Dr B / A District Health Board

Opinion - Case 98HDC13693/VC

Complaint

The Commissioner received a complaint from Mrs A concerning the care and treatment that her husband Mr A received from Dr B, neurosurgeon at a public hospital. The complaint is that:

- *Dr B did not fully inform Mr A or provide him with an assessment of the expected risks and side effects before undertaking spinal surgery on Mr A on 26 August 1997.*

- *Further to this, between 2 September and 8 September 1997 Dr B did not take reasonable and timely action to treat the leaking spinal fluid experienced by Mr A following spinal surgery on 26 August 1997.*

Investigation

The Commissioner received the complaint on 2 April 1998 and an investigation was commenced on 26 June 1998. Information was obtained from the following:

Mr A	Consumer
Mrs A	Complainant / Wife of Mr A
Dr B	Provider / Neurosurgeon
Ms C	Manager, Customer Services, the public hospital
Dr D	Specialist in radiotherapy
Dr E	General practitioner
Dr F	Radiation oncologist, public hospital
Dr G	Neuropathologist

Mr A's medical notes were obtained and reviewed by the Commissioner. The Commissioner sought independent advice from a consultant neurosurgeon.

Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Background

In 1974 Mr A underwent an operation to remove a spinal cord tumour. During the operation the surgeon found that only a biopsy was possible and tissue samples were taken for testing. The dura (the thickest and outermost of the three connective tissue membranes surrounding the brain and spinal cord) was left open. The tumour was seen to be excessively vascular (full of blood vessels) and Mr A subsequently had radiotherapy to this area.

In March 1984 Dr D, specialist in radiotherapy and oncology referred Mr A to Dr B, neurosurgeon, as Mr A had developed some neck pain and frontal headaches. In a letter to Dr D dated 22 March 1984, Dr B stated that Mr A had mild paraparesis (partial paralysis of the lower extremities) with sensory disturbance in his legs and advised Dr D that he could see Mr A if his symptoms got worse.

Information Gathered During Investigation

In June 1997 Mr A consulted his general practitioner, Dr E, because he had increasing pain and mobility problems. Dr E referred Mr A to the Pain Clinic at a rehabilitation unit, which referred him for a MRI scan. The MRI scan was performed on 30 July 1997 at the public hospital. Dr F, radiation oncologist at the public hospital referred Mr A to Dr B.

On 8 August 1997 Mr A consulted Dr B at the outpatient clinic of the public hospital. During the consultation, Dr B showed Mr A the MRI scan and explained his condition to him. Mr A stated to the Commissioner, "*I was given a very technical explanation of exactly what was causing my health problem regarding leg and back pain*".

The scan showed a large multi-loculated cystic component containing some solid components inferiorly. Dr B considered that Mr A had a recurrent tumour. At the time there was no reason for him to believe that the original tumour diagnosis was incorrect. However, subsequently, neuropathologist Dr G re-reviewed the 1974 biopsy test sections with Dr B and found there was "*no evidence of tumour whatsoever …*". Dr B suggested to Mr A that he have an operation to relieve the pressure on his spinal cord.

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Opinion - Case 98HDC13693/VC, continued

Information Gathered During Investigation *continued*

Dr B said he explained the difficulty of the operation and the possible complications involved in this type of surgery. Dr B advised that he had explained to Mr A that:

> "*… entering this cyst surgically would not be expected to worsen his neurological deficit as microsurgical techniques would be used to minimise such a likelihood. … [T]he inevitable outcome without any intervention would be paraplegia at some stage in the future – this was explained to [Mr A].*"

Dr B said he also explained that with the dura having been left open originally and with the extensive previous laminectomy (surgical cutting into the backbone to obtain access to the spinal cord) and the radiotherapy, re-operation was more difficult. Dr B advised the Commissioner that he explained to Mr A that due to these factors Mr A was at greater risk of a cerebrospinal fluid (CSF) leak post-operatively, "*… with delayed wound healing and wound infection [as compared to the situation] if no neurosurgery nor radiotherapy had been performed previously*".

Dr B advised the Commissioner he explained to Mr A that there was always a risk of infection resulting from the type of surgery he was to have. This risk was increased significantly for Mr A as an old wound was to be re-explored. However, careful aseptic techniques would be used and Mr A would be given antibiotic cover as a precaution. Dr B advised the Commissioner he explained to Mr A that, because of the increased infection risk, Dr B would be required to undertake careful wound closure, with the skin sutures remaining in for a longer period of time than would be normal. Dr B advised that he explained to Mr A that if a CSF leak did occur further surgical management would be required.

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Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Information Gathered During Investigation *continued*

Dr B advised that he had not believed Mr A was:

> "*… at significantly greater risk of developing such a dense arachnoiditis as indeed has happened and if I had honestly felt that the likelihood of his developing the poor outcome that he had indeed manifested and in which I assume is due to dense arachnoiditis was at all significant then I would of course have discussed this issue with him and his wife in more detail and in as much as one can ever cover every possible contingency - one cannot.*"

Dr B advised the Commissioner in his response to the provisional opinion that:

> "*I informed the patient and his wife that he would be admitted to hospital the day before surgery, would be nursed supine on complete bedrest for the first five days postop and would then be gradually mobilised and the sutures would be removed on the 14th postoperative day; I said that he may be able to go out on leave toward the end of this time.*"

Mr A disputed that Dr B had explained the risks of the operation. He stated that "*at no stage before the surgery on August 26th 1997 was [I] told about a CSF leak and further surgery risk."* Additionally, Dr B did not inform him that surgery of this type would never be easy. Instead he stated that he was informed:

> "*… at worst you will be no worse than you are now but I am confident you could be a lot better.*"

Mr A stated that Dr B had advised that:

> "*Possible outcome of surgery was explained as 'at worst you will be no worse at best we could relieve some symptoms'.*"

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Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Information Gathered During Investigation *continued*

In response to the provisional opinion Mr A stated:

> *"At no stage were any possible difficulties of the operation or recovery explained. Only after the second operation did [Dr B] say it was always going to be a possibility with all the previous history. He informed [Mr A] of the dura left open in the original operation [1974] after the first operation August 1997. We believe he discovered this detail during the 1997 operation. Never had a CSF leak mentioned as both [Mr and Mrs A] had to inquire what CSF fluid was after Sept 8th when it was officially discussed. [Mr A] asked at the outpatient appointment, as previously mentioned, of any risks or delays to recovery and when he was concerned at the answer of 'little or no risks' went to his GP for confirmation."*

> "*If there was a hint of risk regarding neurological deficit [Mr A] would have delayed until Oct/Nov as Sept was a busy month as a self employed real estate business owner, was the month he and [Mrs A] were shifting house and he would have put measures in place to ensure a temporary manager was available if necessary to run the business. On the contrary [Mr A] specifically questioned risk and gave those reasons but was told there was little or no risk, nothing to worry about and in fact felt the whole procedure was straightforward and his appointment was short and quite lighthearted.*"

Mr A explained to the Commissioner that the appointment he had with Dr B lasted approximately 30 minutes in length. Dr B tentatively booked a date for Mr A to be admitted to hospital on 25 August 1997.

The Commissioner noted that Dr B did not write up clinical notes of this consultation, but wrote a letter dated 13 August 1997 to Dr F, with copies to Dr E and the Pain Management Clinic, informing them of the consultation and the information he had given Mr A.

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Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Information Gathered During Investigation *continued*

Dr B stated in the letter to Dr F:

> "*I explained* [to Mr A] *the likely nature of his pathology – of 'recurrent' Grade III* [a way of describing the extent of a malignant tumor, used to plan appropriate treatment and predict prognosis] *astrocytoma* [brain tumor] *with an associated intramedullary cystic* [a closed sac in or under the skin lined with epithelium and containing fluid or semi solid material] *component and an associated syringomyelic cavity* [a chronic progressive disease of the spinal cord] *extending up the spinal cord. My recommendation was that we should re-operate on him to open the multi-loculated cystic component and therefore decompress the nerve roots and spinal cord that will be expended peripherally around this and attempt to decompress or at least biopsy the enhancing inferior component. Although surgery of this nature is not easy, I felt that I could do this with little or no risk of making his neurological deficit worse, and hopefully he may gain some function. We have tentatively arranged for him to be admitted here on 25/8/97 for surgery the following day …*"

Mr A advised that after the appointment with Dr B, he had had an appointment with Dr E seeking reassurance and to check that everything was alright. Mr A stated that Dr E had advised him that he should be guided by what Dr B told him.

Mr A decided to go ahead with the surgery and confirmed this with Dr B. He explained to the Commissioner that the decision to have the operation was a big consideration for him as he was self-employed and he thought that if he was going to be off work more than seven to ten days he would need to employ a manager.

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Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Information Gathered During Investigation *continued*

Admission to hospital for operation: 26 August 1997

Mr A was admitted to hospital on Monday 25 August 1997. The medical admission was recorded by the house surgeon on the ward round: "*49yo* [year old] *admitted for operation: decompress nerve roots and spinal cord, biopsy inferior compartment.* … [Patient] *has felt marked deterioration since* [6 months] *ago* [with] *patchy loss of sensation of legs becoming complete*". Mr A signed the Consent and Indemnity form used by the district health board for his upcoming surgery for "*biopsy of the spinal cord lesion*". The form stated "*I also consent to such further or alternative measures as may be found to be necessary during the course of such operation …*". Mr A was given Dexamethosone (a steroid) in the ward prior to the operation.

On 26 August 1997 Dr B operated on Mr A and re-explored his lower thoracic and upper lumbar spine for the intradural cyst and removed the L2 level haemangioblastoma (benign tumor). The notes documented that Mr A was anaesthetised for this operation from 10.00am until 1.30pm. Mr A's skin was closed in two layers. No drainage system was placed in the wound site. Intravenous (IV) antibiotics, amoxycillin and flucloxacillin, were started in theatre. Two more doses ordered by Dr B were given to Mr A post-operatively in the ward.

Following the operation on 26 August 1997 Dr G reviewed the specimens which had been taken from Mr A and found the removed tumour to be benign.

Post-operative recovery

Post-operatively, the medical and nursing notes document that Mr A was on bed rest as requested by Dr B until 30 August 1997 when he began to mobilise with two hourly turns being performed to prevent the development of pressure areas. His notes record that his wound was satisfactory from 27 until 30 August 1997. He was also noted to be afebrile (without fever) during this time. Dr B saw Mr A on 27, 28 and 29 August 1997.

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Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Information Gathered During Investigation *continued*

On 1 September 1997 Dr B saw Mr A and documented "*slight swelling superior aspect*" of his wound and that Mr A was well. On 2 September 1997 slight ooze from Mr A's wound site was noticed and documented by a nurse. The medical and nursing notes on 3 September 1997 documented "*No ooze from the wound*". Dr B reviewed Mr A on the ward round and documented "*fluid collection superior aspect*". On 4 September 1997 *"Wound dry and intact"* was documented. On his ward round on 4 September 1997 Dr B noted fluid collection at the wound site but considered that Mr A was well enough to go home on weekend leave from 5-8 September 1997. He planned to remove Mr A's sutures on his return to hospital on Monday 8 September 1997. Mr A explained to the Commissioner that prior to the weekend leave he was up mobilising, recuperating as planned, walking with a frame and was looking forward to going home for the weekend.

The Commissioner noted that Mr and Mrs A's recollection of the wound leakage was different to that documented in the medical and nursing notes. Mr A advised the Commissioner that the wound began to leak on Wednesday 3 September 1997 with his clothing becoming wet. However, Mrs A advised the Commissioner that from Monday 1 September 1997 damp seepage had appeared which caused damp patches on Mr A's clothing and continued to drip on and off.

Mr A stated to the Commissioner that both the ward nurses and Dr B knew about the leak from Wednesday 3 September 1997, were looking at it daily and ward staff had indicated to him and his wife that they were unconcerned about the dampness.

Dr B reviewed Mr A again on Friday 5 September 1997. He aspirated (removed) fluid from the upper part of the wound and documented, "*The swelling re-accumulated within minutes – CSF - patient to lie on back or when sitting to use a towel or padding to press on wound - can have weekend leave, sutures out Monday*". The aspirated fluid was sent for testing and the preliminary laboratory results were reported at 6.29pm on 5 September 1997. The result showed "*no organisms seen*". The culture (growing colonies of micro-organisms to determine infection) result was to follow.

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Dr B / A District Health Board

Opinion – Case 98HDC13693/VC, continued

Information Gathered During Investigation *continued*

In response to the provisional opinion Mr A stated the following with regard to the documented statement '*patient to lie on back or when sitting … wound'*:

> "*This was the documentation which implies it was the advice given to the patient. In fact the only conversation held regarding the 'ooze' on that Friday was an instruction from [Dr B] to 'be on your back or sit up when you're home with a towel at your back – you'll be fine'. Both [Mr and Mrs A] assumed this fluid was just 'wound discharge' as no comment was made about it other than the above recorded. Mr A was given weekend leave as arranged.*"

Dr B stated to the Commissioner:

> "*I personally inspected his wound on Monday 01/09/97, Wednesday 03/09/97, Thursday 04/09/97 and of course Friday 05/09/97 – when I aspirated CSF from the upper end of the wound. On none of these occasions was there a CSF leak nor any evidence in the wound that there had been a CSF leak.*"

Mr A was assessed prior to his weekend leave by the medical and nursing team to decide what dressing to use on the wound site. A large bandage was placed on the wound site and the medical notes documented that Mr A was advised to be on his back or when sitting to use a towel or padding to press on the wound. Mr A explained to the Commissioner that he was not aware of what the leak was and presumed it was normal ooze from an operation site. Mr A left for weekend leave on 5 September 1997 with advice from nursing staff that he could return to the ward at any time during the weekend or telephone the ward with any questions.

Mr and Mrs A advised the Commissioner that prior to the weekend leave, Dr B had advised them that he was pleased with Mr A's progress. Dr B told them that the only reason for Mr A to stay in hospital was for rehabilitation. Mr A had progressed in his recovery to the point where he had used a walking frame independently and competently for the last three days and had stood easily from a sitting position without support.

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Dr B / A District Health Board

Opinion – Case 98HDC13693/VC, continued

Information Gathered During Investigation *continued*

Weekend leave

During the weekend leave on Saturday 6 September 1997, Mr A woke early with a pounding headache, vomiting, neck pain and drowsiness. Mr and Mrs A both considered this could be the 'flu'.

On Sunday September 7 Mr A awoke with increased leaking from the wound. Mrs A rang the hospital around 8.00am and explained that Mr A had 'flu' symptoms and there was *"fluid pouring from the back"*. Mrs A advised the Commissioner that the ward had told her there was no urgency for Mr A to return to the ward due to these reported 'flu' symptoms. Mrs A informed ward staff she would bring Mr A back in the afternoon.

On arrival back at the hospital Mr A appeared very sleepy and a house surgeon was called. The house surgeon requested 15 minute neurological observations and for the surgical registrar to be contacted. The house surgeon documented in diagram form that there was a lump over the upper wound of the back, there was fluid streaming out of the wound and slight erythema (redness or inflammation) at the wound site. It was documented in the medical notes that the clinical signs did not indicate meningitis. Blood cultures were taken for testing and it was documented in the notes that Mr A would be commenced on antibiotics if his temperature increased. A re-culture of fluid from the wound was ordered. After a telephone discussion with the on-call consultant, a neurosurgeon, the surgical registrar stitched the bottom of the wound to try and stop the leak and to decrease the risk of infection.

Mrs A advised that Dr B was called to come in to review Mr A but would not come, as it was his weekend off and had advised that another surgeon could review Mr A. However, Dr B was adamant that he was not contacted about Mr A on Sunday 7 September 1997. There is no documentation to suggest Dr B was contacted. Dr B stated that in 16 years of consultant neurosurgical practice he has never stated that he is "*off duty*" in respect of a patient under his care.

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Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Information Gathered During Investigation *continued*

Mr A stated in his response to the provisional opinion that:

> *"… The registrar explained to [Mrs A] he would phone [Dr B] straight away. [Mrs A] was in the ward which was quiet at the time and was aware the registrar spoke to someone on a first call and reported to her – 'I'm to phone the specialist on duty now'. He definitely made two phone calls. …"*

Over the night of 7 September 1997, two hourly neurological observations were undertaken on Mr A, which showed no abnormalities. His notes record that he was afebrile.

Dr B saw Mr A on the morning of 8 September 1997. He documented that Mr A had CSF leaking from the wound and that his wound was slightly inflamed. Dr B took a further specimen for cultures. The previous swab taken from the skin suture site showed gram-positive cocci. Dr B documented, "*I will regard him as having a low grade meningitis – and culture for Friday's sample - coagulase negative staph*". Dr B recorded in the medical notes that intravenous (IV) fluids and IV vancomycin (an antibiotic) 1gram BD (twice daily) were to be commenced.

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Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Information Gathered During Investigation *continued*

Mr A stated in response to the provisional opinion that:

> *"[Dr B] commented on the medications required for [Mr A] on 8th Sept. but left the ward without charting any for him. [Mrs A] requested nursing staff have him chart these medications during the morning but by 1.00pm after asking several times was told [Dr B] was now in theatre and the registrar was off the ward. [Mrs A] and [Mr A], in considerable pain and very concerned, then asked that 'anyone in the hospital able to write a script be contacted' and by 1.15pm medication was begun. We still have little idea of exactly what has caused the permanent damage and wonder if delays in medication and damage from leakage and infections were a problem.*
>
> *Also [Mrs A] had on Wed 10th Sept a heated discussion with [Dr B] during a ward round in front of [Mr A] where she commented 'it was a pity the spinal fluid or leak caused a problem last week and in the weekend'. [Dr B] said 'on no account was there any question of CSF leak before the weekend'. It was a few days later [Mr and Mrs A] requested a copy of the ward notes and read a report written prior to the weekend with documentation 'CSF leak?' among other notes."*

The laboratory reported in the evening of 8 September 1997 that the culture of the specimen taken on 5 September 1997 was "*10ml of orange fluid … Very scanty growth of Coagulase negative STAPHYLOCOCCUS* [infection]".

The laboratory further reported on 8 September 1997 at 6.23pm that there was a moderate growth of Streptococcus (infection) Group G in Mr A's wound from the specimen taken on 7 September 1997. At 12.50pm on 9 September 1997, the specimen taken on 7 September 1997 was "*considered sensitive to Penicillin*".

On the morning of 9 September 1997 Mr A was seen by the registrar who documented that Mr A was "*feeling better … decreased headaches, decreased nausea … no pain … wound dry … no CSF leak*". The nursing notes of 9 September 1997 documented that Mr A's wound was leaking, so he was lying flat and having regular turns.

Dr B / A District Health Board

Information Gathered During Investigation *continued*

In the afternoon of 9 September 1997 the house surgeon documented in the medical notes that Mr A was to continue with his vancomycin until the laboratory had reported specifically what antibiotics could be used in the treatment of Mr A's infection.

During the evening Mr A was reviewed by the duty house surgeon as his wound was leaking sufficiently to soak through his pyjamas and the sheet. The house surgeon noted that Mr A had a slight frontal headache and he was "… *very anxious about the wound leaking*". The house surgeon noted that Mr A did not have signs of meningism (an abnormal condition characterised by irritation of the brain and spinal cord and by symptoms that mimic those of meningitis) or photophobia (abnormal sensitivity to light). The house surgeon discussed Mr A's condition with the neurosurgical registrar and documented that the registrar had advised that there was no need to call Dr B yet. The house surgeon documented that neurosurgical registrar had advised that the wound needed two sutures, a new dressing and elastoplast, and that Mr A was to continue to lie flat. Additionally the house surgeon documented that neurosurgical registrar had advised that the worst thing that could happen was that Mr A would have a headache and it was documented "… *not a life threatening situation*". The surgical registrar took a swab of the wound and placed sutures in Mr A's wound.

Mr A advised in his response to the provisional opinion that:

> *" 'Not a life threatening situation' was often used when [Mr A] queried lack of pain relief or long delays in treatment promised or regular treatments being missed out."*

Early on 10 September 1997 Mr A complained of chest pain and he was reviewed by the duty house surgeon. GTN spray (treatment for angina) and oxygen were administered. An ECG (electrocardiogram: heart tracing test), ABG (arterial blood gas: blood test), chest x-ray, full blood count and other blood tests were taken. No heart problem was found but Mr A was advised he probably had a chest infection.

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Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Information Gathered During Investigation *continued*

Dr B advised the Commissioner in his response to the provisional opinion that while he did not believe or confirm that Mr A had a chest infection, he charted additional antibiotic cover for Mr A's *"presumed low grade meningitis"*. On the ward round on 10 September 1997, Dr B documented that he had explained the current problem to Mr and Mrs A.

On 10 September 1997 the laboratory reported that the culture of Mr A's swabs taken on 8 September resulted in the Streptococcus Group G being sensitive to antibiotics including vancomycin and penicillin, and the Staphlococcus also being sensitive to antibiotics including vancomycin and flucloxacillin, although resistant to penicillin.

Operation: 16 September 1997
On 11 September 1997, Dr B made a decision to re-explore the entire wound under general anaesthetic on 16 September 1997, as there had been further CSF leakage through the lower part of the wound, which he had sutured. The wound continued to leak pus and clear fluid. Dr B advised the Commissioner that he was not able to treat the CSF leak surgically until Mr A's infection had been treated. Dr B further explained that any surgical intervention in the presence of wound infection would have risked spread of the infection into the region of the cauda equina nerve roots and spinal cord. Dr B advised the Commissioner he explained this to Mr and Mrs A on more than one occasion verbally and with the use of diagrams and pictures. However, this is not documented in the notes.

On 16 September 1997 Dr B re-opened the thoracic lumbar wound for repair of CSF leak with dural repair using fat and connective tissue from Mr A's right thigh. Post operatively, Dr B wrote on the operation report that Mr A was to have bed rest and be nursed flat. He was to have IV antibiotic and fluids as charted and the drain in his wound was to be on "*gravity drainage*".

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Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Information Gathered During Investigation *continued*

Dr B advised the Commissioner that he believed if Mr A had any meningitis from the period of 6 September 1997 prior to the time of his second operation of 16 September 1997, "*it was an extremely low graded infection and very adequately covered with antibiotic therapy*".

At the time of his operation Mr A was receiving IV vancomycin (commenced on 8 September 1997) and IV flucloxacillin (commenced on 9 September 1997). The vancomycin was continued until 25 September 1997 and the flucloxacillin until 3 October 1997.

Mr A was given IV gentamycin from 21 September until 2 October 1997 and Augmentin IV from 25 September until 3 October 1997, as the laboratory reported back on 24 September 1997 that fluid taken from Mr A's wound on 23 September 1997 had "*heavy growth of Escherichia Coli*" (bacteria).

Mr A had hyperbaric treatment (the administration of 100% oxygen which is a greater than normal atmospheric pressure, and is undertaken in a chamber to facilitate wound healing) on 14 October 1997 but he was unable to tolerate it. Despite this, the wound gradually settled down and Mr A was transferred to the Spinal Injuries Unit on 20 October 1997 for ongoing rehabilitation for paraparesis/corda equina syndrome (partial paralysis of the lower extremities) and he was discharged from there on 19 December 1997. Dr B wrote to a specialist at the rehabilitation unit on 4 December 1997 with a summary of the inpatient care provided to Mr A and advising the specialist, "*I will review [Mr A] in neurological outpatient's clinic in three months time and if there are problems in the interim please feel free to contact us*".

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Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Information Gathered During Investigation *continued*

Mr A stated in response to the provisional opinion that:

> *"[Dr B] also gave [the rehabilitation unit staff], on [Mr A's] transfer from [the public hospital] to [the rehabilitation unit], the instruction that he would visit [Mr A] in [the rehabilitation unit] within the week to check the wound and remove stitches. He did not arrive at the appointed time and [the rehabilitation unit] staff tried for 6 further days to contact him as they didn't feel they could over-ride his instructions. Eventually he said to take them out when they did reach him by phone."*

Dr B consulted with Mr A at the neurological outpatients clinic on 4 February 1998 and wrote to the rehabilitation unit specialist on 10 February 1998 advising that he had had a discussion with Mr A concerning the original diagnosis of astrocytoma of the spinal cord, radiation, his deteriorating neurological deficit before the surgery in September 1997 and the:

> "*… fact that his legs are weaker now than preoperatively. He has strong expectations about the 'nerves regrowing' with an expected significant improvement in leg function/power – I told him that he should not have too high an expectation of a significant degree of neurological recovery ….*"

Mr A had a MRI scan performed at the public hospital on 20 April 1998 with a follow-up consultation with Dr B on 14 May 1998. Dr E received a letter from this consultation dated 20 May 1998 informing her that at this consultation Mr A was advised that:

> "*… with the increased signal of fibrosis/arachnoiditis in and around the cauda equina nerves the likelihood of [Mr A] regaining a significant improvement in lower leg function was not great …. I would encourage [Mr A] to* make *all the adaptation he can to his dense paraparesis ….*"

A further MRI scan was performed on 30 June 1998 and Mr A had a follow-up consultation with Dr B in the outpatients department on 20 July 1998, with Mrs A in attendance.

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Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Information Gathered During Investigation *continued*

The Commissioner noted that Dr B advised Dr E in a letter dated 23 July 1998 following this consultation, that he had given Mr A the option of having Dr B continue as his consultant neurosurgeon involved in his care. Dr B stated that this option had been given to Mr A "… *in view of the discussion and correspondence that has been between the patient, ACC, the Health and Disability Commissioner, and myself. [Mr A] answered in affirmative that he wished me to continue as the Consultant Neurosurgeon involved in his care …*". Dr B advised Dr E that from this consultation Mr A understood that if there was any significant deterioration in his neurological status, and any problem with his upper limbs, then Dr B could be contacted with a view to reviewing Mr A at short notice.

Ms C, manager of customer services at the public hospital, advised the Commissioner that since August 1997 Dr B's practice has been to summarise the detail of the content of the discussion about all aspects of treatment, including the potential risks and records it in the patient's clinical notes before the consent form is signed. In addition, for some patients after attending outpatient clinics prior to admission for surgery, a letter recording the discussion and agreement for treatment is now sent not only to the general practitioner, but also to the patients themselves. Ms C stated:

> "*This has proved particularly helpful for some patients where the treatment choices are more complex, and ensures that by the time of admission any unanswered questions can be resolved to their satisfaction.*"

Mr A advised in his response to the provisional opinion that:

> "*… [Ms C] implies that [Mr A] did not understand explanations and that the GP, under the new system, could explain these again and answer any questions. Some detail was given in the letter sent to [Dr E], in his case, prior to the operation which [Mr A] fully understood. She preferred [Dr B] answer any questions regarding his surgical procedures and risks. The difficulty in [Mr A's] case was the lack of information given by [Dr B], and the disregard for spelling out honestly the risks involved even when directly asked. No new system of letter given to GP's and patient would have resolved this situation.*"

Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Advice to the Commissioner

The Commissioner obtained advice from an independent neurological advisor who stated:

> *"(1) [Dr B] examined [Mr A] at 10.30 a.m. on 5.9.97. His entry in the hospital notes was '7ml of straw coloured fluid aspirated from the upper part of the wound. CSF sent for culture. The swelling reaccumulated within minutes – CSF. Patient to be on back or when sitting to use a towel or padding to press on the wound. Can have weekend leave. Sutures out Monday'. The laboratory report on the same day was '10ml of orange fluid. Gram stain: no organisms seen'. It was not until 9.29 a.m. on 8.9.97 that it was possible to report the result of the culture. There was a very scanty growth of coagulase negative staphylococcus. [Mr A] was then started on the appropriate antibiotic treatment.*
>
> *It appears that on 5.9.97 [Dr B] made the diagnosis of CSF cyst within the wound; what is known as pseudomeningocoele. Had he known that the cyst was infected, I very much doubt that he would have allowed [Mr A] to have weekend leave.*
>
> *Another entry in the hospital records following [Dr B's] note was 'patient has gone on leave for the weekend and will return on Monday about 8.30 a.m. He is aware that he can return to the ward at any time or phone the ward re any queries'. I would have thought that [Mr A] would have contacted the ward when he woke up early on 6.9.97 with symptoms he had not had when he left the hospital: the pounding headache, vomiting, neck pain and drowsiness. Only with the benefit of hindsight, [Mr A] should have been kept in hospital on 5.9.97.*

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Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Advice to the Commissioner *continued*

(2) According to the hospital records, the only documentation of leakage from the wound was on 2.9.97 p.m., 'slight ooze noticed from the wound'. On 3.9.97, 9 a.m., 'fluid collection superior aspect' and nocte 'nil ooze, haematoma remains'. On 4.9.97 at 7.30 a.m. 'fluid collection superior aspect of the wound' and at 2 p.m. 'wound dry – intact'. On 5.9.97 at 10.30 a.m., '7ml of straw coloured fluid aspirated from the upper part of the wound'. Thus on 5.9.97 there was a CSF collection in the wound (pseudomeningocoele) but no leakage.

(3) Dealing with a recurrent tumour of the spinal cord in a patient with already compromised neurological function is not easy especially since the findings during the operation were different to the presumed preoperative diagnosis. I believe that [Mr A] received appropriate management but the profuse leakage during the weekend leave with the subsequent meningitis led to this outcome.

(4) It appears from [Dr B's] letter to [Dr F] on 13.8.97 that [Dr B] thought that [Mr A's] tumour was recurrent Grade III astrocytoma with cystic component in which case he would drain the cyst and take a biopsy of the solid part of the tumour. I suspect this is why [Dr B] felt that this type of surgery carried little or no risk of making the neurological deficit worse. I suspect that had [Dr B] known that he was going to perform a more formidable operation in removing a spinal cord haemangioblastoma, he would have warned [Mr A] of a definite risk of making his neurological deficits worse.

Continued on next page

Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Advice to the Commissioner *continued*

(5) In his letter to [the Commissioner] dated 10.8.98, [Dr B] said that he made [Mr A] aware of the greater risk of CSF leak postoperatively and with delayed wound healing and wound infection in his case. According to medical literature, laminectomy wound infection occurs in 0.9-5% of cases (Shektman et al: Management of Infected Laminectomy Wounds, Neurosurgery, 35: 307-9, 1994). It is generally accepted that [the risk of infection and delayed wound healing] increases in re-exploration operations as is the case with [Mr A]. It appears to me that the information given to [Mr and Mrs A] was adequate.

(6) Culture of the CSF collected at 10.20 a.m. on 5.9.97 yielded a very scanty growth of coagulase negative staphylococcus. This result became known at 6.29 p.m. on 8.9.97. Examination of the CSF collected at 9.15 a.m. on 8.9.97 showed the CSF glucose to be [zero] mmoI/L (normal is 2.8-4.4). This result was phoned at midday on the same day. Culture of the same fluid yielded moderate growth of Streptococcus Group G. This result was reported at 10.33 a.m. on 9.9.97. These results of examination of the CSF indicated meningitis.

(7) [Mr A] was not put on antibiotics before he went on weekend leave because there was no evidence of infection in the CSF specimen collected at 10.20 a.m. on 5.9.97. The report at 6.29 p.m. on the same day stated, 'no organisms seen on gram stain'. The culture yielded very scanty growth of coagulase negative Staphylococcus but this result was not known until 6.29 p.m. on 8.9.97. It takes at least 24 hours for cultures to grow organisms.

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Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Advice to the Commissioner *continued*

(8) It is doubtful whether continuation of antibiotics from the first operation would have prevented the occurrence of the meningitis. In fact it is possible that the continuation of the antibiotic from the first operation would have made it difficult to isolate the responsible organism when meningitis occurred. The usual practice regarding prophylactic antibiotic therapy is to start it at the onset of the operation and to continue it for 24 hours postoperatively. On the other hand, a significant number of neurosurgeons do not believe in prophylactic antibiotic therapy when doing 'clean' operations.

(9) The usual management of a CSF leak after spinal operations is conservative to start with. This includes resuturing the skin at the site of the leak, bed rest in slight Trendelenburg position, preferably with the patient prone to reduce pressure on the leakage site and pressure dressing. If this fails operative repair is indicated provided infection has not taken place. In the presence of infection, antibiotic treatment has to be started and the operation is postponed until the infection is under control.

(10) It appears to me, having read [Dr B's] operation note on 26.8.97, that he closed the wound in the accepted appropriate manner, 'the neodura and the lower spinal dura at T12 level was now closed with a combination of continuous and interrupted sutures of 3/0 nuralon. The fibrotic paravertebral muscles and the fascia were now closed with multiple sutures of heavy PDS and the skin closed in two layers as well – no drainage being used'. Had this not been a second operation [26 August 1997] on a patient not treated previously with radiotherapy, CSF leakage would have been highly unlikely.

(11) The issue to have been addressed would have been not to allow [Mr A] to go on weekend leave and/or for [Mr A] to have been back to hospital in the morning of 6.9.97.

Continued on next page

Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Advice to the Commissioner *continued*

(12) With the only recorded CSF leak in the hospital notes being a slight ooze on 2nd September 1997, the possibility of CSF leak during the weekend leave starting on 5.9.97 was remote. Still I would probably have advised the family of this possibility.

(13) Surgeons' personalities differ. Some are more optimistic than others are and with this goes the scenarios they give their patients. As stated before, I suspect that had [Dr B] known that he was going to perform a more formidable operation than he had originally thought, he would have informed [Mr A] of the possibility of worsening of his preoperative neurological deficits.

(14) It appears from [Dr B's] letter to [Dr F] on 13.8.97, 'surgery of this nature is not easy' and from his letter to [the Commissioner] on 10.8.98, that he made [Mr A] aware of the difficulty involved in and the possible complications of a redo operation. My impression is that probably [Dr B] should have highlighted what he said more and [Mr A] should have had less expectations from the operation. I do not believe that [Dr B] misled [Mr and Mrs A] by the technical information he gave them, but it is possible that the information was open to misinterpretation.

(15) In conclusion, I believe [Dr B] provided [Mr A] with care that complies with the accepted professional standards and that there was no delay in treatment. It is regrettable that [Mr A] was allowed to have weekend leave and that he did not contact the ward or [Dr B] personally in the morning of 6.9.97."

Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Response to Provisional Opinion

Dr B

Dr B stated with regards to points 3, 4 and 13 in the independent neurological advisor's advice that:

> *"I should point out that following this man's first operation [at the public hospital] on 26/08/1997 his neurological deficit was not worse. Furthermore following his developing the CSF leak on 06/09/1997 and the low grade meningitis his neurological deficit was not worse; following reoperation on 16/09/1997 his neurological deficit was not worse – his deficit did worsen subsequently with the second episode of meningitis and by this stage what we now know was the development of a dense inflammatory arachnoiditis involving the cauda equina.*
> …
> *In my preoperative discussions with this patient and his wife concerning the MRI findings and the surgical procedure relevant to these MRI findings: I approached this topic with a reasonable technical approach as I do with all patients so that they understand the principles of what is going to be undertaken surgically and therefore any difficulties that may be encountered. If this patient and his wife perceive this as being too technical then I apologise, but I would hope that in such a situation the patient and family would feel free to indicate this and that they required a further or different line of discussion or explanation. If they felt my manner was not conducive of this then I apologise.*
>
> *My discussions were of course strongly based on what was assumed to be a certain pathological condition i.e. a malignant spinal tumour which had been originally been operated on many years before and which had undergone high dose radiotherapy and subsequent cystic change. I had no idea then (and I think it is quite unreasonable to expect an inkling of this) that the pathology was going to be quite different, indeed a benign vascular tumour and not a malignant spinal cord tumour.*

Continued on next page

Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Response to Provisional Opinion *continued*

The first operation did proceed smoothly and straightforward and the subsequent small defect in the neodura which was the source of the later CSF leak was not at all apparent or seen at the time of closing the neodura at the first operation. In my explanation to the patient and his wife preoperatively I stated that he would be admitted to [the] ward the day prior to surgery, would undergo the surgery on the next day and that I expected that surgery would not be straightforward in terms of having to dissect the layer of neodura and to close this as carefully as possible – this layer was never as good as the original layer of dura – this was explained to the patient and his wife. I furthermore stated that the patient would then be nursed for five days supine and on complete bed rest in order to allow the sutured neodura to seal and therefore to minimise the likelihood of a CSF leak, I told them that he would then be mobilised on the sixth postoperative day and that the skin sutures would be left in for a total of fourteen days as the healing in irradiated tissues was delayed and this meant that sutures would have to remain in for this period of time. I also told him that the risk of wound infection was slightly higher in such patients who have undergone reoperation particularly when there has been previous irradiation, but modern antibiotic management was generally able to deal with such infections. As regards his time in hospital postoperatively therefore he was informed that there would be five days of complete bedrest and then gradual mobilisation and if the wound was satisfactory he could look at a period of leave at home from the 7th postoperative day onwards with the sutures not being removed until at least the 14th postoperative day and then providing the wound was healing satisfactorily.

Finally and as I stated previously, his adverse outcome with regard to deteriorating neurological function in his legs with a more dense paraparesis is associated with the dense adhesive arachnoiditis that has occurred as a response to reoperation and a low grade spinal meningitis and the degree of arachnoiditis is a very unpredictable pathological event and really out of the ordinary and I did not expect this nor predict this outcome."

Continued on next page

Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Response to Provisional Opinion *continued*

Dr B stated in relation to his communication with Mr and Mrs A that:

> *"The information I gave [Mr and Mrs A] prior to the first operation was in my opinion, quite comprehensive and detailed (and perhaps too technical) but neurosurgery of this nature is indeed very technical. If the patient was not able to understand some of the detail I would then expect the patient would let me know by way of questions or ask for simpler explanations in a language that he could understand. …"*

Dr B stated in relation to his information disclosure that:

> *"The only two options available to this patient at that time – and these were explained to him, were that by undertaking no neurosurgical intervention progressive paraplegia would occur whereas by undertaking operation with what was believed to be the pathology at the time, we may be able to avoid this inexorable outcome or to delay its occurrence. …*
>
> *… I did discuss risks of worsening his neurological deficit which assuming the diagnosis preoperatively (which proved to be incorrect) was truthful and realistic … . I stated that the patient would be admitted to hospital the day prior to surgery, would then be nursed supine with complete bedrest for five days postoperatively and then gradually mobilised with a view to possible interim leave from hospital not earlier than seven days postoperatively with the sutures to be removed whilst an inpatient (although perhaps on leave on 14th postoperative day). You are quite right to say that it is not reasonable for [Mr A] to know every possible circumstance that could occur to him in the upcoming surgery, also it should be remembered that it is not possible for the surgeon to know every possible circumstance either. As I have mentioned previously this man's neurological deficit remained unchanged following the operation of 26/08/1997 and was initially unchanged following reoperation and only deteriorated with the development of his second episode of meningitis and the densities of arachnoiditis."*

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Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Response to Provisional Opinion *continued*

Dr B stated in relation to the consent given by Mr A:

> *"It is important not to confuse the lead up and the details of the first operation of 26/08/1997 with the unexpected adverse outcome that resulted following his developing the second bout of meningitis and density of arachnoiditis following reoperation on 16/09/1997. … I reiterate that I talked to the patient and his wife "on more than one occasion verbally and with the use of diagrams and pictures" and whilst the notes did not document this course of action the fact remains that I did so in what I believed was an honest and usefully descriptive (but verbally and with visual aids) manner and again I would have hoped and expected that if the patient and/or relatives did not understand what was being described they would let me know the information was given in a way that they did not understand and appreciate. Such imparting of information has to be a two way process."*

Dr B further stated in response to the Commissioner's provisional opinion:

> *"I accept that with regard to the Code of Health and Disability Services Consumers' Rights and with regard to my communication with this patient that at the end of the day he has felt inadequately informed and with regard to this I apologise to the patient. I am familiar with the Code of Health and Disability Services Consumers' Rights and am indeed one of the medical advisors at [the public hospital]. With regard to my practices in relation to effective communication, I have always made considerable efforts to communicate in a manner commensurate with a patient's background, intelligence and insight and will always continue to do so. I am sure that my abilities in this regard will never be perfect but I can assure you that I would regard this aspect of medicine as of the utmost importance and have always and will continue to strive to maintain a high standard of communication with patients and relatives and this of course includes informed consent.*

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Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Response to Provisional Opinion *continued*

Finally as regards writing full notes in patients' files – I have always made special efforts to document patients' histories, neurological findings and radiological findings in fine and accurate detail. The documentation of discussions as regards indications for, risks of and outcomes of surgical interventions is more difficult and can be extremely time consuming and in some situations (e.g. acute surgery) may be quite impractical. Pressure of work will quite often not allow such written documentation to be undertaken in detail and in practical terms this is going to mean that doctors may well have to avail themselves more and more of the technology of audio and/or video recording of consultations/interviews (as is indeed done in parts of the USA) and discussions in the future."

The Public Hospital

The public hospital made the following comments in response to the Commissioner's provisional opinion:

*"**Informed Consent***

We concur with your view that Right 5, 6 and 7 work together and a finding of breach of one may lead to a finding of breach of the others. We do not, however, believe that a finding of breach is justified.

Firstly, the reference to a 'technical explanation' is somewhat misleading as this explanation involves a detailed look at x-rays and use of diagrams and/or plastic models. It would be more appropriate to describe this as providing an 'explanation including the use of x-rays and diagrams'.

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Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Response to Provisional Opinion *continued*

Obviously consumers have a right to effective communication but communication is a two way process. Your own adviser acknowledges this with his comment that '[Mr A] should have had less expectations from the operation'. Your own adviser also stated that he did not believe that '[Dr B] misled [Mr and Mrs A] …' and that 'it appears to me that the information given to [Mr and Mrs A] was adequate'. This being so we do not believe it is appropriate for you to reach a decision which conflicts with your own adviser.

As you are aware, a provider is not in breach of the Code if the provider has taken reasonable actions in the circumstances to give effect to the rights and comply with the duties in the Code. In this case [Dr B] provided a full and detailed explanation of what was causing his problems including the use of visual aids. [Dr B] made all reasonable attempts to be approachable so that [Mr and Mrs A] could ask appropriate questions.

We accept in retrospect that [Mr and Mrs A] felt uncomfortable asking for further information, but in the circumstances because of the possibility of the consumer it was not reasonable for [Dr B] to know this.

In relation to Right 5(1) you state 'I concur with my adviser that [Dr B] should have fully informed [Mr A] of the difficulties involved during the first operation, post-operatively and then of the possible complications of the subsequent operation he had on 16 September, 1997'. It is of course axiomatic that consultants should advise patients of significant risks in relation to all surgery. The paragraph as it is written seems to contain implied criticism that [Dr B] did not advise [Mr A] of the difficulties involved in the various procedures. After carefully reading the advisors statement contained in the provisional opinion we do not believe this interpretation can be sustained.

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Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Response to Provisional Opinion *continued*

In relation to Right 6(1)(b) the suggestion from the Commissioner's office is that Dr B should have listed in the medical records the potential risks involved in the surgery. We certainly recommend that surgeons should note in the patients medical record that risks have been explained but it is not common practice in this hospital or in hospitals generally for all the potential risks to be detailed. In this case a letter to [Dr F] and [Dr E] which forms part of the medical record noted in general terms that the surgery 'was not easy' and [Mr and Mrs A] have confirmed that [Dr B] did indeed advise them that surgery was not going to be easy. The most reasonable interpretation of this is that it indicates that the risks of surgery were outlined. We do not believe that this being the case it is possible for [Mr and Mrs A] to maintain that [Dr B] told them nothing about the risks or side effects of the surgery.

Overall we believe that there is not enough information on which to find a breach of Right 5(1), 6(1)(b) and 7(1). In retrospect we accept that [Mr and Mrs A] may not have fully understood the procedure and the information provided. However, the provider is not in breach of the Code if the provider has taken reasonable actions in the circumstances to give effect to the rights and comply with duties in this Code. In this case we believe that the actions [Dr B] gave to fully explain the procedure (including the risks involved) were reasonable actions in the circumstances to give effect to these rights. We therefore believe it is not justifiable to find a breach of the Code in the circumstances.

Having said this, we are very aware that this patient has had an adverse outcome and that [Mr and Mrs A] have had difficulty coming to terms with this outcome. Additionally, their complaint has been under an internal and external investigation for three years and the extended delay in resolving it is likely to have increased [Mr and Mrs A's] dissatisfaction.

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Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Response to Provisional Opinion *continued*

In the circumstances we believe an apology would be appropriate even if the finding of breach was not sustained. We also believe that the recommendation in relation to familiarisation with the Code and review of the practices are inappropriate in the circumstances. [Dr B] is a Medical Advisor for [the public hospital] and is very familiar with the Code and who has an educative role for other senior staff. Even if it was accepted (and it is not) that [Dr B] did not have a full understanding of the Code at that time it must be remembered that this surgery took place three years and three months ago before the Code was well understood through the industry and before [Dr B] was a Medical Advisor.

Additionally, an internal review of this process three years ago made it clear that although an explanation was given [Mr and Mrs A] felt disempowered and therefore did not question [Dr B] as they should. As a result [Dr B] now incorporates as part of his consultation invitations for patients to question him on any aspect of his explanation and makes extra efforts to ensure that an environment is created so that patients do not feel intimidated in asking questions. In the circumstances we believe it would be more appropriate if breaches are found for these recommendations to be altered to reflect that any remedial action, if necessary, has already occurred."

Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Code of Health and Disability Services Consumers' Rights

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

RIGHT 4
Right to Services of an Appropriate Standard

2) Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.

RIGHT 5
Right to Effective Communication

1) Every consumer has the right to effective communication in a form, language, and manner that enables the consumer to understand the information provided. Where necessary and reasonably practicable, this includes the right to a competent interpreter.

RIGHT 6
Right to be Fully Informed

1) Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including –

…

b) An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option; …

2) Before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, needs to make an informed choice or give informed consent.

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Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Code of Health and Disability Services Consumers' Rights *continued*

RIGHT 7
Right to Make an Informed Choice and Give Informed Consent

1) Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.

Other Relevant Standards

The Medical Council of New Zealand, 'Medical Practice in New Zealand: A Guide to Doctors Entering Practice' (1995)

13. THE PATIENT'S MEDICAL RECORD

Private Clinical Records

13.1 "*[A] doctor is expected as part of the quality of service provisions to maintain adequate records.*"

Inadequacy of Patient Information/Records as a Form of Misconduct

13.2 "*… the absence of some written, possibly now computer, record of annotation invariably makes the task of establishing the truth very difficult.*"

Opinion: No Breach - Dr B

Right 4(2)

Wound management

In my opinion, Dr B did not breach Right 4(2) of the Code of Health and Disability Services Consumers' Rights in relation to his management of Mr A's wound.

Mrs A advised that the leakage from Mr A's back started on 1 September 1997, however Mr A stated that it started on 3 September 1997. Dr B documented that he assessed Mr A's wound on 1, 3, 4 and 5 September 1997 and noted that the wound was dry, despite a fluid collection in the wound. On 5 September 1997, fluid was aspirated from the wound and sent to the laboratory for testing.

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Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Opinion: No Breach - Dr B ***continued***

Prior to Mr A going on weekend leave he was given a comprehensive explanation by ward staff and instructed by Dr B to return to the hospital at any time or to telephone the ward with any queries.

On Mr A's return from weekend leave on 7 September 1997, the house surgeon noted that there was fluid leaking from the wound, which was subsequently re-cultured for infection. On the morning of 8 September 1997 when Dr B reviewed Mr A, he noted CSF leaking and took further specimens and commenced antibiotics. The wound was noted to be leaking until surgery was performed on 16 September 1997 to stop the CSF leak.

My advisor informed me that Dr B's management of Mr A's wound, when the CSF was noted and aspirated for culture on 5 September 1997, was conservative and in line with usual practice if a CSF leak is found. Additionally, resuturing the skin at the site of the leak was undertaken and Mr A was placed on bed rest in slight Trendelenburg position. The preliminary laboratory results received on 5 September 1997 showed no evidence of infection. Once the cultures were received on 8 September 1997, Dr B was able to initiate the necessary antibiotics for the infection.

Between 7 September and 16 September 1997, Dr B and staff on the ward dressed Mr A's wound regularly and continued administering antibiotics until a decision was made to surgically intervene to stop the CSF leak. This was not able to occur until Dr B was sure the infection was under control.

I accept my independent advice that there was no undue delay in providing treatment to Mr A. In my opinion, Dr B's management of Mr A's wound complied with professional standards and did not breach Right 4(2) of the Code.

Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Opinion: Breach - Dr B

In my opinion Dr B breached Right 5(1), Right 6(1)(b) and Right 7(1) of the Code of Health and Disability Services Consumers' Rights in the following respects:

Informed consent

Gaining informed consent is essential before any procedure is provided. In terms of the Code of Rights, informed consent is not a one-off event, but a process comprised of three parts:

- effective communication between the parties,
- provision of all necessary information to the consumer (including information about options, risks and benefits), and
- consent freely given by a competent consumer.

These three parts work together and are represented in the Code by Rights 5, 6 and 7 respectively. In my opinion, the process that Dr B followed to gain informed consent from Mr A was not sufficient to meet the standard required under the Code.

Right 5(1)

Under Right 5(1), consumers have a right to effective communication, to receive information in a manner and form that enables them to understand this information. The onus is on the provider to give information to a consumer in a manner that the consumer understands.

It is apparent to me that Dr B gave information about risks to Mr A in a manner which was open to misinterpretation and misundertanding. Dr B considered that he advised Mr A of the risks of the proposed surgery, including potential post operative complications, which in fact transpired and resulted in a worsening of Mr A's neurological deficit. Yet, Dr B emphasised to Mr A that there were little or no risks involved in the surgery. Mr A came away from the consultation with the impression that the operation would be straightforward, with no significant risks. I acknowledge that it was not Dr B's intention to mislead Mr A.

Continued on next page

Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Opinion: Breach Dr B *continued*

While the letter from Dr B to Dr F of 13 August 1997 does not clarify exactly what information Dr B gave Mr A about risk, in my opinion, it supports the impression Mr A gained that there was little risk, if any associated with the surgery.

I note that while my advisor considered that the information provided was adequate, this opinion was based on Dr B's version of events (which is disputed). It is significant to note that the independent advisor commented that assuming Dr B did provide the information about the risks, Dr B should have highlighted the difficulties more, to ensure Mr A had a realistic expectation of the risks of surgery.

In my opinion, Dr B did not take reasonable steps to ensure that the information about risks was adequately communicated in a manner that was fully understood by Mr A. Dr B's failure to communicate effectively is a breach of Right 5(1) of the Code.

I note that since August 1997 Dr B has changed his practice. Dr B now incorporates as part of his consultation invitations for patients to question him on any aspect of his explanation and makes extra efforts to ensure that an environment is created so that patients do not feel intimidated in asking questions. I commend Dr B on making these changes to his practice.

Right 6(1)(b)

Right 6(1)(b) of the Code sets out a list of information that a reasonable consumer in Mr A's circumstances might expect to receive from a health provider. This is not an exhaustive list. A reasonable consumer in Mr A's circumstances would expect to receive a detailed explanation of the expected risks of the surgery.

Dr B mainatains that he explained the difficulty of the operation and the possible complications involved in this type of surgery. Dr B said that he explained to Mr A that he was at a greater risk of a CSF leak post-operatively, with delayed wound healing, wound infection and further surgery.

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Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Opinion: Breach – Dr B *continued*

Conversely, Mr A maintains that he specifically questioned Dr B about the risks and explained why this information was so important to him. Mr A said that Dr B led him to believe that there were no real risks. Mr A disputed that Dr B advised him of the possible complications of surgery. He stated that Dr B did not explain CSF leakage, delayed wound healing due to the past operation, or of any possible wound infection.

After the consultation with Dr B, Mr A had an appointment with his general practitioner, Dr E, for reassurance regarding the surgery. Mr A's decision to have the surgery, particularly at that time, was clearly important to him, as he was self-employed and if there was a possibility that he was going to be off work for a long period he would need to employ a manager.

Although Dr B's recollection is that he did explain these risks, whatever information he gave to Mr A about these risks was clearly not sufficient to meet the standard of what Mr A reasonably expected to be told about the risks in the situation he faced. It is significant to note that Mr A sought reassurance from his general practitioner about the surgery.

Dr B had an obligation to ensure Mr A was provided with all relevant information including information about what could reasonably occur to him during and after the surgery. The onus is on Dr B to prove that he provided Mr A with the information. In my opinion Dr B failed to provide sufficient information to Mr A prior to surgery and therefore breached Right 6(1)(b) of the Code.

Right 7(1)

In my opinion Mr A did not receive the information necessary to enable him to make an informed choice and give informed consent to the operation on 26 August 1997. What information Mr A did receive was not communicated to him in a manner that enabled him to understand the information provided. Therefore in my opinion, Dr B breached 7(1) of the Code.

Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Opinion: No Breach

Right 5(1), Right 6(1)(b), Right 7(1)

The Public Hospital

Informed consent

In my opinion the public hospital did not breach Right 5(1), Right 6(1)(b) or Right 7(1) of the Code of Health and Disability Services Consumers' Rights. While the public hospital would expect their medical practitioners to fully explain all aspects of the treatment to their patients, the public hospital can not be expected to be responsible for the individual communication styles of its medical practitioners. I have noted that the public hospital has since prepared a comprehensive Informed Consent Policy and introduced a new Agreement to Treat Form, and undertaken an extensive education programme on informed consent with all clinical services. I commend the public hospital on these initiatives.

Other Comments

The ward, the public hospital

I note that Mr and Mrs A were also concerned about the timeliness with which staff of the ward acted in response to Mr A's changing condition following his return to the ward after weekend leave on 7 September 1997. I have not found it necessary to determine whether the ward staff breached the Code in this respect. However, in terms of Mrs A's complaint, I make the following comment on the actions of the ward staff from 7 September 1997:

During the week leading up to Mr A's weekend leave, staff of the ward and Dr B were aware of the status of Mr A's wound and documented this. Slight ooze from the wound was noted only on 2 September 1997. On 5 September 1997, Mr A was given information to contact the ward or to return to the ward if required. When Mr A returned to the ward following his weekend leave on the afternoon of 7 September 1997 due to changing health, steps were taken to assess his medical needs. Mr A was assessed by the house surgeon who discussed his condition with the registrar, blood tests and specimens were taken, hourly neurological observations were recorded and instructions given for the administration of antibiotics if Mr A's temperature increased. The following morning Dr B assessed Mr A further, took specimens, checked the laboratory reports that were available and commenced antibiotics for him.

Continued on next page

Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Other Comments *continued*

In my opinion, the interventions of the employees of the public hospital, Dr B and staff of the ward were reasonable actions in the circumstances to ensure that Mr A was assessed and treated in a timely manner appropriate to his condition.

Record keeping

The Medical Council of New Zealand sets standards for record keeping by medical practitioners. In accordance with these standards Dr B had a professional obligation to adequately document the consultation with Mr A. Additionally, where there is an absence of notes related to a patient, establishing the truth is very difficult.

I note that the letter sent to Mr A's general practitioner and to the Oncology Department at the public hospital documented the consultation with Mr A, including the advice Dr B provided to Mr A. It is most unfortunate that Dr B did not record the advice he maintains he provided Mr A in relation to risks and potential complications. While I acknowledge that in some circumstances it is difficult and/or time consuming to record the potential risks advised to a patient, in these circumstances it would not have been difficult to do so. In my opinion, Dr B could easily have documented the advice he gave Mr A about risks in his letter.

I am pleased to note that Dr B now summarises the detail of the content of the discussion about all aspects of treatment, including potential risks, and records it in the patient's clinical notes before the consent form is signed. In addition, for some patients after attending outpatient clinics prior to admission for surgery, he sends a letter recording the discussion and agreement for treatment not only to the general practitioner, but also to the patients themselves. I recommend that other specialists adopt this practice unless there is good reason not to do so in a particular case.

Dr B / A District Health Board

Opinion - Case 98HDC13693/VC, continued

Actions:
Dr B

I recommend Dr B takes the following actions:

- Apologises in writing to Mr A for breaching the Code of Health and Disability Services Consumers' Rights. This letter is to be sent to the Commissioner who will forward it to Mr A.

Other Actions

A copy of this opinion will be sent to the Medical Council of New Zealand. An anonymised copy of this opinion will be sent to the Royal Australasian College of Surgeons for educational purposes.