



Consent

INFORMATION SUITABLE FOR SOUTH AFRICA

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1.00

Introduction

A patient's informed consent to investigations or treatment is a fundamental aspect of the proper provision of dental care. Without informed consent to treatment, a dentist is vulnerable to criticism on a number of counts, not least those of assault and/or negligence - which in turn could lead respectively to criminal charges and/or civil claims against the dentist. Furthermore, the question of consent arises increasingly at the heart of complaints to the Health Professions Council of South Africa (the HPCSA) on matters on professional ethics and conduct.

It is self-evident, therefore, that every practising dentist, therapist and hygienist needs not only a thorough understanding of the principles of consent, but also an awareness of how to apply these principles in the wide variety of circumstances that can arise in the practise of dentistry.

The law is continually changing and developing, as the courts interpret both the common law and legislation. The doctrine of precedent means that judgements from a higher court will bind a lower court. At the same time, clinical knowledge and ability have developed, and this makes the interpretation of what constitutes informed consent and who can give it, a constantly changing perspective.

Clinicians have a responsibility to ensure that every effort is made to keep abreast of changing standards, to show not only that the optimum treatment is being given to their patients, but also that the patients themselves have had the best opportunity to be involved in decision making about the care of their bodies.

Nearly eighty years ago, Judge Cardozo in a case in America declared:

*"Every human being of adult years and sound mind has a right to determine what shall be done with his own body"*¹

The concept of patients' rights, adult responsibility and a mind sound enough to understand, are embodied in the principles of consent. The requirements of consent are set out in the National Health Act and are discussed in more detail below.

When considering consent, it is important to ask a number of questions.

- What does the patient or the patient's carer need to know and understand?
- Is the patient capable of understanding?
- Does the patient have capacity to give consent?
- If not, is the carer not only capable, but also qualified to consider the best interests of the patient?
- Is consent given voluntarily?
- Does the law of the land give any guidance on the value of the opinion of dentists, patient or carer?
- Does the law resolve any conflict between patient and carer?

An understanding of the law concerning consent must bear in mind the relevant articles of the South African Constitution's Bill of Rights which might be invoked in medical law cases, notably Article 11 (protection of right to life); Article 10 (right to have your dignity respected and protected); Article 12 (right to freedom and security); Article 14 (right to privacy); Article 15 (right of freedom of belief and opinion); Article 12 (right to bodily and psychological integrity) and Article 27 (right to emergency medical treatment).

These Articles may seem somewhat distant from dental practice but a dispute about consent to treatment or the right to withhold or withdraw consent, might involve consideration of a number of these Rights.

¹ *Schloendorff v Society of New York Hospital* 105 NE 92 [NY 1914]

2.00

Aspects of autonomy

Depending on where one goes in the world, autonomy can mean different things. In most western countries, the moral principle of consent is reflected in a respect for personal autonomy as soon as a person is able to make decisions for him/herself. Here, the growing emphasis on patient autonomy in recent years contrasts with the historical position – sometimes described as the “Doctor knows best” era of medical paternalism.

In some countries, although certainly no longer in South Africa medical paternalism is alive and well and patients may still be happy to defer to whatever their treating clinician is recommending for them, with little or no questioning or challenge. In some cultures personal autonomy may not be regarded as being quite so important and the roles of the families or elders within families may have a far greater influence.

These national and cultural differences become all the more significant now that both patients and healthcare professionals have become more mobile, and dentists find themselves treating more and more patients from different cultures. South Africa is highly multi-cultural, and yet few dentists have undertaken any specific training to help them to understand and prepare themselves for the possible implications - this is another reason why consent has again become such a hot topic medico-legally.

In South African medical law the case of *Castell v De Greef* (1994)² was a landmark case insofar as informed consent is concerned. In this case, it was found that the question of whether or not a potential risk or danger should be disclosed to a patient depends on certain circumstances. Firstly, it should be determined whether a reasonable patient, if warned of the risk or danger, would be likely to attach significance to it. Secondly, it should be determined whether the practitioner is, or should reasonably be aware, that the patient, if warned of the risk, would be likely to attach significance to it. It was stated in this case that “the consent to the planned procedure constitutes a justification that excludes the wrongfulness of the medical treatment and its consequences”. It was also determined that a practitioner has a legal duty to obtain a patient’s informed consent to any medical intervention.

There are several aspects of autonomy which need to be considered, including

Choice

A centrally important feature of patient autonomy is the right of a patient to make a clear choice.. That choice needs to be made according to the patient’s own values and priorities.

A reasonable choice to one person may not be reasonable to another (including the treating practitioner) because this clinician may not hold the same personal values as the patient who is making the choice.

This conflict in perspectives sometimes arises in dental practice when patients ask dentists or other dental professionals to proceed with treatment which is at odds with the dentist’s own values, ethics and professional judgement. Here both parties have the right to hold their view, and sometimes the solution is for the clinician to withdraw from treating the patient.

Free will

A second feature of autonomy is the need to ensure that any decisions are taken freely, voluntarily and without coercion. This is easier to say than to achieve. Coercion can be overt or more commonly it may be subtle. From an early age humans learn to adapt to situations and to make the best of situations to their own advantage. Our codes of conduct and values influence the way that we behave and react to situations. Even with the best intentions we often try to influence how others might act around us.

An example in dentistry might be a teenage child who presents with his/her parents for orthodontic treatment. The parents clearly want the child to have orthodontic treatment for cosmetic reasons and the orthodontic treatment may even be judged to be in the child’s best interests by both parents and the treating practitioner(s). The child may have a malocclusion that is severe and would greatly benefit from the proposed treatment. But notwithstanding the best of intentions on the part of the parents, the child may still feel coerced into having treatment which goes against his / her own wishes as regards their own body. In many countries parents may even have a legal right to make a decision on behalf of a child, notwithstanding a child’s personal preferences.

² *Castell v De Greef* 1994 (4) SA 408 (C)

If one examines consent purely from the point of view of autonomy then any consent obtained in that situation may not be valid if the child has not made the decision with his / her own free will. Even if the child agrees, a clinician may find it difficult to ensure that there is no undue influence being placed upon the child in reaching that decision. We will discuss this further at 3.00 and 4.02 below.

2.01

Influence

We can influence patients consciously or subconsciously by the way in which we communicate with them. For example

The words we use

Whether the words are written or spoken, a patient's perception can easily be influenced by the words that we choose to use. Some patients will be particularly reactive or sensitive to the use of certain words (eg. "cut", "drill", "inject", "bleeding", "painful" etc); when you are discussing a procedure face to face you can usually see this reaction, and deal with it there and then. But when you use the same words in a letter, you don't get this opportunity.

Our voice

The pace at which we speak, how loudly or softly, and how clearly we articulate our words, the pitch and timbre of our voice, can all influence how others might react to what we say. If we want to stress or emphasise something important, we should speak more slowly and clearly, and perhaps a little louder. This helps to differentiate this information from less critical discussions, during which we might speak a little quicker and with less emphasis.

In general, a higher pitch conveys nervousness or uncertainty, while a lower pitch – particularly when accompanied by speaking more slowly – tends to communicate calm, confident authority and a feeling that everything is under control.

Non verbal communication ("body language")

Our eyes, our face, our posture, our gestures, will all form part of the message that a patient receives when we are communicating with them. Sometimes deliberately, sometimes unconsciously, we send the patient non-verbal signals that either accentuate, or detract from the actual words we might have used. Good eye contact communicates honesty and sincerity whereas avoidance of eye contact suggests the reverse.

Images

Many dentists use leaflets, brochures and pictures, videos and commercial CD/DVD programmes, to complement any verbal explanations of procedures. These, too, can often lead a patient to form a particular opinion. Some (especially those sold with the intention of promoting the uptake of a particular form of treatment, rather than providing general information and patient education) are intended to make one form of treatment sound a lot more attractive than alternative options.

These visual aids can become pivotal evidence if and when a dispute arises over what a patient was and was not told, and the extent to which they might have been misled or denied important information. All the more reason, therefore, to reassess all the information material that you use, and to reflect upon how fair, balanced and accurate it is. The risk of a one-sided picture being created in the patient's mind is greater when using material that has been created by manufacturers and suppliers. Not all such leaflets fall into this trap – but unfortunately for the dentists concerned, many do, making it much easier for the patient to suggest that they were "talked into" or "sold" some dentistry without having been made fully aware of its possible risks and limitations.

2.02

Respect

This brings together the ethical and human dimensions of consent (see opening section 1.00), and can be summarised as dealing with patients as we would wish to be dealt with ourselves, or as we would hope and expect that another health professional might deal with us or a member of our family.

It is not our right to carry out treatment on another person, without fully involving them in the decision-making process. It is not fair, moral or decent to deprive another person of their right to have their dignity

respected and protected and their right to bodily and psychological integrity, as entrenched in the Bill of Rights. For a healthcare professional to act in such a way in relation to someone under their care is particularly unacceptable, given the special relationship of trust that exists (or should exist) between a patient and that healthcare professional.

Giving patients choices is one way of showing our respect for them, but a patient cannot exercise that choice unless they have sufficient, meaningful and balanced information to support that process. These principles are entrenched in the National Health Act, which requires that a patient be informed inter alia, of the patient's health status, the available treatment options and the benefits, risks and costs thereof. These principles are also contained in the Consumer Protection Act, which strives to improve patient awareness, encourage disclosure and creates a duty to make sure that patients understand the terms of the treatment provided.

In any relationship between a lay person and a professional person there tends to be a wide gulf between the relative levels of knowledge and understanding. It is the professional person's responsibility to close that gap by being prepared to spend time and effort in sharing their special knowledge of the procedure(s) in question, and their likely outcome, so that the patient is better placed to understand the options available to them.

Making this investment of time and effort helps to build a stronger relationship of trust and confidence between you and the patient, as well as laying the foundations for an effective, valid consent process.

3.00

Competence

In order both to understand the information provided, and to give the necessary authority for consent, a patient must be competent. "**Competence**" in this context means the patient's ability to understand the explanations given, about:

- The nature and purpose of a particular procedure;
- Its likely effects and risks;
- Any alternative treatment and how these alternatives might compare; and
- The costs of treatment

Only if a patient is competent to consent, can the patient's consent be considered valid. The patient may lack competence for a number of reasons; they might be unconscious or suffering some temporary or permanent form of mental impairment. On the other hand, a very young child will clearly not have the competence to consent to a dental procedure.

On the subject of children, most children eventually reach an age where they can grasp relevant facts about their body and about proposed treatment to their body. A few children are never, even when adulthood is reached, capable of properly understanding the information given to them and then must therefore be considered incapable of giving consent.

In order to protect children, laws exist in many countries defining the age at which children can normally be considered capable of making their own decisions in this respect. In South Africa, the relevant legislation is to be found within the Children's Act. It permits an individual who is over the age of 12 years, and of sound mind, to give a legally valid consent to dental treatment without the assistance of a parent. In the event of surgery, a child older than 12 years and younger than 18 has to be assisted by a parent when giving consent. If the child is under the age of 12 a parent should give consent to treatment or surgery.

Dentists should always try to confirm that both the child and the parent understand the treatment to be given. Even in cases where it is believed that the child may be capable of giving consent which would negate the need to obtain parental consent, it is still wise to try to seek the child's permission for a discussion with the parent to confirm their agreement.

Consideration should be given to refusing treatment (except in an emergency) if concern remains about the quality of the understanding and agreement of both child and parent.

A parent can consent to the treatment where the patient who is under the age of 12 (or older but of insufficient maturity to give consent) refuses treatment; however, in dentistry, in the majority of cases treatment is unlikely to be successfully provided where the patient refuses. Dental Protection would thus

advise that it is appropriate to try to encourage the patient and consenting adult to reach a consensus.

4.00

Authority

4.01

Competent adults

Clearly, in the case of an adult aged 18 years or over who is of sound mind, he/she has the authority to give or withhold consent to any treatment proposed for himself/herself, and it could be held to be an act of assault to violate the patient's autonomy and right of self determination by providing treatment against his/her declared wishes.

4.02

Children

Most children eventually reach an age where they can grasp relevant facts about their body and about proposed treatment to it. They can give consent to treatment, but the degree of understanding can vary in relation to the complexity of the treatment envisaged. A few children are never, even when adulthood is reached, capable of properly understanding the information given to them and must therefore be considered incapable of giving consent.

In South Africa the Children's Act of 2005 states that the age of majority in South Africa is 18 years. Accordingly, any person who is older than 18 years of age and of sound mind, may consent to his or her own treatment.

In the case of a patient who is under the age of 12 years, the minor's parent or guardian should give consent to treatment. In respect of children over the age of 12 but younger than 18 (who have sufficient maturity and the mental capacity to understand the benefits, risks, social and other implications of the treatment) may provide informed consent for medical treatment without the assistance of a parent or guardian. In the event that the proposed treatment involves surgery, then such a child should be assisted by a parent or guardian.

4.03

The incompetent adult

In the National Health Act provision is made for certain persons to consent to treatment and / or surgery on behalf of mentally incompetent patients where such patients are unable to give consent and have not mandated someone in writing to give consent on their behalf. In such circumstances a person authorized by the Court (such as a curator) may consent on behalf of the patient, alternatively the patient's spouse, partner, parent, grandparent, major child, or brother or sister (in order of priority) may consent on behalf of the patient.

In the HPCSA's Guidelines³ on informed consent, inter alia, the following guidelines are provided in assessing the patient's mental capacity:

1. A person must be assumed to have capacity to consent or refuse medical intervention, unless it is shown that the person cannot understand information presented in a clear way.
2. If a patient's choice appears irrational, or does not accord with the health care practitioner's view of what is in the patient's best interests, this is not evidence in itself that the patient lacks competence. In such circumstances, it is suggested that it be reviewed with the patient whether all reasonable steps have been taken to identify and meet the patient's information needs.
3. Where healthcare practitioners need to assess a patient's capacity to make a decision, they should consult the guidance issued by the relevant professional bodies.

3 Guidelines for Good Practice in the Healthcare Professions Seeking Patients' Informed Consent: The Ethical Considerations Booklet 9

Assessing lack of capacity

An individual's capacity must be assessed specifically in terms of their capacity to make a particular decision at the time it needs to be made.

This means that a person may lack capacity to make a decision about one issue but not about others. Care must be taken not to judge an individual's capacity merely by reference to their age, appearance or medical condition.

Supporting the person to make the decision for themselves

It is important to take all possible steps to try to help people make a decision for themselves before deciding that someone lacks capacity to make a particular decision.

In supporting someone to make the decision themselves it is important to provide all necessary relevant information. Guidance on supporting a person to make the decision themselves should be provided.

Two-stage test of capacity

Any practitioner assessing someone's capacity to make a decision for themselves for the purposes of the Act should use the two-stage test of capacity.

- Does the person have an impairment of the mind or brain, or is there some sort of disturbance affecting the way their mind or brain works?
- If so, does that impairment mean that the person is unable to make the decision in question at the time it needs to be made?

Assessing the ability to make the decision

A person is unable to make a decision for himself if s/he is unable:

- To understand the information relevant to the decision;
- To retain that information;
- To use or weigh that information as part of the process of making the decision; or
- To communicate his decision (whether by talking, using sign language or any other means).

The person must be able to hold the information in their mind long enough to use it to make an effective decision. However, people who can only retain information for a short while must not automatically be assumed to lack the capacity to decide.

Any question as to whether a person lacks capacity must be decided on the balance of probabilities.

4.05

Best interests

If a person has been assessed as lacking, or is reasonably believed to lack, capacity to make the decision in question or to give consent and no one is available or authorized to give consent on behalf of that person it is then necessary to weigh up what is in the person's best interests. An act done or a decision made for or on behalf of a person who lacks capacity must be in that person's best interests.

A person trying to work out the best interests of a person who lacks capacity to make a particular decision should:

Encourage participation

Do whatever is possible to permit and encourage the person to take part, or to improve their ability to take part, in making the decision.

Identify all relevant circumstances

- Try to identify all the things that the person who lacks capacity would take into account if they were making the decision or acting for themselves
- Try to find out the views of the person who lacks capacity, including:
 - The person's past and present wishes and feelings – these may have been expressed verbally, in writing or through behaviour or habits.
 - Any beliefs and values (e.g. religious, cultural, moral or political) that would be likely to influence the decision in question.

- Any other factors the person themselves would be likely to consider if they were making the decision or acting for themselves.

Avoid discrimination

- Not make assumptions about someone's best interests simply on the basis of the person's age, appearance, condition or behaviour.

Assess whether the person might regain capacity

- Consider if the person is likely to regain capacity (e.g. after receiving medical treatment). If so, can the decision wait until then?

Consult others

- If it is practical and appropriate to do so, consult other people for their views about the person's best interests and to see if they have any information about the person's wishes and feelings, beliefs and values. In particular, try to consult:
 - Anyone previously named by the person as someone to be consulted on either the decision in question or on similar issues.
 - Anyone engaged in caring for the person.
 - Close relatives, friends or others who take an interest in the person's welfare.

Avoid restricting the person's rights

- See if there are other options that may be less restrictive of the person's rights.
- Weigh up all of these factors to work out what is in the person's best interests.

4.06

Record keeping

A detailed record should be kept of the decision process for assessing the best interests of that person for each relevant decision. The record should set out:

- How the decision about the patient's best interests was reached;
- What the reasons for reaching the decision were;
- Who was consulted to help work out best interests; and
- What particular factors were taken into account.

4.07

Information given to a patient

There are differing views held throughout the English speaking world on what constitutes the answer to the question "What does the patient need to know?"

As stated above, in South Africa there has been a shift from medical paternalism to patient autonomy. In terms of the National Health Act, a practitioner should inform a patient of the following:

The patient's health status (except in cases where there is substantial evidence that such a disclosure would be contrary to the best interests of the patient);

The range of diagnostic procedures and treatment options generally available to the patient;

The benefits, risks, costs and consequences generally associated with each option; and

The patient's right to refuse health services.

It is important to explain the above to patients in layman's terms. Furthermore serious and common risks or complication should be explained to the patient (as well as the implications thereof). If a risk is particularly uncommon, a health care practitioner will not necessarily be required to explain this to the patient, unless the patient enquires about this or it is particularly significant to this specific patient.

In order to decide whether or not a potential risk or complication should be explained to a patient, the case of *Castell v De Greef* should be considered. As stated above, in this case the test of whether or not

a risk or complication should be disclosed to a patient, is whether or not a reasonable patient, if warned of the risk or complication, would be likely to attach significance to it; or the practitioner is aware or should reasonably be aware that the particular patient would be likely to attach significance to this risk. A patient should also be given, if appropriate, sufficient time to consider the information provided by the practitioner and to ask questions before giving consent.

How much advice should be given and how consent should be recorded will depend upon the merits of the individual case. When a patient sits in the dental chair, it can be assumed that implied consent to a non-invasive examination only has been given. Any invasive technique that might include periodontal probing, radiographs, blood tests and diagnostic cavities would require further consent from the patient and it is dangerous to rely upon the assumption of "implied consent" to these further procedures.

Consent would normally be obtained verbally after explaining the need for the investigation and any possible sequelae.

Once the investigations are complete, the patient is entitled to advice on diagnosis and treatment planning. Where a number of alternative treatment plans are available, the choice should be explained, together with the merits and disadvantages of each plan. If a preference for one particular plan is offered, it is helpful to the patient in making a choice, if the reason for the preference is given.

Patients cannot properly consider treatment options if they are not given information on sequelae and prognosis, if either of these is pertinent. For example, where the extraction of a third molar tooth is to be undertaken a possible sequel (eg. a risk of one in ten of transient lingual paraesthesia) occurring, would certainly merit a warning to the patient⁴. Patients have a right to know if their lifestyles may be compromised by a side effect of treatment. When the incidence of a possible complication is very slight, it is often considered to be in the best interests of the patient not to warn and thus risk frightening the patient, but the significance of the above possibility is very real to a professional singer, for example and a failure to elicit any relevant information about a patient and to warn them accordingly could be legally disastrous.

4.08

Material risks

In an Australian case (*Rogers v Whitaker*)⁵, the High Court of Australia ruled that a 1 in 14,000 risk of blindness associated with a procedure, should have been disclosed to a patient. In this example, the patient was already almost blind in one eye and the doctor should have warned of the possible risk of blindness to the other eye no matter how slight in these circumstances, regardless of whether the patient had expressly asked the question or not.

The High Court said,

"A risk is material if in the circumstances of the particular case, a reasonable person in the patient's position - if warned of the risk - would be likely to attach significance to it, or where the medical practitioner is (or should reasonably be) aware that the particular patient - if warned of the risk - would be likely to attach significance to it."

The test used in this case is very similar to the test that was formulated in *Castell v De Greef* (and discussed above), which is applicable in South Africa. Where there is a high risk of failure or post-operative complication, the patient should be warned and it is advisable that a specific entry naming the complication be made on the record card in confirmation that the patient was warned thereof.

Many claims involving paraesthesia and also immediate dentures are successful simply because it cannot be shown later that the patient was specifically warned of the possible post-operative complications.

While on the subject of information, cost (in some branches of dentistry at least) becomes an important facet of consent. Without the knowledge of the financial and social implications of treatment, a patient cannot give a proper commitment. Where treatment is to be protracted, involved or expensive, it is worthwhile writing to the patient with an explanation of the treatment, the time it will take, prognosis,

⁴ Blackburn C.W., Bramley P. lingual nerve damage associated with removal of third molars, Br. Dent J. (1989) 167: 103-107

⁵ *Rogers v Whitaker* (1992) 109 ALR 625-631 [1993] 4 med LR 79-82 (High Court of Australia)

sequelae and costs. The patient can then have the opportunity to raise any enquiries before agreeing the treatment and making an appointment.

In terms of the Consumer Protection Act a practitioner has a duty to inform a patient of the costs of treatment in advance. If extensive and expensive treatment is planned, a detailed cost estimate should be provided to the patient in advance.

Language is also an important element in obtaining consent. If the patient speaks a different language from the dentist an interpreter may be indicated. Whenever the common language is not the first language of either patient or dentist, then care should be taken to ensure that the points have been properly explained and understood. All specialities tend to have their own shorthand and nomenclature, and care should be taken to avoid dental “jargon”, which can also be a barrier to effective communication.

An explanation should be simple and clear. The patient’s failure to grasp information would be the dentist’s responsibility, if it can be shown that the language of the explanation was simply not understood by the patient. Special care should be taken with deaf, partially sighted or blind patients.

Consent is often given by a patient because of the apparent advantages or benefits of a particular line of treatment. Care should be taken to ensure that the information given is balanced and accurate, and can be substantiated. Statements such as “your crown will last for life”, or “your molar root treatment will be 100% successful” or “I guarantee you will have no problem” may dramatically weaken the value of the consent contained. It can also enable a patient to bring a successful claim for breach of contract at a later stage, even when no negligence is present.

Where treatment is unusual or experimental, it is important that the patient should fully understand the situation and it is worthwhile to get the patient to sign a Statement to the effect that they recognise the controversial or relatively untried nature of the treatment and accept that the risks are greater and perhaps even unknown.

Even when all the relevant facts and explanations are given to a patient, confirmation must still be obtained that the patient can understand them. This raises the question of “competence” or the patient’s capacity or ability to understand, which will now be considered.

4.09

Evidence base

Some clinicians believe that patients must be provided with every last detail of the evidence base, in order to enable them to assess the information objectively and to compare alternative treatment options. Not only is this another onerous prospect for the clinician, it also fails to recognise two important aspects of the consent process.

Firstly, it is not sufficient for the clinician to present the patient with information in terms that would be meaningful to another clinician; the evidence base is useful to inform a clinician, but this is usually very different from what the patient needs to know, and how this information needs to be presented.

Secondly, while the evidence base provides information regarding what treatment is most likely to succeed, or fail, it takes no account of the particular situation and circumstances of an individual patient. Take, for example, an oral surgeon who gives a standard warning to every patient that (for example) the incidence of inferior dental nerve damage associated with the surgical removal of lower third molars, is less than one in a thousand.

Patient (A) has a fully erupted lower third molar, with the pre-operative radiographs showing a separation of at least 8mm between the inferior dental nerve bundle, and the roots of the tooth. Patient (B), on the other hand, has a deeply impacted third molar, where the radiographs suggest a very close or intimate relationship between the roots and the inferior dental nerve. The clinician’s standard warning is clearly irrelevant and inappropriate to both of these patients.

This illustrates the danger of giving the same information to every patient, and the importance of personalising any information provided, for each individual patient.

In some situations, it is clear from the clinical records that there has been at least some discussion of a particular risk, or a range of risks, in advance of treatment. But when bringing a subsequent complaint or claim, a patient will often maintain that these risks, while mentioned in passing, had been discussed in a

dismissive way, as if to suggest that the risk was so small or so remote as to be almost hypothetical or theoretical, rather than a real and immediate possibility to be considered.

Clinicians will often do their very best to be reassuring – particularly when dealing with nervous patients – but one must guard against doing this in a way which leads a patient to attach little or no significance to the warning or information in question. Patients, however apprehensive, must be left in no doubt as to the nature and extent of any risks of care and treatment that they are contemplating.

4.10

“Informed” consent

For as long as healthcare professionals are encouraged to believe that providing information to a patient is alone sufficient for the purposes of obtaining a valid consent, we will continue to do our patients a disservice. The continued use of the term ‘informed consent’, used without qualification and without fully understanding the pitfalls of this perspective of consent, is certainly not helpful.

It perpetuates an outdated and paternalistic approach to patient care and those who continue to use this term do need to appreciate that the focus should be on understanding, rather than the provision of information alone. It is for precisely this reason that Dental Protection stresses that consent forms serve only to confirm some of the details of the information provided; they tell us little or nothing about the communication process, the questions asked, the replies given and the level of understanding achieved by the time the ‘consent’ was eventually given. Nor do they provide any insight into whether or not any undue influence was exerted upon the patient when reaching a decision. This is why a detailed contemporaneous record will often be far preferable to a signed consent form alone.

Perhaps the most convenient and concise confirmation of the prevalent abuse of the term ‘informed consent’ comes from one of the most highly respected and widely acknowledged authorities in the field of Medical Law, Sir Ian Kennedy and Prof Andrew Grubb. In their definitive textbook, “Medical Law”⁶ they write:

“The aphorism *informed consent* has entered the language as being synonymous with valid consent. This, of course, not so and is in fact unhelpful. It gives only a partial view. The requirement that consent be informed is only one, albeit a very important ingredient of valid consent. Furthermore, the expression ‘informed consent’ begs all the necessary questions (*which are the subject of the following section*); for example, how informed is informed?”

Judges in certain other jurisdictions have found more helpful ways to encapsulate the essential principles of consent. Amongst the best of these is the term “enlightened consent”, which captures very nicely the idea that a patient needs to be put into a position from which they can understand the key issues which will influence their willingness (or otherwise) to undergo a particular procedure.

A patient sometimes consents to a particular line of treatment because of the apparent advantages or benefits as described by the dentist. Care should be taken to ensure that the information given is balanced and accurate, and that any claims (as to likely success) can be substantiated. Statements such as “your crown will last for life”, or “your molar root treatment will be 100% successful” or “I guarantee you will have no problem” may dramatically weaken the value and validity of the consent contained.

Where treatment is unusual or experimental, it is important that the patient should fully understand the situation and it is worthwhile to get the patient to sign a statement to the effect that they recognise the controversial or relatively untried nature of the treatment, and accept that the risks are greater and perhaps even unknown.

For a clinician to say “I obtained informed consent from the patient”, or (worse still, as often heard in a hospital setting) “I consented the patient” rather implies that this clinician is in a position to determine the point at which the patient has been given sufficient information in order to make a rational choice. This is almost as paternalistic as giving the patient no information at all, on the time-honoured “doctor knows best” principle. But a patient who is given only some of the relevant facts and considerations regarding a specific procedure, may well be very happy to proceed, while the same patient, if given some additional information, may not. “Informed consent” will always be a misnomer if the patient remains unaware of a further relevant fact that could have influenced their decision.

6 Kennedy I, Grubb A; Medical Law; Butterworths London 2000

Similarly, consent cannot be said to be “informed” if the patient misunderstands the information, perhaps because of the words used, or the way in which the information is imparted. At the beginning of the consent process the clinician has the advantage of knowing much more than the patient, about what the procedure involves, about its risks, benefits, limitations, about alternatives and how they compare in each of these respects and also in terms of relative costs. On the other hand, the clinician may also be at a similar disadvantage in knowing relatively little about the patient, and his/her life and personal circumstances.

The clinician must therefore ask the patient the right questions in the right way, at the right time, and needs to listen carefully to the patient’s responses, in order to gain an insight into any additional information that this particular, individual patient might require in order to decide whether or not to proceed. Any failure to elicit this information, if it might be material to the patient’s decision, is more likely to be used to criticise the clinician, than to criticise the patient for not having volunteered the information without prompting. Patients, after all, may not understand why the information is even relevant, let alone important.

Choosing to withhold certain information – for example, the risks or limitations of procedure A – or declining to mention the option of procedure B at all, is always fraught with dento-legal risks. It will be argued that the resulting ‘consent’ cannot be valid because it was based on only a selected sample of the information that could and should have been provided to the patient.

Taken to an extreme, one might reach a position where the clinician is placed in a situation where every detail of every procedure, and every possible adverse outcome (however minor or rare) would need to be explained to the patient before starting any treatment. Clearly this would place an impossible burden on the clinician.

In non-emergency cases the emphasis should be on ensuring that a patient has sufficient knowledge, in advance of treatment, of:

- The purpose
- The nature of the treatment (what it involves)
- The likely effects and consequences
- Risks, limitations and possible side effects
- Alternatives and how they compare
- Costs.

When patients believe that they have been denied sufficient information they often feel angry, misled or indeed violated or assaulted. These are powerful, destructive feelings that are likely to destroy any relationship of trust upon which consent is founded.

Traditionally healthcare practitioners in South Africa have been reluctant to discuss costs with patients before treatment is provided. Times have changed and patients have become less inclined to foster long-term loyal relationships with healthcare practitioners.

Failure to obtain informed financial consent from a patient may lead to a disciplinary investigation by the HPCSA and allow the patient to avoid payment of your invoice. It is therefore professionally and commercially prudent to ensure that patients are properly informed of the likely costs of treatment and that a note of such a discussion be kept in the patient records.

4.11

Communication

There is in reality the inter-dependence between the patient and dentist that requires both parties to communicate effectively so that a decision can be made that respects patient autonomy. It is obviously important that the dentist also feels comfortable with proceeding. Effective two-way communication is therefore a corner stone of the consent process.

Consent is all about communication and a relationship of trust between a patient and a healthcare professional. It relies on a total respect for patient autonomy as far as the patient’s capacity will allow. The “best interest” principle, whilst having a valuable role in special needs and emergency situations, needs to be cautiously applied because of the risk of paternalism. These dilemmas are not unusual in dentistry and helpful advice is always at hand from Dental Protection.

5.00

Aspects of consent

The HPCSA is involved in various matters of consent, as ethical issues which reflect upon the professional conduct of a dentist. The HPCSA identifies the following essential to getting consent as:

- Knowledge of the nature or extent of the harm or risk;
- Appreciation and understanding of the nature or the harm or risk;
- That the patient consented to the harm or assumed the risk; and
- The consent must have been comprehensive (ie. extended to the entire transaction, inclusive of its consequences).

The Guidance puts flesh on the bones of these basic principles and all dental registrants are advised to familiarise themselves with the Guidance.

5.01

Is consent given voluntarily?

In order for consent to be valid, it must be given freely and voluntarily, without any pressure or influence being brought to bear on the patient. This pressure might be from a family member, parent or a health care professional. It is important when seeking to obtain consent that you satisfy yourself that consent has been freely given.

These types of situation will rarely arise in dental practice but when issues of authority and competence confuse the picture, for example in decisions concerning orthodontic treatment of teenagers, you should be considering who is driving the decision to accept treatment. Equally undue pressure should never be exerted on a patient who is unsure about whether to accept a complex, expensive treatment plan. They should be given all the alternatives, and plenty of time to think about their choice prior to starting treatment.

5.02

General anaesthesia and sedation

When receiving treatment under general anaesthesia or sedation, the patient is temporarily deprived of their capacity to give a valid consent to treatment. This makes it all the more important that they understand what is proposed in advance of the treatment because it will not be possible to refer to them once treatment is under way. It is also undesirable for the consent process to be carried out immediately prior to the administration of the anaesthesia or sedation, because patients are likely to be preoccupied with or anxious about what lies ahead. Ideally, the consent process should take place at a prior visit, giving the patient time to reflect upon the information provided, and to raise any further questions when they arrive for the procedure to be carried out.

The treatment proposed, the risks involved in the treatment, and any alternative treatments. All the procedures involved in the anaesthesia/sedation, and in the dental treatment itself, must be explained to the patient. The onus is on the dentist to ensure that all necessary information and explanations have been given to the patient or parent / guardian, either by the dentist or by the anaesthetist. It is not acceptable for these explanations to be given by a member of the practice staff, unless that person is able to answer any questions and understands the procedure

But providing treatment for a sedated or anaesthetised patient can raise other complications where consent is concerned. In the middle of treatment you notice that there is a cavity on an adjacent tooth to the one that you are treating. Do you fill it to avoid the need for further sedation or leave it and run the risk of the patient being inconvenienced? Does it make a difference if the patient has travelled a great distance for treatment? These are questions that are difficult to answer other than by saying that it depends upon the patient. The “best interests” consideration needs to be weighed carefully against the question of patient autonomy and choice, bearing in mind the fact that some patients might be more than happy for a clinician to proceed whilst others would want the opportunity to influence and to take a specific decision in relation to a specific further item of treatment.

In some cases one could pre-empt this by discussing such possibilities with a patient in advance of treatment – but unforeseen circumstances can always arise. It is the classic dilemma of paternalism against autonomy and there is no “one size fits all” answer.

5.03

Consent forms

Many dentists hold the firm, but mistaken, belief that they have secured proper consent to dental treatment by obtaining the patient's signature on a consent form. The fact that a patient has signed a form does not mean that the treatment proposed has been understood or accepted, and the quality of consent can never be determined solely by a signature which may truly "not be worth the paper it is written on". What matters more is obviously whether or not the consent has been properly obtained, by understanding and applying the principles of competence, information and authority as outlined above.

Written consent forms, especially those of the "I give my consent to any treatment" variety, are often worthless, if insufficient consideration has been given to the above factors. More important than a signature on a consent form is a properly documented patient's record, which show clearly that all the necessary pre-treatment steps have been taken, including explanations and agreements.

5.04

Warnings

A prerequisite of obtaining consent from a patient is a full exchange of information regarding any risks, drawbacks and limitations of the proposed treatment. It is important to be able to demonstrate that any appropriate warnings were given, and here the most valuable information would be a carefully made entry in the patient's record and/or a warning/advice sheet. If the latter is an integral part of a written consent form signed by the patient (with a copy retained by the patient), then so much the better.

Dental Protection is often asked by members why we do not publish "approved" consent forms that include suitable for use in various situations and circumstances. Such requests fail to recognise the broader issues raised throughout this document. For us to provide such consent forms would imply that to obtain the patient's signature on such a form would be a valid consent; a misapprehension which we are keen to avoid. We are keen to emphasise that consent is essentially a process of communication, and of a transfer of knowledge and understanding from dentist to patient. The value of clinical records and consent forms is dependent upon the extent to which they document and detail that exchange of information.

We would be happy, in any event, to offer any member our views on any proposed information/advice sheets and/or proposed consent forms which a dentist was planning to use.

6.00

Consent checklist

The patient should be aware of the purpose, nature, likely effects, risks, and chances of success of a proposed procedure, and of any alternatives to it. The fact that a patient has consented to a procedure on one occasion, does not create an open-ended consent which can be extended to subsequent occasions. Consent must be obtained for specific procedures, on specific occasions. Ask yourself:

- Is the patient capable of making a decision? Is that decision voluntary and without coercion in terms of the balance/bias of the information given, or the timing or context of its provision?
- Does the patient actually need the treatment, or is it an elective procedure? If an elective procedure, the onus upon a clinician to communicate information and warnings becomes much greater.
- What do I think will happen in the circumstances of this particular case, if I proceed with the treatment? Have I communicated this assessment to the patient in clear terms? Can I give an accurate prediction? If not, is the patient aware of the area(s) of doubt?
- What would a reasonable person expect to be told about the proposed treatment?
- What facts are important and relevant to this specific patient? (If I don't know, then I am probably not ready to go ahead with the procedure anyway).
- Do I need to provide any information for the patient in writing? Has the patient expressed a wish to have written information? (Am I relying upon commercial marketing material produced by manufacturers and/or suppliers? If so, is this information sufficiently balanced in the way it is presented?)
- Do my records accurately and sufficiently reflect the details of the communication process? Will they allow me to demonstrate – perhaps many months or years from now – what information was given to the patient, on what terms, and what was said at the time?
- Does the patient understand what treatment they have agreed to, and why? Have they been given an

opportunity to have any concerns discussed, and/or have their questions answered?

- Does the patient understand the costs involved, including the potential future costs, in the event of any possible complications?
- Does the patient want or need time to consider these options, or to discuss your proposals with someone else? Can you/should you offer to assist in arranging a second opinion?
- If you are relatively inexperienced in carrying out the procedure in question, is the patient aware of this fact? Are they aware, (if relevant) that they could improve their prospects of a successful outcome, or reduce any associated risks, if they elect to have the procedure carried out by a specialist or a more experienced colleague?
- If the technique is relatively untried or of an experimental nature, has the patient been made aware of this? Included here are any procedures for which the evidence base is limited or absent.

7.00

Summary

1. First and foremost, respect any patient's fundamental right to decide whether or not they wish to proceed with any dental treatment.
2. Assess the patient's competence to consent, bearing in mind their age and their ability to understand
 - a. the nature of the proposed treatment
 - b. its purpose
 - c. any risks and limitations
 - d. comparisons with any alternative treatment options which are available (including that of doing no treatment at all)
3. Satisfy yourself regarding the authority of the patient (or that of anyone else acting on the patient's behalf) to give consent to the proposed treatment.
4. Provide the patient with as much information as is appropriate and relevant (and as is required by the patient) regarding the points raised at 2 (a) (b) (c) (d) above. Invite questions from the patient, and answer any such questions fully, truthfully and fairly, trying to avoid making any dismissive comments about any possible risks.
5. Satisfy yourself that consent has been given voluntarily.
6. Bear in mind (see appendix) the situations where it might be sensible to give written information/warnings as part of the process of obtaining a valid consent from the patient.
7. Keep good and careful records of all matters concerning the question of consent.