



# Human guinea pigs? The ethics of undergraduate and postgraduate student involvement in medical training in South Africa

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Irrespective of theoretical and skills laboratories training, clinical competencies need to be honed through real patient contacts. South African (SA) medical training takes place mainly in tertiary hospitals. Most patients come from disadvantaged backgrounds, are scientifically naïve, have difficulty communicating with medical staff and may be intimidated by their surroundings. These patients may be particularly vulnerable and resigned to insidious paternalism. The question is whether authentic informed consent is actually provided by these patients for their involvement in medical training. Implied consent for this purpose is invalid. I justify the demand for explicit consent on the grounds of ethical and regulative frameworks. The human rights of patients and the dictums of the SA National Health Act and the Health Professions Council of SA should actively be promoted and upheld. I conclude with practical suggestions intended to stimulate debate and action at institutional and clinical departmental levels.

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Contrary to what the title might imply, I refer not to research subjects, but to guinea pigs of another ilk. Indeed, South Africa (SA) has a well-institutionalised and developed ethics review system. Clinical researchers should be trained in and comply with SA good clinical practice<sup>[1]</sup> and international ethical research guidelines and standards. SA research ethics committees and institutional review boards are rigorous in their demands for authentic informed consent (IC) for research subjects. Regrettably, however, there are no comparable structured courses and requirements for ethics at the clinical patient-professional interface, and perhaps there should be, although all medical students undergo an approved ethics training programme. What concerns me and inspired this article is the question as to what extent patients in training hospitals in SA are used as 'training material' for medical students and registrars *without being fully informed and providing explicit IC*. Before responding to this question I shall argue that the metaphorical elephant in the room is a fundamental asymmetry in the doctor-patient relation.<sup>[2]</sup> Furthermore, the social and economic circumstances of many patients attending SA training hospitals exacerbate this asymmetry, contributing to the disempowerment of patients, increased vulnerability and resignation to the inevitable – to being used as 'training material' even if without explicit prior IC. First then, let us examine the asymmetrical professional-patient power relation.

## Asymmetry in the doctor-patient power relation

The power asymmetry between doctor and patient, favouring the doctor, has influenced the nature of the professional-patient relation and the development of bioethics. This disparity has several roots, including:

- Knowledge asymmetry: medical students and registrars (synonyms: clinical assistants, trainees, residents) spend the formative years of their careers acquiring knowledge, clinical acumen and practical experience that define them as professionals. They are expected to remain students for the duration of their professional lives through continued professional development (CPD). In the eyes of society, they are figures of authority, and patients consult with practitioners because they are regarded as knowledgeable. However, the knowledge differential, given the nature of the knowledge in question, creates a power differential. The knowledge of diseases, their natural courses, possible treatments and prognoses translates into power over those conditions and over the patient. The antidote to inherent paternalism is to level the knowledge playing fields and promote the ability of patients to make decisions regarding their treatment, i.e. to promote patient autonomy. Yet providing sufficient contextual information leading to authentic IC for all examinations, diagnostic and therapeutic procedures and treatments may be problematic and insufficient.<sup>[2]</sup> Clinicians are aware that informing patients explicitly and comprehensively is impossible, hence the argument that we should 'rethink' the principles and practice of IC.<sup>[2]</sup> The knowledge/power asymmetry may lead to therapeutic misconception.<sup>[3]</sup> Patients who are simultaneously clinical research subjects may misconceive the nature of research-associated treatments and misunderstand the nature of clinical research. It is not uncommon for them to believe that such treatments will always benefit them and are tailored to their needs. Clinical research usually has totally different ends depending on the aims of research and the underlying research protocols, with fixed treatment regimens and often placebo arms, or tests one drug against another.

- Control of discourse: Foucault<sup>[4]</sup> described how the creation and control of discourse may be applied to create power relations and lead to eventual control. Many patients, arguably not those attending SA training hospitals, are well informed and have other means of obtaining information. Nevertheless, contextual medical discourse remains controlled by the medical profession, aided by the doctor's allusion to 'higher authority'. The extent of this phenomenon depends on the practitioner's elected language, communication skills and general behaviour and demeanour, and the socioeconomic status of the patient.
- Vulnerability: all patients are vulnerable because of the psychosocial implications of disease. Vulnerability may increase in direct relation to the seriousness of the disease and treatment, and inversely to socioeconomic standing, education levels and insight. Patients may have no option but to place their trust in those who provide care, and may be totally reliant on such care, for example, in intensive care settings. Vulnerability further distorts the patient-doctor power relation.

### Power relations in the public health setting

Some or all of the factors described above operate when patients are admitted to SA state hospitals. Vulnerability is exacerbated through poverty, language and communication difficulties, diseases such as AIDS and tuberculosis, the awe inspired by the white coat, logistics related to transport and the local availability of facilities, and unfamiliarity with procedures, medicoscientific discourse and the nature of treatments. To top this, patients may not fully appreciate their rights as enshrined in the SA Bill of Rights,<sup>[5]</sup> the SA National Health Act No. 61 of 2003<sup>[6]</sup> (NHA) and Patients' Rights Charter,<sup>[7]</sup> and are likely to be unfamiliar with the ethics guidelines of the Health Professions Council of SA (HPCSA). The latter are described in 16 booklets under the general title *Ethical Guidelines for Good Practice in the Health Care Professions*.<sup>[8]</sup> Nevertheless, an increasing number of state patients may decide to sue when harm befalls them or their children.<sup>[9]</sup> Vulnerable patients may become intimidated, marginalised and resigned to their fate, raising few questions regarding their rights and treatment. They may not want to jeopardise their treatment by being 'difficult', and rely on the beneficence, integrity and good intentions of their medical carers; ergo, the nascence of a new paternalism. Student training takes place in various settings, from primary-care clinics and private consulting rooms through to tertiary hospitals. The quality of professional care may not be consistent at all levels, yet the general standard of care in the SA training environment is high. However, it is equally important that patient treatment should be ethically sound and in accordance with the HPCSA guidelines. It is a fundamental responsibility of every member of the healthcare team to recognise, respect and, where possible, further patients' human rights, irrespective of whether patients are aware of these guidelines and rights or not.<sup>[10]</sup> Unfortunately there is no evidence that IC principles are adequately applied at the SA student-patient interface. This is regrettable, given the fact that without student-patient interaction student training is impossible.

### Real-life training of medical students

The training of medical students is based on an apprenticeship model,<sup>[11]</sup> albeit that unusual demands have to be met, e.g. the

aspiration to high ethical standards. Clinical skills laboratories (CSLs) and models are in wide use in all undergraduate and many postgraduate medical training, and even some CPD programmes. CSLs assist in preparatory instruction and may limit student-patient interaction, but in the end, what is learned theoretically and in CSLs has to be applied to and practised and perfected in human subjects. It would be impossible to train medical students without using human subjects. The ready availability of human 'training material' for hands-on training contributes to the quality of medical training in SA. Each patient is unique, and each student-patient interaction presents unique opportunities and challenges. The end result is obviously beneficial to society as a whole, and consequently society is greatly indebted to these unknown and unsung heroes. One may argue that the *quid pro quo* is excellent care and additional personal attention. However, in a study in which patients were not explicitly made aware of their role in training and generally agreed that they would have consented had they been asked, they maintained that their consent *should* have been obtained.<sup>[12]</sup>

### Patients as guinea pigs?

Relying on available international literature, in the absence of SA data, patients are not necessarily explicitly informed that they are to participate in student/registrar training, and do not always provide explicit and comprehensive IC.<sup>[13-15]</sup> Patients are not always informed that the person examining or treating them is a student, not a doctor. Some students may even introduce themselves as 'doctor'.<sup>[16]</sup>

The question is, *should* patients be so informed, and if so, why and how? *Explicit* consent would not be required if, as has been fallaciously argued, we could be sure that all patients admitted to training hospitals appreciate their secondary role as 'training material' and *implicitly* agree to this by being admitted to what they should know is a training institute.<sup>[17]</sup> However, we should not presume that patients appreciate that they are entering a training institution, comprehend the nature of medical training and accept and implicitly consent to becoming participants in such training. Firstly, there is little evidence to support this assumption.<sup>[18]</sup> Secondly, patients are entitled to know the identity of those providing treatment. Without being specifically informed, they are unlikely to appreciate the complex hierarchy of their care team, from junior students through to professors or department heads.<sup>[19]</sup> Thirdly, vulnerable patients may be unaware of their rights as human beings and patients, including the right to refuse and the requirement of explicit consent. The factors that promote vulnerability intensify the asymmetrical power relation, and diminish the patient's ability and enthusiasm to question, but rather encourage them to succumb to unintended paternalism. Implied consent is problematic and should never be presumed, particularly not blanket consent for a variety of, at that point, unknowns. HPCSA Booklet 4<sup>[19]</sup> expressly warns about the legitimacy of implied consent (clause 14): 'Consent must at all times be expressed and not implied.' It is inappropriate to assume that patients admitted to training institutes are sufficiently informed to justify their implied consent for participation as human subjects purely for training purposes.

Apart from this, SA guidelines are quite clear in requiring specific IC for all examinations and procedures. To start with, the SA Bill of Rights (clause 10) refers to each person's 'inherent dignity and the right to have their dignity respected and protected'.<sup>[5]</sup> The SA

Patients' Rights Charter (HPCSA Booklet 3, clause 2.2)<sup>[7]</sup> reiterates that 'everyone has the right to participate in decision-making on matters affecting one's own health', and in 2.6, the right to 'know the person that is providing healthcare' and to 'be attended to by only clearly identified healthcare providers.' Chapter 2 of the NHA deals with informed consent, and in 6.1 and 7.1 reiterate the requirement for informed consent. HPCSA Booklet 4 deals more comprehensively with the subject, and among others, states the following requirements in terms of information that should be supplied to the patient:

'3.1.3.8. 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;

3.1.3.9. Whether students will be involved, and the extent to which students may be involved in an investigation or treatment.'

Booklet 4 (at 18.2) legitimises the sharing of a patient's health-related information 'to the extent that it is necessary to enhance the quality of care to be provided to that patient and the patient has given consent to treatment and disclosure of such information to another healthcare practitioner'. Medical students are legitimate members of the healthcare team, as are paramedical staff, nurses and therapists, and information may be shared with them. The same exacting standards of maintaining patient confidentiality apply to all.

The conclusion is that patients should be explicitly and fully informed about the extent of the involvement of students. What is less obvious is whether the requirement of informing *ipso facto* extends to obtaining consent; in the prior clause (3.1.3.8, cited above), this clearly does not, and the reasonable deduction is that patients need only be informed and not asked to consent to the participation of students. This is contrary to most international norms and practices<sup>[20]</sup> and my own inclination, but excludes specific student-patient interactions, e.g. taking history, physical examination and procedures such as phlebotomy. For non-invasive contact, a simple introduction and explanation, including an explanation of why the examination will aid the student in his/her training (e.g. 'you have a heart murmur'), plus explicit uncoerced but verbal consent by the patient, should suffice.<sup>[20]</sup> For phlebotomy, an explanation of the intended tests and verbal consent would serve. Formal written consent should be obtained for intimate examinations.<sup>[21,22,12]</sup> The student should make an appropriate note of all consent conversations in the patient's folder or notes, and should be aware of what information has already been shared and discussed with the patient. Students should not be the harbingers of bad, or in fact *any*, tidings. This is an ideal opportunity for training of a different kind – for students to hone their communication skills and practise the art of obtaining IC.

Since student contact with patients can occur at various levels, it may be advisable that a relatively senior team member at admission explain why and how students will be involved and that students may act as valued care team members, e.g. performing phlebotomy. The role of students who attend and assist at operations should also be explained. Consent should be obtained if preoperative intimate examinations for training purposes are envisaged, and students should reobtain consent. The consent requirement helps to keep track of the number of students who examine a specific patient, to prevent overtaxing any individual.

*Not complying* with the HPCSA ethical rules and ignoring the SA Bill of Rights may in itself have serious consequences. Furthermore, the autonomy argument and the right to bodily integrity and privacy trump any argument that might be presented to oppose specific IC. Examples of such arguments are:

- obtaining IC in these situations is impracticable
- patients may refuse
- it places an additional unnecessary burden on both patient and an already taxed healthcare team
- for the sake of distributive justice, allocating a little less time to each patient is better than giving some none
- the societal value of proper training outweighs any individual autonomy concerns
- patients will not be harmed, and may be advantaged
- patients implicitly consent and this is sufficient.

Supplying information about student participation in outpatient settings, and obtaining consent, may be more problematic. Nevertheless, expediency is not an excuse, and concise verbal consent will suffice. This, too, is an art that has to be learnt and developed.

### Intimate examinations of patients under general anaesthesia

A particular conundrum that has attracted a lot of media attention is medical students performing intimate pelvic examinations. This can take place in outpatient and ward settings, and is integral to proper student training. When done in wards without supervision, written IC is advisable, as is the presence of a chaperone (nurse). In outpatient settings, supervision is likely, and verbal consent should be sufficient, since a witness is present. However, a controversy has developed around medical students doing these examinations on anaesthetised patients prior to surgery *without specific consent*. The utilitarian justification for these examinations is that women are not harmed because they are unaware, that these are ideal conditions to learn how to perform pelvic examinations and that society at large ultimately benefits. It is fallacious to argue that persons can only be harmed if they are aware of the harm; millions of South Africans were harmed because their human rights were denied under apartheid, even if they were unaware that such rights existed. Several groups of students, including Israeli<sup>[23]</sup> and American<sup>[24]</sup> students, have objected to being expected to examine patients under these circumstances. A multicentre study in Wales, England and Australia confirmed both this expectation and students' discomfort.<sup>[25]</sup> Specific guidelines exist in various jurisdictions, but there is consensus that these clinically unnecessary examinations violate patients' rights to privacy and bodily integrity, and may constitute assault *unless fully informed prior consent is obtained*.<sup>[17]</sup>

### Student procedures and risk

With respect to actual procedures performed by students as part of the healthcare team, including suturing wounds, phlebotomy, deliveries and lumbar punctures, special care has to be taken to minimise risk and harm through adequate pre-training, assessment and supervision. Where appropriate, patients should be informed of these measures. It is likely that risks may nevertheless be increased in inexperienced hands, although few empirical data exist to quantify

these risks.<sup>[16]</sup> There is, however, some anecdotal SA evidence that medical students may be required to perform procedures for which they do not feel adequately prepared, without specific IC.<sup>[26]</sup> It might be counterproductive to overplay risks, yet they should not be underplayed and be presented as a matter of fact. The possibility of patient refusal to be examined/treated by a student is no excuse to deny patients the information they require to make decisions.

## Registrars, midwives and therapists in training

A special case has to be made for house officers, registrars (particularly in the surgical and gynaecological disciplines, and in anaesthesiology), midwives and therapists who are in training. I focus on surgical and anaesthesiology registrars, since the argument is more pertinent. These healthcare providers are both students and qualified doctors. Moreover, they are at various levels of training, knowledge, expertise, experience and clinical acumen. However, they are, as yet, not qualified specialists. They work under different levels of supervision, or no direct supervision, depending on the type of procedure performed, attendant risks, their own experience and expertise and the availability of senior personnel to act as supervisors. Even if not in close attendance in the operating suite, consultants should always be available to consult or assist. Personnel who supervise junior staff may be held accountable for mistakes and preventable complications. Senior registrars are usually skilled at their art. Training is customarily well structured and monitored, and no one should be put in a position where (s)he is required to perform beyond his/her experience or expertise. That being said, each operation is unique, and adds to the experience of the operator. It is precisely to cater for the unexpected and unusual that experience is required.

The decision as to what surgical procedures a registrar should be allowed to perform has both objective and subjective aspects and implications. Objectively, supervisors (consultants) should assess the registrar's eligibility to perform more advanced procedures. Subjectively, each registrar is expected to comply with the guidelines in HPCSA Booklet 2, clause 21: 'A practitioner shall perform, except in an emergency, only a professional act (a) for which he or she is adequately educated, trained and sufficiently experienced,<sup>[27]</sup> so a registrar may be held personally accountable if (s)he performs surgery beyond this pale and complications ensue. The word 'certified' is omitted from this clause. The onus is on the doctor to decide what is within his/her grasp, and to justify decisions if required.

It therefore seems reasonable to deduce that there is no requirement to supply additional information to the patient, and a registrar may perform surgery judged within his/her capabilities provided:

- authentic IC is obtained and the provisions of the NHA and HPCSA guidelines on IC are met
- patients are informed about the identities of all members of the healthcare team, and specifically about who will finally take responsibility
- a proper and effective supervision system is in place to evaluate and review the registrar's competence
- the registrar complies with Clause 21(a) above.

Strict adherence to such protocols could ultimately be to the patient's benefit.

However, this set of circumstances and requirements applies *only* to clinically indicated diagnostic and therapeutic interventions. A different scenario exists when examinations and interventions are performed which have no diagnostic or therapeutic value, i.e. for instructional reasons only. To start with, there is a grey area where instruction and therapy coexist. Take as an example, firstly, pelvic examination of a patient under general anaesthesia preceding a decision to perform either a vaginal or abdominal hysterectomy (or just preceding surgery). A registrar who will assist at the operation co-examines the patient, and the consultant who will make the final decision and perform the surgery first elicits the registrar's opinion before making his/her own known. The registrar has a dual role: that of professional assistant, for which no specific additional consent is required, and also that of trainee, for which consent should possibly be obtained. A second example to which I have been exposed has to do with training anaesthesiology registrars to use aids to endotracheal intubation. These are helpful to intubate difficult airways when visualisation of the vocal cords is impossible during direct laryngoscopy, or when the patient's head should not be moved, e.g. with unstable cervical spine fractures. Examples of these aids are fibre-optic intubating scopes and a type of airway which is placed in the pharynx to cover the larynx, and through which an endotracheal tube can be passed blindly. Training on normal healthy subjects undergoing routine surgery is required to ensure smooth and less stressful utilisation in emergencies, when these aids can save lives. There may also be clinical indications for the use of these aids. The murkiness of these scenarios is that it is up to the professionals involved to determine which role predominates or should apply, particularly if adjudging the encounter to be predominantly educational requires extra effort, forethought and time to obtain prior consent. It is unlikely that there will ever be any repercussions if the policy in a particular unit maintains that the educational aspects of encounters such as these be habitually underplayed, on the face of it rendering additional consent unnecessary. However, professionals have an additional responsibility to protect and advance the rights of their wards when the latter are incapacitated (e.g. anaesthetised) and cannot fend for themselves. Ethics is, after all, an aspirational endeavour, whereas rules invariably set a minimum standard. Consideration should also be given to the message that our actions and practices may send out to junior staff, nurses and students, which could either further or negate the importance of ethically sound practice. The importance of role models in practical ethics education should not be overlooked.

In the cases quoted above, no real harm was done. In other instances, the potential for increased harm or risk may exist. A good example is anaesthesiology registrars learning to perform spinal and epidural blocks. The dura should not be punctured when doing epidurals, but it is well documented that the risks of dural puncture, among other procedures, are inversely proportional to the experience of the operator.<sup>[28]</sup> Dural puncture with a large-bore epidural needle may cause severe headaches owing to leakage of cerebrospinal fluid, requiring follow-up invasive treatment. Unless otherwise informed, when IC is obtained it is implied and the patient accepts that the caregiver is appropriately competent. On top of this,

HPCSA Booklet 2, clause 21, clearly requires that practitioners, except in emergencies, only perform professional acts 'for which he or she is adequately educated, trained and sufficiently experienced'.<sup>[26]</sup>

## Quo vadis?

In this section I outline some general principles and thoughts without being over-prescriptive. It is left to institutes where training is provided, hospital authorities and departments and clinical specialties, guided by clinical ethics committees and e.g. the Council for Health Service Accreditation of Southern Africa (COHSASA) IC and ethics standards<sup>[29]</sup> to consider how these principles should be applied. Institutes should monitor and regularly audit the authenticity of IC for patient participation in medical training. My reflection will cover, firstly, attitudes towards patients, and secondly, institutional and departmental policies, practices and procedures, and is intended to promote dialogue and appropriate action within institutions and departments. Note that I have focused on undergraduate and postgraduate medical students, but my comments are applicable to all registered healthcare students who interact with patients.

To begin with, following clause 9 of the SA Bill of Rights<sup>[5]</sup> and Clause 5.6 of HPCSA Booklet 1,<sup>[10]</sup> it should be our firm conviction that any form of discrimination has no place in authentically ethical medical practice. Just because patients attend state hospitals, and may not be educated or be illiterate and medically/scientifically naive, may not know their rights and may trust those who care for them, is no licence to discriminate. Ethically speaking, the ideal is that all patients be treated equally, because human rights are universal. Procedures need to be in place and appropriate steps taken to ensure that their rights are upheld and promoted.<sup>[10]</sup>

Secondly, each institute should develop a set of ethical principles (a credo or mission statement if you like) that should govern the treatment of patients. Necessary principles should be developed by clinical ethics committees, and should include:

- a reference to distributive justice and non-discrimination
- the assurance that no examinations or procedures will take place without expressed IC
- confirmation that medical and ethical principles and guidelines governing medical practice and ancillary services will be upheld
- a statement that the interests of patients will always predominate.

This poster-sized notice or a separate dedicated notice should declare that the institute trains medical personnel, and provide details of student and registrar training as it might affect patients. It should confirm that appropriate supervision of training always applies and measures are in place to minimise risk and prevent harm, and that the patient's prior consent will always be sought. Complaints procedures should be outlined. This should be written in understandable lay terms and language, translated into all languages locally used, and clearly displayed at all public hospital entrances and throughout the institute. The Patient's Rights Charter should be displayed in the same way. Each patient should be given copies of these documents to read in his or her own time. A ward sister or other appropriately trained staff member, or the student to whom the patient will be allocated, should explain these documents and co-sign with the patient, confirming comprehension. Regular audits of this process should be performed to ensure compliance.

The ethos of the institute should reflect its mission statement. Each institution should reflect on and develop principles and guidelines

on student interaction with patients, particularly regarding IC for all patient interactions. The Consensus Statement<sup>[20]</sup> developed by the healthcare faculties of the universities of Auckland and Otago is an excellent departure point. Note that the act of providing IC is voluntary. This implies that patients have the right to refuse participation in student training, and may not be coerced. Most patients are likely to consent, but may not be penalised or abandoned if they do not.<sup>[16]</sup> Where the meeting of service delivery and training may cause inherent tensions, particularly where procedures are performed purely for training purposes, departments should be sensitive to the requirements for specific IC and develop appropriate policies to guide the management of IC. Guiding principles are that training should always be appropriately supervised and consented to, and that patients should not be exposed to additional harm or risk. Risks cannot invariably be prevented (such as in the epidural headache example described above), but can be curtailed. Departmental policies and procedures should ensure that they are, and patients be informed accordingly.

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