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Mind the Gap
The culture of consent

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INTRODUCTION

If you've ever been fortunate to travel to London, you probably have encountered the Underground. When travelling on the London underground each stop comes with the pre-recorded warning in a crisp British accent to "Please mind the gap". This occurs at every stop. At first the warning seems arbitrary, and unnecessary – since the gap appears non-existent. But once you move out of the city centre (the ideal location) this gap widens and widens until it seems completely impassable. Where a warning to "mind the gap" seems facetious for a whole new reason.

This is much like society. We are warned about gaps in our society, and at times this too seems redundant. This is often because we are perceiving it from the "ideal "scenario. In a privileged society – you may not even think there is a gap. But as you move further from the "ideal" these gaps become more significant – much like the underground system.
So where are our gaps in society, and more to the point, how is this impacting our health care system?
Some of the identified gaps include:

- 1st vs 3rd world countries
- Private vs public hospitals
- Language barriers
- Culture differences
- Literacy levels
- Gender roles
- Religion
- Doctors and patients

And with these, at times, unacknowledged gaps in our system – it is not the clinician that feels the brunt of this, but rather the patient. And where I want to focus on this gap specifically, is in the consent process.
With so many gaps – How valid is the consent process, and is it achieving its goals?

To start, we need to see where it all began – the evolution of consent.

EVOLUTION OF INFORMED CONSENT

Milestones in Informed Consent. [1]

The dual concepts of 'consent' and 'informed consent' are still evolving. Informed consent is not an ancient concept and the term first appeared in 1957. [2] Let us review this Evolution.

Ancient Times:

Medical ethics developed predominantly within the profession of medicine throughout the ancient to early modern periods. The classic Hippocratic oath obligated the physician to protect the patient from harm and provide medical benefits, and became the primary focus of medical ethics. [2] However no serious thought was given to issues of consent or self-governance by patients, as the main concern was how to disclose information to patients without harming them with abrupt revelations of bad news. [2] The amount of information exchanged with patients by the doctor was up to their prudence and discretion. [2] Withholding information and even outright deception were regularly justified as morally appropriate means of avoiding such harm. The idea was even promoted with emphasis on the principle "First, do no harm". [2]

1800's: Thomas Percival's historic *Medical Ethics* (1803) continues in this same tradition of omissions of truth for the patients benefit. [2] Percival promoted benevolent deception in that the patient had the right to the truth, provided that this truth was not in conflict with that which would help the patient. [2]

The American Medical Association (AMA) accepted the Percival hypothesis in its 1847 "Code of Medical Ethics." [2]

1900: The first documented use of the informed consent process in a research study is seen when written contracts between researchers and participants are used in Walter Reed's Yellow Fever Experiment. [1]

1914: A series of judicial decisions in the early 1900's lay the foundations for the principle of patient autonomy. [3]

Schloendorff v Society of New York Hospital - Mary Schloendorff sued the Society of New York Hospitals for performing surgery on her without prior consent. The treating physician removed a tumour from her abdomen, when she had only consented to a diagnostic procedure. She won the case, the judge ruled that the physician was liable for battery because he violated an "individual's fundamental right to decide what is being done with his or her body." [3] [4] This established that the patient was an active participant in the treatment decision process. [1][3]

Pratt v Davis- Mrs Parmelia J. Davis filed a suit against her surgeon for battery after he performed a hysterectomy without her consent. [3] The physician failed to disclose that he intended to perform a hysterectomy to treat Mrs Davis's epileptic seizures. [3] The surgeon acknowledged intentionally misleading Mrs Davis, and claimed that due to her epilepsy, she was not competent to give consent or to deliberate intelligently about her situation. [3

1932: Bad blood.

The Tuskegee Experiment was conducted between 1932 and 1972 in the Unites States. These studies were carried out on a group of 400 African Americans with syphilis. The men were promised free medical care as an incentive for participation in the study, however were deceived and never informed of their syphilis diagnosis. They were told they were being treated for "bad blood". None of the infected men were treated with penicillin despite the fact that, by 1947, the antibiotic was widely available and had become the standard treatment for syphilis. [5]

The 40-year Tuskegee Study was a major violation of ethical standards. Its revelation led to the Belmont Report as well as laws and regulations for the protection of human subjects in studies. [5]

1947: The Nuremberg trials. This event unquestionably influenced thoughts regarding informed consent. [1] The Nuremberg military tribunals unambiguously condemned the Nazi experiments in their review of "crimes against humanity." [1] The Nuremberg code was developed in response to the trials where Nazi doctors performed unethical experiments during World War II. The code was the first major international document to provide guidelines on research ethics. It made voluntary consent a requirement in clinical research studies, emphasizing that consent can be voluntary only if: participants are able to consent, are free from coercion and can comprehend the risks and benefits involved. [6] The Code requires informed consent for all experiments. It also specifies that experiments must be conducted by qualified personnel, as well as be scientifically necessary. [7]

1957: *Salgo v. Leland Stanford Jr. Board of Trustees*. This is the first time the phrase "informed consent "is used. [1] [3] Mr Martin Salgo underwent a procedure to evaluate the extent of the arteriosclerosis of his aorta. The procedure complicated and resulted in permanent paralysis of his lower limbs. Mr Salgo sued for lack of disclosure of this potential risk. The court found his physicians liable for failing to disclose information that Mr Salgo would need to make an informed decision. [3] This was the first legal case to identify the need to provide the patient with information regarding the potential benefits and risks of any medical procedure. [3]

1964: The Declaration of Helsinki is adopted by the World Medical Association. [6] [3] These are 12 principles to guide physicians on ethical considerations related to biomedical research. It serves to emphasise the distinction between medical care that directly benefits the patient versus research that may or may not provide direct benefit. [6]

1979: The Belmont Report. This report sets forth three principles underlying the ethical conduct of research: autonomy, beneficence and justice. [6] The Belmont Report explains how these apply to research practices.

Now: In the last century, there has been a move from the traditional 'doctor knows best' model of healthcare. [8] The transition over the past decades has been from a paternalistic approach towards a shared decision-making process. [9]

WHAT IS INFORMED CONSENT

So, what exactly is informed consent?

The informed consent process is pervasive throughout the healthcare system. Clinicians and researchers are required to ensure that patients understand the potential risks and benefits that result from the procedures they are offered. These patients are asked to acknowledge their understanding by signing a document—an informed consent form. [1] Informed consent is an ethical and legal requirement. [6]

The essential components of valid informed consent are: [9] [10]

- Competence
- Information
    - Disclosure
    - Understanding and appreciation of information disclosed
- Voluntariness in decision making
- Ability to express a choice

Informed consent can therefore be defined as the process which has occurred when a competent person has received comprehensive disclosure, understands and appreciates the disclosure, acts voluntarily and consents to the intervention. [10]

Competence

Competence refers to the ability to perform a task – which is task and context-specific. The key elements establishing competence are age and decisional capacity. [10]

a) Age

- The age of full legal capacity in South Africa is 18.
- Legally, children of 12 or older may consent to a proposed treatment on their own behalf if they have the maturity to understand the implications of the proposed treatment.
- If the treatment is surgical, the child's consent must be accompanied by a parent or guardian's written assent. [10]

b) Decisional Capacity

The 2 dominant principles of decisional capacity are:

- Adults are presumed to be competent to make decisions – a lack of capacity must thus be demonstrated and documented. [10]
- Minors are presumed to lack decisional capacity – maturity to decide must be demonstrated and documented. [10]

When evaluating decisional capacity, the health care provider must ensure that the patient understands the information provided, appreciates the consequences of the treatment as well as being able to reason about the treatment. [10]

Should an adult lack decisional capacity, the surrogate hierarchy for obtaining consent is as follows: [10] [11]

1) Advance directive
   if there is no advance directive, or it is not clinically relevant one of the following surrogates (in order of precedence) may make decisions on the patient's behalf
2) A proxy mandated in writing by the patient to make decisions on his/her behalf
3) A person authorized by law or a court order
4) The patient's spouse or partner
5) Parent
6) Grandparent
7) Adult child
8) Brother or sister

The National Health Act allows for emergency treatment to prevent either death or irreversible damage to a patient's health, provided the patient has not previously refused such treatment. [10] [11] In these circumstances, the superintendent of the hospital, clinical manager or the person in charge should be informed and may grant permission for the procedure to occur in the hospital without consent. [10] If no surrogate exists or if the patient has never been mentally competent, or if his or her beliefs, values and preferences are unknown, the best interest's principle should be applied by choosing the option a reasonable person would be most likely choose. [11]

Best interest principle

The "best interests" principle dictates that healthcare providers should consider all clinical options which are indicated. This includes considering the patient's previously expressed preferences- including an advanced statement, knowledge of their circumstances, third party contributions and which option least limits future choices, including non- treatment. [10] [11] [12] Should conflict exist between the healthcare provider's opinion and a proxy's opinion, legal

advice should be obtained with a view of applying for a court order. It is imperative that all reasons for providing treatment are documented in patients with impaired decisional capacity. [10] [11]

Regarding paediatric decisional capacity – It is beyond the focus/ scope of this booklet. Refer to HPCSA ruling – reference 8,9,10

Information

According to the National Health Act (NHA) 2003 it is an offence to provide a health service to a user without the user's informed consent. Thus, a patient must have full knowledge of his/her treatment. [10] [11]

As stated in the HPCSA guidelines and according to NHA - Every healthcare provider must inform the patient (user) of: [12]

a. The user's health status. (except in circumstances where there is substantial evidence that the disclosure of the user's health status would be contrary to the best interests of the user) [12]
b. The range of diagnostic procedures and treatment options available [12]
c. The benefits, risks, costs and consequences associated with each option [12]
d. The user's right to refuse health services and an explanation of the implications, risks and obligations of such refusal. [12]

The healthcare provider must (where possible) inform the user in a language that the user understands and, in a manner, which considers the user's level of literacy. [10]

The exceptions to this rule are: [11]

- an emergency where delay would result in the death or serious harm to the patient,
- when mandated by law or a court order, or
- where failure to treat the patient would result in a serious risk to public health. If the patient lacks capacity, and a proxy or family member is consenting on the patient's behalf, that person must be given all the necessary information to give informed consent. [11]

When providing information, health care practitioners must do their best to find out about the patients' individual needs and priorities. A patients' beliefs, culture, occupation or other factors may have a bearing on the information they need in order to reach a decision. [12] Health care practitioners should not make assumptions about patients' views but discuss these matters with them and ask them whether they have any concerns about the treatment or the risks it may involve. [12] These are important considerations as each patient will take a different view on the implications of the risks and benefits, depending on his or her personal priorities. A patient who earns his living playing piano, is likely to place greater significance on a risk of brachial nerve damage, no matter how small that risk might be. [11]

The HPCSA has indicated the following as the minimum information a patient requires before they are in a position to provide informed consent: [10] [11]

- Details of the diagnosis, and prognosis, and the likely prognosis if the condition is left untreated.
- Uncertainties about the diagnosis, including options for further investigation prior to treatment.

- Options for treatment or management of the condition, including the option not to treat.
- The purpose of a proposed investigation or treatment; details of the procedures or therapies involved, including subsidiary treatment such as methods of pain relief; how the patient should prepare for the procedure; and details of what the patient might experience during or after the procedure, including common and serious side effects.
- For each option, explanations of the likely benefits and the probabilities of success; and discussion of any serious or frequently occurring risks, and of any lifestyle changes which may be caused or necessitated by the treatment.
- Advice about whether a proposed treatment is experimental.
- How and when the patient's condition and any side effects will be monitored or re-assessed.
- The name of the doctor who will have overall responsibility for the treatment and, where appropriate, names of the senior members of his or her team.
- Whether students will be involved, and the extent to which students may be involved in an investigation or treatment.
- A reminder that patients can change their minds about a decision at any time.
- A reminder that patients have a right to seek a second opinion.
- Where applicable, details of costs or charges which the patient may have to meet.

Voluntariness

Any coercion in obtaining consent, whether overt or covert, invalidates the informed consent process. [10] All patients should be asked whether they have any misgivings about their treatment, before proceeding. Patients that are incarcerated, detained by police or immigration services may be particularly vulnerable and should be informed that they may refuse treatment if they so wish.

Under the Mental Health Act 2002, involuntary and assisted mental health care patients do not lose their right to consent to treatment for illnesses other than mental illnesses, except where "a mental health care practitioner deems a user to be incapable of consenting to treatment or an operation due to mental illness or intellectual disability". [10] In these cases, a court-appointed curator or a family member may consent on the patient's behalf. If none of these people are available, the head of the institution may grant consent. [10] [11]

THE NITTY GRITTY OF CONSENT – WHO, WHAT, WHEN, WHERE AND WHY?

Who should take consent?

Consent is a process centred on the discussion of the proposed treatments benefits, side effects and potential complications, and as such the person who takes consent must be able to disclose all the necessary information to the patient. Ideally the person taking consent and the person providing the patient's care should be one and the same. [11] Since this is not always feasible, obtaining consent may be assigned to others providing that they are adequately qualified and trained and have appropriate knowledge of the proposed investigation or treatment, as well as understand the risks involved. The person taking consent should also be compliant with the HPCSA's guidelines. [11]

The doctor who delegates responsibility for obtaining consent still remains responsible for ensuring that their patients have been given sufficient time and information to make an informed decision before undergoing treatment. [11] They also need to ensure that their consent to proceed is valid. [11]

When should consent be taken?

Regarding elective procedures, consent is often taken in the outpatient department weeks or months prior to the admission for surgery. There is no specific time limit on consent taken in advance. [11]

In this time period patient's may have more questions that arise, new information about the procedure may arise or their condition may change in the interim. Therefore, it is good practice to confirm consent prior to the procedure. And this confirmation should be documented in the patient's medical records. [11]

According to the MPS supplement as a general principle of good practice patients should be given plenty of time to think about their options before they consent, if the treatment is not urgent. They should also be encouraged to ask further questions. [11]

It's not just about the form

"Please sign here "- the intricacies of consent for medical treatment can be embodied in these three words. However, high-quality informed consent requires much more than a piece of paper to sign. [4] The signing of a consent form does not in itself constitute actual consent – its role is mainly evidentiary. [8]

Although this process of patient-physician communication involves much more than getting a patient to sign a written consent form, it is the very formality and finality of that signed document that distinguishes full informed consent from the routine patient education that occurs in nearly every clinical encounter. [4] Still it must be kept in mind that the signed consent form is rendered completely ineffective if the patient is not capable of understanding it. [4] This fact is poorly recognised by many healthcare professionals. [4] The consent form is but a part of the process which should include helping the patient achieve a better understanding of the procedure and its implications as well as the risks and other alternatives. [8]

ANAESTHESIA AND CONSENT

Do we need anaesthetic consent?

The attainment of informed consent from the patient is a constitutionally protected right in South Africa. [7] South African law (National Health Act No. 61 of 2003) - specifies that informed consent is required prior to performing any procedure on a patient. [13] In state hospitals in the eThekwini municipality, the existing practice of consent in anaesthesia is often an informal interaction between the patient and anaesthetist. [6] Often a single consent is obtained by the surgeon, giving the patient the false impression that anaesthesia and surgery are indistinguishable. [14]

While it is not the task of the anaesthetist to acquire surgical informed consent, it is the duty of the anaesthesia provider to ensure that consent is legally valid for both the administration of the anaesthetic and the performance of the surgical procedure. Consent that is taken inappropriately or incorrectly is legally indefensible - therefore, anaesthetists are expected to be familiar with the laws governing informed consent. [1] [7] Through being "familiar with the law" doctors can ensure that they are performing their jobs correctly, providing quality service to patients and potentially avoid unnecessary litigation from incorrect consent taking practices. [7]

Naidu et al feel that informed consent in anaesthesia is an absolute necessity. [14] Their support of it was that it allowed doctors and patients the opportunity to discuss, evaluate and agree on

the best possible management for the patient, as well as increase patient awareness of anaesthesia as a discipline. [14] Majority of the patients surveyed in their study felt that a written consent on a standardised anaesthesia-specific consent form would improve the current consent process. [14]

Anaesthesia and the law

So how familiar are we as anaesthetists with the law? A questionnaire done in 2018 amongst South African anaesthetists by Mamoojee et al evaluated their knowledge of informed consent laws and found the following: [7]

- 167 participants were included, and the average score was 60% - indicating suboptimal understanding of consent laws, and further implying that in only 6/10 situations is legally valid consent being obtained. [7]
- The highest and lowest scores were on questions assessing the Mental Health Care Act and the Children's Act - achieving 88.92% 51.82% respectively. [7]
- Other trends: A decreasing knowledge in Choice of Termination of Pregnancy Act with increasing years after graduation.
- Overall scores improved with higher professional designation and attendance at formal training on consent. [7]

Table 1: Mean score by law tested [7]

Question	Law tested	Mean score % ± SD
1	The Choice of Termination of Pregnancy Act No. 92 of 1996.	71.26 ± 35.74
2, 6, 7, 8, 10	The Children's Act No. 38 of 2005.	51.82 ± 17.84
3, 5	The National Health Act No. 61 of 2003.	59.52 ± 21.84
4	The Mental Health Care Act No. 17 of 2002.	88.92 ± 22.23
9	The Sterilisation Act No. 44 of 1998 (amended 2005).	64.67 ± 26.31
Overall		60.08 ± 12.61

What was concerning out of this study is that anaesthetists scored lowest on questions assessing knowledge of the Children's Act and the National Health Act. [7] This could be due to inadequate training at an undergraduate level; lack of a formal subject on ethics and medical law in undergraduate curricula; no requirement for certification in ethics and medical law for doctors; and lack of continuing education on the law during the postgraduate phase. Mamoojee felt that there was also a lack of interest in the subject matter. [7]

Factors affecting questionnaire performance included years after graduation from medical school, professional designation, years of anaesthetic experience and attendance at formal postgraduate training on informed consent. [7] What was also seen was that the knowledge of more junior staff was poorer than that of their senior counterparts, which is particularly problematic as it is the junior doctors that are often tasked with obtaining consent. [7]

BARRIERS TO INFOREMD CONSENT

At the heart of it – informed consents' noble intentions are to respect and protect the patients right to autonomy. Its additional challenge is that it is a legal process as well as a clinical one. [8] Yet despite its noble intentions – it remains flawed and is difficult to get right. The following act as barriers to our current consent process:

1. The changing relationship between physician and patient
2. Lack of clinician time
3. Physician concerns about giving too much information
4. Stronger legal implications
5. Language barriers
6. Health literacy
7. Clinicians inability to detect patient's lack of comprehension
8. Cultural issues, religious influences and ethical principles
9. Situational factors: stress, timing
10. Poor quality of consent form and related educational materials
11. Patient perceptions
12. The hierarchy of ethical pillars
13. Vulnerable populations

The changing relationship: Does Dr know best?

Modern medicine is seeing a shift from the "good old days "where medical paternalism was a prominent practice. [4] The doctor- patient relationship has evolved. Patients were often considered to be too ignorant to make decisions on their own behalf and so doctors learned to become comfortable with making these decisions for them. [15] Today patient-centred care has replaced the doctor-dominated relationship. Responsibility now lies with the doctor to "understand the patient as a unique human being" and doctors are now required to fulfil both a technical expert and supportive interpersonal role. [15]

The patient profile has changed as well. Medicine has become more option-filled and complex, with patients now having more choices. [4] In addition to this, information is now readily available at their fingertips, and patients are expecting more choices. We now have the development of information saturated, but knowledge starved patients. [16]

The modern therapeutic relationship is currently defined by shared decision making between the doctor and patient. This has shifted the health care framework away from the traditional paternalistic model, yet some still argue the paternalism of the current consent process. [8] Also given the dual role of consent as a legal requirement between doctor and patient, the process can also be seen as harmful to the therapeutic relationship. [17]

And so further evolution is required of the doctor, in that they are ideally situated to bridge the gap between medical expertise, the legal requirements of consent and the protection of the autonomous needs of the patient.

Lack of clinician time

Modern medical practice places financial pressures on doctors to keep visits short and turnovers high. This further impacts the time spent consenting patients. Given more time for informed consent, it is likely clinicians would spend more time explaining the procedure, its benefits, its potential complications, and alternative options. [4] Although the apparent lack of time may also just reflect the perceived priority of informed consent. [4]

Physician concerns about giving too much information

How much does one tell the patient? Do physicians need to mention all possible risks, including the incredibly rare ones that can lead to unnecessary worry? Or just stick to the common ones? Should they utilise the professional standard of risk or "reasonable person" criteria?

The "professional standard," is where physicians are required to inform patients only of the risks and benefits of a procedure that another *physician* would find reasonable. [1] Whereas the notion of "reasonableness" indicates that the physician discloses information on benefits and risks that a "reasonable person" would want to know. [1] The Association of Anaesthetists of Great Britain and Ireland (AAGBI) advocate that patient should be informed of all material risk. [2] A material risk is one that a reasonable person in the patient's position would regard as significant. Universally, this is thought to be an incidence of 1%. [14]

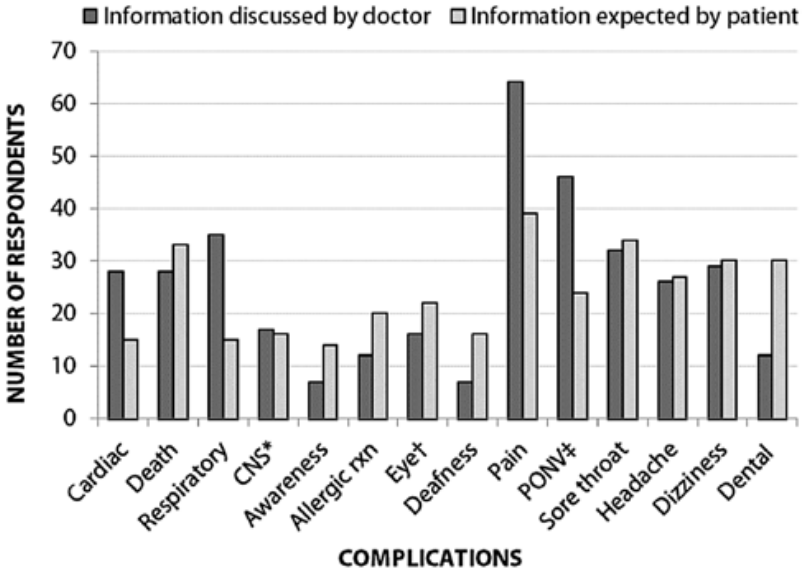
Whether one relies on the "professional standard" or the "reasonable person" criterion for informed consent, the difficulty of how much information to share with patients to fulfil the obligation of informed consent remains controversial. [1] Often robust and exhaustive explanations can cause patients to 'switch off' or unnecessarily scare patients and impede the consent process. [4] [8] However, simultaneously not providing such information may be deemed negligent consenting practice. On its own, an overly generic consent form without any significant accompanying education (such as the quick request for a signature while the patient is on the trolley) is not adequate. Alternatively, an exhaustive list of all the potential risks may be difficult for patients to understand. Thus, creating a "Catch 22" situation for clinicians. [8]

But what do patients want to know?

There is a disconnect between the patient and doctor and what either consider to be a significant risk. A 1996 questionnaire administered to patients in New Zealand highlighted the incongruities between levels of importance and weight given to the various aspects of consent by patients versus their treating clinicians. [18] The greatest divergence between patient and doctor were the importance of technical details of the procedure, cost to the country, qualifications of the doctor, experimental and non-conventional treatment options and whether the doctor would have the procedure if they were in the position of the patient. [18] Patients were more concerned with outcomes, that is quantity and quality of life, while doctors were more concerned about "process" including the general nature of the procedure and consequences of the procedure. [18]

In a study of obstetric patients, Patee et al. found that patients wanted to be informed of all complications associated with epidural analgesia including the low-risk ones. [19] A Perth study showed that their patients wanted to be informed about the risks of postoperative nausea and vomiting and postoperative pain. [20] Whereas the most pressing concerns for Canadian patients were awareness, CNS complications and death. [7]

In our own patient population at Inkosi Albert Luthuli Central Hospital (IALCH), Naidu et al showed that patients were most concerned about postoperative pain, sore throats and death. [14] Of the IALCH patients - 97% were satisfied with the pre-anaesthetic interview, and 79% did not wish to be given any more information during the preoperative interview than what had already been discussed with them. [14] The decision to continue with surgery and anaesthesia for 92% of patients was not dependent on the amount or depth of information that was imparted to them in the preoperative interview. [14]



*CNS (central nervous system): refers to problems with concentration and memory. †Eye: includes blurred vision and temporary or permanent blindness. ‡PONV: refers to postoperative nausea and vomiting.

Figure 1: Information disparities between doctors and patients in IALCH – for General Anaesthesia

More legal and less medical

Society has also become more litigious. The face of informed consent is changing, and its strict and legalistic regulation has led to a shift from prioritizing patient protection to protecting institutions and providers. [1] The purpose of consent forms is often unclear, and patients frequently perceive them as a form of legal protection for hospitals and treatment centres rather than as a source of information. [4] One of the issues is that the consent process has become more complex and driven by institutional concerns, with less focus on helping the patient get the information they need. [1] Currently informed consent forms seem to be designed to authorise treatment or serve as a liability waiver rather than clarify information or aid patients in decision-making. [4]

Lost in translation – language barriers

South Africa is a linguistically diverse country with 11 official languages, and patients and doctors seldomly share the same first language. [21] Most South African studies have highlighted language as a major barrier to effective healthcare delivery. [9] In a 2001 survey administered to healthcare providers - 73% said that a patient's understanding of treatment advice was the most compromised aspect of care due to language barriers, and 71% said language issues complicated their patients' ability to explain symptoms and concerns. [4]

Despite this diversity English remains the prevailing language of communication within the public sphere. It is often used as the main language for imparting health education in primary health care facilities. [22] However, many patients may lack the ability to comprehend what they hear or read because the average person's actual English comprehension level is five grades below that of the highest level of schooling achieved. [22]

It has also been shown that both patients and staff who have identified themselves as being reasonably fluent in a second language are not always as proficient as they believe, and the

communication disparity between doctor and patients may be underestimated. [23] Compounding this problem is the trend of doctors to be less likely to check the patient's level of understanding if they perceive the patient to be adequately fluent in English. [23]

Misunderstandings can also occur due incorrect or inadequate language translations. Medical translation should be undertaken by trained professional interpreters, however they are not readily available in South African public hospitals. [21] This results in a reliance on translation by staff, relatives, and other patients- who serve to act as untrained interpreters and cultural brokers when necessary. [9] [21] This unofficial translation has been shown to be of poor quality due to misinterpretation, omissions, time pressure, and resentment. [21] The end result is an individual who signs the consent form without being fully aware of what they are signing. [6]

Health literacy – What did the Dr say?

Health literacy refers to the ability to read, understand, and act upon health information to make appropriate health decisions. [4] A person's literacy levels influence one's ability to access information and function in the modern world. [22] A general household survey conducted in South Africa in 2015 found that 7.1% of South Africans were illiterate. [24]

There is often a discrepancy between the patient's highest level of schooling obtained and their literacy level. [1] Health education materials are often written at a higher degree than the patients understanding, and the actual school grade achieved does not accurately reflect a patient's ability to understand written health education materials given to them. [22] These findings were supported in a local study done by Naidu and Gopalan – they found that there was a statistically significant correlation ($p = 0.003$) between the highest level of education achieved by patients and their desire to know all the complications associated with their anaesthesia. [14]

Janse van Rensberg conducted a study assessing the health literacy of South Africans in 2020 and found that although the majority (89.5%) of the respondents declared a grade 11–12 level of schooling, only 42% of the respondents scored at this level in a comprehension test. [22] Most research on this matter concurs that patients' comprehension levels are usually 3-5 grades lower than their word recognition levels when confronted with health information. [22] In Naidu's study the highest level of education in 50% of patients sampled at IALCH was primary school. [14] This reflects a population with inadequate knowledge and means that although patients may be able to read and pronounce commonly used medical terms, they might not be able to comprehend the meaning of the words. [14] [22]

However, defined, health literacy is in short supply. [4] Individuals with low or limited literacy skills have poorer health outcomes and are less likely to seek preventive care or to comply with prescribed treatment. [4] It stands to reason that if patients cannot understand the information they are reading, the primary purpose of the form is completely undermined and negated. [4]

What we are left with is a law stipulating an unachievable level of understanding on the part of those patients who in reality, lack capacity. And the lack of capacity (one of the fundamental features of consent) surely results in an invalid consent?

Clinician inability to detect patient's lack of comprehension

So, what constitutes understanding? This question stands at the crux of the ever-evolving definition of informed consent. And is essential to ensure that the "permission "we receive is truly valid. [1] Falagas et al conducted a systematic review that looked at the extent of patients understanding of different aspects of the informed consent process. [16] The findings from the review indicated that a significant portion of patients may not actually comprehend the risks of the proposed surgery. [16] This was attributed in part to potential emotional factors as well as dependant on the degree of risk associated with the procedure. [16]

Sometimes even a clear consent form and a careful explanation of the procedure will not be enough for a patient to fully comprehend the situation. Clinicians may have trouble believing that the patient does not understand after having spent ten minutes describing the procedure to a patient who appears alert and nods. [4] Currently there is no established method to measure the level of understanding that a participant has about the information given. Thus, it must be assumed that there is a degree of misunderstanding that occurs. [6] It has been shown that many patients, despite extensive efforts, remember or understand little of what they agree to during the consent process. [11] Problems with the current process of consent is that it fails to highlight any of the patient's ignorance; and only serves to affirm the clinician's provision of information. [17]

Cultural issues, religious influences and ethical principles

Beyond language, cultural issues will also affect a patient's understanding of the consent process. Culture-specific models of disease affect how illness is understood by many South African patients. [9] In culture- bound syndromes, terms used to describe symptoms do not always have an easy translation or English equivalent. [9] In other instances set cultural norms and practices may impact the assessment of adequate consent. For example, the cultural reticence in Xhosa patients to question authoritative figures in lieu of it appearing disrespectful may limit the correct interpretation of a patients understanding. [4] [21] Or else a patient shared core belief may rule out proposed treatments, such as administration of blood products. [4]

As it stands there is an increased need for diversity training and cultural awareness in health care workers. [9] Internationally, a large body of literature has been devoted to cross-cultural challenges faced by healthcare professionals. [9] However majority of it is based in first world countries, practising Western ethics. In a systematic review of the literature on cultural competence training for Healthcare Professionals - Chipps et al questioned the relevance of international literature for use in the SA context. She argued that "African people form the majority of the population but most health care professionals (including African health care professionals) have been trained in Western traditions of helping" [1][25]

Western vs Eastern ethics

International guidelines regarding the rights of human subjects are criticized for the priority they place on Western cultural values. [26] The ethical dilemma emerges from the argument that there are fundamental differences about the concept of respect for the autonomy of individuals in different cultures and religions. [26] In countries like India, disease is perceived through social values and power hierarchies based on cultural systems. [6] It is challenging to get a meaningful and ethical informed consent in these settings because of the differences in cultural values in western countries and local customs. [6]

Ubuntu ethics – The African narrative

Ubuntu is defined as the African worldview or perspective of life. Ubuntu ethics conceptualises fundamental human rights in the context of communal rights. According to its philosophy, human rights can only gain meaning in the context of the society in which the individual is living. Essentially - community takes precedence over the individual. [26] Ubuntu ethics deems moral maturity as the ability to consider both community rights and individual rights during the decision-making process. A decision that does not consider communal good and well-being would be unethical. [26] Thus the decision-making process is a collective process rather than an individualistic one. [26]

Contrasting that is liberal individualism, which is a rights-based ethical theory which advocates for the individual. [26] It promotes individual autonomy, and voluntariness of the individual, and overrides the influence of communal interests. This means that individual rights and freedom take precedence over communal well-being and societal norms. [26]

Currently the liberal perspective dominates international guidelines and ethical codes, in fact, giving counsel to the individual during the decision-making process to consider the opinions of the community or to prioritise community well-being above themselves would be considered coercive. [26] Another point of difference between the two theories is in the disclosure of information. In Ubuntu philosophy, disclosing information to the patient about how advanced their cancer is, instead of telling the relatives, would be considered offensive and rude behaviour that could impact the patient's willingness to survive, while in Western culture, it would be regarded as showing respect to the autonomy of the patient. [26]

However, it should not be unexpected that the Western ethical perspectives dominate, since the first few international guidelines on this matter (such as the Nuremberg Code, Belmont Report and Declaration of Helsinki) were either published in Western countries, or written by predominantly Western scientists. [26] Erich Loewy warns against ethical imperialism as one of the dangers of global development of bioethics. Ethical imperialism leads to the tendency "to regard itself as the proper standard for ethical norms and disregards cultural differences and condescend nations whose culture and ethical norms are different". [26]

Situational factors: stress, timing

The temporal relationship of consent influences the process. Factors such as emergency situations, strong emotional influences and the risks inherent to the procedure itself all limit the patient's ability to fully comprehend the medical content and their choices related to it. [4] An excellent example of this is consent in the labouring woman.

In the setting of state hospitals in South Africa, the patients are poorly informed and emotionally unprepared for labour. [27] The limited antenatal education most patients receive, and often emergency hospital presentations further compound the issues of patient autonomy and competence. [27] Often these patients first encounter the anaesthetist under time sensitive circumstances and during emotional distressing periods, and very little time for explanation is available. [2] [27] It must be noted regarding capacity that it is now accepted that neither severe pain nor the prior administration of sedatives and/or opiates invalidates consent. [27]

A key issue is that consent is often seen as a singular event, and not the 'process' of gradual transference of information from surgeon to patient. Consent that is only obtained immediately prior to the planned intervention results in patients having inadequate time for comprehension of the provided information, and results in patients being unable to give truly 'informed consent'. [16] It is essentially consent under duress. Additionally, the, at times hasty, disclosure of benefits, alternatives, risks and complications may be construed as 'talking down' to the patient. [17]

Poor quality of consent forms and related education materials

Most consent forms are too complex for patients. The forms can be difficult to read and the wording may confuse some patients. They are often written at a level requiring a high school education. [4] Furthermore, the quality of the information is highly variable, often missing key elements and at times being simply too generic to be of any value. Additionally, the emphasis on written documentation may undermine the importance of verbal communication between the patient and the practitioner. [4]

Patient Perceptions

Most patients may enter the consent process with preconceived ideas of their anticipated treatment and reluctance or fear for alternative options. [6] Convincing and receiving an informed consent from such patient is most difficult. [6] One challenge to be kept in mind is that patients often receive a plethora of information from various sources, including friends, family, and other healthcare professionals. [3] They can have poor recall as to what they've been told about the potential risks and benefits of a procedure which can cause further confusion regarding their surgical procedure. [3]

The hierarchy of ethical pillars

The word autonomy is derived from the Greek words 'autos', meaning 'self' and 'nomos', meaning 'governance' or 'rule'. [28] Since the release of The Principles of Biomedical Ethics in 1977 by Beauchamp and Childress, autonomy has been widely accepted as one of the four principles of medical ethics together with the principles of beneficence, non- maleficence, and justice. [4] And of the four pillars, autonomy has arguably become the 'principal principle', and one that carries the strongest influence in Western medicine. [28] [29] But has the flawed concepts of autonomy and the false elevation of them above the other pillars not been to medicines detriment? Many ethical questions are now answered foremost with what the patient wants, and not necessarily what the physician or community believe is *best*. [28] [29]

The medico-legal focus of healthcare organisations can wrongly equate the minimum standard of disclosure to the higher ethical standard of respect and understanding. [28] At the centre of these shortcomings is the loss of attention to the individual patient and their vulnerability, as well as to a minimisation of the interdependent nature of healthcare. [28] We need to gain a better understanding of the gap between the ethical intention and practical reality of informed consent. [28]

Vulnerable populations

Vulnerable groups are 'social groups who experience limited resources and consequent high relative risk for morbidity and premature mortality' – they include persons who are incapable of protecting their interests. [6] [30] Defining and analysing vulnerability is a difficult task. There is no clear understanding of vulnerability in the academic literature, yet the concept is important because of its implications for health. [30] The two major classes of vulnerability are: "illness vulnerability" and "access vulnerability". [4] [30] Vulnerable groups include women, children, the aged, ethnic minorities, displaced people, mental health care users and people with disabilities. [4]. [30]

There is a clear connection between informed consent and vulnerability. For a choice to be autonomous three conditions must be met - a person must act with *intention*, with *understanding*, and *without controlling influences.* [29] One of the keys aims of informed consent is the protection of a patient's autonomy. However, its ability to do so becomes strained in the

context of the vulnerable population, since being able to effect autonomous choices may be limited, yet remains a prerequisite for informed consent. [31]. It is also this vulnerable population that are most at risk for abuse and exploitation, and need this right to autonomy and protection safely guarded. [31]

One if the issues in considering a vulnerable population is that vulnerability is often attributed to social groups on the basis of common attributes – e.g. age for children or income for poor people. [31] These are static categories, and vulnerability can vary with context, including social and cultural systems and political and economic trends. [30] [4] Additionally, not all members of vulnerable groups are the same or in need of the same kind and extent of protection. Thus, a group-specific labelling of vulnerability, that does not consider individual differences essentially ranks the principle of non-maleficence higher than autonomy, justice and beneficence. [31]

The best approach currently advocated in dealing with consenting a vulnerable population is to consider vulnerability context-sensitive and relational. [31]

Table 2 The failings of consent [5]

- The law stipulates a level of understanding from patients that decades of research have shown to be impossible to achieve consistently
- Consent forms are not robust documents in a court of law4
- Current consent fails to pick up on patients lacking capacity11
- Consent as it stands remains paternalistic by placing patients in a permissive/passive role
- Listing large numbers of risks to patients immediately before an operation is inhumane, counterproductive, stressful, and is rarely well-informed
- There is no pressure on the system to facilitate excellence in communication or information provision: constructive dialogue is often lacking
- The context of 'consent' in law, such as the age of consent (to sex) and the criminality associated with lack of consent in this context is inappropriate in the doctor–patient relationship
- Consent is usually a one-off episode rather than a process of recurrent interaction and mutual understanding

At this point in time it can be seen with all the above-mentioned barriers that current consenting practice does not achieve its goals, and is failing both doctors and patients. [5]

BUT DO WE REALLY NEED CONSENT?

There can be absolutely no question as to whether we need consent or not. History is littered with atrocities done "in the name of science". The Nazi war experiments and Tuskegee trials are just the tip of this heinous iceberg. By ensuring legitimate informed consent, we can make a stand against these injustices, through providing sound and fair care - with permission. [3]

Although consent is a moral, ethical and professional duty as well as a legal one, there are also a number of benefits gained from the consent process. For the patient, these include an expression of autonomy, as well as allow them to make an informed calculation of the best course of treatment for themselves. [8] The chances that the treatment will succeed are also

increased due to better co-operation. [8] However most significantly it provides the infrastructure for dialogue and communication between doctors and patients and conveys respect for the patient by the medical profession. [8] As a legal obligation it can also serve as evidence for defence against litigation in trespass and negligence. [4][8]

But are we going too far with these "elaborate requirements" for informed consent? Is the promotion of the hierarchy of personal autonomy and personal rights not just overemphasised, or a hallmark of newer generation? On the contrary, these changes should be regarded as a reaction to human rights violations, negligence of individual autonomy, and sacrificing the individual for the good of the society. [26] The afore mentioned breaches of patient autonomy and disregard for the rights of individuals to determine their own fates occurred not too long ago. Hence it is credible to say that the emphasis on individual rights and respect for autonomy is never enough when talking about human subjects. [26]

GAP COVER

So, some of the flaws of our "informed consent" have been revealed. And the gap between patient and doctor seems to be getting wider and wider. So how do we bridge that gap? Or in medical terms – do we have gap cover? We can attempt to tackle these issues in some of the following ways:

Understanding the law

The 2018 Mamoojee study showed that the knowledge of anaesthetists regarding South African laws pertaining to consent is suboptimal. [7] Some of the causative factors raised were attributed to inadequate training at an undergraduate level; lack of a formal subject on ethics and medical law in undergraduate curricula; no requirement for certification in ethics and medical law for doctors; and lack of continuing education on the law during the postgraduate phase. [7]
Some concerns about the impact of years of experience and the concerns of junior doctors adequately performing the consent process were answered by the study by Zajdel et al. where they found that younger doctors had better knowledge of medical law than their older counterparts. [7] This suggests that years of experience as a sole factor does not maintain or improve knowledge of medical law, but that more formal education such as specialisation or postgraduate course attendance is necessary to achieve this. [7] Concerted efforts to address and correct these may improve the legalistic aspects of the consent process and improve its validity.
The Mamoojee study highlighted the deficits in knowledge of consent by anaesthetists– and so keeping ourselves educated and updated on these practices would be a start to bridging this gap.

Understanding the comprehension barrier.

The uni-faceted consent process of issuing verbal information and signing a document should become a thing of the past. Medicine is advancing, and medical treatment options are growing, and the way we impart information to patients should evolve as well. Our population has increased access to multimedia – and the sharing of information should make more use of this. The use of written material or audio-visual media may help overcome comprehension issues, and serve to increase the patients understanding of the information provided. [16]

However sometimes it's just a matter of how nothing becomes real until it is experienced. Even when something is explained comprehensively, it is only until one actually undergoes the

experience that true understanding occurs. This is much like my experience with the Drak Challenge mountain bike race – every year I enter, I read about the 50 km course, I see pictures of technical track and hear stories of people who have been injured. But its only when I'm actually hurtling down the gravel track clocking 40 km/hr – that I truly comprehend the risk – despite my best research. Perhaps it is the same for our patients – and the true comprehension of the procedure only occurs to them during or even after the surgery. So how do we improve this?

A novel idea has come out of Cape Town from a registrar MMED by Jess Purcell Jones et al. They conducted a study where they used a spinal anaesthesia information video in the context of a language and cultural barrier. [21] Their study demonstrated the novel use of smartphones as a display medium for patient information videos, and for utilizing videos to bridge the doctor–patient language barrier. [21] It also introduced a novel use of cellular telephones to distribute such information videos. [21]

Their research found that an appropriate information video may bridge both language and cultural differences, with the potential to reduce patient anxiety and increase satisfaction. [21] With the almost complete penetration of cellular telephone ownership among health care workers, even in developing countries, such videos may be used worldwide to over- come disparities in doctor–patient communication. [21]

Other ways to overcome comprehension issues include providing information about risks along with information on how to cope with them postoperatively. [16] As well as ensuring the presence of a person trusted to the patient during the informed consent process which may support the patient emotionally as well as aid the patient in understanding the information provided. [16]

Understanding the culture

South Africa is country rich in diversity and culture. Experience thus far has shown that we will encounter patients of various backgrounds and diverse cultural norms and ethical values, and we as doctors have to learn to work with and respect such diversity. [26] This requires developing a set of academic and interpersonal skills that allows us to increase our understanding and appreciation of cultural differences and similarities within, among, and between groups – a concept called cultural competence. [26] Cultural competence has been advocated as an organizational strategy to reduce inequalities in healthcare which may result from racial, ethnic and language differences. [9] The aim is to improve health outcomes through reducing cross-cultural misunderstandings by improving healthcare professional's competency to deal with issues related to culture and their patients. [9] The Cross framework is a framework that describes six main positions in developing cultural competence and is measured on a continuum ranging from cultural destructiveness to cultural competence or proficiency. [9]

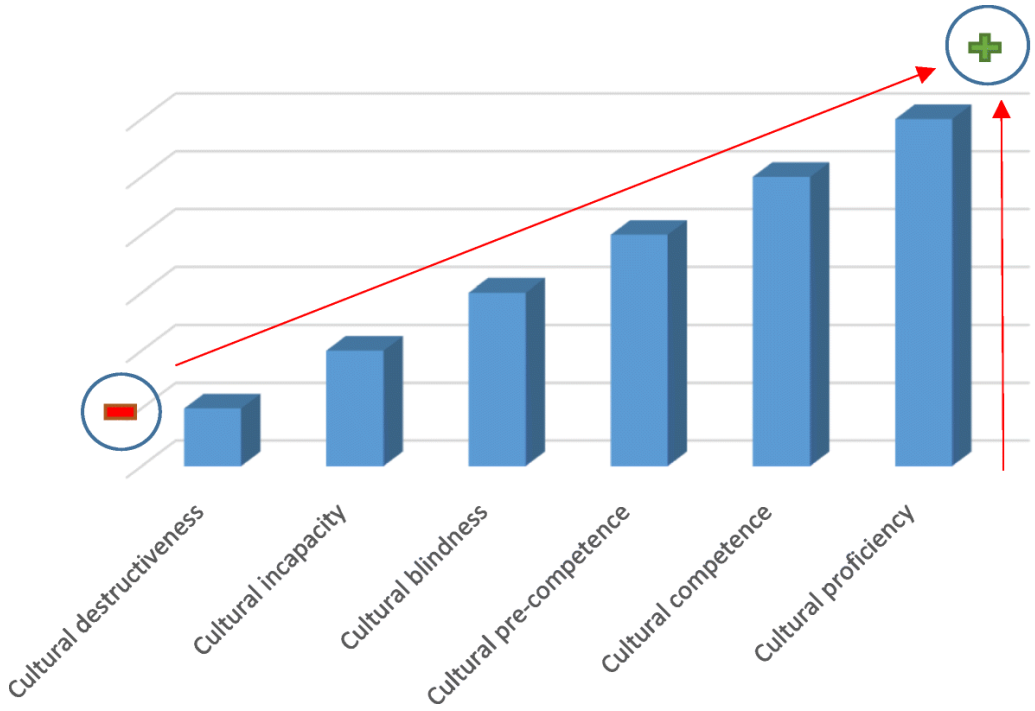


Figure 2: Cross Framework of Cultural competence [9]

Literature in the South African context on cultural competence is however limited, and there is little evidence on how best to train medical students to provide culturally competent care. [9] Training should be directed towards knowledge about culture (facts and cultural traits), specific skills (behaviours), awareness about self and others, and the development of cultural intelligence. [9] Increased emphasis on intercultural communication, multiculturalism and communication ethics in basic communication courses should be encouraged to maximise effectiveness of health care workers in resource-challenged environments. [9]

By learning about the cultural differences and significance in our population we can learn to appreciate them more and tailor our clinical approach with them in mind. Whilst much emphasis in SA is placed on African culture, through prioritising cultural competence in the sphere of healthcare would also allow deeper exploration of additional cultural issues, for example those related to gender roles, religion and sexual orientation in health. [9] We need to cultivate cultural competence and deliberately emphasize it. [9]

Understanding the ethical differences

By revising the decision-making procedure, is it possible to reconcile the differences between Western and Ubuntu ethics? Does emphasizing individual rights and autonomy necessarily demand one particular type of decision making? Is family-facilitated decision making antagonistic to individual autonomy? Or is it an inexorable feature of the decision-making process, since human beings are social beings? Are individual rights breached when involving people within the social network of that individual? [26]

The informed consent process can be more inclusive by embracing values such as interpersonal dependency in communities, ensuring reciprocity of care and by respecting the communal decision-making procedure. [26] This would also serve to silence the critics lamenting the ethical imperialism and Western standards. Sensible ethical considerations can also be practiced through inclusion of local scientists in research and development, consultations with community leaders prior to interacting with the community itself, and respecting cultural and religious norms. [26]

We as practitioners need to remain mindful of the fact that the ethical principles we practice may run contrary to the deepest values of our patients and their families. As such a better understanding of how information is handled needs to be developed. We need to grow an appreciation of our patients' beliefs and values of individuals and their families, and their cultural heritage, life experiences, and social relationships.

Understanding the language

Most medical schools have implemented basic communication skills training to address issues of non-concordance in language. [9] But is it enough? Most of the South African indigenous African languages are concentrated in specific provinces or regions. And the current training program may involve health care professionals changing regions multiple times. This level of multi-lingual mastery is a challenging ask.

We need to explore ways in which to address these. However, the proficiency of more than one official language should be considered a requirement for health care professionals. [9] Provision of post-graduate communication skills training should also be an ongoing process, and not a static offer that occurs in medical school only. Through enabling better communication this will help facilitate some cross-cultural understanding and help foster respect for the culture of patients. [9]

Understanding the consent form

Although the research on improved consent forms has been mixed, some studies have found that when consent forms are improved, patients are more likely to read and understand them before signing. [4] Using a consistent template as a starting point for various procedures also appears to improve consistency and quality in the forms. [4] Through providing *clear* and *simple* information, patient anxiety levels will lower and understanding, and recall will improve, ultimately producing a more deliberative decision-making process. [4]
Adjustments to the form also need to be considered to allow for the integration of the patient's core beliefs that shape their response to accept or refuse treatment – e.g. the refusal of blood. [4]
Essentially, we need to find a balance between contextualising and standardising the consent forms.

Other ways in which the consent forms can be improved is by: [4]

- Recognising the differences in education or literacy levels and provide more help to patients with less education or low literacy.
- To ensure thoroughness in content and consistency in language, employ a consistent outline or template when starting to create informed consent forms for different procedures.
- Use lower reading levels, better formatting, graphics, shorter lengths, and remove unnecessary material.
- Use consent forms as an outline for discussion with patients (e.g. to ensure that all key information about risks and benefits is presented).
- Give patients information or fact sheets that can be taken home. Consider use of multimedia formats (e.g. webcasts, podcasts, DVDs) along with written information to bolster understanding
- Use a "teach back" method in which patients are asked to repeat back the information that has been presented to them.
- Make sure patients are given an opportunity to decline procedures and are aware of their right to do so.
- Consider the Request for Treatment approach

Understanding there are other ways to consent

Once we acknowledge the faults of the informed consent process, we can start to change it - from a 'I consent to...' to a 'I request... [8] In their article "Request for Treatment: the evolution of consent" author Shokrollahi K discusses the novel idea of "Request for treatment" in lieu of "informed consent ". [8] Request for Treatment (RFT) is a new approach to consent which aims to aid patients' understanding of their treatment and facilitate patient – centred care. [8]

This request-based system removes the notion that consent is purely a process to limit litigation, and instils the sense of partnership between doctor and patient. [8] RFT ensures that information is provided at the earliest possible stage, and ensures that patients have enough time to reflect, and reach a well-thought-out conclusion. [8] By altering the narrative to a request for treatment, rather than consenting to it, it attempts to change the passive nature of the patient in the doctor–patient relationship and lessen the potential for paternalism. [8] The goal is for RFT to be non-prescriptive, and to be tailored individually to practices, hospitals or even specific operations or procedures. [8]

Table 3: The role of RFT (patient-centred consent) [8]

Consent using RFT becomes:

- An encompassing mechanism that facilitates, promotes and establishes patient-centred care
- A general approach to – and replacement for – consent, focussing on a mutual process of interaction and doctor–patient communication
- A method of documenting consent that is more robust than traditional consent, and forms the basis of a new in-patient system
- A mechanism to ensure high-quality information provision to patients
- A mechanism to involve patients more in their own healthcare decisions
- A 'soft' method of assessing capacity
- A method of consent for children (parental consent)
- A potential method of assessment and documentation of Gillick competence for those under 16 years of age
- A method of protecting doctors and patients against negligent consenting practice.

CONCLUSION

Consent as the law requires has not been consistently achieved in medical practice for as long as the concept of consent has existed. The same questions regarding the failures of consent that were being asked decades ago are still being asked now. It is clear from the research that patients retain and understand very little regarding their treatment despite best efforts. Furthermore, there appears to be a discrepancy between the understanding of this fact by the medical profession and by the courts.

The principle of autonomy is now so fundamental to society that a patient of sound mind can refuse treatment even if that refusal is foolhardy, and could lead to death of the patient. With so much potentially at stake, it is important to have a robust process for consent not only to uphold patient autonomy and the law, but also to ensure best practice for patients and healthcare professionals.

True informed consent should come from a place of mutual trust and respect. Respect for the patient and their autonomy, but also their function and role in society, and respect and trust for the clinician in that they are practicing with the best intentions. We as health care workers need to respect and appreciate the individualism of the patient, and understand their values may be different to ours, and that doesn't make them wrong, but rather serves as a reflection of the unilateral narrative of our training.

Let us not forget that the original purpose of consent historically is to protect the patient and empower them. We need to ask ourselves if we are doing that or merely ticking the legal box. What we have learnt is that consent is not a signature on a form, but a communication process. And so, look at your current daily practice, and ask yourself - Are you upholding the true nature of consent?

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