

Standards were not followed for obtaining consent for mesh surgery 22HDC01044

The Health and Disability Commissioner has found a doctor breached the Code of Health and Disability Services Consumers' Rights (the Code) for failing to provide adequate information to a woman undergoing mesh surgery.

The woman, in her sixties, consented to a hysterectomy, due to pelvic organ prolapse six months prior to surgery. She does not recall the surgeon mentioning surgical mesh or the risks associated with its use at the time.

The planned surgery was changed – after the woman had been prepped, premedication had been administered, and immediately prior to entering the operating theatre and surgery commencing.

As a result, the woman was unable make an informed choice and give her informed consent to the use of surgical mesh and the surgery performed.

Deputy Health and Disability Commissioner Rose Wall said that the expected standard procedures for obtaining informed consent were not followed and the woman had no understanding of the procedure that was undertaken.

"The standard of care was not met for the patient – as she clearly wanted and expected a hysterectomy at the time. She did not get a hysterectomy but instead underwent a procedure involving surgical mesh," Ms Wall said.

"The timing of the change in surgical plan when the woman was alone, prepped, in her surgical gown and just outside the theatre, typically pressured and nervous, was entirely inappropriate. In my view, anticipating that a consumer is in a position to make an informed choice and give informed consent in such a circumstance is a fundamental failing, and should not have occurred in any circumstance."

The woman and the doctor presented differing accounts of the discussion that occurred immediately prior to the surgery commencing.

The doctor told HDC the woman was aware that she would not be having a hysterectomy, and that the surgery involved surgical mesh, and that there was a discussion with the woman prior to the surgery to repeat the consent and the risk of recurrence of prolapse.

The doctor also said she had previously provided the woman with an information pamphlet on pelvic organ prolapse, published by the Royal Australian and New

Zealand College of Obstetricians and Gynaecologists (RANZCOG), which outlined general risks of surgery and the specific risks of pelvic organ prolapse surgery.

The woman, however, said the doctor did not discuss the mesh-related risks and she initialled the consent form immediately prior to surgery. The words '+/- mesh' are handwritten on the consent form below the description of the procedure, along with a list of risks, but the risk of recurrence of prolapse was not included.

There was also no reference to any of the other risks specific to surgical mesh, such as vaginal scarring/stricture, fistula formation, and persistent pelvic pain (which may be unprovoked). Except for pain during intercourse, these other mesh-related risks were also not referred to in the RANZCOG information pamphlet that was provided to the woman.

Ms Wall concluded that it was unclear what handwritten information was originally included in the consent form signed six months prior to the surgery and what information was added by the surgeon immediately prior to the operation commencing.

She found the doctor in breach of Right 6(1)(b) of the Code, the right to be informed | Whakamōhio, and Right 7(1), the right to make an informed choice and give informed consent | Whakaritenga mōu ake, for not providing the woman with adequate information to allow her to make an informed choice, and for not providing the woman with sufficient opportunity to fully consider the information she was entitled to.

Ms Wall also made adverse comments about Te Whatu Ora because the woman raised a number of concerns after her surgery and multiple staff members (the doctor on the ward and the other hospital staff) did not address her concerns promptly.

Te Whatu Ora has since invested considerable time and effort developing and updating its policies, including its current Informed Consent Policy which places specific emphasis on the use of surgical mesh. Te Whatu Ora and the surgeon involved have provided written apologies to the woman.

The doctor is no longer practising in New Zealand. Ms Wall recommended that if returning to practice in New Zealand, the doctor should implement a system to ensure all treatment options and their associated risks are discussed clearly with patients and documented, and they should consider how they can improve the informed consent process to ensure patients are provided with sufficient time to fully consider the information they are entitled to, before seeking their consent.

11 March 2024

Editor's notes

Please only use the photo provided with this media release. For any questions about the photo, please contact the communications team.

The full report of this case can be viewed on HDC's website - see HDC's 'Latest Decisions'.

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 <u>here</u>.

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

In 2022/23 HDC made 592 quality improvement recommendations to individual complaints and we have a high compliance rate of around 96%.

Read our latest Annual Report 2023

Learn more: Education Publications

For more information contact:

Communications team, Health and Disability Commissioner

Email: communications@hdc.org.nz, Mobile: +64 (0)27 432 6709