Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Inadequate information and consent process for surgical mesh product procedure
19HDC02166

Deputy Health and Disability Commissioner Rose Wall has found a gynaecologist in breach of the Code of Health and Disability Services Consumers' Rights (the Code) for services provided at a public hospital (Te Whatu Ora, previously District Health Board).

The breaches relate to the gynaecological care a woman received involving the insertion of a surgical mesh product (transobturator tape (TOT)). Following the surgical procedure, the woman experienced significant complications, and it was later found that the surgical mesh had eroded through the vaginal wall. The woman also reported a loss of dignity and privacy as a result of the repeated investigations required to identify the cause of the woman's symptoms. The TOT was later surgically removed.

Ms Wall concluded the gynaecologist did not explain the risks of gynaecological surgical mesh adequately to the woman prior to performing the TOT procedure. Accordingly, she found the gynaecologist in breach of the Code for failing to provide the woman with the information a reasonable consumer in her circumstances would expect to receive (Right 6(1)).

"Based on the information available, I am not satisfied that the gynaecologist informed the patient of the risks specific to the surgical mesh procedure, including those of mesh erosion and chronic pelvic pain."

Ms Wall also found the gynaecologist breached Right 7(1) of the Code which gives consumers the right to make an informed choice and give informed consent. "It follows that, without the necessary information, the patient was not able to make an informed choice and give informed consent to the surgery," she said.

"I am also critical that the gynaecologist did not document which alternative treatment options were discussed with his patient and what information was provided about these options," said Ms Wall.

For failing to ensure that clinical documentation complied with professional standards, Ms Wall found the gynaecologist breached Right 4(2).

In numerous previous decisions, HDC has stressed the importance of good record-keeping and the accuracy of clinical records, Ms Wall noted.

"I am critical that the surgery was documented poorly, and that this made it difficult to assess the standard of the surgical technique," Ms Wall said.

Ms Wall acknowledged the woman's comment that her care was not managed with the dignity and traditions of her Māori heritage and undermined her rangatiratanga and stripped her mana.

Since the event the gynaecologist has made a number of changes to his practice. He has stopped using the TOT surgical mesh product and has also markedly increased his level of documentation relating to preoperative counselling.

Te Whatu Ora has also made changes including developing an online course for staff that provides an overview of informed consent and informed consent awareness. This has been included in the hospital's Gynaecology Department junior doctor induction programme.

Additionally, the hospital's urogynaecology team (including the gynaecologist who performed the surgery) has developed new patient information booklets on treatment options for stress urinary incontinence and pelvic organ prolapse and for the management of complications, including options for mesh removal. The patient who was the subject of this breach was part of the consumer working group involved in the development of these booklets.

Taking into account the changes already made, Ms Wall recommended that the gynaecologist:

- Provide a formal written apology to Ms A for the deficiencies identified in the report.
- Complete HDC's online learning course on informed consent (Module 2: What you need to know about informed consent).
- Reflect on the deficiencies in care with respect to documentation standards and the informed consent process to ensure that all treatment options and their associated risks are discussed clearly with patients, and documented on consent forms or in clinic letters.

19 June 2023

Editor's notes

The full report of this case will be available on HDC's website. Names have been removed from the report to protect privacy of the individuals involved in this case.

The Commissioner will usually name providers and public hospitals found in breach of the Code, unless it would not be in the public interest, or would unfairly compromise the privacy interests of an individual provider or a consumer.

More information for the media, including HDC's naming policy and why we don't comment on complaints, can be found on our website here.

HDC promotes and protects the rights of people using health and disability services as set out in the Code of Health and Disability Services Consumers' Rights (the Code).

In 2021/22 HDC made 402 recommendations for quality improvement and providers complied with 98% of those recommendation.

Learn more: Education