General Surgeon, Dr B

A District Health Board

A Report by the

Health and Disability Commissioner

(Case 03HDC05563)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Ms A	Consumer
Mrs A	Complainant, Consumer's mother
Mr A	Complainant, Consumer's father
Dr B	Provider, General Surgeon, the public hospital
Ms C	Registered Nurse, the public hospital
Ms D	Registered Nurse, the public hospital
Ms E	Registered Nurse, the public hospital
Ms F	Registered Nurse, the public hospital
Dr G	House Surgeon, the public hospital
Dr H	Anaesthetist, the public hospital
Dr I	General and Vascular Surgeon, the public hospital

Complaint

On 22 April 2003 the Commissioner received a complaint from Mr and Mrs A about Dr B. The complaint was summarised as follows:

- *Dr B did not provide services to Ms A with reasonable care and skill during a laparoscopic appendicectomy operation on 4 March 2003, during which he cut the inferior vena cava, the psoas muscle and the lumbar artery.*

- *Dr B did not fully inform Ms A of the outcome of her operation on 4 March 2003, in that he did not advise her that he had cut the inferior vena cava, the lumbar artery and the psoas muscle.*

An investigation was commenced on 9 May 2003.

Information reviewed

- Letter of complaint and accompanying documentation from Mr and Mrs A, dated 17 April 2003
- Action notes of conversations between the investigation officer and Mr and Mrs A and Ms A, dated 8 May and 9 May 2003 respectively
- Further information received from Mr and Mrs A, dated 13 May 2003
- Further information received from Mr and Mrs A, dated 6 June 2003
- Incident report forwarded by the public hospital, dated 26 May 2003
- Ms A's public hospital records, forwarded by the public hospital
- Letter of response from Dr B and accompanying documentation, dated 6 June 2003

Names have been removed to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

- Supporting information from Dr I, dated 6 June 2003
- Supporting information from Dr G, dated 25 September 2003
- Letter of response to provisional opinion from the public hospital, dated 16 January 2004
- Letters of response to provisional opinion from Dr B's lawyer, dated 12 March 2004

Information gathered during investigation

Emergency admission
During the morning of 3 March 2003 Ms A, aged 17 years, experienced stomach pain and vomiting. She attended her usual general practitioner at a medical centre and was referred to the public hospital Emergency Department for review. The referral noted "??appendix".

At 1.15pm Ms A was triaged and at 1.30pm she was seen by a casualty officer, and admitted for observation under Dr B's surgical team. The house surgeon on call that night rang Dr B. Dr B diagnosed a mild attack of acute appendicitis from Ms A's clinical presentation, and suggested commencing intravenous antibiotics, Rocephin 1mg daily and metronidazole 500mg eight-hourly. Dr B's management plan for Ms A also included no oral intake, adequate analgesia and anti-emetics. He told the house surgeon to contact him if Ms A deteriorated overnight.

Dr B reviewed Ms A during his ward round at 8.50am on 4 March 2003 and considered that "she was not toxic but had features of right iliac fossa pain, nausea, vomiting, tenderness with mild peritonism at the right iliac fossa and mild elevation of her white cell count".

Surgery
Dr B discussed treatment options with Ms A and informed her that there was "a 50/50 chance her appendicitis would resolve without any treatment, but there [was] an almost 100% certainty she would have further attacks". Following a discussion of the surgical options, Ms A agreed to a laparoscopic appendicectomy and signed a consent form for surgery.

At 1.15pm Ms A was transferred to the operating theatre. The surgical team consisted of:

- Ms E, Nurse Co-ordinator
- Ms D , Circulating Nurse
- A Scrub Nurse
- Dr G, House Surgeon
- Dr H, Anaesthetist
- Ms F, Registered Nurse
- Dr B, Surgeon

Dr H conducted a physical examination and obtained Ms A's medical history in preparation for anaesthesia. Dr H discussed the options of anaesthesia and pain relief, side effects and possible complications from anaesthesia and obtained consent for a general anaesthetic.

Anaesthesia commenced at 1.40pm and surgery commenced at 1.50pm. Dr B placed the camera port via a sub-umbilical longitudinal incision using the Hassan open technique. The camera was introduced and CO_2 insufflation commenced.

Dr B said that the CO_2 gas bottle ran out of gas shortly after insufflation (inflation) commenced and the bottle was replaced. When insufflation recommenced there was a very slow rise in intra-abdominal pressure and consequent slow distension of the abdomen. Dr B said that he checked the flow rate monitor and new cylinder and found no problem with either, and no evidence of port site leakage.

Dr G, the house surgeon who was assisting Dr B, said that following the insertion of the laparoscope another small incision was made in the region of the left iliac fossa and a trocar inserted. Dr B then informed the nursing staff that there was no gas flow. Dr G's account of the timing of Dr B's notification of no gas flow to the nursing staff is confirmed in a written statement prepared by Ms E, Ms D and Ms F. According to this statement, following the abdominal incision and insertion of the laparoscope and gas tubing, Dr B "inserted the 5mm non-disposable trocar into the lower abdomen. … [S]oon after [Dr B] verbalised there was no gas". Ms D left the theatre and returned with a replacement cylinder. When attempting to change the cylinder, Ms D realised that the gas had not been turned on. Once she had turned on the gas supply, Ms D advised Dr B that the cylinder was not empty, rather the gas had not been turned on. Dr B complained that there was still no gas flow. Ms E went to the laparoscopic tower and noted that the abdominal pressure was set to 10 and the flow rate was showing 4 point something. Dr B reiterated that there was still no gas flow and asked for the rate to be increased, and this was done. According to the nurses' statements, "seconds later" Dr B informed them that there was adequate gas flow.

In relation to recommencing the operation, Dr B said:

> "At 8mm Hg there was adequate abdominal distension to allow the placement of a 5mm port under direct vision of the left iliac fossa. Because there was again adequate distention of the abdomen, and intra-abdominal pressure was again adequate, a third 12mm port was introduced at the right upper quadrant … The 12mm port is disposable and comes with a trocar that has a retractile sharp metal tip. I placed this port after an initial skin incision that goes down to the subcutaneous tissue plane. As with any port placements I make, this port was also placed under direct vision. This 12mm port was introduced with required force. There was, however, a sudden drop in pressure deflating the abdomen when this trocar entered the peritoneal cavity. This resulted in an uncontrollable penetration of the trocar towards the posterior abdominal wall. An ooze of blood was seen from the posterior abdominal wall."

Ms E informed me that the abdominal pressure on the laparoflator machine (which delivers gas for insufflating the abdomen) was preset at 10mmHg and therefore it was not possible to know when abdominal distention was 8mmHg. Ms E said that she increased the flow rate only (not the abdominal pressure) and not beyond 6.5L/min. Ms E said that the flow rate is measured in litres per minute.

Dr G said that once the gas flow was rectified and gas began to distend the abdomen, Dr B handed him the laparoscope "to hold and to focus at the right hypochondriac region" while he inserted a further trocar "just below the right subcostal region". Following the trocar insertion significant intra-abdominal bleeding was seen on the video screen.

Ms E said that although she was not looking at the video screen and did not see the blood she heard Dr B say "quick we have to open". Ms E said she disconnected the laparoscopic equipment and Ms D left the theatre to collect the "B" instrument tray for the open laparotomy procedure. Ms E said that she was unaware of the extent of the problem and Dr B "did not communicate in his intonation or his voice that it was serious". Dr H said that it was about ten minutes after the commencement of the operation when Dr B said that an urgent laparotomy was required. Ms E said that she heard Dr B say "something mesenteric". Dr G said that Dr B initially thought that the bleeding was coming from a mesenteric vessel. Dr B requested arterial instruments and Ms E left the theatre to set up the arterial tray. While out of theatre she advised the clinical leader of an unexpected complication in theatre one and that she was unsure exactly what had happened.

Dr H said that the time a major bleed was established until the time the laparotomy was performed was "five to ten minutes at most". Dr B converted the initial infra-umbilical incision to a right paramedian laparotomy incision. At 2.15pm Dr B asked for Dr I to be called. At 2.25pm Dr I arrived in theatre.

Dr B recorded in his operation note:

> "The laparoscopic gear removed and the abdomen was opened via a midline incision. A hole in the posterior abdomen peritoneum just medial to the root of the ascending Meso-colon was seen issuing blood. Bleeding was controlled with finger pressure while further dissection progressed. The right colon was then divided and reflected medially allowing inspection of the retro-peritoneum. A 1cm rent was identified in the vena cava above the pelvic rim. Bleeding was again controlled with finger pressure. … Just lateral to the vena cava however, there was also a breach of the anterior surface of the psoas major muscle with arterial bleeding issuing from it. This rent was enlarged allowing arterial blood within [the] substance of the psoas major possibly a lumbar artery to be oversewn with PDC4-0 achieving good control … Routine appendectomy was performed on a slightly inflamed appendix. Approximate blood loss 800ml."

In relation to his attendance at Ms A's operation, Dr I recalled:

> "I was asked to urgently attend in this young lady's operation – a trocar had inadvertently lacerated the IVC and the region of the right psoas causing significant arterial bleeding. [Dr B] had the bleeding controlled with digital pressure and inspection indicated a 1.5cm vertical laceration in the IVC and significant arterial bleeding from lumbar vessels deep within the psoas muscle on the right.
>
> After extending the abdominal incision superiorly and inferiorly, right ureter was identified and a Satinsky clamp placed on the inferior vena cava and the laceration

repaired with Prolene with good immediate control of the bleeding and no constriction of this vessel.

A little more difficulty was experienced in controlling the lumbar which was rather deep within the psoas muscle. After careful digital palpation to avoid adjacent nerves, this vessel was oversewn with PDS. … all bleeding satisfactorily controlled. The operation was completed by [Dr B]."

Disclosure of complications

Ms A's operation finished at 3.30pm and she was transferred to the recovery ward. Dr B told Ms A that there had been a complication – she had been in theatre for a little bit longer than expected, but it was nothing serious or anything to really worry about. Ms A could not remember when she received this information but thought it was quite soon after she came out of theatre, when she was back in the ward and before she saw her parents. Dr B told Ms A that everything was now under control.

Ms A recalled that Dr B told her:

"There had been a slight nick in a minor vessel during the surgery. He said that … he had to go from laparoscopic to open and my scar was a lot bigger than they had expected it would be. He told me he had accidentally slipped and … it was my inferior vena cava and I kind of panicked a bit because I've done 6th form PE and I knew exactly what it was and exactly what it did, so I kind of freaked out a little bit. But he kind of assured me that nothing else was cut and there was no nerve damage."

Ms A said that it was Dr I who told her about the injury to the psoas muscle and the artery within it.

Mr and Mrs A had been told by Dr B that an appendicectomy took only 30 or 40 minutes maximum. However, Ms A arrived back in the ward at 5.15pm, four hours after being transferred to the operating theatre. Mr and Mrs A had remained at the hospital instead of returning home and were concerned about the length of time their daughter was away. Although Dr H had left a message on their home answer machine suggesting that Ms A might require a blood transfusion, they were unaware of the call.

Mrs A said that the nurse spoke to them initially when Ms A returned from theatre:

"So she just sort of pre-warned us of what we would see and that she is hooked up on a morphine pump and that and I thought oh her appendix must have nearly burst or something you know for it to be that serious and then she said that [Dr B] will come and talk to you when he's finished in theatre, so we then presumed that he was doing more operations after [Ms A] so we just waited until he came back and we just sat with [Ms A], and yeah, I can't quite remember the time, I don't think I wrote down the time when he actually came back from theatre."

Mr A said it was not until 7.30pm that they were able to meet with Dr B. Dr B had continued with his operating list and was not available until this time. Mr and Mrs A recalled that Dr B

told them "the incision had to be greater because there was a complication in surgery" and that "the vena cava vessel was nicked in surgery and that there had been a bit of blood loss". They had no idea what the vena cava was. Dr B told them that the cut was about 8 to 10mm. Mrs A asked if there was any other damage such as nerve damage and Dr B said, "No, everything is fine and she'll make a recovery, she's a strong fit girl."

Mrs A recalled:

> "Yeah, we got home and got a book out and looked up what the vena cava vessel was, because I, I said to [Mr B] for a start, what was the name of that vessel and I said it wasn't the vena cava was it because it was the way it was sort of said it was so dismissive and [Mr B] says yeah I think it was and I looked up this book and I, I couldn't believe it was one of the biggest veins and I, we were really shocked, no wonder she had lost a lot of blood …"

Mr and Mrs A were eventually told by Dr I that another vessel had also been cut and that he estimated the injury to be 1–1.5cm.

Surgical equipment review
The clinical leader in the operating theatre organised for the laparoscopic tower to be examined and the DHB maintenance department sent the equipment to another hospital for review. No problem was identified.

Ms E said that the trocar used by Dr B to insert the ports was "a special dilating trocar" in which the blade comes out when it is pressed into the abdominal wall. Once it strikes a negative pressure (from an inflated abdomen) it retracts. This is a safety measure so that the sharp blade does not damage internal structures.

Discharge and recovery
On Sunday 9 March Ms A was given leave to go home for some of the day, but had to return to hospital as she was having trouble walking and it was really hurting her hip. Ms A was discharged on Monday 10 March with outpatient follow-up with Dr I, as Dr B was on leave. According to the discharge summary, Ms A had an appendicectomy with accidental laceration and suture of the inferior vena cava, psoas muscle and lumbar artery. She also had an intra-operative haemorrhage requiring a transfusion of four units of blood. Mrs A spoke to Dr I about her daughter's hip when they saw him at the time of discharge. Mrs A also asked Dr I whether the other vessel that had been damaged had a name. He informed them that it was a lumbar artery, an artery deep within the psoas major muscle, and that there was a considerable bleed in the muscle.

Two weeks later Ms A was still "tripping", as she could not lift her leg properly. When she mentioned this to Dr I he explained that the psoas major muscle was the muscle that lifts the leg.

Subsequent recovery
One month after the operation Ms A still suffered from weakness in the right leg and a tendency to trip when walking. On 9 April 2003 Dr I noted that Ms A was making steady

improvement although she was still clumsy when walking over rough ground. He recorded that Ms A had sensory loss over the distribution of the genito-femoral nerve, which Ms A thought was lessening.

In July 2003 the family informed me that Ms A experienced numbness in her right leg and had trouble walking a kilometre without getting pain in her hip.

The DHB actions
In March 2002 the DHB first documented concerns about Dr B, although anecdotal concerns about Dr B's competence and skill and his behaviour had apparently been expressed for some time.

In 2002 the DHB had a continuing clinical audit system in place. This computerised system required each surgeon to complete an audit sheet for each operation performed. A monthly report was generated and discussed by the surgeons collectively each month. A report, identifying issues, was then sent to the chief medical advisor (a minimum of nine reports were sent per year). The DHB advised that the surgical audit results for Dr B did not support the anecdotal concerns about Dr B's performance, but that the system is reliant on the surgeon's full and open participation. For this reason, an audit of this process is planned for the next internal audit programme.

Although not finalised in 2002, the DHB also had credentialling processes in place for senior medical staff to ensure continuing competence. In March 2002, following concerns about the outcome of a laparoscopic Nissen fundoplication operation, the DHB restricted Dr B's practice so that he could not perform that operation.

Dr B took study leave for continuing medical education purposes, with a view to re-credentialling in relation to laparoscopic Nissen fundoplication. The DHB wrote to Dr B on 13 and 19 March requesting a structured programme and an outline of his study leave format. On 23 April the DHB wrote to Dr B and requested that he meet with the Clinical Director of Surgical Services and the Professional Advisor, to discuss his continuing medical education programme. A meeting occurred on 30 April in which Dr B reported that he had had limited opportunity to obtain sufficient experience with the operation. The professional advisor documented the DHB's requirement that Dr B undergo formal re-credentialling. On 3 and 29 May the DHB again wrote to Dr B requesting a detailed written report of his continuing medical education programme. On 9 July the DHB documented Dr B's breach of contract in failing to comply with its request to forward a study programme or to complete a written report.

On 26 November 2002 the DHB was notified of concerns about Dr B's competence and behaviour in a letter from the Clinical Director Anaesthesia and Critical Care. Concerns included an altercation between Dr B and the anaesthetist during an operation, which resulted in Dr B threatening the anaesthetist with violence. This complaint was supported by written statements from two operating theatre nurses present. At a meeting between the Clinical Director Anaesthesia and Critical Care, the anaesthetist concerned, the Director of Surgical Services and Dr B to discuss this complaint, Dr B walked out complaining that he was not there to be "told off or lectured to". Other concerns expressed by the Clinical Director of

Anaesthesia and Critical Care concerned Dr B's surgical competence in performing bowel surgery and laparoscopic surgery. The Clinical Director Anaesthesia and Critical Care asked that a formal inquiry into Dr B's behaviour and competence be arranged.

On 16 December 2002 the DHB was notified of a complaint received by the Health and Disability Commissioner concerning laparoscopic Nissen fundoplication services provided by Dr B (HDC Case 02/17107, 24 March 2004). On 20 December a further letter of complaint about Dr B was received from operating theatre clinical leaders and theatre staff.

On 20 December the director of clinical services wrote to Dr B with a formal warning and noted that there was no record of such behaviour previously. On 20 December the Clinical Director Surgical Services notified the Professional Advisor of concerns about Dr B, including the number of ACC referrals following surgery, the Clinical Director of Anaesthesia's concerns about his competence (documented), and undocumented concerns from other colleagues. The Director of Clinical Services noted that although most of the practitioners were unwilling to formalise their concerns in writing, in his view a formal external audit of Dr B's procedures was warranted. On 23 December 2002 the Director of Clinical Services requested that the New Zealand Medical Council conduct a review of Dr B's competence.

On 24 January 2003 the DHB was notified of a further complaint received by HDC in relation to surgical services provided by Dr B (HDC Case 02/14836, 24 March 2004).

The DHB stood Dr B down immediately on notification of the complications with Ms A's surgery. On 7 March 2003 Dr B was withdrawn from practice and placed on sick leave. Dr B is no longer working for the District Health Board.

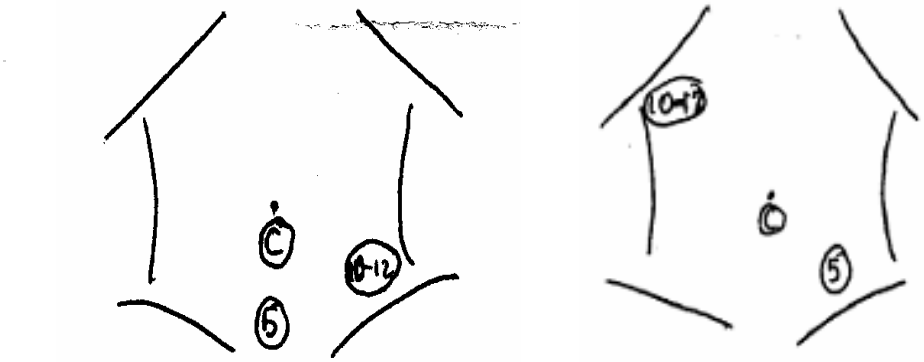
ACC
ACC accepted that Ms A suffered a personal injury as a result of medical mishap owing to the rarity and severity of her injury. Further investigation is in progress on this claim.

Independent advice to Commissioner

The following expert advice was obtained from Dr Ian Stewart, general surgeon:

> "For the purposes of this report I was able to view the complaint letter from [Mr and Mrs A], the nursing report detailing the events in the theatre of [the public hospital] on 04/03/2003, reports and operation notes from both surgeons, [Mr B] and [Mr I]. Also submitted were [the public hospital] notes concerning the admission of [Ms A].
>
> **Expert Advice Required**
>
> **1. How might [Dr B] have accidentally cut the inferior vena cava, the psoas muscle and the lumbar artery during an appendicectomy operation?**

Laparoscopic appendicectomy usually involves the placement of three ports through the abdominal wall (during this report the terms 'ports' and 'trocar' can be used interchangeably). These ports comprised the camera port at or very near the umbilicus and two working ports. The site of placement of these working ports does vary depending on surgeon preference. Probably the most common technique used in laparoscopic appendicectomy is shown in the diagram on the left, what [Dr B] used in this particular case is shown on the right.



(C) refers to camera port
5 refers to size of port in mm
10-12

I have no doubt that during insertion of the right upper quadrant port, the inferior vena cava/lumbar vessel injury occurred. [Dr B] states that he used a trocar with a retractable blade. The mechanism of the ports with retractable blades is such that when they are pushed through the abdominal wall with the pushing pressure on, the blade remains out; the blade will immediately retract when either:-

i) the trocar enters the abdominal cavity; or

ii) pressure is removed from the handle of the instrument.

The likely mechanism of injury is:-

a) either excessive force – pressure on the trocar, such that it entered the abdominal cavity with such speed the blade (although they retract quickly) didn't have time to retract before contact with the IVC (inferior vena cava) and psoas muscle; or

b) [Dr B] applied initial pressure to the trocar and then released this pressure before the instrument had fully traversed the abdominal wall. The blade now would have retracted. [Dr B] would have now found it more difficult to get the trocar through the abdominal wall (because the blade had retracted) and he would have applied greater pressure (and therefore been in less control). With this second pressure the blade probably came out again and then with uncontrollable speed the instrument would have traversed the remaining thickness of the abdominal wall and then with no resistance in

the abdominal cavity, the trocar would have quickly proceeded into whatever was in front of it, in this case the IVC and psoas muscle.

This description (b) may sound complicated but is the most likely mechanism of injury.

With respect to insertion of the ports two other comments should be made:-

i) The positioning of the right upper quadrant port must have been very lateral to have found a path directly to the IVC. This blood vessel is a retroperitoneal structure and with an anterior port (perhaps a more usual site), the ascending colon would 'protect' the IVC. Obviously the right colon was not injured, indicating a very lateral trajectory of the trocar.
ii) In the documents submitted there is a discrepancy in interpretation of events concerning insufflation (this refers to putting CO_2 in the abdominal cavity) and whether or not the CO_2 bottle was empty.

[Dr B] claims the CO_2 bottle was empty and this was the cause of the problems he was having with insufflation. The nursing report however of the events in theatre, claim the reason for the failed insufflation was that the gas supply had **not** been turned on, and in fact the gas bottle was full (at least not empty). They (the nursing staff) **did not** change the bottle, rather just opened the gas supply tap.

[Dr B] uses the confusion over these gas bottles as a possible reason why there was a 'sudden drop in intra-abdominal pressure'. He claims this was the cause of him inserting the trocar without control and too quickly. He offers a somewhat complicated hypothesis to explain how there may have been 'back flow' of CO_2 in the circuit.

As harsh as it sounds, I think this conjecture by [Dr B] is nonsense, even if the bottles were changed. But as is clearly written in the nursing report, the CO_2 bottle was **not** changed; all that was needed was to turn on the inflow tap and this was done.

In summary, all the debate over the insufflation is irrelevant to the injury and should not be used as a mitigating factor.

2. Are such accidents common during an appendicectomy operation?

Such accidents or complications are extremely rare during **any** laparoscopic procedure, let alone a laparoscopic procedure done to remove the appendix.

In trying to gauge the frequency of this complication, any common laparoscopic procedure (appendicectomy, cholecystectomy, antireflux procedure) should be used to compare. The technique of port insertion is the same, irrespective of the operation. Major vascular injury is extremely rare. Reports of cases are anecdotal and usually associated with the Verres needle technique of insufflation. It is now rare to find surgeons using the Verres needle, and the technique described by [Dr B] (Hassan open technique) has gained full acceptance, chiefly to overcome the potential complicating factors associated with the Verres needle.

Inserting ports under direct vision is mandatory and [Dr B] claims he did that. Much more frequent than vascular injuries (but still very rare) are inadvertent perforations of the bowel. This latter injury although still a significant complication, is usually recognised immediately and relatively easily repaired. Because the bowel (small and large bowel) is more superficial and exposed, injuries to the bowel are much easier to explain than injuries to major retroperitoneal blood vessels.

3. [Ms A] suffered an intraoperative haemorrhage. Did [Dr B] detect and deal with this emergency appropriately?

[Dr B] detected the haemorrhage early and made the immediate and appropriate decision to convert the procedure to a laparotomy. He also sent out an immediate call for assistance from [Dr I].

Severe as this complication was, [Dr B] and [Dr I] obviously acted quickly and correctly to save [Ms A's] life. This was a life-threatening complication and required considerable expertise and professionalism to repair the situation. The whole environment would have been very stressful. Once the complication was recognised I believe all concerned (the two surgeons, the anaesthetist and nursing staff) deserve the highest commendation for their actions in the theatre.

The nursing report states [Ms A] went to the recovery ward at 3.40pm on the afternoon of the 04/03/2003. According to a report from [Ms A's] parents, they (the parents) didn't meet with [Dr B] until 5.15pm. [Dr B] apparently cancelled one of his following cases, but proceeded with a further case, a mastectomy. Once [Ms A] arrived in recovery, [Dr B] had an immediate obligation to leave theatre and talk to her parents, rather than wait until he finished another operation. I think it was unwise to continue with the list (his level of stress and anxiety must have been great) and he should have immediately spent time with her parents and explained the situation. That discussion took place after 5.00pm; there was at least an hour, possibly more, when [Ms A's] parents would have clearly known there was a problem and been very upset and agitated. [Mr and Mrs A's] interpretation of that conversation implies that [Dr B] minimised the extent of her injuries. He had an obligation to fully explain:-

(a) what vessel had been injured and particularly the significance of a tear in the IVC (namely, this is a major vessel and a potentially life-threatening situation).

(b) In addition to the IVC injury there was significant bleeding from within psoas muscle, possibly from a lumbar artery.

[Mr and Mrs A] only found out the severity of the injury after getting home and looking up information. It was at that point having finally understood the severity of their daughter's injury that they obviously lost faith in [Dr B].

At that initial meeting [Dr B] had a responsibility, in addition to clearly defining the injury, but also [to] warn [Mr and Mrs A] to the possibility of [Ms A] requiring a blood transfusion.

In Summary

This was a horrific complication with [Ms A's] life threatened, and occurred during a procedure that should have been routine and uncomplicated. Whilst recognising that complications are always a possibility during surgical intervention, the severity of this complication weighed against the relatively minor category of the surgery, in an otherwise uncomplicated patient, means this complication has to be regarded as representing an inferior and inappropriate standard of care. This was a severe departure from a normal standard of care. In the documents as submitted, I found no mitigating factors."

Further expert advice

After consideration of notes of the interviews with the public hospital staff, Ms A, Mr and Mrs A and a statement from Dr G, Dr Ian D Stewart provided the following additional statement, received 4 November 2003:

"My name is Dr Ian David Stewart. I am a general and endoscopic surgeon at North Shore Hospital, Auckland. I have considerable experience in laparoscopic cholecystectomy and appendicectomy and am experienced in port insertion in laparoscopic surgery.

I have considered the additional information supplied concerning the operation of [Ms A] on 4 March 2003 obtained from transcripts of interviews between [Ms A], [Mrs and Mr A], [Dr I], [Dr H], [Ms E], and investigation officers with the Health and Disability Commissioner.

I have also read and reviewed the response from [Dr G].

Anatomy

The distance from where that right upper quadrant port went in through to the retroperitoneal or posterior abdominal wall structures would vary depending on the size of the patient. In a thin person it is probably ten or fifteen centimetres or less. It would not be inconceivable that a long port with the trocar would reach. What is difficult to explain is how that trocar could have got there and avoided other structures on the way. From the information I have read, it possibly didn't avoid nerve tissue. It is difficult to understand how the port or trocar avoided the ascending colon and entered the inferior vena cava. If the trocar came in anteriorly, in front of the ascending colon, then I'm sure there would have been injury either to the colon itself or to the masses of loops of small bowel. Therefore, I think it reasonable to assume the port came in laterally, inferior to the kidney and hit the cava.

Insertion of ports

According to [Dr B], these ports were introduced under vision ie. by watching the screen. Ports are put in by making a small cut to open the skin. The trocar is then inserted into the cut and depending on the type of trocar, either slides in straight away or requires a screwing motion to get it through the abdominal wall. Your hand is outside the patient pushing the trocar in and you are watching that on a screen.

Sometimes, before you actually put the port in, you prod with your finger or the local anaesthetic needle, so you can see where you're going to come out. I believe the trocar had a retractable blade.

The camera port is at the umbilicus and that is inserted under vision. A small cut is made at the umbilicus and the tissues dissected down to the deep layer. This final layer is opened under direct vision, with retractors, so you can prove to yourself that you are in the abdominal cavity. The Hassan port is also inserted under direct vision. This is a larger blunt port, big in order to accept the camera. It is blunt so in the rare situation where there is bowel or some structure very close behind, the amount of damage is vastly minimised. Once the Hassan port is in, the gas source is attached and a pneumoperitoneum developed. While that is occurring the camera can be slid down the port and the whole abdomen visualised. The working ports are only put in once the pneumoperitoneum is established and the whole abdomen visualised. There are one or two situations where ports are put in not directly under vision but that would be very rare. Putting ports in not under vision risks not seeing where that sharp tip is coming through. That applies equally to a retractable or non-retractable trocar. The retractability property of the trocar is a safety mechanism to withdraw the sharp blade once no resistance is met. The trocar can then be taken out and the cannula is left in.

The width of the abdominal wall in a slim person is perhaps only two or three centimetres. Once through the abdominal wall, the distance to where the vena cava is [is] not far. In a slim patient it may be less than 10cm.

Insufflation
Deflation implies that at one stage it was inflated. Once insufflation (inflation) has occurred, the only way gas gets out, is if there is a leak somewhere. Occasionally that happens, particularly around the umbilical port if the hole is a bit big. One of the hassles with any laparoscopic work is getting a leak. A sudden huge leak, where the inflated abdomen suddenly deflates, is very unusual. In fact it only occurs when you've finished and take all the ports out and the whole abdomen deflates.

Insufflation increases the distance between the abdominal wall and the intra-abdominal structures. That is the principle of laparoscopic work; you create a cave to work in. Before when we were talking about the distance from the abdominal wall to the inferior vena cava that was in a no gas (or deflated) situation. With insufflation, as the abdominal wall moves away, these structures get further away.

The assumption is that the trocar went through the abdominal wall above all these structures. I think this trocar must have been inserted laterally because none of the anterior structures were injured.

I think all ports should be put in under vision. As an example when you want a port to come through in a particular place you tap on the outside and can see on the screen where you are tapping. Sometimes what seems the right place on the outside is completely different on the inside. The needle we put the local in with is often a big

help as this can be inserted through the abdominal wall as a guide. The nub of the issue here is that it seems unlikely the trocar that caused the injury was put in under vision.

The rapid desufflation to me implies there must have been gas in there in the first place. There would have been a bit of gas in the system but the taps were turned off. Having the gas tap off is not unusual. If you don't seem to have any insufflation you check with the nursing staff to make sure the gas is flowing. It is not an uncommon scenario. An observation is made that the patient's not filling up with gas, why not? What is difficult to understand is how you can you create a pneumoperitoneum with the gas turned off. The implication is that there was never a pneumoperitoneum developed and the ports were put in without the pneumoperitoneum. In other words they were put in blindly.

Calling for assistance

In this case the operation was started at ten to two. The anaesthetist has told us it was five to ten minutes after the start of the operation when the incident occurred and [Mr I] was requested to attend quarter of an hour later. The relevant timing issue is when he was called. My understanding is that there was a major bleed and [Dr B] decided to proceed to laparotomy so [Mr I] wasn't called until he had opened the patient. I wouldn't be too critical of that in that there are a number of potential bleeding situations much less serious. Unexpected bleeding in laparoscopic surgery is rare but does occur. The first thing we do is if we are not sure if we have control, is to open the patient. [Dr B] would have got a fright to see or to realise suddenly that this was a major retroperitoneal structure, namely the vena cava. As long as at that point he called for assistance I don't think anyone could be too critical. Most surgeons would be able to cope themselves, with the usual sort of bleeding that might go on in this setting.

The decision to proceed with the next case

This was a life threatening situation and I think to be fair to everyone there including [Dr B], he got into a nasty situation but he also got out of it. However, having said that, it is draining emotionally and physically. I think that whatever you're doing you've got to be at your mental and physical best and such a complication as this would weigh heavily on your mind. Clearly things were stable by the time [Ms A] left theatre but the next 24 hours would have been a time of concern for all. I would have difficulty myself getting on and doing some other procedures. To continue, the surgeon is setting himself up if something went wrong in the next case.

Communication

In the list of priorities [Dr B] would have had at that time, trying to give a sensible explanation to all around wouldn't have been easy. The nurses were quite rightly getting very anxious. Such situations get very tense. It is difficult for the surgeon to deal satisfactorily with what's going on at the end of his hands and also deal with other issues.

In [Ms E's] transcript on page 19 she says:

'He never told me what was happening on any level. All I heard him say was something mesenteric to [Dr H] the anaesthetist.'

A mesenteric vessel, one of the vessels that supply the bowel, is perhaps the commonest source of significant blood loss and they can bleed very vigorously. Most surgeons would happily deal with a mesenteric bleed and I doubt he had any notion early on that it was the vena cava.

Information postoperatively
The seriousness of what occurred during the operation was underplayed. I think the fact that [Dr B] kept on with his operating list is another reason why the communication went wrong in this case. After finishing in theatre [Dr B] should have taken [Mr and Mrs A] into a room and spelt it out in words of one syllable, even to the point of getting an anatomy book and saying exactly what happened? That was not done. There were delays and a lot of underplaying the severity. [Ms A] suffered a horrendous complication and the parents were justified for feeling a bit left out of the loop so I can only agree with what they've said. In theory this should have been a very straightforward and uncomplicated procedure. Therefore when it turned out to be a major disaster the parents should not have had to go home and look up medical books. That is an indication that they clearly left the hospital not entirely sure of what went on.

Experience
I do a lot of laparoscopic cholecystectomies. I have done laparoscopic appendicectomies on a number of occasions. The complication in this particular case was the technique of port insertions and the stipulations and guidelines about port insertion are the same whether or not you've taken the appendix out or the gall bladder out. I largely confine my work to laparoscopic cholecystectomy and am experienced in port insertion."

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

1) Every consumer has the right to have services provided with reasonable care and skill.
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
   …
   e) Any other information required by legal, professional, ethical, and other relevant standards, …

Opinion: Breach – Dr B

Surgical misadventure
On 4 March 2003 Dr B commenced a laparoscopic appendicectomy on Ms A, who had presented to hospital the previous day with a history of abdominal pain and vomiting. The procedure required the placement of three ports through the abdominal wall.

Dr B explained that the first port was inserted into a sub-umbilical incision and the camera introduced. According to Dr B, the initial problems with the gas insufflation, necessary for vision in laparoscopic surgery, were resolved. Once adequate abdominal distension was achieved, a second port was inserted under direct vision of the left iliac fossa. Dr B stated that there was again adequate distension of the abdomen and a third port was introduced at the right upper quadrant "under direct vision". According to Dr B, this port was introduced with the required force; however, there was "a sudden drop in pressure deflating the abdomen when this trocar entered into the peritoneal cavity". Dr B said that this resulted in an uncontrollable penetration of the trocar towards the posterior abdominal wall. In his operation note, Dr B recorded that a hole in the posterior abdomen peritoneum was seen issuing blood, a lcm rent was identified in the vena cava above the pelvic rim, there was a breach of the anterior surface of the psoas major muscle with arterial bleeding, and a lumbar artery was possibly oversewn.

The accounts of Dr G and Ms E, Ms D and Ms F in relation to the placement of the three ports differ from Dr B's. Dr G and the three nurses said that the second port (in the left iliac fossa) was introduced following the insertion of the laparoscope and that it was not until after the insertion of the second port that Dr B informed the nursing staff there was no gas flow. Ms D left the operating theatre and returned with a replacement cylinder. When she attempted to change the gas cylinder, she realised that the gas had not been turned on. When she turned on the gas supply, Ms D informed Dr B that the cylinder was not empty, and that the gas had not been turned on. Dr B complained that there was still no gas flow. Ms E said that she increased the flow rate only. Dr G said that once the gas flow was rectified and "gas began to distend the abdomen", Dr B handed him the laparoscope while Dr B inserted the third trocar. Following the insertion, Dr G saw significant bleeding on the video screen.

Mechanism of injury

Ms E explained that the type of trocar Dr B used to insert the ports retracts when it strikes negative pressure such as that achieved by a pneumoperitoneum (gas in the abdominal cavity). My expert advisor, Dr Stewart, commented that the working ports (two and three) should only be put in once the abdomen is fully inflated with gas and the whole abdomen can be visualised. It is "mandatory" to insert ports under direct vision – "all ports should be put in under vision". Insufflation (inflation) by introduction of gas enables safe laparoscopic surgery. Inserting ports without direct vision is a risk as it is not possible to see where the sharp tip of the trocar is. In my expert's opinion, the injury to the inferior vena cava and lumbar vessel occurred during the insertion of the right upper quadrant (third) port. The most likely mechanism of injury was that initial pressure on the trocar was released before the instrument had fully traversed the abdominal wall, requiring Dr B to apply greater pressure and thus reactivating the blade. The blade would then have speedily traversed the remaining thickness of the abdominal wall and met no resistance in the abdominal cavity. In my expert's opinion the third port must have been inserted laterally because none of the anterior structures were injured. The inferior vena cava is a retroperitoneal structure and because the bowel is more superficial and exposed, injuries to the bowel are much easier to explain. I accept my expert advice on this matter.

It is clear from the evidence of the house surgeon and theatre nurses that the second port was not put in under direct vision and was inserted prior to the gas being turned on. Despite Dr B's claim, it seems doubtful that the third port was put in under vision. The evidence strongly suggests that the ports were put in blindly and that no insufflation or pneumoperitoneum occurred. Dr B cited confusion over the gas bottles as a possible reason for a "sudden drop in intra-abdominal pressure" and the cause of his inserting the trocar without control and too quickly. As noted by my expert advisor, this conjecture by Dr B is "nonsense", and irrelevant to the injury Ms A suffered.

Lack of care and skill

I accept my expert advice that the complication experienced by Ms A is extremely rare during any laparoscopic procedure. Although complications may arise during any surgery, the severity of the complication during a procedure that should have been routine and uncomplicated – a minor category of surgery in an otherwise uncomplicated patient – led my expert to conclude that Dr B had exhibited "an inferior and inappropriate standard of care [that] was a severe departure from a normal standard of care". In my opinion, Dr B did not

undertake the appendicectomy operation on Ms A with reasonable care and skill, and breached Right 4(1) of the Code.

Disclosure of complications
Ms A's operation commenced at 1.40pm and finished at 3.39pm on 4 March 2003. She arrived back in the ward at 5.15pm. She said that it "was definitely pretty soon" after she came out of theatre that Dr B told her there had been a complication, a "slight nick in a minor vessel during the surgery" but nothing serious. Dr B told Ms A that the vessel was her inferior vena cava. Ms A knew from her school studies that the inferior vena cava was not a minor vessel and was very concerned.

At 7.30pm Dr B met with Mr and Mrs A and explained that there was a complication in surgery and that "the vena cava vessel was nicked in surgery and that there had been a bit of blood loss". Mrs A asked if there was any other damage such as to the nerve, but Dr B said "no, everything was fine". He did not inform them about the complication to the psoas major muscle or that another vessel had also been cut.

My expert commented that once Ms A arrived in the recovery room, Dr B was obliged to leave theatre and talk to her parents, rather than wait until he finished another operation. Dr B had an obligation to fully explain which vessels had been injured, particularly the significance of a tear in the inferior vena cava, which is a major vessel, that there was significant bleeding from within the psoas muscle, possibly from a lumbar artery, and that it was a potentially life-threatening situation. Mr and Mrs A found out about the severity of the injury only after looking up information at home, which indicates that they left the hospital unsure of what had happened. I agree with my expert that "the seriousness of what occurred during the operation was seriously underplayed". Critical information was not disclosed.

Physicians have a duty of candour and patients have a right to full disclosure when something goes wrong. Open and honest disclosure of surgical complications is consistent with ethical values of honesty and respect for autonomy. Candour promotes trust in the medical profession. Disclosure of adverse events also serves to minimise the potential harm of unknown conditions going untreated. Omission of information or false information about the outcome of an operation calls the doctor's professional conduct into question (see *Skidmore v Dartford and Gravesham NHS Trust* [2003] UKHL 27, House of Lords).

Dr B did not inform Ms A or her parents about the result of the appendicectomy operation, or give an adequate explanation of Ms A's condition. This is information that Ms A would want to know and would expect to receive – and was entitled to under Right 6(1)(a) of the Code. Dr B misled Ms A and her parents about the nature and extent of the complications of the operation. He sought to minimise the seriousness of the injury to the inferior vena cava and omitted to disclose the damage to the lumbar artery and the psoas muscle. Dr B's omission was a serious breach of his professional and ethical duty. In my opinion, in failing to inform Ms A and her parents of the true complications of the surgery, Dr B breached Right 6(1)(a) and (e) of the Code.

Opinion: Vicarious liability – The DHB

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. However, under section 72(5) an employing authority has a defence if it shows that it took such steps as were reasonably practicable to prevent an employee from breaching the Code. Dr B breached Rights 4(1), 6(1)(a) and 6(1)(e) of the Code. In my opinion, the DHB did not take reasonable steps to prevent Dr B from breaching the Code.

This case raises important issues about the obligations of employing DHBs when faced with escalating concerns about an employee's competence and fitness to practise, in particular in relation to the threshold for initiating conditions on practice (restrictions, supervision, or suspension). The DHB has submitted that, at the time, it did not have enough information to place further conditions on Dr B's practice, and that it must consider a range of aspects when making a decision to stand a clinician down. This not only includes competence and fitness to practise, but also industrial and employment issues.

While I acknowledge that DHBs have employment responsibilities to their employees – as a provider of health services – they also have clear legal obligations to their patients. A DHB is subject to the duties specified in the Code of Health and Disability Services Consumers' Rights, whether directly or vicariously as an employer. A DHB is required to take all reasonable steps to ensure that its surgical staff are competent and fit to practise.

Hospitals owe a duty to patients to select, review and monitor staff carefully. A hospital's failure to ensure the competence of its medical and nursing staff through careful credentialling processes creates an unreasonable risk of harm to its patients. The hospital's duty is fulfilled, in part, through periodic review of competence and regular audit. It is also fulfilled by responding appropriately to concerns about a provider's practice. In my view, if a hospital has reasonable grounds for believing that a clinician poses a risk of serious harm to patients' health and safety, it has a duty to immediately place conditions on that person's practice to protect the public. The decision to limit a clinician's practice may be based on a pattern or a single incident of substandard care. It will always be a matter of judgement when that threshold has been reached, and what action is appropriate to protect the health and safety of the public.

In 2002 the DHB had credentialling processes in place for senior medical staff, to ensure ongoing competence. As a result of an adverse outcome of a Nissen fundoplication operation, the DHB restricted Dr B's practice and supported him to re-train in this area of surgery. Dr B did not complete the required continuing medical education. I commend the DHB for restricting Dr B's practice and supporting him to re-train in this area. It is disappointing that Dr B failed to comply with his employer's re-training requirements.

The DHB also had in place a continuous audit system for its surgeons. Each surgeon completed an audit sheet for every operation performed. The audit results of Dr B's practice did not support the concerns raised by staff members. Obviously, the audit provided the DHB with some reassurance about Dr B's practice. However, the DHB noted that an audit depends

on a "clinician's full and open participation". Dr B was reluctant to cooperate with the DHB in his continuing medical education. I am pleased that the DHB is currently undertaking a review of the surgical audit process to ensure that the process is not solely dependent on the cooperation of the doctor under review.

In late 2002 there was an escalation of concerns about Dr B, and the DHB received formal complaints from members of staff. Dr B was involved in an altercation and threatened an anaesthetist with violence. By December 2002, the DHB considered that the level of concern was significant and it initiated an investigation into the concerns raised. The outcome of the investigation was a referral of Dr B to the New Zealand Medical Council for a competence review. At that stage, the DHB did not consider that it had enough information to place further restrictions on Dr B's practice.

The DHB has commented that it relied on the Medical Council's advice on what further action, if any, it should have taken. The DHB was not advised by the Medical Council, at the time it requested, or during the competence review, that further restrictions should be placed on Dr B's practice or that the review process would be lengthy. The Medical Council informed me that while it generally provides advice after a competence review has been completed, in some exceptional circumstances it might provide advice, such as placing restrictions on a doctor's practice, prior to the outcome of the competence review.

It is commendable that the DHB restricted Dr B's practice in early 2002, and referred the concerns about him to the Medical Council for a competence review in late 2002. The DHB stood Dr B down immediately on notification of the complications with Ms A's surgery in March 2003. However, in hindsight, the actions prior to March 2003 were not sufficient to protect the health and safety of Ms A and the public. Competence reviews will usually take months to complete, and hospitals may need to put in place interim protection, such as suspension. Threats of legal action should not dissuade hospitals from acting decisively in the face of serious and broad-ranging concerns about a clinician's practice. The concerns about Dr B had dragged on for many months. In this case, I consider that the DHB should have placed further conditions on Dr B's practice or suspended him altogether pending the outcome of the competence review by the Medical Council.

In forming an opinion on whether the DHB acted reasonably, I appreciate the need to be wary of "hindsight bias". The complications suffered by Ms A, which resulted in Dr B being withdrawn from practice, have not influenced my assessment of whether the steps taken by the DHB were appropriate having regard to all the information available at the time.

On balance, taking into account all the circumstances at the time, I am not satisfied that the DHB took reasonable steps to prevent Dr B from breaching the Code. Accordingly, in my opinion the DHB is vicariously liable for Dr B's breaches of the Code.

Comment

Reporting of competence concerns
It is disappointing to note that while some of Dr B's colleagues had concerns about his competence, only the anaesthetist and the operating theatre nurses were prepared to document their concerns. I draw to the attention of Dr B's colleagues their ethical obligations to formally bring concerns to the notice of the appropriate authority (their employer, in the first instance).

In my view, health professionals have a responsibility to respond to concerns about the competence of a colleague. A fundamental ethical principle of health care – "first, do no harm" – implies that if one is aware that patients may be at risk of harm from the practice of a colleague, one has a duty to act. The New Zealand Medical Association *Code of Ethics* (2002) states that doctors must "take appropriate steps to ensure unsafe … practices on the part of colleagues are curtailed and/or reported to relevant authorities without delay" (para 25). Right 4(2) of the Code requires providers to comply with "ethical and other relevant standards". Thus the ethical responsibility is also a legal obligation.

Competence review
During the course of my investigation I asked the Medical Council of New Zealand about the outcome of Dr B's competence review. The Medical Council requested that I seek the information from Dr B. My request to Dr B (via his legal counsel) for the results of the review was declined. The Medical Council has since advised that there is a condition on Dr B's practice which states that he will undertake his competence programme in a position approved by the Council's Medical Advisor. The District Health Board has informed me that Dr B is no longer working there.

Recent investigations
I note that two recent, contemporaneous investigations of Dr B's surgery in relation to two other patients at the public hospital also resulted in breach findings: HDC Case 02/17107, 24 March 2004 and HDC Case 02/14836, 24 March 2004.

Recommendations

I recommend that the District Health Board apologise to Ms A and her family for its breach of the Code. A written apology is to be sent to the Commissioner and will be forwarded to Ms A.

Follow-up actions

- I have referred this matter to the Director of Proceedings in accordance with section 45(f) of the Health and Disability Commissioner Act 1994 for the purpose of deciding whether any further action should be taken.

- A copy of this report has been sent to the Medical Council of New Zealand, the Royal Australasian College of Surgeons, and the Director-General of Health.

- A copy of this report, with identifying features removed, will be sent to the Chief Medical Advisors of all District Health Boards, the New Zealand Private Hospitals Association and the Royal Australasian College of Surgeons and will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes, upon completion of the Director of Proceedings' processes.

Addendum

At a hearing before the Health Practitioners Disciplinary Tribunal on 19 September 2005, Dr B admitted a charge of professional misconduct, which was upheld by the Tribunal. Dr B was censured and ordered to practise under conditions, that is, that he is supervised for a period for two years from the date of the hearing. A contribution of 25% costs or $20,000 (whichever was the lesser) was also ordered. The Tribunal lifted the interim name suppression order, but Dr B appealed on the question of final name suppression and has been granted further interim name suppression pending the hearing of that appeal.