Gastrointestinal and Hepatobiliary Surgeon, Dr A

A Report by the

Health and Disability Commissioner

Case 09HDC00795

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Overview

In late 2007, 56-year-old Mr B was diagnosed with advanced colon cancer with secondary cancer in the liver. On 1 November he had surgery to remove cancerous tumours in his bowel. Later that month, Mr B's general practitioner referred him to gastroenterology and hepatobiliary surgeon Dr A in his private practice for assessment and ongoing treatment. On 19 November, Dr A discussed the treatment options with Mr B, and provided him with an information booklet about liver cancer diagnosis and treatment. Dr A advised Mr B that without treatment his life expectancy was three to six months, and recommended an oncological treatment, with ongoing chemotherapy. This treatment is costly and is available only through the private sector. Mr B did not have medical insurance, so the costs of the treatment were specifically discussed. Dr A told Mr B that the treatment was non-curative and the cost would be between $35,000 and $45,000. Mr B opted for the oncological treatment.

On 22 November 2007, Mr B was admitted to the private hospital for the insertion of a surgically placed vascular access device. The procedure was undertaken by Dr A, and the oncological treatment was administered. Mr B was discharged on 2 December 2007. On 16 January, Dr A reviewed Mr B and found he had responded well to the treatment. Mr B had his second cycle of chemotherapy at the private hospital and his third and fourth cycles at a public hospital. On 26 March Dr A recommended that, in light of the improvement in Mr B's condition, he should have a further three cycles of chemotherapy.

However, on 25 June Dr A reviewed Mr B and found his cancer was progressing and discussed further treatment options. One was a repeat of the oncological treatment. Mr and Mrs B decided on a repeat of the treatment. They were advised that the cost for this procedure was $18,000 to $20,000. Mr B was admitted to the private hospital on 25 July for the procedure. A study, performed to ensure that it was safe to proceed with the oncological treatment found that the vascular access device was not functioning. Following discussions that morning between Dr A and Mr and Mrs B, a femoral artery catheter was inserted, at additional cost, to allow further oncological treatment. Mr B was discharged on 27 July. Over the rest of 2008, Mr B's liver cancer continued to progress. He died in 2009.

Complaint and investigation

On 27 January 2009, the Health and Disability Commissioner (HDC) received a complaint from Mr B about the services provided by gastroenterology and hepatobiliary surgeon Dr A. The following issues were identified for investigation:

- *The appropriateness of the care provided by Dr A to Mr B from November 2007 onwards.*

- *The adequacy of the information provided by Dr A to Mr B about the risks of proposed treatment (in particular the risk of the surgically placed vascular access device failing) and other management options.*

An investigation was commenced on 12 February 2009.

The parties directly involved in the investigation were:

Dr A	Surgeon/Provider
Mr B	Consumer
Mrs B	Consumer's wife
A private hospital	Private hospital

Information was reviewed from:

- Mr and Mrs B
- Dr A
- The private hospital
- The district health board
- ACC

Others mentioned in this report:

Dr C	Mr B's general practitioner
Dr E	Oncologist, the public hospital

Independent expert advice was obtained from Dr Peter Johnston, a general and hepatobiliary surgeon, and is attached as **Appendix 1**.

Key events

Surgery at a public hospital
In late 2007, 56-year-old Mr B was diagnosed with advanced colon cancer and extensive secondary cancer in the liver. On 1 November 2007, he had a palliative sigmoid colectomy[1] at the public hospital performed by a general surgeon. The general surgeon found that Mr B had a "near obstructing tumour of his sigmoid with liver full of metastases[2]". The surgery was successful in removing the tumour. Although the general surgeon explained to Mr B that his prognosis was poor, Mr B was keen to seek a second opinion regarding curative treatment. Following his discharge from the public hospital, Mr B was referred by his general practitioner, Dr C, to Dr A, a gastrointestinal and hepatobiliary surgeon at the private hospital.

[1] Surgery to remove the sigmoid colon (part of the descending colon that leads to the rectum). The procedure involves cutting into the abdomen, removing the diseased area of the bowel and joining the two healthy ends of the bowel either by stapling or stitching.
[2] Secondary cancers.

Initial consultation at the private hospital
On 19 November 2007, Mr B attended his first appointment with Dr A, accompanied by his wife, Mrs B, to discuss treatment options.

Dr A told Mr and Mrs B that there are limited treatment options for advanced metastatic bowel cancer affecting the liver, and they are "almost always ultimately unsuccessful". He said that the first and usual approach is systemic chemotherapy,[3] which is available through public hospitals. However, it is never curative. Positive responses to this treatment are short-lived, for about four to seven months before the cancer progresses. This treatment is associated with a degree of toxicity that can sometimes be severe. Mr B was not keen on this option as he had witnessed a number of friends have major problems with this treatment.

The second approach is regional therapy that directs cancer treatment to the liver alone, thereby minimising ongoing toxicity and side effects to surrounding organs. Large doses of radiation are directed to the tumours in the liver through the hepatic artery. This oncological treatment is usually given via a surgically implanted vascular access device in conjunction with ongoing chemotherapy. To maintain patency,[4] the device must be flushed with heparin solution at least once every four weeks when it is not in use.

The cost of the initial surgery to place the vascular access device and to deliver the oncological treatment was approximately $35,000–$45,000. Dr A advised HDC that although most patients have only one oncological treatment, approximately 10% of individuals require a second delivery, usually nine to 18 months later. The cost of repeat treatment varies according to the manner in which it is delivered. When it is given through an existing functional vascular access device, the treatment costs are an extra $18,000–$20,000. When the oncological treatment is delivered through a femoral artery catheter, there is a further cost of around $5,000–$7,000, taking the total additional cost to approximately $22,000–$25,000.

Mr B was impressed by Dr A's advice about the oncological treatment's superior response rate and its lack of associated side effects. He told Dr A that he preferred the approach offered by Dr A. Dr A provided Mr and Mrs B with a copy of a patient information booklet about liver cancer, diagnosis and treatment.

Dr A recalls:

> "… I gained the impression that [Mr B] held a view that systemic chemotherapy in his situation was relatively futile. He had read my patient information booklet and we had a detailed discussion at that time. This included the risks, uncertainties and expected benefits of the treatment, the fact that it was not curative, that we hoped with the treatment for a survival time of between 12 and 24 months instead of 3 to 6 months which he might otherwise expect, and we did touch on the possibility of

[3] Treatment with anticancer drugs that are injected into a vein or muscle, or are taken orally. These drugs enter the bloodstream and reach all areas of the body. They can destroy not only the cancer cells but can also affect healthy cells at the same time.
[4] In other words, to keep it open.

> repeat treatment being possible. We also discussed that his ongoing […] chemotherapy should be able to be performed at the public hospital … Because this aspect of his treatment would be conducted at the public hospital there would be no ongoing cost associated with those treatments. However, the cost of the initial treatment, being the surgery and the [oncological treatment], and first cycle of […] chemotherapy which is given during the first admission was discussed. I might say that charges are incurred as services are given. Thus the initial payment of $35,000–$45,000 does not cover the cost of ongoing […] chemotherapy, CT scans and follow-up. …"

Dr A was aware that Mr B did not have any medical insurance. Despite the cost of the treatment, Mr and Mrs B were "very clear that [the oncological treatment] was the right approach for them".

Following the initial appointment, Dr A telephoned the general surgeon, who confirmed that the operation report from the 1 November surgery indicated that the only diseased area was Mr B's liver.

Surgery at the private hospital
Mr B was admitted to the private hospital on 21 November. Dr A performed the surgery on 22 November, which included removal of Mr B's gall bladder and the placement of the vascular access device. Mr B's liver function was measured shortly after the surgery, and he was reported to have a carcinoembryonic antigen (CEA)[5] level of 49.7µg/mL.[6]

On 30 November, the oncological treatment was given to coincide with the first four-day cycle of chemotherapy. There were no difficulties encountered, and Mr B was discharged on 2 December 2007.

Follow-up care between January and June 2008
Mr B's second cycle of chemotherapy was administered by Dr A on 16 January 2008. His third and fourth cycles were administered at the public hospital.

On 8 May, the public hospital oncologist Dr E wrote to Dr C to advise him that Mr B had been reviewed at the medical outpatient clinic that day and appeared to be in good health. Dr E noted that Mr B's CEA had increased slightly and he had arranged for him to have a sixth cycle of chemotherapy. He noted that he had not made any plans for Mr B to be seen again by the public hospital, at that stage, and would await instruction from Dr A.

On 18 April and 16 May 2008, Mr B's vascular access device was flushed by a district nurse. Over May–June 2008, he underwent additional liver function tests, which reported an increase in CEA levels to 7.5µg/mL and 30.8µg/mL respectively.

[5] Antigen found in the blood of patients suffering from colon cancer and other diseases and otherwise normally found in fetal gut tissue. CEA is a tumour marker normally performed to follow up on known cancer in a patient.
[6] The normal range is between 0–3.4 µg/mL.

On 25 June, Dr A reviewed Mr B, noting that his rising CEA indicated his disease was progressing. A CT scan showed no cancer in his lungs or abdomen, but he had developed some new sites in his liver. Mr B was concerned about the disease progression, and discussed his options with Dr A. Dr A advised Dr C in a letter dated 26 June:

> "Unfortunately this means that [Mr B's] … chemotherapy has not been particularly helpful and is not worth persisting with. Although [he] knows that systemic chemotherapy is an option he does not wish to consider this at the present time, and possibly not at all. He has witnessed a number of friends who have had major problems with the chemotherapy and this has been discouraging for him. I have given him some reassurance to say that not all individuals find the [systemic] chemotherapy that difficult and it might well be worth a trial at some point.
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> The other option is a repeat [of the oncological treatment]. [Mr B] did have an excellent response the first time seven months ago and we can be reasonably confident of similar benefit again. … I have suggested to [Mr B] that his prognosis from now without further treatment is probably in the order of 6-9 months, and that if he wishes to have further oncological treatment I would suggest that this be done in the next couple of months. … In the meantime it would be good if his [vascular access device] was flushed on a monthly basis to maintain patency in case he seeks to have further oncological treatment."

Dr A stated that because Mr B's vascular access device had not been flushed for six weeks when he saw him on 25 June, he flushed it himself, without any difficulty. He explained that if the device is not patent there is increased pressure required to flush it, with concomitant pain for the patient. Dr A advised Mr B that the cost of a repeat oncological treatment was high, in the vicinity of $18,000 to $20,000. Mr B stated that he was inclined towards this option, but needed to discuss it with his wife. Dr A did not explore the possibility that the device might not be functional when they came to repeat the oncological treatment, in which case there would be additional costs. Dr A stated that if he had had any inkling the device would be non-functional he would certainly have discussed the issue with Mr B. However, as he was able to flush it on 25 June he was satisfied that it was functioning at that time. He said, "I had no reason to believe that the [device] would not be usable in the next few weeks, and such a possibility was relatively unlikely." As a result he considered the likelihood of such an event was so low as to be not "worthy of mention" given that it was functioning so well a month prior to the treatment. He said that he is specific about risks "of any real magnitude" and "responds to all questions", but "understandably" Mr B did not ask about the costs of replacement of the vascular access device.

On 30 June, Mrs B telephoned Dr A to discuss her husband's treatment. Dr A recalls that he discussed the cost and the relative merits and possible benefit of a repeat treatment with Mrs B, but did not include the costs of replacing the device if it was found to be occluded. Mrs B was "very clear" that her husband should have repeat oncological treatment, and that they would manage the additional cost, though not easily. Dr A said that after this discussion with Mrs B, he made arrangements for Mr B to have a repeat oncological treatment.

Second admission to the private hospital
On Friday morning 25 July 2008, Mr B was admitted to the private hospital for the repeat oncological treatment. Prior to the surgery, a study with a radioactive tracer was conducted to check that it was safe to proceed with the treatment. This revealed that the vascular access device was not functioning. Dr A had a detailed discussion with Mr B about his options: either not to proceed with the oncological treatment, or to perform a CT angiogram to check the patency of the hepatic artery and, if it was patent, introduce a femoral artery catheter to administer the treatment As part of the discussion, Dr A indicated that the financial implication of needing a femoral artery catheter was likely to be $5,000–$7,000 more than the expected procedure. He recalls that Mr and Mrs B were "very adamant" that treatment should proceed.

Dr A stated that as Mr and Mrs B's decision was made late on Friday morning, he was aware that "there was no time to lose because of the decay in the treatment product". Dr A managed to obtain the services of a diagnostic and interventional radiologist at short notice for the interventional radiology procedure that afternoon.

The repeat oncological treatment was delivered uneventfully.

Mr B remained in hospital for another two days, and was discharged on 27 July.

Concerns about costs associated with blocked device
On 30 July 2008, Mrs B wrote to Dr A expressing concern about the cost of the repeat treatment. She stated:

> "[My husband] and I both came away feeling quite disillusioned and unsure of our own situation as regards the blocked [device] and alternative procedure. I understand that there will always be risks involved in any such treatment and we were prepared for these. However, we both felt that the extra $7,000 on top of the original amount was unfair especially in a situation which was beyond our control. …
>
> It seems fair that some if not all of this amount should be covered by the Clinic. Please understand that we are so grateful for the extra quality time you have given us with [him], without you we would (as a family) be finished. However, I needed to let you know my thoughts on this at such a terrible time in our lives."

On 6 August, Dr A wrote to Mr and Mrs B to sympathise with their difficulty in understanding why the device was no longer functioning. He said, "Periodically this is what happens and there is nothing we can do about it." He provided a breakdown of costs and said that he would meet the costs of the CT scan and study, which came to $1,000. However, the private hospital was not able to reduce the costs further.

On 21 August, Dr A telephoned Mrs B to discuss her concerns. He wrote to Dr C the same day to advise him that Mr and Mrs B were "confused" about the problems related to the vascular access device. He said, "I know [Mrs B] will come and talk to you about this." Dr A advised Dr C that the device had not come out, but had become occluded — that this is the body's reaction to a foreign object and occurs in a proportion of patients, but occurred a little earlier than normal in Mr B. Dr A said he did not recommend a laparotomy in Mr B's case, and asked Dr C to arrange a CEA, liver tests and a full

blood count for around 25 August, and then at four-weekly intervals with copies of the test results to be sent to the private hospital.

Dr A said that following the second oncological treatment Mr and Mrs B were anxious for him to replace the device so the chemotherapy could be reintroduced, "even at a potential further cost to them of around another $20,000", which he discouraged.

Follow-up care between October and December 2008
A follow-up review in a large public hospital near his home was planned for 20 October 2008. After returning home, Mr B asked that the follow-up appointment be changed to 22 October 2008, and the venue changed to the private hospital.

On 21 October 2008, Mr B cancelled his appointment with Dr A and stated that he would prefer to have his CT scan at the public hospital, "for financial reasons". Dr A was agreeable and indicated that he would review the CT scan if a copy was forwarded to him. However, it is unclear why Mr B did not then undergo a CT scan of his liver.

The appointment with Dr A was rescheduled to 12 November 2008. However, on 7 November, Mrs B telephoned Dr A to cancel the appointment, and stated that they would get back to him regarding their preferred location for the next follow-up review. That same day, a review at the public hospital Medical Outpatient Clinic was scheduled with Dr E. Mr B did not attend this appointment.

On 5 December 2008, Mr B was seen by Dr E. Mr B's main complaint was fatigue, which Dr E noted was "somewhat worse now than prior", and he also complained of intermittent nausea and non-specific abdominal pain. On examination, Dr E noted that there was no adenopathy[7] and nothing abnormal in Mr B's abdomen. Dr E reviewed Mr B's 1 October blood test results, and noted that his CEA had increased to 42.3 (on 25 August his CEA was 19.4.), and that there was "quite significant disturbance of liver function test". Mr B was advised of the need for a further CT scan. Blood tests were ordered, and a further review was planned for two weeks' time. Mr B was also told that he might have to undergo systemic chemotherapy if there was evidence of disease progression beyond the liver.

Mr B had a CT scan on 19 December 2008 which showed that the numerous metastases on the right lobe of his liver had increased in size. On 22 December, an ultrasound examination indicated that the metastases had spread to both lobes of Mr B's liver.

Events in 2009
On 9 January 2009, Mr B was scheduled to see Dr E to discuss the results of the December investigations, but he did not attend. Dr E wrote to Dr C to advise him that Mr B had missed the appointment and asked whether the distance Mr B had to travel from home might have been a factor. He advised Dr C that there was "little in terms of therapeutics" that could be offered to Mr B. Dr E had no further contact with Mr B.

Mr B died a short time later, aged 58.

[7] Enlarged lymph nodes, which may be caused by localised or generalised infection, inflammatory conditions or malignancy.

Complaint
Mr B advised HDC that he had no complaint with the treatment he received up until July 2008. However, he did have issues with the costs, which "seem to be on the excessive side for some parts of the procedures". Mr B was concerned at the "huge extra expense, in a very short time" of the femoral catheter insertion, which was needed because of the failure of the vascular access device. Mr B stated:

> "I was unaware of the potential for [the device] to fail, and of the consequences, both medically and expense-wise. … Follow-up [….] with chemo was not possible as the [device] was closed, so treatment was terminated. … I wonder why the [device] was not re-fitted. I also wonder why it's still in place since it's not functioning. … My concern is that this process has taken all my funds, and then some: extra costs have come unexpectedly, the original course was not completed, and I am thinking that I have been financially taken advantage of."

Mr B stated that he was unable to complete his treatment because the vascular access device failed. He had always understood that medical professionals provide treatment free of charge to remedy treatments that have failed.

Dr A's response
Dr A advised HDC that although 12 cycles of chemotherapy are usual, this may be modified for a number of reasons, such as tumour progression while receiving the chemotherapy. He stated that the second oncological treatment was not part of the course of treatment. Although around 25–33% of vascular access devices fail, failure is not generally a specific impediment to further treatment, as the hepatic artery can usually be accessed by a percutaneous catheter, as was the case for Mr B. Dr A stated that for these reasons he does not discuss the possibility of failure of the vascular access device with all patients. He has never heard of any reputable medical practitioner who financially guarantees the outcome of treatment.

Dr A advised ACC on 17 October 2008:

> "It is unlikely that I would have specifically mentioned [device] failure to [Mr B] prior to surgery. The most important component of [Mr B's] treatment was to the [oncological treatment]. I have never encountered a situation where the [device] failed before we were able to administer the [oncological treatment] on the first occasion. … In [Mr B's] case, we … only learned of the [device] failure because we planned another [oncological] treatment… (which we do in around 10% of patients). Even so, we don't know whether the failure of response to chemotherapy was related to failure [of the vascular access device] or not, i.e. we just don't know just when the [device] failed. Failure to achieve the desired outcome is certainly discussed prior to the placement of the [device], although there is not necessarily full discussion about the component cause of that failure."

In relation to the cost of treatment, Dr A stated, "It is clearly extremely regrettable that [Mr B] and his family have taken up all their funds, and in his terms 'and then some'." He noted that the cost to them was around $2,000 in excess of the upper limit of what he had estimated it might cost and that although he has sympathy for Mr and Mrs B's

situation, "I do not think they can reasonably expect a refund." Dr A said Mr and Mrs B were "both well informed ahead of incurring the cost at each step along the way, including on the day in which a femoral catheter became necessary. They did choose to proceed with the catheter placement in spite of the additional costs that would be incurred."

Dr A advised HDC, "I did personally meet the cost of his CT scan and … study which was in the order of $1,000."

On 15 June 2009, Dr A wrote to Mrs B. He acknowledged that the benefit that Mr B gained through a second oncological treatment was "only achieved through substantial financial sacrifice for you, [your husband] and your family". Dr A stated, "It is regrettable that this treatment is still only available to patients who meet the full costs themselves." He continued:

> "The purpose of this letter is simply to record again how sorry I am that the whole process was not a more straight forward and manageable one for you all. That the [device] should fail and a different method of administration of the second dose be required, was an additional difficulty for you all. I am sorry that that occurred, and I am sorry if you feel that you should have been prepared by me at an earlier time for that possibility. There always seem so many things that need to be said and covered in the circumstances we all found ourselves in. I apologise again that you were not fully made aware of the possibility that the [device] would not function.
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> I am sure you know well how hard I try for my patients and how sorry I am when additional grief for a patient and a family arises because of issues with the treatment along the way. Once again, please accept my apology for any additional grief I have caused through my actions."

ACC
In late 2008, Mr B submitted a treatment injury claim to ACC. The injury was stated as "failure of [vascular access device] to deliver the necessary treatment". On 7 November 2008, ACC declined the claim on the basis that it did not meet the criteria for a treatment injury. On 12 January 2009, Mr B wrote to ACC to appeal its decision. The ACC review hearing occurred on 4 September 2009. The appeal was dismissed and the original decision affirmed.

Opinion: Breach — Dr A

Adequacy of information
In late 2007, Mr B was diagnosed with extensive liver metastases from sigmoid colon cancer. He was referred to gastroenterology and hepatobiliary surgeon Dr A in his private practice for an assessment of treatment options.

Dr A spent some time with Mr and Mrs B describing the treatment options. He advised them that there were limited treatment options for advanced metastatic bowel cancer affecting the liver, and that any option was almost always ultimately unsuccessful. He

described systemic chemotherapy, which has short-lived positive responses associated with a degree of toxicity that can be severe. Mr B was not keen on this option as he had witnessed a number of friends have major problems with this treatment.

Dr A told Mr and Mrs B that there was an alternative approach, which directs the cancer treatment to the tumours within the liver via a surgically placed vascular access device. Dr A outlined the cost associated with this treatment, which was approximately $35,000 to $45,000. $15,000 of this is the treatment component. Dr A was aware that Mr and Mrs B did not have health insurance, and provided them with a patient information booklet on liver cancer diagnosis and treatment.

Mr B opted for this approach because of Dr A's advice about its superior response rate and lack of associated side effects, despite the cost that would cause him and his family financial hardship. Dr A administered the treatment on 30 November 2007. However, in June 2008, it was evident that Mr B's cancer was not responding. Mr B decided, after further discussion with Dr A, to repeat the oncological treatment. Dr A flushed the vascular access device on 25 June 2008 and believed that at that time it was patent. On 25 July 2008 when the radiation treatment was about to begin it was found that the device was occluded and not functioning. Mr B needed a further costly procedure, a femoral artery catheter insertion, to enable him to have the oncological treatment.

Mr B complained that neither Dr A nor the booklet he provided mentioned the possibility of the vascular access device failing. He said that the femoral catheter was inserted at the private hospital at "huge extra expense because of the failure of the [vascular access device]". Mr B stated, "I was unaware of the potential for [the device] to fail, and of the consequences, both medically and expense-wise." As a result, he was not able to complete his full course of treatment by way of the vascular access device.

Dr A considers that medical practitioners never financially guarantee the outcome of treatment. I accept that surgery does not come with a money-back guarantee. However, patients do need to be informed of significant risks that may arise in the course of treatment.

Dr A accepts that he is unlikely to have specifically mentioned failure of the vascular access device to Mr B prior to the 21 November 2007 surgery, because the most important issue to be discussed was the oncological treatment. Around 25–33% of these vascular access devices fail, but this is not generally a specific impediment to further treatment, as the hepatic artery can usually be accessed by a percutaneous catheter. For these reasons he does not discuss the possibility of device failure with all patients. Dr A stated, "Failure to achieve the desired outcome is certainly discussed prior to the placement of the [device], although there is not necessarily full discussion about the component cause of that failure."

My expert advisor, general and hepatobiliary surgeon Dr Peter Johnston, considered that Dr A's consent practice was "adequate for the situation". He agrees that where there are many issues to discuss, the clinician will focus on the more important ones, and that the details discussed will vary from patient to patient. It is more important for the issues

relevant to the patient's immediate needs to be explained and understood, than for an exhaustive list of possibilities to be covered.

Dr Johnston qualified his advice about the adequacy of Dr A's information disclosure as follows:

> "It could also be said that it would have been better if the information booklet had been more specific on the possibility of [device] malfunction. This could be considered for future editions. Doctors perhaps tend to accept as given the fact that any plastic tube may block, fall out or become infected, but patients may not be aware of this."

I agree that Dr A went to considerable lengths to provide Mr and Mrs B with information he considered relevant about treatment options. However, in my view, further information needed to be disclosed when Mr B was considering whether to repeat the oncological treatment. Dr A advised HDC that "technically the mode of delivery is generally considered to be a detail" and that as he was satisfied that the device was functioning on 25 June 2008, he had no reason to believe that it would not be usable in the next few weeks. He had assessed the possibility of device failure as low and did not consider it necessary to raise the possibility with the patient.

On the basis of the information Dr A provided to them, Mr and Mrs B opted for oncological treatment, unaware that the vascular access device could fail and what the medical and financial consequences of this would be. Dr A's failure to inform Mr B of the possibility that the access device might fail and his options should that occur resulted in Mr B having to make an urgent decision on 25 July, pressured by the knowledge that delay would result in decay of the treatment product. Mr B pointed out that had he known in advance of the relatively high likelihood of blockage (25–33%), he would have had the opportunity to reflect on his alternatives.

Given the need to flush the device on a monthly basis to maintain patency and the 25–33% chance overall of failure of the vascular access device, I am not persuaded that it was reasonable for Dr A to conclude, based on his ability to flush the device on 25 June, that there was little risk of its failure in one month's time. I consider that when repeat of the oncological treatment was raised and discussed with Mr B on 25 June and Mrs B on 30 June, Dr A should have discussed the possibility that the vascular access device might be blocked by the time of treatment on 25 July, what that would mean, and the cost implications.

Information about the possibility of failure of the vascular access device was information that a reasonable consumer in Mr B's circumstances would expect to receive, in light of the medical and financial implications should this occur. I conclude that Dr A did not give Mr B adequate information, and breached Right 6(1)(b) of the Code of Health and Disability Services Consumers' Rights.[8]

[8] Right 6(1)(b) of the Code states: "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances would expect to receive, including — [a]n explanation of the

Opinion: No breach — Dr A

Appropriateness of care
On 22 November 2007, Dr A performed surgery on Mr B at the private hospital and inserted a vascular access device, so that Mr B could be given oncology treatment directly into his liver. On 30 November, Mr B was given the oncological treatment and the first four-day cycle of chemotherapy, which he had agreed to.

Mr B received six cycles of chemotherapy at the private and public hospitals. Initially there was considerable regression in his liver tumours. The vascular access device was flushed by a district nurse on 18 April and 16 May 2008. In May and June 2008 blood tests indicated that Mr B's cancer was progressing.

Dr A reviewed Mr B on 25 June and organised for him to have a CT scan. The scan indicated that there was no cancer in Mr B's lungs and abdomen, but he had developed some new metastases in his liver. Dr A noted that the vascular access device had not been flushed for six weeks and did so himself on 25 June, noting that the device was working.

Mr and Mrs B advised Dr A that they wished to repeat the oncological treatment, and Dr A proceeded to organise for Mr B to be admitted to the private hospital for a radiological study of the vascular access device before the treatment. The initial radiological test indicated that it was not working.

Dr Johnston advised that over time, any intravascular device can become occluded by a combination of clotting and overgrowth of the lining of the artery.

Because the treatment product had already been ordered and has a short life, an urgent alternative needed to be arranged. Dr A decided that the best course of action was to insert an angiographic catheter into Mr B's femoral artery in his groin, to access his hepatic artery system. This was discussed with Mr and Mrs B and they agreed to proceed.

Dr A was able to obtain the services, at short notice, of diagnostic and interventional radiologist to introduce the femoral artery catheter late on the afternoon of 25 July. The repeat oncological treatment was delivered uneventfully. Mr B remained in hospital for two days. When he was discharged it was planned that he would be regularly reviewed by Dr A.

In October, Mr B's blood tests showed a "significant disturbance" in his liver function tests, which indicated that he had not responded favourably to the repeat oncological treatment. In November Mr B advised Dr A that his preferred location for follow-up was the public hospital. Mr B was monitored by oncologist Dr E at the public hospital

options available, including an assessment of the expected risks, side effects, benefits, and costs of each option."

Medical Outpatient Clinic. Radiology examinations on 19 and 22 December confirmed that the cancer had advanced. Mr B died in February 2009.

Dr Johnston advised that Dr A provided an appropriate standard of surgical care, including the care of the vascular access device. I conclude that Dr A did not breach the Code in relation to his standard of care.

Recommendations

I recommend that Dr A:

- amend his patient information booklet to include specific information on the possibility of malfunction of the surgically placed vascular access device;
- pay Mrs B $5,000 towards the additional costs incurred in relation to insertion of the femoral artery catheter following the failure of the vascular access device.

Follow-up actions

- A copy of this report will be sent to the Medical Council of New Zealand, ACC, and the private hospital.
- A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Royal Australasian College of Surgeons and the New Zealand Private Surgical Hospitals Association, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix 1

Independent advice to Commissioner — General and hepatobiliary surgeon Dr Peter Johnston

I am asked by the Health and Disability Commissioner to provide an opinion on this case. I have read and agreed to follow the Commissioner's Guidelines for Independent Advisors.

My qualifications are MB ChB (1978) FRACS (1985). I have practised General and Hepatobiliary Surgery since 1985.

Information provided to me by the Commissioner includes:

- Complaint, including ACC advice
- Information from [Dr A]
- Information from [the private hospital]
- Information from [the district nurse]
- Clinical record
- Patient information booklet [regarding liver cancer] by [Dr A], published by the private hospital

[At this stage, Dr Johnston sets out the questions asked by HDC which have been omitted as they are repeated in the body of his report.]

1. Please comment generally on the care provided to [Mr B] by [Dr A]

The facts of this case are not in contention, and do not need to be repeated in detail. The late [Mr B] was found to have sigmoid colon cancer with extensive liver metastases in late 2007. He underwent resection of the sigmoid colon tumour [at a public hospital] in November 2007. Following this [Mr B] saw [Dr A] for consideration of oncological treatment. This was agreed to by [Mr B] and [Dr A]; an operation was performed on 22.11.2007 to place the device for delivery of this treatment and subsequent chemotherapy. The oncological treatment was carried out, and considerable regression of the tumour noted. After 6 months, during which time [Mr B] had intermittent chemotherapy through the device, it was noted that his tumour marker blood tests were again rising, indicating a failure to keep the disease under control. Further oncological treatment was discussed and agreed to. This treatment was organised and [Mr B] admitted for this. In spite of no problems having been experienced from the device during the chemotherapy, the initial radiological test before administering the treatment dose indicated that it was not working. An urgent alternative was arranged, urgent because of the short life of the treatment product. This was access to the hepatic artery system via an angiographic catheter in the femoral artery in the groin. This entailed considerable unexpected expense for [Mr B]. The substance of his complaint is that he should not have had to pay for what was effectively a failure of the treatment device, that the charges were excessive. [Mr B] previously lodged a claim with ACC, on the basis that the device failure was treatment injury, and that he did not know of the possibility of such a failure. That claim was not accepted; the external medical reviewer for ACC, Mr Andrew Connolly, raised the issue of the adequacy of the informed consent process for insertion and use of the device, and this in turn is the background of the Commissioner's specific requests of my report.

I have studied all the information provided. [Dr A] gives a detailed account to the Commissioner, and this is corroborated by all the other information. The issue of consent requires to be discussed in detail, but in all other respects I am satisfied that the standard of care provided was at least adequate. The issue of the cost of the unexpected angiographic procedure is well covered by [Dr A], and it is clear from this that the costs were standard for the private health care sector. In response to [Mr B's] contention that revision procedures for treatment failures are usually provided without cost, I would agree with [Dr A] that this is not the expectation. The facility, material and procedure costs need to be met; at times the surgeon will offer a rebate on his or her particular component of the fee as an expression of sympathy or more usually to facilitate correction of the problem. [Dr A] was not in a position to waive any of the fees for the angiographic procedure.

2. *Please comment on the adequacy of the care of the device after [Mr B's] discharge from hospital*

The care of the device appears to have been standard, and I do not see a problem here. Over time, any intravascular device can become occluded by a combination of thrombus and intimal (the lining of the artery) overgrowth.

3. *Please comment on the adequacy of [Dr A's] informed consent procedures, with specific comment on the consent he obtained prior to inserting the device*

[Dr A] explains his usual practice with discussion of the procedure and the issues covered in obtaining informed consent. He considers that he probably did not discuss the issue of malfunction of the device with [Mr B]; the information booklet does refer obliquely to the possibility of device problems, without spelling out what these are. I would accept [Dr A's] explanation of his consent practice, and agree that in situations where there are many issues to discuss, the clinician will focus on the more important ones. The details discussed will vary from patient to patient, as [Dr A] says, and the clinician assesses the level and detail of information provided according to individual patient's perceived need and understanding, and according to the more pressing clinical priorities. Having the most important issues understood is much more relevant to the patient's immediate needs than providing an exhaustive list of possibilities.

In my opinion, the consent process appears to have been adequate for the situation; it could also be said that it would have been better if the information booklet had been more specific on the possibility of device malfunction. This could be considered for future editions. Doctors perhaps tend to accept as given the fact that any plastic tube may block, fall out or become infected, but patients may not be aware of this.

4. *Any other comments you wish to make.*

[Dr A's] long letter to the Commissioner is thorough and considered, and it may help the late [Mr B's] family to see this in full."