Obstetrician and Gynaecologist, Dr B

A Report by the

Health and Disability Commissioner

Case 08HDC08813

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Overview

On 2 February 2004, Ms A (aged 29 years) was referred by her general practitioner to gynaecologist Dr B with suspected endometriosis.[1] After assessing Ms A on 9 February 2004, Dr B recommended a "look see" laparoscopy,[2] surgical treatment of any endometriosis, and a tubal patency test.[3] Ms A decided to go ahead with the recommended procedures, and the surgery took place on 12 February 2004. During the operation, Dr B found that Ms A had polycystic ovary syndrome (PCOS)[4] so she performed a treatment procedure known as ovarian drilling or "golf-balling".[5] Dr B did not obtain Ms A's consent to drill her ovaries.

Informed consent is at the heart of the Code of Health and Disability Services Consumers' Rights. This report focuses on Ms A's right to make an informed choice about the surgical services she received, and the adequacy of Dr B's documentation.

Complaint and investigation

The Health and Disability Commissioner (HDC) received a complaint from Ms A about the services provided by Dr B. The following issues were investigated:

- *The appropriateness of the care provided by Dr B to Ms A between February 2004 and August 2005.*
- *The adequacy of the information provided by Dr B to Ms A between February 2004 and August 2005.*

An investigation was commenced on 5 September 2008.

[1] Endometriosis is a condition in which tissue similar to the lining of a woman's uterus grows in places outside her uterus. Endometriosis can cause pain and irregular menstrual bleeding, and can compromise fertility in some women.
[2] Laparoscopic surgery, commonly known as keyhole surgery, is performed using tubular instruments which are passed through small incisions in the wall of the abdomen. A small camera inserted through one of the ports allows the surgeon to view the patient's internal anatomy and perform the procedure/s.
[3] A tubal patency test, or dye test, involves the passing of dye through a woman's Fallopian tubes to determine whether they are open or blocked.
[4] Polycystic ovary syndrome is a condition characterised by the development of multiple cysts on the ovaries. It can cause acne, increased hairiness, and irregular periods, and can compromise fertility.
[5] Ovarian drilling is a laparoscopic procedure involving the burning of multiple small, deep holes in the surface of a woman's ovary. At the end of the procedure the ovary looks like a dimpled golf ball, hence the procedure is sometimes referred to as ovarian "golf-balling".

Parties involved

Ms A	Consumer
Dr B	Obstetrician and Gynaecologist/Provider
Dr C	General practitioner
Dr D	General practitioner
Dr E	Obstetrician and Gynaecologist
A private hospital	Private healthcare provider

Also mentioned in this report

Dr F	Anaesthetist

Information was reviewed from:

Ms A
Dr B
Dr C
Dr E
The private hospital
A medical laboratory

Independent expert advice was obtained from gynaecologist Dr Tal Jacobson (see Appendix 1). Dr B obtained expert advice from gynaecologist Dr John Tait (see Appendix 2).

Information gathered during investigation

Background

General practitioner referral to Dr B
On 2 February 2004, Ms A (aged 29 years) was referred by her general practitioner, Dr C, to gynaecologist Dr B. Ms A had a history of suprapubic tenderness on her right side and "knife-like" period pain which worsened throughout her cycle and became more severe each month. At times Ms A found the pain to be unbearable. In the previous month she had been admitted to hospital as a result of significant lower abdominal pain and adnexal tenderness,[6] particularly on the right side.

Dr C queried whether Ms A had endometriosis and suggested that laparoscopic surgery might be indicated. She noted that Ms A's appendix and an ovarian cyst had been removed in the past. Dr C also noted Ms A's relevant clinical history.

[6] Accessory organs or tissues, for example the relationship of the fallopian tubes and uterus.

First consultation with Dr B
On 9 February 2004, Ms A had her first consultation with Dr B. She agreed that Ms A's family history and symptoms were strongly suggestive of endometriosis. In her reporting letter to Dr C of the same day, Dr B wrote:

> "I agree that in the first instance we do have to have a 'look see' laparoscopy and the treatment (resection and ablation[7]) of endometriosis if it is present. She would certainly benefit from this in view of symptom control, fertility management and ongoing prognosis and management. A tubal patency test at that time would also be warranted at the age of 29 and this was offered and accepted today."

Dr B provided Ms A with a general information document for women undergoing the laparoscopic procedures of "endometriosis surgery, ovarian cystectomy[8] — or — oophorectomy[9] or ovarian drilling". The document provided general information about laparoscopic procedures and the associated risks, as well as information about matters including the cost of care, informed consent and bookings, postoperative care, what to expect during the recovery period, and relevant contact details. Dr B also provided Ms A with a basic information sheet about tubal patency testing.

Ms A signed a consent form for an operation described as "Laparoscopy and Treatment to Endometriosis + [tubal patency test]". Since Ms A wanted to have the laparoscopy as soon as possible in light of her university studies, the operation was booked for 12 February 2004.

Dr B reported the details of the consultation to Dr C by letter on 9 February 2004.

File note
Dr B provided a separate file note which she claims is an accurate and contemporaneous record of preoperative discussions and Ms A's informed consent to some of the surgical procedures that she performed, including ovarian golf ball drilling.

This file note is dated 8 February 2004 and initialled by Dr B. It states:

> "[Ms A] has decided to go ahead with an exploratory laparoscopy, adhesiolyisis [sic], resection of Endometriosis and ovarian cystectomy/golf balling (may have cystic ovaries, lot of adnexal pains on and off) if and as required and any other necessary surgery I may consider will be beneficial for her at the time of laparoscopy to resolve her ongoing pain. We discussed this in depth face to face at many occasions and this **is now her informed consent process recorded FYI.**"[10]

The file note was provided to HDC with additional records (on 10 November 2008) after Dr B's initial response to the complaint (on 18 June 2008) with "notes relevant to the matters raised by the former patient" but no record of Ms A's consent to

[7] "Resection" and "ablation" are terms used to describe the surgical removal of tissue.
[8] An ovarian cystectomy is the surgical removal of an ovarian cyst.
[9] An oophorectomy is the surgical removal of one or both ovaries.
[10] The emboldening appears in the original.

ovarian drilling. Dr B said that the file note and additional records had been "unearthed" from storage "after extensive searching". Her legal counsel said that she did not have the opportunity to review the file containing these "unearthed" records before it was sent to Dr John Tait for his expert advice. The file note is printed on plain, unheaded paper. It contains no information to identify Ms A other than a shortened version of her first name and her initials.

Although there is no record of Ms A's contact with a nurse around this time, Dr B stated that Ms A would have communicated her decision to go ahead with the operation during a telephone conversation with a nurse. Dr B said that Ms A would have called Dr B's nurse to ask her to fix a date for surgery, send the insurance paperwork, and send her the hospital admission booklet and papers.

Dr B's legal counsel subsequently advised that after the consultation on 9 February 2004, Ms A went to see the nurse and preliminary arrangements for surgery were made. Her legal counsel stated that "the decision to go ahead with the operation was made on the basis of the golf ball drilling process to take place only if necessary, which doubtless both patient and doctor hoped would not be the case". He explained that "the golf ball drilling was contemplated but not decided on before the surgery".

12 February 2004 — surgery at the private hospital

On 12 February 2004, Ms A was admitted to the private hospital for her operation and countersigned her consent form. As noted earlier, the consent form was for a "Laparoscopy and Treatment to Endometriosis + [tubal patency test]". The consent form did not refer to ovarian drilling. Following standard preoperative preparation and a nursing briefing, Ms A was taken to theatre.

Dr B performed the laparoscopic operation under general anaesthetic, with local anaesthetic around the instrument insertion sites. The operation was uncomplicated, and Ms A's blood loss was minimal. Her abdominal cavity was easily insufflated[11] with air and Dr B had a good view. She found that Ms A had stage 2 endometriosis[12] and "multicystic" ovaries. Dr B removed all the visible disease in the lining of the abdominal cavity, and around the uterus.

Dr B then drilled Ms A's polycystic ovaries using a procedure known as ovarian drilling or "golf-balling". Dr B advised HDC that she performed this procedure to decrease the weightiness of the ovaries, thus reducing the risk of painful ovarian torsion[13] and avoiding premature loss of ovarian tissue. Dr B noted that ovarian tissue loss in later life leads to menopause and eventual infertility, but it is usually very important to prevent these processes occurring prematurely in young women. She said that ovarian golf ball drilling is an accepted part of current good practice in the treatment of multicystic ovaries.

[11] Gas or powder blown into a cavity, tube or organ to allow visual examination or to remove an obstruction.
[12] Endometriosis is often classified according to the American Society of Reproductive Medicine staging system. There are four endometriosis stages based on the number, location, depth, and size of the endometrial lesions. "Stage 2" endometriosis is considered to be mild.
[13] Twisting or turning.

Dr B recorded the details of the surgery in an operation note as follows:

> "**Operation:** Laparoscopy = excision and resection ablation of endometriosis = [tubal patency test]
> **Surgeon:** [Dr B]
> **Anaesthetist:** [Dr F]
> **Anaesthesia:** GA, local to all port sites and in [the pouch of Douglas]
> Procedure: uncomplicated. Incisions: 0.5 [cm] stab vertical inferior umbilical port, 0.25 cm stabs rest of the abdomen
> Process: easy insufflation. Good views.
> Findings: uterus [normal size]. Ovaries [multicystic] but nil else abnormal. Rt ovarian fossa and left and right lateral wall American Fertility Society stage 2 endometriosis. Resection of all visible peritoneal disease and uterosacrals. Ovarian 'golf-balling – drilling' performed bilaterally
> Peritoneal biopsy taken.
>
> All wounds closed with long term absorbable monocril. Blood loss: minimal."

Dr B's operation note contains her postoperative instructions and discharge information for Ms A. The operation note was copied to the ward and Dr B's rooms, as well as Dr C and Ms A. Her clinical record also contains a series of laparoscopic photographs taken during the operation, including the tubal patency test.

Recovery in the Post Anaesthetic Care Unit
Ms A was transferred from theatre to the Post Anaesthetic Care Unit (PACU). According to Ms A, she "woke up in the recovery room terrified & in agony & complaining of horrific pain. When [she] pulled back the sheet, [she] was covered in blood coming from the site, & it was all over [her] and the sheets." Ms A said she was "knocked straight out & [had] no idea what was fixed, changed or even occurred".

Gynaecologist Dr E was in PACU at the time Ms A was recovering. She explained that, in accordance with hospital guidelines, it is well understood that specialists help PACU staff if their assistance is requested, and specialists certainly assist in any emergency while the patient's own surgeon is being called for. Dr E recalls:

> "I had taken note of [Ms A] in the Recovery Ward since there was a lot of activity around her. She was in pain and looked pale. The nurse was changing the sheet which had blood on it. The nurse asked me to keep an eye on the patient (from a short distance) while she drew up some drugs. I asked her if she had consulted the Specialist regarding the patient's condition and she informed me that she had."

Dr E stated that the next time she saw Ms A was at a consultation with her following Dr C's referral for a second opinion on 1 July 2005.

According to Dr B and the clinical records, Ms A's recovery from her operation on 12 February 2004 was uneventful. It is recorded in the PACU clinical notes that Ms A awoke at 4.10pm and at 4.30pm she complained of severe pain. Anaesthetist Dr F was notified and further intravenous morphine was administered. Since there was

"minimal wound ooze" at the site of Ms A's operation, the wound dressing was reinforced, and Dr B was notified accordingly.

At 5.30pm, Dr B and Dr F were informed of Ms A's continuing severe pain, and further morphine was given to her as directed. At 6.30pm, Ms A's HaemoCue reading was 102g/L,[14] and Dr B and Dr F were asked to assess Ms A because her heartbeat had been rapid since 5.45pm. Dr B saw Ms A at 6.49pm and by this time she was stabilising. Dr B noted that Ms A's umbilical port site wound had bled and clotted so she asked the nursing staff to clean the wound and redress it with pressure. On Dr B's advice, Ms A was transferred to the ward.

Recovery on the ward
During Ms A's recovery on the ward, the nurses were in regular contact with Dr B. Ms A mobilised at times but she was troubled by pain and intermittent nausea. She received regular pain relief including morphine through her patient controlled analgesia system (PCA), as well as tramadol and paracetamol. At times heat packs were effective in providing Ms A with soothing relief.

There is no record of Dr B visiting Ms A on the ward. However, Dr B stated that it was her "absolutely routine practice" to see each of her postoperative patients daily in 2004.

Discharge — 15 February 2004
According to Ms A, she was "discharged after extra days in hospital, even though [her] pain was immense & [she] was told to only take panadol for pain".

It is recorded in the clinical notes that Ms A was discharged home at 10am on 15 February 2004, 41 hours after the preoperative expected discharge time of 5pm on 13 February 2004. The discharge nurse noted that Ms A was not requiring any pain relief medication, and had reported "a really good sleep". The nurse spoke to Dr B, who was pleased with this information about Ms A's condition.

The nurse changed Ms A's abdominal wound dressing and gave her a supply of dressings for a change in two days. She gave Ms A a discharge summary sheet which directed her to the following discharge information contained in Dr B's operation note:

"**Discharge Information:**
- Expect some bleeding vaginally like a period for a week
- Expect wound tenderness and abdominal 'achiness' for a week to 2 weeks
- The wound will have a watery red discharge for a day or two
- Shoulder tip pains for 2–3 days
- The sutures will dry up and fall off on their own in 6 weeks …"

The operation note also advised Ms A to read her laparoscopy information document carefully as it explains postoperative care, asked Ms A to call Dr B or her nurse if she

[14] A HaemoCue is a portable machine used to measure the level of haemoglobin in a patient's blood.

had any problems, and provided the relevant contact details. It also recommended that Ms A contact her general practitioner if she had any concerns.

In addition to relaying Dr B's discharge instructions, the nurse asked Ms A to call Dr B's nurse to confirm her follow-up appointment in six weeks. She recorded that Ms A raised no further concerns. Ms A left the hospital with her partner.

Recovery following discharge
In the days following Ms A's discharge from hospital, she remained troubled by pain.

On 18 February 2004, Ms A reported her pain to Dr C by phone. Dr C spoke to Dr B's nurse, who undertook to consult Dr B, and then contact Ms A directly to check on her progress. Later that day, Dr B prescribed antibiotics for Ms A.

On 19 February 2004, Dr B received a medical laboratory report indicating that Ms A had a urinary tract infection. Dr B's nurse called Ms A to inform her of this result. The nurse recorded that Ms A told her that she had been taking antibiotics for a day, and although pain had been a problem, it was now under control.

Ms A presented to Dr C again on 20 February 2004. She observed that Ms A had not improved despite starting antibiotics three days previously. Ms A was experiencing continuous "knife-like" lower abdominal pain which increased when she passed urine. She was generally tender, particularly on the right side, above her pubic area. She had a fever, was nauseated, and was unable to tolerate much food, but her bowel sounds were normal. Dr C considered that Ms A's urinary tract infection was not responding to oral antibiotics. She thought intravenous medication was indicated so she referred Ms A back to Dr B for readmission to hospital.

Readmission to the private hospital
On 20 February 2004, Ms A was readmitted to the private hospital, where she remained until her discharge on 23 February 2004. During this period, Ms A received intravenous antibiotics, sedatives, and medication for the relief of her pain and nausea. She was reviewed by a number of medical practitioners, including Dr B and a urologist. Ms A underwent two ultrasound scans which revealed a small collection of fluid in her pelvis. The urologist thought this fluid was probably blood. He advised that the irritation around Ms A's abdomen was probably caused by the collection of blood, and he expected it to settle spontaneously.

Dr B reviewed Ms A on the afternoon of 23 February 2004. She considered Ms A was ready to be discharged, with Panadol for pain relief.

Soon after Dr B's review, a follow-up appointment was arranged for 26 March 2004, and Ms A was discharged home.

Ms A's presentation to her general practitioner
On 24 February 2004, 12 days after her operation, Ms A saw her general practitioner, Dr C, regarding symptoms of withdrawal from her pain medication.

When Ms A presented to Dr C again on 26 February 2004, she was improving. Dr C observed that Ms A's abdomen was still sore but she was not taking any pain medication.

On 1 March 2004, Ms A consulted Dr C with persistent pain. She described it as a constant ache with sharp spasms. On examination, Ms A's abdomen was soft and generally tender above her pubic region, but there was no rebound or guarding. Dr C noted that Ms A had no urinary symptoms and was eating and drinking normally.

During the consultation on 1 March 2004, Ms A and Dr C discussed Ms A's haemoglobin levels during the operation.[15] Her family general practitioner, Dr D, had seen a copy of her postoperative blood results. According to Ms A, he informed her of his concern that her postoperative blood count suggested she had experienced "excessive" blood loss which was at "borderline transfusion levels".

Dr C reviewed the results from the blood sample taken on 13 February 2004, the day after Ms A's operation. She was surprised to see Ms A's haemoglobin concentration was 76g/L, a low reading for a woman in Ms A's circumstances.

During the consultation, Dr C took a blood sample to obtain Ms A's current haemoglobin concentration, and advised her to take iron tablets along with regular Panadol. She also called Dr B to discuss Ms A's postoperative haemoglobin levels. Dr B undertook to investigate the issue, and brought Ms A's follow-up appointment forward to 6 March 2004.

Follow-up appointment with Dr B — 6 March 2004
On 6 March 2004, Ms A attended the follow-up appointment with Dr B as planned.

During this consultation, Dr B and Ms A discussed her concerns about postoperative bleeding. According to Ms A, Dr B said that there was "only a popped or loose stitch" and dismissed Ms A's concerns before declining to discuss the matter further. Ms A recalls that when she raised the issue of her low postoperative haemoglobin reading, Dr B's "excuse" was that a "silly nurse must have taken the bloods from the same arm as [Ms A's] drip".

However, Dr B's letter to Dr C on the day of the consultation depicts a more detailed discussion of Ms A's concerns about postoperative bleeding. In this letter, Dr B noted Ms A's vague recollection of her experience in the recovery room. Dr B said she explained to Ms A that in the recovery room, she experienced a very minor 50cc umbilical skin wound bleed. The bleeding settled with pressure and resolved within the first 12 hours after Ms A's surgery.

Dr B advised Dr C that she informed Ms A that after investigation of the low haemoglobin reading of 76g/L, it was probably either the result of a misread blood sample, or a sample taken from the arm containing her intravenous line. She said that in the latter case, the fluid from the intravenous line may have diluted the blood

[15] Haemoglobin is the part of a red blood cell that carries oxygen. The normal haemoglobin concentration in a woman's blood ranges from 115 to 160g/L.

sample, resulting in a haemoglobin concentration that was lower than the actual concentration of haemoglobin in Ms A's blood.

Dr B reported that she showed Ms A the results of blood tests on 12 (the day of surgery) and 17 February 2004, which gave haemoglobin concentrations of 131 and 125g/L respectively. She advised Dr C of her understanding that a more recent blood test ordered by Dr C showed a haemoglobin concentration of 112g/L.

In fact, Ms A's clinical record includes the laboratory results for three blood tests around the time of her operation. The results of a preoperative blood test on 12 February 2004 show a haemoglobin concentration of 137g/L. The results of a postoperative blood test on 13 February 2004 show a haemoglobin concentration of 76g/L. The results of the blood test ordered by Dr C on 1 March 2004 show a haemoglobin concentration of 117g/L. There are no other laboratory reports in Ms A's clinical record for blood tests during this period.

In her reporting letter to Dr C, Dr B noted that Ms A's postoperative recovery had been complicated by her withdrawal from pain medication. She said that she had informed Ms A that it had been only three weeks since her surgery, and she should expect tenderness, pain, and bloating in the abdomen for at least another three weeks. Dr B informed Dr C that she had prescribed long-term pain relief medication, long-term medication to protect Ms A's stomach, and medication to help her sleep. Dr B reported that she reassured Ms A, and recommended that she "rest her way through" her recovery. In her letter to Dr C, Dr B said:

> "She seemed in better condition after we had a long chat. I have reassured [Ms A] that I will do everything in my power to help her overcome this period and also be completely ethical about making sure that she has every bit of information she requires. She is aware that my practice is a fully transparent one.
>
> She seems much better reassured."

Follow-up appointment with Dr B — 2 April 2004
On 2 April 2004, Ms A attended another follow-up appointment with Dr B. Dr B reviewed Ms A's pain medication and noted overall that she "certainly [did seem] to be improving".

Consultation with Dr E — 1 August 2005
On 1 July 2005, Dr C referred Ms A to Dr E for a second opinion on her ongoing gynaecological symptoms including daily abdominal pain.

During the consultation on 1 August 2005, Dr E and Ms A discussed the findings of the surgery performed by Dr B on 12 February 2004. Ms A states that it was during this consultation that she first found out that she had polycystic ovary syndrome (PCOS), and that Dr B had drilled her ovaries to treat the condition. Dr E's recollection is similar. In her reporting letter to Dr C of 1 August 2005, Dr E wrote:

> "I discussed the operative findings and when I mentioned PCOS, [Ms A] informed me that she has never been told regarding PCOS. She was also never informed that ovarian drilling had been performed for the PCOS."

Dr E informed HDC:

> "I had discussed in detail with [Ms A] the previous operation notes and in particular the operative findings. When I mentioned the [words] 'drilling of the ovaries' [Ms A] got very upset since she had never heard of this before and did not know what it meant, or what it was for. I explained to her the understanding, the procedure, reasons and risks associated with ovarian drilling."

Code of Health and Disability Services Consumers' Rights

The following Rights in the Code of Health and Disability Services Consumers' Rights are applicable to this complaint:

RIGHT 4

Right to Services of an Appropriate Standard

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

RIGHT 6

Right to be Fully Informed

(1) Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including —
- *(a)* An explanation of his or her condition; and
- *(b)* An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option; and
- *(c)* Advice of the estimated time within which the services will be provided; and
- *(d)* Notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval; and
- *(e)* Any other information required by legal, professional, ethical, and other relevant standards; and
- *(f)* The results of tests; and
- *(g)* The results of procedures.

RIGHT 7

Right to Make an Informed Choice and Give Informed Consent

(1) Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.

Relevant professional standards

Medical Council of New Zealand's statement, *The Maintenance and Retention of Patient Records* (August 2001):

1. Maintaining patient records

(a) Records must be legible and should contain all information that is relevant to the patient's care.[16]
(b) Information should be accurate and updated at each consultation. Patient records are essential to guide future management, and invaluable in the uncommon occasions when the outcome is unsatisfactory.

Opinion: Breach — Dr B

Informed consent

The principle of informed consent is at the heart of the Code of Health and Disability Services Consumers' Rights (the Code). Right 6(1) of the Code provides that consumers are entitled to receive all the information that a reasonable consumer, in that consumer's circumstances, would expect to receive. Right 7(1) of the Code provides that apart from exceptional situations,[17] health services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent.

On 12 February 2004, Ms A underwent three procedures performed by Dr B — a tubal patency test, resection of endometriosis, and ovarian golf ball drilling. I am satisfied that Ms A gave her informed consent to the tubal patency test and the resection of her endometriosis. The key issue in this case is whether Dr B adequately informed Ms A about, and obtained her informed consent to, ovarian golf ball drilling.

[16] The Medical Council's statement refers to *Cole's Medical Practice in New Zealand* for further guidance on record management.
[17] Such as provision of life-saving treatment in an emergency, or when a consumer does not have the mental capacity to consent on her own behalf.

Ms A is adamant that she did not consent to ovarian golf ball drilling. She states that it was not until her consultation with gynaecologist Dr E on 1 August 2005 that she realised that she had polycystic ovary syndrome (PCOS) and that Dr B had drilled her ovaries to treat the condition. Ms A's recollection is supported by Dr E, who recorded Ms A's reaction to the information about PCOS and ovarian drilling in a letter to Ms A's general practitioner the same day.

Dr B claims that ovarian golf ball drilling "was part of the work to which Ms A consented".

File note dated 8 February 2004
Dr B provided a file note which she asserts is an accurate and contemporaneous record of preoperative discussions and evidence of Ms A's informed consent to some of the surgical procedures that she performed, including ovarian golf ball drilling. The file note was provided to HDC five months after Dr B's initial response to the complaint, in records "unearthed" from storage "after extensive searching".

The following factors cast doubt on the accuracy and contemporaneity of her file note:

1. Dr B initially advised that the file note was created on the date it carries — 8 February 2004. However, 8 February 2004 was a Sunday, and it was one day prior to Ms A's first consultation with Dr B on 9 February 2004.

   Dr B's legal counsel subsequently acknowledged that the file note was misdated. He said "why it is dated 8 February is not known". Dr B's legal counsel provided a screen dump showing an entry in the private hospital's patient management system on 11 February 2004 which refers to her file note under the title "VIL clinic note 9.2.04". He submits that this supports Dr B's account that she created the file note on 9 February 2004.

2. Dr B recorded that she had discussed the recommended procedures with Ms A "in depth face to face at many occasions". Yet Ms A had only one face-to-face consultation with Dr B (on 9 February) prior to her surgery on 12 February 2004.

   Dr B's legal counsel explained that she produced the file note from a template created in January 2004 to support her practice of reporting to general practitioners. The template was not provided to HDC. However, according to Dr B, it included the reference to previous consultations. Dr B said she "has let herself down not only by misdating [the file note] but also by leaving in the reference to previous consultations". She acknowledges that she "[failed] to correct a template which did not set out the true position".

3. This file note is printed on plain, unheaded paper. All other notes of this kind in Ms A's clinical record appear on Dr B's standard letterhead or hospital stationery.

4. This file note contains no information to identify Ms A other than a shortened version of her first name and her initials. All other patient-specific documents

in Ms A's clinical record, including those created by Dr B, contain a number of identifying details including Ms A's full first name, surname, address, date of birth, and NHI number.

In response to factors 3 and 4, Dr B's legal counsel explained that "the selection of paper depended entirely on the staff member dealing with the file on 11 February [2004]" and that "in the face of the computer record, this is hardly significant".

5. Dr B has recorded and emboldened the phrase this "is now her informed consent process recorded FYI". However, this file note is not addressed to anyone, and there is no indication who it is intended for.

   Dr B initially advised that this phrase forms part of her standard paragraph for recording informed consent and provided three supporting examples from the records of other patients around the time of the events in question. However, these examples also indicate that Dr B routinely records this type of consent information in a letter to the referring doctor.

   Dr B's legal counsel said that Dr B accessed the file note on 11 February 2004 for the purpose of reporting to Dr C. However, Dr B's letter of 9 February 2004 to Dr C records Ms A's decision to proceed with the "look see laparoscopy and the treatment (resection and ablation) of endometriosis if it is present" as well as a tubal patency test. It also records Ms A's desire to book the operation as soon as possible in light of her university commitments, and the operation date of 12 February 2004.

   Dr B's legal counsel later clarified that "The phrase is emboldened in the template. The original purpose of the template was to support a copy being sent to the GP; this did not turn into the actual practice." He said that Ms A's informed consent to the listed procedures, including ovarian golf ball drilling, was recorded in an additional separate file note with no stated recipient because "a template was being used at the time but not as intended or to full effect".

6. The file note is the only documentation of Ms A's alleged informed consent to ovarian golf ball drilling. The procedure is not mentioned within Dr B's contemporaneous consultation record of 9 February 2004, her letter to Dr C of 9 February 2004, or the formal consent form signed by Ms A prior to her operation.

   Dr B's legal counsel responded: "It is correct that it is the only documentation of consent to ovarian golf ball drilling. It is, however, in fact documentation of consent to that [procedure]." She stated that "this [procedure was] not a part of the deliberate pre-planning for the operation; it [was] a [procedure] which must take place if during the operation the indications for it are confirmed to be present". However, I note that Ms A's consent to treatment of endometriosis was documented in the preoperative clinical records although its presence could not be confirmed until the "'look see' laparoscopy".

7. It is curious that the file note is not comprehensive. In the file note, Dr B lists the "exploratory laparoscopy, adhesiolyisis [sic], resection of Endometriosis and ovarian cystectomy/golf balling", but omits the tubal patency test. She also provides justification for ovarian golf ball drilling only. The file note does not explain why the other procedures are indicated.

   In response, Dr B's legal counsel questioned the relevance of this factor. He emphasised that Dr B obtained Ms A's informed consent to the tubal patency test.

8. Dr B explained that she emboldened the phrase this "is now her informed consent process recorded FYI" for emphasis because she was concerned about Ms A's memory given her history.

   According to Dr B's legal counsel, "[Dr B's] explanation that the phrase was emboldened for a particular reason seems to have been the result of looking for a reason; in fact it was emboldened in the template. Too much has happened to [Dr B] & her staff through these complaints after the media articles & subsequent investigations and this case was 6 years ago now. When confronted with such allegations they naturally went looking for reasons."

9. Dr B advised that the most likely time that Ms A communicated her decision to go ahead with the operation, including the ovarian golf ball drilling procedure, was when Ms A called Dr B's nurse and asked her to fix a date for surgery, and to send the insurance paperwork and the hospital admission booklet and papers. Dr B states that the timing and circumstances of consent are verified by Ms A's presentation for surgery with the required paperwork as planned. However, the timing of Ms A's decision is not documented in the file note, and her presentation for surgery with the required paperwork as planned does not verify her consent to ovarian golf ball drilling. In any event, it would seem unusual for a patient to consent to this procedure orally during a discussion with a nurse.

   Dr B's legal counsel responded: "Following the consultation on 9 February, the patient left the doctor and went to see the nurse and preliminary arrangements for the surgery were made, more urgently than usual as it was to take place in three days' time. Clearly the paperwork was attended to. The decision to go ahead with the operation was made on the basis of the golf ball drilling process to take place only if necessary, which doubtless both patient and doctor hoped would not be the case."

10. According to the file note, the ovarian golf ball drilling was being consented to because Ms A "may have cystic ovaries", yet prior to the "look-see laparoscopy", she had not been diagnosed with cystic ovaries or PCOS. There is no other reference to this possibility in the GP referral or the preoperative documentation.

    Dr B's legal counsel responded: "The possibility of cystic ovaries and the possible need for the process in question arose because of the patient reporting

pain as noted, which would put any surgeon on her guard. Just prior to seeing [Dr B] at her clinic the patient had been discharged from [the public hospital's Emergency Department] having presented there with pain in the adnexae. At that time a pelvic adnexal cause was suspected for the pain. This also put [Dr B] on guard. As noted, the golf ball drilling was contemplated but not decided on before the surgery."

11. The information recorded in the file note regarding the alleged informed consent to ovarian golf ball drilling is at odds with Ms A's assertion that until 1 August 2005, she was unaware that she had PCOS and did not know that Dr B had drilled her ovaries. Ms A's assertion is supported by Dr E, who recalled Ms A's reaction to this information, and reported it to Dr C by letter dated 1 August 2005. However, I note that Dr B gave Ms A a copy of her operation note, which documented Ms A's "multicystic" ovaries and the ovarian golf ball drilling procedure.

    Dr B's legal counsel responded: "I am happy that you have noted both what [Dr E] has said about [Ms A's] assertion that she knew nothing about the procedure until August 2005 on the one hand, and the fact that [Ms A] had a copy of the operation note which had made the position clear to her. Given the state of relations between [Dr E] and [Dr B], I doubt that the patient would have received any reassurance or calming influence from [Dr E]."

12. Dr B provided the file note to HDC on 10 November 2008, shortly after her expert Dr John Tait's initial advice (of 22 October 2008) that "there was no specific consent" for ovarian golf ball drilling. It seems a striking coincidence that the fresh information came to light so soon after Dr Tait highlighted this omission when nearly five months earlier, on 18 June 2008, Dr B had failed to provide any record of Ms A's consent to ovarian golf ball drilling.

    Dr B's legal counsel responded by explaining that Dr B's staff recovered the file containing the file note in question from storage in October 2008 and sent it to him direct — without any opportunity for Dr B to review it. Dr B's legal counsel did not copy the file, but sent it to Dr Tait, for urgent consideration. He noted that it was Dr Tait who found the file note in question and drew attention to it. Dr B's legal counsel stated "Coincidence or not, the timing of the discovery of the file and its being passed intact to Mr Tait when found is on the record."

In addition to his response to the specific factors above, Dr B's legal counsel made the following further submissions regarding the file note.

Dr B's legal counsel explained that in 2006 Dr B moved from the private hospital's patient management system to her own clinical records system for her practice. He provided a forensic IT report which indicates that the file note was not created on her own practice computer. According to Dr B's legal counsel, the private hospital's Information Technology Department found that Dr B's file note was "created as a template in January 2004, entered into the patient manager system in February 2004",

and not accessed until after the release of my provisional opinion in this case. He adds that "there is no evidence from [the private hospital] that the note as shown on the patient management page has ever been accessed since 11 February 2004".

In conclusion, Dr B's legal counsel states: "Doctors have only their notes against the patient's word. This note was not ideal. But it does seem incomprehensible that one important alteration to the template would have been made to record something that had not happened and did not become an issue until four years later."

Conclusion
Taking into account all the above factors, and Dr B's response, I do not accept that the file note is a reliable record of a preoperative discussion with Ms A or of her informed consent.

Aside from the words "ovarian drilling" in the title of the generic information sheet about laparoscopic procedures given to Ms A, there is no other reference to the procedure in the preoperative clinical records, and no other evidence of Ms A's consent to it. In light of the absence of reliable records, and the information provided by Ms A and Dr E, I conclude that Dr B did *not* discuss PCOS and the available treatment options, or obtain Ms A's informed consent to ovarian golf ball drilling prior to her surgery on 12 February 2004.

In my view, it is more likely that Dr B first diagnosed Ms A's PCOS during the "look-see laparoscopy" and decided at that time to drill Ms A's ovaries to treat the condition. My expert, Dr Jacobson, commented on this scenario. As discussed in case 07HDC11318, surgical services may be provided to a competent adult in non-emergency situations only if that patient makes an informed choice and gives informed consent, irrespective of what the doctor considers to be in the patient's best interests. In the absence of adequate consent preoperatively, "inadequate consent [cannot] be cured retrospectively".[18]

Notwithstanding Dr B's assessment of Ms A's best interests, there was no legal justification for her to drill Ms A's ovaries without her informed consent. This was not an emergency situation. The decision whether to proceed with this treatment option was Ms A's alone to make. By denying Ms A the right to make an informed choice, Dr B breached Rights 6(1) and 7(1) of the Code.

Documentation

Under Right 4(2) of the Code, Ms A was entitled to services that complied with professional standards. The medical profession maintains clear professional standards regarding documentation of care.

Appropriate documentation is essential for coordination between providers, and to ensure consistency and quality of care. According to the Medical Council's statement

[18] General Surgeon, Dr E, A Private Hospital, A Report by the Health and Disability Commissioner, Case 07HDC11318 (17 October 2008), page 33. Available online at: http://www.hdc.org.nz/

on *The Maintenance and Retention of Patient Records*,[19] "Records must be legible and should contain all information that is relevant to the patient's care." The Medical Council further states:

> "Information should be accurate and updated at each consultation. Patient records are essential to guide future management, and invaluable in the uncommon occasions when the outcome is unsatisfactory."

Unreliable file note

Patient care and investigations should not be compromised by health providers' poor documentation. This point is emphasised in case 03HDC11066[20] and the Health Practitioners Disciplinary Tribunal's subsequent decision.[21] On appeal to the High Court, Courtney J stated:[22]

> "The word of a professional person must be reliable. Patients must be able to rely on their doctors. Those undertaking statutory functions for the protection of the community's interests such as the HDC must be able to rely on the information they are given."

As discussed above, I consider Dr B's file note (dated 8 February 2004) purporting to record preoperative discussions and Ms A's informed consent to some of the procedures that she performed, including ovarian golf ball drilling, to be unreliable.

TPT method and result

Dr Jacobson observed that in the operation note, Dr B did not record the method or result of the tubal patency test (TPT) she performed during Ms A's surgery. He advised:

> "The photographs taken at the time of surgery appear to show bilateral tubal patency but there is no specific documentation in the notes of the result. This is a minor departure from accepted practice and would be viewed by her colleagues with minor or no disapproval."

Dr B noted:

> "The TPT is … a perfectly standard Registrar level procedure that every Registrar should know how to perform. I know of very few if any Consultant surgeons who would have performed many TPT's in their surgical lifetimes who will outline such Registrar level work in extreme detail.
>
> …
>
> It adds to the horrendous volume of notes surrounding our work and is not strictly necessary. Not describing the TPT does not make it any way a clinically less

[19] August 2001.
[20] Available online at: http://www.hdc.org.nz (6 July 2005).
[21] *Re N* (Health Practitioners Disciplinary Tribunal, 58-Med05-15D, 31 August 2006).
[22] *Martin v Director of Proceedings* (High Court Auckland, 2 July 2008, Courtney J), paragraph 117.

> optimal procedure. [Ms A's] laparoscopic photographs that I took show the tubal patency test very accurately."

Dr B later emphasised that her laparoscopic photos showed the result of the TPT for the clinical record. She stated that "even Dr Jacobson says that what he views as a minor departure would be viewed by colleagues with minor or no disapproval".

The Medical Council statement provides that clinical records should contain all the information that is relevant to the patient's care. The standard of documentation is not a sliding scale according to the experience of the surgeon. Nonetheless, I accept that in these circumstances, it was reasonable for Dr B to substitute a written record of the method and result of the TPT with laparoscopic photographs showing tubal patency.

Laparoscopic ports
Dr Jacobson also commented on Dr B's documentation of the size of the incisions, rather than the laparoscopic ports used during Ms A's surgery.

In the operation note, Dr B recorded "0.5[cm] stab vertical inferior umbilical port, 0.25 cm stabs rest of the abdomen". She explained that she actually used a 10mm camera port, but made and documented a 5mm incision, stretching Ms A's skin to fit the port. Similarly, Dr B clarified that she actually used 5mm secondary ports, but made and documented 2.5mm incisions for the same reason. Dr B explained that she makes "minimalistic" abdominal incisions "to fit ports tight, avoid gas leakage and slippage in and out of ports themselves which causes mechanical trauma and increases hernia risks".

Dr Jacobson commented:

> "I do not think that the size of the skin incision is relevant when documenting ports sizes as this is variable depending on a number of factors. In general, the skin incision is usually made to create a snug fit around the port to prevent gas leakage. It is the actual diameter of the port device that is used that reflects the size of the incision that is made in the muscle and sheath layer of the anterior abdominal wall (rather than the skin). This is the key feature in understanding what instrumentation has been used and also considering post operative risks such as port site hernia."

Dr Jacobson advised:

> "[Dr B's] method of documentation of port sizes is confusing and factually incorrect since it does not record the actual ports that have been used. I believe that this serves no purpose other than to suggest that smaller incisions have been used when they are not. This is a moderate departure from accepted practice and would be viewed by her colleagues with minor to moderate disapproval."

In response, Dr B submitted that her documentation of the size of the skin incisions rather than the size of the instruments she used "did not occur to [Dr] Tait[23] as a basis of any kind of disapproval".

I accept Dr Jacobson's advice that Dr B should have documented in her operation note the size of the ports she used, rather than her estimation of the size of the incisions she made.

Conclusion
The Medical Council statement is clear that clinical records should be accurate, contemporaneous (or annotated as retrospective), and sufficient to allow another practitioner to understand what was found and what was done. Dr B's unreliable file note and inadequate records in respect of the laparoscopic ports amount to a departure from professional standards for documentation and a breach of Right 4(2) of the Code.

Opinion: No breach — Dr B

Postoperative care

Ms A was concerned that Dr B did not provide her with adequate postoperative care, particularly in respect of postoperative pain and bleeding. Dr Jacobson advised:

> "There is no evidence from the notes that further surgery or intervention was required due to excessive bleeding. The post operative care in relation to the management of pain and concern regarding bleeding was an acceptable standard of care."

I conclude that Dr B's postoperative care of Ms A was appropriate and she did not breach the Code in this regard.

Recommendations

I recommend that Dr B:

- Apologise to Ms A for her breaches of the Code. This apology is to be sent to HDC by **19 March 2010** and will be forwarded to Ms A.
- Review her practice in light of this report and the comments of my expert.

[23] Dr John Tait provided expert advice on behalf of Dr B.

Follow-up actions

- A copy of this report will be sent to the Medical Council of New Zealand and the private hospital.

- A copy of this report, with details identifying the parties removed except the names of expert advisors Dr Tal Jacobson and Dr John Tait, will be sent to the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, and the District Health Board. These bodies will be advised of Dr B's name.

- A copy of this report with details identifying the parties removed, except the names of expert advisors Dr Tal Jacobson and Dr John Tait, will be sent to the Royal Australasian College of Surgeons, the New Zealand Private Surgical Hospitals Association, Women's Health Action Trust, and the Federation of Women's Health Councils Aotearoa/New Zealand, and placed on the HDC website, www.hdc.org.nz, for educational purposes.

Appendix 1: Independent advice — gynaecologist Dr Tal Jacobson

Initial advice
The following expert advice was obtained from gynaecologist Dr Tal Jacobson:

> "Thank you for letter from the Health and Disability Commissioner dated 29 April 2009 requesting an opinion on this matter.
>
> In providing this advice, I acknowledge that I have read and agree to follow the Guidelines for Independent Advisors (Appendix H) effective date 5 March 2007.
>
> My name is Dr Tal Jacobson and my qualifications are MA (Cantab) MBBS (Lond) MRCOG FRANZCOG. I am a Senior Lecturer in Obstetrics and Gynaecology at the University of Auckland and Consultant in Obstetrics and Gynaecology at Counties Manukau District Health Board. I have specific experience in Minimal Access (Keyhole) Surgery. During my training, I completed a two year Fellowship in Minimal Access Surgery at Bart's and the Royal London Hospitals, London, UK. I am the lead clinician for Gynaecological Minimal Access Surgery at Counties Manukau DHB. I specialise in the treatment of endometriosis, pelvic pain, menstrual disorders and infertility. I run regular training courses to teach various aspects of minimal access surgery to both junior and senior gynaecologists. My research interests are focussed on the safety and ergonomics of minimal access surgery as well as the treatment of endometriosis.
>
> I have been asked by the Commissioner to:
> a) outline the facts on which my advice is based
> b) advise whether I consider [Dr B's] care was of an appropriate standard
> c) consider whether any aspect of this care departed from accepted practice and if so indicate the severity of departure from that standard
> d) advise on any other aspects of the care provided by [Dr B] that I consider warrant additional comment.
>
> [Dr Jacobson listed the supporting documents that HDC provided to him for the purposes of his expert advice. This list has been removed for the sake of brevity.]
>
> **Summary of events:**
>
> **2 February 2004**
> [Ms A] (aged 29 at that time) was referred by her GP ([Dr C]) to [Dr B] (letter dated 2 Feb 2004) with a history of painful periods and pelvic pain and a possible diagnosis of endometriosis. She had had several attendances to an Accident and Medical Clinic and a Hospital Emergency Department over the previous month.
>
> **9 February 2004**
> [Dr B] first saw [Ms A]. In her letter to the GP dated Monday 9 February 2004, [Dr B] described the symptoms of 'knife-like' pain and recommended a '"look see" laparoscopy and the treatment (resection and ablation) of endometriosis if present' as well as tubal patency testing. She noted a history of a previous

appendicectomy and an ovarian cystectomy at the age of 14 […]. She commented that [Ms A] would like the surgery as soon as possible due to her study commitments. The surgery was booked for three days after the initial consultation.

12 February 2004
[Ms A] underwent surgery at the [private hospital] by [Dr B] on Thursday 12 Feb 2004.

The operation is described as *'Laparoscopy + excision and resection ablation of endometriosis + TPT'*.

The findings were described as:- *'uterus NS. Ovaries multicyctic but nil else abnormal. Rt ovarian fossa and left and right lateral wall American Fertility Society stage 2 endometriosis.'*

Photographs were taken at the time of surgery.
'NS' presumably stands for normal size.
'Multicyctic' presumably should read multicystic.

The procedure is described as follows:-

'Procedure: uncomplicated. Incisons: 0.5 stab vertical inferior umbilical port, 0.25 cm stabs rest of the abdomen
Process: easy insufflation. Good views.'

'Resection of all visible peritoneal disease and uterosacrals. Ovarian "golf balling – drilling" performed bilaterally
Peritoneal biopsy taken

All wounds closed with long term absorbable monocril
Blood Loss: minimal'

The histology of the peritoneal tissue biopsies were subsequently reported as:- *'No diagnostic abnormality'* (This is a common finding even when endometriosis is clearly visually identified at laparoscopy.)

Following surgery, the patient was transferred at approximately 1600hrs to the post anaesthetic care unit (PACU). Here, she experienced severe pain on waking and at 1630hrs was treated with Tramadol and a total of 20mg of morphine over 60 minutes. At 1830hrs [Dr B] and the anaesthetist [Dr F] were asked to review [Ms A] due to a persistent tachycardia (raised pulse rate) of 110 beats per minute. A Haemocue result showed the haemoglobin was 102g/l (pre op Hb = 137g/l). [Dr B] reviewed the patient at 1849hrs and at that time the pulse rate had decreased to 97 beats per minute and the blood pressure was normal. [Dr B] was satisfied that there was no excessive bleeding. An indwelling urinary catheter was inserted at this time. The patient was transferred from PACU to the main ward at approximately 2015hrs.

13 February 2004
The urinary catheter was removed at 11am and the patient was mobilising.
A blood result dated this day showed a Hb = 76g/l. There is no evidence of a repeat test to check this result.

15 February 2004
[Ms A] was discharged from hospital.

19 February 2004
A telephone follow-up call was made from [the private hospital] ward nursing staff to [Ms A]. It documents a urine infection being treated with antibiotics and that pain had been a problem but was now under control.

20 February 2004
[Ms A's] GP referred her back to [Dr B] eight days after surgery with persistent abdominal pain, a raised temperature and evidence of a urine infection. She was seen at the [private hospital] by [Dr B's colleague]. Temperature was slightly elevated at 37.6. She was re-admitted and treated with intravenous antibiotics.

21 February 2004
A urologist reviewed the patient. An ultrasound was performed showing 'normal kidneys, bladder empty, free fluid — pelvic collection — probably blood'.
Conservative management was planned.

22 February 2004
[Ms A] was reviewed by [Dr B's colleague]. Temperature 37.2 degrees. Symptoms were improving.

23 February 2004
[Ms A] was reviewed by [Dr B]. She did not have a raised temperature and was discharged home.

1 March 2004
A full blood count was performed and the Hb = 117g/l.

6 March 2004
[Dr B] wrote to GP [Dr C] describing a slow but progressive recovery from surgery. She was started on Arcoxia (a pain killer), ranitidine (an anti-acid), peppermint oil and temazepam (a sedative sleeping tablet).

2 April 2004
[Dr B] wrote to GP [Dr C] describing continued improvement but some ongoing pain.

9 June 2005
[Ms A] had a follow-up appointment with [Dr B] 16 months after surgery. She is described as having had symptom relief for about a year after surgery but recently started to get pain with her periods.

1 August 2005
[Ms A] was referred for a second opinion to [Dr E]. At this appointment, [Dr E] discussed the findings of polycystic ovaries and ovarian drilling procedure in February 2004. This was the first time that [Ms A] became aware that this procedure had been undertaken.

29 August 2005
[Ms A] underwent a laparoscopy by her second surgeon [Dr E]. Extensive adhesions were found throughout the pelvis. Endometriosis was also identified.

29 May 2008
[Ms A] contacted the HDC with concerns about the following aspects of her care:
1) Ovarian drilling / golf balling was performed without her consent and she was not informed after the surgery that it had been performed
2) She was in pain in recovery and required a further procedure to stop bleeding
3) She was concerned that there was excessive blood loss at surgery
4) She was readmitted a week after surgery with infection
5) In June 2008, [Dr B] inappropriately requested [Ms A's] notes from another surgeon.

In the following report I will address specific areas of the case and provide my opinion on the standard of care:-

Consent
[Ms A] states in her complaint to the HDC on 29 May 2008 that she had not consented to surgery to the ovaries (ovarian drilling / golf balling) that was performed by [Dr B] as part of the operation in February 2004 and that she was not informed after the surgery that this procedure (ovarian drilling) had taken place. She says that she only found out about it when it was mentioned by another surgeon ([Dr E]) on 1 August 2005.

A letter by [Dr E] dated 1 August 2005 documents that this was the first time [Ms A] was made aware that laparoscopic ovarian drilling had been performed by [Dr B] on 12 February 2004.

The formal [private hospital] Consent form signed and dated 9 Feb 04 by [Ms A] and signed and dated 12 Feb 04 by [Dr B] states the planned operation as 'Laparoscopy & Treatment to Endometriosis + TPT' (*Tubal Patency Testing*).

There is no preoperative mention of ovarian drilling or golf balling in the formal [private hospital] Consent form, the clinic consultation letter to the GP or in the clinic note.

There is a comment regarding 'golf-balling' in a separate document that is discussed at the end of this report (Appendix [A]). The Health and Disability Commissioner has requested a specific interpretation of this document dependant on different potential alternatives of its origin and therefore it is discussed separately as an appendix.

In the operation note, the ovaries are described as 'Multicyctic' which presumably should read 'multicystic'. The phrase 'multicystic ovaries' is not in common usage. *Polycystic* ovaries are a specific pathology that may be identified preoperatively by ultrasound.

The procedure of ovarian drilling is usually carried out on polycystic ovaries to provoke ovulation. It may be appropriate in women with polycystic ovaries who are having difficulty conceiving because they are not ovulating regularly.

The risks of the procedure include loss of ovarian tissue, potentially decreased ovarian reserve and adhesion formation.

When laparoscopic ovarian drilling was first introduced it replaced an open operation called wedge resection of the ovary where up to 1/3 of each ovary was excised. The operation was performed to increase the likelihood of subsequent spontaneous ovulation from the remaining portion of the ovary.

The laparoscopic procedure originally involved making multiple small deep burns in each ovary using electrical diathermy. Many drill points were made so that the ovary looked like a golf ball with multiple dimples, thus 'golf balling'.

Subsequent studies showed that ovulation could be stimulated with far fewer 'drills' and it is now accepted that only 4 drills per ovary at 4 Watts for 4 seconds is required. This inevitably means that less ovarian tissue is damaged and there may be less adhesion formation.

I would expect [Dr B] to have been aware of this in 2004 and to no longer routinely practice 'golf balling' or to explain and justify in the operation note or subsequent documentation why it has been done.

According to [Dr B's] letter to the GP dated 9 February 2004, [Ms A] had already had previous surgery to the ovary at the age of 14 and therefore, for future fertility, the preservation of ovarian reserve is a particularly important consideration and careful thought and counselling should have been given to whether this was an appropriate procedure.

It is reasonably common that an unexpected finding is made at laparoscopy and the surgeon is expected to act in the patient's best interest. Regardless of the surgeon's actions, if an unplanned or un-consented procedure is undertaken, I would expect that a detailed description of the findings, a justification for the procedure and a detailed description of the procedure would be clearly documented.

In her letter dated June 2008 to the HDC, [Dr B] says that the ovarian drilling was performed to decrease the 'weightiness' of the ovaries and thus reduce the risk of ovarian torsion and avoid premature loss of ovarian tissue.

I am not aware of evidence suggesting a significant increase in the risk of ovarian torsion associated with polycystic ovaries or that drilling reduces that risk. Nevertheless, if [Dr B] believed this to be the case, I would have expected this justification for the surgery to be documented in the operation note in 2004.

In the letter to the HDC dated June 2008, regarding ovarian drilling, [Dr B] says that 'this is part of the work to which [Ms A] had consented'. The Consent to Surgical Treatment form and Consent to Medical Treatment form, both dated 12.2.04 and both signed by [Ms A], do not mention ovarian drilling.

I would expect clear documentation that the unexpected findings (multi or polycystic ovaries) and the justification for ovarian drilling would be explained to the patient as soon as practical after the operation.

In her letter dated 10 November 2008 to the HDC [Dr B] states that the operation findings were explained in the postoperative period and at the follow up appointments to [Ms A].

'*Ovarian "golf balling — drilling" performed bilaterally'* is specifically documented in the operation note and I understand that [Ms A] did have a copy of these notes but there is no further documentation that this was explained or justified to [Ms A]. [Ms A] says that she did not find out about this part of the operation until she was informed by another surgeon in August 2005.

It is possible that a misunderstanding or failure of communication occurred and although [Dr B] thought she explained the findings and the procedure of ovarian drilling it was misinterpreted or forgotten by her patient in the postoperative period and the subsequent follow-up appointments. If this was the case, I would still expect the conversation to be documented since the procedure was not planned or anticipated on the formal consent form.

[Ms A] states in her complaint dated 30 May 2008 that she did not know about the ovarian drilling until she was informed about it by another surgeon. This is also documented by [Dr E] in her letter dated 1 August 2005.

I would expect clear documentation that the unexpected findings (multi or polycystic ovaries) and the justification for ovarian drilling would be explained to the patient as soon as practical after the operation.

It is difficult to determine if there were any significant clinical sequelae from the ovarian drilling. The finding of extensive adhesions at her second laparoscopy in August 2005 could be related to any or all of the following causes:

- Previous surgery
- Infection following surgery
- Recurrence of endometriosis
- Ovarian drilling
- Haemorrhage following the original surgery — leading to a low haemoglobin and the finding of pelvic fluid on ultrasound on 21 February 2004.

It is therefore not possible to directly link the ovarian drilling with any adverse clinical outcome. It is also not possible to exclude it.

Documentation

TPT
There is no record in the operation note of how the 'TPT' (Tubal Patency Test or Dye Test) procedure was done or what the result was. The photographs taken at the time of surgery appear to show bilateral tubal patency but there is no specific documentation in the notes of the result. This is a minor departure from accepted practice and would be viewed by her colleagues with minor or no disapproval.

Port sites
In the operation note it states '0.5mm stab vertical inferior umbilical port, 0.25 cm stabs rest of the abdomen.' The location and number of secondary ports are not documented.

Presumably '0.5mm' is a typo and should read 0.5cm or 5mm.
In her letter to the HDC dated 10 November 2008 [Dr B] states that in fact she used a 10mm port but has documented it as a 5mm port because she stretched the skin. Similarly she used 5mm secondary ports but documented them as 2.5mm for the same reason.

I do not think that the size of the skin incision is relevant when documenting port sizes as this is variable depending on a number of factors. In general, the skin incision is usually made to create a snug fit around the port to prevent gas leakage. It is the actual diameter of the port device that is used that reflects the size of the incision that is made in the muscle and sheath layer of the anterior abdominal wall (rather than the skin). This is the key feature in understanding what instrumentation has been used and also considering postoperative risks such as port site hernia.

[Dr B's] method of documentation of port sizes is confusing and factually incorrect since it does not record the actual ports that have been used. I believe that this serves no purpose other than to suggest that smaller incisions have been used when they are not. This is a moderate departure from accepted practice and would be viewed by her colleagues with minor to moderate disapproval.

Unconsented procedures
Sometimes an unexpected finding such as polycystic ovaries is made at the time of surgery. In these cases the surgeon may consider it in the patient's best interest

to manage an unexpected condition at the time of surgery even if prior consent had not been obtained. This may be perfectly reasonable and justifiable but if the findings and procedure are unanticipated, I would expect the surgeon to:
a) fully document the findings.
b) clearly document the justification for doing the un-consented procedure (in this case laparoscopic ovarian drilling) at that time.
c) provide a detailed explanation of the method used such as the number of drills and power settings used.
d) clearly document that the un-consented procedure had been explained to the patient in the postoperative period or at the subsequent follow-up appointment.

In this case, there is no contemporaneous documentation of the justification for the procedure of ovarian drilling, or of the detail of the method used or that the patient had been counselled afterwards.

In a letter to the HDC dated 10.11.08 [Dr B] provides an explanation for this procedure. [Dr B] suggests that it will reduce the risk of ovarian torsion and preserve ovarian function. This is a potentially plausible explanation but not generally considered to be an indication for this surgery.

The most common justification for laparoscopic ovarian drilling is to induce spontaneous ovulation for subfertile patients with polycystic ovaries. This was not required in this case. If a less common indication for a particular procedure is to be used I would consider it even more important to provide contemporaneous justification for the surgery.

Bleeding
In her complaint dated 30 May 2008 [Ms A] states that when she woke up she was 'covered in blood' and that it was due to a 'loose stitch'.

Her preoperative haemoglobin was 131g/l. At approximately 1830hrs a Haemacue taken in recovery showed a haemoglobin of 102g/l. This would indicate a significant blood loss but Haemacue can be inaccurate and the formal lab report would be needed to confirm this finding.

If the sample was taken from an IV line it may have been diluted and unexpectedly low. If that was thought to be the problem and there [was] still a concern about the condition of the patient, a repeat blood count should be taken from the other arm or after turning off the drip for a few minutes.

[Dr B] reviewed the patient at 1849hrs on 12.2.04 and wrote a detailed note. She was satisfied with her condition and requested that she be transferred to the ward. A further blood test taken on 13.2.04 showed a Hb = 76g/l. This suggests that there may have been significant blood loss at the time of surgery or soon after.
Overall, I think it is likely that there was some postoperative intra-abdominal haemorrhage following the original surgery thus leading to the low haemoglobin and the finding of pelvic fluid on ultrasound on 21 February 2004. Although this

was not investigated any further, [Ms A's] clinical status was stable in the postoperative period.

There is no evidence from the notes that further surgery or intervention was required due to excessive bleeding. The postoperative care in relation to the management of pain and concern regarding bleeding was an acceptable standard of care.

Access to Notes
In her complaint dated 30 May 2008 [Ms A] complains of inappropriate access to her notes by [Dr B]. I am not able to provide expert advice regarding the legalities of access to patient notes in these circumstances."

Further advice

"The Commissioner has specifically asked for an opinion regarding a document provided subsequently by [Dr B] after her review of my preliminary comments regarding consent [Dr B's filenote dated 8 February 2004].

The Commissioner has specifically asked for comments on the following:

'… any observations you have about the filenote, but provide your advice on the adequacy of the information she provided to [Ms A], and her compliance with professional and ethical standards (including documentation) in the following alternatives:

1) The Commissioner determines that the file note was created on 9 February 2004, but misdated 8 February 2004, and is an accurate record.

2) The Commissioner determines that the file note was created retrospectively and is an accurate record.

3) The Commissioner determines that the file note was created retrospectively and is an inaccurate record.'

The following features of this document are notable and make it difficult to determine its role in the consent process.

1) This document was not in original bundle provided for review in August 2008. It is unclear why it was not available at that time.

2) The initial GP referral letter is dated 2 Feb 2004.

3) [Ms A's] initial appointment with [Dr B] was Monday 9 Feb 2004.

4) This document is dated 8 Feb 2004 (this is a Sunday) and is one day prior to their first meeting.

5) Unlike all the other clinical records, this document is unheaded and has no footer. It is not on [private hospital] paper or on [Dr B's] standard headed paper.

6) There is no identification of the patient to whom it relates. The patient is only identified by a shortened version of her first name. At the end of the note it asks for the note to be placed in a file with the same initials as the patient. There is no documentation of the patient's full first name, surname, address, date of birth or NHI number to clearly identify the patient to whom it relates. For a clinical record, a minimum of a patient's full name and one other identifier such as date of birth, NHI number or address would be expected to identify a record as relating to a particular patient. In this case there is inadequate identification of the patient.

7) The document is not addressed to anyone. It is not clear who it is intended for and there is no evidence that it was sent to the patient or her referring GP at any time.

8) The content of a document intended to demonstrate that adequate informed consent was obtained would normally be contained within the contemporaneous consultation letter to the GP, the consultation note or the formal consent form. The specific information regarding laparoscopic drilling is not mentioned in any of these but only in this document. It is not clear why the information is in a separate document with no clear identifying patient details.

9) The document is unsigned by [Dr B].

10) The document is unsigned by [Ms A] and there is no evidence that [Ms A] was aware of the existence of this document.

11) There are only three days between the first consultation and the date of surgery. The document says they have discussed the surgery 'face to face at many occasions'. This is an unusual comment since according to the date of the document they did not meet for the first time until the following day. There is no evidence that [Dr B] had met [Ms A] prior to Monday 9 Feb 2004. If the date of the document is incorrect and should be 9 February 2004, then they will only have met for the first time that day and therefore it is unlikely that they could have discussed the surgery face to face on many occasions.

12) Documentation of consent usually documents the planned procedure and the possible complications. It is not usual to comment on the clinical reasons that the procedure is planned as this is usually contained in the consultation letter. This note documents the planned procedure and then comments on why one particular part of the procedure may be necessary. There is no discussion of why the laparoscopy, adhesiolysis, resection of endometriosis is being planned but comment is specifically made about why 'ovarian cystectomy/

golf balling' is planned. This happens to be the part that was undocumented in the formal consent form, the consultation letter and the clinic note. This strikes me as unusual.

13) It is unclear why the following phrase is specifically in bold type and underlined. '**is now her informed consent process recorded FYI**.' It is also unclear who 'FYI' (for your information) refers to since this document was not addressed to or sent to anyone around the time of surgery.

14) There is no specifics of the 'RCOG….documentation' that is mentioned. These may in fact be RANZCOG (rather than the UK based RCOG) patient information guides. I would expect that the email containing these documents could be located and the contents assessed. The date and edition of the documentation may be relevant.

As requested by the Commissioner, the following comments relate to three different outcomes depending on the specific determination the Commissioner makes regarding the status of this particular document.

1) The Commissioner determines that the file note was created on 9 February 2004, but misdated 8 February 2004, and is an accurate record.

In this circumstance, if this accurately reflects the content of a conversation between [Dr B] and [Ms A] on 9 February 2004, then the information provided to [Ms A] prior to surgery was adequate. A minor error of misdating the document would be an acceptable error. Nevertheless, this document does not adequately identify the patient to whom it refers and therefore its content may not actually relate to this particular patient. Overall, this would be a moderate departure from accepted clinical standards and would be viewed with mild to moderate disapproval by her peers.

2) The Commissioner determines that the file note was created retrospectively and is an accurate record.

In this circumstance, if this accurately reflects the content of a conversation between [Dr B] and [Ms A] on 9 February 2004, the information provided to [Ms A] prior to surgery was adequate. The provision of a retrospective record should always be documented as such and the reason for writing in retrospect should be provided as well as details of when the retrospective record was created. None of this information is provided. In addition, this document does not adequately identify the patient to whom it refers and therefore its content may not actually relate to this particular patient. Overall, the retrospective documentation with no justification for being retrospective and no record of when it was created would be a major departure from accepted clinical and ethical standards and would be viewed by her peers with severe disapproval.

3) The Commissioner determines that the file note was created retrospectively and is an inaccurate record.

In this circumstance, the information provided to [Ms A] prior to surgery was inadequate. The provision of a retrospective record should always be documented

as such and the reason for writing in retrospect should be provided as well as details of when the retrospective record was created. None of this information is provided. In addition, this document does not adequately identify the patient to whom it refers and therefore its content may not actually relate to this particular patient. If this record is both retrospective and deliberately or unintentionally inaccurate, this would be an extreme departure from accepted clinical and ethical standards and would be viewed by her peers with the most severe disapproval."

Appendix 2: Dr B's expert advice — gynaecologist Dr John Tait

Initial advice
Dr John Tait provided the following expert advice for Dr B on 22 October 2008:

> "My name is Dr John Tait, MBBS, FRCOG, FRANZCOG. I am the Clinical Director of the Women's Health Service, Capital & Coast DHB. My particular interest is laparoscopic surgery and the treatment of endometriosis.
>
> *1. Re Consent for Ovarian Drilling*
> Although there was no specific consent for this procedure it would not be unusual to treat unexpected findings at Laparoscopy. However, it would be expected to discuss this with the patient as soon as possible. This would appear to be a significant oversight by [Dr B]. I note that [Dr B] has information pamphlets on Endometriosis and polycystic ovaries which describe the procedures and their risks. However, there is no evidence that [Ms A] received them.
>
> *2. Tubal Patency Test*
> There is no comment about the result of this procedure. There may have been photos or a DVD taken but if not this would be an oversight by [Dr B].
>
> *3. Immediate postoperative management*
> There was no evidence of excessive bleeding from the port sites as documented in the nursing records.
>
> A Haemocue showed a haemoglobin of 102, compared with a haemoglobin of 131 preoperatively however a repeat haemoglobin on 17 February, five days postoperatively, was 125. This would not suggest excessive bleeding. I would also like to note that fluid is used to irrigate the pelvis during laparoscopic procedures which can then leak through port sites postoperatively.
>
> According to the nursing notes pain seemed to be the major problem. [Ms A] was seen by both the anaesthetist and [Dr B] postoperatively and in my opinion [Dr B's] management was appropriate."

Further advice
Dr John Tait provided the following further expert advice for Dr B on 5 November 2008:

> "I have had the opportunity to review [Dr B's] notes on [Ms A] … which has enabled me to make further comments and amendments to my previous report.
>
> *1. Re Consent for Ovarian Drilling*
> There is a statement in the notes that states '[Ms A] has decided to go ahead with an exploratory laparoscopy, adhesiolysis, resection Endometriosis and ovarian cystectomy/golf balling … if and as required ...'
> Also included in the notes are very extensive information sheets regarding these procedures. I note also photos of the operative findings. Therefore the only

remaining issue is whether the findings at surgery and the procedures performed [were] discussed postoperatively with [Ms A].

2. Tubal Patency Test
The photos clearly show tubal patency."