



Informed Consent as a Mandatory Protocol in Medical and Dental Procedures: A Narrative Review of Its Ethical, Legal and Practical Foundations

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ABSTRACT

Background: Informed consent is a cornerstone of contemporary clinical practice, yet in routine medical and dental care it is often reduced to a signature on a form rather than a meaningful exchange between clinician and patient. Objective: To review the ethical, legal and empirical basis for treating informed consent as a mandatory, structured protocol in medical and dental procedures, with particular reference to South Africa, and to propose a minimum operational framework. Methods: A narrative review was undertaken of international ethical instruments, statutes, judicial decisions and peer-reviewed literature addressing informed consent, with emphasis on the movement from professional-based to patient-centred standards of disclosure. Results and Discussion: Ethical doctrine grounded in respect for autonomy, and legal doctrine grounded in bodily integrity, have converged across major jurisdictions on a requirement that patients be told of material risks and reasonable alternatives. South African law, through the Constitution, the National Health Act and the guidance of the Health Professions Council of South Africa, imposes comparable duties. Empirical studies consistently show that patient comprehension and recall of consent information are limited, and that form-focused consent does not guarantee understanding. Interventions such as enhanced forms, extended discussion and the teach-back method improve comprehension. Dentistry raises particular concerns because treatment is frequently elective, irreversible, staged and privately funded. Conclusion: Informed consent should be regarded as a mandatory clinical process, proportionate to risk, supported by documentation but not reducible to it. A six-stage protocol is proposed to assist practitioners in meeting ethical and legal obligations while strengthening trust and shared decision-making.

Keywords: informed consent; patient autonomy; shared decision-making; dentistry; medical law; South Africa

1. Introduction

Every clinical procedure, from a simple dental extraction to major surgery, involves an intrusion on the body of another person. The principle that such an intrusion is justified only by the patient's valid authorisation is now regarded as fundamental to medical and dental ethics and to the law of most jurisdictions. [1,2] Although the principle is widely accepted, its implementation in everyday practice is uneven. Consent is frequently treated as an administrative event, completed by obtaining a signature shortly before a procedure, rather than as a communicative process through which a patient comes to understand and weigh the options available to them. [3,4]

The consequences of this gap are practical as well as ethical. Patients who are inadequately informed may undergo procedures they would have declined, or decline care that would have benefited them. Clinicians who rely on a signature alone may find that it offers little protection when the quality of the underlying discussion is later examined by a court or a regulator. [5,6] In dentistry the problem is especially pertinent, since a great deal of care is elective, many interventions are irreversible, treatment plans extend over multiple visits, and patients commonly bear the cost personally.

The research problem addressed in this review is therefore the discrepancy between the near-universal endorsement of informed consent as a principle and its inconsistent application as a clinical practice. The objective is to examine whether the ethical, legal and empirical literature supports regarding informed consent as a mandatory protocol, that is, a structured and non-optional element of every procedure scaled to its risk, and to propose a minimum framework suitable for medical and dental practice, with attention to the South African context.

2. Materials and Methods

2.1 Study design

This study is a narrative review. A narrative design was selected because the subject spans several disciplines, namely bioethics, health law and clinical communication, and includes primary legal sources that are not amenable to quantitative synthesis.

2.2 Sources and search strategy

Peer-reviewed literature was identified through PubMed/MEDLINE, Scopus and Google Scholar. South African statutory and case law was identified through official legislative sources and the Southern African Legal Information Institute (SAFLII). Search terms included combinations of "informed consent", "patient autonomy", "shared decision-making", "disclosure standard", "material risk", "health literacy", "dental" and "South Africa". Reference lists of key articles and professional guidance documents were also examined.

2.3 Selection and analysis

Foundational ethical instruments, leading judicial decisions from South Africa, the United Kingdom, the United States and Australia, statutes and professional guidance, and systematic reviews or authoritative narrative reviews on consent comprehension and communication were prioritised. Sources were analysed thematically under four headings: ethical foundations, legal standards of disclosure, empirical evidence on comprehension and communication, and application to dental practice. The findings were then synthesised to develop the proposed protocol.

2.4 Ethical approval and informed consent

This review analysed published literature and legal sources only. No patients or human participants were recruited and no identifiable personal data were used. Ethical approval and participant consent were therefore not applicable.

3. Results and Discussion

3.1 Historical and ethical foundations

Modern consent doctrine emerged from two historical sources. The first was judicial recognition of bodily self-determination. In 1914 the New York Court of Appeals affirmed that an adult of sound mind has the right to determine what is done to his or her own body, and that a surgeon who operates without consent commits a wrong. [7] South African courts reached a comparable position early, treating an unauthorised operation as an unlawful invasion of bodily integrity. [8] The phrase "informed consent" itself entered legal usage in the American decision in *Salgo*, which recognised that consent requires disclosure of facts necessary to form the basis of an intelligent decision. [9]

The second source was a response to documented abuses in human experimentation. The Nuremberg Code declared the voluntary consent of the subject to be absolutely essential, and later instruments, including the Declaration of Helsinki and the Belmont Report, elaborated the requirements of information, comprehension and voluntariness. [10-12] These principles were progressively extended from research into routine care, and the World Medical Association's Declaration of Lisbon affirms the patient's right to self-determination and to receive adequate information before any procedure. [13]

Philosophically, informed consent is most commonly justified by respect for autonomy, understood as the capacity for self-governance free from controlling interference and from inadequate understanding. [2] On this account consent is not a formality ancillary to treatment but a moral transformation: it converts what would otherwise be a wrongful intrusion into a permissible act. Beneficence, non-maleficence and justice support the same conclusion by emphasising that better-informed patients make decisions more consistent with their own values, are better placed to cooperate with treatment, and are treated with equal respect irrespective of their social position. [1,2]

3.2 Legal standards of disclosure

The central legal question has been how much information must be disclosed. Courts have answered along a spectrum, summarised in Table 1. Under the professional standard derived from *Bolam*, the adequacy of disclosure was judged by what a responsible body of practitioners would have disclosed, and the House of Lords largely retained this approach for disclosure in *Sidaway*. [14,15] The weakness of that approach is that it allows clinical custom, rather than the patient's informational needs, to define the content of consent.

Table 1. Principal standards of disclosure and representative authorities

Standard of disclosure	Jurisdiction	Representative authority
Professional (responsible body of practitioners)	England (historical position)	<i>Bolam</i> ; <i>Sidaway</i> [14,15]
Reasonable patient / material risk	United States	<i>Canterbury v Spence</i> [16]
Material risk, with patient-specific enquiry	Australia	<i>Rogers v Whitaker</i> [17]

Standard of disclosure	Jurisdiction	Representative authority
Material risks and reasonable alternatives	United Kingdom (current position)	Montgomery v Lanarkshire Health Board [6]
Knowledge, appreciation and consent; reasonable-patient test of materiality	South Africa	Castell v De Greef; Broude v McIntosh; National Health Act s 6 [18-20]

The patient-centred alternative developed in the United States, where the court in *Canterbury* held that the scope of disclosure is determined by the patient's need for information material to the decision, rather than by medical custom. [16] Australia adopted a similar approach in *Rogers v Whitaker*, adding that a risk may be material if the practitioner knows or should know that the particular patient would attach significance to it. [17] In *Montgomery* the United Kingdom Supreme Court departed from the *Bolam* model, requiring disclosure of material risks and reasonable alternative treatments, and describing the patient as an adult capable of understanding that medical treatment is uncertain. [6] The House of Lords in *Chester v Afshar* further demonstrated the importance courts attach to the right to be informed by modifying ordinary causation reasoning where a failure to warn deprived the patient of the opportunity to decide. [21]

The convergence of these decisions is noteworthy. Although they differ in detail, each treats disclosure as a duty owed to the patient and measured by the patient's decision-making needs. A clinician who adopts a uniform, procedure-specific protocol is therefore better placed to satisfy the law in any of these jurisdictions than one who relies on individual judgement about what patients ought to know.

3.3 The South African framework

In South Africa the obligation has constitutional, statutory, common-law and professional dimensions. Section 12(2) of the Constitution protects the right to bodily and psychological integrity, including security in and control over one's body, and the right not to be subjected to medical or scientific experiments without informed consent. [22] At common law, valid consent requires that the patient had knowledge of the nature and extent of the harm or risk, appreciated and understood it, and consented to it. [18,23] In *Castell v De Greef* the Cape court rejected the professional standard for disclosure in favour of a test based on what a reasonable patient would consider material, and the Supreme Court of Appeal has since affirmed the requirements of knowledge, appreciation and consent. [18,19]

The National Health Act codifies and extends these principles. Section 6 requires that a user of health services be informed of his or her health status, the range of diagnostic procedures and treatment options generally available, the benefits, risks, costs and consequences generally associated with each option, and the right to refuse. It further requires that information be conveyed, where possible, in a language the user understands and in a manner that takes into account the user's level of literacy. Section 7 provides that health services may not be provided without informed consent, subject to limited exceptions including written consent, court order or statutory authority, and circumstances in which failure to treat would pose a serious risk to public health or to the health of the user. [20] Section 8 requires that users be involved in decisions affecting their health. [20] Section 129 of the Children's Act permits a child over twelve years of age who is of sufficient maturity to consent to medical treatment, and, where surgery is proposed, requires that the child also be assisted by a parent or guardian. [24]

The Health Professions Council of South Africa (HPCSA) guidance on seeking informed consent treats consent as an ethical duty of every registered practitioner, including dentists, and emphasises communication appropriate to the patient's language and understanding as well as documentation of the process. [25] South African commentators have consistently emphasised that the practical value of documentation lies in demonstrating that a genuine process took place. [26] It should be noted that the Act does not prescribe written consent for every intervention. A written, procedure-specific record nevertheless provides the best evidence that the statutory elements were addressed, and it is further supported by the patient-record obligations arising under professional guidance and data-protection law. [25,27]

3.4 Elements of valid consent

There is substantial agreement in the literature that valid consent has several components: the patient's capacity, adequate disclosure, comprehension, voluntariness and an authorisation of the proposed course of action. [2,28] Capacity is decision-specific rather than global, and is generally assessed by the patient's ability to understand relevant information, appreciate its application to their own situation, reason about options and express a choice. [29] Disclosure should include the diagnosis, the nature and purpose of the proposed procedure, its material risks, its expected benefits, reasonable alternatives (including no treatment), and the associated costs, since both South African statute and comparative authority treat these as part of the information to which the patient is entitled. [5,6,20]

Comprehension and voluntariness are the elements most readily overlooked. Information that is delivered but not understood does not satisfy the ethical purpose of consent, and decisions made under time pressure, anxiety or perceived social obligation may not be genuinely voluntary. [1,30] For this reason

the General Dental Council expressly frames valid consent as something to be obtained in a manner that ensures the patient has understood the options and has had sufficient time to consider them. [31]

3.5 Evidence on comprehension and the limits of the signed form

Empirical research consistently indicates that consent as commonly practised achieves its purpose only partially. A literature review of patients' recollection of consent information found that recall and understanding are often limited, with risks and alternatives among the elements least well retained. [32] A systematic review and meta-analysis of participants in clinical trials found that understanding of certain consent components was consistently poorer than of others, particularly the more abstract concepts such as randomisation and placebo. [33] Commentators on the current state of consent have also highlighted that lengthy and legalistic forms can obscure rather than clarify information, and that the form has in practice become a means of protecting institutions. [4]

There is encouraging evidence that comprehension can be improved. A systematic review of interventions for medical and surgical consent concluded that enhanced consent forms and extended discussions with a member of the clinical team were more reliably associated with improved understanding than were multimedia tools alone, whose effects were inconsistent. [34] The teach-back technique, in which the patient is asked to explain the information in their own words so that the clinician can correct misunderstanding, was shown to be an effective communication method for patients with low health literacy in the clinical setting in which it was studied. [35] Shared decision-making models likewise structure the conversation around choice, options and decision stages, and have been advanced as a practical route to a reasonable-patient standard of consent. [36,37] Because South Africa is a multilingual society with variable health literacy, these findings have particular relevance to the statutory duty to communicate in a language and manner the patient understands. [20]

Information can also overwhelm. Clinicians therefore have a responsibility to structure disclosure so that the most decision-relevant information is prominent, to pace the discussion, and to avoid presenting patients with large volumes of detail at moments of high anxiety. [30] These findings support the view that a protocol should specify the process of consent, and not merely its documentation.

3.6 Informed consent in dental practice

Dentistry shares the general principles of consent but presents features that make a structured protocol especially valuable. First, much dental treatment is elective or semi-elective, so that a patient can reasonably be given time to consider alternatives, including deferral or no treatment. Second, many interventions are irreversible, including extractions, endodontic therapy, preparation of tooth structure for restorations and the placement of implants. Third, treatment is frequently staged across multiple appointments and may involve significant out-of-pocket cost, so that the financial and temporal consequences of a plan form part of the information that is material to the decision. [20,31]

Material risks differ by procedure and must be disclosed accordingly. Surgical removal of third molars may carry a risk of altered sensation from injury to adjacent nerves, and implant therapy involves a risk of failure of integration and the potential need for further treatment. Endodontic treatment may not preserve the tooth, extensive restorative work may require future replacement, and sedation or general anaesthesia carries additional risks that must be explained separately. Cosmetic and orthodontic treatment raise questions about the patient's expectations of the final outcome, which should be explored and documented. Under the patient-centred standards discussed above, the practitioner must also mention reasonable alternatives, which in dentistry may include referral to a specialist where the proposed treatment lies at the edge of the practitioner's experience. [6,25,31]

Other features of dental practice require attention. Treatment of children requires an understanding of who is legally authorised to consent and of the child's own developing capacity to participate in the decision. [24] Patients with dental anxiety or special needs may require additional time and adapted communication. Consent must also be treated as ongoing, because treatment plans frequently change after a procedure has begun, for example where unexpected pathology is found, and a change of plan that was not covered by the original discussion requires a fresh conversation wherever it is practicable to hold one. It should be noted that the available empirical literature specific to dental consent is smaller than that for medical and surgical settings, and much of the evidence cited here has been generated in medical contexts. The extrapolation to dentistry is reasonable given the shared ethical and legal framework, but it is an extrapolation.

3.7 The case for a mandatory protocol

Four converging arguments support treating consent as a mandatory protocol. The ethical argument is that respect for autonomy requires that the patient's authorisation be sought as a matter of course and not as a matter of clinical discretion. [2] The legal argument is that the Constitution, the National Health Act and the common law impose non-discretionary duties, and that a failure to obtain valid consent exposes the practitioner to both civil and professional liability. [18,20,22,25] The clinical argument is that patients who understand and participate in decisions are better placed to cooperate with treatment and to hold realistic expectations, and the evidence that comprehension is commonly incomplete shows that it cannot be assumed. [32,37] The professional argument is that a protocol applied consistently reduces variability between practitioners and protects patients and clinicians alike. [5,31]

Several objections deserve consideration. The first is that a mandatory protocol will encourage defensive, form-driven practice. This is a legitimate concern, and is the reason the protocol proposed here is defined by process and not by paperwork. The second is that time constraints make extended discussions impractical. The response is that the depth of the conversation should be proportionate to the risk and complexity of the procedure, so that a routine low-risk intervention requires a brief but genuine exchange, while an invasive or irreversible procedure requires more. The third is that

emergencies and patients lacking capacity cannot be accommodated by a rigid protocol. The statutory exceptions in the National Health Act and the rules on surrogate decision-making already address these cases, and a protocol should incorporate rather than ignore them. [20] Finally, it is sometimes argued that detailed disclosure may harm anxious patients. The law allows limited departures from disclosure where it would be contrary to the patient's best interests, but such departures are narrow, must be justified in each case, and should not be used to justify routine under-disclosure. [6,20]

3.8 A proposed minimum protocol

Drawing on the sources reviewed, a six-stage protocol is proposed for medical and dental procedures (Table 2). The protocol is intended as a minimum framework to be adapted to the risk of the procedure and to local professional guidance, and not as a substitute for either.

Table 2. Proposed six-stage informed consent protocol

Stage	Core actions	Documentation
1. Preparation	Assess decision-specific capacity; identify who is legally entitled to consent; determine the patient's preferred language and literacy needs; arrange an interpreter where required; ensure a private and unhurried setting. [20,29]	Record capacity concerns, language used and presence of any interpreter or support person.
2. Disclosure	Explain diagnosis, nature and purpose of the procedure, expected benefits, material risks, reasonable alternatives (including no treatment and referral), costs and consequences, and the right to refuse. [6,20]	Procedure-specific written information; note of the risks and alternatives discussed.
3. Comprehension	Invite questions; use plain language and visual aids; apply teach-back to confirm understanding. [34,35]	Note that understanding was confirmed and any questions asked.
4. Voluntariness and decision	Allow time for reflection, particularly for elective or irreversible treatment; confirm that no pressure is exerted; affirm the right to decline or to withdraw consent. [1,30]	Record the patient's decision and any time given for consideration.
5. Documentation	Obtain a dated, signed, procedure-specific consent form that reflects the actual discussion; give the patient a copy; store records securely. [25,27]	Signed form; clinical note summarising the conversation.
6. Reconfirmation	On the day of the procedure, confirm that the patient's circumstances and wishes are unchanged and verify the site or tooth; seek fresh consent if the plan changes. [5,31]	Date and time of reconfirmation; record of any change in plan.

The protocol is designed to be adopted by individual practitioners and by practices with limited administrative support. Its principal feature is that each stage corresponds to an element of valid consent identified in the literature, so that the protocol can be justified by reference to the underlying ethical and legal requirements. Procedure-specific written information, prepared once and updated periodically, can reduce the time cost of disclosure while improving consistency.

3.9 Limitations

This review has several limitations. As a narrative review it does not follow a formal systematic protocol and is therefore subject to selection bias. The legal analysis is directed principally at South African law and its comparators, and the position in other jurisdictions may differ. Much of the empirical evidence derives from medical, surgical and research settings and not from dentistry. The proposed protocol is derived from the literature and has not been empirically validated, and it would benefit from testing in practice and from the views of patients and practitioners. Legislation, case law and professional guidance change over time, and readers should consult current sources.

4. Conclusion

The ethical, legal and empirical literature supports regarding informed consent as a mandatory element of every medical and dental procedure, but as a process proportionate to risk and not as a signature. Courts in several major jurisdictions, and South African law in particular, have moved decisively

towards a patient-centred standard in which material risks and reasonable alternatives must be disclosed and understood. Evidence that comprehension is commonly incomplete, and that it can be improved through discussion, plain language and teach-back, shows that a signed form alone is insufficient. In dentistry, where treatment is frequently elective, irreversible, staged and privately funded, these considerations apply with particular force.

The six-stage protocol proposed here offers a practical framework for meeting these obligations. Its adoption can strengthen the patient's autonomy, support shared decision-making, improve the defensibility of clinical practice and reinforce public trust in the professions. Further research should evaluate the protocol in dental and medical practice and examine patients' experience of consent in multilingual settings.

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Conflict of Interest

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