

## “The road to hell is paved with good intentions” (St. Bernard of Clairvaux, c. 1150)

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The practice of medicine is guided by the principle of non-maleficence, which was first declared in the Hippocratic Oath as the promise to abstain from doing harm. None of us wish to inflict pain or suffering upon our patients, but unfortunately this may become an unintended outcome in some clinical situations. The article by Hengel et al reviews the medicolegal issues around use of mesh for support of pelvic organ prolapse (POP) and of midurethral slings in the treatment of stress urinary incontinence (SUI). It also serves as an excellent primer on tort law as it applies to medical malpractice and documents cases that have been closed by the Canadian Medical Protective Association (CMPA) regarding the use of mesh in Canada. The message that rings true in this article can be applied to any facet of clinical practice: the importance of informed consent and thorough documentation.

It should be remembered that informed consent is a discussion between the surgeon and the patient. Informed consent is based on the principle of patient autonomy. For the consent to be valid, it must be voluntary, the patient must have the capacity to provide it, and the patient must be properly informed. To start with, patients should be told their diagnosis. They should be informed of conventional acceptable alternatives to the proposed treatment. They should also be informed of the consequences of non-treatment. Surgeon should explain why they are recommending this particular therapeutic intervention (mesh) over the alternative(s). In the course of this discussion, patients should be made aware of the risks of the surgery. The risks for the use of mesh, for instance, would include material risks — those that occur frequently, as well as those that are infrequent, but very serious, including bowel perforation, sling erosion, chronic pelvic

pain, and permanent disability. There may be also special risks that would arise from the patients' particular medical circumstances and these should also be discussed. Most importantly, this discussion should be clearly documented in the medical record and one should not simply rely on a signed consent form. The documentation should include the fact that major risks were discussed, minor but important risks were mentioned, and the patient had an opportunity to ask questions and was given answers. Although some surgeons may rely on handouts and/or videos to augment the informed consent process, it is critical to document the fact that the patient had the opportunity to ask questions subsequent to reviewing these adjuncts and that a discussion between the surgeon and patient did occur. The concept of informed consent being a discussion between the surgeon and the patient is paramount. In addition to the consent discussion being documented in the medical record, it is best practice for the operative note to be dictated immediately after the procedure is performed, including careful documentation of any anatomical differences or difficulties encountered in the provision of the surgical care. It is more difficult to defend a non-contemporaneous operative note dated and timed after a postoperative complication has occurred.

It should be remembered that unintended consequences of surgery do not necessarily constitute lack of standard of care or negligence. As we all know through experience, poor outcomes may occur in spite of our best efforts in the provision of care due to circumstances beyond our control. A well-documented consent discussion and contemporaneous and thorough operating room notes go a long way in assisting the defense of a surgeon in the absence of clear negligence.

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