Informed consent for the use of human products
16HDC00877, 14 June 2018

Orthopaedic surgeon ~ District health board ~ Orthopaedic surgery ~ Allograft ~ Informed consent ~Documentation ~ Rights 4(2), 4(5), 6(1), 6(1)(b), 7(1)

An orthopaedic surgeon recommended that a man who had sustained a neck injury undergo an anterior cervical discectomy and fusion surgery. The surgeon did not recall the discussion but said it was likely that he discussed using an allograft (using donated material) rather than harvesting an iliac crest (hip) graft from the man.

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

The orthopaedic surgeon saw the man again a few months later. The man 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.

On the day of surgery, another orthopaedic surgeon saw the man to obtain his informed consent to the surgery. This doctor does not remember the conversation he had with the man, 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 there was no documented preoperative plan to use an allograft, and he was not aware it was the first orthopaedic surgeon's usual practice to use an allograft.

Following the operation the man said he asked the consenting surgeon three times why his hip was not sore and, each time, the consenting surgeon "talked around the subject".

In the orthopaedic outpatient clinic a few months later, the man said he asked the same questions about his hip bone, and the orthopaedic surgeon told him that no bone was taken from his hip, and that bone from a dead person had been put in his neck. The surgeon did not record that the man had any concerns about the informed consent process.

Findings

The orthopaedic surgeon failed to provide the man with sufficient information about the proposed treatment. As the responsible consultant, overall responsibility for ensuring that the man was provided with sufficient information about the proposed treatment lay with the orthopaedic surgeon. By failing to provide that information, he breached Right 6(1).

The orthopaedic surgeon failed to make it clear to the orthopaedic medical officer and the consenting surgeon that an allograft was planned, and the consenting surgeon was unaware that it was the orthopaedic surgeon's usual practice to use an allograft. Consequently, the clinicians who saw the man were unable to provide him with the necessary information. This failure to ensure quality and continuity of

services was the responsibility of the orthopaedic surgeon. Accordingly, he breached Right 4(5).

The orthopaedic surgeon failed to record his intention to use an allograft, and did not record the information he gave to the man. The man raised concerns regarding the informed consent process and that he had been unaware of the plan to use an allograft, but the orthopaedic surgeon made no record of the conversations. Accordingly, he failed to comply with professional and legal standards and was found in breach of Right 4(2).

It was the consenting surgeon's responsibility to ascertain the planned procedure, so that he would be in a position to inform the man. As there was no information in the clinical records about the graft procedure to be undertaken, the consenting surgeon should have contacted the orthopaedic surgeon to clarify the plan before talking to the man. The consenting surgeon did not inform the man 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 the man's circumstances would expect to receive and without that information the man was not in a position to make an informed choice and give informed consent for the treatment provided. Accordingly, the consenting surgeon was found in breach of Right 6(1) and Right 7(1).

The culture of the district health board 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, it was assumed that the patient did not need to be told that donated material would be used.

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. The DHB did not provide the man with information that a reasonable consumer would expect to receive and, accordingly, was found in breach of Right 6(1)(b).

Recommendations

It was recommended that the orthopaedic surgeon attend training courses on record-keeping and communication with patients and colleagues. It was also recommended that he provide a written apology to the man.

It was recommended that the consenting surgeon and the DHB provide written apologies to the man.

The DHB 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. The DHB 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.

It was recommended that the DHB report to HDC on the steps being taken to ensure full compliance with the use of surgical checklists in the orthopaedic service.