



The importance of documented informed consent

You might be wondering why emphasis is often placed on the importance of obtaining written informed consent from your patients?

Bottom line: Written evidence will always work in your favour in any legal dispute or malpractice claim.

In South Africa, patient consent holds significant importance in medical practice, and there are legal requirements for medical professionals to obtain signed consent from their patients. This is a fundamental aspect of patient autonomy and rights, ensuring that individuals have the necessary information to make informed decisions about their medical care.

In addition to the ethical and legal considerations outlined by the Health Professions Council of South Africa ([HPCSA](#)), securing written informed consent is a crucial aspect of safeguarding both the patient and the healthcare professional. Beyond its role in ensuring ethical medical practice, written consent serves as tangible and invaluable documentation, especially in the context of medical malpractice insurance.

Here are some key points about patient consent in South Africa:

Legal Framework

The [National Health Act of 2003](#) and the [South African Medical Association \(SAMA\)](#) provide comprehensive guidelines and regulations regarding patient consent. These legal frameworks outline the requirements for obtaining informed consent from patients, ensuring that medical professionals adhere to the necessary standards.

Informed Consent

Informed consent is a crucial process through which medical professionals provide patients with relevant information about proposed treatments, procedures, or interventions. Patients should be fully informed about the nature of the treatment, potential risks and benefits, available alternatives, and any potential consequences of refusing treatment.

Consent Form

A Consent Form is a vital document signed by a patient (or their legal guardian in the case of minors or incapacitated persons) before treatment, assessment, or procedures. This form confirms that the patient agrees to the treatment, assessment, or procedure and is aware of any associated risks, providing legal evidence of the same. In cases involving minors or incapacitated persons, their legal guardian and/or next of kin would complete the form.

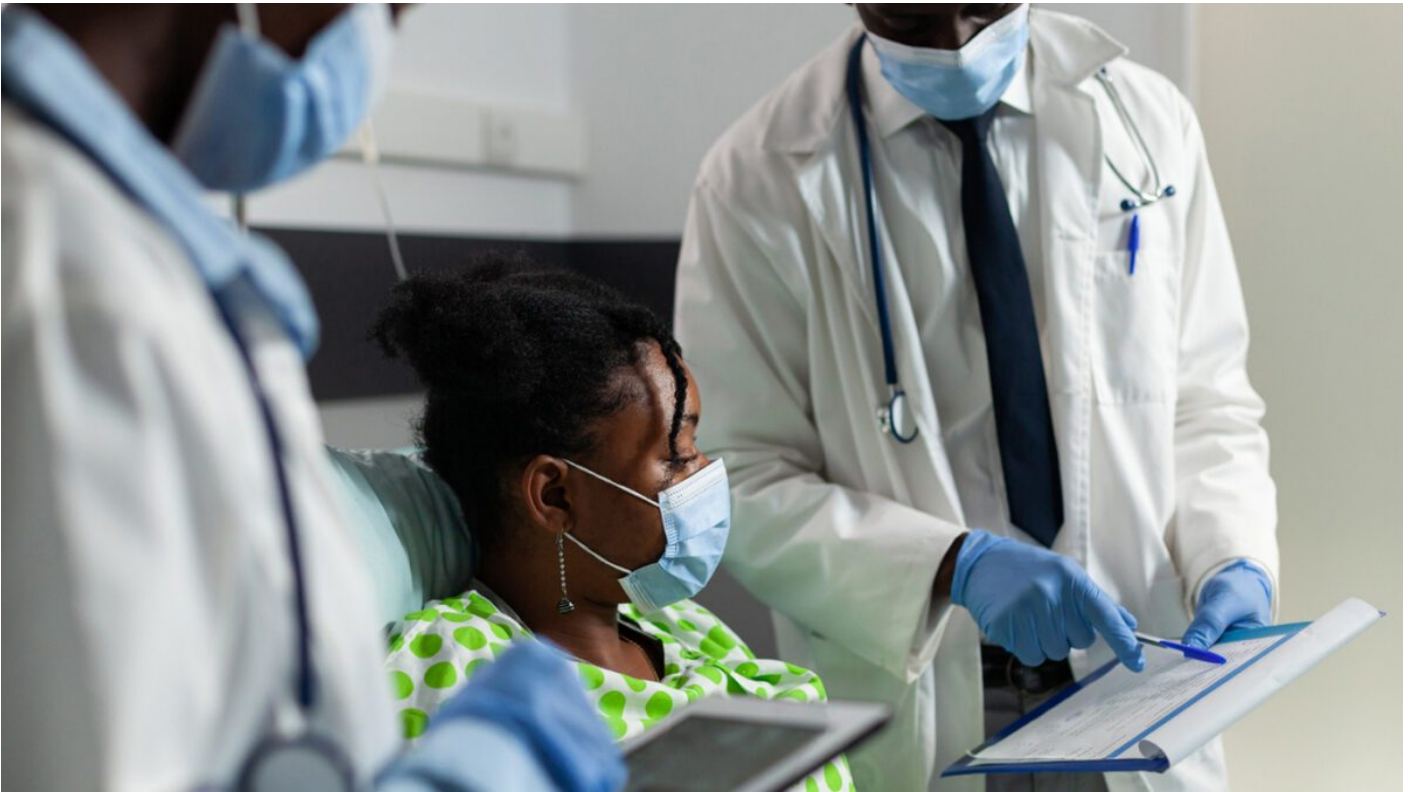
Capacity to Consent

It is crucial that you, as a medical professional, assess the patient's capacity to consent. This involves ensuring that the patient can understand the information provided and make decisions about their care. In cases where a patient lacks the capacity to provide informed consent, different procedures may apply, such as obtaining consent from a legal guardian or next of kin.

Document the consent process

Medical professionals are required to meticulously document the consent process, including specific details of the information provided to the patient, discussions held, and the patient's agreement or refusal.

This documentation serves as a legal record of the consent process, ensuring transparency and accountability in medical practice.



HPCSA's key principles for informed consent

We recommend that you familiarise yourselves with the requirements in terms of obtaining informed consent, which are set out in an [HPCSA booklet](#). You can download the latest version from the [HPCSA's website](#).

The HPCSA typically emphasizes the following key principles regarding informed consent:

- **Voluntariness:** Informed consent must be given voluntarily by the patient without any coercion or undue influence.
- **Information Disclosure:** Healthcare professionals are typically required to provide patients with adequate information about the proposed treatment, including the nature of the procedure, potential risks and benefits, alternative treatments, and the likely consequences of not undergoing the treatment.
- **Comprehension:** Patients should have the capacity to understand the information provided, and healthcare professionals should ensure that patients comprehend the relevant details before obtaining their consent.
- **Competence:** The healthcare professional should assess the patient's competence to provide informed consent. If a patient is not competent (e.g., due to age or mental incapacity), alternative procedures may be required.
- **Documentation:** Informed consent should be documented in the patient's medical records. The documentation should include details about the information provided to the patient, the patient's understanding, and the patient's agreement to the proposed treatment.
- **Ongoing Communication:** Informed consent is not a one-time event; it may need to be revisited if there are changes in the patient's condition or if there are new developments in the treatment plan.
- **Respecting Autonomy:** The guidelines typically emphasize respecting the autonomy and rights of the patient in making decisions about their healthcare.

Remember that these are general principles, and specific details may vary. Always refer to the most recent and relevant guidelines from the [HPCSA](#) or other authoritative sources for the most accurate and current information.



FAQs

Does the healthcare professional have to document the verbal explanation that he gave to a patient to obtain their signature on the consent form?

Yes, the healthcare professional is required to document the verbal explanation given to the patient to obtain their signature on the consent form.

This documentation serves as a legal record of the consent process and should include specific details of the information provided to the patient, discussions held, and the patient's agreement or refusal. It is an essential part of the informed consent process to ensure that patients have been adequately informed about the nature of the treatment, potential risks and benefits, and any alternatives.

What specific information should be included in the verbal explanation to the patient regarding their treatment or procedure to ensure informed consent?

The verbal explanation to the patient should include details about the nature of the treatment or procedure, its purpose, potential risks and benefits, any alternative options available, and the expected outcomes. It should be tailored to the patient's level of understanding and provided in a language and manner that the patient can comprehend.

In cases where a patient lacks the capacity to provide informed consent, what are the appropriate procedures for obtaining consent from a legal guardian or next of kin?

In cases where a patient lacks the capacity to provide informed consent, the appropriate procedures involve obtaining consent from a legally authorized representative, such as a legal guardian or next of kin. This process may involve explaining the treatment or procedure to the representative and ensuring their understanding before obtaining their consent on behalf of the patient.

How should the documentation of the consent process be maintained?

The documentation of the consent process should be maintained meticulously. It should include comprehensive details of the information provided to the patient, discussions held, any specific questions asked by the patient or their representative, and the patient's agreement or refusal.

This documentation serves as a legal record of the consent process and should be stored securely following the regulations and guidelines set by the relevant regulatory authorities in South Africa.

What about research or clinical trials i.e. Special Cases?

In certain situations, such as experimental treatments or research studies, additional requirements for consent may apply. These cases often involve more detailed information and specific consent forms tailored to the nature of the treatment or study.

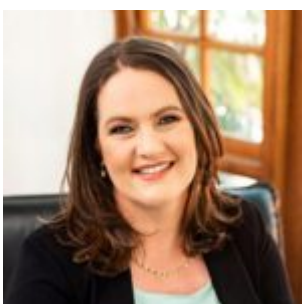
In Conclusion

In essence, obtaining written informed consent is not just a procedural formality but a strategic step in mitigating legal risks and ensuring that medical professionals' practices are well-protected. So, aside from meeting the ethical standards set by the Health Professions Council of South Africa (HPCSA), it should be viewed as a critical aspect of fortifying professional standing and safeguarding practices against unforeseen legal challenges.

By prioritizing the meticulous process of obtaining informed consent, healthcare professionals can uphold the highest standards of patient care while protecting themselves and their practices in an ever-evolving legal landscape.

If you have any questions or concerns about the informed consent process or its implications for your medical malpractice insurance, we recommend seeking guidance from your professional association or legal advisors.

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