Obstetrician and Gynaecologist / A Private Hospital

A Report by the

Health and Disability Commissioner

(Case 00HDC08358)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Ms A	Consumer
Mr B	Consumer's husband
Mr C	Consumer's father
Dr D	Obstetrician and Gynaecologist
A Private Hospital	Private Hospital
Dr E	General Practitioner
Medical Centre	Medical Centre

Ms A's clinical records were obtained. Dr D's notes regarding her pre-operative consultations with Ms A, which would normally be included in the hospital records, were missing from the clinical record.

Expert advice was obtained from an independent obstetrician and gynaecologist, Dr Kevin Hill.

Complaint

The Commissioner received a complaint from Ms A on 15 August 2000 (forwarded from the Medical Council of New Zealand) regarding the services she received from Dr D and a private hospital. Her complaint is as follows:

Dr D did not provide Ms A with an appropriate standard of service. In particular, Dr D:

- *Informed Ms A that the blood test results indicated that she had invasive cancer, although other tests and scans showed nothing unusual and surgery later revealed that Ms A did not have cancer;*
- *Performed a hysterectomy during surgery on 7 May 1999 without obtaining Ms A's consent, although prior to surgery Ms A had clearly stated that she wished to be involved in any decision making;*
- *Did not give Ms A the option of having her uterus returned to her after surgery so that Ms A could bring it home.*

A private hospital did not provide an appropriate standard of service to Ms A. In particular:

- *When Ms A had surgery at a private hospital on 7 May 1999, Ms A was not given the option of having her uterus returned to her after surgery so that she could bring it home.*

An investigation was commenced in January 2001.

Information gathered during investigation

Background
In early 1999 Ms A, aged 40 years and her husband, Mr B, were trying to conceive a child. Mr B had recently suffered testicular cancer and was undergoing a course of chemotherapy. Before his chemotherapy treatment commenced, Mr B had some of his sperm frozen to assist Ms A to conceive. To this end they approached a fertility clinic for assistance. A pelvic ultrasound scan, undertaken in the course of fertility assistance, suggested an increase in the number of identifiable fibroids and the size of Ms A's right ovary, which would decrease her chance of conceiving. It was recommended that Ms A see an obstetrician and gynaecologist specialist for further investigation.

On 12 April 1999 Ms A was referred to an obstetrician and gynaecologist, Dr D, by her general practitioner, Dr E. The letter of referral stated that Ms A had been referred because of "… recent pelvic ultrasound findings, which suggest both an increase in the number of identifiable fibroids, and an increase in the size of her right ovary, since checked by Fertility Associates six months ago".

Initial consultation with Dr D
Dr D first saw Ms A on 27 April 1999. Her husband, Mr B, accompanied her. Ms A informed Dr D that they wanted to have children and that she and her husband had been seeking fertility assistance. She also advised Dr D of her husband's cancer, and the fact that some of his sperm had been frozen prior to his chemotherapy treatment. In contrast, Dr D stated it was her impression that both Ms A and her husband had come to terms with their fertility problems, and that they had decided not to further pursue fertility assistance. The letter of referral to Dr D from Dr E stated, "[Ms A] and her husband [Mr B] have been unable to have children and have been great accepting the fact."

Dr D stated that after taking a detailed history and general examination of Ms A, the ultrasound findings and her various options were discussed. Dr D recommended a laparoscopy (an examination of the abdominal cavity with a laparoscope through one or more small incisions in the abdominal wall), excision of endometriosis (the presence of tissue similar to the lining of the uterus at other sites in the pelvis), an ovarian cystectomy (the removal of cysts from the ovary), and a myomectomy (the removal of fibroids from the muscular wall of the uterus).

On account of Ms A's heavy periods, Dr D also recommended a hysteroscopy (the insertion of a tubular instrument with a light source for observing the interior of the uterus) and a dilation of the cervix and curettage of the uterus (D&C) be performed at the same time. Ms A also complained of upper gut symptoms and therefore a gastroscopy and gall bladder scan was mentioned.

Dr D advised that the resulting risks were discussed in detail, including the small risk of ovarian cancer in 3% of patients. She stated that although this risk was remote, she discussed with Ms A the various treatment options if cancer was found during the laparoscopy, including the option of hysterectomy.

Ms A stated that Dr D "indicated that she would never just do a hysterectomy without consulting me and providing counselling prior to that happening". Ms A further stated that she was informed that it was Dr D's usual policy with ovarian cancer to wake up the patient and prepare her mentally and medically before any further surgery is performed. Dr D confirmed that this was her usual policy in the rare case where previously unsuspected cancer was found during surgery, and that in all other cases where ovarian cancer was suspected, it was her usual policy to counsel and prepare the patient prior to surgery.

After considering the options presented by Dr D, Ms A agreed on a conservative management plan, involving laparoscopic surgery, excision of endometriosis, ovarian cystectomy, hysteroscopy, and a D&C. She did not wish to have a myomectomy. Ms A acknowledged that if her problems continued she might consider more radical surgery at a later date.

A consent form for surgery was accordingly drawn up, giving consent for Dr D to perform a laparoscopy, excision of endometriosis, ovarian cystectomy, hysteroscopy and D&C.

Dr D requested blood tests, and the operation was scheduled for 9 May at a private hospital.

Blood test results
The blood test results were returned with Ms A's CA125 (a marker suggestive of cancer) reported as 317, a high result. The laboratory was phoned to recheck the result, and a repeat CA125 was performed. The repeat test came back with a value of 203, which is still a high result.

On the evening of 2 May 1999 Dr D phoned Ms A to arrange an appointment with her the following morning to discuss the test results. Ms A stated that in the course of the conversation Dr D indicated that there was a high probability she had cancer, and that the situation was very serious.

Second consultation with Dr D
At 8.30am on 3 May 1999, Ms A and her father, Mr C, attended an appointment with Dr D. Because of the short notice, Ms A's husband, Mr B, was unable to attend. Dr D advised Ms A of the test result and its implications. Dr D explained to Ms A that she had never seen such a raised level of CA125 associated with endometriosis/endometriomas, and that a value of 317 would be unlikely with endometriosis. Specifically, Dr D noted that she informed Ms A of the relationship between a raised CA125 and ovarian cancer.

Dr D stated that Ms A raised many questions about the possibility of cancer. Dr D advised that she tried to remain positive by discussing the ultrasound scan findings. She advised Ms A that instead of a laparoscopy she should perform a laparotomy (a surgical incision into the abdominal cavity to examine the abdominal organs). If ovarian cancer was confirmed during the laparotomy, Dr D recommended a total abdominal hysterectomy, bilateral salpingo-oophorectomy (the removal of both ovaries and fallopian tubes), omentectomy, and debulking of the tumour. Ms A was further informed that bowel preparation would be necessary prior to surgery. There appears to have been no discussion,

at this stage, about management in the event that severe endometriosis, and not cancer, was confirmed. Dr D confirmed this. She advised me that she had informed Ms A that the decision regarding either conservative or radical treatment for endometriosis did not need to be made at that consultation, in the absence of her husband.

Ms A appears to have queried whether a laparoscopy, as opposed to a laparotomy, was still an option. Dr D discussed the risk of port-hole metastases (the spread of cancer cells through the port-hole) as a consequence of a laparoscopy in the event of cancer. Dr D stated that Ms A took her advice to have a laparotomy and agreed that the safest and best management should be carried out for her without taking any undue risks, given her previous experience with her husband's cancer. Ms A stated that the decision to have a laparotomy was not related to her husband's cancer, but to the risk of port-hole metastases with laparoscopy.

On 3 May, Ms A also had a CT scan and a chest x-ray. The chest x-ray was normal; however, the CT scan identified a mid-line pelvic mass, described as being mixed cystic and solid. Dr D advised that it was not possible to clearly identify a separate uterus from the mass. Two cystic lesions were identified in the pelvis and assumed to be ovarian masses. No free fluid was present. Dr D stated that because Ms A's haemoglobin was 88, the decision was made to admit her on 5 May for a blood transfusion, and the surgery was scheduled for 7 May.

Ms A wanted to know what her future management would entail if ovarian cancer was confirmed. Dr D said that she briefly discussed chemotherapy, but that at no stage was mortality or life expectancy discussed. Dr D stated that her absolute practice is not to give time factors for anybody's survival, especially a patient whose cancer had not yet been confirmed. Dr D advised me that she continued to mention to Ms A the possibility of severe endometriosis as an alternative diagnosis.

Ms A stated that during the consultation on 3 May Dr D indicated that the high blood test suggested invasive cancer, and advised her that the cancer had probably spread in her body, specifically her stomach and rectum, and that she would require immediate surgery. Following surgery, Ms A would require monthly chemotherapy, which would mean she would lose her hair. Ms A further noted that Dr D advised her that it would be a good sign if she made it until Christmas.

Ms A's father, Mr C, who was present at this consultation, recalled that Dr D had informed Ms A that the test results were not encouraging, and that the high CA125 reading indicated that she had cancer, although she could not confirm to what extent. Mr C stated that Dr D recommended surgery as soon as possible, but he could not recall any discussion regarding a hysterectomy.

Due to the absence of full clinical notes, there is no record of what specifically was discussed during the consultation. There is no record of a management decision being made in the event of severe endometriosis and not ovarian cancer.

New consent form
On 3 May 1999 a new consent form for surgery was completed, and the old one discarded. The new consent form gave permission for operation procedures as follows:

> "*Operation procedure (specialist to complete)*
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> **Admission:** **Scheduled day** Thursday **Date** 6/5/99 **Time** 1900hrs
> **Diagnosis** ? Ovarian carcinoma
> **Operation/Procedure** Laparotomy – TAH + BSO +/- omentectomy + debulking of tumour"

Ms A signed the form. Below her signature, "TAH and BSO" are defined as: "Total Abdominal Hysterectomy and bilateral salpingo-oophrectomy".

Consultation with colleagues
Dr D advised that she phoned two of her colleagues to seek advice on Ms A's case. Dr F advised that he had not seen any patient displaying such raised CA125 levels with endometriomas. Likewise, Dr G, gynaecological oncologist, with whom Dr D discussed the complete case scenario of Ms A, advised that he had never seen such a raised CA125 in endometriosis/endometriomas, and agreed with Dr D's management plan.

Further consultations with Ms A
On the evening of 4 May Ms A and her husband met with Dr D to discuss Ms A's surgery and treatment plan. Monthly chemotherapy with Dr H, oncologist, was to be arranged to follow the surgery. Ms A noted in her diary that they discussed the loss of hair and nausea associated with chemotherapy. Mr B noted that after this meeting he was left with the impression that there was a high possibility Ms A not only had cancer, but invasive cancer.

Dr D stated that from the period between 3 May and prior to the surgery on 7 May, she had numerous long consultations with Ms A and her husband. Dr D stated that she constantly advised Ms A and her husband that the total picture did not add up, and that although the suspicion was of ovarian cancer, the absence of free fluid and the pelvic ultrasound scan findings were reassuring.

Dr D stated that throughout the discussions it became clear that Ms A was extremely worried that she might have future problems, including cysts or cancer. Dr D stated:

> "Throughout the discussions it became clear to me that since we had discussed in detail at the first consultation the understanding of endometriosis and in particular because of the reduced immunity and high oestrogen status the association with various cancers i.e. ovarian, breast, uterine, melanoma and non-Hodgkins lymphoma, that [Ms A] was extremely worried that she may have future problems. This whole sequence of events was affecting her badly emotionally, and as they had gone through a previous trauma in their life, she was worried about what the future held for her particularly in terms of future cysts or cancer. She had therefore said at least on two occasions, that if it was bad endometriosis then everything must be removed because she did not want to worry in the future and wanted to get on with

> her life. She also said many times that she had come to terms with her fertility issues."

Dr D further noted that:

> "On the first consultation conservative surgery was discussed and therefore they understood that I could be very conservative in terms of preserving the uterus and both ovaries. The fear of future malignancies or cysts and future worries was the message I was getting at each consultation. … At no stage did I get any indication that I was supposed to be conservative if there was severe endometriosis and because of the worry of future risks."

Dr D advised me:

> "The conversations were multiple and on the last day I had really appreciated that if there was severe endometriosis then I was supposed to still do the hysterectomy and remove the ovaries. Unfortunately, I did not put this on the consent form which, by this stage, had been filed in the hospital notes."

Dr D also stated that Ms A wanted her husband, Mr B, to be involved with all decisions. Dr D informed Ms A that legally her husband cannot consent on her behalf, but Ms A asserted that she gave full rights of decision-making to Mr B.

Ms A strongly disputes that a hysterectomy was discussed as part of the treatment plan in the event of endometriosis, and that she gave permission for her husband to act on her behalf. Ms A advised that it was clear to her that a hysterectomy was to be performed only in the event of cancer. Mr B stated that at no stage prior to the operation could he recall Ms A giving either verbal or written consent to a hysterectomy in the absence of cancer.

The operation
The operation took place on 7 May 1999 at a private hospital. Dr D made a sub-umbilical mid-line incision in Ms A's abdomen. Upon opening the abdominal cavity, a large amount of retrograde bleeding was noted, as Ms A had started bleeding on the day of the surgery. Dr D noted that an enlarged fibroid uterus and bilateral ovarian endometriomas were firmly stuck to the pelvic side wall. In addition, there were other adhesions in the pelvis and areas of endometriosis. No cancer was identified.

Phone call
At this point in the operation Dr D telephoned Mr B from the operating theatre.

Dr D informed Mr B that there was no sign of cancer. Mr B advised that Dr D stated that she would still need to do a hysterectomy, since Ms A's womb was not in a good condition, and would continue to deteriorate. Mr B asked for Dr D's medical opinion as to whether Ms A had any future risks of forming endometriomas. Dr D advised Mr B that there was a "20-40% chance that Ms A could form future endometriomas", that she "could stitch [Ms A] up and reassess her at a later time, or else the alternative was to do the hysterectomy there and then". However, "in her experience it was more than likely, and a normal trend, for [Ms A] to need to have a hysterectomy in two years' time", and that

"doing the hysterectomy [at that stage] would save a double trauma later on". Mr B advised me that it was clear to him that Dr D was asking him what action she should take given the unexpected outcome. Mr B gave his consent for the operation to go ahead, but he advised me that he had no idea what Ms A would have chosen to do in the circumstances.

Mr B advised me that it was not explained to him or Ms A before the surgery that he might have to make such a major decision during the operation. It was therefore a very difficult decision to make. Mr B stated that in the days preceding the operation, he and his wife were given the impression that Ms A's condition was very serious. He advised that his main concern at the time of the operation was the extent of cancer and the degree to which her life was at risk. He stated that it was made clear to them prior to the operation that it was a "life or death" situation. Had this not been the case, he would have requested that Ms A be stitched up again for reassessment, rather than proceed with the hysterectomy. Mr B noted that although he and Ms A had discussed the possibility of having a hysterectomy, they were ever hopeful that they could have a child. They had made no firm decision about having a hysterectomy in the event of endometriosis and not cancer, which had been mentioned only as a possibility.

Dr D disputed that she indicated to either Ms A or her husband that it was a "life or death situation". She stated that she constantly remained positive and often emphasised the positive clinical findings. Dr D advised me:

> "I phoned [Mr B] from the theatre for the following reasons:
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> 1. To inform him there was no cancer.
> 2. To recheck the decision, as I understood it, which had been discussed over a few days. I explained to him the findings in detail. He asked my medical opinion whether [Ms A] had future risks of forming endometriosis and I replied that there was a 20-40% chance that she could form future endometriomas. His reply was that as we had discussed, she would be extremely worried about what the future holds and if there are any future risks of cysts/cancer then, as we had discussed, to proceed with the hysterectomy and removal of both ovaries. Even at that stage I had no question in my mind that this is what [Ms A] would have wanted."

Dr D stated that she did not feel that she had taken consent from Mr B, but rather had rechecked the expectation and her understanding from the various conversations prior to the surgery. Dr D further stated that she did not inform Mr B that Ms A would require a hysterectomy in two years' time, nor that a hysterectomy would save double trauma later on. Dr D stated that a two or three stage operation can be performed, and is performed, for many patients.

Dr D reiterated that the message she got on multiple occasions was that both Ms A and Mr B were extremely worried about future cancer risks, and Ms A's health.

After the operation

Ms A was shocked when she discovered that Dr D had performed a hysterectomy although no cancer had been identified during the operation. Ms A stated that the first thing she was

told when she awoke from the anaesthetic was that she did not have cancer. She was then told that she had had a hysterectomy, and it just "hit" her. Ms A noted:

> "We had discussed with [Dr D] before the blood tests came back possible options and she indicated that she would never just do a hysterectomy without consulting me and providing counselling prior to that happening. So the initial shock of coming out of the operation with a 10cm cut up the middle of my stomach and finding out she had taken my uterus out, then it dawning on me with disbelief she had taken that step without allowing me as the patient the right to make that decision. She said to me that she wanted me to live with the fact that I never had to make the decision that she made it."

Dr D stated that after the operation:

> "I reassured [Ms A] by making the statement that the pathology and circumstances had made the decision for her i.e. that it was not a normal uterus and ovaries and that [Mr B] and I had had a conversation from theatre regarding the findings."

Dr D advised me that post-operatively she did not have any indication from Ms A that she was not happy with her service. Dr D noted that:

> "She [Ms A] saw the GP a week or two later with some pain which was not related to any complication and even then never mentioned to the GP that she was grieved by anything that I had done on her. She had also seen me twice post-operatively and details of the operation and as to how they were emotionally and physically coping was discussed. At no stage did [Ms A] say that she disagreed with the decision of the hysterectomy and removal of ovaries nor gave me any indication that she was unhappy with me."

Dr D further noted:

> "I also remember asking her whether she needed counselling as both she and her husband had gone through major traumas in the last few years with his cancer, worry of cancer in her and the fast sequence of events leading to surgery. Her also coming to terms with fertility issues etc again was discussed. … [D]espite the fact that I mentioned counselling, she never said to me that she was grieved by me having made the decision for her surgery."

Ms A advised me that she did not confront Dr D with her concerns post-operatively because she was "shocked and traumatised" by the whole event, she was suffering severe physical discomfort in her adjustment to instant menopause, and her own mother was ill. Ms A stated that she no longer trusted Dr D, and she felt that Dr D's actions had disempowered her.

Return of uterus

Ms A was discharged from hospital on 13 May 1999. Ms A's uterus was sent to a medical laboratory for a histology examination. Ms A advised me that her "family ties" on her

mother's side are Maori. At no point was she given the option of having her uterus returned to her after surgery so that she could bring it home to the land. Dr D stated that she did not know that Ms A had Maori blood in her.

A private hospital advised that until this incident it was not its policy to routinely ask patients if they wanted to have their body parts returned. The policy was to rely on patients to advise their wishes. Ms A and her husband did not tell private hospital staff that they wanted body parts removed during her surgery to be returned. Accordingly, Mrs A's uterus was not returned to her.

Independent Advice to Commissioner

The following expert advice was obtained from an independent obstetrician and gynaecologist, Dr Kevin Hill.

> "**1. Was the advice that [Dr D] gave to [Ms A] appropriate in light of the blood test results received?**
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> I note that an ultrasound scan on 6/4/99 showed a uterus containing multiple fibroids, the left ovary was said to be normal but the right ovary was enlarged and contained some low level echoes with a suggestion that this may be due to an endometrioma. [Dr D] correctly requested a CA125 and was perhaps understandably surprised that the result was as high as 317. The upper limit of normal in our laboratory is 65. CA125 levels, which are raised, are suggestive but definitely not diagnostic of ovarian malignancies. It is well known that CA125 levels are also raised in cases of endometriosis and on talking to my gynaecological oncology colleague, [Dr I], he has seen CA125 levels of greater than 1000 in cases of endometriosis, where there is no coexisting malignancy. However, given that the right ovary was not particularly large on ultrasound scan, it is understandable that [Dr D] would not have expected such a high CA125 level if the patient had endometriosis. I note that she went to the trouble of discussing the result with [Dr F] and [Dr G], a gynaecological oncologist who is quoted as saying he had not seen such a raised level of CA125 in endometriosis.
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> Ovarian cancer is not common in young women, the ultrasound scan did not show a particularly large right ovary and there was no free fluid. These findings would tend to make ovarian cancer less likely but I have just operated on a woman with large fibroids who has been found to have bilateral ovarian cancers in normal sized ovaries. On balance, whilst endometriosis would have been the most likely diagnosis, it was quite appropriate to consider the diagnosis of ovarian malignancy.

2. Did [Dr D] give [Ms A] appropriate advice after the chest x-ray and CT scans were received?

The chest X-ray was normal, as is usually the case unless one is dealing with advanced malignancy and therefore did not really add to the diagnostic possibilities. However the CT scan showed mixed cystic and solid appearances. This finding does not distinguish between endometriomas and malignancy. In [our area] our patients are referred to [another area] for gynaecological oncology and one of the guidelines for referral is an ovarian cyst, which has mixed cystic and solid appearances in conjunction with a raised CA125. Whilst some patients are subsequently found to have endometriosis and not malignancy, it is still better to take the conservative line and consider that malignancy might be found at operation. Therefore [Dr D] was quite correct to cover all possible options and advise [Ms A] that a hysterectomy and bilateral salpingo-oophorectomy and debulking of tumour would be necessary if malignancy were confirmed. It would seem to me that the ongoing advice about possible chemotherapy and its side effects were given to [Ms A] directly as a result of [Ms A] asking [Dr D] about these possibilities. [Dr D] refutes the claim that she talked about prognosis and I doubt that any reasonable Doctor would make statements about making it to Christmas when malignancy had not even been confirmed. I fully appreciate that [Ms A] is upset about the outcome but I rather suspect her statement is emotive rather than factual.

3. Was [Dr D's] management plan appropriate?

For the reasons mentioned in answer to Question 2, I believe [Dr D] was correct in having a management plan which included possible outcomes for surgery if endometriosis were found and possible outcomes with regard to malignancy. There appears to have been definite consensus that a laparotomy would be the safer approach rather than laparoscopy. There appears to have been a great deal of consultation between [Dr D] and the patient and her husband. [Dr D] seems certain that the couple did not want conservative management and she clearly states in the first paragraph of her letter that the couple had come to terms with their previous fertility issues and I suspect it came as a great surprise to [Dr D] to read [Ms A's] statement that 'even though the chance of conceiving was low there was still a chance'.

4. The consent issues aside should [Dr D] have proceeded with a hysterectomy?

At operation [Dr D] found an enlarged fibroid uterus as well as bilateral ovarian endometriomas which were firmly stuck to the pelvic side wall. There were other adhesions in the pelvis and areas of endometriosis. Whilst there is increasing consensus that asymptomatic fibroids up to 16 week size, can be managed conservatively, it is very relevant in this case that [Ms A] was not asymptomatic. Not only did she complain of heavy periods but she had a significant iron deficiency anaemia with a haemoglobin of 88gm/l. Therefore most gynaecologists

would feel it was entirely appropriate to deal with this problem i.e. fibroids and anaemia by means of hysterectomy and given the clinical findings of significant endometriosis it would make the decision to carry out a hysterectomy even more sensible. Likewise the decision to remove both ovaries would receive a lot of support from many gynaecologists. There is an excellent article in the Australian and New Zealand Journal of Obstetrics and Gynaecology, November 2000, which suggests that of those women retaining a portion of functional ovarian tissue after endometriosis surgery, a relative rate for development of recurrent pain is 6.1 times greater than women who have had their ovaries removed, and that the re-operation rate is 8.1 times greater. The article provides a contrary argument in favour of ovarian conservation, but given the findings at Ms A's operation I believe [Dr D] made the correct clinical decision.

5. If there is insufficient information to form an opinion what further information should be obtained in the course of this investigation?

Although I have read this file carefully, I do not have the legal expertise to comment on the issue of written consent in this case. It would seem that [Dr D] discussed the possibility of hysterectomy on several occasions but it is not clear to me if [Ms A] would have consented to that option irrespective of findings or whether she would have consented only if malignancy were found. Legal arguments aside, I believe that [Dr D] made correct clinical decisions based on the circumstances and findings at the time of operation and although [Ms A] clearly has regrets at the loss of her fertility, I am sure that there is an extremely high chance she would subsequently end up with the same surgical outcome even if [Dr D] had been conservative at the time of this operation.

I note that you have not asked me to comment on the issue of [Ms A] having the option of having her uterus returned to her after surgery. That issue again opens up a huge legal minefield, as it is still not common surgical practice to offer patients their internal organs after surgery. I have had a number of women who have visited the laboratory during their postoperative convalescence to view their uterus but have never had one wishing to take it home. This issue would also pose huge logistic problems for every laboratory i.e. how long would they have to store the organs before the patient decided on whether or not to take it home.

In summary, apart from the lack of a concise consent form, I believe [Dr D] has acted with professional and ethical standards, which would be provided by the majority of her peers."

Response to Provisional Opinion

Dr D

Dr D advised me that she has never been known not to counsel a patient thoroughly. Dr D stated that after the second consultation, all the discussions between herself and Ms A were directed towards the treatment plan if severe endometriosis was diagnosed, and whether she would prefer conservative or radical treatment for endometriosis. Dr D advised that the conversations and consultations she had with both Ms A, and at times Mr B, were multiple and prolonged, and there were times when she was at the hospital until 11 o'clock at night talking to the couple. Dr D reiterated that by the end of her discussions with Ms A her understanding of Ms A's position was that she would have a total hysterectomy and removal of ovaries if cancer was present, and she had also consented to a total hysterectomy and removal of ovaries in the event of severe endometriosis.

Dr D stated:

> "The discussions on [Ms A's] management always included discussions regarding the possibility of severe endometriosis as opposed to cancer, and focussed on both conservative as well as radical management. Both [Ms A], and [Mr B], emphasised that fertility options were no longer an issue. While there was a swaying of the decision initially as to whether conservative or radical treatment with severe endometriosis would be appropriate for [Ms A], on at least three occasions she informed me that if there was severe endometriosis that hysterectomy and removal of ovaries should be performed. This decision was confirmed prior to the surgery and even the night before the surgery. You can see that we had been discussing the risk of her future endometriomas and that the figure of 30-40% has been used right from the first consultation until even the date of surgery. Any masses or subsequent masses in the abdomen which needed further surveillance work was a concern for [Ms A] and that is where the discussions had been focussed.
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> …
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> I had at every stage also mentioned that despite the possibility of ovarian cancer that there were positive features i.e. no free fluids and that the whole case scenario did not add up. This was the reason why I had consulted two colleagues and always emphasised to the patient the possibility of severe endometriosis rather than ovarian cancer. No matter how reassuring I tended to be, they were obviously quite emotionally affected and worried and informed me that they wanted the best done for them so that they would not have any future health or cancer issues. She had mentioned at multiple stages in the meetings that took place in the hospital that if there was severe endometriosis then she wanted everything taken out. She did not want to live in fear or worry of future cysts, raised CA125 and worry about cancers. She was also concerned about the difficulties in monitoring of ovarian masses."

Dr D expressed concern that some of the statements made by her to both Ms A and my office had been misinterpreted. Dr D advised me that when she stated, "Despite the fact that I mentioned counselling, she never said to me that she was grieved by me having made

the decision for her surgery", she was not suggesting that it was her rather than Ms A who made the decision, but rather that Ms A never indicated to her that she believed Dr D had made the decision. Dr D advised me:

> "I would never say to [Ms A] that I had made the decision for her as I understood that I had her full informed consent to the operation that I undertook."

Dr D further noted:

> "Unfortunately, the raised CA125 and repeat test as well as abnormal CT scan changed the clinical scenario in that the possibility of ovarian cancer was also discussed in detail. Discussions and decisions were then directed for both ovarian cancer and management of severe endometriosis. [Ms A] felt strongly that she could not go through emotional turmoil with monitoring and finding a cyst or abnormal tests. In this light I made the statement meaning that if the CA125 and CT scan had not been abnormal then the decision was as of first consultation, i.e. to be conservative and do a laparoscopic surgery. The statement relating to pathology was that one cannot be sure of cancer if some tests indicate that this could be a possibility."

With regards to the phone call to Mr B during the operation, Dr D stated:

> "I had been asked by [Ms A] that at any stage I could take the consent from [Mr B] since they were extremely close after having gone through cancer. I had informed her that at no stage could I take consent from [Mr B] since this was not legal. She however then requested that at every stage I inform [Mr B] of the progress since he was 'not coping well' and needed support. Knowing this information and request from the patient I had phoned [Mr B] to give him the good news. I had their best interest at heart and wanted to make sure that everything they wanted was what I was doing. This case scenario was unusual and there was extreme demand placed in terms of time and emotional energy that was spent with the couple. In my mind I had no question that I was not asking [Mr B's] consent but merely telling him the good news and just the operative findings briefly, however he started asking me a few questions. This is what I meant when I said that I rechecked the decision. I had merely meant to repeat what was [Ms A's] wish to proceed with hysterectomy and removal of both ovaries if the endometriosis was severe (bad endometriosis is what she had said). Even if there was the slightest doubt I would have done conservative surgery which I do all the time on patients who have requested so, irrespective of their age and fertility issues. I had respected that they had made the decision for health reasons and the fear of future cancers which they had suffered once before in their life. I did not say to [Mr B] that I could 'stitch' [Ms A] and reassess her at a later stage, nor did I seek [Mr B's] consent for the hysterectomy to go ahead … There seems to be confusion in talking about stitching up a patient and reassessing at a later stage which was only mentioned at the first consultation in [relation] to when one does not suspect ovarian cancer and is faced with the situation and has not prepared the patient."

Dr D further stated:

> "In summary I would like to say that I genuinely and deeply cared for [Ms A] and had no question in my mind as to what her decision was. I had no intention of doing anything to her that was going to further traumatise their recovery, not only the immediate recovery but also the future. I had taken these matters into strong consideration during consultations as I always do. I am very grieved that I can not provide the hospital records which would be of great assistance to me but am even more perturbed by the unusual circumstances surrounding the retrieval of records from the hospital as well as the disappearance of clinic records."

A Private Hospital
In response to my provisional opinion, A private hospital wished to clarify the hospital's responsibility in relation to the medical notes that are missing from Ms A's clinical record. A private hospital stated:

> "[Dr D] was led to believe by our administrative staff that all her documented records (preoperative and postoperative) were missing from [Ms A's] file. This is not the case. The postoperative records are (and always have been) present. It is [Dr D] preoperative notes which remain absent."

A private hospital apologised for confusion caused by the missing medical notes, and reiterated that the situation is most unusual.

Code of Health and Disability Services Consumer's 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

(1) Every consumer has the right to have services provided with reasonable care and skill.

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.

…

(9) Every consumer has the right to make a decision about the return or disposal of any body parts or bodily substances removed or obtained in the course of a health care procedure.

Opinion: No Breach – Dr D

Right 4(1)

Ms A had the right to have gynaecological services provided by Dr D with reasonable care and skill. Ms A was concerned that Dr D informed her that she had invasive cancer on the basis of her blood test results, although other tests and scans showed nothing unusual. I am guided by the advice of my expert advisor that Dr D treated Ms A appropriately.

Dr D first saw Ms A on 27 April 1999. Dr D conducted a general examination and took a detailed history. Ms A's ultrasound findings were discussed, and a management plan was agreed upon. At this consultation Dr D also requested a blood test to check Ms A's CA125.

My advisor commented that Dr D was correct in requesting a CA125 blood test. As the upper limit of normal for a CA125 is 65, Dr D was "perhaps understandably" surprised that the result was as high as 317. My advisor noted that raised CA125 levels are suggestive, but definitely not diagnostic, of ovarian malignancies. If Ms A had endometriosis, such a high CA125 level would not have been expected given that the right ovary was not particularly large on the ultrasound scan. On the basis of the blood test results Dr D advised Ms A that if ovarian cancer was confirmed, then the recommended treatment plan would be for a laparotomy, total abdominal hysterectomy, bilateral salpingo-oophorectomy, myomectomy, and debulking of the tumour, followed by monthly chemotherapy.

My advisor stated that although ovarian cancer is not common in young women, and the ultrasound scan findings would tend to make ovarian cancer less likely, Dr D was quite right to cover all possible options and consider the diagnosis of ovarian malignancy. As my advisor noted, "it is still better to take the conservative line and consider that malignancy might be found at operation", although on balance endometriosis was the most likely diagnosis. My advisor also noted that it was appropriate for Dr D to advise Ms A that a hysterectomy and bilateral salpingo-oophorectomy and debulking of tumour would be necessary if malignancy was confirmed.

It is also significant that Dr D phoned two of her colleagues to seek a second opinion on Ms A's case. Both Dr F and Dr G advised Dr D that they had not seen a patient displaying such raised CA125 levels with endometriomas, and agreed with Dr D's management plan. Dr D was guided by this advice.

Naturally, Ms A and her family were very concerned about the possibility of ovarian cancer. Subsequent discussion understandably focused on this possible diagnosis. However, I am satisfied that Dr D's ongoing advice regarding the treatment and

management of ovarian cancer was in direct response to Ms A's questions about these possibilities, rather than indicative of a confirmed diagnosis. I am satisfied that at no point did Dr D state that ovarian cancer was anything more than a possibility to be confirmed during surgery. Endometriosis was still considered a possibility and, as stated by my expert advisor, it was appropriate to consider both possibilities.

I am guided by my expert advisor that "[Dr D] made correct clinical decisions based on the circumstances and findings at the time of operation". Accordingly, in my opinion Dr D did not breach Right 4(1) of the Code.

Opinion: Breach – Dr D

Right 7(1)
Under Right 7(1) of the Code, Ms A had the right to have surgery performed on her only if she made an informed choice and gave informed consent.

The key issue in this case is whether Ms A consented to a hysterectomy in the event that endometriosis, and not cancer, was confirmed during her operation. I accept that Dr D went to extensive efforts to consult with Ms A before the operation, in a caring and considerate manner. However, I am not satisfied that Ms A agreed to a hysterectomy in the absence of cancer, for the following reasons.

Preference for conservative treatment
When endometriosis was the working diagnosis (before her blood tests indicated a raised CA125 and consequently the possibility of cancer), Ms A had clearly indicated that she would prefer a conservative approach to her management. Ms A consented to a laparoscopy, excision of endometriosis, an ovarian cystectomy, and a hysteroscopy. Although myomectomy was mentioned, Ms A indicated that at that time laparoscopic surgery would suffice, acknowledging that if her problems continued she might, at a later date, consider more radical surgery. Neither a hysterectomy nor a bilateral salpingo-oophorectomy was considered for treatment of endometriosis.

The question is whether, given later events, Ms A changed her mind and indicated that she would prefer more radical treatment for endometriosis to be performed during the operation on 7 May.

On 3 May Ms A and her father, Mr C, met with Dr D to discuss her blood test result and its implication. Ovarian cancer was discussed in detail. Whilst a more conservative procedure (laparoscopy) was discussed, Ms A agreed to have a laparotomy, total abdominal hysterectomy, bilateral salpingo-oophorectomy, omentectomy, and debulking of the tumour, signing a consent form to that effect. It is clear that Ms A agreed to a hysterectomy in the event of cancer being confirmed. What is in dispute is whether Ms A also subsequently decided to have this treatment in the event of severe endometriosis.

Although Dr D believed that Ms A wished to have a hysterectomy irrespective of ovarian cancer, Ms A is adamant that she never agreed to have a hysterectomy if she did not have

ovarian cancer. Mr B confirmed that although he and Ms A had discussed the possibility of a hysterectomy, no firm decision was made regarding a hysterectomy in the event of endometriosis and not cancer, and that this was mentioned as a possibility only.

Dr D's assertion is that Ms A subsequently changed her mind and indicated a preference for a hysterectomy in the event of severe endometriosis, even in the absence of cancer.

Dr D met with Ms A and her husband several times from the period between 3 May and the surgery on 7 May. Dr D stated:

> "Throughout the discussions it became clear to me that since we had discussed in detail at the first consultation the understanding of endometriosis and in particular because of the reduced immunity and high oestrogen status the association with various cancers i.e. ovarian, breast, uterine, melanoma and non-Hodgkins lymphoma, that [Ms A] was extremely worried that she may have future problems. This whole sequence of events was affecting her badly emotionally, and as they had gone through a previous trauma in their life, she was worried about what the future held for her particularly in terms of future cysts or cancer. She had therefore said at least on two occasions, that if it was bad endometriosis then everything must be removed because she did not want to worry in the future and wanted to get on with her life. She also said many times that she had come to terms with her fertility issues."

Dr D further noted that:

> "On the first consultation conservative surgery was discussed and therefore they understood that I could be very conservative in terms of preserving the uterus and both ovaries. The fear of future malignancies or cysts and future worries was the message I was getting at each consultation. … At no stage did I get any indication that I was supposed to be conservative if there was severe endometriosis and because of the worry of future risks."

This statement is inconsistent with Ms A's preference for conservative treatment for endometriosis at her first consultation with Dr D.

In addition, it appears that Dr D was herself unsure of Ms A's decision regarding a hysterectomy for endometriosis, as is evidenced by her conversation with Mr B during the operation.

It is difficult to reconcile the conflicting accounts of Ms A and Mr B, on the one hand, and Dr D, on the other. Whilst I acknowledge Dr D's considerable effort to ensure Ms A was adequately informed of her treatment options, it is clear, on the information provided to me, that Ms A, Mr B, and Dr D were not fully aware of the treatment plan should endometriosis be found, and not cancer. The confusion surrounding this matter, as evidenced by all the parties, is a strong indicator that no clear understanding had been reached as to the treatment plan for endometriosis. I emphasise the importance of clear and effective communication in the informed consent process, and the apparent lack of clear and effective communication between Dr D and Ms A in this case.

On the information provided to me I am, however, satisfied that although Ms A indicated that if the endometriosis was severe then she would consider radical surgery, she preferred more conservative treatment and did not consent to a hysterectomy and a bilateral salpingo-oophorectomy on the basis of endometriosis alone. The only clear evidence regarding Ms A's wishes for the treatment of endometriosis is what was canvassed, and consented to, prior to receiving the blood test results on 3 May. It is clear that at that time Ms A preferred conservative management. There is no clear evidence that Ms A subsequently changed her mind in this regard.

Questioning options

During the period between 3 May 1999 and 7 May 1999, Dr D had many discussions with Ms A, in which the options for managing her cancer (for example, discussions regarding the pros and cons of diagnostic laparoscopy) were canvassed. Ms A was anxious to explore all the options, and although she went along with the recommended option of a laparotomy, the discussions indicate that she preferred the most conservative approach appropriate to the circumstances.

Phone call

Dr D noted that she "absolutely believed that after having had multiple conversations with the couple and understood everything that they had said and documented it, that there was no question that the hysterectomy and the removal of the ovaries was what was expected of me".

I note that although Dr D has stated that she had no doubt in her mind that the hysterectomy was what was expected of her, she still felt it necessary, when contacting Ms A's husband during the course of the operation, to "recheck" the decision. The need to "recheck" the decision is inconsistent with her firm belief that "this is what Ms A would have wanted". In this respect, Dr D acknowledged that Ms A's wishes in the circumstances that had eventuated were not clear. In addition, after the operation Dr D "reassured" Ms A that the pathology and the circumstances had "made the decision for her". In my opinion, these factors indicate that Dr D was not clear about Ms A's wishes and had not obtained specific consent to a hysterectomy in the event of endometriosis. Dr D should have stitched up Ms A and re-assessed her at a later time, which was a viable option. This would have allowed Ms A to make a more informed decision at a later date, without the stress of a possible cancer diagnosis.

It was inappropriate for Dr D to telephone Mr B during the operation to "recheck" Ms A's decision. Despite Dr D's assurances that she did not contact Mr B for the purpose of seeking his consent to proceed with a hysterectomy, Mr B noted that he felt like he was being asked for consent to proceed. To contact Mr B during the course of the operation in circumstances where he felt he was expected to make a decision that he was not advised in advance that he might have to make, and which he was not legally entitled to make, was totally inappropriate. Mr B was placed in an invidious situation, particularly since he was naturally elated by the critical information that his wife did not have cancer.

Inadequate documentation

The consent form signed by Ms A on 3 May is ambiguous. On the face of the consent form it appears that Ms A did give consent for a total abdominal hysterectomy and bilateral

salpingo-oophorectomy. However, it is not clear whether this consent was conditional on confirmation of ovarian cancer. I note that the consent form was signed on 3 May, during the appointment at which Dr D informed Ms A that she need not make a decision regarding conservative or radical treatment for endometriosis at that time, in the absence of her husband. This indicates that the consent for surgery form was not intended to encompass consent for treatment in the event of severe endometriosis and not cancer.

In any event, a signature on a consent form is not necessarily determinative that a valid and effective consent has been given. In my view it is unlikely that Ms A gave specific consent to the procedure in the absence of confirmed cancer. In a case involving radical surgery affecting a woman's reproductive capacity, any ambiguity as to the scope of the consent should be resolved in favour of the patient.

Dr D admitted that although during the conversations prior to the operation she understood that Ms A wished to have a hysterectomy in the event of endometriosis, she did not include this on the consent form. It would have been reasonable for Dr D to retrieve the consent for surgery form and amend it, or to ask Ms A to sign a new, amended form. Although Dr D mentions documentation of discussions with Ms A and Mr B throughout this period, no such documentation has been provided to me for consideration. I have been informed that these documents are missing from the clinical records.

I note that the consent form signed by Ms A also stated:

> "I [Patient or Guardian] agree that I have received a satisfactory explanation of the intent, risks, and likely outcomes of the above treatment and operation/procedure and of *any related treatment* that becomes *necessary*" [italics added].

However, there is no evidence that the hysterectomy was "necessary" at the time of the laparotomy procedure. Although Dr D denied that she informed Mr B during the phone call that it was possible for her to stitch up Ms A and reassess her at a later time, I note that Dr D stated that a two or three stage operation can be, and often is, performed.

Dr D did not obtain clear, unambiguous informed consent from Ms A to perform a hysterectomy and bilateral salpingo-oophorectomy as treatment for severe endometriosis. Consent, once obtained, needs to be adequately documented. The documentation should reflect what is discussed and agreed upon by patient and doctor, and should be clear and unambiguous. Unfortunately, despite ample opportunity, that did not happen in this case. Dr D could have reasonably anticipated two outcomes at surgery-ovarian cancer, or severe endometriosis. Dr D had ample opportunity to, and should have, clearly discussed and recorded a management plan for both possible outcomes, before the operation.

Conclusion

In my opinion Ms A consented to a hysterectomy and bilateral salpingo-oophorectomy for ovarian cancer. However, I am not satisfied that Ms A made an informed choice to have a hysterectomy and bilateral salpingo-oophorectomy in the event of endometriosis. I acknowledge that Dr D went to extensive efforts to consult with Ms A, her partner, and her father, in a caring and considerate manner, which was appropriate for Ms A's complicated clinical situation. I also acknowledge that in all aspects of her care, Dr D had Ms A's best interests at heart. However, it is clear that as the provisional diagnosis moved from

endometriosis to cancer, the informed consent process was not clearly managed, as elements of confusion were evident on both sides. Whilst the sequence of events mitigates Dr D's failure to clearly obtain informed consent to perform radical surgery to treat endometriosis alone, it does not totally absolve her fault. Accordingly, in these circumstances, Dr D breached Right 7(1) of the Code.

Opinion: Breach – Dr D

Right 7(9)

Under Right 7(9) of the Code, Ms A had the right to make a decision about the return or disposal of any body parts or bodily substances removed or obtained in the course of a health care procedure. This right is enjoyed by all health consumers in New Zealand, irrespective of their ethnic origins.

Dr D noted that she did not know that Ms A was of Maori descent and acknowledged that Ms A was not given the option to have her uterus returned after it was removed. Dr D advised that it was not her routine practice to ask whether patients want their tissues returned after removal.

By failing to allow Ms A to make a decision about the return of her uterus after surgery, Dr D breached Right 7(9) of the Code. Dr D has apologised for this failure, and has informed me that since this complaint she has inserted the option of tissue return into her patient information sheet for all patients.

Opinion: Breach – A Private Hospital

Right 7(9)

A private hospital advised that Ms A and her husband did not tell hospital staff that they wanted her uterus returned. A private hospital accepts that Ms A was not given the option of having her uterus returned after surgery, so that she could take it home to the land. A private hospital advised me that its policy was not to routinely ask patients if they wanted to have their body parts returned; the policy was to rely on patients to advise their wishes.

In my opinion, by failing to allow Ms A to make a decision about the return of her uterus after surgery, a private hospital breached Right 7(9) of the Code. A private hospital has advised me that it has reviewed the pre-assessment patient questionnaire. The questionnaire now includes a section on "The return of body parts", and the new form is currently being trialled. A private hospital apologises to Ms A for not offering her this choice during her admission in May 1999.

Other Comments

Storage of clinical records

A difficult aspect in this case has been the absence of notes from Ms A's clinical record. Dr D advised that her clinic notes regarding Ms A's first consultation, and pre-operative notes, which are normally included in the hospital records, are missing from the clinical record. This is most unfortunate, as these documents would have aided my investigation and assisted to resolve the discrepancy in Dr D's and Ms A's account of events. I note that Rule 5 of the Health Information Privacy Code 1996 requires health agencies to ensure that health information is stored securely.

In response to my provisional opinion, a private hospital advised me that its Medical Records Committee has been given the task of auditing medical record storage at a private hospital. A private hospital advised that if the Committee finds any non-compliance with legislation relating to the storage of medical records, its systems will be corrected.

Actions

I recommend that Dr D

- Apologise in writing to Ms A for her breaches of the Code. This apology is to be sent to the Commissioner and will be forwarded to Ms A.
- Review her practice in light of this report.

Other Actions

- A copy of this opinion will be sent to the Medical Council of New Zealand.
- A copy of this opinion, with details identifying the patient removed, will be sent to the Chair of the New Zealand Committee of the Royal Australasian College of Obstetricians and Gynaecologists.
- A copy of this opinion with identifying features removed will be sent to the Royal Australasian College of Obstetricians and Gynaecologists, the Royal College of Surgeons, and Women's Health Action, for educational purposes.