# Ethics in Clinical Practice

NINE ETHICS CPD POINTS
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**ONLINE**
**CPD PROGRAMME**

# MIMS ETHICS IN CLINICAL PRACTICE ONLINE CPD PROGRAMME

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# Avoiding medicolegal pitfalls in anaesthesia and critical care

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The practice of anaesthesia in South Africa may be described as a legal minefield at times. The laws that govern our practice include the South African Constitution, the National Health Act, the Children's Act, the Choice on Termination of Pregnancy Act, the Consumer Protection Act and the Health Professions Act. Our patients' rights are dictated by the same laws, as well as the Patients' Rights Charter. In addition, the HPCSA has ethical guidelines advising on practice issues, in addition to reminding us that we are the advocates for our patients.

## What are some of the issues that may arise?

- Informed consent: information
- Informed consent: documentation
- Complications arising from neuraxial and major nerve blocks
- Positioning nerve injuries
- Record keeping
- Believing one's monitor/s
- The recovery room

## Informed consent

One of the most overlooked aspects of our practice that often lands us in hot water is the issue of obtaining informed consent from our patients, both for the anaesthetic and for one's fee. To begin with, one needs to address the question of why one needs consent from the ethical point of view. Essentially, the whole issue hinges on the principle of autonomy (autos means "self"; nomos, "rule"). Gone are the days of paternalism, and the attitude of "I am your doctor and I know what is good for you". Our patients have the right to decide for themselves.

If one looks at the National Health Act of 2003, many of the principles involving autonomy, respect for autonomy and its limitations have been taken into account. Chapter Two of the Act discusses issues pertaining to "Rights and duties of users and health care personnel" and this includes informed consent.

When considering informed consent from the practical point of view, it is easiest to divide the patient groups into the following:

- A person of sound mind over the age of 18 years
- A person of sound mind less than 18 years of age
- A person who is not of sound mind
- A pregnant patient

## A person of sound mind over the age of 18 years

The National Health Act legislates the following:
Every healthcare provider (in this case the anaesthetist) must inform a user of the following:

- The user's health status, unless there is substantial evidence that the disclosure of the user's health status would be contrary to the best interests of the user.
- The range of diagnostic procedures and treatment options generally available to the user. (This implies the various types of anaesthetic that are available for that specific procedure.)
- The benefits, risks, costs and consequences generally associated with each option.
- The user's right to refuse health services and explain the implications, risks and obligations of such refusal.

This information must be communicated by the healthcare provider (the anaesthetist) in a language that the user understands and in a manner which takes into account the user's level of literacy.

In addition, the Act states: "Where a health user is admitted to a health establishment without his/her consent, the health establishment must notify the head of the provincial department in the province in which that health establishment is situated within 48 hours after the user was admitted, unless the user gives consent within 24 hours of admission."

## A person of less than 18 years of age

Interestingly, the National Health Act makes a comment on this as follows: **"**A user who is capable of understanding must be informed, even if he or she lacks the legal capacity to give the informed consent required." We would refer to this as assent.

The remainder of consent issues involving minors are covered by the Children's Act of 2005. The Children's Act defines a child as being under 18 years of age, and yet states the following on the issue of informed consent:

- A child may consent to his or her own medical treatment or to the medical treatment of his or her child IF the child is over the age of 12 years AND the child is of sufficient maturity and has the mental capacity to understand the benefits, risks, social and other implications of the treatment.
- A child may consent to the performance of a surgical operation (and anaesthetic) on him or her or his or her child if the child is over the age of 12 years AND the child is of sufficient maturity and has the mental capacity to understand the benefits, risks, social and other implications of the surgical operation and the child is duly assisted by his or her parent or guardian.
- The superintendent of a hospital or the person in charge of the hospital in the absence of the superintendent may consent to the medical treatment of, or a surgical operation on, a child if the treatment or operation is necessary to preserve the child's life and is so urgent that it cannot be deferred.
- The Minister may consent to the medical treatment of or surgical operation on a child if a parent or guardian of the child unreasonably refuses to, is incapable of, cannot be readily traced or is deceased.
- A High Court or children's court may consent to the medical treatment of, or a surgical operation on, a child in all instances where another person who may give consent in terms of this section refuses or is unable to give such consent.

## A person who is not of sound mind

The Mental Health Care Regulations of 2003 (of the Mental Health Care Act) govern issues pertaining to informed consent in this group of patients.

## The pregnant patient

The Choice on Termination of Pregnancy Act of 1996 and the various amendments dictates some important facts on the issue of informed consent and they are as follows:

A pregnant female of any age may consent to the termination of her pregnancy at various stages of her pregnancy, depending on specific factors. The identity of the woman shall remain confidential.

When one examines the cases involving informed consent that have come before the HPCSA, the main issue has usually been the patient's complaint that there was a lack of information, either on the anaesthetic, or the fees charged.

With regard to the lack of information, the big debate is how detailed does the discussion on "benefits, risks and consequences" need to be, in terms of the National Health Act?

If one consults with the Medical Protection Society, they will tell you that patients need to be informed on absolutely every "risk and consequence", i.e. complication, regardless of how uncommon this is, unless they specifically say "I do not want to know". The latter, however, may possibly be looked at as invalidating the consent, as it is no longer "informed". In other words, known risks should be disclosed when an adverse outcome is common even though the detriment is slight, or when an adverse outcome is severe, even though its occurrence is rare.

## Documentation of informed consent

The HPCSA states that informed consent must have been comprehensive (i.e. extended to the entire transaction, inclusive of its consequences). It is also

recommended that it is documented in writing, and that both the doctor (anaesthetist) and patient sign, with two independent witnesses. If written consent is not possible, then verbal consent is acceptable. However, this should also be witnessed, and consequently documented in detail.

## Neuraxial blocks and major nerve blocks

The big potential medicolegal issue with both neuraxial and major nerve blocks is documenting whether there are any major complications, and when the block wears off. I am told that it is fairly common practice not to check on when the block wears off. This has landed colleagues in trouble with the HPCSA, as well as being sued in the form of a civil claim. Complications have arisen, such as paraplegia after a neuraxial block, or quadriplegia after an interscalene block, and because the patients were not followed up postoperatively with documentation of the time that the blocks wore off, the complications were diagnosed very late, with dire permanent consequences, followed by medicolegal processes.

## Positioning nerve injuries

These are not always avoidable, particularly in elderly and high-risk patients presenting for long operative procedures. The four underlying pathological mechanisms behind nerve injuries are stretch, compression, generalised ischaemia, and metabolic derangement. An identifiable mechanism of injury is found in fewer than 10% of cases. It is therefore logical to identify patients at risk of developing a neuropathy and then to reduce stretch/pressure on nerves during anaesthesia by careful positioning, and check on this at regular intervals. In addition, informed consent beforehand is paramount.

## Record-keeping

It is very difficult to defend one's anaesthetic if the contemporaneous record does not reflect the accurate detail of the anaesthetic administered to a patient. It is accepted that one cannot keep the record during a resuscitation, but then the details need to be completed afterwards. By law, we are obliged to keep records on all of our patients, no matter how short the anaesthetic and procedure. It is almost impossible to defend an anaesthetic if the record is sloppy or lacks detail.

## Our monitors seldom lie . . . believe them

Unexpected complications usually take us by surprise. Consider the following scenarios:

During a hip replacement on a very stable granny, the pulse oximeter stops reading. Our immediate response is to assume it has to be the monitor that is malfunctioning, when in fact our patient has suffered a massive pulmonary embolism.

The young primigravid pregnant patient is having a caesarean section under spinal anaesthesia and she becomes restless and her pulse oximeter tracing disappears. One's immediate response is to check the oximeter probe and monitor, when in fact a high spinal has ensued and the patient needs urgent resuscitation. Many valuable minutes can be lost trying to sort out the monitor, when in fact the patient requires urgent resuscitation. In these types of cases, hypoxia often occurs, with serious consequences for the patient – leading to medicolegal claims.

## The recovery room

Many unfortunate incidents occur in our recovery rooms all over South Africa. Sadly, the most common complication is hypoxia, and, if not managed properly and timeously, results in our patients suffering hypoxic brain damage. This inevitably has some form of legal consequence in the form of an inquest, a civil claim and/or an HPCSA complaint. Our SASA practice guidelines should be a reminder to us all that our duty to our patients is as follows:

"All patients should remain until the anaesthesiologist considers it safe to discharge them from the recovery room according to validated criteria, which include return of protective airway reflexes, stable cardiovascular and respiratory function, full reversal of neuromuscular blockade, absence of nausea and vomiting, and absence of pain.

## The anaesthesiologist is responsible for:

- Supervising the recovery period and authorising the patient's discharge.
- Accompanying the patient to the recovery room and adequately handing him or her over to the nursing staff who will document the patient's condition on arrival and subsequent course in recovery.
- Providing appropriate written and verbal instructions and information to the recovery-room staff for each case.
- Specifying the type of apparatus and the flow rate to be used in oxygen therapy.
- Remaining in the facility until the patient meets the criteria detailed above, or delegating this responsibility to another anaesthesiologist or intensivist.

Airway patency remains the responsibility of the anaesthetist until the patient is able to maintain his or her own airway. Patients should not be left unattended with Guedel® oral airways *in situ*. If airway maintenance is delegated, it remains the responsibility of the anaesthetist. It is also his or her responsibility to ensure that any person to whom airway care is delegated is capable of safe airway management."

Some recovery rooms are better staffed than others, and we all need to be cognisant of to whom we are handing our patient over when we arrive in the recovery room. Is this person trained and able to manage the airway and haemodynamics of our patient?

## Further reading:

1. No 61 of 2003: National Health Act 2004.
2. No 38 of 2005: Children's Act.
3. HPCSA. Seeking patients' informed consent: the ethical considerations.
4. Booklet 9. 2008.
5. HPCSA. General Ethical Guidelines for the Health Care Professions.
6. Booklet 1. 2008.





ETHICS IN CLINICAL PRACTICE

# Ethics in aesthetic procedures not clinically necessary

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A number of aesthetic procedures may not be seen as clinically necessary, yet this does not exclude them from being performed. While not life-prolonging, they may still meet a patient's emotional needs. For example, studies found that botulinum toxin treatment may fulfil both a physical and emotional need and evidence suggests that botulinum toxin may alleviate anxiety and depression.[1] Over the years, cosmetic enhancement has been known to improve patients' employment opportunities, as well as their social and personal lives. The most recent evidence shows the antidepressant effects of botulinum toxin across various indications and injection sites.[2]

In the consultation regarding an aesthetic procedure, the patient's rights and the clinician's duty to explain the procedure and obtain informed consent should be kept in mind. Practitioners have a moral or ethical duty to patients and society. This is enshrined not only in the Constitution (Act No. 108 of 1996), but also the Health Professions Act, 1976 (Act No. 56 of 1974), common law and the ethical guidelines and rules as set out by the Health Professions Council of South Africa (HPCSA).[3,5]

Of course, it is impossible to develop a complete set of ethical prescriptions for every real-life situation and sometimes practitioners will have to work out for themselves what course of action can best be defended from an ethical perspective.[3]

Practitioners should meet the standards of competence, care and conduct set by the HPCSA.[5] On the HPCSA website, we find examples of unprofessional conduct against which the HPCSA may take disciplinary steps (see Table 1). Operational procedures conducted without permission or consent are highlighted.

A successful relationship between the practitioner and patient depends on mutual trust, established by

**Table 1. Unprofessional conduct against which the HPCSA may take disciplinary steps**

| Examples of unprofessional conduct: |
|---|
| • Unauthorised advertising |
| • Over-servicing of patients |
| • Criminal convictions |
| • Improper relationships with patients |
| • Improper conduct of practitioners |
| • Operational procedures without permission or consent |
| • Disclosure of information with regard to patients without permission (confidentiality) |
| • Incompetence with regard to treatment of patients |
| • Excessive fees charged/overcharging |
| • Insufficient care towards patients |
| • Racial discrimination |
| • Rude behaviour towards patients |
| • Prescriptions to already addicted patients |
| • Perverse incentives and kickbacks |

The list is not exhaustive, and practitioners may be charged in terms of the ethical rules and the Act.[5]

respecting patient autonomy (the right to make decisions to undergo or not undergo a treatment, even if refusal may cause harm).[3] Patients should be given sufficient information in a manner that is easily understood, so that they can make an informed decision about their care (informed consent).[3] Practitioners are expected to be aware of the law relating to the procedure, thus requesting the exact information when seeking informed consent from patients.[3,5]

Effective communication is key to enable the patient to make an informed decision. The practitioner must establish the patient's needs and should be knowledgeable about conditions and treatments. Discussion with the patient leads to clarity of objectives and understanding and affirms the patient-practitioner relationship. The patient who makes a proper informed decision is more likely to co-operate with the agreed management of his or her condition and treatment.[5]

The National Patient's Rights Charter bestows certain rights and responsibilities upon patients, which need to be respected by the practitioner (see Table 2).[4]

However, it has to be stressed that, in return, the patient also needs to abide by certain rules (see Table 3). One also has to consider the core ethical values and standards of good practice. Every healthcare practitioner should strive to attain these when interacting with a patient (see Table 4).[3]

- Practitioners should always perceive the best interests or wellbeing of their patients as their primary professional duty, and honour the trust of their patients.
- Practitioners should remind themselves that they are in a position of power and avoid abusing that position.
- Practitioners should be accessible to patients, or make arrangements for when they are not.
- Practitioners should make sure that personal beliefs don't prejudice patient care. Prejudice may include race, culture, ethnicity, social status, lifestyle, perceived economic worth, age, gender, disability, communicable disease status, sexual orientation, religious or spiritual beliefs, or any condition of vulnerability.
- If the practitioner's beliefs may affect the quality of treatment provided, explain this to the patient, and inform them of their right to see another healthcare practitioner.
- Practitioners should not refuse or delay treatment because they believe that a patient's actions have contributed to his or her condition, or because practitioners may be putting their own health at risk.
- Practitioners should apply their mind when making diagnoses and considering appropriate treatments.
- Practitioners should respond appropriately to protect a patient from any risk or harm.
- Practitioners should respond to criticism and complaints promptly and constructively.
- Practitioners should not employ an intern, healthcare provider in community service, or healthcare practitioner with restricted registration with the

**Table 2. Patient rights and responsibilities to which the practitioner must heed**

| **Patient rights:** |
|---|
| 1. A healthy and safe environment |
| 2. Participation in decision-making |
| 3. Access to healthcare |
| 4. Knowledge of one's health insurance/medical scheme |
| 5. Choice of health services |
| 6. Treatment by the named practitioner |
| 7. Confidentiality and privacy |
| 8. Informed consent |
| 9. Refusal of treatment |
| 10. Second opinion |
| 11. Continuity of care |
| 12. Complaints about health services |

**Table 3. Patient responsibilities[3]**

| **Patient responsibilities:** |
|---|
| 1. To take care of their own health |
| 2. To care for and protect the environment |
| 3. To respect the rights of other patients and healthcare providers |
| 4. To utilise the health system properly and not abuse it |
| 5. To know their local health services and what they offer |
| 6. To provide practitioners with relevant and accurate information for diagnostic, treatment, rehabilitation and counselling purposes |
| 7. To advise practitioners of their wishes with regard to their death (advance directives) |
| 8. To comply with the prescribed treatment and rehabilitation procedures |
| 9. To enquire about related costs of treatment and/or rehabilitation and to arrange payment |
| 10. To take care of health records in their possession |

**Table 4. Core ethical values and standards of good practice[3]**

| | |
|---|---|
| Respect of persons | Respect patients as persons; acknowledge their intrinsic worth, dignity and sense of value. |
| Best interest or wellbeing *Non-maleficence:* | Don't cause harm and act in the best interests of the patient, even if it conflicts with self-interest. |
| Best interest or wellbeing *Beneficence:* | Act in the best interests of the patient. |
| Human rights | Recognise the human rights of all individuals. |
| Autonomy | Honour the right of patients to self-determination, to make their own informed choices and to live their lives according to their own beliefs, values and preferences. |
| Integrity | Incorporate these core ethical values and standards as the foundation of the patient's character and practise as a responsible healthcare professional. |
| Truthfulness | Regard the truth and truthfulness as the basis of trust in a professional relationship with a patient |
| Confidentiality | Treat personal and private information as confidential – unless overriding reasons confer a moral or legal right to disclosure. |
| Compassion | Be sensitive to and empathise with the individual and social needs of the patient and create mechanisms for providing comfort and support where appropriate and possible. |
| Tolerance | Respect the rights of people to have different ethical beliefs which may arise from deeply held personal, religious or cultural convictions. |
| Justice | Treat all individuals and groups in an impartial, fair and just manner. |
| Professional competence and self-improvement | The practitioner should endeavour to attain the highest level of knowledge and skills required within his/her area of practice. |
| Community | The practitioner should strive to contribute to the betterment of society in accordance with professional abilities and his or her standing in the community. |

HPCSA, as a locum tenens – or otherwise – in their own or any associated healthcare practice.

- Practitioners should inform patients if they are in the employ of, in association with or linked to, or have an interest in any organisation or facility that could be interpreted by an average person as potentially creating a conflict of interest or dual loyalty in respect of patient care.[5]

In emergency situations, practitioners should provide care within the limits of their practice, education level or training, experience and competency under proper conditions and in appropriate surroundings. If unable to do so, they should refer the patient to a colleague or an institution where the required care can be provided.

Practitioners should give their patients information they have requested or need about their condition and its treatment and prognosis. The information must be given in a language that is easily understood by the patient and in a manner that takes into account the patient's level of literacy and understanding, as well as his or her values and belief system.[5]

Practitioners should not withhold information from a patient regarding investigations, treatments or procedures that they know would be in the patient's best interests. In addition, they should apply the principle of informed consent as an ongoing process, and allow the patient access to his or her medical records.[5]

In order to protect patient confidentiality, written informed consent should be obtained when an aesthetic practitioner wishes to share any information, including, but not limited to, "before-and-after" photography, social media posts and so on.

Where a potential conflict of interest may arise, the practitioner should always seek to give priority to the investigation and treatment of the patient solely on the basis of clinical need. (This includes aesthetic medicines to improve appearance and emotional health.)

Practitioners should avoid over-servicing their patients. They should not recommend or refer patients for superfluous investigations and treatment, and should only prescribe treatment, drugs or appliances that serve the needs of their patients.[6] (For example, applying filler to already dangerously over-filled lips, may have detrimental health outcomes, such as vascular occlusion and necrosis.)

Practitioners should disclose to their patients – verbally or via a displayed notice – any financial interest they may have in institutions, diagnostic equipment, or the like to which they make referrals, if the holding of such interest is permitted by the HPCSA. They should also refrain from coercing patients or their family members by providing them with gifts or any other undue benefit.

Healthcare practitioners have a duty to themselves to maintain and improve the standard of their performance by keeping their professional knowledge and skills up to date throughout their working life. They should acknowledge the limits of their professional knowledge and competence, and do not pretend to know everything. They should observe and keep up to date with the laws that affect professional healthcare practice in general and their practice in particular, and update their skills and knowledge of ethics, human rights and health law, as provided in accredited Continuing Professional Development programmes.[1]

## Consent to investigation and treatment

Patients have a right to be informed about their condition and treatment options. Information may differ among patients, i.e. the nature of the condition, the complexity of the treatment/procedure and the patient's own wishes (such as procedures that are not always clinically indicated, but fulfil an emotional need in a patient).

Patients may need more information to make an informed decision about procedures carrying a high risk of failure or adverse side effects, or any investigation that may affect employment, or their social or personal life.[1,5]

Information should be relayed in a language the patient understands, and should include:

- Details of the diagnosis and prognosis and the likely prognosis if left untreated
- Uncertainties about the diagnosis, including further investigations prior to treatment
- Treatment options, including options not to treat
- The purpose of investigation or treatment, details of the procedure or therapy, supplementary treatment – for example, methods of pain relief, how the patient should prepare for the procedure and details of what the patient may expect during and after treatment, including common and serious side effects

The courts have held that patients must be informed of "material risks" in order to give proper informed consent. A risk is "material" if:

- A reasonable person in the patient's position, if warned of a risk, would attach significance to it, and
- The healthcare practitioner should reasonably be aware that the patient, if warned of risk, would attach significance to it.

No-one should make decisions on behalf of a mentally competent adult, even when requested by a relative or next of kin. The National Health Act advises that patients should be informed of their health status, unless "there is substantial evidence that the disclosure of the patient's health status would be contrary to the best interests of the patient."[3,5]

## Presenting information to patients

Obtaining consent is not an isolated event, and involves continuing dialogue. It is important to discuss treatment options at a time when the patient is best able to understand and retain information. In order to ensure that a patient understands, practitioners should give clear explanations and give the patient time to ask questions.[5]

## Who obtains consent?

Consent should be obtained by the practitioner who undertakes the treatment or investigation. This task may, however, be delegated to a person who:

- Is suitably educated, trained and qualified
- Has sufficient knowledge and understands the risks involved, and
- Acts in accordance to the guidance in Booklet 3 of the HPCSA Ethical Guidelines.

The practitioner remains responsible for ensuring that before a treatment is started, the patient has been given sufficient time and information to make an informed decision, and has given consent.[5]





## The right of patients to information

Patients have a right to information about available health services, presented in a way that is easy to follow and use. The NHA requires practitioners to inform patients of the following:

- The health status of a patient
- The range of procedures and treatment options generally available to the patient
- The benefits, risks and consequences generally associated with each option
- The patient's right to refusal[5]

## Ensuring voluntary decision-making

The patient decides what is in their own best interests, and not the practitioner. Nonetheless, the practitioner may wish to recommend treatment or a course of action to the patient, but must not put pressure on the patient to accept specific advice.

The practitioner must give a balanced view of the options and explain the need for informed consent. He or she must also declare any potential conflict of interest (for example, working for a company, or owning shares in a healthcare facility). Practitioners should do their best to ensure that patients have considered the options and reached their own decisions.[5]

## Emergencies

If a healthcare practitioner administers, for example, a local anaesthetic to which the patient has a reaction, the healthcare provider may provide medical treatment without patient consent, provided the treatment is limited to what is immediately necessary to save a life or avoid significant deterioration of the patient's health. However, healthcare practitioners must respect the terms of treatment of, and any valid refusal made in advance by the patient of which they are aware, or which is drawn to their attention. After the emergency, as soon as the patient has sufficiently recovered to understand, the doctor should tell the patient what has been done and why.[5]

## Establishing capacity to make decisions

Practitioners should presume that every adult patient has the capacity to decide whether to consent, or to

refuse, unless it has been shown that the patient cannot understand information presented in a clear way. If a patient choice appears irrational, or not in line with the doctor's view or patient's best interests, it does not necessarily mean the patient lacks competence. Practitioners should reassess information needs in these cases and follow the guidance issued by relevant professional bodies where competence needs to be assessed.[5]

## Fluctuating capacity

Practitioners should assist patients struggling to retain information or who are only intermittently competent. Record a decision made whilst the patient was competent, including the key elements of the consultation. Review decisions made whilst the patient was competent, at appropriate intervals before starting treatment to establish that the view is consistently held and can be relied on.[4]

If in doubt, it is safer not to treat aesthetically.[5]

## Mentally incapacitated patients (Mental Care Act No. 17 of 2002)

These patients should not be treated in an aesthetic milieu, and constant assessment should be done when obtaining informed consent. For example, practitioners should be wary of the patient with body dysmorphic disorder who may take aesthetic treatments to the extreme.

Practitioners should check how well the patient understood the details and implications of the proposed treatment, and not simply rely on the consent form – especially where the initial consent was obtained by a third party.[5]

## Expressed consent

Patients can consent either orally or in writing. However, written informed consent is paramount where:

- The treatment is complex or involves significant risks or side effects (for example, blindness related to filler treatment)
- Providing clinical care is not the primary purpose of the investigation or examination
- There may be significant consequences related to the patient's employment, as well as social or personal life
- The treatment is part of a research programme

Practitioners must use patient notes or consent forms to detail key elements of discussion with the patient (see Figure 1 on the following pages for an example of a generic informed consent form).[5]

## Implied consent

Practitioners should be careful about relying on patients' apparent compliance with a procedure as a form of consent. Submission in itself may not indicate consent. Consent must be expressed and not implied.[5]

## Reviewing consent

A signed consent form is not always sufficient to say that a patient has given, or still gives, informed consent. Practitioners are urged to review consent where:

- Significant time has elapsed between when consent was given and the proposed treatment.
- There have been material changes in the patient's condition, or any aspect of the proposed treatment plan, which may invalidate the patient's existing consent.
- New, potentially relevant information has become available – for example, about risks of treatment or about other treatment options.[5]

## References:


1. Magid M, Reichenberg J. Botulinum toxin for depression? An idea that's raising some eyebrows. *Current Psychiatry*. 2015 November;14(11):43,46,51-56.
2. Makunts T, Wollmer MA, Abagyen R. Post marketing safety surveillance data reveals antidepressant effects of botulinum toxin across various indications and injection sites. *Scientific Reports.* 2020. 10(1);12851. https://doi.org/10.1038/s41598-020-69773-7.
3. HPCSA. General Ethical Guidelines for the Health Care Profession. Booklet 1. 2016 September. www.hpcsa.co.za.
4. HPCSA. National Patient's Rights Charter. Booklet 3. 2016 September. www.hpcsa.co.za.
5. HPCSA. Seeking Patients' Informed Consent: The Ethical Considerations. Booklet 4. 2016 September. www.hpcsa.co.za
6. HPCSA. Guidelines on Over Servicing, Perverse Incentives and Related Matters. Booklet 11. 2016 September. www.hpcsa.co.za
7. Dhai A, Attie I, van Niekerk J, *et al*. Informed Consent. SAMA Human Rights, Law and Ethics Committee. 2015. www.samedical.org

Figure 1: Generic Informed Consent form[7]

**INFORMED CONSENT – AGREEMENT ENTERED INTO BETWEEN MEDICAL PRACTITIONER AND PATIENT PARTIES:**

Mr/Mrs/Ms.....(Full name and surname)

Identity number.....

(hereinafter referred to as “the patient”) of (full physical addresses):

Residence:.....

.....

Business:.....

.....

and

Doctor/representative.....

(hereinafter referred to as “the doctor” and/or “the representative”) of (full physical address of practice):

.....

.....

Practice code no: .....

MP no:.....

Doctor: .....

**To be completed by Doctor/representative:**

- ☐ I confirm that I have explained the following to the patient in terms of which, in my judgment, are suited to the understanding of the patient and/or to one of the parents or guardians of the patient.
- ☐ The parties’ health and status condition
- ☐ The range of diagnostic procedures and treatment options generally available to the patient
- ☐ The benefits, risks, costs and consequences generally associated with each option
- ☐ The patient’s right to refuse health services and the implications, risks, and obligations of such refusal;
- ☐ The nature and purpose of the proposed operation, investigation or treatment, namely;

  .....

- ☐ The type of anaesthetic, if any (general/local/sedation) .....
- ☐ The possible need for blood or blood products during and after the procedure and the risks associated with receiving blood or blood products

Signature ..... Date .....

Name of doctor .....





**Patient/Parent/Guardian/Mandated person to be completed by patient**

I, the undersigned, state as follows:

- ☐ I am the patient/parent/guardian.
- ☐ The doctor named on this form has explained fully to me the issues listed and ticked above.
- ☐ I confirm that I understand everything that has been explained to me, I have also received answers to all my questions and been informed that, if I want more information, I should ask the doctor.
- ☐ I understand that problem(s) and complications may occur even when the best care, judgment, and skills are used.
- ☐ No guarantees have been made to me by the doctor.
- ☐ I agree to the operation, investigation or treatment as explained to me, and to the use of the type of products as may be considered necessary and in my best interests and can be justified for medical reasons.
- ☐ I have told the doctor that I DO NOT want the procedures below to be carried out without having the opportunity

  to consider them:.....

  .....

  .....

- ☐ I consent to the retention and/or disposal by the health facility and or doctor of any tissue or parts which may require removal.
- ☐ I understand that I may withdraw consent to, or refuse, treatment at any time.

Signature ..... Date .....

Name of Patient/Parent/Guardian .....

# Consent and protection of patient rights in clinical practice

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Obtaining patient consent is vital in the provision of medical services to all patients. Patients have the right to be duly informed about anything concerning their health, as well as the right to participate in the medical treatment to be received from medical practitioners. The patient has to offer their consent, either expressly or tacitly, and it must be done voluntarily, meaning that the patient must understand everything entailing the medical treatment and they must be legally capable of giving consent. Unless the case is exceptional, no treatment can be provided without the patient's consent.

In South Africa, patients' rights are enshrined in a number of statutes, such as the National Health Act 61 of 2003; the Mental Health Care Act 17 of 2002; Choice on Termination of Pregnancy Act 92 of 1996; and the Ethical Guidelines for Good Practice in the Health Care Professions, in line with the Health Professions Act 56 of 1974.

## The law and consent

Medical practitioners are vested with the ethical duty to respect the patient's autonomy, requiring them to adhere to the patient's right to make their own decisions regarding their health and life.[1] Patient autonomy is also provided for in Section 8 of the National Health Act, which demands that the patient be involved in decisions concerning their health and treatment, and as consent is an ongoing process, the patient has to provide consent throughout the medical treatment.[2]

In quantifying the right to consent, the National Health Act provides that patients must be fully informed of "(*b) the range of diagnostic procedures and treatment options generally available to the user; (c) the benefits, risks, costs and consequences generally associated with each option; and (d) the user's right to refuse health services and explain the implications, risks, obligations of such refusal*".[3] Medical practitioners are further required to ensure that the process of informed consent is explained to the patient in a language they understand, and in terms they understand. Therefore, when treating a layperson, communication should be modified to that which a layperson would comprehend.[4]

As required by the National Health Act, Section 9 of the Mental Health Act declares that mentally ill patients cannot receive medical services unless the patient has given consent for such services.[5] The patient's right to consent is further dealt with in Section 5 of the Choice on Termination of Pregnancy Act, which requires that the informed consent of the pregnant woman be obtained, prior to the termination of the pregnancy. Likewise, Section 6 of the Act[6] reiterates that the pregnant woman must be informed of all her rights regarding the medical services to be provided.[7]

Notwithstanding the aforementioned, the patient may refuse to give consent for medical treatment. In the event of consent refusal, treatment should not be given, and "such refusal shall be verbal or in writing, provided that such refusal does not endanger the health of others".[8]

## Who can give consent?

Where the patient is unable to give informed consent for the medical services to be performed, the National Health Act allows for the consent to be given on behalf of the patient. This could be done by a person elected by the patient, in writing, to give the consent. If there is a court order or legislation specifying that consent is required, consent can alternatively be given by either the spouse or partner of the patient; a parent; grandparent; an adult child or sibling of the patient, in that specific order.[9] Similarly, the Choice on Termination of Pregnancy Act permits the patient's guardian, spouse or legal guardian, or a *curator personae,* who is appointed, to give consent on medical matters, on behalf of the patient, when the patient is unable to do so.[10]

## Exceptions

The patient should give informed consent for all medical services to be conducted. However, in some cases this is not possible – for example, when fully informing the patient of their health status would not be in the best interests of the patient, as found in Section 7 of the National Health Act; where specific legislation or a court order permits medical services to be performed without the patient's consent; where non-treatment of the patient would pose a public health risk; and in cases of emergency, where the patient's condition would worsen or result in death, should the patient not receive the medical treatment and the patient has not expressly or tacitly refused to give their consent. It is also permissible to proceed with the medical treatment without the patient's consent, provided that they give said consent within 24 hours of the medical service being provided.[11]

The Mental Health Act, in Section 9, echoes the provisions above. It states that medical treatment can be performed on the patient without their consent, where there is a court order in place allowing for this; and where the patient lacks capacity to consent due to mental illness and non-treatment would result in harm to the patient or others, or in damage to property.[12]

Medical treatment, specifically the termination of pregnancy, can also be performed on a mentally ill or incapacitated patient without their consent, provided that due to their mental illness, they cannot understand the consequences of going through with the pregnancy; or they remain incapacitated or unconscious and would not regain consciousness.[13] Furthermore, Section 5 (5) of the Choice on Termination of Pregnancy Act, allows for the termination of the pregnancy without the patient's consent where continuing with the pregnancy would pose a health or mental danger to the woman or foetus, provided that the consent would have not been denied.[14]

The above is also provided for under Rule 27A relating to a medical practitioner's responsibility towards patients, which states "*A practitioner shall at all times (g) except in an emergency, obtain informed consent from a patient or, in the event that the patient is unable to provide consent for treatment himself or herself, from his or her next of kin.*"[15]

## Protection of patient rights

Patient consent is not only required for the performance of medical services. It is also vital for medical practitioners to obtain and confirm consent when dealing with patient information. The National Health Act stipulates that the patient has to provide consent to medical practitioners in order for their medical records or files to be shared with third parties.[16] This serves to protect the patient's constitutional right to privacy, and patients have a right to expect that their medical information will be held in confidence by medical practitioners.

In summation, it is evident that medical services cannot be provided to patients without said patients providing consent for these services. Informed consent requires that patients are made fully aware of the nature of all medical services, along with the consequences and options thereof. The exceptions that apply to obtaining patient consent are when it is waived by legislation or a court order; it is in the best interest of the patient; or when it is justified in the public interest. The rule of thumb when it comes to informed consent is to remember that the more information the patient has, the more likely they are to make an informed and voluntary decision about their medical care, unless of course, excess information could be detrimental to the patient's health.

Therefore, the law – through the legislation specified above – ensures that the patient's rights are protected, and the failure of medical practitioners to adhere to this legislation makes them liable for a breach of the ethical rules, which could result in having their professional registration suspended by the Health Professions Council of South Africa. Performing medical services without consent could also amount to negligence, and where the patient sustains severe harm as a result, would deem the medical practitioner criminally liable for said actions.

## End notes:

1. This right can be found in Section 12(2) of the Constitution of the Republic of South Africa, 1996, which provides that "*Everyone has the right to bodily and psychological integrity, which includes the right; a) to make decisions concerning reproduction; b) to security in and control over their body; and c) not to be subjected to medical or scientific experiments without their informed consent".*
2. National Health Act 61 of 2003. Section 8 reads:
   *"(1) A user has the right to participate in any decision affecting his or her personal health and treatment.*
   *(2) (a) If the informed consent required by Section 7 is given by a person other than the user, such person must, if possible, consult the user before giving the required consent.*
   *(b) A user who is capable of understanding must be informed as contemplated in Section 6 even if he or she lacks the legal capacity to give the informed consent required by Section 7.*"
3. *Ibid*. Section 6 (1).
4. *Ibid*. Section 6 (2).
5. Mental Health Care Act 17 of 2002. Section 9 (1)(a) provides: "*(1) A health care provider or a health establishment may provide care, treatment and rehabilitation services to or admit a mental health care user only if - (a) the user has consented to the care, treatment and rehabilitation services or to admission*".
6. Choice on Termination of Pregnancy Act 92 of 1996.
7. *Ibid*. Section 6 states: "*6. Information concerning termination of pregnancy A woman who in terms of Section 2 (1) requests a termination of pregnancy from a medical practitioner or a registered midwife or registered nurse, as the case may be, shall be informed of her rights under this Act by the person concerned*."
8. *Guidelines for Good Practice in the Health Care Professions - National Patients' Rights Charter - Booklet 3.* Clause 2.9. Refusal of Treatment.
9. *Supra*, Note 2. Section 7 reads: *"(1) Subject to Section 8, a health service may not be provided to a user without the user's informed consent, unless*
   *(a) the user is unable to give informed consent and such consent is given by a person*
      *(i) mandated by the user in writing to grant consent on his or her behalf; or*
      *(ii) authorised to give such consent in terms of any law or court order;*
   *(b) the user is unable to give informed consent and no person is mandated or authorised to give such consent, and the consent is given by the spouse or partner of the user or, in the absence of such spouse or partner, a parent, grandparent, an adult child or a brother or a sister of the user, in the specific order as listed".*
10. *Supra*, Note 6, Section 5 (4)(b) reads: "*In terms of Section 2, her pregnancy may be terminated during the first 12 weeks of the gestation period, or from the 13th up to and including the 20th week of the gestation period on the grounds set out in Section 2 (1) (b) (i) upon the request of and with the consent of her natural guardian, spouse or legal guardian, as the case may be; or (ii) if such persons cannot be found, upon the request and with the consent of her curator personae*".
11. *Supra.* Note 2. Section 9.
12. *Supra*, Note 5. Section 9.
13. *Supra*, Note 6. Section 5(4).
14. *Ibid*. Section 5(5).
15. *Guidelines for Good Practice in the Health Care Professions - Ethical and Professional Rules of the Health Professions Council of South Africa - Booklet 2.* Rule 27A (g).
16. *Supra*, Note 2. Section 14 states:
    "*(1) All information concerning a user, including information relating to his or her health status, treatment or stay in a health establishment, is confidential.*
    *(2) Subject to Section 15, no person may disclose any information contemplated in subsection (1) unless-*
    *(a) the user consents to that disclosure in writing;*
    *(b) a court order or any law requires that disclosure; or*
    *(c) non-disclosure of the information represents a serious threat to public health*."

## Further reading:


1. Constitution of the Republic of South Africa, 1996
2. National Health Act 61 of 2003
3. Mental Health Care Act 17 of 2002
4. Choice on Termination of Pregnancy Act 92 of 1996
5. Guidelines for Good Practice in the Health Care Professions - *National Patients' Rights Charter - Booklet 3*
6. Guidelines for Good Practice in the Health Care Professions - *Ethical and Professional Rules of the Health Professions Council of South Africa - Booklet 2*






# The rights of minors and the clinician's responsibilities regarding confidentiality


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*"Whatsoever things I see or hear concerning the life of men, in my attendance on the sick or even apart therefrom, which ought not to be noised abroad, I will keep silence thereon, counting such things to be as sacred secrets.'"*[1]

-Hippocratic Oath

Confidentiality is the duty owed by clinicians to their patients not to divulge the information confided to them in the absence of the patient's informed consent.[2] Without the protection afforded by this privilege, patients both young and old would be reluctant to divulge essential information to their healthcare provider for fear of such information becoming public knowledge.[2] Honesty and an accurate history from the patient are essential in order for a clinician to be in a position to render the correct and most appropriate treatment to the patient.[3] It can therefore be said that duty of confidentiality is the foundation upon which trust between doctor and patient is built.[3]

The concept is not so simple when the clinician is faced with a minor patient. In the South African context, a minor is a person below the age of 18 years.[4] Minors do not have the required ability to make informed decisions regarding their healthcare.[5] This poses a challenge to healthcare providers who are faced with the dilemma of whether to proceed with treatment at the request of a minor patient or to seek parental consent. In this context, the minor patient must be assured that what is confided to his or her clinician will remain confidential. If the minor patient has reason to believe that this duty may be breached by the clinician, he or she may avoid disclosing information that is essential in ensuring that a correct diagnosis is made and that the correct treatment is prescribed.[4]

This is particularly important in difficult situations. For instance, a minor patient may require treatment of a sexually transmitted disease, request the termination of a pregnancy, seek medical assistance for depression or request a prescription for an oral contraceptive.[3] How is the situation to be approached? What guidance does the law afford the clinician in these circumstances? In answering these questions, attention must be paid to the laws and ethics that govern the practice of medicine.

Preserving a patient's right to confidentiality is imposed on the clinician not only by statute and the common law, but also by virtue of the Hippocratic Oath.[3] A rite of passage, this ancient oath must be taken by every medical student.[1] In doing so, medical students swear, *inter alia,* to maintain the patient's right to confidentiality.[1] The obligation to uphold the patients' right to confidentiality is therefore a legal and an ethical duty.[3]

From a legal perspective, Section 12 (2) (b) of the Constitution guarantees the right to bodily integrity.[6] This includes the right of all patients to make decisions regarding their reproductive health, as envisaged in Section 12 (2) (a) of the Constitution,[6] as well as their right to "security and control over their body".[6] If a clinician were to infringe these fundamental rights by, for instance, treating a patient without first obtaining his or her informed consent or declining a patient's request for a termination of pregnancy, the clinician would be in breach of constitutionally protected human rights.[7]

What if the patient is a minor? How should the clinician approach the issues of confidentiality and informed consent?

In this regard, the Children's Act 38 of 2005, as amended, provides that a child[8] is competent to make her own decisions regarding her medical treatment provided that he or she is above 12 years of age[8] and has the maturity and mental capacity to appreciate the risks, benefits and implications associated with the proposed course of treatment.[8] Healthcare pro-

fessionals therefore do not require parental consent if they are satisfied that the minor patient is 12 years of age or older and has demonstrated an understanding of the information provided to him or her. His or her informed consent to medical treatment can therefore be accepted. In this regard, it is submitted that clinicians are required to ensure that when explaining risks, benefits and social consequences of treatment/surgery to a minor patient, they do so in language that is easy for the child to understand. If the clinician were to approach the minor's parent or guardian for consent in these circumstances, the clinician would be breaching the duty of confidentiality owed to the patient.

In cases where minor patients are required to undergo a surgical procedure, the Children's Act provides further guidance. It states that patients are competent to consent to a required surgical procedure provided that they are 12 years of age or older,[8] and that they are sufficiently mature to appreciate the risks, benefits and implications of undergoing the surgery.[8] An additional requirement for a surgical procedure is that the minor patient must be duly assisted by either the parents or a legal guardian.[8] It is important for the child to be able to appreciate that a parent or guardian is required to assist in the decision-making process on account of the risk associated with undergoing surgery. In this regard, it can be argued that this is not a breach of confidentiality, but rather a disclosure that is made to a parent or guardian in the child's best interests.

With regard to children below 12 years of age[8] and children 12 years or older, but not sufficiently mature or able to appreciate the risks, benefits and implications associated with undergoing the treatment,[8] the Act provides that informed consent can be obtained from either a parent or the guardian of the child. This is reasonable, considering that if a child is unable to appreciate the information regarding the proposed treatment, how can he or she then provide informed consent?

In the case of a child requiring surgery who is below 12 years of age[8] and lacks the necessary maturity or is not able to appreciate the risks, benefits or implication of such an operation,[8] the clinician is guided by the Act to obtain consent from the child's parent or legal guardian.[8]

There may be instances in which the life of a child depends on urgent surgical or medical intervention.[8] The procedure cannot be postponed for the purpose of obtaining informed consent from either a parent or legal guardian.[8] In this regard, the Act provides that consent can be provided by the superintendent of the hospital or the person in charge of the hospital.[8]

Clinicians may be faced with a situation where obtaining consent from a parent or guardian proves to be challenging. According to the Children's Act, consent can be obtained from the Minister of Social Development in the following circumstances:

- If a child's parent or guardian unreasonably refuses to furnish informed consent in the case of surgery or necessary medical treatment.
- If the parent or guardian refuses to assist the minor patient in providing consent.
- If the parent or guardian is incompetent in terms of providing informed consent/assisting the minor patient, cannot be traced or has passed away.[8]

## Minors and reproductive healthcare

Section 129 of the Children's Act provides clear guidance on how a clinician should approach the issue of informed consent in the context of a minor patient. The Act provides further guidance to clinicians pertaining to reproductive health care when the patient is a minor.

Concerning the issue of access to contraceptives, the Act makes it clear that if a minor below 12 years of age requests condoms from a clinician, such a request may be denied. However, if a minor patient were to confide to a healthcare professional that she has acquired condoms or even contraceptives, such information is to be treated as confidential by the clinician.[8]

The discretion to provide minor patients with condoms (implied by the words "may be denied") does not mean that minors are not afforded the right to make choices regarding reproductive healthcare as envisaged in terms of Section 12 (2) (a) of the Constitution.[6] If a minor were to request other forms of contraception from a healthcare provider in the absence of parental consent (or even that of a caregiver), such contraceptives may be given to the child, provided that certain

criteria are met.[8] In this regard, it is essential that the clinician is satisfied that the child is at least 12 years old,[8] and that he or she is given sound medical advice[8] and examined in order to determine whether any medical reasons exist for him or her not to be granted a request for such contraceptives.[8] It is submitted that these requirements are necessary in order for the clinician to be satisfied that is in the child's best interests that he or she is afforded the requested contraceptives.

The Children's Act does not refer to the issue of termination of pregnancy in the context of the minor patient. In this regard, The Choice on Termination of Pregnancy Act[9] is applicable. The Act provides that a termination of pregnancy can be requested by any female irrespective of her age.[9] A minor child who becomes pregnant and who wishes to terminate such pregnancy is able to do so under the provisions of this Act without having to obtain the consent of a parent or guardian.

The common law also provides guidance to clinicians on how to deal with the issue of consent in the context of the minor patient. One of the cases that is of persuasive value in South Africa is the English decision by the House of Lords, Gillick v West Norfolk and Wisbech Area Health Authority.[12]

This case "establishes that a doctor indeed owes a mature minor patient a duty of confidentiality where the child is competent to form a relationship of confidence, but that is not absolute and will depend on the individual circumstances of the case".[12]

This decision has led to what has come to be known as the "mature minor" or "Gillick-competency" test.[3] The test assesses whether a child below the age of 16 years is competent "to consent to medical treatment when he or she has sufficient understanding and intelligence to understand fully what is proposed".[3]

The position, as stated by Lord Scarman in the Gillick case, is consistent with the provisions of the Children's Act which also requires that the child must display that she is able to understand what is being explained to her before her consent can be accepted. Further, by obtaining consent from a minor patient using these criteria, the clinician will not breach the duty of confidentiality by approaching a parent or guardian for consent.

## An ethical perspective

In practising medicine, healthcare professionals are required to apply the biomedical principles of autonomy, beneficence, non-maleficence and justice.[10] The principle of autonomy requires the clinician to respect that decision-making rests with the patient.[7] Clinicians are required to obtain the patient's informed consent prior to proceeding with the recommended course of treatment or surgery.[11] In the context of the minor patient and the provisions of the Children's Act, the principle of autonomy requires that clinicians treat minor patients who display maturity and understanding as competent patients who are able to provide informed consent to medical treatment. An additional requirement of autonomy is that the minor's right to privacy is upheld.

The principles of beneficence and non-maleficence respectively require the clinician to "do good" and not to "harm the patient."[11] Essentially, clinicians are required to "contribute to the welfare of their patients.[13] The principle of non-maleficence is recognised in Section 27 of the Constitution; it provides that emergency medical treatment cannot be refused to patients in need of such treatment.[7] According to the Children's Act, if consent cannot be obtained by a minor patient, the clinician may look to the hospital superintendent for consent on behalf of the minor. This ensures that the minor's constitutional right to emergency medical treatment is not infringed.

The principle of justice requires that patients are treated fairly and equally.[7] This principle is given expression in Section 9, the equality clause of the constitution.[7] A patient who displays both maturity and intelligence in understanding the information conveyed, has a right to be treated as an autonomous individual and not be discriminated against based on age. The minor patient has a further constitutional right to security and control over his/her body in terms of Section 12 of the Constitution and if he or she chooses to undergo treatment or a procedure, this should be respected, provided that reasonable grounds exist for the decision.

O'Regan J has stated in the case of NM and Others v Smith and Others:[13] " …privacy, liberty and dignity as the key constitutional rights which construct our understanding of what it means to be a human being". It is therefore submitted that in upholding the minor patient's rights to privacy, liberty and dignity, the clinician is under a legal duty to ensure that consent is obtained from a minor patient when it is possible to do so and not to simply contact the parents or guardians because the child is under the age of 18 years. This can be achieved by treating all information confided to the clinician as confidential, within reason. Finally, the clinician should give due regard to the opinions and requests of a minor patient who has displayed the maturity and ability to understand the information conveyed to her by the clinician.

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   Section 129 (5)(b)
   Section 129 (5)
   Section 129 (6)(a)
   Section 129 (6)(b)
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# Rationing in healthcare: Is it fair?

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Health systems and physicians have long battled with questions around the allocation of resources, decisions about who qualifies for a particular treatment, or even access to certain services, and how to make and implement these decisions consistently and transparently.[1,2]

In a healthcare system such as that of South Africa, where financial, physical and human resources are constrained, rational decision-making about resource allocation becomes an imperative. But, as in many countries before us, the issues of how to allocate, who is responsible for making decisions pertaining to allocation, which healthcare elements qualify for allocation, as well as the timing involved, are controversial.

In the healthcare system, medicines – as an identifiable item of spend – present an opportunity for rationing and the application of evidence-based, health economic decision-making tools. Generally, the budget or expenditure on medicines can be fairly easily identified and interrogated, rendering it an attractive target for cost-management interventions. In addition, evidence for the efficacy and safety of medicines is also generally more readily available than for other healthcare interventions, making estimating and comparing the health impacts of these products easier.[3]

One of the common managed care interventions in South Africa is the development and maintenance of medicine formularies, or preferred lists of funded medication, published, maintained and implemented by healthcare funders.

A recent study examining the formulary decision-making process of selecting medicines in the private sector, found that medical schemes and administrators adopted many common approaches when selecting products for medicines formularies, but that very few were actually doing full pharmaco-economic analyses to support decisions made regarding the funding of medicines.

## What is rationing?

From a fundamental health economics viewpoint, expenditure on a particular aspect of healthcare provision means that the spent resources are no longer available for use on some other aspect of healthcare provision, a concept known as “opportunity cost”.[4]

Attempts to ensure that the opportunity costs of expenditure can be justified, and that health resources are used in the “best” possible way, have produced a number of rationing methods.

Rationing in health has been described in a number of ways, but essentially often plays out in a practical reality: denying a potentially beneficial intervention to a patient, or a group of patients, on the grounds of a scarcity of resources.

There are also a number of international documents which refer to the relationship between ethics and healthcare funding. The ethical principles which underpin funding decisions include professional autonomy, informed consent, equity and equality and distributive justice.

A potentially beneficial healthcare intervention could be a programme, a new technology, a medicine or even a referral to a specialist-level of care, all in the name of managing resource use. This rationing can take place explicitly or implicitly.[5]

Explicit rationing generally refers to decisions made by an administrative authority (in South Africa, this may be the Government or private medical insurers) as to the amounts and types of resources to be made available, eligible populations, and specific rules for allocation.

In South Africa, a significant amount of explicit rationing occurs in both the public and private sectors regarding the levels of available technology, benefit designs, the listing of medicines on formularies and expenditure levels on specific disease areas and programmes.

Implicit rationing can take place through mechanisms such as patient cost-sharing, waiting lists, and forcing allocation decisions at a local level by requiring professionals to work within a constrained budget.

## What is “fair” in healthcare?

Fairness is a multifactorial concept, and very complex to evaluate in practice. Fairness includes equity in health outcomes, in access to all forms of care and in financing. Fairness also requires efficiency in management and the allocation of resources within the health system.

When resources are constrained, their inefficient use means that some needs that could have been met are not fulfilled. For the public to have influence over healthcare, fairness must also include accountability. Finally, fairness also includes appropriate forms of patient and provider autonomy.

Daniels and Sabin[6] and Daniels[7] have proposed four characteristics of fair processes in relation to allocation:

- Oversight by a legitimate institution
- Transparent decision-making
- Reasoning according to principles that all parties can accept as relevant
- Procedures for appealing and revising decisions

Fairness is an extremely subjective concept, but ties in with the ethical concept of justice. In order for a resource-allocation decision to be considered fair, it should be procedurally and distributively just. Procedural justice refers to appraisal of the fairness of how decisions are made, whereas distributive justice refers to appraisal of the fairness of decision-making outcomes.[8]

Formulary decision-making, rationing and fairness

If “rationing” is understood as the “limited allocation of health services”, it opens up the question of what rules the allocation process should follow.

As previously mentioned, medicines lend themselves to rationing, using evidence-based and health economic decision-making tools. Legislations and policies both in the public and private sectors of South Africa require administrative bodies to set formularies and determine medicine benefits for patients,[9,10] which requires a myriad of resource-allocation decisions.

Medicine formularies are used throughout the world to set medicines benefits, and are representative of the approach proposed in the World Health Organization (WHO) Model Formulary 2004 and the essential medicines lists of various countries, including South Africa.[11] In addition, South Africa’s own National Guideline for the Development, Management and Use of Formularies contains high-level principles and business rules that inform the development, management and use of formularies in the public health sector, and in private sector health establishments that provide healthcare services on behalf of the public sector.

In terms of these guidelines, the purpose of a formulary is to:

- Identify medicines required to satisfy the needs of the population served by a particular health establishment or group of health establishments;
- Guide management of medicines at all levels of care in accordance with the principles of good governance;
- Inform transparent decision-making in the development and management of medicine-related budgets at all levels of care;
- Promote rational medicine use throughout the healthcare system.

Formularies and committees that oversee them can strongly influence which medications are funded and ultimately prescribed in the public and private sectors. Ultimately, these decisions impact directly or indirectly on health outcomes.

When decisions are made and communicated appropriately, formulary processes can identify, weigh and synthesise best evidence, and guide prescribing toward the most evidence-based choices, helping to direct resource use toward the most efficacious, safest, and cost-effective therapies.[12]

Decisions for formulary inclusion should largely be made in the face of the principle of distributive justice, and often accompanied by health economic assessments. While the latter inform the decision-making process, they should not be the only criteria for including or excluding a specific intervention with regard to a formulary.

In conclusion, "fairness", although seemingly subjective, should be applied as objectively as possible, always taking evidence into account, in order to provide equitable access to the inevitably scarce resources of the healthcare system.

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# Moral considerations in a pandemic: balancing the interests of the individual against the collective


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A pandemic, simply, is a "worldwide spread of a new disease".[1] The clinical severity and method of propagation of the disease help predict its impact and inform the public health response. In the case of an infectious disease pandemic (IDP), the spread of the disease is directly influenced by people's behaviour. The more ubiquitous the mode of transmission, the faster the pandemic grows. Consequently, more restrictive interventions may need to be implemented to curtail it. During an IDP, the ordinary actions of an individual may have far-reaching consequences. In the case of airborne pathogens, the simple act of breathing poses a risk to others, and preventive measures may extend to the extremes of curtailing behaviours that are usually taken for granted. How should society navigate the conflicting demands between diverse human needs and rights at stake during an IDP?

## Individuals as members of society

Human beings are wired to self-preserve. As Bertrand Russell writes: "The primary cause of conflict is egoism: Most people are more interested in their own welfare than in that of other people".[2] Given our complex societal lives and dependencies, however, even our individual self-preservation objectives necessitate certain responsibilities towards the societies in which we live – our survival depends on functioning societies. Sometimes, individual sacrifices are required for the sake of the greater good. A reasonable point prevails for the dial to rest between the extremes of complete disregard for others, and martyrdom. Where exactly is that reasonable point? This is the question at the core of centuries of moral theory: How should we interact with others and society at large? What is our responsibility towards others?

The Rawlsian "veil of ignorance"[3] prompts us to consider the position of vulnerable members of society, by putting ourselves in their proverbial shoes and correcting imbalances in the allocation of rights and resources. Utilitarianism[4,5] guides us to pursue the greatest good for the greatest number of people. In recognition of the power imbalance between the individual and the collective, human rights ethics attempt to define the minimum protection that society should afford its members against the claims of the collective or other individuals. In a modern democracy, individual liberty is valued and protected by constitutional rights.

In modern Western medicine, there is general consensus that a person ought to have freedom and self-determination with regard to his or her own body and health, as long as it does not impose restrictions on others;[6] an essentially libertarian view. In our society, this view extends to freedom of trade, association, movement, and so on.

To what extent can our freedom or autonomy justifiably be curtailed in order to protect others in society? In an IDP, this question becomes central to moral public health decision-making and may have significant consequences for both the individual and society. In answering this question, we should recognise that individual freedom is intricately linked to individual flourishing, the absence of which can be defined as harm.

The question then becomes more tangible: To what extent can the individual be expected to bear harm and/or sacrifice for the benefit of the collective? Most modern democracies practise a departure from pure libertarianism – taxation is as inescapable as mortality. What should happen to the freedom enjoyed in our usual daily lives amidst a pandemic that is fuelled by that very freedom? Should the freedom to move around, to earn a living, to practise religion in a group, to interact with other (consenting) members of society, to exercise commercial choice and participate in a free market and so on, be curtailed? Amidst an overwhelming IDP, other constitutional rights may also be threatened – such as the rights to life, education, privacy, and access to healthcare. Which and whose rights may be trumped by others? A *prima facie* reaction may claim that the right to life is deserving of protection above and at the cost of all others. But is this true in a democratic society?

## Does the right to life trump all others?

Let us consider the right to life posited against the right to bodily integrity. We may consider compulsory quarantine or vaccination in the context of an IDP as justifiably small infringements on individual rights. Their negative impact on the individual is considered minor and is far outweighed by the benefits of sparing many people from infection. This is, in essence, a utilitarian consideration: The sum of benefits, on balance, outweighs the total amount of harm.

Now let us consider a kidney donation. Most of us will agree that it would be morally unacceptable to force a person to donate a bodily organ, even if the harm to the donor is limited, and the donated organ can save a life. Why do we consider the harm of forcefully taking a kidney to save another life too extreme? This exposes an innate appreciation that life is not sacrosanct, that there are certain boundaries around the individual's self-determination and bodily integrity that we are not prepared to cross, even if it comes at the cost of another life. Where do these boundaries lie? We may argue that the kidney-harvesting procedure is highly invasive and carries significant risk to the donor, and even the saving of another life does not justify this. It could translate to "a life for a life" – there is a risk that the unwilling donor might become ill at a later stage in his or her life, without the benefit of two kidneys. There are also the immediate risks of a major surgical procedure. However, millions of people have surgery every day, and with modern surgical techniques, the risk is relatively small. Perhaps our true concern lies with the *permanence* of the impact. The donor will never regrow a second kidney. The harm of the procedure is uncertain in significance, indefinite in duration, and irreversible. This may be the line we generally refuse to cross.

Yet this does not satisfactorily explain our repulsion at the thought of forcing people to donate their organs. We attach significant value to our authority over our body; in the absence of which, we imagine our flourishing to be significantly and, perhaps, irreparably impaired. We insist on protecting this authority, even if it means that someone else may die as a result.

This example hints at the fallacy of viewing the right to life as an end in itself and as incomparable to other rights which contribute towards human flourishing. When faced with the balancing of claims to different rights amidst an IDP, the dichotomy of "lives vs livelihood" can be counterproductive. As Paul Bloom[7] suggests, it may serve us better to rather consider human flourishing (represented by the right to life of the kidney recipient) vs human flourishing (represented by the right to bodily integrity and self-determination of the donor), when assessing conflicting claims in public health decision-making. It is obvious that for the deceased, there can be no flourishing, but we have a threshold for the reasonable impairment of individual flourishing for the sake of others' lives. It seems that the terms for the violation of individual rights are dictated by the nuanced weighing of benefit and harm; crucially, the *extent*, *duration* and *reversibility* of the violation and its consequences for the flourishing of the individual need to be considered.

Let us return to infectious disease. What is an acceptable amount of time an individual should spend in forced isolation to curtail spread of an infectious disease? Two weeks, as in the case of tuberculosis? Lifelong, as could potentially be argued in the case of

extensive drug-resistant tuberculosis (XDR-TB)?[8] We may turn again to utilitarian principles to answer this question. We may conclude that the harm to a minority of individuals as a result of confinement is far outweighed by the sparing of significant harm and even death of countless others, and is therefore, on balance, justified.[8,9] We can also assume the harm of two weeks in isolation to be reversible and relatively minor. Lifelong isolation presents more of a conundrum.

With COVID-19, the calculation was reversed, and almost the entire global population was at some point confined for the benefit of a relatively small group at risk. The fact that the individual rights of billions of people had to be curtailed meant that the duration of countries' lockdowns had to be finite. The longer the duration, the more severe and intolerable the cumulative harm to the flourishing of entire societies became, and the higher the probability of this harm becoming irreversible. Three days would have been wholly tolerable for the sake of potentially saving an uncertain number of lives; three years would have shifted the balance towards irreparable, irreversible, and intolerable harm for billions. A similar argument would apply to the XDR-TB patient in lifelong isolation. Again, the dial of reasonability rests somewhere in between, and shifts based on the *context* and the availability of mitigations of harm, e.g. the provision of humane living conditions in isolation for the XDR-TB patient,[8] or financial stipends, psychological support, and education alternatives for people under COVID-19 lockdown.

While utilitarianism is central to public health decision-making, we inevitably face the trap of consequentialism: not being able to accurately perform the calculation of benefit vs harm, owing to imperfect information. This problem has also become patently tangible in our experience with COVID-19.

Given the novelty of pathogens responsible for pandemics, much of our knowledge comes only in retrospect. With COVID-19, the mortality rate, mode of transmission, optimal management and risk factors were gradually revealed, but were preceded by a rapid spread and significant mortality in some countries.[10] The logical reaction was to err on the side of caution. It was, however, imperative to constantly readjust our assessment of risk as we gained more knowledge about the disease, especially given the extreme public health interventions implemented, and their significant associated harm.

## Public health advisory amidst uncertainty

Uncertainty can be debilitating, especially when the stakes are high. In such scenarios, the recognition of complexity is invaluable. It prompts us intentionally to recognise and understand the limitations of our knowledge,[11,12] to work with the certainties we possess, and to readjust our understanding of all of these dimensions as our certainties expand. By factoring uncertainty into our weighing of potential harm vs benefit when addressing complex public health problems such as IDPs, we can adjust the scales with more confidence. Significant harm with high probability should generally weigh more than the same degree of harm with less probability.

In the COVID-19 confinement scenario, socio-economic collapse and all its harmful consequences are more probable in the context of a developing country than in a developed, socio-economically stable one. This also highlights the necessity to consider the context of an IDP: to recognise the global determinants of health and human flourishing; their intricate relationships to socio-economics, the environment, culture, and so on. With this in mind, it is incumbent on international health advisory bodies to provide context-specific guidance to member states. Blanket advice for complex problems with significant contextual variables may not only be inadequate, but harmful. This also highlights the case for an *interdisciplinary approach* to complex problems such as IDPs: Ideally, the public health advisory should not only consist of expertise in epidemiology and infectious diseases, but should also draw on disciplines such as economics, cultural science, behavioural science, sociology, psychology, education, politics, law, ethics, and even environmental science, where appropriate. This reduces the risk of missing important perspectives of complex problems, and helps predict risks and benefits more accurately.

Amidst IDPs, society looks to the medical fraternity, as harbourers of scientific medical knowledge, for guidance. In addition to the requirements for contextuality and recognition of complexity, it follows from the entrenched tenets of modern Western medicine that such guidance should also be evidence-based (again, with due recognition of the limitations where evidence is absent), agile (adjusting guidance as new evidence and understanding emerge), and clear (towards effective, widespread communication).[13]

## Individual healthcare workers

Clinical practitioners face significant ethics challenges amidst an IDP. The rationing of resources is amplified when there is a sudden, increased demand on healthcare services. Healthcare workers (HCWs) may be tasked with the implementation of curtailments on individual rights: The rules dictating patient autonomy, privacy and confidentiality may shift. Not dissimilar to the challenges to individual members of a society, there is also tension between the professional responsibility of HCWs towards society and the patients they serve, and their personal responsibility towards their own immediate social circle, including their family and household. The basic human rights endowed on all citizens also vest in HCWs – pertinently, the right to their health.

By accepting the responsibility of healthcare provision, the assumption of risk of exposure to infectious disease is implicit. The assumption of risk is, however, not absolute[14] – society cannot expect HCWs to completely disregard their own safety in their service to their patients. This would be a disservice not only to themselves and their immediate social circles, but also to society at large, which is likely to continue requiring healthcare services in the future. Again, the dial of reasonability rests somewhere between self-preservation and martyrdom.

The assumption of risk by the HCW can be navigated as a contract with society – risk is accepted on the provision that there is reasonable mitigation. In the case of an infectious disease, this translates to the availability of adequate personal protective equipment. It should also include the provision of healthcare services to HCWs who may fall ill in the course of their duties, including care for exhaustion and the mental consequences of the stressors that HCWs encounter during an overwhelming IDP. In the absence of reasonable support from society (via its government), it may be reasonable for the HCW to refuse assumption of unmitigated risk.

Where a response to an IDP involves the temporary adjustment of protection of patient autonomy and confidentiality, such adjustments should ideally be guided by legislation and official guidelines. This assumes a fair and considered decision having been made at a societal level, leaving the HCW with some confidence that the infringements required are justified, and that he or she would enjoy legal protection when implementing them. The medical fraternity should be involved in such decisions at a policy level, and the considerations discussed above may be useful in determining its advice to regulators and policy makers.

## Conclusion

IDPs force individuals and societies to re-evaluate their perspectives on responsibility and freedom. Utilitarianism is indispensable in guiding public health interventions, but needs to be nuanced and account for broad, contextual assessments of harm and benefits, including their cumulative impact, duration, complexity, and reversibility. Simultaneously, sober decision-making should recognise the value of human flourishing and its intricate dependencies on human rights and liberties.

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# Social responsibility in a pandemic

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Social responsibility is an important aspect of health disparity worldwide. COVID-19 and the global pandemic required a rapid response utilising a multisectoral approach, to prevent transmission. In South Africa, lockdown rules enforced by the Disaster Act required civil obedience. It was soon evident that social responsibility at an individual, community and societal level would require longer-term intervention through social cohesion and solidarity in terms of not only disease prevention, but also the impact on the economy and social welfare of the population.

The social and economic environment in which people live is indicative of their social wellbeing, status and health. Urgent global health needs and drivers were identified in the one-decade report of the World Health Organization.[1] Later, social responsibility in healthcare was included in the United Nations Educational, Scientific and Cultural Organization (UNESCO) declaration of bioethics and human rights.[2] Social responsibility is an important principle in global bioethics and is used to inform policies and guidelines. The global pandemic of COVID-19 has placed the spotlight on the national healthcare systems of many countries. Normally, these systems are bureaucratic and complex, and in times of crisis, the multi-level decisions that need to be made slow down the necessary critical response. The vulnerability of societies is exposed during pandemics because of the lack of readiness or rapid response to deal with decisions decisively.[3]

COVID-19 has uncovered the poor socio-economic conditions of many South Africans. The pandemic has also disrupted public healthcare as most healthcare workers are now in the frontline and hospitals have had to reprioritise emergency care for COVID-19 patients.[4] The healthcare system is under tremendous pressure to exploit the capacity of both healthcare workers and hospitals to manage and mitigate the impact of COVID-19.

## Public health response in a pandemic

In a crisis, the standard of care shifts to meet the needs of the community. Here, it is important to note that an accountable response is required from various, interrelated governmental institutions. A pandemic necessitates the reallocation of staff, facilities and supplies to meet public health demands. Hospitals have to postpone non-emergency tests and procedures and those in hard-hit areas even have to cancel elective and serious surgeries.[5] The protection of human resources – particularly front-line healthcare workers – during a pandemic is very important in the fight against the disease. Medical staff on various levels are vulnerable to the disease and can become infection transmitters.[3] Care must be taken to ensure that everyone is protected from working with infected patients. The hiring of additional staff to help reduce the long working hours of permanent healthcare workers should be high on the priority list of decision-makers. A special focus should also be placed on looking after the mental health of clinicians and nurses who have to treat critically ill COVID-19 patients, to ensure their mental resilience.[3] Providing medication, food and water to poorly resourced communities forms part of the extension of interrelated responsibilities of Government and other key role-players in civil society and the private sector. Social protection of vulnerable populations, such as the elderly, the homeless and prison inmates, must also be provided to guard against the spreading of disease. These populations are often vulnerable in terms of mental health and stigmatisation.[5]

## Civil obedience and the impact on society

In response to the COVID-19 outbreak, the South African government enforced lockdown regulations through the Disaster Management Act, moving the country into a state of civil obedience. This was intended to slow the rate of new infections and prepare the healthcare system to cope with the inevitable surge. The government further ensured civil obedience by utilising safety and security forces, as well as the military, as a visible mechanism to enforce social compliance and order. Different levels of lockdown, each with their respective prohibitive regulations affecting mobility, such as curfews, and social interaction, were implemented with the aim of preventing the spread of COVID-19. Healthcare became the strategic driver for a multisectorial response in order to flatten the curve of the pandemic whilst ensuring manageable healthcare service delivery. At the same time, citizens had to comply with lockdown regulations.[6] Both these interventions allowed the country, and Government in particular, to obtain the upper hand in responding to this global healthcare crisis. It allowed the mobilisation of an extensive healthcare response, including managing the different stages of the illness through targeted healthcare interventions, such as self-isolation and social quarantine. This reduced the demand on the healthcare delivery system which could have easily become another national disaster as the existing system was not able to meet the demand and supply.

However, it was evident that even with these regulations in place, social responsibility at an individual, community and societal level would require a much longer-term intervention aimed not only at disease prevention, but also at mitigating the negative impact on the economy and social welfare of the people. Various aspects of social and cultural context influence the change in the behaviour of a society. During a pandemic, it is important for the government to instil trust and stability on all levels through regular and consistent communication to communities.[7] Individuals need to have an increased understanding of the virus in order to make responsible decisions regarding their actions. For example, people are more willing to stay at home if they understand that by going to work when they feel ill, they could be infecting an elderly co-worker who suffers from a serious chronic illness.[7]

## Social responsibility transfer and behavioural change

Key to the understanding of the importance of transferring social responsibility is the social ecology model of change where the individual is in a co- and interconnected relation with other social systems. The first sphere of social influence or system is within the micro-level where the individual is influenced by small groups and households or family life, where he or she is "schooled" in what is socially acceptable or not. This is then influenced by mechanisms of social enforcement at a community and organisation level, such as the workplace, which is the meso-level or system. At this level, more formal social relations reinforce acceptable behaviour and punish unacceptable behaviour through a sense of belonging and social cohesion. It is also at this level where opportunities to act on these social responsibilities impact directly on the sustainability of the change. Lastly, the macro-level of influence towards change is where institutions of society formally control and punish change through legislation and laws. This level promotes high levels of social cohesion and solidarity.

Initial interventions during the COVID-19 pandemic were predominantly conducted from a biomedical perspective, with a focus on health protocols and regulations, but it soon became evident that a wider understanding of combined prevention was needed. This included the integration of the biomedical with the social, behavioural and structural drivers of prevention. Biomedical prevention only provided possible short-term scare tactics. The impact of physical and social distancing affected many socio-cultural and -religious organisations negatively. It is evident that key drivers of behavioural change should be integrated to promote a longer-term socialisation towards healthy behaviour and lifestyles, as well as challenging some socially institutionalised practices as barriers of prevention.[6]

Prochaska's Transtheoretical Model (Stages of Change) allows one to unpack these stages of change not only at an individual level, but also at a societal level of social responsibility:[8]

*Stage one* – Precontemplation of the possibility of being at risk and the consideration of short-term

changes. On an individual level, the person will be fearful and try to prevent harm with some immediate changes to lifestyle, but does not consider a period of sustainable prevention. Society is also in a reactive response. Severe interventions are put in place to facilitate civil obedience and the transfer of social responsibility through different social agencies, such as the government.

*Stage two* – The contemplation phase happens when the individual starts to experience some consequences of the risks and then begins exploring possible options to reduce risks, but not in a coherent and consistent way. Society moves into more medium- and long-term alternatives to enforce change by transferring social responsibility back to the individual and at community levels within a national response.

*Stage three* – Serious action is taken by both the individual and society to reduce the risks and prevent the long-term negative impacts of the change on economic and social levels. These actions are then formalised in norms and values which facilitate social responsibility through social cohesion and solidarity.

*Stage four* – Maintenance of the change at both individual and social level occurs through different layers of social influence and re-enforcement, such as peer pressure, the media, social institutions and social leaders. It is crucial that the maintenance stage is absorbed into all spheres of society and creates a positive impact on social cohesion and sustainability.

*Stage five* – Relapses may occur when the individual and society are dealing with the unknown future of change through acts of social disobedience and/or returning to old habits or norms as they are familiar and provide a sense of security. Social relapses and responsibility go hand-in-hand as it is crucial for the individual to internalise the change and society to institutionalise it.

In looking at Prochaska's model of five stages, it is clear that government institutions should be conscious of the importance of a long-term strategy to implement socialisation of healthy behaviour and lifestyles to enable prevention and mitigation of health disparities. Social trust and decisive response from governments during a pandemic is not an automatic response and evolves over time. Looking at responses from other countries during the pandemic, and Singapore, in particular, as being among the first countries being affected by COVID-19, their comprehensive surveillance system to detect as many cases as possible gave them an advantage to contain the virus at the individual level. This strategy has been effective in containing the spread of COVID-19 in the early stages. Singapore has steadily built up its outbreak preparedness by incorporating lessons learnt from the SARS epidemic to ensure clear leadership and direction critical for a coordinated response across all sectors.[9]

## Conclusion

The extended lockdown period and alert-level regulations have had a severe impact on the economic stability and loss of income and employment in this period. The actions that were taken from the South African government, albeit with saving lives from the deadly virus, did not take into account the massive health and economic inequalities of its people. A trusting society where social cohesion and solidarity exist will be able to prevent and mitigate the impact of COVID-19. A long-term strategy is needed to enhance social responsibility on the micro-, meso- and macro level of society to ensure sustainability and resilience.

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# The importance of the Declaration of Helsinki for research on patients and their data

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"Long regarded as central to the contemporary understanding of medical ethics are four principles that must be satisfied in order to fulfil the requirements of moral decision-making. These principles are autonomy, justice, beneficence, and non-maleficence." -*Sherwin B. Nuland*

The World Medical Association's Declaration of Helsinki was developed because of a need to protect individuals from being taken advantage of, or mistreated by, researchers. The Nuremberg Code was drafted after the 1947 International Tribunal where the experimentation on human research subjects in Nazi Germany was highlighted in the proceedings of the Doctors Trial.[1] Most of the Nuremberg Code was incorporated into the Declaration of Helsinki (DoH) which was adopted in 1964. Although not legally binding,[2] it provides a set of rules which form the basis of all good and ethical research. Review committees use the DoH as their guidelines for the approval of any clinical studies performed on humans.

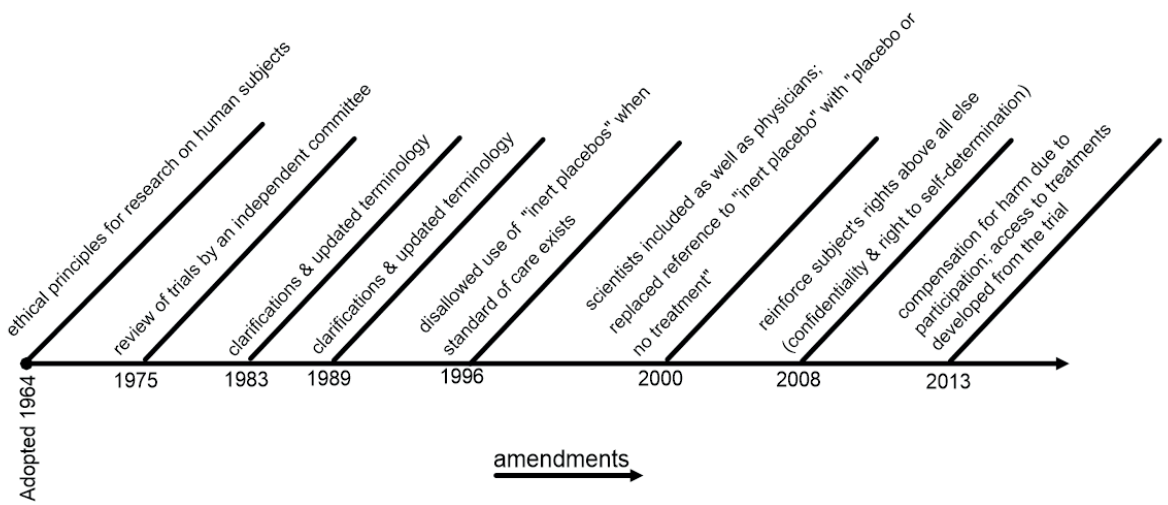
As with all living documents, the DoH is regularly revised when necessary. So far, there have been seven revisions and two additional notes of clarification to the document.[2,3] Some of the main amendments are summarised in Figure 1.

## The importance of the Declaration of Helsinki

The first paragraph of the DoH states its purpose clearly: "The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human research participants, including research on identifiable human material and data."[4]

There are several valuable attributes which make this document so important. Firstly, it is an international guideline formulated by medical professionals to govern research practices. By the nature of the authors, it should be recognised as valuable, reliable, and internationally applicable. It is promoted as outlining the minimum standards to which researchers

**Figure 1. Timeline of amendments to the Declaration of Helsinki**



should adhere. Countries' internal laws govern practices related to clinical trials, but they should never require less than the minimum standards outlined by the DoH. There has been some argument that there are paragraphs or phrases that can be interpreted in more than one way – such as the controversy generated by the revisions suggested for the 2 000 update with the comments on the use of placebos. However, researchers should be striving to achieve the highest ethical standards in their trials rather than looking for ways to manipulate the wording to their advantage.[3] The oversight/review committee therefore must ensure that the study design aligns with the best possible practices. For some time after the latest revision, there was a tendency among some researchers to refer to the DoH of 2008 in their protocols, rather than the 2013 version. This was an attempt to sidestep some of the practices that might have made the undertaking of the trial more arduous for the researchers or potentially more expensive for the sponsors. As with any living document, one cannot choose which of the versions one wishes to utilise, otherwise the benefit of a universal guideline is nullified. In the words of Potter Stewart, Chief Justice of the US Supreme Court, **"**Ethics is knowing the difference between what you have the right to do and what is right to do".

The accessibility of the document is another valuable aspect of the DoH – it is succinct and easy to read, and even a layperson can interpret the principles easily. There is no "fine print" that requires the interpretation of legal and medical jargon. The terminology is straightforward, and the writing is not trying to hide subtle meanings. At all times, the focus is on the protection of the trial research participants – as per paragraph 8 of the DoH which states: "While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research participants."[4]

It is noteworthy that the DoH also strives to protect the environment, as per paragraph 11 which states: "Medical research should be conducted in a manner that minimises possible harm to the environment",[4] as well as respecting the welfare of animals used in research (paragraph 21).

## Patient-informed consent documents (PID)

As the focus is to ensure the rights and interests of the research participants of trials are protected, the informed consent document forms a vital part of any clinical trials. It is here that most of the points laid out in the DoH are clarified for the research participants in the context of the specific research to be undertaken. The language used must be suitable for a layperson with limited education to understand and should be carefully explained to the participant by the investigator. Only once the research participant is satisfied that he or she has sufficient understanding of the clinical trial, is comfortable to proceed, and has signed the consent document, can the investigator begin the process of enrolling the participant into the trial.

In the PID, the specific purpose of the trial is addressed so the research participants know exactly what they will be expected to do, why they have been selected, what the trial procedures involve and the related risks and benefits. At no stage should a trial be conducted if the potential benefits involved have not been deemed to outweigh the risks. The investigator is also obliged to inform the research participants of their protection in terms of confidentiality, and compensation for injury due to trial-related procedures. Confidentiality is of great importance as people are more inclined to participate in research if their identity is protected, especially if the information is sensitive.[5] Truthful information is a fundamental requirement for accurate analysis of research data and if people are not guaranteed the confidentiality of their data, they may be inclined to withhold vital information. Privacy is perceived as a key human right by many and if the confidentiality of data is not assured then many potential research participants might opt to forego participation in the trials. A major concern linked to genetic data is the potential for insurers and employers to penalise those who show any predisposition to a disease or disorder. Use of anonymised data is standard practice in most trials and allows for protection of the participant whilst simultaneously providing authentic medical information.

No undue pressure should be placed on potential research participants to enter the trial (they should be assured of good medical treatment even if they opt not to participate), nor should there be any coercion to participate. For some individuals, even a small incentive could be the difference between providing a meal for their family or going hungry. A researcher should never use a gratuity to incentivise someone to participate in a clinical trial.

If a participant is incapacitated and unable to provide consent, a legal representative will be required to do so on is his or her behalf until such time that the participant may be able to provide consent. In the case of participants being minors, they must be given the information in a format that they can understand and be given the chance to refuse to participate, even if their guardians provide consent on their behalf. An assent document should also be provided for those minors incapable of choosing for themselves.

## Protocol

Obviously, the science of the trial is vital, and the purpose of the investigation should be to advance medical knowledge whilst focusing on the best interests of the patient. The study design must therefore be sound to enable the researchers to obtain sufficient data within the set timeframe, and the data should allow for objective analysis. Evaluation of interventions should focus on their "safety, effectiveness, efficiency, accessibility and quality".[4] If the science is not sound, the data would be invalid and the trial would not be considered ethical as it would not have served a beneficial purpose.

After the trial, the results must be made publicly available, even if they are negative or inconclusive. Whilst a negative outcome may not meet the sponsor's objective, it is still important as other researchers will then not need to repeat the trial. This obviates unnecessary testing on other research participants in the future.

Vulnerable groups need special consideration. If the trial can be completed in a safe population, this option must be followed so as to prevent any form of increased harm (physical, psychological or social) to the group. The term "vulnerable" can be interpreted as referring to (but not exclusive to):

- Any group that could be coerced into participating by the nature of its circumstances (such as prison inmates who may feel pressured to participate because of their subordinate position)
- A group that could be easily identified, thereby running the risk of being stigmatised when the results of the trial are made public
- Any group that could be taken advantage of due to its reduced ability to make informed decisions

By similar implication, groups should also not be excluded from studies if they can derive unequivocal benefit from participating in the trial.

## Conclusion

The realm of medical research is fast-paced and constantly evolving, hence there will always be a need for further revisions of the DoH that accommodate new spheres of study. Genomics, genetic engineering and stem-cell research are fields which may require greater clarity in the near future. The WMA's Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks[6] goes some way towards establishing international uniformity with regard to research on human materials and data. Since some researchers, as well as laypeople, feel greater clarity is needed on certain aspects,[7] there will always be room for public comment on these living documents in order to improve them. One must, however, take care not to overshadow the functionality, practicality and essence of the DoH by turning it into a cumbersome tome of directives. The ultimate aim of ethical medical research is summarised in the basic principle outlined in the DoH which states: "It is the duty of the physician to promote and safeguard the health, wellbeing and rights of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty".[4]

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# The inconvenient truths about dementia treatment: continued patient involvement

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The gradual decline, or sometimes lack of, patient participation in shared decision-making in the medical treatment of patients with dementia, has often been met with legal alternatives such as advance directives of the patients themselves or *curator personae* appointments by the court[1] by which another person can make decisions regarding the healthcare of the patient. Although these alternatives address concerns about executive decision-making functions, the ethical concerns regarding the patient's retained autonomy and dignity come into play. Authorised proxies, such as the court-appointed curators or family members acting on behalf of the patient, may, in certain circumstances, confuse what would be best for the patient with what the patient might have preferred. In these situations, depending on the severity of the impact of dementia, caretakers may try to covertly influence the patient to follow certain instructions, or information may be withheld because it may upset the patient.[5,22]

Studies have shown that some healthcare practitioners often avoid formal discussions about treatment with patients suffering from impaired mental capacity. The strains of the illness often mar constructive engagement between the dementia patient and the healthcare practitioner. This non-communication or poor communication can, amongst other things, be attributed to the practitioner wishing to avoid any psychological and emotional distress in the patient, the pitfalls of coercion tactics or even conflict in the patient's relationship with his or her immediate caregivers and/or curator.[2-5] Continued assessments of the patient's cognitive impairment through periodically investigating the clinical impact of dementia on long-term memory, language use, overall recognition abilities, executive decision-making functions and metacognition, may lead to revised approaches in discussions about treatment with the patient.[2]

## Guidance in uncertainty

The South African National Health Act 61 of 2003, together with the South African Older Persons Act 13 of 2006, provides a legislative framework wherein the ethico-legal issue of deferred consent in dementia patients' ability, can be addressed. Issues arising from this legislative framework, such as the patient's inherent right to refusal of medical treatment, has often presented healthcare practitioners with the moral dilemma of finding a balance between the active decisions of the patient's curator and the patient's autonomy.[5,7-9] Contemporary estate planning has attempted to address this issue by creating a legal instrument for situations where a person may be declared mentally unfit to make decisions regarding him/herself. Living wills, otherwise known as advance directives, were created as tools by which a balance can best be struck between acting in the best interests of the patient and respecting the autonomy of the patient's wishes. Patients can record their preferences for future healthcare in a range of scenarios and also appoint appropriate persons for making these decisions on their behalf when the instructions contained in the advance directives are unclear or silent.

The draft National Health Amendment Bill of 2018 attempted to provide statutory protections for the concept of formalising patient autonomy in future instances of the lack of mental capacity. This was formulated by underpinning the effects of such a living will and by paving a way for the voluntary appointment of a *curator personae* as directed by the patient, but which would be known as a power of attorney for healthcare.[7,10] The effects of the amendment bill would have allocated overriding authority to the latter two legal instruments in protecting the rights and autonomy of the patient. The Bill would also have provided protection to the healthcare professionals who act on the instructions emanating from those two legal instruments and would have diverted possible criminal and civil liability.

Although no statutory protections or guidance on the implications and limits of said advance directives have been forthcoming from the proposed 2018 National Health Amendment Bill[7] as yet, the alternative legal instrument of *curator personae* appointment, in conjunction with the principles of shared decision-making and the existing legislation, can now be used to mitigate the disjoined rights of dementia patients.

## Capability in self and others

Neurological studies investigating decision-making processes in patients with dementia have differentiated between primary and secondary levels of agency. Legal consequences for competency requirements are only attached to the primary decision-making functions in neural activities, such as meta-cognition and executive functions. These include adjusting behaviour according to limitations, active reasoning for weighing up options and considering the different consequences of a solution best suited to an intended goal.[6,11,12] Secondary neural responses in decision-making, such as appreciation for reward, punishment and value, still remain active in patients with dementia as forms of capacity, although they are not acknowledged in competency assessment for legal purposes. Alternative influences on decision-making processes in patients suffering from dementia, aside from the primary levels of agency containing logical analysis, can be grouped as elements of patient autonomy. These factors, which include personal preferences, values, religion, educational levels, occupation and culture, can still contribute to decision-making abilities in overall patient ability such as understanding, appreciation and expressing choice.[14] These decision-making influences that are present despite the patient's varying cognition[6,13-14] give rise to the continued right of shared decision-making principles when treating compromised mental competency in dementia patients.

Shared decision-making in healthcare is a collaborative process by which a healthcare practitioner enters into a dialogue with the patient to make evidence-informed, but value-based, decisions regarding the patient's treatment.[15,17] This process addresses the needs of and respects the autonomy of the patient, based on the primary and secondary levels of decision-making abilities, all the while allowing the healthcare practitioner to impart his or her educated suggestions for treatment options. In this consultative structure, wherein both parties influence each other, patient preferences can be aligned with medical interventions, in a guided attempt to informed consent. The discussion also allows for other decision-influencing factors, such as patient priorities, life circumstances and philosophies, to come to the fore, enabling the practitioner to make adjusted treatment recommendations based on risk management and to convey other appropriate information.[15-17]

Effective implementation of the principles of shared decision-making in dealing with dementia patients is often hampered owing to the legal instruments listed earlier which divert the decision-making responsibilities of the patient to another authorised individual. The subsequent lack of legal authority of the patient, together with the general reluctance of healthcare practitioners to engage in treatment discussions with dementia patients,[18] more often than not dismiss the retained autonomy of the patient.

Referring back to the legislative framework that should address this ethico-legal dilemma, the guiding principles of the Older Persons Act dictate the imperatives imposed on healthcare practitioners to include those patients suffering from dementia in discussions regarding their medical treatment, regardless of their lack of mental capacity and the existence of external legal instruments. The general principles guiding the South African Older Persons Act 13 of 2006 state that all actions or decisions in a matter concerning an older person must respect, protect, promote and fulfil the older person's rights and best interests, subject to legal limitations (such as the active *curator personae* appointments). The Act further states that the older person's inherent dignity must be respected and that the provision of services to an older person must promote the participation of the person in the decision-making process.[8]

## Conclusion

One should keep in mind that although the primary decision-making abilities of meta-cognition and exec-

utive functions are impaired in patients lacking mental capacity, their secondary decision-making abilities directly linked to autonomous expression of self, are still effective and therefore warrant the patients' rights still to be included. The patient should continue to be included in the discussions regarding treatment options despite the presence of legally authorised proxies.[20-21] The underlying principles of shared decision-making and the ethical requirements of informed consent are now shared between the court-appointed *curator personae* and the patient.[5] Both parties should now be consulted in the information-sharing process, with the healthcare practitioner making known his or her views on the disease, the treatment options, and the associated risks and benefits. The combined consultation with the legal instruments (being either the court-appointed *curator personae* or the advance directive/"living will"), together with the secondary level of decision-making faculties of the dementia patient, may enable a balance between the medical contributions of the healthcare professional and the autonomy of the patient's wishes, preferences and treatment goals. This balanced approach addresses concerns of patient coercion and the drowning out of the patient's "voice".[1] By doing this, equal opportunity in the shared decision-making process is given to the parties to understand, to appreciate, to reason and to express a choice for their preferred treatment.[14] This will join the legal-bearing decision-making functions of the *curator personae/*advance directive, with the active secondary decision-making functions of the patient, as influenced by the patient's autonomy.

To give effect to the above-mentioned right of participation of the dementia patient, certain aids can be developed for bridging the gap in the healthcare practitioner's attitude towards the difficulties faced when dealing with the psycho-social effects of dementia. Researchers have suggested creating user-friendly, clear and concise educational material which contains visual presentations, such as graphs or interactive material.[16,18]

In conclusion, the dignity of the dementia patient, as it is currently protected in South African law, together with the neural investigations into the alternative pathways for decision-making functionality, dictates that patients with impaired mental capacity, still have the right to be consulted about their medical treatment. This applies despite the presence of legal instruments replacing decision-making functions with appropriate legal capacity to act. The principles of shared decision-making in healthcare, and more especially mental health, seek to give equal respect to the best interests of the patient, as envisioned in the evidence-based opinion of the treating healthcare practitioner, and the fiduciary duties of an appointed *curator personae*, combined with the personal preferences underscoring the inalienable autonomy of the patient.

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