Insertion of intrauterine device without consent 15HDC01925, 19 December 2016

Private hospital ~ Obstetrician and gynaecologist ~ Mirena intrauterine device ~ Informed consent ~ Rights 7(1)

A woman, aged 36 years at the time, privately consulted a gynaecologist for assessment and management of heavy menstrual bleeding and post-coital bleeding.

The woman signed a consent form for a hysteroscopy, dilatation and curettage, endometrial biopsy and a Novasure endometrial ablation, to take place under general anaesthetic. Prior to the commencement of surgery, a "Time Out" check took place in the theatre, which included reading out the procedure on the consent form.

The gynaecologist experienced technical difficulties with the Novasure machine while attempting to perform the endometrial ablation, and therefore abandoned the procedure.

At this point, the gynaecologist considered several alternative procedures, and had devices for these alternatives brought into the operating theatre. The gynaecologist decided to insert a Mirena intrauterine device into the woman's uterus, despite the woman having declined to have a Mirena inserted on a previous occasion, and not having given consent to have a Mirena inserted on this occasion. The gynaecologist said that he considered the Mirena to be the safest and most easily reversible treatment option.

While in the Recovery Room, the woman discovered what had occurred, and was distressed that a Mirena had been inserted without her consent. The gynaecologist apologised and removed the Mirena.

The principle of informed consent is at the heart of the Code. Pursuant to Right 7(1) of the Code, services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent. It is the consumer's right to decide and, in the absence of an emergency or certain other legal requirements, clinical judgement regarding best interests does not apply. If the consumer will be under general anaesthetic, the Code provides an additional safeguard that consent must be in writing.

It was considered plainly unacceptable that the gynaecologist inserted the Mirena without having first obtained the woman's consent. The woman was particularly vulnerable as she was under a general anaesthetic. The right to decide was the woman's, and she was deprived of it. By inserting the Mirena into the woman's uterus when she had not given informed consent, the gynaecologist breached Right 7(1) of the Code.

Adverse comment was made about a registered nurse, as she was aware of what was on the written consent form but did not query the absence of written consent with the gynaecologist when he began considering alternative treatment options.

Adverse comment was made about the private hospital, as it was considered that this case illustrated a missed opportunity to advocate for the woman when she was under anaesthetic and vulnerable. Furthermore, the expectation set down by the private hospital in its informed consent policy, that "[n]o consent should be presumed", does not appear to have been adhered to.

The Commissioner referred the gynaecologist to the Director of Proceedings for the purpose of deciding whether proceedings should be taken, and recommended that the gynaecologist undertake further education and training on informed consent.

The Director of Proceedings brought disciplinary proceedings in the Health Practitioners Disciplinary Tribunal which resulted in a finding of professional misconduct and subsequent penalty orders. The gynaecologist appealed part of his penalty (three months suspension) in the High Court. The High Court dismissed the appeal and upheld the Tribunal's decision. The Director did not take HRRT proceedings.

The Commissioner recommended that the private hospital:

- a) use an anonymised version of this case for the wider education of its staff and the surgeons who use its facilities, with particular emphasis on informed consent and advocacy for the consumer; and
- b) provide HDC with an update of the corrective actions it has taken since this incident, including copies of the updated consent form and informed consent policy.

The Commissioner recommended that the Medical Council of New Zealand consider whether a review of the gynaecologist's competence is warranted.