Senior Ophthalmology Trainee, Dr B

Consultant Ophthalmologist, Dr C

District Health Board

A Report by the

Health and Disability Commissioner

(Case 13HDC01345)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. In 2013, Mrs A was waitlisted for a right cataract extraction and insertion of an intraocular lens, and a vitrectomy and epiretinal membrane peel.

2. On 27 June 2013, Mrs A was seen in a district health board's (the DHB) ophthalmology clinic (the Clinic) by Dr D, a senior ophthalmology trainee. Dr D was supervised by Dr C. However, Dr C was not present at the consultation.

3. At that consultation, Mrs A signed an "Agreement to Treatment" form providing that the procedure was to be a right eye cataract and epiretinal membrane peel under local anaesthetic (the procedure).

4. Shortly after that consultation, Dr D left the DHB and was replaced by Dr B, another senior ophthalmology trainee.

5. At 8.30am on 13 August 2013, Mrs A presented for the procedure. Mrs A understood that Dr B would be observing during the surgery, and that Dr C would be the operating surgeon. In contrast, Dr B said that he clearly recalls telling Mrs A that he would be the operating surgeon. He said that she was under local anaesthetic and was fully aware throughout the surgery that he was operating.

6. Dr C advised that the procedure is done through a microscope, and both the operator and the observer can view what is going on through the eye of the microscope. Dr B stated that Dr C was watching him closely and advising him steadily. Dr B said that he strictly followed the advice given by Dr C. Mrs A said that she heard Dr C warn Dr B at least three times that he was too close to the macula.

7. During the procedure, Dr B inadvertently touched the Tano scraper onto Mrs A's retina (the adverse event). Dr C stated that the action took less than a second and occurred too quickly for him to prevent it. Dr C took over from Dr B and completed the surgery.

8. Mrs A said that she asked to speak to the doctor before she left the theatre, and expressed her concern regarding Dr C's conversation with Dr B during the procedure. She said that Dr B told her that it was nothing to worry about. In contrast, Dr B told HDC that, as Mrs A was quite anxious, he provided an explanation to her when she was just outside the operating theatre.

9. Dr C stated that Dr B immediately explained the events and next steps to Mrs A. Dr C said that he insists on senior ophthalmology trainees explaining any complications to patients themselves as part of their learning, but that he advises them as necessary.

10. Dr B recorded in the clinical notes that the membrane peel had been performed and there were punctuate retinal haemorrhages, but he did not document the adverse event. The only reference to the adverse event is in Mrs A's discharge summary dated 13 August 2013. Dr B did not record the adverse event in two letters to Mrs A's general practitioner (GP), Dr E, dated 14 and 21 August 2013.

11. Mrs A stated that by the time she went for a follow-up appointment 10 days after the surgery, she was sure that all was not well, because she was not able to read even the largest letters on the test chart with her right eye. She said that Dr B expressed no concern, and did not admit to anything being amiss.

12. Dr B said that he explained to Mrs A that she had a gas bubble in her eye, which temporarily would cause her vision to be worse than previously. He stated that he asked Mrs A to wait until her next appointment before finding out the visual outcome of the operation, and after that he did not have a chance to see Mrs A again, as subsequently she attended the private rooms to see Dr C.

13. On 16 September 2013, Dr C saw Mrs A privately. Mrs A said that Dr C confirmed that her eye had been damaged permanently during the surgery.

Findings

14. Dr B did not explain to Mrs A sufficiently that he was a trainee and that he would be carrying out the surgery on her, and did not inform her of any increased risks resultant from having such delicate surgery performed by a trainee. Accordingly, Dr B breached Right 6(1)(b) of the Code of Health and Disability Services Consumers' Rights (the Code).[1] It follows that Mrs A was not in a position to give informed consent and, accordingly, Dr B also breached Right 7(1) of the Code.[2]

15. Dr B also failed to record the adverse event adequately, and did not disclose the adverse event to Mrs A or her GP appropriately. Accordingly, Dr B failed to comply with professional standards and breached Right 4(2) of the Code.[3] Adverse comment is also made about Dr B's error during surgery.

16. By failing to ensure that open disclosure occurred promptly, Dr C breached Right 6(1) of the Code. Adverse comment is made about Dr C's failure to ensure that details about the nature of the harm and any subsequent action, including disclosure to Mrs A, was documented in her clinical notes.

17. Adverse comment is made about the DHB's systems.

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[1] Right 6(1) of the Code states: "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including —
… (b) An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option …"

[2] Right 7(1) of the Code states: "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."

[3] Right 4(2) of the Code states: "Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards."

Complaint and investigation

18. The Commissioner received a complaint from Mrs A about the services provided to her by the DHB. An investigation was commenced on 10 February 2014. The following issues were identified for investigation:

- *Whether Dr B provided an appropriate standard of care to Mrs A.*
- *Whether Dr B provided Mrs A with adequate information and obtained her informed consent for surgery.*
- *Whether Dr C provided an appropriate standard of care to Mrs A.*
- *Whether Dr C provided Mrs A with adequate information and obtained her informed consent for surgery.*
- *Whether the DHB provided an appropriate standard of care to Mrs A.*

19. The parties directly involved in the investigation were:

Mrs A	Consumer
Dr B	Provider/Senior ophthalmology trainee
Dr C	Provider/Consultant ophthalmologist
The DHB	Provider

Also mentioned in this report:

Dr D	Senior ophthalmology trainee
Dr E	Mrs A's general practitioner
Dr F	Consultant ophthalmologist
Dr G	Ophthalmologist

20. Independent expert advice was obtained from consultant ophthalmologist and vitreoretinal surgeon Dr Keith Small (**Appendix A**).

Information gathered during investigation

Background

21. In 2011 Mrs A had a vitrectomy because of a vitreous haemorrhage in her right eye.[4] On 23 March 2013, Mrs A, then aged 71 years, was seen at the Clinic by ophthalmologist Dr F. At that time, Mrs A had poor vision in her right eye and good

[4] Vitrectomy is the surgical removal of the vitreous gel from the middle of the eye to treat an epiretinal membrane. It may be done if blood in the vitreous gel (vitreous haemorrhage) does not clear on its own. During a vitrectomy, the surgeon inserts small instruments into the eye, cuts the vitreous gel and suctions it out. This is followed by peeling away the epiretinal membrane from the retina. At the end of the surgery, silicone oil or a gas bubble is injected into the eye to keep the retina in place. If a gas bubble is used, sometimes a certain head positioning has to be maintained, such as face down, or sleeping on the right or left side.

vision in her left eye. Mrs A had a moderate–severe cataract in her right eye, and a minimal cataract in her left eye, and had retinal changes that were consistent with a presumed retinal vein occlusion.[5] Her right eye had an abnormal macular[6] with an epiretinal membrane.[7] There was also a mild epiretinal membrane in her left eye.

22. Mrs A was placed on the waitlist for a right cataract extraction and insertion of an intraocular lens,[8] and a vitrectomy and epiretinal membrane peel.

23. On 27 June 2013, Mrs A was seen in the Clinic by Dr D. Dr D was supervised by ophthalmologist Dr C. Mrs A was complaining of blurred vision in her left eye. Dr D recorded the history of Mrs A's presenting problems as:

> "R Cataract
>
> Bil epiretinal membrane
>
> ? Prev (R) central vein occlusion
>
> L Cataract"

24. At that consultation, Mrs A signed an "Agreement to Treatment" form providing that the procedure was to be a "Right eye cataract + epiretinal membrane under LA [local anaesthetic]" (the procedure). The risks documented as having been discussed with Mrs A were raised intraocular pressure,[9] retinal detachment, or further surgery, infection or bleeding. Dr D noted: "[P]atient told to expect improvement but never like fellow eye [secondary to her] prior [branch retinal occlusion]."

25. Dr C was not present at this consultation. He stated that the Clinic where the informed consent was undertaken can have 30 patients booked per morning, some of whom have severe pathology, and so he needs to spend time with those patients. He stated:

> "I cannot realistically see all patients myself and am not expected to by [the DHB]. Rather, I see the more difficult problems or ones which the trainees working in my clinic wish to ask my advice on. Hence, [Dr D] undertook the informed consent process with [Mrs A]. This is the way informed consent processes work in the hospital. All Ophthalmologists are trained to take informed consent, both at medical school and in their ophthalmology training; indeed, consent and communication is specifically examined by our College."

[5] Retinal vein occlusion is a blockage of the small veins that carry blood away from the retina. The retina is the layer of tissue at the back of the inner eye that converts light images to nerve signals and sends them to the brain.
[6] The macular is the sharp focusing area at the back of the human eye. It is an oval-shaped pigmented area near the center of the retina. It has a diameter of around 5.5mm.
[7] An epiretinal membrane is a thin sheet of fibrous tissue that can form on the macula. It acts like a film through which it is harder to see. The film may also contract like scar tissue, which can pull on the delicate retina at the back of the eye.
[8] An intraocular lens implant is a synthetic, artificial lens placed inside the eye, which replaces the focusing power of a natural lens that has been surgically removed, usually as part of cataract surgery.
[9] Fluid pressure inside the eye.

26. In response to the "information gathered" section of my provisional opinion, Mrs A told HDC that she had no expectation that Dr C would be at that consultation, and understood that he needed to prioritise his time.

27. Dr C stated that Dr D had been a senior ophthalmology trainee for almost a year, and interacted very well with patients. Dr C said: "I have no doubt that he would have fully explained that [the Clinic] is a teaching hospital and I am certain that in [Mrs A's] case in particular she knew that she may well be operated on by a [senior ophthalmology trainee] as when she visited me in my rooms afterwards she said that she felt comfortable with [Dr D] and would have been happy for him to operate on her." In response to the "information gathered" section of my provisional opinion, Mrs A said that she would have been happy with Dr D performing the surgery because she had confidence in him, but she did not know that he was a senior ophthalmology trainee.

28. Shortly after that consultation, Dr D left the DHB and was replaced by Dr B.[10] Dr B stated that he had been an ophthalmic surgeon for over a decade overseas, and is a member of two overseas professional ophthalmology bodies.

Presentation for procedure

29. At 8.30am on 13 August 2013, Mrs A presented for the procedure. Mrs A stated: "Prior to going into theatre I was visited by a [Dr B] who had just arrived from [overseas] and I understood he was going to observe during the surgery. Ophthalmologist [Dr C] was the other surgeon." Mrs A also advised HDC that her understanding was that Dr C would be the operating surgeon.

30. Dr B stated that he saw Mrs A in the ward during the preoperative ward round, introduced himself and explained that he would be one of the surgeons working with Dr C that day, and offered to answer any questions. He stated:

> "As part of my usual routine, I went through the risks and benefits of eye surgery involving macular membrane peeling including risk of loss of vision and need for further treatment. [Mrs A] appears to believe I told her I would be observing and she was not aware I would be operating. I clearly recall however telling her that I would be the surgeon operating, together with [Dr C]. She was under local anaesthetic and was fully aware throughout the surgery that I was operating on her with [Dr C] supervising."

31. In response to the "information gathered" section of my provisional opinion, Mrs A's husband told HDC that he was also present during the preoperative discussion. He said that he cannot remember word for word what was said, but clearly recalls Dr B saying that he would be observing the surgery. Mrs A's husband said that there was no discussion about who would be operating, and he took it for granted that it would be Dr C. Mrs A stated: "I do not recall at any of the appointments prior to my surgery being told that I might well be operated on by a doctor still in training."

[10] Dr B is no longer practising in New Zealand.

32. Dr B said that he was sorry to hear that his explanation caused a misunderstanding by Mrs A regarding who would be the surgeon for the operation. In response to my provisional opinion, Dr B stated:

> "I agree that I did not document the discussion that I had with [Mrs A] during my pre-operative ward rounds. I have learnt [a] valuable lesson from this incident and have since then changed my practice in documenting fully about the discussions that I have with my patients including the risks and benefits of the operative procedure. I also have made it my practice to inform and clarify patients of who the operating surgeon will be on every occasion without fail. I can once again confirm that I did not tell [Mrs A] that I will be an observer in the operating theatre. I clearly remember telling her that I am one of the surgeons in theatre for that morning and will be operating alongside with [Dr C]. It is unfortunate that I did not make it clear for [Mrs A] and I sincerely have made a change in my practice since this incident both in discussing clearly and documenting the discussion."

Supervision

33. The DHB advised that Dr G was Dr B's supervisor, but day-to-day supervision was delegated to the consultants in charge of each operating list or clinic according to the timetable created for the senior ophthalmology trainees. Dr C stated that he relies on the DHB to determine which senior ophthalmology trainees are placed under his supervision. Dr C stated: "I was unaware that [Dr B's] supervisor according to the Medical Council was [Dr G] and do not understand what this may or may not mean when I am rostered by [the DHB] to supervise him." Dr C told HDC that the DHB is a training hospital, and senior ophthalmology trainees routinely undertake procedures under the supervision of vocationally registered ophthalmologists, which is part of the process by which they learn and gain experience. He stated that he was the senior person who had primary responsibility for overseeing Dr B during Mrs A's surgery.

Surgery

34. Dr C advised that the steps involved in an epiretinal membrane operation are to:

> "(a) Do a vitrectomy
>
> (b) Stain the membrane
>
> (c) Get an edge of the membrane, using a Tano scraper[11]
>
> (d) Peel the membrane, using forceps
>
> (e) Usually (c) and (d) need to be repeated several times
>
> (f) Check the peripheral retina
>
> (g) Finish the operation"

35. Dr C advised that the procedure is done through a microscope, and both the operator and the observer can view what is going on through the eye of the microscope. He stated that he was scrubbed and sitting next to Dr B, watching through the observer

[11] A Tano scraper is a commonly used instrument with a soft tip on it studded with diamonds.

eyepiece of the microscope Dr B was using to operate. Dr C stated that he was readily available at all times to advise or intervene if required.

36. Dr B said that he started the surgery and completed the vitrectomy and staining of the membrane, and used the Tano scraper to create an edge of the membrane. He then started peeling the membrane with forceps. Dr B stated that, as is usual, he had to alternate between the Tano scraper and the forceps a few times, and that, throughout the procedure, Dr C was watching him closely under the microscope and steadily advising him on the routine.

37. Mrs A stated that she heard Dr C warn Dr B at least three times that he was too close to the macula. She said that he was sounding more alarmed each time he warned Dr B. Dr C stated:

> "As is part of my usual supervision practice, I did remind [Dr B] a couple of times at least to stay as far away as possible from the central fovea itself and to be careful, which obviously [Mrs A] overheard, but I am sure that I wasn't saying this in alarm otherwise I would have immediately taken over. Instead, at the point I was saying this [Dr B] was peeling the membrane quite competently; the more competent one is the closer one tends to get to the fovea as that is where the pathology is and I simply wanted to remind him to be careful of the fovea."

38. Dr B said that Dr C was watching closely and advising him steadily. Dr B stated that he strictly followed the advice given by Dr C.

39. Dr B said that the epiretinal membrane was resistant and difficult to remove. During the procedure, Dr B touched the Tano scraper onto Mrs A's retina. Dr B stated:

> "While positioning my tano scraper to align to the membrane to create edge, however, I made a very brief point of contact with the retina just outside the fovea, resulting in retinal trauma. Clearly this was something that I did not expect to happen and neither did [Dr C]. The contact with the retina happened so quickly [Dr C] did not have any opportunity to intervene. At this point he asked me to stop and took over and completed the rest of the surgery."

40. In response to the "information gathered" section of my provisional opinion, Mrs A said that she recalls hearing Dr C say to Dr B, "[T]hank you I will take over now."

41. Dr B said that he does not recall pressing on the retina with pressure and thinks it was a brief contact to the fovea while he was positioning the instrument.

42. Dr C stated that for no obvious reason Dr B placed the Tano scraper directly on the fovea (the adverse event). Dr C said that the action took less than a second and occurred too quickly for him to prevent it. He said:

> "I immediately said 'stop' and took over, but unfortunately the damage was done in that fraction of a second. This event was totally unpredictable; in all my years of teaching or practice I haven't ever seen anyone touch the fovea during any procedure. I can only speculate that it was a momentary lapse in concentration on [Dr B's] part. I have seen [senior ophthalmology trainees] touch other parts of the

> retina by mistake in the past, and I have also done so myself. However, almost invariably this is not due to putting the instrument in the wrong place but by pressing too hard in the correct place (i.e. misjudging the depth), as one can see where to place it."

43. Dr C stated that most complications caused by trainees can be fixed easily by the supervising surgeon. However, this was something that could not be remedied or improved. He said: "I have never seen this happen before and doubt I will ever see it again in the future."

44. In response to my provisional opinion, Dr B stated:

> "While I ensure my full attention and focus when performing eye surgery in general, I commit a very high level of concentration for procedures such as the peeling of epiretinal membranes which require immense focus and precision. It was extremely unfortunate that the contact happened close to the centre of vision despite my full concentration. I am deeply sorry and will ensure that such accidents never happen. I have since operated and performed many epiretinal membrane surgeries and never had a problem of such nature. I will continue to ensure high standard of care for all my patients and will endeavour to avoid such an event at all costs."

Events following surgery

45. Mrs A said that she asked to speak to "the doctor" before she left the theatre, and expressed her concern to Dr B regarding Dr C's conversation with him during the procedure. She said that she was very worried at this stage and that Dr B told her that it was nothing to worry about.

46. Dr B said that as Mrs A was quite anxious, he provided an explanation to her when she was just outside the operating room, that her membrane peeling was difficult because the membrane was quite adherent and difficult to peel. He said that he also explained that there were areas of retinal touch during the procedure and they had to place a bubble of gas in her eye to help her macula heal. He said that he explained to Mrs A the need for close postoperative monitoring to find out the effect of this during her recovery.

47. Dr C said that Dr B immediately explained the events and next steps to Mrs A. Dr C stated: "I usually insist that [senior ophthalmology trainees] explain any complications to patients themselves because it is an important part of the learning experience, although I advise them as necessary. I do not recall exactly what [Dr B] told [Mrs A], and may not have heard the entire conversation. He also saw her the next day, as is routine."

48. Dr B recorded on the clinical notes that the membrane peel had been performed and there were "punctuate retinal haemorrhages",[12] but did not document the adverse

[12] Retinal haemorrhage is a disorder of the eye in which bleeding occurs into the light-sensitive tissue on the back wall of the eye. Retinal haemorrhages that take place outside of the macula can go undetected for many years. However, some retinal haemorrhages can cause severe impairment of vision. They may occur in connection with posterior vitreous detachment or retinal detachment.

event. In the discharge summary dated 13 August 2013, Dr B recorded: "Area of retinal haemorrhage and swelling at macula due to contact between membrane peeling forceps and retina while attempted peeling of the epiretinal membrane."[13]

49. On 14 August 2013, Dr B reviewed Mrs A and dictated a clinic letter addressed to Mrs A's general practitioner (GP), Dr E (the letter was typed and sent on 16 August 2013). In that letter there is no mention of the adverse event. The letter stated: "[W]e reviewed [Mrs A] in the Eye Clinic. Her right eye is settling down well. She has a good gas fill in her right eye. I have reassured her. We will see her in about 10 days' time and we will keep you informed of any further progress."

50. On 21 August 2013, Mrs A was seen by Dr B in Dr C's clinic. Dr B dictated a further clinic letter to Dr E, in which he stated that Mrs A's right eye was settling down well and had about 40–50% gas fill. Again there is no mention of the adverse event.

51. Mrs A stated that she was sure that by the time she went for a follow-up appointment approximately 10 days after the surgery (21 August 2013), all was not well because she was not able to read even the largest letters on the test chart with her right eye. She said that Dr B expressed no concern, and did not admit to anything being amiss.

52. Dr B explained to Mrs A that she had a gas bubble in her eye, which temporarily would cause her vision to be worse than previously. He stated that he asked Mrs A to wait until her next appointment before finding out the visual outcome of the operation, and that after that he did not have a chance to see Mrs A again, as subsequently she attended the private rooms to see Dr C.

53. In response to my provisional opinion, Dr B stated:

> "I should have better informed [Mrs A] about the nature of the complication and the potential impact that this complication could have on her central vision. I am truly sorry about this. I would like to confirm that it was certainly not my intention to keep information from [Mrs A]. First of all, I have never faced a situation of such nature before. While I have observed and read about retinal trauma happening during membrane peel surgeries, a trauma at such proximity to fovea was something that I have never encountered. I agree that I should have explained to [Mrs A] of the severity of the complication. I sincerely hoped that the trauma would have not a serious and significant adverse effect on her vision. May be this caused in me not stressing the possibility of permanent visual loss to [Mrs A] while I discussed this with her immediately after surgery. It was more the need to wait for the gas to absorb and see the outcome of the surgery that caused me failing to fully explain the possibility of loss of vision to both patient and the GP. I have now learnt valuable lessons and have changed my practice to fully disclose all complications to patients and communicate to the GPs."

54. On 16 September 2013, Dr C saw Mrs A privately. Mrs A told HDC that she made an appointment to see Dr C privately because she wanted confirmation that damage had been done, and to ask him why he did not intervene earlier during the procedure. Dr C

[13] The summary is recorded as being amended by Dr B on 19 September 2013.

said that he explained to Mrs A what had happened. He cannot recall exactly what he said, but believes he gave her a similar explanation to Dr B. Mrs A told HDC that Dr C explained to her that the macular had been damaged. Mrs A stated that when she asked Dr C why he did not intervene sooner, he did not answer her but looked uncomfortable. Mrs A said that Dr C confirmed that her central vision had been damaged permanently during the surgery. Mrs A told HDC that she still cannot read with her right eye.

55. On 18 December 2013, Mrs A had a consultation with Dr C and Dr B. It is recorded that Mrs A's eye had settled from the operation and the gas had dissolved. It was also noted that there was a scar temporal to her fovea, and that they discussed with Mrs A that there was a guarded prognosis with respect to the vision of her right eye. Mrs A was booked for a further follow-up in six months' time.

56. Mrs A advised HDC that on 30 April 2014 she had a consultation with a consultant ophthalmologist at the Clinic to review her case, but the consultant was not able to offer any hope of improvement to Mrs A's vision.

ACC

57. Dr C stated that it was clear that Mrs A's vision would be permanently impaired as a result of the complication and so, following the consultation on 16 September 2013, he requested that Dr B arrange an ACC claim for Mrs A.

58. ACC accepted Mrs A's treatment injury. ACC subsequently deemed the treatment injury to be a 21% disability. Mrs A stated that soon she is going to need cataract surgery on her left eye, but is nervous about undergoing further surgery.

Informed Consent Policy

59. The DHB's Informed Consent Policy (September 2010) states that it applies to all students, and staff in recognised training programmes, as well as registered and employed clinical staff undertaking on-the-job training and further education.

60. The Informed Consent Policy specifically includes comment about a patient's involvement in teaching, and the presence of observers. The policy provides:

> "Patients have a right to consent to or decline involvement in teaching including the presence of observers during treatment or examination. The primary obligation is to provide the patient with sufficient information for them to give or withhold their informed consent. This includes being informed of the identity and qualifications of the provider. … Teaching of qualified staff occurs in a range of situations from undertaking of procedures under supervision to directly observing procedures to discussion of case studies. Teaching therefore covers both the provision of healthcare services and the use and disclosure of health information."

61. The Informed Consent Policy also provides that:

a) there should be an appropriate introduction of the staff member/student and identification of his or her role;

b) where practicable, the request to the patient to allow the involvement of the trainee should be made without the trainee staff member/student being present so the patient is able to freely decide whether or not to be involved in the teaching situation. However, where the trainee/student attends on their own they must obtain the patient's agreement; and
c) verbal discussions about involvement in teaching should be recorded in the clinical record for reference.

Responses to provisional opinion

62. Mrs A was given an opportunity to respond to the "information gathered" section of my provisional report. Where appropriate, her response has been incorporated above. In addition, she noted: "[W]hen the situation had been clarified [Dr B] did apologise to me. I give him credit for that."

63. Responses to my provisional opinion were received from Dr B, Dr C and the DHB. The responses have been incorporated, where appropriate, into the "information gathered" section above and in the section that follows.

64. In response to my provisional opinion, the DHB stated:

> "[The DHB] also accepts the finding that its Informed Consent Policy and actual practice, as exposed in this case, are not aligned and it must therefore review that policy, including related forms, once a final opinion is issued and provide training to all staff across all specialities to ensure future compliance in respect to that revised informed consent policy … [the DHB] accepts that in elective procedures where the option of a more experienced doctor exists and the patient has concerns about the procedure … or the procedure was of an unusually delicate nature, that the provision of additional information about the experience of the person would be practical within the consenting process (it does give rise to an issue of what should occur if the nominated doctor should be reallocated to an acute requirement)."

65. The DHB also stated that Dr B was an experienced ophthalmic surgeon and had every reason to believe he was competent to undertake the procedure. It stated: "[W]ithout the benefit of hindsight neither [Dr B] nor [Dr C] had any reason to believe that there was any increased risk inherent in having this operation undertaken by [Dr B] under direct supervision by [Dr C]."

66. In response to my provisional opinion, Dr B stated:

> "At the outset I would like to express my sincere apologies once again to [Mrs A] for any distress that might have been caused both during and after her eye surgery for removal of cataract and epiretinal membrane … As an Ophthalmic surgeon for [over a decade], I have always ensured high quality of patient care and have never previously faced a situation like this; I will ensure that this is not repeated."

67. In response to my provisional opinion, Dr C stated: "I acknowledge and accept the expert advice provided to you in this matter, as well as your findings."

Opinion — Introduction

68. Mrs A's complaint related to the information provided before and after her surgery on 13 August 2013. She was also concerned about the error that occurred during the surgery, which has caused permanent damage to her central vision.

69. My expert advisor, consultant ophthalmologist and vitreoretinal surgeon Dr Keith Small, advised me that epiretinal membrane surgery is extremely delicate and precise, and is intraocular microsurgery[14] at about the limit of fine manual dexterity. He stated that the centre of the macular in the presence of an epiretinal membrane is often about 1/5th of a millimetre in thickness, and the removal of an epiretinal membrane involves picking up and peeling away a taut, adherent, largely transparent membrane, of at most a few tens of micrometres in thickness, with minimal disturbance of the underlying retinal structures. He stated that a minor loss of control of an instrument, or a misjudgement of depth, has the potential to cause permanent harm to the delicate tissues of the central retina (the macular).

Opinion: Dr B

Informed consent — Breach

70. On 27 June 2013, Mrs A was seen by Dr D. Mrs A signed an "Agreement to Treatment" form, which documents the risks that were discussed with Mrs A as raised intraocular pressure, retinal detachment, or further surgery, infection or bleeding.

71. Dr D noted that he had told Mrs A to expect an improvement, but that her vision would never be as good as that of her other eye. There is no mention in Mrs A's clinical notes of the risks resulting from her surgery being performed by a surgeon in a training role, or of the risk of potential for damage occurring as a result of direct contact between the instrument and the retina. There is also no mention of who would be performing the surgery. Dr Small advised: "In my experience it would be unusual for this to be documented in the clinical notes but it would be normal to discuss this with the patient as part of the consent process."

72. Shortly after this consultation, Dr D left the DHB and was replaced by Dr B.

73. On 13 August 2013, Mrs A presented at the Clinic for the procedure. Mrs A stated that prior to going into theatre she was visited by Dr B, and she understood that he was going to observe during the surgery, and that Dr C was to be the operating surgeon. Mrs A's husband was also present during this discussion, and told HDC that he clearly recalls Dr B saying that he would be observing the surgery. Dr B stated that he saw Mrs A in the ward during the preoperative ward round, introduced himself, and explained that he would be one of the surgeons working with Dr C that day. Dr B stated that he went through the risks and benefits of the surgery, including possible loss of vision and need for further treatment, but he did not document these

[14] Surgery inside the eye using a microscope.

discussions. Dr B recalls telling Mrs A that he would be the surgeon operating, together with Dr C. He stated that he did not tell Mrs A that he would be an observer.

74. Dr B also stated that Mrs A was under local anaesthetic during the procedure, and so was fully aware throughout the surgery that he was operating on her with Dr C supervising. There is no evidence that Mrs A was aware of Dr B's professional status. I do not think it is sufficient to assume that Mrs A agreed to have the operation performed by a trainee because she failed to express an objection once the procedure was under way.

75. Overall responsibility for ensuring that Mrs A was provided with sufficient information about the proposed treatment and obtaining informed consent lay with Dr C. As stated in a leading text: "[O]rdinarily each member of the team of doctors will be deemed to have separately undertaken the care of the patient when so assigned by the responsible consultant. However, the consultant as leader of the team remains responsible throughout …"[15] Dr C explained that the nature of the vitreoretinal service is such that there is not time for him to discuss and document informed consent individually with all his patients. Dr Small advised that, in those circumstances, it was reasonable that a senior ophthalmology trainee, who is at an advanced level of training and experience, should be involved in this delegated responsibility. I accept Dr Small's advice.

76. I have been provided with conflicting evidence as to the information Dr B provided to Mrs A about which surgeon would be operating. Mrs A was under the impression that Dr C would be performing the surgery personally. Mrs A's husband said that there was no discussion about who would be operating, and that he took it for granted that it would be Dr C. Dr B recalls telling Mrs A that he would be the surgeon operating together with Dr C.

77. It appears that Dr B did not make it sufficiently clear to Mrs A that he would be performing the surgery under Dr C's direct supervision. As I have stated previously:[16]

> "[A] patient considering surgery always has the right to receive the information that a reasonable patient in that patient's circumstances would expect to receive … this will include information as to who will be performing that surgery."

78. I have considered the DHB's submission that Dr B was an experienced ophthalmic surgeon and that there was no reason for Dr B to believe there was an increased risk in him performing the operation under direct supervision by Dr C. However, Dr Small advised me that a minor loss of control of an instrument or a misjudgement of depth has the potential to cause permanent harm to the delicate tissues of the central retina (the macula). He advised that it is understandable that such an injury is more likely in the hands of a relatively inexperienced surgeon, and this therefore represented an increased risk to which Mrs A was exposed by virtue of having her surgery performed by a surgeon in a training role. I accept Dr Small's advice.

[15] Kennedy, I & Grubb, A. *Medical Law* (London: Butterworths, 2000), p281.
[16] Opinion 09HDC01565, 5 September 2012, available at www.hdc.org.nz.

79. I note that the Informed Consent Policy requires that any verbal discussion about clinical teaching should be recorded in the clinical notes for reference, and that patients are not to be involved in clinical teaching without them being fully informed and freely giving consent. Despite this requirement, there is no mention in Mrs A's clinical notes of her being informed that a trainee would be undertaking her surgery. Dr B accepted that he did not document the discussion that he had with Mrs A during the preoperative ward rounds. Dr Small stated: "Because such documentation is not present in [Mrs A's] case it is not possible to reconcile the different accounts of what she was advised about the role of the [senior ophthalmology trainee] during the informed consent process prior to her surgery."

80. Baragwanath J stated in his decision in *Patient A v Nelson Marlborough District Health Board*[17] that it is through the medical record that healthcare providers have the power to produce definitive proof of a particular matter (in that case, a patient had been specifically informed of a particular risk by a doctor). Health professionals whose evidence is based solely on their subsequent recollection (in the absence of written records offering definitive proof) may find their evidence discounted.

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

82. I find that Dr B did not explain to Mrs A sufficiently that he was a trainee and that he would be carrying out the surgery, and did not inform her of any increased risks in having such delicate surgery performed by a trainee. I make this finding specifically in relation to the facts of this case. Accordingly, in these circumstances I find that Dr B breached Right 6(1)(b) of the Code. It follows that Mrs A was not in a position to give informed consent and, accordingly, Dr B also breached Right 7(1) of the Code.

Standard of care — Adverse comment

83. Dr B began the surgery and completed the vitrectomy and staining of the membrane, and used the Tano scraper to create an edge on the membrane. He then began peeling the membrane with forceps. Dr C said that as part of his usual supervision practice, he reminded Dr B a couple of times to stay as far away from the fovea as possible. Dr C stated that he was not saying this because he was alarmed, and said that at this stage Dr B was peeling the membrane quite competently, and he was guiding and advising Dr B.

84. Shortly thereafter, Dr B touched the retina with the Tano scraper. Dr B stated that he does not recall pressing on the retina with pressure, and thinks it was a brief contact to the fovea while positioning the instrument. Dr C stated that for no obvious reason Dr B placed the Tano scraper directly on the fovea. Dr C said that the action took less than a second, and occurred too quickly for him to prevent it. He stated:

[17] *Patient A v Nelson Marlborough District Health Board* (HC BLE CIV-2003-406-14, 15 March 2005).

> "I immediately said 'stop' and took over, but unfortunately the damage was done in that fraction of a second. This event was totally unpredictable; in all my years of teaching or practice I haven't ever seen anyone touch the fovea during any procedure. I can only speculate that it was a momentary lapse in concentration on [Dr B's] part. I have seen [senior ophthalmology trainees] touch other parts of the retina by mistake in the past, and I have also done so myself. However, almost invariably this is not due to putting the instrument in the wrong place but by pressing too hard in the correct place (i.e. misjudging the depth), as one can see where to place it."

85. Dr C stated that most complications caused by trainees can be fixed easily by the supervising surgeon. However, this was something that could not be remedied or improved. He said: "I have never seen this happen before and doubt I will ever see it again in the future."

86. Dr Small advised me:

> "Contact between an instrument and the fovea during epiretinal membrane surgery is unlikely and avoiding such contact is a standard principle of such surgery. However it remains a risk due to the great delicacy of this type of surgery and the very fine scale and vulnerability of the tissues involved."

87. Dr Small advised that the standard of care provided to Mrs A by Dr B during the operation was appropriate for a practitioner in his training role, and that the injury was caused by an inadvertent slip. Dr Small stated: "I am confident that he had sufficient training and a record of sufficient surgical competence that it was appropriate for him to be performing [Mrs A's] operation under supervision."

88. However, Dr B was aware that the surgery he was undertaking was extremely delicate and demanded intense concentration. Dr B was reminded at least twice by Dr C to stay as far away from the fovea as possible. Despite these reminders, Dr B inadvertently touched the fovea with the Tano scraper. In my view, this is suboptimal.

89. Dr B has accepted my finding. He told HDC that he "will continue to ensure high standard of care for all [his] patients and will endeavour to avoid such an event at all costs."

Disclosure following surgery — Breach

Disclosure of adverse event

90. Mrs A said that she asked to speak to the doctor before she left the theatre. She expressed concern to Dr B about Dr C's conversation with him during the procedure, but was told by Dr B that there was nothing to worry about. Dr B stated that he spoke to Mrs A straight after the surgery, and explained that there was an unexpected retinal trauma and bleeding, and that the membrane had been quite adherent and difficult to peel. He said that he explained to her that there were areas of retinal touch during the procedure and, as a result, they had to place a bubble of gas in her eye to help the healing of her macular. Dr C said that Dr B immediately explained the events and next steps to Mrs A. Dr C does not recall exactly what Dr B told Mrs A, and said that

he may not have heard the entire conversation. He also said that Dr B saw Mrs A the next day, as was routine.

91. Dr Small advised: "I believe it would have been more appropriate for [Dr B] and/or [Dr C] to explain the seriousness of the situation to [Mrs A] somewhat more thoroughly at this early stage following the operation." I agree.

92. Mrs A stated that by the time she went for a follow-up appointment 10 days after the surgery, she was aware that all was not well because she was not able to read even the largest letters on the test chart with her right eye. However, she told HDC that Dr B expressed no concern, and did not admit to anything being amiss.

93. The Medical Council of New Zealand guideline "Disclosure of Harmful and Adverse Event" (MCNZ Disclosure Guideline) (December 2010) states that when a patient is harmed while receiving medical treatment, MCNZ expects that the patient's doctor will advise the patient of the facts of the harm in the interests of an open, honest and accountable professional relationship. The MCNZ Disclosure Guideline requires that the disclosure be made in a timely manner, and states that it is appropriate to make the initial disclosure as soon as practical, with a more detailed discussion with the patient to follow once the team has had an opportunity to meet and assess the circumstances that led to the patient being harmed. This will also give time for the patient to think about the situation and provide an opportunity to ask for more information. The MCNZ Disclosure Guideline requires that the doctor document in the patient's clinical notes details about the nature of the harm, and any subsequent action, including disclosure to the patient.

94. MCNZ recommends that the patient's clinical notes include who was present during the disclosure, what was disclosed, the patient's reaction, and any issues regarding continuity of care. The MCNZ Disclosure Guideline further states: "[I]f the harm occurred in secondary or tertiary care you must inform the patient's general practitioner."

95. I do not accept that Dr B provided Mrs A with a clear explanation of what had occurred. The situation was obviously serious and unusual, as is evidenced by Dr C's concerned reaction. Dr B had a professional duty to disclose full and accurate information to Mrs A in accordance with his individual duty of care. Dr B has accepted that he should have better informed Mrs A about the nature of the complication and potential impact the complication could have on her central vision. He told HDC that he is truly sorry for this. Dr B told HDC that it was not his intention to keep information from Mrs A, and that he has altered his practice to ensure full disclosure of complications to patients and to communicate with GPs.

Recording adverse event

96. Dr B recorded in Mrs A's clinical notes that the epiretinal membrane peel caused punctuate retinal haemorrhages. Dr Small advised that such haemorrhage is a minor and relatively benign occurrence during otherwise uneventful epiretinal membrane peeling and that, therefore, the statement in the operation record does not record the nature of the injury adequately. Dr Small stated that the information in the medical notes of the significance of the injury to Mrs A's central vision was inadequate.

97. The only reference to the adverse event was in the discharge summary dated 13 August 2013, where Dr B recorded: "Area of retinal haemorrhage and swelling at macula due to contact between membrane peeling forceps and retina while attempted peeling of the epiretinal membrane." I note that the discharge summary is recorded as being amended on 19 September 2013. On 14 August 2013, Dr B dictated a clinic letter addressed to Dr E and, in that letter, there is no mention of the adverse event. A further letter to Dr E on 21 August 2013 again does not refer to the adverse event.

98. Mrs A stated that, at her private appointment with Dr C on 16 September 2013, he confirmed that during the surgery her eye had been damaged permanently.

Conclusion

99. In my view, Dr B failed to record the adverse event adequately, and did not disclose the event to Mrs A or her GP appropriately. Accordingly, Dr B failed to comply with professional standards and breached Right 4(2) of the Code. Dr B has accepted my finding.

Opinion: Dr C

Consent — Adverse comment

100. Dr C stated that because of the nature of the vitreoretinal service, he is unable to discuss and document informed consent individually with all of his patients. The DHB's Informed Consent Policy states that patients have a right to consent to or decline involvement in teaching. The Policy requires that, where practicable, the request to the patient to allow a trainee to be involved in his or her treatment should be made without the trainee being present. As noted above, I am concerned that Mrs A was not sufficiently informed that Dr B was a trainee and that he would be carrying out the surgery, and about the increased risks in having such delicate surgery performed by a trainee. Although I accept that Dr C cannot obtain informed consent from all patients personally, in my view, in the case of a trainee carrying out surgery that can increase the risk of harm to the patient, the responsibility is on Dr C as the supervising ophthalmologist to ensure that appropriate informed consent is obtained. Dr C has accepted my finding.

Disclosure — Breach

101. It is clear that Dr C was supervising Dr B's surgery carefully and, as soon as the adverse event occurred, Dr C took over the surgery. In that regard, I accept that the standard of care provided by Dr C was satisfactory.

102. Under Right 6(1) of the Code, Mrs A had a right to information that a reasonable consumer, in her circumstances, would expect to receive. This included the right to be properly informed about the adverse event. In my view, Dr C had a responsibility, as Dr B's supervisor, to ensure that this occurred. Dr C stated that usually he insists that senior ophthalmology trainees explain any complications to patients themselves because that is an important part of their learning experience. I note that the MCNZ Disclosure Guidelines require that the senior doctor responsible for the patient's care

should disclose the harm to the patient. The MCNZ Disclosure Guidelines also state that if the harm occurred during a procedure undertaken in a team environment, the team should meet to discuss the incident.

103. In my view, it was Dr C's responsibility to ensure that open disclosure occurred promptly and in a manner consistent with the MCNZ Disclosure Guidelines. Accordingly, by failing to ensure that Mrs A was properly informed about the adverse event, I consider that Dr C breached Right 6(1) of the Code.

104. I also note that the MCNZ Disclosure Guidelines require that the doctor document in the patient's clinical notes details about the nature of the harm and any subsequent action, including disclosure to the patient. The only reference to the adverse event was recorded by Dr B in the discharge summary dated 13 August 2013. I am critical that Dr C did not ensure that the adverse event was documented in Mrs A's clinical notes adequately. Dr C has accepted this finding.

Opinion: The DHB

Systems — Adverse comment

105. Mrs A stated that she understood that Dr B would be observing the surgery but not performing it. Mrs A's husband told HDC that he clearly recalls Dr B saying that he would be observing the surgery, that there was no discussion about who would be operating, and that he took it for granted that it would be Dr C. In contrast, Dr B recalls introducing himself to Mrs A and telling her that he would be the surgeon operating, with Dr C supervising. Dr B said he did not tell Mrs A that he would be an observer.

106. The DHB's Agreement to Treatment form does not include provision for recording patient consent to the involvement of doctors in training in the procedure. As a result, there is no documentation to record what information Mrs A was given about who would be performing her surgery, or the increased risk of having a trainee perform the surgery. Dr Small advised me that omitting any reference to the role of trainees in a patient's treatment from the Agreement to Treatment form is an unfortunate omission.

107. Dr Small stated that training is a very common and extremely important part of healthcare that inevitably exposes patients to some increased risk of complications. He stated: "Consequently, it seems to me that the discussion of how the training interaction and its attendant risks will be managed should be a required part of the consent process justifying specific mention in the form signed by the patient and their provider."

108. I accept that, as Mrs A was not under general anaesthetic, informed consent to the procedure being performed by a trainee was not required to be in writing. However, I agree with Dr Small that in these circumstances an adequate record of involvement of trainees should be maintained. I note that this is required by the Informed Consent Policy.

109. Dr C stated that he was not able to see patients individually to obtain consent because of the pressures of work. However, the Informed Consent Policy requires that consent to the presence of a trainee should be obtained where practicable without the trainee being present. In response to my provisional opinion, the DHB stated that it accepts "the finding that its Informed Consent Policy and actual practice, as exposed in this case, are not aligned …". In my view, [the DHB] has a responsibility to have systems in place to ensure that it is practicable to comply with its policies. I am pleased that [the DHB] has agreed to comply with my recommendations (outlined below) and will review its Informed Consent Policy including "related forms and provide training to all staff across all specialities to ensure future compliance in respect to that revised informed consent policy …".

Recommendations

Dr B

110. I recommend that Dr B:

a) Provide a written apology to Mrs A within three weeks of the date of this report. The apology is to be sent to HDC for forwarding to Mrs A.

b) Attend refresher training courses on informed consent and open disclosure, and provide evidence to HDC that this has been done, within four months of the date of this report.

Dr C

111. In response to the proposed recommendations in my provisional opinion, Dr C provided a written apology for forwarding to Mrs A.

112. In my provisional opinion, I also recommended that Dr C attend refresher training courses on informed consent and open disclosure. In response to my provisional opinion, Dr C advised that he has sought placement on a course on mastering adverse outcomes. He also arranged alternative tuition on informed consent and open disclosure. Dr C also advised that he has commenced a course regarding communication after an adverse event, and provided evidence to HDC of his attendance at the first session.

113. I recommend that Dr C provide evidence to HDC that the above-mentioned training has been completed, within four months of the date of this report.

The DHB

114. I recommend that, within four months of the date of this report, the DHB:

a) Review the "Agreement to Treatment" form with a view to including the role of trainees during surgery, and provide to HDC a copy of the updated form.

b) Provide ophthalmology service staff with training on informed consent and open disclosure, in particular the role of senior members of multidisciplinary teams during disclosure of an adverse event.

c) Audit records in the ophthalmology service to ensure that a record of consent to the involvement of trainees has been maintained.

Follow-up actions

115. • A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Medical Council of New Zealand and to the Royal Australian and New Zealand College of Ophthalmologists, and they will be advised of the names of Dr B and Dr C.

• A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to DHB Shared Services and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A — Independent expert advice to the Commissioner

The following expert advice was obtained from Dr Keith Small, Mb ChB, FRANZCO, who works as a consultant ophthalmologist and vitreoretinal surgeon:

> "I have been asked to provide an expert opinion to the Health and Disability Commissioner on the above case and have read and agree to follow the Commissioner's Guidelines for Independent Advisors.
>
> I am Dr Keith Small, Mb ChB, FRANZCO, and I work as a consultant ophthalmologist and vitreoretinal surgeon at Wellington Hospital (Capital and Coast District Health Board) as well as in private practice (The Terrace Eye Centre, Wellington). I am a fellowship trained vitreoretinal specialist having completed two Vitreoretinal fellowships in the United Kingdom. I am actively involved in teaching vocational trainees in ophthalmology and was previously the NZ Director of Training for the Royal Australian and New Zealand College of Ophthalmologists.
>
> I am writing in response to your letter dated 19 June 2014 and will answer each of the eight questions posed as well as the request for further comments.
>
> I have read and considered the information provided by your office regarding the complaint by [Mrs A]. The complaint regards damage to the vision of her right eye during surgery (cataract extraction and IOL [intraocular lens], vitrectomy and epiretinal membrane peel) performed at [the Clinic] on 13 August 2013 by [Dr B] and his supervising consultant [Dr C].
>
> In her complaint, [Mrs A] raises several concerns:
>
> — She believed prior to the operation that [Dr B] was going to be observing the surgery rather than performing the operation himself
> — She understood during the peeling of the epiretinal membrane that [Dr C], who was scrubbed and supervising at close hand was becoming concerned about [Dr B's] technique but did not take over the surgery before damage to her retina had occurred
> — That permanent damage to her central vision was caused by the operation which has in her own words had a devastating effect on her life
> — That there was inadequate communication with her immediately after the operation from the staff involved and that [Dr B] did not admit to any error having occurred when she saw him post-operatively
> — That she believes [Dr B] is incompetent
>
> I will endeavour to address all of these concerns in the process of answering the specific questions in your letter.
>
> 1. **Overall standard of care provided to [Mrs A] by [Dr B]**
>
> I have reviewed [Dr B's] curriculum vitae and the comments from [Dr G] and [Dr C] about his background and his selection and introduction [to the post]. I am confident that he had sufficient training and a record of sufficient surgical

competence that it was appropriate for him to be performing [Mrs A's] operation under supervision.

It is clear that [Dr B] met [Mrs A] prior to the operation and introduced himself to her, and he states that he reiterated the risks of the surgery with her which would have been appropriate given that he had not been involved in the process of formal written informed consent for the surgery, this having been done at the time [Mrs A] was assessed for the surgery by the previous [senior ophthalmology trainee], [Dr D].

There is a notable and important discrepancy between [Mrs A's] stated expectations of [Dr B's] role in the surgery and the expectations of [Drs B and C]. [Mrs A] states that she believed [Dr B] was only going to be observing her surgery whereas in his role as [senior ophthalmology trainee], where he was being trained to perform such surgery, both he and [Dr C] were expecting him to be performing at least some of the surgery himself. It seems clear to me that this matter was not made sufficiently clear to [Mrs A] though the responsibility for this is somewhat complex and cannot be borne by [Dr B] alone. I will discuss this matter further below.

With regard to the surgical procedure itself, epiretinal membrane surgery is extremely delicate and precise, being intra-ocular microsurgery at about the limit of fine manual dexterity. The centre of the macula in the presence of an epiretinal membrane is often about one fifth of a millimetre in thickness and the removal of an epiretinal membrane involves picking up and peeling away a taut and adherent, largely transparent membrane of at most a few tens of micrometres in thickness with minimal disturbance of the underlying retinal structures. A minor loss of control of an instrument or a misjudgement of depth has the potential to cause permanent harm to the delicate tissues of the central retina (the macula). It appears that this is what happened in [Mrs A's] case. From [Dr C's] account it appears that such a slip occurred with direct contact between the Tano membrane scraper (an instrument used to elevate an edge of the epiretinal membrane) without warning.

It is only possible to speculate if this damage was avoidable and it is a known risk of such delicate surgery. It is however understandable that such an injury is more likely in the hands of a relatively inexperienced surgeon and this therefore represents an increased risk to which [Mrs A] was exposed by virtue of having her surgery performed by a surgeon in a training role. Again, this raises questions about the adequacy of the informed consent process that I will address below.

From [Dr C's] account it was clear that he was aware of the significance of the injury to [Mrs A's] macula that had occurred during the surgery and that he regarded it as very unusual. The notes written in the operation record by [Dr B] however appear to state only that the epiretinal membrane peel itself caused 'punctate retinal haemorrhages'. Such haemorrhage is a minor and relatively benign occurrence during otherwise uneventful epiretinal membrane peeling. Thus, the statement in the operation record does not adequately record the nature of the injury. Also, although both [Dr C] and [Dr B] state that [Dr B] gave [Mrs A] an explanation immediately after the surgery that a complication had occurred,

she herself does not recall such an explanation then or at her subsequent appointment with [Dr B] and did not understand that her vision was likely to have been adversely affected. I note also that in the letter to [Mrs A's] general practitioner written by [Dr B] the day after the operation, no mention of the damage to her macula was made. It may be [Dr B] was hoping the injury would not limit [Mrs A's] vision significantly but this is at odds with [Dr C's] account of the injury as he observed it at the time of the surgery.

By my assessment, the standard of care provided to [Mrs A] by [Dr B] prior to and during the operation was appropriate for a practitioner in his training role. In stating this I believe there is evidence the injury was caused by an inadvertent slip in the context of extremely delicate surgery and not by negligence or ill intent. However he failed to adequately record the nature and severity of the macular injury caused by the surgery and appears not to have ensured that [Mrs A] was given an effective explanation of the problem and its significance.

2. The Standard of Supervision [Dr C] provided to [Dr B]

[Dr C] was aware of the level of [Dr B's] training and surgical experience prior to [Mrs A's] operation and was scrubbed and paying close attention to the operation throughout, being ready to intervene and advising [Dr B] during the operation. As soon as the injury occurred [Dr C] took over the surgery to ensure the remainder of the surgery was as safe and efficient as possible. In these respects the standard of supervision provided by [Dr C] was appropriate.

In my opinion, [Dr B] was sufficiently senior to have been relied upon to complete the operation record accurately and I do not believe the understatement of the injury in this record reflects on the adequacy of [Dr C's] supervision. However, [Dr C] clearly recognised that the injury was likely to limit [Mrs A's] chances of recovering central vision and therefore he had a responsibility as [Dr B's] supervisor to ensure that [Mrs A] was properly informed about the nature of the complication. From [Mrs A's] account of the events it appears more could and should have been done in this regard.

3. Are epiretinal membranes resistant to peeling from the retina?

Epiretinal membranes occur in a number of different retinal conditions. Most often, as in [Mrs A's] case they represent the proliferation of a fine contractile membrane of tissue akin to a membrane of scar tissue that grows across the macula over a short space of time in response to an often unidentified stimulus. In lay terms the situation is as if some otherwise insignificant 'wear and tear' disturbance of the retina related to ageing provokes an excessive and inappropriate attempt by the body's repair mechanisms to 'heal the damage' with a membrane of scar tissue. This membrane remains to some extent adherent to the surface of the macula and exerts stress on the underlying tissues as it contracts.

The degree to which these membranes are attached to the macular surface varies a lot from case to case. Some are relatively loosely attached and can rarely even

become detached spontaneously by traction from the overlying vitreous gel. Such membranes require little force when being surgically peeled from the retina though this surgery is always very delicate and requires fine controlled movements of the instruments used. At the other end of the spectrum, some epiretinal membranes can be tightly adherent to the macular surface. These are considerably more difficult to remove and can require repeated attempts at peeling and a greater disturbance of the retinal surface even in the hands of a very experienced and proficient surgeon. Even with sophisticated modern imaging technology, it is often impossible to predict how difficult an epiretinal membrane will be to peel prior to the actual operation.

[Dr B] described [Mrs A's] epiretinal membrane as being 'resistant to peeling'. I cannot dispute this except to point out that the more experienced a VR surgeon becomes the more manageable such cases might seem and the membrane may have seemed less resistant to peeling to a more experienced surgeon such as [Dr C]. This is not to suggest that [Dr B] was experiencing an unreasonable degree of difficulty during the initial attempts to peel the membrane and both his account and that of [Dr C] suggest that [Dr C] would have taken over the surgery at an earlier stage if that had been the case.

I have no difficulty accepting that [Mrs A's] epiretinal membrane was 'resistant to peeling' by [Dr B's] assessment. This was a situation that reasonably could not have been anticipated prior to the surgery and within the range of surgery [Dr B] would be expected to undertake with supervision in his position as [senior ophthalmology trainee].

4. What is the likelihood of an instrument touching the fovea during epiretinal membrane surgery?

As mentioned above, epiretinal membrane surgery approaches the limits of surgical delicacy. The tissue being removed is extraordinarily fine and the tissue of the underlying macula (of which the very centre is termed the fovea) is thin, transparent, intricately organized and susceptible to permanent damage if directly disturbed.

A normal fovea without an overlying epiretinal membrane measures approximately 170 micrometres in thickness with the thickest parts of the surrounding macula being roughly twice this thickness. During epiretinal membrane peeling delicate instruments held directly by the surgeon and used within the eye while viewed through special lenses under magnification with an operating microscope are used to elevate and then peel away a membrane which might be at most only 10 or 20 micrometres in thickness from the surface of the macula while the surgeon watches carefully to ensure minimal disturbance of the macula and fovea occurs.

Because the fovea is the thinnest, and the most highly organized and visually important part of the retina it is generally not safe to directly touch the foveal surface during surgery on the retina. Epiretinal membranes are picked up at a safe distance from the fovea and the elevated edge of the membrane is grasped with

forceps and peeled away with every effort taken to minimize the disturbance of the fovea itself.

It seems very clear to me that the direct contact between the Tano instrument and the fovea during [Mrs A's] operation was the result of an inadvertent slip or movement that was entirely unintentional. Although such a slip was more likely to occur in relatively inexperienced hands I do not believe it was due to a fundamental problem with surgical technique or approach.

Contact between an instrument and the fovea during epiretinal membrane surgery is unlikely and avoiding such contact is a standard principle of such surgery. However it remains a risk due to the great delicacy of this type of surgery and the very fine scale and vulnerability of the tissues involved.

5. Would [Dr C] have had time to intervene?

As mentioned, it seems clear from all accounts of the events that [Dr C] was paying close attention to the surgery up to and including the moment of injury. Although [Mrs A] recalls [Dr C] advising [Dr B] on his technique during the operation this is a normal part of careful surgical supervision and it seems likely that it reflects the fact she was not expecting a trainee to be performing the surgery rather than it reflecting on the adequacy of the supervision provided.

Accepting therefore, as I believe is reasonable, that [Dr C] had no significant cause for concern prior to the injury, and accepting that the injury resulted from a momentary slip, **I do not believe [Dr C] had any opportunity to intervene and prevent the injury from occurring.**

6. The information provided to [Mrs A] regarding the procedure and which individual would be performing the procedure

With regard to her care within [the eye department], [Mrs A] had originally been seen [by Dr F], a consultant ophthalmologist, on 23 March 2013. He advised her at the time that she would be likely to benefit from epiretinal membrane peeling for her right eye at the time of cataract surgery although there was some evidence to suggest her right eye had suffered a retinal vein occlusion which might limit the visual benefit such an operation would offer. [Dr F's] notes indicate that [Mrs A] was seen by [Dr D] ([Dr B's predecessor]) at the time of this initial consultation who agreed that it was appropriate to place her on the waiting list for the surgery.

On 27 June 2013 [Mrs A] signed the standard the DHB 'Agreement to Treatment' form with [Dr D]. This form states that she agreed to undergo 'Right eye cataract and epiretinal membrane under LA'. The standard wording of the form states that the doctor signing the form has explained the reasons and the expected risks to the patient. It also states that the patient has had adequate opportunity to ask questions and that these have been answered to her satisfaction.

[Dr D's] hand written notes from 27 June indicate that [Mrs A] was advised about the likelihood her vision would not improve to the level of that of the other eye. He also notes she was advised of the risks of raised intra-ocular pressure, retinal

detachment requiring further surgery, infection and bleeding and that [Mrs A] wished to proceed with the surgery. There is no mention of who would be performing the surgery. In my experience it would be unusual for this to be documented in the clinical notes but it would be normal to discuss this with the patient as part of the consent process.

It is not clear what [Mrs A's] understanding of the role of the [senior ophthalmology trainee] was prior to her operation. She states clearly in her letter of complaint that she understood [Dr B] would be observing the surgery and not participating in it, whereas the position of [senior ophthalmology trainee] is one in which a surgeon who already has significant proficiency with eye surgery is training to assess and treat complex retinal conditions — a large part of which involves training in surgical techniques.

In [Dr B's] letter of 13 February to the HDC he refers to introducing himself to [Mrs A] prior to the surgery. He states that he clearly recalls telling [Mrs A] that he would be the surgeon operating with [Dr C] supervising. Later in the same letter he reiterates that he is certain he explained his involvement in the surgery to [Mrs A] prior to the procedure and that she made no objection to this.

[The DHB's] 'Agreement to Treatment' form makes no mention of the involvement of doctors in training in the procedure to which the patient is consenting (I will discuss this further below) and there is therefore no documentation prior to the surgery to record what information [Mrs A] was given about who would be performing her surgery.

In the clinical records there is nothing to suggest the information given to [Mrs A] about the procedure and its risks was inadequate. However, there is a clear difference between what [Mrs A] recalls being advised prior to the surgery about who would be doing the operation and what [Dr B] recalls telling her. As I will discuss below, it seems to me that the informed consent documentation does not cover this issue adequately.

7. The informed consent process in this instance.

There is clear documentation in [Dr D's] notes that the potential risks of the surgery were discussed in some detail with [Mrs A] on the day she signed the 'Agreement to Treatment' form, effectively the consent form used by [the DHB]. The nature of this form is such however that no specific mention is made of the involvement in the surgery of a doctor who is in the process of training.

[The DHB has] provided the 'Informed Consent' section of their Board Policy Manual which contains a section on 'Teaching and Observers'. This policy document states that when teaching occurs involving 'someone not qualified to undertake the procedure on their own, an explanation is to be given to the patient and their explicit permission sought'. The document also states that 'where practicable the request to the patient should be made without the trainee staff member/student present so the patient is able to freely decide whether or not to be involved in the teaching situation'.

[Dr C] has explained that the nature of the vitreo-retinal service is such that there is not time for him to individually discuss and document informed consent with all his patients. It is therefore very reasonable that the [senior ophthalmology trainee], who is at an advanced level of training and experience, should be involved in this delegated responsibility but it falls short of the Board's ideal standard of informed consent for a patient's involvement in teaching as noted above.

In my opinion, the omission from [the DHB's] 'Agreement to Treatment' form of any reference to the role of trainees in a patient's treatment is an unfortunate omission. There will of course be many specific features of any individual informed consent discussion that cannot be included in a generic form however training is a very common and extremely important part of health care that inevitably exposes patients to some increased risk of complications. Consequently, it seems to me that the discussion of how the training interaction and its attendant risks will be managed should be a required part of the consent process justifying specific mention in the form signed by the patient and their provider.

I note that in at least some other New Zealand DHBs the form signed by a patient in which they formally request and therefore consent to treatment does include specific mention of training during the procedure.

Because such documentation is not present in [Mrs A's] case it is not possible to reconcile the different accounts of what she was advised about the role of the [senior ophthalmology trainee] during the informed consent process prior to her surgery.

In my opinion, the informed consent process with regard to [Mrs A's] surgery was adequate in most respects but inadequate in its documentation of the role of teaching during her surgery. This is most importantly due to the omission of specific mention of training from [the DHB's] 'Agreement to Treatment' form. This form appears to be the standard form used for documenting informed consent for procedures in [the DHB] and reflects an issue wider than just the discussions between [Mrs A] and her surgeons.

There is an irreconcilable difference between [Mrs A's] and [Dr B's] recollections of the information she was given prior to the surgery about supervised teaching during the procedure.

8. The standard of follow up care provided after the adverse event.

In his letter to the HDC, [Dr B] states that he spoke to [Mrs A] straight after the surgery and explained that there had been unexpected trauma to the retina during the surgery necessitating the use of a gas bubble in her eye and the requirement that she position face-down for a period after the operation. [Dr C's] letter supports this account but [Mrs A] recalls that she was told immediately after the procedure that there was nothing to worry about when she asked about the nature of the discussion during the operation. She does recall the advice to position face-down for five days, which of course was not easy for her.

As mentioned above, the operation note understates the significance of the injury to the fovea which is at odds with [Dr C's] written comment that 'I have never seen this happen before and doubt I will ever see it again in the future'. It seems likely therefore that [Dr B] was hopeful that the damage to [Mrs A's] vision would not be as great as was likely to be the case. I believe it would have been more appropriate for [Dr B] and/or [Dr C] to explain the seriousness of the situation to [Mrs A] somewhat more thoroughly at this early stage following the operation.

Similarly, [Mrs A's] complaint states that [Dr B] expressed no concern about anything being amiss when she was seen at the first post-operative visit. I note that at this point there was still a large amount of gas in her eye which alone would have accounted for a marked reduction in her vision so there was not necessarily any clinical evidence beyond the knowledge of what had happened in theatre to confirm the seriousness of the damage to her central vision at that stage.

[Dr C], when he saw [Mrs A] privately a month after the operation was able to confirm that there was permanent damage to her central vision and it appears clear that he gave her a full explanation of the situation at that point.

The documentation in the medical notes immediately following the operation of the significance of the injury to [Mrs A's] central vision was inadequate. It appears that a more careful explanation of the complication and its significance should also have been given to [Mrs A] by [Dr B] or [Dr C] or both. In other respects her post-operative care was appropriate, including the use of gas and face-down positioning, which was to minimize the risk of more extensive visual damage from the injury.

Other Comments

The injury to [Mrs A's] vision, whilst extremely regrettable and devastating to her is a recognised risk of epiretinal membrane surgery due to the extreme delicacy of the procedure and of the tissues involved. From my reading of the records there is nothing to suggest it was the result of carelessness or the lack of due care. It was appropriate for [Dr B] to be performing this type of surgery under supervision and [Dr C's] careful attention and advice during the procedure as well as his readiness to take over the surgery immediately after the injury occurred were all very appropriate.

The lack of mention in the 'Agreement to Treatment' form of the role of training during surgery is in my opinion inappropriate. In a teaching institution such as this patients both benefit from and are put at some increased risk from the involvement of trainees in their care and this should be specifically addressed as part of the consent process to measure up to the requirements of [the DHB] policy document on informed consent. [Drs D, B and C] all had some responsibility to acquaint [Mrs A] about the role of the [senior ophthalmology trainee] and there is a discrepancy between [Mrs A's] and the doctors' accounts of what was discussed about this pre-operatively. The absence of mention of this from the consent document somewhat

encourages this matter to be inadequately dealt with or indeed omitted from pre-operative discussions with the patient and should be addressed.

In my opinion, [Dr B's] failure to adequately document the severity of the complication at the time and to explain it adequately to [Mrs A] most likely represents his hope that the visual damage would not be severe. Nonetheless, this does represent a departure from the appropriate standard of care in this situation. Without making light of the severe outcome for [Mrs A], I consider that such departures from the appropriate standard of care are likely to be unfortunately common within the very busy healthcare system and I also note that [Dr B] has demonstrated a willingness to learn from this situation. Consequently, by my assessment this represents a mild departure from the appropriate standard of care.

In my opinion, [Dr C] also had some responsibility to ensure adequate documentation of the event had occurred and that a careful and honest explanation of the likely consequences was given to [Mrs A] shortly after the surgery. This also represents a departure from the standard of care [Mrs A] should have reasonably expected. I consider [Dr C's] departure from the appropriate standard of care is mild.

I hope it is clear that my assessment of the severity of the above departures from the appropriate standard of care concerns the documentation and communication involved and does not reflect the severity of impact of the surgical complication itself.

I hope that I have addressed all of [Mrs A's] concerns in the above advice. I do not have any reason to agree with her that [Dr B] is incompetent and I note from his response to the complaint that he has changed his practice significantly in response to this event.

Dr Keith Small FRANZCO September 2014"