Gynaecologist, Dr B / Obstetrician and Gynaecologist, Dr C

Hospital and Health Service

A Report by the

Health and Disability Commissioner

(Case 00HDC07607)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Mrs A	Consumer
Dr B	Provider / Gynaecologist
Dr C	Provider / Obstetrician and Gynaecologist
Mr E	Consumer's husband

The Commissioner obtained independent advice from a gynaecologist, Dr David Cook.

Complaint

On 27 July 2000 the Commissioner received a complaint from the consumer, Mrs A, about treatment she received at a public hospital.

- *On 23 December 1999, at the public hospital, Dr B and Dr C removed Mrs A's left ovary without her consent.*

An investigation was commenced on 7 September 2000.

Information reviewed

- Relevant clinical records were obtained and reviewed.

Information gathered during investigation

Background

On 23 December 1999 Mrs A, aged 40 years, presented at the public hospital with acute left iliac fossa pain (left-sided lower abdominal pain). A pregnancy test was negative. An ultrasound scan showed a complex ovarian cyst on her left side with a small amount of free fluid in the pelvis. Mrs A was examined by the duty consultant, Dr D, and the plan was to perform a laparoscopy if her pain had not settled by the next day. Dr D noted that Mrs A was to be given pain relief overnight and be reassessed in the morning.

The next day Dr B was the acting consultant on duty. Dr B reviewed Mrs A and was concerned that the scan appearance could be consistent with a malignancy, which was a "small but definite possibility at the age of 40 years".

Information provided
Dr B advised me as follows:

> "Because of the ongoing nature of the pain, and the ultrasound findings I agreed with [Dr D] that surgery should be done that day. I counselled the patient personally regarding the procedure and risks of laparoscopy and also discussed what should be done if a malignancy seemed likely at laparoscopy. The patient gave permission for oophorectomy [surgical removal of an ovary] or total pelvic clearance to be performed should malignancy be suspected. If not, she requested that her ovary be conserved. I requested technical support from laparoscopic surgeon [Dr C] for this procedure and discussed the management plan with him prior to obtaining consent from the patient."

Dr B advised me that she spoke to Mrs A before the operation about the risk of bleeding and the risk of infection in a procedure of this kind, and explained that these complications can result in serious surgery becoming necessary.

Dr C considered his involvement in the case to have been of a supervisory nature and did not comment on his contact with Mr E and Mrs A prior to the operation.

During a meeting with representatives from the public hospital on 10 May 2000, Mrs A stated that she had signed a consent form for the ovary to be removed only if it was cancerous.

Mrs A advised me that she was not informed about the risks of bleeding during the procedure or that this could lead to the removal of a healthy ovary.

The consent form, signed by Mrs A, states:

> "I, [Mrs A] agree that
> diagnostic laparoscopy
> ? oophorectomy
> ? proceed to laparotomy and pelvic clearance
> be performed on me.
> I have been able to discuss this with [Dr B] …
> She has explained the reasons and expected risks to me of the procedure relating to my clinical history and condition, and I agree to this treatment/procedure. I have had adequate opportunity to ask questions and have received all the information I want. I understand that I am welcome to ask for more information if I wish."

Dr B requested technical support for the operation from laparoscopic surgeon Dr C, and discussed the management plan with him prior to obtaining consent from Mrs A. Dr B performed the procedure with the help of Dr C and obstetric registrar Dr F, and then assisted Dr C to complete the surgery.

The operation
Dr B informed me that the laparoscopic entry was uneventful and revealed a haemorrhagic (bleeding) cyst on the left ovary, which was bleeding through a small rupture of the capsule (outer layer of the ovary). Mrs A's right ovary appeared normal. Dr B inspected the pelvic organs carefully and found no macroscopic evidence of malignancy. Accordingly, both Dr B and Dr C felt confident enough to make an initial decision to conserve the left ovary according to Mrs A's wishes.

After the initial incision through the capsule, however, there was brisk bleeding which appeared to be originating from deep layers. Despite conservative measures with diathermy, this could not be controlled.

Dr B advised me:

> "At this point we discussed what should be done, taking into account the patient's request for conservative management, her age and parity, the scan appearances, the operative findings and the problematic bleeding. We took a decision which we believed was correct and would result in the minimum morbidity for the patient. This was to perform a laparoscopic salpingo-oophorectomy. The advantages of this, in our view, were:
>
> 1. Speed in achieving haemostasis.
>
> 2. Avoidance of the morbidity of laparotomy.
>
> 3. Security of haemostasis for definite exclusion of malignancy.
>
> The procedure was completed successfully and there were no immediate postoperative complications."

Mrs A informed me that her husband was in the waiting room outside the theatre and should have been consulted regarding the removal of her healthy left ovary. Dr B was unaware that Mr E was in the waiting room. Mr E explained to me that he was present with his wife about an hour prior to her surgery and remained in the waiting room close to the operating theatre area for the duration of the operation.

After the operation Dr B and Dr F visited Mr E and Mrs A in the recovery room and explained what had occurred during the operation and the problems encountered. Mrs A was discharged later that day.

Mr E and Mrs A requested an appointment to discuss the operation with Dr B and this took place on 14 March 2000. Dr B explained that the bleeding during the operation was likely to have come from ovarian vessels and that the best way to contain this was to perform an oophorectomy.

In her response to my investigation, Dr B stated:

"Although this would seem a good outcome from a surgical point of view, I would like to convey my sincere regrets for the disappointment this lady feels at losing her ovary. I believe that removal of an ovary is not a decision to be taken lightly and I can assure [Mrs A] that this was a decision well thought through and discussed intra-operatively. I also believe that the preoperative counselling was in sufficient detail to prepare her for the possibility of oophorectomy, even if the indication for this was not what was expected. My usual practice of detailing each step of the operation and possible complications will from now on include further detail on the kinds of difficult intra-operative decision making that can sometimes arise as exemplified in this case."

Complaint
Mrs A believed that she consented only to removal of a malignant ovary and not a healthy ovary, and that some clinical error occurred during the operation, causing the bleeding. Mr E and Mrs A initially complained to the public hospital. A meeting was held at the hospital on 10 May 2000 in an attempt to address their concerns. During this meeting Dr B apologised that she had not given details of the specific complication of bleeding associated with this type of surgery, when she counselled Mrs A pre-operatively. Dr B explained that her top priority was that there might be cancer. The meeting was unsuccessful in achieving resolution and Mr E and Mrs A complained to my Office.

Independent advice to Commissioner

The following expert advice was obtained from an independent gynaecologist, Dr David Cook:

"Background
Aged 40. Two children. Known fibroid uterus. Otherwise well.

23/12/99
Presented to [the public hospital]. Seen by [Dr D].

There was a four-day history of pelvic pain with no specific features. Afebrile. There were no significant clinical signs.

Elected to go home and return the following day for an ultrasound scan.

24/12/99

0850 An ultrasound scan demonstrated a complex left ovarian cyst 4.8 x 4.8 x 4cms with a small amount of free fluid in the pelvis. [Dr B] discussed options for treatment and in view of the pain and the possibility of malignancy, an urgent laparoscopy was arranged. Following discussion with [Dr C], the duty specialist, a diagnostic laparoscopy and possible oophorectomy was proposed. If there was a strong suspicion of malignancy then a laparotomy, total abdominal hysterectomy

and bilateral salpingo-oophorectomy were recommended. The consent form was worded:

'Diagnostic laparoscopy, ?oophorectomy, ?proceed to laparotomy/pelvic clearance.'

Comment

Whilst not specifically stated I assume that at the age of 40, with two children and a multiple fibroid uterus, future fertility was not a major issue for this patient.

A relatively small ovarian cyst was identified which, in some circumstances might be managed conservatively with a follow-up scan. Many functional ovarian cysts (such as corpus luteum cyst) will resolve spontaneously over a few weeks. In this case however, significant pain and the presence of free fluid in the pelvis were enough to justify urgent laparoscopic assessment. Malignancy would be rare at this age but, in view of the complex nature of the cyst, this was considered a remote possibility.

Regardless of the histological diagnosis there is always the possibility of oophorectomy (ovarian removal) in this clinical situation. I believe this was implicit in the wording of the consent form although it may not have been explicit in the preceding discussion with the patient. The possibility of malignancy prompted the consent for pelvic clearance (the minimum treatment for most ovarian malignancies) whilst the consent for oophorectomy was clearly aimed at lesser pathology but where ovarian conservation was not deemed possible or desirable.

The clinical approach and consent details would be regarded as usual practice in this clinical situation. It appears that oophorectomy was discussed pre-operatively as the patient dictated that the ovary should be conserved unless there was evidence of malignancy. Pre-operative counselling would normally encompass the possibility of oophorectomy for a variety of reasons however, not just malignancy. It appears that this information was either not provided or not registered by the patient.

24/12/99 Operation

A Verres laparoscopy and four port technique were employed. A medium-sized, haemorrhagic left ovarian cyst was identified. There had apparently been a spontaneous rupture with some free blood in the pelvis. There was no suspicion of malignancy. The right ovary and tube, abdomen and pelvis appeared normal.

A laparoscopic ovarian cystectomy was attempted but was abandoned due to difficulties with bleeding. The bleeding appeared to originate from deeper layers in the ovary and was not controllable with diathermy. [Dr C], an experienced laparoscopic surgeon was in attendance at this point. In view of the bleeding the patient's age and the normality of the right ovary, a laparoscopic left salpingo-oophorectomy was performed. The procedure was uncomplicated, as was the immediate post-operative recovery.

Histological assessment of the ovary confirmed a corpus luteum.

Comment
Simple ovarian cysts often have a well-defined tissue plane allowing them to be easily dissected and 'shelled-out' of the ovary with minimal blood loss. The more complex the cyst however, the more difficult the dissection becomes. The attempt at ovarian cystectomy was abandoned at an early point in this case due to bleeding from deeper layers and despite attempts to control it with diathermy and the contribution of an experienced laparoscopic surgeon.

Laparoscopic surgery is regarded as safer than open surgery when performed appropriately however small ovarian cysts can often be managed through small, suprapubic laparotomy incisions with minimum morbidity. However this would not preclude the possibility of removing the ovary if the cyst proved impossible to adequately excise or there was uncontrollable bleeding. Most experienced laparoscopic surgeons would consider that laparotomy confers no advantage. If the cyst cannot be excised safely laparoscopically then it cannot be safely excised.

I agree with [Dr B's] points in relation to the decision for oophorectomy at this point:

1. Speed in achieving haemostasis

2. Avoidance of the morbidity of laparotomy

3. Security of haemostasis

4. Definite exclusion of malignancy

I would add to this list:

5. Definitive excision of pathology. This might have been a benign neoplasm of the ovary for which difficult and potentially incomplete excision may have proved unsatisfactory

6. Preservation of the normal right ovary would be considered sufficient for future female hormone production (and fertility, if desired).

The histology report demonstrated a corpus luteum cyst. The corpus luteum is a normal ovarian structure, which can become cystic and cause significant (occasionally life-threatening) intra-abdominal haemorrhage. It is a commonly detected entity, sometimes requiring laparoscopy to differentiate from other types of ovarian cyst. Even at laparoscopy it can be difficult to accurately diagnose (as in this case) so that cystectomy or oophorectomy are required for histological identification.

28/12/99
The patient presented to the [hospital] with vaginal bleeding and some suspected infection at a laparoscopy port site. Examination revealed minimal bleeding only and this was considered to be a withdrawal bleed due to removal of the corpus luteum cyst. The haemoglobin level was measured at 130 g/L and Norethisterone was prescribed to curtail the bleeding. A 'minor' wound infection was noted but no specific management was deemed necessary.

Comment
These would be regarded as common and minor complications following laparoscopy. No specific treatment was indicated, as both would be expected to resolve spontaneously. The haemoglobin was reassuring whilst the Norethisterone treatment was provided presumably to minimise what was a troublesome symptom for the patient.

28/2/00
A routine eight-week, outpatient follow-up revealed no significant problems. The laparoscopy wounds were well healed. The patient reported occasional lower-abdominal discomfort but no specific management was required. She voiced concern about the removal of an apparently normal ovary and requested further consultation with [Dr B], the operating surgeon.

14/3/00
[Dr B] discussed the operative procedure and outcome in detail. The principal concern was why laparotomy had not been performed in an attempt to secure haemostasis and complete the ovarian cystectomy, thus conserving the ovary. Further explanation was provided. Another opportunity for discussion was offered but, despite the evident dissatisfaction of the patient, this was declined.

Comment
There were no significant post-operative complications. The residual discomfort would be regarded as acceptable at this point and no active management was required.

The dissatisfaction of the patient was recognised and well addressed. [Dr B] carefully and openly discussed the details and outcome of the operation with the option for further discussion if desired. An apology for any deficiency in the pre-operative counselling was also proffered with a commitment to ensure that future, similar cases would be counselled in greater depth.

Summary
[Mrs A] was a forty-year-old with two children, uterine fibroids and a moderate sized ovarian cyst. The latter was the presumed cause of her presentation with pelvic pain and laparoscopy to investigate and manage this was indicated because of the pain and the (unlikely) possibility of malignancy.

It would be common practice to undertake laparoscopy initially in such a case and to envisage ovarian cystectomy if there was no suspicion of malignancy. It would

also be common practice to perform oophorectomy if the cyst could not be easily excised from the ovary or there was doubt and the possibility of malignancy. The decision for oophorectomy would be based on the following:

1. An oophorectomy is often much easier and safer than a difficult ovarian cystectomy and ensures that all the cyst tissue has been excised;

2. An oopherectomy can be safely performed laparoscopically and is potentially associated with fewer post-operative complications than a laparotomy. Laparotomy does not guarantee the avoidance of oophorectomy.

3. The conserved, normal ovary will, to a large degree, compensate for the absence of the other ovary in terms of both fertility and hormone production.

The consent form clearly indicates the possibility of oophorectomy. However, it is unclear whether this was proposed in case ovarian cystectomy could not be achieved or as a method of diagnosing malignancy (when a frozen section of the ovary would be performed intra-operatively to determine whether a hysterectomy should be undertaken).

It would be usual practice to explain pre-operatively that an oophorectomy might be required if it proved impossible to excise the ovarian cyst safely. It is unclear whether this advice was not given or simply not appreciated by the patient.

The laparoscopic oophorectomy procedure was uncomplicated and the post-operative sequelae quite minor so that this would be regarded as a low-morbidity outcome, particularly when compared with a laparotomy procedure.

Histologically the ovary demonstrated a corpus luteum, a normal structure. Pre-operatively however, the presentation did warrant investigation and an oophorectomy was indicated by the troublesome bleeding.

Throughout the case there was good liaison between junior and senior medical staff and the involvement of an experienced laparoscopic surgeon when operative complications arose. Acute and planned follow-up was appropriate and strenuous efforts were made to resolve [Mrs A's] dissatisfaction post-operatively with frank discussion and an apology.

In my clinical experience [Mrs A's] reaction to the oophorectomy is unusual. Most patients understand the need for removal of an ovary when surgery proves complicated, even though ultimately the ovarian histology proves normal. They understand that important disease often cannot be excluded without histological analysis but are reassured that the remaining ovary will compensate. They will usually appreciate the low morbidity and quick recovery of a laparoscopic procedure compared with open surgery.

In conclusion I would regard this clinical scenario and outcome as quite common and the management in this case as entirely satisfactory. The only omission may

> have been failure to emphasise the possibility of oophorectomy for reasons other than malignancy although the art of pre-operative consent involves a compromise between informing of risk without being unduly alarmist. It is clear from [Dr B's] comments that, in future cases, specific advice about oophorectomy will feature prominently in the pre-operative counselling."

My advisor was subsequently asked to clarify whether it would be reasonable for a surgeon to leave a bleeding cyst in place with the cyst still bleeding. He responded as follows:

> "This is entirely a matter of judgement based principally on the amount of bleeding and the need to conserve the ovary. Small amounts of bleeding or an over-riding need to conserve the ovary (e.g. the other ovary is absent) might prompt a conservative approach, albeit with the risk of future bleeding.
>
> In this case:
>
> 1. The bleeding appeared to be of concern
> 2. The other ovary was entirely normal
> 3. The patient was a forty-year-old with two children
> 4. There were difficulties removing the ovarian cyst.
>
> Removal of the ovary in this instance seemed entirely reasonable."

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 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 ...
(b) An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option ...
2) Before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, needs to make an informed choice or give informed consent.

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.

Clause 3 Provider Compliance

1) A provider is not in breach of this Code if the provider has taken reasonable actions in the circumstances to give effect to the rights, and comply with the duties, in this Code.
2) The onus is on the provider to prove that it took reasonable actions.
3) For the purposes of this clause, "the circumstances" means all the relevant circumstances, including the consumer's clinical circumstances and the provider's resource constraints.

Opinion: Breach – Dr B

Rights 6(1)(b) and 6(2)

Mrs A had the right to the information that a reasonable consumer, in her circumstances, would expect to receive. Before making a choice or giving consent, Mrs A had the right to the information that a reasonable consumer, in those circumstances, would need to make an informed choice or give informed consent. The circumstances included Mrs A's express concern that her ovary be conserved unless malignancy were found.

The question is whether Mrs A was given all the information she could reasonably expect to receive in her circumstances. As confirmed by Dr B in her response to my investigation, Mrs A expressed specific concern about losing her ovary. The information given should have included specific advice about the other circumstances in which it might become necessary to remove the ovary. My expert advised that pre-operative counselling would normally encompass the possibility of oophorectomy for a variety of reasons. It would be usual practice to explain pre-operatively that an oophorectomy might be required if it proved impossible to excise an ovarian cyst safely. My expert noted that Mrs A either was not given the information, or that she did not register it.

Dr B stated that usual consent procedures were followed. She talked about risk of infection and risk of bleeding and explained that these complications can result in serious surgery becoming necessary. Dr B was not certain that she specifically told Mrs A that if the ovary started bleeding, it might have to be removed. At the meeting on 10 May 2000, Dr B apologised that she had not given details of the specific complication of bleeding, associated with this type of surgery. However, Dr B stated that she believed the pre-operative counselling was in sufficient detail to prepare Mrs A for the possibility of oophorectomy, even if the indication for this was not what was expected.

In my opinion, Dr B should have specifically discussed the risk of oophorectomy for reasons other than malignancy, as Mrs A had expressed particular concern about losing her

ovary. I do not consider that this was a significant departure from an adequate information disclosure, but I do consider that Dr B failed to give Mrs A all the information that she could reasonably have expected to receive in her circumstances. Although Dr B provided a general explanation of the risks involved in the operation, she did not specifically advise Mrs A of the circumstances in which an oophorectomy might become necessary even in the absence of malignancy. In light of Mrs A's particular stated desire to conserve her ovary, this level of information should have been disclosed.

Accordingly, in my opinion Dr B breached Rights 6(1)(b) and 6(2) of the Code.

I note that Dr B has undertaken to alter her information disclosure procedures to include more specific information about the types of intra-operative decisions that occasionally need to be made.

Opinion: No Breach – Dr B / Dr C

Right 7(1)

Before giving her consent to the operation, Mrs A was advised of the general risks involved in the operation. She was warned that further surgery might become necessary due to bleeding or other complications. I consider that Mrs A did give her consent to the further surgery to remove her left ovary, which became necessary because of unforeseen bleeding during the operation. Accordingly, Drs B and C did not breach Right 7(1) of the Code.

Even if, contrary to my finding above, Mrs A's consent to further surgery did not extend to removal of a healthy ovary, providers are not in breach of the Code if they prove that they took reasonable steps in the circumstances to give effect to a patient's rights (Clause 3 of the Code). As they were aware of Mrs A's wish to conserve her ovary, Dr B and Dr C attempted to stop the bleeding through diathermy. This did not prove effective and the ovary was removed. My gynaecology advisor noted that "removal of the ovary in this instance seemed entirely reasonable".

In these circumstances, I am satisfied that Dr B and Dr C have demonstrated that their actions were reasonable in the face of Mrs A's clinical circumstances.

Opinion: No Breach – Hospital and Health Service

Employers are vicariously liable under Section 72(2) of the Health and Disability Commissioner Act 1994 for ensuring that employees comply with the Code of Health and Disability Services Consumers' Rights. Under Section 72(5) it is a defence for a provider

to prove it took such steps as were reasonably practicable to prevent the employee from taking, or omitting to take, the action that breached the Code.

I am satisfied that the Hospital and Health Service, the legal entity responsible for the public hospital, had taken such steps as were reasonably practicable to ensure that medical staff, including Dr B, were aware of their obligations to provide sufficient information to prospective surgical patients. Accordingly, the Hospital and Health Service (now a District Health Board) is not vicariously liable for Dr B's breaches of the Code.

Actions

- I note that Dr B has apologised to Mr E and Mrs A. Mr E and Mrs A have had the opportunity to meet with Dr B and Dr C to discuss their concerns.
- I also note that Dr B has undertaken to alter her informed consent procedures to include more specific information about the types of intra-operative decisions that occasionally need to be made.

Further actions

- A copy of this opinion will be sent to the Medical Council of New Zealand. A copy of this opinion, with identifying details removed, will be sent to the Royal Australasian College of Obstetricians and Gynaecologists.