Ophthalmologist, Dr A

Registered Nurse, RN B

Laser Eye Surgery Clinic

A Report by the

Health and Disability Commissioner

(Case 16HDC00083)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. On 23 February 2012, Mrs C underwent laser eye surgery at a laser eye surgery clinic (the clinic). The surgical treatment plan was to correct the left eye for long distance vision by creating a thin flap, and to create a thick flap in her right eye and place a KAMRA inlay underneath the thick flap to improve her near vision. Mrs C provided written consent for this treatment plan and consented to receiving the KAMRA inlay in her right eye.

2. After receiving her consent, Dr A proceeded with the surgery, and registered nurse (RN) RN B programmed the laser. RN B accidently programmed the thick flap in Mrs C's left eye. Dr A and RN B have differing recollections of whether a cross-checking procedure occurred.

3. Dr A stated that he stopped and took some time to consider what to do, before talking to Mrs C about it. Dr A told HDC that he then informed Mrs C of the options available to her, and believed he obtained her consent to proceed with the KAMRA inlay in her left eye. Dr A then inserted the KAMRA inlay into her left eye.

Findings

4. By failing to ensure that the correct flap measurements were programmed into the laser machine and by not detecting this error prior to commencing the procedure, Dr A failed to provide services to Mrs C with reasonable care and skill, and breached Right 4(1) of the Code of Health and Disability Services Consumers' rights (the Code).

5. Pursuant to Right 5(2) of the Code, Mrs C had the right to an environment that enabled her and Dr A to communicate openly, honestly, and effectively. In the circumstances of this case where the change in procedure was not due to an emergency, mid-procedure was not an appropriate environment for Dr A to seek Mrs C's informed consent for the change in procedure, and did not allow for effective communication. Accordingly, Dr A breached Right 5(2) of the Code.

6. Right 7(1) states that services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent. Because Dr A discussed the change in procedure with Mrs C during the surgery, while Mrs C was sedated, Mrs C was not able to give adequate consideration to whether she wanted to have the KAMRA inlay inserted in her left eye, and was not in a position to give her consent to the change in procedure freely. Accordingly, Dr A also breached Right 7(1) of the Code.

7. Adverse comment was made about RN B not programming the laser correctly. However, it was considered that Dr A, as the supervising ophthalmologist performing the surgical procedure, had the responsibility to ensure that the measurements were correct.

8. It was found that the errors that occurred did not indicate broader systems or organisational issues at the clinic. It was also found that the clinic took reasonably

practicable steps to prevent the errors occurring. The clinic was not found to be directly liable, or vicariously liable, for Dr A's breaches of the Code.

Recommendations

9. It was recommended that Dr A undertake further training on informed consent processes and effective communication, and provide evidence of attendance at such a course. Dr A has now provided this. It was also recommended that he provide a written apology to Mrs C for his breaches of the Code.

Complaint and investigation

10. On 18 January 2016, the Commissioner received a complaint from Mrs C about the services provided by Dr A at the clinic. An investigation was commenced on 26 September 2016. The following issues were identified for investigation:

- *Whether the laser eye surgery clinic provided Mrs C with an appropriate standard of care between 2011 and 2012.*
- *Whether Dr A provided Mrs C with an appropriate standard of care between 2011 and 2012.*
- *Whether RN B provided Mrs C with an appropriate standard of care in February 2012.*

11. The parties directly involved in the investigation were:

Dr A	Ophthalmologist/provider
RN B	Registered nurse/provider
Mrs C	Consumer/complainant
Laser eye surgery clinic/provider	

Also mentioned in this report:

RN D	Registered nurse

12. Independent expert advice was obtained from an ophthalmologist, Professor Charles McGhee (**Appendix A**), and nurse practitioner, Ms Carol Slight (**Appendix B**).

Information gathered during investigation

13. This report relates to the care provided to Mrs C (52 years old at the time) by ophthalmologist Dr A and the clinic in February 2012. In particular, on 23 February 2012, Mrs C underwent High Definition LASIK eye surgery with a KAMRA inlay.

High Definition LASIK surgery with KAMRA inlay

14. High Definition LASIK is a surgical procedure whereby a laser is used to correct vision. Using a laser, a flap is created in the cornea (front clear window of the eye). The flap is lifted and a different laser is used to reshape the inner layers of the cornea to improve visual acuity, using the consumer's personalised treatment profile. The surgeon then places the flap back in place.

15. A KAMRA inlay is a clear, ring-shaped device intended for use in patients who are unable to focus clearly on near objects or small print and need reading glasses, but do not need glasses or contact lenses for clear distance vision. During LASIK surgery, the KAMRA inlay is placed in one eye under the flap created using a laser. The KAMRA inlay is placed in only one eye to improve close-up vision in that eye, while maintaining distance vision in both eyes.

Background

16. In 2011, Mrs C was dissatisfied with her current state of vision. Mrs C required reading glasses during certain times of the day or when performing certain activities.

17. On 25 October 2011, Mrs C attended an introductory assessment at the clinic regarding laser eye surgery. A clinical assistant documented: "[Mrs C] feels her vision is getting worse and would like to know what options she has … Appears to be suitable for High Definition LASIK."

Initial consultation with Dr A

18. On 28 November 2011, Mrs C consulted with ophthalmologist Dr A at the clinic. Dr A examined Mrs C and documented:

> "Right eye is motor dominant.[1] Left eye is sensory dominant … Right [eye] mixed astigmatism[2] and left eye slightly myopic.[3] Left eye sensory dominant but not myopic enough for reading now. Her best solution is LASIK with right KAMRA inlay."

19. Dr A documented that he had discussed with Mrs C the LASIK surgery, KAMRA inlays, monovision,[4] and Mrs C's presbyopia.[5] Dr A told HDC that he also discussed the potential side effect of dry eye and the risks of surgery. Following the discussion, Mrs C decided to proceed with LASIK surgery with a KAMRA inlay.

[1] The superiority of one eye, where the visual function dominates the other eye. It is that eye (called the dominant eye) that is relied upon more than the other in binocular vision. It is not necessarily the eye with the best acuity (clearest vision). This is established by testing both eyes.
[2] An imperfection in the curvature of the cornea (the transparent front part of the eye).
[3] A mild form of short-sightedness. A short-sighted person can see with clarity only objects that are close up.
[4] A treatment for presbyopia in which the dominant eye is corrected to improve distance vision, and the other eye is corrected for near and intermediate tasks.
[5] Long-sightedness caused by loss of elasticity of the lens of the eye, occurring typically in middle and old age.

20. Dr A told HDC that it is standard practice to place the KAMRA inlay in the eye that is non-sensory dominant, and have the other eye as the distance eye.[6] Dr A stated:

> "The reason we plan to place the KAMRA inlay in the sensory non-dominant eye is that the sensory dominant eye is the most sensitive to distance vision blur and that the KAMRA inlay does normally cause some distance vision blur. Consequently it is considered that the sensory dominant eye should be corrected for distance … It is worth noting that this is quite subjective and that it is not related to how well the KAMRA inlay functions for near vision …"

21. As a result of the ocular dominance testing,[7] Dr A's initial surgical plan was to perform a bilateral LASIK surgical procedure,[8] to correct the left eye for long distance vision by creating a standard 100 micron thin flap[9] and to make a thicker 190 micron flap in the cornea of the right eye, and place the KAMRA inlay underneath the thick flap to improve Mrs C's near vision. The next step would be to use an excimer laser[10] to correct Mrs C's ability to focus on objects.

Consent for surgical procedure

22. On the morning of 23 February 2012, Mrs C arrived at the clinic and signed two consent forms in accordance with the surgical plan. One consent form was for "High Definition LASIK" and the other for the "ACUFOCUS[11] KAMRA Inlay".

High Definition LASIK consent form

23. The consent form stated: "**High Definition LASIK** [emphasis in original] is an alternative to contact lenses or spectacles for the correction of myopia (short sightedness) or hyperopia (long sightedness), with or without astigmatism."

24. The consent form also outlined the surgical procedure and what Mrs C could expect following the procedure. It outlined the possible side effects that would not affect vision, and the potential "reversible complications" that could affect vision. It stated that a possible complication could be dry eye, and that "[m]ost cases [of dry eye] eventually resolve with treatment with lubricating eye drops".

25. Mrs C consented to receiving High Definition LASIK surgery on both eyes.

ACUFOCUS KAMRA Inlay surgical consent form

26. The consent form stated: "The inlay improves the depth of focus, allowing the eye to see near and intermediate distance objects more clearly without limiting distance vision …"

27. The consent form also outlined the surgical procedure and what to expect following the procedure, and the possible complications of the KAMRA inlay.

[6] Eye utilised for long distance vision after LASIK surgery.
[7] A test to establish which eye is the dominant eye.
[8] Using a femtosecond laser that emits concentrated light.
[9] The flap involves making an incision in the circular strip of the outer corneal tissue.
[10] A laser that emits concentrated light and can be used for eye surgery.
[11] Acufocus, Inc., an ophthalmic medical device company that creates KAMRA inlays.

28. Mrs C consented to receiving the KAMRA inlay in her right eye.

29. Both consent forms stated:

> "Should you have any doubts in relation to the nature or benefits of the procedure, post-operative recovery, possible complications or anything else of material concern, you should ask [Dr A] or his staff who will be only too happy to assist."

Consent for pre-medication

30. The consent form stated: "Lorazepam is a mild sedative. We advise that you take this medication to help you relax for your treatment." Mrs C consented to receive 1mg of lorazepam, and this was administered at 8.10am.[12]

Surgical procedure

31. After receiving Mrs C's written and signed consent, Dr A proceeded with the surgery. Dr A told HDC that his ophthalmic technician registered nurse, RN B, and RN D were present during the procedure. Mrs C told HDC that she could not recall RN B being in the room at the time of the procedure.

32. Dr A told HDC that the first step was to create the flaps in the corneas of both Mrs C's eyes using the laser. In accordance with the treatment plan, Dr A intended to create a 190 micron flap in the cornea of her right eye, and a standard thin 100 micron flap in the cornea of her left eye.

33. Dr A told HDC that, following the creation of the flap in the left eye, he realised that RN B had accidentally programmed the thicker 190 micron flap for Mrs C's left eye, rather than the thinner 100 micron flap.

34. The "INTRALASE[13] THEATRE PROTCOL FOR THEATRE ASSISTANT" in place at the clinic at the time of Mrs C's surgery required a cross-checking procedure to take place following the programming of the laser machine and the creation of the flaps. Namely, it required RN B to:

> "Verbalise to doctor
>
> 1. Patient name
> 2. Eye being treated
> 3. Depth
> 4. Diameter …"

35. Dr A stated that the error was made because RN B did not verbally inform him of the programmed flap diameter and thickness in accordance with the cross-checking

[12] Lorazepam is a sedative used to treat anxiety. It can have cognitive side effects such as dizziness, drowsiness, and effects on memory.
[13] A form of LASIK surgery using the IntraLase femtosecond laser machine.

procedure. He told HDC that the cross-checking procedure in place failed to work on this occasion.

36. RN D told HDC that while she was not involved in the cross-checking procedure, she recalls it being completed, but cannot recall what measurements were stated.

37. RN B told HDC that she could not recall the specific details of events given the lapse in time. She stated that "standard checking procedures for Laser surgery at the clinic were definitely followed", and that the cross-checking procedure did take place. RN B stated: "Sadly in this instance, human error occurred and the vital opportunities to identify this error during the cross check process with [Dr A] were lost."

38. RN B told HDC: "I would suggest that the [cross check] did take place … but that [Dr A] was distracted or disengaged from the process, which prevented him from both recalling that it had taken place and identifying the error that had been programmed."

39. Dr A told HDC:

> "An A4 sized treatment sheet was in the laser theatre attached to the eximer laser. This treatment sheet shows all of the relevant data about the patient including the pre-operative refractions, ocular dominance testing as well as the planned flap diameters and thicknesses for each eye. The ophthalmic technician is supposed to then program the femtosecond laser with the planned flap diameters and thicknesses. Before the femtosecond laser is used the ophthalmic technician was supposed to verbally tell the surgeon what the programmed flap diameter and thickness was as a cross check. On this occasion it appears that this was not done."

40. Dr A acknowledged that he and RN B have a different recollection of events.

41. Dr A told HDC that, following the identification of the error:

> "I stopped and took some time to consider what to do at that point. I then talked to [Mrs C] who is also a nurse, and so I thought that she would have an above average understanding of what I was talking to her about. I informed her what had happened and what her options were."

42. Dr A provided two options to Mrs C. He told HDC:

> "Option one was proceeding to make a thick flap in her right eye as well as her left eye and to place the inlay into her right eye as originally planned. Option two was to place the KAMRA inlay into her left eye under the already made thick flap and have her right eye as the distance eye."

43. Dr A told HDC that he explained to Mrs C that his view was that option two would be best for her. Dr A documented that he discussed the error with Mrs C. However, there is no documentation detailing the nature of the information discussed with Mrs C. Dr A told HDC:

> "I explained that since the left eye had the thick flap, that she was basically equally ocular dominant and that as she had been reading with her left eye for the past five years or so that it was quite reasonable to insert the KAMRA corneal inlay into her left cornea."

44. Dr A then inserted the KAMRA corneal inlay into Mrs C's left eye.

45. Dr A told HDC that he believed Mrs C agreed that this was a reasonable change of plan, and that he had received her verbal consent to proceed. However, Dr A stated:

> "Viewing the circumstances with the benefit of hindsight, I would have preferred to stop the surgery and invite [Mrs C] from the surgery room, discuss the options with her over a longer period of time, and provide an updated consent form for her to sign."

46. Mrs C stated that she was very anxious and felt claustrophobic during her surgery, and felt unable to decide whether to consent to the placement of the KAMRA in the left eye when informed of the error.

47. Mrs C told HDC that she can recall Dr A informing her that an error had occurred, but she does not recall the content of what was discussed, and cannot remember giving her verbal consent to the change of plan.

48. Mrs C told HDC that she recalls RN D in the room following the identification of the error, but cannot recall whether RN D said anything to her or Dr A. Mrs C said that she had received a mild sedative prior to her surgery, and this may have affected her recollection.

49. Dr A recalled that RN B and RN D were in the room during the discussion regarding the change in treatment plan following the error, but he cannot be sure given the time that has passed.

50. RN B told HDC that she can recall Dr A informing Mrs C that an error had occurred, but she does not recall the exact wording of the communication. RN B stated: "Further to this, I was not part of, or privy to, any conversations between team members and [Mrs C], regarding the programming error."

51. RN D told HDC:

> "I recall [Dr A] discussing the error with [Mrs C] and that in her case the inlay would function well in either eye. I cannot recall the exact reasons why this was so or the details of the discussion that took place right after the error was identified."

52. Following the surgical procedure, Mrs C experienced postoperative complications, including "very dry eye" and left flap striae.[14] On 29 February 2012, Dr A documented that he "wanted to get rid of the left flap striae". On 1 March 2012, Dr A

[14] Folds in the flap.

removed the striae. Mrs C continued to be dissatisfied with her state of vision and dry eyes following the procedure.

Further information

53. Dr A told HDC that there is no reason for the KAMRA inlay to work better for the restoration of near vision in one eye compared to the other. He said that it should work equally well or equally poorly in someone with two normal, healthy eyes, regardless of which eye is chosen.

54. Dr A also told HDC:

> "I have always understood the importance of informed consent and have endeavored to provide patients with proper informed consent. As such, [Mrs C's] case and HDC investigation has been a salutary lesson for me. I have reflected on your comments and reviewed various guidelines and statements around informed consent and best practice …
>
> There was a failure to follow our normal cross checking process, which meant that [Mrs C] was not provided with services with reasonable care and skill. Because of this case, I am now more vigilant with the pre-operative and intra-operative crosschecking processes."

Changes made to practice

55. Dr A told HDC:

> "We have adopted a much more formal and deliberate 'time out' checking process prior to the patient being treated with either the femtosecond or excimer laser. The time out process involves the ophthalmic surgeon, the ophthalmic technician and the laser theatre nurse. We now stop doing anything else and complete a formal check list together. We have the check list printed and laminated and stuck onto each laser. When the patient is lying on the table we check:
>
> 1. The name and date of birth of the patient
> 2. The procedure that they are having such as … LASIK …
> 3. With … LASIK surgery we check with the patient and the staff members in the laser room whether they are having both eyes corrected for … monovision
> 4. For patients having monovision we ask the patient if they know which eye is going to be the reading eye and which eye is the near eye …"

56. This check has been incorporated into the clinic's standard operating procedures. The procedure, titled "the clinic — Clinical Pathway Laser", states the actions that are to be taken before and during a surgical procedure:

> "Theatre:
>
> Patient identification and procedure confirmed.

> TIME OUT CHECK 1 — entry into theatre
>
> …
>
> Patient identification and iFS procedure confirmed
>
> TIME OUT CHECK 2-iFS
>
> …
>
> Patient identification and excimer procedure confirmed.
>
> TIME OUT CHECK 3-excimer."

57. The checklist titled "TIME OUT/CHECK — ENTRY INTO THEATRE" requires the team to check and verbalise the patient's name, date of birth, address, which eye(s) is/are to be treated, and the type of treatment.

58. The checklist titled "TIME OUT/CHECK — [INTRALASE FEMTOSECOND] LASER" requires the team to check and verbalise the patient's name, date of birth, address, which eye(s) is/are being treated, and the flap diameter and depth.

59. The checklist titled "TIME OUT/CHECK — excimer" requires the team to check and verbalise the patient's name, date of birth, address, which eye(s) is/are being treated, and the type of treatment.

60. RN B told HDC:

> "The immediate change to my practice following this incident … was to obtain verbal acknowledgement from [Dr A], confirming the accuracy of the settings programmed by myself … prior to commencement of the laser flap creation."

Responses to provisional opinion

61. Mrs C, the clinic, Dr A, and RN B were all provided with an opportunity to comment on the relevant sections of the provisional opinion.

62. Mrs C and the clinic had no further information to add.

Opinion: Dr A

63. On 28 November 2011, Mrs C consulted with Dr A at the clinic. Dr A's initial surgical plan was to perform bilateral LASIK surgery, correct the left eye for long distance vision with a standard thin flap and make a thick flap in the right eye, and use the excimer laser to place the KAMRA inlay underneath the thick flap to improve Mrs C's near vision. Mrs C agreed with this treatment plan.

Standard of care — breach

64. On 23 February 2012, Mrs C attended the clinic for her surgical procedure. Mrs C consented to receive LASIK eye surgery and a KAMRA inlay in her right eye.

65. I note that RN D and RN B recalled a cross-checking procedure being completed.

66. It is clear that, during the surgical procedure, RN B programmed the machine to create a thick 190 micron flap for the KAMRA inlay in Mrs C's left eye, instead of her right eye. Dr A and RN B have given different accounts of whether the cross-checking procedure took place. After considering the evidence, I am unable to determine whether a cross-checking procedure occurred. However, I would observe that if it did occur, it was ineffective.

67. My expert advisor, ophthalmologist Professor Charles McGhee, advised that the cross-check processes failed to work on this occasion.

68. As RN B was working under the supervision of Dr A, I am of the view that Dr A had primary responsibility for all aspects of the surgery, including the programming and the cross-checking procedure.

69. By failing to ensure that the correct flap measurements were programmed into the laser machine, Dr A failed to provide services to Mrs C with reasonable care and skill, and breached Right 4(1) of the Code.[15]

Informed consent — breach

70. Following the identification of the error, whereby the thicker flap for the KAMRA inlay was created in Mrs C's left eye instead of her right eye, Dr A stopped the procedure to discuss the error with Mrs C.

71. Dr A provided two options to Mrs C. He told HDC:

> "Option one was proceeding to make a thick flap in her right eye as well as her left eye and to place the inlay into her right eye as originally planned. Option two was to place the KAMRA inlay into her left eye under the already made thick flap and have her right eye as the distance eye."

72. Dr A said that he explained to Mrs C that his view was that option two would be best for her. He stated:

> "I explained that since the left eye had the thick flap, that she was basically equally ocular dominant and that as she had been reading with her left eye for the past five years or so that it was quite reasonable to insert the KAMRA corneal inlay into her left cornea."

73. Dr A told HDC that there is no reason for the KAMRA inlay to work better for the restoration of near vision in one eye compared to the fellow eye. He said that it should

[15] Right 4(1) of the Code states: "Every consumer has the right to have services provided with reasonable care and skill."

work equally well or equally poorly in someone with two normal, healthy eyes, regardless of which eye is chosen.

74. Professor McGhee advised that "[t]heoretically the KAMRA inlay could have been placed in either eye in terms of ocular dominance and underlying refractive error".

75. Dr A told HDC that he believed that Mrs C agreed that the suggested change of plan was reasonable, and he understood that he had received her verbal consent to proceed. Mrs C stated that she had taken a mild sedative prior to her surgery, and felt very anxious during her surgery and was unable to decide whether to consent to the placement of the KAMRA inlay in her left eye when informed of the error.

76. Informed consent under the Code is a process with three essential elements: effective communication between the parties (Right 5); the provision of all necessary information to the consumer (Right 6); and the consumer's freely given and competent consent (Right 7).

77. As the treating clinician, Dr A was responsible for ensuring that he had obtained Mrs C's informed consent to any procedure he carried out on 23 February 2012.

78. I accept that, once the error was discovered, Dr A provided Mrs C with some information about the change in procedure he was proposing prior to the procedure commencing. However, given the lack of documentation detailing the nature of the information discussed with Mrs C, and the limited recall of the three parties involved, I am unable to make a finding as to the precise nature of the information provided to Mrs C and, therefore, whether Mrs C was provided with all the necessary information she required.

79. However, regardless of what information was provided at this point, I have concerns about the effectiveness of Dr A's communication with Mrs C. In my view, mid-procedure was not the appropriate time or environment for Dr A to provide information to Mrs C in light of the fact that Mrs C was very anxious about the procedure, she had been sedated, and the discussion occurred during the surgery.

80. Professor McGhee advised that it would be impossible to achieve fully informed consent mid-procedure. Mrs C had just been told about the complication and was anxious, she was under a laser and it was mid-procedure, which would make it difficult for her to think clearly, and prior to the procedure she had received medication that could significantly affect her thinking processes.

81. Pursuant to Right 5(2) of the Code, Mrs C had the right to an environment that enabled her and Dr A to communicate openly, honestly, and effectively. In my view, in the circumstances of this case where the change in procedure was not due to an emergency, mid-procedure was not an appropriate environment for Dr A to seek Mrs C's informed consent for the change in procedure, and did not allow for effective communication. Accordingly, I consider that Dr A breached Right 5(2) of the Code.

82. Right 7(1) states that services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent. Because Dr A discussed the

change in procedure with Mrs C during the surgery, while Mrs C was sedated, in my view Mrs C was not able to give adequate consideration to whether she wanted to have the KAMRA inlay inserted in her left eye, and was not in a position to give her consent to the change in procedure freely. Accordingly, in my opinion, Dr A also breached Right 7(1) of the Code.

Opinion: RN B

Standard of care — adverse comment

83. On 23 February 2012, Mrs C attended the clinic for her surgical procedure. Mrs C gave consent to receive LASIK surgery in both eyes, and a KAMRA inlay in her right eye.

84. The theatre protocol in place set out the cross-checking procedure to be followed after programming of the laser. The protocol required RN B to verbalise to the doctor the patient's name, the eye being treated, and the depth and diameter of the flaps.

85. Dr A recalls that the cross-checking procedure did not take place; in addition, RN B stated that she could not recall the specific details of events but that the cross-checking procedure was followed. While RN D told HDC that she recalls that the cross-checking procedure took place, she was not directly involved in the procedure.

86. Dr A and RN B have given different accounts of whether the cross-checking procedure took place. After considering the evidence, I am unable to determine whether a cross-checking procedure occurred.

87. My expert advisor, nurse practitioner (NP) Carol Slight, advised:

> "In this case [RN B] either accidently programmed the incorrect eye or the incorrect flap thickness into the laser. This involved a departure from standard level of care of checking the measurements and the eye prior to programming the laser.
>
> The cross check should have highlighted prior to the laser surgery commencement that this was the wrong eye from the programmed measurements."

88. NP Slight also advised:

> "Theatre staff are a team however the responsibility for the oversight of what has been programmed should be the ophthalmologist who is performing the surgery. He has the responsibility over the technician actions.
>
> …
>
> The responsibility for the surgery is the surgeon and this includes ensuring that the correct measurements for the eye are programmed."

89. While I am concerned that RN B did not programme the machine correctly, I consider that Dr A had a responsibility, as the supervising ophthalmologist performing the surgical procedure, to ensure that the measurements were correct.

Opinion: The clinic

Standard of care — no breach

90. As a healthcare provider, the clinic is responsible for providing services in accordance with the Code. In this case, I consider that the errors that occurred did not indicate broader systems or organisational issues at the clinic. Therefore I consider that the clinic did not breach the Code directly.

91. In addition to any direct liability for a breach of the Code, under section 72(2) of the Health and Disability Commissioner Act 1994 (the Act), an employing authority is vicariously liable for any actions or omissions of its employees. A defence is available to the employing authority under section 72(5) if it can prove that it took such steps as were reasonably practicable to prevent the acts or omissions.

92. In 2012, Dr A was an employee of the clinic. Accordingly, the clinic is an employing authority for the purposes of the Act. As set out above, I have found that Dr A breached Rights 4(1), 5(2) and 7(1) of the Code.

93. The clinic provided a copy of the cross-checking procedure in place in 2012, which required RN B to verbalise to Dr A the patient's name, the eye being treated, and the depth and diameter of the flaps.

94. My expert advisor, Professor Charles McGhee, has advised that the cross-checking procedure in place was appropriate. In addition, he has advised that there is no expectation by the Royal Australian and New Zealand College of Ophthalmologists, or guidelines, that require a formal consent policy to be in place.

95. I note the information provided by the parties involved, and the advice I have received from Professor McGhee. I am satisfied that the clinic took reasonably practicable steps to prevent this error occurring. Accordingly, I do not find the clinic vicariously liable for Dr A's breaches of the Code.

Recommendations

96. In my provisional opinion, I recommended that Dr A undertake further training on informed consent processes and effective communication. Dr A has now completed two workshops that included training on informed consent processes and effective communication.

97. It is recommended that Dr A provide a written apology to Mrs C for his breaches of the Code. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Mrs C.

Follow-up actions

98. A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be sent to the Medical Council of New Zealand, and it will be advised of Dr A's name.

99. A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be sent to the Nursing Council of New Zealand, and it will be advised of RN B's name.

100. A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be sent to the Royal Australian and New Zealand College of Ophthalmologists.

101. A copy of this report with details identifying the parties removed, except the experts who advised on this case, will be 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 ophthalmologist Professor Charles McGhee:

> "Further to your request of the 25th May 2016, I have reviewed the materials related to this case and have answered the questions you have posed. I can confirm that I have no conflict of interest with any of the parties involved. However, New Zealand has a relatively small number of ophthalmologists and I do know [Dr A] professionally. We meet briefly perhaps once every year or two at national/international conferences and he has also referred a few patients for my second opinion over the last fifteen years.
>
> Documents provided and reviewed in preparation of this report:
>
> - Letter of instruction, [HDC] 25th May 2016
> - Letter of complaint from [Mrs C]
> - Second opinion from [another ophthalmologist]
> - Response from [Dr A] 10th March 2016
> - Additional Responses from [Dr A]
> - Clinical notes pertaining to [Mrs C]
> - Consent forms for LASIK and KAMRA inlay
>
> ISSUES
>
> 1. The adequacy and appropriateness of the preoperative advice provided to [Mrs C]
>
> I note that [at the time of these events] the subject [was a 52] year old [patient] who increasingly required a near spectacle correction (reading) for presbyopia, having previously relied (well into the presbyopic age group) on her modest left myopia to read without a reading correction.
>
> She had a minimal refractive error pre-operatively with unaided vision of 6/7.5 right and 6/20 left and a spectacle refraction of +0.25/-0.25 x 20 right and -0.62/-0.50 x 105 left enabling her to achieve (normal) 6/6 visual acuity right and left eye respectively.
>
> In the context of an equivalent spherical refraction of +0.12D right -0.87D left, and the patient's stated desire for unaided near vision, the pre-operative advice offered by [Dr A], (as far as can be gleaned from the available notes) in relation to proposed refractive surgery to provide both distance and near vision corrections appears reasonable.
>
> The consent forms appear appropriate and although very technical in places these certainly convey adequate information in respect to benefits and risks; including

the prospect that the KAMRA inlay may not work in a proportion of patients and may be associated with visual side-effects.

The treatment plan was to provide a KAMRA inlay in the right eye and perform a LASIK correction for low myopia in the left eye. However, I believe, the KAMRA inlay could, as [Dr A] suggests, have been inserted into either eye with equivalent results. [Dr A] assessed both motor and sensory dominance and on the basis of sensory dominance (left eye) decided, in discussion with the patient, to position the KAMRA inlay in the (sensory non-dominant) right eye.

However, for completeness, the very minor refractive error in the right eye +0.25/-0.25 x 20 with good unaided vision (6/7.5 or only one line short of best corrected vision), may have led some of [Dr A's] peers to treat the left eye by KAMRA and advise no surgical treatment of the right eye.

2. The appropriateness of the 'cross check' processes [Dr A] had in place at the time of [Mrs C's] procedure

Unfortunately the cross-check processes failed to work on this occasion and a thicker than intended corneal flap was 'accidentally programmed' by the technician (an ophthalmic nurse). In practice, such an error is extremely rare.

The cross checks that were in place, including an A4 treatment sheet attached to the laser with all relevant details is in keeping with the prevailing standard of care.

Unfortunately on this occasion the technician/ophthalmic nurse did not inform the surgeon of the intended final flap diameter and flap thickness prior to the laser being operated.

3. Comment on [Dr A's] failure to follow his cross-checking processes and how this would be viewed by his peers.

The root cause of the creation of the inappropriately thick flap was a) incorrect programming by a staff member under the supervision of [Dr A] and b) the failure to follow the cross-checking procedure i.e. the responsible staff member did not notify the surgeon of the flap dimensions prior to the surgeon applying the laser. This was a significant but entirely avoidable mistake. Indeed, if the normal cross-checking procedure had been observed this mishap would not have occurred.

I believe this would be viewed as a major lapse in standard of clinical practice by peers.

4. Comment on the inadvertent incorrect programming of the KAMRA inlay (LASIK flap) thickness. In particular whether such an error is common or if it can readily be avoided?

Such an error would be extremely uncommon; indeed this is not mentioned in most reviews of complications that occur in Femtosecond LASIK. Though there [is] no good data on this specific complication, publications on complications of the technique per se, would suggest this is likely to occur in less than 1:1000 cases.

This inadvertent event is typically avoided by thorough pre-operative and intra-operative cross-checking processes.

5. Whether [Dr A] managed the error appropriately, in particular:
    a) The appropriateness of the advice provided when the error was identified
    b) Would peers consider it appropriate to discuss an intraoperative error and seek consent for a change in procedure while still in theatre?
    c) If not what course of action would peers have undertaken

Whilst it may have been reasonable, as explained by [Dr A], to advise a change to the surgical plan and place the KAMRA inlay into the left eye when the mistake was noted, it might have been equally reasonable to have simply completed the planned minor LASIK procedure in the left eye (albeit at a slightly deeper than intended depth). Since the left eye had a preoperative central thickness of 557 microns and had a 190 micron LASIK flap (rather than a 100 micron flap), this would still have left a safe residual thickness of approximately 367 microns for the minor LASIK ablation (-0.62/-0.50 x 105 spectacle correction).

However, I believe the main issue here is not whether changing which eye received the KAMRA was in error, more whether a suitably informed consent could be obtained at this stage in order to change the procedure.

I believe that it would be impossible to achieve fully informed consent at this time because:

a) The patient has just been told there has been a complication and would be anxious.

b) The patient is actually under a laser and in mid-procedure — a difficult time to think clearly.

c) It appears that routine pre-treatment may have included the hypnotic drug lorazepam — this may significantly affect thinking processes (benzodiazepine drugs can cause minor confusion and short term memory impairment).

Therefore, I believe most peers would have abandoned the procedure at this point, re-positioned the LASIK flap without further treatment, and have the patient leave the theatre to a quiet place to relax and consider all options — preferably with a support person.

Once fully informed consent was obtained the surgery could have gone ahead on the same day or have safely been delayed to a mutually convenient time in the

knowledge that the patient and the surgeon had considered all possible treatment options.

6. Whether it was appropriate to proceed to place the KAMRA inlay in the left eye instead of the right eye.

Theoretically the KAMRA inlay could have been placed in either eye in terms of ocular dominance and underlying refractive error — but the treatment plan should only have been changed if/when appropriate informed consent had been obtained (see answer to question 5).

7. Whether the subsequent postoperative complications can be attributed to the incorrectly programmed and subsequently placed flap in the left eye, or could these have occurred irrespective of which eye received the inlay? Do these compilations, in any way, represent a departure in the skill and care provided to [Mrs C] by [Dr A]?

The prolonged dry eye symptoms may be attributed in some part to the thicker than planned LASIK flap but typically these symptoms can occur after a LASIK flap of any thickness and usually settle over time as the corneal nerves (cut in the LASIK procedure) regenerate.

The KAMRA inlay appears to be well positioned in terms of depth and in relation to the pupil therefore it is reasonable to presume that the visual symptoms related to the KAMRA inlay would have been equally likely to happen whether the inlay had been placed in the left eye, or the right eye as initially planned.

I do not believe, on the balance of information provided to me, the post-operative complications experienced by the patient represent a departure in the expected skill and standard of care that should be provided by an experienced ophthalmologist and refractive surgeon such as [Dr A].

8. Any other comments on [Dr A's] responses and the overall ophthalmic care provided to [Mrs C]

Simply to note once more that the very minor pre-operative refractive error in the right eye +0.25/-0.25 x 20 accompanied by near normal unaided distance vision (6/7.5), may have led many peers to treat only the left eye. However, this option may have been discussed in appropriate detail with the patient by [Dr A].

At your request I am happy to further clarify any of my comments herein,

Yours sincerely

Professor Charles NJ McGhee

MB, BSc, PhD, DSc, FRCS, FRCOphth, FRANZCO
Maurice Paykel: Professor of Ophthalmology, University of Auckland
Director, New Zealand National Eye Centre."

Appendix B: Independent expert advice to the Commissioner

The following expert advice was obtained from nurse practitioner Carol Slight:

"I have been asked to provide an opinion to the Commissioner on Case Number 16HDC00083.

I have read and agree to follow the Commissioner's Guidelines for Independent Advisors.

Qualifications and Training and experience
I am a Nurse Practitioner Ophthalmology and was registered by Nursing Council in 2007. A Nurse Practitioner in New Zealand must have a Masters of Nursing and this I achieved in 2005 with first class honours. A NZ Nurse Practitioner must also have worked in her area of practice for more than 4 years. They must also maintain 40 hours of professional development every year particularly as we are authorised prescribers.

I have worked in ophthalmology for 26 years as Staff Nurse, Charge Nurse, Clinical Nurse Specialist and Nurse Practitioner.

I am chairperson of the quality group in ophthalmology and therefore write policies and procedures in relationship to many standard procedures that nurses undertake in their everyday roles.

Referral Guidelines
The Commissioner is seeking an opinion on the care provided by registered nurse [RN B] to [Mrs C] on 23 February 2012.

The Commissioner is seeking advice on

1. What is the standard of care/accepted practice?
2. If there has been a departure from standard of care or accepted practice, and how significant a departure is this considered to be?
3. How it would be reviewed by our peers?
4. Recommendation for improvement that may help to prevent similar occurrence in future.

Sources of information reviewed
I have reviewed the Letter of Complaint by [Mrs C] dated 18 January 2016.

I have reviewed [RN B's] response dated 21 October 2016.

I have reviewed the intralase protocol in place on February 2012. This version was dated December 2006.

I did not review the patient notes so cannot comment on what was documented in the notes stating the measurements to be programmed into the femtosecond laser.

I also cannot comment on the checking procedure and if it is documented within the patient's notes.

Factual Summary
November 2011 [Mrs C] dissatisfied with current state of vision

28 November 2011 1st consultation with ophthalmologist

— Treatment options discussed to improve her eyesight particularly two options performed with excimer laser surgery.

— After discussing options with ophthalmologist expressed a desire to proceed with the KAMRA corneal inlay surgery.

— The next discussion involved making a decision as to which of the two eyes to place the KAMRA corneal inlay into and have the fellow eye as the distance eye.

— The ophthalmologist tested [Mrs C's] ocular dominance and established a surgical plan.

— Decided on bilateral LASIK surgery.

— Left eye was to be corrected for long distance vision with a standard thin-flap LASIK procedure.

— Right eye was to be corrected by placing a thick flap and use excimer laser to place the KAMRA inlay under the thick flap to improved [Mrs C's] near vision.

— 23rd February 2012 Ophthalmologist proceeded with surgery

— 1st step to create LASIK flaps using laser

— After creation of the left LASIK flap the ophthalmologist realised that [RN B] had accidently programmed the thicker 190 macron flap in the left eye instead of the right eye.

What is the standard of care/accepted practice?
In the intralase theatre programme provided by [the clinic] it clearly states that the technician should carefully change depth and diameter values according to the patient's operating sheet. According to the theatre protocol when this is bilateral surgery the left eye is always operated on first. This should have been programmed as the thin flap to correct for long distance.

Theatre staff are a team. In the protocol it states that prior to there is then a cross check.

The patient name, eye being treated, depth, diameter and pocket ON or OFF are verbalised.

This occurs before the laser surgery is started.

There is no documentation to say this cross check occurred except in the memory of [RN B] who states that the protocol was followed.

Has there been a departure from standard of care or accepted practice, and how significant a departure is this considered to be?
In this case [RN B] either accidently programmed the incorrect eye or the incorrect flap thickness into the laser. This involves a departure from standard level of care of checking the measurements and the eye prior to programming the laser.

The cross check should have highlighted prior to the laser surgery commencement that this was the wrong eye for the programmed measurements.

Although this is a moderate departure from the standard of care the cross check should have identified that the laser was incorrectly programmed for the left eye.

Theatre staff are a team however the responsibility for the oversight of what has been programmed should be the ophthalmologist who is performing the surgery. He has the responsibility over the technician actions.

How it would be reviewed by our peers?
Peers would feel that there are processes to be followed in a theatre situation. One of the understood procedures is that the cross check or time out is undertaken. The responsibility for the surgery is the surgeon and this includes ensuring that the correct measurements for eye are programmed.

Recommendation for improvement that may help to prevent similar occurrence in future.
There is a document written by Health, Quality & Safety Commission NZ that is titled 'Improving surgical teamwork and communication'. This has been implemented within the DHBs throughout NZ and is to reduce perioperative harm. I have enclosed a copy of this document.

There are three very clear charts identified in this report (please find attached)

1. Page 13 is a start of list briefing
2. Page 15 is a surgical safety checklist
3. Page 17 is an end of list debriefing

The theatre staff are a team and although each have a part to play there are checks that should ensure that all measurements and correct eye are checked prior to surgery commencing.

My recommendation would be that a process is adopted that clearly identifies the theatre protocols especially the cross check. This should then be documented that the check has been completed in the patient's notes.

The intralase theatre protocol should be rewritten to be clearer and easier to follow. Consider dividing into clear defined sections of the whole process. At present the information on the cross check is within the centre of the document and could be missed.

Carol Slight, Nurse Practitioner Ophthalmology"