Health New Zealand|Te Whatu Ora
Te Matau a Māui Hawke's Bay

Dr B

A Report by the

Deputy Health and Disability Commissioner

(Case 21HDC00219)

HEALTH & DISABILITY COMMISSIONER
TE TOIHAU HAUORA, HAUĀTANGA

Contents

Complaint and investigation

1. The Health and Disability Commissioner (HDC) received a complaint from the family of Mrs A about the services provided to her by Health New Zealand|Te Whatu Ora (Health NZ) Te Matau a Māui Hawke's Bay and Dr B. The following issues were identified for investigation:

- *Whether Dr B provided [Mrs A] with an appropriate standard of care in 2019 and 2020.*
- *Whether Health NZ|Te Whatu Ora Te Matau a Māui Hawke's Bay provided [Mrs A] with an appropriate standard of care in 2019 and 2020.*

2. This report is the opinion of Dr Vanessa Caldwell, Deputy Health and Disability Commissioner, and is made in accordance with the power delegated to her by the Commissioner.

3. The parties directly involved in the investigation were:

Mrs A	Consumer
Health NZ Te Matau a Māui Hawke's Bay[1]	Provider
Dr B	Provider/orthopaedic surgeon
Dr C	Provider/anaesthetist

4. Further information was received from ACC and Health NZ Waitaha.

Information gathered during investigation

Introduction

5. On 11 December 2020 Mrs A (then aged 64 years) underwent elective L2/3[2] and L4/5[3] spinal surgery at Hawke's Bay Fallen Soldiers' Memorial Hospital (Hawke's Bay Hospital) performed by orthopaedic surgeon Dr B. Shortly afterwards, Mrs A was found to have sustained a spinal cord injury (SCI) during the surgery. Mrs A was therefore returned to surgery for a procedure to relieve pressure on the spinal nerves (an L1/2/3 posterior decompression) and, during this second procedure, the cord injury at L2/3 was confirmed.

6. Postoperatively Mrs A was managed in the Intensive Care Unit (ICU), but little neurological recovery occurred, and the outcome was an L1 AIS A[4] complete paraplegia (a total loss of

[1] On 1 July 2022 the Pae Ora (Healthy Futures) Act 2022 came into force, which disestablished all district health boards. Their functions and liabilities were merged into Te Whatu Ora|Health New Zealand (now called Health New Zealand|Te Whatu Ora). All references in this report to Hawke's Bay DHB now refer to Health NZ Te Matau a Māui Hawke's Bay.
[2] L2 is the second lumbar spine vertebra.
[3] L4/L5 are the fourth and fifth lumbar vertebrae just above the base of the spine.
[4] The American Spinal Injury Association Impairment Scale (AIS) is a standardised neurological examination used by the rehabilitation team to assess the sensory and motor levels that are affected by a spinal cord injury. Grade A is complete impairment.

motor and sensory function in the legs and impaired bowel and bladder function), which was accepted by ACC as a treatment injury.

7. Mrs A was transferred to specialist care on 21 December 2020 for impairment assessment and ongoing rehabilitation. Her SCI was managed conservatively with no further surgical intervention. Mrs A was discharged from care on 14 April 2021 to her home, where she lives with her husband.

8. Mrs A now has a suprapubic catheter (SPC) (a tube that drains urine through the abdominal wall) and a colostomy (to allow waste to pass out of an opening in the abdomen). She uses a wheelchair and has no sensation or movement below the level of her injury. She continues to have lower back pain and neurogenic (nerve) pain in her left leg.

Events prior to surgery

9. On 23 February 2016 Mrs A presented to Hawke's Bay Hospital, having been referred by her GP because of her back pain and progressive neurological signs in her right leg. Computed tomography (CT) and magnetic resonance imaging (MRI) scans of her lumbar spine on 27 May 2016 showed right-sided disc herniation at the L3/4 level, and Mrs A was placed on the surgical waiting list for spinal decompression surgery, to be expedited given her high risk of neurological deterioration.

10. On 15 December 2016 Mrs A underwent a posterior L2–L5 decompression (removal of bone from the spine) plus an L3/4 fusion (joining of bones). She had an uncomplicated postoperative recovery, but by 15 November 2017 she was again reporting back pain. She had a repeat MRI scan on 13 December 2017, which confirmed moderate L2/3 stenosis (narrowing of the spinal canal) not requiring surgery.

11. On 24 September 2018 Mrs A's GP referred her to the hospital again because of further pain. She was seen by orthopaedic surgeon Dr B on 29 January 2019.

Dr B

12. Dr B was employed by the then Hawke's Bay DHB as an orthopaedic surgeon.

Consultation 29 January 2019

13. Dr B's diagnosis was of adjacent segment disease (degenerative changes in the spinal segments next to a previously fused area of the spine) both above and below Mrs A's previous surgery, associated with a small listhesis (a vertebrae that had slipped forward) at L4/5. Dr B documented that the best way to address this problem and avoid revision surgery was to undertake an L2/3 and an L4/5 O LIF.[5]

[5] An O LIF (Oblique Lateral Interbody Fusion) is a surgical technique for spinal problems that minimises cutting to muscles and uses a single port to access the disc space, fill it with bone material, and then fuse the bones of the lumbar spine. This can be performed as a minimally invasive surgery (MIS) technique. A cage holds the bone graft material. Interbody cages are placed between the bodies of two adjacent vertebrae — after removing the intervertebral disc that typically occupies this space.

14. Dr B documented that Mrs A was happy to proceed with this, and she signed a consent form in clinic. Although Dr B's clinic note proposes an O LIF procedure, there is no mention of any intention to perform a posterior procedure (operating through the back), as Dr B's intention at that time was to avoid operating through the back again.

Consultation 6 August 2019

15. On 6 August 2019 Dr B met with Mrs A in clinic again and documented that she had significant back pain with left leg sciatica and weakness. Dr B documented that the L2/3 and L4/5 O LIF was still indicated, along with an L2–L5 revision posterior fusion (a procedure to adjust or correct previous spinal surgery). Dr B documented having discussed the risks and benefits of the surgery, although there is no detail as to what risks and benefits were discussed. It is also not recorded why the proposed operation was amended to an L2/3 and L4/5 O LIF plus an L2–L5 revision.

16. Dr B told HDC that the initial plan was to complete a standalone L2/3 and L4/5 O LIF with the possibility that at a later date there might be a need to proceed with a staged posterior decompression and instrumentation.[6] Dr B stated that after discussion with Mrs A, it was decided that she would need a two-part procedure. The first part would include a lateral-based procedure (through the side) to place two spacers between the discs at L2/3 and L4/5. The second part of the procedure would be to extend the posterior instrumentation at L3/4 to include L2, L3, L4, and L5. A posterior decompression would also accompany the second stage.

17. Dr B said that consent was received from Mrs A for the typical risks of an O LIF procedure, which included the general risks of surgery such as heart attack, stroke, death, and blindness. Also discussed were specific risks of O LIF surgery, such as infection, wound healing issues, injury to the great blood vessels, the possible need for a blood transfusion(s), injury to the bowel or urinary system, blood clots, failure of fusion, failure of symptoms to resolve, failure of the adjacent spinal segment, neurological injury, thigh pain or weakness, and the possibility of requiring subsequent posterior stabilisation. Dr B said that they also discussed the use of allograft (donated human material).

18. Dr B referred Mrs A for an epidural steroid injection to treat the pain while she was awaiting the surgery. This was undertaken on 25 September 2019, and the anaesthetist recorded that Mrs A was to be reviewed in 6–8 weeks' time, but that review did not take place.

MRI scan

19. Mrs A's last MRI scan had been in 2017. Mrs A was assessed by Dr D in the preoperative clinic on 29 October 2020. Dr D wrote in the plan that it would be discussed with the team whether there was a need for a 'more recent MRI'. Dr D noted that Mrs A had increased back and radicular pain affecting the left leg. Dr D said that it was followed up directly with Dr B via a message on 2 November 2020 about whether an updated MRI was needed for Mrs A, or

[6] A procedure to remove pressure on the nerves and spinal cord.

whether an X-ray would be sufficient, and the response suggested that the X-ray alone would be sufficient.

20. Dr B told HDC:

> 'I unfortunately believed at the time that [Mrs A] had had an MRI within the year prior to her surgery. I now realise that that assumption was incorrect, and her MRI at the time of surgery was out of date.'[7]

Surgery

21. On 11 December 2020 Mrs A presented at Hawke's Bay Hospital for the elective L2/L3 & L4/L5 O LIF. Before the surgery, Mrs A's sister (who was in hospital to receive an epidural for back pain) was prepped for surgery instead of Mrs A. The sisters are twins and have the same date of birth. The error was not detected until Dr B came to talk about the incision to start the surgery and Mrs A's sister pointed out that they had made a mistake and had taken the wrong family member in for surgery.

22. Consultant anaesthetist Dr C stated that the incorrect patient was brought from day surgery into the anaesthetic room and, as part of the sign-in process, the error was picked up.

23. Health NZ apologised for the error.

Neurophysiology

24. Neurophysiological studies are required as part of minimally invasive surgery such as an O LIF. Due to the close proximity of the instruments and implants to intra- and extra-cranial neural structures (part of the nervous system), neuromonitoring[8] provides real-time information on the proximity of these neural structures, in addition to any possible neural breach during the surgery. Neuromonitoring during the procedure was provided by neural monitoring technician Ms E.

Anaesthesia

25. Dr C stated that at the pre-surgery briefing, the specifics of the anaesthetic were discussed with Ms E, and it was agreed that a small amount of muscle relaxant could be used to facilitate intubation,[9] noting that the muscle relaxant would affect neuromonitoring transiently.

26. Mrs A was administered 30mg of rocuronium for intubation with no further muscle relaxant given, and anaesthesia was maintained with sevoflurane and remifentanyl. Dr C noted that Ms E was happy that the rocuronium had worn off enough for accurate neuromonitoring to occur.

[7] The NZ Orthopaedic Spine Society recommends that MRI imaging should be conducted within 12 months before surgery.
[8] A technique used during surgery to assess and protect the nervous system.
[9] Insertion of a tube into the airway to support breathing and provide anaesthesia.

27. Dr C monitored Mrs A during the O LIF procedure. Dr C said that Mrs A maintained stable monitoring of indices relevant to general anaesthesia throughout the procedure. Dr C documented that there were no concerns either before or during the procedure from an anaesthetic perspective, including any abnormal neurophysiological concerns and association with the anaesthesia. Dr C noted that 'the patient was stable throughout the procedure, [and] there was no suggestion of inappropriate blood pressure change consistent with acute injury'.

Signals during surgery

28. Ms E[10] placed neuromonitoring leads on Mrs A's lower limbs, all of which were confirmed to be working.

29. Ms E was employed by Neurology Services Australia Ltd. Both Ms E and Neurology Services Australia Ltd documented all the assessments and monitoring of Mrs A. Ms E used raw electromyography (EMG)[11] and triggered electromyographical monitoring (tEMG)[12] of Mrs A's lower limbs to monitor her neural function.

30. Ms E documented that Dr B was first alerted to an abnormal EMG signal during the L4/5 cage insertion, following which the cage was removed and a new one inserted, with a return to a normal EMG signal.

31. Dr B was again alerted to EMG abnormalities over all muscles monitored bilaterally in the course of malleting (hammering) a trial cage over L 2/3. Ms E stated that they were 'huge bilateral spikes, high amplitude with all muscles spiking' and they occurred over multiple mallet strikes. Ms E told the external reviewers that the recordings for this case were very unusual and that everyone in theatre was well aware that the neuromonitoring was very unusual (the external report explained that big, wide spikes indicate a large amount of muscle activation while small, narrow duration spikes can be seen when malleting).

32. It is recorded that the theatre nurse witnessed Ms E telling Dr B to halt because of the neuromonitoring changes being observed. Discussion then occurred between Dr B and Dr C, and the procedure continued once the recordings had normalised.

33. Dr B agreed that neurological firing was noted on two occasions and stated that the active procedure was stopped immediately. Dr B said that circuits were checked by the neurophysiologist and were deemed to be working properly, and the firing settled of its own accord. Dr B believed that this was consistent with typical firing during malleting and not due to direct neuro compression.

34. Ms G from Neurology Services Australia Ltd stated that the surgeon was alerted to 'EMG training' during both cage insertions. Train patterns (long periods of continuous EMG activity)

[10] Ms E was interviewed for the adverse event review (AER) discussed below. She was not able to be interviewed during HDC's investigation.
[11] A test to measure the electrical activity of muscles and nerves.
[12] Processes measuring muscle response or electrical activity in response to a nerve's stimulation of the muscle.

are related to an ongoing muscle twitch that may be because of continued nerve irritation, pain-related reactivity, light anaesthetic, or a muscle-derived spontaneous twitch. Ms G said:

> 'In terms of this setting the "training" activity may have indicated nerve reactivity from direct irritation of the nerve following either manipulation, or diathermy use, or malleting of a trial cage or cage itself in between the discs space; the activity could have been caused by stretching of the nerve or irritation of the nerve pathway by the impact.'

35. Ms G noted that EMG and tEMG are not a complete set-up for intra-operative neuromonitoring, and that a complete set-up would also include SSEP and MEP (to measure electrical signals from the body to the brain and measure electrical activity in the muscles and nerves following stimulation).

36. Ms G noted that a complete multimodality IONM[13] provides indications of possible real-time changes occurring during a surgical procedure endangering the nervous system and allows for detection, prior to the patient's awakening, of structures that have been impaired. She said:

> 'However, the purpose of an intra-operative neurophysiological assessment is to reduce the risks of post-operative neurological deficit and unfortunately it is often not possible to actually prevent or avoid surgical related impairments of the nervous system.'

37. Dr C stated that at one point, Ms E asked that the surgery be stopped over concerns on her monitor, and the surgery stopped immediately. Dr C said:

> 'At the time there was a lot of intraoperative malleting and banging going on. The technician reviewed her monitors for a period and decided, very clearly articulating that while there had been abnormal activity on the screens she thought that that was due to the intraoperative malleting that was happening and that we could proceed with the case. At no point after this was any concern raised about any subsequent neuromuscular monitoring results.'

38. Dr C stated that Ms E clearly expressed that she felt that the abnormal readings she had detected stopped when the intraoperative malleting stopped, and that they were good to continue with the procedure as planned. Dr C said:

> 'There was no interpersonal tension in the room and I would strongly refute any suggestion that [Dr B] continued with surgery ignoring the advice of the neuromuscular monitoring technician, this is simply factually incorrect.'

39. A junior doctor, Dr F, assisted Dr B during Mrs A's surgery. Dr F said that there were a few instances where the neuro-monitoring team alerted them that the neuro-monitoring device was firing. However, this was short-lived, and they were reassured to continue with the

[13] Intra-operative neurophysiological monitoring — procedures used to monitor neural pathways during high-risk surgery.

operation each time. Dr F saw nothing unusual during the surgery and was surprised about Mrs A's injury.

40. Dr B documented that the surgery proceeded under typical circumstances with standard precautions intra-operatively. Dr B noted that the approach as well as neurological monitoring throughout the case was normal and that 'neurologic monitoring was interpreted to be within normal limits and no indication of neurological compromise were noted'.

Post-surgery assessments

41. Following the surgery, there were concerns about Mrs A's loss of motor function and sensation at L4 and below. An MRI scan was performed, the results of which state:

> 'Post-operative changes following recent O LIF. The cage at L2–3 appears to extend to injury into the spinal canal. The cauda fibers and level of the L2–L3 disc space are compressed by some indeterminate intraspinal material which is not clearly fresh blood. Subtle oedematous changes of conus medullaris [the cone-shaped end of the spinal cord].'

42. A lateral X-ray was then performed, which indicated that the cage at L2/L3 had not entered the spinal canal or changed position.

43. Dr B stated that an injury from the cage did not fit with Mrs A's injuries. Regarding the MRI scan findings, Dr B said: '[N]otable metallic scatter is found at this level, and definitive statement to the posterior extent of the cage is not possible.' Dr B stated that the X-ray findings, both intra- and post-operatively are more reliable than the MRI scan, and both show that the cage is not in the spinal canal.

Second surgery

44. Dr B spoke with another orthopaedic surgeon by phone and discussed possible options. As neither of them were sure of the best path to take, Dr B contacted a senior colleague at a public hospital who suggested that if there were any doubts that this might be a haematoma (clotted blood) or a posterior compression, then to take Mrs A back to theatre for a posterior decompression. Dr B decided to take Mrs A back to surgery immediately.

45. Dr B spoke to Mrs A and explained that it was likely that a haematoma had developed, and that a return to theatre would be desirable. Mrs A agreed. Dr B attempted to contact Mrs A's husband but could not get an answer. Dr B then contacted Mrs A's sister and explained the situation to her. Mrs A's sister said that she would contact the rest of the family.

46. Mrs A was taken back to theatre immediately for an L1/2/3 posterior decompression. Dr B noted that when the posterior bone and ligament were removed, and the dura (the membrane covering the spinal cord) was exposed, it became obvious that an injury to the dura and cauda nerve roots (the nerves at the end of the spinal cord) had occurred and that there was a large dural defect. Some transiting nerves (those that go across the disc and exit the spine at the next level below) were still intact, but many were not. Once the damage to

the cord at L2/L3 was identified, the surgical site was closed. Mrs A was then admitted to the ICU.

Disclosure

47. That night, Mrs A and her family met with Dr B, Dr C, an ICU physician, and an orthopaedic doctor. Dr B documented:

> 'Full disclosure was made to the patient and family at that time about the injuries that had occurred. I apologised to both the patient and the family. Questions that the patient and family had were answered as best as possible. On exam at that time, it did appear the patient had some improvement following her posterior surgery. On the right she [had] increased sensation in the upper leg, as well as some weak return of motors. Definitive testing was not completed at that time due to the emotional state of all involved.'

48. Mrs A's family told HDC that Dr B told them that the nerve monitor showed that the nerves were unresponsive, which was when Dr B stopped the surgery, but then carried on. Dr B also told them that 'the blunt wedge' that was banged in most likely was the instrument that caused the damage, and 'the instrument [should not have been put] into such a small gap'.

49. Dr B met with Mrs A again on 12 December 2020. It is documented in the notes that Dr B explained to Mrs A that there was no clear adverse event that occurred during the first surgery. However, when the disc was opened during the second procedure, other possibilities became apparent, and it was thought likely that an injury was caused by instruments and that the cage was in a 'fine' spot. Dr B repeated the apology, which was accepted, and also requested that an ACC claim be submitted.

50. Although Dr B apologised to the family that the surgery had led to devastating injuries for the patient, Dr B told HDC that it 'was certainly not an admission of careless surgery'.

Further events

51. On 7 January 2021 Hawke's Bay Hospital suspended the use of the oblique and lateral interbody devices (cages) for use in the lumbar spine, during the investigation of this incident.

52. Dr H, a senior staff member, reviewed the case, and Dr B submitted a self-review of the incident. In addition, an external review from the New Zealand Orthopaedic Association was requested. Following receipt of the external review, the Health Services Leadership Team requested that a formal Adverse Event Review (AER) be completed by Patient Safety, which would incorporate both Dr H's internal expert opinion and the external review findings.

Adverse Event Review

53. The New Zealand Orthopaedic Association external review was written by two orthopaedic surgeons, and Health NZ's internal orthopaedic expert review was written by Dr H. The AER identified several concerns, as outlined below.

54. When the surgery was undertaken in December 2020, Mrs A's most recent lumbar spine MRI scan had been in December 2017. The AER notes that this time interval is greater than that recommended by the New Zealand Orthopaedic Spine Society, which advised that MRI imaging should be conducted within 12 months of the surgery. However, the external review considered that not having a more recent MRI scan was unlikely to have had a significant bearing on the case.

55. Mrs A's last documented clinical review prior to her surgery was on 6 August 2019, 16 months prior to the surgery on 11 December 2020. No review occurred after the epidural injection on 25 September 2019 despite plans for this at 6–8 weeks. Dr D had noted the absence of an updated MRI during a preoperative assessment on 29 October 2020, two months prior to the surgery, and that Mrs A's increased back and radicular pain was affecting her left leg. Dr H's internal expert opinion comments that updated information regarding neurological status and clinical symptoms close to or prior to the index surgery may often provide new insight into possible reconsideration of the original surgical decision.

56. Both the internal and external opinions confirm that it was appropriate to offer Mrs A an L2/3 and L4/5 O LIF with an adjunct L2–L5 posterior fusion. However, the external reviewers noted that the use of O LIF L2/3, especially in older female patients with smaller psoas muscles (in the lower back), may come with a higher risk of excessively posterior positioning of retractors when using an O LIF technique, and therefore these patients require particularly careful surgical technique.

57. The AER states that the neurophysiological study in this case was not a full multinodular modality monitoring set-up, which would have been the gold standard. It states that the complementary use of SSEP and MEP allows for close monitoring of the conduction of ascending and descending pathways, while EMG provides feedback only about real-time reactivity. The AER states that a tEMG allows for in-wound electrophysiological mapping.

58. The AER interpreted the increased signal amplitude as either a single compound muscle potential burst or a train of bursts via spikes, which is most commonly caused by a direct or indirect mechanical stress of functional neural tissue itself or to nearby structures (for example, mallet impact on the trial cage being positioned into the disc space). The AER noted that Dr B was notified of the increasing train activity immediately each time it occurred, and the connections with the possible meanings of the increased irritation in the specific areas of recording were all outlined. The presence of a quiet recording at the end of the procedure meant only that no spontaneous muscle activity was going on at that time over the EMG channels monitored.

59. The external reviewers explored the technical ramifications of the spinal surgery and raised concerns about the instrument placements. They stated that it is critical during disc preparation that well-centered and orthogonal fluoroscopic monitoring (a medical imaging technique that uses X-rays to create a moving image of the inside of the body) is performed repeatedly during disc preparation at L1/2. The AER states that the surgical technique of O LIF is 'extremely reliant' upon true orthogonal lateral and AP (anteroposterior — from front to back) image intensifier visualisation of the disc space being operated on. Obtaining these

images is reliant upon optimal patient positioning and monitoring of the patient. This is necessary in order to confirm that the optimal positioning of the dilator/retractor is maintained and also the trajectory of the instruments, malleted trails, and final implant. However, only one intraoperative image of the L2/3 O LIF was available, and the image shows only a single off-centre and rotated image.

60. The external reviewers raised concerns that the cage had been inserted on an abnormal trajectory, which suggested an issue with surgical technique 'as it is critical that the cage insertion instrumentation is "Orthogonalised" to a transverse trajectory [sideways or at an angle] prior to cage insertion. This issue may be compounded if the patient is not adequately positioned pre-operatively [lying on their side]'.

61. The AER states that final position of the L2/3 cage was very posterior. The external reviewers noted that the recommended surgical technique is for central or slightly anterior cage placement, and it is not recommended to place the cage posterior to the centre of the disc space because of the risk of entry to the spinal canal.

62. The conclusion of the AER was that either Mrs A's previous surgery and narrow L2/3 disc space, which required significant distraction preparation and cage insertion, resulted in a breach of the dura; or a specific and direct breach of the dura occurred as a consequence of inaccurate trajectory at the time of disc preparation, trial insertion, and definitive cage insertion; or a combination of the three. The experts considered that the first scenario (narrow disc space) was highly unlikely, and even less likely to cause transection of some nerve roots (as reported by Dr B). Therefore, the second 'inaccurate trajectory' scenario was the most likely explanation for the dural and cauda equina injury that Mrs A experienced following the O LIF procedure.

63. The external review and the internal expert opinion concluded that the technical clinical issues that were attributed to the outcome included:

- Insufficient use of the image intensifier
- Incorrect positioning of the patient and the retractor system
- Incorrect technique of orthogonalisation[14] (placement) of instruments in order to avoid entering the spinal canal
- Incorrect interpretation of the neuromonitoring changes

64. In their opinion, it was unlikely that one or two of these factors alone would have led to this outcome, but that the four factors together compounded and led to the adverse outcome.

Opinion Dr I

65. Dr B obtained an opinion from spinal surgeon Dr I, who largely agreed with the opinion of the two orthopaedic surgeons consulted by the New Zealand Orthopaedic Association.

[14] Orthogonal means that two systems do not interact to influence each other even though they come together at one point.

However, Dr I considered that their views of the neural monitoring were 'somewhat harsh'. Dr I stated that any real conclusions cannot be reached in the absence of transcranial motor-evoked potentials[15] or SSEPs. Dr I said that prior to reviewing this particular case, using only tEMGs would have been the standard of care. Therefore, Dr I believes that Dr B's set-up of the patient and the radiographs used to perform the procedure were within the expected standard of care.

Dr B's response to AER

66. Dr B disagreed with the AER findings and said that the cause of the injury is unknown. Dr B stated that disc preparation occurred under intra-operative imaging guidance, with concurrent neuromonitoring. Dr B stated that intra-operative imaging was completed as usual and was within acceptable limits throughout and, although there is the possibility for an instrument to move out of its intended trajectory within the plane of the X-ray beam, no findings on neuromonitoring were noted that would fit with a direct instrument injury.

67. Dr B stated that the absence of neuromonitoring findings at the time, and the presence of neuromonitoring firing later in the procedure, made a large-scale direct instrument injury during this part of the procedure unlikely. Dr B said that a direct injury to the cauda equina and dura from insertion of the cage also does not fit with Mrs A's injuries that were seen on posterior decompression, and the intra-operative imaging and postoperative imaging make that mode of injury unlikely.

68. Dr B stated that multiple images were taken during the surgery, but those images are rarely 'saved' and are used in a live-time fashion. Dr B said that only saved images are uploaded onto the hospital imaging system, and often these are confined to pertinent or final images of the procedure. That only one intra-operative image was saved is not indicative of the number of images actually taken.

69. Dr B stated that although the cage is at the posterior border of the vertebral bodies, it is not into the canal. Dr B considers that the postoperative MRI findings and report are misleading as notable metallic scatter is found at this level, and a definitive statement regarding the posterior extent of the cage is not possible. Dr B said that the X-ray findings, both intra- and post-operatively are more reliable, and both show that the cage is not in the spinal canal. Dr B stated that it is also unlikely that even if the cage were in that position, as if it were in the canal, it would cause a large-scale injury to the dura and neurological structures.

70. Dr B stated that the neuromonitoring during the trial implant insertion showed global firing, but that was believed to be in keeping with normal mass firing that occurs during impaction of an implant into position. Dr B said that this part of the procedure was also done under intra-operative imaging, and the implant did not breach the posterior line of the vertebral bodies.

71. Dr B agreed that the position of the L2/3 cage was very posterior, but stated that what, if any, effect this had is unclear. Dr B said that due to the significant difficulty in opening the

[15] Electrical signals recorded by electrodes on the scalp to monitor muscle response during surgery.

disc space at that level, the cage was placed slightly more posterior than usual to try to maximise the foraminal opening and the posterior height of the level 2/3 spinal segment.

72. Regarding the neuromonitoring, Dr B stated that the neurophysiologist actively monitors the neurological signals on a computer and provides real-time feedback along with expert analysis and interpretation. Dr B said that during Mrs A's case, mass firing was noted during insertion of one of the trial implants. Dr B was notified of these changes and immediately stopped further insertion and used intra-operative imaging to confirm that the position was acceptable. Dr B stated:

> 'In theatre the actual tracings are not visible to the surgical team, only to the neurophysiologist, and [the neurophysiologist's] interpretation at the time of surgery was that these changes were consistent with normal malleting related phenomena.'

73. Dr B told HDC that the AER comments regarding use of the O LIF technique at L2/3 are slightly misleading. Dr B said that while it is true that the psoas muscle is not at its largest cross-sectional dimension in the upper lumbar levels, the technique is still safely recommended at this level.

74. Dr B told HDC that the AER report also fails to address that an indirect injury from an increase in disc height or cage expansion may have had some role in Mrs A's injuries. Dr B said that given Mrs A's previous posterior procedure, it would not be uncommon for scar tissue to be present around the dura and spinal canal, and if the dura and nerve roots were excessively tethered from previous scar tissue, expansion of the cage may have acted to put excessive stretch on the dura and nerve roots. Dr B considers that a combination of direct and indirect factors was possible, but there was never any indication of injury from the monitoring used during the procedure.

Response from NZOA reviewers

75. The NZOA reviewers considered the responses provided by Dr B and Dr I. They responded:

> 'None of the comments by [Dr B and Dr I] are considered persuasive or relevant with regard to the findings of the NZOA Reviewers … The NZOA Reviewers do not consider the comments or findings in the Report to be inaccurate, and we therefore have no amendments to make to the NZOA Report as provided.'

Credentialling

76. Health NZ Te Matau a Māui Hawke's Bay had a Credentialling Policy for senior medical/dental officers (last reviewed in October 2016). The policy detailed the process of individual and departmental credentialling and included a requirement for two-yearly scope of practice reviews. Each clinician makes a declaration of their scope of practice, which must be approved by the department and signed off by their Head of Department (HoD).

77. The Credentialling Policy states that clinicians are responsible (and have professional accountability) to actively participate in the credentialling process, and to maintain competence within their scope of practice. The HoD and Service Director are responsible for

the individual credentialling process in each department in accordance with the Credentialling Policy.

78. Health NZ told HDC that Dr B's documents give the date of initial credentialling as 7 September 2017, and it was signed by the then HoD. Dr B's stated scope of practice included general and acute trauma and orthopaedic practice. Sub-specialist activities included major joint replacement and general orthopaedics. Conditions and procedures listed as requiring to be referred to tertiary institutes were procedures not appropriate to the then Hawke's Bay DHB and included severe spinal, pelvic, and paediatric trauma and/or orthopaedic disorders.

79. Health NZ said that Dr B completed a scope of practice and procedure checklist that was agreed with the HoD in September 2017 and approved by the chair of the credentialling committee in October 2017. Those documents assess Dr B as competent and regularly performing a number of listed spine procedures, including anterior lumbar interbody fusion (ALIF) and posterior lumbar interbody fusion (PLIF) procedures. However, the list does not include O LIF procedures.

80. Health NZ told HDC that prior to commencing employment at Hawke's Bay Hospital, Dr B was exposed to the O LIF surgical procedure during the fellowship at a public hospital, and attended training courses in three countries subsequently, in addition to a visit with a neurosurgeon in Australia. Health NZ stated that Dr B completed a very comprehensive recognised Spinal Fellowship at the public hospital. However, Health NZ noted that the O LIF procedure was very much in its infancy in New Zealand at that time.

81. Health NZ told HDC that the credentialling procedure notes that Dr B had performed an adequate number of anterior spinal procedures, akin to the O LIF, although Health NZ acknowledged that there is no documentation specifically to support credentialling for the O LIF procedure. Health NZ stated that the HoD at the time of the credentialling was satisfied that given Dr B's level of training and references, Dr B was suitably trained and qualified to embark on such procedures. Health NZ said:

> 'Therefore, it is [Health NZ's] position that, at the time of [Dr B's] appointment to a permanent role with HBDHB, appropriate steps had been pursued to ensure that [Dr B] was capable of performing this procedure.'

82. Health NZ stated that Dr B was not provided with a support surgeon when practice commenced at the hospital. This was a recommendation from one of Dr B's referees, but it is not reflected in the scope of practice assessment. Health NZ told HDC that Dr B's training and credentialling were considered upon appointment, and a scope of practice was agreed with him, but Dr B did not receive the support that was recommended and would have been prudent. Health NZ said that Dr B completed O LIF procedure surgery on 16 patients. Those operations were undertaken by Dr B without spinal surgical peer assistance.

83. Health NZ acknowledged that there was a weakness in the process for credentialling of the scope of practice for new appointees. It said that the Credentialling Policy has been updated and now describes a process to assess and review a clinician's scope of practice, including

introduction of new technology or expansion of a scope of practice. However, Health NZ noted that in many areas of practice it can be difficult to assess precisely for change in a scope of practice versus evolution of practice.

New procedure

84. The O LIF procedure had not been performed at Hawke's Bay Hospital prior to Dr B first undertaking it. Health NZ Te Matau a Māui Hawke's Bay had a policy for the 'Introduction of New or Innovative Clinical Practices or Procedures (Diagnostic, Therapeutic or Prophylactic)' that had last been formally revised in May 2015. New clinical practice is defined as an existing practice that is new to an individual, health provider, professional group, or physical setting. A clinician who proposes to introduce a new practice that alters what is performed must discuss this with the HoD or Clinical Director, and the clinician who is to perform it, and what is to be performed must be considered. The clinician introducing a new procedure is responsible for following the correct procedure for implementation, and the Credentialling Committee has a responsibility to guide and support the process to ensure that due consideration is given to safety and ethical and resource implications.

85. Health NZ told HDC that there are no credentialling documents related to the O LIF procedure, or if there are they are not recorded, which was a breach of the policy.

86. Health NZ said that the Associate Clinical Nurse Manager (ACNM) (Orthopaedics) explained that when a new device is introduced, it is assessed by a Product Evaluation Committee, which is part of the Purchasing Team. This ensures that the source of the device is from a registered company. At the time of these events, the ACNM did not routinely flag the use of new orthopaedic equipment to any other party in the organisation.

87. Health NZ has accepted the following failings:

- Credentialling for Dr B's scope of practice did not meet the policy standards.
- Credentialling for introduction of a new procedure (O LIF surgery) did not meet the policy standards.
- Senior colleague oversight was not documented in the employment process and in the planning for the new procedure.

Responses to provisional opinion

88. Mrs A was provided with the 'information gathered' section of the provisional report. Dr B and Health NZ were provided with the full report. Their comments have been incorporated into this report as appropriate.

89. Mrs A's family provided an impact report detailing the life-changing effect of her injury, including her ongoing pain and distress.

90. Dr B made no further comment on the report.

91. Health NZ Te Matau a Māui Hawke's Bay said that it did not dispute the information gathered during the investigation and accepted the provisional findings.

Opinion: introduction

92. First, I express my sincere empathy to Mrs A and her family for the effects of her life-changing injury. I acknowledge the significant and ongoing impact of these distressing events.

93. The events that occurred have been considered thoroughly in the AER that was informed by an NZOAER review by the two orthopaedic surgeons and Te Matau a Māui Hawke's Bay's internal orthopaedic expert review by Dr H. Having carefully considered this, and all the information provided to HDC, I propose to adopt the findings of the AER. However, I have also considered the extent to which Dr B and Dr I disagreed with the findings.

Opinion: Dr B — breach

Preoperative work-up

94. Mrs A's last documented clinical review prior to her surgery was on 6 August 2019, 16 months prior to the surgery on 11 December 2020. No review occurred after the epidural injection on 25 September 2019 despite plans for this at 6–8 weeks. Dr B said that this was because the injection was for pain relief rather than being diagnostic.

95. Dr D undertook a preoperative assessment on 29 October 2020, two months prior to the surgery. Dr D noted the absence of an updated MRI, and Mrs A's increased back and radicular pain affecting her left leg. Dr H's internal expert opinion comments that often updated information regarding neurological status and clinical symptoms close to or prior to the index surgery may provide new insight into possible reconsideration of the original surgical decision. I agree.

96. Mrs A's last MRI scan had been in 2017. When Dr D assessed Mrs A in the preoperative clinic, Dr D wrote in the plan that it would be discussed with the team whether there was a need for a more recent MRI. On 2 November 2020 Dr D followed up directly with Dr B asking whether an updated MRI was needed for Mrs A, or whether an X-ray would be sufficient. The response suggested that the X-ray alone was sufficient. In contrast, Dr B told HDC:

> 'I unfortunately believed at the time that [Mrs A] had had an MRI within the year prior to her surgery. I now realise that that assumption was incorrect, and her MRI at the time of surgery was out of date.'

97. The AER notes that this time interval is greater than that recommended by the NZ Orthopaedic Spine Society, which advised that MRI imaging should be conducted within 12 months before surgery. I accept this comment, and I am critical that Dr B did not organise for a further MRI to be conducted within 12 months of the surgery.

Surgery

98. Both the internal and external opinions confirm that it was appropriate to offer Mrs A an L2/3 and L4/5 O LIF with adjunct L2–L5 posterior fusion. However, the external reviewers noted that the use of O LIF at L2/3, especially in older female patients with smaller psoas muscles, may come with a higher risk of excessively posterior positioning of retractors with an O LIF technique and therefore these patients require particularly careful surgical technique. Dr B said that while it is true that the psoas muscle is not at its largest cross-sectional dimension in the upper lumbar levels, the technique is still safely recommended at that level. In my view, Dr B should have been mindful of the additional risks of O LIF L2/3 in a patient such as Mrs A.

99. Regarding the neurophysiology, the AER interpreted the increased signal amplitude as either a single compound muscle potential burst or a train of bursts via spikes, which is most commonly caused by a direct or indirect mechanical stress of functional neural tissue itself or to nearby structures (for example, mallet impact on the trial cage being positioned into the disc space). The AER noted that Dr B was notified of the increasing train activity immediately every time it occurred, and the possible meanings of the increased irritation in the specific areas of recording were all outlined. The AER stated that the presence of a quiet recording at the end of the procedure meant only that no spontaneous muscle activity was going on at that time over the EMG channels monitored.

100. Dr B said that mass firing was noted during insertion of one of the trial implants. Dr B was notified of these changes and immediately stopped further insertion and used intra-operative imaging to confirm that the implant position was acceptable. Dr B stated:

> 'In theatre the actual tracings are not visible to the surgical team, only to the neurophysiologist, and [the neurophysiologist's] interpretation at the time of surgery was that these changes were consistent with normal malleting related phenomena.'

101. In my view, it was not the role of the neurophysiologist to interpret the tracings — their role was to report them to the surgeon responsible for operative decision-making.

102. Ms E documented that Dr B was first alerted to an abnormal EMG signal during the L4/5 cage insertion, following which the cage was removed and a new one inserted, with a return to a normal EMG signal. Dr B was again alerted to EMG abnormalities while malleting a trial cage over L 2/3. Ms E said that they were 'huge bilateral spikes, high amplitude with all muscles spiking' and they occurred over multiple mallet strikes. Ms E told the external reviewers that the recordings for this case were very unusual. Ms G said:

> 'In terms of this setting the "training" activity may have indicated nerve reactivity from direct irritation of the nerve following either manipulation, or diathermy use, or malleting of a trial cage or cage itself in between the discs space; the activity could have been caused by stretching of the nerve or irritation of the nerve pathway by the impact.'

103. The theatre nurse witnessed Ms E telling Dr B to halt because of the neuromonitoring changes being observed. Discussion then occurred between Dr B and Dr C, and the procedure

continued once the recordings had normalised. I accept that Dr B stopped each time there was an abnormal EMG signal. I note that Dr C and Dr F both considered that the surgery proceeded normally and were surprised by the adverse outcome.

104. The external reviewers raised concerns about the instrument placements. They stated that it is critical during disc preparation that well-centered and orthogonal fluoroscopic monitoring is performed repeatedly during disc preparation at L1/2 but the images show only a single off-centre and rotated image. The AER states that the surgical technique of O LIF is 'extremely reliant' upon true orthogonal lateral and AP image intensifier visualisation of the disc space being operated on, and obtaining these images is reliant upon optimal patient positioning and monitoring. This is needed to confirm that the optimal positioning of the dilator/retractor is maintained and also the trajectory of the instruments, malleted trails, and final implant. However, only one intraoperative image of the L2/3 O LIF was available.

105. Dr B stated that disc preparation occurred under intra-operative imaging guidance, with concurrent neuromonitoring. Dr B stated that the intra-operative imaging was within acceptable limits throughout and, although there is the possibility for an instrument to move out of its intended trajectory within the plane of the X-ray beam, no findings on neuromonitoring were noted that would fit with a direct instrument injury. Dr B stated that multiple images were taken during the surgery, but these images are rarely 'saved' and the fact that only one intra-operative image was saved is not indicative of the number of images actually taken. I am unable to make factual findings as to the extent of intra-operative imaging.

106. The external reviewers raised concerns that the cage had been inserted on an abnormal trajectory, which suggested an issue with the surgical technique. The AER states that final position of the L2/3 cage was very posterior. The external reviewers noted that the recommended surgical technique is for central or slightly anterior cage placement, and it is not recommended to place the cage posterior to the centre of the disc space because of the risk of entry to the spinal canal. Dr B agreed that the position of the L2/3 cage was very posterior. Due to the significant difficulty in opening the disc space at that level, Dr B decided to place the cage slightly more posterior than usual to try to maximise the foraminal opening and the posterior height of the level 2/3 spinal segment.

107. On 12 December 2020 Dr B told Mrs A and her family that there was no clear adverse event that occurred during the first surgery. However, Dr B told them that when the disc was opened during the second procedure, other possibilities became apparent, and it was deemed likely that an injury was caused by instruments and that the cage was in a 'fine' spot.

108. Subsequently, Dr B has asserted that the cause of the injury is unknown and has disputed the findings of the AER experts. Dr B considers that an indirect injury from an increase in disc height or cage expansion may have had some role in Mrs A's injuries. Dr B said that given Mrs A's previous posterior procedure, scar tissue could have been present around the dura and spinal canal, and if the dura and nerve roots were excessively tethered from previous scar tissue, expansion of the cage may have acted to put excessive stretch on the dura and nerve

roots. Dr B considers that a combination of direct and indirect factors was possible but noted that there was never any indication of injury from the monitoring during the procedure.

109. The external review and the internal expert opinion concluded that the technical clinical issues that were attributed to the outcome included the following:

- Insufficient use of the image intensifier;
- Incorrect positioning of the patient and the retractor system;
- Incorrect technique of orthogonalisation of instruments in order to avoid entering the spinal canal; and
- Incorrect interpretation of the neuromonitoring changes.

110. In their opinion it was unlikely that one or two of these factors alone would have led to this outcome, but that the four factors together compounded and led to the adverse outcome. Having carefully considered the AER findings and Dr B's responses, I adopt the findings of the AER and accept that Dr B's surgical technique was inadequate and below the expected standard of care.

Credentialling

111. The Ministry of Health document Credentialling Framework for New Zealand Health Professionals (2010) recommends that the following practitioner responsibilities be included in credentialling documentation:

- The practitioner actively engages in all aspects of credentialling as a condition of their employment.
- The practitioner proactively collects quality and audit data as 'evidence' of their competence. This may include fulfilling the requirements of a professional organisation.
- The practitioner accepts professional responsibility to report their own and others' diminishing competence.

112. Dr B was a relatively newly qualified consultant (since 2017) and was undertaking complex surgery not previously performed at Hawke's Bay Hospital. Despite a referee having recommended a support surgeon for similar procedures, Dr B did not seek peer support.

113. Furthermore, Dr B was not credentialled to perform O LIF procedures. The Credentialling Policy states that clinicians are responsible (and have professional accountability) to actively participate in the credentialling process, and to maintain competence within their scope of practice. In my view, it was both Dr B's and Health NZ's responsibility to ensure that Dr B was credentialled adequately.

114. The O LIF procedure had not been performed at Hawke's Bay Hospital prior to Dr B first undertaking it. The Health NZ Te Matau a Māui Hawke's Bay policy for 'Introduction of New or Innovative Clinical Practices or Procedures (Diagnostic, Therapeutic or Prophylactic)' required a clinician who proposes to introduce a new practice that alters what is performed,

who performs it, and what is to be performed must consult with the HoD or Clinical Director. The clinician introducing a new procedure is responsible for following the correct procedure for implementation. However, there is no evidence that Dr B complied with the policy, and there are no credentialling documents related to the O LIF procedure.

115. Overall, I conclude that Dr B failed to obtain sufficiently current information on which to make a reasonable decision to conduct this complex surgery, the surgical technique was inadequate, and Dr B failed to comply with the policies in place for credentialling and the introduction of the O LIF procedure. For the above reasons, I find that Dr B did not provide services to Mrs A with reasonable care and skill and breached Right 4(1)[16] of the Code of Health and Disability Services Consumers' Rights (the Code).

Opinion: Health NZ|Te Whatu Ora — breach

116. As a healthcare provider, Health NZ is responsible for providing services in accordance with the Code. It had a responsibility to ensure that new procedures were introduced appropriately, staff were credentialled, and that Mrs A received services of an appropriate standard.

117. I have carefully considered the extent to which the failings in Mrs A's care occurred as a result of individual staff action or inaction, as opposed to systemic and organisational issues. As discussed above, I have concerns about Dr B's surgical technique, but I also consider that there were failures at a systems level.

118. The Ministry of Health document 'Credentialling Framework for New Zealand Health Professionals' (2010) states that provider organisations have ultimate responsibility for the credentialling of particular services provided by their practitioners and must take all reasonable steps to ensure that its health professionals are capable of safely undertaking the clinical responsibilities specified in their contracts. It is a governance responsibility to monitor and maintain the clinical competence of all health practitioners working in the organisation.

119. Health NZ Te Matau a Māui Hawke's Bay has accepted that credentialling for Dr B's scope of practice did not meet its policy standards; credentialling for the introduction of O LIF, which was a new procedure, did not meet the policy standards, and senior colleague oversight was not documented in the employment process and in the planning for the new procedure.

120. The outcome was that a relatively new orthopaedic surgeon was able to introduce a new procedure with minimal oversight or support.

121. The AER states that the neurophysiological study in this case was not a full multinodular modality monitoring set-up, which would have been the gold standard. It states that the

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

complementary use of SSEP and MEP allows for close monitoring of the conduction of ascending and descending pathways while EMG provides feedback only about real-time reactivity. The AER states that tEMG allows for in-wound electrophysiological mapping. I accept that the monitoring was limited, and in my view Health NZ Te Matau a Māui Hawke's Bay should have considered whether this surgery should more appropriately have been conducted in a major hospital.

122. I have concluded that inadequate credentialling, the failure to provide a support surgeon to Dr B, and the lack of compliance with the policy for 'Introduction of New or Innovative Clinical Practices or Procedures (Diagnostic, Therapeutic or Prophylactic)' is reflective of systemic and organisational issues at Health NZ, for which it is responsible at a service level. Accordingly, I find that Health NZ breached Right 4(1) of the Code.

Changes made

123. In terms of the progress of the recommendations of the AER report, Health NZ stated:

a) Dr B was referred to the Medical Council of New Zealand, which undertook a review of Dr B's practice through a PAC.

b) The Credentialling Policy for Health NZ Te Matau a Māui Hawke's Bay has been reviewed and an updated policy implemented. The policy includes detail regarding the credentialling of individual scope of practice and scope of practice review.

124. The Credentialling Policy was updated by the Credentialling Committee and finalised by the Policy Management Advisory Group. The Credentialling Committee meets biennially with Heads of Department for each department and focuses on biennial review of SMO scopes of practice and practice concerns in each department. It also reviews and approves the credentialling of new SMO appointees as they are appointed.

125. The Orthopaedic Department concluded that the O LIF procedure is within the scope of practice of surgeons with appropriate spinal surgery training.

126. Health NZ Te Matau a Māui Hawke's Bay said that prior to December 2023 it did not provide a spinal surgery service due to constraints on surgeon capacity. All planned surgery and acute services were provided in another city or another tertiary centre as required. To facilitate appropriate patients being transferred to the other city for surgery, two senior surgeons from that city held fortnightly video-conference meetings with local spinal surgeons to discuss complex cases. In addition, they held clinics in Hawke's Bay quarterly.

127. Health NZ Te Matau a Māui Hawke's Bay recommenced some spinal surgery in February 2024 when a new surgeon started with the service, and spinal surgery progressed in June 2024, when another surgeon recommenced spinal work. Spinal surgery will develop further when a third spinal surgeon commences employment in September 2025. Health NZ said that an

important part of recommencing and developing the service has been collaboration between local spinal surgeons on individual cases with a view to combined decision-making. This is an extension of what was happening with the Wellington surgeons, and it now occurs between the local surgeons and also between the local and Wellington surgeons.

128. The combined decision-making process includes discussion on whether surgery is appropriate; the type of surgery that is appropriate; and whether surgery should occur locally or in another city. This includes combined consideration of whether Health NZ Te Matau a Māui Hawke's Bay has the required expertise and required technology for the proposed surgery.

129. Local and regional surgeons now work in a much more collaborative manner in the surgery decision-making process than had occurred previously.

Recommendations

130. I recommend that Dr B and Health NZ Te Matau a Māui Hawke's Bay each separately provide a written apology to Mrs A for their breach of the Code. The apologies are to be sent to HDC, for forwarding, within three weeks of the date of this opinion.

131. I recommend that before recommencing providing the O LIF procedure, Health NZ Te Matau a Māui Hawke's Bay obtain expert advice about the neurophysiological monitoring that will be provided and send that advice to HDC.

Follow-up actions

132. A copy of the sections of this report that relate to Dr B will be sent to the Medical Council of New Zealand.

133. A copy of this report with details identifying the parties removed, except Health NZ Te Matau a Māui Hawke's Bay and Hawke's Bay Hospital, will be sent to the Medical Council of New Zealand and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.