaginal discharge, which is often odorous and usually white or grey in colour.
[8] Normal range is 20–380µg/L. Low levels of ferritin are indicative of iron deficiency.
[9] Menorrhagia is the medical term for menstrual periods with abnormally heavy or prolonged bleeding.
[10] Cyklokapron is used to stop or reduce unwanted bleeding.
[11] Mirena is an intrauterine device that is fitted into the uterus and contains a hormone but no copper. Mirena can be used for contraception and to treat heavy menstrual bleeding.

29. Mrs A recalls being prescribed Cyklokapron. She told HDC that she specifically recalls telling Dr B that she had an IUCD in place. Mrs A said that she queried whether the BV could be caused by the IUCD, but Dr B said, "No, no." Mrs A stated: "I trust her, I've known her a long time, she is really good. And so I just took the advice, as you would as a patient."

30. Dr B's notes of the consultation state: "[R]ecall. [Prescription]: Cyklokapron 500mg Tab — 1–3 up to 4 times per day if needed when period becomes heavy (maximum 12 per day). Continue if needed up to 4 days." There is no further documentation of Dr B's assessment or of any discussions that took place (such as Mrs A's history of menstrual bleeding, associated symptoms or contraceptive use).

31. Dr B told HDC that she acknowledges that her note taking was "often lacking", but said that she is able to "reconstruct what occurred during our consultations from my memory, assisted by what notes I did take, and my ordinary practice". Dr B submitted to HDC that "the lack of documentation does not mean that the history taking or assessments themselves were lacking".

Further consultations with Dr B

32. Mrs A saw Dr B on 9 March 2012. The notes record that this consultation was in relation to ongoing ankle pain. Mrs A saw Dr B again on 22 March 2012. The notes record that this consultation was in relation to a fall where Mrs A injured her left knee. There is no mention of any discussion regarding a Mirena device or IUCD replacement or removal in the notes of either consultation.

33. On 16 April 2012, the medical centre telephoned Mrs A requesting she pick up a laboratory request form, as Dr B had ordered blood tests to check her ferritin levels. The results of the blood tests indicated low ferritin levels (16µg/L). Dr B stated that she provided Mrs A with a prescription for iron supplements (Ferro-Tab 200mg) after a telephone consultation, which she was "happy to do in light of [Mrs A's] clinical history and the blood tests which had just come in and which showed low ferritin levels".

Discussion and decision-making regarding Mirena

34. On 17 April 2012, RN E recorded that she had left a voicemail message for Mrs A, which Mrs A later returned. RN E "advised [Mrs A] to pick up [a] script from reception and to come for mirena insertion next week as Dr [B] will apply for [Special Authority] today." This note is the first reference to the Mirena device in Mrs A's clinical record.

35. On 17 April 2012, RN G noted in the clinical record that Mrs A had telephoned the medical centre and wanted "to discuss iron results in relation to having re-insertion of IUD". There are no further notes of that discussion.

36. Dr B explained that although Mrs A was not seen by her on 17 April 2012, there was sufficient information for her to make a subsidy application[12] to cover the costs of the Mirena device. Dr B told HDC that her clinical justification at the time was:

- Mrs A had a clinical diagnosis of heavy menstrual bleeding;
- the bleeding was not responsive to Cyklokapron; and
- Mrs A's ferritin was low (16µg/L).

37. On 17 April 2012, Dr B completed a subsidy approval application for a Mirena device for Mrs A.

Discussion of existing IUCD

38. Mrs A recalls that around April 2012, she and Dr B discussed replacement of her existing IUCD.[13] In particular, Mrs A recalls mentioning that her copper IUCD needed to come out the following month, and that she would be returning to the family planning clinic to have it removed. Mrs A recalls that Dr B then told her that she (Dr B) was able to remove the IUCD.

39. Mrs A recalls showing Dr B the information card that set out the dates on which the copper IUCD had been inserted and was due for removal. Mrs A stated: "I showed her the card and remember taking it from my wallet." She said she showed Dr B the card a month before the IUCD had to be removed, and that Dr B told her that it was "OK" to keep the IUCD for another month until the blood results came back and while they were waiting for the Mirena device. Mrs A told HDC that on the day she had the Mirena inserted, "[Dr B] knew that I was coming in to have the [existing IUCD] out […] and we are replacing it, we are replacing the IUCD."

40. In contrast, Dr B stated: "I certainly discussed contraceptives in the management of menorrhagia but I don't recall asking [Mrs A] specifically about her contraceptive use and history." Dr B told HDC that she was not aware that Mrs A had an IUCD in situ. Dr B stated that she "sincerely regret[s]" that she did not establish that Mrs A already had an IUCD in situ through questioning or from a review of the clinical notes. Dr B acknowledges that she should have specifically asked Mrs A about contraceptive use.

Information given regarding Mirena

41. Dr B told HDC that she is "sure that [she] would have gone over the risks and benefits" of the Mirena device with Mrs A, although any such discussion was not documented in the notes. Dr B stated that she was aware that Mrs A had read a

[12] General practitioners can apply to the Ministry of Health for subsidy by special authority for some medications for their patients if certain prerequisites are met. The prerequisites for subsidy for the Mirena device are: the patient has a clinical diagnosis of heavy menstrual bleeding, the patient has failed to respond to or is unable to tolerate other appropriate pharmaceutical therapies as per the Heavy Menstrual Bleeding Guidelines, and the patient has a serum ferritin level of less than 16µg/L (in the past 12 months).

[13] Mrs A's only physical consultations with Dr B, prior to having the Mirena inserted, were on 1, 9 and 22 March 2012. The discussions recalled by Mrs A are not documented in her clinical record. As noted above, Dr B stated that she had a telephone consultation with Mrs A on 16 April 2012.

pamphlet outlining the risks and benefits of Mirena for patients with menorrhagia prior to requesting it as an option for herself. Dr B told HDC that Mrs A had collected this pamphlet at her visit of 1 March 2012. She told HDC that in accordance with her usual practice, she also would have given Mrs A a pamphlet on Mirena, namely, "the insert from the packet", which covers risks, benefits and follow-up advice.

42. Mrs A advised that she did read about the device, including on the internet and in pamphlets, but that she cannot specifically recall whether the pamphlets came from the medical centre or not. She is unsure as to whether Dr B provided her with any written materials, and told HDC, "She may have, I don't know, but I know I read about it."

43. Mrs A recalls that after a discussion with Dr B of its risks and possible effects, they agreed that the Mirena device would be suitable to help control Mrs A's heavy bleeding. Mrs A told HDC, "We certainly did discuss the effects of the Mirena."

44. On 22 May 2012, Dr B issued a prescription for the Mirena device following approval of the subsidy application. Dr B recorded in the notes, "[C]all for script."

Insertion of Mirena

45. On 1 June 2012, Mrs A attended an appointment with Dr B for Mirena insertion. As noted above, Mrs A told HDC that she had shown Dr B her IUCD information card, which stated the initial insertion date and month for removal of her existing IUCD. As also noted above, Dr B told HDC that she was unaware that Mrs A had an existing IUCD. Dr B told HDC that she performed pelvic and speculum examinations, and the results of these assessments were normal. In particular, Dr B told HDC that Mrs A's uterus was of normal size and not bulky, the cervix appeared to be healthy, no vaginal discharge was noted, and there were no strings from an existing IUCD visible.

46. Dr B did not remove the existing IUCD that was in situ before she inserted the Mirena device.

47. Dr B recorded that the Mirena device was inserted with "some difficulty". Swabs were taken and Dr B issued a prescription for metronidazole 400mg. Dr B told HDC that given Mrs A's past history of BV, she decided to prescribe the prophylactic seven-day course of antibiotics while she was awaiting return of the vaginal swab results.

Follow-up appointment

48. On 13 June 2012, Mrs A attended a follow-up appointment with Dr B to check Mrs A's progress following insertion of the Mirena, and to discuss her swab results (which confirmed BV). Dr B recorded that Mrs A was "still bleeding", the Mirena was in situ, and that the vaginal examination was normal. Dr B recalls performing a pelvic and speculum[14] examination, but this is not recorded in Mrs A's clinical notes. Dr B told HDC that Mrs A continued to have ongoing vaginal bleeding, but that it was not

[14] A medical tool used for examining body cavities.

heavy. Dr B prescribed a course of Provera 10mg[15] to use until the bleeding settled, and told HDC that they discussed the recurrence of BV (which had been treated).

Subsequent appointments

49. Mrs A told HDC that following insertion of the Mirena, she returned to the medical centre on a number of occasions with recurrent malodorous vaginal discharge. Mrs A stated that she experienced a range of other symptoms, including fevers, chest pains, pains down her right arm and fainting episodes.

50. On 11 October 2012, Mrs A attended a consultation at the medical centre with Dr D. The clinical notes record that Mrs A was "here for Mirena check" and presented with "smelly [vaginal discharge]" and had been treated for BV in June 2012. Swabs were taken, and Dr D noted "thread seen in place".

51. On 19 October 2012, Mrs A attended a recall appointment at the medical centre, at which time she was advised that her swab test results (from the swabs taken on 11 October 2012) showed a recurrence of BV. The medical centre told HDC that a seven-day course of metronidazole was prescribed at this appointment. However, this prescription was not recorded in Mrs A's notes.

52. Mrs A told HDC that over time the recurrent discharge "got really bad". She explained that the Mirena was fine in terms of controlling her menstrual bleeding, but that "it was just the discharge that kept coming back". On 1 May 2013, RN H recorded in the clinical notes that Mrs A was "here [to] talk to doctor about iucd removal …" Mrs A was seen by Dr B that day. However, there is no reference to a discussion regarding removal of the Mirena device, only that Mrs A had presented with a cough, fever and on-going "smelly discharge", and a further course of metronidazole was prescribed.

Discovery of two IUCDs in situ

53. In July 2013, Mrs A fell and hurt her lower back. As part of the investigation of her back pain, an X-ray was taken, which revealed two contraceptive devices in her uterine cavity. This was recorded in Mrs A's clinical notes on 20 August 2013. In light of the X-ray results, Mrs A was recalled to the medical centre. She attended an appointment on 28 August 2013 with another GP, who referred her for an ultrasound scan.

54. On 30 August 2013, Mrs A underwent an ultrasound scan of her pelvis, which confirmed the presence of two contraceptive devices in situ. Another GP at the medical centre, Dr I, saw Mrs A the following day and recorded in the clinical notes that she had had an ultrasound scan that had identified two IUCDs in situ, and had been experiencing lower abdominal pain, odorous vaginal discharge, and a fever with chills. Dr I's notes record: "[N]o cold, cough, diarrhoea, nausea on metronidazole this week."

[15] Provera is used to treat abnormal bleeding from the uterus.

55. On 2 September 2013, Mrs A attended a consultation with Dr B, who removed the two IUCDs. Dr B noted "strings of 2 IUDs seen".

Medical centre policy

56. The medical centre told HDC that, at the time of these events, there were no guidelines or policies in place at the medical centre specifically in relation to the insertion of contraceptive implants or intrauterine devices. The medical centre explained that this information comes with each device as a package insert, and is available as an online data sheet through MEDSAFE, which is readily available on each doctor's computer.

57. The medical centre further advised that from a quality of care and patient safety perspective, a general consent form for any procedure was available in the patient management software. That form could be printed and signed by both the doctor and patient if verbal consent is not documented. The signed consent form can then be scanned into the patient's notes.

Changes made since this incident

58. The medical centre advised HDC that it has made the following changes since this incident:

i. An IUCD pre-insertion checklist-screening template has been developed, which will prompt the treating doctor to check the patient's contraceptive history and other details to see if Mirena and/or other IUCDs are safe and appropriate to use. The screening template also provides a recall reminder for medical staff so that the patient can be sent a reminder letter that the IUCD should be removed, and has been updated to be used as a checklist and an audit tool for documenting best practice.

ii. A guideline for doctors inserting contraceptive implants, IUCDs and intrauterine systems has been developed, which informs doctors how to record information so that it is explicit to all medical staff involved in the patient's care (particularly the date of removal).

iii. There are now specific consent forms for IUCD and intrauterine system insertions, and these have been incorporated into the IUCD screening template.

Medical Council of New Zealand performance assessment

59. In June 2014, the Medical Council of New Zealand decided that Dr B was to undergo a performance assessment under section 36 of the Health Practitioners Competence Assurance Act 2003. In February 2015, the Medical Council considered the outcome of the performance assessment and resolved that Dr B met the required standard of competence.

Response to provisional opinion

60. In response to my provisional opinion, Dr B confirmed that she accepted my provisional findings and proposed recommendations. Dr B accepted that she failed to read RN E's clinical notes, which set out that Mrs A had an existing IUCD in place,

and that she inserted a second contraceptive device while Mrs A already had one in situ, and acknowledged deficiencies in her clinical documentation at that time.

61. Dr B submitted that there was no reason to suspect any structural abnormality (ie, existing IUCD) based on the pattern of Mrs A's bleeding, normal cervical smear, normal bi-manual examination and Mrs A's young age. However, she accepts that she did not consider the possible association of an IUCD with Mrs A's complaints of heavy menstrual bleeding and recurrent BV. She also submitted that there were no strong clinical indications to perform further investigations prior to insertion of the Mirena, and that the management plan was clinically appropriate.

62. Dr B advised that she has undertaken further training in the area of management of heavy menstrual bleeding and Mirena insertion, and an audit of Mirena insertions to monitor compliance with recommended process standards. Dr B also advised that she now adheres to best practice requirements for record-keeping, and acknowledges the importance of this in a network of clinics where patients can be seen by different doctors. Good record-keeping is discussed on a monthly basis at the medical centre's peer group meetings and at another group meeting Dr B attends regularly.

63. Dr B said that she has cut down on her working hours and is now taking more time off. She recognises the need for self-care and work-life balance. She has taken the opportunity to reflect on the circumstances that led to this complaint, and to improve her practice as a GP.

64. Neither the medical centre nor Mrs A had any comments to make on my provisional opinion.

Relevant professional standards

65. The Medical Council of New Zealand's publication *The Maintenance and Retention of Patient Records* (August 2008) states:[16]

> "**Introduction**
>
> Records form an integral part of any medical practice; they help to ensure good care for patients and also become critical in any future dispute or investigation.
>
> 01 Maintaining patient record
>
> (a) You must keep clear and accurate patient records that report:
>
> - relevant clinical findings
> - decisions made
> - information given to patients

[16] Available from http://www.mcnz.org.nz/support-for-doctors/resources/.

- any drugs or other treatment prescribed.

(b) Make these records at the same time as the events you are recording or as soon as possible afterwards."

Opinion: Dr B — Breach

Introduction

66. This opinion relates to the care provided to Mrs A by Dr B in 2012. Dr B failed to establish that Mrs A had an existing IUCD in situ, and inserted a Mirena device without removing the existing IUCD. Mrs A subsequently had a fall, necessitating an X-ray of her lower back. The X-ray revealed two contraceptive devices in her uterine cavity.

Reasonable care and skill — Breach

Assessment of contraceptive history

67. I often refer to the mantra "read the notes, ask the questions, talk with the patient".[17] Doing the basics well matters. By her own admission, Dr B did not establish that Mrs A already had an IUCD in situ through questioning, or from a review of the clinical notes. Dr B acknowledges that she should have asked Mrs A specifically about her contraceptive use.

68. RN E recorded in the clinical notes on 16 January 2012 that Mrs A had an "iucd in situ due to come out in May". This was clearly overlooked by Dr B, who saw Mrs A two appointments later. This is unacceptable. In the context of a medical centre where patients may be seen by different GPs or nurses, it is a basic competency that GPs review the notes of their colleagues who have seen the patient previously.

69. Mrs A told HDC that she recalls discussing the replacement of her existing IUCD with Dr B. Mrs A said that she told Dr B she would return to the family planning clinic to have it removed, but Dr B told her that she (Dr B) could remove it. Mrs A recalls showing Dr B the IUCD information card, and that Dr B told her it was "OK" to keep her IUCD for another month while they waited for the Mirena. Mrs A recalls discussing the dates on which the existing IUCD was inserted and due to be removed.

70. It is apparent that Dr B does not recall these discussions, or being shown Mrs A's IUCD information card, and there is no documentation in any of Mrs A's clinical notes of the above discussions. I am persuaded that Mrs A did advise Dr B that she had an existing IUCD in situ. However, given that there are differing recollections of this, no third party to confirm either account, and in the absence of any clinical notes, I am unable to make a finding as to the exact details of these discussions, when any discussions may have occurred, and whether Mrs A showed Dr B the IUCD

[17] Anthony Hill, Health and Disability Commissioner, *NZ Doctor*, 9 March 2011.

information card. In any event, prior to inserting the Mirena, Dr B did not establish whether Mrs A was using contraception and the nature of that contraception.

71. My expert advisor, Dr David Maplesden, considered that Mrs A's current contraceptive use should have been determined as part of an adequate history. He stated that "[h]ad an adequate discussion taken place, this would have included the fact that Mirena is a long-term contraceptive which should have led to confirmation of [Mrs A's] existing contraceptive method (IUCD)". Dr Maplesden considered Dr B's failings in this regard to be a moderate to severe departure from expected standards with respect to management of appropriate processes related to IUCD insertion.

72. I accept that Dr B should have specifically ascertained what contraception Mrs A was using prior to inserting the Mirena in Mrs A. This would most likely have revealed that Mrs A already had an IUCD in situ requiring removal prior to Mirena insertion.

Consideration of causes of menorrhagia and BV

73. In addition, Dr Maplesden noted that Dr B did not "consider the presence of an IUCD in relation to [Mrs A's] complaints of heavy menstrual bleeding and recurrent bacterial vaginosis (both of which have an association with IUCD use)".

74. I consider that Dr B should have queried whether Mrs A's ongoing menorrhagia and recurrent BV infections were related to current IUCD use. Again, this could have revealed that Mrs A already had an IUCD in situ that required removal.

Insertion of Mirena

75. After applying for subsidy approval, which was accepted, Dr B prescribed a Mirena device for Mrs A on 22 May 2012. Mrs A attended an appointment on 1 June 2012 with Dr B. Mrs A told HDC she believed that she was attending this consultation to have her old IUCD removed, and the Mirena device fitted.

76. Dr B told HDC that she performed pelvic and speculum examinations, and the results of these assessments were normal. In particular, Dr B told HDC that Mrs A's uterus was of normal size and not bulky, the cervix appeared to be healthy, no vaginal discharge was noted, and there were no strings from an existing IUCD visible.

77. Dr B did not remove the existing IUCD that was still in place before inserting the Mirena device.

78. Dr Maplesden advised: "[Dr B] inserted an intrauterine device into a patient with a device in-situ which must be regarded as a very significant aberration from expected practice …" I agree with Dr Maplesden. I am concerned that due to her inadequate assessment of Mrs A's contraceptive history, namely her failure to ask Mrs A the appropriate questions, and her failure to observe the IUCD in place, Dr B was apparently unaware of its existence. Dr B proceeded to insert the Mirena while the old IUCD was in situ, resulting in Mrs A having two contraceptive devices in her uterine cavity.

Conclusion

79. There were a number of missed opportunities for Dr B to ascertain that Mrs A had an existing IUCD in situ prior to the insertion of the Mirena. Dr B had a duty to assess Mrs A's contraceptive history adequately prior to inserting the Mirena on 1 June 2012, which she failed to do. Dr B did not ask Mrs A what contraception she was currently using. Dr B failed to read RN E's clinical notes, which set out that Mrs A did have an IUCD in place, and failed to consider alternative causes of Mrs A's heavy bleeding and BV (such as a current IUCD). Dr B then inserted a second contraceptive device while Mrs A already had an IUCD in situ. In my view, Dr B did not provide services to Mrs A with reasonable care and skill and breached Right 4(1) of the Code.

Record-keeping — Breach

80. At the appointment of 1 March 2012, Dr B prescribed Cyklokapron for Mrs A's heavy menstrual bleeding. There is no further documentation in any of Mrs A's clinical notes of Dr B's assessment of Mrs A's heavy menstrual bleeding or the discussions that took place (such as Mrs A's history of menstrual bleeding, associated symptoms or contraceptive use).

81. Dr B told HDC that she acknowledges that her note taking was "often lacking", but that she recalls the consultations with Mrs A. Dr B says she recalls discussing the oral contraceptive pill and Depo Provera as methods for reducing Mrs A's menstrual losses, but says that Mrs A expressed dislike of these options and preferred instead to continue on Cyklokapron. This is not apparent from the clinical records.

82. Dr Maplesden stated: "[T]he complete absence of any documentation related to the history, discussion or management plan for the heavy menstrual bleeding, other than a record that Cyklokapron was prescribed, was a moderate departure from expected standards of clinical documentation …" I accept this advice.

83. Further, while both Dr B and Mrs A recall discussing risks and benefits of the Mirena device prior to it being inserted, there is no documentation of what these discussions covered, when they took place, and what information was provided to Mrs A.

84. The Medical Council of New Zealand's publication *The Maintenance and Retention of Patient Records* (August 2008) states that GPs are required to keep clear and accurate patient records that report relevant clinical findings, decisions made, information given to patients, and any drugs or other treatment prescribed. Dr B did not do this. She did not record adequate clinical notes in relation to the history, discussion or management plan for Mrs A's heavy menstrual bleeding, or in relation to the discussion of the risks and benefits of the Mirena device. Dr B failed to comply with relevant professional standards and, accordingly, breached Right 4(2) of the Code.

Options for management of menorrhagia — Adverse comment

85. Mrs A saw Dr B on 1 March 2012 because of her low ferritin levels. The only documentation of the consultation in relation to Mrs A's heavy menstrual bleeding was a record that Cyklokapron was prescribed. Accordingly, it is difficult to assess the adequacy of Dr B's management of Mrs A's bleeding. However, Dr B says that she

recalls discussing the oral contraceptive pill and Depo Provera with Mrs A as methods for reducing her menstrual losses, but that Mrs A expressed dislike of these options and preferred instead to continue on Cyklokapron. Dr B said that the Mirena device was not discussed as a management option at that time.

86. Dr Maplesden advised that the Mirena device should have been discussed as a potential first-line (unsubsidised) option for management of Mrs A's heavy menstrual bleeding at the appointment on 1 March 2012, and Mrs A's contraceptive history should also have been determined as part of an adequate history. Dr Maplesden advised that all clinically indicated management options, including current IUCD removal (because current IUCD use can be a cause of heavy menstrual bleeding), should have been discussed with Mrs A at that point, and there is no evidence that such discussions took place.

87. It appears that all clinically appropriate options were not discussed with Mrs A at the appointment of 1 March 2012. In particular, Dr B accepts that she did not discuss the Mirena device with Mrs A as a possible option for the management of her menorrhagia. I consider that a reasonable consumer in Mrs A's circumstances would have expected to receive an explanation of all clinically indicated treatment options available for the management of her menorrhagia, including the Mirena device. I am critical of Dr B that this did not occur.

Subsequent management — Other comment

88. Dr Maplesden advised me that Dr B's follow-up management was reasonable in that the Mirena was checked on 13 June 2012 and found to be in place, and a further check was undertaken on 11 October 2012. He stated:

> "I think it was reasonable that metronidazole was prescribed empirically given [Mrs A's] symptoms at this point were suggestive of recurrence of her previous BV infection … There is no reference to the issue of IUCD removal being discussed further. Given [Mrs A's] concerns at her recurrent BV infections, the association between IUCD use and BV should have been discussed further at this point particularly given [Mrs A's] request for IUCD removal. However, I feel prescribing of metronidazole was still a reasonable option provided there had been adequate discussion with the patient beforehand."

89. I accept Dr Maplesden's advice. I am not critical of Dr B's management of Mrs A's recurring BV infections. However, I consider that Dr B should have discussed the possible association between Mrs A's Mirena and the BV infections with Mrs A.

90. I also note that during the vaginal examinations performed by Dr B and Dr D on 13 June 2012 and 11 October 2012 respectively, it was not recorded that two sets of contraceptive device strings were visible. However, in contrast, on 2 September 2013 after it was revealed that Mrs A had two contraceptive devices in her uterine cavity, Dr B performed a vaginal examination and noted "strings of two IUDs seen".

Opinion: The medical centre— No breach

91. The medical centre is a healthcare provider and an employing authority for the purposes of the Health and Disability Commissioner Act 1994. As such, it may be held directly liable for the inadequate care provided to Mrs A, and it may be held vicariously liable for any actions or omissions of its employees and/or agents who have been found to be in breach of the Code.

92. In my view, Dr B's failures in respect of the lack of assessment of Mrs A's contraceptive history, insertion of a Mirena when an IUCD was already in situ, and poor record-keeping, were matters of individual clinical judgement. I do not find that any action or inaction of the medical centre was responsible for these failures. Therefore I find that the medical centre did not breach the Code.

93. I note that Dr Maplesden advised me that measures undertaken by the medical centre following this incident appear appropriate with respect to ensuring relevant history is obtained prior to IUCD or contraceptive implant insertion. I agree, and consider that, in response to this incident, it is appropriate that there is now a screening template that prompts the treating GP to check the patient's contraceptive history, a guideline on recording information in relation to IUCD and intrauterine systems, and specific consent forms.

Recommendations

94. I recommend that Dr B:

a) Provide an apology to Mrs A. This apology is to be sent to HDC for forwarding to Mrs A within three weeks of the date of this decision.

b) Undertake an audit of her standards of clinical documentation against the Royal New Zealand College of General Practitioners' standards and report back to HDC on the results of this audit within three months of the date of this decision.

c) Undertake further education on the assessment and management of menorrhagia, including a review of her technique by a gynaecologist in relation to bimanual and speculum examinations and Mirena insertions, and report back to HDC within three months of the date of this decision to confirm that this has occurred, with a report outlining her reflection on this further education.

95. I recommend that the medical centre audit compliance with its *Guideline for doctors inserting contraceptive implants or intrauterine devices or systems* (including use of the intrauterine consent form and pre-insertion screening checklist), and report back to HDC within three months of the date of this decision with the results of this audit.

Follow-up actions

96. a) 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, the relevant District Health Board, and the Royal New Zealand College of General Practitioners, and they will be advised of Dr B's name.

b) A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A — Independent clinical advice to the Commissioner

Preliminary expert advice

On 28 January 2014, Dr David Maplesden provided the following preliminary expert advice:

> "1. I have reviewed the information on file: complaint from [Mrs A]; response from [the medical centre]; GP notes. I have not reproduced the complaint or notes in detail here as they have been previously summarised.
>
> 2. The standard of clinical documentation relating to the cervical smear performed on 16 January 2012 ([RN E]) was suboptimal in that the appearance of the cervix was not described, in particular whether the IUCD strings were visible. Had they not been visualised when [RN E] had obtained a history of current IUCD use, further investigation to determine whether or not the IUCD remained in situ, and advice on alternative contraception until presence of the device was confirmed, would have been appropriate. This was a mild departure from expected standards of clinical documentation. Management of the bacterial vaginosis (BV) on this occasion was appropriate.
>
> 3. The cervical smear report dated 16 January 2012 included the comment *There are bacteria morphologically consistent with Actinomyces species.* A recent literature review on this subject[18] includes *Approximately 7 percent of women using an IUD have actinomyces-like organisms on a Papanicolaou (Pap) test; only about half of these women will have positive actinomyces culture. If the cervical cytology report indicates actinomyces-like organisms, then we suggest that the woman be notified of the finding and examined. If she is asymptomatic, the cytology finding probably represents colonization. There is no evidence to support antibiotic treatment or IUD removal in asymptomatic women. The woman should be informed that she should contact her health care provider if she develops signs of pelvic inflammatory disease.* While [Mrs A] was informed about her positive BV result, there is no documentation to suggest she was notified of the actinomyces comment. There was no indication to treat the organism based purely on the smear report, but [Mrs A] was entitled to be informed of the result and the significance of the result, and any precautions she should take in light of the result (awareness of symptoms suggestive of pelvic inflammatory disease). This omission was a mild departure from expected practice.
>
> 4. On 1 March 2012 [Mrs A] was provided with a prescription for Cyklokapron by [Dr B] apparently on the basis of heavy menstrual bleeding and reduced ferritin. However, there is no documentation relating to [Mrs A's] assessment including history of bleeding and bleeding pattern, any associated symptoms, current contraceptive use etc. Without documentation of such history, it is difficult to further assess [Dr B's] management of [Mrs A's] bleeding. There are certain

[18] Dean G et Goldberg A. Management of problems related to intrauterine contraception. Uptodate. Last updated December 2013. www.uptodate.com

historical features that would necessitate further investigation by way of bimanual examination and referral for ultrasound, whereas if there were no features to suggest a structural or neoplastic cause for the bleeding, it might have been appropriate for [Dr B] to proceed directly to pharmacological management as was done (see relevant 2007 NICE guidelines[19]). It does seem apparent, however, that [Mrs A's] current contraceptive status was not established, as current IUCD use can be a cause of heavy menstrual bleeding and [Mrs A] does not recall being advised of removal of IUCD as a management option at this point. The paucity of clinical documentation is a moderate departure from expected standards of documentation (severe if there had been no record of prescribing whatsoever). If [Dr B] had not established an accurate history of the bleeding and [Mrs A's] current contraceptive method at this consultation, and prescribed Cyklokapron in the absence of such history, this would be a moderate to severe departure from expected management standards. It is not possible to determine whether the failure to undertake an examination at this consultation, or to order further investigations prior to treatment, is a departure from expected standards as the necessity for these measures is largely dependent on the history obtained. All clinically indicated management options (including IUCD removal) should have been discussed with [Mrs A] at this point and there is no evidence such discussion took place.

5. Clinical notes between 1 March 2012 and 1 June 2012 refer to [Mrs A's] ongoing mild anaemia and reduced ferritin, and arrangements being made to organise Mirena insertion. Again, the clinical documentation is suboptimal in that it is impossible to determine whether the pattern of bleeding represented treatment (Cyklokapron) failure in which case given [Mrs A's] age (42 years) further clinical assessment with bimanual examination and perhaps ultrasound should have been considered before making arrangements for Mirena insertion. [Mrs A] may have fulfilled the criteria for subsidised access to Mirena given her reduced ferritin and if the trial of Cyklokapron had failed to adequately control her symptoms. It seems evident a contraceptive history was not taken prior to insertion of the Mirena which I would regard as a very significant omission, and there is no evidence pregnancy was excluded prior to insertion of the device. There is no documentation suggesting a full discussion of the risks and benefits of the device were discussed prior to insertion, nor that consent for insertion was obtained. Had an adequate discussion taken place, this would have included the fact that Mirena is a long-term contraceptive which should have led to confirmation of [Mrs A's] existing contraceptive method (IUCD). These are moderate to severe departures from expected standards of both clinical management and clinical documentation. It was reasonable to provide empiric treatment with metronidazole at the time of insertion given the history of previous BV and possible signs noted at the time of insertion. If [Dr B] had been aware [Mrs A] had an IUCD in situ and proceeded with Mirena insertion with this knowledge and without removing the existing IUCD, this would be a severe

[19] National Institute for Health and Clinical Excellence. NICE clinical guideline 44 — Heavy Menstrual Bleeding. 2007. Available in summarised form at: http://www.nice.org.uk/nicemedia/live/11002/30403/30403.pdf

departure from expected practice. I am assuming [Mrs A] was under the impression her previous IUCD was being removed at this consultation and that [Dr B] was aware she had an IUCD in situ because she had provided this information on a previous occasion (although not to [Dr B]), it had been recorded in the notes, and [Dr B] had evidently not questioned her further about contraceptive use or the IUCD — such questioning being expected if she was not already aware of the patient's IUCD use. The general discomfort associated with IUCD insertion (and difficulty with the insertion was noted), including application of a tenaculum to the cervix and sounding of the cervix, would make it difficult for the patient to determine whether or not the previous device had been removed at the time of the consultation in question, and it was perfectly reasonable for [Mrs A] to assume the device had been removed as would be expected practice. Therefore, I think any attempt to apportion blame to the patient for the events in question, as implied in [the medical centre] response, is inappropriate.

6. Follow-up management by [Dr B] was reasonable in that the Mirena was checked on 13 June 2012 and found to be in situ and presumably only one set of strings was visible (and no strings visible at the time Mirena insertion was undertaken) although this is in contrast to two sets of strings being visible when [Dr B] removed both devices on 2 September 2013. Another Mirena check was undertaken on 11 October 2012 with presumably one set of strings visible (notes record *thread seen in place*). I think it was reasonable that metronidazole was prescribed empirically given [Mrs A's] symptoms at this point were suggestive of recurrence of her previous BV infection and swab was taken concurrently. [Mrs A] did not consult her providers again with symptoms suggestive of recurrent BV infection until 1 May 2013 when nurse triage notes record also that she was *here for talk to doctor about iucd removal.* On this occasion [Dr B] treated [Mrs A] for an upper respiratory tract infection and also provided empiric treatment for recurrent BV infection. There is no reference to the issue of IUCD removal being discussed further. Given [Mrs A's] concerns at her recurrent BV infections, the association between IUCD use and BV should have been discussed further at this point particularly given [Mrs A's] request for IUCD removal. However, I feel prescribing of metronidazole was still a reasonable option provided there had been adequate discussion with the patient beforehand. Noting the high incidence of BV recurrence[20] and the classic symptoms complained of by [Mrs A], it was probably reasonable to treat empirically on this occasion although some of my colleagues might have taken swabs to exclude alternative or concurrent significant infections given the presence of the IUCD and associated increased risk of developing significant pelvic infection.

(vii) The presence of two IUCDs was noted incidentally when [Mrs A] undertook a lower back X-ray on 17 August 2013 as investigation of persistent back pain following a documented lumbar injury. The abnormality was evidently not detected by [the GP] when he reviewed the films on 17 August 2013 but importantly he discussed with [Mrs A] the need to wait for formal radiologist

[20] Wilson J. Managing recurrent bacterial vaginosis. Sex Transm Infect 2004;80:8–11

reporting before making any further management decisions regarding the back pain. The formal report identifying two IUCDs (not apparently malpositioned) was acknowledged on 20 August 2013 and [Mrs A] contacted on 24 August 2013. She presented for review on 28 August 2013 and was referred for urgent ultrasound and subsequent gynaecology review. The IUCDs were removed with appropriate antibiotic cover on 2 September 2013. Management, once the two IUCD devices were detected, was consistent with expected standards.

(viii) For the reasons described in the body of this report, I feel the overall management of [Mrs A] by [Dr B] departed from expected standards to a moderate to severe degree, and I recommend consideration be given to her referral to the Medical Council of New Zealand for a competency review. The remedial measures undertaken by [the medical centre] appear appropriate with respect to ensuring relevant history is obtained prior to IUCD (or contraceptive implant) insertion."

Further expert advice

On 7 May 2014, Dr Maplesden provided the following additional expert advice:

"1. Thank you for asking me to review my original advice provided on 28 January 2014 taking into account additional information received from [Dr B] and [the medical centre] per [the medical director]. Comments in this report should be read in conjunction with my original advice.

2. [Dr B] — response dated 25 March 2014

(i) [Dr B] acknowledges deficiencies in clinical documentation noted in my original advice.

(ii) [Dr B] states that [Mrs A's] menstrual history was gained at the consultation of 1 March 2012 and her periods were regular but heavy on days one and two. Various options of treatment including combined oral contraceptive and Depot Provera were discussed although Mirena IUS [(intrauterine system)] was not discussed at this point. [Mrs A] preferred to trial Cyklokapron and this was prescribed as a trial.

Comment: Initial management of heavy menstrual bleeding was largely consistent with the NICE guidelines cited in my original advice, although Mirena should have been discussed as a potential first-line (unsubsidized) option and [Mrs A's] current contraceptive use should have been determined as part of an adequate history. These omissions were mild to moderate departures from expected practice, in particular failure to inform the patient of reasonable available management options. However, I remain of the view that the complete absence of any documentation related to the history, discussion or management plan for the heavy menstrual bleeding, other than a record that Cyklokapron was prescribed, was a moderate departure from expected standards of clinical documentation, noting adequate notes were recorded regarding musculoskeletal symptoms [Mrs A] presented with at this same consultation. I am assuming [Mrs A] can recall the discussion recounted by [Dr B] in the latest response. Had there been no questions

regarding menstrual history or discussion of available options, together with the absence of relevant documentation, I would have regarded [Dr B's] management on this occasion as being a moderate to severe departure from expected practice.

(iii) [Dr B] states [Mrs A] contacted the clinic proactively on 17 April 2012 *after reading a pamphlet on menorrhagia from the waiting room.* She expressed an interest in Mirena as an alternative to the currently prescribed Cyklokapron. [Dr B] notes there was sufficient information on file to make a Special Authority application to Pharmac for a subsidised device and this was done. She states [Mrs A's] bleeding *was not responsive to Cyklokapron* and, following repeat blood testing showing further drop in ferritin levels, [Mrs A] had fulfilled the Pharmac criteria for a subsidised device. The prescription was arranged and [Mrs A] presented for Mirena insertion on 1 June 2012. [Dr B] states a speculum and bimanual examination were undertaken prior to Mirena insertion, and [Mrs A] was provided with the information pamphlet from the device manufacturer which provides comprehensive information about the device, complications and follow-up. It is not confirmed whether this pamphlet was provided prior to the procedure, allowing time for [Mrs A] to consider the information and ask further questions if required, or whether it was provided following the procedure. As noted in my original advice, there is no documentation of pre-insertion discussion or consent to the procedure. [Dr B] states that insertion was undertaken within seven days of [Mrs A's] period (which had been very heavy) and there had been no history of missed periods to suggest possible pregnancy. [Dr B] states there was no reason to suspect any structural abnormality based on the pattern of bleeding (regular but heavy, no inter-menstrual bleeding), normal cervical smear, normal bimanual examination and [Mrs A's] young age.

Comment: I remain of the view that clinical documentation was suboptimal on this occasion (although improved from the previous occasion) being a mild to moderate departure from expected standards. Based on the response, I feel it was reasonable for [Dr B] to assume [Mrs A] was not pregnant prior to insertion of the Mirena, and that there was no strong clinical indication to perform further investigations (such as endometrial biopsy or ultrasound) prior to insertion of the device. The degree of discussion undertaken prior to [Mrs A] having the device inserted remains unclear, although [Mrs A] had evidently accessed at least basic information regarding Mirena from the 'waiting room pamphlet on menorrhagia'. If she was provided with the actual product pamphlet prior to insertion, and given time to consider the information contained within the pamphlet and to ask further questions if required, I am satisfied [Mrs A] was able to make an adequately informed choice regarding her treatment. If there was no specific discussion of the risks, side effects and benefits of the device (particularly discussion regarding expected menstrual irregularity for several months following insertion) prior to insertion, I would regard this as a mild to moderate departure from expected standards, acknowledging at least basic information had been accessed by [Mrs A] prior to the procedure. What is clear is that at no stage in [Mrs A's] management prior to insertion of the device did [Dr B] confirm whether [Mrs A] was using contraception and the nature of that contraception, nor did she consider the presence of an IUCD in relation to [Mrs A's] complaints of heavy menstrual

bleeding and recurrent bacterial vaginosis (both of which have an association with IUCD use), and I regard these factors as a moderate to severe departure from expected standards with respect to management of heavy menstrual bleeding and appropriate processes related to IUCD or IUS insertion.

(iv) Comments contained in my original advice in relation to [Mrs A's] treatment for recurrent bacterial vaginosis, and her management following Mirena insertion, remain unchanged.

3. [The medical director's] response (for [the medical centre]) dated 18 March 2014

(i) [The medical director] clarifies there was never any intention in his original response to apportion blame to [Mrs A] for failing to notify [Dr B] she had an IUCD in situ. I accept this clarification.

(ii) [The medical director] questions why, in my original advice, I suggested referral of [Dr B] to the Medical Council of New Zealand for a general competency assessment rather than recommending specific upskilling in the areas of management of heavy menstrual bleeding and Mirena insertion, and an audit of Mirena insertions to monitor compliance with recommended process standards *as these activities would specifically address the deficiencies highlighted.* My original advice was based on the information available to me at the time which gave no reassurance [Dr B] had covered even the most basic aspects of history taking with respect to management of heavy menstrual bleeding, including ascertaining the need for further investigation to exclude the possibility of a sinister cause for [Mrs A's] bleeding (ie minimization or potential harm to the patient). This was coupled with obviously deficient clinical documentation. Finally, [Dr B] inserted an intrauterine device into a patient with a device in-situ which must be regarded as a very significant aberration from expected practice even if no actual harm was done to the patient. These factors combined to make me question [Dr B's] practice and potential risk to other patients, hence my original recommendation for Medical Council review. Having been provided with more detailed information from [Dr B] subsequently, I am somewhat reassured that she took some reasonable steps to ensure [Mrs A] was unlikely to have a sinister cause for her bleeding, and that the management plan she advised was clinically appropriate under the circumstances (although with the somewhat glaring omission regarding her failure to establish, at any point prior to her X-ray, that [Mrs A] had an IUCD in-situ). Nevertheless, I feel [the medical director's] recommendations have some merit and those recommendations, together with a recommendation that [Dr B] undertake a two-pass audit of her standards of clinical documentation against RNZCGP [Royal New Zealand College of General Practitioners] standards, might be considered by the Commissioner when remedial actions are decided."