Orthopaedic Fellow, Dr B

Orthopaedic Surgeon, Dr C

Auckland District Health Board

An Opinion by the

Health and Disability Commissioner

(Case 16HDC00877)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. Mr A, aged 61 years, had an accident in April 2013, which resulted in multiple injuries including rib fractures and a hyper-extension injury to his neck. In 2014 he developed pain in his neck and problems swallowing and doing fine activities with his hands, and he was slightly unsteady on his feet.

2. An orthopaedic and spinal surgeon, Dr C, saw Mr A on 13 August 2014 and recommended that he undergo an anterior cervical discectomy and fusion[1] (ACDF) at C5/6 and C6/7. Dr C cannot recall the discussion but said it was likely that he discussed using an allograft (using donated material from a cadaver) rather than harvesting an iliac crest (hip) graft from Mr A.

3. On 22 January 2015, Mr A was seen by an orthopaedic medical officer, Dr D, for a pre-admission appointment. Mr A recalls being told that bone shavings would be taken from his hip and put between the vertebrae in his neck. Dr D does not recall what he told Mr A but said he would have explained the operation in general terms but not the type of bone graft.

4. Dr C saw Mr A again on 22 April 2015. It was noted that Mr A was having increasing problems, and Dr C tried to expedite the surgery. Mr A said that he was told that the damaged bone between his vertebrae would be repacked with bone from his hip, and that his hip would be quite painful and he might have trouble sitting down after the operation.

5. On 15 May 2015, Dr B saw Mr A to obtain his informed consent to the surgery. Dr B does not remember the conversation he had with Mr A, but said that he relied solely on the available medical records, and he consented the man for the procedure stated in the clinical records. The consenting surgeon said that there was no documented preoperative plan to use an allograft, and he was not aware that it was the first orthopaedic surgeon's usual practice to use an allograft.

6. Dr C performed the ACDF surgery on 15 May 2015, assisted by Dr B, with no complications. Mr A was an in-patient in [ADHB] until 19 May 2015. He said that after the operation he asked Dr B three times why his hip was not sore and, each time, Dr B "talked around the subject".

7. On 1 July 2015, Mr A saw Dr C in the orthopaedic outpatient clinic. Mr A said that he asked the same questions about his hip bone, and Dr C told him that no bone was taken from his hip, and that bone from a dead person had been put in his neck. Mr A stated: "I left that appointment rather upset."

8. Dr C did not record that Mr A had any concerns about the informed consent process.

9. On 2 July 2015, Mr A telephoned Dr C and said that he had been unaware that body parts from someone else would be used during the surgery. Dr C does not recall the details of the conversation but accepts that Mr A told him that he had been unaware that donor bone would be used for his surgery.

10. Dr C did not document the conversation in the clinical records.

[1] Anterior cervical discectomy with fusion is surgery designed to relieve spinal cord or nerve root pressure in the neck by removing all or part of a damaged disc.

Findings

Dr C

11. As the responsible consultant, overall responsibility for ensuring that Mr A was provided with sufficient information about the proposed treatment lay with Dr C. For failing to provide that information, Dr C breached Right 6(1) of the Code of Health and Disability Services Consumers' Rights (the Code)[2].

12. Dr C failed to make it clear to Dr D and Dr B that an allograft was planned, and Dr B was unaware that it was Dr C's usual practice to use an allograft. Consequently, the clinicians who saw Mr A after 13 August 2014 were unable to provide the necessary information to Mr A. This failure to ensure quality and continuity of services to Mr A was the responsibility of Dr C. Accordingly, Dr C breached Right 4(5) of the Code.[3]

13. Dr C failed to record his intention to use an allograft, and did not record the information he gave to Mr A. Mr A raised his concerns with Dr C — on 1 July 2015, 2 July 2015, and again at the postoperative review on 19 August 2015 — regarding the informed consent process and that he had been unaware of the plan to use an allograft, but Dr C made no record of these conversations or the concerns. Dr C failed to comply with professional and legal standards and breached Right 4(2) of the Code.[4]

Dr B

14. It was Dr B's responsibility to ascertain the planned procedure, so that he would be in a position to inform Mr A. As there was no information in the clinical records about the graft procedure to be undertaken, Dr B should have contacted Dr C to clarify the plan before talking to Mr A. Dr B did not inform Mr A that donated material was intended to be used in his surgery, or discuss the other options available to him. That was information that a reasonable consumer in Mr A's circumstances would expect to receive. Accordingly, Dr B breached Right 6(1) of the Code.[5] It follows that Mr A was not in a position to make an informed choice and give informed consent for the treatment provided. Consequently, Dr B also breached Right 7(1) of the Code.[6]

15. Adverse comment was made that if Mr A did attempt to raise his concerns with Dr B after the surgery, Dr B did not pay sufficient attention to what he was told.

Auckland District Health Board

16. The culture of Auckland District Health Board (ADHB) at the time of events was that it was not necessary to obtain consent for the use of donated material if the use of that material carried no risk and, from that, it was assumed that the patient did not need to be told. ADHB

[2] Right 6(1) of the Code states: "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive …"
[3] Right 4(5) of the Code states: "Every consumer has the right to co-operation among providers to ensure quality and continuity of services."
[4] Right 4(2) of the Code states: "Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards."
[5] Right 6(1) of the Code states: "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive …"
[6] Right 7(1) of the Code states: "Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise."

did not provide Mr A with information that a reasonable consumer would expect to receive and, accordingly, breached Right 6(1)(b) of the Code.[7]

Recommendations

17. It was recommended that Dr C attend training courses on record-keeping and communication with patients and colleagues. It was also recommended that he provide a written apology to Mr A.

18. It was recommended that Dr B provide a written apology to Mr A.

19. ADHB agreed to amend its informed consent policy to require explicit consent for the use of allograft material, and to review the "Agreement to Treatment" form with a view to including a prompt for consent to the use of human products in all procedures where human products are used. ADHB also agreed to include in the "Agreement to Treatment" form a space for the surgeon to counter-sign the consent stating that the patient has been informed appropriately if consent has been taken by another clinician.

20. It was recommended that ADHB report to HDC on the steps being taken to ensure full compliance with the use of surgical checklists in the Orthopaedic Service.

Complaint and investigation

21. The Commissioner received a complaint from Mr A about the services provided to him at ADHB. The following issues were identified for investigation:

- *Whether Dr B provided Mr A with an appropriate standard of care between August 2014 and May 2016.*
- *Whether Dr C provided Mr A with an appropriate standard of care between August 2014 and May 2016.*
- *Whether Auckland District Health Board provided Mr A with an appropriate standard of care between August 2014 and May 2016.*

22. The parties directly involved in the investigation were:

Mr A	Consumer/complainant
Dr B	Provider/orthopaedic fellow
Dr C	Provider/orthopaedic surgeon
Auckland District Health Board	Provider

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

Also mentioned in this report:

Dr D	Orthopaedic medical officer
Dr E	Anaesthetist
Dr F	Senior medical officer
Dr G	Clinical Director, Orthopaedic Service
Dr H	House officer

23. Independent expert advice was obtained from an orthopaedic and spinal surgeon, Dr Christopher Hoffman (**Appendix A**).

Information gathered during investigation

Background

24. Mr A, aged 61 years, had an accident in April 2013, which resulted in multiple injuries including rib fractures and a hyper-extension injury to his neck. On 20–21 May 2014 he was admitted to [ADHB] with likely cervical myelopathy[8] with numbness in both hands. Subsequently, he saw an orthopaedic surgeon at ADHB. Mr A told the orthopaedic surgeon that he had constant numbness in his right hand and occasional numbness in his left arm. Mr A also had ongoing pain in his neck, with the pain radiating to the top of his right shoulder, he had problems swallowing and doing fine activities with his hands, and he was slightly unsteady on his feet.

13 August 2014 — Dr C

25. The orthopaedic surgeon referred Mr A to an orthopaedic and spinal surgeon, Dr C, who saw Mr A on 13 August 2014. An MRI scan of Mr A's cervical spine showed broad-based disc bulges at C5/6 and C6/7 with marked narrowing of the central canal at C5/6 and C6/7, with foraminal narrowing,[9] particularly on the right C6/7. Dr C recommended that Mr A undergo an anterior cervical discectomy with fusion (ACDF)[10] at C5/6 and C6/7 with the aim of stopping any further deterioration of his symptoms and, hopefully, "finding some improvement".

26. Dr C recorded that he had a "long talk" with Mr A on 13 August 2014. Dr C told HDC that during the conversation he recommended the surgery, and explained the reason for the surgery and the expected clinical outcomes. Dr C said that the decision to use Cornerstone

[8] A clinical syndrome caused by compression on the spinal cord that is characterised by clumsiness in the hands and gait imbalance.
[9] Foraminal narrowing of the spine occurs when the foraminal canal — the canal through which nerves exit the spine — narrows and becomes constricted. It creates a high risk of nerve compression in the spine. A trapped or compressed nerve root can cause severe, chronic pain that occurs not only at the site of the nerve compression but also through the length of the nerve pathway into the extremities.
[10] An anterior cervical discectomy with fusion is surgery designed to relieve spinal cord or nerve root pressure in the neck by removing all or part of a damaged disc.

cages[11] would have been made before the date of the surgery, as the equipment and cages are sourced from external companies. Dr C stated that it is his standard practice to use cages packed with allograft[12] material for this operation, so it is likely that he discussed using an allograft rather than harvesting an iliac crest (hip) graft. Dr C said: "I cannot recall specific details of the discussions I had with [Mr A] … [I]t is my routine practice to discuss the nature of donor bone tissue when discussing the surgery."

27. There is no documentation in Mr A's clinical records of a discussion about the use of donor bone (allograft) in the allograft cages. Dr C said that it was an oversight on his part not to document the planned procedure.

28. Dr C also stated that generally the discussion about the allograft is done on the day of the surgery, because often the surgeon does not see the patient in the weeks prior to the surgery after the patient has been waitlisted, and the consent process needs to be done close to the time of surgery. He said: "It is therefore standard practice to discuss the specific details and implants at the time of the consent process (closer to or on the day of the surgery)."

29. Dr C stated that he saw Mr A again on 22 April 2015 "when he was noted to be having increasing problems and we tried to expedite his surgery". Dr C said that he discussed with Mr A his concerns about his hands. Mr A recalls Dr C explaining the operation to him and showing him X-rays of where he would be operating. Mr A remembers being told that the damaged bone between his vertebrae would be "repacked with bone from [his] hip". Mr A specifically remembers being told that his hip would be quite painful and he might have trouble sitting down after the operation. He thinks that this conversation took place in April.

Pre-admission appointments

30. On 22 January 2015, Mr A was seen by an orthopaedic medical officer, Dr D, for a pre-admission appointment. Mr A recalls being told that bone shavings would be taken from his hip and put between the vertebrae in his neck.

31. Dr D does not recall Mr A, but said that it is his usual practice to describe the operation a patient will be having in terms that are easy to understand, without unnecessary technical or medical terminology. Dr D stated that it is not his usual practice to discuss specific details of metalware design, brands, metallurgy, artificial graft composition or other implants to be used unless they are specified in writing by the surgeon in the surgeon's clinical letter or on the surgical wait-list form, as that is outside his level of expertise. He stated:

> "In our department, it is routine practice for the final discussion regarding orthopaedic implants to be done by a surgeon performing the operation, at the time the surgical

[11] Cervical cages are used to stabilise the spine and promote bone fusion following interbody fusion surgery in the cervical spine. The hollow design of the cage allows for in situ packing with autograft or synthetic bone substitute.

[12] An allograft is a bone, ligament, cartilage, tendon or section of skin that is transplanted from one person to another. An alternative to using autologous (from the patient's own body) or allogeneic (from a donor) bone grafts during ACDF is the use of cages that are often filled with morselised autologous bone from the surrounding area supplemented with bone graft substitutes (such as crushed allograft, demineralised bone matrix, or synthetics such as calcium phosphate and/or hydroxyapatite). The purpose of cages is to support the segment while bony fusion is promoted through the central void filled with grafting material.

> consent form is completed. This is usually done in the outpatient clinic or on the day of surgery in the pre-op theatre suite waiting area."

32. Dr D documented that he had a general discussion with Mr A regarding the operation recovery time and preoperative instructions. Dr D said he would have explained to Mr A that he would have a "metal plate and screws" inserted into his neck as that is routine practice for that type of fusion. Dr D said he would have discussed in general terms the use of a fusion plate, cage or spacer, and would have discussed the use of bone graft in general terms, but "as there was no mention of bone allograft in the surgeon's letter or surgical waitlist form, [he] would not have discussed types of bone grafts with [Mr A]".

33. Auckland District Health Board (ADHB) stated that Dr D was not aware that allograft was being used.

34. Dr D said that Mr A did not raise particular concerns, and indicated that he would be happy to sign the consent with the surgeon on the day of the operation. Dr D said that the pre-admission appointment was the only involvement he had with Mr A.

35. Mr A also attended an anaesthetic pre-assessment.[13] He was seen by an anaesthetist who told HDC that he does not obtain consent for the anaesthesia at the time of the anaesthetic pre-assessment, and he "routinely avoid[s] discussing the proposed surgical plan in any detail". He said that he would not have discussed the bone allograft implantation. There is no record of any discussion about postoperative pain relief for pain from a bone graft taken from the iliac crest.

Informed consent 15 May 2015

36. On 15 May 2015, Dr B[14] saw Mr A to obtain his informed consent to the surgery.

37. Dr B told HDC that he did not have any discussion with Dr C about the proposed surgery prior to obtaining informed consent from Mr A. Dr B said: "I would certainly remember any such discussion/meeting had it occurred." Dr C said that it is his standard process to discuss with the spinal fellow upcoming procedures and how they would be performed. He said it is his practice to go over the history and imaging findings and discuss how the procedure would be performed, the positioning of the patient, and the type of operating table that would be used. He said that he would discuss the implants to be used and any other relevant details. He stated:

> "I do not usually record these conversations. Due to the length of time that has passed since this procedure, I cannot recall the specific conversation that would have taken place between [Dr B] and me regarding [Mr A]."

38. Dr B stated that he relied solely on the available medical records, and he consented Mr A for the procedure stated in the clinical records (which was also the procedure Mr A was booked for in the surgical list). Dr B said that it is his usual practice to go through the clinical records and surgical booking form prior to consenting the patient, and if any

[13] The assessment relates to the suitability for, and risks of, the anaesthetic, and informed consent for the anaesthesia is not obtained at that time.
[14] Dr B is a qualified and certified orthopaedic surgeon, who at the time of these events was working as a fellow at ADHB.

discrepancy is noted between what has been explained to the patient during clinic visits preoperatively and what is in the available clinical records, he would seek further clarification from the operating surgeon, but in the absence of any specific instruction, he would not consent the patient for anything not stated in the clinical records.

39. Dr B said that there was no documented preoperative plan to use an allograft, and he was not aware that it was Dr C's usual practice to use an allograft. Dr B noted that the procedure can be performed without the use of an allograft or iliac crest bone graft, and many surgeons use bone graft substitutes. He stated that he does not remember being told that allograft cages would be used in the surgery. He said that during his time at ADHB he never specifically consented a patient for an allograft.

40. Dr B does not remember the conversation he had with Mr A, but said that if the use of an allograft had been planned preoperatively, it would have been an oversight on his behalf not to have documented having discussed that with Mr A at the time of obtaining consent.

41. Mr A said that Dr B told him that he would have a sore neck and a sore hip because bone was going to be taken from his hip to be used in the operation. Mr A said: "I signed the consent form thinking this is what is to be done."

42. Dr C stated that it would have been his expectation that Dr B would have provided and documented the full informed consent process regarding the procedure Mr A would undergo, including the use of an allograft. Dr C stated: "I was under the expectation that if there was uncertainty regarding the nature of the procedure or consenting process that this would have been discussed with me." He said: "I would not have delegated the task to [Dr B] had I not thought he was completely up to speed with [Mr A], the surgery and the use of allograft." Dr C said that Dr B was familiar with the procedure of ACDF and had completed it previously, which was why he (Dr C) felt confident in delegating the task of conducting the preoperative consenting process. Dr C stated that the failure to mention the allograft during the consent process "was an oversight by our service".

43. Anaesthetist Dr E said that he was the specialist anaesthetist attending Mr A on the day of his surgery. With regard to consent for the anaesthetic, Dr E stated: "As neither the operating room list nor the consent form mention requiring bone graft — and I cannot recall any discussions to that effect — it is likely we were not aware bone grafting was required." He said that this was not unusual for ACDF surgery. He added that he does not recall the surgeons discussing or deliberating on the use of bone graft, allograft, or other implant.

44. The agreement to treatment form signed by Mr A and countersigned by Dr B states that the procedure to be performed was an "[a]nterior cervical discectomy and fusion (ACDF), C5/6 and C6/7". The agreement to treatment form does not have any space or prompt relating to donated tissue.

45. Dr F, stated that the allograft used in Mr A's surgery had been sterilised to a point that the graft was no longer living tissue — it had become a manufactured scaffold onto which the patient's own bone would build. Dr F said:

> "There are thousands of procedures in which an allograft is used in New Zealand and world-wide each year. It is not standard practice to seek express consent to the use of the

> allograft as there are no particular risks inherent in the product … thus there is no contemporaneous written record that [Mr A] was specifically appraised of this aspect of the surgery before it occurred."

46. The Clinical Director for the Orthopaedic Service, Dr G, stated that the use of allografts is not uncommon. He added:

> "The current process [at ADHB in 2016] is for the bone graft or allograft to be placed in the consent. This is discussed with the patient, including the benefits and risks of the procedure and the graft before the patient signs the consent form."

47. In response to the provisional opinion, ADHB stated:

> "Familiarity with the use of these materials and increasing confidence re their safety has not led to surgeons being casual or cursory in their use. Orthopaedic Surgeons are acutely aware of the psychological and physical implications for patients who may be about to receive transplanted or processed tissue from deceased persons."

Surgery and postoperative care

Preoperative checks

48. On 15 May 2015, prior to the commencement of the surgery, the surgical safety checklist protocol was followed. The form indicates that the process is that the sign-in identifying the patient takes place outside the operating room and that, in the operating room, the details of the procedure are checked against the consent and confirmed with the patient. Dr C stated that the surgical safety checklist is completed by the preoperative nurses outside the operating room and that Mr A's identity was confirmed outside the operating room.

49. The form states, "Checklist complete in the OR", beneath which there are three boxes for "Sign in", "Time", and "Signout", each of which have been ticked. The form is not signed, and it is unclear from the ticks on the form whether the procedure was checked against the consent and confirmed with Mr A in the operating room. Dr C stated: "There are no notes on this form that indicate that the procedure was checked against the consent and confirmed with [Mr A]."

50. ADHB stated that there is no written record that Mr A was informed that an allograft was going to be used. A nurse consultant said that she spoke with the three nurses and anaesthetic technician involved, and none of them can recall Mr A or any discussion about using iliac crest or allograft material. She said that all three nurses noted that often an allograft was not documented on the consent form, "but they would assume [it] was verbally discussed as a part of the informed consent process".

Surgery

51. Dr C performed the ACDF surgery on 15 May 2015, assisted by Dr B, with no complications.

Postoperative care

52. On 16 May 2015, Mr A was seen by Dr C during a consultant ward round. Dr C does not recall Mr A raising any issues with him during the ward rounds.

53. Dr B stated that he was not present on the 16 May 2015 ward round as he was on call for orthopaedic emergencies.

54. On 18 May 2015, a house officer, Dr H, recorded that Mr A was seen by Dr B at around 7.43am, and that Mr A was making satisfactory progress. An X-ray was requested, and the plan was for Mr A to be discharged if he made good progress with the physiotherapist. There is no record of Mr A having asked why his hip was not sore. Dr B stated that when he saw Mr A he "would have used this opportunity to explain and answer all of [Mr A's] queries".

55. The records state that on the morning of 19 May there was a "fellow ward round", and that Mr A was making satisfactory progress and could be mobilised wearing a soft collar and discharged home with advice to avoid heavy lifting. Again there is no mention of Mr A having asked about his hip.

56. Dr B said that he does not recall Mr A raising any serious issues or specific concerns with him during the ward rounds. Mr A said that during his stay in hospital after the operation he asked Dr B three times why his hip was not sore and, each time, Dr B "talked around the subject".

57. Mr A was an in-patient in ADHB until 19 May 2015.

Postoperative review 1 July 2015

58. On 1 July 2015, Mr A saw Dr C in the orthopaedic outpatient clinic. Mr A's pain had improved, and a plan was made to review him in 6–8 weeks' time. Mr A stated that during this appointment he discussed the way he had been treated by Dr B, and Dr C told him that he could ask him anything he wanted to know about his treatment.

59. Mr A said that he asked the same questions about his hip bone, and Dr C told him that no bone was taken from his hip, and that bone from a dead person had been put in his neck. Mr A stated: "I left that appointment rather upset." Dr C did not record that Mr A had any concerns about the informed consent process, and told HDC that this could have been because he (Dr C) viewed the matter of donor bone as an ordinary follow-up question post surgery.

60. The following day (2 July), Mr A telephoned Dr C and said that he had been unaware that body parts from someone else would be used during the surgery. Mr A said that Dr C asked what Dr B had told Mr A before the operation, and Mr A replied that nothing was said about donor bone, and he was told that his own hip bone would be used.

61. Dr C agreed that Mr A rang him on 2 July, but again does not recall the details of the conversation. Dr C accepts that Mr A told him that he had been unaware that donor bone would be used for his surgery. Dr C recalls going over Mr A's concerns and worries to the best of his ability, given that he was not involved in the consent process. Dr C accepts that he should have met with Mr A to discuss his concerns face to face.

62. Dr C stated: "As I was out of [ADHB], on the date he rang me, it was my oversight that our telephone discussion was not documented in his hospital records." Dr C does not recall Mr A being particularly concerned or distressed during any of their appointments.

63. Dr C said that he spoke to Dr B about Mr A's concerns, but cannot recall specifics of the conversation. Dr C stated:

> "I would most likely have explained to [Dr B] that when allograft is used it is so important to ensure it is explained in the informed consent process so the patient is fully informed and consents to it."

64. Dr B does not recall Dr C speaking to him about how he (Dr B) obtained Mr A's consent. Dr B stated that as he was Dr C's fellow, it was routine for them to speak many times on most days regarding patient care. Dr B said: "Although I cannot recall any conversation directly relating to the above, such a conversation may have occurred."

Postoperative review 19 August 2015

65. Dr C saw Mr A again on 19 August. Mr A's pain had improved. Mr A said that he asked whether Dr C had spoken to Dr B, and Dr C said that he had done so and the situation would never happen again. Dr C agrees that they discussed Mr A's concerns, but again cannot recall any details of the conversation.

Auckland District Health Board — further information

66. ADHB stated that it is the policy of the surgical service that consent be undertaken by, or directly under the supervision of, the operating surgeon. ADHB agrees that the consenting process for Mr A fell short of the recommended and required standard. It considers that the communication between staff within the service was below standard, as neither Dr D nor Dr B were aware that an allograft cage was to be used, which was a significant cause of the ensuing difficulties.

67. ADHB stated that there is no contemporaneous evidence that postoperatively Mr A raised his concerns about the use of an allograft.

68. ADHB said that the matter was discussed in detail at the Orthopaedic Department monthly meeting. A meeting with Mr A was arranged, attended by orthopaedic surgeon Dr G and a spinal surgeon. The situation was discussed with Dr C.

69. ADHB said that changes have been made to practices within the Orthopaedic Department, including recording of any discussion relating to the use of either autograft[15] or allograft. In addition, it is now recommended that notes be made of conversations (including telephone conversations) in sufficient detail to allow for appropriate subsequent confirmation and management of difficulties.

70. ADHB said that in future when an allograft cage is to be used, the patient will be provided with a brochure,[16] generally supplied by the company that provides the allograft, so that the patient has complete knowledge of the use of the allograft and of its safety. Dr G said: "On behalf of the service I would again convey apologies to [Mr A] for the distress that he has suffered."

[15] A graft of tissue from one point in a person's body to another part of the same person's body.
[16] ADHB provided HDC with a copy of the brochure. It does not explain what "allograft" means or provide information about the options available.

Mr A — further information

71. Mr A stated that he lodged a claim with ACC, which was accepted. He said that he has had a psychiatric assessment and is now seeing a psychologist to assist him on how to forget that he has someone else's bone in his neck.

Informed consent policy

72. ADHB's "informed consent" policy (August 2009) states:

> "The primary responsibility for ensuring information is imparted lies with the person who is responsible for the procedure. In some situations it is impracticable for all information to come from the health professional conducting the procedure. In such cases an appropriate health professional familiar with the treatment or procedure and with adequate knowledge of the risks and benefits of the treatment or procedure should impart the information."

73. The informed consent policy also states: "The patient has the right to be accurately and adequately informed about a proposed procedure or treatment and to agree or refuse to have that procedure or treatment."

74. The policy states that the question of what information is required for informed consent to a procedure must be assessed from the point of view of the reasonable patient in the particular patient's circumstances.

75. The informed consent policy makes no mention of the specific consenting of allograft material, although it does cover the use of blood products extensively.

Dr B — comment

76. Dr B no longer practises in New Zealand. He stated that he is sorry for any grief and distress his actions or omissions have caused Mr A.

Dr C — comment

77. Dr C apologised to Mr A "for the distress he explains he has endured".

Responses to provisional opinion

78. Responses were received from Mr A, Dr C, Dr B, and ADHB. The responses have been incorporated into the report where appropriate.

79. Mr A and Dr B made no further comments.

80. Dr C stated that he let down Mr A and himself with the lack of documentation.

Opinion: introduction

81. In this case, the absence of any detail in the clinical notes, and the limited recall of the clinicians involved, means that it is not clear precisely what Dr C or Dr B told Mr A prior to his surgery. However, what is clear from Mr A's behaviour post surgery is that he expected

to have bone harvested from his hip to repair the damaged bone in his neck, and was not aware that bone from a cadaver would be used.

Opinion: Dr C — breach

Information provided to Mr A

82. Dr C stated that he had a "long conversation" with Mr A on 13 August 2014. He cannot recall the specific details of this discussion, but said that it is his routine practice to discuss the nature of donor bone tissue when discussing surgery and, as it is his standard practice to use an allograft for this operation, it is likely that he discussed that, rather than talking about harvesting an iliac crest graft. Dr C saw Mr A again on 22 April 2015, when he discussed Mr A's concerns about his hands.

83. Mr A recalls Dr C explaining the operation to him and showing him X-rays of where he would be operating, and being told that the damaged bone between his vertebrae would be "repacked with bone from [his] hip". Mr A remembers being told that his hip would be quite painful and he might have trouble sitting down after the operation. He thinks that this conversation took place in April 2015.

84. Dr C stated that generally the discussion about the allograft is done on the day of the surgery, because the consent process needs to be close to the time of surgery.

85. In my view, the provision of the required information and obtaining informed consent are not a single event — providing information and an explanation about the options and the risks and benefits of each is a process that Dr C should have begun on 13 August 2014 and reiterated on 22 April 2015, including an explanation of the planned procedure, that an allograft was proposed, what an allograft means, and the options available.

86. As noted above, it is not clear precisely what Dr C told Mr A, but if Dr C did discuss an allograft, it was not in terms that Mr A understood. I accept Mr A's account that he was not aware that bone from a cadaver would be used in his surgery. This was information that a reasonable consumer in Mr A's situation would expect to receive.

87. As the responsible consultant, overall responsibility for ensuring that Mr A was provided with sufficient information about the proposed treatment lay with Dr C. For failing to provide that information, I find that Dr C breached Right 6(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[17]

Continuity of care

88. Furthermore, although I accept that Dr C had a conversation with Mr A on 13 August 2014, I am critical that Dr C failed to record in the clinical notes the information he provided to Mr A. My expert advisor, orthopaedic and spinal surgeon Dr Christopher Hoffman, stated that there was a departure from accepted practice in that on 13 August 2014 Dr C failed to document the discussion with Mr A adequately.

[17] Right 6(1) of the Code states: "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive …"

89. I am particularly concerned that Dr C did not record his intention to use an allograft. That failure resulted in subsequent clinicians not discussing the allograft with Mr A. In order for Dr B to have been in a position to conduct the informed consent process, he needed to have been aware of the type of graft proposed.

90. Dr B stated that he did not have a meeting with Dr C to discuss Mr A's surgery, and did not know that an allograft was to be used. Dr C said that it is his standard practice to discuss with the spinal fellow the upcoming procedures and how they are to be performed, including the implant to be used, but he cannot specifically recall the conversation. I am unable to make a finding as to whether there was a conversation between Dr C and Dr B about Mr A's procedure. However, it is clear that Dr B did not know that Dr C planned to use an allograft.

91. In my view, Dr C should have communicated his plans adequately to other staff involved with Mr A, by recording the planned procedure in the clinical records. Dr C stated that his expectation was that had there been uncertainty regarding the nature of the procedure or consenting process, it would have been discussed with him. However, that necessitated Dr B recognising the uncertainty, and it appears that he did not.

92. Mr A had the right to expect co-operation among his providers to ensure quality and continuity of services. Dr D was required to discuss with Mr A the surgery and recovery period. Dr C expected that Dr B would explain the allograft at the time the informed consent was completed. However, Dr C failed to make it clear to Dr D and Dr B that an allograft was planned, and Dr B was unaware that it was Dr C's usual practice to use an allograft. Consequently, the clinicians who saw Mr A after 13 August 2014 were unable to provide the necessary information to Mr A. This failure to ensure quality and continuity of services to Mr A was the responsibility of Dr C. Accordingly, I find that Dr C breached Right 4(5) of the Code.[18]

Record-keeping

93. The Medical Council of New Zealand statement "Maintenance and Retention of Patient Records" (2008) states:

> "(a) You must keep clear and accurate patient records that report:
>
> - relevant clinical findings
> - decisions made
> - information given to patients
> - any drugs or other treatment prescribed.
>
> (b) Make these records at the same time as the events you are recording or as soon as possible afterwards."

94. In my view, Dr C's record-keeping was poor. As stated above, he failed to record his intention to use an allograft, or the information he gave to Mr A. I am concerned that

[18] Right 4(5) of the Code states: "Every consumer has the right to co-operation among providers to ensure quality and continuity of services."

although Mr A raised his concerns with Dr C — on 1 July 2015, 2 July 2015, and again at the postoperative review on 19 August 2015 — regarding the informed consent process and that he had been unaware of the plan to use an allograft, Dr C made no record of these conversations or the concerns. Dr C said that he spoke to Dr B about Mr A's concerns, but again failed to make any record of the conversation.

95. Dr C failed to comply with professional and legal standards and, accordingly, also breached Right 4(2) of the Code.[19]

Opinion: Dr B — breach

96. Dr B said that there was no documented preoperative plan to use an allograft, and he was not aware that it was Dr C's usual practice to use an allograft. Dr B does not remember being told that allograft cages would be used in the surgery. As Dr B did not expect material from a cadaver to be used in Mr A's surgery, he did not obtain Mr A's consent for it.

97. Dr B said that he did not have a meeting with Dr C to discuss the planned procedure, and noted that the procedure could be performed using bone graft substitutes. Dr B stated that his usual practice was to further elaborate the plan that had been discussed by the consultant during the clinic visit, based on the available records. Dr C said that it is his usual practice to discuss upcoming surgeries with the spinal fellow, but does not recall a conversation with Dr B about Mr A. I am unable to make a finding as to whether there was a conversation between Dr C and Dr B about Mr A's procedure. However, I accept that Dr B did not know that Dr C planned to use an allograft.

98. Dr B saw Mr A on 15 May 2015 to obtain his consent. Mr A said that Dr B told him that he would have a sore hip after the surgery, because bone would be taken from his hip. Dr B does not recall what he told Mr A but, as outlined above, Dr B was not aware that an allograft would be used. I accept Mr A's evidence that Dr B did not discuss the use of donated tissue.

99. Given the various possible options for undertaking this surgery, I consider that it was Dr B's responsibility to ascertain the planned procedure, so that he would be in a position to inform Mr A. In my view, as there was no information in the clinical records about the graft procedure to be undertaken, Dr B should have contacted Dr C to clarify the plan before talking to Mr A.

100. Dr Hoffman advised that it would have been expected practice for Dr B to have outlined the procedure in detail when he obtained consent from Mr A and, in particular, to have discussed whether a bone graft was to be harvested from the iliac crest or whether an allograft was to be used.

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

101. The agreement to treatment form signed by Mr A and counter-signed by Dr B states that the procedure to be performed was an "[a]nterior cervical discectomy and fusion (ACDF), C5/6 and C6/7".

102. I accept that the use of an allograft resulted in minimal additional surgical risk for Mr A. However, in my view, that is not the issue. People have very different views about the use of donated tissue, and it was Mr A's right to choose whether he wished to consent to the use of donated bone products. In order to make that choice, he required information about the options available, including the risks and benefits of each.

103. Dr B's failure to ascertain the information he needed before finalising the informed consent process was poor, and meant that he did not inform Mr A that donated material was intended to be used in his surgery or discuss the other options available to him. That was information that a reasonable consumer in Mr A's circumstances would expect to receive. Accordingly, Dr B breached Right 6(1) of the Code. It follows that Mr A was not in a position to make an informed choice and give informed consent for the treatment provided. Consequently, Dr B also breached Right 7(1) of the Code.[20]

Opinion: response to concerns — adverse comment

104. Dr B does not recall Mr A asking why his hip was not sore. Dr B stated that when he saw Mr A on 18 May he thinks he "would have used this opportunity to explain and answer all of [Mr A's] queries". Dr B also thinks that he would remember Mr A's queries if he had mentioned them, but he does not recall Mr A doing so.

105. Dr Hoffman noted that if Mr A did raise his concerns during a round, it would be a deviation in the standard of care not to record those conversations, given that they raised a concern regarding the nature of the procedure undertaken.

106. If Mr A did attempt to raise his concerns with Dr B, I am critical that Dr B did not pay sufficient attention to what he was told.

Opinion: Auckland District Health Board — breach

107. With regard to the practice at ADHB at the time of these events, Dr F stated:

> "There are thousands of procedures in which an allograft is used in New Zealand and world-wide each year. It is not standard practice to seek express consent to the use of the allograft as there are no particular risks inherent in the product … thus there is no contemporaneous written record that [Mr A] was specifically appraised of this aspect of the surgery before it occurred."

108. The ADHB informed consent policy states: "The patient has the right to be accurately and adequately informed about a proposed procedure or treatment and to agree or refuse to have

[20] Right 7(1) of the Code states: "Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise."

that procedure or treatment." The policy also states that the question of what information is required for informed consent to a procedure must be assessed from the point of view of the reasonable patient in the particular patient's circumstances.

109. I accept that the use of an allograft resulted in minimal additional surgical risk for Mr A. However, in my view the determination of what information must be provided to a patient is not an assessment of risk. Mr A had the right to choose between the available options and, had he wished, could have chosen not to have an allograft even if the risk was increased. In my view, a reasonable person in Mr A's circumstances would want to know whether the surgery would include a procedure on his hip, and whether or not the use of donated material was planned.

110. The informed consent policy in place at the time makes no mention of the specific consenting of allograft material, although it does cover the use of blood products extensively. The agreement to treatment form does not have any space or prompt relating to donated tissue.

111. Dr Hoffman advised that the standard of care/accepted practice regarding the express consent for the use of bone graft materials would begin with a detailed discussion with the patient regarding the materials to be used in the reconstruction, and would include whether those materials were allograft. Dr Hoffman's opinion is that express consent should be obtained to use an allograft. I agree. I note that ADHB has accepted that there should be explicit consent for the use of human tissue.

112. I am concerned that the culture of ADHB at that time was that it was not necessary to obtain consent for the use of donated material if the use of that material carried no risk and, from that, assumed that the patient did not need to be told. I accept that the clinical treatment provided to Mr A was not of concern. However, in my view, providing services with reasonable care means operating a system that ensures that patients do not receive services unless they have been fully informed and have given consent to them. ADHB did not provide Mr A with information that a reasonable consumer would expect to receive and, accordingly, breached Right 6(1)(b) of the Code.[21]

113. In my view, ADHB should amend its informed consent policy to make it clear that it is its expectation that explicit consent is obtained for the use of allograft material, and amend the consent form to provide for the recording of that consent.

Recommendations

Dr C

114. I recommend that Dr C:

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

a) Attend training courses on record-keeping and communication with patients and colleagues, and provide evidence of attendance and the content of the courses to HDC within four months of the date of this report.

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

Dr B

115. I recommend that Dr B provide a written apology to Mr A within three weeks of the date of this report. The apology is to be sent to HDC for forwarding to Mr A.

Auckland District Health Board

116. I recommend that Auckland District Health Board implement the following improvements and provide evidence to HDC of completion of these actions within four months of the date of this report:

a) ADHB has agreed to amend its informed consent policy to require explicit consent for the use of allograft material. I recommend that ADHB provide HDC with a copy of the amended policy.

b) Review the "Agreement to Treatment" form with a view to including a prompt for consent to the use of human products in all procedures where human products are used, and provide HDC with a copy of the amended form.

c) ADHB has agreed to include in the "Agreement to Treatment" form a space for the surgeon to counter-sign the consent stating that the patient has been informed appropriately if consent has been taken by another clinician. I recommend that ADHB provide HDC with a copy of the amended form.

d) In the provisional opinion I recommended that ADHB review the consistency of the use of surgical checklists in orthopaedic surgery, and report to HDC on the outcome, including steps being taken if the practice is found to be inconsistent. ADHB stated that regular audit data on the use and consistency of surgical checklists is provided to the Health Quality & Safety Commission. ADHB provided the data for the Orthopaedic Service, which shows that the process was incomplete in 13% of cases. I recommend that ADHB report to HDC on the steps being taken to ensure full compliance with the use of surgical checklists in the Orthopaedic Service.

117. I recommend that within three weeks of the date of this report Auckland District Health Board provide a written apology to Mr A. The apology is to be sent to HDC for forwarding to Mr A.

Follow-up actions

118. A copy of this report with details identifying the parties removed, except the expert who advised on this case and ADHB, will be sent to the Medical Council of New Zealand and

the New Zealand Orthopaedic Association, and they will be advised of the names of Dr C and Dr B.

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

Appendix A: Independent advice to the Commissioner

The following expert advice was obtained from Christopher Hoffman, an orthopaedic and spinal surgeon:

> "Thank you for asking me to provide an opinion to the Commissioner on case number 16/00877. I have read and agreed to follow the Commissioner's guidelines for independent advisors.
>
> I am the Clinical Leader of the Orthopaedic Department at Capital & Coast District Health Board (CCDHB), based at Wellington Hospital. I have been the Clinical Leader since 2014. My qualifications are MBChB (University of Otago) 1984, and FRACS (Orthopaedic surgery) 1992, Post Graduate Diploma in Clinical Epidemiology (University of New South Wales) 1993, Fellowship Training in Spinal Surgery and in Orthopaedic Trauma (University of Toronto, Canada) 1994–5. I am drawing on my experience as an orthopaedic spine surgeon involved in the care and treatment of orthopaedic spinal conditions dealt with both in the private and public sector. I am involved in the private sector in my role as the Medical Director of The Back Institute (TBI Health) and I practice at Mana Orthopaedics Ltd in Porirua.
>
> I have been asked to provide advice on the adequacy of the care provided to Mr A. I have no significant conflicts of interest to declare. I have informed you that I know Dr C and the members of the Orthopaedic Department at [ADHB] as surgical colleagues. I did not train with Dr C, nor Dr B, nor have I worked in the same hospital as either of them.
>
> **Documents Provided**
>
> I have been provided with:
>
> 1. [Mr A's] letter of complaint dated […] (partially redacted).
> 2. Record of a phone call between [Mr A] and HDC dated 8 February 2017.
> 3. ADHB's response dated 30 June 2016 and attachments (including clinical notes).
> 4. ADHB's letter dated 8 July 2016 and attachments.
> 5. ADHB's letter dated 26 October 2016.
> 6. ADHB's letter dated 1 February 2017 and attachments (including further clinical notes).
> 7. ADHB letter dated 13 March 2017 and attachments.
> 8. ADHB letter dated 15 March 2017 and attachments.
> 9. ADHB letter dated 29 March 2017 and attachments.
> 10. [Dr B's] letter dated 8 November 2016.
> 11. [Dr B's] letters (1 and 2) dated 23 March 2017.
> 12. [Dr C's] letter dated 13 March 2017.
>
> I have been asked by the Commissioner to comment on the following:
>
> 1. With reference to ADHB [Dr F's] letter to the HDC dated 13 March 2017 whether expressed consent should be sought for the use of allografts (including Cornerstone cages) in orthopaedic surgical procedures.

2. The adequacy and appropriateness of [Dr C's] decision to use an allograft Cornerstone cage in the ACDF procedure. When answering this question, please state at what point it would be expected that a decision to use an allograft Cornerstone cage would be made (i.e. before or on the day of the procedure).
3. The adequacy and appropriateness of the pre-operative care provided to [Mr A] before and on 15 May 2015 (day of the procedure). Please include comment on whether details of the allograft should have been discussed with [Mr A]: a) during the preoperative consultations with [Dr C] and/or [Dr D], b) when [Dr B] obtained consent from [Mr A] for the ACDF procedure on 15 May 2015.
4. The adequacy and appropriateness of the ACDF procedure performed on [Mr A] by [Dr B] and [Dr C].
5. The adequacy and appropriateness of the postoperative care provided to [Mr A] by a) junior medical staff prior to his discharge from [ADHB] on 19 May 2015, b) [Dr B] — please include comment on the appropriateness of the actions taken by [Dr B] if [Mr A's] version of events is accepted, c) [Dr C] — please include comment on the appropriateness of the steps taken by [Dr C] following notification from [Mr A] that he was not aware that an allograft had been performed.
6. The adequacy and appropriateness of the documentation made by relevant medical staff caring for [Mr A] including but not limited to a) [Dr C], b) [Dr B], c) any other clinician you consider relevant.
7. The adequacy and appropriateness of the care provided by ADHB to [Mr A]. Please include comment on whether any systems issues contributed to the standard of care provided, including but not limited to the adequacy of the informed consent policy and processes current at the time of these events (May 2015).
8. Any other matters you consider clinically relevant to comment on.

For each question please advise:

a) What is the standard of care/accepted practice?

b) If there has been a departure from the standard of care or accepted practice, how significant a departure do you consider this to be? (i.e. mild, moderate or significant.)

c) How it would be reviewed by your peers.

d) Recommendations for improvement that may help to prevent a similar occurrence in the future.

Summary of Facts

The following summary of facts paraphrases the information provided as an appendix in your letter of referral and includes additional information that I have extracted from the medical records. I have provided additional commentary where there is differing versions of events. At the time of these events [Mr A] was aged 61 years and complained of ongoing pain in both his arms. This was found to be due to severe

foraminal stenosis identified on an MRI scan. The MRI had been organised following an admission to [ADHB] on 21 May 2014 under the care of [an] orthopaedic surgeon.

On 13 August 2014 [Mr A] met with [Dr C], orthopaedic surgeon, to discuss the findings of the MRI scan and the proposed surgical intervention. [Dr C] records that he outlined the procedure of anterior cervical discectomy and fusion to be undertaken at the C5/C6 and C6/C7 levels. [Dr C] records that [Mr A] works as a […] having previously been an […].

Comment:

In the telephone conversation of 8/2/17 between HDC and [Mr A], [Mr A] says he cannot remember the conversation between himself and [Dr C] that occurred in August 2014.

[Dr C] has not recorded the details of the discussion around the procedure but has stated several times in his letters of explanation to you that he does not use bone taken from the iliac crest; rather, he routinely uses allograft and it would have been his usual practice to have explained that during this consultation.

It seems unlikely [Dr C] would have explained the procedure of Iliac Crest Bone Grafting as it was not his usual practice to take such grafts. It is more likely that he described the use of an allograft cage as was his practice. He may not have made it clear to [Mr A] what an allograft cage was made of or how it was produced.

22 January 2015

[Mr A] attended a pre-assessment clinic for both anaesthetic and orthopaedic review. He was seen by [an anaesthetist] for the anaesthetic assessment. There is no record of any discussion being had about postoperative pain relief for a bone graft taken from the iliac crest. An iliac crest graft donor site wound is painful and a discussion about postoperative pain management would have been appropriate if that was the expected procedure.

[Mr A] was seen by [Dr D], Orthopaedic MOSS, who recorded that 'I have discussed the operation and recovery time with [Mr A] and also covered preoperative instructions.' and, 'He is happy to see [Dr C] again on the date of surgery to complete consent.'

Comment: No record is made as to whether there was any discussion about the use of iliac crest bone grafting, nor any record of a discussion regarding the use of allograft.

[Mr A] recalls being told that he would have bone graft removed from his hip for the procedure. At both these appointments the procedure is recorded as 'anterior cervical discectomy and fusion C5/C6, C6/C7.'

It is not clear how many previous cases of ACDF [Dr D] had seen and reviewed at this clinic. As there was no mention of the type of graft to be used in the clinical records to that point, [Dr D] may have described the procedure in general terms as it might be described in a textbook.

Such a description would usually outline the use of Iliac crest bone graft to reconstruct the disc space as this was the traditional method when the technique was first developed over 50 years ago (Cloward procedure described in 1958).

22 April 2015 — [Dr C] preoperative consultation

Because of ongoing symptoms, [Mr A] was seen by [Dr C] for further review. [Dr C] records that [Mr A] reported increasing problems with coordination of his hands and pain down into his right arm.

[Dr C] records that [Mr A] is 'on the waiting list for two-level ACDF'. He notes that there will be an attempt to try to expedite this.

Comment: There is no record of any discussion being made about the procedure in detail at this appointment. It seems the focus of this appointment was for [Mr A] to report that his symptoms had become more troublesome and to request [Dr C] to expedite the procedure.

In the telephone conversation of 8/2/17 between HDC and [Mr A], [Mr A] says he cannot remember the conversation between himself and [Dr C] that occurred at the appointment of 13 August 2014, but says he remembers specially being told by [Dr C] at the April 2015 appointment that the gaps between the vertebrae would be 'repacked with bone from my hip' and that [Dr C] said his hip would be quite painful after the operation and he might have some trouble sitting down postoperatively.

This is at odds with [Dr C's] practice of not using iliac crest graft. In his letter of 13 March 2017, [Dr C] says that it is 'routine practice to discuss the nature of donor bone tissue when discussing the surgery.'

Given the timing and purpose of this appointment — ie after the pre assessment appointments and with the aim of bringing forward the date of surgery due to clinical deterioration, it seems unlikely that the grafting method was discussed in detail.

15 May 2015 — consent and surgery

[Mr A] signed a consent form prepared and signed by [Dr B]. The form states that [Mr A] agreed to 'anterior cervical discectomy and fusion (ACDF) C5/C6 and C6/C7'. [Mr A] in his letter of complaint states that he was told that he would have removal of bone from his hip and remembers [Dr B] telling him that he would have a sore neck and hip after the operation.

Comment: There is no record of the type of graft to be used on the consent form. The consent taken in this case seems to be a composite consent in that the use of the word 'fusion' implies that a bone graft would usually be used and it is usual that this would be discussed at the time the procedure was agreed to and booked several months earlier.

It would be usual to add 'Iliac Crest Bone Graft' to the consent and mark the affected hip bone if that was to be done. There is no record of any mark being made on the iliac crest.

It would be usual to document the use of locally acquired femoral head allograft as it has to be specially ordered from the NZ Blood Transfusion Service Bone Bank.

Commercially available allograft is ordered from the supplier when needed, and high volume items might be held as stock at the hospital. It would be usual to discuss and document the use of an allograft cage at the clinic when booking the surgery, and to revisit this during the consenting process immediately preoperatively.

[Dr B's] letters of explanation do not make it clear how often he had consented patients for this procedure and what he had done on previous occasions. From his letter of 8 November 2016, he states […]. It would be relevant to know what his experience of ACDF grafting practices was at that point. In particular, it would be relevant to know if at that time he was aware of the practice of [Dr C] to routinely use allograft cages. If he was not then he may have described the technique as [Mr A] remembers, outlining the use of iliac crest bone graft, given the medical records to that point do not specially state that allograft cages were to be used.

15 May 2015 — anaesthetic consent

The anaesthetic consent was taken by [an anaesthetist who] documents a discussion regarding the general anaesthetic and she records a number of relevant items — allergy/breathing support/tube/sore throat/teeth risk/postoperative nausea and vomiting/pain/ monitoring BP/heart/ breathing'. [Mr A] and [the anaesthetist] signed the anaesthetic section of the consent form.

[The anaesthetist] was working under the supervision of [Dr E], anaesthetist. The procedure was recorded as 'Anterior cervical discectomy and fusion C5/C6 and C6/C7'.

Comment: Pertinent to this is that there is no discussion with [Mr A] regarding the pain that would be anticipated should an iliac crest bone graft be undertaken. It therefore seems that the anaesthetic team did not anticipate an iliac crest graft being harvested and therefore made no mention of any pain related to that procedure.

15 May 2015 — operating note

The operating note records the anterior cervical discectomy and fusion C5/C6 and C6/C7 and that Cornerstone allograft cages were inserted and an Atlantis plate was placed anteriorly. There were no complications during the surgery.

Comment: The Cornerstone cages are inert calcium cages manufactured from donated human bone tissue and prepared in the United States in a suitably registered laboratory. The Atlantis plate is a titanium plate held in place with titanium screws on the anterior cervical spine to hold rigid the reconstruction.

Post-operative stay

Following his operation [Mr A] was an inpatient in [ADHB] until 19 May 2015. I have reviewed the clinical notes and have constructed the following summary:

On 15 May 2015 [Dr B] recorded the procedure by a handwritten note in the clinical records noting that he and [Dr C] had conducted the operation. [Dr C] dictated a record of the operation that was typed in to the notes.

On 16 May 2015 the house officer [Dr H] recorded that a Consultant ward round (CWR) had been undertaken. This occurred at 8:45 a.m. on Saturday 16 May 2015. The note records 'drain out today, TROC when mobile'.

([Dr H] has recorded that [Dr C] was present at this consultant ward round the morning after surgery. He also recorded that the drains were to be removed and that a trial of indwelling urethral catheter could be undertaken when the patient was mobile.)

On 17 May 2015 no medical officer review occurred. I note that there were regular nursing notes made. These all record the positive progress that [Mr A] made following surgery on 16 and 17 May. The nurse on the afternoon shift of Sunday 17 May 2017 recorded that the patient was in a very low mood, '[Personal issues], patient had this accident and is feeling really upset — ? [Social Worker] input — psychological needs.'

On 18 May 2015 house officer [Dr H] recorded that the patient was seen by the Fellow, [Dr B], on the ward round at 7:43 am, (FWR = Fellow Ward Round). [Mr A] was reported to be making satisfactory progress. An x-ray was requested and the plan was for the patient to be discharged if he made good progress with the physiotherapist.

On 19 May 2015 [a house officer] saw [Mr A] at 3:00 a.m. because he was complaining of chest pain. [The house officer] undertook routine observations of the patient, recorded that they were stable and made plans to organise a troponins blood test to rule out a myocardial infarction (heart attack). He arranged for a chest x-ray to be done. [The house officer] instructed that [Mr A's] morphine dosage should be increased. He asked for oxygen to be administered to keep [Mr A's] oxygen saturation levels above 92%.

On the morning of 19 May at some time between 7:30 a.m. and 10:30 a.m. (there is no timestamp on the note made and these times represent the times of the previously recorded note and the note made subsequently) [Dr H] recorded that a Fellow ward round (FWR) had been undertaken and that [Mr A] was making satisfactory progress, could be mobilised in a soft collar and discharged home with advice to avoid heavy lifting, with an outpatient appointment to be made for two weeks with the general practitioner.

At 10:30 a.m. that day the chest x-ray was recorded as being undertaken. [A] house officer made a note at 11:10 a.m., recording that the x-ray had been reviewed and was satisfactory and that a plan was made for [Mr A] to continue with his discharge. At 11:25 a.m. [The house officer] completed the orthopaedic discharge summary. In it, he noted 'the operation completed 15/05/2015 with nil complications' and that [Mr A] 'remained well on the orthopaedic ward postoperatively, stable in an Aspen collar'. A note was made that [Mr A] had experienced pain in the early hours of 19 May 2015 but that pain had settled and that [Mr A] was subsequently cleared for discharge by the multidisciplinary team.

[The] plan on discharge was 1) home, 2) stay in an Aspen collar, 3) no heavy lifting for six weeks, 4) GP review in two weeks, 5) orthopaedic outpatient clinic in six weeks.

[Mr A] was advised that if he had any further chest discomfort or developed any fevers or a productive cough he should see his own family doctor or in an emergency come directly to the hospital Emergency Department.

On 22 May 2015 [Mr A] did present to the Emergency Department with some increasing cervical pain located in his throat. He was assessed, admitted via the Orthopaedic Department and subsequently discharged on 25 May with a plan for follow up with [Dr C] in six weeks. He was given advice to continue wearing his collar and a prescription for pain relief was provided.

[Dr C's] postoperative reviews

[Dr C] is recorded as having seen [Mr A] the day after his surgery on 16 May 2015 at 0845 hours as part of his consultant ward round on the Saturday morning following surgery (CWR and [Dr C] are circled by the House surgeon on the ward round proforma record for that day). No specific record is made of the conversation between them, and neither made reference to this interaction in their letters to the Commissioner.

On 1 July 2015 [Dr C] saw [Mr A] in the Orthopaedic Outpatient Clinic, where he recorded that [Mr A's] 'pain is much better than it was preoperatively … his x-rays today are satisfactory … he can come out of his collar'. [Dr C] made a plan to review [Mr A] in six to eight weeks 'to see how he is getting on'.

Comment: [Mr A] states that it was at this consultation that he was informed that an allograft had been performed and no bone had been taken from his hip. [Mr A] said that he telephoned [Dr C] the following day and told him that 'I was unaware that body parts from someone else were going to be used inside of me'.

On 19 August 2015 [Dr C] saw [Mr A] in the Orthopaedic Outpatient Clinic and recorded that [Mr A's] pain 'has markedly improved … x-rays are satisfactory … I have reassured him that he is doing very well following his surgery and at this stage we do not need to do anything further. I am happy to see him back if there are any problems or concerns but will not arrange any further follow up.

Comment: [Mr A] stated that at this consultation he asked [Dr C] if he had spoken with [Dr B] and he said 'yes and it would never happen again'. [Dr C] told the HDC that he talked with [Dr B] postoperatively regarding [Mr A's] concerns but he cannot recall the specifics of that conversation.

In my review of the medical records, there is no record of [Mr A] raising any concerns regarding the use of an allograft or the lack of iliac crest graft in the clinical notes made by the medical staff, nor is there any record of it being recorded by the nursing staff in their notes. During his in-hospital stay, comment was made that he was feeling depressed in particular because of [personal matters]. No specific comments were recorded by the nurses that he had raised any concerns regarding his lack of an iliac crest graft.

On 18 May 2016 [Dr C] recorded that [Mr A] was doing well one year postoperatively and that his x-rays: 'are excellent and show that the allograft is gradually undergoing substitution with his own bone. At this stage there is nothing further we need to offer him. I am happy that he keeps up with his level of activity. If he has any problems or concerns I would be happy to see him back but at this stage happy to see the follow up end.'

Opinion

1. *With reference to the ADHB [Dr F's] letter to the HDC dated 13 March 2017 whether express consent should be sought for the use of allografts (including Cornerstone cages) in orthopaedic surgical procedures.*

The use of allografts in orthopaedic surgery has evolved over time. In New Zealand, the establishing of regional tissue banks (bone banks) under the supervision of the NZ Blood Transfusion Service over the last 3 decades has led to increasing use of femoral head allograft. The femoral heads are harvested during total hip replacement. The arthritis affects the joint lining and during hip replacement surgery the ball of the 'ball and socket' hip joint is removed, appropriately tested and stored in a frozen condition. Initially the use of the bone required it be matched by blood typing similar to the process used when using donated blood. Express consent would usually be undertaken in such circumstances. It would usually be by way of an informed discussion with the patient about the use of the donated bone and would usually be linked with the use of donated blood products. Most patients who consent to have blood products would usually consent to the use of donated bone.

It might not have been universally recorded separately in the surgical consent form on the basis that the use of the word 'fusion' implied the need for bone graft and the consent would have been considered a consent for a composite procedure. The use of this donor bone would usually be explicitly consented for during the initial discussion about the procedure.

Allograft bone is now available from commercial suppliers, mostly based in the United States of America. The particular allograft used by [Dr C] in this case is a piece of donated human bone that has been processed extensively to remove soft tissue and essentially leave a framework of inert bone, which is used for its structural support in the disc space as in this case. The bone is usually harvested immediately after death, along with other organs like kidney, heart, lung, cornea and liver.

There are other bone graft materials that are also available that have been manufactured from harvested bone. These include demineralised bone matrices.

The standard of care/accepted practice regarding the express consent for the use of these products would begin with a detailed discussion with the patient regarding the materials to be used in the reconstruction and would include whether those materials were allograft. This might include the provision of a written description of the operation and the graft option that is to be used. [Dr C] in his letter of 17 October 2016 says that it is his standard of care to provide that information during his consenting process.

[The] CMO in [their] letter of 26 October 2016 reports comments made by [Dr G] Clinical Director of the Orthopaedic Service where he states 'the current process is for the bone graft or allograft be placed in the consent'.

This is at odds with the remarks made by [Dr F] in [their] letter of 13 March 2017. [Dr F] records comments made by [Dr G] who says 'the Orthopaedic Service unanimously agreed that the consent for this patient should have included reference to allograft'.

[Dr F] then later states that 'It is not standard practice to seek express consent to the use of allograft as there are no particular risks inherent in this product'.

I am unable to explain how [Dr F] came to that view […] It is at odds with the view of the Orthopaedic Department at ADHB as expressed by [Dr G] and reported by ADHB CMO.

It is my opinion that express consent be obtained either verbally or in writing regarding the use of allograft. It is my view that this represents the standard of care in the orthopaedic community in New Zealand. This is the standard that the ADHB Orthopaedic Department operates at, and [Dr C] has stated it is his usual practice to do so when he describes in detail the procedure of ACDF using allograft.

2. *The adequacy and appropriateness of [Dr C's] decision to use an allograft Cornerstone cage in the ACDF procedure. When answering this question please state at what point in time it would be expected that a decision to use an allograft Cornerstone cage would have made (i.e. before or on the day of the procedure).*

There is an increasing use of commercially available allograft material in reconstruction following cervical discectomy as it avoids the use of iliac crest bone graft donor site morbidity. It is therefore entirely appropriate that [Dr C] would recommend the use of an allograft Cornerstone cage in an ACDF procedure. It would be expected that this choice of graft reconstruction would have been made at the initial discussion undertaken on 13 August 2014 and that it would be reinforced during discussions at the pre-admission clinic and be ultimately confirmed on the morning of surgery during the documenting of the surgical consent.

The recording of the discussion at the consultation between [Mr A] and [Dr C] on the 13 August 2014 lacks any detail about the reconstruction to be used. [Dr C] records 'I have had a long talk with this gentleman today', implying a full discussion about the procedure in detail with the risks and benefits of various options being considered. The decision to use allograft reconstruction at the ACDF surgery was not recorded. No reference was made to any written information that might have been given to [Mr A] at that time that might have explained the procedure in more detail.

It would be extremely unusual to have to make the decision to use allograft on the day of surgery or during the surgical procedure itself unless some unexpected event occurred. Subsequent disclosure to the patient with an explanation would follow.

It is my opinion that there has been a departure from accepted practice by [Dr C] in that he failed to adequately document the discussion about the use of allograft with [Mr A]

on the 13th August 2014. It seems likely he had the discussion with him about using allograft rather than harvesting iliac crest graft given that is his usual practice.

Our peers would view this departure as mild given the lack of serious harm that resulted from this oversight. Increasingly, surgeons provide written information to patients about intended procedures covering relevant issues with the clear instructions to seek clarification if there are any concerns. The use of such information brochures is encouraged by the Royal Australasian College of Surgeons.

3. *The adequacy and appropriateness of the preoperative care provided to [Mr A] before and on 15 May (day of procedure). Please include comment on whether the details of the allograft should have been discussed with [Mr A] a) during the preoperative consultations with [Dr C] and/or [Dr D] and b) when [Dr B] obtained consent from [Mr A] for the ACDF procedure on 15 May 2015.*

a) It would be usual for the discussion that [Dr C] had with [Mr A] about the need for the surgery and how the surgery would be undertaken to include a discussion regarding the type of graft to be used to reconstruct the disc following discectomy. That preoperative discussion occurred on 13 August 2014 and [Dr C] has recorded that it is his usual practice to disclose this information at that time. [Mr A] has no recollection of the details of that consultation with regards to this point.

It would be usual for [Dr D] to reinforce the details of the procedure at the time of the preoperative assessment. That would be particularly relevant for the anaesthetic team if a graft was to be harvested from the iliac crest because it would have a significant impact on the postoperative pain management. There is no record of that in the anaesthetic note and therefore it seems unlikely that the anaesthetic team believed that an iliac crest graft was to be used. It is conceivable that [Dr D], who is a Medical Officer Special Scale, was unaware of the detail of the graft material to be used and reverted to a generic textbook historical description of the procedure, which would have included a discussion about the use of graft taken from the iliac crest. It is my opinion that this is most likely where the information regarding the use of an iliac crest graft was first presented to [Mr A].

The lack of adequate documentation of the details of the procedure — both in the clinical letter from the appointment of 13 August 2014 and in the surgical booking records — has led to [Mr A] developing a differing view from [Dr C] as to what graft will be used in his surgery. There should have been a consistent approach about this matter from the medical staff involved.

b) When [Dr B] obtained the consent from [Mr A] for the ACDF procedure on 15 May 2015, it would have been expected practice for him to have outlined the procedure in detail and in particular to have discussed if a bone graft was to be harvested from the iliac crest or if an allograft was to be used. He would have been required to make a mark (arrow with a skin pen) on the neck and if there was to be a graft taken he would have made a mark on the iliac crest on the side from which the graft was to be harvested. There is no record of that having occurred. I suspect that there was very little discussion about the material to be used in the reconstruction on the morning of 15 May 2015. [Dr B] cannot remember any of the detail. [Mr A's] recollection is that he was told that he would be sore from the hip donor site.

It is unclear as to how many times [Dr B] had obtained consent for this procedure prior to [Mr A's] surgical procedure on 15 May 2015. If [Dr B] had regularly obtained the surgical consent for an ACDF on behalf of [Dr C] in the past, then he would have been aware that an iliac crest graft was not going to be taken and that instead an allograft was going to be used. It is unclear from [Dr B's] letter how often he had obtained the consent for an ACDF on behalf of [Dr C] prior to 15 May 2015.

It would be the accepted standard of care that there was consistency in the information provided to [Mr A] about the surgical procedure that he was to undergo. The ability of the subsequent medical team members to reinforce the correct nature of the procedure would have been made easier if [Dr C] had recorded in detail the nature of his discussions with [Mr A] when they were undertaken on 13 August 2014. If he had recorded in his letter that the ACDF was to involve the use of a commercially available allograft, then the procedure would have been more accurately described and recorded by [Dr D] at the pre-assessment process and there would have been more clarity around the consenting on the morning of the surgery by [Dr B].

There has been a minor departure of accepted practice regarding the recording of the procedure to be undertaken. It has not been recorded in sufficient detail to enable a consistent approach to be taken by the medical team involved in the care of [Mr A].

Our peers would view this with some concern. In their letter of 26 October 2016 [the] CMO records that [Mr A's] complaint had been discussed at the ADHB Orthopaedic Department monthly meeting. [The CMO] records 'The current process is for the bone graft or allograft be placed in the consent. This is discussed with the patient including the benefits and risks of the procedure and the graft before the patient signs the consent form.'

It was also recorded in that letter by [the CMO] that emphasis was now placed on it being advisable to record on the consent where the bone graft is being taken from, i.e. autograft from the patient or allograft from outside the patient, and that the particular source of the allograft was important particularly not only when it was obvious such as with donated femoral head bone but also when it was not such as with commercially available allograft. This is reinforcing the recording of express written consent for the use of allograft.

There has been a breakdown in communication between [Dr C] and [Dr B] about the details to be recorded in the surgical consent. It was [Dr C's] expectation that [Dr B] would describe again the nature of the surgery and the use of allograft when taking the consent of [Mr A] on the morning of surgery.

Our peers would view this breakdown as mild given the minimal additional surgical risk involved in this situation. Very few patients who have consented to the use of donated blood products would not consent to the use of bone products especially if the nature, benefits and minimal risks for their use was appropriately described in advance. The psychological harm that has occurred here will have been compounded by the way in which the information was provided and the additional stress [Mr A] was under (following [personal matters] as reported to the nurses on the Sunday after surgery) as well as perhaps his previous work as […].

4. *The adequacy and appropriateness of the ACDF procedure performed on [Mr A] by [Dr B] and [Dr C].*

From the records provided, it seems the ACDF procedure was entirely appropriate and suitably adequate in decompressing the spinal cord, decompressing the foraminal narrowing and stabilising the affected segments by way of reconstruction using the allograft and Atlantis plates. The care appears to have been provided to a high standard. There is no departure from the accepted practice and it would be considered appropriate by our peers. There is no recommendation for improvement regarding the actual procedure undertaken.

5. *The adequacy and appropriateness of the postoperative care provided to [Mr A] by a) junior medical staff prior to his discharge from [ADHB] on 19 May 2015 …*

The medical records have been appropriately made by the junior medical staff on each day that [Mr A] was seen postoperatively. He was seen by [Dr C], the operating surgeon, on the morning after surgery. He was not seen by his medical team on the Sunday but the following Monday he was seen by the Fellow, [Dr B], and this was appropriately recorded. I have also read the nursing notes made at the same time and they do not record anything at odds to the information recorded by the junior medical staff. It therefore seems that an appropriate standard of care was provided by the medical staff in the recording of daily medical information prior to [Mr A's] discharge. There does not appear to be any departure from the accepted standard of care and the records would be reviewed favourably by their peers. There is no recommendation for further improvement in regard to the medical records made.

It is important to note that the concerns raised by [Mr A] in his complaint about the postoperative care was related to his understanding of what surgery that he thought was to happen and what transpired and how these concerns were addressed when he raised them. The junior medical staff would not have considered this an issue for them to be concerned about in the postoperative period as it was at this point an issue about the lack of an iliac crest wound — a good thing they might have assumed.

b) [Dr B] — please include comment on the appropriateness of the actions taken by [Dr B] if [Mr A's] version of events is accepted …

[Dr B] is a foreign-trained orthopaedic surgeon who was working as an orthopaedic spinal Fellow under the supervision of [Dr C]. It is unclear whether [Dr B] was present at the ward round on the Saturday morning, 16 May 2017. His first Fellow ward round was recorded as occurring at 7:43 a.m. on 18 May 2015 and on 19 May 2015 (no time recorded). There were appropriate records made by the house officer on those days regarding the routine checks made after such surgery. The records indicate that [Dr B] undertook his duties appropriately.

[Mr A's] version of events is that he sought clarification with [Dr B] as to why an iliac crest graft had not been taken. There is no mention of this conversation being made in either the medical records or the nursing records. If [Mr A] had been significantly concerned by the lack of an iliac crest graft, then it would not be unusual for it to have been mentioned to the nursing team looking after him and for them to have recorded it. No such record exists.

It is noted in the nursing notes on Sunday evening that [Mr A] was feeling 'very low in mood' [because of personal matters].

If [Mr A's] version of events regarding this is accepted, it would seem unusual that [Dr B] had not raised the issue with [Dr C] immediately and that [Dr C] might then have taken appropriate steps to visit [Mr A] and explain why an iliac crest graft had not been taken. [Dr B] in his letters of explanation does say that he did discuss it with [Dr C].

It therefore seems that he did take seriously the concerns raised by [Mr A] and passed those on to the senior surgeon. That would seem to have been an appropriate accepted practice in such circumstances. It would be the expectation of the consultant surgeon supervising [Dr B] that if any concerns were raised with [Dr B] he would pass those on to the relevant consultant surgeon.

c) [Dr C]

It is unclear from the medical records whether [Dr C] became aware of the concerns [Mr A] had raised whilst still in hospital regarding the lack of a hip wound. [Dr C] did undertake a postoperative round on the morning after surgery and if [Mr A] had had any immediate concerns that would have been the appropriate time for them to have been addressed with [Dr C]. It does not appear that this occurred. It was some days later (the following Monday) that [Mr A] says he raised the issue with [Dr B]. [Dr B] is said to have raised these with [Dr C] but there is no record of that conversation having occurred and there is certainly no record of [Dr C] visiting [Mr A] during the later stages of his in-hospital stay to discuss the apparent change in surgical plan.

It appears that [Dr C] first became aware of [Mr A's] concern at the six-week follow up mark. Again, it seems that he answered [Mr A's] questions appropriately and had a further discussion with him by phone the next day. It is at this point that further face-to-face communication with [Mr A] would have been appropriate if [Dr C] had realised the significant concern that [Mr A] had with the apparent change to an allograft from the expected iliac crest graft. The expected standard of care would have been to arrange a further consultation to address these issues as soon as they were raised. [Dr C] clearly felt that at that time he had adequately explained the rationale for the surgical approach taken. In such circumstances it is sometimes necessary to remind the patient of the conversations that have been had at the initial consultation (if those conversations had in fact occurred). This is a useful strategy to allow patients to recall information that they were told but have subsequently forgotten. No written information was provided to [Mr A] at the consultation on 13 August 2014, which is a further way of providing consistency with regard to the information provided about the detailed nature of the procedure to be undertaken.

[Dr C] has subsequently apologised for the lack of clarity regarding this and for the lack of consistency with regard to the consenting process and the recording of this process. When [Dr C] became aware that there were ongoing concerns held by [Mr A] regarding the type of graft used, he outlines in his letter of 17 October 2016 that he discussed this with [Mr A]. Unfortunately he does not recall the details of those conversations, nor are they recorded in the concordant medical record taken at the time. It is recommended that such information is recorded contemporaneously, documenting the conversations appropriately in the medical record.

6. *The adequacy and appropriateness of the documentation made by relevant medical staff caring for [Mr A] including but not limited*

a) [Dr C] ...

[Dr C] did not record in detail the nature of the conversation he had with [Mr A] regarding the nature of the procedure, nor the type of graft to be used to reconstruct the cervical spine following the discectomy. He does record that he 'spent a long time' discussing the procedure with [Mr A]. He also records that it is his usual practice to discuss the nature of the procedure and the nature of the reconstruction to be undertaken and specifically the use of commercially available allograft Cornerstone cages and titanium plates. Subsequently there is no record during the in-hospital stay of any concerns raised by [Mr A] with regard to the nature of the graft reconstruction. There is no record in the outpatient notes of any concerns raised by [Mr A] regarding the nature of the graft used. [Dr C] does have a recollection that a conversation occurred but he has not recorded the details of it.

This is a mild breach of accepted practice in that it essentially makes it difficult to verify whether conversations did occur and the detail to which they occurred. The lack of appropriate documentation makes it difficult to comment on the adequacy of the conversations.

[Dr C's] documentation with regard to the actual clinical problem is appropriate, the recording of the operation is appropriate and the details recorded in the follow-up notes are appropriate. It would seem unlikely that [Dr C] therefore would fail to record a conversation with [Mr A] if the seriousness of [Mr A's] concerns had been adequately recognised by [Dr C].

b) [Dr B]

[Dr B] undertook the consent process on the morning of surgery. He signed the consent for an ACDF C5/C6 and C6/C7.

He then assisted with the surgical procedure undertaken by [Dr C]. It is not clear how much of the procedure was done by either surgeon, but in these circumstances the procedure is often undertaken as a combined procedure as part of the learning process. [Dr B] has not recorded in the operating note any inconsistency between the consent he took and the subsequent procedure that was undertaken. He has recorded appropriately and accurately the nature of the procedure and the use of the Cornerstone cages. It seems unlikely that he would have done that if he had consented [Mr A] for iliac crest grafting. [Dr B] appears to have made adequate notes with regard to the operation. [Dr B] in the consenting process has not recorded the nature of the bone graft to be used to reconstruct the discectomy. It would seem appropriate that such a recording was made on the consent form and [Dr B] has failed to do that.

[Dr B] attended [Mr A] on several postoperative ward rounds. Those notes were recorded by the house surgeon, [Dr H], and it appears that [Dr B's] assessment postoperatively was appropriate.

No comment was made regarding any concerns [Mr A] allegedly raised regarding the lack of an iliac crest graft. It seems unusual that that was not recorded by the house

surgeon at the time given the description [Mr A] has provided regarding the conversation that was said to have occurred. If the conversations did occur, it would be a deviation in the standard of care not to record those conversations given that they raised a concern regarding the nature of the procedure undertaken. It is not clear why if such a conversation did occur it was not recorded by [Dr H] or by [Dr B] by way of a separate medical note. It would be usual for such a note to be made by a junior medical staff member if a concern had been raised and that staff member had telephoned the consultant surgeon to seek advice or to notify them of the concern of the patient.

c) any other clinician you consider relevant.

I think it is important to note that the anaesthetic staff did not discuss with [Mr A] any concerns regarding an iliac crest graft or its inclusion in the postoperative pain management. It seems that from the notes the surgical and nursing staff were not anticipating the use of an iliac crest graft in the reconstruction of the ACDF. This expectation of the anaesthetic team is consistent with the pre-assessment process undertaken by the anaesthetic doctors on 22 January 2015.

7. *The adequacy and appropriateness of the care provided by ADHB to [Mr A]. Please include comment on whether any systems issues contributed to the standard of care provided including but not limited to the adequacy of the informed consent policy and processes current at the time of these events.*

The surgical procedure recommended by [Dr C] was appropriate and the use of Cornerstone cages was the routine in reconstruction following ACDF. This has not been adequately recorded in the clinical note made on 13 August 2014. That lack of clarity leads to confusion in the subsequent consultations by the medical staff who saw [Mr A]. There is no record in the orthopaedic pre-assessment on 22 January 2015 as to what graft material would be used in the reconstruction. The use of 'ACDF' as a composite description leads to that lack of clarity.

The current informed consent policy makes no mention of the specific consenting of allograft material. The use of blood products is extensively covered in the consent policy. The Orthopaedic Department when it reviewed [Mr A's] complaint reinforced the need for explicit consenting of the use of human tissue, be it either locally harvested and stored femoral head allograft or commercially available and processed human donor bone. It seems [Dr B] was not aware of this expectation.

There appears to have been a communication breakdown on the morning of surgery between [Dr B] and [Dr C]. The recognised problem with taking consents for surgical procedures by junior medical staff has been dealt with in other DHBs by the need for the senior surgeon to countersign the consent. The Consent Form used at Capital & Coast District Health Board has a section for the person performing the procedure to verify the consent particularly when it is taken at another time by another person.

The 'Time out' process instituted at the Auckland DHB as part of the national roll-out by the Health Quality and Safety Commission requires the surgical consent to be read out loud by the surgical team immediately prior to incision to ensure that it has been recorded appropriately and that all details regarding the consent are adequately recorded. It appears from the comments made by the nursing team in the operating

theatre at [ADHB] that the consenting of allograft material is not always explicitly documented on the consent form. This would particularly be the case when commercially available material off the shelf is used.

It would be the expectation that the use of that material had been previously discussed and appropriately recorded by the surgeon. The Orthopaedic Department during its audit of this particular complaint reiterated that it is appropriate that the use of allograft is appropriately recorded. At the three-monthly complication review the emphasis again was made to all the Orthopaedic Department staff that appropriate consent be completed prior to any surgical intervention and in particular if allograft was to be used that reference should be made to the use of allograft. It would seem appropriate that the consent policy at Auckland DHB is updated to include explicit statements regarding the appropriate recording of allograft use.

8. *Any other matters you consider clinically relevant to comment on.*

On 17 May 2015 in the nursing notes it is recorded that [Mr A] was 'very low in mood, [personal issues] patient has had this accident and is feeling really upset — ? SW [Social work] input, ? psychological needs.'

In the medical notes, in the orthopaedic discharge clinical summary dated 19 May 2015 it is recorded that [personal issues]. It is also recorded that he worked as […]. It is noted in the letter of 13 August 2014 by [Dr C] that [Mr A] had previously been an […] and now worked as a […]. It seems unusual that [Dr C] had recorded in his letter that [Mr A] had been an […] previously and that this disclosure had not led to a discussion about the appropriateness or not of the use of human donor bone if [Mr A] had a concern about this.

The Auckland DHB has taken appropriate steps to try to address the issues raised by [Mr A]. I note that he has seen a psychiatrist for care to help him come to terms with the fact that he now has donated human bone in his neck, a situation that he is unlikely to have agreed to had he understood the full nature of the graft material. I note the comment made in the nursing note on the Sunday after surgery regarding his mood and [personal matters] — factors that would impact on his ability to cope with the graft issue.

I note that the ADHB has gone to appropriate lengths to meet with [Mr A] and discuss the nature of allograft and the extremely low risk of any adverse outcome occurring with the use of such graft. The reason that the material is used ever more frequently now is because it obviates the need to take an iliac crest bone graft, which is often the cause of long-term morbidity. I note he had agreed to blood and blood products if needed.

Summary

[Mr A] underwent an uncomplicated ACDF C5/6 C6/7 for cervical stenosis/foraminal stenosis. He was under the belief that he would have an iliac crest bone graft to reconstruct the disc spacers. [Dr C] says he explained the procedure when they agreed to proceed with it and at this consultation [Dr C] says he would have explained the use

of allograft bone. [Mr A] has no recollection of this conversation. The consultation notes are not explicit on this point.

At subsequent appointments at pre-assessment clinic there is no record of any discussions about the use of iliac crest graft or allograft. It is possible that the medical staff at these consultations might have described the use of an iliac crest graft. [Dr C] saw [Mr A] again due to concerns about deterioration and the desire to expedite the surgery. It seems unlikely that [Dr C] would have described the use of iliac crest bone graft given he does not use that technique. It was [Mr A's] recollection that [Dr C] did explain this technique. There is no record of this conversation in the medical records.

On the day of surgery, the Orthopaedic Spine Fellow who worked with [Dr C] for 10 months, met [Mr A] for the first time and took the consent for ACDF C5/6 C6/7. There is no record of the type of graft to be used. [Mr A] recalls that [Dr B] explained that graft would be taken from the iliac crest. It is not clear how long [Dr B] had been working at the ADHB at this point. He had completed 18 months post graduate training in Sydney and may have seen the technique before. Given the medical records did not record the preference of [Dr C] to use allograft, it seems likely [Dr B] explained the technique as [Mr A] recalls. When the surgery was completed apparently differently to the consented procedure, [Dr B] should have alerted [Dr C] immediately. This did not occur.

Following the surgery, [Mr A] became aware he did not have a hip wound. [Mr A] didn't raise this with [Dr C] on the first postop day — the Saturday morning ward round. [Mr A] says he did raise it with [Dr B] on the ward wounds the following Monday and Tuesday morning. At that point he was making good progress and the junior medical staff other than [Dr B] would not have realised the significance of his questions.

[Dr B] says he did raise the issue with [Dr C], but there is no medical note recording this. [Mr A] recalls [Dr B] becoming uncomfortable with his further questioning but nothing is done to resolve this concern until [Mr A] questions [Dr C] at the first post-operative visit. [Dr C] tells [Mr A] the reason there is no hip wound is because allograft cages were used to reconstruct the disc spaces. The level of concern [Mr A] had about the use of allograft was not immediately realised by [Dr C]. [Mr A] was concerned about the conflicting information he was given and this appears to have compounded his distress about the use of allograft. When [Mr A] rang the next day to express alarm at what had happened [Dr C] responded by explaining he would raise the communication confusion with [Dr B].

[Dr B] is an Orthopaedic Spinal Surgeon training [overseas]. The communication difficulties that have occurred between [Dr B] and [Dr C] and between [Dr B] and [Mr A] may well be as a result of cultural issues arising due to [Dr B's] background. He seems to have displayed a pattern of behaviour where he shies away from confronting issues and would prefer to avoid resolving problems in a direct manner. In his letters he has acknowledged he has learned a lot from this complaint and its resolution.

The Orthopaedic Department at ADHB have also managed this complaint appropriately once the issues were fully grasped. The recording of the use of allograft in the surgical

consent has been reaffirmed as the standard of care the department operates to. [Dr B] who has left the country has written apologising for his actions and the distress that has arisen.

[Mr A] has met with the ADHB Department Clinical Leader [Dr G] and [a spinal surgeon] to have explained further the rationale for the use of allograft.

[Mr A] is receiving appropriate psychiatric help to address his concerns about the use of donor bone in his surgery. This help will no doubt also cover any unresolved grief associated with [personal matters]. It will be reassuring to [Mr A] that the allografts have healed and the surgery has gone well. [Mr A] will have no iliac crest donor site morbidity.

I have included the information regarding Cornerstone tissue from the manufacturer, Medtronic, along with the consent form of Capital and Coast DHB.

Kind regards

Yours sincerely

Chris Hoffman
ORTHOPAEDIC AND SPINAL SURGEON"