Informed Consent in Healthcare Ethics

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As a healthcare practitioner, you may think of your role as one in which your main accountabilities are to assess an individual's health and to deliver appropriate care interventions. However, after landmark clinico-legal disputes in Australian and UK Courts over the last decades[1], this paradigm has changed to now require your participation as an ethical negotiator, assisting your patients in deciding if a proposed intervention is the right approach for them[2].

How big is the issue and what are the real risks?

Legal and regulatory frameworks are clear and there is an unquestionable need to comply with them. There is also evidence to show that when patients' opinions and concerns are taken into consideration, they are more satisfied and there is lower incidence of clinico-legal cases[3].

The literature recommends focusing on how you discuss risks with your patients[4]. Material risks should be disclosed avoiding the simplistic approach of reducing them to percentages, where if the incidence is considered too low, they aren't disclosed. What needs to be at the forefront of the conversation is the fact that it is not only the nature and likelihood of the risk happening that is an issue, but the impact on the life of the patient, **that** particular patient, if it occurred, and the importance to **that** patient of the benefits of the treatment, and the alternatives available.

Let's consider the following scenario:

Theresa, a 39-year-old patient diagnosed with severe endometriosis attends a highly regarded specialist O & G, Dr M, who recommends her to undergo a hysterectomy. At the consultation, Theresa agrees to the intervention but expresses her desire to keep as much of her reproductive system as possible. She mentioned she had always hoped to become a mother one day, even though she was coming to terms with the fact it may not happen in a conventional way for her. She mentioned there was no history of ovarian cancer in her family, thus she would prefer that only surgical procedures that are absolutely necessary to be performed. Dr M appropriately takes Theresa's consent to a "hysterectomy plus any other procedure deemed necessary". Dr M has admitting rights at Best Private Hospital (BPH) and schedules the surgery to take place in four weeks' time as he is away until then. Following protocol, Dr M sends the signed consent to BPH with other relevant paperwork.

Unexpectedly, Theresa experiences intense pain seven days after the consultation and attends BPH Emergency Department (ED). Through an arrangement between BPH and a company named Emergency Department Doctors Pty Ltd (EDD P/L), EDD P/L provides the medical personnel working in the ED and BPH provides the nursing personnel, premises and equipment. The attending ED physician assesses Theresa and recommends she is admitted having the hysterectomy performed as soon as possible. Because Theresa's specialist is away, the BPH contacts the next practitioner on the rotating roster, Dr K. Theresa agrees to have the intervention with Dr K and is admitted to BPH.

The next morning, Dr K reviews Theresa's health records and informs her that in his opinion, it would be best for her to have the procedure that day to which she agrees. Unfortunately, during the procedure there were unforeseen complications caused by scarring from previous surgery. Dr K determined in addition to the hysterectomy it is in Theresa's best interests to also perform a bilateral salpingo-oophorectomy and proceeds accordingly. When Theresa found out how the operation had proceeded, she complained to the hospital and threatened to refer the matter to her solicitor. She alleged that Dr K should have not performed the bilateral salpingo-oophorectomy.

What were the issues in this case? Did the hospital and/or EDD P/L and /or Dr K obtain valid informed consent to perform this procedure?

There is no magic formula or template to completely assess an informed consent. Each case has its own set of circumstances and the evidence is considered on its merits. Independent peer expert opinion is paramount, however you would need to consider a few things to answer these questions. Firstly, as an objective test, do you think a reasonable person, in the position of Theresa, would likely attach significance to the hysterectomy and bilateral salpingo-oophorectomy? Secondly, as a subjective test, was Dr K aware, or should have reasonably been aware, that Theresa was likely to attach significance to that information?

The fact Theresa had expressed her wish to keep as much of her reproductive system as possible, indicates a positive answer to both questions. Following the surgery, she could have opted for an egg retrieval, had the bilateral salpingo-oophorectomy not taken place. The question remains as to whether this was appropriately recorded by Dr M in Theresa's health records.

Was there valid informed consent from Theresa in respect of the bilateral salpingo-oophorectomy?

No, unless one of the issues discussed pre-surgery was that a bilateral salpingo-oophorectomy might be necessary, and a clear explanation of the implications of this procedure in light of Theresa's desire to have children had been discussed. If Theresa had not been told that a bilateral salpingo-oophorectomy could have been necessary but admits, or the court concludes, that had she been told she would have consented to it, Dr K would still be liable in trespass but not negligence and any damages would be minimal.

What are the possible repercussions for Dr K now?

There are several potential outcomes. There could be a civil claim in negligence, due to failure to obtain informed consent. A query could also be put forward as to whether the operation was performed to the standard of "a reasonable O&G". The complaint could carry action against Dr K, which could affect his accreditation at the hospital. There could be escalation to Ahpra.

Lessons to be learned

MIPS advises practitioners to ensure valid informed consent to treatment is obtained by following effective guidelines, including:

- Explain to patients it is their right to choose and discuss any concerns and procedures in a two-way conversation.
- Deliver information objectively to address patients' expectations.
- Disclose information about diagnosis, relevant procedures, associated risks and benefits, alternative treatments, potential outcomes and what to expect after a procedure.
- Tailor your communication approach to suit your patients' health literacy level and cultural background. You may use graphics, icon arrays, statistics graphs to support your explanations.
- Have the conversation as early as possible in the therapeutic process and allow enough time to address any concerns.
- Have a plan to address challenging issues.
- Record all information in the patient's health record (this is your primary protection).

From MIPS' experience, this collaborative approach promotes high quality health outcomes, a lower risk exposure both to the patient and the healthcare practitioner and higher patient satisfaction levels.

If you have any questions regarding your membership or your professional practice, contact MIPS on 1800 061 113.

[1] Cheluvappa, R., & Selvendran, S. (2020). Medical negligence-Key cases and application of legislation. Annals of Medicine and Surgery, 57, 205-211.

[2] Mazur, D. J. (2016). High Court decision making in informed consent: Movement to to the reasonable person in the patient's position standard and focus on severe adverse outcomes of low chance (probability) of occurrence. International Journal of Ethics, 12(3).

[3] Valentine, S., Majer, J., Grant, N., Ugoni, A., & Taylor, D. M. (2020). The Effect of the Consent Process on Patient Satisfaction With Pain Management: A Randomized Controlled Trial. Annals of Emergency Medicine.

[4] Naik, G., Ahmed, H., & Edwards, A. G. (2012). Communicating risk to patients and the public. British Journal of General Practice, 62(597), 213-216.