General Surgeon, Dr B

A Private Hospital

A Report by the

Health and Disability Commissioner

(Case 07HDC13222)

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Overview

In May 2007, a general surgeon performed varicose vein surgery on a woman at a private hospital. She developed postoperative complications of swelling and leaking from the surgical wound and underwent further surgery in June 2007. The leaking recommenced and, during a further operation later in June, an anterior wall of the femoral vein was punctured, leading to a sudden massive venous haemorrhage. The woman required resuscitation and blood transfusion. The vein was repaired and she was transferred to another private hospital able to provide high-dependency monitoring. The woman made a satisfactory recovery.

Complaint and investigation

On 24 July 2007, the Health and Disability Commissioner (HDC) received a complaint from Mrs A about the services provided by Dr B. An investigation was commenced on 13 August 2007. The Private Hospital and Dr B, general surgeon, were notified that the following issues were to be investigated:

- *The adequacy of perioperative services provided to Mrs A by Dr B between 22 May and 26 June 2007*

- *The appropriateness of the postoperative investigations Dr B ordered on 25 and 26 June 2007 to detect the source of the lymphatic leak.*

On 1 February 2008, the investigation was extended to include the following issue:

- *The adequacy of the information provided by Dr B to Mrs A in relation to her surgery performed on 22 May, 19 June and 26 June 2007.*

The parties directly involved in the investigation are:

• Mrs A	Consumer/Complainant
• Mr A	Complainant
• Dr B	Provider/General surgeon
• The Private Hospital	Private hospital

Other parties involved in Mrs A's care include:

• Dr C	General surgeon
• Dr D	Vascular surgeon
• Dr E	Anaesthetist
• Dr F	Anaesthetist

Independent expert advice was obtained from general and hepatobiliary surgeon Dr Peter Johnston.

During the course of the investigation, Mr and Mrs A raised various concerns about the care received. Having considered all of the information gathered, I have identified the following key questions to be answered:

(a) Was it reasonable to propose surgery in light of Mrs A's previous procedures?

(b) Was Mrs A provided with sufficient information regarding the risks and benefits of the operations?

(c) Was Dr B's perioperative care appropriate?

(d) Were the postoperative investigations Dr B ordered on 25 and 26 June 2007 to detect the source of the lymphatic leak appropriate?

(e) Did Dr B perform the third operation (on 26 June) with reasonable care and skill?

(f) Was it appropriate for that operation to take place at the Private Hospital?

(g) Given that the restriction on his operation rights at the Private Hospital precluded him performing major surgery there, was it appropriate for Dr B to perform that operation there?

(h) Did Dr B manage the complications appropriately and provide adequate follow-up care?

Summary of events

Background facts
Dr B is a general surgeon, and has been a Fellow of the Royal College of Surgeons since 1971. His special clinical interests include management of varicose veins. He has operating privileges at several private hospitals. Since August 2001 Dr B has been restricted from undertaking any bowel or major surgery at this Private Hospital.

By April 2007, Mrs A, then aged 34 years, had been troubled by varicose veins[1] for 15 years, and had undergone surgery on four occasions. In 1992 and again in 1996 a surgeon had performed procedures on her right leg, but the varicose veins had recurred. In May 1996 Mrs A saw Dr B for the first time, and in October 1996 he successfully operated on her right leg. In May 1997 Mrs A again consulted Dr B with pain in her right knee which responded well to an elastic stocking. Dr B also recommended elastic stockings for her during her pregnancy in 1998.

In May 1999 Mrs A was troubled with severe Raynaud's disease[2] in her hands, feet and nose. Dr B arranged blood tests, which showed no diagnostic abnormalities. She saw him again in January 2004 with varicose veins, this time in her left leg. Dr B operated on the veins with satisfactory results.

The recurrence of possible varicosities
On 12 April 2007, Mrs A consulted Dr B after both legs began aching. On examination Dr B found no varicosities or apparent swellings, but because of Mrs A's history he considered varicose veins the likely cause. He organised ultrasound investigation of the legs to establish the diagnosis before proceeding. At this appointment Mrs A explained that she was going overseas for three months and that was why she was consulting him. She was hoping to get the issue sorted out before she and her husband went away.

On 7 May 2007, the ultrasound scan revealed that the deep veins in both legs were normal. While the right long saphenous vein[3] was normal, there was a tributary vein in

[1] Varicose veins are abnormally swollen (dilated) and tortous (twisted) veins.

[2] A condition where abnormal spasm of the blood vessels causes a diminished blood supply to the local tissues.

[3] The saphenous veins drain blood from the foot. The long saphenous vein (which is the longest vein in the body) runs up the inside of the leg to the groin, where it joins the femoral vein.

the right pelvis that was "incompetent".[4] The left long saphenous vein was also incompetent.

There is a dispute as to the preoperative discussion regarding treatment options. I have discussed this further below under "Disputed facts — discussion and findings".

First procedure — 22 May 2007
On 22 May 2007, Dr B performed Mrs A's varicose vein surgery at the Private Hospital. Dr B made an incision about a centimetre below the previous scars in the right groin. He dissected vulval varicosities and removed them, cut out a small section of the right long saphenous vein and divided and tied off some other veins coming through from the inside of the pelvis. On the left groin, he also made an incision slightly below the previous scar and then stripped[5] out the upper section of the left long saphenous vein.

After surgery Mrs A noticed that drains had been inserted, even though she had not been informed that she would have them. Her surgery took four hours, which was longer than the two to three hours expected, and Dr B did not explain why. Mrs A was vomiting after surgery and did not feel at all well. Dr B reviewed Mrs A on 23 May, and it was decided that she would remain in hospital for another night, as she remained nauseated and felt unwell. Dr B saw Mrs A again on 24 May, before she left hospital.

Postoperative complications and investigations
On 26 May, Dr B removed the drains and groin sutures. Mrs A returned on 28 May to have the remaining sutures removed. Dr B advised Mrs A to wear elastic stockings for another two weeks and return to see him in three weeks.

On Saturday 2 June, Mrs A telephoned Dr B to advise that she had developed a large swelling in her right groin. Dr B told her that the swelling was probably a collection of lymph due to damage to lymphatic channels during surgery.[6] He arranged to see her immediately and aspirated 20ml of clear lymph fluid from the swelling. Dr B placed a pressure dressing on the right groin area in the hope that the swelling would not reform. However, the swelling recurred and Mrs A developed a continuous leak of lymph fluid from the wound in her right groin. Dr B aspirated 20mls from the swelling on 6 June and 22mls on 9 June.

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[4] An "incompetent" vein is one that has ballooned out to a diameter exceeding the size of its valves. This pulls the valves apart so that they cannot snap shut on backward pressure. When the larger veins balloon out and the condition persists for months or years, the affected veins can become elongated and therefore twisted or "serpentine". These enlarged serpentine veins are darker than normal veins, because blood stagnates there, and are known as varicose veins.

[5] Vein stripping means the excision, or removal, of large veins and the closing off of smaller vein tributaries.

[6] The lymphatic system is a network of vessels that conveys electrolytes, water, protein, etc in the form of lymph fluid from the tissue fluids to the bloodstream.

On 14 June, under local anaesthetic, Dr B inserted a small suction drain through the swelling and asked Mrs A to record the amount of drainage each day. Over the next 24 hours approximately 350ml discharged from the drain, with the amount gradually reducing over the next three days. By 18 June, the swelling had reduced, but was diffuse and the surrounding areas were pink. Dr B considered that this might indicate an infection and so, although Mrs A's temperature was normal, he commenced antibiotics.

Second procedure — 19 June 2007

Dr B was sure that Mrs A had a lymphatic leak, and so on 19 June 2007 he admitted her to the Private Hospital for exploration of the right groin. The parties do not agree on the discussion that took place before this operation. This is discussed further below.

Dr B extended the original wound upwards to improve access and surgically explored the wound. After a thorough search, he could find no leaking lymphatic nodes. He sutured the extended portion of the wound and left the old groin wound edges unsutured to allow fluid to escape. He considered that the wound edges were lying nicely together and would heal well without sutures.

When Dr B saw Mrs A on 20 June, she reported very little leakage. However, on 22 June the wound started leaking profusely. Dr B arranged a lymphoscintogram[7] (also known as a scintiscan) in an effort to find the position of the leakage. On 25 June 2007 the lymphoscintogram was performed and it showed evidence of lymphatic leakage in the right femoral triangle (the groin). The leak was noted above and below the surgical incision, and it appeared to be deep in the subcutaneous tissue, rather than just below the skin.

Third operation — 26 June 2007

On 26 June Dr B again undertook surgery on Mrs A at the Private Hospital, to re-explore the wound and attempt to tie off the leaking lymph nodes. Again there is a dispute about information provided prior to surgery.

Before operating, Dr B first attempted a lymphangiogram[8] in an effort to mark out the lymphatic channels in the groin, but they did not show up. Mrs A found this procedure very painful.

[7] A lymphoscintogram is a diagnostic imaging test that permits high resolution imaging of peripheral lymphatic vessels by the injection of a tiny amount of a radioactive material (tracer) to visualise the drainage of fluid by the lymphatic system.

[8] In a lymphangiogram a blue dye is injected between the toes, allowing the lymphatic vessels to be visualised on the top of the foot. Once the lymphatic vessels are identified, a small incision is made and a catheter inserted into a lymphatic channel in each foot. An oily contrast agent (dye) is then slowly injected up the legs and abdomen.

Surgery was commenced at 2.15pm. Dr B commenced with vertical incisions around the old groin wound in the area identified by the scan. He was exploring for a lymph node about five centimetres below the original groin incision. The femoral vein was buried in dense fibrous tissue. A strong self-retaining retractor was used to open the wound to improve visibility and access. At approximately 3.10pm, when attempting to dissect the area further, there was a sudden massive venous haemorrhage from the femoral vein. There was an estimated 1500ml blood loss at this stage, and Mrs A's blood pressure dropped to 50/19.

Response to complication

Dr B was able to make a temporary repair to the vein, stop the bleeding and temporarily close the wound, but with great difficulty. There is a confluence of very big veins in this area and none of them could be accessed to control the bleeding without stopping the bleeding first. Dr B therefore had to suture the hole in the femoral vein and the surrounding fibrosis almost blindly in a deep and fast flowing pool of blood. He succeeded in doing this and stopped the blood loss.

Dr B sought assistance from general surgeon Dr C, operating in the adjacent theatre, to undertake a more permanent repair. Dr C arrived, looked in the wound and suggested that because it was "re-do" operation it would be wise to get a vascular surgeon to attend. Having tried one vascular surgeon, who was unavailable, Auckland Hospital vascular surgeon Dr D was contacted at approximately 4pm and agreed to attend immediately.

Dr B asked one of the nurses to contact Mrs A's husband. She was unable to reach him on the home number or mobile, but asked the ward nurse to watch out for him and reassure him. The ward nurse later confirmed that Mr A had arrived and been spoken to.

Blood transfusion

In the meantime, the anaesthetist, Dr E, put in a second venous line for fluid replacement. Mrs A needed a blood transfusion. After stabilising Mrs A with 3½ litres of plasma substitute, Dr E ordered cross-matched blood, rather than utilising the supply of universal donor (O–) blood at the hospital.

Dr E asked Dr F, an anaesthetist in one of the other theatres, to assist in inserting an arterial line so he could more accurately assess her blood pressure. The arterial line was placed at 3.49pm. Dr F suggested using the universal donor blood. Because Mrs A was of child-bearing age, Dr E wanted to wait for group-specific blood.[9]

[9] Type O negative blood is considered the universal blood donor type, but it may have antibodies that cause serious reactions during a transfusion. Ideally, blood transfusions are done with donated blood that is an exact match for type and Rh (Rhesus) factor. Small samples of the recipient's and donor's blood are mixed to check compatibility in a process known as cross-matching. Of women of childbearing age, 80% are Rh positive and will not have a problem receiving Rh positive blood. Those

The blood took longer to arrive than expected. Dr E advised HDC that if he had known how long it would take to have the blood cross-matched, he probably would not have waited. I acknowledge that the use of uncross-matched blood in this situation is open to debate. In a report obtained by the Private Hospital, an anaesthetist advised that some anaesthetists would feel it should be used, but others would not.[10] In this case, Mrs A was stable, with no co-morbidities, Dr B had controlled her bleeding, and blood was on its way. Dr E had obtained good perfusion by the time Dr D arrived.

Repair by Dr D

Dr D arrived at the Private Hospital at approximately 4.30pm, the journey taking some 30 minutes due to heavy traffic at that time of day. He observed that Dr B had successfully controlled the bleeding from the femoral vein with sutures and had closed the skin wound in a temporary fashion. There was no ongoing bleeding at this time.

Dr D recommended formal re-exploration and repair of the femoral vein. He waited for the cross-matched blood to arrive. The transfusion started at 4.59pm, and surgery then proceeded. Dr D removed the temporary suture and found a small hole in the front of the common femoral vein. After he had cleared the area, he was able to repair the injury with sutures. The vein was not narrowed by the repair and he was able to maintain blood flow with anticoagulation rather than more extensive surgery. Mrs A's total blood loss was 1700ml, and the blood transfusion totalled 1027ml.

Mrs A was transferred to recovery at 6.20pm. At the request of the nursing staff, at 7.45pm Mrs A was transferred to another private hospital where high dependency monitoring could be provided as part of postoperative care. Dr B accompanied her in the ambulance, with Dr E following in his car. Dr B visited Mrs A at this hospital on 27 June and 28 June and visited her at home after she was discharged on Friday 29 June.

Because Dr D was going to be out of the country for a few days, Dr B cancelled a weekend away so that he could provide support to Mrs A if needed. He telephoned her on Saturday 30 June and she told him that the wound dressing was intact but the district nurse was not coming until the Monday, so Dr B arranged for his practice nurse to visit Mrs A on Sunday 1 July to renew her groin dressing. Dr B kept in touch with her by daily telephone calls until 5 July when his nurse asked Mrs A to arrange an appointment for renewal of sutures and review, but she advised that the district nurse had removed the sutures.

Mrs A transferred her care to Dr D, who at a follow-up visit on 13 July 2007 reported that she had made a very satisfactory recovery, although there was still some swelling

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20% who are Rh negative may become sensitised to the Rh factor if they receive a unit of Rh positive blood. A subsequent pregnancy can be affected by sensitisation, resulting in conditions such as Rh disease.

[10] The Private Hospital provided HDC with a copy of its Clinical Task Committee review, including a report from an anaesthetist.

in her foot as a result of the lymphangiogram that was attempted prior to surgery on 26 June.

Comment from Dr B
Dr B explained that in retrospect he thought that the injury to the femoral vein was caused by the fact that the tension in the wound split the fibrous tissue, which was still inflamed from the previous operations and adherent to the underlying vessels. The split in the fibrous tissue tore the anterior wall of the common femoral vein. Dr D also thought the laceration to the femoral vein was due to the very rigid fibrotic nature of the tissues in the groin from multiple previous surgeries, and that this led to the tearing of scar tissues (including the front wall of the femoral vein) when retractors were used to open the wound.

Dr B advised the Private Hospital management that he has operated on many patients who have had previous operations, and never had a problem of this sort before. What happened to Mrs A was a very rare event that he has not experienced in 30 years of surgery.

Dr B apologised for the lack of operation notes, explaining that he had accompanied the patient to the other private hospital and remained there until she was settled and her warfarin therapy started. (He then made a retrospective record.)

Dr B has discussed the case with two senior colleagues for educational purposes. He has reviewed every aspect of the case, including his preoperative explanation and documentation. He intends to improve the recording of information given to patients.

Dr B deeply regrets damaging Mrs A's vein, and the ongoing difficulties she experienced, and repeats the apology expressed in his letter of 13 September 2007 to HDC.

Disputed facts — discussion and findings

The parties dispute the nature and content of preoperative counselling prior to the three procedures in May and June 2007.

First operation — 22 May 2007
Following the ultrasound on 7 May 2007 Dr B next saw Mrs A on 17 May 2007, and discussed the findings. There is a dispute about which treatment options were discussed. Dr B advised HDC that he suggested that Mrs A might be better off wearing elastic stockings on her overseas trip (planned for August), since he knew that an operation would be difficult because there would be a lot of scarring in the deeper tissues from her previous surgery. He said that Mrs A wanted surgery before her trip. Therefore he made arrangements to explore both groins under anaesthetic on 22 May

2007 at the Private Hospital. Dr B recorded "would like op[eration]" in Mrs A's records. His notes make no reference to information about different options or discussion of risks.

Mrs A advised HDC that she knew Dr B intended to explore the right groin and possibly strip the saphenous vein on the right and the long saphenous vein on the left. She told Dr B, at the first consultation in April, that she "wanted to get it sorted out before we went away [on their overseas trip in August]". She does not recall Dr B discussing treatment options other than surgery and is certain he did not offer her conservative management. She had the sense that everything would be very straightforward, and arrangements were made for her to have surgery the following week (on 22 May). She expected to be in theatre for two to three hours and to go home the next day.

Mrs A insists that there was "absolutely" no discussion of associated risks. She does not recall being told about scar tissue from previous surgery and the accumulated effects of subsequent surgeries. Mrs A understood the operation was for routine stripping of some varicose veins, as on previous occasions. The day before her surgery she had a chest cold and this was the only risk she discussed with Dr B.

Mr A recalls being present at some of his wife's preoperative consultations with Dr B over the years. Mr A said that there was never much discussion; Dr B would examine Mrs A's legs and suggest a course of treatment and more or less get on with it. While he cannot recall dates of appointments, he does remember accompanying Mrs A to one appointment with Dr B before her May 2007 surgery. He recalls Dr B explaining that surgery would be required but that he did not mention any alternative treatment options. In earlier years Dr B had treated Mrs A with injections and stockings, which Mr A understood to be conservative management. On this occasion Mrs A's legs were really aching and there seemed to be no question that she would need surgery.

On 17 May 2007, Mrs A signed a standard consent form for the proposed surgery, which stated:

> "I confirm that I have received a satisfactory explanation of the reasons for, risks and likely outcomes of the procedure/operation/treatment, and the possibility and nature of further related treatment including a return to theatre, should any complications arise.
>
> I have had an opportunity to ask questions and understand that I may seek information at any time and participate in decision making about my treatment."

Second procedure — June 2007

Mrs A does not recall there being any discussion of treatment options prior to the second procedure. She advised HDC that Dr B told her that she had an infection (treated with antibiotics) and that further surgery was required. Dr B explained that lymph nodes are small and one may have been "accidentally nicked" during the first surgery.

Dr B advised HDC that lymphatic leaks usually stop spontaneously but Mrs A was worried it might not do so before her planned trip and, because he could not reassure her about that, he "reluctantly" re-explored the groin. He said that he also told her that he might have to make a vertical incision to improve access, and she agreed to this.

Mrs A signed a standard consent form for Dr B to explore her right groin, which he scheduled for the following day. There is no record of Dr B's discussion with Mrs A about the risks of this procedure. Given that Dr B has said that he was reluctant to re-explore the groin, I find it surprising that he did not record a fuller discussion of the risks and benefits in his notes.

Decision to operate for the third time

Mrs A states that before agreeing to the third procedure, "absolutely" no information was provided about the risks of another operation. She recalls Dr B explaining that lymph nodes were hard to see and "fix". He did not tell her that the leakage might stop spontaneously if left alone. She was also not informed that there was any risk of bleeding or damage to blood vessels. Mrs A recalls that Dr B said that scar tissue was present, but did not explain the implications for her.

Mr A was also present at this consultation. He explained that Mrs A was unable to drive because of her leaking surgical wound. Mr A recalls that no other options apart from surgery were discussed. He recalls Dr B explaining that lymph nodes were small and "hard to find". No information was given about possible complications or risks of the surgery. Mr A did not become aware of the possible impact of scarring until after the third surgery.

Dr B advised HDC that he explained to Mrs A that he had been unable to find the explanation for, or source of, the leak, but was hopeful that surgery would improve matters for her. He said that he fully discussed the implications of another operation and that he advised Mrs A that the dissection would be difficult. He explained to Mrs A that a lymphoscintogram should be performed to locate the source of the lymphatic leak before he took her to theatre. Dr B stated that Mrs A wanted him to explore the wound again and, in view of the profuse discharge, which was quite distressing for her, there did not seem to be any alternative. Further, he said:

> "On 22 June 2007 I gave [Mrs A] what I considered were the only viable treatment options being a lymphatic scintigram with the possibility of surgery, depending on the results of the scintigram."

Dr B recorded: "Still v.wet. Arrange scintigram and re explore Tues." Mrs A signed the standard consent for surgery form, as outlined above.

Finding of fact

Having considered all of the information before me, I conclude that Mrs A's recollections of discussions are more likely to be accurate than those of Dr B. I think it

is unlikely that Dr B properly advised Mrs A of treatment options other than surgery. My reasons for preferring Mrs A's version are:

(a) her recollection that discussions that took place before the 22 May and 26 June operations contained no mention of risks or the possibility of conservative treatment is corroborated by Mr A. In particular, there was no discussion of the wearing of stockings instead of surgery. This was something that Mrs A had done before.

(b) Dr B says that he was "reluctant" to perform surgery on 14 June, and yet his notes make no reference to the discussion of other options or his advice as to why operating on 14 June might not be advisable.

(c) Dr B says that on 22 June 2007 he gave Mrs A the "only viable treatment options", which were scintigram and surgery. That indicates that Dr B did not consider conservative treatment a viable option, and so it seems unlikely that he discussed that with Mrs A.

Findings on key questions

In considering the appropriateness of Dr B's care of Mrs A, I have been assisted by advice from Dr Peter Johnston, a general surgeon (see Appendix), and from Dr Ross Blair, a general surgeon who provided advice to the Private Hospital's Clinical Task Committee. I consider below each of the questions that need to be answered.

(a) Was it reasonable to propose surgery in light of Mrs A's previous procedures?

When Mrs A presented to Dr B in April 2007, she had had three previous procedures for varicose veins in her right leg and one procedure on her left leg. Dr Johnston advised that the treatment options were relatively straightforward: to operate or not. As with any same-site repeat surgical procedure, scar tissue from previous surgeries was potentially a complicating factor. Mrs A was receiving her fourth, fifth and sixth procedures in the right groin region. Clearly, there was a significant risk that scarring would add to the complexities of surgery. Dr Johnston emphasised the possibility of lymphatic leakage resulting from further surgeries due to the build-up of scar tissue. Dr Blair also noted that lymph leakage following groin exploration is not uncommon.

Lymph leakage often resolves spontaneously. Dr Johnston advised that ideally, rather than operating on 19 June 2007, Mrs A should have been treated conservatively, with a view to surgery should the problem persist. However, on researching the literature on this topic, he found a lack of clarity.

I conclude that the decision to operate on any of the three occasions was not necessarily a wrong one. There was no apparent issue that Mrs A was unfit for

surgery. Dr B's peers would likely have considered surgery appropriate in the same circumstances, but full discussion of the implications of the previous procedures to the groins was necessary.

(b) Was Mrs A provided with sufficient information regarding the risks and benefits of the operations?

Given that Mrs A's surgery on 22 May was her fourth surgical exploration of her groin, Dr B should have specifically addressed the risks of repeated same-site surgery. Mrs A developed a lymphatic drainage problem followed by an infection. Dr Johnston said it was reasonably foreseeable that the lymphatic system would be damaged. One of the risks that should have been discussed was the risk of bleeding.

Prior to Mrs A's surgery on 26 June Dr B should have explained that because this was the sixth time this area had been operated on, there was an increased risk of haemorrhage. The operation was to take place in a small area of her groin containing a number of important structures including blood vessels which, if damaged, might haemorrhage, and that the likelihood of damage to blood vessels was increased because of the amount of scar tissue.

I conclude that Mrs A was not advised that conservative treatment was an option or of the increased risks associated with repeat-site surgery. Therefore, she was not provided with sufficient information before the operations.

(c) Was Dr B's perioperative care appropriate?

Dr B reviewed Mrs A a number of times and made himself available when contacted. I note that on Saturday 2 June, when Mrs A contacted him regarding the swelling in her groin, he arranged to see her immediately and aspirated some fluid. She had further consultations on 6 June and 9 June 2007. Dr Johnston advised that the management of the surgical wound was appropriate and that the insertion of a drain on 14 June 2007 was a suitable way of managing fluid collection that is persisting. I also acknowledge that Dr B took the precaution of commencing antibiotics on 18 June when he was concerned that the pink areas surrounding the groin swelling might indicate an infection.

Following the third operation (26 June) Dr B was attentive in his follow-up care. Dr B accompanied his patient to the second private hospital, visited her for the next three days, had his practice nurse visit her on Sunday 1 July to redress the groin wound, and maintained daily contact with her until 5 July.

Accordingly, I find that Dr B's care from 22 May until 26 June was appropriate.

(d) Were the postoperative investigations Dr B ordered on 25 and 26 June 2007 to detect the source of the lymphatic leak appropriate?

On 25 June Dr B performed a lymphoscintogram and on 26 June he attempted a lymphangiogram. Dr Blair advised that there were no further investigations that could be done perioperatively to detect the exact site of the lymph leak. There is no suggestion that following surgery on 26 June 2007 any immediate investigations were required, and Mrs A's care was then transferred to Dr D. I am satisfied that the investigations that were performed on 25 and 26 June to detect the source of the leak were appropriate.

(e) Did Dr B perform the third operation (on 26 June) with reasonable care and skill?

Despite the life-threatening haemorrhage Mrs A suffered, there is nothing to suggest Dr B did not perform the third operation to an appropriate standard. The increased risk of haemorrhage was a foreseeable complication within that procedure, rather than an adverse event caused by lack of surgical skill. Dr Johnston advised that "this particular surgical mishap could occur in the very best of hands". I conclude that the operation was performed with reasonable care and skill.

(f) Was it appropriate for the operation to take place at the Private Hospital?

Dr Johnston considered that there was a definite risk of haemorrhage as a result of this being the sixth operation in the groin region. Therefore, Dr B should have planned for such a contingency. Dr Johnston believes that Dr B underestimated the difficulty of the surgery. It was an error of judgement to undertake the surgery at the Private Hospital without assistance and without readily accessible blood products if a transfusion was required. Dr Johnston stated:

> "… [Dr B] states that he has done revision groin surgery many times without problem, and this can be accepted, but my own experience, which includes a large volume of major surgery, is that repeat surgery for veins in the groin can be very technically demanding and must be approached with that in mind. Given that there was a restriction on his practice and the potential difficulty of the case, [Dr B] would have been wise to discuss the surgery in advance with [the Private Hospital], and I would view his omission of this with moderate disapproval."

I therefore find that in the circumstances it was not appropriate for the operation to take place at the Private Hospital.

(g) Given that the restriction on his operation rights at the Private Hospital precluded him performing major surgery there, was it appropriate for Dr B to perform that operation there?

Dr Johnston said that the Private Hospital will need to comment on what it considers "major surgery". On the minor, moderate and major scale the Private Hospital

classified Mrs A's surgery as moderate. Accordingly, I am satisfied that Dr B was not operating outside the terms of his agreement with the Private Hospital.

(h) Did Dr B manage the complications appropriately and provide adequate follow-up care?

Dr Johnston, Dr Blair and Dr D all conclude that Dr B's response to the haemorrhage was appropriate. Dr B took the correct course of action, by establishing control of the haemorrhage and seeking further assistance to complete a definitive repair. I note that Dr B accompanied his patient to another hospital, visited her for the next three days, had his practice nurse visit her on Sunday 1 July to redress the groin wound, and maintained daily contact with her until 5 July. I am satisfied that Dr B responded well to the haemorrhage and provided good follow-up care.

Opinion

Breach — Dr B

Information disclosure
Dr B knew Mrs A's history well, having performed surgery for her recurring varicose veins over a number of years. In May 1997 and August 1998, Dr B treated Mrs A's varicose veins conservatively by applying elastic stockings. In January 2004 he opted for surgical correction. Mrs A had experienced both treatment options.

I am satisfied that Mrs A was not aware of the risks associated with previous scar tissue before her operations in May or June 2007. I understand that each time Mrs A had a surgical correction of her varicose veins it increased the risks of complications. In my view this must impact on the decision about whether surgical correction should be favoured over conservative management.

Mrs A had the right be fully informed and to make an informed choice about which treatment option she preferred in light of the attendant risks. This required a careful explanation about the nature of her condition, the benefits and risks of surgery, and other treatment options (including their benefits and risks) open to her. It was important she knew that repeating surgery created denser scar tissue and increased the risk of damage to anatomical structures, and what that meant for her situation.

Dr Johnston noted that damage to lymph vessels is almost inevitable with this surgery and that lymph leakages might correct spontaneously. I am not convinced Mrs A knew that the lymphatic system can correct spontaneously if left alone. If she was able to tolerate the distress caused, she might have avoided further surgery. The doctor's explanation must be tailor-made to the patient's condition. One explanation does not fit all.

Mrs A signed a standard consent form on 17 May 2007, confirming that Dr B had provided a satisfactory explanation of the reasons for, risks, and likely outcomes of the surgery, including the possibility and nature of further treatment should complications arise. By its very nature the form gives permission for the surgeon to operate. It does not provide any information about alternative treatment options that may have been discussed at the time. Mrs A was invited to ask about further treatment and complications but, in my view, the onus was not on Mrs A to ask the right questions. It is no answer that she had an opportunity to ask questions and knew she could participate fully in any treatment discussions. Dr B had an obligation to volunteer the information Mrs A needed and to record their discussions.

It would also have been helpful if Dr B had explained to Mrs A that she would have drains inserted after surgery, and following surgery it would have been a good idea to discuss with her what had happened in surgery and why it had taken four hours instead of the two to three predicted. Mrs A was vomiting after surgery and did not feel at all well. She remained in hospital for another night. In those circumstances it is understandable that she felt concerned and confused as to the success of the operation.

Mrs A had the right to the information that a reasonable patient, in her circumstances, would expect to receive, including an explanation of her condition (both pre- and postoperatively), and her treatment options, including the expected risks, side effects and benefits of each option. I conclude that Dr B did not provide this information and breached Right 6(1)(a) and (b) of the Code of Health and Disability Services Consumers' Rights (the Code).[11]

Harm minimisation

Dr B also had a duty to provide Mrs A with surgical services of an appropriate standard and, in particular, in a manner that minimised potential harm to her as a patient (see Right 4(4) of the Code).[12]

In my view Dr B underestimated and inadequately planned Mrs A's surgery on 26 June. As already noted, he explained that in retrospect he thought that the injury to the femoral vein was caused by the fact that the fibrous tissue, which was still inflamed from the previous operations, was adherent to the underlying vessels. When that tissue split, the anterior wall of the femoral vein opened. Dr D also thought that the very rigid fibrotic nature of the tissues in the groin from multiple previous surgeries led to

[11] *Right 6(1) of the Code provides: 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;…

[12] *Right 4(4) of the Code provides: Every consumer has the right to have services provided in a manner that minimises the potential harm to, and optimises the quality of life of, that consumer.*

the tearing of scar tissues, including the front wall of the femoral vein when retractors were used to open the wound.

When planning the surgery Dr B should have seen that the risk of haemorrhage was reasonably foreseeable (albeit perhaps not the severity of the haemorrhage). He should have had contingency plans for just such an event. He should have considered the need for assistance and whether the Private Hospital could provide the appropriate level of support (including cross-matched blood supplies) for such a technically challenging operation. The failure to appropriately plan Mrs A's surgery on 26 June, to take account of the possibility of complications, amounted to a failure to provide surgical services in a manner that minimised potential harm. In these circumstances Dr B breached Right 4(4) of the Code.

Opinion: No breach — Dr B

Perioperative and postoperative care
As noted above, Dr B reviewed Mrs A a number of times between 22 May and 26 June 2007, and made himself available when contacted. On Saturday 2 June, when Mrs A contacted him regarding the swelling in her groin, he arranged to see her immediately and aspirated some fluid. She had further consultations on 6 June and 9 June 2007. The insertion of a drain on 14 June 2007 was a suitable way of managing fluid collection that is persisting. I also acknowledge that Dr B took the precaution of commencing antibiotics on 18 June when he was concerned that the pink areas surrounding the groin swelling might indicate an infection.

Dr Blair advised that there were no further investigations that could have been done perioperatively to demonstrate the exact site of the lymph leak. Dr Johnston advised that Dr B's postoperative services and investigations were appropriate. The literature supports Dr B referring Mrs A for lymphoscintogram, as it is the only useful investigation in these circumstances.

Following the surgery on 26 June, Dr B accompanied Mrs A to another hospital and attended her daily until 29 June and maintained daily telephone contact until 5 July.

In my opinion Dr B provided Mrs A with appropriate perioperative and postoperative care during and following all three procedures, and did not breach the Code in this respect.

Opinion — The Private Hospital

Vicarious liability

Under section 72 of the Health and Disability Commissioner Act 1994 ("the Act") an employing authority may be liable for acts or omissions by an employee, an agent or a member, where the employing authority is also a health care provider.[13] Dr B is a consultant surgeon at the Private Hospital, using the equipment, facilities and nursing support at the Private Hospital.

The Private Hospital does not accept that doctors using its facilities are "agents" and points out that the public are told the doctors are independent from the hospital.

In previous cases,[14] I have taken the view that notwithstanding the arms-length "visiting privileges" arrangement, specialists may be agents of the private hospitals where they provide services. Ostensibly, such practitioners are represented to the public as being associated with these hospitals where they work, and the private hospitals retain some degree of control over the practitioners, including the ultimate sanction of not renewing clinical privileges. In my view, visiting practitioners may be agents of the private hospitals where they provide services, within the meaning of section 72(3) of the Act.

Section 72(3) provides that anything done or omitted by a person as the agent of an employing authority shall, for the purposes of this Act, be treated as done or omitted by that employing authority as well as by the first-mentioned person, unless it is done or omitted without that employing authority's express or implied authority, precedent or subsequent. Under section 72(5) it is a defence for an employing authority to prove it took such steps as were reasonably practicable to prevent the employee from acting or omitting to act in breach of the Code. Section 72(5) can also be applied as a defence to liability under section 72(3).

[13] Section 72(1) of the Act states that the term "employing authority" means a health care provider or a disability services provider. Section 3(a) of the Act states that a health care provider includes a person for the time being in charge of providing health care services within the meaning of the Health and Disability Services (Safety) Act 2001. The Private Hospital provides health care services within the provisions of the Health and Disability Services (Safety) Act 2001.

[14] 01HDC04847 (3 May 2003) and 99HDC06799 (24 May 2002).

Dr B's breaches of Right 4(4) and Right 6 of the Code relate to his failure to appropriately plan surgery and offer explanations to Mrs A. Dr B did not act outside the terms of his agreement with the Private Hospital.

In my view, these omissions were attributable to individual clinical decisions by Dr B and could not realistically have been prevented by the Private Hospital imposing any conditions on his visiting privileges. The Private Hospital is therefore not vicariously liable for Dr B's breaches of the Code.

Other comments

Pain in foot
Mrs A stated that on 14 June 2007 when Dr B inserted a drain in her groin, although local anaesthetic was used, the incision was painful. Dr B commented that the reason for the painful puncture was probably inadequate spread of the local anaesthetic and that, in retrospect, he should probably have allowed more time for the anaesthetic to work.

On 26 June 2007 Dr B performed a lymphangiogram, which involved injecting Mrs A's foot with methylene blue dye to mark out the lymphatic channels in the groin. Mrs A found these injections particularly painful. She stated:

> "I was apprehensive about the injection but wanted my lymph node fixed. As soon as he injected me I started crying and asking him to stop as it was hurting. [H]e didn't stop straight away, telling me that I was being brave. I yelled at him to stop. [H]e took the needle out and said that it would be better for him if he could put in some more. I was still crying and said no.
>
> …
>
> My foot went so swollen I couldn't move my toes or walk on it. And the dye never went anyway except across my foot. To this day I haven't got feeling in the top of my foot — it's like I have been burnt. I was taken to surgery and got really upset as my foot was really sore."

Dr B acknowledged that the methylene blue injection was painful for Mrs A and he thought she may have experienced some form of allergic reaction.

Injections in the foot can be very painful, and it seems that Mrs A's foot did not resolve quickly, with swelling being evident at her postoperative consultation with Dr D. I note that Dr B did not immediately stop attempting the lymphangiogram when asked to. However, when he failed to gain consent to try again, he did not persist.

Nothing in the available information suggests that Mrs A's ongoing problems resulted from any lack of skill on Dr B's part.

I recommend that Dr B take more care to ensure that local anaesthetics have taken effect and listen more carefully to his patients' requests to cease a very painful procedure, to avoid distress.

Hand tremor
On 14 June, when Dr B injected local anaesthetic in her groin, Mrs A noticed that he had a "bit of a shake" in his right hand.

Dr B advised HDC that both of his hands shake; it is a congenital condition he has had for some time and it has never interfered with his work. He has not had any occasion to report the matter to the Private Hospital. Dr Blair stated, "I know a number of surgeons who suffer from such an intention tremor which is often hereditary and does not affect their ability to undertake fine surgical manipulations." Similarly, Dr Johnston noted that a benign essential tremor can certainly be compatible with safe surgical practice.

It is understandable that Mr and Mrs A raised their concern about Dr B's hand tremor, but having considered all information, there is nothing to indicate that it in any way contributed to the outcome of any of Mrs A's procedures.

Follow-up actions

- A copy of this report will be sent to the Medical Council and the Royal Australasian College of Surgeons.

- An anonymised copy of this report (naming only the experts who advised on this case) will be sent to the New Zealand Private Surgical Hospitals Association and placed on the Commissioner's website, www.hdc.org.nz, for educational purposes.

Appendix — Independent Surgical Advice

The following expert advice was obtained from Dr Peter Johnston:

> "I have been asked to provide expert advice to the Health and Disability Commissioner on this complaint. …
>
> **Expert advice required:**
>
> *To advise Commissioner whether, in your opinion, [Dr B] provided an adequate standard of care to [Mrs A] and, in addition, answer the following questions:*
>
> I will comment on the questions in turn, and summarise my conclusions following that. The comments [Dr B] makes at the beginning of his account are very important to note: the 22.5.07 operation was [Mrs A's] fourth operation on veins in the right groin, as I understand it, and the subsequent operations were thus the fifth and sixth. The possibility of difficult surgery with complications, in particular lymph leakage bleeding and infection. In a second or subsequent operation on veins in the groin, lymph leakage is really an unavoidable complication as each operation will disrupt the small lymph channels which then become embedded in scar tissue and are liable to be disrupted further at the next procedure.
>
> 1. *In relation to [Dr B's] surgery on 22 May 2007, what standards apply in this case?*
>
> The standards would be that the surgery be a correct treatment for the condition, the patient is adequately informed of the benefits and risks of the surgery, and that the patient be fit for the proposed surgery.
>
> 2. *Did [Dr B's] surgery comply with those standards and, if not, please explain any deviation from appropriate standards?*
>
> The surgery was appropriate for [Mrs A], as an ultrasound scan showed filling of the long saphenous vein from pelvic veins and from another site lower in the leg. It appears there was no issue that [Mrs A] was unfit for surgery. The details of the informed consent discussion are not recorded but [Dr B] notes he was somewhat reluctant to undertake surgery and suggested elastic stockings in the first instance. [Dr B] also records recognition of the increased difficulty inherent in re-operation on veins in the groin. Presumably he communicated this to the patient. There is nothing to suggest the consent process was inadequate.

3. *Was [Dr B's] perioperative care appropriate, such as inserting a drain on 14 June 2007?*

[Dr B's] care was appropriate, he reviewed her a number of times and made himself available to be contacted The management of the surgical wound was appropriate; inserting a drain in that fashion can be a useful wa[y] of managing a fluid collection which is persisting.

4. *Did [Dr B's] surgery of 19 June 2007 comply with appropriate standards and, if not, please explain any deviation from appropriate standards?*

In general, the standards are those noted in answer to the first part of the first question. In relation to benefits and risks, one assumes these were discussed. [Dr B] notes that he was rather reluctant to do this surgery as these problems usually will resolve with time but [Mrs A] had an overseas trip approaching. The indications for and timing of surgery in an established lymph leak or lymphocele are not well defined. My understanding of usual Australasian practice would be to operate if the problem was not improving with conservative treatment. I have reviewed current surgical literature on this topic but very little concrete information can be obtained. One of the standard textbooks Rutherford: Vascular Surgery states, in the same paragraph and in the same context, that these problems should be operated if the problem does not resolve quickly, and also that they often can be managed with expectant treatment. This is a reflection of the lack of clarity around the management of this problem.

In my opinion the ideal option would have been to treat conservatively at this stage. Attempting to resolve an issue surgically to fit in with the patient's other activities is a dilemma which quite often arises, and in this instance was not unreasonable, in my view.

5. *Was the lymphoscintogram, conducted on 25 June, the appropriate investigation and, if not, what would have been the appropriate investigation?*

Yes, there is recent surgical literature which indicates that this is a useful investigation in these circumstances. There are no other useful investigations.

6. *In relation to [Mrs A's] surgery performed on 26 June 2007, was the surgery appropriate and, if not, please report on the surgery/treatment [Dr B] should have undertaken?*

The comments made above about the need for and timing of surgery for lymph leakage again apply. One gets the impression that there was still a degree of pressure on the situation in relation to the projected overseas trip. However, given that there was evidently a large volume of leakage, a further attempt at resolving this surgically at this time could not be criticised.

> This was now the sixth operation in this area. [Dr B] would have been aware that this was likely to be a technically challenging operation, with a definite risk of haemorrhage, which unfortunately did occur in [Mrs A's] case. It is a matter of judgment for the surgeon based on his or her skill and experience as to what this risk might be in an individual case, and whether he or she is the correct person to do this surgery, and in what level of surgical care. This particular surgical mishap could occur in the very best of hands. The hospital in which the surgery was done was obviously not optimal for this eventuality, given the length of time required to access blood for transfusion, and this choice again is a matter for the surgeon, in discussion with the patient if necessary to judge.

Additional advice

Dr Johnston provided the following further advice:

> "I am asked by the Commissioner to provide expert advice on aspects of the care provided to [Mrs A] by [Dr B]. This follows my previous advice on this case, to which I refer.
>
> I have read and agreed to follow the Commissioner's Guidelines for Independent Advisors. My qualifications are MB ChB, FRACS; my experience in this area is as a General Surgeon, since 2005 practising Upper GI, Hepatobiliary and Transplant surgery, and having practised in General surgery including varicose vein surgery as consultant surgeon from 1986–2005.
>
> My instructions from the Commissioner are to give opinion on specific questions, which I will repeat below in turn, in italics, with comment after each.
>
> …
>
> In addition to the information available for review at my last report, there are now transcripts of separate interviews with [Mr and Mrs A], the [the Private Hospital] records, and a letter from [Dr B] to [the HDC investigator] dated 22.7.08. There is also a letter from the Commissioner to [Dr B] 1.2.08 requesting an interview, which one assumes did not take place.[15]
>
> **Adequacy of information**
>
> 1. *Please comment on whether you consider that [Dr B] provided [Mrs A] with adequate information, including:*
>
> The explanation [Dr B] provided to [Mrs A] about her condition; [Dr B] records the relatively basic information he gave to [Mrs A] at each stage; [Mrs A's] account of this is that the information and opportunity for discussion was fairly

[15] Dr B declined an offer to attend an interview with HDC.

limited, but she was content to accept this and let the expert do his job. The information may have been enough for [Mrs A].

2. *The information [Dr B] provided to [Mrs A] about the possible treatment options for her condition (particularly at the consultations 17 May, 18 June and 22 June) …*

The treatment options at each stage were relatively plain, either to operate or not; however, choosing between these options would not have been an easy matter and should have needed an amount of discussion. It would seem from [Mr and Mrs A's] interviews that full discussion had not taken place, just an acceptance that surgery would be done. One recognises from the interview transcripts that these events took place under an increasing degree of emotional pressure related to the lack of success with controlling lymph leakage from the groin, and the projected overseas trip. This pressure would have negatively affected both parties in their ability to engage in full discussion. [Mrs A's] account implies a relatively 'closed' discussion process in which she followed his recommendation without questioning it in detail. In retrospect it is easy to say that between doctor and patient, the wrong 'call' was made in undertaking this surgery close to a projected important trip, but on balance conclusion is that the information provided was not adequate for the circumstances. The Commissioner asks that any deviation from an acceptable standard be assessed as mild, moderate or major; in my view this would be between mild and moderate. The doctor's obligation is to try to remain objective in such a situation, difficult though this may be.

3. *The information [Dr B] provided to [Mrs A] about the risks of the proposed surgical procedures, particularly the risks of the surgery performed on 26 June 2007.*

[Dr B's] letter states that he discussed deep venous thrombosis, the difficult nature of the surgery, possibility of prolonged surgery, and possibility that the aim of the surgery (correction of the lymph leak) might not be achieved. I take this to refer to the last operation. In the interview transcript, [Mrs A] is asked about discussion of risks in relation to the first (22 May) operation, and answered that there was no such discussion. Given that this was to be her third exploration of the groin, it would be necessary to discuss risks specifically, in that such surgery can at times be very difficult. Omission of such a discussion is less than adequate care, and, if correct, would be viewed by peers with moderate disapproval. In relation to the 26 June operation, [Mrs A] does not recall any specific discussion of risks, only a brief conversation during a dressing of the wound, at a time when [Mrs A] was emotionally upset. Neither [Mrs A nor Mr A] felt they had been advised of any risk of haemorrhage. It should be noted, however, that research has shown that patients retain only a part of what information is given at a consent discussion, so this question must remain

somewhat open, although it does appear that the consent process was less than adequate. [Mrs A] should have been told of a risk of bleeding.

Standard of care

Please also detail your reasons for confirming or amending your opinion on the standard of care [Dr B] provided to [Mrs A], including.

1. Whether [Dr B] took sufficient steps to avoid the complication that occurred

I will take 'the complication that occurred' to refer to the haemorrhage which occurred at the 26 June operation. The main ways in which such a complication could be avoided are to recognise the difficult nature of the surgery in advance, to allow sufficient time for the procedure, to use a relatively 'defensive' operating technique (in the sense used in the term 'defensive driving', not 'defensive' in the legal sense), and to abandon the procedure or ask for help if progress is not being made. I would confirm the view expressed in my previous report, that these issues cannot be assessed on the basis of a single case with this outcome. If the Commissioner were aware of other operative problems in [Dr B's] practice, he could choose to review cases as a group.

2. Whether [Dr B] gave sufficient consideration to the resources available at [the Private Hospital] given the potential for difficulty/complication

Probably not. [Dr B] may have underestimated the potential difficulty of the surgery; given that the first (22 May) procedure took 4 hours (according to the anaesthetic record) considerable difficulty should have been expected with subsequent procedures. Again, it is not possible to make a definitive judgement on the basis of one case, but the sum of the evidence available leads me to believe that [Dr B] did make an error of judgement in underestimating this case, and this judgement would be viewed with a mild level of disapproval by surgical peers.

3. Whether [Dr B] should have undertaken the surgery given the restrictions on his practice and his 'benign essential tremor'

The restrictions on [Dr B's] practice at [the Private Hospital] were not known to me at the time of writing my first report. These restrictions are stated by [the] Hospital Manager, to be that [Dr B] does not undertake any bowel or major surgery at [the Private Hospital]. What could be defined as major or otherwise would have been up to [the Private Hospital] to define with [Dr B]; [Dr B] states that he has done revision groin surgery many times without problem, and this can be accepted, but my own experience, which includes a large volume of major surgery, is that repeat surgery for veins in the groin can be very technically demanding and must be approached with that in mind. Given that there was a restriction on his practice and the potential difficulty of the case, [Dr

B] would have been wise to discuss the surgery in advance with [the Private Hospital], and I would view his omission of this with moderate disapproval.

Regarding the 'benign essential tremor', this can certainly be compatible with safe surgical practice. I have attempted to search the surgical literature for information on this but have not been able to come up with useful recommendations. A surgeon with a medical or health issue, particularly a visible one, would be wise to place himself/herself under occasional medical review; [Dr B] does not comment on this.

4. *Whether [Dr B] (or the anaesthetist) should have used the universal blood product available at [the Private Hospital]*.

It is recorded in the [the Private Hospital] notes (I take this to be by the anaesthetist) that the haemoglobin (Hb) dropped to 40g/l. My own practice would be to recommend transfusion when the Hb is 60 or below, and this is supported by published reviews of transfusion practice I have located. This would be modified by knowledge of whether the source of bleeding had been corrected, and how far away the matched blood was, i.e. if the bleeding had been controlled, the matched blood was 10–15 minutes away or less and the patient previously fit and without cardiac disease, waiting would have been acceptable. I cannot determine these facts from the information provided. If the Commissioner needs more specific advice on this issue, it could be sought from a Specialist Anaesthetist."

[1] Schulman, C, Cohn, S 2004. Transfusion in surgery and trauma. Critical Care Clinics 20: 281–297.

[2] Goodnough, L 2007. Transfusion triggers. Surgery 142: S67–S70.