

Sufficient informed consent to medical treatment of adults: legal and ethical perspectives from Malawi

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Abstract

This special communication discusses the current legal and ethical requirements for informed consent to medical treatment of adults in Malawi. It analyzes the scope of the laws and code of ethics on professional discipline, including criminal privilege for surgeries and clarifies when insufficient disclosures entitle patients to compensation under civil law. Inconsistencies and uncertainties in the law are made apparent.

It evaluates to which degree disclosure standards of other Commonwealth jurisdictions (e.g. the case of *Montgomery*) would be suitable for the health care setting of a country like Malawi that is characterized by shortages of resources, high illiteracy rates and a communitarian cultural context. Doctor-patient communication is not alien to African culture and part of sufficient informed consent. In order to balance the need for efficiency in health care delivery, accountability for quality care, fairness and effective patient-doctor communication the authors suggest to adopt the reasonable patient test only, if a defence of heavy workload on case-to-case basis is introduced at the same time. This does not dispense the need for organisational diligence on part of the institutional health care provider within its capacity.

Keywords: law, ethics, medical negligence, patient rights, disclosure, damages, duty of care, workload, Montgomery, defence

Introduction and methods

Malawi has an over-burdened health system with free public primary health care services and costly private care available to few individuals. With growing awareness for patient rights and ethics¹⁻² a case study on the prevailing practice in surgery at a public tertiary hospital revealed that the practice is seeking broad consent only³, which may often be construed not as sufficiently informative⁴. While socio-medical research⁵, and recent legislation⁶ address consent to HIV testing in Malawi, the law on consent to other non-invasive or invasive treatment is fragmented and cannot be readily accessed by health practitioners. Current literature covers only practice of informed consent from the ethical or social perspectives on health care choices⁷, patient comprehension (mostly focused on high income countries⁸ except for circumcision⁹) informed consent to research¹⁰ but does not cover the legal perspective. Chima's study demonstrates a need of health practitioners for clarity on legal requirements. Such clarity is relevant for civic and medical education with respect to better patient rights, litigation-risk-management in hospitals and to avoid a distortion of health equity through unwarranted incidents of liability.

This special communication by an interdisciplinary research team consisting of an ethicist, legal scholar and public health researcher/medical practitioner fills this gap through a desktop review on the current legal requirements concerning doctor-patient communication with a competent, adult patient¹¹ in Malawi. The study employs legal analysis of legislation, case law and comparative law perspectives¹². It is complemented by ethical reasoning to suggest possible law reforms introducing sufficient informed consent as a form of informed consent. After an overview of the current law and ethical codes of consent the authors propose

informed consent as part of an on-going patient-doctor¹³ communication process as an adaptation to the socio-economic and cultural context of Malawi and give reasons for it.

Types of consent, civil and criminal consequences

Consent to research and consent to treatment differ legally, because consent to research generally cannot be waived¹⁴ since it is derived from human dignity¹⁵. Typically, it involves unknown risks for the research participant. Consent to treatment can be waived. It is rooted in the Commonwealth law tradition¹⁶ and anchored in the right to personal liberty and bodily integrity¹⁷⁻¹⁸. Doyal points out that even such a waiver would require an element of risk awareness¹⁹. Both types of consent need capacity and competence, disclosure, voluntarism, understanding and decision-making²⁰.

Malawi shares the Common Law tradition under which lack of broad consent to the nature of treatment would lead to damages in tort for trespass to person (assault or battery²¹) in civil law or to criminal sanctions for unlawful assault²² or unlawful wounding²³. According to the surgical privilege²⁴ in the Penal Code, a doctor who performs a surgery *lege artis*, in good faith and for the benefit of the patient is criminally not responsible²⁵. A doctor, who assumed s/he acted for the benefit of the patient but objectively did not, is justified, if this mistake was honest and reasonable²⁶. Apart from that, section 246 of the Penal Code criminalizes reckless negligent medical treatment²⁷. The purpose of the law (patient protection) points to an interpretation that considers seeking of consent and communication as part of medical treatment.

Legal instruments which provide for mandatory treatment are the Public Health Act, Childcare Protection and Justice Act and Mental Treatment Act²⁸. The details are beyond the

scope of this article, however they all need to be understood in conjunction with section 44 of the Malawi Constitution, 1994 (Syracuse principles for limitation of human rights). In emergencies where a patient is unable to consent the doctor needs to act in the best medical interest of the patient²⁹. According to Guidelines of the Malawi Medical Council the most senior practitioner, if possible witnessed by a second practitioner, should give consent in consultation with the parent or guardian, according to best interest of the patient³⁰. The requirement to communicate about the course of treatment taken arises afterwards; in *Kalea v Attorney General* the patient – herself a nurse – was not told about a *placenta accreta*³¹, which was discovered during a C-Section and was left in her womb. The lack of knowledge about the associated risk of infection with the chosen approach prevented the timely detection of complications³².

In addition, section 11 of the Anatomy Act Cap 34:03 on donation of organs, blood or tissue from a living person prescribes the need for consent of the person or his spouse/close relative. It is silent on advance directives. This type of consent is considered to be a separate legal category, because it typically involves only risks and no health benefits for the donor.

Consent to treatment can be given in any form, even implied³³. However undue influence, coercion or fraud invalidate consent³⁴. Patients insufficiently informed about material risks of the proposed treatment and possible alternatives (lack of informed consent), may claim damages for professional negligence in civil law, if the non-disclosed risk occurs and the information would have been significant³⁵ to affect the patient's decision-making process. Lack of disclosure of material risks does not automatically mean that there was no broad consent. In any case, understanding of the nature of consent is required³⁶. For an overview of types of consent see Table 1.

Requirements under professional code of ethics

In Malawi dissatisfied patients tend to complain to the Malawi Medical Council for alternative dispute resolution or disciplinary measures or hospital Ombudsmen because they are easier to access than courts. Doctors are legally obliged to act ethically and ethically to act legally. Professional misconduct can lead to warning, suspension or de-registration as disciplinary measures³⁸. The Code of Ethics for Doctors by the Medical Council of Malawi gives ethical guidance on professionalism which could be used by courts to interpret a doctor's duty of care in negligence cases or in appeals against decisions of the Disciplinary Committee.

"The Council urges all practitioners to ensure that as far as possible informed consent is obtained before any procedure is carried out on a patient. Where the procedure is a major one, a written consent shall be obtained. In obtaining informed consent a practitioner shall explain the full nature, extent and potential complications of the procedure to be carried out on the patient."

Currently there is no Malawi specific case law⁴⁰ on the question what needs to be disclosed for informed consent or on the meaning of "as far as possible", which suggests to employ comparative legal methods to resolve the dilemma. Current case law from other Commonwealth countries is instructive though not binding for Malawi.

Comparative law on standards for informed consent

In the past, English courts had used the same standard

for negligence and informed consent cases: What would a reasonable doctor do or inform a patient about (Bolam test)?⁴¹ India with a large illiterate patient population continues to use the doctor's perspective test because of its practicability, and the need to reduce health care costs⁴². In contrast, American and Canadian case law asked what would a *reasonable prudent patient* want to know⁴³. Such patient-centered perspective was also adopted by Australia⁴⁴ and South Africa⁴⁵. However, the two positions merged closer⁴⁶, when English courts demanded that the patient should not be put unnecessarily at risk⁴⁷, thereby shifting power from the medical expert evidence back to the judges⁴⁸. Finally, in 2015 the UK Supreme Court adopted in the landmark ruling, called *Montgomery, the "reasonable-patient-test"*⁴⁹.

*"The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it."*⁵⁰

Informed consent means no over- or under- informing though some scholars fear that the Montgomery interpretation will lead to the former⁵¹. Both approaches of doctor and patient perspective oblige the former to answer a patient's questions truthfully and give therapeutic privilege⁵². That means exceptionally full disclosure is not necessary, if it would lead to unintended harm for the patient, even though deceit would usually be a vitiating factor for consent.

The following reasons led to the change in the *Montgomery* case: a paradigm shift in patient attitude/expectations, new means for accessing health information by patients, alignment of clinical practice and ethical recommendations in practice guidelines in the UK, the emphasis of patient autonomy in the modern human rights system, an influence of the European Union in the past years, and a growing awareness that treatment choices do not solely depend on medical reasons. Critics argue that the judges in the *Montgomery* case did not sufficiently consider that the patient could have actively sought further information⁵⁴. Furthermore it does not follow a holistic approach, rather artificially splitting up the communication and decision-making process⁵⁵. In this particular case there were contradictory treatment guidelines, which made it difficult for a doctor to know the legally required alternatives for disclosure, which meant that health practitioners were left at the mercy of courts⁵⁶.

Application of informed consent to treatment in Malawian context

Malawi applied the general standard for professional negligence (Bolam test from Britain)⁵⁷ in the medical malpractice cases *Kalea v Attorney General*, 1993⁵⁸ and *Mtileni v Registered Trustees of Blantyre Adventist Hospital*, 2006⁵⁹. However, there is no reported court case on non-disclosure of risks in treatment decisions. Cases for isolated lack of informed consent are also rare in other countries and tend to be combined with other negligence claims⁶⁰. Human Rights are guaranteed in Malawi's Constitution in accordance with international standards. The country is a signatory to the Universal Declaration on Bioethics and Human Rights, 2005⁶¹ which speaks in favor of strengthening patient rights. For Malawi the authors propose "sufficient informed

Table 1 Types of consent

TERMINOLOGY OF CONSENT			<i>Implications</i>
Form of giving/seeking consent	Express/explicit = directly in written or spoken word	Implied/implicit = through conduct, circumstances	<p><i>Any form is allowed</i></p> <p><i>Express written consent is recommended for major interventions</i></p> <p><i>Consider collection of evidence for case management</i></p>
Requirements for any valid consent	Capacity/competence, voluntarism (no coercion, no undue influence, no deceit), no serious mistake as to nature of consent),		<i>Invalid consent = no consent</i>
Broad consent	Information about general nature of intervention without details about its risks.		<p><i>Lack of broad consent may lead to assault (civil law)</i></p> <p><i>Exceptions: necessity, mandatory treatment</i></p> <p><i>Disciplinary consequences</i></p> <p><i>Surgical privilege S. 243 Penal Code if done lege artis, in good faith and for patient's benefit</i></p>
Informed consent	Information on material risks and benefits, alternatives, consequences of non-treatment, ...		<p><i>Lack of it leads to damages if non-disclosed risk materializes and it would have affected patient's decision-making.</i></p> <p><i>Disciplinary consequences</i></p>
Standards of disclosure in medical care	What is considered as material information in medical treatment? (Discern from standards for informed consent to clinical research.)		
USA, South Africa, Canada	Reasonable prudent patient test (Canterbury) – also referred to as informed consent		
England (formerly), India	Reasonable doctor's perspective (Bolam) – also referred to as real or true consent as opposed to American doctrine of informed consent		
England (modern)	Reasonable patient perspective (Montgomery)		
Malawi	<p>Inconclusive case law</p> <p>Indirect binding force of ethics guidelines: for major procedures inform as far as possible about full nature, extent, possible complications</p> <p>Note: Kalea case on post-intervention communication as part of duty of care</p>		
Authors' suggestion	<p>Sufficient informed consent</p> <ul style="list-style-type: none"> - Reasonable patient perspective that extends also to financial aspects - Exception: defence in a particular overburdened workplace situation – consent reduced to what a reasonable doctor in such context would consider as necessary and reasonable to disclose - Sufficient communication for responsible patient behavior for recovery and as part of healing process - Inform unreasonable patient who reject treatment with basic information to enable him/her to re-evaluate his/her decision - (Display of mediation and complaint mechanisms as requirement for operation of health facility) 		

consent” as a standard for informed consent practice in Malawi. The word “sufficient” emphasizes the need to prevent unnecessary under- or over- information of the patient and at the same time points to sufficient protection of health personnel, that face ethical dilemmas in a climate of growing litigation⁶². Sufficient informed consent is summarized as follows and reasons will be explained below:

a) Disclosure of all essential information, that a reasonable patient in that position would likely attach significance to (including medical risks, alternative treatments, financial aspects) and that is not detrimental to his/her health (maintaining therapeutic privilege)

b) Introduction of defence on case-to-case basis in situations of heavy work-overload, when it would be justifiable to

apply the standard of what a reasonable doctor would have disclosed.

c) In case of an uninformed refusal of care due to obviously distorted beliefs, prejudice, ignorance or superstition the health practitioner has a duty to provide the patient with basic, appropriate information in a simplified and understandable way to enable him to appreciate at least the nature of the treatment.

d) Doctors shall inform the patient how s/he can take a responsible, active role in the healing process. (Kalea-case)

e) Display of information on mediation or complaint mechanisms on malpractice or corruption as requirement for operating a health facility.

Cultural aspects and lessons from traditional healers for patient communication

Being habitually used to reduced autonomy in life due to economic hardship is no justification for even further reducing the autonomy of Malawians regarding their treatment. In high-income countries such as the United States many people were factually deprived from exercising a free choice due to lack of health cover, however their informed consent matters⁶³. Even though views on consent and value of individualistic or relational autonomy⁶⁴ differ in various cultures⁶⁵ the paternalistic practices of last centuries, which have been abandoned by the Western world itself, cannot be maintained in Malawi by arguing that it would be a cultural expectation. Muula's survey on patients' preferences for treatment decision-making in a Malawian hospital showed that only 18% of them opted for decision-making by the health professional alone⁶⁵. An involvement of family members as counsels should be allowed but not be obligatory. Maroon studied how in rural Malawi people do choose between Western medicine and African therapeutics⁶⁷. Though culturally it is unpopular to talk about bad events⁶⁸, patient communication is an integral part of Malawian culture. Gaining a holistic understanding of the patient's need, situation and communication are pillars of African traditional healers' decision making and part of healing and care in a spirit of *ubuntu*⁶⁹. Consultation is a pre-requisite for accepting leadership. Traditional healers are good at confidence building through listening, paying attention and giving detailed explanations on dosage, timing of concoctions and required behavior⁷⁰. Hence, the informed consent process should ideally be part of a wider communication process between patient and doctor, possibly contributing to a more holistic healing approach and creating a basis of trust for improved treatment adherence.

Valid informed consent is possible even in developing countries with high illiteracy levels when sufficient time, effort and resources are spent on communication⁷¹. From a legal point of view, a thumbprint suffices only as consent, if the patient had been aware of the content of the document. If explanation and content of a document materially differ⁷², the signature or thumbprint usually carries no effect (*non est factum* doctrine⁷³). English courts protected patients even further and require evidence for patient's understanding⁷⁴.

Issues to be disclosed in resource-poor settings

A typical issue in resource-limited settings but often not sufficiently clarified in Western ethical discourse is that only one or not the required type of treatment is available⁷⁵. Here the reasonable patient test matters. For example, if the patient received only analgesics but not the required malaria

drug, s/he must be made aware of the limits of possible treatment. Relying on placebo-effect would be irresponsible. If known therapies are available in a private health care facility or elsewhere, the patient should be made aware of it. The above ethical guidelines of the Medical Council of Malawi explicitly cover only nature, extent and complications of treatment but not alternatives.

Every medical choice entails a financial decision which has a particular high impact on low-income households. In private medical care it would be ethical and fair consumer practice to inform patients on immediate and long-term cost implications⁷⁶. Continuous holding of patients without informing them of treatment failure is unethical and illegal.

Uninformed refusal of care and duties of information

Doctors may also be faced with outright, uninformed refusal of care by illiterate patients with cultural scientific misperceptions or distorted beliefs⁷⁷ about the harmful nature of a beneficial intervention or by educated patients with medical treatment prejudice (e.g. anti-vaccine movement). Based on the principle of beneficence or the notion of empathy in ubuntu which entails considering the patient's value of life⁷⁸, such patients should be given basic information to reconsider their initial intuitive decision in an attempt to avoid harm due to lack of knowledge. Informed consent is then only a second step. It is recommended to document a refusal as a defence in case of an eventual litigation for lack of (emergency) treatment⁷⁹.

Differences in the Malawi Health Care Setting – need for medical practitioner protection?

Ensuring that patients understand the information required to make a decision will inevitably take some effort and time. However, the Malawian health care system is affected by a general shortage of medical personnel and a chronic severe workload for medical staff in the public sector (2 doctors, 38 nurses and 22 non physician clinicians/100 000 people). In some, but not all workplaces Kant's categorical imperative (*what is fair for one is fair for all*) is difficult to apply since the time spent on one patient is lost for another one⁸³. Limited access to other sources of information about treatment and a low adult literacy rate (62.5%⁸⁴) aggravate both the need and the workload with extra time for explanations. The mentioned Code of Ethics refers to only what is "possible". Due to similar challenges, Indian courts maintained the "reasonable doctor test", though with a strong caution to the medical profession⁸⁵. Health lawyers and ethicists should reflect how to manage the ethical dilemma/conflict of duties arising with heavy workload. Common law does not sufficiently provide for necessity as a defence in tort⁸⁶. It is practically impossible to give evidence which other waiting patient would have died, if the doctor would have taken time for informed consent, because the doctor is not always aware of the situation of the other sick person from an ex-ante perspective. The sufficient-informed consent suggested by the authors is a hybrid; acknowledging patient rights and at the same time avoiding time loss in pressurized situations by introducing an exceptional justification. The authors propose that high workload in a particular work setting or situation in a particular health facility should be a valid defence against lack of fully informed consent for better health care efficiency. In order not to undermine the duty to seek informed consent in general, the defendant needs to give evidence on the exact

circumstances that constitute overload (e.g. staffing levels in the organisation or staff ratio on number of births per night etc.)⁸⁷. In case of prolonged overtime guidance can be taken from maximum working hours in sections 36-37 of the Employment Act, 2000. The Workload Indicators for Staffing Manual by WHO offers a methodology to determine optimal Activity Standards in a local context which reflect the time necessary for a well-trained, skilled and motivated worker to perform an activity to professional standards in the local circumstances⁸⁸. Countries like Australia and some states in the U.S. even introduced legislation on minimum nurse-patient ratios depending on type of ward and time of shift⁸⁹. The workload defence is used on case-to-case basis and still requires the health practitioner to inform the patient as far as can reasonably be expected according to a reasonable doctor's perspective in the given circumstances. It does not dispense the organisational duties of care of the health care provider within its capacity. Ethically it is justifiable to choose the lesser evil when one is faced with a dilemma between infringing on patient care or patient autonomy⁹⁰; a lack of immediately needed care is more probable to lead to physical harm than a non-disclosed possible risk in context of medical treatment with other benefits. Hence, the suggested defence cannot automatically be applied to other forms of medical negligence. South African experience has shown that high legal standards and culture of litigation created a serious danger for functionality of its health care system⁹¹. The suggested approach has the advantage that it adjusts itself to future improvements in the health care system without repeated intervention by the lawmaker. It would be desirable to clarify and harmonize legal and ethical standards for Malawi in this manner.

Transparency on mediation or complaint mechanisms

Legal definitions of rights do not always produce the desired social outcome⁹². Application and enforcement of a system of legal standards can be guided by the LEGS (Leadership, Ethics, Governance, Systems) framework. At least literate patients can be empowered to raise concerns about breaches of the law and find suitable mediators through requirement of a visible display with contact details of Quality Assurance Manager of the organisation, Hospital Ombudsman or Medical Council of Malawi and Malawi Nurses and Midwives Council and Corruption Hotline, if any. General civic education on importance of adherence to prescriptions, on patients' rights and duties charter is desirable. One can think of making the display a constituent element for validity of consent, but for practical reasons and consistent implementation its introduction as regulatory requirement for operating a health facility would be preferred.

Ethical approval

This is a legal and ethical desktop review using secondary data and literature review. Therefore, this desktop review does not need approval from ethics committee.

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Authors' contributions

This is an inter-disciplinary research. The first author contributed with legal research and reasoning and prepared the first draft and revisions. The second author contributed

to medical questions. The third author contributed to ethics and revisions. All authors contributed to the final draft.

Conclusion

In an overburdened health care setting one needs to balance the need for efficiency with respect for patient autonomy and patient protection. The authors conclude that there is a need for ethical and legal clarification and harmonisation on disclosure standards in civil law and Code of Ethics. Standards on sufficient, informed consent need to be developed considering the socio-economic and cultural context. The authors propose sufficient consent as a way to raise patient protection from the current practice to the reasonable patient standard but with exceptions in settings of work overload of health personnel in particular circumstances. Further research is needed to draw the line between quality and quantity of information from a reasonable patient's perspective and the effects of framing of information during communication.

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24. Penal Code Cap 7:01 (Malawi), s. 243.
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