

Inadequate consent for use of donor tissue

Background

1. On 2 July 2015, Mr A underwent allograft surgery on his wrist performed by Dr B, to address issues from a previous injury. Allograft is the transplantation of bone tissue from one person (the donor) to another person (the recipient). The donor is usually a deceased person or persons.
2. On 17 November 2015 at a post-surgery review when advised that the allograft procedure he had involved another person's bone tissue, Mr A told Dr B he was upset about this as it was against his cultural and religious beliefs and that he wished he had been told about this before surgery. Mr A identifies as Māori. Dr B told HDC he was not aware of Mr A's ethnicity at the time.
3. The surgical and anaesthesia consent form for the surgery (dated 2 July 2015) refers to the use of a "bone graft" which was signed by Mr A. The consent form does not expressly state allograft or make reference that Mr A would receive tissue from another person. There is nothing further in Mr A's clinical records to suggest that this term was explained as well as where and who this bone came from.
4. Dr B told HDC his usual practice at the time would have been to discuss allograft as it has a better success rate and less trauma for the person (than using their own bone). Due to the passage of time, he cannot recall the exact conversation had with Mr A. However, he acknowledges that after the discussion on 17 November 2015 it was clear that he had not adequately explained the process to Mr A.
5. Dr B has offered an apology and advised he has since changed his practice to ensure he is aware of cultural and religious beliefs of patients and ensures there is adequate discussion and recording of the allograft process including where the donor material has come from.
6. Dr B was provided the opportunity to comment on my provisional decision. Dr B wished to highlight the challenges in engaging with Mr A noting that at times communication was difficult and hampered by Mr A's distress, trauma and chronic pain. Dr B stated that due to these challenges, a standard informed consent process (i.e. fulsome discussion on procedure/treatment) could not be achieved.

Provisional decision – Dr B - breach

7. Right 6(1) of the Code of Health and Disability Services Consumers' Rights (the Code) states that the consumer has the right to information that a reasonable consumer, in that consumer's circumstances, would expect to receive. Right 7(1) outlines that informed consent can only be given when a person has made an informed choice. In Mr A's case, this does not appear to have occurred.

Names have been removed to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

8. Mr A underwent surgery that involved the use of another person's tissue. There are no clinical records to indicate that a discussion was held with Mr A about this, and the signed consent form although noting 'bone graft' did not specify 'allograft', or contain specific information that bone tissue from another person would be used. In my view, a reasonable consumer in Mr A's circumstances and of any ethnicity would expect to receive an explanation of what an allograft is comprised of, including where and who (if possible) this bone came from as part of the informed consent process.
9. Dr B has acknowledged that the information provided to Mr A at the time was inadequate.
10. Acknowledging there may have been challenges with engagement and communication, I am of the view that it remains the responsibility of the consenting professional to ensure the person receives the information they need, to be able to provide fully informed consent for the procedure. In the absence of clearly understood verbal information, clear written information such as inclusion of the specifics of the procedure on the consent form could be provided to bridge the information gap. This did not occur in Mr A's case. In circumstances where it appears that fully informed consent cannot be achieved, then consideration should be given to not proceeding.
11. For the reasons outlined I find Dr B in breach of Right 6(1) of the Code and consequently, right 7(1) of the Code, the right to make an informed choice and give informed consent. Put simply, Mr A's consent was not informed by relevant information he was entitled to receive.

Educational comment - Dr B

12. I acknowledge that Dr B was not aware of Mr A's ethnicity and as such I have not made any criticism of specific considerations of the consent process in that regard and the findings apply to any patient. That said, the use of donor material does have significant implications for people of different ethnicities, cultures and faiths and it is important to acknowledge the cultural implications the inadequate information had on Mr A as a Māori man. Adequate disclosure of the the allograft process, specifically that bone tissue was to be received from a deceased person would have ensured sufficient time to undertake cultural processes which would make this an acceptable procedure to undergo and that the correct tikanga and kawa were engaged. Culturally safe care is fundamental to achieving positive health outcomes and experiences for whānau Māori.
13. I acknowledge that since this event, Dr B has altered his practice to ensure he is aware of cultural and religious beliefs of patients to ensure culturally safe care. I encourage him to continue to do so.

Other information

14. 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 Health New Zealand | Te Whatu Ora is in the process of developing a national informed consent policy and I intend to engage in this process to strengthen obtaining appropriate informed consent for the use of allograft bone, and specifically what written information should be provided to consumers.



Recommendations

15. I recommend that Dr B
 - a) Provide a written apology to Mr A for the deficiencies identified in this report. The apology is to be sent to HDC, for forwarding to Mr A within three weeks of the date of this report;
 - b) Within 3 months of the date of this final report complete an audit on all allograft procedures performed by him in 2025, to determine the degree of compliance with adequate information provision (including recorded discussions of where and who the donor material is received from), cultural safety considerations and consent processes.
16. A copy of the final report with details identifying the parties removed, except Dr B will be sent to the Medical Council of New Zealand (MCNZ), and a copy of the final report with details identifying the parties removed placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Dr Vanessa Caldwell
Deputy Health and Disability Commissioner

