

Medical information therapy and medical malpractice litigation in South Africa

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In South Africa, increases in both the size and amount of medical malpractice claims have resulted in a move towards so-called defensive medicine, and have had devastating emotional effects on healthcare professionals. Among several recommendations for addressing these consequences, the first author's recent doctoral study critically analysed evidence-based patient choice as a partnership model in clinical decision making. This study indicated that none of the key skills of this approach are completely adequate in honouring the principle of respect for autonomy in clinical decision making. Instead, the study proposed the concept of medical information therapy – an expanded conception of the generic concept of information therapy – as an adequate approach to reconciling the opposing perspectives of patients and healthcare professionals in a therapeutic alliance. Recent case law, as well as relevant provisions of the National Health Act, emphasise patient autonomy, as well as the notion of shared decision making in the context of informed consent. The South African healthcare context is characterised by specific challenges affecting the process of obtaining informed consent. The article submits that the concept of medical information therapy will help address the significant increase in litigation against healthcare practitioners based on a lack of informed consent, in both the public and private healthcare sectors.

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Following global trends, medical malpractice litigation in South Africa has recently increased, in both the size and amount of claims filed against healthcare practitioners.^[1,2] The results have included a move away from compassion-centred care towards so-called defensive medicine,^[3] and the devastating emotional effects of malpractice lawsuits on healthcare professionals.^[4] Pepper and Nöthling Slabbert^[5,6] offer several recommendations for how to address these consequences, including:

- better self-policing, including peer review by the medical profession itself
- improving communication between medical staff
- the participation of healthcare professionals in continued professional development
- properly informing patients about practitioners' personal skills and their right to second opinions
- using medically trained judges in medical malpractice suits
- using an independent counsellor in the resolution of medico-legal disputes
- recognising the value of collegiate support and mentoring
- better educating members of the public.

While medical malpractice litigation remains a source of serious concern to the healthcare industry globally, recently these recommendations became the focus of the first author's doctoral study on the ethical issue of patient autonomy and its establishment and maintenance.^[7]

The study critically analysed evidence-based patient choice as a partnership model in clinical decision making, by judging it in terms of the ethical principle of patient autonomy as reflected in the four elements of informed consent: competence, disclosure, understanding and voluntariness.

This analysis indicated that evidence-based patient choice points the way to a potential future scenario in which patients and professionals will operate as real partners, have shared goals and make joint decisions on best approaches in healthcare. However, none of the key skills involved in evidence-based patient choice – namely shared decision making, risk communication, decision analysis and the use of decision aids – are completely adequate for honouring the principle of respect for autonomy in clinical decision making. Huge gaps still exist between the ideal and current practices of the partnership model,^[8] and the study argued that evidence-based patient choice faces serious challenges that defeat its objectives, and challenge the individualisation of the provision of information in healthcare.

On the basis of this analysis, the study aimed to determine an adequate approach to the establishment and maintenance of patient autonomy in clinical decision making, by exploring the challenge of the individualisation of the provision of information in healthcare. This exploration revealed the following important aspects.

By further developing the philosophical foundations of evidence-based patient choice, the study disclosed the central and complex position of the concept of personal identity in these foundations.^[9] Elaborating on this theme, the study considered continental philosophical perspectives on the separate autonomy-related challenges facing patients and healthcare professionals in the evidence-based patient choice context; the constitution of meaning in illness; the danger of abstractions and informational manipulation in healthcare; and the complexity of applying the principle of respect for autonomy in medical practice.

To address these findings, the study proposed a broadened understanding of the generic concept of information therapy. This

generic concept is understood as the timely prescription and availability of evidence-based information, in order to meet the specific needs of individuals in the process of sound decision making. This broadened concept could constitute an adequate approach to the complexity of the individualisation of information provision in healthcare, and therefore also to the establishment and maintenance of patient autonomy in clinical decision making. However, the study indicated that an agent with particular qualities will be required to administer this broadened concept, and pave the way for patients and healthcare professionals to reconcile their perspectives in a therapeutic alliance.

A broadened understanding of the concept of information therapy

The evidence-based patient choice approach insists on unprecedented access to information, considering this a vital element in the attainment of its goals.^[10] The study indicated that, from the perspective of information science, it is considered impossible to tap into the real value of information resources and technologies without a clear understanding of the human processes involved in transforming information into knowledge.^[11] For this reason, it is inadequate merely to recognise the central importance of information, or to provide it through predominantly technical means.

The study therefore argued that the provision of information in healthcare needs to be individualised. This would be achieved by embedding it in the human processes of sense making, knowledge creation and decision making, through which information is transformed into insight, knowledge and action.^[11] A broadened understanding of the concept of information therapy also recognises that information, insight and knowledge are created in individuals' minds through a dynamic and disorderly social process, which unfolds in layers of cognitive, affective and situational contingencies.^[11] The study argues that this provides an adequate approach to the complexities of the contemporary understanding of personal identity, and to the application of the principle of respect for autonomy in everyday medical practice.

The information therapist as a postmodern ethics consultant

The study examined the human processes through which information is transformed into insight, knowledge and action, and noted that these are thoroughly inter-subjective^[12] and demand the interventions of an agent acting in postmodern fashion – that is, recognising that in contemporary society, moral decisions are always provisional and subject to circumstance and that new answers are constantly needed in response to constantly changing environments.^[13] It argued that the information therapist has to not only mediate relevant and significant information between the medical professional and the patient, but also act as an ethics consultant, since the mediation of information fundamentally represents an ethical act that requires the establishment of a truthful relationship. This demands time and patience.^[9] As such, the information therapist will act as an official delegate of healthcare professionals, within the third phase of the development of the medical profession^[14] and according to the guidelines of the Health Professions Council of South Africa (HPCSA).^[15] Furthermore, the therapist will respond to an increasing international demand for the provision of information outside the clinical consultation.^[16]

Information therapy and the establishment of a therapeutic alliance in healthcare

The study concluded that instead of widening divides between patients and healthcare professionals by introducing even more instruments of patient advocacy, illness should be regarded as not only attached to a patient or perceived by a healthcare professional, but as an entity or a challenge that lies somewhere between patients and healthcare professionals.

What needs to be recognised is that it is not only patients who are in need of empowerment in the clinical situation, but also doctors. Both parties therefore share not only the challenge of identifying with the interpretational schemes of communicative partners in general, but of the unshareability of illness in particular. They are also challenged by the immense reality of suffering. This reality cannot be adequately addressed within the current parameters of the clinical situation, and therefore demands the establishment of a therapeutic alliance^[7] in healthcare. This alliance will be capable of establishing an awareness of the interdependence of human beings and do justice not only to patient autonomy, but also to the interventions of healthcare professionals.^[17]

Medical information therapy as an approach to medical malpractice litigation in South Africa

In order to comply with HPSCA guidelines, the study suggested that information therapists should be qualified healthcare professionals^[15] with additional background in philosophy, bioethics, information science, health informatics and law. They could therefore aptly be referred to as medical information therapists. Although the official recognition of a new member of the healthcare team will pose formidable challenges, it is envisaged that this will contribute positively to redirecting healthcare from defensive to compassion-centred medicine. It will also transfer suffering as an inescapable and mysterious entity from the private world of the individual to an intersubjective domain where it can be jointly assessed, addressed and borne.

Informed consent

A medical practitioner's obligations have traditionally been framed in terms of obligations of beneficence. However, the human rights movement, with its increased focus on patient autonomy, has signalled a move away from this traditional beneficence model of medical ethics to a model of autonomy. With the focus on the quality of a patient's understanding and consent instead of the medical practitioner's obligations, patient autonomy and self-determination have become the *leitmotiv* in the law regarding medical decision-making.^[18] The Constitution of the Republic of South Africa^[19] recognises both autonomy and self-determination in the provisions of the right to bodily and psychological integrity (Section 12) which includes the right to security in and control over one's own body; the right to privacy (Section 14); and the right to life (Section 11), among others. As a founding value of the Constitution, dignity (Section 10) is particularly relevant in the healthcare context.

The shift to patient autonomy and self-determination was preceded by the formulation of abstract principles found in foundational texts, such as various ethical codes, guidelines, legislation (e.g. the National

Health Act)^[20] and the Constitution. The notion of participatory decision-making has been particularly emphasised in recent case law.

Allegations based on lack of informed consent usually allege that a physician failed to fulfil the duty to supply the patient with all material information about the risks and alternatives for the proposed treatment, or that a physician administered treatment beyond what was authorised by the patient. The landmark case of *Castell v. De Greef*^[21] established a patient-centred test for disclosure. In terms of this test, a doctor should disclose all information and risks to which a reasonable person in the patient's position, if warned of these risks, would be likely to attach significance, or to which a reasonable doctor in this situation should be aware that the specific patient, if warned of these risks, would be likely to attach significance. For the consent to be comprehensive, continuous dialogue between doctor and patient is essential. The patient should also be supplied with relevant information about post-operative treatment. Unfortunately, the court did not provide further guidelines regarding the implementation and application of this judgment to patient autonomy.

In a subsequent judgment, *Oldwage v. Louwrens*,^[22] the court *a quo* applied the patient-centred test of *Castell*. However, on appeal,^[23] the professional standard for disclosure (eg. that of medical judgment for disclosure, as was followed in the 1976 case of *Richter v. Estate Hammann*),^[24] was preferred.

The doctrine of informed consent was codified in law in the National Health Act.^[20] Section 6 of the Act lists the scope and nature of the information that should be disclosed. It states that every healthcare provider must inform a user of

- The user's health status, except where there is substantial evidence that this disclosure would be contrary to the user's best interests
- The range of diagnostic procedures and treatment options generally available to the user
- The benefits, risks, costs and consequences generally associated with each option
- The user's right to refuse health services.

Section 6(1) is premised on an extensive understanding of informed consent, requiring that the diagnosis and alternatives to the proposed treatment be divulged as well as the risks, costs and consequences inherent in the procedure. One exception is mentioned, namely when disclosure would be contrary to the patient's best interests. Section 6(2) requires that this disclosure be made in a language that the patient understands and in a manner that takes into account the patient's level of literacy. This must be read together with Sections 7, 8 and 9. While Section 7 provides for the exceptions to the general requirement of informed consent, Section 8 provides healthcare users with the right to participate in decisions affecting their health, thus promoting shared-decision making. The right to self-determination has been extended in Section 8, which provides that a patient's informed consent is required even though he/she has previously been treated and the necessary consent was obtained. The Section also provides for the participatory decision-making of individuals who cannot give consent, but who can participate in decision-making up to a certain extent.

At present, there are no guidelines explaining the modalities of communicating health information or the risks pertaining to these, including directions as to how to determine patients' information needs. A totally objective test that leaves the standard of disclosure

with the doctor is clearly favouring the doctor unduly, whereas a completely subjective test would place an unfair burden on the healthcare practitioner, requiring him or her to second-guess a patient's choices.

In practice today, the process of obtaining informed consent is inconsistent, formalistic and superficial. Those practitioners who know that autonomy is important in the doctor/patient relationship may become more passive, whereas others who are willing to provide patients with a range of choices may become hesitant to give recommendations, if they are uncertain whether they may be perceived to be too paternalistic.

Introducing a medical information therapist

Medical practitioners often complain that the legal doctrine regarding informed consent wastes time and is impracticable, as patients are often unable to comprehend the complexities relating to their medical condition or illness. The practitioner's ethical duty to heal may also be perceived to be more significant than the legal duty to inform. Other factors that contribute to the problem of informed consent include:

- the duty to seek informed consent is often delegated to attending nursing staff, who may not be familiar with the relevant legal requirements
- determining the positive law on the application of the doctrine is a challenge as it requires a complex understanding of the multilayered approach in medical law, which relies on a consideration of the Constitution, the common law, applicable legislation, professional guidelines and case law. Few healthcare practitioners are in a position to make this determination
- obtaining informed consent in a developing country such as South Africa may be compromised by a lack of infrastructure and resources, as well as cultural and educational differences
- obtaining informed consent may pose a challenge where patients are illiterate.

Obtaining informed consent in accordance with established legal requirements is a comprehensive, time-consuming, ongoing and participatory process. It will be carried out more effectively if the medical information therapist becomes part of the health practitioner-patient interaction. The therapist would be able to address some of the challenges identified in obtaining informed consent. One immediate foreseeable benefit would be a decrease in the number of patients instituting legal action against medical practitioners based on lack of informed consent and possibly also alleged negligence.

Professional medical negligence is often the reason for litigation. Negligence generally means that the defendant failed to foresee the possibility of harm (injury/death) occurring in circumstances where the reasonable person in the defendant's position would have foreseen the harm, and have taken steps to prevent or avoid it. In the medical context, the test of the reasonable man is upgraded to refer to the reasonable medical expert (general practitioner or specialist) in the same circumstances. The principles of the law of delict require that the undisclosed risk must materialise and cause the patient harm in order to establish liability and for a claim to realise. The patient must prove that the lack of informed consent was the cause of the adverse medical outcome. There are many difficult elements that must be proven in order to establish legal liability, among

them: that the conduct caused the harm; causation; wrongfulness (unlawfulness); fault; and loss/harm.

Although the test for medical negligence is an established test in law, it is often asked how this legal test finds application in medical practice. Healthcare practitioners often don't know exactly what is required to meet the legal standard to avoid legal liability when consulting patients. A medical information therapist would not only be able to understand the legal requirements relating to informed consent, but would have sufficient training to ensure that extra-legal factors receive enough attention, in an attempt to ensure that consent is truly voluntary and informed. Obtaining voluntary consent from minors is a specific challenge in the South African healthcare context. Information therapists could play an invaluable role in aligning the consent provisions contained in the National Health Act^[20] and the Children's Act,^[25] particularly with regard to their practical implementation.

Informed consent, contract and the business model in healthcare services

In the context of healthcare, obtaining informed consent in the context of the contract between the healthcare practitioner and the patient is fraught with problems. Firstly, the law of contract is not an ideal vehicle for regulating relationships involving health service delivery. Secondly, the patient's bargaining power is greatly diminished as a result of the services involved, the patient's own mental and physical state of health, and the expertise and economic power that the healthcare professionals and health establishments may hold.

This is very clear from the case of *Afrox Healthcare Bpk v. Strydom*,^[26] in which the Appellate Division affirmed that a service provider (in the private sector) may contract out of delictual liability by means of a waiver or exemption clause in the contract signed by the respondent, even though this waiver effectively authorises the person in whose favour it has been made to act in a manner that is unconstitutional, e.g. infringing the patient's rights to bodily and psychological integrity and dignity. This unsatisfactory position has now been addressed in the Consumer Protection Act,^[27] which provides that a consumer may not be required to waive any liability of the supplier on terms that are unfair, unjust or unreasonable.

Civil wrongdoing in the context of the law, in the context of health service delivery, raises the question of the balance of power between doctor/hospital and patient, and whether this considerable power advantage affects which claims in the law address claims in delict. The patient is very vulnerable here, as the service provider may be far more knowledgeable about the fine technical detail of various treatment options and relative levels of risk. The patient is unable to assess the level of personal skill and expertise of the service provider. Patients are already in a vulnerable physical and psychological state when they are referred to healthcare practitioners and establishments. Failure to adhere to acceptable standards of care by healthcare establishments may be extremely costly to patients, who have to compete on an already unequal footing when attempting to seek redress for harm suffered. Many of these problems may be greatly diminished through the involvement of the medical information therapist.

Conclusion

The doctrine of informed consent in its current legal form is not effective in ensuring patient autonomy and self-determination. Patients should be active participants in the decision-making process.

Leaving this to the medical practitioner alone puts a huge burden on the practitioner to care for the patient on different levels. Informed consent requires more than notification and involves a process of acknowledgement, deliberation and understanding.

Shared decision making, risk communication, and decision analysis, which may include the use of decision aids, do not feature in the present legal framework regarding informed consent. A shift towards a therapeutic alliance between doctor and patient is the most viable solution to the present shortcomings. This alliance will ensure that information presented to the patient is individualised, ultimately leading to a decrease in medical negligence litigation.

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