

Obstetrician and Gynaecologist, Dr B
Obstetrician and Gynaecologist, Dr C
Southern District Health Board

A Report by the
Health and Disability Commissioner

(Case 14HDC00991)



Health and Disability Commissioner
Te Toihau Hauora, Hauātunga

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Executive summary

1. Ms A, who had a left ovarian cyst, was booked to have a laparoscopy on 22 March 2013, performed by obstetrician and gynaecologist Dr C at a public hospital (the hospital). On 5 March 2013 Ms A (aged 51 years) saw Dr C preoperatively.
2. In 2009, Ms A had expressed anxiety about what she considered was a family history of ovarian cancer. Dr C was not aware of a resulting genetic counselling report, as Southern District Health Board (SDHB) administrative staff had not put the report on the clinical record. The most recent tumour marker results available to Dr C were from April 2012.
3. On the morning of 5 March, Ms A consented to surgery. There is no documentation on file outlining that operative risks specific to Ms A were discussed with her. Dr C said that he discussed specific risks of surgery with Ms A and provided written information in the form of a leaflet. Ms A said that Dr C broadly discussed risk and that she could not recall whether any information leaflet was provided to her.
4. Tumour marker blood test (CA125) results were ordered by Dr C and a risk of malignancy index (RMI) calculated in the afternoon following his consultation with Ms A on the morning of 5 March. Dr C then telephoned Ms A about the tumour marker result (which was negative) received on the afternoon of 5 March. Dr C could not recall whether he discussed an RMI score with Ms A. Ms A told HDC that he did not. The telephone call and RMI calculation are not documented.
5. The surgical procedure carried out on 22 March 2013 was complicated owing to adhesions. An operative injury to the bladder occurred, which was repaired by a urologist called to assist in theatre.
6. At 4pm on 22 March 2013, Dr C handed over to consultant obstetrician and gynaecologist Dr B. Ms A had a difficult postoperative course. A senior house officer, Dr D, reviewed Ms A over the weekend of 23 and 24 March. Dr D communicated the possibility of a ureter or bowel injury, instigated a number of investigations, and brought her concerns to the attention of Dr B, on three occasions, the first by telephone at 8pm on 23 March.
7. On the morning of 24 March, Dr B reviewed Ms A. Dr B's impression was that, potentially, medication side effects explained her nausea. A differential diagnosis of bowel injury was made. Dr B did not order investigations. He considered that the likelihood of a CT scan providing useful diagnostic information so soon after a significant laparoscopic procedure remained low.
8. By 12.15am on 25 March, Ms A's urine output had decreased. It had been "minimal to none" over the previous four hours. The laboratory informed Dr D that the blood cultures had grown a gram negative bacillus. Dr D telephoned Dr B, but Dr B did not review Ms A personally or arrange a surgical review.
9. On 25 March 2013 it was considered at an early morning team meeting handover that Ms A must have a bowel perforation. Ms A was referred to the surgical team. She had

a laparotomy that day, and faecal peritonitis from two holes in the sigmoid colon was discovered. Ms A had further surgery including a colostomy, and additional surgery 48 hours later. Ms A was cared for in ICU and then transferred to the ward. Ms A later developed a fistula from her bladder to the rectal stump. Ms A was discharged to the care of surgeons at a DHB nearer her family.

Findings

10. While it was accepted that Dr C telephoned Ms A about the tumour marker result on the afternoon of 5 March 2013, criticism is made that Dr C discussed the proposed surgery with Ms A on the morning of 5 March 2013 without the knowledge of important clinical factors (the tumour marker result and a quantified risk of malignancy) — factors that were relevant to a preoperative discussion and Ms A's consideration of whether or not to proceed with surgery.
11. Although it was accepted that some of Dr C's peers would consider it appropriate for Dr C to have commenced the procedure given his level of skill, adverse comment is made that Dr C did not appreciate, or think critically about, the potential surgical difficulties he might face given Ms A's history of extensive adhesive disease.
12. Dr C did not meet his obligations to keep clear and accurate clinical and surgical records. Accordingly, he failed to comply with professional standards, and breached Right 4(2) of the Code.¹
13. Postoperatively, there was a delay in Dr B recognising that Ms A might have a bowel injury, given that the possibility had been brought to his attention on more than one occasion, particularly once the blood culture results were available, and he made a decision not to review Ms A personally or refer her for surgical review. Accordingly, Dr B failed to provide services to Ms A with reasonable care and skill and, therefore, breached Right 4(1) of the Code.²
14. It was found that SDHB had overall responsibility for the series of deficiencies in care experienced by Ms A. In addition, at the commencement of Dr C's employment, and at the time of Ms A's surgery, Dr C was not made aware of RANZCOG guidelines pertaining to performing advanced operative laparoscopy. SDHB's surgical consent form in use at the time had no space for the purpose of recording risks specific to the patient. There were several administrative shortcomings identified in this case. SDHB therefore failed to ensure that Ms A was provided with services with reasonable care and skill, and breached Right 4(1) of the Code.

Recommendations

15. The Commissioner recommended that Dr C:
 - a) Have an independent colleague review a random selection of his surgical consent forms from the last 12 months to report on whether specific surgical

¹ Right 4(2) states: "Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards."

² Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."

- risks/concerns for each patient are written on the consent form, and report the results to HDC.
- b) Provide HDC with a copy of the template (as recommended by his supervisor) used in his dictation in relation to information discussed in the consent process, to be dictated at the beginning of the operation note and also handwritten on the operation note.
 - c) Provide a formal written apology to Ms A.
16. In the provisional report, the Commissioner recommended that Dr B provide a formal written apology to Ms A. In response, Dr B provided an apology letter. It was also recommended that in the event that Dr B wishes to return to New Zealand to practise, the Medical Council of New Zealand consider whether a review of Dr B's competence is warranted.
17. The Commissioner recommended that SDHB provide HDC with a detailed update report on the progress and effectiveness of all steps taken by it to improve service as a result of this case, including:
- a) Surveying new and existing employees in the Women's Health Surgical Service regarding their awareness of the RANZCOG guidelines for performing laparoscopic procedures, and confirming that RMO and SMO orientation includes this information.
 - b) Reviewing complex cases from the last six months to confirm that SMOs regularly discuss complex cases at multidisciplinary meetings as part of expected practice, and discuss general and specific operative risk with patients.
 - c) Providing to HDC a copy of the latest Women's Health Service policy addressing "Less Commonly Performed Gynaecology Procedures", re-emphasising the importance of guidelines for complex procedures.
 - d) Providing to HDC a copy of the amended Women's Health Service surgery surgical consent form showing that there is now space for adequate documentation of the proposed procedure and possible risks.
 - e) Providing results from the recent gynaecology surgery audit, benchmarking KPIs against comparably sized hospitals/DHBs.
 - f) Conducting a random review of clinical administration processes to ensure that a copy of all clinical information generated in the hospital service, and from external consultations, is placed in the clinical record.
 - g) Conducting a review of administrative pathways in relation to complaints lodged with the DHB, to confirm that appropriate processes are followed and that all surgical clinicians are aware of that process.
 - h) While not a focus of this report, confirming to HDC all steps it routinely takes to fully and accurately ascertain and review the performance history and complaint/litigation history of overseas trained clinicians applying for roles with SDHB.

18. The Commissioner recommended that RANZCOG consider whether the wording of the consensus statement “*C-Trg 2, Guidelines for performing advanced operative laparoscopy*” requires revision, and report the outcome of this consideration to HDC.
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Complaint and investigation

19. The Commissioner received a complaint from Ms A about the care provided to her by SDHB.
20. An investigation was commenced on 3 March 2015. The following issues were identified for investigation:
- *Whether Ms A received care and services of an appropriate standard from Southern District Health Board.*
 - *Whether Ms A received care and services of an appropriate standard from Dr C.*
 - *Whether Ms A received care and services of an appropriate standard from Dr B.*
21. The key parties referred to in the report are:

Ms A	Consumer, complainant
Southern District Health Board	Provider
Dr B	Obstetrician and gynaecologist
Dr C	Obstetrician and gynaecologist
Dr D	Senior house officer
Dr E	Obstetrician and gynaecologist
Dr F	Urologist
Dr G	Obstetrician and gynaecologist

22. Information from ACC and the Medical Council of New Zealand was also reviewed.
23. Independent expert advice was obtained from an obstetrician and gynaecologist, Dr Jenny Westgate, Honorary Associate Professor in Obstetrics and Gynaecology (**Appendix A**).
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Information gathered during investigation

Relevant clinical background

24. Ms A’s obstetric/gynaecological clinical history included a Caesarean section and a tubal ligation. In June 2009 Ms A (then aged 47 years) underwent a total abdominal

hysterectomy (TAH)³ and right oophorectomy⁴ at the hospital. The surgery was converted from an intended laparoscopic assisted vaginal procedure⁵ to a laparotomy,⁶ owing to the presence of multiple adhesions (scar tissue).

25. In July 2009, at an outpatient follow-up appointment, Ms A expressed anxiety about a family history of ovarian cancer (which she said had occurred in a close relative). A locum consultant obstetrician and gynaecologist referred Ms A for genetic counselling.
26. The ensuing genetic consultation report, dated 19 February 2010, was sent to Ms A and copied to the locum consultant obstetrician and gynaecologist. However, by that time, the locum consultant obstetrician and gynaecologist was no longer working for SDHB, and a copy of the report did not make its way into the hospital notes at that time.⁷
27. The report concluded that the NZ Cancer Registry did not contain a confirmed diagnosis of ovarian cancer in Ms A's relative, and it was unlikely that Ms A's relative had had a high grade ovarian cancer. Based on the family history available, the report did not consider that Ms A met the criteria for high-risk management and removal of ovaries.
28. On 23 November 2010 Ms A attended an outpatient clinic appointment with obstetrician and gynaecologist Dr E.⁸ Ms A had some pain at the umbilicus. A physical examination showed no abnormality. However, Ms A was teary and depressed. A plan was made to start hormone replacement therapy (HRT). A CT scan⁹ of the abdomen and pelvis was also arranged.
29. On 16 December 2010 Ms A's CT scan showed a left pelvic adnexal mass of approximately 5–6cm in size, most likely arising from the left ovary.
30. On 20 December 2010 Ms A attended an outpatient clinic appointment with Dr E to follow up the CT scan. Ms A was very anxious. Dr E requested a pelvic ultrasound scan and tumour marker tests (CA125¹⁰ and CEA¹¹).

³ Removal of the uterus.

⁴ Removal of the ovary.

⁵ A procedure using laparoscopic techniques to remove the uterus (womb) and/or tubes and ovaries through the vagina.

⁶ A surgical procedure involving a large incision through the abdominal wall to gain access to the abdominal cavity.

⁷ The SDHB clinical records provided to HDC contain an annotated copy that indicates that the report was added to the file on 9 January 2014.

⁸ Dr E is vocationally registered with the Medical Council of New Zealand.

⁹ Computed tomography scan. The CT scan can reveal anatomical details of internal organs that cannot be seen in conventional X-rays.

¹⁰ CA125 is a protein that is a tumour marker. It is a substance found in greater concentration in tumour cells than in other cells of the body. CA125 is present in greater concentration in ovarian cancer cells than in other cells. A normal result is less than 35 units per ml.

31. The ultrasound conducted on 25 January 2011 showed several 18mm follicles/cysts on the left ovary. No complex pelvic adnexal mass was seen, and it was considered to have resolved, and no other abnormality was detected.
32. On 11 November 2011 Ms A was seen again in the outpatients clinic by Dr E's registrar. The tumour marker result was negative. The resulting clinic letter stated that Ms A had attended the clinic "worried about the mass". The registrar also mentioned in his clinic letter that the follow-up scan showed that the cyst had resolved, and that the tumour marker results were normal. The registrar recorded Ms A's concern that her family member had had ovarian cancer and that the cancer had occurred when her family member was in her sixties. The registrar concluded that this did not necessarily indicate a familial increased risk.
33. On 23 November 2011 a repeat pelvic ultrasound was taken, which indicated a result similar to the scan of 25 January 2011.
34. In March 2012, Ms A suffered a myocardial infarction (heart attack) and underwent stenting of a coronary lesion.
35. On 24 April 2012 Ms A was admitted to hospital with diverticulitis.¹² A pelvic CT scan at that time showed a complex 28mm cyst on the left ovary.
36. On 26 July 2012 Ms A was referred from the hospital's surgical service to Dr E at gynaecology outpatients at the Women's Health Service.
37. On 7 August 2012 an ultrasound (ordered by the surgical service) was performed, which indicated a left septated (divided into two parts) cystic mass.

Dr C

38. Obstetrician and gynaecologist Dr C¹³ began employment with SDHB some time before the events in question. He was employed in accordance with DHB credentialing policy at the time.¹⁴ Dr C underwent a structured and documented month-long programme of induction and orientation.
39. Dr C's supervisor, required by the Medical Council of New Zealand for the first 12 months of his employment, was Dr E. Dr E was very experienced. No issues were identified during Dr C's supervision period.

¹¹ Carcinoembryonic antigen (CEA) is a protein found in many types of cell but associated with tumours and the developing fetus. CEA is tested in blood. The normal range is <2.5ng/ml in an adult non-smoker, and <5.0ng/ml in a smoker.

¹² Inflammation of a diverticulum (a small bulging sac, especially in the colon, causing disturbance of bowel function).

¹³ Dr C trained overseas and had a five-year surgical case log including laparoscopic surgery. He obtained provisional registration with the Medical Council of New Zealand, and vocational registration was issued. He is a Fellow of RANZCOG.

¹⁴ SDHB policy *Credentialing Policy for Senior Medical Officers*. Document number 000/791/0048. This includes verification of an individual's credentials on initial application for appointment, and ensuring that qualifications and positional requirements are congruent.

Training in laparoscopic gynaecology

40. Dr C's obstetrics and gynaecology residency overseas involved advanced laparoscopic surgery training.¹⁵ Dr C advised HDC that he had performed 250 laparoscopic cases prior to coming to NZ, including total laparoscopic hysterectomy (TLH) surgery.¹⁶ Since the start of his employment at the hospital until May 2015, Dr C had performed over 70 TLHs.
41. SDHB's response to HDC¹⁷ stated that Dr C had training and experience in Level 5 RANZCOG procedures (discussed below), but that he did not wish to be preceptored to perform Level 6 procedures.

Medical Council of New Zealand

42. At the commencement of this investigation, HDC concurrently referred Dr C to the Medical Council of New Zealand (MCNZ) in accordance with section 34(1)(a) of the Health and Disability Commissioner Act 1994.
43. On 1 May 2015 MCNZ advised HDC that it would undertake a Performance Assessment in relation to Dr C. On 29 October 2015 MCNZ advised HDC that Dr C met the required standard of competence.

RANZCOG guidelines

44. RANZCOG has published guidelines pertaining to the performing of advanced operative laparoscopy.
45. Dr C told HDC that he was not aware of the RANZCOG guidelines at the commencement of his employment or at the time of Ms A's surgery.
46. SDHB told HDC that Dr E is aware of the guidelines, although she believes that many senior medical officers (SMOs) are not aware of them, and she considers the RANZCOG guidelines to be important given that, according to the RANZCOG website, there is no recognised subspecialty for laparoscopic surgery.
47. The RANZCOG consensus statement "*C-Trg 2, Guidelines for performing advanced operative laparoscopy*"¹⁸ outlines the levels of skill required to perform various procedures. It states:

" ...

Skill Level 3

Laparoscopic ovarian cystectomy and oophorectomy when there is normal anatomy ...

¹⁵ This involved over 200 laparoscopic surgeries while Dr C was in residency.

¹⁶ Dr C provided copies of his surgical work record.

¹⁷ The SDHB response to HDC includes detailed input from Dr E.

¹⁸ First endorsed 1993. November 2010 version. See: http://www.ranzcog.edu.au/component/docman/doc_view/982-c-trg-2-guidelines-for-performing-advanced-operative-laparoscopy-html.

Skill Level 5

This level is an advanced level. This includes total laparoscopic hysterectomy, laparoscopic Burch and laparoscopic myomectomy.

Skill Level 6

Procedures at this level are as follows: laparoscopic pelvic floor repair, AFS level 4 endometriosis surgery. This is excisional surgery and not ablation. Laparoscopic removal of residual ovaries with significant distortion of the anatomy. Laparoscopic oncological procedures such as laparoscopic pelvic lymph node and para-aortic lymph node dissection and radical hysterectomy. To perform level 5 and 6 surgery, as well as laparoscopic suturing, surgeons should have completed formal preceptorships or Fellowship training under the supervision of appropriately skilled laparoscopic surgeons ...”.

48. Dr C stated:

“The RANZCOG guidelines could be better clarified to the surgeons especially those educated outside of New Zealand. I am though a RANZCOG Fellow. I am performing Level 5 surgeries routinely and was observed [during] my first year of work by a known Level 6 surgeon ...”.

Preoperative outpatient clinic appointment — 5 March 2013

49. On 5 March 2013 Ms A was seen at a gynaecology outpatient clinic by Dr C. Ms A had no apparent symptoms from her ovarian cyst. The appointment was booked as a 20-minute consultation. Dr C told HDC that prior to the meeting he reviewed Ms A’s file.

Discussion and consent

Clinical history

50. Dr C told HDC that he discussed Ms A’s surgical and clinical history with her, including her admission for diverticulitis and her past hysterectomy.¹⁹

51. Dr C told HDC:

“[Ms A] and I discussed her previous hysterectomy including the conversion from laparoscopic to an open procedure. [Ms A] did inform me that the reason for conversion was adhesions around the uterus that prevented completion of the procedure laparoscopically.”

52. Dr C stated that initially he counselled Ms A based on the information in her chart at that time. He said that he had reviewed Ms A’s chart before seeing her and had noted the ultrasound and CT scan history and the diverticulitis history, and said that if Ms A’s previous surgery note from 2009 had been in her chart, he would have seen it.

53. Dr C said that he also discussed with Ms A her heart stenting and myocardial infarction.

¹⁹ Dr E’s operation note from June 2009 is on Ms A’s SDHB clinical file.

54. The genetic counselling report of 19 February 2010 was not in the SDHB clinical record, and therefore was not available to Dr C. Dr C stated that Ms A did not mention to him that she had seen a genetic counsellor, or that her close relative (who Ms A said had had ovarian cancer) was still alive. Ms A stated that she did not mention the genetic counselling report to Dr C as she understood that it would be in her clinical records.
55. Dr C said that on examination the mass was palpable on the left-hand side, and it was approximately the size it had been on the most recent (April 2012) ultrasound. Ms A told HDC that Dr C did not mention this to her.

Operative risks

56. Dr C told HDC that he discussed operative risks with Ms A. He stated:
- “I discussed, as I usually do, possible injury to bowel, bladder, ureters, blood vessels, bleeding, and infection; we also discussed her willingness to receive a blood transfusion if needed. She signed the consent form and when ask[ed] if she had questions [she] indicated no ...”.
57. Dr C told HDC that he explained her condition and the options available to Ms A. In relation to the option of surgery, he advised HDC that he explained the expected risks, and that this included the potential for Ms A’s known adhesions to make the surgery more complicated, and thus more risky. Ms A told HDC that she does not remember this. She said she clearly remembers that Dr C discussed the usual surgery risks, but that is all she remembers.
58. Dr C told HDC that the conversation was framed around an increased likelihood of complications, which in turn would increase the likelihood of needing to convert to open surgery. He said that she was engaged and understood what was being discussed.
59. Dr C said that he gave Ms A a copy of the RANZCOG patient information leaflet on laparoscopy,²⁰ as was his usual practice. This is not documented.
60. Ms A told HDC that she could not recall whether Dr C gave her any written information or a pamphlet, but she was “99.9%” sure that she did not receive written information. Ms A said that Dr C broadly discussed risk beforehand. She told HDC:
- “Towards the end of the brief [appointment] I had with [Dr C] he said something along the lines of you are aware of the risks associated with surgery and I then believed I would have probably signed the consent form ... I just can’t remember signing the form. I was not handed any information on this surgery. I left the [appointment] with a blood test form only.”
61. There is no documentation (in the outpatient notes, the operative consent form, or in Dr C’s dictated clinic letter of 5 March 2013 to Ms A’s GP) regarding the operative risks that Dr C says he discussed with Ms A, and specifically there is no mention that

²⁰ The detailed RANZCOG four-page A4 pamphlet *Laparoscopy: A guide for women*. Edition number two. Copy provided to HDC.

Dr C advised Ms A of the particular risks of surgery in her case (ie, the risks of ureteric, bladder and bowel injury given her previous hysterectomy, adhesive disease, and recent diverticulitis).

Risk of malignancy

62. Ultrasound scanning and measurement of tumour markers in the blood, specifically CA125 level, enable the calculation of a Risk of Malignancy Index (RMI)²¹ to help guide further management.²²
63. At the time of the 5 March 2013 appointment, Dr C had not obtained the recent tumour marker results or RMI calculation, so these were not discussed with Ms A during the appointment.

Conservative management

64. The cyst measured 43 x 21 x 21mm. SDHB told HDC that there was an option to manage it conservatively, initially with surveillance by interval scans and tumour marker testing.
65. SDHB told HDC that if a patient desired conservative management then she would have a follow-up ultrasound and a CA125 test in two to three months' time, as well as follow-up in a Gynaecology Oncology multidisciplinary meeting, but this would not be usual for a complex cyst in a postmenopausal woman.
66. Dr C told HDC that he discussed with Ms A the treatment option of a conservative surveillance approach, but that she was concerned about a risk of malignancy and wanted the mass removed. Dr C also told HDC that Ms A was aware of conservative management, having undergone it previously. Dr C said that, to him, Ms A seemed anxious to have the surgery.

Surgical route

67. Dr C told HDC that he discussed the surgical route with Ms A. He said that as Ms A did not want a long recovery, she wanted to try a laparoscopic approach.
68. Dr C stated: "During the consultation, [Ms A] continued to express her strong preference for surgery. I considered [Ms A's] preference reasonable, subject to an updated CA125 test and the possibility of further imaging."
69. Dr C said that it was discussed that if a laparoscopic approach was not possible after viewing the pelvis (due to adhesions, for example), the surgery would need to be converted to an open procedure, and that Ms A understood this.

²¹ Risk of Malignancy Index (RMI) estimates the risk of malignant ovarian cancer based on an initial workup using information from serum CA125 results, menopausal status, and ultrasound.

²² Women with a low RMI can have conservative treatment with their gynaecologist, which may involve observation only or laparoscopic oophorectomy. Women of medium or high risk should be referred to the regional Gynaecology Oncology Unit for discussion at a multidisciplinary meeting (MDM).

70. SDHB told HDC that adhesions are not an absolute contraindication to a laparoscopy being undertaken.
71. Dr C dictated this aspect of his discussion in a 5 March 2013 clinical letter to Ms A's GP (see below).

Operative consent form

72. The operative consent form, completed on 5 March 2013 and signed by Ms A and Dr C at the clinic, is for a "left salpingo oophorectomy" procedure.²³ The form contains the standard wording: "[T]he nature, effects, common complications and risks of the above procedure and the other options available to me for this condition have been explained to my satisfaction and I understand them ...".
73. No specific risks are written on the consent form. The consent form has no space designated for this purpose. Dr C said that the consent form does not contain a written record of all the information he gave verbally.
74. SDHB stated:

"The usual informed consent process for all surgeries is to outline risks, benefits and alternatives with discussion of bleeding, infection, injury to the bowel, bladder, ureters, blood clots in the legs or lungs, anaesthetic risk and risk of needing a transfusion and additional risks related to this specific procedure including possibility of converting to laparotomy and possibility of occult cancer and other risks depending on the procedure."

Documentation regarding indication for surgery

75. Dr C's written communications about the indications for surgery (discussed below) outline his concerns about the mass being malignant.
76. The clinical records include an elective surgery form completed and signed by Dr C at the clinic appointment on 5 March 2013. A question on the form asks whether the procedure is a "diagnostic or surgical procedure for premalignancy or malignancy". The "yes" box is ticked and, therefore, it instructs that the Clinical Priority Assessment Criteria (CPAC) assessment score is deemed to be 100 (the maximum).
77. Dr C told HDC that he ticked this box because it was a procedure for a possible malignancy, and that "[Ms A] was a perimenopausal lady with a complex septated ovarian cyst that I could not prove was benign without histology".
78. To help explain any delay in Ms A's ability to start her new job, Dr C also wrote a letter to Ms A's future employer, which mentioned his concerns.
79. SDHB's response to HDC states: "At the time [Dr] C was highly concerned at the possibility of malignancy associated with the mass and in his opinion surgery was the most appropriate treatment."

²³ The surgical removal of a fallopian tube and an ovary.

80. SDHB's summary of events outlined: "[Dr C] advised [the DHB] that surgical removal of the cyst was the best course of action."
81. Dr C later told SDHB that he considered discussing the case with the Gynaecology/Oncology multidisciplinary meeting, but decided not to do so on the basis that the clinical findings available, and the perceived level of patient concern, meant that proceeding with surgery was an appropriate course of action.
82. Dr C told HDC that he felt some institutional pressure to operate on adnexal masses in a timely fashion, owing to media reports at the time of a case of a patient who had travelled to Australia in order to have timely surgery.

Ultrasound and tumour marker tests

83. On 5 March 2013 the most recent ultrasound scan available to Dr C was that performed seven months previously, on 7 August 2012. The most recent tumour marker results available to him were those from April 2012.
84. After his discussion with Ms A, Dr C ordered further tumour marker blood tests. Dr C also ordered an ECG.
85. Dr C then dictated his clinic letter to Ms A's GP, dated 5 March 2013, which states:

"... [Ms A] ... has had a persistent left ovarian cyst now for approximately two years. She has had negative tumour markers, the most recent of which was April 2012, however an ultrasound later that year shows that the cyst is persisting.

I have reordered tumour markers, however as she has menopausal symptoms I feel at this point it is reasonable to remove the ovary, and eliminate any concerns of ovarian carcinoma. As you know [Ms A] does have a family history of ovarian cancer and is quite concerned with this possibility. I have also ordered an ECG evaluation that she will get before seeing Anaesthesia for pre-operative check. I am hopeful that we will be able to remove the ovary laparoscopically, and it can be a day case, but she is aware that if, for any reason, we are not able to accomplish the surgery laparoscopically, we will proceed with an open case which will require possibly a hospital stay.

As there is a family history, and this cyst has been present for quite some time, I will try to expedite as much as possible her surgery date and also she does have a job waiting for her, which she is concerned about having any sort of delays. I will also send a letter to her future manager explaining the situation so hopefully this will help with any problems with her upcoming job ...".

86. Dr C's clinic letter was not copied to Ms A. Dr C told HDC that his clinic letter communicates that he and Ms A had talked about the surgical approach and its risks.
87. SDHB told HDC: "[T]he routine practice in our department is to score all cysts using the Risk of Malignancy Index triaging tool." SDHB also responded that it could not

find in the literature any recommendation on a time frame for when an ultrasound should be repeated for use in the Risk of Malignancy triaging tool.

88. Dr C told HDC that he triaged Ms A's cyst using the triaging tool, the April 2012 ultrasound, and the CA125 result. The clinical records reflect that the CA125 tumour marker results were available to Dr C on 5 March 2013.
89. Dr C told HDC that he received and checked the CA125 tumour marker result (11 units per ml) in the afternoon following Ms A's appointment on 5 March 2013 (and the production of his clinical letter), and he was then able to calculate the RMI as 99, which is a low risk of malignancy.

Telephone call

90. Dr C told HDC that the repeat CA125 was available that afternoon and, after receiving it and calculating the RMI result, he called Ms A and told her that the result was negative and not in the malignant range, and provided further counselling during the call. In particular, Dr C said he told Ms A that the result indicated that the cyst was not malignant, but that some risk remained. He advised Ms A that surgery remained indicated, but she would not require referral to a specialist oncologist.
91. Ms A told HDC that when the blood test result came back, Dr C telephoned her with the tumour marker result. Ms A recalls that she was told that the result was negative. She said that she was relieved and asked Dr C if that meant she should still go ahead with surgery. She told HDC that Dr C advised her that she should, as it was unknown what the cyst might do in the future. Ms A said that Dr C did not say anything about oncology to her.
92. Dr C also told HDC:

“The repeat CA125 was available that afternoon and [Ms A] admits that I called her with the result and told her it was negative and not in the malignant range. Further counselling occurred during this call ... I can't recall whether I told her the number or not, but the RMI is a triaging tool ... The main thing that [Ms A] needed to know was the CA125, the RMI is a tool that helps us to decide if the patient should be presented at Gynaecology Oncology MDM ...”.
93. Ms A told HDC: “I can categorically state that [Dr C] did not discuss the ‘RMI index’.” Ms A said that she had never heard of the term at the time.
94. Ms A told HDC that Dr C counselled her during the telephone call “by saying despite the CA125 was negative he would ‘still strongly recommend’ that I proceed with this surgery as there was no guarantee that my health status would remain as such”.
95. The RMI calculation and telephone call were not documented by Dr C.
96. Dr C stated: “I have taken on board the need to better document this calculation in the records.”

97. Dr C said that at that RMI level, the mass is presumed to be benign, and it was reasonable to remove it at the hospital.²⁴
98. Dr C also said that this result did not eliminate the risk of malignancy, but lowered it to the point that Ms A did not require referral to a gynaecological oncologist.
99. In relation to a repeat ultrasound, Ms A told HDC:
- “[Dr C] did not request a new Ultra Sound Scan, he went into surgery with the results of an 8 month old scan result. I even said to him as I was walking out the door from the [appointment] that he had not given me a form for a new scan, he acknowledged it and said we didn’t need one.”
100. Dr C said that he discussed Ms A’s case with a radiologist, and they felt that another ultrasound was not needed owing to the complexity of the cyst and its presence on examination. Dr C also told HDC that there had already been a wait for a clinic appointment since the ultrasound, and to order another ultrasound possibly would have delayed a clinic appointment further. This information was not documented by Dr C in the clinical notes.
101. SDHB told HDC that given that the RMI was 99, suggesting a low risk of malignancy, it believed that a laparoscopic approach was not inappropriate in this situation.

Timing of surgery

102. The surgery was scheduled (as day surgery) for 22 March 2013. On 5 March 2013 Ms A completed a health assessment form for her pre-anaesthetic check, which was scheduled for 11 March 2013.
103. Dr C told HDC that Ms A called and visited the administration office on multiple occasions to ask when her surgery would take place. Dr C said that he interpreted these visits as Ms A being concerned that she should have her surgery promptly. There is no reference to this in the notes.
104. Ms A stated that she telephoned and called into the office several times. She stated that she visited to check whether a surgery date had been made or to have questions answered, as she was soon to be re-locating and wanted to know what was happening.
105. Ms A told HDC that some of her visits were to try to cancel the operation, and she was encouraged by Dr C to go ahead with the operation in case her cyst was malignant. Ms A told HDC:

“I tried to get out of having this surgery on 3 different occasions ... which I personally feel is more important than the brief [appointment] I had with [Dr C].

²⁴ Dr C told HDC that an oophorectomy is permitted to be performed at the hospital if the RMI is less than 200. This is based on general advice to Southern DHB from another DHB’s gynaecological oncologist. Removal of a suspect mass at the hospital is not cancer staging surgery.

The first time was when the cancer screening blood test for ovarian cancer came back negative, he phoned me with the result and when I said I don't think I will go ahead with it he then put pressure on me saying it was his opinion I should have the surgery."

106. Ms A told HDC that on a second occasion, which she believes may have been shortly after her preoperative assessment with the anaesthetist, she telephoned an administrator and said she had changed her mind about having the surgery. Ms A stated that she recalled this as the anaesthetist had recommenced her on aspirin. Ms A also told HDC that she was not feeling confident about the surgery at that point. Ms A said: "[T]he PA then got [Dr C] to phone me and again pressure was placed on me to go ahead with this surgery." This is not documented in the clinical record.
107. Ms A said that the third occasion is not so clear in her memory. She said that she made several calls regarding cancelling the surgery.
108. Dr C said that he does not recall Ms A trying to cancel her surgery, but he does remember her visiting the Women's Health administration offices to ask questions about how soon the surgery would be. Dr C said that if a request for a cancellation had been made, it would have been actioned given the difficulties faced with access to surgical theatre time. He said that if a patient telephones and cancels surgery, the usual administration process is to suspend the surgery, reschedule an outpatient appointment for further evaluation/clarification, and then offer the patient a new date.
109. A statement from a surgery booking administrator was obtained by Dr C. The booking administrator stated that, to the best of her knowledge, Ms A would appear in their office at Women's Health to ask questions about when her surgery could be done. The booking administrator stated that on some of Ms A's visits she [Ms A] would ask her if she thought Ms A should have the surgery, but she was never asked by Ms A to cancel the surgery.
110. In response to this point, Ms A told HDC: "I wonder if these visits to her office sound like someone who had a strong preference for surgery?"

Pre-anaesthetic check

111. On 11 March 2013 Ms A underwent a pre-anaesthetic check, which was documented.

Laparoscopic surgery, 22 March 2013

112. On Friday 22 March 2013 Ms A underwent the planned surgery. The day surgery commenced at 11.57am and ended at 1.25pm, and was performed by Dr C. A locum surgeon assisted.²⁵
113. Dr C told HDC that the surgery went ahead as described in the dictated operation note. The operation note describes the surgery as "laparoscopic removal of left ovary

²⁵ The locum surgeon is registered with the Medical Council of New Zealand within the general scope of practice. SDHB told HDC that the surgeon confirmed to it that he had read the operation notes and that he agrees with the content of the notes.

and portion of left tube, adhesiolysis²⁶ and inadvertent cystotomy [a small hole in the bladder] and cystotomy repair”.

114. The procedure uncovered a large amount of adhesive disease throughout the pelvis, more prominently on the left side. A left ovarian cyst was found. The cyst turned out to be slightly larger (4 x 2.5 x 5cm) than estimated from the scan, and was benign (a mucinous cystadenoma²⁷).

Bladder injury

115. An inadvertent operative injury to the bladder occurred during surgery. This was laparoscopically repaired by a urologist (Dr F), who was called in to assist in theatre.
116. Dr C’s operation note states:

“... 10mm trocar²⁸ inserted through the base of the umbilicus. Area underneath trocar insertion site was inspected and was without any trauma. We did note a portion of bowel adhered to the anterior abdominal wall approximately 2cm away from the umbilical port. We also noted a large amount of omentum²⁹ attached to the anterior abdominal wall predominantly on the left side. There was also some bits of omentum attached to the right side of the pelvis. Unfortunately the left ovary appeared to be totally buried within omental adhesions. At this point we inserted a suprapubic port under direct visualisation and a right lower quadrant port under direct visualisation. These were 5mm ports ... we were able to ... gently remove the omental adhesions away from the ovary exposing a small portion. We then ... were able to remove adhesive bands from the ovary ... the distal part of the ovary was still densely adherent. We then ... were able to remove most of the rest of the ovary except for a small band attached to the most distal part of the ovary ... We inspected the base of this banded area and it appeared there was a small, approximately 0.5cm x 0.5cm hole which appeared to be within the bladder ...”.

117. Dr C’s operation note does not feature any comment regarding the proximity of the bowel to the adhesions around the ovary, or whether the bowel was specifically checked for damage after repairing the bladder.

118. Dr C told HDC:

“Upon entry into the umbilical trocar I looked circumferentially around the site and saw no injury; also while reviewing the notes it became apparent that I had placed a 5mm scope in one of the lower abdominal trocar ports to place the ovary

²⁶ Severing of adhesive bands done by laparotomy or laparoscopy.

²⁷ An ovarian mucinous cystadenoma is a benign tumour that arises from the surface epithelium of the ovary.

²⁸ A sharp pointed instrument equipped with a cannula, used to puncture the wall of a body cavity and withdraw fluid or to introduce an endoscope.

²⁹ A membranous double layer of fatty tissue that covers and supports the intestines and organs in the abdominal area.

in an endocatch bag³⁰ and viewed the bag at the umbilical port which would be a second check of the entry trocar site. The ovary was removed with the cyst not ruptured within the patient. There was a cystotomy [bladder injury] recognised and a urologist, [Dr F], was called in to repair this which he did laparoscopically.”

119. SDHB told HDC:

“[Dr C] ... looked around for signs of malignancy and described in detail in the operation report, all the adhesions found which demonstrate that the abdominal cavity was checked. In his notes [Dr C] described placing the ovary unruptured in an endocatch bag and then drained it into the bag so that the ovary was able to be removed. The ovary, once in the bag, never again touched the patient. The ovary was suspected to be benign so no pelvic washings were done for cytology examination. [Dr C] is clear that this was diagnostic surgery not cancer surgery ...”.

120. Dr C told HDC that he placed the endocatch bag through the umbilical port, which would have been a double check of the umbilical port site in addition to the circumferential look upon the 10mm port placement. However, he did not document this.

Bowel injury

121. Ms A suffered a bowel injury during the surgery, which was not discovered at that time.

122. Dr F’s clinic letter of 8 May 2013³¹ stated the following about the surgery:

“[The surgery] resulted in a recognised bladder injury at the time of the surgery which was repaired laparoscopically. Unfortunately what wasn’t recognised [at the time] was the fact that the camera port had gone in and out through the sigmoid colon³² on the way into the peritoneal cavity ...”.

123. Dr C told HDC that after removal of the ovary he checked and inspected the area and recognised the bladder injury but did not see any bowel injury. He said that he did not believe the bowel injury was a trocar injury because: the injury location in the sigmoid colon/rectum is not beneath or near the umbilicus; he used dilating trocars and it is difficult to perforate bowel with this type of trocar; and the ovary was located over the injured area of bowel and would have prevented the injury from trocar insertion.

124. Dr C felt that there may have been a thermal injury that ruptured later, or perhaps a weakened area where the dissection had taken place that ruptured. He also felt that a ruptured diverticulum was a possibility.

³⁰ A specimen pouch used in surgery.

³¹ To urology staff at the second DHB.

³² The last part of the large intestine leading to the rectum.

125. Dr C later told ACC that thermal injury was caused by the LigaSure device³³ (the only cautery device used during the surgery). He said that there were two sites of cautery use and, due to the location of the bowel injury, it was most likely that the bowel injury occurred during its use in transecting a thick adhesive band holding the ovary to the anterior wall of the abdominal cavity.
126. Dr C stated to ACC:³⁴

“At the time of surgery the bowel injury would not have been detectable because the burned area would appear normal and only later would it break down and rupture. The bladder which was in an unusual position had a visible injury because the thick adhesive band contained a sliver of bladder within it and the cystotomy was detected as soon as the ovary was released from this tether ... The ovary, at the time of injury of the bowel, was totally free from any adhesions to the bowel; and the bowel was thought to be clear when the adhesive band between the ovary and the bladder was transected. The bowel injury was totally unanticipated and unusual, being caused by heat from the ligasure.”

Identification of bowel injury

127. SDHB was of the view that a theory that bowel injury occurred at the time of trocar placement is reasonable considering that 50% of complications with laparoscopic surgery occur at the time of trocar placement. Dr C’s techniques as described to Dr E were appropriate with trocars placed under direct visualisation using dilating trocars, and Dr C appropriately described circumferentially reviewing the umbilicus after placement of the sub-umbilical port.
128. SDHB acknowledged that another theory is that faecal peritonitis³⁵ occurred due to a perforated diverticulum (as Ms A had endured diverticulitis earlier). Some aspects of the surgery are a risk factor for perforation.
129. As stated by SDHB, in Dr E’s view:

“[T]he injury most likely occurred with adhesiolysis as the area of injury was low at the sigmoid colon which supports the idea that it occurred with lysis of adhesions. There is a risk of bowel injury in the setting of adhesions regardless of whether laparoscopy or laparotomy is performed.”

130. SDHB considered that Dr C’s technique was appropriate and the indication for surgery also appropriate.

Level of laparoscopic surgical skill required

131. Dr C stated: “I believe [Ms A’s] surgery was a Level 3 [procedure] since this is the level of laparoscopic oophorectomy. [Ms A’s] procedure was only different in that there were multiple adhesions.”

³³ An electrothermal tissue sealing device.

³⁴ In an email to an ACC case manager dated 23 May 2013.

³⁵ Resulting from faecal material in the peritoneal cavity.

132. SDHB was of the view that laparoscopic removal of residual ovaries with significant distortion of the anatomy is a Level 6 procedure as per the RANZCOG guidelines, but that “[Ms A] had a different clinical situation as she had an ovarian cyst and these are routinely removed by laparoscopy. In other words, [Ms A’s] surgery was not a level 6 procedure.”
133. SDHB stated that “the procedure undertaken — salpingo-oophorectomy — is not listed in the RANZCOG guidelines for advanced laparoscopic surgery”. It said that Dr E believed that other surgeons would agree that it would be reasonable for a generalist obstetrician/gynaecologist to place the laparoscope to determine the feasibility of completing the procedure.
134. SDHB told HDC that Dr E stated that “a laparotomy rather than laparoscopy would not remove the risk of bowel injury where adhesions already exist ... Bowel injury is a known complication of any pelvic surgery where there are adhesions, regardless of whether it is performed by laparoscopy or laparotomy.”
135. SDHB also stated that Dr E said that Dr C had training and evidence of competent practice in advanced laparoscopic gynaecology and, therefore, it was appropriate for Dr C to place the laparoscope.

Ms A’s postoperative care

Friday 22 March

Handover

136. Dr C verbally handed over the in-patients in his care, including Ms A, to the on-call consultant for the weekend, obstetrician and gynaecologist Dr B,³⁶ at around 4pm on the afternoon of Friday 22 March 2013. Dr B told HDC that his impression at handover was that Ms A was going well and that Dr C did not anticipate any further complications with postoperative recovery.
137. The clinical notes record that Dr C also saw Ms A at 9.20am on Saturday morning (just before leaving for the weekend). Dr C documented his review.
138. Ms A was stable. Her blood pressure was 120/55mmHg, her pulse was 75bpm, her respiration rate was 15 breaths per minute, and her temperature was 36.8°C. She complained of right quadrant tenderness, and her pain was attributed to gas (CO₂) from the laparoscopy, trapped under her diaphragm. Overnight Ms A had been started on oxybutynin³⁷ for bladder spasms, and nitrofurantoin³⁸ as a prophylaxis for bladder infection. Bowel sounds were heard but Ms A had not had a bowel movement.

³⁶ Dr B is a Fellow of an overseas college of obstetricians and gynaecologists and a Fellow of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists. Dr B obtained vocational registration with the Medical Council of New Zealand. At the time of writing Dr B is no longer practising in New Zealand.

³⁷ Medication used to relieve urinary and bladder difficulties by decreasing spasm.

³⁸ An antibiotic used to treat bladder infection.

139. Dr C recorded a management plan in the clinical notes, which included ambulating that day, a potential discharge the next day, and an outpatient visit with him to have the catheter removed.
140. Dr C told HDC that he saw Ms A on the Saturday morning to see how she was and explain what had happened and apologise. The clinical entry does not mention explaining or reviewing the operative events with Ms A, nor was there a record of an apology for the bladder perforation.
141. Dr C told HDC:

“In retrospect I should have documented the discussion about the bladder injury. I did arrange for [Ms A’s] follow up in clinic to have the catheter removed which would imply that the discussion of the injury had occurred ... The tendency not to document apologies is a remnant from [my overseas] medical environment, I am endeavouring to change.”

Saturday 23 March

142. Over the weekend of 23 and 24 March 2013 Ms A was reviewed on a number of occasions by the on-call senior house officer (SHO), Dr D.³⁹ Dr D told HDC that she was telephoned by nursing staff owing to Ms A’s decreased oral intake and low urine output. Dr D said that she was aware that the earlier surgery had been difficult, and that Ms A had bladder spasm and retained gas. Ms A had a low grade temperature of 37.5°C overnight.

Review

143. Dr D first saw Ms A at 4pm on 23 March 2013. Ms A had continued pain and nausea. She declined anti-emetic medication as it made her feel worse. Dr D recorded that Ms A looked well, and had oxygen saturations of 93% on 2 litres of oxygen and 90% on room air. Her blood pressure was 105/55mmHg, heart rate 80bpm, and respiration rate 15 breaths per minute, with an afebrile (non-fever) temperature of 37°C.
144. Ms A showed signs of dehydration, and her urine output had been less than 25ml/hr over the previous 10 hours. Her abdomen was soft but diffusely tender. Blood tests showed a normal full blood count with a potassium level of 3.1mmol/L (normal range 3.5–5.3mmol/L).
145. Dr D diagnosed postoperative nausea, pain secondary to the bladder spasm and trapped CO₂, and hypovolaemia.⁴⁰ She increased Ms A’s intravenous (IV) fluids and added potassium, stopped the cyclizine,⁴¹ prescribed additional oral potassium, and encouraged normal oral fluid intake and mobilising once Ms A was more settled. Instructions were given to call Dr D if the urine output remained low.

SHO contacted

³⁹ Employed by SDHB. Dr D was PGY3 at the time of these events. She was a senior house officer in obstetrics and gynaecology under the supervision of the consultant team including Dr C and Dr E.

⁴⁰ Decreased volume of circulating blood.

⁴¹ An antihistamine used to treat nausea and dizziness.

146. At 5.30pm Dr D was called by the nurses as Ms A was in pain with a bladder spasm. She had 40ml of blood-stained urine in the catheter bag (since the previous review). Ms A told nurses that her bladder felt full, so a bladder scan was undertaken. This showed a minimal volume of urine in the bladder. A new IV line was inserted. Fentanyl⁴² (25mcg) was given, and this was effective in relieving the pain. The catheter was flushed, and this dislodged a small clot.
147. By Saturday mid-evening (around 8pm) Ms A had ongoing nausea and was unwell, and had some abnormal recordings (a fever of 38.8°C, and oxygen saturations of 93% on 2 litres of oxygen and 88% on room air). Other observations were generally stable, with a heart rate of 91bpm, blood pressure of 130/60mmHg, and respiration rate increasing to 25 on room air. Her tongue was dry and her abdomen was diffusely tender with guarding. Bowel sounds were scant, and urine output had been 50ml/hr in the past three hours. A chest examination revealed decreased air entry.
148. At that point Dr D, noting the fever, queried infection and the possibility of bowel and/or ureteric injury. Dr D's notes include her impression:
- “1. Post op fever 2. ? Ileus
? intra abdo infection given difficult surgery [and bladder injury]
? Bowel/ureteric injury ...”
149. Bloods and cultures were taken and IV antibiotics were started. Dr D gave instruction for the placement of a nasogastric tube (NGT),⁴³ and for a catheter specimen of urine. Dr D suggested chest physiotherapy.

Call to consultant, Dr B

150. At approximately 8pm Dr D recorded a plan for a chest X-ray and an abdominal X-ray. She then telephoned Dr B and discussed Ms A.
151. Dr D told HDC: “[Dr B] advised me to continue treatment as planned and not for urgent imaging that evening.” The frequency of oxybutynin was increased. The plan for imaging was then crossed out.
152. Dr B told HDC that he felt that while bowel perforation was possible, it was “not high on the list of likely diagnoses”. He felt that the bladder perforation was the more likely source of the pain and possible sepsis.
153. It was agreed to wait for blood and urine test results and the response to IV antibiotics (cefuroxime and metronidazole).
154. Dr B did not review Ms A or arrange imaging of her abdomen. He stated:

“I did not request radiology investigation as laparoscopy involves the insufflation of gas and irrigation with fluid which are the very signs of a bowel perforation on

⁴² A synthetic opiate painkiller.

⁴³ A thin, plastic tube is inserted through the nostril, down the oesophagus, and into the stomach. Liquid nutrients can be delivered via this method.

CT. I did not consider that a CT scan would provide any valuable information when I was called on Saturday evening ...”.

155. Dr B also stated:

“I did not think that a CT scan would be useful this soon after laparoscopy. The radiographic evidence for bowel perforation is intra-abdominal fluid and/or gas. For the first few days following a laparoscopic procedure like [Ms A’s] there will always be fluid and gas in the abdomen. Therefore, differentiating normal and abnormal signs is likely impossible as irrigation fluid and carbon dioxide would still be present.”⁴⁴

156. Blood test results (at 8.40pm) showed a haemoglobin level unchanged at 140g/L (normal range 130–175), and the white cell count⁴⁵ was down to 11.4×10^9 cells/L (normal range being $4.0\text{--}11.0 \times 10^9$ /L). Potassium levels had improved to 3.5 (normal range 3.5–5.3mmol/L), sodium was 131 (normal range 135–145mmol/L), creatinine⁴⁶ was normal at 80, and C-reactive protein (CRP)⁴⁷ was 232mg/L (a normal result is <5mg/L).

157. Nursing staff telephoned Dr D at around 9.30pm as Ms A’s systolic blood pressure⁴⁸ had decreased to 97mmHg and her urine output was 25ml/hr. Fluids were increased and her urine output improved. Dr D requested two-hourly observations.

Sunday 24 March

Review

158. At 8am Dr D reviewed Ms A. She had responded well to use of the nasogastric tube. Ms A asked Dr D about HRT because of the hot flushes she had experienced.

159. On examination Ms A was flushed but had a normal temperature, her heart rate was 80bpm, blood pressure was 117/62mmHg, respiration rate was 20, oxygen saturation was 94% on 3 litres of oxygen, her abdomen remained diffusely tender with guarding, and bowel sounds were scant.

160. Dr D documented the possibilities of ileus (an intestinal obstruction) and bladder spasm pain, and bowel injury.

161. Dr D directed that Ms A could have sips of fluid but nothing to eat. Blood tests were to be repeated, and it was noted that Ms A was for consultant review that morning.

⁴⁴ As part of his response to HDC, Dr B provided a supporting statement from a colleague outlining her view that within the first 48 hours and possibly longer after a laparoscopy, CT would not be a helpful investigation to determine whether a bowel perforation has occurred.

⁴⁵ White blood cells help to fight infection.

⁴⁶ A creatinine blood test helps determine kidney function. The normal range may be 0.84 to 1.21 milligrams per decilitre (74.3 to 107 micromoles per litre), although this can vary from laboratory to laboratory, between men and women, and by age.

⁴⁷ A protein produced by the liver. Levels rise in response to inflammation.

⁴⁸ The blood pressure when the heart is contracting. It is specifically the maximum arterial pressure during contraction of the left ventricle of the heart. The time at which ventricular contraction occurs is called systole.

Consultant review

162. Dr B reviewed Ms A on a ward round at 10.30am.
163. Ms A was feeling unwell and sore, and was dry retching, but had opened her bowels that morning. Her observations were stable. Ms A was afebrile, her heart rate was 95bpm, and her blood pressure was 115/60mmHg. Her urine output that morning was 35ml/hr, but blood stained.
164. Blood test results showed a stable haemoglobin and white cell count, but the CRP level had increased to 342. An abdominal X-ray (AXR) showed that the nasogastric tube was placed correctly. Ms A was still tender on examination. Dr B's impression was that Ms A was stable, with morphine side effects potentially explaining her symptoms of nausea, and with a differential diagnosis of a bowel injury.
165. The IV non-steroidal anti-inflammatory (NSAID) parecoxib was added, antibiotics were continued, observations were decreased to 4-hourly, oxybutynin was stopped and replaced with VESicare, and instructions were given that Ms A should mobilise.
166. Dr B told HDC:
- “At this point, although an intra-abdominal infection was still a possibility, the lack of fever and normal white blood count made this seem less likely. My impression was that [Ms A] was improving. On the other hand, medication issues from the day before, with multiple changes, made me think that narcotic side effects may be contributing significantly to the clinical picture ...”
167. Dr B did not order any investigations at that time. He said: “On Sunday, not only was [Ms A] stable and generally improving through until approximately midnight, but the likelihood of a CT scan providing useful diagnostic information so soon after a significant laparoscopic procedure remained low.”

SHO contacted

168. Nurses called Dr D again during the evening shift. Ms A was feeling better and asked to have her nasogastric tube removed. This was approved by Dr D over the telephone. Ms A was also using incentive spirometry⁴⁹ at that point.
169. At 9.10pm Dr D reviewed Ms A as she required help with her IV line. Ms A was brighter and her nausea had decreased, although she was still dry and her urine output had dropped to 100ml over the last 8.5 hours. Ms A was afebrile. Her abdominal tenderness had improved. Her fluids were increased.

Monday 25 March

170. Dr D was contacted by nurses and attended at 12.15am. Ms A's urine output had decreased. She was mildly short of breath and her abdomen felt distended, her bowels had opened twice, and there was no increase in her pain.

Laboratory result

⁴⁹A device that provides the patient with visual or other feedback during efforts to achieve a predetermined respiratory flow or volume — useful in increasing inspiratory volume.

171. At around midnight, the laboratory informed Dr D that the blood cultures had grown a gram negative bacillus — a bacteria that had most likely come from the bowel.
172. Ms A's observations were a respiration rate of 24, saturation of 90% on two litres of oxygen, heart rate 96bpm, blood pressure of 104/59mmHg, and she was afebrile. Her urine output had been minimal over the past four hours, and two litres of fluid had been given over the course of the evening. Her jugular venous pressure (JVP) was normal. Ms A had mild pitting oedema, and a chest examination showed fine crepitations (crackle) bibasally (in both lungs). Her abdomen was distended and tympanic.⁵⁰ Her heart sounds were normal, and her calves were soft and non-tender.
173. Dr D's impression was 1) oliguria⁵¹ secondary to parecoxib or ureteric injury; 2) mild fluid overload only; 3) shortness of breath likely due to atelectasis⁵² and abdominal distension rather than fluid overload and pulmonary oedema.

Consultant contacted

174. Dr D telephoned Dr B at this point owing to her concerns.
175. Dr B told HDC:

“The positive blood culture indicated that there was a higher likelihood of an intra-abdominal injury beyond the cystotomy. Given the patient's stable observations and clinical picture, I felt that maintaining the urine output so as to prevent Acute Renal Failure was of immediate concern and made the decision to obtain a surgical review [later that] morning. I now regret the timing of that decision.”

176. The clinical notes record:

“Discussed with consultant
— For frusemide IV
— If [urine output] not improved next 2 hours, further frusemide dose as charted
— Bloods mane [in the morning] [and] consider need for imaging
— slow fluids”.

177. Ms A was given IV frusemide, and blood tests and consideration of imaging were planned for the morning.
178. In its response to HDC, SDHB stated that at midnight on Sunday, when the gram negative bacillus was isolated from the blood culture taken on 23 March 2013, this should have prompted a review and consultation with the general surgeons at that time, as this is pathognomonic⁵³ for bowel injury.

Review

⁵⁰ Drum-like sounds heard over air-filled structures during an abdominal examination.

⁵¹ Very low amounts of urine.

⁵² Incomplete inflation of the lung.

⁵³ Characteristic for a particular disease.

179. At 7.15am Dr D reviewed Ms A, who was in more pain, had vomited once, and was thirsty. Her observations had generally deteriorated (heart rate 128bpm, blood pressure 125/75mmHg, oxygen saturation 93% on 2 litres of oxygen, respiratory rate 24, afebrile). Ms A found it easier to breathe when sitting up. Her abdomen was more tender and distended than previously. Initially her urine output had increased to 30–100ml/hour with frusemide, but it had then dropped again.

180. Dr D told HDC:

“I recall being concerned that [Ms A] was still intravascularly depleted but possibly had symptoms of pulmonary oedema as well. I took bloods, increased maintenance fluids, made plans for [Ms A] to be nil by mouth, and planned for morning team review and consideration of CT abdomen.”

Handover meeting 25 March

181. Ms A’s condition over the weekend was discussed at an 8am team handover meeting that morning. Dr D handed over her on-call duties. She stated:

“I attended morning handover with all the O&G doctors and informed the team of my increasing concern for her state and possible need for general surgery review and return to theatre.”

182. It was considered at the handover meeting that Ms A must have a bowel perforation. Dr E was the on-call specialist on 25 March, and she reviewed Ms A and referred her to the surgeons with a diagnosis of possible bowel injury.

183. SDHB told HDC that the signs and symptoms of possible bowel injury were present over the weekend but not recognised as such. However, SDHB advised that a number of investigations were completed including blood cultures and an ultrasound of the bladder, and Dr D discussed the possibility of bowel injury with Dr B.

Further surgery required

184. At 9am on 25 March Ms A was seen by the surgical team and, at 12.30pm, was taken to theatre for a laparotomy. It was discovered that Ms A had faecal peritonitis from two perforations in the sigmoid colon. The histology report mentions perforations and surrounding acute inflammation, but does not mention evidence of a thermal injury. Dr C told HDC that he was devastated by the news from the surgical team.

185. Ms A had a peritoneal lavage, with a sigmoid colectomy⁵⁴ and an end sigmoid colostomy (a Hartmann’s procedure).⁵⁵

186. On 27 March Ms A had a “second look” laparotomy and washout, and refashioning of the end colostomy and then final closure of the wound.

⁵⁴ Removal of part of the left side of the colon.

⁵⁵ The Hartmann’s procedure involves resection of the rectosigmoid colon with the creation of a colostomy.

187. Ms A was treated in the Intensive Care Unit with IV antibiotics and nasogastric tube feeding. Her recovery was complicated by a slow resolving ileus.
188. Ms A was transferred to the surgical ward on 1 April 2013. On 2 April 2013 it was noted that Ms A had passed urine from her rectum.
189. On 5 April Ms A was found to have a fistula between her bladder and rectum, requiring a catheter to remain in place.
190. On 23 April Ms A was ready for discharge. She was discharged to the care of a surgeon and a urologist in another region, as she wanted to be closer to her family.
191. Ms A required further surgery at least six times to repair damage from the initial surgery. She has had many ongoing health issues.

Further information — Dr B

192. Dr B also told HDC:
 - Postoperative recovery of operative laparoscopy cases is much more variable than obstetric cases.
 - It is very common for patients to develop atelectasis (collapse of small airways) immediately following abdominal surgery. This is usually associated with fever. This is treated with incentive spirometry or physiotherapy, as happened in this case. Ms A did not have clear signs of bowel injury. The WCC was improving.
 - “I did not request radiology investigation as laparoscopy involves the insufflation of gas and irrigation with fluid which are the very signs of a bowel perforation on CT. I did not consider that a CT scan would provide any valuable information when I was called on Saturday evening. On Sunday, not only was [Ms A] stable and generally improving through until approximately midnight, but the likelihood of a CT scan providing useful diagnostic information so soon after a significant laparoscopic procedure remained low.”
 - Ms A’s evaluation was going to be inherently difficult as she had already had an intra-abdominal complication. With hindsight, it can be seen that she was showing early signs of bowel perforation; however, at the time it was not clear.
 - “I personally reviewed the patient on the Sunday morning when she appeared to be slightly improved. Just after midnight on Monday morning I was made aware of the positive blood culture, but [Ms A] had been started on antibiotics after her initial fever and was now afebrile. I felt that she could be reviewed [later that] morning. I accept with hindsight that on receiving the positive blood culture I should have asked the surgeons to review her at that time rather than in the morning. I made an error of judgement and I apologise sincerely for this.”

Subsequent events

193. Dr C told HDC that on Tuesday 26 March 2013 he and Dr E visited Ms A in the ICU, and Dr C apologised. Dr C completed an ACC injury claim form that day. The claim

was for a cystotomy and bowel perforation. Dr C also spoke with ACC staff over the next few months. A DHB Incident Notification Form was not completed at this time.

194. On 24 May 2013 ACC wrote to Ms A approving cover for bowel injury, peritonitis, further surgery and its associated sequelae secondary to removal of the ovary.
195. On 21 October 2013 SDHB received a letter from a patient advocate on Ms A's behalf about the care Ms A had received. SDHB told HDC that administrative processes regarding logging and co-ordinating a response to the complaint were not followed, and there was a delay in investigating the incident.
196. On 20 November 2013 an SDHB Incident Notification Form was completed retrospectively.
197. On 4 December 2013 Ms A's complaint was acknowledged. On 10 December 2013, SDHB wrote to Ms A advising that a formal review of her care was to be conducted.

SDHB Serious Adverse Event Report

198. In December 2013, SDHB commenced a Serious Adverse Event (SAE) Review. This was completed by a review team of five senior staff. Ms A's case was classified with a Severity Assessment Code (SAC)⁵⁶ score of 2 (meaning that an incident notification form should have been completed within 2 hours).

External expert review

199. As part of the SAE report, SDHB arranged for a review of Ms A's care to be undertaken by a consultant obstetrician/gynaecologist, Dr G.⁵⁷ This review was undertaken in January 2014. Dr G interviewed Dr C during the review.
200. Dr G made the following key findings:

- The decision to perform laparoscopic surgery, given the information known to the surgeon at the time, was reasonable.
- While aware that Dr C believes he did directly visualise entry, Dr G was of the view that the initial trocar site was not directly visualised by placing the scope in one of the accessory ports and looking at the initial puncture site. Likewise, the scope and port from the original puncture were not removed under direct vision.
- Dr G advised that “[t]he abdominal entry technique was reasonable and meets acceptable standards. The lack of direct visualisation of the entry site and not removing the scope under direct vision is suboptimal. Performing these steps would not necessarily prevent the injury but may have diagnosed the injury at the

⁵⁶ The Severity Assessment Code (SAC) is a numerical rating which defines the severity of an adverse event and, as a consequence, the required level of reporting and investigation to be undertaken for the event. The New Zealand Incident Management System *Guide to using the Severity Assessment Code* outlines that the Severity Assessment Code (SAC) is the method used by any person who has identified an incident, to determine the appropriate action to take. The score is ascertained by rating the consequence of the incident and its likelihood of occurrence.

⁵⁷ Dr G is vocationally registered and is a Fellow of RANZCOG and ACOG.

time of the initial operative event if the mechanism of the injury was a through and through puncture of the bowel with the initial entry port.”

- The mechanism of the injury to the bowel cannot be definitively ascertained. The two most likely mechanisms of injury would include a puncture of the large bowel with the initial port entry, or direct injury during the dissection. The likely mechanism, in his view, was from trocar puncture. His concern was that the injury was not recognised at the time of the initial surgery.
 - He considered the documentation of the surgical procedure to be reasonably complete and of sufficient detail.
 - The postoperative care provided was substandard. Ms A was afebrile and experiencing significant nausea and vomiting on postoperative day one. The degree of bowel symptoms required a nasogastric tube on postoperative day 1 after surgery. Imaging by CT scan or consultation with the general surgery team should have occurred at this time.
 - There was a delay recognising that Ms A’s recovery was not progressing as would be expected, and that the signs and symptoms exhibited early in the postoperative course after complicated laparoscopy, should have alerted to the possibility of bowel injury.
201. The SAE report was completed on 23 June 2014, and Ms A was provided with a copy of the report the following week.
202. Key findings made by the SAE review team were:
- The genetic counselling report of 19 February 2010 was not filed in the hospital notes and was not available to Dr C on 5 March 2013.
 - The available consent form used in this case may not have enabled full documentation of relevant information.
 - The different perspectives of Ms A and Dr C and communication about the need to proceed to surgery do not appear to have been recognised at the time of the consultation. Dr C reported that Ms A was concerned about the possibility of familial cancer risk and he was influenced by her anxiety and keenness to complete surgery before relocating.
 - Taking into account Ms A’s history of several abdominal operative procedures, it was reasonable to conclude that any further surgery could have been expected to be technically complex because of the presence of bowel adhesions to the abdominal wall. This increases the risk of bowel injury in any subsequent surgery, regardless of whether it is done by laparoscopy or as an open procedure. Bowel injury is a known but rare complication of laparoscopic surgery.
 - While a more up-to-date ultrasound (than the 7 August 2012 scan referred to by Dr C) would have been appropriate, it may not have changed the recommendation for surgery.
 - There was delayed recognition of bowel injury post surgery.

SAE recommendations

203. The SAE report made the following recommendations:

- Make sufficient time available for preoperative evaluation of complex cases at specialist appointments.
- Review clinical administration to ensure that a copy of all clinical information generated in the hospital service, and from external consultations, is placed in the clinical record.
- Review the Women’s Health Service surgery consent form.
- Encourage SMOs to discuss complex cases at multidisciplinary meetings as part of best practice.
- Remind SMOs of the RANZCOG guidelines for laparoscopic procedures.
- Remind SMOs of the signs that might suggest a problem if the course of recovery following laparoscopy is not as expected.
- Ensure administrative pathways in relation to complaints lodged with the DHB are consistent, and that all SMOs are aware of the process and are supported in the event they are involved in an incident review.

Changes to practice

204. SDHB advised that it made the following changes:

- In October 2014, clinical leaders developed a draft Women’s Health Service policy addressing “Less Commonly Performed Gynaecology Procedures” re-emphasising the importance of guidelines for complex procedures.
- The surgical consent form was reviewed to ensure space for adequate documentation of the proposed procedure and possible risks. A DHB-wide consent form is being developed.
- DHB staff were reminded about the importance of full documentation of all clinical interactions, and about the signs and symptoms of possible bowel injury following abdominal surgery.
- All new employees in the Women’s Health Service are to be advised to review guidelines present on the RANZCOG website, including those for laparoscopic surgery.
- A proposal to change clinic processes to include consents being performed in the clinic (at the same time as the outpatient appointment rather than the preadmission appointment) was not adopted after the Root Cause Analysis (RCA) was completed.
- The hospital performed a gynaecology surgery audit, and Key Performance Indicators (KPIs) were benchmarked favourably against two other large public hospitals.

205. Dr C is now aware of the RANZCOG guidelines. He has begun to write out specific risks/concerns for each patient on the consent form. In addition, as recommended to him by Dr E, he will use a template in his dictation in relation to information discussed in the consent process, to be dictated at the beginning of the operation note and also handwritten on the operation note.
206. Dr B reflected on his practice and stated: “Given the insidious presentation of [Ms A’s] bowel perforation I believe that I will be quicker in the future to consult with others about the options available for investigation and diagnosis.”

Responses to provisional report

Ms A

207. Ms A’s response to the “information gathered” section of the provisional report has been incorporated where appropriate.

SDHB

208. SDHB responded that it considered the report to be helpful and thorough. It accepted the recommendations. It had no further comments to make.

Dr B

209. Dr B’s response has been incorporated into the “information gathered” section of the report where appropriate.
210. Dr B provided a written apology letter for forwarding on to Ms A.
211. Dr B’s response includes the following points:

- “[Dr D] contacted me in the early hours of Monday morning to advise me of the blood cultures and having that information I was of the view surgical review could occur later that morning. I accept in hindsight and knowing what I do now that I could have called for surgical review at 1am rather than 8am (albeit acknowledging that in reality it may not have made a difference) and for that, as I have said, I am sorry ...”.
- “Given that [Ms A] appeared to be improving ... and that laparoscopic bowel injuries are rare and difficult to diagnose, especially when additional complications were known to be present ... it did not become clear that [Ms A] had a bowel injury until she started to deteriorate and blood cultures were received close to 1am on Monday morning.”

212. Dr B said that identification of a bowel injury is particularly difficult when signs or symptoms are not obvious or can be attributed to other things occurring postoperatively. This difficulty is not unique to this case and is supported by the fact that the median time to diagnosis of a bowel injury is three days.
213. Dr B stated: “[O]n the Monday morning, it was not that I was being careless or that I did not acknowledge or understand there was a probable issue but rather that, as [Ms A] had been started on antibiotics and was afebrile, I did not think the time between

1am and 8am would make a significant difference and she would likely only get seen at that time in the circumstances in any event. That said, I stand by my apology I did not call for surgical review hours before it subsequently occurred.”

214. Dr B also stated: “It should be remembered that [Ms A] was clinically improving and was not showing clear signs of bowel injury until early Monday morning. Knowing what we know now, it is easy to identify some signs of perforation in hindsight, but at the time it was not clear.”

Dr C

215. Dr C’s legal representative submitted a response to the provisional report, which included a separate submission from Dr C. Those responses have been incorporated into the “information gathered” section of the report where appropriate.

216. In addition, Dr C responded: “When [Ms A] presented with a history of a left complex ovarian mass that had increased in size ... in a postmenopausal woman who reported that her [close relative] had ovarian cancer the pressure to not miss a cancer was there.”

217. Dr C’s legal representative stated:

“It is accepted that [Dr C] did not have an up-to-date RMI at the 5 March 2013 consultation. That is why he took the responsible step of telephoning [Ms A] to discuss the result and confirm whether she wished to proceed. Taking the consultation and subsequent telephone call together, [Dr C] did *not* counsel [Ms A] without knowledge of an up-to date RMI calculation ...”.

218. Dr C also stated: “If I had not operated and the complex ovarian cyst was later found to be malignant ... I would have not treated [Ms A] appropriately. Also the Genetic Consult was not in the chart and [Ms A] did not share her knowledge of its results, so my support for the surgical option was influenced by my impression that [Ms A] had a first degree relative who had ovarian cancer ...”.

219. Dr C accepted the finding that his documentation did not comply with professional standards. He responded that he has since made a concerted effort (including having had audits conducted of his surgical cases) to improve documentation of the consent process. He would now document in the letter to the GP, on the surgical consent form, and in the surgical note the risks of the particular surgery explained to the patient, and that the patient consented to the procedure. Dr C said that he can only sincerely apologise for not documenting as expected, and that the need for this documentation has been made very clear to him. Dr C has also attended professional development educational courses in laparoscopy, and a RANZCOG revision course.

Opinion: Preliminary comment

220. I have a number of concerns regarding the standard of care Ms A received on the clinical pathway from her preoperative outpatient clinic appointment on 5 March 2013 through to her bowel injury being identified three days postoperatively on 25 March 2013. My concerns are centred on the following:
- a) The discussion with, and level of information provided to, Ms A by Dr C prior to the 22 March surgery.
 - b) Whether it was appropriate for Dr C to perform the surgery given Ms A's clinical history and circumstances and his skill level.
 - c) The standard of laparoscopic surgery performed by Dr C on 22 March 2013.
 - d) The overall standard of Dr C's documentation.
 - e) The quality of postoperative care Ms A received from Dr B, including the delay in recognition of her bowel injury given Ms A's particular clinical circumstances.
 - f) SDHB's handling of the incident and Ms A's complaint.
221. These concerns are examined in more detail below.
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Opinion: Dr C

Information provided to Ms A — Adverse comment

222. On 5 March 2013 Ms A saw Dr C preoperatively at the gynaecology outpatient clinic.

Clinical history

223. Dr C told HDC that he discussed Ms A's surgical and clinical history with her, including her past hysterectomy, which had been converted to a laparotomy owing to adhesions. Dr C told HDC that he had reviewed Ms A's clinical file prior to the clinic appointment.
224. My expert advisor, Dr Jenny Westgate, advised that this history was "highly significant and indicates that any subsequent surgery, by either laparoscopy or laparotomy, was also likely to be complicated by intra-abdominal adhesions".

Operative risks

225. Dr C told HDC that he discussed the operative risks with Ms A, and this included the potential for Ms A's known adhesions to make surgery more complicated, and thus more risky. He said that he gave Ms A a copy of the RANZCOG patient information leaflet on laparoscopy, as was his usual practice. This action is not documented.
226. Ms A recalls that the appointment was brief and Dr C broadly discussed risk, in relation to the usual operative risks. She cannot remember further discussion about risk. Ms A told HDC that she could not recall whether she was provided with any

leaflet. There is no documentation on file (in the outpatient notes, the consent form, or the clinic letter to the GP) that Dr C discussed the specific risks of surgery with Ms A.

Risk of malignancy

227. On 5 March 2013, the most recent ultrasound scan available to Dr C was that performed seven months previously, on 7 August 2012. The most recent tumour marker results available to Dr C were those from April 2012. Up-to-date tumour marker results and RMI calculation were not obtained by Dr C until that afternoon, and so the degree of risk (for malignancy) had not yet been determined or quantified to enable an informed discussion with Ms A about this during the clinic appointment.
228. Following receipt and review of the CA125 tumour marker result (11) on the afternoon of 5 March 2013 (and after the consent form had been signed) Dr C calculated the RMI as 99 and telephoned Ms A. Ms A told HDC that she was told that the result was negative. She said that she was relieved and asked Dr C if that meant she should still go ahead with surgery. She told HDC that Dr C advised her that she should, as it was unknown what the cyst might do in the future. Ms A said that an RMI score was not discussed with her. Neither the RMI nor the telephone call was documented by Dr C.
229. Dr C told HDC that the repeat CA125 was available that afternoon, and he called Ms A and told her that it was negative and not in the malignant range, and provided further counselling during the call. Dr C told HDC that he cannot recall whether he discussed the RMI number with Ms A.
230. Dr C stated: “[Ms A] was told the result indicated the cyst was not malignant but that some risk remained. My advice to [Ms A] was that surgery remained indicated, however she would not require referral to a specialist oncologist.”
231. Dr Westgate advised that Dr C’s telephone call did cover off the issue of informing Ms A that her cyst was likely to be benign. Dr Westgate was of the view that as Ms A’s CA125 values had been stable, Dr C’s conclusion was reasonable, and that based on some of the guidelines available in 2013 Ms A’s RMI of 99 would have been regarded as low risk, and Dr C’s advice was consistent with those guidelines.
232. I note that there is evidence in Dr C’s subsequent written communications regarding the indications for surgery, that he still had concerns that the mass might be malignant. Dr C stated that the lower RMI score did not completely eliminate the risk of malignancy, but lowered it to the point that Ms A did not require referral to a gynaecologist oncologist.

Conservative management

233. Dr C told HDC that he discussed a conservative surveillance approach with Ms A, but that she was concerned about a risk of malignancy and wanted the mass removed. Ms A disputes this, and says that she tried to cancel the surgery on more than one occasion, and felt pressure from Dr C to have the surgery in case her cyst was malignant.

234. I note that Dr C's clinic letter of 5 March 2013 to the GP states: "As there is a family history, and this cyst has been present for quite some time, I will try to expedite as much as possible her surgery date and also she does have a job waiting for her, which she is concerned about having any sort of delays."
235. While I accept that Ms A's recollection is that she tried to cancel the surgery, I cannot make a finding whether Dr C pressured Ms A into surgery.

Surgical route

236. Dr C told HDC that he discussed the surgical route with Ms A. He told HDC that as Ms A did not want a long recovery, she wanted to try a laparoscopic approach. Dr C said he discussed with Ms A that if a laparoscopic approach was not possible after viewing the pelvis, the surgery would need to be converted to an open procedure, and that Ms A understood this.
237. Dr C's clinic letter to the GP states: "I am hopeful that we will be able to remove the ovary laparoscopically, and it can be a day case, but she is aware that if, for any reason, we are not able to accomplish the surgery laparoscopically, we will proceed with an open case which will require a possible hospital stay."

Information provided to Ms A

238. It is difficult to determine accurately the precise nature of the discussion had and the information imparted to Ms A by Dr C at the preoperative clinic on 5 March 2013. I have been provided with conflicting accounts. Dr C said that he discussed specific risks with Ms A. Ms A said that Dr C broadly discussed risk and that she could not recall whether any information leaflet was provided to her. She later told HDC that she was 99.9% sure that she did not receive written information.
239. There is no documentary evidence (in the outpatient clinical records, the consent form, or the clinic letter to the GP) that Dr C discussed the operative risks specific to Ms A's surgery in the context of her previous clinical history and the likelihood of adhesions.
240. I have considered all the evidence and, in the circumstances, I am unable to make a finding whether Dr C provided Ms A with information about the risks of surgery specific to her case prior to her consenting to the surgery.
241. However, I am concerned that Dr C discussed the proposed surgery with Ms A on the morning of 5 March 2013 without the knowledge of important clinical factors (including the quantified risk of malignancy, which was calculated later that afternoon after the clinic was conducted and after consent had been obtained) — factors that were relevant to a preoperative discussion and Ms A's consideration of whether or not to proceed with surgery.
242. While I accept that Dr C later telephoned Ms A about the CA125 result, as Ms A acknowledges, Dr C said that he does not recall whether he discussed the RMI. Ms A is adamant that he did not discuss an RMI figure.

243. Dr Westgate advised me that she is not concerned about the decision to operate. I am satisfied, based on the advice I have received (acknowledging that clinical guidelines on RMI cut-off points related to the level of risk in existence from 2010 to 2013 were subject to changes and evolved in this period), that Dr C's advice to Ms A that surgery remained indicated was reasonable in the circumstances.

244. However, I agree with the following advice from Dr Westgate:

“[Dr C] counselled [Ms A] about the need (or not) for surgery on her ovarian cyst without knowledge of up to date tumour marker blood test results or an RMI calculation. This is below the recommended standard of practice for the management of ovarian cysts in postmenopausal women ...”.

245. I am critical that Dr C discussed the proposed surgery with Ms A on the morning of 5 March 2013 (when Ms A consented to the surgery) without the knowledge of important clinical factors (including the CA125 result and a quantified risk of malignancy) — factors that were relevant to a preoperative discussion and Ms A's consideration of whether or not to proceed with surgery. This was suboptimal on Dr C's part.

**Appropriateness of decision to perform laparoscopic surgery —
Adverse comment**

246. RANZCOG has published guidelines pertaining to advanced operative laparoscopy. I have some concerns that Dr C, a Fellow of the College who routinely performed Level 5 surgery, was not aware of the RANZCOG guidelines at the time of Ms A's surgery. In my view, Dr C ought to have been aware of the guidelines. Dr C said that the RANZCOG guidelines could be better clarified to surgeons, especially those educated overseas.

247. I note that there is a degree of clinical debate regarding the level of laparoscopic skill, as per the guidelines, required to perform Ms A's surgery.

248. The operative consent form, completed on 5 March 2013 and signed by Ms A and Dr C at the clinic, is for a “left salpingo oophorectomy” procedure. Dr C stated that he believed Ms A's planned surgery was a Level 3 procedure, since this is the level for a laparoscopic oophorectomy, and that Ms A's procedure “was only different in that there were multiple adhesions”.

249. I note that as part of SDHB's response, Dr E's view was that while laparoscopic removal of residual ovaries with significant distortion of the anatomy is a Level 6 procedure (per the RANZCOG guidelines), “[Ms A] had a different clinical situation as she had an ovarian cyst and these are routinely removed by laparoscopy. In other words, [Ms A's] surgery was not a Level 6 procedure.”

250. SDHB told HDC that Dr E also stated that “the procedure undertaken — salpingo-oophorectomy — is not listed in the RANZCOG guidelines for advanced laparoscopic surgery”, and that she believed that other surgeons would agree that it would be reasonable for a generalist obstetrician/gynaecologist to place the laparoscope to

determine the feasibility of completing the procedure. In her view, Dr C had training and evidence of competent practice in advanced laparoscopic gynaecology and, therefore, it was appropriate for Dr C to place the laparoscope.

251. The SAE review finding was that given Ms A's history of several abdominal operative procedures, it was reasonable to conclude that any further surgery could have been expected to be technically complex because of the presence of bowel adhesions to the abdominal wall. It noted that this increases the risk of bowel injury in any subsequent surgery, regardless of whether it is done by laparoscopy or as an open procedure.

252. Dr Westgate advised:

“My advanced laparoscopy colleagues have informed me that a large cyst is often easier to remove as the growing cyst stretches out the adhesions and enables the tissue planes to be identified more clearly. However, in [Ms A's] case the left ovary and cyst measured only 4.3 x 2.1 x 2.1 cm which is not much larger than an ovary alone. Furthermore, [Dr C's] operation note recorded that the bladder was pulled markedly towards the left side, there was quite a bit of adhesive disease on the left side of the pelvis involving bowel, omentum and the lateral and anterior abdominal walls. He also described the left ovary as being completely buried in adhesions. I respectfully submit that these comments are consistent with significant distortion of the anatomy and hence a Level 6 procedure.”

253. Dr Westgate told HDC that she discussed this case (anonymised) with colleagues. She advised that some of her colleagues thought it would be acceptable for gynaecologists with skills at level 3 to 5 to commence such operations with a laparoscopy to assess whether the ovary and cyst could be removed laparoscopically.

254. Dr Westgate, and some of her other colleagues, considered that the history of an unsuccessful attempt at a laparoscopic hysterectomy plus an adnexal mass in a woman after an abdominal hysterectomy meant that the chance of a successful laparoscopic procedure was so low that they would perform the operation by laparotomy and avoid exposing the patient to the additional risk of a laparoscopy.

255. Dr G, the SAE reviewer, suggested that either approach would be acceptable.

256. Dr Westgate advised:

“The key aspect is not the decision to commence the operation by the laparoscopic route but the decision to continue with laparoscopic removal of the ovary in the light of the severe adhesive disease.”

Conclusion — appropriateness of decision to perform laparoscopic surgery

257. I acknowledge that there is divided opinion on the appropriateness of the decision to perform laparoscopic surgery in Ms A's case, and that some of Dr C's peers would consider it acceptable for Dr C to have commenced the procedure given his level of skill.

258. However, I note my expert's comment:

“[T]he technical difficulties in this case were highly predictable given [Ms A's] past history and I am not sure whether [Dr C] recognised this pre-operatively ...”.

259. I accept Dr Westgate's advice on this point. In my opinion, Dr C's statement that Ms A's procedure “was only different [from a Level 3 procedure] in that there were multiple adhesions” is evidence that he did not appreciate, or think critically about, the potential surgical difficulties he might face given Ms A's serious adhesive disease. I am critical of Dr C in this regard.

Standard of laparoscopic surgery performed

260. On 22 March 2013 Ms A had laparoscopic day surgery. The operation note details that the surgery undertaken was “laparoscopic removal of left ovary and portion of left tube, adhesiolysis and inadvertent cystotomy [a small hole in the bladder] and cystotomy repair”. The procedure was complicated owing to adhesions. A left ovarian cyst was found, which turned out to be slightly larger than previously thought (now 4 x 2.5 x 5cm) and benign.
261. Dr C advised HDC that upon entry into the umbilical trocar he looked circumferentially around the site and saw no injury. Dr C did not document that he had placed the endocatch bag through the umbilical port.
262. Later, Dr C told HDC that after reviewing the notes (while preparing his response) it became apparent to him that he had placed a 5mm scope in one of the lower abdominal trocar ports to place the ovary in an endocatch bag, and he had sighted the bag at the umbilical port.
263. The ovary was removed with the cyst not ruptured within the patient. An inadvertent operative injury to the bladder occurred during surgery. This was laparoscopically repaired by urologist Dr F.
264. Dr C said that after removal of the ovary he checked and inspected the area and recognised the bladder injury but did not see any bowel injury. Dr C's operation note does not document the proximity of the bowel to the adhesions around the ovary, or whether he specifically checked the bowel for damage after the bladder was repaired.
265. During Ms A's later postoperative course it was discovered that she had also suffered a bowel injury.
266. Dr F's clinic letter of 8 May 2013 documented that the surgery had resulted in a recognised bladder injury at the time of the surgery, which was repaired, but, according to his letter, what was not recognised at the time was “the fact that the camera port had gone in and out through the sigmoid colon on the way into the peritoneal cavity”.
267. Dr C told HDC that he did not believe that the bowel injury was a trocar injury because: the location in the sigmoid colon/rectum is not beneath or near the

umbilicus; he used dilating trocars and it is difficult to perforate the bowel with these; and the ovary was located over the injured area of bowel and would have prevented the injury from trocar insertion.

268. Dr C felt that there may have been a thermal injury that ruptured later, a weakened area where the dissection had taken place that ruptured, or a ruptured diverticulum. Dr C later told ACC that thermal injury was caused by the LigaSure device (the sole cautery device used during the surgery).

269. SDHB was of the view that the theory that bowel injury occurred at the time of trocar placement was a reasonable theory considering that 50% of complications with laparoscopic surgery occur at the time of trocar placement. It stated that Dr E considered that Dr C's techniques as described to her were appropriate with the dilating trocars being directly visualised by Dr C.

270. Dr E opined:

“[T]he injury most likely occurred with adhesiolysis as the area of injury was low at the sigmoid colon which supports the idea that it occurred with lysis of adhesions. There is a risk of bowel injury in the setting of adhesions regardless of whether laparoscopy or laparotomy is performed.”

271. SDHB advised that Dr E was of the view that Dr C's technique was appropriate and the indication for surgery also appropriate.

272. Dr G stated, after discussing the surgery with Dr C, that while Dr C believed he had visualised entry directly, he (Dr G) was of the view that the initial trocar site was not visualised directly. Dr G said:

“The abdominal entry technique was reasonable and meets acceptable standards. The lack of direct visualisation of the entry site and not removing the scope under direct vision is suboptimal. Performing these steps would not necessarily prevent the injury but may have diagnosed the injury at the time of the initial operative event if the mechanism of the injury was a through and through puncture of the bowel with the initial entry port.”

273. Dr G felt that the two most likely mechanisms of injury would include a puncture of the large bowel with the initial port entry, or direct injury during the dissection. The likely mechanism, in his view, was trocar puncture.

274. Dr Westgate opined that in her view the bowel injury is more likely to have occurred during adhesiolysis.

275. Dr Westgate concluded:

“[Dr C's] decision to commence the operation laparoscopically is acceptable. His decision to continue with a laparoscopic removal of the ovary is less clear. In retrospect we know that both the bladder and bowel were injured which undoubtedly raises concerns. I accept that surgical complications can indicate a

technically difficult operation rather than lack of surgical expertise. [Dr E] considers that [Dr C's] surgical skill was adequate to perform this operation ... Overall, [Dr E's] reassurance of [Dr C's] surgical skill is enough to convince me that there was no departure from an acceptable standard of surgical skill in [Ms A's] operation."

Conclusion

276. I accept Dr Westgate's advice. I acknowledge that the mechanism of bowel injury is not definitive in this case.

Documentation — Breach

277. I am concerned that there are a number of instances where the standard of Dr C's clinical documentation was lacking. In particular:

- a) As noted above, there is no documentary evidence (in the outpatient clinical records, the consent form, or the clinic letter to the GP) that Dr C discussed the operative risks specific to Ms A's surgery, in the context of her previous clinical history and severe adhesive disease.
- b) Once the cancer screening blood test was available on the afternoon of 5 March 2013, Dr C telephoned Ms A with the result. The RMI calculation and telephone call are not documented.
- c) Dr C's operation note on 22 March 2013 does not document that he placed the endocatch bag through the umbilical port.
- d) Dr C's operation note does not document the proximity of the bowel to the adhesions around the ovary, or whether he specifically checked the bowel for damage after the bladder was repaired.

278. The Medical Council of New Zealand's statement on "Maintenance and retention of patient records"⁵⁸ states that doctors:

"... must keep clear and accurate patient records that report:

- Relevant clinical findings
- Decisions made
- Information given to patients

...

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

279. Dr Westgate advised that Dr C's documentation of the consenting process was absent and falls below an accepted standard of practice to a severe degree.

⁵⁸ August 2008.

280. Dr Westgate also advised that Dr C's documentation of the steps taken to ensure that there was no damage to the bowel during the operation are not of an acceptable standard.

281. Dr Westgate was of the view:

“If the bowel injury occurred during entry, as [Dr G] believes, then [Dr C's] record of the process he followed to ensure bowel had not been damaged at this site was inadequate.

If the bowel injury occurred during adhesiolysis, as [Dr E] believes, then [Dr C's] documentation of steps taken to ensure the bowel was not in the operative field are inadequate.”

Conclusion — documentation

282. As I have stated previously, “the importance of good record keeping cannot be overstated. It is the primary tool for continuity of care and it is a tool for managing patients.”⁵⁹ Dr C did not meet his obligations to keep clear and accurate clinical and surgical records. Accordingly, in my opinion, Dr C failed to comply with professional standards and, therefore, breached Right 4(2) of the Code.

Opinion: Dr B

283. Dr C verbally handed over the care of Ms A to Dr B, at around 4pm on Friday 22 March 2013. He was the clinician with overall responsibility for Ms A over the weekend. I have concerns about the quality of postoperative care Ms A received from Dr B, particularly the delay in recognition of Ms A's bowel injury given her symptoms.

284. Ms A was reviewed on a number of occasions by the on-call SHO, Dr D, over the weekend of 23 and 24 March 2013. Dr D turned her mind to the possibility of a ureter or bowel injury, instigated a number of investigations, and appropriately brought her concerns to the attention of Dr B for guidance and advice.

285. In particular, on 23 March, Dr D queried infection and the possibility of bowel and/or ureteric injury. Bloods and cultures were taken and IV antibiotics were started. Dr D telephoned and discussed Ms A with Dr B. Dr B advised her to continue treatment as planned and directed that Ms A was not for urgent imaging that evening. Dr B did not review Ms A, and stated:

“I did not request radiology investigation as laparoscopy involves the insufflation of gas and irrigation with fluid which are the very signs of a bowel perforation on CT. I did not consider that a CT scan would provide any valuable information when I was called on Saturday evening ...”.

⁵⁹ Opinion 10HDC00610, available at www.hdc.org.nz.

286. On 24 March Dr B reviewed Ms A on a ward round at 10.30am. Blood test results showed that Ms A's CRP level had increased to 342. Dr B's impression was that Ms A was stable, with morphine side effects potentially explaining her symptoms of nausea, with a differential diagnosis of a bowel injury.
287. Dr B told HDC that although an intra-abdominal infection was still a possibility, the lack of fever and normal white blood count made this seem less likely. His impression was that Ms A was improving but that narcotic side effects might have been contributing significantly to her clinical picture. He considered that the likelihood of a CT scan providing useful diagnostic information so soon after a significant laparoscopic procedure remained low.
288. At about midnight on 25 March, the laboratory informed Dr D that the blood cultures had grown bacteria — a gram negative bacillus, which had most likely come from the bowel. She reviewed Ms A, who had deteriorated, and then telephoned Dr B and discussed Ms A. Dr B did not review Ms A personally or arrange a surgical review.
289. Dr B told HDC:
- “The positive blood culture indicated that there was a higher likelihood of an intra-abdominal injury beyond the cystotomy. Given the patient's stable observations and clinical picture, I felt that maintaining the urine output so as to prevent Acute Renal Failure was of immediate concern and made the decision to obtain a surgical review [later that] morning. I now regret the timing of that decision.”
290. After a team handover meeting that morning, Dr E reviewed Ms A and referred her to the surgical team with a diagnosis of possible bowel injury.
291. Dr B said his overall view was that Ms A's evaluation was going to be inherently difficult as she had already had an intra-abdominal complication, but with hindsight he said that he can see that Ms A was showing early signs of bowel perforation, although at the time this was not clear. He stated: “I accept with hindsight that on receiving the positive blood culture I should have asked the surgeons to review her at that time rather than [later that] morning. I made an error of judgement and I apologise sincerely for this.”
292. I note that SDHB acknowledged that the gram negative bacillus isolated from the blood culture should have prompted a review and consultation with the general surgeons at that time, as the result is pathognomonic for bowel injury.
293. In addition, the SAE review noted the significance of Ms A being afebrile and experiencing significant nausea and vomiting on postoperative day one. The degree of bowel symptoms required a nasogastric tube on postoperative day one. The SAE review also noted that imaging by CT scan or consultation with the general surgery team should have occurred at that time.

294. In my view, a key point in the clinical timeline is when the blood culture results became available and were relayed to Dr B in the very early hours of Monday 25 March.

295. Dr Westgate advised:

“I accept the difficulties of assessing [Ms A’s] post operative course in view of the fact that she had a documented complication. However, [Dr B’s] failure to recognise that [Ms A] was likely to have a bowel injury on Sunday night when the blood culture results were relayed to him, and his failure to review her personally or refer her for a surgical consultation despite her deteriorating condition is below an acceptable standard of practice and the departure is severe. I believe that the majority of my peers would agree with this assessment.”

296. I accept and agree with this expert advice. I acknowledge that Ms A had a complicated laparoscopy and postoperative course. However, I am concerned that there was a delay in Dr B recognising that Ms A might have a bowel injury given that the possibility had been brought to his attention on more than one occasion.

297. I remain particularly concerned that once the blood culture results were available to him, Dr B did not review Ms A personally or refer her for a surgical review. In my opinion, Dr B failed to provide services to Ms A with reasonable care and skill and, accordingly, he breached Right 4(1) of the Code.

Opinion: Southern District Health Board

298. I am critical of the care provided to Ms A by individual staff of SDHB, as set out above. As I have stated previously, while individual clinicians need to be competent in their clinical assessment and management of patients, staff also need to be supported by systems that guide good decision-making and promote a culture of safety.⁶⁰ District health boards are responsible for the operation of the clinical services they provide, and are responsible for service failures.

Clinical care provided by SDHB staff

299. Ms A did not receive the standard of care to which she was entitled. In my view, SDHB must bear overall responsibility for the series of deficiencies Ms A experienced throughout her clinical care pathway. Specifically:

- Ms A did not have all the information she required in order to make an informed choice and give informed consent regarding her surgery.
- Dr C did not appreciate, or think critically about, the potential surgical difficulties he might face given Ms A’s history of extensive adhesive disease.

⁶⁰ Opinion 09HDC02089, 4 July 2012.

- Dr C did not meet his obligations to keep clear and accurate clinical and surgical records.
- Postoperatively, there was a delay in Dr B recognising that Ms A might have a bowel injury, despite the possibility having been brought to his attention on more than one occasion. When blood culture results were available, he did not review Ms A personally or refer her for surgical review.

RANZCOG guidelines

300. While I am of the view that Dr C ought to have been familiar with the RANZCOG guidelines, I am concerned that he told HDC that at the commencement of his employment he was not made aware of the RANZCOG guidelines pertaining to the performing of advanced operative laparoscopy.
301. Dr C said he felt that the RANZCOG guidelines could be better clarified to surgeons educated outside of New Zealand. While SDHB considers the RANZCOG guidelines to be important, it acknowledged that Dr E believed that many SMOs were unaware of the guidelines.
302. I note that remedial steps were taken as a result of this case, in that all new employees in the Women's Health Service are now advised to review the guidelines present on the RANZCOG website, including those for laparoscopic surgery. SDHB clinical leaders developed a draft Women's Health Service policy addressing "Less Commonly Performed Gynaecology Procedures", re-emphasising the importance of the guidelines for complex procedures.
303. However, at the time of Ms A's surgery the overall lack of clarity and awareness of the guidelines was, in my view, unsatisfactory.

Consent form

304. I am critical that the surgical consent form in use at the time had no space to record risks specific to the patient.
305. Dr Westgate advised: "I believe the consent form should be revised to include a section for the documentation of risks discussed with the patient. Many DHBs did this some years ago."
306. I agree that this would serve as an additional prompt to clinicians. I note that the surgical consent form has now been reviewed to provide space for adequate documentation of the proposed procedure and possible risks.

Administrative shortcomings

2010 report

307. This case has also highlighted that administrative issues were a contributing factor to the events that occurred.
308. The genetic consultation report of 19 February 2010 (a clinically relevant piece of information for Dr C) was addressed and sent to Ms A and copied to the locum Ms A had seen at the hospital. By that time the locum was no longer working for SDHB.

However, a copy of the report was not entered into the hospital notes until this case was reviewed, and so was not available to Dr C on 5 March 2013.

309. I am critical of this system deficiency. I note that clinical administration was subsequently reviewed to ensure that a copy of all clinical information generated in the hospital service, and from external consultations, is placed in the clinical record.

Complaint

310. I note that the SAE Review determined that Ms A's injury warranted an SAC score of 2, which meant that an incident notification should have been logged around the same time as the ACC treatment injury claim form was completed. This was not done.
311. On 21 October 2013 SDHB received a letter from a patient advocate about Ms A's treatment. SDHB told HDC that administrative processes regarding logging and co-ordinating a response to the complaint were not followed, and there was a delay in investigating the incident.
312. On 20 November 2013 an Incident Notification Form was completed retrospectively. On 4 December 2013 Ms A's complaint was acknowledged. On 10 December 2013, SDHB wrote to Ms A advising that a formal review of her care was to be conducted.
313. I am critical of the delays that occurred in managing the matter and processing the ensuing complaint. This was suboptimal and should have occurred in a more timely manner.

Conclusion — SDHB

314. In my opinion, for the reasons outlined above, SDHB failed to ensure that Ms A was provided with services with reasonable care and skill and breached Right 4(1) of the Code.

Other comment — Dr C's employment

315. Dr C was employed by SDHB in accordance with DHB credentialing policy at the time. Dr C underwent a structured and documented month-long programme of induction and orientation. Dr C's supervisor for the Medical Council of New Zealand for the first 12 months of his employment was very experienced. No issues were identified during Dr C's supervision period. Dr C's overseas obstetrics and gynaecology residency involved advanced laparoscopic surgery training. Dr C had training and experience in Level 5 RANZCOG procedures.
316. I accept that SDHB's assessment of Dr C's credentials and competence prior to his employment was reasonable.

Recommendations

317. I recommend that Dr C provide a formal written apology to Ms A. The apology is to be sent to HDC for forwarding, within three weeks of the date of this report.
318. I recommend that Dr C, within three months of the date of this report:
- a) Have an independent colleague review a random selection of his surgical consent forms from the last 12 months to report on whether specific surgical risks/concerns for each patient are written on the consent form, and report the results to HDC.
 - b) Provide HDC with a copy of the template (as recommended by his supervisor) used in his dictation in relation to information discussed in the consent process, to be dictated at the beginning of the operation note and also handwritten on the operation note.
319. In the provisional report I recommended that Dr B provide a formal written apology to Ms A. In response, Dr B provided an apology letter, and this will be forwarded to Ms A.
320. I recommend that in the event that Dr B wishes to return to New Zealand to practise, the Medical Council of New Zealand consider whether a review of Dr B's competence is warranted.
321. I recommend that RANZCOG consider whether the wording of the consensus statement "*C-Trg 2, Guidelines for performing advanced operative laparoscopy*" requires revision, and report the outcome of this consideration to HDC within four months of the date of this report.
322. I recommend that Southern District Health Board, within three months of the date of this report, provide HDC with a detailed update report on the progress and effectiveness of all steps taken by it to improve service as a result of this case, including:
- a) Surveying new and existing employees in the Women's Health Surgical Service regarding their awareness of the RANZCOG guidelines for performing laparoscopic procedures, and confirming that RMO and SMO orientation includes this information.
 - b) Reviewing complex cases from the last six months to confirm that SMOs regularly discuss complex cases at multidisciplinary meetings as part of expected practice, and discuss general and specific operative risk with patients.
 - c) Providing a copy to HDC of the latest Women's Health Service policy addressing "Less Commonly Performed Gynaecology Procedures" re-emphasising the importance of guidelines for complex procedures.

- d) Providing to HDC a copy of the amended Women's Health Service surgery surgical consent form showing that there is now space for adequate documentation of the proposed procedure and possible risks.
 - e) Providing results from the recent gynaecology surgery audit, benchmarking KPIs against comparably sized hospitals/DHBs.
 - f) Conducting a random review of clinical administration processes to ensure that a copy of all clinical information generated in the hospital service, and from external consultations, is placed in the clinical record.
 - g) Conducting a review of administrative pathways in relation to complaints lodged with the DHB, to confirm that appropriate processes are followed and that all surgical clinicians are aware of that process.
323. While not a focus of this report, I recommend that SDHB also confirm to HDC all steps it routinely takes to fully and accurately ascertain and review the performance history and complaint/litigation history of overseas trained clinicians applying for roles with SDHB.
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Follow-up actions

324. A copy of this report with details identifying the parties removed, except the expert who advised on this case and SDHB, will be sent to the Medical Council of New Zealand, and it will be advised of the names of Dr C and Dr B in covering correspondence.
325. A copy of this report with details identifying the parties removed, except the expert who advised on this case and SDHB, will be sent to the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, and it will be advised of the names of Dr C and Dr B in covering correspondence.
326. A copy of this report with details identifying the parties removed, except the expert who advised on this case and SDHB, will be sent to DHB Shared Services, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent expert advice to the Commissioner

The following expert advice was obtained from an obstetrician and gynaecologist, Associate Professor Jenny Westgate:

“Thank you for asking me to provide advice on this case. I am a Fellow of the Australian and New Zealand College of Obstetricians and Gynaecologists and am on their Expert Witness Register. I work as a general O&G Specialist and I provide medical opinions for the ACC. I have no conflict of interest in this case. I have worked briefly as a locum O&G specialist at Southern DHB. Dr C was not employed at the hospital at that time. I have read the documents you sent to me as listed in your first letter of instruction and the additional documents sent in July 2015 following submission of my first report.

Clinical Summary

[Ms A] had an elective laparoscopy to remove a left ovarian cyst on Friday 22nd March 2013 performed by [Dr C]. The procedure was complicated due to adhesions and an operative injury to the bladder was identified and repaired by a urologist who was called to assist in theatre. Postoperatively [Ms A] had a difficult postoperative course with pain and fever and low urine output. It was not until Monday 25th that it was realised that [Ms A] must have a bowel injury and referral was made to the surgeons. She had a laparotomy that day at which fecal peritonitis from two holes in the sigmoid colon was discovered. [Ms A] had a Hartman’s procedure and a colostomy. She had a second look laparotomy and washout 48 hours later and the wound was closed. [Ms A] was cared for in the intensive care department and then transferred to the ward. She continued to have on and off fevers and problems with her urinary catheter. On 2nd April it was noted that she had passed urine from her rectum. It became obvious that [Ms A] developed a fistula from her bladder to the rectal stump. [Ms A] was discharged to the care of a surgeon in [another region] as she wanted to move to be closer to family. She has required at least 6 further surgeries to repair damage from the initial surgery.

You have asked me to comment on the following issues.

1. What information, including risks and alternative treatment, is usually provided to patients prior to performing surgery to remove an ovarian cyst?
2. Appropriateness of the decision to perform the initial surgery.
3. Appropriateness of the decision to perform laparoscopic surgery rather than open surgery.
4. The standard of care taken in performing the operation including —
 - a. failure to identify the bowel injury during surgery.
5. The standard of post operative care including —
 - a. delay in identifying bowel injury and

- b. following identification of bowel injury.
6. Appropriateness of the recommendations made in the Root Cause Analysis.

In the request for further expert advice you asked

7. Whether I wish to make changes or additions to my original report in the light of the additional information provided in July 2015 and the response of Southern DHB and [Drs C and B].
8. Overall Standard of care provided by:
 - i. [Dr C]
 - ii. [Dr B]
 - iii. Southern DHB

You wish me to comment on

- a) what is the standard of care/accepted practice?
 - b) If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider it?
 - c) how would it be viewed by your peers.
9. Appropriateness of the policies and procedures in place at Southern DHB.

Comments

The comments made in this report have been modified based on the new information provided in July 2015.

1. What information, including risks and alternative treatment, is usually provided to patients prior to performing surgery to remove an ovarian cyst?

I think it is more helpful to address Question 2 first and then come back to this question.

2. Appropriateness of the decision to perform the initial surgery.

The decision to perform surgery in [Ms A's] case was contingent on three main issues:

- How likely was it that the cyst was malignant.
- Did surgery in [Ms A] case carry risks above and beyond usual surgical risk.
- Agreement from [Ms A] that she understood the indications for surgery and the risks involved and was prepared to go ahead with the operation.

a) Malignant potential.

In a woman of 52 years of age, the most important consideration is the possibility that the cyst is malignant. To that end women should be investigated with a transvaginal ultrasound and measurement of tumour markers in the blood,

specifically Ca-125 level. This will enable the calculation of a Risk of Malignancy Index (RMI) to guide further management. Women with a low RMI can have conservative treatment with their gynaecologist which may involve observation only or laparoscopic oophorectomy. Women of medium or high risk should be referred to the regional Gynaecology Oncology Unit for discussion at a Multidisciplinary Meeting (MDM).

Reference: RCOG GreenTop Guidelines Number 34. Ovarian cysts in Postmenopausal women. 2003, reviewed 2010. (pdf provided)

In [Ms A's] case, the most recent scan available to [Dr C] was performed 7 months ago in August of 2012. [Dr C] did order tumour marker blood tests but did not wait for the results before planning the surgery.

[Dr C] has advised the Commissioner that he did check the Ca125 tumour marker result in the afternoon following the clinic and calculated the RMI as 99, which is low risk. He also discussed [Ms A's] case with a radiologist who advised that a repeat scan was not required. This information is not recorded anywhere in the notes.

b) Evaluation of surgical risk.

[Ms A] had a history of an attempt at a laparoscopic operation to perform a hysterectomy which was thwarted by too much scar tissue (adhesions) in her abdomen from multiple previous surgeries. The laparoscopic procedure had to be abandoned and hysterectomy was performed through a standard incision in the abdomen. This is highly significant and indicates that any subsequent surgery, by either laparoscopy or laparotomy, was also likely to be complicated by intra-abdominal adhesions. Following this [Ms A] had an abscess next to her large bowel due to diverticulitis which was managed conservatively which may have further increased her risk of adhesions, particularly to bowel.

In my first report I questioned whether [Dr C] had read the operation note from the hysterectomy operation or spoken to the operating surgeon so as to assess [Ms A's] operative risk and to inform the type of operation and route of entry to the abdomen which would be best for her. [Dr C] has subsequently advised the Commissioner that:

'[Ms A] and I discussed her previous hysterectomy including conversion from laparoscopic to an open procedure. [Ms A] did inform me that the reason for conversion was adhesions around the uterus that prevented completion of the procedure laparoscopically.'

This indicates to me that [Dr C] did not read the operation note himself.

c) Discussion with [Ms A] about surgical risks and alternatives.

There is no documentation by [Dr C] of the operative risks that he discussed with [Ms A], and specifically there is no mention that he advised her of the increased risk she had of bowel damage due to her high likelihood of adhesions. Often after

a hysterectomy a remaining ovary can become adherent to the lateral pelvic wall close to the ureter or come to rest lower in the pelvis and become adherent to the bladder. Therefore [Ms A] should also have been advised specifically of her increased risk of ureteric, bladder and bowel injury given her previous hysterectomy and recent diverticulitis.

[Dr C] advised the Commissioner that he did discuss operative risks with [Ms A], including the risk of damage to the bladder and bowel. He gave [Ms A] a copy of the RANZCOG patient information leaflet on laparoscopy but in my opinion [Ms A] should have additionally been made aware of the specific increased risks of surgery in her case.

There are three opportunities for gynaecologists to record that they have discussed specific risks with a patient. The first is in the outpatient notes, the second is on the operative consent form and the third is in the dictated letter to the GP. [Dr C] did not avail himself of any of these opportunities despite [Ms A's] markedly increased surgical risk.

1. What information, including risks and alternative treatment, is usually provided to patients prior to performing surgery to remove an ovarian cyst?

The information patients require prior to surgery to remove an ovarian cyst is firstly why does the cyst need to be removed, secondly how the operation will be done and what are the operative risks and thirdly what are the alternative management approaches.

a) It appears that [Ms A] had no symptoms from her small ovarian cyst. Therefore the indications for removal were the possibility of malignancy. [Dr C's] clinic letter and his subsequent report to the Commissioner noted that [Ms A] had a family history of ovarian cancer and was concerned that she might have cancer. However, in the absence of recent tumour marker results and an RMI calculation the degree of risk was never quantified for [Ms A's] consideration.

b) There is no documentation to show that [Ms A] was made aware of her increased risk of surgical complications.

c) [Ms A] needed to be aware that conservative management of the cyst was an option. The cyst was actually quite small on scan (43 x 21 x 21 mm) and her RMI was low. [Ms A] could well have been advised to manage the cyst initially with surveillance by interval scans and tumour markers given her surgical risk factors.

[Dr C] has advised the Commissioner that he discussed the option of conservative [management] with [Ms A] but she remained concerned at a risk of malignancy. [Dr C] stated that [Ms A] did not reveal to her that she had seen a genetic counsellor who advised that she was not at particularly high risk, nor that [Ms A's] [close relative] was still alive.

The DHB Adverse Event Report has pointed out the difference in understanding of events around the issue of the need for surgery. [Dr C] has stated that he

performed the operation because [Ms A] was concerned at the risk of malignancy as her [close relative] had had ovarian cancer. He also advised the Commissioner that [Ms A] was very keen to have the surgery as soon as possible as she wanted the matter resolved before she moved to another town and another job. Both of these aspects are documented in [Dr C's] letter to the GP. [Dr C] has also advised that [Ms A] called and visited the administration office on multiple occasions to ask when her surgery would take place.

[Ms A] has expressed anxiety about having ovarian cancer in the past. In 2010 she was seen by [Dr E] in outpatient clinic after a CT scan showed a 6cm mass on the left. [Dr E] arranged a followup scan and tumour marker blood tests. In November 2011 a letter from [Dr E] stated that [Ms A] had attended the outpatient clinic 'worried about the mass'. [Dr E] mentions that the follow-up scan showed the cyst had resolved and the tumour markers were normal. [Dr E] also noted [Ms A's] concern that [a close relative] had had ovarian cancer. [Dr E] discovered the cancer occurred in her [close relative's] 60s and concluded that this did not indicate a familial risk was present. Both [Mr and Ms A's] complaints comment that [Dr E] had advised conservative management of a larger cyst as the tumour markers were normal. The previous clinic letters should have been available in [Ms A] notes for [Dr C] to read.

[Ms A] has stated that she did not want the operation, tried to cancel it twice but was encouraged to go ahead with the operation by [Dr C] in case her cyst was malignant. I note that [Ms A] has not complained that she was not fully informed of the risk of complications of the surgery.

[Dr C's] communication about the indications for surgery repeatedly refer to his concerns that the mass may be malignant.

- On the Surgical Booking form, [Dr C] indicated that [Ms A] had a 'suspicion of malignancy'. [Dr C] has advised the Commissioner that he did so as he could not be sure it was not malignant without histology and it also would effectively expedite the timing of her surgery.
- [Dr C's] letter to [Ms A's] future employer [mentioned his concerns].
- [Southern DHB response dated 24/9/14 noted]:
'At the time [Dr C] was highly concerned at the possibility of malignancy associated with the mass and in his opinion surgery was the most appropriate treatment.'
- On 15/4/15, [the DHB wrote in its] summary of events:
'[Dr C] advised that surgical removal of the cyst was the best course of action.'

3. Appropriateness of the decision to perform laparoscopic surgery rather than open surgery.

RANZCOG has a guideline about the performance of advanced operative laparoscopy. According to the classification system in this guideline laparoscopic surgery in [Ms A's] case would require a gynaecologist with laparoscopic skills at the highest level (Level 6 of 6 levels). The description and training requirements outlined below. I have highlighted the statements relevant to this case.

'Skill Level 6

*Procedures at this level are as follows: laparoscopic pelvic floor repair, AFS level 4 endometriosis surgery. This is excisional surgery and not ablation. **Laparoscopic removal of residual ovaries with significant distortion of the anatomy.** Laparoscopic oncological procedures such as laparoscopic pelvic lymph node and para-aortic lymph node dissection and radical hysterectomy. To perform level 5 and 6 surgery, as well as laparoscopic suturing, **surgeons should have completed formal preceptorships or Fellowship training under the supervision of appropriately skilled laparoscopic surgeons.**'*

Reference: RANZCOG Guideline C Trg 2. Guidelines for performing advanced operative laparoscopy. Consensus statement of the Royal Australian & New Zealand College of Obstetricians & Gynaecologists (RANZCOG) and the Australasian Gynaecological Endoscopy & Surgery Society (AGES), 2010. (pdf provided)

Southern DHB do not agree with my assessment that [Ms A's] surgery would require level 6 laparoscopic skill. [Dr E] maintains that the presence of an ovarian cyst outweighs the presence of adhesions and therefore the procedure was a Level 5, not Level 6. My advanced laparoscopy colleagues have informed me that a large cyst is often easier to remove as the growing cyst stretches out the adhesions and enables the tissue planes to be identified more clearly. However, in [Ms A's] case the left ovary and cyst measured only 4.3 x 2.1 x 2.1 cm which is not much larger than an ovary alone. Furthermore, [Dr C's] operation note recorded that the bladder was pulled markedly towards the left side, there was quite a bit of adhesive disease on the left side of the pelvis involving bowel, omentum and the lateral and anterior abdominal walls. He also described the left ovary as being completely buried in adhesions. I respectfully submit that these comments are consistent with significant distortion of the anatomy and hence a Level 6 procedure.

Finally, it should also be noted that the Southern DHB adverse event report also drew attention to the RANZCOG Guidelines for performing complex laparoscopic surgery. I suggest there would be no reason to do so unless they also were of the opinion that [Ms A's] laparoscopic procedure was at the upper end of the scale of difficulty.

Southern DHB have provided evidence that [Dr C's] credentials and experience were thoroughly vetted during the appointment process.

[Dr E], who is a very accomplished laparoscopic surgeon, had advised the Commissioner that she supervised [Dr C] closely for the first year of his appointment and is confident about his surgical abilities.

In discussing this case (in an anonymised form) with colleagues some thought it would be acceptable for gynaecologists with skills at level 3 to 5 to commence such operations with a laparoscopy to assess whether the ovary and cyst could easily be removed laparoscopically. If this were not the case then the operation could be continued via a laparotomy. Others (myself included) considered that the history of an unsuccessful attempt at a laparoscopic hysterectomy plus an adnexal mass in a woman after an abdominal hysterectomy meant the chance of a successful laparoscopic procedure was so low that they would perform the operation by laparotomy and avoid exposing the patient to the additional risk of a laparoscopy. [Dr G], the expert reviewer chosen by the DHB for its review of this case also suggests that either approach would be acceptable.

The key aspect is not the decision to commence the operation by the laparoscopic route but the decision to continue with laparoscopic removal of the ovary in the light of the severe adhesive disease. The individual laparoscopist must make that decision based on his or her assessment of the difficulty of the procedure, their own skill levels and the degree of increased risk this carries for the patient. [Dr E] points out that unintended organ damage does not necessarily mean poor technique or negligence in difficult cases. [Dr C] has explained that [Ms A] requested a laparoscopic operation so her recovery would be swift to allow her to move and commence her new job soon. What level of risk of bowel or bladder injury would she be willing to tolerate to achieve this end? Was this scenario ever discussed with her?

**4. The standard of care taken in performing the operation including —
a. failure to identify the bowel injury during surgery.**

Southern DHB have questioned my suitability to address this question as they politely point out that I have not indicated what level of laparoscopic expertise I have. I am happy to report that I operate at Level 3 of the RANZCOG criteria. However, I respectfully point out that management of postmenopausal ovarian cysts is a common gynaecological problem. In cases where the patient and I come to a decision to remove these surgically I have to assess the degree of surgical risk and decide by which route to operate or whether to refer to a more experienced laparoscopist if the patient prefers a laparoscopic operation. Furthermore, if unexpected adhesive disease is encountered even a level 3 laparoscopist needs to know how to ensure they have not damaged the bowel on entry and to be sure to document the degree of adhesive disease seen. Finally, when on call I am responsible for the postoperative care of women after advanced laparoscopic procedures and am very used to having to assess the likelihood of unintended injury based on my reading of the operation note and my assessment of the patient's clinical condition.

Southern DHB appear to have misread my initial report because in their response to the Commissioner they incorrectly stated:

'Dr. Westgate is asserting that the injury occurred with placement of the trochars.'

No, I am not. I clearly indicated that [Dr G], the expert chosen by Southern DHB to review this case, stated in his report that both he and the general surgeon involved in [Ms A's] care believe that the bowel injury occurred during trochar placement. He then made the following comment:

'The lack of direct visualisation of the entry site and not removing the scope under direct vision is sub-optimal.' And later adds *'but does not necessarily constitute substandard care.'*

I find these two statements difficult to resolve. Significant adhesive disease was noted on entry with [Dr C's] operation note stating that there was bowel adherent to the anterior abdominal wall near the umbilicus. I could well imagine that a level 3 laparoscopist who did not follow standard practice and missed a trochar related bowel injury would be deservedly criticised.

[Dr C] has now advised the Commissioner that he must have inspected the underside of the entry port as he did place the laparoscope into another port so he could use the large entry port to remove the ovary from the abdomen.

[Dr E] herself suggests that the bowel injury is more likely to have occurred during adhesiolysis, just as the bladder injury did. I am inclined to agree (if I am allowed to). However, I note that one striking omission from [Dr C's] operation note is mention of the proximity of the bowel to the adhesions around the ovary. During a difficult dissection I would normally expect to read a comment that care was taken to ensure the bowel was not injured during dissection of the ovary. [Dr C] has advised the Commissioner that both he and the urologist checked the bowel thoroughly for any damage after repairing the bladder injury. This was also not documented in the operation note.

If the bowel injury occurred during entry, as [Dr G] believes, then [Dr C's] record of the process he followed to ensure bowel had not been damaged at this site was inadequate.

If the bowel injury occurred during adhesiolysis, as [Dr E] believes, then [Dr C's] documentation of steps taken to ensure the bowel was not in the operative field are inadequate.

5. The standard of post operative care including —

a. delay in identifying bowel injury

The DHB Incident report states that [Dr C] did not visit [Ms A] over the weekend (the surgery having taken place on a Friday) because he was scheduled to attend an out of town clinic on Monday and was [not available in the weekend]. [Dr C]

advised that he verbally handed over his in-patients to the on call consultant for the weekend at around 4pm that afternoon.

The clinical notes show that [Dr C] did see [Ms A] at 0920 on Saturday morning. He examined her and attributed her severe pain to bladder spasms and gas from the laparoscopy trapped under her diaphragm. He outlined a management plan in the notes which included an outpatient visit with him to have her catheter removed. It is interesting to note that this clinical entry, which he wrote himself, did not mention that he explained or reviewed the operative events with her, nor was there a record of any apology for the bladder perforation. [Dr C] has subsequently advised the Commissioner that he did offer [Ms A] an apology but did not record this in the notes.

[Ms A] was reviewed acutely multiple times by the on call Senior House Officer (SHO) over the weekend. By the mid-evening she was very unwell with very abnormal recordings (fever of 38.8, oxygen saturations of only 88% on room air). At that point and also the following morning the SHO realised there was a possibility of bowel and or ureteric injury. She discussed this with the consultant on Saturday evening who ordered blood and urine tests and intravenous antibiotics but specifically declined to arrange any imaging of [Ms A's] abdomen. The consultant reviewed [Ms A] the following morning (Sunday) but made no recommendations to investigate the cause of [Ms A's] problems. Again [Ms A] was reviewed several times by the SHO during the day. At around midnight the lab informed the SHO that [Ms A's] blood cultures had grown a bacteria — a gram negative bacillus which is a bacteria which most likely came from her bowel. Also [Ms A] had a very low urine output and was even more unwell. Despite being given this information which overwhelmingly pointed to a very sick patient with a bowel perforation the on call specialist simply advised that a diuretic be given to try to improve urine output. [Dr B] has advised the Commissioner that in hindsight he realises that at that point he should have referred [Ms A] to the surgeons for their assessment. It was only the following day when [Ms A's] plight over the weekend was discussed at the morning hand-over meeting that [Dr E] immediately recognised that she must have a bowel perforation. [Dr E] reviewed [Ms A] and referred her to the surgeons with a diagnosis of possible bowel perforation.

b. following identification of bowel injury.

[Ms A] was seen by a general surgeon at 0900 hours on Monday 25th and was taken to theatre for a laparotomy at 1230. Management of her condition thereafter seems to have been appropriate but further comment on this area is outside my scope of practice.

6. Appropriateness of the recommendations made in the Root Cause Analysis.

1. Lack of documented RMI. The Root Cause Analysis (RCA) has dealt with a wide number of issues. However, they have completely omitted any comment about the lack of appropriate assessment of the risk of malignancy of [Ms A's]

ovarian cyst. Southern DHB have advised that the reviewers subsequently advised that they did not find the RMI documented anywhere but as the case did not warrant MDM review (as the RMI indicated low risk) they felt this explained the lack of documentation. They have not commented on the advisability of counselling women (or not) about the need for surgery without an RMI being available for the patient's consideration. They have, however, pointed out the different accounts of [Dr C] and [Ms A] with respect to the indications for surgery and acknowledged [Dr C's] lack of documentation of the consent process.

2. Consent form.

I believe the consent form should be revised to include a section for the documentation of risks discussed with the patient. Many DHBs did this some years ago. However, the other key issue around consent which has not been recognised in the RCA report is that of reminding SMOs that they need to record that they have discussed general operative and specific operative risks with patients booked for surgery. Preferably, the patient-specific risks discussed with each patient should be recorded.

3. SMOs need to be aware of RANZCOG Guidelines on laparoscopic surgery.

This seems to me to be an acknowledgement that [Dr C] had perhaps misjudged the difficulties he would face in performing laparoscopic oophorectomy given [Ms A's] extensive adhesive disease. If he had realised the level of difficulty likely to occur he may (should) have discussed the case with a colleague like [Dr E].

7. Overall Standard of care provided by:

i. [Dr C].

A. Decision for surgery/Consent Process.

If [Ms A's] account of the decision for surgery is correct then [Dr C] insisted that [Ms A] have an operation which involved a high risk of surgical complications despite the fact that he knew her RMI was normal and she had expressed repeatedly that she did not want the operation. This would be a most severe departure from accepted care.

If [Dr C's] account of [Ms A's] request for surgery on the basis of her anxieties about having a cancer is correct then there is no documentary evidence to show that:

- he adequately assessed the surgical risk involved by reading the previous operation note and reviewed previous management decisions concerning her previous adnexal mass
- he reassured [Ms A] that her risk of malignancy was low once he obtained the blood test results
- he advised [Ms A] of her increased risk of injury to bladder and bowel although [Dr C] has assured the Commissioner that he did discuss these risks with [Ms A].

Irrespective of which account is more likely, it is possible to comment on the following:

1. [Dr C's] documentation of the consenting process is absent and falls below an accepted standard of practice. The departure is severe and has placed both him and his department at considerable risk. I believe that the majority of my peers would agree with this assessment.

2. [Dr C] counselled [Ms A] about the need (or not) for surgery on her ovarian cyst without knowledge of up to date tumour marker blood test results or an RMI calculation. This is below the recommended standard of practice for the management of ovarian cysts in postmenopausal women according to RCOG Guidelines. Given [Ms A's] surgical risk factors and the small size of the cyst I believe this was a moderately severe departure. I believe that the majority of my peers would agree with this assessment.

b. Surgical approach

[Dr C's] decision to commence the operation laparoscopically is acceptable. His decision to continue with a laparoscopic removal of the ovary is less clear. In retrospect we know that both the bladder and bowel were injured which undoubtedly raises concerns. I accept that surgical complications can indicate a technically difficult operation rather than lack of surgical expertise. [Dr E] considers that [Dr C's] surgical skill was adequate to perform this operation. However, the technical difficulties in this case were highly predictable given [Ms A's] past history and I am not sure whether [Dr C] recognised this pre-operatively. I believe the comments made by the Southern DHB review of the case indicate the reviewers were also concerned about this aspect of his care. Overall, [Dr E's] reassurance of [Dr C's] surgical skill is enough to convince me that there was no departure from an acceptable standard of surgical skill in [Ms A's] operation.

However, I do believe that [Dr C's] documentation of the steps taken to ensure there was no damage to bowel during the operation are not of an acceptable standard. The departure is at the mild end of the scale. I believe that the majority of my peers would agree with this assessment.

ii. [Dr B]

I accept the difficulties of assessing [Ms A's] post operative course in view of the fact that she had a documented complication. However, [Dr B's] failure to recognise that [Ms A] was likely to have a bowel injury on Sunday night when the blood culture results were relayed to him, and his failure to review her personally or refer her for a surgical consultation despite her deteriorating condition is below an acceptable standard of practice and the departure is severe. I believe that the majority of my peers would agree with this assessment.

iii. Southern DHB

Southern DHB appear to have made a thorough assessment of [Dr C's] credentials and competence prior to his employment. His first year of work was supervised by an experienced laparoscopic surgeon [Dr E]. The Departmental policy of all

medical staff attending the morning hand-over meetings gives ample opportunity for discussion of unusual or difficult cases and for collegial support.

I have not addressed the DHB handling of [Ms A's] case review or complaint as these issues were not part of my brief.

8. Appropriateness of the policies and procedures in place at Southern DHB.

I have no additional comments. Please see 7iii.

Please contact me if you require further information.

Kind regards

Jenny Westgate FRANZCOG, DM
Honorary Associate Professor in Obstetrics and Gynaecology
University of Auckland.”

Dr Westgate provided the following further comments:

“Thank you for asking me to provide additional information on this case. I have read the information you provided in your letter to me dated 6 September, 2016. This letter provided responses from [Dr C] and his legal representative regarding the counselling provided to [Ms A]. I will respond to each of the 3 questions posed in turn.

1. Provide clarification whether there is a particular or explicit aspect of the RCOG Guidelines which applied to [Ms A's] case.

The RCOG Greentop Guideline No. 34 on the management of ovarian cysts in postmenopausal ovarian cysts is one of a number of Guidelines which provide advice on management in women with postmenopausal ovarian cysts such as [Ms A]. The RCOG Guidelines covers diagnosis, assessment of risk of malignancy and surgical management. Obviously some of the material discussed did not apply specifically to [Ms A's] case but much of it does.

The Guidelines do not state how recent the ultrasound scan used to calculate the RMI should be. [Ms A's] scan was 7 months previous to the clinic appointment. [Dr C] discussed the issue of a repeat scan with a radiologist and was advised that this was not required.

The Guidelines were updated this year and now contain some additional advice which pertains to [Ms A's] case. Women with an RMI of <200 are described as being low risk, in line with other published guidelines. In addition, a new recommendation states:

‘A woman with a suspicious or persistent complex adnexal mass needs surgical evaluation.’ (page 5 and page 20).

Given that [Ms A's] cyst had increased in size between ultrasounds performed on 26/4/2012 and 8/8/2012 and that the cyst was described as complex on the scan a recommendation for surgical management is consistent with the 2016 version of the Guideline. However, the Guideline also states:

‘Some women requiring surgical intervention are at substantial risk of perioperative morbidity and mortality. In such instances, repeat imaging often is safer than immediate operative intervention, although the frequency of repeat imaging has not been determined.’ (page 20)

This qualification would clearly apply in [Ms A's] case.

2. Comment on whether [Dr C's] subsequent telephone conversation with [Ms A] later on that day (the day of the outpatient appointment) regarding her results would be considered sufficient in the circumstances.

[Dr C] has advised the Commissioner that he obtained [Ms A's] Ca125 result in the afternoon following her clinic appointment and advised her by telephone that the result was negative and not in the malignant range. He also counselled her further during the telephone call. I believe this does cover the issue of informing [Ms A] that her cyst was likely to be benign. As [Ms A's] Ca125 values had been stable for all 3 samples taken (20/12/2010, Ca125=12, 25/4/12, Ca 125 = 11 and 5/3/2013, Ca125 = 11) this was a reasonable conclusion. As far as I can tell, [Dr C] did not calculate the RMI but based on other (non RCOG) guidelines available in 2013 her RMI of 99 would have been regarded as low risk.

3. Comment on the claim made by [Dr C's] legal representative that an RMI score of 99 does not constitute low risk.

[Dr C's] legal representative has stated that an RMI of 99 is not low risk and states that the RCOG Guideline stated that an RMI of 25 to 250 is regarded as moderate risk and a flow chart recommends surgery. These comments are correct based on the RCOG Guideline written in 2003 and updated in 2010.

However, these concerns are not relevant to the question at hand. My concern is not that a decision to operate was made but that a decision to perform the operation was made without documented evidence of:

1. an assessment of the risk of malignancy and a discussion about this with [Ms A].
2. recognition of [Ms A's] high risk of unintended surgical injury and communication of this increased risk to [Ms A].

Ideally assessment of the malignant potential of [Ms A's] cyst should have been by RMI but at the least a Ca125 should have been considered. There is now evidence that [Dr C] did obtain the Ca125 result the same day of the clinic visit, assessed it as showing a low risk of malignancy and communicated this to [Ms A] in a telephone call.

The recommendations in the 2010 version of the RCOG Guideline were based on one study conducted in 1993. However, the flow chart referred to in that version of the Guideline also recommends that women with a score of 25 to 250 should be referred to a cancer unit for laparoscopy or laparotomy. If the legal representative wishes to use this document to support [Dr C's] management they will need to explain why [Dr C] did not follow the guidelines and refer [Ms A] to a gynaecological oncology unit for surgery.

Soon after the 2010 version of the RCOG guideline was released subsequent reviews by other groups incorporated information not included in that update. These include the NICE Guidelines for ovarian cancer published in April 2011 which used an RMI cut off of 250 to indicate a high risk of ovarian cancer and referral to an oncology unit. They made no other recommendations based on RMI level. The Scottish guidelines published in 2013 reviewed the recent literature and suggested a cut off of 200 to separate low and high risk which has also been used in the most recent RCOG version of the Guideline released this year. Thus, as I stated earlier, [Dr C's] advice was consistent with recognised non RCOG Guidelines available in 2013.

If there are further questions or further clarification is required please contact me by email.

Kind regards

Jenny Westgate FRANZCOG, DM
Honorary Associate Professor in Obstetrics and Gynaecology
University of Auckland.

References:

NICE. Ovarian cancer: the recognition and initial management of ovarian cancer. April 2011. Developed for NICE by the National Collaborating Centre for Cancer.

Scottish Intercollegiate Guidelines Network. Management of epithelial ovarian cancer. SIGN publication no. 135. Edinburgh: SIGN; 2013.”