

Inadequate consent for use of donor tissue during surgery

Introduction

1. On 29 September 2023, this Office received a complaint from Mrs A about the care she received from orthopaedic surgeon Dr B. This complaint concerns a lack of informed consent for the use of donor tissue (allograft) during surgical treatment for her right ankle instability.

Background

2. Mrs A first saw Dr B on 24 February 2023 after being referred by her general practitioner following an ankle injury 20 January 2023.
3. Mrs A told the Health and Disability Commissioner (HDC) that Dr B explained the surgery options on two occasions: during this appointment, and on the day of surgery. The options included inserting three screws into her ankle bone and using an artificial fibre to connect to the screws or using her own tissue (autograft) which would involve using a ligament from her thigh to place in her ankle. Mrs A agreed to the use of artificial fibres or her own tissue.
4. Dr B told HDC that on these two occasions, he explained the surgical options for ankle lateral ligament reconstruction 'using autograft ... or allograft'. The ACC form recorded use of 'allograft/autograft' and the consent form that Mrs A signed recorded the use of allograft.
5. Mrs A attended hospital for surgery on 12 June 2023, where allograft (a donor ligament) was used.

After surgery

6. Dr B told HDC that he explained his use of allograft to Mrs A the morning after surgery, which Mrs A disputes.
7. Eleven days after the surgery, Mrs A looked through a bag of bandages she had been given when discharged and found a card reading 'turn grief into grace', which referred to allograft. She said she became confused as she was not aware she had received any donor parts.
8. At the two-week follow-up appointment on 26 June 2023, Mrs A showed the card to Dr B and asked for an explanation. It was at this appointment she became aware that allograft had been used during her surgery.

Further information

9. Mrs A told HDC that Dr B never asked about her cultural/religious beliefs or views on receiving somebody else's body parts. Mrs A is concerned that she did not have a chance to refuse the use of someone else's tissue and noted that the use of donor tissue has had an impact on her mental health.

10. Dr B apologised for any dissatisfaction Mrs A felt and stated that he had no knowledge of Mrs A's cultural/religious beliefs and did not expect allograft use to impact Mrs A's mental health.
11. Dr B told HDC that the records showed that Mrs A was obviously informed about potential allograft use, however, he noted that it appears that Mrs A did not fully realise what this meant. Dr B said that he made his best efforts to ensure that Mrs A understood and was cognisant of the process and said that he was under no impression prior to surgery that she did not understand what it meant to use allograft.
12. Dr B advised HDC that he will be more specific in the future if he intends to use any donor body parts and he is also committed to improving his communication in the future.

Decision

13. 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 Mrs A's case, this did not occur.
14. I have given weight to Mrs A actions upon finding the card and asking the provider for clarification as evidence that she did not know prior that allograft contained donor tissue. Despite the word allograft being used in the ACC form and the consent form she signed, she did not understand that this referred to donor tissue.
15. I disagree with Dr B's statement that the records showed that 'Mrs A was obviously informed.' I consider there to be a difference between recording the use of allograft in the aforementioned documents and the patient having received a clear and concise explanation of what the word allograft means and the implications of this. I note that Dr B acknowledges that Mrs A may not have realised the meaning of allograft, despite his assertion that he made his best efforts to ensure she understood.
16. I am critical that Dr B was unaware of Mrs A's beliefs and that he did not think that using donor tissue may affect Mrs A's mental health. I remind Dr B that it is his responsibility to ensure sufficient information is provided about proposed interventions/procedures so that underlying patient cultural/religious beliefs can be surfaced where there may be impacts for the patient and thus can be managed sensitively and in partnership with the patient.
17. Dr B has stated that Mrs A did not raise any concern regarding her cultural beliefs in relation to allograft during his initial explanations of the process. As I do not consider the meaning of allograft was well enough explained to her, I do not consider that there was an opportunity for her beliefs around this to come to light.
18. Mrs A underwent surgery that involved the use of another person's tissue. I find that Mrs A was not given enough information and did not understand until after her surgery that an allograft ligament had been used. In my view, a reasonable consumer in Mrs A's circumstances should expect to receive an explanation of what an allograft comprises, in

plain language, including where and who (if possible) this tissue came from as part of the informed consent process so she could make an informed choice about whether this was something she would agree to and or provide time for her to prepare appropriately for the procedure. I consider that the plain language description of allograft should also have been added to the consent form. In the absence of clearly understood verbal information, clear written information in an allograft leaflet should be provided before surgery.

19. For the reasons outlined above, I find Dr B in breach of Right 6(1) of the Code and, consequently, right 7(1) of the Code, which is the right to make an informed choice and give informed consent. Put simply, Mrs A's consent was not informed by the relevant information she would reasonably expect to receive.
20. I acknowledge that Dr B does not agree with this decision.

Recommendations

21. I recommend that Dr B:
 - a) Provide a written apology to Mrs A for the deficiencies identified in this report. The apology is to be sent to HDC, for forwarding to Mrs A, within three weeks of the date of this report.
 - b) Within three months of the date of this report, undertake education on communication and the importance of patient cultural/religious perspectives in clinical care and report back to HDC that this has been completed.
 - c) Within three months of the date of this report, produce an allograft patient information sheet which explains in plain English what this procedure entail and what considerations may be helpful for patients to consider. This patient information sheet should be given to patients at the consultation stage if allograft is considered a surgical option, in order to enhance the consent process.

Follow-up actions

22. A copy of this report will be sent to the Medical Council of New Zealand.
23. A copy of this 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