Urological Surgeon, Dr B

A Private Hospital

Registered Nurse, Ms C

A Report by the

Health and Disability Commissioner

(Case 08HDC20258)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Overview

This report discusses informed consent to robotic-assisted laparoscopic prostatectomy — a relatively new procedure in New Zealand — and the need for the surgeon to disclose to the patient preoperative information about the duration of the procedure and associated risks, as well as information about the surgeon's previous experience of performing the surgery.

In 2007, Mr A, aged 69, developed prostate problems, which initially were successfully treated with doxazosin. In 2008, his PSA levels were rising. He had a biopsy on 12 August 2008 which showed cancer. Dr B communicated the results by telephone to Mr A while he was on holiday overseas and explained the treatment options. Mr A agreed to have robotic surgery and was booked for surgery at a private hospital on 16 October. He arrived back in New Zealand two days before the scheduled surgery. On 15 October he had a consultation with Dr B. Mr A was given information about the procedure and told the operation would take five to six hours. The operation took place at the private hospital on 16 October.

Technical difficulties were encountered and the operation took approximately 11 hours. Mr A was positioned in steep negative Trendelenburg (a head-down tilted position) with his legs raised and supported in stirrups. His legs could not be removed from the stirrups and lowered during the operation because that would require time-consuming repositioning of the robot.

Immediately after the operation, Mr A experienced severe leg pain. On 17 October he had an ultrasound scan that revealed a deep vein thrombosis (DVT). His condition worsened and Dr B suspected he had compartment syndrome in his leg. Mr A was transferred to a public hospital where he underwent ten further operations on his leg and suffered renal failure. He has been left with a significant loss of mobility and ongoing leg pain.

Complaint and investigation

On 9 December 2008 the Health and Disability Commissioner (HDC) received a complaint from Mr A about the services provided by the private hospital, Ms C and Dr B. The following issues were identified for investigation:

- *Whether Dr B provided Mr A with adequate information to make an informed choice about the options available to treat his prostate cancer, including an assessment of the expected risks, side effects and benefits of each option.*

- *Whether Dr B adequately explained to Mr A the innovative nature of the proposed robotic-assisted laparoscopic prostatectomy.*

- *Whether it was appropriate for Dr B to undertake a robotic-assisted laparoscopic prostatectomy on Mr A.*

- *Whether Dr B provided Mr A with surgical services of an appropriate standard on 16 and 17 October 2008.*
- *Whether registered nurse Ms C treated Mr A with respect.*
- *Whether the private hospital provided Mr A with health services of an appropriate standard on 16 and 17 October 2008.*

An investigation was commenced on 31 March 2009.

The parties directly involved in the investigation were:

Mr A	Consumer
Dr B	Urological Surgeon
Ms C	Registered Nurse
A private hospital	Provider
Dr D	Anaesthetist
Dr E	Urologist
Dr F	Orthopaedic Surgeon

Others mentioned in this report:

Ms H	Clinical Charge Nurse
Dr G	Chief Operating Officer

Independent expert advice was obtained from specialist urologist Professor John Nacey (see **Appendix 1**).

Information gathered during investigation

Initial treatment for raised PSA
In 2007, when Mr A was 69 years, his medical practitioner referred him to urological surgeon Dr B for assessment of "bothersome urinary symptoms and a climbing although still normal PSA of 3.9". He saw Dr B on 10 July 2007. Dr B noted that, on examination, Mr A looked well, and that he had a "moderately enlarged clinically benign prostate" and a small 1cm encysted hydrocele on the left cord. Dr B noted in a letter to the medical practitioner:

> "I am not worried regarding his PSA which is quite acceptable considering the size of his prostate and is still within the normal range in any case. His urinary symptoms would justify commencing treatment with an alpha blocker and he is going to build up to the full therapeutic dose of Doxazosin 4mg nocte. I have arranged to review him when he gets back from his [overseas] trip in October with a repeat flow test and questionnaire."

On 16 October 2007, Dr B saw Mr A again and noted that he had had a good response to the doxazosin. Dr B advised him to continue with the Doxazosin but suggested that he needed to "start thinking" about surgery, and explained laser prostatectomy.

Biopsy
On 1 August 2008, the medical practitioner wrote to Dr B to advise that Mr A's PSA was rising. Dr B saw him on 4 August 2008 and talked to him about the advisability of having a biopsy. Dr B explained to Mr A that there was little sense in having the biopsy performed immediately before going overseas, because an adverse diagnosis could spoil the trip and, as the disease was slow moving, there was no immediate necessity to undertake a biopsy. There was also the possibility that Mr A could suffer a biopsy-related complication while overseas. However, a few days later, Mr A contacted Dr B to tell him that after discussion with his wife, he had decided to have the biopsy before going away.

Mr A decided to have the biopsy at that time because he believed it was better to know where he stood rather than leave it. Also, Dr B had told him that he did not like to operate before six weeks post-biopsy to give things time to settle down. Mr A had researched prostate surgery and thought he also had to have an MRI and/or scan before the surgery.

The biopsy was performed on 12 August 2008.

Information about the surgery
In early September Dr B contacted Mr A overseas by telephone to advise him that the biopsy showed cancer. Dr B said that without the aid of anatomical models and diagrams it was difficult to convey the appropriate information. Normally after a positive biopsy he takes an hour with the patient discussing the nature of the condition and the various options for treatment. However, he did have two "reasonably long" conversations with Mr A by telephone. Dr B recalls that Mr A was already aware of robotic surgery from internet research, and he talked to Mr A about this, as well as the potential treatment options, such as external beam radiation or brachytherapy.

Dr B stated that because of Mr A's pre-existing significant urinary difficulty, considerably enlarged prostate and poor flow, he advised him that either form of radiation therapy would be less effective than surgical treatment. The options of standard open surgery and robotic-assisted laparoscopic prostatectomy were discussed. While Mr A was still away he decided to proceed and was booked in for the robotic surgery.

Dr B recalls:

> "[Mr A] indicated an interest in proceeding with robotic surgery and in view of the unusual circumstances I made particular arrangements so that he would have the opportunity to have a long talk to me the day prior to surgery in my office. His appointment was booked in so that he was the last patient of the day and when he attended on the 15th of October we spent more than an hour talking over the diagnosis and discussing surgery in detail.

> Although it was not my standard practice the patient was anxious regarding the possibility of metastatic spread and I arranged staging bone scan and CT scans for his return."

Mr A arrived back in New Zealand two days prior to the surgery and had a scan on the morning of 15 October, before his appointment that afternoon with Dr B. At that consultation Dr B showed Mr A diagrams of the male reproductive organs and explained how the surgery was to be done. Dr B stated that he talked about robotic laparoscopic prostatectomy and told Mr A that it was a relatively new procedure in New Zealand and experience in it was limited. He advised HDC that his patients are given a "well balanced presentation of the relative clinical merits and disadvantages of standard open surgery versus robotic surgery including the differences in cost".

Mr A advised HDC that he was not told that robotic-assisted laparoscopic prostatectomy was a relatively new procedure in New Zealand. He said that if he had been told this it would have caused him to reconsider his options. Mr A said he elected to have the laparoscopic surgery because he had read that it was less invasive and there was better recovery. He thought laparoscopic and robotic surgeries were one and the same and was not aware that there was a difference. He "clearly remembers" being told that robotic surgery would take five to six hours[1] and is adamant that had he been aware that the procedure would take longer, he would have opted for the standard abdominal operation.

Mr A signed the consent for surgery form, for "robotic prostatectomy". The form was countersigned by Dr B. The form indicated that the complications that Dr B had explained were "infection, bleeding, general post op complications, open conversions, incontinence, rectal injury, stricture, erectile dysfunction".

Anaesthetic information

Anaesthetist Dr D advised HDC that Dr B's patients routinely complete a detailed anaesthetic questionnaire, which forms the basis for the discussion that Dr D has with them, either in person or on the telephone. He recalls that, because Mr A had only just returned to New Zealand, he spoke to him on the night before the surgery. He explained the nature of the anaesthetic, the recovery process, pain relief, and how Mr A's return to normal function would be managed. Dr D said that he mentioned the problems associated with positioning for lengthy robotic surgery including nerve injury, pressure sores, deep vein thrombosis and pulmonary embolus, and pain in the shoulders, sacral areas and legs. Also mentioned was the possibility of raised intra-ocular pressure associated with the head-down position used, which can cause blindness.

Dr D stated that he gave Mr A an opportunity to ask questions, but he appeared satisfied with the information provided and asked no further questions.

[1] Mr A was also provided with an information sheet, "Radical Robotic Prostatectomy", that stated, "The surgery takes approximately 5–6 hours and you will spend a further 1 hour–2 hours in the recovery area before returning to your room."

Admission to the private hospital
Mr A was admitted at 6.30am on 16 October. Dr D saw him, the previous discussion was repeated, and Mr A was given a further opportunity to ask questions and discuss any issues of concern. Mr A signed the anaesthetic consent form in Dr D's presence.

Mr A was fitted with TED compression stockings preoperatively.

Surgery
Mr A was checked in to the operating room at 8am on 16 October 2008. The anaesthetic was started at 8.18am and the surgery commenced at 9.10am.

The theatre record, the "Perioperative Nursing Record", noted that the operative procedure was "Robotic assisted radical prostatectomy and aspiration L hydrocele. Repair of inguinal hernia (laparoscopic). Repair of umbilical hernia via cannula port site."

Dr B stated that 45 minutes was taken to repair an inguinal hernia, as Mr A had requested, prior to starting the prostatectomy.[2] The surgery started well, but Dr B stated that the prostatectomy was "more difficult than normal due to a relatively narrow pelvis and also due to a degree of posterior inflammatory reaction which can sometimes occur after biopsy". Dr B stated that as he recognised that this was going to be a difficult case, he asked the opinion of a colleague, urologist Dr E, who attended the surgery. Dr E "gave suggestions which helped me get back on track".

Dr E recalls Dr B asked for his opinion early on the afternoon of the operation. When he arrived in the theatre, Dr B was dissecting through the posterior bladder neck and wanted his opinion whether he was dissecting in the correct plane to gain access to the seminal vesicles[3] and vas deferens.[4] Dr E stated that this aspect of the operation can be challenging, and he has himself had difficulty clearly identifying the plane. He recalls that Dr B continued with the dissection and dissected the seminal vesicles in the correct plane, with no injury to the rectum or adjacent structures. Dr E stated, "At this point it looked like the operation was going well and my further opinion was not required."

The surgery took longer than expected because of the repair of the inguinal hernia and technical difficulties with the surgery. Dr B stated that a "minor buttonhole" resulting from a perforation of the bladder just above the bladder neck required suture closure at the end of the case. This added approximately 30 minutes to the surgery time. Dr B stated:

> "Therefore surgery was very prolonged. However, bleeding was very limited and there was no point during the procedure when conversion to open surgery was deemed necessary due to haemorrhage or failure to progress the dissection. Moreover, there is no generally agreed time limit for this procedure, nor is there any intraoperative way of monitoring leg perfusion which could have led [Dr D] or myself to know that a compartment syndrome

[2] Dr B wrote on 22 October 2008 that the hernia repair took 35 minutes.
[3] Accessory sex glands that open into the vas deferens before it opens into the urethra.
[4] Pair of ducts that conduct spermatozoa from the epididymis to the urethra.

> was likely to develop and thus decided to bail out and convert to open surgery."

Dr D said that the theatre team took great care with Mr A's positioning to minimise the consequences of his being in the Lloyd Davis and Trendelenburg positions[5] for a long time. Dr D advised HDC that Mr A's legs were supported in Yellow Fin stirrups which are designed to hold the feet as a boot would, and so minimise pressure under the popliteal fossa (back of the knee) and to the calf and peroneal nerve areas. The theatre team also took the precaution of inspecting and attempting to relieve Mr A's lower legs at intervals throughout the procedure. Silicon pads were laid over the bean bag to protect pressure areas, his arms were bandaged with orthoband, and his head was supported on a Rik pillow. Dr D stated that all the theatre staff were aware of the risks Mr A was exposed to by the positioning and took a "careful and precautionary approach" to his care. However, Mr A's legs could not be removed from the stirrups and lowered during the operation because that would require the repositioning of the robot, which is time consuming.

The surgery was completed at 8.17pm. The overall duration of the surgery was approximately 11 hours.

Recovery Room
The Recovery Room record notes that Mr A was transferred to Recovery at 8.20pm. The Recovery Room nurse's notes record his time of return to consciousness as 8.40pm, and that he was given analgesia as prescribed for "painful legs". Dr D recorded that he found no abnormality on examining Mr A's legs in Recovery and expected that the pain was caused by muscle cramps, which had been his experience with previous cases. Dr D left Recovery half an hour later, after Mr A had woken. He was satisfied with Mr A's condition at that time.

At 2130 [9.30pm] Dr D was telephoned and informed that Mr A had "severe pain in both legs".

The nurse noted that after Mr A was given intravenous morphine he was able to tolerate a calf massage. His pressure areas were checked and redness was noted on the dorsal aspects of his buttocks and both feet. He was positioned on his right side to relieve the pressure on his buttocks.

Surgical ward
Mr A was transferred to the ward at 10.15pm. The receiving ward nurse noted the pressure areas on his left and right buttocks, left and right upper thighs, right elbow and the metatarsals of both feet. At 10.30pm, he was sleeping.

At midnight, Mr A was given intravenous Panadol 1gm for calf pain and 1mg of intravenous morphine at 12.20am. The nursing record states that Mr A was "very drowsy" and his urinary catheter was draining small amounts of "moderate haematuria[6]".

[5] Special operating table postures for patients undergoing surgery on the pelvis.
[6] Blood in the urine.

The next nursing note was at 4am on 17 October, when he was reported to be more settled after a further dose of intravenous Panadol. Two-hourly pressure area cares were given, and the skin on his buttocks was noted to be "very red".

Mr A believes that, in light of the severity of his pain during the night, the staff should have considered the possibility of complications.

17 October 2008 — RN Ms C
Mr A recalls that when he awoke "first thing" on the morning of 17 October, he immediately reported to Registered Nurse Ms C that he had very severe, "unbearable" lower leg pain. He recalls:

> "There was no mistaking the brusque and callous manner with which she disposed of my severe discomfort. When I called her again some 20 mins later I was made to feel I was just a nuisance, with no substance to the pain I was suffering. She originally said to me she had 8 other patients to attend to. … A scan was only offered after I insisted on it, as no other treatment was offered or provided."

Ms C denies that she spoke in a "brusque" or "callous" manner, which is not in her nature nor part of her practice after more than 40 years' nursing experience. She also provided evidence to HDC that when she started work at 7am on 17 October, her case load that shift was four patients, not eight as Mr A claims. She did a round of her patients, and saw Mr A last because she wanted to "sort out" his leg pain which had been reported at handover. He told her that his left leg was particularly painful and felt that it was because it was pressed hard against the foot of the bed.

Ms C asked for a bed extension. Once it was in place, Mr A told her that it made a difference. Ms C recalls that he rang the nurse call bell about 20 minutes later, at 8am, and told her that his leg pain had returned and was severe. Ms C examined his leg and found it painful to touch and slightly warmer than the right leg. Both legs were a normal colour, but she decided to measure his legs. The left calf was 42cm; the right 39cm. Pedal pulses were present in both legs.

Mr A advised HDC that Ms C was incorrect in stating that both his legs were normal in colour. He stated, "I could see the discolouration through my stockings and was worried a clot had formed. It was only my insistence to check this out with a scan that one was arranged at all."

Ms C reported her findings to the Clinical Charge Nurse, Ms H. Ms H stated that she and Ms C suspected that Mr A had developed a deep vein thrombosis (DVT), and as the doctors had not arrived on the ward at that time, Ms C telephoned Dr B to advise him of the situation.

Ms C advised HDC that she spoke to Dr B and asked him to make the necessary referral to Radiology for an ultrasound for Mr A. Dr B said he would also like Mr A to have blood tests. Ms C completed the laboratory request forms for the blood tests.

At 9am, Ms C telephoned Radiology to ask if the referral for Mr A had been received, because he was becoming increasingly anxious. She understood that Dr B had not made the referral. The clerk took Mr A's details and advised Ms C that there were no appointments available until later that afternoon. Ms C told the clerk that Mr A's situation was urgent and asked her to fit him in at the earliest possible time. Ms C was advised that Radiology could take him at 11.30am.

Dr B advised HDC that when he spoke with Ms C at 9am, he made the decision for Mr A to have a lower leg ultrasound scan. He said that he spoke with the radiographer at Radiology to expedite the scans so that they would be done that morning. Dr B said that Ms C would not have been aware of these "behind the scene phone calls".

After Ms C had spoken to the Radiology clerk, she went to Mr A's room to tell him that he would be having a scan of his left calf at 11.30am. Mr A told her that he wanted his right calf to be scanned too. Ms C told Mr A that she was unable to insist on this, but the technicians would use their discretion and make the decision, and that she would convey his request to them when she accompanied him to Radiology.

Shortly after this, Mr A's son, who was visiting, overheard Ms C talking about Mr A in a critical manner to the receptionist in the public reception area. He admonished Ms C for speaking about his father in such a way.

Ms C recalls that around this time, she spoke to the ward receptionist on an unrelated matter, and said "something along the lines of 'that man [Mr A] is going to drive me insane, he is now wanting both legs to be examined'." A man standing at the reception desk asked her if she was talking about Mr A. Ms C confirmed that she was, and the man, whom she now knows was his son, left and went into Mr A's room.

Ms H recalls speaking to Mr A's son, who had called at the nursing desk and "insisted" that his father's right leg also be scanned to rule out DVT in that leg. Ms H explained to him that the radiologist would assess Mr A and "most likely" do this, but it was the doctor's call.

Ms H said she could see that Mr A's son was concerned and spoke to Ms C. Ms C told her that Mr A appeared to be unhappy about the care he was receiving. Ms H said she would speak to Mr A and his family.

Ms H stated that when she entered the room Mr A appeared to be asleep. She introduced herself as the ward Charge Nurse to Mrs A and two family members. Ms H told the family that she was aware of Mr A's pain levels and the need for an ultrasound, and that Dr B was operating and would arrive to see Mr A as soon as possible. She talked about pain relief options for Mr A and asked him to ring the nurse call-bell if he needed extra pain relief. Mr A told Ms H that Ms C seemed too busy to bring him anything. Ms H explained that Ms C was busy outside his room trying to organise his treatment, but she had provided him with regular pain relief. Mr A's son, who had been speaking on his mobile, addressed Ms H and told her to "sort that nurse out" as he had heard her making judgements about his father. Ms H told Mr A's son that she was unaware of this, and would address the matter with Ms C. Ms H recalls

that Mrs A asked her not to say anything to Ms C as they were more than happy with the care that she had provided thus far.

Ms C said Ms H discussed Mr A's son's complaint with her. She stated that Ms H asked Mr A if he wanted another nurse assigned to him, but he declined.

Mr A denied this: "To say that my family were happy for nurse [Ms C] to continue with my care is unbelievable. We weren't given any alternative. The opposite is closer to the truth."

Ms C said that when she helped Mr A into a chair beside the bed for a wash, he had difficulty standing on his left leg. She transferred him back to bed with assistance from a Health Care Assistant, and gave him two Panadol tablets at 10am and 10mg of short-acting OxyNorm at 11am for his pain. She took Mr A to Radiology at 11.30am for the scan. The radiologist advised Mr A and Ms C that both legs would be scanned, as this is routine practice. The scan revealed that Mr A had a deep vein thrombosis (DVT).

Ms C advised HDC that she thought Mr A was happy with the treatment he was receiving because at the end of her shift he thanked her.

Ms C acknowledges that her comment at the reception area was "an unfortunate lapse of professionalism". Ms C believes that she did everything she could to give Mr A the best treatment, and is "sorry that he underwent all the suffering he did".

Follow-up management
When Mr A returned to the ward, Dr B had arrived and prescribed an anticoagulant, subcutaneous Clexane, which was given at 1.45pm, the blood expander Gelofusion, and Plasmalyte for fluid maintenance. Mr A's compression TED stockings were refitted after Dr B's examination and the ultrasound. His urinary output was measured hourly and a urine specimen sent to the laboratory for testing. Dr B planned to review him again later that day.

Mr A stated that Dr B knew at 1pm that he had a clot in his leg, that it was extremely painful and swollen, and that his urine output was low. He said, "Yet he let me languish in this deteriorating condition for another 7 hours until my life was in danger and surgical intervention became an emergency."

At 2.30pm Ms C recorded that Mr A had been given the Clexane as charted and that he was to have warfarin 10mgs at 6pm as charted. The warfarin was duly given.

At 6pm, it was noted that his urinary output was low, only 15–20mls per hour. Mr A reported that he had increasing tightness in his left calf. He was given a further dose of OxyNorm, and Dr B was notified. Dr B stated that he would be in shortly.

At 6.30pm, Mr A's left calf measured 44cm. Dr D advised HDC that when he saw Mr A at 6.30pm, he found that he had loss of sensation on the dorsum and sole of the foot, was unable to plantar-flex the foot, and had reduced dorsi-flexion of the foot. Mr A reported that his left lower leg felt wooden.

Dr D said that these findings, together with reduced urine output and the presence of myoglobin in Mr A's urine, led him to a presumptive diagnosis of compartment syndrome.[7] Dr D telephoned an orthopaedic colleague for advice on how to expedite referral of Mr A to a public hospital for treatment. Dr B arrived on the ward at 7pm, while Dr D was making this call. Dr D and Dr B discussed the situation and Dr B then telephoned the public hospital orthopaedic, intensive care and renal doctors to expedite treatment, while Dr D arranged transport. Dr D stated that he and Dr B were concerned that there should be no delay at the public hospital in decompressing the muscle compartments in Mr A's leg.

The public hospital orthopaedic surgeon Dr F advised HDC that Dr B told him that he was concerned about his patient at the private hospital, who he thought might have compartment syndrome. Dr B said that a DVT had been found on a scan, and that Mr A had a very painful, tense leg. Dr F recommended that Dr B transfer Mr A to the public hospital without delay. He advised that Mr A should be kept on nil per mouth, so that his compartment pressures could be measured and he could be surgically decompressed if necessary.

Dr B told Dr F that Mr A's renal function was poor, with low renal output and marked myoglobinuria.[8]

The public hospital

Mr A arrived at the public hospital at 8.09pm on 17 October. His compartment pressures were monitored and compartment syndrome was confirmed. Dr F decided to perform an immediate fasciotomy,[9] and Mr A was taken to theatre for this procedure at 10.30pm.

Mr A's renal problems were managed by the renal physicians, and he was transferred to the Intensive Care Unit for immediate ongoing care before transfer to Ward 10, an orthopaedic ward.

Mr A underwent ten further wound washouts and debridements between 19 and 31 October. His renal function gradually improved over the duration of his stay in Ward 10. He was discharged home on 28 November 2008 but his wound still required daily dressings.

Follow-up

Dr B advised HDC that on one of the visits he paid to Mr A at the public hospital, he told him that the private hospital's management had arranged a follow-up meeting. Dr B recalls that Mr A was "a little perplexed as to the point of the meeting". Dr B explained that it would be an opportunity for Mr A and his family to "get some better insight into the pathology of compartment syndrome and to convey our apologies to them and discuss how such events might not occur in the future".

[7] Compartment syndrome is an acute medical problem following injury, surgery or repetitive and extensive muscle use, in which increased pressure (usually caused by inflammation) within a confined space (fascial compartment) in the body impairs blood supply.
[8] A condition that occurs as a result of muscle damage.
[9] Surgical incision of the connective tissues enclosing the muscle groups.

The private hospital initially scheduled a meeting for Mr A and his family for the end of November, but at that time Mr A was still in the public hospital. Dr B asked the private hospital's Chief Operating Officer's PA to defer the meeting for two weeks.

Mr A complained that when the meeting began at 5.30pm on 11 December 2008, Dr B and Dr D were not present. Mr A was upset and angered by their absence. The theatre manager went to request their attendance. Drs B and D arrived at the meeting at 6.20pm.

Dr B stated that he and Dr D were not involved in the scheduling of the meeting. He would not have suggested a late afternoon meeting on a Thursday, because this is their regular operating day, which frequently runs long into the evening.

Dr D advised HDC that the surgery Dr B had scheduled for Thursday 11 December was expected to finish at 4pm, well before the start of the meeting. He said that as he and Dr B had wanted to attend the meeting, they started the surgery early at 7.30am. When it became apparent in the early afternoon (between 1pm and 2pm) that the finish time might be later, Dr D telephoned the PA to warn her that they might be late for the meeting. He said:

> "We were concerned at causing distress and inconvenience to the [family] and others and wondered whether it might be better to postpone the meeting. The message she passed to us from [Dr G] was that this was not advisable. I kept her updated on our progress through the afternoon.
>
> We sincerely apologised to [Mr A] and his family as well as the others present, on arrival at the meeting and hoped that [the family] would understand us not abandoning our patient until safe to do so."

Notes were taken during the meeting. It concluded at 7.10pm with Mr A stating that he was "totally disappointed" with the outcome.

On 17 December, the private hospital's Medical Advisor wrote to Mr A:

> "In attempting to address the significant issues following your major cancer surgery at [the private hospital] may I thank you and your family for coming to the hospital to meet with senior staff, the surgeon and anaesthetist.
>
> The facts raised in discussion by you and your family are accepted as significant and serious. There is an ongoing review of these with the respective medical and nursing staff.
>
> There is to be a detailed review of the complex medical issues relating to such surgery and their potential complications.
>
> Whilst an apology to you and your family may not address the profound distress or personal injury sustained by you following this major surgery, on behalf of [the] Hospital I extend a sincere apology for the events that have occurred."

Dr D stated that, as a result of Mr A's complications, a meeting was held involving the anaesthetic, surgical and nursing colleagues to learn from his case and prevent a similar occurrence in the future. Dr D also gave a presentation on Mr A's case at an anaesthetics and mortality meeting for the same reason.

Dr B wrote to Mr A on 18 December 2008 apologising for the distress he had experienced and stating that steps had been taken to try to minimise the chance of a similar problem in the future.

On 31 December 2008, Mr A was reviewed at the orthopaedic outpatient clinic by an orthopaedic registrar. The orthopaedic registrar explained to him that it was unlikely that he would recover the full sensation on the sole of his left foot, and it was likely that he would have difficulties with walking on uneven ground because of the loss of propulsive power in his left leg, as most of the posterior compartment had been debrided. There was no evidence of DVT and he was told that he needed no further anticoagulant therapy.

Subsequent information

ACC
On 4 December 2008, ACC accepted Mr A's treatment injury claim on the basis that the injury he suffered was not an ordinary consequence or necessary part of treatment.

Dr B's response to incident
Dr B stated that Mr A's return date from holiday left a very narrow window for arranging scans and discussion prior to the surgery. The flight two days prior to surgery may have "set the scene" for the initial calf DVT.

Dr B noted that the complication of "well leg compartment syndrome" occurring in urological surgery is rare and he has never seen it in 15 years of urology practice. There is very limited literature on this specific issue and "with the benefit of hindsight certain measures might be taken to minimise the risk of this occurring again". Dr B advised that the significant factor is the duration of surgery. This was his first year of embarking on such a different approach to radical prostatectomy, and it is "unfortunately quite slow" compared to the standard operation.

Dr B acknowledges that Mr A's surgery was very prolonged, but there was no point during the surgery where he deemed it necessary to convert to open surgery because of haemorrhage or failure to progress the dissection. There is no time limit for the procedure nor were there any steps he could have taken to anticipate the development of compartment syndrome. Dr B advised HDC that major complications can also occur after standard open prostatectomy, but for the most part these complications relate to intraoperative haemorrhage rather than patient positioning. However, there have been cases of patients developing gluteal necrosis after a standard open prostatectomy. Dr B advised:

> "• I have over a decade's experience in performing open radical prostatectomy, an experience of hundreds of cases.

- The robotic procedure was first performed 2001. After several years of exponential uptake, robotic prostatectomy overtook open prostatectomy in the United States in 2007 and now approximately 70% of this form of major cancer surgery is undertaken in this manner in the USA (therefore thousands of cases annually yielding a substantial literature and body of experience accessible to surgeons in other countries). …

- In New Zealand, 3 surgeons performed well over 100 cases within the first year of this technique being introduced locally and already 20% of New Zealand's radical prostatectomies are being performed with the Da Vinci robot. …

Unfortunately, although a minimally invasive approach, the nature of the radical prostatectomy is that it remains a major cancer operation. This is a complex multi-step operation which requires a considerable case load to become proficient that cases are comparable in duration to standard open surgery. Inevitably, sooner or later, despite the generally lower morbidity of this approach, a major complication would occur and the nature of these complications may be somewhat different to the complications which pertain to the standard open surgery. We have taken steps to minimise the risk of this complication. Specifically, we have discontinued the use of TED anti-thrombotic stockings during these cases which may well impair overall leg perfusion and we have altered intraoperative leg positioning to lower the overall perfusion gradient during surgery. I have also visited [an expert colleague in Sydney], and observed several of his cases and sought his advice regarding time saving efficiencies during these surgeries."

Dr B further advised HDC:

"It certainly wasn't our intention to be in any way avoidant as regards the meeting and arriving late certainly was not our intention.

… I accept the Commissioner's findings [of lack of informed consent].

With regard to the proposed recommendations, I have reviewed my informed consent procedures. From now on my informed consent discussions will include specific mention to the patient of whether a procedure is well established or relatively new in urological practice. I will discuss whether I have extensive experience of the procedure or whether in the latter circumstance that my experience is limited and I will quantify that experience. I will endeavour to ensure that patients have sufficient time to reflect on their options before proceeding with surgery."

The private hospital

The Chief Operating Officer, Dr G, provided HDC with information supported by documentation relating to the hospital's usual positioning for laparoscopic prostatectomy and robotically assisted laparoscopic prostatectomy, procedures to prevent calf pressure and DVT, processes for introducing innovative surgical procedures and credentialling processes for surgeons.

Dr G also provided a summary of the actions taken by the hospital to address Mr A's complaint against Dr B and Ms C. Dr G stated:

> "A sentinel event investigation was instigated once the seriousness of [Mr A's] complications were communicated to [the private hospital]. The findings of this investigation however, did not indicate any need to question the care that [Ms C] had delivered."

Impact on Mr A
Mr A has ongoing pain in his back and leg and does not have normal function in his leg. He was previously active and "walked 10kms daily before the op", but has now been told it is improbable that he will ever return to full health.

In October 2009, Mr A described the impact of these events on him:

> "It is nearly a year since I suffered this drastic medical misadventure, (mistake, error, stuff-up, call it what you will!) at the hands of the above who I hasten to blame, but I worry that with the passage of time, the horror of this experience may have waned in the eyes of the authorities. I sincerely hope not, as I continue to bear the consequences of their lack of professional judgement, such as non-stop discomfort/pain in my legs and back, restricted mobility, for every moment of every single day … and additionally I fear for any future patients who face the operation I had, by these very same people."

Relevant Code provisions

The following rights in the Code of Health and Disability Services Consumers' Rights (the Code) 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 —
(a) An explanation of his or her condition; and
(b) An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option;
…

(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.

Opinion: Breach — Dr B

Information about nature of procedure
Before making a choice or giving consent, every patient has the right to the information that a reasonable patient, in that patient's circumstances, needs to make an informed choice or give informed consent.[10] Full information is likely to be needed by a patient being offered a relatively new or innovative procedure. The information given to Mr A prior to the choice of procedure was provided in two "reasonably long" telephone conversations. Dr B also took into account that Mr A had obtained information about surgical options from the internet. Following the telephone conversations, Mr A chose to proceed with robotic-assisted laparoscopic surgery.

Mr A claims that he was unaware that there were three options available to him: standard open surgery, laparoscopic surgery or robotic-assisted laparoscopic surgery. He thought laparoscopic surgery and robotic-assisted laparoscopic surgery were one and the same. He says that he was also not told that robotic-assisted laparoscopic surgery was a relatively new procedure in New Zealand.

After Mr A had made his choice and his surgery had been booked, Dr B had an hour-long consultation with him on the day before the surgery, during which the diagnosis and surgery were discussed. He was shown a PowerPoint presentation which explained the differences between the three options. Following this consultation, Mr A signed the consent form. My expert advisor, Professor Nacey, concluded that "the information Dr B provided to Mr A about the surgical procedure was adequate".

I have some reservations about the information provided to Mr A. It is unwise to assume that a patient has been adequately informed by way of internet research, as the information obtained may be inaccurate or the patient may not have understood it. It is also not good practice to provide information about surgical choices on the evening before the operation, particularly in cases where the procedure is not urgent, as this does not allow adequate time for reflection. Furthermore, if the patient has already chosen a particular procedure, he or she may be less attentive to the information provided. Mr A commented that the consent form was a "form filling exercise" that

[10] Right 6(2) of the Code.

was necessary to obtain the treatment he needed. He said, "I ask you, what choice does a patient have?"

Despite these reservations, I conclude that the general information Dr B provided to Mr A about the nature of the proposed surgical procedure was adequate.

Information about duration of procedure and risks
Factors specific to this surgery increased the risks, including the head-down tilt and positioning of the legs. The critical factor was the length of time the patient was in this position. In light of the increase in risk with an extended operation, it was unwise for Dr B to agree to prolong the operation by also undertaking a hernia repair.

Dr B stated that the hernia repair took 30 to 45 minutes and the repair to the bladder perforation 30 minutes. The overall operation took around 11 hours. His previous experience over ten operations had been a duration of six to nine hours. The information provided to Mr A prior to surgery clearly stated the duration of the operation would be five to six hours. Dr B's PowerPoint presentation stated that robotic-assisted surgery took six hours, whereas non-assisted laparoscopic radical prostatectomy would take around three hours. The information provided to Mr A was inaccurate in light of Dr B's previous history in carrying out this surgery and the additional time necessary for the hernia repair.

Mr A could not effectively assess the risks in order to make an informed choice without accurate information about the time Dr B had previously taken to perform this surgery. My expert advised: "The learning curve of laparoscopic surgery, with or without robotic assistance, means that in most cases the operating time will be longer than that of open surgery until the surgeon has gained the necessary experience to perform the operation in an efficient and timely manner. Most published series report a learning curve of between 20–25 cases."

The consent form Mr A signed on 15 October lists "infection, bleeding, general post op. complications, open conversion, incontinence, rectal injury, stricture and erectile dysfunction" as the risks. The form states the operation length as "300". There is no mention of the particular risks arising from extended periods in a head-down position or the circumstances in which it might be necessary to revert to open surgery, such as the surgery being unusually prolonged. Mr A stated that had he been aware that the procedure would take longer than five to six hours, he would have opted for the standard abdominal operation.

Information about surgeon's experience
Robotic-assisted laparoscopic surgery is a relatively new procedure in New Zealand. At the time he operated on Mr A, Dr B had completed 18 such procedures. Dr B told Mr A that it was a relatively new procedure in New Zealand, that experience thus far was limited, but the clinical outcomes had been very satisfactory. He did not discuss his own lack of experience.

Professor Nacey advised:

> "Of importance for [Dr B] is that he is still on the learning curve for robotic-assisted laparoscopic radical prostatectomy and therefore will not be expected to perform the operation as quickly as a surgeon more experienced with this robotic procedure. This is an accepted part of all surgical experience and is to be expected with the learning involved with new technologies."

My expert stated that Dr B's inexperience "contributed to the unexpected long duration of Mr A's operation, which in turn has been the major factor contributing to the rare and extremely troublesome complication of well-leg compartment syndrome".

I consider that the relative inexperience of the surgeon in the chosen operation technique is a matter that a reasonable patient would want to know before making a choice to proceed.

Conclusions
I conclude that Dr B had a duty to inform Mr A that he had limited experience with robotic-assisted laparoscopic surgery. He also had a duty to inform Mr A of the length of time he had previously taken to carry out robotic-assisted laparoscopic surgery, that the risks of complications increased if time taken for the surgery was prolonged, and what those risks were. By failing to do so, Dr B breached Rights 6(1)(b) and 6(2) of the Code. It follows that Mr A did not give informed consent to the operation and Dr B also breached Right 7(1). Dr B accepts that he breached these provisions of the Code.

Opinion: No breach — the Private Hospital

I accept Professor Nacey's advice that the private hospital took appropriate steps before the introduction of robotic-assisted laparoscopic prostatectomy.

Mr A complained that staff were slow to react to his worsening condition. However, Professor Nacey advised that the private hospital provided appropriate postoperative management to Mr A. I conclude that the private hospital did not breach the Code.

Adverse comment: Nurse Ms C

Ms C's comment about Mr A at the public counter was inappropriate and showed a lack of respect for Mr A and his right to privacy. Ms C acknowledges that her comment was "an unfortunate lapse of professionalism".

Ms C's clinical care was of a good standard. She acted promptly when the pain in Mr A's left leg became severe at 9am, by re-notifying Dr B. She kept clear detailed records of Mr A's condition, and impressed upon Radiology that his ultrasound examination was urgent.

Ms C's lapse on this occasion should not mar her long record of nursing service. However, I remind her of her obligation to treat all patients with dignity and respect at all times.

Follow-up actions

- A copy of this report will be sent to the Medical Council of New Zealand, the Nursing Council of New Zealand, and the Accident Compensation Corporation.
- A copy of this report identifying only Dr B and the expert who advised in this case will be sent to the Royal Australasian College of Surgeons.
- A copy of this report with details identifying the parties removed, except the expert who advised on the case, will be sent to the Urological Society of Australasia and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix 1

Independent advice to Commissioner — Urologist John Nacey

The following expert advice was obtained from Professor John Nacey, specialist urologist and Professor in the Department of Surgery, University of Otago, Wellington.

"I have been asked to provide expert advice to the Health and Disability Commissioner on case 08/20258. I have read and agree to follow the Commissioner's guidelines for independent advisors. I graduated MB ChB from the University of Otago in 1977 and undertook specialist training in Urology being awarded Fellowship of the Royal Australasian College of Surgeons in 1984. 1 subsequently undertook a doctorate by thesis in 1987 (MD, University of Otago, awarded with Distinction). I have practised as a specialist Urologist since 1986 and have maintained an active teaching and research programme for undergraduate and postgraduate students. My specialist research interest is benign and malignant prostate disease and I have published extensively in this field. I am a past examiner in Urology for the Royal Australasian College of Surgeons, and act as a referee for several medical publications and have an editorial role in some of these. In addition to my clinical practice I am Professor in the Department of Surgery, University of Otago, Wellington.

Expert Advice Required

[Here Professor Nacey lists the information provided, and the questions asked of him, which are referred to again in his advice.]

Background

[Dr B] undertook initial assessment of [Mr A] on 10 July 2007. [Mr A] had 'bothersome' lower urinary tract symptoms with examination showing a moderately enlarged and clinically benign prostate. His urinary flow rate was reduced at 11ml/sec and his serum PSA was normal at 3.9ng/ml. On the basis of these findings [Dr B] prescribed Doxazosin in order to improve the urinary symptoms. Follow-up on 16 October 2007 confirmed a good response to the medication. [Mr A] was discharged back to the care of his general practitioner with a request that annual prostate screening be continued.

[Mr A] was referred back to [Dr B] on 1 August 2008 following a further PSA blood test that showed an increase to 6.1ng/ml. Because of the rapid rise in the PSA since the previous measurement [Dr B] proceeded with prostate biopsies in order to determine whether or not the increase was due to underlying prostate cancer. The biopsies were performed on 12 August 2008. Subsequent microscopy confirmed adenocarcinoma of the prostate Gleason score 4+4=8 in a single core from the left lobe of the prostate.

[Mr A] was on an overseas holiday at the time [Dr B] received the biopsy results. [Dr B] telephoned [Mr A] in early September 2008 with the results and discussed

the diagnosis of prostate cancer. This was in addition to previous discussions about treatment options in the event that prostate cancer was confirmed. It was agreed that [Mr A] would undergo robot-assisted laparoscopic prostatectomy.

[Mr A] returned home on 13 October 2008. On 15 October he underwent staging investigations that showed no evidence of local spread of the tumour or metastatic disease. [Mr A] had a further consultation with [Dr B] where the surgery was further discussed. This included a PowerPoint presentation of the procedure.

On 16 October 2008 [Mr A] was admitted for surgery to [the private hospital]. The hospital records indicate anaesthesia commenced at approximately 0800hrs. The patient was positioned for surgery at 0853hrs with pelvic access and insufflation at 0922hrs. The operation finished at approximately 2000hrs, giving a total surgical time of around ten hours. The operation started with laparoscopic repair of a left inguinal hernia. The prostatectomy appears to have been technically difficult. Factors contributing to the technical difficulty were the patient's anatomically narrow pelvis, an awkward dissection plane posterior to the prostate (attributed to inflammation following his prostate biopsies) and an inadvertent perforation of the bladder that required repair. During the procedure [Dr B] sought the advice of his urological colleague, [Dr E].

Following surgery [Mr A] was transferred to the recovery area. He complained of 'sore legs' and was assessed by [Dr D], the anaesthetist for the case. [Dr D] found no abnormality on examining the legs and expected that the pain was caused by muscle cramps, which had been his experience with previous cases. His viewpoint was reinforced by a phone call from the recovery nurse who advised that the pain was improving with morphine and massage of the legs.

The following day at 0800hrs [Dr B] phoned the ward to check [Mr A's] progress. He was advised of [Mr A's] calf discomfort but it was not thought to be severe. At 0900hrs [Dr B] was called back and advised that the left calf pain had become severe and associated with left calf swelling. [Dr B] then arranged for a Doppler Ultrasound scan to check for evidence of deep [vein] thrombosis (DVT). The scan was performed at 1130hrs and the diagnosis of below knee DVT was confirmed.

[Dr B] saw [Mr A] at 1300hrs and commenced anticoagulation. That afternoon [Mr A's] urine output dropped and his serum creatinine increased to 342jimol/L (108tmol/L preoperatively) indicating renal failure. [Mr A] was assessed by [Dr D] who diagnosed well-leg compartment syndrome following discussion with an orthopaedic surgeon. As part of this diagnosis [Mr A] had myoglobinuria secondary to rhabdomyolysis [damage and breakdown] from the compartment syndrome. [Mr A] was transferred to [the public hospital] at 2000hrs and underwent decompressive fasciotomy at 2230hrs [involves incising the tissue or 'compartment' that contains the muscles thereby releasing the pressure and preventing further injury].

[Mr A] spent three days in the intensive care unit and required dialysis from 18 October through 30 October for his renal failure. He was returned to theatre on postoperative days 3, 5, and 7 for debridement [dead tissue from the fasciotomy sites]. Eventually ten orthopaedic procedures including debridement, washout and left calf closure were performed in the month after the initial fasciotomy.

On 20 November [Mr A] was transferred to [the public hospital] AT & R. He was discharged home on 28 November with further care undertaken by the District Nurses.

At assessment in February 2009 [Mr A] was noted to have good urinary flow, some urgency, some positional urinary incontinence and loss of spontaneous erections. He had ongoing calf swelling and his renal function was near normal.

The care provided by [Dr B] to [Mr A]

1. What is the risk of compartment syndrome occurring as a result of laparoscopic prostatectomy?

The lower leg is divided into compartments by a layer of fascia that encloses the muscles. The anterior compartment is at the front between the tibia and fibula. It contains the muscles that pull the foot and toes up towards the knee. The medial compartment is on the inside aspect of the shin. The muscles which bend the toes during pushing off are in this compartment. The posterior compartment is the largest, and contains the calf muscles, which attach to the Achilles tendon and push the ankle downwards during running and jumping. The lateral compartment on the outside of the shin contains the muscles that turn the sole of the foot outward.

Compartment syndrome is well-known and occurs when the volume of the muscles, blood vessels and nerves become too big for the space within the compartment. This leads to an increase in pressure within the compartment and may result in muscle and nerve damage. There are two main categories. Acute compartment syndrome typically occurs subsequent to a traumatic event, most commonly fractures. Symptoms worsen acutely, and irreversible nerve injury and muscle necrosis occur within hours. Chronic compartment syndrome is a recurrent problem that occurs with exercise or work. It is usually seen in competitive athletes. It often occurs bilaterally and may be reproducible at a specific exercise distance or time interval.

An uncommon and less well-known category is the 'well-leg compartment syndrome'. This develops almost exclusively in patients who have been placed in either the lithotomy [on back with knees bent and thighs apart] or Trendelenburg position [on back with the feet higher than the head] during surgery. The most important factor determining the likelihood of this problem is the length of time the patient is maintained in either of these positions. Data from a study at the Mayo Clinic examining limb pressures in different lithotomy positions suggest one in 3500 patients will experience abnormally high limb pressure. However,

actual reported cases are rare with only 16 urological patients described in the world literature to 2004.

The clinical picture of well-leg compartment syndrome is the same as for any limb-compartment syndrome. Because the complication is unexpected and the patient is anaesthetised the diagnosis is frequently delayed, so the residual motor-sensory deficit may be severe, even after fasciotomy.

2. Is the risk any greater if the surgery is robotic-assisted?

Factors associated with an increased risk of well-leg compartment syndrome include the duration of the procedure, limb position, the degree of head-down tilt with ankle height above heart level, body habitus, intermittent pneumatic calf compressors, compressive leg wrappings (TED stockings), peripheral vascular disease and intraoperative hypotension.

Robot-assisted prostatectomy requires a significant degree of head-down tilt. This keeps the abdominal contents towards the head of the patient and out of the operative field, thereby facilitating good surgical exposure. Intermittent pneumatic calf compressors and compressive leg wrappings (TED stockings) are also used as these significantly reduce the incidence of DVT. These factors are common to laparoscopic prostatectomy and robot-assisted laparoscopic prostatectomy. The point of difference is the operating time. Published series show a higher incidence of well-leg compartment syndrome in procedures lasting longer than six hours. If the robot-assisted procedure takes longer to undertake than non-assisted laparoscopic prostatectomy then the risks of developing compartment syndrome will be greater.

3. Was the information [Dr B] provided to [Mr A] about the surgical procedure adequate?

[Dr B] informed [Mr A] of the diagnosis of prostate cancer by phone in early September 2008. The phone conversation was necessary as [Mr A] was on holiday [overseas] at the time, making face-to-face meeting impossible. [Dr B] had a subsequent phone conversation with [Mr A] before he returned to New Zealand on 13 October. From the documentation provided it is apparent that [Dr B] discussed treatment options with [Mr A] during these calls, with [Dr B] believing that [Mr A] had also obtained some information about surgical options from the internet. [Dr B] met with [Mr A] on 15 October where the diagnosis and surgery were discussed 'in detail'. The conversation included treatment options and a PowerPoint presentation. The PowerPoint presentation explains the technical aspects of the surgery in some depth and is supplemented with good quality intraoperative images. The presentation covers the comparison with non-assisted laparoscopic radical prostatectomy and open radical prostatectomy. The potential complications of urinary incontinence, erectile difficulties, bleeding and pain are listed, as are the contraindications to surgery. These include general cardiac problems, coagulation disorders, glaucoma, and previous abdominal surgery. [Dr B's] presentation also describes the greater time that the robotic

procedure ('six hours') is likely to take than the non-assisted laparoscopic radical prostatectomy ('three hours').

In addition to the information provided by [Dr B], [Mr A] also completed a preoperative anaesthetic questionnaire and had a discussion with [Dr D] about the proposed anaesthetic and anaesthetic risks. This included the nature of the anaesthetic, the recovery process and pain relief, positioning on the operating table and the risks of nerve injury and pressure areas on the skin, blindness due to raised intraocular pressure from the head-down position, and the risks of deep vein thrombosis and pulmonary embolus. This information would be regarded as comprehensive coverage of the possible risks.

No mention was made of compartment syndrome, but this is not surprising given the rarity of this adverse event.

It is therefore apparent that the information [Dr B] provided to [Mr A] about the surgical procedure was adequate.

4. Did [Dr B's] surgical approach comply with professional standards?

The [private hospital] notes provide a high level of detail about the course of events through [Mr A's] admission. It is evident that the surgical team were meticulous in their perioperative management, particularly the attention to positioning and protection of pressure areas, and DVT prevention. These measures included the use of silicon pads to protect pressure areas, appropriate support for the head, and TED stockings with Flowtron intermittent pneumatic compression leggings for DVT prevention. Anticoagulant medication was not used because of the risk of intraoperative bleeding.

[Dr B] positioned [Mr A] in the steep Trendelenburg position with the legs slightly elevated. The surgical access, including port access, insufflation and docking with the robotic device appears to have been routine. [Dr B] experienced technical difficulties dissecting behind the prostate due to peri-prostatic inflammation. This was the main contributing factor to the extended time taken for the procedure. Technical difficulties are an inherent risk of all surgical procedures and are not a reflection of poor technique or poor judgement on the part of the surgeon. Of importance for [Dr B] is that he is still on the learning curve for robot-assisted laparoscopic radical prostatectomy and therefore will not be expected to perform the operation as quickly as a surgeon more experienced with this robotic procedure. This is an accepted part of all surgical experience and is to be expected with the learning involved with new technologies. Many surgeons consider the learning curve complete when they are 'comfortable' with robot-assisted laparoscopic radical prostatectomy. However, a more appropriate and measurable definition is that the learning curve is complete only when the surgeon performs an operation equivalent to non-assisted laparoscopic radical prostatectomy. In most published series this is around two to three hours. [Dr B] has now performed 19 of these procedures with an average surgical time of around six hours.

It is therefore apparent that [Dr B's] surgical approach did comply with professional standards.

5. Was [Dr B's] postoperative management of [Mr A] appropriate?

[Dr B] was involved with an operating list [elsewhere] on the day after the surgery and was therefore unable to visit [Mr A] that morning. Nevertheless, [Dr B] phoned the ward to check [Mr A's] progress. He was advised that [Mr A] had an 'adequate' urinary output and that [Mr A] had calf discomfort. This was 'not thought to be severe' and [Dr B] appears to have been satisfied with [Mr A's] progress at this time. Following the call from the ward nurse at 0900hrs advising of the 'fairly severe' left calf pain and swelling, [Dr B] acted promptly to organise a leg vein Doppler ultrasound scan. On receiving confirmation of the DVT [Dr B] assessed [Mr A] and anticoagulation was commenced. [Dr B] appears to have kept good communication with the ward staff and [Dr D], and liaised closely with the staff at [the public hospital] once the diagnosis of compartment syndrome was made and the arrangements for transfer to [the public hospital] had been agreed. [Dr B] and [Dr D] met with [Mr A] and his son and explained the nature of the complication and the reason for referral. [Dr B] continued to provide the expected level of care to [Mr A] once he had been admitted to [the public hospital] ICU and subsequently in the [the public hospital] orthopaedic ward.

It is therefore apparent that [Dr B's] postoperative management of [Mr A] was appropriate.

The care provided by [the private hospital] to [Mr A]

1. What is the responsibility of a surgical hospital in relation to one of its surgeons providing new procedures to patients?

The introduction of any new surgical procedure requires, above all, a requirement that the procedure has been proven or is expected to provide an overall improvement to health outcomes through greater life expectancy or better quality of life. Once this criterion has been met, the hospital has an obligation to the community that appropriate procedures and policies are in place to achieve the expected surgical outcome while at the same time ensuring staff and patient safety.

A detailed and comprehensive business case must be the first step to ensure that the new procedure is affordable and fits with the 'core business' of the institution. This includes determining the fee structure required and the preparedness of private insurers to meet any of the costs to patients.

The hospital must also have in place a credentialling committee that can scrutinise the qualifications and training of the surgeon who is intending to perform the procedure. This includes additional training specific to the new procedure. The committee would ordinarily make a recommendation regarding

approval or otherwise to the Chief Executive. The surgeon must hold current medical registration in New Zealand and meet the CME requirements of the Royal Australasian College of Surgeons. The surgeon must also hold appropriate indemnity insurance.

In most cases the hospital will also have in place audit procedures, usually under the auspices of a dedicated audit committee. This would be used to monitor outcomes from a newly introduced procedure.

[The private hospital] appears to have been methodical and diligent with the introduction of robot-assisted laparoscopic prostatectomy. The hospital already had in place a formally constituted credentialling committee, and a clinical advisory committee charged with audit. A business case was prepared taking into account the impact of this high cost technology, and the hospital worked closely with [a hospital in] Sydney, to assist with detailed planning thereby utilising the experience of an internationally recognised institution.

[Dr B] undertook training in robotic surgery [in America] and [Australia]. A workshop was then held at [the private hospital] by [a Professor from Melbourne]. Additional training, which included training for [the private hospital] nurses, was undertaken at [the hospital in Sydney].

The first procedures performed at [the private hospital] were under appropriate proctoring arrangements.

It is therefore apparent that [the private hospital] fully met its responsibilities as a surgical hospital in relation to one of its surgeons providing new procedures to patients.

2. Were the systems in place at [the private hospital], in relation to robotic-assisted laparoscopic prostatectomy, adequate?

[The private hospital] has developed very good clinical pathway documentation for laparoscopic robotic surgery. Some of this derives from generic material common to many surgical procedures, but careful attention has been paid to the specific requirement of robotic surgery and close attention has been paid to the guidelines used in [Sydney] and the expertise gained from [America] and [Melbourne].

The clinical pathway provides a checklist for the health care team during patient admission to hospital, the perioperative period, and the immediate postoperative period.

In [Mr A's] case the clinical pathway has been followed, and there is good documentation to support this.

In addition, and as noted above, credentialling and clinical advisory committees are in place to ensure appropriate standards continue to be met.

It is therefore apparent that the systems in place at [the private hospital], in relation to robotic-assisted laparoscopic prostatectomy, were adequate.

3. Was [the private hospital's] postoperative management of [Mr A] appropriate?

Following the robot-assisted laparoscopic radical prostatectomy [Mr A] was transferred to the recovery room as the first stage in his postoperative course. The record keeping during this time has been clear and detailed and confirms that [Mr A] was closely monitored and the nurses communicated promptly and effectively with [Dr B] and [Dr D]. In particular, the nurses paid close attention to the potential complications of pressure areas on the skin, deep [vein] thrombosis, and cardio respiratory problems. They acted promptly after identifying the reduced urine output and the likelihood of renal failure at the time the diagnosis of compartment syndrome was made.

It is therefore apparent that [the private hospital's] postoperative management of [Mr A] was appropriate.

Summary

Robot-assisted laparoscopic prostatectomy is a well-established procedure in North America and Europe and is being increasingly adopted in Australia and New Zealand as one of the methods for treating localised cancer of the prostate. [Dr B] has undergone appropriate training and proctoring for this operation, and although has performed 19 procedures is still on the learning curve. This has contributed to the unexpected long duration of [Mr A's] operation, which in turn has been the major factor contributing to the rare and extremely troublesome complication of well-leg compartment syndrome.

In my opinion [Dr B] has provided [Mr A] with a standard of care which his peers in New Zealand would find acceptable.

Furthermore, in my opinion, [the private hospital] has provided an appropriate standard of care that would meet international benchmarks for best healthcare practice.

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Supplementary expert advice to Commissioner

"I have been asked to provide an opinion as to the length of time a patient undergoing robotic prostate surgery might reasonably be positioned in a steep negative Trendelenburg position with the legs raised and supported in stirrups, in light of the known risks of extended time in that position.

Comment

Laparoscopic radical prostatectomy was developed as a means of reducing the inherent morbidity associated with conventional open radical prostatectomy. Specifically, the laparoscopic procedure utilized very small skin incisions for telescopic access and provided a shorter postoperative recovery due to much less pain and little in the way of restricted mobility. Laparoscopic surgery involves a steep learning curve. The aim for all surgeons is to gain the benefits of the laparoscopic approach while at the same time completing the operation in a timeframe close to that which can be achieved with the conventional open procedure.

A more recent addition to the laparoscopic armamentarium has been the assistance provided by 'robots' and this has led to the procedure of robotic laparoscopic radical prostatectomy. In real terms these devices are not robots at all, but computer telemanipulators. Essentially they are an extension of the surgeon's hand and are advocated in the belief that they allow accurate manipulation of the instruments, good vision supporting good manipulation, and, particularly, because they are appropriate tools for decreasing the learning curve of laparoscopy. The aim is for these instruments to eventually become true robots where they will be able to perform, under human control, some or all surgical procedures.

The learning curve of laparoscopic surgery, with or without robotic assistance, means that in most cases the operating time will be longer than that of open

surgery until the surgeon has gained the necessary experience to perform the operation in an efficient and timely manner. Most published series report a learning curve of between 20–25 cases. To my knowledge there are no standards that make reference to a maximum acceptable length of procedure and there is no defined cut-off point at which a surgeon should abandon the laparoscopic approach and revert to the conventional open operation. To some extent this is because severe adverse reactions (such as compartment syndrome) are rare even with long operations. However, as more published data becomes available on severe adverse effects of lengthy (greater than six-hour) procedures then surgeons will undoubtedly set their own limits at which the laparoscopic approach should be abandoned. Benchmarks are already set for the average length of time for laparoscopic robot-assisted prostatectomy. These are derived from the published series. Setting a standard stating the maximum length of time that a procedure should take is more problematic given the huge number of variables that determine operating time. It always defaults to the judgement of the surgeon and his awareness of the risks.

What this case has highlighted is the need for all urologists to be made aware of these risks. If an outcome from this complaint was a recommendation that the Urological Society of Australasia highlight the risks (including compartment syndrome) to its members then this is likely to offer considerable benefit to all patients undergoing these types of procedures."