HEALTH & DISABILITY COMMISSIONER
TE TOIHAU HAUORA, HAUĀTANGA

Inadequate information provided about use of donor bone tissue

Complaint

1. On 1 June 2023, Miss A (aged 14 years at the time) sustained a tibial plateau fracture and was admitted to hospital. Subsequently, on 4 June 2023, she underwent an open reduction internal fixation (ORIF)[1] with an allograft, which is the transplantation of bone tissue from a deceased person or persons to the recipient. As Miss A was aged under 16 years at the time, her mother, Ms B, completed the consent forms for the surgery. As the person responsible for making the decision and providing consent, this report focuses on Ms B's experience.

2. Ms B raised concerns with the Health and Disability Commissioner (HDC) about the informed consent process for the surgery, specifically that she and Miss A were only told about the use of donor bone immediately before surgery, and they were not provided any information on the origin of the bone. Ms B expressed distress at this, as the bone was to be inserted into Miss A's tinana [body] and eventually would be absorbed by her tinana.

3. Ms B told HDC she and Miss A would have liked to have received this information earlier to enable them to process it and engage the correct tikanga processes and protocols, rather than being able to do this only postoperatively.

My decision

4. Having reviewed all the information, I find the hospital in breach of Right 5(2) for a lack of effective communication and of Right 1(3) for a lack of culturally appropriate care. I also make criticism of Dr C for inadequate record keeping.

5. I have outlined the reasons for my decision below.

Events leading up to surgery

1 June 2023

6. Miss A was admitted on 1 June and assessed as likely requiring surgery. The hospital told HDC that a bone graft procedure (which may include allograft) is always considered for tibial plateau fractures. A consent form for ORIF was signed by Ms B on this day. There is nothing in the clinical records to indicate potential bone graft was discussed with Miss A and Ms B on this day or as part of the initial consent process. Miss A was made 'nil by mouth' for further review by orthopaedics in the morning.

2 June 2023

7. During morning orthopaedic rounds, surgery was again raised and a CT scan scheduled to further assess the fracture. The CT scan showed the severity of the injury and indicated an

[1] A surgical procedure for repairing fractured bone using either plates, screws, or an intramedullary rod to stabilise the bone.

increased likelihood of a bone graft. Surgery was scheduled for the following day (3 June 2023).

8. The orthopaedic team were updated about the CT scan, and the orthopaedic House Officer spoke with Ms B about the CT result. The hospital told HDC that the House Officer did not discuss the surgical options with Ms B or Miss A at this time, as this would be completed by senior members of the orthopaedics team. No information has been provided to HDC to indicate that senior members of the orthopaedics team or other staff discussed surgical options with Miss A or Ms B on 2 June.

9. Also on 2 June 2023, Miss A and Ms B were visited by Te Pou Kōkiri, who support whānau Māori in hospital to ensure that their cultural needs are upheld and honoured in hospital. The hospital told HDC that Te Pou Kōkiri can attend discussions with clinicians should the patient or whānau wish to have this support and that a request for support prior to surgery would be seen as important and the on-call Te Pou Kōkiri would come in to be with whānau.

10. Te Pou Kōkiri were not engaged again during Miss A's admission until 6 June 2023, after her surgery, as part of Ms B's concerns about the consent process.

3 June 2023

11. On the morning rounds, Miss A was seen by a Registrar on behalf of a Senior Medical Officer (SMO). The recorded plan was for ORIF surgery, after review by the SMO. No further notes were recorded on what was discussed, whether information was provided about the planned procedure and potential bone or allograft, or whether any alternative options were discussed. It is not clear whether the SMO subsequently reviewed Miss A.

12. In the afternoon, Miss A was seen by a doctor on behalf of the weekend on-call SMO Dr C. This doctor's notes state 'explained bad fracture, won't heal well naturally. Needs surgery' and that Miss A was scheduled for the operating theatre tomorrow. It is not clear from the notes whether Miss A and Ms B were provided any more detail on the procedure, whether bone graft or allograft was being considered, or what other surgical options were available.

13. Attention to more urgent surgeries meant that Miss A's surgery was deferred until the following day.

4 June 2023

14. There are conflicting versions regarding what information was provided on the day of surgery.

15. Dr C recalled speaking to Miss A and Ms B preoperatively about the likelihood of using an allograft in the surgery as well as the benefits and risks associated with this. Dr C told HDC that he understood the cultural importance of discussing the allograft with Miss A and Ms B and recalled explaining that the allograft comes from the bodies of deceased people from overseas. Dr C told HDC that he felt this discussion was done in a "non-rushed manner" and there was time to explain the risks and benefits and answer any questions. Dr C told HDC that his usual practice at the time would be to discuss the use of an allograft with the patient and their whānau and include this on the consent form.

16. Ms B told HDC that she was advised about the use of another person's bone at the point that Miss A was prepped and ready to be taken for surgery and that she was not told the bone was from a person (or persons) of an unknown origin. Until that point, Ms B understood that Miss A would have surgery that involved the insertion of a metal rod. Ms B told HDC that she was handed the anaesthetic consent form and, while she was trying to read and sign it, the doctor was talking to her and mentioned a bone graft. Ms B told HDC that she asked questions about the bone but was told that it would be discussed later. Dr C disputes this and told HDC that he has previously postponed or cancelled surgeries where he was not satisfied that the consumer/whānau wished to proceed.

17. Ms B told HDC that, at the time, she felt alone, vulnerable, and worried that if she spoke up with any concerns the surgery would be cancelled, and subsequently she felt pressured to consent. Ms B explained that she felt conflicted between Miss A's need for surgery, fear of surgery being cancelled, and her strong belief in not having bone placed inside Miss A without any information on where it came from or without the opportunity to adequately digest the information and perform appropriate karakia.

18. The consent form for anaesthetic contains a section for blood/blood products, under which in black ink it states 'RBC/allograft bone'. This form is signed my Ms B and dated 4 June 2023.

19. The consent form for surgery states, 'left tibial plateau ORIF'. It is signed by the Registrar and Ms B and appears to have been completed in blue ink on 1 June 2023. Risks and benefits of the ORIF procedure are listed.[2] An addition has been made to the form in black ink (the same as the anaesthetic form) of "P [potential] bone graft". This change to the consent form is not signed or dated by either Dr C or Ms B. There are no further notations in black ink to indicate that the specific risks or benefits of allograft/bone graft have been discussed.

20. There is no information on the consent form or other clinical records to indicate that the term allograft was explained, or that the discussion points mentioned by Dr C in paragraph 15 were covered, including that the graft came from deceased persons from an unknown place.

The hospital informed consent policy[3]

21. There is no specific policy or guidance covering consent for the use of allograft.

22. The general informed consent policy outlines that the primary responsibility for ensuring adequate information is given and fully informed consent is obtained sits with the person who is responsible for the procedure,[4] and this responsibility can be delegated to another suitably qualified medical professional.[5] The policy also requires that any information given to the patient (in the process of obtaining consent) should be documented in the patient's health record by the health professional obtaining the consent.[6] The policy requires that sufficient time be allowed for the patient to read any written information and discuss this and any verbal information with whomever they wish and that they have a right to have

[2] Pain, bleeding, infection, blood clots, damage to surrounding structures, failure of fixation.
[3] The hospital region's policy – this may differ between the hospital locations.
[4] Section 7.1.
[5] Section 7.2.
[6] Section 7.7.

another person or persons present during the discussion related to the proposed treatment or procedure, including a patient advocate if requested.[7]

Other information

23. Dr C has offered an apology and noted that information about the allograft 'should have been delivered earlier' to allow Ms B and Miss A to consider this part of the operation. Dr C stated that ideally, conversations about the operation being performed would occur as far in advance as possible but that this is not always possible with trauma cases in a busy hospital.

24. In its initial response to HDC, the hospital acknowledged that, after Miss A's CT scan on 2 June, it was clear that the use of a bone graft would likely be needed. The hospital similarly offered an apology and acknowledged that there was 'certainly an opportunity to discuss the procedure with the whānau earlier'. The hospital acknowledged that ideally Miss A and Ms B would have been provided with information about the bone graft before being in the preoperative area. However, the hospital stated that it feels that Miss A and Ms B were given 'adequate opportunity to consider the information, ask questions, and either withdraw consent or request a delay to the operation'.

25. The hospital told HDC that it contacted Ms B to offer a hui to address these concerns but that she declined.

Decision The hospital — breach

The right to effective communication

26. Right 5(2) of the Code of Health and Disability Services Consumer's Rights (the Code) states that a consumer has the right to an environment that enables both consumer and provider to communicate openly, honestly, and effectively. I have concerns about the way in which information that any reasonable person would expect to know about a procedure was communicated to Miss A and Ms B, as detailed below.

27. Having reviewed all the information, I found no evidence that the possibility of a bone or allograft being used, or what this was, was communicated to Miss A or Ms B before being placed in the preoperative area and their discussion with Dr C on 4 June. Until this discussion with Dr C immediately before the operation, Miss A and Ms B were under the impression that the planned surgery was ORIF and likely involved the insertion of a metal rod. This is in line with the original consent form signed by Ms B on 1 June, which referred only to ORIF.

28. After the CT results of 2 June, it was apparent to the orthopaedic team that Miss A required complex surgery that was likely to involve the use of a bone graft or allograft. The House Officer advised Ms B of the CT result but did not discuss any surgical options. The hospital's information and consent policy specifies that the responsibility for such discussions sits with the person performing the procedure or their delegate. I accept that on 2 June it was appropriate for the House Officer to not discuss surgical options with Miss A and Ms B and for this conversation to instead occur the following day with more senior members of the orthopaedics team.

[7] Sections 6.3, 6.4, and 6.5.

29. On 3 June, both orthopaedic teams (standard and on call) were aware of the severity of the fracture and that bone or allograft was likely, and Miss A was made 'nil by mouth' to prepare for surgery. It is clear there was intent to perform surgery that day if possible.[8] On this basis, and noting the hospital's statement that bone graft is considered for all tibial plateau fractures, I consider that, at this point, the hospital had an obligation to effectively communicate the critical information about the potential bone or allograft to Miss A and Ms B in line with the requirements in the Code. This did not occur.

30. Consequently, on the day of surgery, Miss A and Ms B were presented with entirely new information about the procedure and required to decide in a very pressurised environment: they were in the pre-operation room, the required surgery had already been postponed twice, and they were concerned about experiencing any further delays to Miss A's treatment.

31. Although Dr C recalls having had a comprehensive discussion with Ms B and Miss A about the bone graft procedure, the response from Ms B indicates that she was not informed about the composition of an allograft or the origin of the bone. Similarly, the clinical records contain no evidence that a discussion was held with Ms B and Miss A about this, and the signed consent form does not contain specific information that bone from another person would be used or outline any discussed risks or benefits of the allograft procedure.

32. Having considered both Dr C and Ms B's statements regarding what information was discussed on 4 June, I accept that a conversation was had that mentioned allograft and some information provided but find that the information was insufficient and lacked clarity such that Ms B remained unaware of key information that was reasonable for her to know. I am concerned at the timing and environment in which this conversation occurred.

33. I consider that Dr C was placed in a pressurised situation to provide information critical to the informed consent process, which should have been communicated by the orthopaedic teams earlier. For this reason, I consider the failure to communicate key information effectively prior to surgery is a systemic issue rather than an individual one.

34. Although Miss A's injury was acute, the surgery was not, and there were multiple opportunities for the hospital to effectively communicate critical information about the procedure to Miss A and Ms B on 3 June when it was clear that an allograft was likely to be used. That some information was provided immediately before surgery, in my view, does not meet the threshold to ensure that Miss A and Ms B received effective communication from the hospital. The hospital policy requires that sufficient time is allowed to read and discuss any information and have other people present, including an advocate, if desired. In the circumstances of Miss A and Ms B's case, this does not appear to have occurred.

35. The hospital submitted that Miss A and Ms B were given an adequate opportunity to consider the information, ask questions, and either withdraw consent or request a delay to the operation. I disagree. With the new information presented at such a late stage in the process, Miss A and Ms B did not have time to adequately consider the new surgical procedure (which had significant cultural implications) or discuss the new procedure with

[8] In consideration of other more urgent cases.

other people if needed to ensure a supported approach (such as other whānau or Te Pou Kōkiri) and were under significant pressure and stress to make a decision in the moment. Although it is difficult to know what was discussed with Miss A and Ms B concerning the risks and benefits of allograft, even if the necessary discussions did take place at that time, the imminence of the surgery left insufficient time for the implications of the procedure to be considered and to engage the correct tikanga processes and protocols to make this decision acceptable within a te ao Māori worldview.

36. Miss A and Ms B had a right to an environment that enabled open, honest, and effective communication with health providers. Having reviewed all the information, I do not consider that the hospital created an environment in which key information that any person would expect to know was communicated effectively to Miss A and Ms B to ensure a safe consenting process.

37. For these reasons, I find the hospital in breach of Right 5(2) of the Code.

Provision of culturally appropriate care — breach

38. Right 1(3) of the Code explicitly states that services should take into account the 'needs, values, and beliefs of Māori'.

39. In ao Māori, allograft bone and its use is viewed as kōiwi. Kōiwi holds cultural architectural significance for Māori, with the key part of kōiwi being 'iwi' (as in strength, bone/s, and people, including DNA). DNA is a physical embodiment of whakapapa,[9] mauri,[10] tapu,[11] and wairua[12] connections to tīpuna (ancestors), which remain strong and do not diminish with time or quantum. Therefore, kōiwi is regarded as tapu, as the essence of the kōiwi becomes woven into the whakapapa of the person receiving it.

40. As kōiwi has its own mauri and wairua, tikanga and kawa practices need to be engaged, especially when the origins of the kōiwi are unknown. Tikanga and kawa practices lift the tapu of the kōiwi and ensure it is safe to enter the tinana of the person receiving it. When kōiwi is used without appropriate tikanga and kawa, it can have adverse effects on the Te Whare Tapa Whā[13] of both the individual receiving the kōiwi and their whānau.

41. As Miss A's ethnicity was listed as Māori, and Te Pou Kōkiri had met with whānau after admission, this should have signalled to the hospital that additional consideration was needed when formulating a care plan involving the potential use of an allograft. The hospital has not provided any information on how the orthopaedics team considered Miss A's

[9] Whakapapa provides a continuous lifeline from those who existed previously to those living today and encompasses everything that is passed from one generation to the next, from one ancestor to the next, and from the deceased to the living.
[10] The life force, vital essence, essential quality, and vitality of a being, entity, or object.
[11] Tapu represents sacredness, spiritual significance, reverence, and restriction. It encompasses spiritual and cultural boundaries that promote respect, balance, and appropriate behaviour and interactions with ao wairua (spiritual world) and ao kikokiko (physical world).
[12] Spiritual essence connecting individuals to the divine, ancestors, and the natural world.
[13] Te Whare Tapa Whā model of Māori Health: https://www.health.govt.nz/maori-health/maori-health-models/te-whare-tapa-wha

cultural needs when determining options for treatment or whether further engagement or consultation with Te Pou Kōkiri was considered to assist in their decision-making.

42. Consideration should have been given to involving Te Pou Kōkiri in any expected discussions with Miss A and Ms B about the use of an allograft, as part of providing Miss A with comprehensive clinical and culturally appropriate care. Disclosing the potential use of an allograft at an earlier date would have ensured that the correct tikanga and kawa were engaged and that Miss A and Ms B's cultural values were upheld. Culturally appropriate care is fundamental to achieving positive health outcomes and experiences for whānau Māori.

43. As kōiwi has significant meaning for Māori and is tapu, the hospital has a responsibility to ensure that the use of kōiwi (or allograft) is disclosed at the earliest opportunity to ensure that the correct tikanga and kawa can be engaged. However, this was not reflected in the care provided to Miss A, with multiple opportunities for discussion on allograft missed.

44. Although the use of an allograft was ultimately discussed, the proximity of this discussion to surgery meant that Miss A, Ms B, and their whānau could not engage with their tikanga and ensure that Miss A and ngā kōiwi were culturally prepared for her surgery. For these reasons, I find the hospital in breach of Right 1(3) of the Code.

Dr C – adverse comment

45. The informed consent policy requires any information given to the patient, (in the process of obtaining consent), should be documented in the patient's health record by the health professional obtaining the consent.[14]

46. Although the terms 'allograft' and 'bone graft' were listed on the consent forms, the use of these terms alone is insufficient to inform consumers about what the procedure entails or to adequately capture the discussion on the procedure, including any risks, benefits, and concerns raised.

47. The surgical consent form signed on 1 June initially only covered ORIF and was amended to include "P [potential] bone graft'. This amendment was not dated or signed by either Dr C or Ms B and so provides no clarification on whether Miss A and Ms B were fully informed on the details of procedure.

48. Dr C had a responsibility to document the information provided to Miss A and Ms B as part of the consent process. This did not occur, and I am critical of Dr C for his lack of critical record keeping.

Responses to my decision

49. Ms B was provided with the opportunity to comment on the 'events leading up to surgery' section of my report. Ms B confirmed her recollection of events that they were briefly told about a bone graft but not provided any further details on where the bone graft came from. Ms B emphasised the importance of patients/whānau being fully informed before the pre-operation room to give time and space for whānau to gather and karakia and to discuss other options that may be available.

[14] Section 7.7.

50. The hospital was provided with the opportunity to comment on my decision. It acknowledged the importance of effective communication and recognises that, in this instance, the system did not support this for Miss A. It further acknowledged that the provision of culturally appropriate care did not meet expected standards on this occasion.

51. Dr C was also provided with the opportunity to comment on my decision. He reiterated his version of events that information about the procedure was discussed but acknowledged that no written information was provided at the time and that this could be improved. Dr C outlined that house officers and registrars usually document a summary of discussions that are had with patients and their whānau and acknowledged that it was not done in this instance.

52. Dr C told HDC that he intends to discuss this case with his junior doctors and senior medical officer colleagues to recommend that junior staff accurately document conversations regarding consent and consider developing a department-wide policy on bone graft discussions to help guide future practice. Dr C also told HDC that, in future cases where a person has not been consented, he will ensure their surgery is postponed until they have been provided with clear written and verbal information about the procedure and have had the opportunity to discuss with anyone they wish. Additionally, he will dictate his own operation notes to ensure there is a detailed section regarding any discussions held with patients/whānau.

Other information

53. This Office has received multiple complaints relating to the informed consent process for allograft procedures, which highlights a wider systemic issue. Currently, there is no national policy or guidance on obtaining informed consent for the use of allograft bone, particularly in relation to Māori consumers. I am aware that the hospital is in the process of developing a national informed consent policy, and I intend to engage in this process to strengthen the obtaining of appropriate informed consent for the use of allograft bone and the information that should be provided to consumers.

Recommendations and follow-up action

54. I recommend that the hospital at the national level:

a) Within 3 months of the date of this report, create a standardised pamphlet on the use of allograft bone, which can be provided to consumers and their whānau. This should include an ao Māori perspective on kōiwi.

b) In the new informed consent policy, include a section about informed consent for the use of allograft bone and what information should be provided to consumers.

c) In the new informed consent policy, include a section about the cultural significance of kōiwi for Māori and how staff can work with their district's Māori Health Service to provide culturally appropriate care for whānau who require an allograft.

55. I recommend that the hospital provide a written apology to Miss A and Ms B for the deficiencies identified in this report. The apology is to be sent to HDC, for forwarding to Ms B, within three weeks of the date of this report.

56. I recommend that Dr C provide a written apology to Miss A and Ms B for the deficiencies identified in this report. The apology is to be sent to HDC, for forwarding to Ms B, within three weeks of the date of this report.

57. A copy of the final report with details identifying the parties removed will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Dr Vanessa Caldwell
Deputy Health and Disability Commissioner