Urologist, Dr C

A District Health Board

A Report by the

Health and Disability Commissioner

(Case 04HDC11624)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Mrs A	Consumer (deceased)
Mr A	Consumer's husband
Mrs B	Complainant/Consumer's sister
Dr C	Provider/Urologist, genitourinary surgeon
Dr D	General practitioner
Dr E	Radiation oncologist
Dr F	Urologist

Complaint

On 9 July 2004, the Commissioner received a complaint from Mrs B about the services provided by genitourinary surgeon Dr C to her sister, Mrs A. The following issues were identified for investigation:

1. *Whether Dr C should have consulted other appropriate providers about the management of Mrs A's condition prior to the partial cystectomy surgery conducted on 7 November 2003;*

2. *Whether Dr C's decision to conduct partial cystectomy surgery was appropriate;*

3. *Whether Dr C should have taken a biopsy of Mrs A's fistula tract during the cystoscopy conducted on 2 April 2004.*

An investigation was commenced on 21 April 2005.

Information reviewed

Information was received from:

- Mrs B
- Dr C
- Dr E
- The Chief Executive Officer, the District Health Board

Mrs A's clinical records were obtained from the District Health Board.

Independent expert advice was obtained from Professor John Nacey, urologist.

Information gathered during investigation

In 2003 Mrs A, aged 52 years, had a history of at least 20 years of poor bladder function with recurrent infection and significant voiding problems. She managed these problems with intermittent self-catheterisation for 12 to 15 years, under the care of her general practitioner, Dr D.

Dr C first saw Mrs A in July 1991 on a referral from Dr D for review of her ongoing problems. Dr C advised her to have a cystoscopy and urethral dilation because of her long-standing history and unresolved symptoms. This procedure was carried out on 23 July 1991 and Mrs A was followed up post-procedure on a regular basis by the public hospital's outpatient clinic.

August/September 2003
On 29 August 2003, Dr D faxed a request to Dr C for an urgent appointment for Mrs A whose urinary problems had worsened. Dr D's referral outlined Mrs A's symptoms as follows:

> "Over the past 1/12 [month] she had several episodes of frequency and dysuria [pain passing urine]. Her recent MSU [mid stream urine] showed no infv [infection], but large blood and debris.
>
> Now she is in significant pain, passing clots of blood PU [per urethra] & mucus and debris."

Dr C saw Mrs A that day. He noted that Mrs A was complaining of discomfort in the supra-pubic area and voiding small amounts of urine. She felt that despite using a catheter to empty her bladder every three hours she was not able to achieve total bladder emptying, and her urine was very smelly, thick and cloudy. On examination Mrs A was tender in the supra-pubic area, but the remainder of her abdomen showed no abnormality. Dr C advised Mrs A, in light of her previous history and recent symptoms, to undergo a cystoscopy and urethral dilation. Dr C wrote to Dr D on 29 August 2003 to inform him of his assessment of Mrs A. Dr C stated, "This lady requires cystoscopy, urethral dilatation and bladder washout which I will carry out on Wednesday 3 September 2003."

Mrs B recalled that her sister "waited for weeks" in September for an appointment for the cystoscopy examination at the public hospital. She stated that Mrs A was "eventually advised by Dr C" that if she paid to have the procedure done as a private patient at a private hospital he would be able to do the cystoscopy as a day-surgery procedure within a week. "This procedure eventually took place on 1 October in [a private hospital]. The family decided to take this option as they felt the ongoing delay was detrimental to [Mrs A]."

Dr C responded that "[Mrs A] did not wait for weeks on [a] [public hospital] waiting list, as she was never placed on such a list". The cystoscopy was arranged and

performed at a private hospital at Mrs A's request. The records show that Dr C carried out the cystoscopy and urethral dilation for Mrs A on 3 September 2003. He washed out the bladder and resected an area of necrotic tissue, measuring 2–3cm in diameter, from the anterior wall of the bladder. The resected material was sent for histological examination.

Mrs B stated that after the procedure, while in the theatre recovery room, Mrs A suffered considerable pain which was very difficult to bring under control. She recalls being told by Mrs A that the anaesthetist apologised to her, saying that he was unaware that the cystoscopy was going to be anything more than that, and that the level of anaesthetic he had given was not sufficient for pain control for a tumour removal. As a result Mrs A suffered considerably and had to stay overnight at greater expense than anticipated.

Mrs A was returned to the ward following the procedure where the details of the operation were discussed with her and her husband. She was discharged within 24 hours with a urethral catheter draining into a leg bag.

On 9 September, Dr C saw Mrs A to discuss the findings of the histological examination of the tissue resected from her bladder, which showed invasive squamous cell carcinoma with muscle invasion. The findings were discussed in detail with Mrs A and her husband. Dr C ordered a CT scan of Mrs A's chest, abdomen and pelvis. He ordered a full blood count, liver function and biochemical profiles and a urine test for culture, sensitivity and cytology.

On 9 September, Dr C wrote to Dr D to inform him that histological examination of Mrs A's bladder tissue confirmed carcinoma, that he had "discussed various treatment options with [Mr and Mrs A]", and that he would see Mrs A again after he had the results of a CT scan of her chest, abdomen and pelvis.

The CT scan performed on 12 September showed no abnormality of the lungs, kidneys and abdominal organs, apart from a suspected haemangioma (benign tumour of blood vessels) on the anterior aspect of the right lobe of the liver. The radiology report of the scan stated that the urinary bladder wall showed marked thickening, "especially posteriorly where the wall thickness is approximately 3cm. Residual tumour or tumour recurrence cannot be ruled out." The scan also found that Mrs A's uterus was bulky and had a lobular outline suggestive of fibroids.

On 16 September, Dr C saw Mr and Mrs A to explain the CT scan results. Dr C stated that he discussed with Mr and Mrs A the various treatment options available in light of the CT scan findings.

Dr C completed a District Health Board elective surgery booking form on 16 September 2003 which confirms that he planned to perform a subtotal cystectomy and hysterectomy for Mrs A, estimating an operating time of five to six hours. Dr C did not provide a signed consent form for this surgery.

Dr C wrote to Dr D on 16 September, stating:

> "CT scan of the chest, abdomen and pelvis shows no abnormality of the chest and the abdomen but the bladder wall is markedly thickened and indeed she has a very large uterus which is secondary to fibroids. Rest of her abdomen and pelvis shows no abnormality and there appears to be no extravesical extension of her squamous cell carcinoma from the bladder.
>
> Various treatment options were discussed and at this point I will carry out cystoscopy, urethral dilatation, laparotomy and subtotal cystectomy at [the public hospital] as soon as I can arrange for her admission. If I have to remove the bladder totally I will also embark on removing the uterus at the same time and she will have to have an ileal conduit. [Mrs A] is agreeable to this."

Mrs A saw Dr C again on 14 October and informed him that she was managing well. Dr C stated that for "technical reasons" he was not able to arrange for Mrs A to have the surgery at the public hospital until 7 November 2003. Dr C did not explain what the "technical reasons" were.

There is discrepancy in the information provided regarding Dr C's consulting with other clinicians prior to undertaking the November surgery on Mrs A. Mrs B believes that prior to the surgery Dr C discussed her sister's case with specialists — radiation oncologist Dr E, and urologist Dr F — who recommended that Dr C consider a full bladder removal rather than the 80% removal and hysterectomy Dr C planned, because Mrs A's cancer was a particularly invasive type and was known to spread rapidly. Mrs B stated, "The consensus of opinion of doctors prior to partial removal of the bladder was to remove all of the bladder thereby giving Mrs A a fighting chance, but a partial removal has effectively given her no chance at all." She recalls that Dr C disagreed with the recommendations of Drs E and F and proceeded with the surgery he planned — a partial cystectomy.

Dr C stated: "I have not discussed [Mrs A's] condition nor her details with anyone".

Dr E stated: "I do not recall any consultation either in person or by telephone prior to the operation being done. … I do not have any written proof of whether or not I was consulted prior to surgery, but I do remember the case very well and am certain that I was not."

Dr F advised that Dr C did not discuss Mrs A's case with him.

There is no evidence that Dr C consulted with Dr E or Dr F at this time.

On 7 November 2003, Dr C performed the surgery on Mrs A at a public hospital. He performed a subtotal cystectomy, removing all the visible tumour involving the bladder, and a hysterectomy.

Dr C explained why he did not perform a total cystectomy:

> "Although the bladder wall was thickened there was also healthy normal looking bladder wall of lower bladder 25–30% when compared to the bladder wall at the fundus, suggesting that there was no macroscopic tumour seen at the resected bladder wall margins. I hence carried out a sub-total cystectomy and not a total cystectomy as I felt it was a better option for [Mrs A] and there would be less morbidity. Had the bladder walls at the resected margins looked unhealthy, or even suspicious, I would have carried out a total cystectomy. This as you know was discussed with [Mrs A] and was in her consent form. I was indeed surprised to see the histological report which showed poorly differentiated squamous cell carcinoma extending through the muscle wall in some areas and that the resected margins were also infiltrated with squamous cell carcinoma — microscopic. Had the CT examination or the intra-operative findings suggested otherwise, I would have carried out a total cystectomy and not a sub-total cystectomy."

Mrs A was discharged on 13 November 2003. A discharge letter from Dr C's registrar to Dr D advised that Mrs A had an "uneventful recovery" and was discharged home with a catheter in situ and a urinary drainage leg bag.

Dr C saw Mrs A on 25 November. He stated that she was "looking well and was recovering from the procedure satisfactorily". He discussed the histological report with her in some detail and suggested radiotherapy to her bladder as the lateral margins of her resected bladder showed microscopic tumour. Dr C referred Mrs A to Dr E, enclosing copies of the histological reports. In his referral letter dated 25 November, Dr C stated, "I personally think [Mrs A] will require your help and will therefore appreciate if you can please see her as soon as possible."

Dr C saw Mrs A again on 5 December and noted that she was doing well but was still waiting to be seen by Dr E.

Dr E saw Mrs A on 11 December 2003:

> "I first saw [Mrs A] one month after surgery, on 11 December 2003. I do recall a phone call from [Dr C] two to three weeks prior to that, i.e. one to two weeks after her surgery, when he discussed the clinical details. I do recall being slightly surprised during that conversation as to the operation she had. …
>
> It seems the reason [Dr C] chose a partial cystectomy was because of [Mrs A's] young age and the desire to avoid her having an ileal conduit which can be associated with long term problems. If I had been consulted prior to surgery I would have definitely counselled against either partial cystectomy or radiotherapy, and would have recommended total cystectomy accepting the disadvantages of that."

Dr E wrote to Dr C (copied to Dr D) on 11 December 2003, stating:

> "Thank you for referring this pleasant lady whom I saw today with her brother and sister-in-law. … I understand that her urine function post surgery has been very poor now requiring self catheterization every 2 hours or so day and night. She is reluctant to consider an indwelling catheter.
>
> I think this lady requires further treatment in view of the presence of positive margin. They would indicate a very significant risk of local recurrence within the bladder. Options would include either a course of radiotherapy to the bladder or alternatively re operation with total cystectomy and urinary diversion. I have discussed these with [Mrs A] and we think it is reasonable to proceed with a course of radiotherapy in the first instance. This will be planned before Christmas and will start immediately after New Year. I have explained to her the aim and possible adverse effects of this in particular. I think it is unlikely to make her bladder function significantly worse both in the short and long term and this may require either an indwelling urethral or supra-pubic catheter or possibly urinary diversion if the symptoms are intolerable."

Dr C saw Mrs A on 24 December and prescribed her a course of antibiotics for a urinary tract infection.

Mrs A started radiotherapy and chemotherapy on 5 January 2004. She was having ongoing symptoms of urgency, frequency, dysuria, perineal and supra-pubic pain, nausea and anaemia. She was admitted acutely to the public hosptial by the oncology and haematology teams for assessment and control of her symptoms. Investigations were conducted to rule out renal failure and hypercalcaemia, and a repeat CT scan was ordered to identify whether there was progressive or metastatic disease. Mrs A completed her radiotherapy and chemotherapy treatments in mid- February. Because she reacted adversely to the treatment, she remained as an inpatient at a public hospital for many weeks. Dr D was notified of the admission and advised that he would be informed of further developments.

Dr E dictated a letter to Dr C on 1 March (received on 15 March) to advise that Mrs A had completed her course of radical chemo/radiotherapy as an inpatient.

Dr E dictated a further letter to Dr C on 23 March (received on 2 April) to inform him that the CT scan he had performed on 10 March showed a fluid collection just inside the lower abdominal anterior abdominal wall, which appeared to connect with the bladder and indicated that a fistula (an abnormal opening) had developed. Dr E informed Dr C that a fine-needle biopsy showed inflammatory tissue only and no sign of recurrent tumour, but cultures of aspirated material grew coliform bacteria, indicating the possibility of bowel involvement. He considered it likely that there had been tumour present that had broken down and that Mrs A might require further surgery involving urinary diversion, management of any possible involved bowel loop, and consideration of resection of any recurrent tumour, if possible.

Dr C saw Mrs A again on 24 March 2004. He wrote to Dr E that day to advise him that he had reviewed the CT scan and discussed the findings with Mrs A. He stated: "I cannot say if the fistula is connected to the bladder or is just to a cavity which may be draining serous fluid." Dr C informed Dr E that if he was able to see the fistula on examination under anaesthesia and cystoscopy planned for 2 April, he would consider performing a fistulogram at that time and would inform Dr E of the result of the examination.

Dr C arranged for Mrs A to be admitted to the public hospital for an examination under anaesthetic (EUA) and cystoscopy on 2 April. The examination confirmed that a fistula had developed between Mrs A's mons pubis and the anterior aspect of her bladder. Dr C inserted a catheter to drain the bladder "in the hope that the fistula would close, spontaneously, in due course". He stated:

> "The doctors in [the ward] were personally notified by me of the findings and her further investigations and management. I also personally spoke to [Mrs A] and informed her of what I had found and what we needed to do next. She accepted my views. This discussion took place in the Recovery Ward."

His record of the examination noted that he planned to perform a fistulogram "ASAP".

Mrs A was discharged on 8 April. The discharge letter provided to Mrs A and Dr D outlined the reasons for her admission and informed Mrs A:

> "You developed a wound in your lower abdominal wall, which we think is probably a connection to your bladder due to the tumour. Arrangements have been made for you to see [Dr C] for further investigations and then [Dr E] will see you again and decisions can be made about further treatment."

The section of the letter under the heading "Recommendation to GP" stated:

> "[Dr C] has reviewed her and scheduled an EUA with cystoscopy and possibly a fistulogram. Following this further decisions can be made regarding further treatment. She has been scheduled for further follow-up with [Dr E] in 2 months time, but this may be brought forward pending the results of [Mr C's] investigations. … Not surprisingly [Mrs A] is quite anxious and emotional about her current situation. She was commenced on citalopram, lorazepam and clonazepam to try to assist her with this. Her mood gradually lightened and she became eager to know what the next steps would be. Her lorazepam was halved and the clonazepam gradually reduced. The oncology counsellor was involved throughout her stay. … [Mrs A] was discharged from [the ward] on 8/4/04 to await follow-up with [Mr C] and then [Dr E]."

Mrs B stated that the family waited a "very long time" to hear the results of the tests taken during the cystoscopy, and that Mrs A and the family were put under "undue stress" by Dr C's delay in communicating the results.

On 23 April, Mrs A had a sonogram involving the passage of a tiny feeding tube through the fistula opening in the mons pubis. Contrast medium was injected into the tube and filled a small cavity in the anterior abdominal wall, demonstrating the fistula track between the skin and the anterior aspect of the bladder. It is unclear who organised this examination, as the radiology report noted "Copies have been sent as requested by: — [Dr E]." There are two copies of this report, one of which has been stamped "Surgical Unit — 5 May 2004 Received" and appears to have been initialled by Dr C. The second copy, also apparently initialled by Dr C, is annotated "See ASAP".

Dr C did not comment on the fistulogram.

Dr E dictated a letter to Dr C on 11 May (received on 31 May) noting that he had not received information about the result of Mrs A's EUA and cystoscopy on 2 April. He stated that he believed Mrs A's symptoms of swelling of her right leg, pain and the development of the fistula could be the result of recurrent cancer within the pelvis, but he was unaware whether recurrent cancer had been confirmed. Dr E outlined treatment options if this was the case and stated:

> "Whether or not she has recurrent tumour in the pelvis, she would probably not be a candidate for attempted surgical removal of this in view of the previous extensive surgery, radiotherapy and likely infection, fibrosis, etc. It is therefore quite a difficult management situation. I understand you are seeing her in a few days and I will discuss this with you prior to that."

Mrs B complained about Dr C failing to keep an appointment to see Mrs A at the hospice during the weekend of 15/16 May 2004 to discuss the "long awaited results and further care/treatment for Mrs A ".

Dr C stated that Mrs A had an appointment to see him at his rooms, but this appointment was cancelled. He agreed to visit Mrs A at the hospice during that weekend. However, he was unable to keep the appointment due to urgent employment issues which had arisen at that time.

Mrs A's condition deteriorated rapidly over the following two to three months. She developed ureteric obstruction as a result of tumour growth, which was managed by surgical insertion of drainage catheters into the pelvis of her kidneys. However, she continued to deteriorate and subsequently died.

Additional information

Dr C
Dr C stated:

> "Perhaps I should have carried out frozen section biopsy of the bladder wall margins on the operating table to confirm or rule out any evidence of tumour in her remnant bladder at the resected margins. The remnant part of her bladder about — 25% of the original bladder that was conserved looked very healthy to the naked eye when compared with the rest of the bladder which was removed. I was not even suspicious of any microscopic spread into her normal healthy looking part of the bladder that was conserved. …
>
> I do not feel now, or in hindsight that a biopsy of the fistula would have made any difference in her management or the outcome, given that the earlier histology showed a poorly differentiated tumour, infiltrating all layers of the bladder wall — indicating poor prognosis. The appearance of the fistula to my mind was nothing other than recurrence of tumour despite having had a course of radical radiotherapy and chemotherapy. The fistula may have been caused following radiotherapy and chemotherapy and further potentiated as a result of Prednisone which she had, during and after radiotherapy and chemotherapy. Had I biopsied the fistula on 2 April 2004 it would have never healed and was likely to make it more troublesome. …
>
> I agreed to visit [Mrs A] at the Hospice during the weekend 15th – 16th May 2004. This was not possible due to circumstances beyond my control [employment-related pressures and ongoing disputes with the DHB]. …
>
> [Mrs A] was treated with dignity, respect, promptly and appropriately at all times. She was kept well informed."

Dr E
Dr E stated that Dr C's failure to biopsy the fistula (which was caused by recurrent tumour) did not have any impact at all on management and would not have had an impact on the eventual outcome.

The District Health Board (the DHB)
The DHB's Chief Executive Officer confirmed that there was an employment dispute with Dr C at the time the subject matter of this complaint arose. The DHB submitted that it had for some time been "seriously concerned about aspects of Dr C's attitude and behaviour", including concerns about his communication with patients and staff.

Independent advice to Commissioner

The following expert advice was obtained from Professor John Nacey, a urologist:

"I have been asked to provide an opinion to the Health and Disability Commissioner on case 04/11624/WS. I have read and agree to follow the Commissioner's guidelines for independent advisors.

I graduated MB ChB from the University of Otago in 1977 and undertook specialist training in Urology being awarded Fellowship of the Royal Australasian College of Surgeons in 1984. I subsequently undertook a doctorate by thesis in 1987 (MD, University of Otago, awarded with Distinction). I have practised as a specialist Urologist since 1986 and have maintained an active teaching and research programme for undergraduate and postgraduate students. My specialist research interest is benign and malignant prostate disease and I have published extensively in this field. I am a past examiner in Urology for the Royal Australasian College of Surgeons, and act as a referee for several medical publications and have an editorial role in some of these. I am Dean of the Wellington School of Medicine and Health Sciences, a position I hold concurrently with my clinical practice.

Expert Advice Required

I have been asked to advise the Commissioner whether in my opinion [Dr C] provided [Mrs A] with services of an appropriate standard. In particular:

1. Should [Dr C] have consulted with other appropriate advisors about the management of [Mrs A's] condition prior to undertaking the surgery on 7 November 2003? If so, why?
2. Was [Dr C's] decision to perform a partial cystectomy appropriate?
3. If not, why not? What should he have done?
4. Was [Dr C's] management of the fistula appropriate?
5. What would have been the advantage of taking a tissue biopsy at this time?

If, in answering any of the above questions, I believe that [Dr C] did not provide an appropriate standard of care, I have been asked to indicate the severity of his departure from that standard.

Sources of information

The following documentation has been provided by the Commissioner and reviewed by myself:

1. Letter of complaint from [Mrs B] to the Commissioner, received on 9 July 2004, marked with an 'A'. (Pages 1 to 6).
2. Response from [Dr C], and accompanying supporting documentation, dated 14 October 2004, marked with a 'B'. (Pages 7 to 77).

3. Letter from [Dr E] to the Commissioner, dated 1 December 2004, marked with a 'C'. (Pages 78 & 79).
4. Letter from [the District Health Board], and accompanying clinical records, to the Commissioner, dated 17 May 2005, marked with a 'D'. (Pages 80 to 145).
5. Letter from [Dr C] to the Commissioner, dated 20 May 2005, marked with an 'E'. (Pages 146 to 147(a)).
6. Notes taken during a telephone conversation with [Mrs B] on 15 September 2005, marked with an 'F'. (Page 148).

Background

[Mrs A] (52 years) had a history of recurrent urinary tract infections secondary to incomplete bladder emptying since 1985. She first saw [Dr C], Urologist of – [a city], in July 1991 who performed a cystoscopy and urethral dilatation. [Mrs A] was followed at the Urology outpatient clinic at [a public hospital] on a regular basis.

On 29 August 2003 [Mrs A] was referred urgently to [Dr C] by her general practitioner [Dr D]. She was troubled by urinary frequency with pelvic discomfort and incomplete bladder emptying. [Dr C] advised further cystoscopy and urethral dilatation. The cystoscopy was performed on 2 September 2003. Necrotic tissue was seen on the anterior wall of the bladder and resected. The resected tissue was sent for histological examination.

The histology report showed the resected tissue to be invasive, keratinising (high grade) squamous cell carcinoma with invasion of the muscularis propria and arising in an area of squamous metaplasia.

On 9 September [Dr C] advised [Mrs A] of the histologic findings. In order to stage the tumour he requested a CT scan of the chest, abdomen and pelvis. This showed a thick walled bladder and bulky uterus. [Dr C] advised [Mrs A] that she required surgery and discussed the options of either partial or total cystectomy (where he would perform an ileal conduit), with or without hysterectomy.

On 7 November [Dr C] performed a partial cystectomy and hysterectomy.

The removed tissue contained a 6 x 9 cm portion of bladder wall. This contained a 6 cm area of ulceration in the centre with a necrotic base. Histology confirmed a poorly differentiated squamous cell carcinoma with squamous metaplasia of the remaining bladder mucosa. The margins of the removed bladder tissue were positive for tumour indicating that the tumour removal had been incomplete.

Because of the incomplete tumour removal additional treatment was required and [Dr C] referred [Mrs A] to [Dr E], radiation oncologist. [Dr E] saw [Mrs A] on 11

December 2003 and subsequently commenced a course of radiotherapy and chemotherapy which was completed in mid February 2004. [Mrs A] tolerated the treatment badly, developing ongoing pelvic and perineal pain with bowel upset and bladder symptoms requiring an indwelling urinary catheter.

In March 2004 [Mrs A] developed a fistula between the bladder and skin of the perineum anterior to the urethra. She also had further symptoms of disease progression including lymphoedema of the legs and deteriorating general health.

On [Dr E's] recommendation [Dr C] performed a cystoscopy and examination under anaesthetic on 2 April 2004. At this examination no tumour was visible within the bladder. The fistula was seen and not biopsied. A urethral catheter was inserted.

Over the next two to three months [Mrs A's] condition deteriorated. She developed ureteric obstruction secondary to the tumour and was managed with bilateral nephrostomies.

[Mrs A later died of her disease.]

Questions posed by the Commissioner

1. Should [Dr C] have consulted with other appropriate advisors about the management of [Mrs A's] condition prior to undertaking the surgery on 7 November 2003? If so, why?

Squamous cell carcinoma is an uncommon bladder tumour accounting for less than 5% of all bladder malignancies. There is a well established association between chronic inflammation and the transformation of the normal bladder lining (made up of transitional epithelium) into squamous epithelium. This may then progress to squamous cell carcinoma, as seen with [Mrs A]. The natural history of squamous cell carcinoma of the bladder is of early invasion and extremely poor prognosis.

Given the uncommon nature of this disease, its occurrence in a relatively young patient and poor prognosis it would have been prudent for [Dr C] to have discussed this case with his colleagues before embarking on any definitive treatment. This especially applies to early discussion with the radiation oncologists whose opinion would have been invaluable in informing the appropriate course of management.

I believe this is a moderate departure from the expected standard of care.

2. Was [Dr C's] decision to perform a partial cystectomy appropriate?

Partial cystectomy is an attractive option for many patients and physicians, because it implies bladder preservation with surgical removal of the affected part of the bladder. However, great caution must be exercised in recommending partial cystectomy in the management of high-grade, invasive bladder cancer. In fact, very few candidates are appropriate for segmental resection. In the two largest series reporting the results of segmental resection, fewer than 5% of more than 5,400 patients who presented with a primary invasive bladder cancer were deemed appropriate candidates for this option, and there have been no substantial series reporting results in the last 20 years.

The problem with partial cystectomy is the reality that the epithelium remote from the primary cancer is under the same carcinogenic influence that resulted in the primary cancer. The probability of recurrence or understaging the initial cancer places patients who choose partial cystectomy at great risk for recurrence and ultimate death from metastatic disease. An ideal patient for partial cystectomy is one who has a normally functioning bladder with good capacity, a first-time tumour recurrence with a solitary tumour, and a tumour location in an area that allows for a 1- to 2-cm margin of resection. In addition, it is essential that multiple selected biopsies remote from the primary tumour have been performed and that these show no epithelial atypia (abnormal cells) or overt malignant change.

Absolute contraindications include carcinoma-in-situ elsewhere in the bladder or multifocal tumours. Relative contraindications to partial cystectomy include high-grade tumours, tumours located at the trigone or the bladder neck, and tumours that would require ureteral reimplantation.

On this basis partial cystectomy was contraindicated for [Mrs A]. Her bladder was thick walled with poor function and low capacity, the tumour was high grade and the bladder mucosa apart from the tumour had undergone squamous change. This is not surprising with squamous cell carcinoma. Unfortunately [Dr C] did not perform biopsies of the apparently normal bladder prior to performing the partial cystectomy which would have provided him with ample evidence that total cystectomy was the procedure of choice.

I believe this is a severe departure from the expected standard of care.

3. If not, why not? What should he have done?

For the reasons provided in paragraph 2 above the only reasonable approach in this patient was total cystectomy. There was no place for partial cystectomy, and primary treatment with external beam radiation therapy has not been shown to be effective.

4. Was [Dr C's] management of the fistula appropriate?

[Dr C] correctly performed a cystoscopy and examination under anaesthetic to evaluate the fistula. [Dr C] identified the fistula at cystoscopy and reported that the surrounding bladder showed no evidence of tumour. [Dr C] assumed that the fistula was secondary to the radiation therapy. While biopsy of the fistula tract would have been standard practice and would have provided useful information, the fact that this was not done does not appear to have materially affected the subsequent course of events.

5. What would have been the advantage of taking a tissue biopsy at this time?

Biopsy of the fistula would have provided evidence of tumour (or otherwise) along the fistula tract. This would have informed subsequent management options such as excision of the tract or a conservative approach.

References

Skinner DG, Lieskovsky G. Management of invasive high-grade bladder cancer. In: Skinner DG, Lieskovsky G, eds. *Diagnosis and management of genitourinary cancer,* vol. 1. Philadelphia: WB Saunders, 1988:295.

Utz DC, Schmitz SE, Fugelso PD, et al. A clinicopathologic evaluation of partial cystectomy for carcinoma of the urinary bladder. *Cancer* 1973;32:1075.

Rous SN. Squamous cell carcinoma of the bladder. *J Urol* 1978;120:561.

Please contact me directly if I can be of further assistance with this case."

Additional advice
In relation to biopsy of the fistula target, Professor Nacey confirmed that this would be "the usual or most accepted method of practice".

Responses to Provisional Opinion

Dr C
In response to the provisional opinion, Dr C stated "I did my best for this lady" and "acted honourably". Had he seen a tumour anywhere else, he would have removed it. Dr C said that he took her age into consideration and decided not to remove the bladder. If she had been 70 years of age, he would have said there was no point, the bladder could not have been preserved and he would have removed it. All his training has been to remove the bladder, but because Mrs A was young, he explained to her that he would try to preserve her bladder.

Dr C stated, "For this lady to die so quickly it was obviously in other organs away from the bladder. It must have been very aggressive." Dr C believes the outcome would not have been different if he had removed the bladder.

Dr C stated that he has operated on thousands and removed plenty of bladders. Mrs A was on prednisone and had undergone radiotherapy which would have complicated the healing a "little bit more", and this affected his decision to take the biopsy of the fistula. An MRI scan would have revealed more but was not available.

Dr C said that after he left the public hospital he could not go back, even to look at the medical records of his patients. He always tries to do his best for his patients, but "one circumstance compounded the other".

The DHB
The DHB's Chief Executive Officer advised that "[The DHB] is in agreement and supportive of your findings and provisional report".

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

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

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

…

4) *Every consumer has the right to have services provided in a manner that minimises the potential harm to, and optimises the quality of life of, that consumer.*

5) *Every consumer has the right to co-operation among providers to ensure quality and continuity of services.*

Relevant standards

Medical Council of New Zealand, "Good Medical Practice — A Guide for Doctors" (2002):

> **"Providing a good standard of practice and care**
>
> 1. All patients are entitled to good standards of practice and care from their doctors. Essential elements of this are professional competence; good relationships with patients and colleagues; and observance of professional ethical obligations.
>
> …
>
> 3. In providing care you must
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> …
>
> - be willing to consult colleagues;
>
> …
>
> - keep colleagues well informed when sharing the care of patients;
> - provide the necessary care to alleviate pain and distress whether or not cure is possible; …"

Opinion: Breach — Dr C

Background
At the time the subject matter of this complaint arose, the relationship between Dr C and the DHB was under strain because of disputes relating to the management of the public hospital urology service and Dr C's employment status. In my view, while the ongoing dispute between Dr C and the DHB may have affected Dr C's practice, it is not relevant to Dr C's clinical decision-making in this case. Employment disputes outside of the doctor–patient relationship do not mitigate poor clinical decision-making.

Consultation with colleagues
Rights 4(1) and 4(2) of the Code of Health and Disability Services Consumers' Rights (the Code) give every patient the right to have services provided with reasonable care and skill, and in compliance with professional standards. Right 4(4) affirms that a patient has the right to services provided in a manner that minimises harm and optimises the quality of their life; Right 4(5) requires providers to co-operate with each

other "to ensure quality and continuity of services". The Medical Council of New Zealand expects that in providing care doctors must be willing to consult colleagues. Mrs A's family complained that Dr C failed to consult with colleagues about the management of Mrs A's condition and as a result caused her considerable suffering and gave her "no chance at all".

On 2 September 2003, Dr C performed a urethral dilatation and cystoscopy on Mrs A to establish the cause of her long-standing bladder problems. During this procedure he also washed out her bladder and resected an area of necrotic tissue from the bladder wall. The resected material was sent for histological examination.

On 9 September, Dr C informed Mrs A that he had found invasive squamous cell carcinoma in her bladder. He discussed the various treatment options with Mrs A and recommended that she consider his preference for a subtotal cystectomy and, because the bladder was adhering to the wall of the uterus, a hysterectomy. Dr C did not give his reasons for choosing this procedure.

Mrs A's family is under the impression that Dr C consulted specialists about the treatment options for Mrs A and that they recommended that he not perform a subtotal cystectomy, but he ignored this advice. There is no evidence that Dr C consulted any colleagues about this surgical decision. Dr E is clear that he was not consulted and stated that if he had he "would have definitely counselled against" partial cystectomy and would have recommended total cystectomy.

Independent urologist advisor Professor John Nacey advised that squamous cell carcinoma is an uncommon bladder tumour accounting for fewer than 5% of all bladder tumours. Squamous cell carcinoma of the bladder invades the surrounding tissue early and has a very poor prognosis. Professor Nacey stated that, given the uncommon nature of the disease, the poor prognosis and Mrs A's relatively young age, "it would have been prudent" for Dr C to have discussed this case with his colleagues before deciding on any definitive treatment. He should have had early discussions with the radiation oncologists whose opinion would have been invaluable in deciding the appropriate course of treatment.

In my view, Dr C's failure to consult his colleagues was not consistent with sound clinical decision-making and good quality care. It had the potential to, and ultimately did, affect the quality of Mrs A's life. In these circumstances Dr C breached Rights 4(2) and 4(5) of the Code.

Decision to perform a partial cystectomy

Dr C stated that Mrs A agreed to his performing a partial cystectomy after he discussed the various treatment options. He recommended partial cystectomy to Mrs A in light of her relatively young age. At the time he was unaware of how aggressive her tumour was.

As noted above, Dr E stated that, had he been consulted, he would have encouraged Dr C to reconsider his decision to perform a partial cystectomy on Mrs A.

Professor Nacey advised that partial cystectomy is an attractive option for many patients and doctors because it implies preservation of the bladder. However, great caution must be exercised when recommending partial cystectomy when managing high-grade, invasive bladder cancer. The epithelium remote from the primary cancer is exposed to the same carcinogenic factors that have caused the primary cancer and therefore the patient is at great risk of recurrence and death from metastatic disease. Professor Nacey advised that the ideal patient for partial cystectomy is one with a normally functioning bladder with a solitary first-time tumour in a good location that allows for a 1–2cm margin for resection. It is essential that multiple sites remote from the primary tumour are selected for biopsy to ensure that there are no other areas undergoing malignant change. Absolute contraindications to partial cystectomy include carcinoma in situ elsewhere in the bladder or multifocal tumours.

Mrs A's bladder was thick-walled with poor function and low capacity, the tumour was high-grade, and the lining of the bladder away from the tumour had undergone cancerous change. Professor Nacey stated that on this basis partial cystecomy was contraindicated for Mrs A and it was "unfortunate" that Dr C did not perform multiple biopsies of her bladder prior to going ahead with the surgery, as this would have provided him with ample evidence to reconsider his decision.

I accept Professor Nacey's advice that Dr C's decision to perform a partial cystectomy in these circumstances was "a severe departure from the expected standard of care". In these circumstances Dr C breached Rights 4(1) and 4(4) of the Code.

Biopsy of fistula

Five months after the November 2003 surgery Mrs A developed lower abdominal discomfort. She was seen by Dr E who had become involved in Mrs A's care following the surgery. Dr E organised for her to have an abdominal CT scan on 10 March 2004. The scan identified a build-up of fluid in her lower abdomen just inside the anterior abdominal wall, which appeared to be connected to her bladder. Dr E considered that this was possibly a fistula, the result of recurrence of the cancer. He performed a fine-needle biopsy of the lesion. Although it showed inflammatory changes only, Dr E was concerned about this development. Dr C reviewed the CT scan and decided to perform an examination under anaesthesia and cystoscopy on 2 April 2004. Dr C's examination confirmed that there was a fistula. Dr E saw Mrs A again on 11 May but had not been informed of the result of the examination on 2 April. Dr E wrote to Dr C noting that he was unaware of the results of the EUA and cystoscopy, and querying whether recurrent cancer within the pelvis had been confirmed as the cause of Mrs A's ongoing symptoms.

Dr C assumed that the fistula was secondary to the radiation therapy. In response to the provisional opinion, Dr C stated that Mrs A's healing capabilities had been

compromised by the prednisone and radiotherapy treatment and this affected his decision not to take a biopsy.

Professor Nacey stated that it would have been standard practice for Dr C to have biopsied the fistula tract. A biopsy would have provided evidence of a tumour (or otherwise), and influenced subsequent management options such as excision of the tract or the adoption of a conservative approach. Professor Nacey advised that, although Dr C's failure to biopsy the fistula "does not appear to have materially affected the subsequent course of events", it was not consistent with "the usual or most accepted method of practice".

In my view, Dr C's failure to biopsy Mrs A's fistula and to communicate his findings to the other doctors involved in managing Mrs A's care had an impact on the planning of subsequent management options. In these circumstances, Dr C breached Rights 4(1) and 4(4) of the Code.

Opinion: No Breach — The District Health Board

Vicarious liability
Employers are vicariously liable under section 72(2) of the Health and Disability Commissioner Act 1994 for ensuring that employees comply with the Code of Health and Disability Services Consumers' Rights. Under section 72(5) of the Health and Disability Commissioner Act 1994, it is a defence for an employing authority to prove that it took such steps as were reasonably practicable to prevent the employee's breach of the Code.

Dr C breached the Code because of his poor clinical decision-making with regard to Mrs A's care and treatment, and his failure to consult colleagues. In my view, the DHB cannot be held vicariously liable for Dr C's independent clinical decision-making in this case. It is of concern, however, that the DHB appears to have been stalemated in its attempt to resolve major and long-standing concerns about aspects of Dr C's attitude and practice. I accept that the Board was required to follow due process with respect to Dr C's employment status, but to allow concerns about a clinician's practice to remain unresolved due to employment-related issues risked compromising patient safety.

In responding to the provisional opinion, the DHB's Chief Executive Officer stated:

> "[R]egarding the suggestion that an employer ought to have taken immediate action to address concerns about an employee's practice, notwithstanding the requirement to follow due process in employment related issues. … Where such concerns are not clinical competency concerns, but rather behavioural as was the case here, it is difficult to understand what immediate action can be taken other

> than employment related (disciplinary) action which requires due process to be followed. … [T]his requirement [to take immediate action] may have the affect of putting employers between a rock and a hard place, having to choose in such circumstances which forum it feels has the best chance of defending its actions. In that regard it is worth considering that a personal grievance represents a significant cost to District Health Boards."

I recognise the difficulties that DHBs face when the concerns about a clinician's practice primarily involve behavioural issues. I also acknowledge that not following due process when imposing disciplinary action can expose the employer to a personal grievance claim. However, a DHB's first duty must always be to safeguard its patients. Behavioural issues, no less than clinical competence concerns, can place patients at risk and must be addressed. I am confident that the Employment Court would take account of a DHB's responsibility to its patients. As noted by Judge Finnigan in *Air New Zealand Ltd v Samu* [1994] 1 ERNZ 93 at p 95, "[W]here safety is genuinely involved in the operations of an employer it is not just another ingredient in the mix, another factor to be taken into account. Safety issues have a status of their own."[1]

Other Comment

Mrs B complained that after Mrs A had her EUA and cystoscopy on 2 April 2004, the family waited a long time for Dr C to give them the results of the examination and explain the cause of Mrs A's symptoms. This delay placed the family under "undue stress". She said that Dr C made a commitment to visit Mrs A in the hospice to discuss the "long awaited results and further care/treatment for Mrs A ". Dr C did not keep that appointment.

Dr C stated that he had spoken with Mrs A in the recovery room after the examination, that she "accepted [his] views", and he fully informed the ward doctors of the findings and his management plan. However, for the following reasons I am inclined to the view that Dr C did not inform Mrs A of the results of the EUA and cystoscopy:

[1] The decision was affirmed by the Court of Appeal in *Samu v Air New Zealand Ltd* [1995] 1 ERNZ 636 (CA).

- The discharge letter from the ward on 8 April does not give any indication that the result of the examination was known at that time. It noted that Mrs A would be followed up by Dr C and Dr E after Dr C conducted additional investigations.

- Dr C has not provided any clinical records relating to his involvement in Mrs A's care after 23 April 2004.

- By letter dictated on 11 May, Dr E wrote to Dr C noting that he had not been informed of the results of Mrs A's 2 April examination.

- The DHB had serious concerns about Dr C's communication with both patients and staff.

- Dr C's employment with the DHB ended on 18 May 2004, under very difficult circumstances. He indicated that this was a stressful time for him and acknowledged that it was because of these employment issues that he failed to keep his appointment to see Mrs A and her family at the hospice.

By not providing the results of the April examinations to Mrs A and her family and his medical colleagues, Dr C added to the anxiety and stress of his patient and her family, and impeded appropriate management. These factors adversely affected the quality of the last weeks of Mrs A's life.

I recommend that Dr C's communication with patients and colleagues be addressed as part of a review of his competence by the Medical Council.

Follow-up actions

- Dr C will be referred to the Director of Proceedings in accordance with section 45(2)(f) of the Health and Disability Commissioner Act 1994 for the purpose of deciding whether any proceedings should be taken.

- A copy of this report will be sent to the Medical Council of New Zealand with a recommendation that the Council review Dr C's competence.

- A copy of this report, with details identifying the parties removed, will be sent to the Royal Australasian College of Surgeons and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes on completion of the Director of Proceedings' processes.

Addendum

On 30 January 2007 the Health Practitioners Disciplinary Tribunal upheld one charge of professional misconduct against Dr C. It concluded the expert evidence showed that the failure to perform a total cystectomy constituted conduct which fell far short of that to be expected of a reasonably competent urologist and that it was malpractice (neglect of a professional duty) and negligence (a breach of duty in a professional setting). It considered that a finding of professional misconduct was needed to protect the public, maintain professional standards and punish the practitioner.

Dr C was censured, fined $5000.00 and ordered to pay 30% of the costs of the investigation and prosecution. He was also ordered to practise under conditions that he join a peer review group, undergo a clinical audit and practise under the supervision of a urologist. Interim name suppression was lifted.