Gynaecologist, Dr A

Obstetrics and Gynaecology Trainee, Dr B

Auckland District Health Board
(now Te Whatu Ora Te Toka Tumai Auckland)

A Report by the

Health and Disability Commissioner

(Case 20HDC01208)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report concerns the care provided to a woman on 6 March 2019, in particular the failure of clinicians to ensure that local anaesthetic had been administered prior to beginning a gynaecological procedure.

Findings

2. The Commissioner considered that the administration of local anaesthetic was a basic step in the procedure, and that the operating doctors had responsibility for applying the local anaesthetic prior to commencing the gynaecological procedure. The Commissioner found both the gynaecologist, who was acting in the role of supervisor and was the most senior doctor involved in the procedure, and the registrar who performed the procedure, in breach of Right 4(1)[1] of the Code. The Commissioner considered that the gynaecologist should have ensured that anaesthetic was administered appropriately and should have noticed when it was not and intervened before the loop electrode was used. The Commissioner considered that the registrar shared responsibility for ensuring that the basic requirement for anaesthetic was undertaken and noted that the registrar was a senior registrar who was experienced in the procedure.

3. On balance, the Commissioner was satisfied that the issues in this case were primarily the responsibility of the individual clinicians involved. However, the Commissioner was critical that Te Whatu Ora had failed to upload the woman's consent form to her file, and identified that a more empathetic approach was warranted after this adverse event, including personal contact to assist the woman in her recovery.

4. The Commissioner noted the differing recollections regarding whether the registrar and the gynaecologist had notified the woman of their respective roles — that of trainee and supervisor — when seeking her consent for the procedure. While ultimately the Commissioner was unable to make a finding in this respect, she took the opportunity to remind both doctors and Te Whatu Ora Te Toka Tumai Auckland of the need, when undertaking procedures, to clearly identify clinicians and their roles to the patient, and to ensure that consent is obtained in circumstances where teaching is taking place. She also noted that it is important to keep adequate records of those discussions.

Recommendations

5. The Commissioner recommended that Te Whatu Ora Te Toka Tumai Auckland consider implementing as a requirement the practice of using saline wash at the end of all gynaecological procedures that use iodine and consider updating its adverse event policy to require a follow-up telephone call to patients who have suffered an adverse event or have been particularly distressed during their treatment or appointment.

6. The Commissioner recommended that both the registrar and the gynaecologist provide a formal written apology. In response to the provisional report, the gynaecologist provided HDC with the apology.

[1] The right to have services provided with reasonable care and skill.

Complaint and investigation

7. The Health and Disability Commissioner (HDC) received a complaint from Ms C about the services provided by Dr A and Dr B at Auckland District Health Board (ADHB) (now Te Whatu Ora Te Toka Tumai Auckland).[2] The following issues were identified for investigation:

- *Whether Dr A provided Ms C with an appropriate standard of care in March 2019.*
- *Whether Dr B provided Ms C with an appropriate standard of care in March 2019.*
- *Whether Auckland District Health Board provided Ms C with an appropriate standard of care in March 2019.*

8. The parties directly involved in the investigation were:

Dr A	Gynaecologist
Dr B	Obstetrics and gynaecology trainee
Ms C	Consumer/complainant
ADHB	Group provider

9. Further information was received from:

RN D	Registered nurse
Medical centre	
National Cervical Screening Programme	

10. Independent advice was obtained from an obstetrician and gynaecologist, Dr Anne Sissons (Appendix A).

Information gathered during investigation

Background

11. Ms C, aged in her twenties at the time of events, received the results of a cervical smear test that showed abnormal squamous cells.[3] On 6 March 2019, Ms C attended the colposcopy clinic at Greenlane Clinical Centre for a large loop excision of the transformation zone (LLETZ)[4] to remove the abnormal cells.

[2] Previously known as Te Whatu Ora|Health New Zealand. On 1 July 2022, the Pae Ora (Healthy Futures) Act 2022 came into force, resulting in all district health boards being disestablished. All references to ADHB in this report now refer to Te Whatu Ora Te Toka Tumai Auckland.
[3] A type of cell found throughout the body. Without treatment, abnormal cells in the cervix may develop into cervical cancer (pre-cancerous cells).
[4] Treatment to remove abnormal cells in the cervix.

12. This report concerns the care provided to Ms C on 6 March 2019, in particular the failure of clinicians to ensure that local anaesthetic had been administered prior to beginning the procedure.

LLETZ procedure — 6 March 2019

13. A LLETZ procedure uses an electrical wire loop (or diathermy[5] loop), inserted vaginally, to remove any abnormal cells in the cervix. It is a day-stay procedure that requires only local anaesthetic to numb the area. Usually it takes only 5–10 minutes to complete.

14. For Ms C's procedure, Dr A (a gynaecologist), Dr B (an obstetrics and gynaecology registrar), and RN D were present. Dr A was supervising Dr B while Dr B performed the LLETZ. RN D undertook the setup of the procedure room and was available to assist the doctors during the procedure if needed.

15. A vaginoscopy was undertaken first. This involves examining the whole vaginal tract (including the vaginal walls and surface of the cervix) with a colposcope (a magnifying lens) and using an iodine dye to identify any areas of abnormal cells. A vaginal biopsy was not deemed necessary, so the LLETZ procedure was commenced.

16. There are varying recollections of the surgery, but it is accepted by all parties that the procedure was commenced without local anaesthetic being administered, causing significant pain to Ms C. The recollections provided to HDC follow.

Ms C

17. In her complaint to HDC, Ms C stated that weeks prior to the procedure, she was advised that it would be performed under local anaesthetic. She stated that she signed the consent form accepting this and received a pamphlet describing the anaesthetic.

18. Ms C told HDC that as the procedure was about to begin, the doctor told her: 'Now you're going to hear a buzz from the machine but you won't feel a thing.' Ms C stated that when the doctor commenced the procedure, she 'was filled with the most incredibly horrific pain' and was screaming as she felt the electrically surging wire 'cut through' her cervix.

19. Ms C told HDC that she was then told by one of the staff that they 'had to get through that loop before they could address the pain', and that she was scolded for shaking and was held down in an attempt to keep her still. She said that at no point during the procedure was she apologised to or told that a mistake had been made. In response to the provisional decision, Ms C stated that RN D held her hand to comfort her. Ms C said that Dr B told her that her legs were shaking and interfering with the procedure and asked her to control them. Ms C also stated that the doctor who administered the local anaesthetic was Dr B.

20. Ms C was then asked whether she would like to reschedule the procedure so that it could be completed under general anaesthetic, or if she wanted to continue with the procedure.

[5] A diathermy loop is a small loop of wire that produces heat through high-frequency electric currents. The clinician uses a camera for visibility and puts the loop through the vagina and into the cervix to cut and remove abnormal cells. The removed section of the cervix is sent to a laboratory for examination of the cells.

Ms C told HDC that at this time, her body was experiencing 'immense shock and pain'. However, she said that she was afraid that the cells would develop into cancer if left untreated, and so she agreed to continue. She stated that she was unsure that she would be able to return to Greenlane Clinical Centre after the pain she had felt, and that her choice to complete the procedure was made out of 'fear and necessity'.

21. Ms C told HDC that she also experienced a burning sensation during the procedure, but when she raised this, the clinicians did not respond to her concerns. She stated that she suffered burns to her vagina and upper thighs from the iodine.

Dr B

22. Dr B told HDC that once the vaginoscopy had been performed, she began the LLETZ procedure by performing a 'touch test' (which involves touching the loop briefly to the cervix wall) to ensure that the electrical current was working. She stated that this test caused Ms C a significant amount of pain, causing her to yell out, and it was then realised that anaesthetic had not been administered before the test. Dr B told HDC that the LLETZ loop was removed immediately without reactivation, and all staff apologised to Ms C. Dr B stated that she then swapped places with Dr A, who called for and administered the local anaesthetic. Dr B told HDC that she does not remember any of the staff holding Ms C still or down or scolding her for moving.

23. Dr B told HDC that there was no local anaesthetic syringe on the procedure tray,[6] and this resulted in a delay of 'not more than 5 minutes' as the syringe was prepared and the local anaesthetic was administered. Dr B said that following the procedure, she returned to the clinic room and RN D apologised to her for the equipment not being present. Dr B stated that she reassured RN D and told her that it was her own responsibility to administer the local anaesthetic and notice if it was missing from the setup. Dr B stated that she can recall this conversation clearly.

24. Dr B told HDC that she does not recall Ms C mentioning any burning sensation (such as from the iodine), apart from 'when the loop was applied to the unanaesthetised cervix'. Dr B noted that iodine is not applied to a patient's thighs and stated that had they been aware of a burning sensation, the clinicians would have tried to relieve this by douching the vagina with saline solution and offering pain relief. ADHB told HDC that usual practice in the colposcopy clinic when patients complain about iodine burning is to 'offer to wash the vagina out with saline via a speculum in the clinic room, or offer the patient saline to take to the toilet to self-douche'.

25. In response to the provisional opinion, Ms C disagreed with Dr B's recollection that a 'touch test' was done, and that it took less than five minutes before the local anaesthetic was injected. Ms C also stated that after the procedure, she mentioned the burning sensation multiple times but it was brushed off, and she was told to use the wet wipes in the corner, which she did with no relief.

[6] The tray holding the items to be used for the surgery.

Dr A

26. Dr A told HDC that the traditional sequence for a vaginoscopy is:

1. Dye (iodine) application to the vagina;
2. If a vaginal biopsy is needed, inject local anaesthetic;
3. Take a vaginal biopsy.

27. The sequence for LLETZ is:

1. Inject local anaesthetic to the cervix (done first as it can take a while to set in); then
2. Dye application on the cervix;
3. Perform LLETZ (with electro-cautery[7]) on the cervix.

28. Dr A said that as iodine dye had already been used for the vaginoscopy, the clinicians likely made a 'mental shortcut' and assumed that they had already numbed the cervix. Dr B agreed that this may have contributed to her thinking that local anaesthetic had already been applied.

29. Dr A told HDC that when supervising a trainee performing a LLETZ, usually she stands behind the trainee and observes all steps. She said that she did not notice that the local anaesthetic solution had not been injected into the cervix, which is why she did not intervene. She acknowledged that this was an error of judgement on her part, and that it was a significant omission and a breach of standards.

30. Dr A stated that after Ms C reacted to the LLETZ loop, the three clinicians stopped the procedure immediately and apologised. Dr A told HDC that she swapped roles with Dr B immediately and injected the local anaesthetic to numb the cervix. Dr A said that they then gave Ms C some time to breathe. Dr A told HDC that when Ms C indicated that the pain had settled, they asked her if she would prefer to defer the LLETZ procedure to another day and schedule it with general anaesthetic, or to continue that day with the local anaesthetic. Dr A said that Ms C confirmed her consent to proceed. Dr A stated that she then completed the LLETZ, successfully removing the pre-cancerous cells from Ms C's cervix. Dr A stated that she remained in the procedure room until Ms C went to the recovery room and ensured that Dr B demonstrated empathy and apologised to Ms C.

31. Dr A told HDC that she does not recall any scolding or gestures similar to holding Ms C down, and that these would not have been appropriate actions in any circumstances. Dr A said that it is possible that RN D may have placed a supportive or kind hand on Ms C's shoulder. Dr A also told HDC that owing to the time elapsed, she cannot recall whether or not the prepared anaesthetic was on the trolley.

[7] Electrocautery is a procedure that uses heat from an electric current to destroy abnormal tissue (such as lesions or tumors) or to control bleeding during surgery.

32. In response to Ms C's concern about iodine burning, Dr A told HDC that undergoing a vaginoscopy with a LLETZ increases the risk of symptoms such as vaginal irritation or burning sensations. She acknowledged that while this information is in the LLETZ pamphlet, it could have been emphasised to Ms C verbally on the day of the procedure. Dr A told HDC that it is also possible that Ms C developed a late reaction to the iodine, which would not have been picked up during her time in the clinic.

RN D

33. RN D told HDC that she set up the procedure tray on a trolley about an hour before the procedure. She said that there was 'a dental syringe and four ampules of local anaesthetic', which she described as standard for a LLETZ procedure, and that 'one ampule was drawn into the syringe with the needle attached (with a cap on) ready to be used'.

34. RN D said that during the procedure, she stood at Ms C's shoulder with a view of the trolley, and facing Dr B and Dr A, who were at Ms C's feet. RN D told HDC that after Dr B began to use the LLETZ device, Ms C cried out, and Dr B said 'local'. RN D said that at this point she looked at the tray and saw that the cap was still on the syringe, which made her realise that the local anaesthetic had not been administered. She said that following this, the anaesthetic was administered to Ms C immediately. While Dr B and Dr A told HDC that it was administered by Dr A, RN D told HDC that it was administered by Dr B. The Gynaeplus records provided to HDC by the Ministry of Health record that the 'trainee then proceeded to numb the cervix', referring to Dr B as the trainee. Gynaeplus is a digital record-keeping system used by Te Whatu Ora for gynaecology procedures in numerous clinics.

35. RN D cannot recall exactly what she did or said to Ms C during the procedure but said that she did not scold her or hold her down. RN D recalled that Ms C was anxious during the procedure, so it is likely that she held her hand or rubbed her arm and asked her to try to stay relaxed and still. RN D said that during these procedures it is important that the patient is relaxed and still, and scolding and rough handling would not help with that. She said that usually she talks with the patient to distract them and help them to relax, and she may hold their hand or rub their arm. Ms C told HDC that she recalls RN D giving her a hand to squeeze.

36. Regarding iodine burns, RN D said that some patients do describe the iodine used in vaginoscopies as causing a prickly or burning sensation, but she does not recall Ms C mentioning this. RN D noted that iodine is not applied to a patient's thighs.

Post-procedure

37. Ms C told HDC that following completion of the procedure, she had to climb over a tray of bloody medical instruments to get down from the examination table. She said that she was not assisted with this, and because she was feeling shaky from the procedure, she almost fell over. Dr B told HDC that she does not recall this, and she is sure that either she or RN D would have helped Ms C to get off the colposcopy bed. RN D and Dr A did not provide HDC with any comment on this concern.

38. ADHB told HDC that usual practice following a LLETZ is to observe the patient for 20 minutes in the recovery area, where they will be offered tea and biscuits and checked by the nurse

for any pain or bleeding. Written discharge information and contact phone numbers for after-hours questions are provided to the patient. ADHB said that this expectation was met in Ms C's case.

39. Ms C told HDC that when she was in the recovery room she asked RN D why the procedure had been so painful. Ms C said that it was only then that she found out that local anaesthesia had not been administered initially, and she was under the impression that the clinicians involved in her procedure had not intended to inform her about this. Ms C said that when she experienced pain during the procedure, she was told that the doctors would 'administer more local', implying that some local had already been administered.

40. Ms C told HDC that after the procedure, the doctor disappeared without a word, and she was left with only RN D, who appeared to be shaken. It is unclear whether the doctor in this statement refers to Dr B or Dr A. Dr A told HDC that Dr B checked in on Ms C in the recovery room, and she (Dr A) checked on Ms C before she was discharged. Dr A stated: '[I was] also shaken by the pain we had involuntarily caused.' Dr A said that she and RN D assessed Ms C after the 15-minute recovery period, and Ms C declined further pain relief and confirmed that she was able to walk.

41. Dr B told HDC that Ms C was escorted to the post-procedure lounge and monitored for 15 minutes following the procedure. Dr B said that Ms C was debriefed about what had happened, and that she apologised for the error and reassured Ms C that any further procedures could be done under general anaesthetic to avoid further distress.

42. In response to the provisional opinion, Ms C stated that she was checked on after the procedure but that her concerns were not addressed adequately. She said that she was not given an assessment in recovery, and she received no debrief.

Subsequent events

43. A standard follow-up appointment at the colposcopy clinic was booked for six months after the procedure, to take a follow-up cervical smear to ensure that all abnormal cells had been removed. Dr A told HDC that Ms C did not present for her follow-up appointment and would not speak to her over the phone when she called to follow up. Dr A said that she then wrote a letter to Ms C and copied in her GP to apologise, and to discuss options for future care.

44. In response to the provisional opinion, Te Whatu Ora stated that prior to this, the medical team were unaware that Ms C had ongoing concerns. However, it acknowledged that a greater effort could have been made to contact Ms C in the days following her procedure.

45. Te Whatu Ora stated:

> 'Had our team persisted in following up with [Ms C], a six-month period would not have elapsed before she received a formal apology from our organisation and, importantly, the opportunity to offer [Ms C] support to deal with her trauma would not have been missed. This is a significant learning for the staff involved and for our Women's Health service in terms of how we follow-up with patients following adverse events.'

46. Dr B agreed that the follow-up of the complaint could have been managed better, including informing clinicians at the time of the complaint.

Further information

Consent process

47. Following the notification of HDC's investigation, Ms C read the responses provided to HDC by Dr A. Dr A's response stated: 'A RANZCOG O&G registrar, [Dr B], was attending my clinic as a trainee under supervision.' Ms C told HDC that prior to reading this statement, she did not know that Dr B was a trainee. Ms C said:

> 'I would never have agreed for a trainee to carry out such a procedure on me, being in my reproductive years and yet to have a child, I would not take any risks with regard to this.'

48. Dr A told HDC that she asked Dr B to complete the consenting process with Ms C. Dr A stated:

> '[W]hen a trainee is known to me and has demonstrated this skill previously, as it was the case, I leave the consenting process to the trainee and simply ensure it has been signed by checking the document on the bench when I enter the colposcopy room.'

49. Dr A said that Dr B was a 'very skilled trainee who ha[d] already performed LLETZ procedures'. Dr A stated that a consent form was signed between Dr B and Ms C after the pre-procedural discussion, and she did not repeat the preoperative discussions with Ms C before the procedure began.

50. In her statement to HDC, Dr B said that when she called Ms C in from the waiting room for her procedure, she introduced herself as the doctor working with Dr A that day in the clinic. Dr B said that she obtained verbal consent from Ms C on the day of the procedure but did not have her sign anything physically. Dr B said that it is routine to discuss the procedure, risks involved, and post-procedure care, and she believes she did so with Ms C.

51. In response to the provisional opinion, Dr B noted that she explained to Ms C that there would be a nurse and Dr A, the consultant, helping with the procedure. Dr B believes she would have introduced herself and her role as is her usual practice. Dr B stated: 'I am sorry that [Ms C] did not understand the roles of the clinicians in the room as I thought that we had made these roles clear to her.'

52. RN D said that once Ms C was in the consulting room and in her gown, she helped to position her on the examination couch and explained the procedure. RN D cannot recall her exact interactions with Ms C but said that at this point it is standard for her to ask the patient if they have received the LLETZ pamphlet, which contains contact information for any issues or queries after the procedure. RN D said that it is also her usual practice to repeat the pamphlet information verbally at this time.

53. In their statements to HDC, none of the providers specifically state that Ms C was told that Dr B was a trainee.

Consent form

54. In her complaint, Ms C referred to signing a consent form prior to the procedure, but she told HDC that she was never told that a registrar/trainee would be carrying out the procedure.

55. ADHB told HDC that the signed consent form was never scanned into the hospital system, so could not be found. A consent form signed by Ms C was therefore not provided to HDC, so it is not known whether Ms C's signed form mentioned Dr B being a trainee.

56. ADHB told HDC that although the document was not scanned into the patient record, Ms C's complaint refers to the consent form for anaesthetic, so ADHB is confident that its usual process was followed. ADHB said that usual process is to discuss risks and benefits at the time of the appointment/procedure and obtain written consent before the form is scanned and uploaded to the patient's electronic clinical record. It is unclear why the form was not scanned and uploaded to Ms C's clinical record in this case.

Ms C

57. Ms C has been receiving counselling and support from her GP for post-traumatic stress disorder (PTSD) due to these events.

58. Ms C stated:

> 'I was not treated with dignity or respect. I did not [receive] care befitting of regulations on standard of care. I signed consent outlining that I would [receive] local [anaesthetic] prior to the operation. I did not consent to what I was put through.'

ADHB

59. ADHB provided HDC with several relevant policies that were in place at the time of the events, including its Clinical Record Management Policy and Informed Consent Policy.

60. The Clinical Record Management Policy is in place to ensure that all patient information held by ADHB is managed according to legal, professional, and ethical standards. Regarding documentation in patient clinical notes, the policy states that 'documentation in the clinical record is the responsibility of the treating clinician'.

61. The Informed Consent Policy breaks down the three elements of informed consent as effective communication with the patient, provision of all necessary information to the patient, and the patient's freely given and competent consent. Relevant to this case, it states that informed consent 'is not filling out forms, but rather the exchange of information'.

62. The Informed Consent Policy outlines that the primary responsibility for imparting information and obtaining consent lies with the person who is to carry out the treatment or procedure. Regardless of who undertakes the consenting process, the name of the health professional who is to perform the procedure must be documented on the consent form. If the specific clinician is not known at the time of taking consent, then the patient must be advised of this verbally, and this should be documented. In the situation where a trainee is

to perform a procedure, the policy states that the name of both the trainee and the supervisor should be documented.

63. The policy states that there must be an appropriate introduction of the staff member and identification of their role, and, where practicable, the request regarding whether the patient wants to be involved in teaching should occur without the trainee staff member present, to allow the patient to decide freely. It must also be made known to the patient that they have the right to withdraw from teaching at any stage, and that refusal or withdrawal will not jeopardise their care.

64. The policy states that verbal discussion about involvement in teaching should be recorded in the clinical record for reference. The policy also states:

> 'A patient has the right to be treated with respect and must consent to or decline involvement in teaching … The patient must be provided with sufficient information to give or withhold consent. This includes being informed of the identity and qualifications of the provider.'

65. Ms C's 'Gynaeplus' records were obtained by HDC from the Ministry of Health. The document from the day of the procedure is not signed, so it is unclear which clinician filled it out. It is dated 6 March 2019. The notes section states:

> 'Local [anaesthetic] injected only after first Loop contact with cervix. Patient sore. Trainee then proceeded to numb cervix. Patient agitated and upset. Apologies given. Procedure completed.'

66. The form records Dr A as the colposcopist but does not name Dr B or RN D.

Dr A

67. Dr A told HDC that it is regrettable that no contact was made with Ms C in the immediate postoperative days to address the resulting pain or distress caused. Dr A acknowledged that the lack of contact may have contributed to Ms C's distress. Dr A told HDC: 'I am really sorry that our services did not follow her up more closely at the time, and would do things differently if I could.'

Dr B

68. Dr B agreed that it would have been beneficial to check in with Ms C in the days following the procedure. Dr B told HDC that she made one attempt to call Ms C, but when this was unsuccessful, she did not try further, and did not document her attempt at contact.

69. In response to the provisional opinion, Dr B stated that recently in discussion with a colleague she was reminded of a conversation from March 2019 with that colleague that confirms that, contrary to her statement to HDC in April 2021, she did in fact follow up with Ms C in the days following the LLETZ procedure. Dr B stated that she was able to speak to Ms C and received reassurance from her that she was okay. However, there is no entry in the clinical record documenting this conversation, and due to the time elapsed since the events, Dr B was unable to provide the telephone records.

70. Dr B told HDC that she is 'deeply sorry that this has happened to [Ms C] and … so sorry for the pain caused and any issues subsequent to this procedure with her physical and mental health'. Dr B said that she did not intend to cause pain or distress, or leave Ms C feeling unsupported following this event, and it is regrettable that no contact was made sooner.

Responses to provisional opinion

71. Ms C was given the opportunity to comment on the 'information gathered' section of the provisional report, and her comments have been incorporated throughout the report where relevant. In addition, Ms C reiterated her experience and how it still impacts her mental health negatively to this day.

72. Te Whatu Ora was provided with the full provisional report for comment. It acknowledged this adverse event as a result of human error, as well as how traumatic the consequences of this mistake were for Ms C. However, Te Whatu Ora stated that it is concerned about the finding that individual clinical staff are in breach of the Code of Health and Disability Services Consumers' Rights (the Code) for failing to provide a reasonable standard of care when genuine human error occurred. Te Whatu Ora stated:

> 'As an organisation we accept that human error is inevitable. Whilst we acknowledge the role of individual accountability under the Code, we consider that it is the role of the organisation to understand the science of human factors and human fallibility and work to ensure that there is reflection, learning and system change to reduce the chance of errors reaching the patient (i.e., we seek to make our systems and processes more resilient and "error tolerant").'

73. Te Whatu Ora considered it unduly harsh to find that Dr A and Dr B have breached the Code.

74. Dr A was provided with the sections of the provisional report that relate to the care she provided, for comment. Dr A considers that the retention of the provisional finding that she breached the Code cannot be justified, and that it is an 'impossible standard to set that doctors must be infallible'. Dr A agreed with Te Whatu Ora's opinion that it is unduly harsh to find her in breach of the Code.

75. Dr A said that as submitted by Te Whatu Ora, responsibility for the genuine and isolated error would be more appropriately vested at an organisational level. She said that it is the role of Te Whatu Ora to understand the role of human factors and human fallibility and work to ensure that there is reflection, learning, and system change to reduce the chance of errors reaching patients. Other comments made by Dr A have been incorporated within the report where relevant.

76. Dr B was provided with the sections of the provisional report that relate to the care she provided, and her comments have been incorporated throughout the report where relevant.

Opinion: Preliminary comment

77. Ms C attended ADHB's Greenlane Clinical Centre on 6 March 2019 for treatment of pre-cancerous lesions in her cervix. While ultimately the procedure was successful, it was commenced without local anaesthetic, causing Ms C to experience pain.

78. ADHB employees Dr A, Dr B, and RN D were all involved in the procedure and present in the clinic room for the entirety of the procedure.

79. At the outset, I note that it is entirely foreseeable that proceeding without anaesthetic would cause significant pain, and accordingly particular care is required to ensure that anaesthetic has been administered prior to commencing the procedure. It is unacceptable that a tool that uses heat and electrical current was applied to an extremely sensitive area, the cervix, essentially to burn abnormal cells from it — without appropriate anaesthetic. It is clearly below the reasonable standard of care to fail to administer it.

80. Independent clinical advice was obtained from a specialist obstetrician and gynaecologist, Dr Anne Sissons, to assist me in my consideration of this incident. Dr Sissons, Dr A, and Dr B acknowledged that it is standard procedure to administer local anaesthetic prior to using the loop.

81. Initially, Dr Sissons considered that omitting to use local anaesthetic in this case was a severe departure from the accepted standard of care. However, later she revised her advice to a 'minor departure' from the standard of care. She considers that the failure to administer anaesthetic was a 'mental oversight', and she believes that it was an isolated event and extremely unlikely to recur. In a further opinion, Dr Sissons stated that the clinicians intended to use local anaesthetic, and there was no intent not to provide the recognised standard of care. Therefore, once recognised, the anaesthetic was applied.

82. I acknowledge that the providers involved did not intend to commence the procedure without first administering local anaesthetic. However, the focus of my investigation is to determine whether Ms C's rights were breached, notwithstanding the fact that such a breach may have arisen from a human error. Where it is evident that a consumer's rights have been breached under the Code, it is my role to identify that breach and make recommendations for improvement. Put differently, a breach finding is not intended to be punitive, but is intended to uphold rights to which consumers are entitled and ensure provider accountability where appropriate.

83. I discuss each provider's responsibility for that failure separately below.

Opinion: Dr A — breach

84. At the time of events, Dr A was an experienced senior clinician. Dr A performed Ms C's procedure alongside senior registrar Dr B.

85. It is not in dispute that Ms C's cervix was not anaesthetised prior to the LLETZ procedure.

86. Dr A told HDC that she believes the reason she did not notice that the local anaesthetic had not been administered was because iodine dye had already been applied to the cervix during the vaginoscopy. Dr A said that she did not intervene when Dr B began the test of the LLETZ loop, because she had not noticed that the local anaesthetic solution had not been injected. Dr A, in her initial response to this complaint, acknowledged that this was an error of judgement on her part, and that it was a significant omission and a breach of standards.

87. Both Dr A and Dr B told HDC that the LLETZ procedure normally begins with anaesthetic, followed by iodine, but as the cervix had already been treated with iodine, they may both have made a 'mental shortcut' and assumed that the anaesthetic had already been administered. As the most senior doctor involved in the procedure, and given that she was acting in the role of supervisor, Dr A should have ensured that anaesthetic was administered appropriately and should have noticed when it was not, and should have intervened before the loop electrode was used.

88. There are conflicting recollections regarding whether the anaesthesia syringe was present on the procedure trolley. RN D said that the syringe was prepared with anaesthetic and on the trolley with its cap on when Ms C reacted to the LLETZ. Dr B stated that the syringe was not on the trolley, and there was a delay of less than five minutes while the local anaesthetic was prepared and administered. I am unable to make a finding on which recollection is correct.

89. However, regardless of whether or not the local anaesthetic was available, the operating doctors were responsible for applying the local anaesthetic and should have obtained it prior to commencing the procedure. Administration of local anaesthetic was a basic step in the procedure. As stated previously, Dr A acknowledged that this was a significant omission and a breach of standards.

90. As discussed in the preliminary comments to this opinion, initially Dr Sissons considered that omitting to use local anaesthetic in this case was a severe departure from the accepted standard of care. However, she later revised her advice to a 'minor departure' from the standard of care. Dr Sissons considers that the failure to administer anaesthetic was a 'mental oversight', and that it was an isolated event, extremely unlikely to recur, and there was no intent not to provide the recognised standard of care. In response to my provisional opinion, Dr A's lawyer submitted that in light of Dr Sissons' revised opinion, and having regard to Dr A's reflection and learning from what occurred and measures put in place to ensure that a similar error does not occur, it would be unduly harsh to find that Dr A breached the Code. They noted that it would be an 'impossible standard to set that doctors

must be infallible. Mistakes in medicine are inevitable; unfortunately, things will sometimes, without any intent, be "missed".'

91. I do not accept that a lack of intention is determinative in assessing whether the standard of care has been met in a particular case. Nor do I accept that the applicable standard is that doctors must be infallible. Right 4(1) of the Code requires that every consumer has the right to have services provided with reasonable care and skill. The standard of care applicable in the present case is the care and skill that an ordinarily careful peer of the clinicians involved would exercise under similar circumstances. Most clinicians would have ensured that local anaesthetic was applied prior to commencing the LLETZ procedure. I remain of the view that Dr A failed to provide Ms C with an appropriate standard of care by failing to ensure that she was anaesthetised prior to performing the LLETZ procedure, and, accordingly, I find that Dr A breached Right 4(1) of the Code.

Opinion: Dr B — breach

92. Dr B was the treating clinician for the beginning of Ms C's procedure on 6 March 2019. Dr B was a senior registrar under the supervision of Dr A and had several years' experience. Dr B had performed numerous colposcopies and had experience in LLETZ procedures.

93. Dr B and Dr A explained to HDC that the omission in administering the local anaesthetic likely occurred because the iodine dye had already been applied for the vaginoscopy, and in LLETZ procedures, usually the iodine is applied after the anaesthetic has been administered.

94. Through her lawyer, Dr B told HDC that she agrees with Dr Sissons' amended advice that her omission to use local anaesthetic is a minor departure from the standard of care. Dr B agrees that there was no intent not to provide the recognised standard of care. As discussed earlier in this opinion, I do not accept that a lack of intention is determinative in assessing whether the standard of care has been met in a particular case.

95. I have carefully considered the circumstances of this case. Right 4(1) of the Code requires that every consumer has the right to have services provided with reasonable care and skill. The standard of care applicable in the present case is the care and skill that an ordinarily careful peer of the clinicians involved would exercise under similar circumstances. Most clinicians would have ensured that local anaesthetic was applied prior to commencing the LLETZ procedure. Omitting to anaesthetise Ms C was a significant error, which has had an ongoing impact on her. I accept that other clinicians were present, including Dr A in a supervisory capacity, but as Dr B was a senior registrar experienced in the procedure, she shared responsibility for ensuring that the basic requirement for anaesthetic was undertaken. I consider that Dr B failed to provide Ms C with an appropriate standard of care by failing to ensure that she was anaesthetised prior to performing the LLETZ procedure, and, accordingly, I find that Dr B breached Right 4(1) of the Code.

Opinion: Te Whatu Ora — adverse comment

Failure to anaesthetise

96. Dr Sissons advised that all three health professionals present during Ms C's procedure 'would have been aware that it is standard procedure for the cervix to be infiltrated with local anaesthetic prior to using the loop'.

97. Te Whatu Ora told HDC that it agrees with Dr Sissons that omission to use local anaesthetic was a minor departure from the standard of care. Te Whatu Ora submitted that the departure did not warrant a breach finding and expressed concern that HDC should find that individual clinical staff are in breach of the Code for failing to provide a reasonable standard of care when genuine human error has occurred.

98. Te Whatu Ora submitted:

> 'As an organisation we accept that human error is inevitable. Whilst we acknowledge the role of individual accountability under the Code, we consider that it is the role of the organisation to understand the science of human factors and human fallibility and work to ensure that there is reflection, learning and system change to reduce the chance of errors reaching the patient (i.e., we seek to make our systems and processes more resilient and "error tolerant").'

99. I have carefully considered whether the failure to anaesthetise Ms C was the result of any systems issues in place at the time. It is certainly concerning that all three health professionals present failed to appreciate that anaesthetic had not been given before commencing the procedure. I also accept that there are conflicting recollections as to whether the necessary actions were undertaken before starting the procedure, including whether the anaesthesia syringe was prepared and present on the procedure trolley. However, I note Dr Sissons' advice that she does not think it is material to the incident whether the local anaesthetic was available or not, as Dr B and Dr A were responsible for applying the local anaesthetic and should have obtained it prior to commencing the procedure. On balance, I am satisfied that the issues in this case were primarily the responsibility of the individual clinicians involved.

100. I note that at this time ADHB did not have a checklist for preparing the necessary materials correctly prior to beginning the procedure, but that a pre-procedure checklist has since been introduced. While such a checklist may have assisted the clinicians in remembering to administer the local anaesthetic (had it been in use at the time), I do not consider the lack of a checklist to have been a key issue in this case. I consider that the failure to administer anaesthetic was an issue for which the individual clinicians were responsible, rather than a systems issue at ADHB.

Consent documentation

101. Ms C's patient notes contain no documentation of the consenting conversation, and the consent form Ms C recalls signing was not uploaded to her file and now cannot be located.

This is concerning, as the investigation into key issues to be determined in this complaint is somewhat compromised by the absence of the consent form.

102. ADHB's Clinical Record Management Policy states that documentation in the clinical record is the responsibility of the treating clinician. I remind ADHB that the Health (Retention of Health Information) Regulations 1996 requires providers to keep health records for a minimum of 10 years from the date of the last service provision.

Postoperative care

103. It is clear that this was an unexpected and traumatic event for Ms C, caused by clinical error. Although it appears that Ms C was provided with standard postoperative care, my clinical advisor noted that a more empathetic approach would have been to include further post-procedure contact to assist Ms C in her recovery. I agree.

104. I note that both doctors signalled retrospectively that they would have liked to have contacted Ms C to check on her wellbeing. I also acknowledge that in response to my provisional opinion, Dr B stated that recently she was reminded that she did follow up with Ms C in the days following the LLETZ procedure.

105. Notwithstanding Dr B's new evidence, Te Whatu Ora may wish to consider a clearer system of follow-up (in the form of a policy, procedure, or guideline) for patients who have suffered an unexpected outcome or trauma from medical error, or otherwise encourage staff to do so, in the spirit of restoring trust in the therapeutic relationship. This would ensure that patients who experience adverse events continue to attend future appointments and can address any outstanding concerns.

Opinion: RN D — other comment

106. RN D was present in the procedure room for the entirety of Ms C's procedure, and she prepared the trolley prior to the procedure. RN D told HDC that when one of the doctors called out 'local', she realised that the syringe was still on the trolley with the cap on, and that it had not been used.

107. Owing to her positioning near Ms C's shoulder, I consider that RN D would not have had a clear view of what the doctors were doing at the time of the procedure. She also said that she was focused on Ms C at this time. RN D noted that she did have a clear view of the trolley, and, as an experienced nurse in the colposcopy clinic, this may have been a missed opportunity to recognise that the local anaesthetic had not been administered. However, the responsibility for administering the anaesthetic rested with the doctors, and I am not critical of her in this respect.

Opinion: Dr A, Dr B, and RN D — other comment

Iodine burns

108. Ms C stated that during the procedure she reported a burning sensation and, when she returned home, she noticed that she had chemical burns on her thighs from the iodine.

109. Dr B told HDC that she does not recall Ms C mentioning any burning sensation (from the iodine), and RN D stated that while some patients do describe the iodine used in vaginoscopies as causing a prickly or burning sensation, she does not recall Ms C mentioning this. Both Dr B and RN D noted that the iodine is not applied to a patient's thighs. Dr A told HDC that it is possible that Ms C developed a late reaction to the iodine, which would not have been picked up during her time in the clinic.

110. With the evidence above, in particular the differences in recollection around whether or not Ms C expressed that she felt a burning sensation during the procedure, I am unable to make a finding as to whether this occurred or whether the clinicians heard Ms C's complaint. Although conjecture, I note that Dr A may not have realised that the iodine was causing an issue when dealing with the aftermath of forgetting to anaesthetise Ms C, or that her complaints about pain may have been misinterpreted. Dr A has advised that she has changed her practice, and now washes out the vagina with water or saline after every procedure. I consider this to be an appropriate response and am pleased that this is something she now teaches to trainee doctors.

Holding down Ms C

111. Ms C told HDC that after the testing of the loop on her cervix, she was then told by one of the staff that they 'had to get through that loop before they could address the pain', and that she was scolded for shaking and was held down in an attempt to keep her still. In response to the provisional decision, Ms C stated that RN D held her hand to comfort her. Ms C said that Dr B told her that her legs were shaking and interfering with the procedure and asked her to control them.

112. Dr A and Dr B told HDC that they do not remember any of the staff holding Ms C still or down or scolding her. RN D said that she cannot recall exactly what she did or said to Ms C during the procedure, but she did not scold her or hold her down. RN D recalled that Ms C was anxious during the procedure and said that it is likely that she held her hand or rubbed her arm and asked her to try to stay relaxed and still.

113. I am satisfied that RN D likely touched and spoke to Ms C with the reported intention to calm and reassure her.

114. While acknowledging Ms C's interpretation of events and experience, I am not satisfied on the evidence that staff inappropriately restrained or reprimanded Ms C.

Continuation of procedure and postoperative care

115. Once the local anaesthetic had been injected (after the first loop contact with Ms C's cervix), Ms C was asked if she would prefer to delay and finish the procedure under general

anaesthetic. Dr Sissons advised that it was reasonable to continue to complete the procedure under local anaesthetic if the patient was amenable to this but said that a general anaesthetic would have been indicated if Ms C was significantly distressed. While appreciating the competing issues weighed up by Ms C at this time, and her conclusion that she had no real choice but to proceed, the clinicians appear to have been unaware of the extent of Ms C's distress and took at face value her consent to continue with the procedure.

116. Ms C told HDC that following her procedure, she was not given assistance to get down off the procedure table and had to climb over a tray of bloody instruments. Dr B told HDC that she cannot recall the exact circumstances but believes either she or RN D would have helped Ms C down. RN D and Dr A did not comment on this.

117. It is difficult to make an evidential finding on what occurred. No one can specifically recall helping Ms C, and Ms C is the only person who has provided a recollection of her post-procedure care. This is a learning point for the clinicians involved, as post-procedural care is an important aspect of medical care and building trust with a patient, especially when an adverse event has occurred.

Consent around trainee presence — educational comment

118. Ms C told HDC that she did not become aware that Dr B was a trainee doctor until she received the information from HDC. Ms C said that being in her reproductive years and having not yet had a child, she would never have agreed to a trainee carrying out this kind of procedure.

119. At the time of events, Dr B was a qualified doctor with several years' experience. She had performed 32 colposcopies and 11 LLETZ procedures as a trainee of the programme. Accordingly, although Dr B may have been in a training programme and consequently a 'trainee', she had experience in performing the procedure Ms C underwent, although was required to be supervised.

120. However, the question remains as to whether Ms C should have been informed that Dr B was a trainee. Consumers must be informed about any proposed participation in teaching and their consent to teaching obtained.[8] In the context of teaching situations, this office has also found that a doctor's role and status, and reason for their presence, should be made clear to consumers.[9] Despite Dr B having experience in performing LLETZ procedures, it is accepted that she was not certified to conduct the procedure alone, and was performing it under Dr A's direct supervision. It may be that in this supervision context teaching was taking place, although this is not certain. Noting the position I have reached below, I do not

[8] Right 6(1)(d) of the Code.
[9] Opinion 03HDC05435.

consider it necessary to determine whether teaching was occurring necessitating specific consent to that teaching.

121. In addition, the Code does not explicitly require providers to tell consumers about their qualifications, but simply to answer honestly if asked.[10] However, this Office has previously found that information regarding who will be performing a consumer's surgery is information that a reasonable consumer would expect to receive, particularly if that person is in training.[11] I endorse those findings and further note that those principles are reflected in ADHB's policy, which requires appropriate introduction of staff members and identification of their role.

122. Furthermore, in my view, consumers undergoing sensitive examinations should know beforehand who will be involved and what their role will be. Taking this, and the matters outlined in paragraph 123 into account, it follows that when seeking Ms C's consent, Dr B and Dr A should have notified Ms C of their respective roles — that of trainee and supervisor.

123. Turning then to what can be established on the evidence. I accept that as the clinician who obtained Ms C's consent, Dr B introduced herself to Ms C and identified herself as working with Dr A in performing the procedure. However, Ms C's evidence is that she was not aware that Dr B was a trainee, although she is unclear whether the involvement of trainees was mentioned on the informed consent form. As the consent form has been lost, regrettably I am unable to determine whether Dr B's status as trainee was noted on the form.

124. In the absence of the relevant contemporaneous documentation, I am left with an element of doubt regarding what may have been imparted to Ms C in respect of the role of trainees and, therefore, am not prepared to conclude that there was a breach of the Code. However, I take this opportunity to remind both doctors and Te Whatu Ora Te Toka Tumai Auckland of the need, when undertaking procedures, to clearly identify clinicians and their roles to the patient, and to ensure that consent is obtained in circumstances where teaching is taking place. It is also important to keep adequate records of those discussions.

[10] Right 6(3) of the Code.
[11] Opinions 09HDC01565, 13HDC01345, and 16HDC01498.

Changes made since events

125. At the time of events, there was no systematic check-up prior to performing the LLETZ procedure. However, Te Toka Tumai reviewed its processes and prepared a checklist to ensure that all the materials required are set up prior to the procedure. A check of the consent form has also been added as a step on the pre-procedure checklist.

126. Dr A told HDC that she now makes an effort to wash out the vagina with 20–30ml of water or saline at the end of all procedures that use iodine, to decrease the risk of vaginal burns. She said that she teaches this to all trainees under her supervision.

127. In response to the provisional opinion, Dr B told HDC that she has taken steps to change her practice to ensure that the issue that has been the subject of this complaint never occurs again, including the following:

- Always checking the setup of the trolley;
- Vigilance with local anaesthetic administration especially if a procedure involves additional features, eg, vaginoscopy, that are not routine;
- Washing out the vagina with saline post vaginoscopy;
- Carefully documenting every telephone conversation with patients; and
- Ensuring that patients understand the individual roles of each member of the clinical team assisting with their procedure.

Recommendations

128. I recommend that Te Whatu Ora Te Toka Tumai Auckland:

a) Reflect on Dr A's practice of saline washing at the end of all gynaecological procedures that use iodine and consider implementing this as a requirement. Te Whatu Ora is to provide HDC with the outcome of this consideration within three months of the date of this report.

b) In line with the recommendation of my independent advisor, Dr Sissons, update its adverse event policy to require a telephone call follow-up to patients who have suffered an adverse event, or are particularly distressed during their treatment or appointment. Evidence that this has been done is to be provided to HDC within three months of the date of this report.

129. I recommend that Dr B provide a formal written apology to Ms C for the deficiencies in care identified in this report. The apology should be sent to HDC within one month of the date of this report, for forwarding to Ms C.

130. In response to my provisional recommendations, Dr A provided HDC with a formal written apology to Ms C for the deficiencies in care identified in this report.

Follow-up actions

131. A copy of this report with details identifying the parties removed, except Te Whatu Ora Te Toka Tumai Auckland, Greenlane Clinical Centre and the independent advisor on this case, will be sent to the Medical Council of New Zealand, and it will be advised of Dr A's and Dr B's names in covering correspondence.

132. A copy of this report with details identifying the parties removed, except Te Whatu Ora Te Toka Tumai Auckland, Greenlane Clinical Centre and the independent advisor on this case, will be sent to the Royal Australian and New Zealand College of Obstetricians and Gynaecologists and Te Tahū Hauora | Health Quality & Safety Commission, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent clinical advice to Commissioner

The following independent advice was obtained from Dr Anne Sissons:

'1. My name is Anne Sissons. I have been asked by the HDC to review the documents and give my opinion on the care provided to [Ms C] by [Dr A] and [Dr B] on 6th March 2019. I have read and agree to follow the Commissioner's guidelines for Independent Advisors.

2. My qualifications are MB.ChB. 1982 (University of Manchester), Dip. Obst. 1985 (University of Otago), MRNZCOG 1991 and I have been a Fellow of RANZCOG since 1993. I have been continuously registered as a Specialist Obstetrician and Gynaecologist with NZMC since January 1994. I also have current CQIP certification. The Cervical Quality Improvement Program (C-QuIP) is a RANZCOG Quality Assurance activity for practising colposcopists. Certification of participation covers both diagnostic and therapeutic colposcopy streams.

3. My current practice is as a part time SMO at Nelson Marlborough DHB (Wairau Hospital) where one of my responsibilities is running the colposcopy service. Prior to 2020 I worked in private practice offering a combination of private gynaecology including colposcopy in Christchurch, and the provision of general obstetrics and gynaecology as a locum, to various DHBs.

4. Potential conflict. I am unaware of any conflict.

5. I have received and reviewed the following documents:

- Letter of complaint dated 6 July 2020.
- ADHB's response dated 11th August 2020.
- Letter to patient dated 25th September 2019 from ADHB.
- GP records from the medical centre.

6. I have been asked to comment on the following:

1. the care provided by [Dr B];
2. the care provided by [Dr A] including her supervision of [Dr B] and other staff;
3. the consenting process;
4. the pre-operative set-up and checking;
5. the decision to proceed with the vaginoscopy following the anaesthetic incident;
6. the investigation/questioning by staff about the burning sensation [Ms C] experienced during/following the procedure;
7. the discharge information and follow-up instructions;
8. the post-operative care received; and
9. the standard of documentation.

7. Background.

On 6 March 2019, [Ms C] underwent a vaginoscopy. [Dr A] was the consultant responsible. [Dr B], O&G trainee, assisted [Dr A]. [Dr B] consented [Ms C]. ADHB does not have a copy of the consent form.

Following the equipment set-up, [Dr B] tested the LLETZ loop electrode against [Ms C's] cervix to ensure enough local had been administered. [Ms C] immediately experienced severe pain and it was realised that no local anaesthetic had been administered.

Following administration of local anaesthetic and consultation with [Ms C], the procedure recommenced and was successfully completed. Following the procedure, [Ms C] was escorted to the post-procedure lounge and was monitored for 15 minutes.

8. The care provided by [Dr B]

I have not been provided with any contemporary documentation written by [Dr B] or [Dr A] at the time of the events or any response from [Dr B] after the complaint was made. I am therefore relying on the response which was written by [Dr A] dated 30th July 2020, so over one year after the event.

A LLETZ under local anaesthetic is a common procedure in a colposcopy clinic. This response describes [Dr B] discussing the procedure with [Ms C], including the use of local anaesthetic, and then obtaining signed consent.

It then describes [Dr B] performing a vaginoscopy including applying iodine dye. [Dr B] then omitted to infiltrate the cervix with local anaesthetic but proceeded directly to apply a LLETZ loop electrode to excise the abnormal area on her cervix. This caused pain as the area had not been anaesthetised and then [Dr A] took over and applied local anaesthetic.

[Dr B] was a trainee and performing the procedure under the direct supervision of [Dr A]. There was also a nurse present who would also have been familiar with the LLETZ procedure. All three health professionals would have been aware that it is standard procedure for the cervix to be infiltrated with local anaesthetic prior to using the loop. I struggle to understand how all three missed this error. However as a trainee under supervision [Dr B] should have been reminded to use the local anaesthetic. [Dr A] admits that she did not notice this step had been omitted.

9. The care provided by [Dr A] including her supervision of [Dr B] and other staff.

There are discrepancies between [Dr A's] and [Ms C's] accounts and no records provided written from the time of the procedure.

[Dr A] admits she did not notice that the step of using local anaesthetic had been omitted. As the supervising doctor present she should have been observant of this and intervened before the loop electrode was used.

Once she became aware she took over the procedure and according to her report immediately administered the local anaesthetic. [Ms C's] recollection differs from this in that she states she was initially scolded for moving and then feels it was maybe 20 minutes before any anaesthetic was administered. I cannot comment on which recollection is correct.

I have never witnessed a LLETZ being performed without anaesthetic so I cannot gauge how painful it would have been. [Dr A] applied local anaesthetic when the error was recognised and I would expect this to have removed the pain. At that stage the procedure could have been deferred and so a conversation with [Ms C] reportedly (by [Dr A]) happened offering her the options of continuing or planning the procedure under a general anaesthetic on another day.

I think that it could be reasonable to continue to complete the procedure under local anaesthetic if the patient was amenable to this. However if the patient was as distressed as described in her complaint I would have thought a general anaesthetic would have been indicated. Again there are discrepancies between [Ms C's] and [Dr A's] reports on how the completion of the LLETZ proceeded. As I have not been provided with any other report of the events it is hard to judge.

10. The consenting process

In [Ms C's] complaint she describes the procedure she was having, the reason she was having it and that it would be under local anaesthetic. She agrees she signed a contract for this (although this cannot be found). She was given a pamphlet which I assume was a copy of the ADHB handout on LLETZ treatment. I think that she was given adequate information to make informed consent. I also understand that as she was having the procedure under local anaesthetic this consent does not have to be in writing.

11. The pre-operative set-up and checking

I have not been given adequate information to comment on this but there is nothing in the documentation to suggest any deficiency in this.

12. The decision to proceed with the vaginoscopy following the anaesthetic incident.

The vaginoscopy preceeded the anaesthetic incident so I assume this question relates to the decision to proceed with a LLETZ.

I refer to my comments in my point 9 ie. I think that it could be reasonable to continue to complete the procedure under local anaesthetic if the patient was amenable to this. However if the patient was as distressed as described in her complaint I would have thought a general anaesthetic would have been indicated. Again there are discrepancies between [Ms C's] and [Dr A's] reports on how the completion of the LLETZ proceeded. As I have not been provided with any other report of the events it is hard to judge.

13. The investigation/questioning by staff about the burning sensation [Ms C] experienced during/following the procedure.

Approximately 10% of women experience some burning sensation following the application of iodine and while this is usually shortlived it can be eased by douching the vagina with saline. It is unfortunate that this was not recognised and offered although it is rare to still be causing issues several days later.

14. The discharge information and follow-up instructions.

The documents provided to me have adequate discharge information including with contact numbers to ring if there are issues.

15. The post-operative care received.

It sounds as though [Ms C] was given the standard post operative care. It may have been beneficial for the unit to have been more empathetic and kept in contact with [Ms C] to assist her in her recovery. I note that [Dr A] regrets this did not happen.

I see that [Ms C] declined further follow up at Greenlane Clinical Centre. I hope that this has happened in another setting as she definitely requires follow up cervical cytology and HPV testing.

16. The standard of documentation.

The HDC has not been provided with any documentation recorded at the time of the consultation.

The Cervical Screening Programme requires all publicly funded colposcopy episodes to be directly entered into a database called Gynae+. I suspect this occurred in this case. The database is not conducive to getting documentation out of it for review of cases such as this. Most DHB colposcopy clinics solely use this database for their record keeping and so I am not surprised that the documentation is not forthcoming.

However I would have expected some communication to the GP at the time of the colposcopy visit, and no copy of this has been provided. Many colposcopy clinics print a letter generated directly from the database but others dictate a letter separately.'

The following further advice was obtained from Dr Sissons, to clarify and quantify the identified departures as mild, moderate, or severe:

'I, Anne Sissons has been asked to clarify the following by the HDC. Here are the questions and my responses.

1. Whether omitting to use local anaesthetic was a mild, moderate or severe departure from the standard of care?

I regard it as a severe departure from the standard of care and I expect the majority of my peers would agree.

2. Was [Dr A's] failure to notice that the step of using local anaesthetic had been omitted a mild, moderate or severe departure from the standard of care?

I regard it as a severe departure from the standard of care and I expect the majority of my peers would agree.

3. I note the factual discrepancy about proceeding following the local anaesthetic incident. On the consumer's version (that she was very distressed), was there a departure from the standard of care with a) proceeding and/or b) not offering a general anaesthetic? If so, was the departure(s) mild, moderate or severe?

On the consumer's version I regard not abandoning the procedure and offering a general anaesthetic as a severe departure from the standard of care and I expect the majority of my peers would agree.

4. Was there a departure from the standard of care with regards to the investigation/ actions taken in response to/questioning by staff about the burning sensation [Ms C] experienced during/following the procedure? If so, was the departure a mild, moderate or severe departure from the standard of care?

I regard it as a mild departure from the standard of care and I expect the majority of my peers would agree.

5. HDC did not receive any clinical documentation and we understand none exists. Please comment on whether this lack of record constitutes a departure from the standard of care and if so, whether a mild, moderate or severe departure?

I regard it as a severe departure from the standard of care and I expect the majority of my peers would agree. However I expect there is some documentation within the Gynae+ reporting system which may be available for review. In the DHB I work in the nurse makes a completely separate note from the doctor's one and if this happens in the ADHB then this might also be available.

6. Was the lack of communication with the GP a departure from the standard of care and if so, whether a mild, moderate or severe departure?

I regard it as a severe departure from the standard of care and I expect the majority of my peers would agree.'

The following further advice was obtained from Dr Sissons after further information was received:

'1. I, Anne Sissons, received an email on 4th June 2021 providing additional documentation and asking for further advice. The additional documents attached were:

1. Statement from [doctor who reviewed the case] dated 29th March 2021.
2. Email correspondence dated 2nd June between [HDC] and [the quality manager] clarifying documentation sent to/received by HDC.
3. Clinical notes 1. A colposcopy photo taken 6th March 2019 for [Ms C].

4. Clinical notes 2. Clinic letters
    a) To [the GP] (GP) from [Dr B] (registrar) dated 6/3/2019
    b) To [Ms C] from [Dr B] dated 14/3/2019
    c) Pathology report [reference number] on LLETZ specimen collected 6/3/2019
5. Letter from [the] (CMO ADHB) dated 29th April 2019
6. Letter to [HDC] from [Dr A] dated 10/5/21
7. GP notes from 01 Mar 2019 to 31 July 2019.
8. Datix incident review printout from ADHB
9. ACC file including request for further information dated 10/10/2019 sent to [the] (GP) with attached response. This includes:
    a) GP notes from 4th Oct 2019 and 14 Oct 2019,
    b) letter from [Dr A] to [Ms C] dated 25/9/2019,
    c) notes from ADHB urgent mental health services dated 24/9/2019,
    d) further copies of letters to [the] (GP) from [Dr B] (registrar) dated 6/3/2019 and to [Ms C] from [Dr B] dated 14/3/2019
    e) Letter to [the GP] from Dr … dated 6/12/2018
    f) Pathology report [reference number] on LLETZ specimen collected 6/3/2019
    g) Letter from [Dr A] to [Ms C] dated 25/9/2019
    h) Letter from ADHB Mental Health Services to [the GP] dated 22/10/2019
    i) colposcopy records from visit on 6/3/2019 (printout from Gynae+)
    j) Letter from Dr … to [the GP] dated 7/11/2019
    k) ACC mental injury assessment dated 25/Aug/2020 from Dr …
    l) ACC letter accepting claim for PTSD following failed local anaesthetic for LLETZ dated 30/10/2020
    m) Clinic letter to ACC manager regarding ACC claim dated 20/11/2019 signed by [Dr A].
10. Statement from [RN D] dated April 2021.
11. Statement from [Dr B] dated 26 April 2021

2. The additional information asked for in light of this new information is:

1) Whether any of the new information provided in the responses changes any aspects of your initial advice;
2) The adequacy of the follow-up actions taken after these events.
3) Whether ADHB should have had a pre-procedure checklist at the time of these events, or any other systems in place to ensure that anaesthetic was administered prior to the procedure beginning.
4) Whether you have any further comments to make in regards to the care provided to [Ms C] by [Dr B], [Dr A], [RN D] and ADHB.

5) Whether you have any further recommendations to prevent a similar occurrence of these events.

3. I then received a further email from HDC dated 10th June 2021 with an attached email correspondence between [HDC] and [Ms C] dated 9th June 2021. I was asked to comment on [Ms C's] concern that she was not informed that a trainee would be performing her surgery.

4. I have reviewed my original reports dated December 2020 and answers to further questions dated 10th December 2020.

5. Whether any of the new information provided in the responses changes any aspects of your initial advice;

I have reviewed all the additional documents and would like to modify my advice to the Commissioner. Paragraph 8 of my original report headed *The care provided by [Dr A]* should now read [Dr B]. I would like to make the additional comments pertaining to this. I have now been given copies of records made at the time. There is no dispute that the local anaesthetic was omitted. The reason given was that the steps in the process had been changed with the iodine dye applied before infiltrating the cervix with local anaesthetic, and the staff involved had all made a "mental shortcut" in forgetting to use the local anaesthetic as the cervix was already painted. There is disagreement whether the local anaesthetic was available on the tray. [Dr B] states in her report (dated 26 April 2021) that she clearly recalls calling out "local" when the incident happened, recognising there was no local on the tray and that the nurse had to get the appropriate equipment (I assume the ampoules and syringe). [Dr A] does not comment on whether the local anaesthetic was available in her statement. [RN D] states that when [Dr B] called out "local" she looked at the tray and saw the local had not been used. However I do not think it is material to the incident whether the local was available or not; the operating doctor and the supervisor were responsible for applying the local anaesthetic and should have obtained it prior to commencing the procedure. I regard it as a "mental oversight" by both doctors.

6. In Paragraph 9 of my original report headed *The care provided by [Dr A] including her supervision of [Dr B] and other staff.* As already stated [Dr A] seems to have had a mental oversight on this incidence. It is difficult to understand from the various reports how distressed [Ms C] was once the anaesthetic had been administered.

7. In the Gynae+ database record of the event which usually would have been the first record made the event is described as: "Local [anaesthetic] injected only after first loop contact with cervix. Patient sore. Trainee then proceeded to numb cervix. Patient agitated and upset. Apologies given. Procedure completed". In the letter dictated on the same day it was reported as "[Ms C] was in pain following this and uncomfortable but happy to proceed. Once local anaesthetic had been administrated the procedure was well tolerated."

8. Once recognised both doctors and the nurse state in their reports that [Dr A] immediately took over and applied the local anaesthetic. This was appropriate but

differs from the Gynae+ record. They also all state that [Ms C] was happy to continue and there were no further problems. They also state that they do not recall [Ms C] being unduly distressed after the application of the local anaesthetic.

9. In my original opinion I stated "I think that it could be reasonable to continue to complete the procedure under local anaesthetic if the patient was amenable to this. However if the patient was as distressed as described in her complaint I would have thought a general anaesthetic would have been indicated." Again there are discrepancies between [Ms C's] and [Dr A's] reports on how the completion of the LLETZ proceeded. As I have not been provided with any other report of the events it is hard to judge. There is still discrepancy between the clinical team's and [Ms C's] accounts but all the clinicians involved agree that [Ms C] agreed to proceed, and tolerated the finishing of the procedure well (this would have been a short passage of time after the local anaesthetic had been administered; I expect less than one minute).

10. I conclude that once the incident had been recognised it is most likely that [Dr A] acted appropriately by taking over the procedure and completing it safely with [Ms C's] consent.

11. In my original report: Paragraph 16. Standard of documentation. I would like to change this to "The documentation that I have now received is complete and to a satisfactory standard. There is no departure from standard care."

12. In regard to the second letter I sent in relation to specific questions I would like to change my responses.

12.1. Whether omitting to use local anaesthetic was a mild, moderate or severe departure from the standard of care?

On reflection I would like to change my opinion to a "mild to moderate departure from the standard of care" but also would like to state that I believe it was an isolated event and extremely unlikely to ever recur.

12.2. Was [Dr A's] failure to notice that the step of using local anaesthetic had been omitted a mild, moderate or severe departure from the standard of care?

On reflection I would like to change my opinion to a "mild to moderate departure from the standard of care" but also would like to state that I believe it was an isolated event and extremely unlikely to ever recur.

12.3. I note the factual discrepancy about proceeding following the local anaesthetic incident. On the consumer's version (that she was very distressed), was there a departure from the standard of care with a) proceeding and/or b) not offering a general anaesthetic? If so, was the departure(s) mild, moderate or severe?

On the consumer's version (if correct) I regard not abandoning the procedure and offering a general anaesthetic as a moderate to severe departure from the standard of care and I expect the majority of my peers would agree. However the clinical records

suggest that the consumer settled after the application of the local anaesthetic, agreed to proceeding with the procedure and tolerated it. Therefore I wish to state that I cannot conclude there was any departure from standard care. It is possible that completing the procedure occurred very quickly and [Ms C] does not recall this part of the procedure as it was likely to be brief and painless. This could account for the discrepancy between the consumer's recall and that of the clinicians.

12.4. Was there a departure from the standard of care with regards to the investigation/actions taken in response to/questioning by staff about the burning sensation [Ms C] experienced during/following the procedure? If so, was the departure a mild, moderate or severe departure from the standard of care?

It is not clear what questioning occurred. The burning sensation was not recorded by the staff. When it occurs it is usually very short-lived and does not affect the legs. If it had been reported to the staff, then not offering saline douche is a very mild departure from the standard of care.

12.5. HDC did not receive any clinical documentation and we understand none exists. Please comment on whether this lack of record constitutes a departure from the standard of care and if so, whether a mild, moderate or severe departure?

The records were complete and to a satisfactory standard so there was no departure from the standard of care.

12.6. Was the lack of communication with the GP a departure from the standard of care and if so, whether a mild, moderate or severe departure?

There was satisfactory communication with the GP and so no departure from the standard of care.

13. The adequacy of the follow-up actions taken after these events.

I have received a report from [the doctor] who reviewed this case after the incident. I also have an electronic copy of the record entered into the "Datix" system.

13.1. I understand that the standard policy was to observe any woman having a LLETZ for 20 minutes and enquire about their well-being. I understand this happened and there is no record of [Ms C] reporting either ongoing pain or burning. I also understand that a post procedure information sheet with contact details for the colposcopy nurse was given and [Ms C] did not make contact about her concerns after the procedure. None of any of the medical records (including the GP's) refer to any ongoing issues related to this event until 23rd Sept 2019. The staff at the colposcopy clinic were unaware of any issues until she declined to attend for a follow up colposcopy on 25 Sept 2019.

13.2. The datix record shows that it was reported on the day of incident. It was reviewed and closed the following week. At that time there was no evidence that [Ms C] had ongoing distress and so had been recorded as SAC4, minimal. With the information available this was the correct assessment.

13.3 I have been provided with a "LLETZ checklist" created after this event. It is a simple checklist which allows staff to confirm that all equipment is present and working and should prevent situations like this from recurring.

14. Whether ADHB should have had a pre-procedure checklist at the time of these events, or any other systems in place to ensure that anaesthetic was administered prior to the procedure beginning.

I am not aware of any DHB having a specific checklist to ensure a practitioner infiltrates local anaesthetic before this type or any other type of procedure performed under local anaesthetic in an outpatient environment. Therefore I do not think they should have been expected to have such a document.

15. Whether you have any further comments to make in regards to the care provided to [Ms C] by [Dr B], [Dr A], [RN D] and ADHB.

This almost certainly was an isolated event which will be well remembered by the practitioners and I do not expect it would ever happen again in their care.

16. Whether you have any further recommendations to prevent a similar occurrence of these events.

16.1 I would recommend that when any adverse event or a patient being distressed by a procedure that there is phone contact made by a member of staff to check that the consumer is OK.

16.2. I would suggest that written documentation of the post procedure verbal check up in the waiting room is made.

17. I was asked to comment on [Ms C's] concern that she was not informed that a trainee would be performing her surgery.

The trainee, [Dr B], was a qualified doctor with several years' experience. She had performed 32 colposcopies and 11 LLETZ procedures. She had completed the colposcopy on line program. RANZCOG requires proof of performing a minimum of 10 LLETZ procedures to obtain their Cquip certification. [Dr B] therefore had already fulfilled the criteria for competency for LLETZ procedures. It is not documented what had been discussed in the consenting process.'

The following advice was obtained from Dr Sissons on 16 September 2023:

'I, Anne Sissons, have been asked to clarify the following by the HDC. Here are the questions and my responses.

Whether omitting to use local anaesthetic was a mild, moderate or severe departure from the standard of care? I would like to change this to a minor departure of care. My reason is that the clinicians intended to use local anaesthetic. There was no intent to not provide the recognised standard of care and once recognised the anaesthetic was applied.

Was [Dr A's] failure to notice that the step of using local anaesthetic had been omitted a mild, moderate or severe departure from the standard of care? I would like to change this to a minor departure of care. My reason is that the clinicians intended to use local anaesthetic. There was no intent to not provide the recognised standard of care and once recognised the anaesthetic was applied.'