

MEDICINE AND THE LAW

Obtaining informed consent for a sterilisation in the light of recent case law

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The need to obtain informed consent prior to any sterilisation is a very well-established ethical and legal obligation. South African law, however, does not specifically state who is responsible for obtaining informed consent before performing a sterilisation. This has implications for the liability of a surgeon or gynaecologist in circumstances where the informed consent is defective. Due to the vagueness of the applicable law, a surgeon or gynaecologist might be held liable, even in situations where he/she did not obtain the consent and relied on a nurse or assistant to procure the relevant informed consent. This article explores the relevant statutory law and canvasses two legal cases that came before the court regarding defective informed consent and the resultant liability for damages. We also make recommendations for proposed amendments to the current law to provide further clarity.

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The ethical-legal obligation to obtain informed consent from patients before any medical procedure or operation is undertaken is a well-established principle in legislation^[1] and the common law.^[2] In this article, the authors, however, focus specifically on the unsettled issue of obtaining informed consent for a sterilisation (this article is based partially on the PhD thesis of C J Badul – refer to author contributions below). Informed consent is a positive right in terms of the right to bodily integrity^[3] and a defence for doctors facing civil claims for damages (*volenti non fit injuria* [there can be no injury to a person who has voluntarily consented]).^[4,5] Even though the ethical-legal framework for consent is well established, one of the unresolved complexities is the question of who bears the legal duty to obtain the consent or ensure that consent has been obtained for a sterilisation. This is a broad issue involving the potential liability of a surgeon for failing to personally obtain and record the consent of a patient, and it has come before the courts in relation to two sterilisation cases.^[6,7]

In *Pandie v Isaacs*^[6] the court grappled with this point, but failed to make a definitive finding on whether the surgeon or the nurse had to take responsibility to ensure that consent had been properly obtained and documented. However, in the *Government of Namibia v LM and Others*^[7] case, the court held that the duty lay with the medical practitioner to procure written informed consent. This article explores the relevant legislation, case law and guidelines with regard to sterilisation to ascertain on whom the duty rests to obtain informed consent.

Consent to a sterilisation – the South African ethical-legal framework

The Sterilisation Act No. 44 of 1998^[8] (the Act) provides that the patient requesting the sterilisation must be >18 years of age and capable of consenting in writing to the procedure. The Act^[8] specifies that consent must be free from coercion and must be provided after an unambiguous explanation of the proposed procedure, including information on its permanency or reversibility. Finally, the Act^[8] states that the patient must be advised that their consent may be withdrawn at any time before the sterilisation is performed.

Although the Act^[8] is silent on who is responsible for providing this information and obtaining written consent, there are ethical guidelines dealing with this point, which have been issued by the Health Professions Council of South Africa (HPCSA).^[9]

The guidelines state that it is the duty of the healthcare practitioner to obtain the patient's informed consent before any treatment is given.^[10] Nevertheless, the guidelines allow a practitioner to delegate the task of obtaining informed consent, provided the final responsibility remains with the healthcare practitioner.^[10] Furthermore, where a patient's informed consent was obtained by a third party, the healthcare practitioner must nevertheless ascertain from the patient how well they understood the proposed procedure and its attendant risks.^[10] Ensuring that the signed copy of the consent form is in the file, is inadequate.^[7]

Recent case law on consent to a sterilisation

Pandie v Isaacs

Pandie v Isaacs^[6] related to a civil claim for damages by a woman who argued that she had been sterilised without her full and informed consent. Isaacs alleged that she was offered the opportunity to be sterilised when she undergoes her caesarean section, but declined. When she was admitted to hospital, she was presented with a pre-drafted consent form that was prepared based on her doctor's admission letter. It indicated that she was to have a caesarean section and be sterilised. Isaacs refused to sign the consent form, indicating that she only wished to undergo a caesarean section and not a sterilisation. The nurse advised her to inform the surgeon of this change regarding the procedures, which she did not do. Isaacs only became aware that she had been sterilised when the theatre nurse held up a jar and showed her the severed portion of the fallopian tubes.

The court held that, in terms of the Act,^[8] written consent was required, which had not been obtained in this case. Nevertheless, obtaining written consent was, in practice, the function of the nurse and Dr Pandie could not be held liable for negligence for failing to confirm the contents of the consent document with Isaacs. The

court further held that in the event of the patient changing her mind, there would be a duty on the nurse to bring this to the attention of the gynaecologist. In coming to this conclusion, the court relied on expert evidence that it was not a common practice among surgeons to personally check written consent forms before operating.

Government of Namibia v LM and Others

In the *LM*^[7] case, 3 HIV-positive women claimed that they had been sterilised, without their voluntary consent, while undergoing caesarean sections in state hospitals in Namibia. The Namibian Supreme Court found that the written consent taken from the women did not mean that there was informed consent.^[7] If practitioners are to rely on the *volenti non fit injuria* defence, they must be able to prove that all elements of the defence as set out in *Castell v de Greef*^[2] are present, including: disclosure of all material risks and voluntariness.^[7] In this case, the court held that an obligation was placed on healthcare professionals to obtain consent from a patient:

‘... sterilisation allows time for informed and considered decisions ... health professionals are under an obligation to assess the patient and point out the risks involved in particular procedures so as to enable the patient to make an informed decision and give informed consent.’^[7]

Discussion

Although the Act^[8] is silent as to who ought to obtain informed consent from the patient wishing to be sterilised, we submit that the court in the *Pandie*^[6] case erred in suggesting that a surgeon may delegate this task to a nurse. We have five reasons for adopting this approach. Firstly, although the Act^[8] does not specify where the legal obligation to obtain consent lies, the HPCSA guidelines are clear on this point. In *Jansen van Vuuren and Another NNO v Kruger*,^[11] the then Appellate Division, when dealing with an HIV-positive patient’s right to confidentiality, held that patients have a right to expect that their medical practitioner complies with the professional guidelines. Given that the ethical guidelines require the surgeon to take responsibility for obtaining consent, regardless of whether they delegate part of this task, it was inappropriate of the court to suggest that liability could potentially be placed at the feet of the nurse. Secondly, in defending a civil claim, a surgeon is able to rely on the defence of *volenti non fit injuria*. It would, however, be very difficult for them to prove all elements of the defence if they did not themselves obtain the consent. Thirdly, the court only gave one rationale for the nurse rather than the surgeon being responsible for obtaining consent, i.e. because it was an accepted practice within the profession.^[6] It is submitted that this is insufficient. Expert evidence that this is a practice in hospitals is not a justification for failing to comply with professional ethical guidelines. The court in this instance ought to have found the conduct wrongful, as based on the approach in the *Jansen van Vuuren*^[11] case. Surgeons are duty-bound to ensure that consent is obtained properly. Fourthly, the complexity of transferring the task of consent obligation to a nurse would be: which nurse would be liable? There may be several nurses who are involved in the consent process, such as the ward and theatre nurses. Finally, the *Pandie*^[6] case is out of step with the approach taken in other similar jurisdictions, such as in Namibia.

Conclusion

The duty to obtain informed consent before a sterilisation is clear – both in terms of the Act^[8] and common law. However, the Act^[8] does not deal with on whom this consent rests, and it has only recently

come before the courts.^[8] We submit that despite the silence in the Act^[8] on this issue, there is an express duty on the surgeon, given the HPCSA guidelines. The Namibian courts have gone further by requiring that surgeons obtain and document consent before a sterilisation.^[7] We submit that this is the correct approach.

We make two recommendations. Firstly, we suggest an amendment to the Act^[8] to ensure that there cannot be any misunderstanding regarding the consent obligations and that involuntary sterilisations do not occur in the future. It must be clarified who has to take consent from the patient. This change will be broadly beneficial, as it will protect all persons considering sterilisation as a form of birth control. In this regard, the proposed recommendations in italics and underlined, as set out below, are an addition to section 4 of the Sterilisation Act.^[8]

‘Consent

4. For the purposes of this Act, “consent” means consent given freely and voluntarily without any inducement and may only be given if the person giving it has –

- (a) been given a clear explanation and adequate description of the –
 - (i) proposed plan of the procedure; and
 - (ii) consequences, risks and the reversible or irreversible nature of the sterilisation procedure;
- (b) been given advice that the consent may be withdrawn any time before the treatment;
- (c) signed the prescribed consent form and
- (d) written consent may only be obtained before the onset of labour by a surgeon or gynaecologist performing the procedure.

Secondly, we recommend that hospitals develop standard operating procedures that ensure that there is space on the consent form for the surgeon to sign and make any notes they deem necessary regarding the consent procedure. This will ensure that the surgeon is aware of whether consent has been obtained in every case prior to the procedure being performed.

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1. South Africa. National Health Act No. 61 of 2003.
2. *Castell v de Greef* 1994 (4) SA 408 (C).
3. South Africa. Constitution of the Republic of South Africa Act No. 108 of 1996.
4. *McDonald v Wroe* 2006 (3) All SA 565 (C).
5. *Christian Lawyers’ Association v National Minister of Health (Reproductive Health Alliance as Amicus Curiae)* 2005 (1) SA 509 (T).
6. *Pandie v Isaacs* (A135/2013, 1221/2007) [2013] ZA WCHC123.
7. *The Government of the Republic of Namibia v LM and Others* (SA 49/2012) [2014] NASC 19 (3 November 2014).
8. South Africa. Sterilisation Act No. 44 of 1998.
9. Health Professions Council of South Africa. Guidelines for Good Practice in the Health Care Professions. General Ethical Guidelines for Reproductive Health. Booklet 13. Pretoria: HPCSA, 2008. <http://www.hpcs.co.za> (accessed 1 December 2017).
10. Health Professions Council of South Africa. Guidelines for Good Practice in the Health Care Professions. Seeking Patients’ Informed Consent: The Ethical Considerations. Booklet 9. Pretoria: HPCSA, 2008. <http://www.hpcs.co.za> (accessed 1 December 2017).
11. *Jansen van Vuuren and Another NNO v Kruger* (675/91) [1993] ZA SCA 1450; 1993 (4) SA 842 (AD); [1993] 2 All SA 619 (A) (28 September 1993).

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