Neurosurgeon, Dr B

A Private Hospital

A Report by the

Health and Disability Commissioner

(Case 04HDC11462)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Mr A	Consumer
Dr B	Provider/ Neurosurgeon
Mr C	Provider/Chief Executive Officer, a private hospital
Dr D	General Practitioner
Ms E	Nurse
Dr F	Neurosurgeon
Dr G	Chairman of the private hospital Medical Advisory Committee

Complaint

On 6 July 2004, the Commissioner received a complaint from Mr A about the services provided by Dr B and a private hospital. The following issues were identified for investigation:

- *The adequacy and appropriateness of the care and treatment provided by Dr B to Mr A in December 2003, including:*
    - *the appropriateness of the choice of operation performed on 18 December 2003, namely, a posterior lumbar interbody fusion between lumbar vertebrae L3 and L4 (PLIF);*
    - *the adequacy of the standard of care provided during the PLIF procedure.*
- *The adequacy of response by the private hospital to Mr A's concerns following the PLIF performed on 18 December 2003.*

An investigation was commenced on 3 November 2004.

Information reviewed

Information from:
- Dr B
- Mr A
- A Private Hospital
- A District Health Board
- Medical Council of New Zealand

Independent expert advice was obtained from Dr Nicholas Finnis, neurosurgeon.

Information gathered during investigation

Background
Mr A, aged 40, was referred to Dr B, neurosurgeon, by his general practitioner, Dr D, as he had back pain that was interfering with his ability to lead a normal life. In a letter to Dr D dated 24 September 2003, Dr B described his diagnosis of a "right L3 root lesion which seems to be caused by an L3/4 spinal stenosis precipitated by a spondylolisthesis at L3 level due to a Pars intra-articularis defect".

Dr B outlined the options for managing the problem. These included decompression of the nerve root alone, a posterior lumbar interbody fusion, and a posterolateral fusion with pedicle screw instrumentation. Based on the findings in the MRI scan, Dr B stated:

> "I would favour a posterior lumbar interbody fusion [PLIF] and nerve root decompression for this problem and suggested that would carry a very good chance of stabilising the level so that there was no recurrent nerve root compression and would have a very low risk of creating any nerve root damage … something less than 5%. Of that the likelihood of permanent nerve root damage would be less than 1%."

Dr B did not order preoperative dynamic X-rays because he considered that there were adequate indications for a PLIF operation.

18 December 2003 — day of operation
On 18 December 2003, Mr A was admitted to a private hospital for the PLIF operation recommended by Dr B.

Dr B described the surgery in his letter to ACC, dated 28 January 2004:

> "When the lumbar spine was opened, the first problem that was encountered was excessive bleeding at the site of the spondylolisthesis. The normal measures were used to try and control this but all the bone surfaces appeared to be bleeding quite briskly.
>
> It was extremely difficult to localise the disc and eventually needle localisation was used to try and steer us into the disc space. Despite the fact that we appeared to be in exactly the right position to enter the back of the disc, osteophytic and bone-like tissue was encountered and it was quite difficult to open the disc space itself. Eventually the disc was opened to reveal some residual oedematous disc material of a highly degenerate nature but the bone on either side of the disc was quite weak. The standard [PLIF] kit was then used with the sleeve to protect the nerve roots from the drill, but this was extremely difficult to insert because of the anatomical problems with the disc space. Eventually a graft site was prepared for the interbody fusion cage even though that site impinged on the disc space itself and, therefore, it was difficult to set the cage home. The sleeve retractor was removed and the hand held retractor inserted to facilitate the introduction of the screw cage and retract the lumbar theca (containing the roots forming the cauda equina) while a second attempt was made to insert the fusion cage into the graft site. When this did not bind and had to be withdrawn, an inspection of the cavity was carried out. It was found that the lumbar theca (presumably containing cauda equina within it)

had prolapsed into the screw hole from behind the hand held retractor and had been compromised by the second attempt to insert the screw cage. At this stage I realised that there was danger not only of having crushed in part the lumbar spinal roots but also of doing more damage should the attempt to insert a cage be persisted with. The theca appeared intact and appeared to have a CSF [cerebrospinal fluid] leak but there was no evident hole to be sutured. I therefore carefully retracted the theca and enclosed roots out of the way so that I could gain access to the graft site and used the bone chips that we had left to pack the cavity in the vertebral body of L3 and the disc space of L3/4 which had been cleared of disc material.

I then withdrew the retractor and attempted to identify any obvious breach in the lumbar theca but none was visible and so closed the wound in layers and the patient was woken up."

Ms E, the scrub nurse, assisted Dr B during the operation. She recalled:

"[Dr B] stated 'there was a dural tear'. I asked if he wanted … to suture it. He said it wasn't necessary.

There was considerable blood loss … approximately 900mls … including some CSF.

While I was filling the cage with bone graft which took a few minutes [Dr B] continued some reaming. I was away from the surgical site which meant I wasn't retracting the nerve.

[Dr B] attempted to insert the cage — this was unsuccessful. He decided to use bone graft only, and not the cage.

I was required to remove the bone from the cage which meant I was away from the surgical site again for a few minutes.

[Dr B] commented on:

- the blood loss — I asked if a drain was necessary and he said no;
- nerve damage. Said he was very anxious about this. The nerve did look compromised/frayed in part."

Mr A returned to the ward at 7.05pm. The progress notes record that he was numb in both feet, being unable to feel his toes being touched. The recovery room record states:

"Nursing staff asked [Dr B] whether any special consideration re movement and position — surgeon said no special consideration needed."

Mr A was reviewed by Dr B at 8.15pm. He recorded in the progress notes:

> "Good movement of legs.
> Minimal ankle and toe movement.
> Sensation intact.
> Plantars intact and sensitive. Perineum feels OK.
> Catheterize if necessary overnight.
> I will check [in the morning]."

The nursing staff on night duty recorded that Mr A had "diminished movement" in his feet and toes, although he had some movement in his legs. However, Mr A recalls that he had no voluntary movement in his legs:

> "I recall having to use my arms / hands to bend my legs, and have others assist [to] place my legs on the pillows beneath them. 'Spasmodic' involuntary movement may have occurred."

The care plan completed on 18 December states, in reference to postoperative mobilising, "up with brace, if ordered by surgeon".

19 December 2003 — first postoperative day
Dr B reviewed Mr A at 9.15am on the morning of 19 December. He recorded:

> "Good in himself
> Moving legs and knees well. …
> Perineal sensation absent
> Can feel catheter movement
> Situation explained fully
> Needs back brace lumbar support
> Try catheter out tomorrow am."

At 2.00pm the nursing staff recorded that a "moderate ooze" was visible under the wound dressing and that Mr A had stood with assistance from the physiotherapist, using a frame for support and wearing a brace. Dr B stated that normal practice for mobilisation following a PLIF operation is supervised mobilisation starting three to four days after surgery, and that Mr A was mobilised on the first day postoperatively since "there was no reason to believe [Mr A's] back was unstable", as the "bony work that would be done to site the fusion cage was not carried out". Dr B stated that there is no standing order at the private hospital for nursing and therapy staff covering the postoperative period of a PLIF operation.

Mr A stated:

> "I had very good upper body strength and fully supported my body weight [with] my arms. My legs dangled beneath me with some movement being achieved by a slight 'swing' of the upper body and hips. By lifting each hip, walking was simulated."

At 10.00pm the nursing staff recorded that there had been no change in Mr A's sensation from Dr B's earlier assessment in the morning. It was also recorded that Mr A was stood out of bed once during the evening, and that there was further "ooze" under the wound dressing, which had been renewed from earlier in the day.

20 December 2003 — second postoperative day
Dr B reviewed Mr A's progress on the morning of 20 December:

> "No real change today.
> Some more feeling in ankles.
> Perineal sensation unchanged.
> Catheter to stay until tomorrow.
> Continue gentle mobilisation."

The nursing and physiotherapy record states that Mr A was stood out of bed on three occasions in the morning, and twice in the afternoon/evening, and that he continued to take most of his weight through his arms.

21 December 2003 — third postoperative day
Mr A was reviewed by a physiotherapist, who recorded at 9.40am that he was walked to the shower with the use of a walking frame and assistance from two people.

The progress notes record that at 10.30am the wound dressing was "soggy" with a suspected cerebrospinal fluid (CSF) leakage, and Mr A was complaining of a slightly stiff neck and a headache. A new dressing was applied. Dr F, the on-call neurosurgeon providing cover for Dr B, was informed, and the end of the bed was elevated, with Mr A being placed on bed rest.

Dr F noted that the wound was clean, but that CSF was leaking. He ordered that the foot of the bed be elevated (which had already been done by nursing staff), and recommended a Redivac drain on gravity drainage for two to three days.

Dr B attended at 6.00pm to assess Mr A, and recorded:

> "Brisk CSF leak from back.
> Minimal improvement in sensory and motor function.
> For transfer to [a public hospital]."

The clinical record at 10.00pm states that a pressure dressing was applied, and that CSF was "evident through [the] sutures".

22 December 2003 — fourth postoperative day
Having been maintained on bedrest, Mr A was transferred to the public hospital at 11.15am; prior to transfer, his wound was redressed, with 40–50ml of CSF estimated in the old dressing.

Further treatment and rehabilitation — the public hospital and a rehabilitation centre for assessment and rehabilitation
On 22 and 24 December, attempts were made at the public hospital to control the CSF leak by the use of skin sutures, but on 28 December a surgical repair was performed which resolved the leak.

On 6 January 2004, Mr A was transferred to a rehabilitation centre for assessment and rehabilitation, and was eventually discharged home on 16 February. Further rehabilitation care was provided at a spinal clinic, where Mr A was admitted in May 2004.

ACC medical misadventure claim
Mr A made a claim to ACC for medical misadventure. On 11 March 2004, the claim was accepted as medical mishap. The summary of the medical misadventure report states:

> "ACC has determined that you suffered neurological deficit caused by the spinal surgery on 18 December 2003. There is no evidence that this injury was a result of medical error. The complication of the operation meets the rarity and severity criteria for medical mishap. Therefore, ACC has accepted your claim for medical misadventure."

In reaching their decision, ACC obtained expert medical advice from Dr Graeme MacDonald, neurological and spinal surgeon. He stated:

> "It is recognised as being difficult to guarantee improvement in the level of low back pain following such a fusion procedure, but it would appear that the treatment provided was appropriate, and both the development of the cerebrospinal fistula, which is not particularly uncommon, and the cauda equina injury which is very rare, were complications of this treatment."

Clinical governance at the private hospital
The private hospital is governed by a Chief Executive Officer (CEO) and a Medical Advisory Committee (MAC). The role of the MAC is to maintain an overview of clinical quality and advise the CEO on any relevant issues. Applications for accreditation are submitted to the CEO, who in turn refers them to the MAC for consideration. Under section 7 of the private hospital By-Laws, the CEO has the power to modify, suspend or terminate clinical privileges if there is a risk to patient safety.

Accreditation at the private hospital
The private hospital does not employ medical practitioners, but grants practitioners rights to practise within the hospital, on application. Dr B was therefore not an employee, but an accredited professional with admitting rights to the hospital. Accreditation to practise at the private hospital is governed by the private hospital By-Laws and a letter of agreement for clinical privileges.

Section 11 of the private hospital By-Laws for Accredited Professionals states:

> "Patients will be admitted upon request from an Accredited Professional, except in the following circumstances:
>
> - where such admission might constitute a danger to staff or other patients;
> - where adequate facilities for the proposed management are not available;
> - where proposed treatment or procedure is contrary to the Code of Ethics of the Hospital … ;
> - where admission is specifically refused by the CEO."

Section 18 of the By-Laws states:

> "Fundamental to the maintenance of admitting rights at [the private hospital] is the participation by all surgical and anaesthetic Accredited Professionals in the process of surgical audit. Surgical audit involves the submission of information on morbidity, mortality and complications for each procedure carried out at [the private hospital], plus the compulsory attendance at surgical audit meetings where analysis and interpretation of that data is undertaken. …
>
> Surgical Accredited Professionals are required to complete a Surgical Audit Form for each procedure undertaken by them at [the private hospital]. The forms will include among other things a description of the problem, pre-operative and final diagnoses, length of stay, and any complications peri-operatively or post-operatively. …
>
> It is expected that every surgical Accredited Professional attend all Surgical Audit meetings. … The Surgical Audit Convenor will provide the CEO with:
>
> - A record of meetings held;
> - A register of Accredited Professionals who attended;
> - A list of those Accredited Professionals who have missed three of the last six Audit meetings without giving valid reasons for their absence."

Section 18.6.1 states:

> "The CEO may suspend or terminate Clinical Privileges for those surgeons and anaesthetists who consistently fail to meet the requirements for Surgical Audit, including the completion of data and attendance at meetings."

Standing orders
Section 10.2.1 of the By-Laws states:

> "The responsible Accredited Professional shall … provide in writing, routine Standing Orders to nursing staff which are to be updated and signed annually or more often as requested by the Director of Nursing or Charge Nurse."

Complaint to the private hospital
On 3 February 2004, Mr A wrote to Mr C, CEO of the private hospital, asking for an investigation into the events of his operation of 18 December 2003, and requesting that he be provided with a copy of the investigation report.

On 19 February 2004, Mr C wrote to Dr B:

> "We … discussed that [Mr and Mrs A] have asked me to undertake a detailed investigation of the circumstances, particularly peri-operatively, which led to [Mr A's] present condition. While I have responded to [Mr and Mrs A] with certain information, this would not constitute a detailed investigation. Nevertheless I am compelled to ensure that [the private hospital] is, and is seen to be, providing the highest standards of excellence in care. In this sense it is both a protection on the hospital and for you to ensure that if there are any questions about surgical practice they are addressed appropriately. I am grateful that you are agreeable to involving the hospital's Medical Advisory Committee regarding the next steps. I have written to the Chairman of the Committee, [Dr G], outlining the details of the case and seeking his advice as to what my next steps should be."

In his letter to Dr G, dated 19 February 2004, having outlined Mr A's case, Mr C stated:

> "While I have responded [to Mr A's complaint] with information regarding the observations of nursing staff involved [in his] care, I have stopped short of undertaking a detailed investigation. Nevertheless I am compelled to consider a more detailed investigation for two reasons:
>
> 1. The reputation of the hospital depends on us providing, and being seen to provide, the highest standard of peri-operative care.
> 2. If there is any factor about the case which can be avoided in the future that uncertainty should be eliminated.
>
> I seek the Committee's advice about the appropriate next steps to be taken."

A letter acknowledging receipt of his letter of 3 February 2004 was sent to Mr A from Mr C's personal assistant on 3 March 2004, stating: "You can expect to hear from [Mr C] shortly about the issues you have raised."

On 16 March 2004, the MAC met and discussed Mr A's case. Four recommendations were made:

> "…
>
> 1) A full and frank disclosure of all information relating to this case should be made available to the patient if requested. The committee acknowledges that this might not be possible based on insurer's instructions.
>
> 2) Adverse outcomes are possible in all surgical procedures. It would not be appropriate to request an independent expert opinion in this particular case.
>
> 3) [Dr B] be requested to meet with [Dr G], [an orthopaedic surgeon and a member of the MAC], [the private hospital's Director of Nursing] and [Mr C] to discuss the above case, issues relating to scope of practice, attendance at audit meetings and other performance related matters.
>
> 4) Prior to this meeting, [Dr B] is to provide an audit report of his PLIF operations (procedure numbers and complications) performed at [the public hospital] and [the [private hospital] during the past 5 years.
>
> At this stage the committee recommended that an external investigation wasn't required."

Mr C wrote to Mr A on 19 March 2004. Mr C concluded:

> "[I] am satisfied that, apart from the surgical complications which have been described by [Dr B], the nursing care was of a high standard and as detailed in the Operation Note, Recovery Note and Nursing Progress Notes that have been supplied to you.
>
> I note that you have sought a full independent investigation into the surgery. As [the private hospital] was a part of the delivery of the care to you, it is not possible for us to undertake an independent investigation. However I need to point out to you that the Health and Disability Commissioner is available to undertake an investigation into whether or not your rights … have been breached."

Dr G wrote to Dr B on 25 March 2004, advising him of the four recommendations from the MAC, and that he would be in touch to arrange a meeting (as stated in recommendation 3).

On 8 April 2004, a meeting was held under the auspices of a special meeting of the sub-committee of the MAC. Present at this meeting was Dr B, Dr G, Mr C, an orthopaedic surgeon and the Director of Nursing. Detailed minutes were taken of the meeting, which lasted from 7.00pm until 8.10pm.

The minutes of the meeting record that after he described the incident, Dr B was asked by the Director of Nursing about the surgical assistant for the procedure, who was the scrub nurse:

> "[The Director of Nursing] questioned if there was satisfactory assistance provided during the procedure. [Dr B] advised yes. [Mr C] asked about the use of dedicated surgical

assistance, whether or not this would be the case in [the public hospital] and if so why no dedicated assistant was in attendance at [the private hospital]. [Dr B] replied that having had this experience he would not do the [operation] again without a dedicated assistant.
…

[Mr C] queried whether it was appropriate to be retracting the nerves from the surgical site with one hand and working on the disc space with the other hand as was the case when the scrub nurse was away from the table working on the graft. [Dr B] said that when the fixed retractors are in position it is possible to work around the disc space without having to hold the retractor. On the second attempt to evacuate the disc space he was having trouble with the fixed retractors and used a hand held [retractor]. It is at this point he believed he probably should have waited for the scrub nurse to come and assist. …

[The orthopaedic surgeon] respectfully advised that there was a perception amongst the medical fraternity that [Dr B] was having a little more bad luck than one should. … [Dr B] advised that he had been worrying about this sort of thing and that in the first half of 2002 he noticed an increase in his complication rate which was not attributable to any particular changes in surgical technique. … [Mr C] asked if he had talked to others about this trend and [Dr B] advised he had done so with other colleagues around the country through peer review process and the Public hospital audit.

[Dr G] asked if [Dr B] thought he should continue to do PLIFs. [Dr B] said it is difficult to know how to react to one case but he thought that if it was to arise again he definitely would like another consultant to assist."

At the meeting, Mr C requested that Dr B provide details of his dural tear rate from the surgical audit process.

On 14 April 2004, Dr G wrote to Mr C, and sent a copy of the letter to Dr B. Two recommendations from the sub-committee of the MAC were communicated to Mr C:

"Recommendation 1:

[Dr B] must be assisted by a Specialist Neurosurgeon or Orthopaedic Surgeon (with experience in Instrumental Spinal Fixation Surgery) when performing Instrumental Spinal Fusion procedures at [the private hospital].

Recommendation 2:

[Mr C] appoints two Surgical Specialists to audit the Spinal procedures performed by [Dr B] at [the private hospital] during the past 5 years. They should also assist and observe his surgical practice for the next 6 months and make a formal report to the Medical Advisory Committee by the end of 2004."

These recommendations were taken to the private hospital Board. Recommendation 1 was amended to state:

> "[Dr B's] scope of practice be restricted to exclude Instrumental Fusions pending the outcome of the audit mentioned in recommendation 2."

The amended recommendations were accepted by the MAC on 12 May 2004 and were subsequently agreed to by Dr B.

On 16 June 2004, an "in committee" session of the MAC took place to discuss Dr B. The minutes record:

> "It was agreed that a combined meeting with DHB and other representatives take place as soon as possible. [Dr G] (as Medical Advisory Chairman) and [Mr C] (as [the public hospital] CEO) would be attendees at such a meeting. [Dr B] should not be present at an initial meeting.
>
> Close observation of [Dr B's] practice over the next six months is recommended. At this point just reinforce recommendation 1 and 2 from the last meeting."

Dr F agreed to assist with Dr B's operations.

At the meeting of the MAC on 13 July 2004, Dr G stated that he had spoken with the DHB and other representatives regarding the proposed meeting, and that he planned to hold it "next week".

At the following MAC on 15 September 2004, Dr G reported that the expected meeting with DHB and other representatives "had not taken place but he would organise".

At the next MAC on 13 October 2004, Dr G reported that the meeting had still not occurred.

At a meeting on 5 November 2004 a meeting took place involving Dr G and three other representatives. Dr G wrote to the meeting chair on 22 December 2004:

> "The purpose of the meeting was to discuss concerns relating to [Dr B's] clinical performance.
>
> We unanimously agreed that the appropriate course of action was to refer our concerns to the New Zealand Medical Council with the expectation that the Council would undertake a clinical competency review. …
>
> Has the Medical Council been formally notified of the decision reached at our meeting?"

On 10 November 2004, Dr G reported to the MAC:

> "The meeting [on 5 November 2004] discussed what to do about general concerns regarding [Dr B's] competencies and it has been decided to discuss this directly with [Dr B]. The Medical Council will also be contacted following the meeting with [Dr B] to table concerns. …
>
> [Dr B] has not responded to requests for audit data regarding his PLIF outcomes and dural tear rate, and [Mr C] will write to him reminding him of the need to do this."

On 6 January 2005, the DHB Chief Medical Officer wrote to Dr G in response to the letter sent to the meeting chair on 22 December 2004. He stated:

> "[T]here were … potential issues that were raised at that meeting that has prompted me to ask the Clinical Leader of Neurosurgery … to at this stage informally review the audit data of the department.
>
> It needs to be clearly stated that at this stage [the District Health Board] would not be in a position to support an approach to the Medical Council to undertake a clinical competency review of [Dr B's] work."

Mr C wrote to me on 16 March 2005. He stated:

> "You will recall … my undertaking to send you the report of [Dr F] following his observation of [Dr B's] technique."

Dr F's letter to Mr C, dated 19 January 2005, stated:

> "I have had the pleasure of assisting and observing [Dr B] in nine operations, eight of which were on the cervical spine and one was on the lumbar spine. All the operations were done using the generally accepted techniques and I found [Dr B] technically proficient.
>
> I do not recommend any general or specific remedial action."

In his letter of 16 March 2005, Mr C further stated:

> "The very few spinal fixation procedures undertaken by [Dr B] does not give us sufficient information to determine [Dr B's] competency to undertake these procedures and therefore we have taken the step of reducing his scope of practice to exclude spinal fixation surgery. In doing so we make no judgements about his competency to undertake this procedure and he is still credentialed to perform discetomy/laminectomy surgery at [the private hospital]."

On 1 April 2005, the Professional Standards Manager at the Council advised me that the Council had not received formal notification to perform a clinical competence review of Dr B's practice.

My Office wrote to the Chief Executive Officer of the DHB on 13 June 2005, requesting details of the audit performed of Dr B's practice. In a letter dated 22 June 2005, the Chief Executive Officer declined to provide the information, on the basis that the audit was a protected quality assurance activity under the Health Practitioners Competence Assurance Act 2003. He stated:

> "I note your concern that without reference to the audit data you will be unable to determine whether or not you need to take this matter further. However, I would like to inform you that [Dr B] is currently undergoing a Medical Council of NZ competency review initiated by [the District Health Board's Chief Medical Officer] and [another represntative]."

In a letter dated 19 August 2005, the Registrar at the Council, advised:

> "At its meeting held on 22 June 2005 Council resolved that there would be a review of [Dr B's] competence to practise medicine in the vocational scope of neurosurgery.
>
> This review will be a broad based assessment covering diagnosis, patient management, surgical skills and communication/interaction with patients and colleagues."

Requests to attend surgical audit — the private hospital
On 19 February 2004 Mr C wrote to Dr B:

> "I have been analysing the surgical audit compliance and attendance. I note that your compliance with surgical audit paper work is more or less up to date but that you do not attend the bi-monthly surgical audit meetings. Given circumstances of the [Mr A] case I feel that it is politic that you do so."

The minutes of the meeting held on 8 April 2004 state:

> "[L]ast Tuesday's Surgical Audit meeting was the first one [Dr B] had attended (at [Mr C's] request) in the last 18 months or so. As this was a requirement for ongoing clinical privileges at [the private hospital] [Mr C] advised [Dr B] that it would be prudent to maintain his attendance."

In his letter dated 11 May 2005, Mr C stated:

> "During [the MAC meeting of 8 April 2004] the issue of dural tear rates was raised and a further request was made by [Dr G] … for [Dr B] to supply dural tear rate data from the Surgical Audit database. By the end of last year that information had not been provided and on the 22nd December I wrote to [Dr B] reminding him of the request to do so. To date I have not had a reply and I shall be following this up with [Dr B] this week."

Mr C informed my Office on 8 August 2005 that Dr B had still not provided this information, and that he had informed Mr C that the audit data held by the DHB was incomplete, but he was intending to remedy this.

On 15 August 2005 Dr B provided information on the dural tear rates that had been requested of him by Mr C on 8 April 2004. As only one dural tear appeared on the surgical audit database, Dr B reviewed all the relevant clinical notes to ascertain that there had in fact been four dural tear cases at the private hospital.

Dr B provided the following data for his spinal operations at the public hospital and the private hospital:

Combined figures for the public and private hospital:

- 147 spinal operations, with 7 CSF leaks/dural tears;

Separate data:

- The public hospital: 99 spinal cases from 1 October 2003 until 30 July 2005, 3 CSF leaks/dural tears.

- The private hospital: 48 spinal cases since 1995, 4 dural tears.

Dr B provided details of 15 PLIF patients who had been treated at the public hospital from June 1998.[1] On 8 April 2004 Dr B stated that he had undertaken 12 PLIF procedures "over the past five or so years", with ten performed at the public hospital and two at the private hospital.

Independent advice to Commissioner

The following expert advice was obtained from Mr Nicholas Finnis, neurosurgeon:

> "I have been asked to provide an opinion to the Commissioner on case number 04/11462.
>
> You have enclosed with your request the document 'Commissioner's Guidelines for Independent Advisors' and I confirm that I have read and will agree to follow the guidelines.
>
> My qualifications are: Bachelor of Human Biology 1980 and Bachelor of Medicine and Bachelor of Surgery 1983. I qualified as a General Surgeon and became a Fellow of the Royal Australasian College of Surgeons in 1992. I continued to train in Neurosurgery and gained my fellowship in Neurosurgery for the Royal Australasian College of Surgeons in 1997. I have had post-fellowship training at Frenchay Hospital, Bristol U.K. with further specialist training in complex spinal surgery. I have been a Consultant

[1] Mr A was on the list of PLIF patients treated at the public hospital that Dr B provided to my Office, counting as the 16th patient on the list.

Neurosurgeon in New Zealand since 1998, working initially at Dunedin Public Hospital and subsequently have taken up a position as a Consultant Neurosurgeon at Christchurch Public Hospital. I work in the private sector with operating rights at Southern Cross Hospital and St Georges Hospital, Christchurch. My sub-specialty of interest in neurosurgery is complex spinal surgery. I have experience and training to practice all techniques of lumbospinal fusion including anterior and posterior interbody fusion as well as lumbar posterolateral fusion with pedicle screw instrumentation.

My instructions from the Commissioner are to address the issues around the complaint.

The adequacy and appropriateness of the care and treatment provided by [Dr B] to [Mr A] in December 2003, including:

- the appropriateness of the choice of operation performed on 18 December 2003, namely a posterior lumbar interbody fusion between lumbar vertebra L3 and L4 (PLIF).

- the adequacy of the standard of care provided during the PLIF procedure.

This report is based on the information from the documents sent to me by the Commissioner. I have read and become familiar with the content of the supporting information as follows:

Supporting Information

1. Response by [Dr B] to complaint, with enclosures (page 1 to page 23).

2. Notification of investigation letter, including complaint (page 24 to page 29).

3. Documentation from [the private hospital], investigating the matter (page 30 to page 38).

4. Clinical record (page 39 to page 82).

[Dr B] has written to [Dr D], General Practitioner, on 24 September 2003 giving his opinion on the management of [Mr A] following his consultation with the patient. In this letter he has stated that his problem is caused by an L3/4 spinal stenosis contributed to by a spondylolisthesis at L3. [Dr B] states that he has discussed the management of the problem with [Mr A]. He states that he has outlined when most people proceed to operative intervention and that is when the pain is significant enough to interfere with aspects of their lives. [Dr B] has also stated options in surgical management including decompression of the nerve root alone, a posterior lumbar interbody fusion, and a posterolateral fusion with pedicle screw instrumentation. He has mentioned the advantages and disadvantages of these various operations. He has stated that in his opinion he felt that the posterior lumbar interbody fusion technique following the decompression would be the most appropriate. He has included information with regards to complications, including nerve root damage which he felt was less than 5%. He felt the

likelihood of permanent nerve root damage would be less than 1%. He felt that there was no reason to delay operative management and felt it was reasonable to go forward for this. You have included with [the] documentation the booking form for [the private hospital], and in this a consent form is included. [Mr A] has signed the consent form for a posterior lumbar interbody fusion at the L3/4 level to be performed by [Dr B]. This consent form has included, amongst other statements, that the patient has understood the nature, effects and common complications of the procedure and that other options available to the patient have been discussed.

Information regarding the hospital admission at [the private hospital] for the purpose of the operation is given in the hospital notes, as well as further documentation subsequently from letters by [Dr B] and statements given by the nurses in theatre and recovery. Mr A was pre-admitted to the ward at [the private hospital] on 17 December 2003 and was seen by [Dr B] at this time and the consent form signed. On 18 December he was admitted to the ward at 13:30 hours and went to theatre with the commencement of the anaesthetic for the operation at 15:00 hours. [Dr B] performed the operation which he titled: 'posterior lumbar decompression and attempted cage fusion' and the anaesthetist was […]. [Dr B] has written in the notes the following operative note for the procedure:

> 'Longitudinal incision L3,4,5.
>
> L3, 4, 5 space marked. Resection of (very) weakened lamina and facet joints extended to allow cage to be inserted. Retractor used to isolate (nerve) roots. Wedge introduced into disc space — opened up. Heavily calcified and difficult to open disc space. Disc space identified at lower edge of cavity and drill introduced.
>
> Hole drilled for cage — more disc material removed.
>
> Cage introduced but did not bind in disc space.
>
> Removed and hole explored.
>
> Retractor reintroduced and cage reintroduced but did not bind.
>
> Withdrawn — CSF in wound.
>
> N(erve) roots inspected — dura breached but unclear actually when.
>
> Roots appeared in continuity.
>
> Cavity packed (with) bone chips and disc space also packed.
>
> Closed in layers.'

[Dr B] has subsequently provided further detail about the operation in his letter for the Medical Misadventure Unit on 28 January 2004. [Dr B] found a number of problems during the course of the operation. [Dr B] found excessive bleeding which appeared to be coming from the bone surfaces. He also found it difficult to localise the disc space and an

image intensifier was brought in to help with this. Despite the localisation the instrumentation was placed over the vertebral body, and from the minutes of the special meeting of the sub-committee of the Medical Advisory Committee held at [the private hospital] on 8 April 2004 it is stated 'between the needle and putting the spacer through, the spacer must have gone proximal to the disc space.' [Dr B] had difficulty in opening up the disc space itself and encountered largely osteophyte and bone-like tissue and he did find some oedematous disc material. [Dr B] had problems with proper positioning of the operating sleeve used to protect the surrounding structures including the nerve roots. [Dr B], in his letter of 28 January 2004, states that he thought that this was because of difficulty related to the anatomical problems of the disc space. In the minutes of [the private hospital] Medical Advisory Committee it is stated that the instrument was placed over the vertebral body itself instead of the disc space.

[Dr B] states that he prepared the graft site through the operative sleeve and prepared the cage to insert into this. He stated 'it was difficult to set the cage home' and in his operative note states that the cage did not bind into the disc space. At this stage the operating sleeve was removed and to re-insert the cage again he used a hand held retractor to retract the lumbar theca. Again he found that the cage did not bind and this was withdrawn to inspect the cavity. [Dr B] states in his operative notes that on withdrawal of the cage there was CSF in the wound. He states that the dura was breached and nerve roots were visible. [Dr B] states that the nerve roots appeared in continuity in his operative note but in his letter was concerned about having crushed the lumbar spinal roots. In the report by [Ms E], scrub nurse, it is stated that [Dr B] commented that there was nerve damage and he was anxious about this. It is stated that the nerves did look compromised and frayed in parts. In the report by [a circulating nurse], she says that [Dr B] said there had been a dural tear and that he was concerned that there may have been some nerve damage. Because of ongoing concern of further injury to the nerve roots [Dr B] did not attempt to continue with the insertion of the cage for the purpose of the fusion. He states at this stage in his operative note he packed the cavity with bone chips and that the disc space was also packed. [Dr B] did not identify any obvious breach in the lumbar theca and no formal repair could be attempted. It is stated by the scrub nurse, [Ms E], that Gel foam was used prior to closure.

During the course of the operation [Dr B] was assisted by the scrub nurse. This was […] for the initial part of the operation but later [Ms E]. [Ms E] states in her report that [Dr B] was continuing the operation with reaming while she was filling the cage with bone graft. During this time [Dr B] had removed the operative sleeve and was holding the hand held retractor himself.

The operation started with the anaesthetic at about 15:00 hours and finished at about 17:30 hours when he was in recovery. The operative time therefore was about two and a half hours including the anaesthetic. The nursing intra-operative record records blood loss of approximately 900 ml. 3 litres of Ringers lactate solution was given and the blood pressure and pulse during the course of the operation was satisfactory. When the patient was awake in recovery, [Dr B] states in his letter of 28 January, that he had initially partial loss of sensation in the lower lumbosacral segments but it was difficult to be sure

about the extent of the nerve injury. In the recovery room record the nurses have stated that the patient felt the feet to be very heavy and tight. The report of […] states [Dr B] visited the recovery two to three times, and that of [Ms E] states that [Dr B] was with the patient in recovery for some time and spoke to [Mr A's] wife. The recovery room record states that the nursing staff asked [Dr B] whether there were any special considerations particularly about movement and positioning and that he said that there were no special considerations needed. In the report from [the recovery staff nurse], she states that [Dr B] was asked if special neurological observations or nursing instructions were required and he stated that none were required at this stage. In the report by [a second recovery staff nurse], it was stated again that [Dr B] did not feel that special considerations were required and no neurological observations were necessary. [The second recovery staff nurse] states that at 19:00 hours there was no noticeable ooze or swelling at the operative site. [The private hospital] notes state that the patient returned to the ward at 19:05. It is recorded by the nurse that he felt numbness in both feet and he was unable to feel his toes being touched. There was a slight ooze from the dressing. At 20:15 hours [Dr B] reviewed the patient on the ward and mentioned he had good movement of his legs but minimal ankle and toe movement. Sensation was intact. He records 'plantars intact and sensation in the perineum feels okay'. His plan was to check him further in the morning. The nurses overnight have recorded that numbness had persisted and there was diminished movement in the feet and toes.

[Dr B] reviewed [Mr A] on 19 December 2003 at 09:15 hours. He states that he was moving his legs and knees well. Sensation was reduced in the right L5 and S1 distributions and there was no toe movement. On the left there was partial L5 and absent S1 sensation and movement was absent on the feet, toes and ankles. Perineal sensation was absent but he could feel catheter movement. [Dr B] stated that he explained the situation fully. [Dr B] stated that he needed a back brace for lumbar support and to try catheter removal the following morning. It is stated in the nursing record on 19 December 2003 at 14:00 hours that [Mr A] mobilised to the standing position with a physiotherapist and nurse. A brace was used. Moderate wound ooze was recorded at 14:20 hours. The physiotherapy input on 19 December 2003 also records that he was stood with the frame.

[Dr B] reviewed the patient on 20 December and recorded that there was no real change. He had some movement in his ankles. Perineal sensation was unchanged. He felt that the catheter should stay in and that he should continue gentle mobilisation. Motor and sensory abnormalities were recorded during the day by the nursing staff and physiotherapist. [Dr B] records in his letter of 28 January 2004 that during his care in the ward it became evident that there had been more serious injury to the nerve than originally had been apparent.

On 21 December 2003 it is recorded by the physiotherapist at 9:45 hours that [Mr A] was mobilised and stood by the bed and walked to the shower with a frame and two people to support him. At 10:30 the nurses have recorded the suspicion of CSF leakage and that [Dr F] (neurosurgeon covering [Dr B]) was notified. Following this the patient was lying prone in the bed with one end elevated. [Dr B] reviewed the patient at 18:00 hours and confirmed the brisk CSF leak from the back. He also felt there was minimum

improvement in sensory and motor function. At this stage he arranged transfer to [the public hospital]. In his letter of 28 January 2004 he states that because his injuries were quite serious requiring more extensive rehabilitation and that as Christmas was approaching the transfer to [the public hospital] was probably more appropriate. In his notes he wished to have EMG and nerve conduction tests as well as probably an MRI scan. The patient's transfer letter by the nurses of 21 December stated that his main problems were that of CSF leak from lumbar fusion wound and diminished sensation of the perineum and lower limbs since surgery. He was however, alert and fully aware of the post-operative complications. [Mr A] was admitted to [the public hospital] on 21 December 2003 and was discharged on 6 January 2004. No notes are available to me during the course of this admission; however, I have a copy of the patient's transfer letter of 6 January. In this letter it is stated that his diagnosis is one of the post-op cauda equina injury and post-op CSF leak. It is mentioned that surgical repair of the CSF leak was required on 28 December 2003. In the discharge letter from [the rehabilitation centre] dated 18 February 2004 […] summarises some of the events as an inpatient in [the public hospital]. She states that initial attempts to control the leak were with skin sutures on 22 December 2003 and on 24 December 2003. Because this was unsuccessful [Mr A] went forward for surgical repair on 28 December. The neurophysiological tests were done on 5 January 2004 and these indicate complete degeneration of L5 and S1 motor nerves and an absence of motor unit potentials in both sides of the anal sphincter (S2 to 4). At discharge to [the rehabilitation centre] the transfer letter states that he had decreased sensation in his lower limbs and perineum and required a frame to mobilise. He had no anal sphincter tone and wasn't continent.

[Mr A] was admitted to [the rehabilitation centre] for rehabilitation on 6 January 2004 and remained there until 16 February 2004. His assessment and progress is documented in the discharge summary put together by the various rehabilitation services on 18 February 2004. […] wrote the medical report and states that he had a cauda equina lesion with complete loss of motor and sensory function below L3. … Further details of his progress is given in the summary by the social workers, occupational therapists, continence therapists, psychologists, physiotherapists, and the nursing staff.

[Mr A] was transferred to [the spinal clinic] following discharge from [the rehabilitation centre]. I have no documentation with regards to the progress during the course of this admission. [Mr A], in his letter to the Health and Disability Commissioner on 29 June 2004, has indicated that it would have been more appropriate to have been transferred to [the spinal clinic] earlier as he perceives the standard of rehabilitation and care given to patients with his problems were better than that that could be provided at [the rehabilitation centre]. […] has responded to this issue with a letter to [the Chief Medical Officer at the District Health Board], on 12 November 2004. In this it is stated that there were many reasons for remaining in [the city] which was initially for close monitoring by [Dr B]. It was felt that during the rehabilitation period [Mr A] progressed quickly and plans were made for discharge with home modification. They also felt that there were relatives in [the city] which may be of support. [Mr A] has stated in his letter of 29 June 2004 that had he known the facilities available at [the spinal clinic] he would not have remained in [the city]. [Dr B] has written a letter on 29 November 2004 to […]stating

that the alternatives for rehabilitation at both [the rehabilitation centre] and [the spinal clinic] were discussed with [Mr A] and his wife. He felt that because it was not clear as to the permanency of the injury, and that because of the surgical issues, initial rehabilitation should be at [the rehabilitation centre]. [Mr A's] progress was to be reviewed and referral to [the spinal clinic] made if appropriate.

[A orthopaedic surgeon] has written a letter to [Dr D], General Practitioner, with comments about his operative management. [The orthopaedic surgeon] states that it is his opinion that screw cage fusion was not the most appropriate way to manage his isthmic spondylolisthesis and that it would be difficult if not impossible to insert two cages at the L3/4 level. He had reviewed the post-operative scans which showed that drilling occurred significantly below the disc which he felt accounted for the unexpected blood loss. He states that he did not understand why formal posterolateral fusion was not performed or why pedicle fixation was not performed. He felt it was unlikely that further surgery would improve [Mr A's] neurological status but that given his significant ongoing back pain consideration should be given for revision of fusion with pedicle fixation.

Expert advice is required on two general questions and seven specific questions regarding the case. From the information given above I am able to give an opinion on the questions proposed.

General questions

1. How many operations would a surgeon need to regularly perform to maintain competence in the PLIF procedure as performed by [Dr B] on 18 December 2003? Please give reasons for your view.

I would consider two to three operations per year sufficient to maintain competence in the PLIF procedure. I would accept this relatively low number in a surgeon who would do a far greater number of standard decompressive procedures such as a discectomy or laminectomy in the lumbar spine. The reason for the relatively low number of procedures carried out to maintain competence is that the technically difficult part of the operation is largely achieving adequate access to the disc space and decompression of the bony structures around this area, such as the facet joints, to facilitate the instrumentation. The decompressive techniques used are identical to those which are used for operations to decompress the spine with disc disease or more general spondylotic processes. The use of the instruments for the purpose of inserting a cage is relatively simple and provided that the steps are followed, is generally straightforward. Two to three operations per year would be sufficient to maintain familiarity with the instrumentation and some of the idiosyncrasies of the technique. [Dr B] had done 12 operations in five years or a little over two per year. I would consider this sufficient to maintain familiarity with the technique. The difficulty [Dr B] had was initially related to access problems. Firstly it was bleeding obscuring his view, and secondly it was difficulty in finding and distracting the disc space. Had these two problems of access been absent then the technique of instrumentation may well have been without inciden[t]. The limitation in making a

judgement of this nature is the purely subjective opinion an answer like this must have given the absence of any stronger data to base this information on.

2. What information should a surgeon give to a patient prior to the operation performed on 18 December 2003? In particular, please comment on information relating to complication rates, likely outcomes and the individual surgeon's own outcome data.

The information given to a patient prior to the operation performed on 18 December 2003 were those which would be sufficient for an informed consent for the procedure. These can be broken up into different parts necessary for the patient to understand his problem, the procedure involved and expected outcome including complications.

A. Diagnosis.
The surgeon should give his opinion on the likely diagnosis of the problem. This should be based on the correlation between the patient's symptoms and various imaging findings. The degree of correlation should be mentioned to the patient so that they are able to appreciate some of the uncertainties involved in this process. If applicable other possible diagnoses need to be discussed if this is likely to be relevant. For the operation of lumbar decompression and PLIF procedure it would be necessary to explain the component of the problem which is of neurogenic origin whereby the decompressive procedure would be necessary. It would be necessary then to explain the component of the problem which is likely due to the mechanical aspects of the problem which is to be dealt with the fusion technique.

B. Treatment options
Following the discussion of diagnosis the options of management should be introduced. For any spinal problem including that which [Mr A] presented with, both conservative and interventional or surgical procedures should be discussed. The conservative approach involves a number of non-operative techniques in the management of lower back pain and other spinal problems. This involves the use of the combination of a number of medical, physical, minor interventional techniques as well as modification of lifestyle in an attempt to control the pain and [minimise] the impact on the patient's life. Surgery should be introduced as an option in management.

C. Indications for surgery
Patients should be advised on the indications to proceed to a surgical approach. This is largely on failure of conservative management which has been optimised for a reasonable period of time. The duration of time would be dependant on the individual factors of the patient's problem. In most situations for chronic lower back pain it would be considered appropriate after about six months to one year of optimal conservative management. In [Mr A's] case he is said to have experienced problems for a period of about two years and according to the letters of [Dr B] on 29 November 2004 and [the orthopaedic surgeon] of 16 September 2004 he appeared to be having considerable problems with this.

D. Surgical Options
The various surgical options should be discussed with the patient. Very often different approaches are possible to deal with the same problem or to deal with different aspects of

the problem. Discussion of the surgical options involves the patient to have some choice in what approach may be better for themselves based on what they feel is their dominant problem. In [Mr A's] case he had both a radicular problem of pain in his leg as well as back pain from a mechanical cause. The approach is therefore one to decompress a nerve root to correct the radicular component and to supplement this with a fusion procedure to correct the mechanical component. A decompressive procedure alone would be acceptable and the advantage of this is a smaller operation that is involved to achieve this, however, it has the disadvantage of not addressing the mechanical component of the problem that is the back pain. Various fusion techniques are possible and this involves either an interbody fusion approached either anteriorly or posteriorly and this may be supplemented with pedicle screw fixation. An isolated posterolateral fusion with pedicle screw instrumentation is also possible following decompression.

E. Operative Technique
A brief discussion of the operative technique should be done and the expected early post-operative course. Information regarding hospital stay, length of time with restricted activity and the likely duration to normal activity should also be indicated. It is important to indicate the length of time off work.

F. Expected Outcome
The expected outcome of the surgical procedure should be discussed with reference to the patient's problem. At this stage it is extremely important to mention about the uncertainty of outcome and to establish realistic expectations of outcome from the patient. In nearly all spinal procedures there is a proportion of patients who will have an unsatisfactory outcome for a number of reasons. The details of this may not necessarily need to be portrayed at this stage however, this can be related to uncertainty of diagnosis and incompleteness of recovery, often more importantly, as well as technical issues. Prediction of outcome for the individual patient is often difficult to make. Outcome of treatment of the radicular component of the problem is often different to that of the mechanical component. General outcome data from the literature may be used and in cases similar to [Mr A's] this may be stated as a favourable response of 90% with a radicular component and about 70–80% for the mechanical component. The individual surgeon may not have accurate figures for their own practice, however, they should mention their own experience with the procedure and certainly if they have limited experience in this and if outcome is less favourable than what is found in reports.

G. Complications
The common complications must be mentioned for the procedure. It is not possible in a consent situation to go over every possible complication that may arise. It is important however, to try and establish with the patient an understanding of various complications which can arise from different aspects of the procedure. Any operation could have problems with an anaesthetic and there are complications which are common to any surgical procedure such as wound infection and post operative haematoma. The complications more specifically related to a spinal operation should be mentioned. In particular, this is injury to the neural elements or its surrounding sac. The rates of injuries to these structures are well presented in the literature and figures can be given to the

patient. The rate of new neurological deficits related to nerve root injury is about 4–15% in most studies (2, 4, 7). Most of these however are transient and function returns to normal within a few months. It is more rare, perhaps about 1%, that injury is permanent. The incidence of dural tears is reported in the literature between 6–15% (2, 4, 7). The long term complications of graft failure and the implications need also be mentioned. This would largely relate to problems of failed fusion and ongoing back pain or instability at that segment. The literature describes well the fusion rates with the interbody technique which is about 90–95% however, this would imply one in ten to one in twenty patients will have problems with the fusion and this needs to be pointed out (1, 2, 4–7).

[Dr B] in his letter of 24 September 2003 to [Dr D], the patient's G.P, has outlined clearly many of the issues mentioned above for the purpose of consent. These issues if understood by the patient should have been sufficient to have made an informed consent. [Mr A] has signed the consent form on 17 December for the operation of posterior lumbar interbody fusion at L3/4. The document states that it has been explained to him and that he understands to his satisfaction the nature, effects and common complications of this procedure. It states the other options available have also been discussed. It also states that other unexpected treatments/procedures are sometimes necessary. I would consider that these two documents indicate that reasonable efforts for proof of consent have been undertaken and that sufficient information has been given to the patient for this purpose.

Specific Questions:

3. Was the choice of operation appropriate based on the information made available to [Dr B]? Please give reasons for your views.

I would consider the operation of L3/4 posterior lumbar interbody fusion appropriate for the problem which [Mr A] presented with. [Mr A] had symptoms of an L3 radiculopathy and a posterior approach is necessary to adequately decompress the nerve root. It was appropriate to supplement this procedure with a fusion given the mechanical back pain experienced and the spondylolisthesis at this level shown on imaging.

The operation of posterior lumbar interbody fusion has been well established and the findings of many recent clinical studies support the use of this as a safe and effective means of achieving lumbar arthrodesis. Most clinical series report fusion rates between 90–96% (1–7) and their use and results are well described in the papers by McCarthy P.C. and Maryland T. (6) and Agazzi S., et al (1). Clinical outcome studies have demonstrated favourable outcome[s] for this procedure for mechanical back pain in 80–90% (1, 4, 5, 7).

Posterior lumbar interbody fusion can be used as a stand alone technique or with supplemental pedicle screw fixation. The need for supplemental pedicle fixation has been an area of some controversy. Biomechanical studies have reported the high degree of stabilisation in the motion segment with the use of cages alone and no significant increase in stiffness was achieved when pedicle screws were added (Brodeke D.F., et al 1997, Agazzi S., et al 1999 (1)). Screw cage fixation has advantages over other interbody cages in being more stable and less subject to migration. The cages impart immediate stability to the spinal motion segment by utilising the tension forces of the annulus by

intervertebral body distraction. The association of distraction/compression further enhanced by threads screwed in the end plates provides the early stabilisation (5). The addition of further bone graft material or additional pedicle screw fixation does not appear to be necessary to achieve early stabilisation, fusion, and a positive clinical outcome. Several clinical studies using stand alone cages placed by a posterior lumbar technique have supported this (2, 4, 5, 7, 8).

The technique of posterior lumbar interbody fusion has certain advantages over the posterolateral fusion with pedicle screw fixation. There is a mechanical advantage to interbody fusion in that bone graft material is placed in the centre of segmental motion so that the lever arm of vertebral motion is the shortest giving the method the greatest theoretical potential for inhibiting motion. This also enables a smaller volume of bone to achieve fusion. The bone graft material is also surrounded by the vertebral body with consistent nutrition from the circulatory bed of the vertebral body spongiosa (7). There are also definite surgical advantages in that much more limited exposure is required to technically fuse the spine. It does avoid the need for extensive muscle stripping exposures with associated paraspinous denervation and atrophy often associated with the posterolateral fusion technique (2). This in general has been shown to be of benefit in the peri-operative course with shorter operative times, less blood loss, quicker discharges from hospital and quicker return to work than other fusion techniques (3). It has also been shown to be more economically favourable than more extensive fusion techniques (8) and there is earlier closure of workers compensation claims than with other techniques (3). There is also an increasing recognition in the role of the intervertebral disc in the generation of chronic lower back pain. The intervertebral disc is therefore becoming more of a primary focus for the management of chronic back pain and supplemental interbody fusion to failed posterolateral fusion has been shown to be beneficial.

Posterolateral fusion with pedicle screw instrumentation provides immediate stabilisation and eventually a solid fusion. This technique is more widely familiar being used not only for degenerative disease, but also the primary technique used for stabilisation for problems arising from neoplastic, infective, and traumatic processes causing instability. Most spinal surgeons therefore are more familiar with the posterior and posterolateral approaches due to their training and experience and therefore have been shown to be more likely to recommend this approach where both approaches may be appropriate (6). The very rigid immobilisation imparted by pedicle screws is not necessary for many degenerative problems.

Spondylolisthesis of Grade I has not been considered a contra-indication of stand alone PLIF cages. Spondylolisthesis of Grade I or less was accepted within the selection criteria used in the 'Investigational Device Exemption (IDE) Study' for posterior lumbar interbody fusion methods (7). In the study published by Kuslich S.D., et al (4) on the use of cages for lumbar interbody fusion 12% of 947 patients had a spondylolisthesis. Patients with spondylolisthesis were also included in the studies by Elias W.J., et al (2) and Matge G., et al (5).

I would not consider that the L3/4 level [is] a contra-indication for the posterior lumbar interbody fusion technique. [The orthopaedic surgeon], wrote on 16 September 2004 that he felt it was difficult, if not impossible, to insert two cages at the L3/4 level. This has not been the experience of others. In the study by Elias W.J., et al (2) looking at the outcome of 67 patients, of these nine were inserted at the L3/4 level and of these three at the L2/3 level. In the report by Matge G., et al (5) he describes a case (case 2) where two cages were placed at the L3/4 level and includes in his paper a photograph of this. In the series reported by Agazzi S., et al (1) he mentions of two patients out of 84 which required fusion at the L2/3 level.

In conclusion I would support that the use of stand alone L3/4 interbody cages placed by the posterior technique for the purpose of fusion and that it was an appropriate choice for the management of [Mr A]. The posterolateral fusion with pedicle screw instrumentation would have been another option however, the advantages of a posterior interbody fusion technique as described above are such that a surgeon familiar with the technique would be certainly able to advise this.

4. Were the appropriate investigations performed pre-operatively? Please give reasons for your views.

The information supplied makes it difficult to answer this question accurately. Two documents from the supporting information make reference to the pre-operative pathological changes in the spine. Both make descriptions which would have been determined from an MRI scan. The first is the letter by [Dr B] dated 24 September 2003 to the patient's G.P. [Dr D]. The second is the letter by Dr B dated 28 January 2004 to the Medical Misadventure Unit. There is no reference of other investigations done although this does not mean they have not been done.

I would consider the minimal investigation required to make a decision on operative management would be the MRI scan which has been done. The MRI scan will show the structure of the vertebral elements, their alignment and any spondylotic changes. The MRI scan will also show spondylotic changes within the disc and any associated end plate changes. The MRI scan can accurately look at the neural elements to determine if there is any nerve root entrapment. [Mr A] had an MRI scan and the description by [Dr B] indicates that there was a Grade I spondylolisthesis at L3/4 with Mobic changes in the end plates of both vertebra. The spondylolisthesis was secondary to a pars interarticularis defect. The MRI scan identified spinal stenosis interpreted as the cause for the right L3 nerve root lesion.

I would have considered it helpful to have included dynamic x-rays of the lumbar spine with views done in both flexion and extension to determine the degree of mobility at the L3/4 level. This would give an assessment of the degree of instability at this level and may help to decide on the appropriate fusion technique, in particular whether pedicle screw instrumentation should be supplemented to aid in the stability. [Dr B] mentioned in his letter of 28 January 2004 that on the basis of the MRI scan he felt the L3/4 level to be fairly stable such that as not to require a full trans pedicular or interlaminar stabilisation

in addition to the posterior lumbar interbody fusion. Also some degree of instability can be assessed indirectly with an MRI scan and some chronic instability must be assumed with a spondylolisthesis. The information available from the static MRI scan is different to what is attainable with dynamic x-rays.

I would not consider lumbar discography to be of any additional help in this situation. The interpretation of the provocative discogram is controversial at best and given the isolated changes at L3/4 as described above, would add little to the decision making with regards to management.

The various studies looking at posterior lumbar interbody fusion have tended to use predominantly the MRI scan for decision making regarding management. Plain x-rays and dynamic X-rays are also used in most studies. Discography is not uniformly used and tends to be used more on a selective basis (2, 3, 4, 5).

From the information supplied, I would consider that the minimal appropriate investigations have been done prior to surgery. I would have considered however dynamic X-rays to have been advisable to collect further information about the degree of stability however, not absolutely necessary given the degree of spondylolisthesis. As mentioned above, some degree of instability can be assumed by the MRI scan and distraction using threaded titanium cages impart some stability to the motion segment.

5. Should any other investigations have been performed pre-operatively? Please give reasons for your views.

I would have considered it advisable to have obtained dynamic X-rays of the lumbar spine, done in both flexion and extension. This would determine the degree of instability at the L3/4 level with more confidence than the static lumbar MRI scan. If excessive instability is demonstrated then this may lead one to favour supplementation of the interbody technique with pedicle screw internal fixation. Dynamic X-rays are used to supplement the MRI findings in the research papers on posterior lumbar interbody fusion (2, 3, 4, 5). Some degree of instability must be assumed with the presence of the spondylolisthesis however, this may be relatively minor, particularly if the anterolithesis is relatively minor (spondylolisthesis Grade I). Given the stability achieved by the distraction and fixation with threaded titanium screws a minor degree of instability assessed pre-operatively may not necessarily imply the need for pedicle screws.

I would not consider discography to be of any help in this case. Interpretation of the results are controversial at best and given his clinical presentation and MRI findings would add nothing to the decision making.

6. Should [Dr B] have opted to discontinue or altered the operation at any stage during the procedure. If yes, please state at what stage, and why? If no, please explain reasons.

[Dr B] made an appropriate decision to abandon the operation when clear complications had arisen resulting in the dural breach and nerve root injury. [Dr B] should have discontinued the operation at this stage, which he did, and his decision at this time

therefore, I would consider appropriate. In review of the operation prospectively with the information available to [Dr B] at the time I do not think it was necessarily necessary to make a decision to abandon the operation prior to this time. It is quite clear from the operative description that the surgery was difficult largely due to visualisation of the disc space and access to the disc once it was identified. Epidural bleeding can often be troublesome however, neurosurgeons are trained in techniques to manage this and this alone, if controllable, may not necessarily mean the operation should be abandoned. [Dr B] recognised the difficulty in identifying the disc space and ordered an X-ray which was appropriate and therefore became happy that the disc space was identified. It appears that the marker may have moved between the X-ray and the insertion of the subsequent instrumentation which [Dr B] was unaware of and therefore could not make an appropriate decision to either alter his technique or abandon the operation at that time. He continued the operation on the assumption that he was in the correct position, which later proved to be wrong and therefore led to further difficulties and the subsequent complication. When the complication arose the appropriate decision to abandon the fusion procedure was made.

In the retrospective analysis of the operation it is clear to see that it would have been appropriate to have perhaps abandoned the operation when difficulties had arisen such as identification of the disc space accurately and entering the disc because of the associated osteophyte abnormality around it. It is therefore easy to assume in retrospect that perhaps the correct decision was to abandon the interbody technique of fusion and perhaps following the decompressive component of the procedure supplement this with a posterolateral fusion with pedicle screw instrumentation. These sorts of statements however, are made in hindsight with awareness of the complication that has arisen and may not have been predictable during the course of the operation.

I do not therefore feel that with the information available to [Dr B] that he necessarily needed to make a decision to abandon the operation although it is well appreciated that the operation was difficult.

7. Should [Dr B] have commenced the planned operation without a dedicated assistant? Please give reasons for your view.

I would not consider it necessary to have commenced the planned operation with a dedicated assistant. The technically demanding aspects of the operation largely involve the decompressive procedure, including medial facectectomy and discectomies which are routinely done without necessity for additional assistance. In most situations the assistance of a scrub nurse is all that is required.

The instrumentation technique for inserting threaded titanium screws for the purpose of the PLIF operation is relative[ly] straightforward where additional assistance outside that provided by the scrub nurse would not normally be necessary.

8. Should Dr B have requested a dedicated assistant or medical assistant at any stage during the operation? If yes, what stage and why? If no please give reason for your view.

In my opinion I would consider it to have been appropriate for [Dr B] to have requested a dedicated assistant when it became apparent that the operation was technically more difficult than what had been assumed pre-operatively. It may well have been appropriate to have called for an assistant when excessive bleeding was encountered as assistance with suction at this time to clear the blood and facilitate better views of the operative site can be helpful. Assistance may also be given for retraction of the theca and nerve root during work on the disc space.

It is possible … the absence of assistance during certain critical steps of this operation … had a direct result on the subsequent complications. In the letter of 28 January 2004 by [Dr B] he indicates that he had difficulty in using the sleeve operating channel which protects the thecal sac and nerve roots and removed this to replace it with a hand held retractor. The hand retractor was held by [Dr B] who used this to insert the screw cage. Retraction of the thecal sac with a hand held retractor simultaneously with the insertion of a screw cage, which would often require some force, would be difficult. The hand held retractor which is supplied with the fusion set cannot fully protect the dura and could have easily been displaced upwards or dorsally, therefore exposing the crossing nerve root and thecal sac to the instrumentation and make it susceptible to injury. It is likely that this was the reason leading to damage of the nerve root and thecal sac following the subsequent insertion of the screw cage.

The confidence a surgeon has to operate without dedicated assistance is highly variable and will differ between surgeons. Some surgeons with their particular operative technique would feel happy in many situations without dedicated assistance and therefore the degree of judgemental error impossible to quantify. It is therefore difficult to determine whether a standard of care has [been] breached. In the prospective analysis it may well be that [Dr B] was happy to continue without an assistant. Clearly in retrospect given the outcome of surgery it would be easy to assume that an assistant would have been helpful. In general therefore I can conclude that it would have been reasonable to have requested a further assistant when the difficulty had arisen however, I do not think this was a breach of any standard medical practice. I would have considered it important, however, to have assistance with the retraction of the thecal sac and nerve root while inserting the screw cage rather than holding this and simultaneously placing the screw. Assistance in this situation could have been done by the scrub nurse.

9. Was [Dr B's] decision not to perform a pedicle screw fixation fusion or a formal posterolateral fusion appropriate? Please give reasons for your view.

The issue of the posterolateral fusion with pedicle screw instrumentation could have been considered pre-operatively when the appropriate type of fusion was being considered and secondly during the course of the operation when it became apparent that an interbody fusion was difficult or not able to be achieved.

The issues regarding the appropriateness in the initial decision making process, that is regarding the suitability for a posterolateral fusion with pedicle screw instrumentation as opposed to the posterior lumbar interbody fusion, was discussed in the answer to

Question 3. In general I would consider it perfectly appropriate to have offered a posterior lumbar interbody fusion. This is based on the suitability of this operation to achieve fusion with positive clinical outcome in patients with the problem as displayed by [Mr A]. A stand alone posterolateral interbody fusion using threaded titanium screws could be expected to achieve fusion rate of up to 96% with a positive clinical outcome of 80% which would match the results of a posterolateral fusion (1, 2, 4–8). The presence of a spondylolisthesis is not a contra-indication (2, 4–7) and the L3/4 level can be used for this technique (1, 2, 5). The advantages of the PLIF operation are well recognised and compared to that of the posterolateral fusion largely is the result of the much less extensive exposure required and therefore avoiding extensive muscle stripping with the associated paraspinous denervation and atrophy.

I do not think [Dr B] needed to have abandoned the operation for the purpose of pedicle screw instrumentation given his appreciation of the operation with the information that was available to him which he thought at the time was correct. Although it is well appreciated that the operation was difficult due to bleeding and access problems, [Dr B] thought he had overcome these difficulties and had access to the disc space appropriately and was able to place an interbody fusion cage. Excessive epidural bleeding, access problems, and identification of disc spaces are problems which are encountered during the course of surgery on the spine and surgical techniques are developed to help and overcome these problems. [Dr B] appeared to have gone through the process appropriately however, did not realise that despite the image intensifier localisation the instrumentation was done adjacent to the disc space. Prior to the complication of the dural tear and nerve root injury he assumed that the posterior lumbar interbody fusion could have been done and therefore he could not have necessarily made a decision to change to a posterolateral fusion. Once the complications of dural tear and nerve root injury had occurred then I do not think it was appropriate at this stage to continue with a posterolateral fusion given the additional surgery that would have been required to achieve this and that to abandon the operation at that time was appropriate. The packing of bone chips into the assumed disc space was certainly appropriate and was an attempt to possibly achieve some form of interbody fusion although without the support of a titanium cage. It was a method used prior to cage technology.

In the retrospective analysis of the operation and the knowledge of the subsequent events it is easy to assume that the correct response may well have been to abandon the interbody operation and go ahead with a posterolateral fusion with pedicle screw instrumentation. In the minutes of the Medical Advisory Committee of [the private hospital] it is stated that [Dr B] does not do screw fusions and he wasn't trained, nor comfortable to do it. It is entirely speculative whether a surgeon with experience in both techniques may have been more inclined to abandon the interbody fusion to proceed with a posterolateral fusion. From the minutes of the Medical Advisory Committee [Dr B] agreed that it may have been more suitable to have changed to a posterolateral fusion when there was difficulty with finding the disc space. This again however, is a judgement made in retrospect.

In summary I therefore do not feel that a decision not to proceed with a posterolateral fusion with pedicle screw instrumentation is necessarily inappropriate. Despite the difficulties [Dr B] did feel he had accessed the disc space and was proceeding with the technique of interbody fusion until the complication of dural tear arose. At this stage he abandoned the operation which I would consider appropriate given the complication that had arisen. The appropriateness to change to posterolateral fusion with pedicle screw instrumentation is a judgement that is made on retrospect knowing the outcome.

In your document titled: Expert Medical Advice: 04/11462 you have stated that I should mention any other aspects of care provided by [Dr B] that I would consider for additional comment. An issue requiring comment is the management of the dural breach leading to extravasation of CSF. At the time of the operation the actual dural tear could not be seen and this may have been the case if the tear was ventral. In this situation a formal repair cannot be done. There is little record in the information given as to the subsequent processes intraoperatively to achieve some impairment of CSF egress and subsequent CSF collection or leakage post-operatively. [Dr B], in his operative note states that the wound was simply closed in layers. The operative scrub nurse, [Ms E], states in her report that gel foam was used. It may well have been appropriate at this stage to have used a fat graft around the epidural space. This could be supplemented if available by various forms of tissue glue of which there are now some commercially available products. Post-operatively I would consider it standard practice to have kept the patient flat in the bed for a period of at least two to four days. I note in the nurse's record that [Mr A] was mobilised the first day post-operatively. This increases the lumbar intrathecal pressure which can maintain the egress of CSF and prevent the injured area to heal. I consider the subsequent management however, appropriate with the necessity for re-exploration and repair at a later date given the ongoing problems.

References:

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3. Hacker, R.J. Comparison of Interbody Fusion Approaches for Disabling Low Back Pain. Spine 22 (6): 660–666, 1997.

4. Kuslich S.D., et al. The Bagby and Kuslich Method of Lumbar Interbody Fusion. Spine 23 (11): 1267–1279, 1998.

5. Matge G. and Lecercq T.A. Rationale for Interbody Fusion with Threaded Titanium Cages at Cervical and Lumbar levels. Results on 357 cases. Acta Neurochirurgica (Wien) 142: 425–434, 2000.

6. McAfee P.C. Interbody Fusion Cages in Reconstructive Operations on the Spine. The Journal of Bone and Joint Surgery 81-A (6) : 859–880.

7. Ray C.D. Threaded Titanium Cages for Lumbar Interbody Fusions. Spine 22 (6): 667–680, 1997.

8. Ray C.D. Threaded Fusion Cages for Lumbar Interbody Fusions. Spine 22 (6): 681–685, 1997.

Further advice
Further advice was obtained from Dr Finnis:

"You wrote to me on 28 June asking for further comment regarding the complaint of [Mr A]. You have enclosed with this your letters to [Dr B] dated 19 May and 21 June as well as [Dr B's] response dated 15 June and 22 June 2005.

I will answer your questions in turn for clarification.

1.1 I would consider [Dr B's] decision to not perform dynamic X-rays to be acceptable practice by his peers. The investigations he had done would however be the minimal acceptable investigations prior to this procedure and I would have considered dynamic X-rays to be advisable and maybe helpful in the decision making however not mandatory.

1.2 I do not think the outcome of [Mr A's] operation would have been altered if dynamic X-rays had been performed. With what information is available I would have anticipated that mobility would not have been excessive and that this would not have altered [Dr B's] decision to go forward for a stand alone posterior lumbar interbody fusion.

2.1 The presence of a dural tear or dural damage during the course of surgery in general would alter the number of days a patient would be nursed flat post-operatively. When lying flat this reduces the CSF pressure in the thecal sac and minimises the egress of CSF allowing the area to heal. When a person is standing, the pressure in the lumbar thecal sac is much higher enhancing the egress of CSF and impairing healing. The exception to the rule may be in a situation where a good repair of the dura has been achieved and the surgeon is confident that the CSF egress is unlikely with the increased pressure.

2.2 I would not consider that mobilising [Mr A] on the first post-operative day to be considered acceptable practice by his peers. I would consider that the departure from acceptable practice would be moderate.

3. [Dr B's] decision to continue with a PLIF procedure was not inappropriate. Change to a posterolateral fusion with pedicle screw instrumentation always remained an option at the time but not mandatory. The operation was appropriately abandoned when the complication arose.

4. There is nothing further in [Dr B's] response that would alter the content of my initial report. [Dr B's] response to your questions [has] been related to his practice around mobilisation of a PLIF procedure and has not made reference to the presence of the dural injury and CSF leak. It may be helpful to ask specifically of [Dr B] his general plan of management following a dural injury and more specifically the repair undertaken and the

> mobilisation regime advised for [Mr A]. I agree with [Dr B's] comment in the email on 21 June 2005 that in the absence of performing a PLIF normal mobilisation could occur however, it is unclear when making this statement if he has taken in consideration the presence of a dural tear."

In relation to the responsibility of a surgeon in providing standing orders for postoperative care, Dr Finnis clarified that it is the surgeon's responsibility to ensure that there are appropriate standing orders.

Responses to provisional opinion

The Private Hospital

Standing orders
Mr C advised:

> "[The private hospital] follows the Ministry of Health's *Guidelines for the Development and Operation of Standing Orders* (November 2002). It has a complete set of Standing Orders for all specialties, surgeons and procedures (in a general sense) and is diligent about ensuring they are reviewed and signed off annually."

Mr C stated that there are no standing orders at the private hospital for the postoperative management of patients undergoing PLIF procedure, but that Dr B has standing orders for spinal surgery, and that "an uncomplicated PLIF is managed post-operatively in exactly the same way as a posterolateral spinal fusion with instrumentation. I am advised … that the mobilization protocol would be identical in both procedures."

Mr C stated that although very few PLIF procedures are now performed at the private hospital, in the "1990's the private hospital managed PLIF procedures frequently. … The senior nursing staff involved in Mr A's care were quite familiar with the PLIF procedure."

Dural tear rate
Mr C commented that although Dr B's dural tear rate was higher at the private hospital than at the public hospital, "the rate was still well within the acceptable limits quoted by empirical research. … Mr Finnis provides an empirical reference … of a rate between 6 and 15%. Dr B's rate fell well within those acceptable limits."

Surgical audit
Mr C stated that the MAC has instituted the following amended practice regarding compliance with surgical audit:

> "1. There will be a six monthly review of the audit attendance. Surgeons who appear as though they will not comply with the 'three out of six' rule will be written to reminding them of their obligations.

2. At the end of each year the Committee will review the privileges of those accredited professionals who have not complied with this requirement.

3. The review will consider, among other things, the volume of cases undertaken, participation in audit at other hospitals, compliance with paperwork and other extenuating circumstances e.g. absence through sabbatical, conference leave etc.

The Committee has resolved that it would not be appropriate to arbitrarily suspend or terminate privileges in these circumstances, but recognizes that much closer scrutiny of attendance and a higher compliance rate is preferred."

Mr C commented on the fact that not all of Dr B's cases that involved dural tears had been recorded on the audit system:

"If [Dr B] fully complied with the paperwork I fail to see how those cases would not appear on the [audit] system. This brings into question [Dr B's] compliance with the paperwork requirements, and we will be reviewing the quality of the information in the Surgical Audit database. That review will include a review of why [Dr B's] data did not appear."

Dr B

Dr B accepted that the provisional opinion was "very fair".

Further advice

Further advice was obtained from Dr Finnis following receipt of the responses to the provisional opinion.

Dr Finnis stated that standing orders for PLIF procedures would be incorporated into the standing orders for general lumbar spine fusion procedures and need not necessarily be separate.

Dr Finnis advised that it would not have been possible to repair the nerves damaged with microsurgery. The injury would have involved "quite extensive areas of the nerves with combinations of tears and stretch type injury. Simple suturing would not be possible, nor would it heal such that function could be regained."

Code of Health and Disability Services Consumers' Rights

The following Right in the Code of Health and Disability Services Consumers' Rights is applicable to this complaint:

RIGHT 4
Right to Services of an Appropriate Standard

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

Other relevant standards

"Good Medical Practice — A Guide for Doctors" (Medical Council of New Zealand, October 2003):

> "[You must] take part in regular and systematic medical and clinical audit, recording data honestly. When necessary you must respond to the results of audit to improve your practice, for example by undertaking further training."

Summary

The injury that Mr A suffered on 18 December 2004, during what was expected to be relatively routine surgery, was tragic and has significantly affected his and his family's lives. It is understandable that he has questioned whether the incident was avoidable or resulted from a poor standard of surgery. Guided by Dr Nicholas Finnis, who provided expert neurosurgical advice, I am satisfied that the damage that occurred to Mr A's spinal cord was not as a result of a poor standard of care, but was an unfortunate and unforeseeable accident.

Nonetheless, although it was not the cause of the injury that Mr A suffered, I am concerned about the care he received postoperatively. In relation to the postoperative care, I consider that Dr B breached the Code of Health and Disability Services Consumers' Rights. I am also critical of Dr B's failure to comply with surgical audit requirements at the private hospital.

Opinion: No Breach — Dr B

Choice of procedure
Mr A was concerned that Dr B decided on the PLIF technique when other options may have been more appropriate. In particular, Mr A queried whether an isolated posterolateral fusion with pedicle screw instrumentation would have been more appropriate in his case.

Dr Nicholas Finnis, in providing independent neurosurgical advice, stated:

> "I would consider the operation of L3/4 lumbar interbody fusion appropriate for the problem which [Mr A] presented with. [Mr A] had symptoms of an L3 radiculopathy and a posterior approach is necessary to adequately depress the nerve root. It was appropriate to supplement this procedure with a fusion given the mechanical back pain experienced and the spondylolisthesis at this level shown on imaging. … The technique of posterior lumbar interbody fusion has certain advantages over the posterolateral fusion with pedicle screw fixation."

Execution of surgery
Dr B advised ACC of the complications that arose during Mr A's surgery. There was excessive bleeding at the operation site and dense bony tissue at the back of the disc, which made it difficult to open. Dr B needed to use a hand-held retractor when the sleeve retractor could not be accurately placed. An inspection of the cavity revealed that the lumbar theca had been compromised by the second attempt to insert the screw cage. Dr B noted that there was a possible dural tear and the appearance of a CSF leak. On that basis, he decided to abandon the PLIF procedure, packed the site with bone chips and closed the wound.

Dr Finnis advised that Dr B made the appropriate decision to abandon the operation when it was clear that complications had arisen with a dural tear and nerve root injury. Dr Finnis noted that the surgery was made difficult by the visualisation of the disc and access to the

disc once it was identified, but did not consider that there was any reason to abandon the operation at an earlier stage.

On the basis of this advice, I am satisfied that it was appropriate for Dr B to advise Mr A of the surgical options for managing his lower back pain, recommend the posterior lumbar interbody fusion technique, and abandon the operation when it was apparent that complications had arisen.

Opinion: Breach — Dr B

Postoperative care
Mr A was initially stood on the first day postoperatively, 19 hours after he returned to the ward from the operating theatre. On the second postoperative day, Mr A was stood on five recorded instances, and assisted with a short walk.

On the morning of the third postoperative day, Mr A was walked to the shower with use of a frame and the assistance of a physiotherapist. By 10.30am it was noted by nursing staff that Mr A had developed a headache and a stiff neck, and that the dressing was damp. A CSF leak was suspected, and this was confirmed by Dr F, then Dr B.

Dr B considered that it was acceptable for Mr A to be mobile so soon after surgery because the PLIF procedure had not progressed to the stage where the spine would be unstable. However, at the time of surgery a dural tear had been suspected because of the leak of CSF into the wound, and a repair of the dura had not been attempted because the specific point of leakage could not be identified.

Dr Finnis advised:

> "The presence of a dural tear or dural damage during the course of surgery in general would alter the number of days a patient would be nursed flat post-operatively. When lying flat this reduces the CSF pressure in the thecal sac and minimises the egress of CSF allowing the area to heal. When a person is standing, the pressure in the lumbar thecal sac is much higher enhancing the egress of CSF and impairing healing. The exception to the rule may be in a situation where a good repair of the dura has been achieved and the surgeon is confident that the CSF egress is unlikely with the increased pressure. …
>
> I would not consider that mobilising [Mr A] on the first post-operative day to be considered acceptable practice by his peers. I would consider that the departure from acceptable practice would be moderate."

The recovery room record stated that the nursing staff asked whether Mr A required any special consideration in relation to movement and position, but that Dr B said there were "no special considerations needed". The care plan was insufficiently detailed to provide guidance. It stated "up as directed by surgeon".

I accept that the nursing and therapy staff followed the limited postoperative mobilising orders given by Dr B, and that their management of Mr A, when the CSF leak became apparent, was prompt and appropriate. However, I do not consider that the nursing and therapy staff at the private hospital were provided with appropriate guidance to care for Mr A postoperatively, in particular in relation to his mobilisation. Although Mr C stated that the senior staff involved in Mr A's care were "quite familiar" with the PLIF procedure, I believe that guidelines (in the form of standing orders or standard care plans) should be available to assist all staff, as it cannot be assumed that experienced, senior staff will always be present.

Summary
In my view, Mr A was mobilised too early in the postoperative period. Although the vertebra may have been stable, as stated by Dr B, a dural tear had been clearly identified during surgery, and had not been repaired. Consequently, Mr A should have been nursed flat for a longer period. Dr B should have given more specific instructions for Mr A's postoperative mobilisation, and should have restricted Mr A's mobility. In this respect, Dr B failed to provide services with reasonable care and skill, and therefore breached Right 4(1) of the Code.

Other matters

Preoperative investigations
Dr B carried out an MRI scan to assess the damage to Mr A's lower back, and to assist him in deciding whether surgery would address the complaint. Dr B explained that he did not order preoperative dynamic X-rays because he considered that there were adequate indications for a PLIF operation.

Dr Finnis advised that the minimal appropriate investigations were carried out prior to surgery:

> "I would have considered dynamic X-rays to have been advisable to collect further information about the degree of stability however, not absolutely necessary given the degree of spondylolisthesis."

Dr Finnis advised that the decision not to perform dynamic X-rays would be considered acceptable practice by Dr B's peers, and that the outcome of the operation is unlikely to have been different if dynamic X-rays had been used. However, Dr Finnis advised that dynamic X-rays may have been helpful in the decision-making process. I draw my expert's comments to Dr B's attention.

Assistance during surgery
Dr B was assisted during surgery by the scrub nurse, Ms E. At one stage during the surgery Ms E was away from the operating table, and Dr B was operating unassisted. His recollection was recorded in the minutes of the meeting on 8 April 2004:

> "On the second attempt to evacuate the disc space he was having trouble with the fixed retractors and used a hand held [retractor]. It is at this point he believed he probably should have waited for the scrub nurse to come and assist."

Dr Finnis advised:

> "[I]t would have been reasonable to have requested a further assistant when the difficulty had arisen … however, I do not think this was a breach of any standard medical practice. I would have considered it important, however, to have assistance with the retraction of the thecal sac and nerve root while inserting the screw cage rather than holding this and simultaneously placing the screw."

Dr B subsequently advised that if he performs another PLIF operation, he will request the assistance of another surgeon.

Opinion: No breach — The private hospital

I am satisfied that the private hospital responded appropriately to Mr A's concerns and provided him with adequate information. Although Mr A requested that an independent review of his operation be performed, Mr C appropriately recommended that Mr A write to the Health and Disability Commissioner if he sought an independent investigation.

Mr C did not inform Mr A of the subsequent recommendations from the MAC, relating to audit and specialist assistance, nor of the restriction of Dr B's scope of practice. However, I do not consider that the private hospital was required to inform Mr A of these matters, which related to its contractual arrangement with Dr B.

Vicarious liability — The private hospital

Employers are responsible under section 72(2) of the Health and Disability Commissioner Act 1994 for ensuring that employees comply with the Code. Under section 72(5) it is a defence for an employing authority to prove that it took such steps as were reasonably practicable to prevent the employee from breaching the Code.

Dr B breached the Code in his postoperative management of Mr A. I consider that this breach was an individual clinical error and could not reasonably have been prevented by the Private Hospital. Accordingly, no issue of vicarious liability on the part of the private hospital arises.

Other comments — patient safety in private hospitals

A private hospital has an obligation to maintain and monitor the competence of the surgeons who practise on its premises. This duty of care is recognised both by statute and common law.

The Code of Health and Disability Services Consumers' Rights applies to all health care providers, including private hospitals, and there is an organisational duty to provide services with reasonable care and skill (Right 4(1)). This duty of care has been considered in several Health and Disability Commissioner reports, most recently in the Tauranga Hospitals Inquiry.[2]

The duty on hospitals to ensure practitioners are competent is also recognised in common law. In *Roylance v General Medical Council* [1999] 3 WLR 541, the Privy Council stated that "the care, treatment and safety of the patient must be the principal concern of everyone engaged in the hospital service".

Participation in audit
One aspect of the duty of care is the need for routine audit and effective peer review of clinical standards. The need for "regular and systematic … clinical audit" is also recognised by the Medical Council in "Good Medical Practice — A Guide for Doctors" (2003). Dr B was required to be involved in regular surgical audit meetings under section 18 of the private hospital By-Laws.

In the 18-month period to April 2004, Dr B did not attend a single private hospital surgical audit meeting. The CEO, Mr C, would have been aware of this fact as he was regularly supplied with the list of the accredited doctors who failed to attend three of the previous six meetings without valid reasons.

Eventually, on 19 February 2004, Mr C wrote to Dr B, stating:

> "I have been analysing the surgical audit compliance and attendance. I note that your compliance with surgical audit paper work is more or less up to date but that you do not attend the bi-monthly surgical audit meetings. Given circumstances of the [Mr A] case I feel that it is politic that you do so."

At the meeting on 8 April 2004 Mr C also informed Dr B that it would be "prudent" to attend the surgical audit meetings.

In granting clinicians the right to use their facilities, private hospitals owe patients a duty to ensure that those clinicians are carefully selected and monitored. If a private hospital has reason to believe that a clinician may pose a risk of harm to patients, it has a duty to respond

[2] Tauranga Hospitals Inquiry, www.hdc.org.nz, Opinion 04/07920 (18 February 2005).

immediately to minimise the risk.[3] This is not simply a matter of "prudence" or acting in a "politic" manner — it is critical for patient safety.

According to the data provided, Dr B had an 8.3% dural tear rate at the private hospital (4 out of 48 spinal operations), and a 3% dural tear rate (3 out of 99 spinal operations) at the public hospital. Given that his dural tear rate was almost three times higher at the private hospital, Dr B should have made much greater effort to participate in surgical audit meetings. Dr B admitted to an awareness of an increase in complications "in the first half of 2002". He had been involved in the public hospital audit processes, yet had failed to participate at the private hospital.

It is of significant concern that Dr B failed to participate in surgical audit at the private hospital, and that the private hospital failed to respond promptly to ensure that Dr B remedied the situation.

I note that the private hospital has now taken measures to ensure that accredited professionals comply with the requirement to be involved in surgical audit.

Audit data
Dr B was asked in April 2004 to supply audit data for his PLIF operations, including the dural tear rate for his spinal operations. Despite further prompting in December 2004 and May 2005, Dr B did not provide the dural tear rate data. Dr B eventually provided the information in August 2005 as a result of my enquiries, but in order to obtain accurate information he needed to review the clinical notes of all the cases, as only one of four known dural tears had been recorded on the audit database.

I am concerned that it took Dr B 16 months to provide the information about dural tears. Had the data been recorded in Surgical Audit Forms, as required by the private hospital By-Laws, the information would have been readily accessible.

I am also concerned that there may be errors in the audit system used by the private hospital. Accurate and relevant surgical audit data must be collected in a timely manner, and the surgical audit system must be able to provide meaningful and accurate data when questioned.

I note that the private hospital is undertaking a review of the quality of the information in its Surgical Audit database, including a review of why Dr B's data "did not appear".

Meeting with the District Health Board and other representatives
The Tauranga Hospitals Inquiry highlighted the importance of hospitals having effective information sharing systems. Hospitals should consult with relevant registration authorities[4] and co-ordinate their actions with other hospitals to avoid delays, duplication of process and conflicting outcomes. Privacy concerns should not prevent hospitals from sharing

[3] Tauranga Hospitals Inquiry, www.hdc.org.nz, Opinion 04/07920 (18 February 2005).

[4] Under section 34 of the Health Practitioners Competence Assurance Act 2003.

information about a practitioner's competence. Patient safety must be the paramount consideration.

On 16 June 2004, it was decided at the MAC that there should be a meeting between representatives from the private hospital, the DHB and other representatives to discuss concerns about Dr B's clinical performance. Although the need for this meeting was raised again at the MAC on 13 July, 15 September and 13 October, it did not take place until 5 November 2004, almost six months after the original decision to hold the meeting "as soon as possible".

It was sensible and appropriate for the private hospital to confer with representatives of the places where Dr B worked. However, it is concerning that it took almost six months for a formal meeting to be arranged. The private hospital should have ensured that this meeting took place with greater urgency. In response to the provisional opinion, Mr C explained that "it was agreed [by the MAC] that the most appropriate facilitator of the meeting was either [the DHB's Chief Medical Officer] or [the MAC Chairman]". However, the concerns were held by the private hospital (rather than by other organisations), and it should have ensured that the meeting occurred promptly.

Medical Council of New Zealand competence review
It was agreed at the meeting on 5 November 2005 between senior staff of the University, the DHB and the private hospital that it was appropriate to refer Dr B to the Medical Council of New Zealand for a competence review. I note that the Medical Council met on 22 June 2005 and resolved to undertake a review of Dr B's competence to practise medicine in the vocational scope of neurosurgery.

Recommendations

I recommend that Dr B take the following actions:

- Apologise to Mr A for his breach of the Code. The apology to be sent to the Commissioner's Office to be forwarded to Mr A.
- Regularly attend the private hospital surgical audit meetings.
- Comply with the private hospital requirements for surgical audit data collection.
- Review his standing orders and guidelines for the postoperative management of spinal operations.
- Discuss this case at a national meeting of neurosurgeons in New Zealand.

Follow-up actions

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

- A copy of this report, with details identifying the parties removed, will be sent to the New Zealand Private Surgical Hospitals Association, and placed on the Health and Disability Commissioner's website, www.hdc.org.nz.

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