Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

A Decision by the Deputy Health and Disability Commissioner

(Case 21HDC02688)

Introduction

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

2. This decision discusses the care provided to Ms A on 1 June 2021 by Dr B[1] who, at the time, was a first-year general practitioner (GP) registrar in training at a medical centre. The report considers whether consent and assessment processes were followed appropriately to exclude pregnancy reliably prior to the insertion of a Jadelle device.

3. The following issues were identified for investigation:

- *Whether Dr B provided Ms A with an appropriate standard of care on 1 June 2021.*
- *Whether the medical centre provided Ms A with an appropriate standard of care during May 2021–June 2021 (inclusive).*

4. The parties directly involved in the investigation were:

Ms A	Consumer
Dr B	GP registrar

[1] Dr B is a member of the Royal New Zealand College of General Practitioners.

Dr C	GP
Medical centre	Group provider

5. Initial clinical advice was provided by Dr David Maplesden (Appendix A), and further clinical advice was provided by Dr Fiona Whitworth (Appendix B).

Background

6. The purpose of Ms A's appointment on 1 June 2021 was to access contraception following the birth of her baby three months previously. Ms A had a Jadelle device inserted and underwent a smear test.

7. On 23 September 2021 Ms A discovered that she was approximately 20 weeks pregnant, and she complained to HDC on 31 October 2021. The pregnancy had a significant impact on Ms A as she did not feel able to cope with another young baby so soon, and the pregnancy was too advanced for a termination to be considered. Ms A was also concerned about the possible effects of a Jadelle on the baby during the pregnancy.

8. The timeline leading up to Ms A's complaint is detailed below.

26 May 2021

9. On 26 May 2021 Ms A discussed contraception with the staff at the medical centre over the phone. She expressed a preference for a Jadelle device as she was familiar with this form of contraception, having had the device previously.

27 May 2021

10. Ms A was scheduled for a telephone consultation with GP Dr C[2] on 27 May 2021 to discuss contraception and to arrange a Jadelle insertion. Dr C was unable to contact Ms A, and therefore no consultation took place. As Dr C was aware of the urgency for reliable contraception, and Dr B had more availability, Dr C arranged for Ms A to see Dr B for a Jadelle insertion and a smear test on 1 June 2021.

11. Dr B had been trained in Jadelle insertion prior to the events. Dr C told HDC that Dr B had observed her inserting a Jadelle, and Dr C had supervised Dr B inserting a Jadelle and was comfortable that she was competent in the procedure and the associated sexual health consultation, including the assessment of contraceptive needs.

12. Dr C sent a text message to Ms A informing her that Dr B could insert the Jadelle and do a smear test at the same time as the appointment for her baby's immunisations. Dr C also sent information about the Jadelle through the Manage My Health patient portal[3] and asked Ms A to write back if she had any questions. Ms A told HDC that she was not provided with any information through Manage My Health. However, the medical centre provided

[2] Dr C is a Fellow of the Royal New Zealand College of GPs and has been supervising GP registrars in Jadelle insertion and removal at the medical centre for several years.
[3] Patient portals are secure online sites provided by GPs, in which patients can access their health information and interact with their general practice.

evidence that the Jadelle information was uploaded on 27 May 2021 and recorded in the clinical record. There is no evidence that Ms A responded.

13. The Jadelle information supplied to Ms A at the time focused on the device itself and possible side effects. It did not include any reference to the requirement for a pregnancy test prior to insertion, although it did state that usually insertion occurred within five days of a period starting, to ensure that the consumer was not pregnant. The information said that the device was 99% effective (about one person in 100 will get pregnant while using the device). There was no specific information on ensuring that the consumer was not pregnant prior to the menstrual cycle resuming following giving birth.

14. Dr C also instructed the practice nurse to contact Ms A and establish whether she was exclusively breastfeeding, and, if not, to offer condoms as an interim contraceptive method. The nurse was instructed to offer Ms A an iodine[4] supplement if she was exclusively breastfeeding. The nurse contacted Ms A and offered her condoms, which were declined.

1 June 2021

15. Ms A attended the scheduled appointment with Dr B on 1 June 2021. The clinical notes record that prior to insertion, consent for a Jadelle was obtained, the likely side effects were discussed, and an opportunity was provided for Ms A to ask questions. The Jadelle and smear test procedures were documented clearly, but there is no documentation of any discussion on the possibility of pregnancy, or of a pregnancy test being completed.

16. This Office was provided with a copy of the consent form printed at the time of events, which was unsigned. The form states: 'My GP has done a pregnancy test today and I understand this can be negative if I have become pregnant within the last week. I have been give[n] a pregnancy test to check at home in one month.' There is no documentation confirming that a pregnancy test was completed or offered to Ms A. Furthermore, Dr B's documentation did not refer to any discussion of pregnancy risk, recent contraception use/method, or menstrual cycle in the postnatal period.

17. Ms A confirmed to HDC that a pregnancy test was not completed and there was no discussion on contraception use or the risk of pregnancy, prior to the Jadelle insertion.

18. Dr B's response to HDC outlined her usual process for inserting a Jadelle, which includes gaining informed consent by discussing the procedure, complications, efficacy, removal, and side effects and providing an opportunity for questions, and reliably excluding pregnancy either by a urine pregnancy test or utilising the Faculty of Sexual and Reproductive Healthcare (FSRH) criteria.[5]

[4] Iodine is essential for the production of maternal and fetal thyroid hormones that regulate the development of the fetal brain and nervous system.

[5] https://www.fsrh.org/standards-and-guidance/documents/ceuguidancefertilityawarenessmethods/#:~:text=The%20effectiveness%20of%20changes%20to,98%25%20effective%20at%20preventing%20pregnancy.

19. Dr B was unable to recall the consultation with Ms A on 1 June 2021 due to the length of time that had passed but told HDC that she could not find any reason to deviate from her normal practice. However, Dr B acknowledged that as Ms A 'had been seen by a senior GP only a few days previously, [she] may also have thought that the GP ha[d] excluded pregnancy based on the fact [that] she advised the patient to use contraception up until the Jadelle insertion'.

20. GP records show that a pre-formatted Jadelle written consent form was generated but a signed form was not uploaded to the medical centre's practice management system. Dr B was unable to explain why the consent form was not signed and uploaded. The clinical record states that consent was obtained, and the likely side effect of irregular bleeding was discussed. Dr B told HDC that she would have discussed the content of the consent form prior to the insertion procedure. However, there is no documentation of a discussion on the information included in the consent form.

Post insertion

21. On 23 September 2021 Ms A felt small movements in her abdomen and completed a pregnancy test, which returned a positive result.

22. The pregnancy was confirmed on 30 September 2021 and estimated to be at 20 weeks' gestation. An ultrasound scan on 7 October 2021 dated the pregnancy at 22+1 weeks' gestation, which meant that Ms A would have been pregnant at the time of the Jadelle insertion.

23. The Jadelle was removed on 28 October 2021.

24. A formal apology letter from the medical centre was sent to Ms A on 9 October 2023.

Responses to provisional report

Ms A

25. Ms A was given an opportunity to comment on the 'information gathered' section of my provisional report but did not provide a response.

Dr B

26. Dr B was provided with a copy of relevant sections of the provisional report and given an opportunity to comment. Dr B confirmed to HDC that she did not have any comments.

The medical centre

27. The medical centre was provided with a copy of the provisional report and given an opportunity to comment. The medical centre's comments have been incorporated under the 'recommendations' section.

Opinion: Dr B — breach

Introduction

28. Ms A attended an appointment on 1 June 2021 to access reliable contraception following the birth of her baby three months previously. She already had two children and was not wanting another at this time. On 23 September 2021 Ms A was informed that she was approximately 20 weeks pregnant. It was too late to consider a termination and Ms A was concerned that having a Jadelle inserted while pregnant may have harmed the baby.

29. The issue under consideration is whether the consent and assessment process on 1 June 2021 was carried out and documented adequately prior to the insertion of the Jadelle. This includes whether pregnancy was excluded reliably either by a pregnancy test or established criteria.

Assessment

30. In forming my decision, I am guided by my clinical advisors, Dr Maplesden and Dr Whitworth. Dr Maplesden outlined four possible scenarios (see Appendix A), and I have carefully considered each scenario against the information on file.

31. The possible scenarios were as follows:

(i) There was no assessment of risk of pregnancy undertaken by Dr B, no pregnancy test performed prior to insertion of the Jadelle, and no advice given regarding post-insertion barrier contraception.

(ii) It was reliably established that Ms A was using the lactational amenorrhoea method (LAM) as contraception.

(iii) Risks of pregnancy were discussed, including last unprotected sexual intercourse (UPSI), no use of LAM, and UPSI was ≥ 21 days previously, pregnancy test was performed and was negative.

(iv) Risks of pregnancy were discussed, including last UPSI, no use of LAM, and UPSI was within 21 days of current date, pregnancy test was performed and was negative.

32. The adequacy of pre-procedure assessment, scenario (ii) proposed by Dr Maplesden, advised that if LAM of conception was reliably established, then there would have been no indication for performing a pregnancy test or post-insertion contraception (per cited FSRH guidance) and management would have been consistent with accepted practice. LAM is a period of temporary infertility that accompanies breastfeeding and is marked by the absence of monthly periods, which reduces the risk of pregnancy to 2%, provided that the baby is under six months of age, and the mother is exclusively breastfeeding and has not menstruated since delivery. Ms A had given birth three months previously, and therefore it was reasonable to check whether this method was being used. Dr C instructed the practice nurse to contact Ms A and establish whether she was breastfeeding exclusively and, if so, the practice nurse was to offer an iodine supplement.[6] In this instance, Ms A was offered

[7] The Ministry of Health recommends that healthy pregnant and breastfeeding women take a daily 150mcg iodine-only tablet from confirmation of pregnancy until the discontinuation of breastfeeding.

condoms, which she declined. The practice nurse had been instructed to offer condoms if Ms A was not breastfeeding exclusively. There is no detail in the clinical notes to show the discussion and rationale for offering Ms A condoms, but if the practice nurse followed Dr C's instructions, and I have no reason to assume that the instructions were not followed, condoms would have been offered if Ms A was not using LAM as a method of contraception. In any event, in my view there was insufficient information documented in the clinical record about whether or not the LAM method was being used, and Dr B needed to ascertain this information from Ms A directly in order to assess whether or not a pregnancy test was required.

33. Scenario (iii) and (iv) outline that pregnancy risk was discussed and a pregnancy test performed. Ms A told HDC that Dr B did not discuss contraception use with her or the risk of pregnancy, and the clinical record does not document this having been discussed. Ms A informed HDC that a pregnancy test was not done, and she was not given a pregnancy test to take home.

34. Given the passage of time, Dr B does not recall the consultation but told HDC that her usual practice involved reliably excluding pregnancy by urine test or FSRH criteria. However, there is no documentation to support that pregnancy risk was discussed or a pregnancy test completed, or that the FSRH criteria were used. In addition, the consent form, which states 'my GP has done a pregnancy test today', was generated but not signed.

35. Although I have placed some weight on Dr B's usual practice, there is insufficient evidence to support that these topics were discussed, or her usual actions taken. I have placed more weight on the contemporaneous clinical record, which did not document this discussion despite clearly and thoroughly documenting all other aspects of the consultation. I have also considered Ms A's recollection provided to HDC a few months after the consultation, and that Dr B told HDC that she may have assumed that a senior GP had excluded pregnancy based on advising Ms A to use contraception prior to Jadelle insertion. On balance, I find that it was more likely than not that Dr B did not discuss the risk of pregnancy with Ms A, provide advice on post-insertion contraception, or exclude a pregnancy (by urine test or FSRH criteria) on 1 June 2021.

36. I consider that on balance, scenario (i) outlines the most likely course of events. In this scenario, I consider that a departure from accepted practice occurred, based on the finding that there was no assessment of risk of pregnancy undertaken by Dr B, no pregnancy test performed, and no advice given regarding post-insertion barrier contraception. Dr Maplesden advised that the above actions would represent a severe departure from accepted practice. Dr Whitworth concurred with this independently and advised that this type of scenario would represent a moderate to severe departure. I accept this advice.

37. Dr B told HDC that she may have made an assumption that a consultation had occurred with Dr C on 27 May 2021 and that pregnancy had been excluded based on the advice to use contraception. Dr Whitworth advised that based on the wording of the clinical entry of 27 May 2021, it is not clear whether this was a telephone or in-person consultation.

38. I accept that Dr B may have made a reasonable assumption that a consultation had occurred with Dr C. I also accept Dr Whitworth's advice to be cautious when making assumptions regarding important clinical facts and always to reclarify these. In my view, it was Dr B's responsibility to clarify important clinical information prior to proceeding with the Jadelle insertion. I am critical of Dr B's failure to reliably establish the method of contraception being used by Ms A and to test for pregnancy prior to the insertion of the Jadelle.

Conclusion

39. In making this decision I have taken into consideration that at the time of the consultation, Dr B was a first-year registrar who was still undergoing training as a GP. Although Dr B was a junior doctor at the time of the events, she had prior experience with the process of Jadelle insertion and had been assessed as competent to manage the consultation independently, including all steps associated with the insertion of the Jadelle, which included the consent process and pregnancy testing. For this reason, notwithstanding her junior status, I am holding her accountable for the shortcomings in her clinical practice on this occasion. I acknowledge the changes that Dr B has made to her practice as a result of this complaint and the additional training she has completed.

40. In my view, Dr B omitted to discuss the method of contraception used by Ms A prior to the consultation, and to establish clearly whether Ms A could be pregnant and offer a pregnancy test. As such, Dr B failed to provide services to Ms A with reasonable care and skill and breached Right 4(1) of the Code.

Informed consent — adverse comment

41. I am critical of the lack of a completed consent form and acknowledge that although a form was generated, it was not signed by either Ms A or Dr B. The lack of signature by either party draws into question whether the information included in the consent form was discussed. The clinical record notes that consent for Jadelle insertion and the side effects were discussed, but there is no evidence to support that a full discussion of all the information included in the consent form took place.

42. The consent form contains the phrase 'My GP has done a pregnancy test today' and 'I have been give[n] a pregnancy test to check at home in one month'. If the consent form had been discussed and completed correctly, these phrases would have led to further enquiry and either a pregnancy test being completed, or the consent form being adjusted prior to signing. Ms A told HDC that she was not given a pregnancy test to take home and there is no evidence to indicate that one was provided.

43. I am critical of the consenting process that occurred on 1 June 2021. Although the clinical documentation records that consent was established and side effects discussed, the consent form, containing information on pregnancy testing, was unsigned.

44. I accept that consent to the surgical procedure was established. However, as a pregnancy test was not completed and the consent form was unsigned, there is no evidence to establish that the sexual health component of the consultation, including the risk of

pregnancy, was carried out. In addition, the consenting process was incomplete because the documentation was not signed and uploaded into the patient management system.

Medical centre — other comment

Supervision — no breach

45. Dr C was supervising Dr B during her time with the medical centre. Prior to instructing the practice nurse that Dr B was now able to carry out a Jadelle insertion consultation independently, Dr C had demonstrated a consultation and had observed Dr B leading a consultation. Dr B had also come to the medical centre with previous experience in Women's Health and Jadelle insertion. Dr C took steps to assess Dr B's skill and competence and therefore provided adequate supervision prior to approving independent practice.

Documentation — other comment

46. I am mindful of Dr Maplesden's advice that there is a deficiency in clinical documentation of 1 June 2021 in that if contraception, cycle, risk of current pregnancy (including last unprotected sexual intercourse) and need for pregnancy test was considered, this should have been documented, as should the result of any test undertaken or the fact that a kit was provided to the patient if this was the case. Dr Whitworth was also mild to moderately critical of the lack of documentation of this component of the consultation, assuming that Dr B followed a set routine and there was a discussion on contraception and pregnancy risk.

47. I accept the above advice and have considered the sexual health aspect of the consultation, where it would be expected that contraception and risk of pregnancy was discussed. The complete lack of documentation of this discussion, alongside the fact that other aspects of the consultation were documented clearly, suggests that this discussion was not documented because it did not occur. If this was the case, and there was a rationale for not discussing contraception, rather than an omission to follow usual process, the rationale should have been documented.

48. Dr Whitworth identified some documentation concerns by staff at the medical centre. I accept Dr Whitworth's advice on the quality of Dr C's clinical entry of 27 May 2021. Dr Whitworth identified that the type of contact that occurred with Ms A is not clear and that a GP unfamiliar with the client (a locum GP) would not have been able to determine from the clinical note whether or not there had been patient contact. Dr Whitworth was mildly to moderately critical of this.

49. Dr Whitworth further advised that the practice nurse's note of 27 May 2021 lacks detail regarding the offer of condoms to Ms A, and this implies that two possible scenarios could have occurred — either condoms were offered and contraception was declined, or Ms A was asked if she was exclusively breastfeeding (LAM) and was offered condoms because she was not. Ms A declining condoms opens the possibility that she declined because she was exclusively breastfeeding or was using another form of contraception. There is no information in the clinical note to clarify what was discussed.

50. I accept Dr Whitworth's advice and trust that the medical centre clinicians take heed of this feedback and are attentive to their documentation in future to ensure that it is both clear and fulsome.

Other comment

51. I am unable to determine whether the failure to complete the consent process and upload the document to Ms A's file was a one-off incident or indicative of a systems issue. I have therefore made a recommendation designed to assess whether further action is required.

Changes made since events

52. Dr B has expressed her deepest apologies to Ms A for her unplanned pregnancy and has reflected on her practice. Dr B told HDC that she has not undertaken Jadelle insertion independently since receiving Ms A's complaint and has reviewed the FSRH guideline, as recommended by Dr Maplesden.

53. Dr B has developed a template, which she now uses to ensure that risk of pregnancy is reliably assessed and documented prior to every Jadelle insertion. The template includes prompts to assess last menstrual period, last episode of unprotected sexual intercourse, current contraception, pregnancy test result, post-insertion barrier contraception, and provision of follow-up pregnancy test. There is also a prompt to ensure that the consent form has been signed by both parties. A copy of the template has been provided to HDC.

54. Dr B has completed additional training, provided by the Family Planning Association, in contraceptive counselling and contraceptive implant theory. A copy of the certificates of completion has been provided to HDC.

55. The medical centre expressed its sincere apologies to Ms A for the distress she has experienced and said it hopes the improvements it made will give Ms A assurance that the standard of care for the Jadelle procedure will be of high quality in the future.

56. The medical centre has updated its Jadelle consent form and added a standardised procedure template for Jadelle insertion to its patient management system. A copy of the procedure has been provided to HDC. In addition to completing a pregnancy test on the day of Jadelle insertion, the medical centre now provides consumers with a pregnancy test to complete 3–4 weeks post insertion.

57. The medical centre has also developed a contraception implant insertion (Jadelle) procedure policy, which has been added to its orientation manual.

58. Dr C has completed additional training offered by the College of Sexual and Reproductive Health. She has also completed the Family Planning Association learning module on contraception counselling.

Recommendations

59. I acknowledge the additional training and system changes that have been made by Dr B, Dr C, and the medical centre since Ms A's complaint, to prevent a similar situation occurring to other women.

60. In my provisional opinion I recommended that the medical centre audit the last 10 Jadelle insertion procedures performed and report on the number of consent forms that were signed by both the consumer and doctor and uploaded into the patient file. In response to my proposed recommendation, the medical centre provided a copy of the results of an audit of its last 10 Jadelle insertions, which confirmed that in all cases a consent form was signed, and a pregnancy test completed. I therefore consider this recommendation to have been met, and no further follow-up is required.

61. I recommend that Dr B provide a formal written apology to Ms A for the breach of the Code identified in this report. The apology is to be sent to HDC, for forwarding to Ms A, within three weeks of receiving my decision.

62. I ask that Dr B complete the recommendations suggested by Dr Maplesden by auditing the last three Jadelle insertions she has undertaken to ensure that there are no omissions in documentation, and that the advice provided is consistent with FSRH guidance. A report of this audit is to be provided to HDC within six weeks of receiving my decision.

63. I recommend that Dr B complete the HDC online learning module on informed consent. Evidence of completion is to be provided to HDC within six weeks of receiving my decision.

Follow-up actions

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

65. A copy of this report with details identifying the parties removed, except the clinical advisors on this case, will be sent to Health New Zealand|Te Whatu Ora and 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 in-house advice was obtained from Dr David Maplesden on 31 May 2022:

'…

1. My name is David Maplesden. I am a graduate of Auckland University Medical School and I am a practising general practitioner. My qualifications are: MB ChB 1983, Dip Obs 1984, Certif Hyperbaric Med 1995, FRNZCGP 2003. Thank you for the request that I provide clinical advice in relation to the complaint from [Ms A] about the care provided to her by [Dr B]. In preparing the advice on this case to the best of my knowledge I have no personal or professional conflict of interest. I agree to follow the Commissioner's Guidelines for Independent Advisors.

2. I have reviewed the following information:

- Complaint from [Ms A]
- Response from [Dr B]
- GP notes [medical centre]

3. [Ms A] states she attended [Dr B] at [the medical centre] on 1 June 2021 for the purpose of having the implantable progestogen contraceptive device Jadelle inserted (rods into upper arm). She states: I was not asked if I was pregnant or to do a pregnancy test to ensure I was not pregnant at the time. The device was inserted and in September 2021 [Ms A] felt fetal movements and was confirmed as being around 20 weeks pregnant. This was an unplanned pregnancy which [Ms A] did not want but termination was not an option by the time the pregnancy was discovered. [Ms A] is concerned that [Dr B's] failure to exclude pregnancy prior to inserting the Jadelle has left her in a stressful and difficult situation including concern about potential risk to the unborn child.

4. [Ms A] ([DOB]) was due to give birth to her second child around 26 February 2021 (based on pregnancy scan, precise date of delivery not known). On 26 May 2021 she contacted [the medical centre] requesting insertion of a Jadelle contraceptive device. She had a telephone consultation with [Dr C] the following day to discuss the request further. Notes refer to [Ms A] being around three months post-partum with Jadelle information booklet (per Health Navigator[1] according to provider response) to be provided per the patient portal. Arrangements were made for [Dr B] to insert the device and undertake cervical smear concurrently ([Ms A] had a history of abnormal cervical cytology). [Dr C] has documented: needs to ensure adequate contraception in meantime eg condoms unless exclusive breastfeeding (offer iodine if it is breastfeeding). Later that day a practice nurse has documented confirming an

[1] https://www.healthnavigator.org.nz/media/14801/jadelle-patient-booklet.pdf Accessed 31 May 2022

appointment on 1 June 2021 for insertion of the Jadelle and offered condoms — pt declined.

5. It is difficult to confirm the detail of discussion undertaken with [Ms A] in relation to the Jadelle device, but the written information apparently forwarded to her is comprehensive. The information includes: To make sure that you are not pregnant, the implants should be inserted within 7 days of the first day of your period, or immediately or within 7 days after abortion. If they are inserted at any other time your doctor will need to make sure you are not pregnant before insertion and you will need to use an additional non-hormonal (barrier) method (e.g. condoms) for the following 7 days. Based on [Dr C's] comments, it appears there was an assumption [Ms A] was using the Lactational Amenorrhoea Method (LAM) 2 for contraception although more detail confirming this was the case might have been expected. The method is around 98% effective at preventing pregnancy provided the baby is under six months old, the mother is exclusively breastfeeding and has been amenorrheic since delivery.

6. Despite there not being much information in [Dr C's] notes regarding [Ms A's] current contraceptive method and/or risk of pregnancy, I would expect this issue to be clarified by the doctor inserting Jadelle prior to insertion. This has some importance in that the FSRH guidance[3] referred to by [Dr B] in her response (see Appendix 1) makes firm recommendations with respect to pregnancy testing and additional contraception around the time of implant insertion in a postnatal patient. These recommendations form the basis for my comments in section 13.

7. The Health Navigator Jadelle pamphlet apparently provided to [Ms A] makes it clear the device should not be inserted if the patient is pregnant or thinks they might be pregnant and includes the following comment: To make sure that you are not pregnant, the implants should be inserted within 7 days of the first day of your period, or immediately or within 7 days after abortion. If they are inserted at any other time your doctor will need to make sure you are not pregnant before insertion and you will need to use an additional non-hormonal (barrier) method (e.g. condoms) for the following 7 days.

8. [Ms A] attended [Dr B] on 1 June 2021. [Dr B] notes in her response that she is an experienced Jadelle inserter and she invariably follows a step by step process for the insertion process. This is described as: I use a process of gaining informed consent by discussing the procedure itself, possible complications, efficacy, removal, side effects and to ensure any questions or concerns are addressed. It is also my usual practice to

[2] https://www.fsrh.org/standards-and-guidance/documents/ceuguidancefertilityawarenessmethods/#:~:text=The%20effectiveness%20of%20changes%20to,98%25%20effective%20at%20preventing%20pregnancy. Accessed 31 May 2022

[3] FSRH Clinical Guideline: Progestogen only implant (February 2021). https://www.fsrh.org/standards-and-guidance/documents/cec-ceu-guidance-implants-feb-2014/ Accessed 31 May 2022 NB This guidance refers to the implant available in the UK (etonogestrel) but principles of management are the same as would be expected with Jadelle. UPSI — unprotected sexual intercourse; LAM — lactational amenorrhea method; PT — pregnancy test; EC — emergency contraception

do a urine pregnancy test before the jadelle insertion or to use the FSRH (Faculty of Sexual and Reproductive Healthcare) criteria to reliably exclude pregnancy. I must emphasise that it is my usual process before every jadelle insertion to reliably exclude pregnancy in the manner listed above. [Dr B] is unable to recall the details of the consultation in question but does not feel there was any reason for her to vary from her routine practice.

9. GP records indicate a preformatted Jadelle written consent form was generated but a signed form was not uploaded to the PMS. [Dr B] states: *It is also my usual practice to have both the patient and myself sign the consent form and then have it scanned into the patient's records. I cannot state why the signed form was not uploaded on this occasion, but note that the documentation for jadelle insertion consent occurred that day.* The consent form (unsigned — see Appendix 2) is comprehensive and of good quality. It includes the statement: *My GP has done a pregnancy test today and I understand this can be negative if I have become pregnant within the last week. I have been given a pregnancy test to check at home in one month.*

10. [Dr B's] notes dated 1 June 2021 read as follows:

> "Here for jadelle insertion and smear. Previous CIN2 on colposcopy 2012. On yearly smears. No abnormal bleeding. Has received 2x HPV vaccines — 2011. Consented for jadelle insertion. Has had a jadelle previously, no questions. Discussed likely side effect of irregular bleeding."
>
> "Jadelle insertion — Left upper arm, aseptic technique. 5mL lidocaine subdermally. Cleaned with chlorhexidine. 5mm incision over old scar. 2x jadelle rods inserted with trochar subdermally. Both rods palpable under skin. Steristrips, dressing, crepe bandage."

Smear details were recorded and Plan:

"1.Cervical smear sent; 2. Safety netted to seek medical review if signs/symptoms of wound infection 3. Advised to see GP if bothered by irregular bleeding after 3 months 4. Recall for 4 years"

There is no reference to discussion of pregnancy risk, recent contraception use/method or menstrual cycle in the postnatal period. There is no record of pregnancy test being performed or supplied to [Ms A], nor the need for post-insertion contraception for a week (if that was relevant). It is unclear if the reference to incision over the old scar refers to previous use of the Jadelle implant.

11. [Ms A] presented to [a doctor] at [the medical centre] on 30 September 2021 having had the impression of fetal movements in her abdomen. She was noted to have a 20-weeks size uterus and ultrasound scan on 7 October 2021 confirmed the pregnancy as 22+1 weeks giving an estimated delivery date of 9 February 2022. This suggests [Ms A] conceived around 19 May 2021 meaning she would have been around 13 days post-conception at the time the Jadelle was inserted. While most urine pregnancy kits would

be expected to detect a pregnancy by this stage, given there is some variability of sensitivity between kits and the dates estimated may also vary within one or two days, and the test sample (if taken) would not have been a first morning urine, I am unable to state categorically that a urine HCG would have been definitely positive had it been performed on 1 June 2021.

12. There is a deficiency in clinical documentation of 1 June 2021 in that if contraception, cycle, risk of current pregnancy (including last UPSI) and need for pregnancy test was considered, this should have been documented as should the result of any test undertaken or the fact a kit was provided to the patient if this was the case. This makes it difficult to refute [Ms A's] assertion that there was no such discussion or testing undertaken. The absence of a signed consent form on file further complicates this assessment although the form was generated. These deficiencies in documentation I believe are mild to moderate in nature taking into account the information contained in the consent form and that the remainder of the consultation was well documented. However, the absence of such documentation may have more severe consequences for [Dr B] under the circumstances.

13. I believe there are several scenarios to consider.

(i) There was no assessment of risk of pregnancy undertaken by [Dr B], no pregnancy test performed prior to insertion of Jadelle and no advice given regarding post-insertion barrier contraception. I believe this scenario represents a severe departure from accepted practice as would the scenario of [Dr B] proceeding with Jadelle insertion if a pregnancy test was performed and was positive.

(ii) It was reliably established [Ms A] was using LAM as contraception. While this should have been documented, there was no indication in this scenario for performing a pregnancy test or post-insertion contraception (per cited FSRH guidance) and management was consistent with accepted practice aside from the documentation deficiency. Some providers might offer a pre-insertion pregnancy test in any case given the 2% failure rate of LAM.

(iii) Risks of pregnancy were discussed including last UPSI, no use of LAM and UPSI was ≥ 21 days previously, pregnancy test performed and was negative: mild to moderate departure from accepted practice in that advice for barrier contraception for one week post insertion should have been provided.

(iv) Risks of pregnancy were discussed including last UPSI, no use of LAM and UPSI was within 21 days of current date, pregnancy test performed and was negative: mild to moderate departure from accepted practice in that there is a recommendation to discuss emergency contraception in this scenario, and for barrier contraception for one week post-insertion and repeat urine pregnancy test three weeks after the most recent UPSI.

14. [Dr B] has acknowledged the deficiency in her documentation and to avoid this issue in the future she has developed a prompting template to ensure all areas covered

in the consent and insertion process are recorded. I recommend [Dr B] review the cited FSRH guidance and that she audits notes relating to the last three Jadelle insertions she has undertaken to ensure there are no omissions in her documentation and the advice she has provided to the patient is consistent with current FSRH guidance.'

Appendix B: In-house clinical advice to Commissioner

'1. My name is Fiona Whitworth. I am a graduate of Oxford University Medical School and I am a practising general practitioner. My qualifications are: MA 1991,BM BCh 1994, DCH 1996, DCRCOG 1996, MRCGP 1999, PGCMed Ed 2011, FRNZCGP 2013, PGDip GP 2016, FAEG 2020. Thank you for the request that I provide clinical advice in relation to the complaint from [Ms A] about the care provided by [Dr B]. In preparing the advice on this case to the best of my knowledge I have no personal or professional conflict of interest. I agree to follow the Commissioner's Guidelines for Independent Advisors.

2. Documents reviewed

1/11/21 Complaint

6/12/21 S14 response and Clinical Notes [medical centre]

4/8/22 Email Trail from [Ms A] and HDC

9/10/23 Email and information from [Dr B]

11/10/23 [Medical centre's] response to notification

3. Complaint

[Ms A] attended [Dr B] at [the medical centre] on 1/6/21 to have an implantable progestogen contraceptive device Jadelle inserted for long term contraception. She states she was not asked if she was pregnant or requested to undertake a pregnancy test prior to the insertion. On 23/9/21 she felt foetal movements and undertook a pregnancy test which was positive. This was an unplanned pregnancy which [Ms A] did not want, however she was found to be of a gestation that precluded an abortion. She states this put her under considerable stress due to also having [other young children]. She is additionally concerned re the effect of Jadelle on the developing baby.

Clarification email from [Ms A] 1/8/2022

[Ms A] was asked several questions to which she has stated that at the consultation with [Dr B]. She has stated — '*[Dr B] did not mention any thing about pregnancy or the risk of Being pregnant. She didn't ask me to do a pregnancy test … Nothing was mentioned to me about what contraception I was on and what to prevents … [Dr B] failded to do her job correctly as she did not ask me to do a pregnancy test whether there was a risk or not it's compulsory that it is done.*'

4. Provider response(s)

3/12/2021 S14 [Dr B]

[Dr B] has expressed her sincere apologies and acknowledged the distress that [Ms A] has undergone.

It is stated that *'on 27 May 2021 the patient saw my senior GP colleague to request a jadelle … it was explained to her that she needed to use a reliable form of contraception in the interim. She was also sent written information from healthnavigator.org.nz about*

the jadelle on Manage My Health. A subsequent phone call from the nurse documented that the patient declined condoms.'

She has stated that she follows a set process every time she inserts a Jadelle — *'I use a process of gaining informed consent by discussing the procedure itself, possible complications, efficacy, removal, side effects and to ensure any questions or concerns are addressed. It is also my usual practice to do a urine pregnancy test before the jadelle insertion or to use the FSRH (Faculty of Sexual and Reproductive Healthcare) criteria to reliably exclude pregnancy.'*

She notes that *'I have no recollection of going outside my normal practice and would have had no reason to do so.'*

Given that this is her standard practice although not documented I am inclined to accept that she did not deviate from her standard practice and that she established that she used the FSRH criteria[4] to reliably exclude pregnancy.

She has also potentially made an assumption based on her colleague's notes *'As [Ms A] had been seen by a senior GP only a few days previously, I may also have thought that the GP had excluded pregnancy based on the fact she advised the patient to use contraception up until the jadelle insertion.'*

This assumption would have been reasonable given the wording of the clinical entry. However, I would caution in making assumptions and with regard to important clinical facts it is always best to reclarify these. In fact, in this case [Ms A] had not had a clinical consultation with [Dr C] as the notes implied — there had only been a clinical note as the GP had been unable to contact [Ms A].

I am mild to moderately critical of the ambiguity of this clinical entry on 27/5/2021.

She notes that she has documented that she obtained consent for Jadelle insertion and that this would have meant that she followed the process outlined in the consent form.

She noted that the scan on 7/10/21 would have implied a last menstrual period at 4/5/21.

She has reflected on the case and accepted that her notes were not adequate. She has altered her documentation practice to utilize a series of prompts which include '*outcome of the urine pregnancy test, post-insertion contraceptive advice, and the advice to repeat the pregnancy test in 4 weeks*'.

Comment

It appears that [Dr B] was under the impression that [Ms A] had seen [Dr C] on 27/5/21 to discuss Jadelle and that contraception requirements had been discussed with her

[4] https://www.fsrh.org/standards-and-guidance/documents/fsrh-clinical-guidance-quick-starting-contraception-april-2017/ accessed 6/5/24

including the need to use reliable methods. Additionally, that written information had been sent to reinforce this advice and that a subsequent phone call from the nurse had documented that [Ms A] had declined condoms.

The clinical entry on 27/5/21 did not state that this was not a clinical contact and only a note. It would have been best practice to have documented this as a patient note only and that the patient had not been seen.

Comment

Given [Dr B's] standard practice is to follow a step by step process I feel it is likely that she discussed contraception and the risk of pregnancy but did not document this possibly due to the time constraints of the consultation (undertaking cervical screening in addition to Jadelle insertion).

I note that [Dr B] has reflected on the case with a gynaecologist who [Dr B] says has stated — '*They advised that if a urine pregnancy test was done, given the variability in both ultrasound dating and also when ovulation occurs within the menstrual cycle, it is possible that the patient was not pregnant at the date of jadelle insertion and/or had an early pregnancy that was not detectable at the time.'*

3/10/2023 S14 [Dr B], Additional S14 in response to letter from HDC 1/9/23

This was written to reply to questions and to Dr Maplesden's report.

In this [Dr B] reiterates that she had printed out the consent form and that she would have followed her standard process to discuss its contents '*and discussed whether there was any risk of pregnancy, the nature of [Ms A's] menstrual cycle, her contraception use and any need for post-insertion barrier conception.'*

She acknowledges that her documentation was inadequate.

Regarding pregnancy assessment she notes — *'I knew that Jadelle should not be used in the context of pregnancy or potential pregnancy. It was my practice at the time to perform a pregnancy test or to exclude pregnancy using the FSRH criteria. If a pregnancy test was undertaken, as previously advised it would be my regular and established practice to record the outcome of this in the medical records'.*

[Dr B] has noted that she has made significant changes to her practice and has reviewed the FSRH guidance and has subsequently updated an insertion template. Of note [Dr B] has included the criteria for reasonably excluding pregnancy in this as well as having a printed copy on her desk. This also includes a prompt to complete the consent form.

Since the complaint [Dr B] has also completed additional theoretical training in LARC — MOH and in 2023 undertook practical training.

1 She has completed family planning training in contraceptive counselling and contraceptive implant theory.

2 She has attended the Goodfellow Symposium workshop on contraception and abnormal uterine bleeding in 2023.

3 She has reviewed the Ministry of Health's *New Zealand Aotearoa's guidance on contraception (December 2020)* and *Nga Paerewa Health and Disability Services Standard (NZS 8134:2021)*.

In her reply she has again expressed her deepest apologies for the stress experienced by [Ms A] and has endeavored to improve as a GP as a result of the complaint with regard to communication with patients and clinical record keeping.

11/10/2023 S14 [the medical centre]

This has included a response from [Dr C], [the practice nurse] and computer records.

It is noted that at the time of the incident [Dr B] was under the supervision of [Dr C] a college trainer for GPEP. It is noted that [Dr B] was a college employed registrar.

Regarding standards of clinical documentation, they have stated "*good clinical documentation forms part of a GPEP1s training and while the quality varies over time and from trainee to trainee, it is generally of a high quality. Improvements tend to be made gradually over time through a process of self-reflection with support and guidance from their supervisor/teacher."*

It is noted since the complaint they have updated their Jadelle consent form and added a standardized procedure template for Jadelle insertions to the PMS.

It is noted that re pregnancy assessment — *"In addition to completing a pregnancy test on the day of insertion, we will also now provide a pregnancy test from our practice advising the woman to complete this in 3–4 weeks post Jadelle insertion*."

It is noted "*[Dr C] has completed [a course] offered by the College of Sexual & Reproductive Health in late 2022. …"*

Additionally, there is now the expectation that GP registrars complete the Family Planning Association learning module on Contraception Counselling prior to starting Jadelle insertions at the practice.

There has been a formal letter of apology sent to [Ms A] from the practice.

27/9/2023 S14 [Dr C]

…

She notes re [Dr B's] experience — "*She came to our practice already trained in jadelle insertion from her previous role …."*

She notes that "*I had observed her inserting a jadelle. She showed competence in the jadelle insertion procedure and in assessing contraceptive needs and conducting a sexual health consultation.*"

Regarding contact on 27/5/21 — it is stated that

1 A telephone consultation was booked but that there was no answer.

2 A text message was sent instead —

"Hi [Ms A], I couldn't get through on your phone to discuss the jadelle.

I sent some info on the patient app for you to read. Write back to me on the app if you have questions. [Dr B] can put the jadelle in on Tues 1st at the time of baby's immunisations 10am. She can do your smear at the same time. [Dr C]"

3 This was followed with a message on Manage my Health — "jadelle page of the New Zealand Health Navigator patient information site".

This is confirmed to have been sent at 9.16am on 27/5/21 as per screen shot attached in practice response.

4 A task was sent to the nursing team requesting appropriate action including — "*need to ensure adequate contraception in meantime eg condoms unless exclusive breastfeeding (offer iodine if is breastfeeding) jadelle info via MMH".*

[Dr C] notes that the practice nurse did undertake a telephone call and that she was aware of the need to offer contraception as per the clinical notes.

With regard to actions since the complaint. [Dr C] has:

A completed the 2022 … course regarding LARC and is using this now ...

B Completed FPA Learning Module on contraceptive counselling

C Established that it is her current practice to offer a pregnancy test on the day of insertion and also at 3–4 weeks post insertion.

D Has developed a template for Jadelle insertion for the practice.

E Reviewed the practice consent form for Jadelle insertion.

<u>11/10/2023 S14 [the practice nurse]</u>

It is stated that [the practice nurse] contacted [Ms A] on 27/6/21 confirmed her appointment time and also offered condoms for contraception which was declined.

I note it is not clear why these were declined — possibly using LAM and therefore not needed or possibly personal preference.

Review of clinical records and Timeline with comment

It is noted that at the time of the consultation [Dr B] was a first year GP registrar who had previously undertaken work in Obstetrics and Gynaecology at [a] Hospital where she was trained on Jadelle insertion. She has reflected that during this training she was taught a step-by-step process.

27/5/2021 Notes from [Dr C]

Noted that [Ms A] had a 3/12 [baby] and was requesting Jadelle insertion. This would be free due to [Ms A] having a community service card. It is noted that she is due her cervical screening. It is noted "*need to ensure adequate contraception in meantime eg condoms unless exclusive breastfeeding (offer iodine if breastfeeding) … jadelle info via MMH".*

In the provided S14 [Dr C] notes that she did not speak to [Ms A] as there was no answer when called but instead a text message was sent and a message sent by portal on MMH.

Comment

If a locum GP was reviewing the record it would not be clear that this had not been a patient contact. It may be assumed that it had been a telephone or in person contact.

I am mildly to moderately critical that the type of patient contact was not clear.

27/5/2021 MMH portal message

This contains appropriate information on Jadelle insertion. It contained the advice *"To make sure that you are not pregnant, the implants should be inserted within 7 days of the first day of your period, or immediately or within 7 days after abortion. If they are inserted at any other time your doctor will need to make sure you are not pregnant before insertion and you will need to use an additional non-hormonal (barrier) method (e.g. condoms) for the following 7 days."*

Comment

However [Ms A] states in her email of 4/8/2022 that she never received this and therefore did not read it.

The S14 from [the medical centre] confirms that this was sent however.

27/5/2021 [Practice nurse] call

A telephone call has occurred in which the time of the Jadelle insertion has been confirmed. The notes state "*offered condoms — pt declined".*

Comment

These notes are very brief and lack detail. The notes imply 2 scenarios — 1 Condoms were offered for contraception and declined. 2 As per the request by [Dr C], [Ms A] was asked if she was exclusively breastfeeding (LAM) and offered condoms if not.

The fact that condoms were declined possibly therefore implying that she was exclusively breast feeding. However, in this scenario [Dr C] has requested that she be on iodine, — it may be that this was offered also but that [Ms A] had these at home.

I am mildly to moderately critical that this documentation is unclear.

It has led to ambiguity in clinical information with regard to contraception use and may have led to incorrect assumptions being made with regard to [Ms A's] contraceptive coverage.

1/6/2021 [Dr B] GP Consultation

It is noted that [Ms A] has attended for cervical screening and Jadelle Insertion.

Her cervical screening history and previous abnormalities and subsequent colposcopy are clearly documented.

The notes state "*Consented for jadelle insertion. Has had a jadelle previously, no questions. Discussed likely side effect of irregular bleeding"*

The documentation of Jadelle insertion and Smear are clear. There is a clear follow up plan re possible complications — wound infection and irregular bleeding. A recall has been set for Jadelle removal.

A copy of an unsigned consent form which had been generated has been provided.

This noted—

1 Consent is given to have Jadelle Insertion.

2 The procedure and complications have been explained.

3 The Jadelle patient information book has been provided.

4 My GP has done a pregnancy test today and I understand this can be negative if I have become pregnant in the last week. I have been given a pregnancy test to check at home in one month.

Comment

I am aware of the Jadelle consent form that is used by [Dr B]. She has stated in her notes that this has been discussed and consented in the consultation.

I note that the signed copy of the consent form is not in [Ms A's] clinical record as would be the case normally.

[Dr B] has noted in her S14 that she follows a set routine of discussion during Jadelle insertion consultations.

If it is assumed that this all occurred then **I am mildly to moderately critical that there is no documentation regarding discussion** of recent contraception use or method, her

menstrual cycle and to the risk or possibility of pregnancy (including Unprotected Sexual intercourse — UPSI).

It is plausible that based on [Dr C's] notes it was assumed that [Ms A] was using the Lactational Amenorrhoea Method for contraception. **I am mildly to moderately critical** that if this was discussed by [Dr B] in her consultation as she states is her standard practice that this was not further documented in her notes.

It should be noted that — If using LAM effectively there would be no absolute requirement to undertake a pregnancy test prior to insertion. If LAM was continued for 1 week post insertion there again was no requirement for post implant additional contraceptive use or for post insertion pregnancy test at 4 weeks.

However it should be noted that there is a 2% failure rate of LAM and this may have been important to discuss with [Ms A].

30/9/20211 GP consultation

It is documented that [Ms A] felt some foetal movements and had a positive pregnancy test. Appropriate investigations were arranged.

7/10/2021 Anatomy scan

Gestational age 22 weeks and 1 day. EDD is 9/2/2022. No abnormality detected on scan.

Comment

If there is an assumption of a 28-day cycle with a mid-month ovulation then this scan would indicate a possible conception date of 19/5/2021 (working on LMP 5/5/2021).

Hence when the Jadelle was inserted she would have been approximately 13 days post conception. It should be noted that these dates may have some variability (10 days). Whilst most urine pregnancy test kits are able to detect a pregnancy at this stage there is still some margin of error — some tests may produce false negatives at early stages of pregnancy especially if the sample is not an early morning sample.

It is therefore possible that even a pregnancy test performed on 1/6/21 would have been negative even though [Ms A] was pregnant.

It should also be noted that there is some inaccuracy in utilising a second trimester ultrasound to give gestational age and the dates can be incorrect by a margin of 10 days.[5]

[5] Committee Opinion No 700: Methods for Estimating the Due Date. Obstet Gynecol. 2017 May;129(5):e150–e154.

2. Points of clarification

A [Ms A] has stated that she did not receive an email with any information re Jadelle — this was clearly sent via portal — it is unclear why it was not received.

B It is not clear what information was discussed during the telephone call from the practice nurse to [Ms A].

3. Clinical advice

Faculty of Sexual and Reproductive Health — Jadelle insertion.

It should be noted that this states

A Jadelle is thought to be over 99% effective. I note this is not 100% effective and so it is still possible for pregnancy to occur.

B The Implant insertion assessment criteria sheet the history should include contraceptive history, menstrual history including LMP, recent sexual history (including considering the need for STI testing), medical history including medications and allergies.

C It is noted that pregnancy can be reasonably excluded if the patient has no signs or symptoms of pregnancy and is fully breast feeding, amenorrhoeic and is less than 6 months postpartum. Additionally, this is the case if a woman has not had intercourse for more than 21 days and has a negative urine pregnancy test.

This allows a Quick start to contraception. See Appendix 1

D It is noted that if a woman has UPSI within 21 days then a pregnancy test may give a false result (sensitive to an hCG level of 20 mIIU/ml).

E It is noted in FSRH — contraception after pregnancy that "*Women may be advised that, if they are less than 6 months postpartum, amenorrhoeic and fully breastfeeding, the lactational amenorrhoea method (LAM) is a highly effective method of contraception.*"

The LAM form of contraception is approximately 98% effective at preventing pregnancy if

- Fully or nearly fully breastfeeding day and night (no other liquids given or only water, juice or vitamins given infrequently in addition to breastfeeds). No long intervals between feeds day or night (e.g. >4 hours during day and >6 hours at night)

4. Comment

It is difficult to elucidate what occurred in the consultation of 1/6/21 regarding discussion of current risk of pregnancy. There are several possible scenarios, and I will comment on the impact of each:

A. If [Dr B] discussed the consent form and followed her normal processes as she stated — this would have included discussion re current contraceptive method.

If this was LAM then there was no absolute requirement for a pregnancy test and the quick start insertion of the Jadelle was appropriate.

If LAM was continued, then there would be no requirement for additional contraception or a pregnancy test at 4 weeks.

However, [Ms A] has stated that no discussion re potential pregnancy occurred or contraceptive method.

As both these statements differ, and neither is correctly documented, it is difficult to draw conclusions as to the occurrences on the day.

I note however that the consent form is proven to have been printed and that [Dr B] has documented that she obtained consent which in turn implies that due process was followed.

It is unfortunate that the practice systems failed, and the form was not scanned onto the notes.

In this case I am mildly to moderately critical only of the lack of documentation.

B. [Dr B] did not discuss the risk of pregnancy and contraceptive use in the consultation and relied upon the documentation of [Dr C] and the practice nurse. I note that [Dr B] had thought that [Ms A] had had an actual consultation with [Dr C]. It is plausible that she assumed that her GP supervisor and teacher of Jadelle insertions had already established the use of LAM given the nursing note of [Ms A] declining the need for condoms.

If this had been the case, I am mildly to moderately critical of such an assumption as it is always best practice to ascertain clinical information yourself regarding pertinent aspects in this case the risk of possibility of pregnancy and whether the Quick start for Jadelle with no pregnancy test could be undertaken.

The implication of this scenario is that a Jadelle has been inserted without clear knowledge re pregnancy risk.

This would be a moderate to severe departure from clinical practice standards.

C. If LAM was not being utilized then [Dr B] may have discussed the risks of pregnancy, and it is possible that a pregnancy test was undertaken by [Ms A] for [Dr B].

However, this is not documented in the notes or recollected by [Ms A]. It is therefore unlikely that this occurred.

If the last date of unprotected sexual intercourse (UPSI) was over 21 days prior to insertion then the pregnancy test would be assumed to be accurate. If it was negative, then a Jadelle could be safely inserted but the use of condoms as additional contraception would be required for the next 7 days with a pregnancy test at 4 weeks.

If the last UPSI was under 21 days and there was a negative pregnancy test then [Ms A] should have been advised re the need for emergency contraception, risk of false negative pregnancy test, the need for post insertion condom use for 7 days and the need to repeat a pregnancy test 3 weeks post last UPSI or the option to defer the insertion.

In both of these options I would be mildly to moderately critical regarding the clinical care and level of clinical documentation.

To conclude — it is impossible to define what did occur in the consultation. [Dr B] has stated she had no reason to deviate from her standard practice, however she did not document pertinent facts. She has since reflected on the case. There are mitigating circumstances in that she had just started in her training post in general practice and was under supervision from an experienced colleague. However, [Ms A] states that she did not enquire re contraception and potential pregnancy. It is likely that [Ms A] was pregnant at the time of the Jadelle insertion although this may have not been picked up on a urine pregnancy test at that point. If using LAM she may have been one of the 2% failure rate.

Since this episode she has undertaken a substantial amount of additional training in contraceptive health and developed personal systems to improve her clinical care.

I would advise that she writes to [Ms A] with an apology and keeps a clear log of her insertions that she is able to audit against FSRH standards.'

Appendix 1

FSRH Clinical Gudeline — Quick Starting Contraception (April 2017)

https://www.fsrh.org/standards-and-guidance/documents/fsrh-clinical-guidance-quick-starting-contraception-april-2017/

All methods of contraception can be quick started at any time if it is reasonably certain that there is no risk that the woman could be pregnant.

Box 1: Criteria for reasonably excluding pregnancy

Healthcare practitioners can be **reasonably certain** that a woman is **not currently pregnant** if any one or more of the following criteria are met **and** there are no symptoms or signs of pregnancy:

- She has not had intercourse since the start of her last normal (natural) menstrual period, since childbirth, abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease.
- She has been correctly and consistently using a reliable method of contraception. (For the purposes of being reasonably certain that a woman is not currently pregnant, barrier methods of contraception can be considered reliable providing that they have been used consistently and correctly for every episode of intercourse.)
- She is within the first 5 days of the onset of a normal (natural) menstrual period.
- She is less than 21 days postpartum (non-breastfeeding women).
- She is fully breastfeeding, amenorrhoeic AND less than 6 months postpartum.
- She is within the first 5 days after abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease.
- She has not had intercourse for >21 days AND has a negative high-sensitivity urine pregnancy test (able to detect hCG levels around 20 mIU/ml).

She is fully breastfeeding, amenorrhoeic AND less than 6 months postpartum.

Quick start can also be considered if a high-sensitivity urine pregnancy test (HSUP) is negative, but there is a potential risk of very early pregnancy from recent unprotected sexual intercourse (UPSI). Women who choose to quick start contraception when very early pregnancy cannot be excluded can be reassured that the vast majority of the available evidence suggests no adverse impact of fetal exposure to contraceptive hormones on pregnancy outcomes or risk of fetal abnormality.

Table 1: Percentage of women experiencing an unintended pregnancy within the first year of use with typical use and perfect use (modified from Trussell *et al*.[56])

Method	Typical use (%)	Perfect use (%)
No method	85	85
Fertility awareness-based methods	24	0.4–5
Female diaphragm	12	6
Male condom	18	2
Combined hormonal contraception*	9	0.3
Progestogen-only pill	9	0.3
Progestogen-only injectable	**6**	**0.2**
Copper intrauterine device	**0.8**	**0.6**
Levonorgestrel intrauterine system	**0.2**	**0.2**
Progestogen-only implant	**0.05**	**0.05**
Female sterilisation	0.5	0.5
Vasectomy	0.15	0.1

Long-acting reversible contraception/contraceptive methods in bold.
*Includes combined oral contraception, transdermal patch and vaginal ring.

Table 2: Additional contraceptive requirements (condoms/abstinence) when starting contraception excluding after ulipristal acetate emergency contraception administration

Method	Day of menstrual cycle*	Days of additional contraception required
Combined oral contraception	1–5	0
	6 onwards	7
Zoely® COC	1	0
	2 onwards	7
Qlaira® COC	1	0
	2 onwards	9
Combined transdermal patch and vaginal ring	1–5	0
	6 onwards	7
Progestogen-only pill (traditional/desogestrel)	1–5	0
	6 onwards	2
Progestogen-only injectable and implant	1-5	0
	6 onwards	7
Levonorgestrel intrauterine system	1–7	0
	8 onwards	7
Copper intrauterine device	Any start day	0

*Day 1 is defined as the first day of natural menstrual bleeding; it does not apply to withdrawal or unscheduled bleeding in women already established on hormonal contraception. Healthcare practitioners must consider on an individual basis whether a bleed following oral emergency contraception constitutes a natural menstrual bleed. Criteria may include whether the bleeding occurred close to the time of expected menstruation and whether the bleed was characteristic of the woman's usual menstrual bleeding.