General Practitioner, Dr B

Medical Centre

District Health Board

A Report by the

Health and Disability Commissioner

(Case 13HDC00903)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Table of Contents

Executive summary

1. Ms A had a history of high grade cervical abnormality, duplicate cervixes and a bicornuate uterus. In 2004 she was diagnosed with CIN III of the larger left cervix, CIN involving the endocervical margin, and high grade CGIN of the smaller right cervix. This was treated successfully.

2. In 2008 Ms A enrolled at a medical centre. Her general practitioner was Dr B. On 18 December 2008 Ms A had a cervical smear test carried out by Dr B. Dr B took a sample from both Ms A's cervixes. Dr B sent the two samples with one specimen referral form to a medical laboratory (Laboratory 1) for testing. Dr B noted on the form that Ms A had two cervixes. Two samples were received by the laboratory but only one report was issued, as there was no indication as to which site/cervix each sample was taken from. Ms A's smear sample report was returned as normal.

3. On 19 February 2010 Ms A had a further smear performed by Dr B. Dr B said she took a cervical smear sample from both cervixes. One specimen referral form was sent to Laboratory 1, which did not indicate the number of specimens collected. The laboratory receipt stamp indicates that only one sample was received by the laboratory. Laboratory 1 said that it received and processed only one sample. Dr B received one result report, which documents that the result was normal.

4. On 2 July 2012 Dr B performed two smear tests for Ms A (one for each cervix) and noted that the larger left cervix bled on being touched and had a lumpy appearance. Dr B sent two specimen referral forms and two specimens to Laboratory 2 for testing. As Ms A had symptoms of inter-menstrual bleeding, Dr B advised her that a referral to a specialist was required.

5. On 4 July 2012 Dr B received a smear test result from Laboratory 2, which documented that the result was normal. While the result form had a Laboratory 2 identification number, there was nothing to indicate to Dr B which cervix the result related to, or that this was result one of two. Dr B's expectation was that there would be only one result, and so she sent the referral to the gynaecology clinic for colposcopy with the normal result attached.

6. The referral set out details of Ms A's relevant cervical history from 2004 and current history. The gynaecology clinic placed Ms A on the Colposcopy Outpatient waiting list assigning her a grading of "low grade" with a follow-up time of within six months. The DHB acknowledged that even with the normal result, Ms A was incorrectly graded and should have been graded as semi-urgent, with a follow-up timeframe of one to three months.

7. On 5 July 2012, the medical centre received the second smear test result relating to Ms A. Again there was nothing to indicate the specific specimen site or that this was result two of two. The specimen result was abnormal but this result was mistakenly filed as a duplicate by an unknown person. No action was taken regarding the abnormal smear result.

8. Ms A's symptoms of inter-menstrual bleeding continued and, on 1 November 2012, she returned to Dr B asking to be referred to a private gynaecologist as she did not want to wait six months. Following a biopsy on 3 December, Ms A was informed that she had cervical cancer and underwent a radical hysterectomy.

Findings

9. It was found that Dr B's care of Ms A was suboptimal in that Dr B failed to discuss with Ms A any option of specialist involvement prior to Ms A complaining of inter-menstrual bleeding in July 2012, and failed to ascertain whether there should have been two results after sending two specimens with two forms. Accordingly, the Commissioner found that Dr B breached Right 4(1)[1] of the Code of Health and Disability Services Consumers' Rights (the Code).

10. While the primary responsibility relating to the tracking of Ms A's smears lay with Dr B, it was found that, at the time, the medical centre did not have in place an adequate laboratory test result tracking system; there was no system in place to alert staff of abnormal test results; there was no record of who filed a particular result; and a result could have been filed without the ordering clinician being made aware of it. The medical centre failed to provide services to Ms A with reasonable care and skill and, accordingly, I find that it breached Right 4(1) of the Code.

11. Criticism was also made of the DHB for incorrectly grading Ms A's referral, and of Laboratory 2 for inadequately recording on the result forms of 4 and 5 July 2012 which sample the result related to.

Complaint and investigation

12. The Commissioner received a complaint from Ms A about the services provided to her by Dr B, the medical centre and the DHB. The following issues were identified for investigation:

- *Whether Dr B provided an appropriate standard of care to Ms A between November 2008 and July 2013.*
- *Whether the medical centre provided an appropriate standard of care to Ms A between January 2012 and July 2013.*
- *Whether the DHB provided an appropriate standard of care to Ms A between January 2012 and July 2013.*

13. The parties directly involved in the investigation were:

Ms A	Consumer/complainant
Dr B	Provider
Medical centre	Provider

[1] Right 4(1) of the Code states that "every consumer has the right to have services provided with reasonable care and skill".

DHB	Provider
RN C	Registered nurse

Also mentioned in this report:

Dr D	Obstetrician and gynaecologist
Dr E	Obstetrician and gynaecologist
Dr F	Obstetrician and gynaecologist consultant
Dr G	Gynaecologist
Dr H	Gynaecology oncologist
Dr I	Gynaecology oncologist

14. Information was reviewed from:

Laboratory 1
Laboratory 2
National Cervical Screening Unit

15. Independent expert advice was obtained from a general practitioner, Dr Penny Warring (**Appendix A**), a registered nurse, Rosemary Minto (**Appendix B**), and a gynaecologist, Dr Donna Hardie (**Appendix C**).

Information gathered during investigation

Background

16. Ms A (31 years old in 2013) had a history of high grade cervical abnormality (abnormal smears). She had a bicornuate uterus[2] with a double cervix. Previously, in 2004, while living overseas, Ms A had been diagnosed with CIN[3]III[4] of the larger left cervix, CIN 1 of the smaller right cervix and CIN involving the endocervical margin, and high grade CGIN[5] of her smaller right cervix. In June 2004, while overseas, Ms A underwent a loop biopsy of both cervixes. A transvaginal scan taken in September 2004 showed no additional pathology, and the decision was made that surgery was not needed at that stage. Ms A had regular follow-up while overseas by gynaecology specialists, which involved consultations, smears and colposcopy examinations.

17. A report dated 8 January 2006 written by an obstetrician and gynaecologist overseas, Dr D, indicated that Ms A should be seen by him in one year's time for a colposcopy, and she was given an appointment for 7 December 2006. Dr D advised that if Ms A's

[2] Double uterus.
[3] Cervical intraepithelial neoplasia (CIN) refers to abnormalities of the outer squamous cells of the cervix.
[4] CIN1 relates to mild changes, CINII to moderate changes, and CINIII indicates more severe changes that affect the full thickness of the surface layer of the cervix.
[5] Cervical glandular intra-epithelial neoplasia (CGIN), also known as adenocarcinoma in situ, refers to abnormalities of the inner glandular cells of the cervix, and is a separate disease process that affects different cells compared with CIN.

smears were normal at that time then she could return to her GP's care. There is no record that Ms A attended a further appointment before she moved to New Zealand.

18. In May 2007 Ms A enrolled at a clinic where she had cervical smears performed. Ms A's notes document that she was sent a letter regarding yearly recalls for gynaecological cytology. Early in 2008 Ms A became pregnant and gave birth later that year.

19. On 13 November 2008, Ms A enrolled with Dr B at the medical centre.

20. Ms A's gynaecology records (from her previous doctor overseas and from the clinic where she had the smears performed) were requested by Dr B shortly after Ms A enrolled at the medical centre. Following her enrolment Ms A received yearly cervical smear recalls, but she advised HDC that she does not recall Dr B discussing specialist involvement in her care until she became symptomatic in July 2012. There is no reference in the clinical notes documented by Dr B to indicate that the option of specialist involvement was discussed with Ms A.

Smear procedure

21. At the time of these events (2008–2012) there were no Ministry of Health or National Cervical Screening Unit (NCSU) guidelines relating to the management of women with two cervixes. Therefore, there were no guidelines outlining how to carry out the smear procedure in those circumstances. However, the Ministry of Health's National Cervical Screening Unit advised HDC that the appropriate course of action at that time, for a woman with two cervixes, was to:

> "… take a sample from each cervix using a separate cervibroom for each, and placed in two separate liquid based cytology (LBC) vials (specimen containers). It is important that each LBC vial clearly identifies which cervix (e.g. right or left) the sample was taken from to allow the lab to report specifically for each cervix. To avoid any confusion the smear taker can provide a separate laboratory request form for each LBC vial and the laboratory will process as separate samples. This would be recorded in the NCSP[6] register as the woman having had 2 event IDs reported from the laboratory to the register and will clearly identify the cytology result for each cervix as this can be different."

2008 — smear

22. Ms A's clinical notes document that on 18 December 2008 she had a smear performed at the medical centre by Dr B. Dr B documented in Ms A's medical notes for this appointment: "2 cervix — one hard to find and hard to enter."

23. Dr B advised HDC that she took a cervical smear sample from both Ms A's larger left and smaller right cervixes. Dr B completed one specimen referral form. She noted on it that Ms A had two cervixes and sent it to Laboratory 1. The form did not state which sample referred to which cervix. The laboratory receipt stamp confirms that two samples were received by the laboratory. Laboratory 1 confirmed that two

[6] The National Cervical Screening Programme — put in place by the NCSU to manage smear results and renewals.

samples were processed, but that only one report was issued, as there was no indication as to which site/cervix each sample was taken from. Laboratory 1 further advised that "[a]s both slides were screened with no abnormality detected, one report was issued".

24. Laboratory 1 stated:

> "[I]f a smear indicates that the patient has 2 cervixes and takes a sample from each and clearly identifies each vial as Left or Right cervix, then we would report each separately and indicate on each report whether [it] is the Left or Right cervix. If we just receive two vials however with no indication of each being from a different site, we process both vials and issue one report."

25. It is documented in the report that the smear sample returned as normal.

2009

26. On 18 December 2009, the medical centre sent Ms A a recall letter advising her to arrange to have her annual smear taken. Dr B said that Ms A failed to contact the medical centre, and attempts to contact her by telephone were unsuccessful.

2010

27. On 15 January 2010 a second recall letter was sent to Ms A reminding her that she was due for her annual smear.

28. On 19 February 2010 Ms A had a smear performed by Dr B. Ms A's medical records for this visit are not clear as to whether a sample was taken from both cervixes. Dr B said that at this appointment she took a cervical smear sample from both the larger left and the smaller right cervixes, and stated: "I am confident that 2 smear samples were obtained and supplied to the laboratory."

29. One specimen referral form was sent to Laboratory 1, and it does not indicate the number of specimens collected or that Ms A had two cervixes. The laboratory receipt stamp indicates that only one sample was received by the laboratory. Dr B received one result report, which documents that the result was normal. Laboratory 1 advised HDC that it received only one sample and therefore processed one sample and produced one report.

2011

30. Dr B said that Ms A was not recalled for her annual smear in early 2011 as Dr B had incorrectly allocated Ms A a three-year recall following her February 2010 smear. However, the medical centre received a reminder from the National Cervical Screening Programme (NCSP) regarding Ms A's smear being overdue, and the mistake was noted and corrected by one of the practice nurses. Ms A was recalled for a smear on 2 June 2011, but this did not occur because she was pregnant. On 19 September 2011 Ms A presented to the medical centre with an ongoing cough, and was seen by a GP registrar. Ms A mentioned that she had miscarried recently. The GP did not note that Ms A's cervical smear was due; therefore, no smear was carried out in September 2011.

April 2012 — visit to registered nurse and smear test

31. On 16 April 2012 Ms A contacted the medical centre to book a routine smear test. On 19 April 2012, she saw registered nurse (RN) RN C. RN C documented in Ms A's notes that her history included abnormal smears, and that she now complained of some inter-menstrual and post-coital bleeding. RN C told Ms A that this was not normal and that she should see Dr B, regardless of the result of the smear. This is documented in Ms A's medical notes: "[A]dvised to see GP re post coital bleeding and IM bleeding."

32. RN C said that she had never before come across someone with two cervixes, and she had some difficulty in locating the second cervix. RN C stated:

> "[I] located Cervix 1 easily and took a sample with a cytobrush and after initially being unable to see a second cervix I repositioned the speculum and spotted cervix 2, taking another sample from this one. I used two separate brushes as I put one in a pottle before repositioning the speculum and locating the second cervix, using a second brush to get a sample."

33. RN C advised that she noted no abnormality but there was a small spot of bleeding, which may have been a result of contact with the cytobrush. She advised that this is "not at all uncommon". She further advised HDC:

> "I saw no need to call [Dr B] in to look at two cervixes that apart from the fact that there were two of them, appeared satisfactory to me. We were not permitted to interrupt [Dr B] over something which did not pose a problem, which at this stage was the case … Had I been unable to locate both cervixes, or had there been any obvious abnormality I would have endeavoured to call [Dr B] in to check [Ms A]."

34. RN C stated: "I believe that I used two pots and put a cervibroom and a cytobrush in each and sent both samples to [Laboratory 2]."[7]

35. One specimen referral form was sent to Laboratory 2. It states: "[P]t has 2 cervixes cytobrush used on both." It further states: "Smear Site … Cervical smear x2." The form does not specify which smear related to which cervix.

36. Laboratory 2 provided HDC with a copy of its daily worksheet of specimens received. This documents that one vial was received on 19 April 2012. Laboratory 2 advised HDC that as only one vial was received, only one report was processed. The result returned as normal.

37. Laboratory 2 stated:

> "In the event that a patient has 2 cervix, Laboratory 2 would expect to receive 2 referrals and always produce 2 reports. In the instance of 19 April 2012, as noted on the form 'Pt has 2 cervixes cytobrush used on both' but only one vial received — it was assumed that the 2 cervix smears were done with the same brush."

[7] There are two laboratories in the area providing a cervical cytology service. Prior to 2012 the medical centre used Laboratory 1, but in 2012 it began using Laboratory 2.

38. RN C stated to HDC: "[I]f, as Laboratory 2 states, only one pot was used … the fact remains that the result was normal. One positive brush/broom would have 'contaminated' all of them and an abnormal result would have been declared. The result of the 19/4/12 was normal."

39. On 23 April 2012 RN C sent Ms A a letter stating that her smear had returned as normal and reminding her to see her GP about the post-coital and inter-menstrual bleeding. The letter stated: "Should your symptoms which you discussed with me at the time of your smear persist, I suggest you make an appointment with your doctor."

July 2012 — smear test

40. On 2 July 2012 Ms A returned to the medical centre, as her intermenstrual and post-coital bleeding symptoms were continuing. Because RN C had had trouble finding the second smear site in April, Ms A also asked Dr B to perform another smear test, as she wanted "to be sure the nurse had done a good job".

41. It is documented in Ms A's notes that Dr B performed two smear tests (one for each cervix), and that there was "bleeding on just touching [larger] [cervix] — lumpy appearance to [cervix]". Dr B also noted "friable tissue[8] on [larger] [cervix]".

42. Ms A advised HDC that Dr B told her that her cervix looked "very red and 'angry' and bled very easily to the touch".

43. Dr B advised Ms A that she intended to refer her for a colposcopy regardless of the smear result.

44. Two specimen referral forms were sent to Laboratory 2, one stating that it was for the larger cervix, and one stating that it was for the smaller cervix. Laboratory 2's daily worksheet of specimens received documents that two specimens were received. A Laboratory 2 laboratory receipt stamp on the referrals confirms that two laboratory requests were made and that two specimens were sent to Laboratory 2 for testing.

45. Dr B advised HDC that it was a busy consultation, and stated:

> "[I]n the '15 mins' (probably 35–40 mins) 8 forms were written: 6 lab forms, and ACC M45 and radiology form. As a minor skin surgery also had been done, there was likely to have been a practice nurse in the room assisting with the minor surgery at that point at a minimum providing trolley and tidying up at the end. The nurse would have been wanting to clear the room for the next patient to help patient flow and to remove the specimens from previous cervical smear and minor surgery. The cervical smear form filling would have been rushed and presumably was done by myself, but could have been printed by the nurse and completed by myself."

[8] Tissue that is easily broken or torn. It can be a result of infection or damage to the tissue from injury or disease.

Smear test result from Laboratory 2 and referral for colposcopy

46. On 4 July 2012, Dr B received a smear test result from Laboratory 2, which documented that the result was normal. The result did not state which cervix it referred to, although it had on it a code matching the sample code Laboratory 2 placed on the specimen referral form for the smaller (right) cervix sample.

47. Dr B said that as she thought there would be only one result, as had occurred previously with Ms A's double smear tests, she attached that result to a referral to the gynaecology clinic for the colposcopy, which was based on her concerns about Ms A's inter-menstrual bleeding.

48. Dr B noted in the referral letter that there was uncertainty about the smear performed earlier that year, that Ms A had a "previous high grade history noted on smear results", "bleeding +++ on just touching [larger cervix]", on-going bleeding with intercourse, and a lumpy appearance of one cervix. Dr B also noted on the referral that a colposcopy was required "regardless of result". In the history section, Dr B noted: "CIN III — Ca insitu cervix." The referral was marked as "semi-urgent". Dr B did not record on the referral Ms A's history regarding the high grade CGIN of the smaller cervix.

49. On 5 July 2012 a second smear test result relating to Ms A arrived at the medical centre. This documented that the specimen result was abnormal. Again the result did not state which cervix the result referred to, although this time it had a code on it matching the sample code Laboratory 2 placed on the specimen referral form for the larger (left) cervix sample.

50. Dr B advised HDC that this result was mistakenly filed as a duplicate. Dr B and the medical centre stated that it is not known who filed it. Dr B initially advised that it could have been considered a second scanned result rather than a new result and filed by herself. She subsequently advised HDC that she did not see this result.

51. The medical centre advised HDC that, about a week before Ms A's smear was taken, the medical centre merged with another medical centre. The two medical centre computer databases had been merged by Medtech, and during this time there was a lot of duplication of results due to the merging of the two medical centres' databases.

52. Dr B further advised HDC that due to the merger her login was changed, which resulted in her being locked out of some of her previous records, and put her behind in some aspects of her work. She also advised that it was the peak season for viral illnesses and, therefore, she was working very long days. Dr B said that she always took two smears for Ms A, one for each cervix, and stated: "I do not know why [Laboratory 2] issued two reports on this occasion. All previous smear reports for [Ms A], despite her having two cervix, had been returned as one report."

53. Dr B further advised that she was not aware of any "rule" or advice from the National Cervical Screening Unit in regard to what happens when two cervixes have been sampled and, because Ms A's circumstances were uncommon, there was no in-house procedure to follow. Dr B said that she was unaware that sending two laboratory forms with the two samples would change the laboratory response and lead to two

results, as the medical centre had only ever received one "outcome" following laboratory assessment for cervical smears. Dr B advised that she had "presumed that this was due to the cervical smear register recording the final outcome of the smear taking activity for that date, much like a colposcopy session when a number of specimens are taken but there is one summary outcome, not a number of separate reports".

54. Dr B also noted that although Ms A's circumstance was uncommon, there had been a number of occasions in the past where both Thinprep cervical smear samples and glass slide cervical smears for the same person had been sent on the same day, due to patient request, and the medical centre had only ever had one outcome report for the cervical smears from the laboratory. Dr B advised that her expectation would have been for "a final outcome of the relevant assessments just as in a colposcopy, as the final clinical decision making is reliant on that result. Multiple results cause confusion."

55. The NCSP register records Ms A's smear results in 2007, 2008, 2010 and April 2012. Only one result is recorded for each of these dates, other than July 2012, where two results for Ms A's cervical smears are recorded.

56. On 6 July 2012 Dr B sent a letter to Ms A advising her that the smear test was "negative for intraepithelial lesion or malignancy" but that "given the cervical bleeding with slight touch" Ms A had been referred to the gynaecology clinic.

57. The triaging colposcopist, senior obstetrician and gynaecologist Dr E at the gynaecology clinic, advised HDC that Ms A's referral was received at the public hospital on 5 July 2012. He further advised that two normal smear reports were enclosed with the referral, one from 19 April 2012 (the smear carried out by RN C) and one from 2 July 2012.

Grading

58. On 10 July 2012 Dr E graded[9] Ms A's referral and assigned her as "low grade", which has a follow-up time of within six months.

59. The DHB advised HDC that colposcopy grading in 2012 was performed in accordance with the National Cervical Screening Unit's NCSP Policies and Standards: Section 6 "Providing a colposcopy service". At this time, however, there were no specific NCSP standards or policies relating to the triaging of a referral for colposcopy for the symptoms of inter-menstrual and post-coital bleeding in the presence of a normal smear. Dr F advised that such referrals were graded based on the grading clinician's assessment of the possible malignancy.

60. The DHB stated that other than the NCSP guidelines, there are no separate DHB policies/guidelines for colposcopy grading, "likely because it has always been

[9] The DHB advised this Office that all referrals received into the hospital must be graded within 10 days of referral. Referrals were graded from 1–6, with the time frames as per the requirements of the NCSP.

performed by the same person(s)" and as the Ministry of Health NCSP guidelines are followed.

61. The DHB said that the association of malignancy with the symptoms of inter-menstrual bleeding and post-coital bleeding alone is weak. Therefore, historically, such patients were triaged to be seen for a non-urgent colposcopy (within six months). However, as post-coital bleeding is a suspicious symptom that can be associated with malignancy, a decision had been made (prior to the time of these events) at the public hospital that patients with a normal smear result and such symptoms should be seen semi-urgently (within one to three months) (or earlier at the discretion of the colposcopist, depending on the information in the referral letter). The DHB advised HDC that this is not documented anywhere, as "it is common knowledge to the two colposcopists that perform the grading". However, Dr E advised this Office: "I do not recall any rules for grading of colposcopy referrals being present in 2012 when I graded the referral in question."

62. Dr E said that Ms A was graded as low grade/non-urgent because "[he] was guided by the practi[c]e of [his predecessor] who graded referrals with post coital bleeding and a normal cervical smear as non-urgent".

63. The DHB advised this Office that "the previous practi[c]e of grading women with normal smears and post-coital bleeding to have a non-urgent colposcopy was followed inadvertently". Dr B had noted in the referral letter that Ms A had a "previous high grade history", "bleeding +++ on just touching [larger cervix]", on-going bleeding with intercourse and a lumpy appearance of one cervix. Dr B also noted: "CIN III — Ca insitu cervix." Dr F noted that it was unfortunate that the abnormal smear result was not included in Dr B's referral, but also stated that she believed that "there was enough information in the referral to allow the grader to assign a triage score".

64. On 11 July 2012 the DHB sent Ms A a letter (copied to Dr B) confirming that Ms A had been placed on the Colposcopy Outpatient waiting list and that the referral had been graded as "routine", with an approximate waiting time of six months.

65. Dr B advised HDC:

> "I would have liked [Ms A] to have been given higher priority particularly given her history. However, I had already provided the public hospital with details of [Ms A's] history and symptoms and so I assumed the specialist had graded her taking this information into account. … [Ms A's] smear results … had always, as far as I was aware at the time, returned normal. I suspected the cause of her symptoms was early endometriosis, rather than cervical cancer."

National Cervical Screening Unit

66. Meanwhile, the NCSP had noted the abnormal smear result of 2 July 2012 on its register and, therefore, as per its policy, on 2 August 2012 sent Ms A a letter stating: "Your smear taken on 02 July 2012 shows some cells have abnormal changes … Please contact your smear taker to discuss your result if you have not already done so." Ms A does not recall this letter, and she did not contact Dr B, and Dr B was not sent a copy of the letter.

67. As Ms A had been referred to the DHB, and this had been noted on the NCSP register, there was no reason for NCSP to follow up. The National Cervical Screening Unit advised HDC that if cancer indicative results are received on the register, staff contact smear takers to check that an urgent referral has been sent to colposcopy for a follow-up appointment within seven days. However, at that stage there was nothing to indicate cancer.

November 2012 — Further consultation

68. Ms A's symptoms continued and, on 1 November 2012, she returned to Dr B asking to be referred to a private gynaecologist, as she did not want to wait six months. On 4 November 2012, Dr B wrote a referral letter to gynaecologist Dr G at a private clinic requesting that Ms A be considered for colposcopy.

December 2012

69. On 3 December 2012 Ms A went to see Dr G. Dr G examined Ms A and took a biopsy. On 10 December 2012 Ms A returned and was informed that she had cervical cancer (adenocarcinoma). This was registered on the NCSP register, and Dr G referred Ms A to a gynaecology clinic in a main centre.

70. On 12 December 2012 the DHB contacted Ms A regarding Dr B's referral and her non-urgent colposcopy. Ms A advised the DHB that she was seeing a private consultant, and she was removed from the DHB's waiting list.

71. On 18 December 2012 Ms A went to see gynaecology oncologist Dr H in the main centre. Dr H suggested that she would need a hysterectomy and possibly also radiotherapy. As he was going on leave, he referred Ms A to Dr I, at the same clinic.

72. Ms A said: "I had to wait weeks to find out how advanced my cancer was and how we would proceed, as you can imagine not knowing where you stand is not easy."

January 2013 — Hysterectomy

73. On 7 January 2013 Ms A saw Dr I. Dr I documented in Ms A's medical notes for this visit:

> "Preference is for hysterectomy over wide local excision.
> Retain ovaries
> hormonal reserve
> to retain follicles aware other advice could [be] contrary to this.
> For open radical hysterectomy/retain ovaries."

74. Ms A underwent a radical hysterectomy, conserving her ovaries. Radiotherapy was not considered necessary.

75. Following her surgery, Ms A's insurance broker advised her that her trauma insurance had been declined owing to her symptoms showing within the stand-down period of three months, which started in June 2012. Ms A was advised that her medical notes showed that she had an abnormal smear in July 2012. However, Ms A did not recall receiving the NCSP letter in August 2012, and so it was not until her visit to Dr G in

December that she understood that there was a problem. Subsequently she telephoned the medical centre and learnt that a second smear result had been received in July 2012 and had reported abnormal findings.

76. Ms A was diagnosed with a secondary tumour in January 2014. She subsequently had chemotherapy and radiotherapy. Currently Ms A's cancer is in remission and it is documented in her medical notes as being "probably cured".

Further information

The medical centre

77. At the time of these events (July 2012) the medical centre had in place the medical centre's policy on Reports and Test Results. This outlined the following:

- All incoming medical reports are seen and actioned by the appropriate member of the practice team who requested these (or a designated deputy).
- It is usually acknowledged on the computer record if further results are awaited.
- Results are placed during the day on the doctors' trolley.
- The doctor is responsible for collecting, reading and sorting these results.
- The doctor looks at results in electronic format as well as in paper format.
- The requestor (or designated deputy) indicates that he or she has read the report by signing it, or by making an entry directly on the laboratory test result in the electronic record before filing it.
- Laboratory results are filed in Medtech by the requestor.
- There is no tracking system for laboratory tests.

78. The medical centre advised HDC that these events led to it reflecting on the smear-taking programme and enabled it to refine the programme and make it robust. It advised that it will continue to refine and update the programme so that an error such as this will not be repeated. The medical centre advised: "We acknowledge, accept, and are extremely remorseful for our part in the error in the patient journey of [Ms A]."

79. The medical centre advised HDC that since these events the following changes have been made:

1. Clinical notes received from new registered patients are scanned onto the patient's file electronically, and ongoing clinical data received is also scanned onto the patient's file and then placed in the GP inbox.
2. Nurses and/or support staff are no longer able to open up and file laboratory test results. All tests must be referred to a GP for review, and the test remains on-screen until reviewed. This ensures that laboratory test results are not filed away without review/action by a GP.
3. If the smear taker is concerned about the condition of the cervix, or if he or she considers that the quality of the smear is not of a high standard owing to difficulty visualising the cervix or any other factor that reduces the quality of the smear, the smear taker must seek assistance or refer the patient.

4. If the patient has abnormal signs or symptoms she is referred by the smear taker to the GP or for colposcopy/biopsy as per Standard 602 of the NCSP.

5. Although the NCSP does not have guidelines on smear protocols for a double cervix, the medical centre's policies and procedures now state that "patients with 2 cervixes get 2 smears each with their own cyto-brush and own pottle generating their own lab number and result. Each result is followed up individually." the medical centre also now ensures that two separate referral forms are sent to the laboratory when two smear samples are taken, and ensures that two reports are received from the laboratory. This is noted in the notes and placed as a task on Medtech.

6. Four half hourly discussion/training meetings have been introduced with GPs, the practice manager, nurses and healthcare assistant, to discuss, review and agree improvements to the practice, including the cervical smear recall programme. In addition, Ms A's case has been discussed anonymously during training sessions with existing and new staff members, to ensure that staff are aware of the requirement to capture all information accurately.

7. An audit was undertaken of all patients to identify those at higher risk, ie, those patients with a history of high-grade cervical abnormality and all those who have required historic colposcopy or surgical invention. Improvements to the medical centre's computer system have allowed the medical centre to group these patients so that they are able to monitor screening and follow-up treatment closely. The practice nurses review this group of patients on a weekly to fortnightly basis to ensure that patients are contacted immediately should they require a smear recall. The practice nurses also audit the list of patients on a monthly basis to ensure ongoing accuracy of information (ie, to ensure the patients are being screened at regular time intervals) and that records are accurately amended when the patient falls pregnant or suffers a miscarriage.

8. The triaging of referrals is being monitored by the medical centre more closely. Using the computer system, the medical centre operates a classification system to assist with the review of ongoing treatment and care. For example, if a patient is graded low priority by the public hospital in circumstances where the medical centre has classified the treatment or investigation as a higher priority requirement, the doctor is able to check the referral priority noted on the system, and the medical centre is then able to follow up with the hospital to discuss and review the reasons for the allocated priority grading. In certain circumstances, a team member is allocated to "lobby" for a higher priority referral and/or to lobby for the acceptance of a referral where a referral has been declined.

9. When a patient is due for a cervical smear recall, the patient will be recalled at least three times within three to four months. The medical centre now sends an initial recall letter advising the patient that it is time for the smear test and emphasising the importance of the investigation. If no response is received, the medical centre sends at least two further reminders; one reminder is usually by telephone. In 2013 the medical centre introduced "TXT2 REMIND", and advised that it has received a favourable response from patients. Letters and telephone calls continue to form part of the recall programme.

10. If patients fail to respond to the various recall contacts made, an "alert" drop-down is noted on the patient's clinical notes, and the patient's Medtech recall is highlighted red so as to ensure staff are able to identify when a patient has failed to attend for a review screening. This serves as a prompt to discuss the overdue cervical smear with the patient during consultations. At the end of each month, Dr B checks all of the recall lists to ensure that the medical centre is attending to all relevant recalls.

11. The medical centre has a cervical smear audit every three months. The senior practice nurse and Dr B continue to review the list of those overdue on a three-monthly basis.

12. All smear takers at the medical centre now use a common template form upon completion of the cervical smear consultation. All smear takers following up these results complete a second common template form detailing the result, recall, result notification, and management plan (including referral if relevant) for each patient.

Dr B

80. Dr B advised that "the senior Practice Nurse has also arranged to liaise with those who run the cervical smear takers' programme to discuss how training in the administration of the cervical smear programme at a practice level might be adopted to deal with these issues to ensure adequate training is provided".

The DHB

81. The DHB advised that it does not base grading solely on the smear test results; instead all information in the referral is noted and used to prioritise the grading.

82. The DHB further advised:

> "A cervix with suspicious symptoms plus a normal smear is a very common referral to our Colposcopy Clinic. The risk of malignancy in women with post-coital bleeding between the age of 25 and 34 is incredibly low, less than one percent (one in 5600). These women therefore are … [graded to] be seen on a semi-urgent basis (one to three months). If ANY referrer reports findings suspicious of malignancy, these women are seen within 7 days (regardless of the smear report). The most common 'lump' we see in clinic is a nabothian cyst, again a benign finding, therefore the description given by the GP, did not raise a high suspicion of cancer. Also if any GP is truly concerned about malignancy, they are able to call our service to discuss the priority given to their patient, and this extra information is taken into consideration and re-prioritisation can (and does) occur."

83. In response to this complaint, the DHB created a policy for the triaging of colposcopy gradings. It advised that this was created to ensure that all colposcopists are aware of the NCSP requirements and that all grading will be done in a standardised fashion. The policy for referrals graded as Priority 6 (such as those referred with a suspicious cervix or suspicious symptoms such as post-coital bleeding) states:

> "Priority 6 — Other (as per grader).
> — Post coital bleeding/normal cervix/normal smear — see within 3 months
> — Suspicious cervix/normal smear — see within 3 months

— Suspicious cervix/previous High grade squamous intraepithelial lesion (HGSIL[10]) — see within 4 weeks
— Suspicious cervix or post coital bleeding + concerns of malignancy — see within 2 weeks."

84. The DHB acknowledged that it made an error in Ms A's grading and stated that based on the information outlined in the referral letter, Ms A should have been categorised as a semi-urgent patient (and therefore seen within one to three months). The DHB further stated that if the abnormal result had been attached to the referral, Ms A "would have been seen within four weeks". Following these events, the DHB instigated a serious event process. It also concluded that patients such as Ms A should be seen as semi-urgent. Patients in Ms A's situation (young, with previous cervical abnormalities/previous abnormal smear and post-coital bleeding) will now be graded to be seen within the four-week time frame (as per the new policy document above).

85. Dr F advised HDC: "Since [Dr E] has been doing the grading in 2002, neither he nor I am aware of missing any other cases of cervical cancer during our grading process."

Laboratory 2

86. Laboratory 2 completed a retrospective review of Ms A's smear test of 19 April 2012 (as per their policy when a consumer is later found to have cervical cancer). The review found abnormal glandular cells consistent with adenocarcinoma, despite the smear test result having been reported as normal at the time. According to Laboratory 2 this can happen and, as long as Laboratory 2's error rate remains under 20%, this is not seen as a deviation from expected standards (Laboratory 2's error rate for that year is under 10%).

87. The 2 July 2012 smear samples had been coded by Laboratory 2. The smaller (right) cervix sample code matches the code in the report identifying the normal smear (received by the medical centre on 4 July 2012). However, the report does not state which cervix it relates to. The larger (left) cervix sample code matches the code provided by Laboratory 2 in its report to Dr B identifying the abnormal smear (received by the medical centre on 5 July 2012). This report also does not state which cervix it relates to.

The National Cervical Screening Unit

88. The National Cervical Screening Unit advised HDC that "[t]he NCSP sends reminder letters to women (after an appropriate time period allowing for provider follow up) … after an abnormal smear is recorded. The programme is a backup for providers and women." The programme also sends overdue reminders, regarding abnormal cervical smear reports, to patients' doctors when there is no follow-up.

89. The NCSP register records Ms A's smear results in 2007, 2008, 2010 and April 2012 as normal. Only one result is recorded for each of these dates, other than July 2012,

[10] High grade squamous intraepithelial lesion. A medical term given to a category of cervical dysplasia detected through a Pap smear. An HGSIL result indicates that more defined changes in the size and shape of cells has been detected, indicating moderate to severe cervical dysplasia. HGSIL is not cervical cancer, but when left untreated can lead to cervical cancer.

where two results for her cervical smears are recorded, one assessed as a possible high grade smear (and a recommendation made for specialist assessment), the other smear assessed as negative. The National Cervical Screening Unit advised that it was noted that a referral was made by the smear taker, and that the colposcopy clinic booked the woman as "low grade" with a follow-up time of within six months.

90. Following this case, NCSP policies and standards for providing a colposcopy service have been updated. Under the title "Women who require gynaecological assessment and possible colposcopy" it notes that women referred for gynaecology assessment (who may also be referred for colposcopy) may have:

- An abnormal-appearing cervix
- Irregular bleeding
- Post-coital bleeding
- Pelvic pain

91. The updated policy states that "these women should ideally be seen within two to four weeks of receipt or referral. This will depend on the clinical concern about invasive cancer. A decision to undertake colposcopy on these women will be at the discretion of the gynaecologist and should be discussed with the referring clinician" (emphasis in original).

Responses to provisional opinion

92. Ms A, Dr B, the medical centre, the DHB and Laboratory 2 were given the opportunity to respond to relevant sections of my provisional opinion.

93. Ms A stated she had no comment to make. The DHB provided a written apology for Ms A which has been forwarded onto her and it had no further response to make regarding my provisional opinion.

94. Laboratory 2 stated it felt my recommendation made in relation to it was a fair one. The medical centre accepted the findings and Dr B had no further response.

Opinion: Breach — Dr B

Specialist gynaecologist involvement

95. Ms A had a bicornuate uterus with two cervixes, and a history of high grade cervical abnormality.

96. My expert advisor, GP Dr Penny Warring, advised me that anatomical abnormalities such as a bicornuate uterus and double cervix, as well as the structural orientation and size of the cervixes, can make it difficult for a GP to obtain a reliable sample from the cervix. She further explained that in the case of a double cervix, a false negative result is possible if either one of the cervixes is not sampled adequately due to physical and

structural restraints, and that in her view specialist involvement would be accepted practice in these circumstances.

97. I note that there was specialist involvement in Ms A's care until 2005. However, it appears that Ms A did not attend the final follow-up colposcopy appointment booked for December 2006 while she was overseas. In May 2007 Ms A enrolled at a clinic in New Zealand where smears were taken, and then had a baby in September 2008 before enrolling with Dr B in November 2008. Ms A does not recall Dr B discussing specialist involvement in her care until Ms A became symptomatic in July 2012. There is no reference in the clinical notes documented by Dr B to indicate that Dr B did discuss the option of specialist involvement with Ms A.

98. I note my expert's advice that specialist involvement should have occurred and, taking into account Ms A's past history, I consider that, at the time of Ms A's enrolment, Dr B should have at least discussed with Ms A the option of specialist involvement. I am critical that she did not do so, and consider that without a discussion of the available options Ms A was denied the opportunity to make her own decision about specialist involvement and, therefore, was not able to be a full partner in her own healthcare.

Smear taking

99. At the time of these events, there were no guidelines relating to the cervical screening of women with two cervixes. However, the National Cervical Screening Unit advised that the expected practice at the time was to:

- take a sample from each cervix using a separate brush for each one;
- place the samples into separate vials;
- clearly identify on each vial which cervix (eg, right or left) the sample was taken from (to allow the laboratory to report specifically for each cervix); and
- provide a separate laboratory request form for each vial to avoid any confusion. The laboratory would process as separate samples.

2008 smear

100. On 18 December 2008, Ms A had a smear performed by Dr B. Dr B took a cervical smear sample from both Ms A's cervixes. Dr B sent one specimen referral form to Laboratory 1. Dr B noted on the form that Ms A had two cervixes. The laboratory receipt stamp confirms that two samples were received by the laboratory.

101. Laboratory 1 advised this Office that if a smear taker indicates that the patient has two cervixes and takes a sample from each and clearly identifies each vial as either left or right cervix, then it would report each separately and indicate on each report whether it is the left or right cervix. Laboratory 1 further advised: "If we just receive two vials however with no indication of each being from a different site, we process both vials and issue one report."

102. Laboratory 1 agreed that two samples were processed but only one report issued, as there was no indication as to which site/cervix each sample was taken from. It further advised: "As both slides were screened with no abnormality detected, one report was issued." Ms A's smear sample returned as normal.

103. Dr Warring advised me: "When sending in more than one pathological sample it is accepted practice to clearly label each sample with the site it was taken from. This would enable the treating practitioner to know which site had the abnormality, if an abnormal result was returned."

104. From the evidence I have before me, I am unable to make a factual finding as to whether each vial was clearly labelled or not. I accept, however, that only one specimen referral form was sent and only one report was issued.

2010 smear

105. On 19 February 2010 Ms A had a smear performed by Dr B. Dr B said that she took a cervical smear sample from both the larger left and the smaller right cervix, and stated: "I am confident that 2 smear samples were obtained and supplied to the laboratory."

106. Only one specimen referral form was sent to Laboratory 1, and it did not indicate the number of specimens collected. The laboratory receipt stamp indicated that only one sample was received by the laboratory. Laboratory 1 advised this Office that it received and processed only one sample. Dr B received one results report, which documented that the result was normal.

107. I am unable to make a factual finding as to whether or not Dr B provided two separate samples to Laboratory 1. I accept, however, that only one specimen referral form was sent and only one report was issued.

2012 smear

108. On 2 July 2012, when Dr B was made aware of Ms A's symptoms and the fact that Ms A was not confident that RN C had managed to get two smear samples in April, Dr B repeated the smear tests for Ms A. Dr B took a sample from each cervix and noted that the larger left cervix bled on being touched and had a lumpy appearance. Dr B advised Ms A that she intended to refer her for a colposcopy regardless of the smear result.

109. Dr B advised that the medical centre was very busy that day, and that two specimen referral forms and two specimens were sent to Laboratory 2 for testing. One form stated that it was for the larger cervix, and the other form stated that it was for the smaller cervix.

110. On 4 July 2012, Dr B received a smear test result from Laboratory 2, which documented that the result was normal. However, that result did not state which cervix the result referred to, although it had a code on it that matched the sample code Laboratory 2 placed on the specimen referral form for the smaller (right) cervix sample. Dr B would not have known which cervix this related to.

111. Dr B thought that there would be only one result, as had occurred previously with Ms A's double smears in 2008 and 2010, and so she attached the 4 July result to a referral to the gynaecology clinic for colposcopy and sent the referral immediately.

112. Ms A's referral, received at the public hospital on 5 July 2012, enclosed two normal smear reports, one from 19 April 2012 (the smear carried out by RN C) and one from 2 July 2012 (the normal smear result received on 4 July 2012).

113. On 5 July 2012, a second smear test result relating to Ms A was received by the medical centre. This documented that the specimen result was abnormal.[11] The medical centre advised that this was mistakenly filed as a duplicate, and no action was taken regarding the abnormal smear result.

114. On 6 July 2012 Dr B sent a letter to Ms A advising her that her smear test was "negative for intraepithelial lesion or malignancy" but that "given the cervical bleeding with slight touch" Ms A had been referred to the gynaecology clinic. Dr Warring advised that it is the responsibility of the smear taker to check for and advise the patient of the patient's smear results, and is critical that despite taking two cervical smears and sending two specimen referral forms with two specimen vials to Laboratory 2, Dr B failed to ensure that she had reviewed two cytology reports from Laboratory 2.

115. I acknowledge Dr B's advice that the medical centre had only ever received one "outcome" following laboratory assessment for cervical smears. I further note Dr B's presumption that this was due to the NCSP register recording the final outcome of the smear-taking activity for that date, much like a colposcopy session when a number of specimens are taken but there is one summary outcome, not a number of separate reports.

116. As Dr B was not expecting two results she did not look for two reports. A compounding factor was the fact that Laboratory 2 did not adequately record on the result form which sample the result related to, and that Dr B had never received two results previously.

117. However, regardless of her previous practice (which had resulted in her receiving only one report), on this occasion Dr B sent two samples, with two different specimen referral forms and, therefore, in my view, she still had a responsibility to check the result to see whether it referred to two smear test results and, if not, to check with Laboratory 2 as to whether two results would be provided.

118. While I acknowledge that Laboratory 2 did not state clearly which site it was reporting on, I note Dr Warring's advice that Dr B failed to identify and track a potentially significant and urgent result. Dr Warring further advised me:

> "[I]n cases like this, where there is identified high risk and something different or atypical about the case — in other words needing to watch out for two cervical smear reports instead of one, or watching out for a cervical smear report in a patient with high risk, accepted practice is for the treating doctor to set a task in the patient management system to look for two results — thus ensuring that the

[11] This has on it a code that matches the sample code placed on the specimen referral form by Laboratory 2 for the larger (left) cervix sample.

general practitioner is reminded to look for the result and the test result is not missed."

119. I acknowledge that Dr B was not expecting two results; however, I consider that Dr B was insufficiently cautious and that, in this situation, where she had sent two samples and two forms for the first time, she should have been proactive in identifying whether or not she had received results from both samples.

Referral to the public hospital gynaecology clinic

120. On 4 July 2012, Dr B sent Ms A's referral for a colposcopy to the public hospital's gynaecology clinic. She marked it "semi-urgent".

121. The public hospital's gynaecology clinic placed Ms A on the Colposcopy Outpatient waiting list, assigning her a grading of "low grade" with a follow-up time of within six months. I note the DHB's advice that the information provided on the referral form was adequate for a semi-urgent grading (I comment on this further below).

122. On 11 July 2012 the DHB sent Ms A a letter (copied to Dr B) confirming this.

123. Dr Warring advised me that when the public hospital's gynaecology clinic returned Ms A's referral as a low priority grading, it was Dr B's responsibility to chase this up and insist that Ms A be seen sooner, based on Ms A's symptoms. I also note the DHB's response that GPs can call the service to discuss the priority given to their patient, and that re-prioritisation does occur.

124. However, I note that Dr B was unaware of the positive smear result, and I acknowledge her advice that, although it would have been her preference for Ms A to have been given higher priority given her history, Ms A's history and symptoms had been provided to the grading specialist to take into account, Ms A's smear results had been consistently normal for some time, and Dr B suspected that the cause of Ms A's symptoms was early endometriosis, rather than cervical cancer.

125. Ms A's inter-menstrual and post-coital bleeding symptoms continued, however, and on 1 November 2012 she returned to Dr B asking to be referred to a private gynaecologist.

126. In my view, prior to Ms A returning to her in November, Dr B had failed to advocate for her patient appropriately. She failed to review the clinical situation and follow up with Ms A regarding her symptoms. It would have been appropriate for Dr B to have attempted to expedite Ms A's appointment or to have offered a private referral prior to Ms A returning to her in November.

Conclusion

127. Ms A advised that following her enrolment at the medical centre in 2008 and up until she developed inter-menstrual bleeding in 2012, Dr B did not discuss with her any options for specialist involvement for ongoing monitoring and surveillance. There is no indication in Ms A's clinical notes that a specialist referral was discussed prior to July 2012. I am critical of this as, without a discussion of the available options, I consider that Ms A was denied the opportunity to make her own decision about

specialist involvement and, therefore, was not able to be a full partner in her own healthcare.

128. In 2008 Dr B sent two samples and one specimen referral form to Laboratory 1. In 2010, it is not known how many samples were sent, but Dr B sent only one specimen referral form to Laboratory 1. On each occasion Dr B received only one result. This led her to expect only one result in 2012, despite having sent two specimen referral forms on that occasion. I am concerned that Dr B sent two specimen referral forms with two specimens to Laboratory 2 but failed to ascertain whether she should have received two results.

129. In July 2012, Dr B referred Ms A for a colposcopy at the public hospital's gynaecology clinic. She marked the referral "semi-urgent". The public hospital's gynaecology clinic placed Ms A on the Colposcopy Outpatient waiting list, assigning her a grading of "low grade" with a follow-up time of within six months. Ms A returned to Dr B in November as her symptoms remained, and requested a private referral. I am critical that prior to Ms A returning, Dr B failed to follow up with Ms A regarding her symptoms. Prior to November, it would have been appropriate for Dr B to attempt to expedite Ms A's appointment at the public hospital's gynaecology clinic or offer a private referral.

130. I consider that Dr B's care of Ms A was suboptimal in that she failed to discuss with her patient any option of specialist involvement at the time of Ms A's enrolment and, although a semi-urgent referral was made for colposcopy in July 2012, Dr B failed to review the clinical situation prior to her patient returning to her in November 2012, to determine whether Ms A had been seen or if she had a firm appointment time, and to assess the current status of her patient's symptoms. Dr B was presented with a patient who had had some degree of abnormal vaginal bleeding since prior to April 2012, an atypical appearance to her cervix, and a history of previous high grade abnormality, yet no attempts had been made to expedite the appointment or offer a private referral.

131. Most significantly, in July 2012 Dr B failed to ascertain whether there should have been two results after sending two specimens with two forms and, in consequence, she failed to follow up a material test result. Accordingly, Dr B failed to provide services to Ms A with reasonable care and skill and breached Right 4(1) of the Code.

Opinion: Breach — The medical centre

132. On 2 July 2012 Dr B performed two smear tests for Ms A and sent two specimen referral forms and two specimens to Laboratory 2 for testing.

133. On 4 July 2012 Dr B received a smear test result from Laboratory 2. This documented that the result was normal but did not record adequately which sample the result related to. The result was seen and followed up by Dr B.

134. On 5 July 2012 a second smear test result relating to Ms A was received by the medical centre. This documented that the specimen result was abnormal, but again the form did not record adequately which sample the result related to. The medical centre advised HDC that at this time there was a lot of duplication of results owing to the merging of the two medical centre databases in the previous week, and that this result was mistakenly filed as a duplicate. Dr B and the medical centre stated that it is not known who filed the result. Dr B initially advised that it could have been considered a second scanned result rather than a new result and filed by herself. She subsequently advised HDC that she did not see the second result. The error of not recognising that this was a second result and that the result was abnormal led to no action being taken regarding the abnormal smear result.

135. While I find that the primary responsibility relating to the tracking of Ms A's smears lay with Dr B, I accept Dr Warring's advice that at the time of these events, the medical centre did not have in place an adequate laboratory tracking system to ensure that incoming test results or other investigations were being sighted and actioned by the team member who requested them (or by a designated deputy). Likewise, I accept Dr Warring's advice that "[t]he merge of a Medtech patient management system does not preclude a practice from this responsibility".

136. Following Ms A's complaint, the medical centre has reflected on the smear-taking process and made significant changes. I note in particular that these include a robust laboratory tracking system, and a protocol for laboratory result checking and filing, and that the practice also now ensures that two separate specimen referral forms are sent to the laboratory when two smear samples are taken, and ensures that two reports are received from the laboratory. In addition, all tests must now be referred to a GP for review, and the test remains on-screen until reviewed, to ensure that laboratory test results are not filed away without review or action by a GP.

137. While acknowledging the thorough review and changes now implemented by the medical centre following these events, I am critical that the medical centre did not have in place an adequate laboratory test result tracking system at the time, that there was no system in place to alert staff to abnormal test results, that there is no record of who filed a particular result, and that an abnormal result may have been filed without the ordering clinician being made aware of it. Overall, I consider that the medical centre failed to provide services to Ms A with reasonable care and skill and, accordingly, breached Right 4(1) of the Code.

Opinion: Adverse comment — the DHB

138. During the time of these events, there were no specific NCSP standards or policies relating to the triaging of a referral to colposcopy for symptoms of inter-menstrual and post-coital bleeding in the presence of a normal smear. The DHB advised my Office that historically such patients were triaged to be seen for a non-urgent colposcopy within six months.

139. It further advised, however, that prior to the time of these events, the two staff members involved in colposcopy gradings at the public hospital made the decision that, as post-coital bleeding is a suspicious symptom that can be associated with malignancy, patients with such symptoms and a normal smear result would be seen semi-urgently (within one to three months) or earlier at the discretion of the colposcopist, depending on the information in the referral letter. However, this decision was not documented.

140. On 10 July 2012, despite the above decision, Dr E graded Ms A's referral and assigned her a grading of "low grade", which had a follow-up time of within six months. Dr E does not recall any rules for grading of colposcopy referrals being present in 2012 when he graded the referral in question. Dr E said that Ms A was graded as low grade/non-urgent because he was guided by the practice of his predecessor, who had graded referrals with post-coital bleeding and a normal cervical smear as non-urgent.

141. My expert advisor, gynaecologist Dr Donna Hardie, confirmed that there were no specific national policies at that time relating to the triaging of a referral for colposcopy for symptoms of inter-menstrual or post-coital bleeding in the presence of a normal cervical smear.

142. The DHB has acknowledged that Ms A's referral was incorrectly graded and should have been graded as semi-urgent, with a timeframe of one to three months. The DHB said that "the previous practice of grading women with normal smears and post-coital bleeding to have a non-urgent colposcopy was followed inadvertently".

143. I am critical that the accepted practice was not followed on this occasion, and that Dr E did not know of the decision that had been made at the time he graded Ms A. This highlights the importance of documenting policies. I note that the DHB has since changed its policy around grading, and this is now documented.

144. I further note that in response to these events the DHB instigated a serious event review and concluded that patients in Ms A's situation (young, with previous cervical abnormalities/previous abnormal smear and post-coital bleeding) will now be graded to be seen within the four-week timeframe.

Opinion: Adverse comment — Laboratory 2

145. On 2 July 2012, Dr B performed two smear tests for Ms A (one for each cervix). Dr B told HDC that it was a busy consultation and that the "cervical smear form filling would have been rushed".

146. Two specimen referral forms were sent to Laboratory 2, one stating that it was for the larger cervix, and one stating that it was for the smaller cervix. Laboratory 2's daily worksheet of "specimens received" documents that two specimens were received. A

Laboratory 2 receipt stamp on the referrals confirms that two laboratory requests were made and that two specimens were sent to Laboratory 2 for testing.

147. Laboratory 2 told HDC that for patients with two cervixes, it would expect to receive two referrals, and would then always produce two reports.

148. On 4 July 2012, Dr B received a smear test result from Laboratory 2, which documented that the result was normal. The report did not state which cervix the result referred to, although it had on it a code matching the sample code Laboratory 2 placed on the specimen referral form for the smaller (right) cervix sample. In addition, there was nothing to indicate to Dr B that this was result one of two taken on 2 July.

149. Dr B thought that there would be only one result, as had occurred previously with Ms A's double smear tests, so she attached that result to a referral to the public hospital's gynaecology clinic for the colposcopy, based on her concerns about Ms A's bleeding.

150. On 5 July 2012 a second smear test result relating to Ms A arrived at the medical centre. This documented that the specimen result was abnormal. Again the report did not state which cervix the result referred to, although it had on it a code matching the sample code Laboratory 2 placed on the specimen referral form for the smaller (right) cervix sample. In addition, there was nothing to indicate to Dr B that this was result two of two taken on 2 July. This result was mistakenly filed as a duplicate and no action was taken.

151. I am critical that Laboratory 2 did not record adequately on the result form which sample the result related to. If it had stated which cervix the result related to, Dr B may have queried whether a further result was due.

Recommendations

152. I recommend that Dr B provide a written apology to Ms A for her breach of the Code. The apology is to be sent to HDC within three weeks of the date of my final report, for forwarding to Ms A.

153. I recommend that the medical centre:

a) Provide a written apology to Ms A for its breach of the Code. The apology is to be sent to HDC within three weeks of the date of my final report, for forwarding to Ms A.

b) Review the operation and effectiveness of the process whereby all tests must be referred to a GP for review and the test remains on-screen until reviewed so as to ensure that laboratory test results are not filed away without review/action by a GP, and report back to HDC within three months of the date of my final report.

154. I recommend that the DHB review the effectiveness of its grading process and report back to HDC within three months of the date of my final report.

155. I recommend that NCSP consider copying patients' doctors in on its correspondence with consumers regarding abnormal results, in order to provide a safety net.

156. I recommend that Laboratory 2 ensure that result reports clearly identify which cervix a report refers to in cases of patients with two cervixes, and report back to HDC within three months of the date of my final report.

Follow-up actions

157.
- A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be sent to the Medical Council of New Zealand and the Royal New Zealand College of General Practitioners, and they will be advised of Dr B's name.

- A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be sent to the Royal Australian and New Zealand College of Obstetricians and Gynaecologists and the National Cervical Screening Unit.

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

Appendix A: Independent general practitioner advice to the Commissioner

The following expert advice was obtained from general practitioner Dr Penny Pawson (née Warring):

"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] and [the medical centre]. In preparing the advice on this case to the best of my knowledge I have no personal or professional conflict of interest.

1. **Documents reviewed**
   a. [The] National Screening Unit 5 November 2013 (NCSP)
   b. Letter of response [Dr B] [the medical centre] 20 August 2013, 13 May 2013
   c. Clinical records [the medical centre]
   d. [Dr F], O & G Consultant [the public hospital] letter to [Dr B] 29th May 2013
   e. Letter [the] Practice Manager [the medical centre] 23rd August 2013.

2. **Complaint**

[Ms A] advises that in July 2012 she went to the GP with post coital bleeding. The GP performed a cervical smear. The GP diagnosed bacterial vaginosis and treated her for this. The smear came back abnormal but [Ms A] advises that she was not informed of the result. In November 2012 [Ms A] went back to the GP as she still had vaginal bleeding. She asked to be referred to a specialist privately. The specialist ([Dr G]) ordered a cervical biopsy. The specialist told her that she had cervical cancer. She then saw [Dr H]. [Ms A] advises that [Dr H] advised her cone biopsy would not be enough and she may need a hysterectomy and possibly radiotherapy. In December 2012 she was referred to [Dr I]. She was diagnosed with stage 1B1 cervical cancer. [She underwent a hysterectomy].

[Ms A] maintains that her GP's delay in diagnosis led to a delay in treatment of some 4–5 months, as she would have been seen at [the public hospital] within 20 days of receipt of a referral stating an abnormal smear, had the GP noted the abnormality on her cervical smear in July.

3. **Provider response(s)**

Cervical cancer is a disease with a long latency period, taking on average 10 to 20 years to develop. This means that screening for the detection and treatment of precursor (precancerous) lesions can be very effective for women who participate regularly in a screening programme.[8]

The National Cervical Screening Programme (NCSP) advises that it is the responsibility of the smear taker to advise women who have had a cervical smear of their results. Women are also advised to follow up their results if they are not reported to them.

NCSP advises that [Ms A's] first cervical smear was in May 1998 (aged 15 years) and the result was negative. Her next smear was 9 years later in 2007, aged 25, and the result was also negative. Subsequent smears in December 2008, February 2010 and April 2012 were also negative. NCSP advise that they have no record of a previous high grade abnormal smear for [Ms A].

NCSP advise that in July 2012 there were two cervical smears results, taken on the same day and recorded in the register, one was assessed as a possible high grade smear (and a recommendation made for specialist assessment), the other smear was assessed as negative.

On the 2nd August 2012 a letter from [the] National Cervical Screening Programme (NCSP) was sent to [Ms A] at her confirmed home address stating 'Your smear taken on 2 July 2012 shows some cells have abnormal changes … Please contact your smear taker to discuss your result if you have not already done so.'

NCSP advise that histology results recorded on the Register from a specimen taken on 3 December 2012 as invasive adenocarcinoma. Subsequent vault smears taken on 3rd April 2013 and 24 July 2013 have been negative.

[Dr B], [Ms A's] GP states in her letter 'I was concerned that in [Ms A's] case both my clinical concern after seeing her cervix and her history of both a past high grade smear and of ongoing abnormal vaginal and post coital cervical bleeding had been ignored by the doctor triaging her referral letter (at [the DHB]). ([Dr F], O & G Consultant) also felt that from [Ms A's] point of view the delay had not altered the final outcome.'

[Dr B] advises she was working in difficult circumstances in early July 2012 as she was in the process of amalgamating two clinics and had Medtech merging two practices databases.

4. Review of clinical records

[Ms A] has a rare congenital bicornuate uterus with a double cervix. This explains why two cervical smear results were recorded on the Register.

Clinical Comment: Congenital uterine anomalies in the general population are estimated to have an incidence of 0.001–10%.[3]

[Ms A] attended the practice nurse in April 2012 and underwent a smear as she was concerned about her symptoms.

She then saw [Dr B] on the 2nd July 2012 with vaginal bleeding after sex.

02-Jul-2012

Subjective

Cx smear — there is uncertainty about the Cx smear performed earlier this year — the nurse expressed to the patient uncertainty about getting the second cx. Given there is ongoing bleeding at intercourse the smear should be repeated

Objective

Bleeding +++ on just touching larger cervix

— lumpy appearance to cervix

2nd smaller cervix looked fine but was covered with blood from when the first cervical smear was taken

Cervix larger

Assessment

Friable tissue on lger cervix

? BV

Plan cervix smear, swabs

Colposcopy regardless of result — from appearance WH GOPC

… History … CIN III — Ca in situ — cervix

Clinical Comment: A copy of the laboratory request form sent by [Dr B] to NCSP on the 2nd July 2012 has not been provided. This information would be relevant in order to see whether [Dr B] mentioned the previous CIN III, and the need for two reports for duplex cervixes.

There are two cervical smear results for the 02 July 2012

1. *'Negative for intra-epithelial lesion or malignancy. Annual smears are indicated because of previous high grade abnormality.'*
2. '*There are atypical squamous cells present. A high grade squamous intraepithelial lesion cannot be excluded (ASC-H)… Referral for specialist assessment is indicated.'*

Clinical Comment: Whilst NCSP advise in their letter to the HDC that they have no record of a previous high grade abnormality, yet they have recorded this since 01-01-2006 on the NCSP Register 'Cytology Test Synopsis Source MIG — Data migration Grade HIGH Grade', and include this in their reporting. There is evidence that NCSP had been advised by [Ms A's] general practice that [Ms A] had both two cervixes and a previous diagnosis of high grade abnormality.

Note: Nurse Practitioner Laboratory Referral/Information provided to NCSP 19 Apr 2012 '*for cervical smear … Last smear: Feb 2012 normal. Previous Cx Hx: 2008 normal, had smears overseas abnormal cells & had ? colposcopy … IMB (intermenstrual bleeding): has had some about 3–4 weeks ago PCB (Post Coital Bleeding) twice recently Cx: Appearance: normal, pink, sl bleeding ? contact ? end of menstruation.'*

Then in bold '***pt has 2 cervixes cytobrush used on both***'

Clinical Comment: *For the optimal recommendation for recall and/or referral to be made for each cytology sample, laboratories must ensure that a woman's full and current screening event history is available at each stage of the screening process and in their analysis.*

Recommendations for recall or referral must be based on the cytological findings of the present slide and the woman's complete gynaecological history in accordance with the Guidelines for Cervical Screening in New Zealand (Ministry of Health 2008).

Laboratory staff must obtain the full and current screening history from the NCSP Register for all women in the gynaecological screening programme.[10]

A referral was made to [the public hospital] gynaecology clinic by [Dr B] on the 4th July 2012 based upon the abnormal appearance of the cervix and a normal cervical smear result.

'for colposcopy given history and current symptoms. Has a previous high grade history noted on smear results, has 2 cx, cx tend to bleed with intercourse.'

Clinical Comment: [Dr B] did not elaborate further on [Ms A's] relevant past history of high grade smear, which may have be useful to the Colposcopist who was assigned grading for that day.

[Dr B] states that the *'second cervical smear result was received by the clinic at 11:15am on the 05/07/2012. This was never seen by myself or I would have sent the referral a second time either by [Laboratory 2] delivery or by fax to the Gynaecology Colposcopy Clinic pointing out the seriousness of the second result.'*

Although the second abnormal result was received on the 5th July, and [Dr B] knew that she had taken two cervical smears from two separate cervixes, [Dr B] wrote to [Ms A] on the 6th July 2012 stating:-

'*I have seen the cervical smear result. I have referred you to gynaecology clinic given the cervical bleeding with slight touch*.' [Dr B] then includes the NORMAL cervical smear result in her letter to [Ms A].

'Negative for intra-epithelial lesion or malignancy. Annual smears are indicated because of previous high grade abnormality.'

Clinical Comment: According to NCSP Policies and Standards[10], the laboratory will report on <u>all</u> cytology samples received.

However, [Dr B] states '*As you will see from the past we never received 2 results for her cervical smears regardless of her 2 cervices including the earlier April 2012 cervical smear taken by the nurse. At that point I have never received 2 results from [Laboratory 2] or any other lab ever for anyone, even when 2 specimens had been sent for whatever reason. I assumed a judgement was made about the cervix in total and that was provided …'*

Clinical Comment: It is the responsibility of the smear taker to advise women who have had a cervical smear of their results. Therefore, if the GP ordered two cervical smear tests, then the GP is responsible for checking the result of both tests.

The RNZCGP Cornerstone Standards Aiming for Excellence 2011 state that *the practice must have an effective system for the management of clinical correspondence, test results and other investigations.*[11]

24.1 There must be a documented policy that describes how laboratory results, imaging reports, investigations and clinical correspondence are tracked and managed.

24.2 All incoming test results or other investigations are sighted and actioned by the team member who requested them or by a designated deputy

24.3 Patients are provided with information about the practice procedure for notification of test results

24.4 The practice can demonstrate how they identify and track potentially significant investigations and urgent referrals

24.5 A record is kept of communications with patients informing them about test results

[The] effective tracking of laboratory results does not necessitate a computerised patient management system. If a computerised system is known to be inadequate or unavailable, then a paper-based tracking system can take its place until such time as the computerised system is available.

In her defence, [Dr B] states that [Ms A] would have received the letter from NCSP advising of an abnormal smear result and that this should have prompted [Ms A] to contact her to enquire why she had received this letter if her smear was normal. However, patients trust their GP to take responsibility for their health, and this second letter may have been confusing for [Ms A], as she had already received a reassuring letter from her GP — including a copy of a normal smear result. Given she had a hard copy of a normal smear result from her GP whom she trusts, it would not be surprising if she then disregarded a [letter] from the NCSP, assuming it to be an error.

[Dr B] also maintains that NCSP subsequently changed [Ms A's] record to a normal smear on the 19th July 2012. And that NCSP need to take some responsibility for the error. (I have been unable to locate such an entry on the 19th July 2012 in the record provided by NCSP.)

Clinical Comment: *Reporting changes to results*

If as a result of a review or later re-screen, there is a change to a woman's result, the revised result must be forwarded with updated recommendations, interpretation and information on the smear adequacy to the smear taker and the NCSP Register.[10]

Upon receipt of [Dr B's] referral dated 6th July 2012, [the colposcopy clinic] assigned [Ms A] as Grade 4: LSIL 'low grade' with a follow up time being 'within six months'.

Clinical Comment: Cervical smears are a type of screening test, rather than a diagnostic test. As such, screening tests are most suitable for asymptomatic patients. Patients with signs or symptoms require diagnostic testing, and in the case of cervical pathology, the most widely used diagnostic testing in New Zealand are colposcopy and biopsy. Cervical smears can be unreliable in the presence of signs or symptoms suggestive of invasive cancer due to the presence of inflammation. *In 30% of new cases of cervical cancer, the patient had recently had a 'PAP' (cervical smear that was interpreted as negative.*[12] *The New Zealand Cervical Screening Guidelines*[8] *state 'if a woman is symptomatic or there is concern about the clinical appearance of the cervix, she must be investigated appropriately with colposcopic assessment.'*

On the 29th May 2013, [Dr F], O & G Consultant [the public hospital] wrote to [Dr B].

'I have been asked to write to you regarding a serious incident review report for your patient [Ms A] …

It is noted that unfortunately she was only referred with her normal smear. As you know she also had an ASUS-H smear that was not attached to the referral. She was graded to be seen within a six month time frame which was not ideal. If her ASUS-H smear had been attached to the referral she would have been graded to be seen within four weeks.

The key issue identified was that she was incorrectly graded as a low grade and to be seen within six months. We have therefore ensured a departmental consensus of how soon we should see patients with suspicious symptoms — which is currently within 3 months.'

5. Summary

In July 2012 [Ms A] presented to her GP [Dr B] with intermenstrual and post coital vaginal bleeding. She had a known history of high grade cervical abnormality CIN III — diagnosed and treated overseas in 2006, and was also known to have duplicate cervixes.

She had previously had a smear in April that year which was reported as normal.

On the 2nd July 2012, [Dr B] took a cervical smear from each of [Ms A's] two cervixes. It is not clear what [Dr B] wrote on the laboratory request form to the NCSP as a copy of the laboratory request form sent by [Dr B] to NCSP has not been provided.

It would be beneficial to obtain this information in order to know whether [Dr B] mentioned her clinical findings on examination, the previous CIN III in 2006, the presence of two cervixes and the need for two reports.

NCSP, as per their Policies and Standards document, reported on both cytology samples.

There were two results, one for each cervix. These results were recorded on the National Cervical Screening Register on the same date, one was assessed as a possible high grade smear (and a recommendation made for specialist assessment), the other smear was assessed as negative, but with the recommendation for annual smears based on a reported previous high grade abnormality.

It is the responsibility of the smear taker to advise her patient of her cervical smear results. [Dr B] failed in her responsibility to notify [Ms A] of her abnormal smear result, which was evident on the second smear. [Dr B] also failed to forward this abnormal result to the [DHB] Gynaecology Outpatients along with her referral.

Given the clinical context, this is a moderate departure from the expected standard of care.

[Dr B] failed to have an adequate laboratory tracking system in place to ensure that incoming test results or other investigations are sighted and actioned by the team member who requested them or by a designated deputy. [Dr B] failed in identifying and tracking potentially significant investigations and urgent referrals. The merge of a Medtech patient management system does not preclude a practice from this responsibility. In the absence of a computerised system, a practice can temporarily convert to a paper based one.

The lack of an adequate laboratory tracking system is a moderate departure from the expected standard of care.

[Dr B] maintains that NCSP only produces one smear report even when two smear samples are sent for cytology; and that this is the reason that she presumed that [Ms A's] smear was normal, based on her experience of only ever receiving one report for two samples belonging to the same patient. However, this would go against NCSP Policies and Standards.[10]

It would be beneficial if NCSP could provide further comment as to their policy for dealing with 2 smear specimens from the same patient. Does NCSP provide a separate report for each and all specimens received?

It would also be beneficial for the NCSP to advise whether they have retained and reviewed previous slides for the 42 months prior to [Ms A's] diagnosis of adenocarcinoma as per the NCSP Policies and Standards[10].

If NCSP have reviewed [Ms A's] previous slides have they identified any reading or reporting errors. If so, was a high grade abnormality seen or suspected on earlier slides.

[Dr B] was aware of [Ms A's] previous high grade abnormality (CIN III — 2006); yet [Ms A] did not have annual smears as recommended.

Instead she had smears taken in 2007, 2008, 2010, and twice in 2012. As per RNZCGP Cornerstone Guidelines[11] [the medical centre] is responsible for having

an adequate screening and recall system in place. *The practice must also regularly audit screening and recall activities to review its effectiveness in reaching eligible target populations.* It would be beneficial to find out whether [the medical centre] had set-up a regular cervical smear recall for [Ms A], and at what frequency.

Was [Ms A] sent reminder letters for her annual smear in 2009 and 2011, or did the recalls in either or both of these years not occur? What system does [the medical centre] have in place when at-risk patients fail to respond to a cervical smear recall? Has [Dr B] audited her recall system, if yes, what were the results?

A full copy of [Ms A's] clinical notes from [the medical centre] dating from 2006 to July 2012, including detailed history of [Ms A's] previous high grade cervical abnormality, and gynaecological history, classification list, recall letters, laboratory results received, and copies of laboratory forms written would be beneficial in order to fill in some of the missing gaps in this enquiry.

Lastly, an expert gynaecologist's opinion may be valuable in answering the following question:-

1. Please provide your opinion on the assigned Colposcopy grading of [Ms A] based on the clinical information provided by [Dr B] in her referral letter of the 4th July 2012.
2. If the result of the second smear had been provided by the GP, would this have altered the assigned Colposcopy grading, or outcome for [Ms A]?
3. Would, in your opinion, [Dr B's] provision in her referral letter of a somewhat vague past history of a high grade smear (CIN III) have affected [Ms A's] Colposcopy grading?
4. How soon should [Ms A] have been seen at the Colposcopy Clinic based on her presentation of 2 July 2012?
5. Please comment on the grade of cervical cancer when it was diagnosed in December 2012.
6. Had her cancer been diagnosed earlier, in July 2012, would this have made any difference to her treatment and prognosis?
7. An overall opinion regarding this case.

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Dr Penny Warring"

Further expert advice was received from Dr Warring on 22 April 2014.

"Thank you for the request that I provide further clinical advice based upon new medical information, in relation to the complaint from [Ms A] about the care provided by [Dr B] and [the medical centre]. In preparing the advice on this case to the best of my knowledge I have no personal or professional conflict of interest.

Documents reviewed

a. [The] National Screening Unit 5 November 2013 (NC SP)
b. Letter of response [Dr B] [the medical centre] 20 August 2013, 13 May 2013
c. Clinical records [the medical centre] 2006–2012
d. [Dr F], O & G Consultant [the public hospital] letter to [Dr B] 29th May 2013
e. Letter [the] Practice Manager [the medical centre] 23rd August 2013
f. Further response [Laboratory 2] 8th April 2014

This report is to be read in conjunction with my opinion of 8th January 2014.

Summary

[Ms A] enrolled with [Dr B] at [the medical centre] on the 13th of November 2008.

In April 2012, and again in July 2012 [Ms A] presented with intermenstrual and Post coital vaginal bleeding, the first time to the practice nurse and on the second occasion, to her GP [Dr B].

[Dr B] was well aware of [Ms A's] history of high grade cervical abnormality CIN (Cervical Intra-epithelial Neoplasia) III, duplicate cervixes, and bicornuate Uterus, having directly sought and obtained [Ms A's] previous gynaecology records from [overseas] on the 11th May 2009.

These records contained the following information:

Whilst [Ms A] was [overseas] she underwent a colonoscopy in 2003 for cervical warts. Then in April 2004, she underwent a second colonoscopy and was found to have CIN III in her larger, left cervix, and CIN l in her smaller, right cervix. In June 2004, [Ms A] underwent a partition loop biopsy of her double cervix. The loop biopsy of the larger left cervix confirmed CIN III with clear margins. However, the loop biopsy of the smaller right cervix confirmed high grade CIN involving the endocervical margin and also high grade CGIN (Cervical Glandular Intra-epithelial Neoplasia).

The [overseas gynaecologist] then writes in her report, dated 28th September 2005 '*Following this it was planned that she should have a transvaginal scan in order to assess what further surgery would be needed and that this should be done in such a way as to conserve her child bearing capabilities ([Ms A] has never been pregnant). This scan was undertaken in September 2004 and this scan confirmed a bicornuate uterus with double cervix. No additional pathology was noted … At this stage she was referred to [another hospital] as she moved to this area. She appears to have attended clinics in [the area] on two occasions … She came to see me at the beginning of September and requested that she be referred for colposcopy investigation locally … I would be grateful if she could be offered an appointment and followed up.'*

It is clear from this correspondence that [Ms A's] cervical condition necessitated close follow-up by consultant gynaecologists during her period of time [overseas].

[Ms A] had a further smear and colposcopy on the 8th December 2005 [overseas], this was reported as normal.

[Ms A] had a smear [performed upon her return to New Zealand on the 1st May 2007], this was reported as negative.

[Dr D], Consultant obstetrician and gynaecologist [overseas], wrote in his report dated the 8th January 2008, that he recommended that she is seen in one year's time in his clinic.

[Ms A] enrolled with [Dr B] on the 13th November 2008.

[Dr B] performed a cervical smear on the 18th December 2008. However, only one cervical smear sample was received by the laboratory and therefore one report was returned. The records are not clear as to whether samples were taken from both cervixes or not.

[Dr B] sent a smear recall letter one year later on the 18th December 2009. A further letter followed dated 15th January 2010, stating that the practice had had difficulty contacting [Ms A] to give her some laboratory results, as she had possibly changed phone numbers, and that she was still due for her next cervical smear.

[Ms A] then had her next cervical smear on the 19th February 2010. However, once again, only one cervical smear sample was received by the laboratory and therefore one report was returned. The records are not clear as to whether samples were taken from both cervixes or not.

On the 25th February 2010 a letter was sent to [Ms A] by the practice advising that her smear was normal.

Then there was a delay. Her next cervical smear Recall Letter was not sent until the 2nd June 2011. [Dr B] explains that an error had occurred and [Ms A's] cervical smear recalls were put at 3 yearly instead of annually. By the time this error was noted and corrected, [Ms A] was pregnant, so her recall was set to be 3 months after giving birth. However, [Ms A] had a miscarriage. The opportunity was not taken at this point to reschedule a sooner smear and [Ms A] was not recalled for a smear until the 20th May 2012, now more than 2 years after her last smear.

However [Ms A] presented to the practice nurse for a smear sooner than this, on the 19 April 2012, as she had developed intermenstrual and post coital bleeding.

The nurse took a smear, and advised [Ms A] to book in to see [Dr B]. The nurse wrote a detailed history on the laboratory referral form including 'cytobrush used on both (cervixes)' and '2 x smear'. However, only one cervical smear sample was received by the laboratory and therefore one report was returned. Furthermore, from [Dr B's] notes 2nd July 2012:-

Cx smear — there is uncertainty about the Cx smear performed earlier this year — the nurse expressed to the patient uncertainty about getting the second Cx.

'*[Laboratory 2] confirms one vial received 19 April 2012 [reference number 1]. The usual process for receipt of more than one vial is to identify, label and process and report separately.'* [The] CEO

On the 23 April 2012, [Ms A] was sent a letter from the practice advising that her smear was normal.

[Ms A] returned to see [Dr B] on the 2nd July 2012. Her intermenstrual bleeding and post coital bleeding had persisted. [Dr B] noted that her cervix looked

abnormal 'lumpy' on examination. She took a smear from each cervix, and made two separate referral forms this time. Two samples were received by [Laboratory 2]. Two reports were received into [Ms A's] patient inbox. [Dr B] only noted the normal result and advises that she did not see the other abnormal result, and that she was not expecting two reports.

The second cervical smear result was received by the clinic at 11.15am on the 05/07/2012. This was never seen by myself or I would have sent the referral a second time either by [Laboratory 2] delivery or by fax to the Gynaecology Colposcopy Clinic pointing out the seriousness of the second result.

As you will see from the past we never received 2 results for her cervical smears regardless of her 2 cervices including the earlier April 2012 cervical smear taken by the nurse. At that point I have never received 2 results from [Laboratory 2] or any other lab ever for anyone, even when 2 specimens had been sent for whatever reason. I assumed judgment was made about the cervix in total and that was provided …'

However, the only time that the practice did send two cervical smear specimens for [Ms A] on the same day to the laboratory for analysis, appears to be the 2nd July 2012.

On the 4th July 2012, [Dr B] sent a referral letter to the [DHB] Gynaecology Department, requesting a colposcopy appointment due to [Ms A's] cervical symptoms previous high grade abnormality, and abnormal appearing cervix.

For colposcopy given history and current symptoms. Has a previous high grade history noted on smear results, has 2 Cx, Cx tend to bleed with intercourse.

However, [the] colposcopy clinic assigned [Ms A] as Grade 4: LSIL 'low grade' with a follow up time being 'within six months'.

Cervical smears are a type of screening test, most suitable for patients who do not have any symptoms. They are not a diagnostic test. Patients with signs or symptoms do require diagnostic testing, and in the case of cervical pathology, the most widely used diagnostic testing in New Zealand is colposcopy and biopsy.

The New Zealand Cervical Screening Guidelines[1] state '*if a woman is symptomatic or there is concern about the clinical appearance of the cervix, she must be investigated appropriately with colposcopic assessment'.*

On the 29th May 2013, [Dr F], O & G Consultant [the public hospital] wrote to [Dr B]

'I have been asked to write to you regarding a serious incident review report for your patient [Ms A] …

It is noted that unfortunately she was only referred with her normal smear. As you know she also had an ASUS-H smear that was not attached to the referral. She was graded to be seen within a six month time frame which was not ideal. If her ASUS-H smear had been attached to the referral she would have been graded to be seen within four weeks.

The key issue identified was that she was incorrectly graded as a low grade and to

be seen within six months. We have therefore ensured a departmental consensus of how soon we should see patients with suspicious symptoms — which is currently within 3 months.'

However, cervical smears can be unreliable in the presence of signs or symptoms suggestive of invasive cancer due to the presence of inflammation. *'In 30% of new cases of cervical cancer, the patient had recently had a PAP' (cervical smear that was interpreted as negative.*[2]

Following [Ms A's] abnormal smear of 3 December 2012 (invasive adenocarcinoma), [Laboratory 2] performed a retrospective analysis for the 42 month period prior to the confirmed high grade abnormality. [Laboratory 2] found that the previous negative cytology of 19 April 2012 needed to be revised to 'glandular cells consistent with adenocarcinoma'. However, [Laboratory 2] points out the low sensitivity of the Cervical Smear screening test in detecting high grade squamous abnormalities, and that glandular lesions are even more difficult to detect with cervical smear.

The clinical information provided on the request forms for all 3 specimens was adequate (as enclosed). When 2 vials were received the form and the specimen were clearly identifiable and labelled (note: notation of in-house check on specimen [reference number 2]). The quality of the request information received was excellent and had no impact on the nature or accuracy of the reporting.

Retrospective viewing of the 19 April specimen [reference number 1] was undertaken as part of the NCSP Policies and Standards, specifically standards 521 and 522. All negative cytology ([reference number 1]) in the 42 month period prior to a hi-grade result ([reference number 2]) is required to be reviewed as part of the standard. At this stage the previous negative cytology was revised to 'glandular cells consistent with adenocarcinoma.'

Laboratories are required to review (and report to the NCSP) negative results within 42 months prior to a confirmed high grade abnormality. The nominal standard is that not more than 20% of these should be classified as abnormal on review. We are comfortably under this limit (<10%) and none of the other performance indicators suggest we have a problem with low sensitivity. Our high grade abnormality rate and positive predictive values are comparable with other New Zealand laboratories.

The sensitivity of the Cervical Smear in detecting high grade squamous abnormalities in patients is low (approx. 60%). The sensitivity of screener in detecting abnormalities is high but not 100%. Glandular lesions are even more problematic. There will always be false negative results and some of these will be laboratory false negatives. Given this no single case can reasonably be used as an indicator of performance. [The] CEO.

Comments:
When [Ms A] enrolled with [Dr B] in November 2008, [Dr B] obtained [Ms A's] history of high grade cervical abnormality UN III (2004), duplicate cervixes, and

bicornuate uterus. The specialist gynaecologist in her letter of September 2005 had recommended annual appointments at the Colposcopy Clinic and had discussed that further surgery may be needed.

It would have been appropriate at this point, given [Ms A's] gynaecological history, for [Dr B] to engage [Ms A] with the [DHB] Gynaecology Team, in order that regular Colposcopy appointments and surveillance could be arranged. The reasons are firstly that [Ms A] had regular colposcopic follow up [overseas] for a high grade cervical abnormality, and secondly that cervical smears are a screening test for asymptomatic women and are not to be used as a diagnostic test.

In December 2008, February 2010, and Apri1 2012, the laboratory received only one cervical specimen for analysis, and one request form. The clinical notes are unclear as to whether both cervixes were sampled although the nurse noted she had difficulty with the second smaller cervix in April 2012. Hence One Cytology report was provided to the practice on each occasion.

It was only on the 2nd July 2012 when two cervical specimens were received by the laboratory, two specimens were processed, and both were reported on.

In February 2011, the practice failed to recall [Ms A] for an annual smear, due to incorrectly allocating [Ms A] a 3 year recall following her February 2010 smear.

The practice then recalled [Ms A] for a smear in June 2011, but [Ms A] was noted to be pregnant in July 2011. [Ms A] was under the care of a midwife. Consideration could have been given at this point for a referral to the high risk pregnancy clinic at [the public hospital] given her known bicornuate uterus although [Ms A had a successful pregnancy and birth.]

The practice then missed the opportunity to arrange a cervical smear for [Ms A] when she presented on the 5th September 2011 having miscarried […] weeks earlier.

In April 2012, when [Ms A] presented with intermenstrual and post coital bleeding, the practice nurse recommended that [Ms A] should see [Dr B] for review regarding her abnormal cervical symptoms. Particularly in a patient with a significant past history of high grade abnormality these symptoms require urgent follow-up as they are suggestive of cervical cancer.

This presented a missed opportunity for the practice nurse to call [Dr B] into her room to review [Ms A] at the time. Alternatively the practice nurse may have considered discussing [Ms A's] current symptomatology with [Dr B] that day, so that [Dr B] could have arranged for [Ms A] to come in for an urgent appointment with her.

However, [Ms A] did not see [Dr B] for nearly 3 months.

On the 2nd July 2012, [Dr B] took a cervical smear from each of [Ms A's] cervixes, and sent off two laboratory request forms. She was concerned about [Ms

A's] persistent symptoms and the abnormal appearance of the larger left cervix, and sent off a referral to the Colposcopy Clinic.

[Dr B] sent two specimens each with its own laboratory request form, but failed to look for two cytology reports.

NCSP follow their Policies and Standards[3] and do report on all samples received.

They have also reviewed previous slides for the 42 months prior to [Ms A's] diagnosis of invasive adenocarcinoma in December 2012 and found the presence of glandular cells consistent with adenocarcinoma in the 19 April 2012 sample. [Laboratory 2] have reported that their smear analysis meets the required performance indicators.

It is the responsibility of the smear taker to check for and advise her patient of her cervical smear results. [Dr B] failed in her responsibility to notify [Ms A] as well as the [DHB] Gynaecology Outpatients of the abnormal smear result.

[Dr B] is the primary advocate for her patient. She was concerned about [Ms A's] symptoms and abnormal appearing cervix. She sent a referral to [the public hospital] Colposcopy Clinic on the 4th July 2012. However, when the referral was returned low priority, it was [Dr B's] responsibility to chase up the Colposcopy Clinic if she felt that [Ms A's] symptoms and signs were suggestive of cervical cancer, and to insist that her patient was seen sooner.

[The public hospital's] Colposcopy Clinic failed to give [Ms A] a high priority colposcopy appointment, i.e. to be seen within 4 weeks, despite her past hístory of high grade lesion, and current symptoms and signs suggestive of cervical cancer. The Clinic has subsequently advised that the reason for the low priority grading was the normal smear. However, cervical smears can be unreliable in the presence of signs or symptoms suggestive of invasive cancer because of the presence of inflammation. Therefore, it seems to have been a significant oversight of [the] Colposcopy Unit, to effectively ignore [Ms A's] significant signs and symptoms and to assign [Ms A] a Grade 4 low priority appointment based on a 'normal' smear result.

I would consider this to be a moderate departure from the expected standard of care.

Overall, [Dr B's] management of [Ms A's] cervical condition has been a moderate to severe departure from the expected standard of care. She has failed to follow through on important referrals, recalls, and investigations. Her approach to [Ms A's] care seems to have been casual, and disorganised.

References

1. The Guidelines for Cervical Screening in New Zealand. Published in August 2008 by the National Screening Unit, Ministry of Health, PO Box 5013, Wellington.www.nsu.govt.nz/Files/NCsp/NCsp Guidelines_ALL_small(l).pdf. PDF file

2. Jin XW, Sikon A, Yen-Lieberman B. *Cervical Cancer Screening: Less testing, smarter testing.* Cleveland Clinic Journal of Medicine. 2011 Nov; 78(1 l):737–47.

3. https:////www.nsu.govt.nz/.../NCSP_Policies_and_Standards_Section_5_Providing a Laboratory Service

4. RANZCOG (Royal Australian and New Zealand College of Obstetrics and Gynaecology). 2002. Guidelines for Referral for Investigations of Inter-menstrual and Postcoital Bleeding. Statement No. C-Gyn 6.

   www.ranzcog.edu.au/publications/statements/C-gyn6.pdf"

Further expert advice was received from Dr Warring on 18 August 2015:

"Thank you for the request that I provide further clinical advice to the Commissioner in relation to the complaint from [Ms A] about the care provided to her by [Dr B]. In preparing the advice on this case I have read and agree to follow the Commissioner's Guidelines for Independent Advisors. To the best of my knowledge I have no personal or professional conflict of interest.

The issues that the Commissioner is seeking advice on is:

- Whether [Dr B's] response, dated 1 September 2014 changes your previous advice in any way, in particular, [Dr B's] comments and the further information provided by [Laboratory 1], regarding [Ms A's] smears taken in 2008 and 2010; and
- Whether [the medical centre's] response changes your previous advice in any way.
- Please also comment on anything else you consider relevant.

1. Documents reviewed

a. Clinical Records as provided by [Dr B] [the medical centre]
b. Letter of response [Dr B] [the medical centre] dated 1 September 2014
c. Letter of Response Directors [the medical centre] (undated)
d. Email from [Laboratory 2] dated 27 July 2015
e. Email from [Laboratory 1] dated 10 August 2015
f. [Ms A's] screening history
g. HDC Expert opinion Dr Penny Warring 6 January 2014, 22 April 2014

2. Further Response

- [Ms A] (31 years old at the time) had a bicornuate uterus with a double cervix. In 2003, when she was living [overseas], she underwent a colposcopy for cervical warts.
- One year later, in April 2004 she underwent colposcopy and was diagnosed with CIN III, of her larger Left cervix; and CINI of the smaller Right cervix. CIN refers to abnormalities of the outer squamous cells of the cervix.
- In June 2004, [Ms A] underwent loop biopsy of both cervixes. This confirmed CIN III of the Left cervix with clear margins, and high grade

CIN involving the endocervical margin and also high grade CGIN (Cervical Glandular Intra-epithelial Neoplasia, which is also known as Adenocarcinoma in situ) of the smaller Right cervix.

- CGIN refers to abnormalities of the inner glandular cells of the cervix, and is therefore a separate disease process that affects different cells as compared with CIN.
- At this time [Ms A] was followed up closely by specialist gynaecologists — in September 2004 a transvaginal scan was undertaken to see what further surgery may be required, with a plan that any surgery would be done in such a way as to conserve her child bearing capabilities. As no additional pathology was found, further surgery was not needed at that stage.
- [Ms A] moved to [another region]. She was referred on by her current specialist to a new specialist for regular gynaecology follow up [in that region].
- [Ms A] was followed up regularly by the gynaecology specialists with consultation, smear and colposcopy.
- The latest [overseas] report dated 8th January [2006], written by [Dr D], obstetrician and gynaecologist], indicated that [Ms A] should be seen by him in one year's time.
- [Ms A] returned to New Zealand and enrolled with [Dr B] at [the medical centre] on the 13th of November 2008.
- (As per [Dr D], [Ms A] was now due for a specialist gynaecologist appointment with colposcopy and smear.)
- [Dr B] performed a cervical smear on the 18th November 2008. Given [Ms A's] high risk cervical history as outlined above, and ongoing specialist surveillance and monitoring [during her time overseas], I consider that on enrolment with [the medical centre], accepted practice would have been for [Dr B] to refer [Ms A] to [the] Gynaecology Colposcopy Clinic for regular specialist follow up and review. [Dr B] did not do this.
- [Dr B] was aware of the details of [Ms A's] cervical history as she had obtained [Ms A's] [overseas] gynaecology records on the 11th May 2009.
- The fact that [Dr B] chose instead to treat [Ms A] herself, I consider to be a moderate to severe departure from accepted practice. I consider that my peers would agree with this view.
- With regards to the **18 December 2008 cervical smears**, [Dr B] maintains that she took a cervical smear sample from both the larger Left and the smaller Right cervixes.
- With anatomical abnormalities such as a bicornuate uterus and double cervix, structural orientation and size of the cervixes can make it difficult for a GP to get a reliable sample from the cervix. [Dr B] wrote in her clinical records that day '2 cervix — one hard to find and hard to enter'. In other words, a false negative result is possible if either one of the cervixes is not sampled adequately due to physical and structural restraints. Early specialist involvement would be accepted practice for this reason alone.
- A previous history of loop biopsy of the cervix also makes obtaining a reliable cervical smear sample in the general practice setting challenging. This would be another valid reason for onward referral to a specialist.

- [Laboratory 1] confirms that two cervical smear samples were received and processed on this day. One report was issued. [Laboratory 1] has advised that if each vial clearly indicated Right or Left cervix then they would report each separately and indicate on each report whether it was the Right or Left cervix. 'If we just receive two vials however with no indication of each being from a different site, we process both vials and issue one report.'
- When sending in more than one pathological sample it is accepted practice to clearly label each sample with the site it was taken from. This would enable the treating practitioner to know which site had the abnormality, if an abnormal result was returned.
- With regards to the **19th February 2010 cervical smears**, [Dr B] maintains that she took a cervical smear sample from both the larger Left and the smaller Right cervixes, and is confident that 2 smear samples were obtained and supplied to the laboratory. [Laboratory 1] confirms that only one sample was received and processed. The clinical records are not clear as to whether both cervixes were sampled or not. Had they both been sampled, but only one vial used, then this would make it difficult for the treating doctor to interpret an abnormal result without knowing which site it referred to (Left or Right Cervix).
- Given [Ms A's] history of different disease processes affecting the two cervixes it would be best practice to sample each cervix and put the sample in separate, clearly labelled vials. That being said, one school of thought may be that in putting two cervical smear samples in one vial, if an abnormality is found, then the patient would undergo colposcopy with a gynaecologist anyway, in which case both cervixes would be sampled.
- It is commonly accepted practice that specimens sent to the lab will be labelled correctly. This includes first and last name, date of birth and/or NHI number, time and date of specimen collection, and requesting doctor's name. Histology specimens will be labelled with the site that corresponds with the request, as well as type and numbering of the samples[4]. Multiple specimens requiring individual diagnoses would be expected to be placed in separate containers.
- I note that the lab forms that were sent did not indicate on the form what number of specimens were collected. This is a good point of reference for the lab staff when the specimen arrives at the lab. The lab staff then know what has been collected and can look for any outstanding specimens not received knowing they have been collected.[4]
- In cases like this, where there is identified high risk and something different or atypical about the case — in other words needing to watch out for two cervical smear reports instead of one, or watching out for a cervical smear report in a patient with high risk, accepted practice is for the treating doctor to set a task in the patient management system to look for two results — thus ensuring that the general practitioner is reminded to look for the result and the test result is not missed.
- Identification errors can be classified as preanalytic, analytic, and postanalytic. All 3 types are of concern to pathologists. Preanalytic, or 'clinical', errors can be addressed by standardisation of the specimen

collection process and feedback to clinical staff. Labeling errors have been categorized as class 1, typographical errors with no clinical consequences; class 2, minor errors unlikely to have clinical consequences; and class 3, errors that are significant and have the potential to detrimentally impact patient care.[2]

- With regards to the **19 April 2012 smears**, I note that on the **16 April 2012** [Ms A] called the practice asking for a smear with [Dr B]. Instead she was offered a smear with the practice nurse.
- [Dr B] maintains that the practice nurse [RN C] took two cervical smears, and that a smear sample was taken from each cervix with a cytobrush. [Laboratory 2] confirms that only one vial was received. The records suggest but do not confirm that both cervixes were sampled. Only one vial used.
- During this **19 April 2012** consultation [Ms A] advised of her previous abnormal cells overseas, her post coital (PCB) and intermenstrual bleeding (IMB). The nurse noted sl bleeding on contact. She advised [Ms A] to see the GP re post coital bleeding and intermenstrual bleeding.
- It was important at this point to exclude a malignancy and I would consider accepted practice in a patient with this history and clinical presentation for the nurse to talk with the GP directly.
- When [Dr B] sent her referral to the [the public hospital] gynaecology clinic on the **4th July 2012** the referral was not adequate as it did not clearly state the specific details of [Ms A's] relevant cervical history — in other words:- CIN III, larger Left cervix 2004; CIN involving the endocervical margin and also high grade CGIN smaller Right cervix 2004.
- This information, along with the current clinical symptoms and presentation, and importantly the result of her second smear, would have resulted in a colposcopy appointment within four weeks.
- I note that the recent records provided by [Dr B] show an entry dated **02-Jul-2012 IBx: Gynaecological Cytology - ? High grade squamous** … this result has been electronically signed off by '**RUPS**'.
- I compare this with my previous opinion, where I have noted that [Dr B] states 'the second cervical smear result was received by the clinic at 11:15am on the 05/07/2012. This was never seen by myself or I would have sent the referral a second time …'
- Abnormal results are usually colour coded in red, in the PMS system or with some other alert, so that the general practitioner's attention is drawn to look at the abnormal result.
- [Dr B] has explained that she has never received two results for her cervical smears regardless of her two cervixes, and this is the reason why she did not look for two reports despite sending in two vials and two referral forms — labelled 'smaller cervix' and 'larger cervix'.
- [Dr B] advises that she would have notified [the] Colposcopy clinic immediately if she had been aware of the second abnormal smear. However, it is the responsibility of the smear taker to look for the cervical smear result and advise her patient of her result.

- Therefore, as [Dr B] ordered two cervical smear tests, [Dr B] is responsible for checking and informing her patient of the result of both tests.
- [Dr B] did not check and inform her patient of the second result. She also did not forward this abnormal result of the second smear to the [DHB] Gynaecology Outpatients. Had she done this, [Ms A] would have been seen for a Colposcopy within 4 weeks.
- I understand that the practice was going through a transition period whilst it was amalgamating with another practice. Irrespective of this, it is the practice's responsibility to ensure that an adequate laboratory tracking system is in place, whether this be paper or computer based.
- When the referral to [the] Colposcopy Clinic was returned 'routine' with an approximate waiting time of 6 months, [Dr B] says that she assumed that the specialist had graded [Ms A] taking the details of her history and symptoms into account that she had provided.
- As stated above, the cervical history provided by [Dr B] had inadequate detail.
- Secondly, as outlined above, I believe that [Ms A] should have been referred for Gynaecology Specialist review and follow up in November 2008, when she first enrolled with the clinic. I consider that my colleagues would agree with this view.
- [Dr B] also states at this stage she suspected early cervical endometriosis, but I note that this is not documented in her clinical notes.
- The cervix is regarded as an infrequent localization for endometriosis. In a colposcopic examination series published in 1987, the incidence of cervical endometriosis was reported to be between 0.11% and 2.4%.[5]
- Most patients with endometriosis of the cervix do not have any symptoms.[5,6,7]
- The most commonly reported symptoms in patients with endometriosis are painful menstruation, typically involving abdominal cramps (60% to 80%), pelvic pain (30% to 50%), and infertility (30% to 40%).[6] [Ms A] did not complain of any of these symptoms.
- [Ms A's] principal complaint was of inter-menstrual bleeding and post-coital bleeding. Menstrual irregularity is reported by only 10% to 20% of patients who have endometriosis, with a lower incidence in patients with cervical endometriosis[5,7]. In Veiga-Ferreira's series, only 2 of the 16 cases of cervical endometriosis complained of irregular bleeding (12.5%).[5]
- Based on [Ms A's] symptoms, clinical signs on examination and past history of CIN III, larger Left cervix 2004; CIN involving the endocervical margin and also high grade CGIN smaller Right cervix 2004, accepted practice would be for the GP to seek to exclude a cervical malignancy.
- As described above, cervical endometriosis is an uncommon diagnosis and would be a low diagnostic possibility given [Ms A's] presentation.
- Cervical Cancer affects 7 in 100,000 NZ women.

3. Opinion

Whether [Dr B's] response, dated 1 September 2014 changes your previous advice in any way, in particular, [Dr B's] comments and the further

information provided by [Laboratory 1], regarding [Ms A's] smears taken in 2008 and 2010.

In my view, [Dr B's] response provides further evidence that supports my previous opinions. In essence there were multiple systemic and GP initiated errors in this case. When [Ms A] first enrolled at the [the medical centre], [Dr B] decided to treat [Ms A] herself, instead of refer [Ms A] to a specialist gynaecologist for ongoing monitoring and surveillance. Review of the 2008 and 2010 smears reveals pre-analytical clinical errors in labelling brought about by a lack of standardisation or method to the specimen collection process. Recalls for annual cervical smear screening fell through due to an inadequate patient recall system. There were deficiencies in laboratory tracking so that important results were missed. It is the responsibility of the GP to follow up on test results and have an adequate test tracking system in place. [Dr B] did not check for and inform her patient of the second cervical smear result. [Dr B] did not forward this abnormal result of the second smear to the [DHB] Gynaecology Outpatients. In July 2012 [Dr B] considered that [Ms A's] presenting signs and symptoms were most consistent with cervical endometriosis, an atypical condition that does not match [Ms A's] cervical history and clinical presentation. Accepted practice would be to take appropriate steps to exclude a malignancy. It is the responsibility of the GP to advocate for her patient. When [Ms A's] Gynaecology referral was returned 'routine' [Dr B] did not chase up the Colposcopy Clinic. In my view [Dr B's] management of [Ms A's] cervical condition represents a moderate to severe departure from accepted practice. I believe that my peers would agree with this view.

Whether [the medical centre's] response changes your previous advice in any way.

The practice has made significant positive changes. This includes morning discussion/training sessions, a robust laboratory tracking system, protocol for laboratory result checking and filing, protocol for nurse practitioner smears and escalation of problems identified; the practice now ensures that two separate referral forms are sent to the laboratory when two smear samples are taken and ensure that two reports are received from the lab, a cervical smear audit is performed every 3 months, there is a quarterly review of cervical smear recall lists, there has been introduction of a common form (template) for cervical smear consultations, audit of higher risk patients, introduction of enhanced recall activities, monitoring of the triaging of referrals.

It also remains my opinion that [Dr B's] management of [Ms A's] cervical condition from November 2008 to January 2013 represents a moderate to severe departure from accepted practice. I believe that my peers would agree with this view.

Please also comment on anything else you consider relevant.

When [Ms A] enrolled at the [the medical centre], [Dr B] obtained her gynaecological records. These records revealed that [Ms A] was under careful specialist monitoring and surveillance in the [overseas] with the clear intent that this surveillance should continue. I consider that [Dr B's] decision to treat [Ms A] herself instead of refer [Ms A] to a specialist gynaecologist for ongoing

monitoring and surveillance was practising outside of her scope of clinical expertise.

In July 2012 [the] Colposcopy Unit relied on the normal smear in making the routine grading for [Ms A], with less importance placed on the symptoms that [Ms A] 'Has a previous high grade history noted on smear results, has 2 cx, tend to bleed with intercourse'. Had [Dr B's] referral been more detailed, as outlined above, this may have made a difference. I note that [Dr F] 29th May 2013, advises that the department now has a consensus on how soon they should see patients with suspicious symptoms — and they have changed their assessment system to see patients with suspicious symptoms within 3 months.

If you have any further questions regarding this opinion please do not hesitate to contact me.

Dr Penny Warring

Independent Clinical Advisor

References

1. Cervical Screening in New Zealand. A brief statistical review of the first decade. National Screening Unit New Zealand. Published in February 2005 by the National Cervical Screening Programme, Ministry of Health, PO Box 5013, Wellington, New Zealand.
2. Layfield LJ, Anderson GM. Specimen Labelling Errors in Surgical Pathology. An 18-Month Experience. DOI:10.1309/AJCPHLQHJ0S3DFJK (2010). American Journal of Clinical Pathology, 134, 466–470.
3. [Laboratory 2 Specimen Collection Best Practice Tips].
4. [Laboratory 2 Specimen Collection Guidelines]
5. Veiga-Ferreira MM, Leiman G, Dunbar F, Margolius KA. Cervical endometriosis: facilitated diagnosis by fine needle aspiration cytologic testing. Am J Obstet Gynecol. 1987; 4(pt 1):849–856.
6. Shaw RW (1993) An Atlas of Endometriosis. Carnforth: Parthenon Publishing Group Ltd.
7. Seval MM, Cavkaytar S, Atak Z, Guresci S. Postcoital bleeding due to cervical endometriosis. BMJ Case Rep. 2013;2013."

Appendix B: Independent registered nurse advice to the Commissioner

The following expert advice was received from RN Rosemary Minto on 18 August 2015:

"I, Rosemary Minto, have read and agreed to follow the Guidelines for Independent Advisors as described in the documentation I have received from the Office of the Health and Disability Commissioner.

I am a Registered Nurse and adult family Nurse Practitioner, having graduated from Tauranga Hospital School of Nursing in 1983. I received a Masters in Health Practice in 2006 and gained NP registration in 2008. I have worked in general practice since 1999 and have been a smear taker since that time.

My instructions from the Investigator for this report are to provide advice on the following:

1. The appropriateness of two smear samples taken from two cervix and appearing to have been placed in the one specimen vial.
2. The appropriateness of [RN C's] care of [Ms A] and the followup advice to her on the 19th April 2012, taking into account [Ms A's] history.
3. [RN C] not referring [Ms A] for a colposcopy following the 19th April 2012 appointment.
4. Any other issues arising from these facts and the information provided.

I have been provided with the following information:

Copies of [Ms A's] medical notes from her appointment with [RN C] on the 19th April 2012
Statement from [RN C] dated 17th December 2014
Copy of specimen form sent to [Laboratory 2] dated 19 April 2012
Copy of report from [Laboratory 2] regarding the above specimen
Copy of the Guidelines for Independent Advisors, effective from 31 July 2014

Opinion
In my deliberations of this issue I have utilized the National Screening Unit Cervical Smear guidelines (2010), The National Screening Unit Guidance on HPV screening, and the NZ Nursing Council Competencies for Registered Nurses.

I have assumed that as a smear taker [RN C] attends regular professional education updates regarding cervical smeartaking.

a. The appropriateness of two smear samples taken from two cervix and appearing to have been placed in the one specimen.

1a. In my opinion two separate samples — one from each cervix — should have been taken and submitted for testing.
1b. This is a failure by [RN C] to meet Competencies for Registered Nurses 2.1: Provides planned nursing care to achieve identified outcomes to a moderate degree.

b. The appropriateness of [RN C's] care of [Ms A] and the follow up advice to her on the 19th April 2012, taking into account [Ms A's] history.

The documentation provided by [RN C] shows that the history taking prior to the smear lacked accuracy around [Ms A's] previous NZ smear history.

2a. The implication of this is that if [Ms A] had previous history of a positive human papilloma virus (HPV) this should have been identified and a further test for this requested at time of cervical smear.

The Cervical Screening programme guidance on HPV screening (NSU 2010) summary states HPV screening should include 'Women (all ages) treated for a high-grade lesion, to help assess whether the lesion has been completely resolved. Includes 'historical testing' for women on annual smears for previous high-grade lesions and with negative smears since, to assess whether they can return to routine 3 yearly screening'.

2b. This is a failure to meet Competencies for Registered Nurses 2.2: Undertakes a comprehensive and accurate nursing assessment of health consumers in a variety of settings, and Competency 2.3: Ensures documentation is accurate and maintains confidentiality of information to a mild degree.

2c. The follow up advice given by [RN C] to [Ms A] was appropriate as an RN and smear taker.

c. [RN C] not referring [Ms A] for a colposcopy following the 19th April 2012 appointment.

The normal cervical smear result provided by [Laboratory 2] on the 23rd April 2012 was normal. As per NSU guidance (2010) this would indicate that a referral for colposcopy was not necessary.

3a. In my opinion [RN C] not referring [Ms A] for a colposcopy at this time was appropriate given the normal smear result.

References:

National Screening Unit (NSU) (2010). Guidelines for Cervical Screening IN New Zealand
https://www.nsu.govt.nz/health-professionals/national-cervical-screening-programme/cervical-screening-guidelines

National Screening Unit (NSU) (2010). Guidance for HPV screening Update
https://www.nsu.govt.nz/publications/guidance-hpv-testing-update-1-april-2010

Nursing Council of New Zealand (2007). Competencies for Registered Nurses.
http://www.nursingcouncil.org.nz/Nurses

Regards

Rosemary Minto, RN/Nurse Practitioner"

Appendix C: Independent gynaecological advice to the Commissioner

The following expert advice was provided by a gynaecologist, Dr Donna Hardie:

> "I have been asked to provide an opinion to the Commissioner on case number C13HDC00903. I have read and agree to follow the Commissioner's Guidelines for Independent Advisors.
>
> I was admitted as Member of the Royal College of Obstetricians and Gynaecologists in 1988 and as a Fellow of the Royal Australia and New Zealand College of Obstetricians and Gynaecologists in 1992. I was appointed to Northland Health Ltd, now Northland District Health Board, as a Specialist Obstetrician and Gynaecologist in 1992 and have continued in that role to the present day. I have been a practising colposcopist since 1992 and have fulfilled the requirements of the RANZCOG Colposcopy Quality Improvement Programme as a certified colposcopist, current until January 2015. I was a Colposcopy Representative on the Development Team for the 2008 National Cervical Screening Programme [NCSP] 'Guidelines for Cervical Screening in New Zealand'.
>
> *I have been asked to:*
> Comment on the DHB's triaging of [Ms A's] referral, in particular:
>
> 1. Whether the assigned colposcopy grading of [Ms A] was appropriate, based on the clinical information in the referral letter of 4 July 2012, and, if not, what grading would have been appropriate;
> 2. Whether, if the second smear test results had been provided with the referral, this have altered the assigned colposcopy grading or the outcome for [Ms A];
> 3. The quality of information in the referral letter dated 4 July 2012 (leaving aside that only one result was attached) and whether the triaging colposcopist should have sought further information before assigning a lower grade;
> 4. Whether, if [Ms A's] adenocarcinoma of the cervix had been diagnosed in July 2012, this would have made a significant difference to her treatment or prognosis;
> 5. Whether the [Laboratory 2] review findings warrant review of processes or whether this is within the realm of expected practice regarding the margins of error in assessment of cervical screening cytology;
> 6. Any other comments on the care provided.
>
> In each instance it would be helpful if you would advise:
> a. What is the standard of care?
> b. Has there been a departure from that standard?
> c. How significant a departure is it?
>
> I have reviewed the following information:
>
> - Copy of [Ms A's] complaint dated […]
> - Copy of [Dr B's] responses dated 20 August 2013 and 24 February 2014

- Copy of the National Screening Unit's responses dated 5 November 2013 and 7 February 2014
- Copy of [Laboratory 2's] response dated 8 April 2014
- Copy of the DHB's response dated 23 May 2014
- Copy of [RN C] and [Dr B's] laboratory requests dated 19 April 2012 and 2 July 2012, [Ms A's] smear test results and screening history report and [Dr B's] referral letter to the DHB dated 4 July 2012
- Copy of [Ms A's] relevant clinical records from [Dr I]
- Ministry of Health. National Cervical Screening Programme. Operational and Quality and Policy Standards Manual 2005. Chapter 5. Provided a Laboratory Service
- Ministry of Health. National Cervical Screening Programme. Operational and Quality and Policy Standards Manual 2006. Chapter 6. Provided a Colposcopy Service
- National Cervical Screening Programme Policies and Standards. 2011 Section 4: Providing a Smear Taking Service.

Case summary:

[Ms A] attended for a cervical smear on 19/04/12. She reported to her smear taker, [RN C] that she was experiencing intermenstrual (between periods) and post coital (after intercourse) bleeding. She was known to have two cervices and [RN C] states on the laboratory form submitted to [Laboratory 2] with the smear specimen that both cervices were sampled with the same cytobrush (the instrument used to take the cervical smear). A past history of 'abnormal cells' and [Ms A's] current symptoms are also stated on the laboratory request form. No further information about the past history of abnormal cells is available either in the GP notes or in [Ms A's] NCSP Screening History Report. [RN C] notes only that the previous episode was overseas. [RN C] recommended that [Ms A] see her GP because of her symptoms.

The smear was reported as normal.

On 02/07/12 [Ms A] saw [Dr B] because of continued symptoms of intermenstrual and post coital bleeding. [Dr B] noted that one of the cervices bled when the smear was taken and that this cervix looked lumpy. She took two smears, one from each cervix. The smears were sent as separate specimens to the laboratory, each smear had its own laboratory request form.

[Dr B] received a normal smear report on 04/07/12. That same day she sent a referral to the gynaecology clinic at [the public hospital] requesting colposcopy because of [Ms A's] symptoms and cervical appearance and past history of a high-grade abnormality of the cervix.

A second smear report was received by the general practice on 05/07/12 and filed but not recognised as being different from that received the day before.

[Dr B] notified the patient of the normal result only.

[Dr B's] referral letter to the gynaecology clinic at [the public hospital] requests a colposcopy appointment because of 'history and current symptoms'. She notes the

patient has a history of a high-grade abnormality of the cervix, has two cervices, and a tendency to bleed with intercourse. Her examination findings note: 'bleeding +++ on just touching lger cx — lumpy appearance to xc.' Her assessment was: 'Friable tissue on lger cervix ? BV' (Bacterial Vaginosis, BV, is a bacterial inflammation of the vagina and cervix). The normal smear results from April and July are attached to the referral letter along with a vaginal swab result, a urine specimen results from 02/07/12 and a full blood count and ferritin level from March 2012.

I have not seen a copy of [the] Gynaecology referral triage notes but the NCSP Screening History Report shows the referral was graded as low grade, timeframe for colposcopy of 6 months.

In November 2012 at [Ms A's] request, because of ongoing symptoms, [Dr B] referred her to [Dr G]. She was seen in December 2012 and a diagnosis of cervical adenocarcinoma was made on biopsy. She was referred to [another clinic] and in January 2013 [Dr I] undertook a Radical Hysterectomy by way of treatment.

A retrospective review as required by NCSP standard 522 revealed that the smear taken in April 2012 reported as normal was revised to 'glandular abnormalities consistent with adenocarcinoma.'

Opinion

Question 1

Whether the assigned colposcopy grading of [Ms A] was appropriate, based on the clinical information in the referral letter of 4 July 2012, and, if not, what grading would have been appropriate.

In 2012 there were no specific NCSP Standards or Policies relating to the triaging of a referral to colposcopy for symptoms of intermenstrual or post coital bleeding in the present of a normal cervical smear.

In the absence of proscriptive policies from NCSP, most Gynaecology units across New Zealand developed their own policies taking into account their resource constraints. [Dr F], in her reply to the Commissioner has stated that the information in the referral letter of 4th July 2012 would usually have resulted in a semi urgent grading at [the public hospital]. This would have translated to being seen within one to three months.

The grading of the colposcopy as low-grade therefore did depart from the usual standard of care, and could be regarded as a missed opportunity for earlier diagnosis. On the assumption that [Ms A] would have been seen three months after referral this may have resulted in the diagnosis being made only two months earlier. I believe therefore that this is not a significant departure.

Question 2

Whether, if the second smear test result had been provided with the referral, this would have altered the assigned colposcopy grading or the outcome for [Ms A].

If the second smear report had been provided with the referral it would definitely have altered the assigned colposcopy grading and the recommendation would have been that she should be seen within 4 weeks of receipt of referral.

'NCSP Standard 602.

Women who have high grade smear abnormalities should receive colposcopy within one month of referral.'

The failure of the General Practice to forward the second smear report is a significant departure from the standard of care.

I do not think it is possible for me to say if this would definitely have altered the outcome for [Ms A] but it is possible that a delay of five months in diagnosis may have allowed for disease progression.

A Gynaecological Oncologist's opinion could be sought on this question. [Ms A] states in her letter to the Commissioner that ACC has an opinion from an Oncologist that diagnosis in July would not have made a difference to her outcome.

Question 3
The quality of information in the referral letter dated 4 July 2012 (leaving aside that only one result was attached) and whether the triaging colposcopist should have sought further information before assigning a low grade.

The quality of information in the referral letter was adequate.

The triaging colposcopist did not need to seek further information; there was enough information to grade the referral as semi urgent.

Question 4
Whether, if [Ms A's] adenocarcinoma of the cervix had been diagnosed in July 2012, this would have made a significant difference to her treatment or prognosis.

If [Ms A's] adenocarcinoma had been diagnosed in July it would have been unlikely to alter her treatment.

It is more difficult to determine if the delay made a significant difference to prognosis. As noted above, a delay in diagnosis of 5 to 8 months theoretically may have allowed for disease progression.

Question 5
Whether the [Laboratory 2] review findings warrant review of processes or whether this is within the realm of expected practice regarding the margins of error in assessment of cervical screen cytology.

[Laboratory 2] reviewed [Ms A's] previous smears in accordance with NCSP Standards.

'Standard 522: All cases with a high grade diagnosis on either histology or cytology must have a review of any prior smears reported as negative or benign/reactive in the previous 42 months.'

This standard related to Quality assurance, and the relevant Appendix defines an acceptable level of not more than 20% false negative smear results. [Laboratory 2] state, in their reply to the Commissioner, that their false negative smear results rate is under 20%. I presume they have quoted their rate in 2012. This quality assurance measure of process is therefore within the expected margins of error in assessment of cervical screening cytology.

Other comments
1. A referral to colposcopy of gynaecology outpatients could have been made after [Ms A's] April appointment.

'NCSP Policies and Standards. 2011. Section 4. Providing a Smear taking service. A Woman with any visible abnormality of the genital tract or cervix, or abnormal vaginal bleeding, must be referred to a gynaecologist for further investigation regardless of the cytological findings.

A normal or unsatisfactory smear can occur in the presence of an invasive carcinoma of the cervix or endometrial carcinoma. Clinical suspicion of cancer overrules a normal smear report.'

[RN C] did advise that further investigation of the symptoms were needed and she recommended [Ms A] see her General Practitioner. If her advice had been followed diagnosis may have been achieved earlier.

2. NSCP may have policies, which apply to a situation where there has been a breach of NCSP Standards in assigning colposcopy grading or if colposcopy has not occurred within the timeframe specified by the standards.

3. NCSP Standard 501 relating to provision of a Laboratory Service should also apply in [Ms A's] case.

'Standard 510: Full re-screening must be performed for cervical cytology in the Following categories:

- All abnormal (ASCUS/AGUS+) cervical cytology
- All cervical cytology from women with an abnormal smear history who have had 2 or fewer normal smears since the abnormal diagnosis
- All cervical cytology from women with: suspicious clinical conditions, abnormal bleeding, observed cervical abnormalities, immunosuppression, STD, and colposcopy patients
- All unsatisfactory (A3) cervical cytology
- All cervical cytology where there has been shown to be a discrepancy between the primary screening result and the rapid re-screening result.'

I cannot tell from the smear reports provided if this has occurred. [Laboratory 2] could provide that information.

4. [Dr B], on behalf of [the medical centre] and [the public hospital] can be commended for their open communication and prompt investigations into the circumstances of this case. Both have sought to communicate with [Ms A] and have been open in their subsequent communications especially with regard to the shortcomings of their respective services. They have also instituted changes to their services in an attempt to prevent such lapses from occurring again.

If I can be of further help please contact me at the above email or postal address.

Yours Faithfully,
Donna Hardie."