Anaesthetist, Dr B

Surgeon, Dr C

Otago District Health Board

A Report by the

Health and Disability Commissioner

(Case 04HDC04340)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Ms A	Consumer
Dr B	Provider/ Anaesthetist
Dr C	Provider/ Surgeon — Otorhinolaryngologist
Dr D	Teaching Fellow/ Surgical registrar
Dr E	General practitioner
Mr F	Chief Executive Officer, Otago DHB

Complaint

On 15 March 2004, the Commissioner received a complaint from Ms A about the services provided by Dr C, surgeon, and Dr B, anaesthetist. The following issues were identified for investigation:

Dr C

- *Whether prior to surgery on 16 October 2002, Dr C provided Ms A with adequate information about the treatment options available to her, including the benefits and risks associated with those options, for her to make an informed choice about her care and treatment.*

- *Whether Dr C provided Ms A with services of an appropriate standard. In particular:*
  - *whether Dr C's recommendation for endoscopic laser surgery was appropriate in Ms A's case; and*
  - *whether Dr C performed the endoscopic laser surgery on 16 October 2002 with reasonable care and skill.*

Dr B

- *Whether prior to surgery on 16 October 2002, Dr B provided Ms A with adequate information about the risks associated with the administration of anaesthetic for the planned procedure for her to give informed consent to the anaesthetic.*

- *Whether on 16 October 2002 Dr B provided Ms A with services of an appropriate standard. In particular:*
  - *whether Dr B administered the anaesthetic to Ms A with reasonable care and skill.*

An investigation was commenced on 16 July 2004.

Names (other than Dunedin Hospital, Otago District Health Board, HDC independent expert advisors and ACC's expert advisors) have been removed to protect privacy. Identifying letters have been assigned and bear no relationship to the person's actual name.

Overview

Ms A has required a number of procedures since birth to treat a severe narrowing (stenosis) of her airway. In October 2002, the surgeon managing her care at Dunedin Public Hospital (DPH), Dr C, recommended laser surgery to treat the stenosis.

The operation was performed on 16 October 2002. After Dr B had anaesthetised Ms A, it was found that the stenosis was more severe than assessed at the preoperative clinic, and that the smallest size of laser-proof endotracheal (ET) tube available was too large to be used. Consequently, a non-laser-proof ET tube was introduced and the decision was made to continue with the procedure. Dr D, surgical registrar and Teaching Fellow, performed the procedure under Dr C's supervision.

During the procedure an airway fire occurred, resulting in full-thickness mucosal burns to the subglottis, glottis and laryngeal surface of the epiglottis, with minor burns to the tracheal mucosa, mucosa of the main bronchi and the oropharynx. In addition, the ET tube melted in the fire, with 2cm of the distal end falling into the bronchus, beyond reach of the equipment available. A further attempt to retrieve the lost portion of ET tube failed. On 17 October 2002, Ms A underwent a tracheostomy to recover the lost portion of the ET tube. This further attempt was successful, and Ms A was eventually discharged home on 29 October 2002.

Ms A made a claim to ACC for medical misadventure, and ACC ultimately made a finding of medical error against both Drs C and B.

Ms A continues to have treatment at DPH for tracheal stenosis.

Information reviewed

Information from:

- Ms A
- Dr B
- Dr C
- Dr D
- Otago District Health Board
- A second District Health Board
- ACC.

ACC made available expert advisor reports from:

Names (other than Dunedin Hospital, Otago District Health Board, HDC independent expert advisors and ACC's expert advisors) have been removed to protect privacy. Identifying letters have been assigned and bear no relationship to the person's actual name.

- Dr Peter Blake, otolaryngologist and head and neck surgeon[1]
- Dr Nick McIvor, otolaryngologist and head and neck surgeon[2]
- Dr Vaughan Laurenson, anaesthetist[3]
- Dr Malcolm Futter, anaesthetist.[4]

Independent expert advice was obtained from Dr Catherine Ferguson, otolaryngologist and head and neck surgeon, Dr Bren Dorman, otolaryngologist and head and neck surgeon, and Dr John Walker, anaesthetist.

Information gathered during investigation

Background

Ms A had a history of respiratory problems relating to airway stenosis that had developed following surgery performed soon after her birth. At 10 days of age, because of the stenosis, Ms A had a tracheostomy tube inserted which was eventually removed when she was 21 years old; Ms A was left with permanent respiratory stridor.[5] She was well known to the ear, nose and throat (ENT) service at Dunedin Public Hospital (DPH), which she had attended regularly for treatment of a recurring stenosis of the glottic larynx, subglottis and trachea.

On 26 June 2002, Ms A (then aged 33) consulted Dr E, her general practitioner. Dr E recorded in his clinical record:

> "Requesting referral to ENT for consideration of subglottic dilatation.
> This has been done in the past at approx. 18 month intervals.
> Hasn't had it done for 3 years now.
> Increased symptoms suggestive of a problem the next 4–5 months. Episodes of choking on saliva, [associated] cough, voice deeper, difficulty in talking. Increased stridor episodes."

Dr E referred Ms A to the ENT department at DPH, and Dr C subsequently assessed Ms A on 1 October 2002, writing to Dr E in a letter dated 10 October 2002:

[1] Reports to ACC, dated 25 November 2002, 15 January 2003, 27 September 2004.
[2] Report to ACC, dated 11 March 2003.
[3] Report to ACC, dated 17 February 2003.
[4] Reports to ACC, dated 25 November 2002, 21 January 2003.
[5] Stridor: Noisy breathing, particularly on inspiration, generally caused by laryngeal obstruction.

> "I agree that [Ms A] would benefit from microlaryngoscopy, tracheoscopy, possible KTP laser ablation of glottic and subglottic scar tissue and then perhaps Mitomycin C[6] application to prevent further fibrosis."

Chronology

Preoperative clinic — 15 October 2002

On 15 October 2002, Ms A attended the ENT pre-admission clinic at DPH and was separately assessed by Dr B and Dr C.

Dr B discussed with Ms A the risks associated with a general anaesthetic and the likelihood of airway oedema following laser surgery, and the risks of reactive airway, particularly in view of her asthma and smoking. As he had not experienced an airway fire during laser treatment in 15 years of anaesthetic practice and considered its incidence to be "extremely rare", Dr B did not discuss this risk with Ms A. He stated that it was not standard practice in Dunedin Hospital (or, to his knowledge, in New Zealand or overseas) to discuss airway fire with patients undergoing laser surgery. The Chief Executive Officer (CEO) of Otago District Health Board (ODHB) confirmed:

> "At the time of [Ms A's] incident the majority of anaesthetists in this Department would not have mentioned airway fire as part of the informed consent. It was seen as more of a surgical issue."

The anaesthetic record for the intended procedure includes a section for the preoperative visit, and this section was completed by Dr B. He recorded Ms A's history of previous general anaesthetics, asthma, and smoking. Dr B recorded "mild wheeze", and the anaesthetic plan was recorded as "GA" — general anaesthetic. No record was made of the discussion about potential risks of anaesthesia or about the formation of a tracheostomy. Dr B stated:

> "I was made aware of the potential narrowness of [Ms A's] airway in the pre-admission clinic. … This was confirmed on my clinical examination. I told [Dr C] that I was planning to use the copper Benjet tube for intubating [Ms A] because laser was going to be used."
>
> Because of the narrowness of her airway, Dr C and Dr B recommended to Ms A a tracheostomy as the procedure of choice to maintain her airway. However, Ms A made it known that she did not want a tracheostomy. Dr C stated that Ms A said to him that "she would rather die than have another tracheostomy".

[6] Mitomycin C: antibiotic used during chemotherapy, but used in Ms A's case to reduce scar formation, as Mitomycin C applied topically after laser surgery reduces collagen synthesis, which is the basis for scar formation.

Ms A stated to ACC:

> "I did express very firm views around having a tracheostomy. I was very sensitive to having a tracheostomy as a result of growing up with one as a child. [Dr C] was suggesting putting a tracheostomy in just to go in and have a look at the situation. When I expressed to him my firm views about a tracheostomy, he said nothing about there being a fire risk, no doubt because he intended using a metal tube. If the surgery had been stopped, then my first preference would have unquestionably been that a smaller metal tube should be obtained or made. If there were no other reasonable options and there were risks to me, then I would have agreed to a tracheostomy. Indeed, I did agree the very next day."

Dr C stated:

> "[Dr B] and I were both aware that this was a challenging area of ENT surgery and anaesthesia. We conferred at the preoperative clinic. We agreed that, if possible, we would use a standard copper Benjet tube employed at Healthcare Otago which is a modification of the Benjet.[7] If this proved to be impossible then we would proceed with a paediatric Benjet. We felt that, at this stage, the risk to [Ms A] of airway fire was certainly less than 1% and that this risk was outweighed by potential benefits in terms of [Ms A's] restricted exercise tolerance and physical handicap looking after her children."

In his affidavit dated 29 July 2004, Dr C stated:

> "The risk of airway fire is significantly less than 1%. My understanding from the discussion that I had with [Ms A] before the surgery was that a risk that small would not have overridden her absolute desire not to have a tracheostomy."

In his undated report on Ms A's inpatient care for the purposes of the ODHB internal inquiry into the incident, Dr C described the risks of an airway fire as being "an uncommon but a very significant complication of endoscopic laser airway surgery".

[7] Benjet: Also referred to as Benjamin jet tube, after Dr Bruce Benjamin, one of the designers of the tube. It was developed in the 1970s to facilitate microlaryngeal surgery.

In response to the provisional opinion, Dr C stated:

> "Based on my personal clinical experience I consider the risk of an airway fire is less than 1% and therefore, it was my opinion that the risk of an airway fire occurring was so remote that it was not relevant to the preoperative discussions. I also did not discuss with [Ms A] the risk of an airway fire as it is my understanding that surgeons are not compelled to discuss complications with patients undergoing surgical procedures where the rate of complication was less than 1%. If this principle was extended to include significant complications where the clinician felt that discussion of such complications (when rare) could produce undue anxiety for patients and jeopardise that individual's likelihood of undergoing a procedure which might be highly beneficial for their quality of life or life expectancy, then this would further support my decision not to discuss such an event with that patient."

There was no record made preoperatively by Dr C of Ms A's insistence that a tracheostomy not be performed. On the consent form, signed by Ms A on 15 October 2002, there are two sections that have been left blank or incomplete:

> "1. Possible further actions that could be required in this operation or procedure: [left blank]. My consent does/does not [neither crossed out] include this operation or procedure if it proves to be required.
>
> 2. I realize that in exceptional circumstances it may be found during the course of the operation or procedure that further or alternative operative measures are necessary in my/the patient's [neither crossed out] best medical interest. I do/do not [neither crossed out] give consent to such additional measures being carried out given that they are consistent with current medical practice."

The consent form has been signed twice by Dr C: first, as the consenting doctor, and, secondly, as the doctor who will perform the operation. There is no record on the preoperative or perioperative documents that the involvement of another surgeon was discussed with Ms A.

A document titled "Pre-operative questionnaire", unsigned and undated, has been provided by ODHB as part of Ms A's clinical record. Ms A's name, or data that would identify her, is not recorded on this document. The person completing the checklist has indicated that he or she has agreed to medical student involvement during the administration of the anaesthetic. Ms A does not recall completing a preoperative questionnaire; if she had, she stated that she would have signed it, "as I do with all [other] documents".

Dr C was listed on the Clinical Practice Register at DPH as being accredited for the use of KTP laser, as well as CO_2 and Nd YAG lasers.[8] Dr D, ENT Teaching Fellow, was not on the Clinical Practice Register as being accredited for laser use.

Surgical fire
The surgery took place under general anaesthetic at DPH on 16 October 2002. Dr B was the anaesthetist and the procedure was performed by Dr D under the supervision of Dr C. Also present during the procedure were an anaesthetic nurse, a scout (circulating) nurse and a technician.

Ms A was informed when she arrived in theatre that medical students would be observing her surgery.

After Ms A had been anaesthetised, it was found that, due to the narrowness of Ms A's glottic inlet, the smallest size of laser-proof ET tube could not be used. Dr C advised me that "there is no such thing as a KTP laser-proof tube". Dr C stated:

> "A narrower version of the copper modified Benjet had not been thought of and was therefore not available."

Therefore, a plastic, paediatric Benjet ET tube was used. The CEO of ODHB stated:

> "The plastic Benjet tube has been used in Dunedin for many years especially in cases scheduled for examination and biopsy. Likewise a copper version, which was developed and manufactured in Dunedin, has also been used by us, for nearly 20 years, without significant problems with its use. It is used predominantly for cases involving laser surgery."

Dr B does not recall whether Dr D made any recommendation regarding the use of the plastic paediatric Benjet tube. Neither the anaesthetic nurse nor the technician recalls any discussion regarding the choice of ET tube to be used.

Dr B stated:

> "I was very concerned about [Ms A's] airway maintenance during the procedure. I suggested inserting a copper Benjet [laser-proof ET] tube for the procedure. [Dr C] advised me to insert a plastic Benjet tube initially in order to assess [Ms A's] airway and then decide the further airway management depending on … his findings. [Dr C] also told me that [Ms A] was not willing to have a tracheostomy."

[8] Document dated 19 April 2001.

Dr C stated:

> "Following induction of anaesthesia and [Dr B's] findings that he could not successfully negotiate a standard copper modified Benjet into the airway, he utilised the standard paediatric Benjet. … [Dr B] and I concurred in the operating theatre that we felt it was safe to proceed."

In his response to the provisional opinion, Dr C further stated:

> "[Dr B] had to make a decision about what tube could be utilised to establish anaesthesia in this case. However, given that there is no such thing as a KTP laser-proof tube and only one tube would fit, I did not take issue with the material the tube was made of."

Dr B stated:

> "I had made clear my reservations about using the plastic endotracheal tube with laser to the surgeon. …
>
> I initially anaesthetised [Ms A] intubating her with the plastic Benjet tube to maintain her airway. [Dr C] then assessed her airway and informed me that he preferred to work with this plastic Benjet tube rather than a copper tube because her airway was extremely narrow (even narrower than anticipated) and that the copper tube would not allow sufficient room around the tube to allow for him to work to relieve her subglottic stenosis. …
>
> Proceeding with the laser treatment was essentially the surgeon's decision. I had made my recommendation that a copper endotracheal tube was safer and more appropriate for a laser surgery. …
>
> Ideally I would have preferred to have administered less than 40% oxygen to reduce the chances of combustion. … However this was not possible as a blender was not made available in theatre that would have enabled me to control the oxygen concentration.[9] In my clinical assessment … [Ms A] would have definitely required more than 50% oxygen to ensure adequate oxygenation."

Dr B stated in his report for the ODHB internal inquiry:[10]

> "We decided to go ahead and do the KTP laser with the plastic paediatric Benjet tube because no other option was available."

[9] The CEO of ODHB confirmed: "I can support the statement that an oxygen/air blender was not available at Dunedin Hospital at the time of this airway fire."
[10] Report for purposes of the ODHB internal investigation, undated.

Dr B stated to ACC:[11]

> "The use of the Benjet tube in these type of cases is not so well known in New Zealand."

However, in response to the provisional opinion, Dr B stated that he and Dr C "have used the plastic Benjet tube in several similar surgery cases in the past without any incident".

The laser was set to continuous mode during the procedure, rather than pulse mode. The CEO of ODHB advised:

> "Pulse-mode is less efficient in the destruction of dense soft tissue. In this case with substantial amounts of subglottic fibrous tissue pulse mode would be ineffective. …
>
> There are situations where pulse-mode is more appropriate. For example, when treating vascular lesions and when attempting to blanch tissues rather than ablate tissue. There are also times when brief high bursts of energy are required, such as the fashioning of an opening in thin bone. …
>
> I am also advised that one should also consider whether pulsed mode really would have altered the risk of an airway fire in a very stenotic subglottis with high concentrations of oxygen. … Pulsed mode does not stop the laser firing, and does not change the level of oxygen in an enclosed space. The frequency of firing in pulsed mode is not so infrequent that there would have been a significant fall in oxygen concentration between laser firings. So the creation of sufficient energy for oxygen at high concentrations to support a fire would still have been a risk."

Dr C described in his internal report the equipment that was in use: "A Hopkins rod endoscope, a paediatric Benjet and a KTP laser fibre and sucker in the airway."

In Dr C's response to the provisional opinion, he advised that he "commenced the laser surgery and after lasering without incident for sometime, [he] believed it was safe and appropriate for Dr D to contribute towards the surgical procedure". Following handover to Dr D, an airway fire occurred. Dr C then took over the procedure from Dr D.

Dr C described what he considered to be the cause of the fire:

> "Unfortunately charring and also high concentration of oxygen in the vicinity of the laser surgery work (thanks to the narrow glottic inlet which prevented dilution of the oxygen with room air and the cork in the bottle effect produced by the Benjet, endoscope, and laser fibre and sucker in the airway) resulted in the fire."

[11] Brief of evidence to support application for review of ACC decision, dated 9 December 2003.

Although the fire was promptly put out, Ms A sustained full-thickness mucosal burns to the subglottis, glottis and laryngeal surface of the epiglottis, with minor burns to the tracheal mucosa, mucosa of the main bronchi and the oropharynx. The 2cm long distal end of the ET tube was found to have melted off and fallen into Ms A's respiratory tract, partially blocking the left mainstem bronchus. Dr C informed ACC:

> "Attempts were made to introduce an adult bronchoscope to achieve ventilation and safety of the airway and to allow retrieval of the end of the Benjet tube. However, an adult bronchoscope was too wide to negotiate the glottic inlet. A paediatric bronchoscope was successfully passed but was too short to allow removal of the Benjet tip which could be observed in the distal airway."

Ms A, who was still unconscious due to the anaesthetic, was transferred from the operating theatre to the intensive care unit for ventilation and observation overnight.

A further, unsuccessful attempt was made at 10:30am on 17 October to remove the ET tube tip using a bronchoscope. It was concluded that a tracheostomy needed to be performed in order to retrieve the ET tube tip. [Ms A] was subsequently woken at 2:50pm on 17 October and consented to the operation.

At 8:00pm on 17 October, a tracheostomy and the removal of the ET tube tip was performed by [Dr C]. A further bronchoscopy was performed on 23 October to review the extent of the damage from the fire. [Ms A] remained in hospital until her discharge with a tracheostomy on 29 October.

Post-discharge
On 13 November, the Clinical Practice Group Manager, wrote to the ODHB Chief Medical Officer. The clinical practice group manager stated:

> "Further to my notification of a recent airway fire, involving [Ms A], please find attached a complete set of documentation supporting the incident and subsequent investigation …
>
> From an ENT service provision perspective, this incident is now considered closed."

On 26 November, a meeting was held involving Ms A, members of her family, Dr C and the ODHB Chief Medical Officer. The notes of the meeting state that Dr C described the procedure, and included a discussion about the difficulties encountered during the procedure. The involvement of Dr D was not recorded as having been discussed or mentioned in the notes of the meeting.

Dr C, Dr D and Dr B have left New Zealand and are currently practising overseas.

Ms A continues to require treatment for tracheal stenosis and associated conditions.

Other matters

Dr D

Dr D had been granted temporary registration with the New Zealand Medical Council for the period from 5 July 2002 to 14 June 2003, having qualified overseas. His job description stated:

> "Assessment and Continued Care
> Under supervision of specialist medical staff and in consultation and liaison with nursing staff and other members of the service ensure provision of care to patients in an effective and courteous manner. …
>
> Limitations on Authority
>
> 1. The patient's care is primarily the responsibility of your consultant. While this may be delegated to you to varying degrees he/she must always be aware of your service activity.
>
> 2. Except in exceptional circumstances all major clinical decisions must have the clear confirmation of the consultant."

The CEO of ODHB advised:

> "Review of this incident has determined that the airway fire was managed well and in accordance with the ODHB CO_2 laser usage guideline. … It is of note that this document is dated 23 October 2002, which is [one week] after the incident. However there was a preceding draft document and therefore ODHB had a policy in process for this rare event, and it was applied properly. …
>
> I would like to emphasise that our position as an organization is that internal investigation into Dr C's surgical management of [Ms A's] condition found no error on his part, neither was there any error found on the part of [Dr B]. …
>
> [Dr C] was operating with an advanced trainee in Otolaryngology who was performing the procedure under the direct supervision, via the operating microscope, of [Dr C]. In my view, and that of our Chief Medical Officer … this neither alters the facts surrounding the case, nor any lines of clinical responsibility that have previously been established."

In response to a request for further clarification about Dr D's involvement, the CEO stated:

> "It was [Dr C's] opinion that [Dr D] was sufficiently experienced to perform this surgery under his supervision. [Dr C] was present at all times that [Dr D] was participating in this procedure and had an active role in directing exactly what was done and when. …

> I became aware of [Dr D's] involvement in this incident when [Dr B] noted it in correspondence in August 2004. … My understanding is that the investigation concluded that [Dr D's] role in the incident was not of significance as he was under direct supervision of [Dr C] and because [Dr C] took full responsibility for the incident. …
>
> With reference to laser competence, I am informed by [the Clinical Leader] of ORL, that [Dr D] was enrolled in a higher training programme [overseas] and had been exposed to laser surgery both [overseas] as well as (under supervision of [Dr C]) in New Zealand. [Dr D] had been observed performing laser surgery by [Dr C] prior to this procedure."

In response to the provisional opinion, Dr C stated:

> "[Dr D] completed his training [overseas] from a recognised Higher Surgical Training Post. He was eligible to apply for his Certificate of Completion of Surgical Training from [an overseas college]. This certificate was completed in December 2002. [Dr D] was a Teaching Fellow in Otolaryngology, Head and Neck Surgery and was a fully trained surgeon. In the context of his entry into New Zealand, he was a trainee under my supervision.
>
> In October 2002, the unit that [Dr D] and I were working in was the only unit in New Zealand performing KTP laser surgery to the subglottic region. Whilst unique in New Zealand, this did not mean that the unit was the only unit in the world performing this type of surgery. Many units in the United Kingdom and the United States perform KTP laser airway surgery and have been doing so for several years."

Dr D stated:

> "I was part of [Dr C's] team and had sessions in theatre with him along with 2 other registrars. It was standard practice for all members of [Dr C's] team to assist at a clinic where patients were assessed just before their operation.
>
> However on the week of the operation, I was the only trainee who had not gone to a registrar conference and therefore the only trainee who could have been present with [Dr C] at his clinic.
>
> In view of the time elapsed, I cannot recall whether I was introduced to [Ms A] before the operation under investigation, though it was likely that I was present at this clinic."

Dr C further stated:

> "[Dr D] became involved in the administration of the surgical procedure for [Ms A] partway through that procedure. His involvement terminated at the point at which the airway fire occurred. [Dr D] was shown the relevant pathological anatomy, by me, using a Hopkins rod endoscope. [Dr D] was already highly skilled in the recognition of

normal anatomy of the larynx and trachea by this method. The relevant surgical landmarks were pointed out. The position of the paediatric Benjet in the airway was demonstrated and, in particular, its relationship to the area where surgical intervention was to be undertaken. During [Dr D's] involvement in the surgical procedure, I stood at his left shoulder. This allowed me to observe, through the rigid laryngoscope, down to the level of the vocal cords. I was able to observe the relationship between the Hopkins rod endoscope and the Benjet and the laser fibre and carrier. At 10–15 second intervals I was able to observe through the Hopkins rod endoscope what was happening at the site of operation. During the period of lasering [Dr D] was giving a commentary on his progress and what difficulty he was encountering. To the point of airway fire there were none. When the airway fire occurred, I administered the cold water jet to the airway to extinguish the fire. I was able to do this because I was so closely positioned next to [Dr D]. … At the time of the airway fire, [Dr D's] involvement was effectively ended. Thereafter I was responsible for all aspects of the delivery of surgical care which included re-intubation of [Ms A's] airway.

[Dr D] was not involved in the pre-operative discussion that decided [Ms A's] treatment. [Dr D] became involved in [Ms A's] treatment at the time of her pre-admission visit where she was seen by myself and by [Dr B]. He was also attendant in theatre at the time of [Ms A's] arrival in the operating room.

[Dr D] undertook a portion of the surgical procedure as outlined above. Additionally, during [Ms A's] recovery from the airway fire and subsequent attendance at Healthcare Otago and for her subsequent surgical treatment, [Dr D] was involved in her pre-operative, peri-operative and post-operative care.

[Dr D] was not involved in the decision making process which led to the use of the paediatric Benjet. That decision was made by me in conjunction with [Dr B]. [Dr D] made no recommendation. [Dr D] did not venture an opinion on the use of the paediatric Benjet, especially not one of objection.

'Usual coordination measures were in place between surgeon and anaesthetist' means that the surgeon, whether that be [Dr D] or myself, who is operating the laser is responsible for indicating to the anaesthetist that cessation of ventilation is required for further laser surgery. It is the responsibility of the anaesthetist to indicate to the surgeon when that cessation of ventilation can take place and what the safe duration of cessation of ventilation might be. These measures were in place at all times during the procedure. …

A second eye-piece was not used. We do not have a beam-splitter for the Hopkins rod endoscope which allows second eye-piece visualization. A camera system is available which allows any attendant in the operating theatre to observe the procedure on a monitor. However, with the KTP laser, there are bright laser pulse flashes which are damaging to the camera. A coloured lens system is available which cuts down the laser

> light pulse intensity and prevents camera damage but which, unfortunately in this circumstance, cut down the general ambient light level to the point at which insufficient detail could be observed of the target area. I consider at all times that [Dr D's] knowledge of the normal anatomy and pathological anatomy, and his skills and experience in laser surgery were sufficient to allow him to operate the laser safely without my direct observation at all times. I was viewing the operation site at 10–15 second intervals and was observing the procedure down the rigid laryngoscope to the level of the vocal cords at all times. …
>
> [Ms A] was aware, pre-operatively, that [Dr D] was helping in surgical intervention under my supervision. [Ms A] was aware, post-operatively, of the nature of the surgical team who has been involved in her care. However, at all times, with regards to the description of the surgical procedure, its complications and risks, and the delivery of care both at the surgical procedure and subsequent surgical interventions, I made it quite clear that I was the supervising surgeon and took responsibility for what happened under my supervision.
>
> I am satisfied that [Ms A] was aware that [Dr D] might perform part of the procedure. I am certain that this happened at the pre-operative visit."

Dr D's involvement in Ms A's procedure was not recorded on the following documents:

- ODHB Incident Report (16 October 2002, completed by Dr C);
- ODHB anaesthetic record of the operation (16 October 2002, completed by Dr B);
- ODHB clinical record of the operation (16 October 2002, completed by Dr C);
- Dr C's report accompanying the ODHB Incident Report (undated);
- Dr B's report accompanying the ODHB Incident Report (undated);
- Dr C's letter to Dr E described as "ENT OPERATION NOTE" (24 October 2002);
- Meeting between ODHB management and Ms A (26 November 2002);
- Dr C's report of the incident to ACC (2 December 2002);
- Dr B's report of the incident to ACC (10 January 2003);
- Dr C's letter to ACC (18 July 2003);
- Dr B's statement to ACC (9 December 2003);
- Submissions by counsel for Dr B to ACC (10 March 2004);
- Dr C's affidavit for the purposes of the ACC review (29 July 2004);[12]
- Dr C's report to HDC on receipt of notification of Ms A's complaint (26 August 2004).

In a letter dated 1 November 2002, Dr D wrote to Dr E describing the events of the procedure. "The surgeon" is recorded as "[Dr D/Dr C]". Dr C stated that Dr D's involvement was also mentioned in the operation note and the "ODHB operative log".

[12] Dr C stated: "I am the surgeon who performed the surgery on [Ms A] on 16 October 2002."

On 8 June 2005, Ms A was asked by my Office about her knowledge of Dr D's involvement. Ms A's lawyers responded:

> "At no time either before or after the operation on 16 October 2002 did [Ms A] have any knowledge of the involvement of a [Dr D]. She advises that when being readied for surgery on 16 October, and about to be put under general anaesthetic, she was advised that what she understood to be some medical students were going to observe the procedure. No specific consent was sought from her as to their presence and observations. At no stage did she give any consent for a [Dr D] or any other person to be involved in the procedures. …
>
> [Ms A] has only become aware [of Dr D's] involvement … from us contacting her in relation to your letter of 8 June 2005. She had no prior knowledge of any suggestion as to [Dr D's] involvement."

As Dr D is currently working overseas, the appropriate Medical Council was asked to provide his contact details, but did not respond. A Dr D, working as an ENT consultant, was identified in an overseas town. He was contacted and asked whether he had been involved in Ms A's care on 16 October 2002. Dr D responded:

> "I am replying … to confirm that I was involved in the care of the mentioned patient."

Accident Compensation Corporation
On 22 October 2002, Ms A lodged an injury claim with ACC. As part of her application she wrote:

> "I am unsure of who else was present or responsible as I was under a general anaesthetic."

Ms A further advised ACC:[13]

> "[Dr C] … explained to me that he had discussed with [Dr B] during the course of the laser surgery the need to cover the tube with fireproof material, but that there was not enough room. I understand from what [Dr C] was saying that both he and [Dr B] appreciated that there was a risk of fire. That … had never been explained to me."

On 21 November 2002, ACC accepted Ms A's claim as medical misadventure while continuing to investigate the case. During the course of the investigation, reports were obtained from surgeons Dr Nick McIvor and Dr Peter Blake, and anaesthetists Dr Vaughan Laurenson and Dr Malcolm Futter.

[13] Brief of evidence in relation to Dr B's application for review, dated 11 March 2004.

Dr Nick McIvor
Dr McIvor, head and neck surgeon, advised ACC:

> "In summary, I believe this is a case of medical error. The patient was not warned about an airway fire presumably as the surgeon thought the risk was so low. The patient was adamant that she did not want a tracheostomy which made it difficult for the surgeon and in retrospect if he had considered it impossible to laser the stenosis without having combustible material in the trachea then he either should have refused to take the case, insisted on a tracheostomy, or at least discussed the risks of an airway fire. … Ideally this case should have been managed without a tube and with either the patient spontaneously breathing or with jet ventilation between the vocal cords out of phase with lasering. If the stenosis was too tight then a tracheostomy was necessary."

Dr McIvor further stated:

> "The surgeon felt it necessary to place a plastic Benjet airway into the trachea and it was his responsibility to minimize the risk of combustion. The plastic is thin and highly combustible and in this situation the tube sustained a transecting burn with loss of the distal tip into the lower airway. The surgeon states that this was not the initial material to combust but rather the wall of the trachea with secondary spread to the tube. While it seems unlikely that the tube was transected at a specific point by a fire of this nature and it is more probable that a reflected beam hit the tube itself, the explanation is still possible. Tracheal tissue when lasered may char and then glow. It is the surgeon's responsibility to ensure that as soon as the tissue starts to glow, the laser is turned off, particularly in an oxygen-rich environment. It is probably also wise for the surgeon and anaesthetist to coordinate their actions to ensure that the patient isn't receiving a jet of oxygen at the time of the laser strike. Whether this occurred is not stated."

Dr Peter Blake
Dr Blake, head and neck surgeon, advised ACC:

> "Both surgeon and anaesthetist should have been aware of the dangers inherent in attempting to manage the airway and use a laser in this fashion. In retrospect I am sure that both parties will agree that the correct course of action was to have abandoned the procedure once it was apparent that the airway could not be adequately maintained either by use of oxygen jet ventilation (which does not involve the use of a tube) or by the use of a small copper tube, or other laser safe tube. It was time to wake the patient up, explain what had happened and talk at a suitable time thereafter about other treatment options. …
>
> The surgeon should have appreciated the dangers inherent in using the laser close to an unguarded plastic endotracheal tube and the anaesthetist should also have been aware of the risks. Both are jointly liable for this outcome."

Dr Blake provided a second report to ACC, following responses from Drs C and B. Dr Blake stated:

"Whilst it is true that the risk of laser fires in the reported literature is very low, this is only because considerable precautions are taken to avoid them. …

At the point when it was discovered that the only way of securing [Ms A's] anaesthetic for the proposed surgical intervention was by way of using an unprotected plastic Benjet tube, the risk profile for the procedure dramatically changed. …

It is my view that the risk of a laser fire under these circumstances was well in excess of 1%. Indeed, I feel that the risk of a laser fire here was such that both surgeon and anaesthetist should not have proceeded past the point of the establishment of a satisfactory airway. At that point they should have stepped back from the case, decided that it was not safe to go on and accepted that they would have to wake the patient up and put to [Ms A] a new set of risk factors."

Dr Blake stated in his third report to ACC:

"[Dr C] states that in his opinion the risk of the fire was considerably less than 1%. In my opinion, the fire was more probable than not under those circumstances. … No anaesthetist I have worked with would countenance going on with the procedure if the procedure was elective, no safe alternative was available and it was feasible to wake the patient up and accept abandoning the procedure. …

The second issue that I wish to comment on is contained in … [Dr C's] affidavit in which he states, '[Ms A] also suggests that she would have agreed to a tracheostomy had she been informed there was a risk of fire in her airway if she proceeded without a tracheostomy. I disagree with that. [Ms A] made it abundantly clear to me that she wished at all costs to avoid further tracheostomy formation. I think her precise words to me were "I would rather die than have another tracheostomy". This vehement statement left no room for negotiation'.

There is corollary to [Ms A's] statement and the corollary is that [Ms A] is effectively asking the surgeon for a guarantee that the planned intervention will succeed. In other words, this is the requirement for complication-free and successful surgery. That requirement … places a very onerous burden on the surgeon. That is especially so in this case because [Ms A's] airway problem was complex and difficult to manage. I would venture that it would be a brave surgeon indeed who would agree to undertake surgery on a patient under those circumstances. In my view that issue should have been explored and dealt with at length before any surgery was undertaken. If [Ms A] really was of the view that under no circumstances was she prepared to accept a tracheostomy, then my own personal view would be that I would decline to operate. I just would not be happy to undertake surgery with an airway problem of that nature where there is a significant degree of unpredictability both about what might or might not be achieved at the time of surgery and what might happen in the postoperative period over the next few days."

Dr Malcolm Futter
Dr Futter, anaesthetist, advised ACC. Although he concluded that in his opinion what occurred was medical mishap rather than medical error, he stated:

> "Given the potentially serious consequences of an airway fire … it is perhaps surprising that airway fire was not mentioned preoperatively, particularly when it was recognised that in response to the patient's wishes the planned treatment was already 'non-standard'."

Dr Vaughan Laurenson
Dr Laurenson, anaesthetist, advised ACC. He stated:

> "If an error occurred it was the decision to use the laser after the examination under anaesthesia had revealed that the subglottic stenosis was too narrow to allow the passage of the laser proof tube. This would have been a decision of both the anaesthetist and surgeon involved. The only choice would have been to abandon surgery altogether which would have left [Ms A] untreated. As I was not privy to the consultations before surgery, which would have affected the decision to proceed, I am not prepared to find that this was a case of error."

ACC accepted Ms A's claim as medical error on 3 June 2003; a copy of the decision, with copies of all seven of the reports attached from the four expert advisors consulted, was sent on 3 June 2003 to Drs C and B.

Dr B filed an application for a review of the finding of medical error against him. In his application he stated:

> "From a surgical and anaesthetic point of view, a tracheostomy was preferred. In view of [Ms A's] declinature I was advised by the surgeon that an alternative means of ventilation had to be used. … There were risks with this procedure that would not arise with my preferred option of a tracheostomy so it was important for the surgeon to take great care in the use of and direction of the flame."

The application was dismissed on 16 December 2004. The reviewer stated:

> "I believe that both parties [Dr C and B] failed to advise [Ms A] of the risk of airway fire … I believe that there being such a risk, there was an obligation on both the Surgeon and the Anaesthetist to advise [Ms A] of those risks. Had they done so she may have had second thoughts about proceeding with the tracheostomy.
>
> Having accepted that there was a lack of informed consent by [Mrs A] in respect of the procedure chosen, it follows that Dr B bears responsibility also about the decisions made on [Ms A] during the course of surgery.
>
> ACC's decision is upheld and the application for review is dismissed."

The manager of Treatment Injury and Patient Safety, ACC,[14] informed me in a letter dated 12 August 2005 that ACC had no knowledge of [Dr D's] involvement in [Ms A's] care until advised by my Office.

Dr C has previously apologised to Ms A for the events that occurred.

Guidelines and articles
The document "Protocol for use of KTP laser in main operating theatre" that was current on 16 October 2002 stated:[15]

> "Laser is not to be used unless a clinician with registered laser competency is present in theatre."

Dr B provided an article to ACC in support of his application for a review of the medical error decision. The author commented on the relative rarity of airway fires (0.5–1.5%) and also commented on the use of oxygen:[16]

> "The mixture of airway gases becomes an important issue when any type of potentially flammable endotracheal tube is used. Combustion is more vigorous when excess oxidizer is present, and most clinicians recognize the need to reduce the [oxygen concentration] below [40%] or to the minimum concentration consistent with patient oxygenation."

Dr B provided a copy of an article written by Dr Bruce Benjamin,[17] the inventor of the Benjet tube. Dr Benjaman reported that "[t]he tubes have been used extensively in the last two years and have been found satisfactory in over 100 adults and 100 children, with no complications attributable to the tube".

In his response to notification of Ms A's complaint, Dr B provided a copy of an article that stated:[18]

> "Three main techniques are currently available to avoid the fire hazards associated with the use of conventional endotracheal tubes during laser surgery of the airway: no tube in the airway, protection of the external surface of a conventional tube, or use of a non-combustible tube."

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[14] Previously the Medical Misadventure Unit.
[15] On 23 October 2002, ODHB introduced a new procedure for the use of the laser in the operating theatre. The procedure states: "**Important**: The clinician operating the laser must be registered as competent under the criteria set by the ODHB Laser Safety Committee."
[16] Rampil, I J, "Anaesthetic considerations for laser surgery", Anaesth Analg (1992) 74: 424–435.
[17] Benjamin, B and Gronow D, "A new tube for microlaryngeal surgery", Anaesth Intens Care (1978) 7: 258.
[18] Hermens, J M, Bennet, M J, and Hirschman, C A, "Anaesthesia for laser surgery", Anaesth Analg (1983) 62: 218–229.

Dr B provided a published case report of an airway fire. The conclusion of the article stated:[19]

> "The risk of fire is always present when increased oxygen concentration and high energy sources (laser and electrocautery) are present in close proximity. With care this risk can be minimized."

Independent advice to Commissioner

Surgical advice
The following expert advice was obtained from Dr Catherine Ferguson, otolaryngologist and head and neck surgeon:

> "Thank you for asking me to provide a report on this case.
>
> I have read the Guidelines for Independent Advisors, supplied by the Office of the Health and Disability Commissioner, and I agree to follow these guidelines.
>
> I am a Vocationally Registered Otolaryngologist, Head and Neck Surgeon, practising general otolaryngology, including CO_2 laser laryngeal surgery. However I do not have any experience with the use of the KTP laser in laryngeal surgery.
>
> I have been asked to provide independent expert advice about whether [Dr C] provided an appropriate standard of care to [Ms A].
>
> The information I have reviewed is as follows:

Supporting Information

- Letter of complaint from [Ms A's barrister] on behalf of [Ms A] dated 15 March 2004 (pages 1–3) marked 'A'.
- Record of telephone conversation with [Ms A] on 29 June 2004 (page 4) marked 'B'.
- Response from [Dr B] to the Assistant Commissioner dated 6 September 2004 including a copy of four journal articles (pages 5–45) marked 'C'.
- Response from [Dr C] to the Assistant Commissioner dated 26 August 2004 (pages 46–51) marked 'D'.
- Response from the Otago District Health Board (DHB) to the Assistant Commissioner dated 8 September (pages 52–54)

[19] Wegrzynowicz, E S, et al, "Airway fire during jet ventilation for laser excision of vocal cord papillomata", Anesthesiology (1992) 76: 468–469.

marked 'E'.

- Letter from HDC to the DHB dated 24 September 2004 and the related response dated 6 October 2004 (pages 55–57) marked 'F'.
- Letter from [Ms A's barrister] to HDC dated 9 June 2004 including a copy of a newspaper article (pages 58–62) marked 'G'.
- Letter from [Ms A's barrister] to the Commissioner dated 28 July 2004 (pages 63–64) marked 'H'
- Affidavit of [Dr C] dated 29 July 2004 (pages 65–69) marked 'I'.
- [Ms A's] clinical records from Dunedin Hospital (pages 70–216) marked 'J'.
- Documentation relating to [Ms A] from the DHB including its guidelines on the use of the CO_2 laser (pages 217–281) marked 'K'.
- [Ms A's] records from [a public hospital] (pages 282–334) marked 'L'.
- [Ms A's] records from ACC (pages 335–504) marked 'M' including:
  1. Report from [Dr C] for the purposes of the Medical Misadventure claim dated 2 December 2002 (pages 365–369).
  2. Report from [Dr B] for the purposes of the Medical Misadventure claim dated 10 January 2003 (pages 371–373).
  3. Record of the meeting of the Medical Misadventure Panel on 16 April 2003 (pages 375–381).
  4. Brief of evidence by [Dr B] dated 9 December 2003 (pages 431–436).
  5. ACC submission in response to an application by [Dr B] for review of the ACC's Medical Error decision, dated 9 March 2004 (pages 438–449).
  6. Submission by counsel for [Dr B] for a review of the finding by ACC of Medical Error, dated 10 March 2004 (pages 451–465).
  7. Brief of evidence of [Ms A] dated 11 March 2004 (pages 466–469).
  8. Submission by counsel for [Ms A] dated 11 March 2004 (pages 470–475).
  9. Second brief of evidence of [Ms A] dated 5 November 2004 (pages 476–480).
  10. Provisional report from Dr Peter Blake (advisor to ACC)

Names (other than Dunedin Hospital, Otago District Health Board, HDC independent expert advisors and ACC's expert advisors) have been removed to protect privacy. Identifying letters have been assigned and bear no relationship to the person's actual name.

dated 25 November 2002 (pages 481–487).
11. Report from Dr Malcolm Futter (advisor to ACC) dated 25 November 2002 (pages 488–489).
12. Report from Dr Blake dated 15 January 2003 (pages 490–496).
13. Report from Dr Futter dated 21 January 2003 (pages 497–498).
14. Report from Dr Vaughan Laurenson (advisor to ACC) dated 17 February 2003 (pages 499–500).
15. Report from Dr Nick McIvor (advisor to ACC) dated 11 March 2003 (pages 501–504).

In addition, I have obtained the following documents:

The consent form for surgery 16 October 2002

A copy of the Laser Log

The KTP protocol from HealthCare Otago

Australian/New Zealand Standard: 'Guide to the safe use of lasers in health care'.

Factual Summary:

The 34-year-old [Ms A] had a long history of airway problems relating to airway stenosis she developed following an injury at birth. At 10 days of age she had a tracheostomy tube inserted which was removed in 1990 when she was 21 years old and which left her with permanent respiratory stridor. She was well known to the ENT service at Dunedin Hospital which she attended regularly for treatment of her recurring stenosis of the glottic larynx, subglottis and trachea.

[Ms A] was also a known asthmatic.

Referred by her general practitioner in [a city], on 30 September 2002 [Ms A] was seen by a respiratory physician at [a public hospital] who referred her to [Dr C], consultant with the ORL, Head & Neck Surgery Department at Dunedin Hospital. [Dr C] saw [Ms A] on 1 October 2002 and formed an opinion that she would benefit from microlaryngoscopy, tracheoscopy and possible KTP laser of glottic and subglottic scar tissue. This was planned for a later date and brought forward to 16 October 2002.

On 15 October 2002 [Ms A] was seen at the hospital's preadmission clinic by [Dr B], an anaesthetist. [Dr B] advised that he discussed with [Ms A] the risks associated with general anaesthetic and the likelihood of airway oedema following laser surgery and the risks of reactive airway particularly in view of her asthma and smoking. As he had not experienced an airway fire during laser treatment in the 15 years of his anaesthetic

practice and considered its incidence to be 'extremely rare', he did not discuss this risk with [Ms A].

Because of the narrowness of her airway, [Dr C] and [Dr B] recommended to [Ms A] a tracheostomy as a procedure of choice to maintain her airway. However, [Ms A] made it known to them that she did not want a tracheostomy.

In line with standard practice at Dunedin Hospital, [Dr B] was meant to assess [Ms A] during the pre-admission clinic and obtain her 'informed verbal consent'. [Dr C] took the written 'informed' consent.

On 16 October 2002 [Ms A] underwent endoscopic (KTP) laser surgery under general anaesthetic at Dunedin Hospital. The procedure was performed by [Dr C] with [Dr B] acting as the anaesthetist. Due to the narrowness of [Ms A's] glottic inlet and unavailability of a sufficiently small standard copper Benjet tube, an unprotected plastic paediatric Benjet tube was used in the process.

During the laser procedure an airway fire occurred. Although it was promptly put out, [Ms A] sustained full thickness mucosal burns to the subglottis, glottis and laryngeal surface of the epiglottis with minor burns to the tracheal mucosa, mucosa of the main bronchi and the oropharynx. Because the top of the Benjet was burned through and lost in the left main bronchus, a 'semi-elective' tracheostomy to retrieve the end of the Benjet and to safeguard the airway was performed.

The complaint is summarised as follows:

- *Whether prior to surgery on 16 October 2002, [Dr C] provided [Ms A] with adequate information about the treatment options available to her, including the benefits and risks associated with those options, for her to make an informed choice about her care and treatment.*

The only preoperative records I have been able to obtain are a letter dated 1st October 2002 from [Dr C] to [Ms A's] general practitioner, [Dr E]. In this letter, [Dr C] describes the type of surgery he had planned for [Ms A] and that this had been discussed with her. The details of what were discussed are not mentioned.

I have also obtained a copy of the HealthCare Otago consent form for the operation of 'endoscopic KTP laser to subglottic and glottic stenosis', signed by both [Ms A] and [Dr C] on 15th October 2002. Although there is a section provided to document possible further actions that could be required in the operation or procedure, this part of the consent form has not been completed.

Although it is mentioned subsequently in several places by both [Dr C] and [Ms A] that [Ms A] was adamant she did not want a tracheostomy, this is not documented preoperatively. As this was such an important factor in the decision regarding the type

of surgery offered, I think that it should have been very carefully documented. While this factor may have influenced the decision making at the time of the incident on 16 October 2002, it does not appear that this was ever mentioned as a possibility should any complications arise.

I am unable to comment if [Ms A] was provided with adequate information about the treatment options available to her, including the benefits and risk associated with these options as there is no written record of this discussion. There is certainly no mention of the possibility of airway fire in any of the available documentation.

I am concerned that adequate records were not kept in this case, particularly as it was a complex and difficult revision surgery, in an already compromised airway, where the chances of problems would have been greater than usual.

- *Whether [Dr C] provided [Ms A] with services of an appropriate standard. In particular:*
    - — *whether [Dr C's] recommendation for endoscopic laser surgery was appropriate in [Ms A's] case*
    - — *whether [Dr C] performed the endoscopic laser surgery on 16 October 2002 with reasonable care and skill.*

[Dr C's] recommendation for endoscopic laser surgery was appropriate in [Ms A's] case. Other options had not been proven to be particularly successful and therefore I think that the decision to proceed with laser surgery to improve her airway was the correct decision. However, I do not think that [Dr C] had been involved with the care of [Ms A] prior to this time and he would not have been particularly familiar with her airway difficulties. It therefore seems that further options, if the laser surgery proved impossible at the time of surgery, should have been considered, documented and indeed discussed with [Ms A] prior to surgery.

I do not think that [Dr C] performed the endoscopic laser surgery on 16th October 2002 with reasonable care and skill. This is because he made the decision to proceed with surgery when it was apparent that the situation had changed and was not as expected. I refer to the fact that he was unable to use the planned laser copper tube to provide a safer airway and he then made the decision to proceed using the Benjet tube without considering the possible consequences or alternative treatment options available to him at that point.

I have also been asked to comment on the following 13 questions as detailed below:

1. *Was the full extent of the narrowness of [Ms A's] glottic inlet known prior to the procedure to determine whether the standard copper modified Benjet tube could be used during the procedure?*
   I do not think that the full extent of the narrowness of [Ms A's] glottic inlet was known prior to the procedure to determine whether the standard copper modified

Benjet could be used during the procedure. However, I have not been able to access any old notes which specifically state any findings pre-operatively.

2. *How high and significantly different was the risk of airway fire with the use of the unprotected plastic paediatric Benjet tube used and should this have been discussed with [Ms A] before the procedure?*
   Although the unprotected paediatric Benjet tube has been used in selected paediatric cases without fire, I am not sure whether it has ever been used with the KTP laser. However the Australian/New Zealand Standards 'Guide to the safe use of lasers in health care' quite specifically states that non-flammable endotracheal tubes or especially wrapped tubes should be used during laser surgery to the airway because of the increased risk of fire. I do not think that [Dr C] was anticipating having to use this tube and therefore did not feel that he needed to discuss the risk of fire with [Ms A]. However, I do feel that when the situation changed so that he could only proceed if using an unprotected tube, then he should have stopped the procedure and discussed this increased risk with [Ms A].

3. *Should [Ms A] have been informed of the risk of airway fire particularly in the view of the fact that there was a possibility that the standard copper modified Benjet tube may not be used?*
   I do not know if [Dr C] considered the possibility that the standard copper modified Benjet tube would not have been used, and he therefore felt that the risk of airway fire was low.

4. *Given that during the procedure it became apparent that the standard copper modified Benjet tube could not be used, should the procedure have been abandoned pending consultation with [Ms A]?*
   Once it became apparent that the standard copper modified Benjet tube could not be used, the situation changed significantly, and the risk profile changed significantly. At this stage I think that the procedure should have been abandoned pending consultation with [Ms A].

5. *What were the risks in [Ms A's] case of the procedure being stopped, anaesthesia reversed and readministered at a later date?*
I emphasise that I have no formal anaesthetic training and therefore my opinion is not an expert one.

   [Ms A] already had some degree of airway compromise and her airway may have been worse following reversal of anaesthesia. Therefore she may have required additional airway support in the early post anaesthetic phase.

   There is no suggestion in her notes to suggest that re-intubation or re-anaesthesia would have been particularly hazardous in her case.

6. *[Dr C] commented that 'given that we had utilized this technique several times before without incident, [it] was felt that this was the safest way to proceed'. How appropriate and applicable was this in [Ms A's] case?*
I have no details of the previous cases that [Dr C] is referring to, although it seems that [Ms A's] situation was particularly unique in a patient with an already compromised airway and other risk factors such as chronic obstructive airway disease. This would not be such a problem in children in whom the procedure may have been used before.

7. *How common is the use of the standard paediatric Benjet tube in laser surgery and is any special protection of the tube necessary during the procedure?*
I am not familiar with the degree of use of the standard paediatric Benjet tube in laser surgery. A reference has been provided, stating that special protection of the tube is not necessary, although all other references would support special protection of any form being used in laser surgery.

8. *Did [Dr C] have options other than to use the unprotected plastic paediatric Benjet tube? If so, what were these alternatives?*
If [Dr C] wished to proceed with the laser surgery, then it seems that there was no other tube available suitable to work around with the laser. His two alternatives were to proceed directly with a tracheostomy without reversing the anaesthesia and not discussing this with [Ms A] (but possibly discussing it with her next-of-kin), or reversing the anaesthesia, explaining the situation and then proceeding on the basis of her informed decision at that point.

9. *[Dr C] stated that 'there was no equipment that could have been ordered that could perform the surgery in a different way'. Should a fire-resistant tube of a size required by [Ms A] have been available at Dunedin Hospital?*
I think that this is a unique situation and I do not necessarily think that a fire resistant tube of a size required by [Ms A] should have been available at Dunedin Hospital. I gather that a suitable tube is now available following this incident but I think it would have been more reasonable to abandon the procedure at the time and either perform the surgery in a different way, that is, with a tracheostomy in place, or to wait for a suitable tube to be procured.

10. *Who in this case had the primary responsibility to decide whether to proceed with the procedure and what tube was used?*
    The person in this case having the primary responsibility to decide whether to proceed with the procedure and what tube was used was [Dr C].

11. *Were adequate laser equipment safety protocols in place at Dunedin Hospital at the time and were these followed in [Ms A's] case?*
    I have a copy of the use of the KTP Laser Protocol used at Dunedin Hospital which is to be used in association with the Otago District Health Board General Laser Safety protocol. There is no mention of any restriction on the type of tube to be used during laser surgery and therefore it seems that the laser safety equipment safety protocols were followed in [Ms A's] case.

12. *Was the procedure performed with reasonable care and skill?*
    Because of the issues mentioned above, I do not think that the procedure was performed with reasonable care and skill. The decision was made to continue when it became apparent that the equipment planned could not be used and the hazards were greater.

13. *How appropriate was it in this case for the laser to be used in the 'continuous mode' rather than 'pulse mode' and was the explanation provided by the DHB ([Mr F's] letter of 6 October 2004) reasonable?*
    I accept the explanation provided by the Otago District Health Board regarding the use of the laser in the continuous mode rather than the pulse mode. I myself have no experience with the use of the KTP laser but it appears that the continuous mode use is more effective in cases where dense scar tissue is to be divided and this was the case in [Ms A's] situation. However, this was likely to increase the risk of airway fire in the oxygen rich environment provided by the Benjet tube in the already narrow airway.

    I have found this a very difficult report to write. There is very little preoperative information regarding the initial discussion between [Ms A] and [Dr C], and a lot of comments have been made in hindsight. This emphasises the need for full and accurate documentation of all patient consultations, particularly concerning the informed consent process.

    I appreciate that [Dr C] was trying to avoid a tracheostomy at all costs for [Ms A] but I contend that he had a duty of care to consider the risks involved by trying too hard to avoid a tracheostomy. He found himself in the difficult situation of a narrower airway than expected, but he made the mistake of continuing with his initial plan of management, without thinking through the new set of risks. This has resulted in a very unfortunate outcome for [Ms A] and in fact she ended up having the tracheostomy which is the very thing she wanted to avoid.

If the decision had been made to postpone the surgery in the light of the initial findings intraoperatively, then [Ms A] may well have needed to have a tracheostomy, but would have been able to make an informed decision about this in a supportive environment and would have avoided the airway fire.

I would like to emphasise that while I consider that [Dr C] did not provide [Ms A] with an appropriate standard of care, his mistake was an error which occurred while he was trying his hardest to do what he thought at the time was the best thing for his patient, knowing her wishes. I think that this could be regarded as an error of judgement or of inexperience, rather than a serious breach of patient rights."

Further surgical advice
Further advice was obtained from Dr Ferguson in relation to Dr D's involvement in Ms A's care:

"Thank you for asking me to comment further on this case. Since receiving my report, dated 1 April 2005, you have been informed that the procedure on 16 December 2002, when the airway fire occurred, was performed by [Dr D], Teaching Fellow. Further information was requested from [Dr C], Consultant Surgeon, and [Dr B], Consultant Anaesthetist. [Ms A] was also asked about her knowledge of [Dr D's] involvement. It has not been possible to contact [Dr D].

I have considered my previous report in light of [Dr D's] involvement. The only amendments or additions I would like to make pertain to the complaint summarised as:

- *[Whether] prior to surgery on the 16 October 2002, [Dr C] provided [Ms A] with adequate information about the treatment options available to her, including the benefits and risks associated with those options, for her to make an informed choice about her care and treatment.*

In addition to the comments I have previously made at this point, the possibility of the surgery being performed by a Teaching Fellow should have been clearly discussed and documented and written consent signed by [Ms A] regarding this. The rest of my comments still stand.

In addition in the complaint summary:

- *Whether [Dr C] provided [Ms A] with services of an appropriate standard. In particular:*

– *whether [Dr C's] recommendation for endoscopic laser surgery was appropriate in [Ms A's] case; and*

— *whether [Dr C] performed the endoscopic laser surgery on 16 October 2002 with reasonable care and skill.*

The addition I would like to make to this part of my report, in addition to my previous comments, is that I do not think that this was a suitable case to be performed by a Teaching Fellow in light of the difficulties that were encountered at the beginning of the operation when the decision was made to change to the Benjet tube. At this point, as previously discussed, the risks of the operation dramatically increased and therefore in the light of the decision to proceed with the surgery, the Teaching Fellow should not have been involved at that point.

In addition I have been asked to comment on the following six questions:

1. *Was the guidance and supervision of [Dr D], as described by [Dr C] in his letter, dated 2 June 2005, adequate and appropriate?*

Although I do not think that [Dr D] should have been involved in the surgery at all, the degree of supervision described by [Dr C] does seem to be adequate, although again I do not think it is appropriate (see my comments above).

2. *You commented in your first report on information that should have been provided to [Ms A] pre-operatively. Does the additional information describing [Dr D's] involvement cause you to amend your view on what information [Ms A] should have been given pre-operatively?*

I certainly think that in this situation, with a difficult airway problem and an unusual situation, the involvement of a Teaching Fellow should have been very carefully explained to [Ms A]. I have already commented that I think the written summary of pre-operative consent is inadequate and I certainly consider that [Dr D's] planned involvement should have been carefully documented.

3. *I enclose a copy of the Medical Council of New Zealand's Council statement: 'Information and Consent', April 2002. I refer in particular to paragraph 21, 'Consent should be obtained for involvement of trainees in the care of patients. The patient should be informed about the extent of the involvement of the trainee and the trainee's experience.' Is this Council statement applicable in the circumstances of this case?*

The Medical Council statement is certainly applicable in the circumstances of this case, particularly given the difficulty of the situation and the degree of expertise required.

4. *Should [Dr D's] involvement in the procedure have been recorded, if so where?*

The operation note that has been included with the documents I have been provided is a dictated operation note, dictated 23.10.02, some 7 days after the actual operation. This is in the form of a letter to the General Practitioner. The detail of the operation is recorded and in this letter it states that the Surgeons are D/C. This is the only mention of [Dr D's] involvement, although he in fact has dictated the letter. Therefore his involvement in the procedure is recorded and it is not usual practice in this situation to state which parts of the surgery are being performed by which particular operator. I would like to comment however that there does not seem to be any earlier record of the operation than this and I cannot find a theatre record intraoperatively that mentions the involvement of [Dr D].

5. *You stated in your first report, 'Once it became apparent that the standard copper modified Benjet tube could not be used, the situation changed significantly, and the risk profile changed significantly. At this stage I think that the procedure should have been abandoned pending consultation with [Ms A].' Please comment on the appropriateness of the decision for [Dr D] to continue with the procedure once it was found that a copper modified Benjet tube could not be used.*

I have already touched on this aspect in my earlier comments. I certainly think that when the situation became quite different and difficult, that a Teaching Fellow should not have been involved in the surgery.

6. *Are there any aspects of care provided by [Dr C] that you would consider warrant additional comment?*

[Dr C] has stated in his letter of the 2 June 2005 that he takes full responsibility for the surgery and the subsequent airway fire as he is the supervising surgeon. Although it was [Dr D] who was operating the laser at the time of the airway fire, it was certainly under [Dr C's] guidance and therefore I do not feel that any blame should be attached to [Dr D]. My only comments relate that this should have been documented preoperatively, intraoperatively and postoperatively in more detail. I commend [Dr C] for not trying to shift the blame onto [Dr D]."

Anaesthetic advice
The following expert advice was obtained from Dr John Walker, anaesthetist:

"*Purpose*
To provide independent expert advice about whether [Dr B] provided an appropriate standard of care to [Ms A].

Introduction
Whenever I have practiced (or taught) ORL anaesthesia I have always been keenly aware that there is an airway shared by the anaesthetist and surgeon and close attention, dialogue and professional trust must be maintained at all times to

minimise any potential harm to the patient, who by the very nature of requiring such surgery is already compromised.

This is particularly so during microlaryngoscopy which is further complicated when a laser is involved.

I would like to make the point that laser microlaryngoscopy is a dynamic event and every move should be subject to scrutiny as to potential benefits and hazards to the patient and medical staff.

I have answered each question as posed in turn. I will comment on the two general points asked in the initial brief after answering the specific questions as then the opinion will be better understood in context.

1. *Was the full extent of the narrowness of [Ms A's] glottic inlet known prior to the procedure to determine whether the standard copper modified Benjet tube could be used during the procedure?*

   I can only say no from the provided written evidence.

   The patient obviously knew that her airway had narrowed because her functional abilities had deteriorated and so she sought medical help.

2. *How high and significantly different was the risk of airway fire with the use of unprotected plastic paediatric Benjet tube used and should this have been discussed with [Ms A] before the procedure?*

3. *Should [Ms A] have been informed of the risk of airway fire particularly in the view of the fact that there was a possibility that the standard copper modified Benjet tube may not be used?*

   I will answer both of these questions together as they are asking a variant of the same question.

   From what I have read the exact degree of narrowing was not appreciated by the surgeon and anaesthetist until the patient was under general anaesthesia and the larynx examined under direct vision. I am sure that both of them thought that the modified copper Benjet tube could have been able to have been used prior to the patient being anaesthetised.

   Thus the anaesthetist was not in a position to preoperatively discuss the exact type of endotrachael tube to be used and because of that the increased risk if a plastic unprotected tube was going to be used.

Thus I do not think it would be reasonable to expect a discussion on the specific anaesthetic technique and attendant risk associated with each method. I do think a general discussion was warranted.

Unfortunately the risk of airway fire is (and was) increased by the use of unprotected plastic endotracheal tubes be it a Benjet or other types in the presence of a laser being used in close proximity.

For completeness surprisingly even with a metal laser resistant tube there is still a risk of thermal injury. From my Internet search I did not find any direct reference to a copper Benjet tube. However that is not surprising as it was a locally produced device.

With the benefit of hindsight and the fact that laser fires are a risk in all microlaryngoscopies involving a laser, regardless of the anaesthetic technique used, it would have been prudent to discuss the risk in general terms. However this was 3 years ago and the expectations revolving around consent processes have been extensively discussed and modified since then. This can be seen in the simple fact that there was no expectation for a written anaesthetic consent in Dunedin at that time. I would like to point out there are many potential risks associated with any anaesthetic, however in the fit and healthy patient, only the likely common problems are discussed. The risk profile changes with the required surgery and the necessary anaesthetic to enable the surgery to be carried out. For example in major bowel surgery, often the anaesthetist administers an epidural for intraoperative and postoperative pain relief. This additional procedure should then be discussed and a brief outline of potential problems be covered in the consent process. In addition both the anaesthetist and surgeon should consider any significant co-morbidities as their presence can significantly increase the risk of surgery independently of the surgery and anaesthesia. An example of this is the patient with cardiac disease (say angina) who has a higher risk profile no matter what the type of intended surgery.

In the case of [Mrs A] it would have been prudent to discuss (and I am sure some of these points were covered either by the surgeon or the anaesthetist):

- Her narrowed airway and treatment options and the risks and benefits associated with each option;
- In her case when she announced she wished to avoid an elective tracheostomy, you would point out the common problems associated with microlaryngoscopy if tracheostomy was not done initially;
- The use of a laser and potential problems (ideally including laser fire) in conjunction with the microlaryngoscopy;
- Her co morbidities, particularly her asthma and smoking in the face of her narrowed airway;
- The potential need for a tracheostomy regardless of the treatment plan, for example post operative swelling / oedema of the airway post treatment.

As can be seen by the written evidence, the surgeon and the anaesthetist agreed that the lowest risk and therefore ideal first option would have been an elective tracheostomy. Once this had been refused by [Mrs A] it did limit the surgical options and in turn the anaesthetic options. All of the above would have been in the first instance the domain of the surgeon in terms of written consent. Usually the anaesthetist enters the scene after the patient and surgeon have agreed upon a treatment plan. Thus the anaesthetist can only reinforce the specific risks already alluded to by the surgeon and those associated with the chosen anaesthetic technique.

4. *Given [Dr B's] expressed reservations about using a plastic endotracheal tube with laser, should he have discussed the possibility of an airway fire with [Ms A]?*

With the benefit of hindsight the anaesthetist should have discussed the risk of an airway fire pre operatively but this would not have been easy to quantify until the extent of the airway narrowing was known. This would not have been evident until the patient was anaesthetised and the airway examined under direct vision. Thus the anaesthetist (and indeed surgeon) was not in a position to discuss specifics until the patient was anaesthetised.

5. *Given that during the procedure it became apparent that the standard copper modified Benjet tube could not be used, should the procedure have been abandoned pending consultation with [Ms A]?*

As I stated earlier this type of surgery and anaesthesia is a dynamic process closely involving the surgeon and anaesthetist.

Thus on its own the fact that the standard copper modified Benjet could not be used would not be a reason to have abandoned the procedure. However if in addition, the surgery would involve the use of a plastic paediatric unprotected Benjet tube (signifying a much reduced airway compared to that of a normal adult) and surgical access was reduced (meaning the laser would be used in close proximity to the plastic tube) and the oropharyngeal access and ventilation was limited (potential build up of high oxygenation concentrations increasing the risk of fire) these facts would be clear indications to abandon the procedure and wake the patient. When the patient had recovered from the anaesthetic, the whole topic of surgery and anaesthesia could be re-discussed. The surgeon and anaesthetist would have the knowledge of increased risk because of the extent of the airway narrowing and then available options to deal with the complications.

It was at this point that the surgeon and the anaesthetist made an error of judgment in continuing surgery.

6. *What were the risks in [Ms A's] case of the procedure being stopped, anaesthesia reversed and readministered at a later date?*

   The risks appear to have been not a great deal higher than that for a routine general anaesthetic but increased by the fact she had a narrowed airway, a component of reversible airways disease and she smoked.

   The risks are difficult to give in numerical terms but at that point there appears to have been no difficulty in maintaining an airway and the patient apparently had no other acute medical problems. They were not so high that they outweighed abandoning the procedure versus pressing on.

7. *How common is the use of the standard paediatric Benjet tube in laser surgery and is any special protection of the tube necessary during the procedure?*

   This is a difficult question to answer directly backed by fact in the form of actual numbers of microlaryngoscopies performed per year in New Zealand and the number involving a Benjet tube versus other techniques.

   The hazards of an airway fire when a plastic ET (or initially red rubber tubes) tube is used in the presence of a laser have been known for over 20 years. Because of this risk various other protected endotracheal tubes and techniques were developed. I can only comment on my understanding of local practice (that is in Auckland) of anaesthesia for laser surgery. I can only recall seeing the use of a Benjet tube being used once as registrar and that was for non-laser surgery. There were case reports in the 1980s where the plastic leaflets supporting the tube became detached and retrieval required a bronchoscopy which led to them falling out of favour and a report of a Benjet tube catching fire in conjunction with laser surgery. Local practice in Auckland over the last 10 years to the best of my knowledge is to use laser protected tubes or a no tube spontaneously breathing technique when a laser is involved. I have never seen or previously heard described the modified copper Benjet tube as described in the written material. I understand it was manufactured for them locally in Dunedin.

   If a plastic non laser resistant tube (be it a Benjet or any other type) is to be used then firstly the surgeon must be very careful to ensure that the laser beam is kept well away from the tube.

   The exposed tube near the area to be treated should be covered with wet surgical patties.

   Non-reflective instruments should be used to limit or prevent reflected laser light.

   The tube can be carefully wrapped in laser resistant foil tape. Unfortunately this is not always possible and it also can bring special problems such as increased abrasion of the tissues and the laser can also be reflected off any shiny surface.

8. *Did [Dr B] have options other than to use the unprotected plastic paediatric Benjet tube? If so, what were these alternatives?*

   From my reading of the provided written material, given the narrowness of the patient's airway there were no other suitable tubes available at Dunedin hospital for [Dr B] to use. The smallest diameter of the laser resistant is 4.5 mm; the plastic paediatric Benjet tube is 3.5mm (deduced off the Internet). He makes the point that the intended modified copper Benjet tube was too large.

   The only other option would be the use of a tubeless technique using an intravenous infusion of anaesthetic via an intravenous cannula. This involves either jetting the oxygen into the trachea under direct vision or in a spontaneous breathing patient insufflation of oxygen. Both these techniques require:

   - A suitable patent airway which should be unobstructed;
   - The oxygen concentration should be kept as low as possible;
   - Pooling of high concentrations of oxygen avoided;
   - A patient with no other medical conditions that complicate the safe oxygenation of the patient.

   Thus, in this case, [Dr B's] options were limited.

9. *[Dr C] stated that 'there was no equipment that could have been ordered that could perform the surgery in a different way'. Should a fire-resistant tube of a size required by [Ms A] have been available at Dunedin Hospital?*

   I am not sure that such a commercially available tube was (and is) currently available. It is my understanding that similar problems exist for paediatric laser surgery of the airway where the diameter of the airway is small due to the size of the child's trachea.

10. *Who in this case had the primary responsibility to decide whether to proceed with the procedure and what tube was used?*

    This is a difficult situation and one where a discussion over the merits of proceeding versus the potential risks should occur between the surgeon and the anaesthetist. In this sort of surgery and requirements of the anaesthetic, the responsibility is jointly shared between the two specialists. The choice of tube and airway management is primarily that of the anaesthetist as that is his area of expertise. To emphasize this point, the choice of laser and how it is used is the surgeon's choice. However as I stated both parties are responsible for patient safety and if either felt it was inappropriate to continue then they should have said so and the procedure abandoned.

11. *Were adequate laser equipment safety protocols in place at Dunedin Hospital at the time and were these followed in [Ms A's] case?*

    The material relating to laser safety provided is as follows:

    - Record K: Documentation relating to [Ms A] from the DHB including its guidelines on the use of the CO_2 laser (pages 217–281) marked 'K';
    - A copy of the Laser Log;
    - The KTP protocol.

    I cannot answer this question on the basis of the provided material due to the fact the provided material dates after the incident occurred.

    Ideally there should be written guidelines around the use of any laser and any particular safety precautions that should be followed. A log should be kept on the specific cases that the laser was used and any relevant demographic and information required. (See the guidelines in files.)

12. *Was the procedure performed with reasonable care and skill?*

    The only lapse in this case was the decision to proceed with the Benjet in place and the tight operating conditions. I am sure that both the surgeon and anaesthetist were performing their jobs to the best of their abilities at all times. Indeed this is evident by the immediate response when the airway fire was determined. Their response and actions were a textbook case of damage control and to minimize any ongoing trauma. Ironically the patient was kept intubated overnight to allow her to consciously agree to tracheostomy the next day to retrieve the lost piece of Benjet tube.

13. *How appropriate was it in this case for the laser to be used in the 'continuous mode' rather than 'pulse mode' and was the explanation provided by the DHB ([Mr F's] letter of 6 October 2004) reasonable?*

    I am unable to answer this question directly as it outside my area of expertise. It has been commented upon by the ACC surgical experts.

    - *Whether prior to surgery on 16 October 2002, [Dr B] provided [Ms A] with adequate information about the risks associated with the administration of anaesthetic for the planned procedure for her to give informed consent to the anaesthetic.*

    From what I can determine from the provided written material supplied, [Dr B] did give, in the most part, adequate information about the risks associated with the administration of anaesthetic for the planned procedure. However this was in a verbal form and not specifically documented in the notes.

His only lapse appears to be not giving information about the hazards of laser fire. I think that it is only very minor when you consider that the degree of airway narrowing was not known and he expected to be able to use the laser resistant copper Benjet tube. [Ms A] was advised to have an elective tracheostomy to minimise risk, which she declined.

- *Whether on 16 October 2002 [Dr B] provided [Ms A] with services of an appropriate standard. In particular, whether [Dr B] administered the anaesthetic to [Ms A] with reasonable care and skill.*

I think at worst the anaesthetist and surgeon were guilty of not stopping when it was realized that a paediatric Benjet tube was required to maintain an airway to allow the use of the laser. (This point has been dramatically highlighted by the expert ORL surgeon.)

An elective tracheostomy was really the only safe option at this point.

This was only a **mild departure** (in context) from the appropriate standard.

I would like to comment that both the anaesthetist and surgeon provided ongoing care for [Ms A] following the mishap. To the best of what I can determine the anaesthetist [Dr B] gave at least another 3 anaesthetics to [Ms A] in the follow up treatment period without any noted complications.

The ACC experts were well aware of the trauma the patient suffered and I am sure were keen to ensure that the patient received appropriate assistance to help cope with this awful complication of laser microlaryngeal surgery."

Responses to provisional opinion

Dr C
Ms A's consent to Dr D's involvement
Dr C stated:

> "I am certain that [Dr D] was present at the pre-admission clinic on the day prior to [Ms A's] surgery and was introduced to [her] at that time. This was normal practice in the unit prior to and after [Ms A's] case. That is to say that the nature of the team of clinicians providing care to any patient was explained pre-operatively and the role that the individual members of the team played was explained to the patient. This is part of the normal process of delivery of care to informed consent given to any patient passing through the unit. [Ms A] was no exception. …
>
> You have also not considered the affects of antegrade and retrograde amnesia associated with anaesthesia. [Ms A] required sedation and ventilatory support in addition to general anaesthesia for a period of approximately 24 hours. Subsequently she was subject to a second general anaesthetic. The well described phenomenon of amnesia seriously undermines the credibility rather than the veracity of [Ms A's] statements in relation to [Dr D's] involvement in her care. …
>
> Whilst I have no doubt that [Ms A] believes she was unaware of [Dr D's] involvement, this is not correct. In addition it was normal practice to explain to any patient, pre-operatively, the role of each individual member of the team that were to be involved in their case. To the best of my knowledge this was explained to [Ms A].
>
> Further, [Ms A's] incorrect recollection of events could be attributed to the well recognised peri-operative memory dysfunction which occurs in these sorts of circumstances."

Appropriateness of Dr D's involvement in procedure
Dr C stated:

> "The unit was a training unit and as such it was expected that surgical trainees where appropriate, and under supervision by experienced consultant surgeons, would perform part or all of the surgical procedures in that unit. In a complex case the trainee would perform part of the surgical procedure. This is what happened with [Ms A's] case.
>
> In reading your opinion there seems to be some confusion as to the amount of involvement of [Dr D] in the surgical procedure. I commenced the laser surgery and after lasering without incident for sometime, I believed it was safe and appropriate for [Dr D] to contribute towards the surgical procedure. I made the decision to involve [Dr D] in the knowledge that he had completed higher surgical training [overseas], and he had received laser surgery training [overseas]. [Dr D] was supervised by me at all times during the surgery.

In New Zealand it is the norm for trainees to finish their surgical training in New Zealand, and then travel overseas, predominantly to the United Kingdom or the United States for further sub-specialty training that is not provided in New Zealand. Trainees select units where specialist procedures, not previously demonstrated to them, are commonly performed. It is in this way that they will become experienced in novel procedures. Similarly, what was happening in KTP laser airway surgery in Dunedin at that time was not in common Otolaryngology Head and Neck Surgery practice in New Zealand. However, it was being performed in Dunedin on a regular basis. To involve the senior trainees under my supervision in such a way would be considered normal practice.

I have some concern with the expert independent advice relied upon in the opinion and I disagree with their conclusions. The experts who you have consulted are not sufficiently experienced in this surgical procedure, nor do I agree with their opinion that the procedure was difficult and not suitable for a trainee. If expert opinion from surgeons who regularly employ this technique of laser surgery in the airway was sought, then I am certain that the conclusion would be different.

Dr Ferguson's opinion finds no fault with the level of supervision afforded to [Dr D] or with the standard of care provided to [Ms A]. Dr Ferguson also commends my actions in assuming responsibility for what happened during the surgery.

I am of the view that [Dr D's] involvement in the provision of care was appropriate in this case. As I have said earlier the unit was a training unit and therefore, trainees are expected to participate in the delivery of surgical care in procedures that were common place or regularly employed in that unit. [Dr D] was under supervision by me at all times during the procedure."

Informed consent
Dr C stated:

"Based on my personal clinical experience I consider the risks of an airway fire is less than 1% and therefore, it was my opinion that the risk of the airway fire occurring was so remote that it was not relevant to the preoperative discussions. I also did not discuss with [Ms A] the risk of an airway fire as it is my understanding that surgeons are not compelled to discuss complications with patients undergoing surgical procedures where the rate of complication was less than 1%. If this principle was extended to include significant complications where the clinician felt that discussion of such complications (when rare) could produce undue anxiety for patients and jeopardise that individual's likelihood of undergoing a procedure which might be highly beneficial for their quality of life or life expectancy, then this would further support my decision not to discuss such an event with that patient.

I note you have based your opinion on the written opinions of expert witnesses who are all respected consultant Otolaryngologist, Head and Neck surgeons. It must be noted that not only have these expert witnesses never performed such a procedure, none have indicated ever observing KTP laser surgery to the subglottic region. I mean no disrespect, but without any experience of performing or even observing the procedure I am of the opinion that they cannot be reasonably be described as experts in this procedure. I do not agree with the assessment of risk which is given by the expert witnesses on which you have based your opinion in this respect.

One important issue that the expert witnesses' reports commented on was the issue of a fire proof tube or a tracheostomy tube. I agree that a silver tracheostomy tube is indeed very difficult to ignite using a KTP laser, but it is incompatible with ventilator mountings and is not suitable for surgical procedures. It must be noted that there is no such thing as a KTP laser-proof tube whether it be plastic (wrapped in silver foil), red rubber or copper. The tubes that are used for ventilation on patients with tracheostomies are either plastic or plastic coated in aluminium, these are not laser-proof. Plastic, plastic wrapped in foil and copper Benjets are also not KTP laser-proof. The copper Benjets that are available at Healthcare Otago were constructed to the specification of Professor Ian Stewart whose expert opinion has not been sought in this respect. They are not constructed to any ISO standard.

The narrower copper Benjet was constructed by the hospital biomedical engineering service following the airway fire in a belief that a narrower tube was required and would help. The copper Benjets were developed for carbon dioxide laser surgery. The carbon dioxide laser does not penetrate the copper tube. It does not follow that to establish a tracheostomy and proceed or to use a narrower copper Benjet and proceed would have eliminated the risk of airway fire or even reduce it substantially. Reduction of risk in this case is achieved using the laser fibre (suction) carriers and very close observation of fibre position using a Hopkins Rod Endoscope. This was our standard practice."

Documentation
Dr C stated:

"With the benefit of hindsight I accept [the] criticism in that my records inadequately documented the pre-operative discussion with [Ms A] in the case record and on the consent form. This case is not a reflection of my usual record keeping and I have never been criticised for my records prior to this complaint. Accordingly, I apologise to you and to [Ms A] for this failing."

Otago District Health Board
Informed consent
ODHB stated:

> "Although in retrospect it would have been prudent to have included the risk of airway fire in the consent process, [ODHB] maintains its position that airway fire is a rare complication of those microlaryngoscopies using laser. …
>
> We further note that the consent documentation and process at [ODHB] since the time of this incident, has been developed such that a more detailed and comprehensive recording of consent process is now supported and expected."

Documentation
ODHB accepts that Drs C and B failed to keep clear, accurate, and contemporaneous record of the preoperative discussion with Ms A, especially regarding her options and choice of airway management.

Involvement of trainee
The CEO submitted "[Dr C's] approach to this aspect of the preoperative discussion is in accordance with current practices and … the advice from the Medical Council of New Zealand is insufficiently defined to make it clear that there has been a change in emphasis of the word 'trainee' between 1998 and 2002."

ODHB stated:

> "This raises a complex issue for operating teams which may involve a number of medical practitioners at various levels … who may undertake a myriad of procedural activities that contribute to the complete surgery performed. Often it is a surgical team of doctors undertaking the procedure rather than one surgeon, and the dynamics of this team approach have a certain complexity of operative behaviour and task allocation.
>
> Thus in cardiac surgery for example, there may be a general surgery trainee, and one or more cardiothoracic trainees, working together with the consultant surgeon. … It is not common practice to try to quantify this involvement of trainees to the specific level of detail that your opinion suggests would make practice compliant with the Code."

Lack of candour
ODHB stated:

> "[T]he involvement of [Dr D] in the procedure was known by those advising [Dr C] during the process of investigation and that although it may be considered inappropriate in retrospect, it became the dominant view that it was [Dr C's] responsibility … to take full responsibility for the incident and not to confound that responsibility with [Dr D's] involvement. …

> We believe that it was not a lack of candour on the part of [Dr C] and others at ODHB that led to [the] decision that [Dr D's] role not be emphasised, but rather that the belief that the grade of the surgeon probably made no difference to the fire happening.
>
> Notwithstanding the above, the internal investigation is not detailed and appears to have made conclusions without documenting the process that led to such conclusions. In retrospect it has *not* been useful to have accepted that [Dr C] take sole responsibility for the incident as the supervising surgeon and thus failed to quantify the role of [Dr D] in the procedure.
>
> We accept that a trainee's role in a high risk procedure is a significant issue, and the consent in this regard has been discussed previously. We accept that the ODHB did not inform [Ms A] of [Dr D's] specific involvement, and that this was a decision made at the time of the internal inquiry and the process of decision making in this regard is not specified within the inquiry report documentation that we have available to us.
>
> We also stress that [Dr C] felt very responsible for the incident and after discussion with members of staff no longer working at the ODHB, the dominant view was for [Dr C] to take full responsibility for the incident. It would appear in retrospect that the management of this incident and the focus on supporting [Ms A], and her medical misadventure claim (as well as supporting [Dr C] in an emotionally highly charged incident), that this decision was not the most appropriate one to have made.
>
> We also accept that the ODHB investigation was less than ideal in this regard and served neither the ODHB nor [Dr C] well in its lack of careful documentation."

The CEO of ODHB advised that the recommendations relating to the laser usage guidelines and medical staff training will be acted on in 2006. There will be a teaching session for senior doctors and registrars to ensure that they are aware of the guidelines, and the lasers themselves.

ODHB has also instigated training in the investigation of critical incidents, in association with the Ministry of Health.

The ODHB Clinical Board is reviewing the requirement for patients to be fully informed when consent for treatment is obtained, in particular when involvement in training is proposed.

Dr B

Risks of surgery
Dr B stated:

> "At all times the surgeon and I made the best decisions under the circumstances in the best interests of [Ms A]. It actually would have been very easy on my part to say this was too difficult a case and not done anything for her. [Ms A] had a seriously

> compromised quality of life because of her airway narrowing and we did our best to relieve it whilst trying to respect her very strong wish — almost an order — not to do a tracheostomy. I also maintain that there was a clear risk she might have presented with an acute airway emergency later if we had stopped the surgery. …
>
> There [was] no disagreement between myself and [Dr C] about proceeding with the surgery. I clearly stated … that although I expressed my reservations, I agreed to proceed with surgery with the paediatric Benjet."

Dr B commented on the use of the KTP laser:

> "The KTP laser has the high tissue penetration capability compared to CO_2 laser[s] because of [the] laser wavelength. Therefore the chances of reflected laser beam hitting the tube is much less in KTP laser compared to CO_2 laser. The KTP laser was applied through fiberoptic. Therefore it can be placed accurately without any reflection."

Dr B commented on the use of 100% oxygen:

> "It is standard practice in Dunedin Hospital [to use] the 100% oxygen wall outlet to drive the jet ventilation. …
>
> In [Ms A's] case the entrainment of air at the port of exit from the tube was possibly limited because of her narrowed airway. However I was ventilating her lung using jet ventilation for more than 10 minutes before the incident. This indicates that there was enough room available around the Benjet tube for her to passively expire the gas as well as for the surgeon to work with the laser to relieve the stenosis. Therefore it is definitely not 100% oxygen and also difficult to quantify the exact percentage of oxygen in this technique."

Dr B stated that he raised the issue of the lack of equipment that would provide less than 100% at the anaesthetic morbidity meeting, and that as a result of his actions this equipment is now available.

Dr B commented that he believed that the majority of the expert opinions obtained by ACC and my Office were in his favour.

Dr B repeated that it was not standard practice to discuss the risk of airway fire with patients undergoing laser surgery.

In relation to Dr D's involvement, Dr B stated:

> "Usual practice was [for] the consultant surgeon to take informed consent from [the] patient for his/her trainee to operate. It is not my normal practice to scrutinize every consent form to determine whether permission from the patient was obtained for the trainee to perform a procedure in each and every case.

> On 16th October 2002, when [Dr D] started operating the laser under supervision of [Dr C], I had simply assumed that [Dr C] had obtained informed consent for [Dr D] to operate. I do not have any control to say whom should or should not operate from the surgical team especially [when] the consultant surgeon is available inside the operating room."

Dr B obtained expert advice from an anaesthetist at an overseas hospital. In relation to whether the risks of airway fire should have been discussed with Ms A, the anaesthetist stated:

> "With laser surgery, the risks of laser surgery are always considered and precautions are taken to keep the risks at a minimum. Whether the risks of fire were enough in this case to specifically warn [Ms A] preoperatively is debatable. The commonest source of ignition in surgical airway fire is surgical diathermy, not laser but we don't routinely warn patients of the fire dangers of surgical diathermy. …
>
> It was not the initial intention to use a plastic tube in the airway. Only after direct laryngoscopy was it evident that the copper tube could not be used safely. The paediatric Benjet tube had proved successful to allow such laryngoscopy to be performed safely. Preoperative discussion regarding airway fire could only have been in very general terms."

The anaesthetist commented that once "[Ms A's] airway had been fully assessed under general anaesthetic it could have been very difficult to reverse anaesthesia and wake [her] in order to discuss the options at a later date". The anaesthetist stated that the "shared airway is a joint responsibility of both the surgeon and anaesthetist. … Both surgeon and anaesthetist are equally responsible. Either can call an end to the procedure."

The anaesthetist further stated that "the anatomy of the airway of [Ms A] might have caused pooling of oxygen rich gas mixtures but this would be impossible to predict at the time of surgery".

The anaesthetist, for Dr B, stated that "with the use of CO_2 laser the risk of airway fire would be significantly higher with the use of a plastic tube in the airway. KTP laser is applied via a fiberoptic and can be more accurately placed and is less susceptible to accidental reflection. The chance of inadvertently hitting a flammable object in the airway should be significantly less in the case of KTP laser than CO_2 laser".

The anaesthetist also commented:

> "From evidence read by me and from personal experience I would consider that this is a peculiar case, well outside the normal scope of laser airway surgery. Both the surgeon and the anaesthetist were constrained by the patient's desire to avoid a tracheostomy.
>
> The surgery continued in the safest way possible in this patient. She had been safely anaesthetised and to wake a patient having had no surgery for which she undertook the

risks of anaesthesia would surely represent a disservice to that patient. It is unfortunate that a tissue fire occurred but it was promptly dealt with and no permanent harm was done to the patient."

Further expert advice

The responses to the provisional opinion from ODHB, Dr C, and Dr B were sent to my independent experts Dr Ferguson and Dr Walker.

Dr Ferguson
Dr Ferguson stated:

"I do not think I need to alter my advice but I would like to make the following comments.

The involvement of [Dr D] and whether or not [Ms A] was aware of his involvement is a difficult matter to resolve. … However, I stand by my opinion that the involvement of [Dr D] was inappropriate, particularly once it became apparent that the standard endotracheal tube could not be used.

In addition, [Dr C] comments that neither I nor the other Consultant Otolaryngologists commenting on this case have any experience with using the KTP laser in the airway as he does. I agree that this is certainly the case but in general terms I think that my opinion regarding the wisdom of continuing the case under changed circumstances still stands."

Dr Walker
Dr Walker stated that the responses to the provisional opinion did not alter his views. He commented:

"Both the anaesthetist and surgeon provided ongoing care for [Ms A] following the mishap. To the best of what I can determine … [Dr B] gave at least another 3 anaesthetics to [Ms A] in the follow up treatment period without any noted complications.

I was surprised by the … appearance (and involvement) of the Surgical Fellow. The point has been well made by [Dr Ferguson] but I would like to emphasise my surprise that he was operating on such a difficult case even though the surgical consultant was at his shoulder.

The final point I would like to make is to dispute the opinion given by [Dr B's] expert anaesthetic witness. … [Ms A] had a markedly narrowed airway and this was not

helped by the fact that she continued to smoke and required bronchodilators. However it appears she was managing without marked restriction during most of her activities of daily living.

I am sure, once the degree of airway narrowing had been determined and prior to any manoeuvres that might cause any tissue oedema, that the anaesthetic could have been reversed and the patient awoken. I would emphasise that it would not be ideal but we have a patient who had a major reluctance to a tracheostomy."

Further independent advice — laryngology
As a result of Dr C's response to the provisional opinion, additional expert advice was obtained from Dr Bren Dorman, otolaryngologist and head and neck surgeon. Dr Dorman is experienced in the use of the KTP laser in laryngology.

"Thank you for your letter requesting expert advice on this case.

I have read the guidelines for Independent Advisors supplied by the Office of the Health and Disability Commissioner and have agreed to follow these guidelines.

I am an Otolaryngologist, Head and Neck Surgeon (Vocationally registered) and my practice involves general otolaryngology, head and neck surgery and I have particular expertise in laryngology, complex airway management and laser surgery.

I have reviewed the information provided by the Health and Disability Commissioner and this includes the following:

[here Dr Dorman records the documents provided]

…

I have carefully studied the significant amounts of information involved in this case and looked at relevant related literature.

The factual summary of the case has been well documented by the various parties and the previous expert advisors.

The complaints are summarised as follows:

- *Whether prior to surgery on 16 October 2002, [Dr C] provided [Ms A] with adequate information about the treatment options available to her, including the benefits and risks associated with those options, for her to make an informed choice about her care and treatment.*

- *Whether [Dr C] provided [Ms A] with services of an appropriate standard. In particular:*

- *whether [Dr C's] recommendation for endoscopic laser surgery was appropriate in [Ms A's] case*
- *whether Dr C performed the endoscopic laser surgery on 16 October 2002 with reasonable care and skill.*

I have been asked to comment on the following aspects of this case.

A. Please comment generally on the standard of care provided by [Dr C].

If not answered above, please advise the Commissioner on the following points, giving reasons for your view:

B. Please comment generally on [Dr C's] response to the provisional opinion.
C. Please comment specifically on [Dr C's] comments on the use of KTP lasers.
D. In the circumstances that presented at the pre-operative clinic, should [Ms A] have been informed of the possibility of airway fire prior to surgery?
E. In the circumstances present after the examination under anaesthetic, was it appropriate for the procedure to continue?
F. If [Dr C] had intended that the registrar was to be involved in the procedure, please state how he should have obtained fully informed consent. If this consent should have been documented, please state where, and what should have been documented.
G. Was it appropriate for a registrar to have been involved in [Ms A's] procedure to the extent described by [Dr C]?

I have been asked to provide independent expert advice about whether [Dr C] provided an appropriate standard of care to [Ms A].

A) Standard of care provided by [Dr C]

In this case the standard of care provided to the patient falls below what I would expect from a specialist otolaryngologist. The reasons are outlined as follows.

From the outset this was clearly a complex case and from experience with airway problems and in particular, stenoses in the glottis, subglottis or trachea, I am fully aware that the clinical findings at the time of endoscopy of the airway can differ from pre-operative assessment. This must be taken into account when advising the patient preoperatively about surgical and medical management. This is the time when other options of management are discussed. There is no documentation that other options were fully discussed with the patient. [Dr C] recognises and comments on the need for endoscopy and palpation to assess the adequacy of the airway and for clearer evaluation of the pathology present. He would also know that the pre-operative findings can differ quite markedly from those found at endoscopy. With this in mind he should have discussed the possibility that the airway could be

narrower than expected and that other forms of treatment may be required.

When one is confronted with a case such as this the potential for a serious complication to arise is quite significant. The fact that the risk of an airway fire was felt to be less than 1% and thus did not warrant discussion with the patient is not accepted. The reason that the documented incidence of laser fire in the airway is reported to be less than 1% is because so many precautions and safety checks are in place for these procedures. The risks associated with any particular procedure are dependent on many factors including the complexity of the procedure, the expertise of the surgeon and the anaesthetist and the particular patient profile.

We already know from this patient's profile (airway stenosis, smoking and asthma) that the anaesthetist had concerns about maintaining adequate oxygen concentration during the procedure. It is highly likely that she would also have significant airway irritability. To undertake such a case involves a full explanation to the patient about the reasons to proceed with the operation, the potential benefits and also a careful explanation of the risks. Details of the actual procedure in general terms, so that the patient can understand, who is involved in the surgery, discussion of all the possible complications and the proposed after care would be expected to have taken place. With complex airway management discussion should also involve explanation of the strategy if the proposed elective procedure cannot proceed as planned. Looking through the information that has been available to me I note that there is no written record of any of these discussions having taken place.

In a case such as this, if the surgeon is considering the possibility that a registrar or a Fellow carry out some of the surgery it is imperative that the patient know. It is probably more prudent to have the registrar or the Fellow increase their involvement and enhance their technical skills in more straightforward cases rather than one as complex as this. The pre-operative situation in [Ms A's] case changed when the endoscopy was carried out and closer evaluation of her airway was possible, revealing an airway that was narrower than expected. The situation was significantly altered in that the anaesthetist was unable to use the planned delivery method for anaesthesia and apparently no other alternatives were felt to be acceptable. In such circumstances judgement needs to be carefully considered as to whether it is appropriate for a registrar or Fellow to then become involved in the case.

All cases should have clear documentation in the clinical notes as to what has been discussed with the patient, what alternative options have been offered and what choices have been made.

Clinical judgement requires constant re-evaluation of the situation at hand. If, as in this case, the airway was considerably narrower than expected, then at that time serious consideration should be given to other possible strategies. I do not accept that the only option was to proceed. In this particular case given the pre-operative stance by the patient that she did not wish to have a tracheostomy, it may have been

more appropriate to stop the case and wake the patient. This would then provide an opportunity for the surgeon, the anaesthetist and the patient to re-evaluate the clinical situation and choose another management path.

The patient does not appear to have received an acceptable standard of care particularly with respect to fully informed consent, involvement of other doctors (Training Fellow) and whether any alternative management strategies or other options were considered.

I regard these as a moderate departure from acceptable standards.

I have been asked to comment on [Dr C's] response to the provisional opinion.

B) [Dr C's] response to the provisional opinion

Involvement of [Dr D]

(i) [Ms A] not informed of [Dr D's] involvement

The difficulty here is that there is no documentation in the notes regarding the possible involvement of [Dr D] in this case. In particular there is no documentation relating to the fact that [Dr D] was a Teaching Fellow and that he would be carrying out some of the procedure. It is accepted practice that the surgeon would advise the patient about the involvement of another doctor. If the consent forms do not specifically contain a section relating to observers or other participants in the surgical procedure then this should be written in the clinical notes.

(ii) Involvement of [Dr D] was inappropriate

All University training units involve registrars and Fellows at various stages in their training. Their specific involvement in any particular case is dependent on the judgement of the senior surgeon as to the trainee's level of expertise. Whether they should be involved at all, how much they should do and whether the patient agrees that they can carry out some or all of the procedure is always determined pre-operatively. This discussion is between the senior surgeon and the patient and clearly in this case there is no evidence that this took place.

With respect to laser surgery in the airway, the principles of the delivery of laser energy are similar. The actual mode of delivery varies and the reaction of the various soft tissues and fluids that the laser impacts also varies. The wave length of the light results in different tissue reactions. One must remember that the problem in this case is that of a laser fire. This can occur with any type of laser and not specifically a KTP laser. I have used all type of lasers and have seen the tissue effects in lots of different circumstances.

With my experience in managing patients with tracheal, subglottic, glottic and supraglottic stenoses, I do not regard the cases as straightforward. One of the most important areas to consider in managing these patients is the various anaesthetic strategies. The anaesthetist and surgeon need to liaise pre-operatively and they need to have a planned strategy to follow if the circumstances surrounding the procedure change. In this case, when the airway was noted to be narrower than expected and a plastic Benjet tube had to be used instead of a copper one, the circumstances changed significantly. It was then inappropriate for [Dr D] as a Training Fellow to be involved.

Duty of Candour

I note the Health and Disability Commissioner's comments relating to Duty of Candour. I have not seen any documentation that relates to [Dr D's] involvement in this case when [Dr C] discussed the events surrounding the airway fire with members of the Otago District Health Board.

In a case such as this where a serious complication has arisen there should be clear documentation outlining all of the involved parties, both in reports and what was discussed in meetings.

Informed consent

(i) Failure to adequately inform [Ms A] of the risks

As stated previously in complicated cases where the risks can be significant, all of the potential risks should be discussed. I feel there is an error of judgment in choosing not to mention the possibility of an airway fire in this case. The case involves a complex airway stenosis in a patient with co-morbidities. The risk of producing anxiety in the patient because serious complications are discussed is outweighed by the risk of an airway fire which can be severe and in some cases fatal. This particular case does involve a laser induced airway fire in a compromised airway and the fact that the previous expert witnesses have never performed such a procedure using a KTP laser is irrelevant. Laser fires can occur in many situations and having an oxygen enriched environment pooling in a confined space with inflammable material in close juxtaposition warrants discussion between the surgeon and the patient about the possible risks that a fire could occur.

Documentation

The clinical records show inadequate documentation of pre-operative discussions and this is acknowledged by [Dr C].

Standard of Surgery

(i) Airway narrower than assessed pre-operatively

The issue here is the fact that the surgeon acknowledged that the airway was narrower than assessed pre-operatively and in those circumstances re-evaluation of the clinical situation was warranted and if necessary a change in strategy. Given the comments made by the anaesthetist, [Dr B], about which tube could be utilized to establish anaesthesia, coupled with the fact that a KTP laser was planned to be used on the subglottic stenosis, consideration should have been given to the question 'Is it safe to proceed with this case under these new, changed circumstances?' To then proceed with the case using a flammable plastic Benjet tube, use the KTP laser in the close proximity to the plastic Benjet tube and to allow a Training Fellow to use the KTP laser in these circumstances is very risky.

(ii) Use of non-laser-proof ET tube

The tube used in this case can be ignited by any laser including the KTP laser. The fact that the anaesthetist had to make a decision about what tube could be utilized to establish anaesthesia warranted re-evaluation of the situation. There are other methods by which anaesthesia can be carried out in these cases but in this particular case a choice was made to proceed with the case using a flammable tube in close proximity to the application site for the laser. The fact that a fire occurred in this case shows that a direct or indirect laser beam can ignite flammable material when it is in close proximity. The comment 'By this means, safety is assured' is not valid. Safety is not assured because of the construction of the instruments and the delivery method used. The risk may be reduced but it is still present. A classic example of this is where there is an area of damage to the laser fibre and part of the laser beam can be inadvertently directed into a non-protected area.

(iii) High concentration of oxygen

It is acknowledged that the Venturi effect will dilute the percentage of oxygen delivered to the respiratory tract. The amount of dilution varies considerably and is dependent on the pressure of the delivered oxygen and the space around the tube and the endoscope to allow indrawing of room air. In a confined space with a narrowed outlet, in this case due to the stenosis, the concentration of oxygen in the operative area would be higher than expected. The actual percentage would be difficult to measure however. It is likely however that it would be greater than 30% inspired oxygen. Ignition of flammable material in an oxygen enriched environment

can occur at quite low percentages but the current guidelines state that the risk is regarded as lower if the percentage of inspired oxygen is kept at or below 30%.

(iv) Involvement of [Dr D]

Comment has been made on this previously. I think that his involvement in this particular case was inappropriate once the situation changed with respect to the patient's airway.

The following sections relate to the further requests for comment.

C) The use of KTP Lasers

This clinical situation has arisen from the use of a KTP laser on a patient with subglottic stenosis. The same situation could have arisen using other forms of fibre delivered laser energy. There are no special features of a KTP laser which make this complication any less likely to occur. One important issue is whether the case should have proceeded given the continually changing circumstances during the actual procedure.

D) [Ms A] informed of the possibility of airway fire prior to surgery

In the circumstances that were present at the pre-operative clinical consultation, [Ms A] should have been informed of the possibility of an airway fire. [Dr C] specifically states that he does not consider this necessary because his assessment of the risk of fire in this situation is less than 1%.

As I have stated above, all serious complications should be discussed with the patient before surgery.

E) Appropriateness of the procedure to continue after the examination under anaesthetic

This issue is one of the issues at the centre of this case. When the circumstances changed during the examination under anaesthetic and the airway was noted to be significantly narrower than expected it was then appropriate for the surgeon, [Dr C], to re-evaluate the situation. To then proceed with the case using a flammable plastic Benjet tube, use the KTP laser in the close proximity to the plastic Benjet tube and to allow a Training Fellow to use the KTP laser in these circumstances is very risky. I would consider that as a result of this choice, in this combination of circumstances, the decision to proceed was inappropriate.

F and G) Obtaining Fully Informed Consent

If [Dr C] had intended that the registrar was to be involved in the procedure, fully informed consent should have been carried out with open discussion with the patient, explaining the level of expertise that [Dr D] had and what his role in the

procedure would be. Given that [Dr C] was the primary surgeon in the case, these facts should be clearly documented in the notes and accepted by the patient before allowing [Dr D's] involvement. Documentation should take place in the clinical notes and specifically on the consent form. If the consent form does not have a specific section relating to observers or other persons being present or participating in the procedure then it is even more important that documentation in the clinical notes is quite clear in this regard. The issue is 'informed' consent which means that the patient clearly understands what they are consenting to and who will be carrying out the surgical procedure.

I don't believe that [Dr C] provided an appropriate standard of care in several areas of his management as outlined above.

I regard this as a moderate departure from that standard.

My biggest concern is the issue relating to consent and advising patients about potential risks and complications with procedures. It is also imperative that doctors are willing and able to re-evaluate a clinical situation and choose a different strategy if necessary. I feel that there has been an error of judgement in this regard. Given all these findings I feel that [Dr C's] peers would review his conduct with moderate disapproval.

I note that [Dr C] took full responsibility for the event and expeditiously managed the further treatment of the patient and this should be acknowledged."

Names (other than Dunedin Hospital, Otago District Health Board, HDC independent expert advisors and ACC's expert advisors) have been removed to protect privacy. Identifying letters have been assigned and bear no relationship to the person's actual name.

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.

RIGHT 6
Right to be fully informed

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

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

(d) notification of any proposed participation in teaching and research, including whether the research requires and has received ethical approval;
…

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

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

Other relevant standards

Medical Council of New Zealand, "Good Medical Practice — A Guide for Doctors" (February 2000):

"Domains of competence: …

1. *[In providing care, you must] keep clear, accurate, and contemporaneous patient records that report the relevant clinical findings, the decision made, the information given to patients and any drugs or other treatment prescribed.*

…

25. *If you disagree with your team's decision, you may be able to persuade other team members to change their minds. If not, and you believe the decision would harm the patient, tell someone who can take action. As a last resort, take action yourself to protect the patient's safety or health."*

Medical Council of New Zealand, "Information and Consent" (April 2002):

"1. Trust is a vital element in the patient–doctor relationship and for trust to exist, patients and doctors must believe that the other party is honest and willing to provide all necessary information that may influence the treatment or advice. …

…

21. *Consent should be obtained for involvement of trainees in the care of patients. The patient should be informed about the extent of the involvement of the trainee and the trainee's experience."*

New Zealand Medical Association, "Code of Ethics" (March 2002):

"45. Teaching involving direct patient contact must … wherever possible [be undertaken] with the consent of the patient …

46. *Wherever possible, patients should be given sufficient information on the form and content of the teaching, and adequate time for consideration, before consenting or declining to participate in clinical teaching. …*

47. *Patients' understanding of, or perspective on, their medical problems may be influenced by involvement in clinical teaching. Doctors must be sensitive to this possibility and ensure that information is provided in an unbiased manner, and that any questions receive adequate answers."*

Medical Council of New Zealand, *Cole's Medical Practice in New Zealand* (2001):

> *"Overseas trained doctors entering NZ and obtaining registration from the Medical Council will be expected to make themselves familiar with the legal, regulatory and professional ethical conduct requirements that are the norm for this country. …"*

Standards Australia, "Guide to the safe use of lasers in health care" (Australian/New Zealand Standard, AS/NZS 4173:1994):

> *"9.11 FIRE PRECAUTIONS …*
>
> *…*
>
> *(b) … For laser application to the aerodigestive tract, it is recommended that only non-flammable endotracheal tubes or specially wrapped red-rubber or 100% silicone tubes should be used. …*
>
> *APPENDIX A*
> *SAFE PRACTICES DURING SPECIALIST PROCEDURES*
> *…*
>
> ***A2.2 Inspired oxygen concentrations** … It is advisable that, where possible and giving due care to the inspired oxygen requirements of an individual patient, anaesthesia for laser endoscopy be given using an air/oxygen mixture with less than 30% inspired oxygen. …*
>
> ***A2.4 Endotracheal tubes** Unprotected bare rubber, silicone and PVC endotracheal tubes should not be used in instances where the laser beam may strike the tube. Suitably foil-wrapped or flexible metal tubes should be used."*

Opinion: Breach — Dr B and Dr C

Documentation

Drs C and B were required to keep clear, accurate, and contemporaneous records in relation to their preoperative discussion with Ms A.

Although little documentation of the preoperative consultation occurred, it is clear that Ms A was strongly opposed to any procedure that required her to have a tracheostomy. I accept Dr B's statement that Dr C informed him of Ms A's wish not to have a tracheostomy. However, neither Ms A's wish to avoid a tracheostomy, nor her strong statement that she would rather die than have a tracheostomy, was documented by Dr C or Dr B. The consent form included sections that were suitable for noting such information. These were not completed by Dr C. Dr B failed to record this information on the anaesthetic record as part of his preoperative assessment. This was important information which Drs C and B took

into consideration when deciding on the course of treatment and which restricted the options available to them. As the tracheostomy was not performed solely at Ms A's insistence, it was even more necessary that this information be recorded.

My surgical advisor, Dr Ferguson, commented:

> "As [Ms A's wish not to have a tracheostomy] was such an important factor in the decision regarding the type of surgery offered, I think that it should have been very carefully documented. …
>
> I am concerned that adequate records were not kept in this case … "

Dr Dorman advised:

> "We already know from this patient's profile (airway stenosis, smoking and asthma) that the anaesthetist had concerns about maintaining adequate oxygen concentration during the procedure. It is highly likely that she would also have significant airway irritability. To undertake such a case involves a full explanation to the patient about the reasons to proceed with the operation, the potential benefits and also a careful explanation of the risks. Details of the actual procedure in general terms, so that the patient can understand, who is involved in the surgery, discussion of all the possible complications and the proposed after care would be expected to have taken place. With complex airway management discussion should also involve explanation of the strategy if the proposed elective procedure cannot proceed as planned. Looking through the information that has been available to me I note that there is no written record of any of these discussions having taken place."

In my opinion Drs C and B breached Right 4(2) of the Code by failing to keep a clear, accurate, and contemporaneous record of the preoperative discussion with Ms A, especially regarding her options and choice of airway management.

I note that, in response to the provisional opinion, Drs C and B accepted that their standard of documentation was below required standards.

Standard of surgery

Decision to offer laser surgery

Dr Ferguson advised that the decision to treat Ms A's stenosis with laser surgery was appropriate, but that "further options, if the laser surgery proved impossible at the time of surgery, should have been considered, documented and indeed discussed with Ms A prior to surgery". I accept that the initial decision to treat Ms A's stenosis with laser surgery was appropriate, and that Dr C did not breach the Code in this regard.

Decision to continue with surgery
Due to Ms A's condition, her intended surgery was complex. Dr Blake, advising ACC, considered that the intended surgery was "complex and difficult", and Dr Ferguson advised that this was a "complex and difficult revision surgery, in an already compromised airway, where the chances of problems would have been greater than usual". Dr Dorman advised:

> "[T]his was clearly a complex case and from experience with airway problems and in particular, stenosis in the glottis, subglottis or trachea, I am fully aware that the clinical findings at the time of endoscopy of the airway can differ from preoperative assessment. This must be taken into account when advising the patient preoperatively about surgical and medical management."

In my opinion, Drs C and B were aware at the preoperative stage that the intended surgery was far from straightforward, with an inherent level of risk.

Once the procedure began, further risks were encountered by Drs C, D and B. I consider that, in light of the specific risks, discussed below, the doctors should not have proceeded with the surgery, notwithstanding Ms A's wish to avoid a tracheostomy.

I also consider that Dr B shared responsibility for the decisions made to continue with surgery. My view is supported by my anaesthetic advisor, Dr Walker, who stated that "both parties were responsible for patient safety and if either felt it was inappropriate to continue then they should have said so and the procedure abandoned". Drs Laurenson and Blake, advising ACC, also considered that the decision to proceed with surgery was a joint decision between Drs C and B.

Risk 1 — airway narrower than assessed preoperatively
Soon after Ms A was anaesthetised, it was found that her stenosis was more severe than had been assessed at the preoperative clinic. Indeed, the stenosis was so narrow that a laser-proof tube of such a gauge had not been manufactured. Dr C referred to the combined effect of the narrowed airway and the equipment being used for the procedure as the "cork in a bottle effect", which resulted in a high concentration of oxygen at the operation site, thus raising the risk of an airway fire.

The anaesthetist, in providing Dr B with expert advice in response to the provisional opinion, stated that "the anatomy of the airway of Ms A might have caused pooling of oxygen rich gas mixtures but this would be impossible to predict at the time of surgery".

My anaesthetic advisor, Dr Walker, considered that "if … the surgery would involve the use of a plastic paediatric unprotected Benjet tube (signifying a much reduced airway compared to that of a normal adult) and surgical access was reduced (meaning the laser would be used in close proximity to the plastic tube) and the oropharyngeal access and ventilation was limited (potential build up of high oxygenation concentrations increasing the risk of fire) these facts would be clear indications to abandon the procedure and wake the patient".

Consequently, once the narrowness of Ms A's airway was discovered at the time of surgery, it became even more risky to continue the surgery without the formation of a tracheostomy.

Risk 2 — use of non-laser-proof ET tube
From their statements, there is disagreement between Drs C and B about whose decision it was to proceed with a non-laser-proof ET tube. Dr C stated that the choice of the non-laser-proof tube was Dr B's; Dr B stated that the decision was Dr C's. In response to the provisional opinion, Dr B stated that "[T]here [was] no disagreement between myself and Dr C about proceeding with the surgery. I clearly stated in my statement that although I expressed my reservations, I agreed to proceed with surgery with the paediatric Benjet". In Dr C's response to the provisional opinion, he stated that "Dr B had to make a decision about what tube could be utilised to establish anaesthesia in this case. However, given that there is no such thing as a KTP laser-proof tube and only one tube would fit, I did not take issue with the material the tube was made of." Irrespective of who made the decision, one doctor could have vetoed the decision to proceed. My opinion is supported by paragraph 25 of "Good Medical Practice — A Guide for Doctors":[20]

> "If you disagree with your team's decision, you may be able to persuade other team members to change their minds. If not, and you believe the decision would harm the patient, tell someone who can take action. As a last resort, take action yourself to protect the patient's safety or health."

To repeat Dr Walker's advice:

> "[B]oth parties are responsible for patient safety and if either felt it was inappropriate to continue then they should have said so and the procedure abandoned."

As neither doctor objected to the use of the non-laser-proof ET tube, and Dr B stated that "*We* decided to go ahead" with the procedure (my emphasis), I conclude that both of the doctors agreed with the decision to continue with the procedure from here on. Thus I consider that the responsibility is shared.

Dr B stated that he had no option but to use the non-laser-proof tube; this is clearly incorrect. Drs B and C had the option of stopping the procedure and waking Ms A, and both Dr Ferguson and Dr Walker advised that this is precisely what should have happened at the point where a laser-proof tube could not be used. Similar advice was given to ACC by Dr Blake. Dr Dorman advised:

> "I do not accept that the only option was to proceed. In this particular case given the pre-operative stance by the patient that she did not wish to have a tracheostomy, it may have been more appropriate to stop the case and wake the patient. This would then

[20] Medical Council of New Zealand, February 2000.

> provide an opportunity for the surgeon, the anaesthetist and the patient to re-evaluate the clinical situation and choose another management path."

I have noted Dr C's comments that there "is no such thing as a KTP laser-proof tube" and that "[i]t does not follow that to establish a tracheostomy and proceed or to use a narrower copper Benjet and proceed would have eliminated the risk of airway fire or even reduce it substantially". Dr C also states that he considers that "[r]eduction of risk in this case is achieved using the laser fibre (suction) carriers and very close observation of fibre position using a Hopkins Rod Endoscope".

The anaesthetist, for Dr B, stated that "[w]ith the use of CO_2 laser the risk of airway fire would be significantly higher with the use of a plastic tube in the airway. KTP laser is applied via a fiberoptic and can be more accurately placed and is less susceptible to accidental reflection. The chance of inadvertently hitting a flammable object in the airway would be significantly less in the case of KTP laser than CO_2 laser."

However, I remain of the view that proceeding with a plastic paediatric Benjet tube *did* increase the risk of the tube catching fire, which is indeed what occurred.

Risk 3 — high concentration of oxygen
Dr B stated that he would have preferred to use a lower percentage concentration of oxygen than the equipment available supplied, which delivered 100% oxygen. Dr B's view is supported by the article he provided to ACC, in which the author states that the lowest concentration of oxygen consistent with patient oxygenation should be used because of the risk of fire. The Australian/New Zealand Standard, "Guide to the safe use of lasers in health care", states that "less than 30% inspired oxygen" should be used during laser surgery.

Dr Dorman advised:

> "In a confined space with a narrowed outlet, in this case due to the stenosis, the concentration of oxygen in the operative area would be higher than expected. The actual percentage would be difficult to measure however. It is likely however that it would be greater than 30% inspired oxygen. Ignition of flammable material in an oxygen enriched environment can occur at quite low percentages but the current guidelines state that the risk is regarded as lower if the percentage of inspired oxygen is kept at or below 30%."

I consider that the risks associated with continuing with surgery were increased by the use of 100% oxygen, and that Dr B, and probably Dr C, would have realised this, given their familiarity with the equipment. Although I accept that this was the only equipment available, Drs C and B should have considered the increased risk of using a higher than recommended percentage of oxygen along with the other risks, when deciding whether to continue with the procedure.

Risk 4 — laser mode
The laser was delivered in continuous mode, rather than pulse mode. Having considered the ODHB response as to the choice of mode, Dr Ferguson stated:

> "I accept the explanation provided by the Otago District Health Board regarding the use of the laser in the continuous mode rather than the pulse mode. … However, this was likely to increase the risk of airway fire in the oxygen rich environment provided by the Benjet tube in the already narrow airway."

It follows that the choice of laser mode, although appropriate clinically, raised still further the risks associated with proceeding with the operation.

Risk 5 — involvement of Dr D
The last risk introduced to the procedure was that Dr D performed the procedure under Dr C's supervision. I fully accept that doctors must learn, that DPH is a teaching hospital, and that Dr C was providing close supervision and guidance. Nevertheless, I consider that for a trainee, however advanced, to be invited to participate added to the risks associated with this procedure.

Dr B stated that the use of the Benjet tube in the circumstances presented by Ms A's case was "not so well known" in New Zealand. This was a further reason for Dr D not to perform this procedure.

Dr Walker advised that the clinical situation presented to Drs C and B at the point where a laser-proof ET tube could not be used was a clear indication to abandon the procedure and "wake the patient". He commented that "the surgeon and anaesthetist made an error of judgment in continuing surgery".

Dr Ferguson stated:

> "I do not think that the procedure was performed with reasonable care and skill. The decision was made to continue when it became apparent that the equipment planned could not be used and the hazards were greater. …
>
> I do not think that this was a suitable case to be performed by a Teaching Fellow in light of the difficulties that were encountered at the beginning of the operation when the decision was made to change to the Benjet tube. At this point … the risks of the operation dramatically increased and therefore in the light of the decision to proceed with the surgery, the Teaching Fellow should not have been involved at that point."

Dr Blake, in advising ACC, stated:

> "It is my view that the risk of a laser fire under these circumstances was well in excess of 1%. Indeed, I feel that the risk of a laser fire here was such that both surgeon and anaesthetist should not have proceeded past the point of the establishment of a

> satisfactory airway. At that point they should have stepped back from the case, decided that it was not safe to go on and accepted that they would have to wake the patient up and put to [Ms A] a new set of risk factors."

Dr Blake further stated:

> "Whilst it is true that the risk of laser fires in the reported literature is very low, this is only because considerable precautions are taken to avoid them."

Dr Dorman also agreed that Dr D's "involvement in this particular case was inappropriate once the situation changed with respect to the patient's airway".

Summary
Dr B provided an article that refers to the three methods by which clinicians can reduce the chances of an airway fire: no tube in the airway, protection of the external surface of a conventional tube, or use of a non-combustible tube. The approach taken by Drs B and C was none of these methods. They chose to perform a high-risk revision procedure with the added risks of: a severely narrowed operating field; using a non-laser-proof ET tube, the use of which was "not well known" in New Zealand; a higher than preferred oxygen concentration; and with the procedure performed by a trainee using a laser in a mode that had an increased risk of airway fire. Dr Blake advised ACC that, in his opinion, "the fire was more probable than not under those circumstances". I note that Dr Blake's opinion did not take into account Dr D's involvement, as ACC was unaware of his involvement when obtaining expert advice.

Dr Ferguson referred to the Australian/New Zealand Standard, "Guide to the safe use of lasers in health care", when she stated that a flammable tube should not be used, unless it is protected from the laser. Drs C and B did not adhere to this guideline. The same guidelines state that less than 30% oxygen should be administered. Dr B believed that Ms A needed "more than 50% oxygen to ensure adequate oxygenation", but the use of 100% oxygen was contrary to the prevailing guidelines, and raised the level of risk significantly.

I accept that a blender was not available at the time. On its own, the risk of using 100% oxygen may be considered minor, but there was a cumulative effect of all of these risks, and the clinicians should have considered the risks as a whole.

Dr Blake also stated that the published occurrence of airway fires is low because "considerable precautions are taken to avoid them". In performing this operation, Drs C and B took inadequate precautions to prevent an airway fire.

Drs C and B chose to continue with surgery in the presence of recognisable and compounding risks that were apparent at the time. The decision to allow Dr D to continue to perform the procedure in the presence of such risks was ill-considered.

Dr Dorman commented on the decision to continue with the procedure following Ms A's examination under anaesthetic:

> "This issue is one of the issues at the centre of this case. When the circumstances changed during the examination under anaesthetic and the airway was noted to be significantly narrower than expected it was then appropriate for the surgeon, Dr C, to re-evaluate the situation. To then proceed with the case using a flammable plastic Benjet tube, use the KTP laser in the close proximity to the plastic Benjet tube and to allow a Training Fellow to use the KTP laser in these circumstances is very risky. I would consider that as a result of this choice, in this combination of circumstances, the decision to proceed was inappropriate."

In these circumstances, Drs C and B failed by some way to provide services to Ms A with reasonable care and skill, and breached Right 4(1) of the Code. By failing to comply with the standard "Guide to the safe use of lasers in health care", specifically in relation to the use of a non-laser-proof ET tube, Drs C and B also failed to comply with professional standards and breached Right 4(2) of the Code.

Opinion: Breach — Dr C

Informed consent

Disclosure of risks and options

Under Right 6(1)(b) of the Code of Health and Disability Services Consumers' Rights (the Code), Ms A was entitled to the information that a reasonable patient in her position would expect to receive, including an explanation of the options available, an assessment of the expected risks, side effects, benefits and costs of each option. Under Right 7(1), services should have been provided to Ms A only if she had made an informed choice and given informed consent.

There is no doubt that Ms A consented to the procedure on 16 October 2002, nor is there any dispute between the parties that the risk of airway fire was not raised preoperatively. The pertinent issue is whether Drs C and B should have informed Ms A about the risk of an airway fire.

Dr B considered that the risk of airway fire was so remote as not to require discussion; Dr C considered the risk of an airway fire as less than 1% based on his personal clinical experience, and therefore not needing to be discussed. However, Drs C and B stated that at the preoperative stage they discussed the potential use of a non-laser-proof ET tube, as they considered that there was a possibility of finding that the stenosis was more severe than assessed at the preoperative clinic. Dr B stated there would be "risks … that would not arise with my preferred option of a tracheostomy". One of those risks was of an airway fire.

Clearly, Drs C and B were aware at the preoperative stage of the possible need to proceed with Ms A's surgery using a non-laser-proof ET tube. Dr C described an airway fire in his report to ODHB as an "uncommon but a very significant complication".

All three of my expert advisors stated that Ms A should have been advised of this risk. Dr Catherine Ferguson, otolaryngologist and head and neck surgeon, advised that when Dr C could only proceed using an unprotected tube, then "he should have stopped the procedure and discussed this increased risk with Ms A". Dr John Walker, anaesthetist, advised that "a general discussion was warranted". Dr Bren Dorman, otolaryngologist and head and neck surgeon, is experienced in the use of the KTP laser. He advised:

> "When one is confronted with a case such as this the potential for a serious complication to arise is quite significant. The fact that the risk of an airway fire was felt to be less than 1% and thus did not warrant discussion with the patient is not accepted. The reason that the documented incidence of laser fire in the airway is reported to be less than 1% is because so many precautions and safety checks are in place for these procedures."

In the responses to the provisional opinion, Dr C stated that it was his "opinion that the risk of an airway fire occurring was so remote that it was not relevant to the preoperative discussions". Dr B advised that it was not standard practice for an anaesthetist in Dunedin Hospital in 2002 to discuss airway fire with patients undergoing laser surgery. The Otago District Health Board advised that "at the time of Ms A's incident the majority of anaesthetists in this Department would not have mentioned airway fire as a part of the informed consent. It was seen as more of a surgical issue." The anaesthetist providing Dr B with expert advice in response to the provisional opinion, stated that "[w]hether the risks of fire were enough in this case to specifically warn Ms A preoperatively is debateable. The commonest source of ignition in surgical airway fire is surgical diathermy, not laser but we don't routinely warn patients of the fire dangers of surgical diathermy."

Doctors are not expected to provide a detailed explanation of all the risks, however remote, that may be associated with a procedure. However, I do not accept that the risk of airway fire was so remote that it did not need to be mentioned. Nor is a 1% risk an automatic cut-off point for disclosure.[21] It depends on the specific context. Given Ms A's strong wish to avoid a tracheostomy, it was particularly important that she understood all the possible risks and consequences of this request.

I am not persuaded by Dr C's submission that information about significant complications can be withheld "where the clinician [feels] that disclosure of such complications (when rare) could produce undue anxiety for patients and jeopardise that individual's likelihood of undergoing a procedure which might be highly beneficial for their quality of life or life

[21] See Opinion 98HDC19009, 19 January 2001 — disclosure of less than 1% risk (www.hdc.org.nz/files/pageopinions/98hdc19009.pdf).

expectancy". The so-called "therapeutic privilege" to withhold potentially alarming information is not consistent with patient autonomy or patient-centred care based on a true partnership between doctor and patient.

A key aspect of the clinician's skill is to contextualise information about risks and provide it in a sensitive and balanced way, so that the informed patient can make her own decision about the proposed "highly beneficial" procedure. Ms A was denied that opportunity.

I accept Dr Dorman's advice:

> "I feel there is an error of judgment in choosing not to mention the possibility of an airway fire in this case. The case involves a complex airway stenosis in a patient with co-morbidities. The risk of producing anxiety in the patient because serious complications are discussed is outweighed by the risk of an airway fire which can be severe and in some cases fatal. This particular case does involve a laser induced airway fire in a compromised airway and the fact that the previous expert witnesses have never performed such a procedure using a KTP laser is irrelevant. Laser fires can occur in many situations and having an oxygen enriched environment pooling in a confined space with inflammable material in close juxtaposition warrants discussion between the surgeon and the patient about the possible risks that a fire could occur."

I conclude that Dr C failed to give an adequate explanation of the risks to Ms A, specifically the risk of an airway fire. I do not consider that this disclosure was a responsibility of the anaesthetist. Dr C breached Right 6(1)(b) of the Code by failing to provide the information Ms A needed, as a reasonable patient, to give informed consent. As the operation proceeded without Ms A's fully informed consent, Dr C also breached Right 7(1) of the Code.

I deal below with the issue of informed consent in relation to Dr D's involvement.

Involvement of trainee

As he was directly responsible for Dr D in his performance of the procedure, it was Dr C's responsibility, rather than Dr B's, to ensure that Ms A consented to Dr D's involvement. Dr C accepts this responsibility.

Obviously doctors need to learn the skills required to perform their job, including the practice of clinical skills. However, such training must comply with the Code and with relevant professional standards. For a trainee to be allowed to practise on an anaesthetised patient without the patient's consent is wrong — ethically, professionally, and legally.

I endorse paragraph 21 of the Medical Council's statement on "Information and Consent":

> "Consent should be obtained for involvement of trainees in the care of patients. The patient should be informed about the extent of the involvement of the trainee and the trainee's experience."

Right 6(1)(d) of the Code also required Dr C to inform Ms A of the proposed participation in Dr D's training.

Dr Ferguson agreed that it was important to inform Ms A of Dr D's involvement in her surgery:

> "I certainly think that in this situation, with a difficult airway problem and an unusual situation, the involvement of a Teaching Fellow should have been very carefully explained to [Ms A]."

Dr Dorman concurred:

> "In a case such as this, if the surgeon is considering the possibility that a registrar or Fellow carry out some of the surgery it is imperative that the patient know."

On 22 October 2002, Ms A stated in her application for cover to ACC that she was "unsure of who else was present or responsible as I was under a general anaesthetic". On being asked during my investigation about her knowledge of Dr D's role, Ms A stated that she had no knowledge of Dr D's involvement in the procedure until informed by my Office on 8 June 2005.

In contrast, Dr C stated that he was "certain" that Ms A was aware of Dr D's intended role at the preoperative clinic. In response to the provisional opinion, Dr C repeated that, to the best of his knowledge, Ms A was aware of Dr D's intended role. Dr C ascribed Ms A's inability to recall Dr D's involvement to "well recognised peri-operative memory dysfunction which occurs in these sorts of circumstances".

Ms A faced a complex elective procedure being performed. She was naturally very anxious about the outcome. In these circumstances, Dr D's proposed involvement should have been carefully discussed and documented by Dr C. This discussion was not documented and, having reviewed all the available evidence, I am not persuaded that it occurred. Accordingly, Dr C's failure to notify Ms A of her participation in Dr D's training was a breach of Right 6(1)(d) of the Code.

There is certainly no evidence that Ms A was told about Dr D's level of experience. This was a breach of professional standards set by the Medical Council, and therefore also a breach of Right 4(2) of the Code.

Other comment

Duty of candour
The Medical Council of New Zealand makes the following statement in relation to overseas-trained doctors practising in New Zealand:[22]

> "Overseas trained doctors entering NZ and obtaining registration from the Medical Council will be expected to make themselves familiar with the legal, regulatory and professional ethical conduct requirements that are the norm for this country."

I am concerned about Dr C's lack of candour when responding to investigatory authorities in New Zealand, specifically in relation to the involvement of Dr D in Ms A's procedure.

Prior to being specifically asked about Dr D's role, in his description of the procedure to my Office and in his reports to the internal inquiry and to ACC, Dr C referred to "me", "I" and "the surgeon" when referring to the person performing the procedure. This created the impression that he was the sole surgeon performing the operation. This impression is reinforced by both his references to his own clinical outcomes when estimating the level of risk of an airway fire, and the clinical record of 15 and 16 October 2002 where mention of Dr D is not made. In particular, I note that Dr C provided an affidavit for the purposes of the ACC investigation on 29 July 2004, in which he stated:

> "I am the surgeon who performed the surgery on [Ms A] on 16 October 2002."

These statements were misleading. Dr C commenced the surgery, and Dr D took over some stage into the procedure under Dr C's supervision. Dr C subsequently took over the surgery at the point the airway fire occurred. That is how Dr C should have described the surgery in his accounts to the various inquiries.

ODHB explained that Dr C's "sense of personal responsibility" led him to accept sole responsibility for the incident and to fail to mention Dr D's role.

In my opinion, Dr C's failure to mention Dr D's involvement in the surgery (either to Ms A, in particular during the meeting on 26 November 2002, or to the various inquiries) was at best misguided.

Otago District Health Board's internal investigation
The CEO of ODHB, in his response to questions asked specifically about Dr D's role, stated that Dr D's participation in Ms A's procedure was considered at the time of the internal inquiry and concluded as "not of significance". The suggestion that it was not

[22] Medical Council of New Zealand, *Cole's Medical Practice in New Zealand* (2001).

significant for a high risk procedure to be performed by a trainee without the consent of the patient is of concern. I also note that ODHB failed to inform Ms A of Dr D's involvement.

My Office was provided by ODHB with all the documents relevant to Ms A's case. There is no record of any discussion of, or comment about, Dr D's involvement. As Dr D was the surgeon, there should have been some reference in the documents to his actions, the relative responsibilities of Dr C and his trainee, and the extent of supervision provided by Dr C.

The failure to discuss this critical issue, and to inform Ms A, detracts from the quality of the ODHB investigation.

As noted by Dr Dorman:

> "In a case such as this where a serious complication has arisen there should be clear documentation outlining all of the involved parties, both in reports and what was discussed in meetings."

In response to the provisional opinion, ODHB accepts that "a trainee's role in a high risk procedure is a significant issue", and that "in retrospect" the decision not to inform Ms A of Dr D's involvement was "not the most appropriate one to have made". ODHB also accepts that the investigation was less than ideal and "served neither the ODHB nor [Dr C] well in its lack of careful documentation".

Vicarious liability — Otago District Health Board

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

Dr C breached the Code by failing to obtain Ms A's properly informed consent. I consider that the documentation available was appropriate and that sufficient resources and opportunity were available to obtain Ms A's consent. Accordingly, ODHB is not liable for this breach.

Drs B and C breached the Code by failing to provide services of an appropriate standard to Ms A. The decisions made by Drs B and C were their own, and in most respects appear not to have been affected by any shortage of resources. (Dr B pointed out that equipment was not available that would have allowed him to provide oxygen at less than 100%; it is now available.) In the circumstances, ODHB is not liable for Drs C and B's failure to provide services of an appropriate standard.

Dr C also breached the Code by failing to obtain Ms A's consent to the involvement of Dr D in her surgery; I do not consider that ODHB is vicariously liable for this breach of the Code.

Actions taken

Laser usage guidelines
I note that the laser usage guidelines now in use at ODHB (approved on 23 October 2002) state:

> "The clinician operating the laser must be registered as competent under the criteria set by the ODHB Laser Safety Committee."

Dr D was not registered as competent, and was the user of the laser on 16 October 2002 — seven days before the introduction of the guidelines. ODHB may wish to consider amending the laser usage guideline to take into account the need for training; as it stands, doctors cannot learn this important skill.

Laser-proof ET tube
ODHB has informed me that narrower laser-proof ET tubes are now available if required.

Follow-up actions

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

- A copy of my final report, with details identifying the parties removed (but naming Dunedin Hospital and Otago District Health Board), will be sent to the New Zealand Medical Association, and all District Health Boards in New Zealand, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Names (other than Dunedin Hospital, Otago District Health Board, HDC independent expert advisors and ACC's expert advisors) have been removed to protect privacy. Identifying letters have been assigned and bear no relationship to the person's actual name.