HEALTH & DISABILITY COMMISSIONER
TE TOIHAU HAUORA, HAUĀTANGA

A Decision by the Deputy Health and Disability Commissioner

(Case 22HDC02083)

Introduction

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

2. The report discusses the care provided to Mx A[1] by Dr B[2] at a sexual health clinic (the clinic).

3. On 23 August 2022, HDC received a complaint from the Nationwide Health and Disability Advocacy Service (the Advocacy Service) regarding the care provided to Mx A by Dr B in March and April 2021. Mx A's complaint concerns Dr B's failure to insert a new Jadelle[3] contraceptive implant after the removal of Mx A's pre-existing Jadelle implant. Mx A subsequently became pregnant several months later and underwent a termination of pregnancy and several investigations to locate an implant that was not there.

4. The following issue was identified for investigation:

   - *Whether Dr B provided Mx A with an appropriate standard of care in March and April 2021.*

5. The parties directly involved in the investigation were:

Mx A	Consumer/complainant
Dr B	Provider/general practitioner (GP)
The clinic	Non-subject provider

Background

6. In 2016, a Jadelle contraceptive implant was inserted into Mx A's arm. Mx A stated that in 2018, the clinic advised that the implant would need to be removed before it expired in mid-

[1] Mx A is non-binary (an umbrella term for all genders other than female/male or woman/man).
[2] Dr B is qualified in the vocational scope of 'Family Planning and Reproductive Health'.
[3] A form of contraception (to prevent pregnancy) for long-term use (up to five years). The implant is inserted beneath the skin on the inside of the upper arm. The insertion is performed by a doctor. Although the implant may be removed at any time, it must be removed no later than five years after insertion.

Names have been removed to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

September 2021.[4] Mx A told HDC that pregnancy is a 'major fear' for them, and, as a result, several proactive steps were taken (including telephoning the clinic months prior to check when their implant was due to expire and booking an appointment in advance to ensure that there were no lapses in contraception).

7. On 31 March 2021 Dr B telephoned Mx A, as Mx A did not attend a 'pre-Mirena'[5] consultation. Dr B documented the following: 'Likes to get Jadelle change not Mirena insertion … Confirmed appointment for next Wednesday [7 April 2021]. Implant change instead of Mirena insertion.'

Appointment 7 April 2021

8. Mx A attended the scheduled appointment with Dr B at the clinic on 7 April 2021. The clinical notes state that the pre-existing Jadelle implant was 'removed without any problems under sterile circumstances through a single incision', a '[b]andage [was] applied and woundcare advice given', and the '[c]lient [was] feeling well after[wards]'.

9. However, Dr B did not insert a new Jadelle implant and documented that Mx A had '[d]eclined contraception'. In addition, Dr B did not document matters relating to informed consent in the clinical notes or complete the clinic's written consent forms.

10. Mx A stated that they were 'very clear' about wanting a new (replacement) Jadelle implant at the same appointment when the pre-existing implant was removed. Mx A said that when they left the clinic on 7 April 2021, they were under the impression that the pre-existing Jadelle implant had been removed and replaced with a new Jadelle implant.

New implant not inserted and incorrect clinical notes

11. Dr B acknowledged that they are 'not able to justify why [Dr B] did not reinsert a new pair of Jadelle [implants], especially in view of [Dr B's] acknowledgment of [the] Jadelle change in the previous week'.

12. In addition, the clinic stated that upon review of the clinical record it agreed that:

a) Mx A was specific in their instruction at the time of making the appointment — the removal *and replacement* of Jadelle implants.

b) Mx A clearly declined the option of a Mirena IUD (prior to their appointment on 7 April 2021), and the stated outcome in the clinical record was for a Jadelle replacement/ change.

[4] It was documented in the clinical notes that the clinic told Mx A that the implant would expire on 16 September 2021.

[5] Another form of contraception for long-term use (between 3–10 years), in which an intra-uterine device (IUD) is inserted into the uterus.

c) Dr B's clinical records were not factually correct, namely the statement that Mx A 'declined contraception'.[6]

13. The clinic stated that it audited Mx A's clinical notes and found that Dr B wrote the notes at the 'conclusion of [the] appointment at 1.31pm'. Therefore, there was 'no ability for [Dr B] (or any other staff member) to alter these after this time'.

Consent

14. The clinic stated that it had a standard operating procedure (SOP) for 'Implant (Jadelle) Removal' at the time of events, which included the following points:

a) 'All clients should be fully informed before implant removal …'

b) Under the title 'Reason for removal': '… Is other contraception required? ... An implant change can be completed in a single appointment, refer also to the implant insertion agreed practice.'

c) 'Written consent is obtained and recorded in the client record for implant procedures.'

d) 'Contraceptive effect is lost immediately unless alternative contraception started by the time of removal.'

15. In addition, the SOP for 'Implant (Jadelle) Insertion' stated:

a) Special training applies for implant insertions.[7]

b) Under the title 'Removal': 'Discuss future contraception or pre conception care … If another implant is chosen, it can be inserted straight away using the same incision.'

16. The clinic told HDC that its usual organisational practice is to complete a consent form, with two separate consent forms relating to contraceptive implant consent: the 'Contraceptive Implant Consent' form,[8] and the 'Removal of Contraceptive Implant Consent' form. The clinic told HDC that Dr B has acknowledged that 'had [the consent forms] been completed … it would have resulted in a further conversation regarding an implant insertion'.

17. In addition, the clinic stated that as part of its COVID-19 response, it aimed to reduce high-touch activities and consents were completed verbally. However, the clinic said that at the time of events,[9] 'consents should have reverted to [being] printed and signed'. The clinic acknowledged that its framework guidelines and communications to staff at the time made 'no mention' of consent, and this could have accounted for Dr B's failure to obtain Mx A's signed consent.

[6] The clinic offered to amend Mx A's clinical record to include the following: 'Notes amended Under Rule 7 of the Health Information Privacy Code — following client request to reflect factual appointment. Notes written on 7 April at 1.31pm are not factually correct. "Plan — declined contraception" is not factual or correct and it has been removed. Client had expected Jadelle to be reinserted.'

[7] The clinic told HDC that at the time of events Dr B had received training on implant insertion.

[8] This covered instances where an implant was inserted and/or changed.

[9] In April 2021 [the region] was in Level 1 of the COVID-19 Protection Framework.

Communication

18. At the time of events, the clinic had a 'toolkit' document available to staff outlining specific guidance on issues for trans and gender-diverse consumers. The document emphasised the importance of 'effective communication' and included a flow chart with questions to prompt conversation with consumers. For example, under the title of '[w]ays of discussing sexual activity in an inclusive way', it states: 'Is there a possibility that any of your partners could get you pregnant? If so, are you using birth control?'

19. Further, under the topic of contraception, the document stated that the clinician was to provide 'support' to the consumer in several areas, including '[u]nderstanding risk factors, [e]liminat[ing] contraception that will not work for the client and explain[ing] why' and providing '[e]xtra time if possible' during the consultation.

Subsequent events

20. At the end of 2021, Mx A left New Zealand. While overseas, Mx A became pregnant. Mx A stated that this was a 'huge shock', and the termination was an 'extremely traumatic experience'.

21. Mx A said that as a result of this incident, they were required to take a 'significant amount of time' away from work. This included the time taken for the initial appointment, for several appointments relating to the termination of pregnancy and follow-up care, to process the emotional trauma caused by the incident, and for X-rays and ultrasound scans to locate an implant.

22. Mx A stated that when the X-rays and scans did not locate an implant, their GP advised them to request their clinical notes from the clinic (as further scans might be required to locate the implant). Mx A said that on reviewing the clinical notes, they discovered that Dr B had recorded that contraceptive had been declined post-removal of the existing Jadelle implant. Mx A felt that it was 'utterly absurd' to suggest that they would deny contraception and queried whether Dr B had noted this as an afterthought or to cover up Dr B's mistake. In addition, Mx A told HDC that they consider it 'incredibly poor practice' that Dr B did not make detailed clinical notes and that the documentation did not accurately reflect what had occurred during the appointment on 7 April 2021.

Proposal for an agreed breach

23. On 22 August 2024 I advised Dr B of my intention to investigate Mx A's complaint and proposed that Dr B agree to a breach of Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[10] This option was proposed as a pragmatic option to resolution, while recognising Dr B's actions to resolve the complaint and improve relevant aspects of Dr B's practice to date.

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

24. On 9 September 2024 Dr B agreed to the proposed breach of the Code. Dr B confirmed that several changes had been made to their practice (discussed further below) and that 'there ha[d] been no further incident, or similar incident' since.

25. I acknowledge the ongoing traumatic effect of this event on Mx A and their desire to prevent this from occurring to others in the future. I thank Mx A for bringing these issues to the attention of HDC.

Response to provisional opinion

Mx A

26. Mx A was given an opportunity to respond to the 'information gathered' section of the provisional report and had no further comments.

Dr B

27. Dr B was given an opportunity to respond to the provisional report. Dr B stated that they agreed with the provisional opinion and has now changed their clinical practice to always obtain signed consent.

The clinic

28. The clinic was given an opportunity to respond to the provisional report and confirmed that key members of its Senior Leadership Team reviewed the report. The clinic told HDC that it has already offered to file an ACC Treatment Injury claim on Mx A's behalf. Further comments made by the clinic have been incorporated into the report where relevant.

Opinion: Dr B — breach

7 April 2021 appointment — breach

29. Under the Code, Dr B is required to take reasonable care and skill in the provision of health services. I acknowledge that Dr B has accepted responsibility for the following failings (as outlined in the letter sent to Dr B on 22 August 2024):

a) Dr B did not review the clinical notes about the reason for Mx A's appointment.

b) Dr B did not confirm the nature of Mx A's visit at the appointment on 7 April 2021.

c) Dr B failed to insert a new Jadelle implant at the appointment on 7 April 2021.

d) Dr B incorrectly documented that Mx A had declined further contraception on 7 April 2021.

30. I commend Dr B's willingness to accept responsibility and make changes to practice since this event. Nevertheless, it is clear that Dr B made significant errors in the provision of care, which has had significant adverse consequence for Mx A.

31. I consider Dr B's failure to replace Mx A's Jadelle implant to be particularly concerning given Dr B's specialised qualifications in this area and experience working at the clinic, which included 'special training for implant insertions'.

32. Accordingly, I find Dr B in breach of Right 4(1) of the Code for failing to provide services to Mx A with reasonable care and skill.

Informed consent and documentation — adverse comment

33. Under the Health and Disability Commissioner Act 1994, '… no health care procedure shall be carried out without informed consent'.[11] This is reaffirmed in the Code, which states that consumers have the right to make an informed choice and give informed consent.[12] As outlined in this report, Dr B did not complete written consent forms for Mx A's appointment on 7 April 2021.

34. I note that the clinic's SOP stated that written consent was required to be 'obtained and recorded in the client record for implant procedures'. Nevertheless, I accept the clinic's submission that it failed to communicate changes made to its informed consent process during the COVID-19 pandemic, and I consider that this may have contributed to Dr B's failure to obtain *written* consent from Mx A. However, given the invasive nature of the procedure (the insertion of an implant into a consumer's arm) and potential side effects and risks, and to avoid any cause for confusion about the purpose of the consultation, I consider that it would have been best practice for Dr B to have obtained written consent from Mx A.

35. Further, I am critical that there is no evidence on the clinical record to indicate that Dr B conducted a full verbal discussion of all the information contained in the consent form prior to or during the appointment on 7 April 2021. As stated in guidance from the Medical Council of New Zealand (MCNZ):[13]

a) Patient records reflect a doctor's reasoning and are an important source of information about a patient's care.

b) Doctors must maintain clear and accurate patient records, including decisions made and the reasons for them, consent given and requests or concerns discussed during the consultation.

c) The doctor is responsible for what they record about a patient.

36. In my view, Dr B's failure to provide the correct treatment to Mx A (the removal of the pre-existing Jadelle implant *and* insertion of a new implant) is indicative of Dr B's failure to obtain and document Mx A's informed consent adequately, and I am critical of this.

[11] Section 20(1)(a) of the Health and Disability Commissioner Act 1994.
[12] Right 7 of the Code.
[13] Medical Council of New Zealand (2020). Managing patient records: https://www.mcnz.org.nz/assets/standards/0c24a75f7b/Maintenance-patient-records.pdf.

37. As discussed by the MCNZ,[14] obtaining consent is a process of shared decision-making, which helps providers to understand a consumer's medical condition and the options for treating (or not treating) that condition, and it is critical that providers 'take the time to ask questions so [they] understand what matters to [the consumer], and what [are] their concerns, wishes, goals and values'.[15]

38. I am pleased that Dr B has since attended informed consent training (discussed further below), and I have proposed further recommendations to address any outstanding concerns.

Communication — educational comment

39. As outlined previously, the clinic's SOP for 'Implant (Jadelle) Removal' required Dr B to consider whether other contraception was required. The SOP stated: 'Contraceptive effect is lost immediately unless alternative contraception [is] started by the time of removal.'

40. I consider that if Dr B was under the impression that Mx A did not want a new Jadelle implant, then during the appointment Dr B should have provided Mx A with safety-netting advice about the risk of pregnancy and alternative contraception. In my view, this would have prompted a discussion about contraception, in which Dr B (or Mx A) may have identified that a new Jadelle implant had not been inserted during the appointment.

41. In addition, I note that the clinic's 'toolkit' highlighted the importance of discussing risk factors and contraception options with trans and gender-diverse consumers. I encourage Dr B to continue to develop competency in effective communication, as it is a critical component in ensuring that people of all orientation and gender identities receive acceptable and appropriate health services.

No alterations to clinical record — other comment

42. Mx A's complaint questioned whether Dr B had altered the clinical record after the appointment to state that Mx A had 'denied contraception'.

43. As discussed above, the clinic conducted an audit of the relevant clinical record and found that Dr B had written the clinical notes at the conclusion of Mx A's appointment at 1.31pm. The clinic confirmed that its clinical documentation system did not allow for a clinician's notes to be altered once written into the clinical record.

44. I accept the clinic's findings and have no criticism in respect of this issue.

[14] Medical Council of New Zealand (2021). Informed Consent: Helping patients make informed decisions about their care. Statement-on-informed-consent.pdf.
[15] See Right 1(3) of the Code.

Opinion: The clinic — educational comment

45. As discussed above, the clinic made changes to its informed consent process in response to the COVID-19 pandemic. This included 'reducing high touch activities', which resulted in its informed consent processes occurring verbally.

46. The clinic told HDC that at the time of the incident, the informed consent process 'should have reverted to printed and signed'.[16] However, the clinic acknowledged that it failed to communicate the reversion to standard (written) informed consent processes to its staff, which may have accounted for Dr B's failure to obtain written consent from Mx A.

47. I accept that given the infectious nature of COVID-19, many healthcare providers turned to alternative consenting methods, including verbal consent. However, I am critical of the lack of intra-organisational communication by the clinic and consider that staff should have been made aware of this important change to its process. Therefore, I encourage the clinic to continue to improve the quality of its communication with the clinic staff, including in the context of informed consent and emergency management.

Changes made since events

Dr B

48. Dr B stated that they are sincerely apologetic for the 'adverse and unwanted outcome' that occurred in this case, and has made the following changes to practice:

a) Dr B documents the reason for the booked appointment and the actual appointment (if they differ).

b) Dr B completed the Medical Protection Society workshop on 'Reducing Medicolegal Risk'.

c) Dr B undertook informed consent training (as required by the clinic — see below).

d) Dr B underwent a competence review in collaboration with the clinic's manager and medical advisor. Dr B told HDC that as part of this review, an implant insertion and removal on a consumer was carried out, observed by a senior doctor who found Dr B to be compliant with the standard of care.

The clinic

49. The clinic stated that it 'could not apologise enough' for the trauma caused by this incident. The clinic said that it has made the following changes:

a) Discussed this complaint with the Senior Management Team.

b) Reviewed the appointment process to ensure that clinicians are clear on the appointment requirement when with a consumer.

[16] As [the region] was in the lowest level (Level 1) of the COVID-19 Protection Framework.

c) Reminded all staff to ensure that they are aware of the reason for the visit and to double check this with their clients at the time of appointment.

d) Required all the clinic clinicians to complete informed consent training, which reiterated the need to clarify the reason for the visit and ensure that the client understands what they are consenting to.

e) Merged its removal/insertion consent forms to prompt recognition of dual services.

Recommendations

Dr B

50. I recommend that Dr B:

a) Provide a further written apology to Mx A for the breach of Right 4(1) of the Code, including an acknowledgment of the traumatic effect of the pregnancy on Mx A. The written apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Mx A.

b) Provide evidence of attendance (for example, a certificate) at the 'Reducing Medicolegal Risk' workshop, and a written reflection on the learnings and how these will be applied in practice. This is to be provided to HDC within three months of the date of this report.

c) Undertake further education/training on clinical documentation and effective communication. The education/training should be in conjunction with, or endorsed by, MCNZ. Evidence of attendance (for example, a certificate) and a written reflection on the learnings and how these will be applied in practice are to be provided to HDC within three months of the date of this report.

The clinic

51. I recommend that the clinic:

a) Re-offer to amend Mx A's clinical record and assist with relevant applications, such as to ACC, as appropriate. Evidence of communication with Mx A (for example, a letter) is to be provided to HDC within three weeks of the date of this report.

b) Review the education/training provided to staff on Jadelle implant removal and insertion, informed consent, and communication (including relevant SOPs [17] and supporting documents) and report back to HDC within three months of the date of this report.

Follow-up actions

52. A copy of this report with details identifying the parties removed will be sent to the MCNZ, and it will be advised of Dr B's name.

[17] Noting that the Jadelle implant SOPs are due to be reviewed.

53. A copy of this report with details identifying the parties removed will be sent to the New Zealand College of Sexual and Reproductive Health and the MCNZ and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Names have been removed to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.