

# COVID-19 and its impact on informed consent: What should health professionals tell their patients or their proxies?

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Given the increasing number of ethical and legal issues arising from the impact of the COVID-19 epidemic on informed consent by patients, it is necessary for health professionals to explain to patients how the measures taken to combat the spread of the virus impact on their right to give informed consent. Patients need to be reassured that wherever possible, health professionals are ethically bound to obtain informed consent from patients before they subject them to diagnostic testing and treatment, but at the same time, have to comply with the demands of the law. While the South African Constitution, statutory law and the common law all recognise a person's right to consent before being subjected to treatment or surgical operations, it is necessary to take remedial steps, because of the dangers of spreading the potentially fatal COVID-19 virus, to prevent this. Such steps may involve compelling patients to be screened, tested and treated – sometimes without their consent. Guidance is given to healthcare professionals on how they should counsel their patients, and what they should tell patients about the impact of the COVID-19 regulations on healthcare professionals' ethical and legal duties regarding the obtaining of informed consent, as well as on whether, if asked, employers can compel their employees to undergo testing without consent, and what to tell patients about this.

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The COVID-19 pandemic has given rise to a number of ethical and legal issues arising from its impact on informed consent from patients. The South African (SA) government has imposed strict measures to combat the spread of the virus, some of which impact on the patient's right to give informed consent for screening, testing and treatment of the COVID-19 virus. Patients need to be reassured that wherever possible, healthcare practitioners are ethically bound to obtain informed consent from patients before they subject them to diagnostic testing and treatment, but have to comply with the demands of the law. Healthcare practitioners, therefore, need to explain the ethical and legal situation to their patients. To assist with this, the following issues are discussed: (i) the ethical rules regarding informed consent; (ii) the law regarding informed consent; (iii) the COVID-19 regulations and their impact on informed consent; and (iv) whether employers may compel their employees to undergo testing for COVID-19.

## Ethical rules regarding informed consent

The ethical and professional rules of conduct of the Health Professions Council of SA (HPCSA)<sup>[1]</sup> require that patients are not diagnosed or treated without their informed consent (rule 27(a) and (g)), and that a practitioner must explain to patients the benefits, costs and consequences associated with each service option offered (rule 7(6)).

In terms of the HPCSA's general ethical guidelines for healthcare professionals,<sup>[2]</sup> healthcare practitioners should: (i) give their patients the information they ask for or need about their condition, its treatment and prognosis; (ii) explain the information to their patients in a language that they understand and in a manner that takes into account their level of literacy, understanding, values and

belief systems; (iii) refrain from withholding from their patients any information, investigation, treatment or procedure that the healthcare practitioner knows would be in the patient's best interests; and (iv) apply the principle of informed consent as an ongoing process (para 5.3.1 to para 5.3.4).

The HPCSA's guidelines on ethical considerations regarding informed consent<sup>[3]</sup> state that patients have a right to information about their condition and the treatment options available to them. Such information may vary depending on the nature of the condition, the complexity of the treatment, the risks associated with the treatment or procedure and the patient's own wishes (para 3.1.1). The guidelines (para 3.1.4) then draw the attention of practitioners to the requirements of the National Health Act No. 61 of 2003 (section 7).<sup>[4]</sup> The guidelines also state that healthcare practitioners should respond honestly to any questions raised by patients and, as far as possible, answer them as fully as patients require, including when patients ask about other treatments that are unproven or ineffective (para 3.2). Healthcare practitioners should not withhold information necessary for decision-making unless they judge that disclosure of some relevant information would cause the patient serious harm (para 3.3.1).

The HPCSA informed consent guidelines<sup>[3]</sup> specifically deal with consent to screening and testing, which are particularly relevant in the context of the COVID-19 regulations. The HPCSA accepts that:

'Screening or testing of healthy or asymptomatic people to detect genetic predispositions or early signs of debilitating or life-threatening conditions can be an important tool in providing effective care. However, the uncertainties involved in screening or testing may be great, for example, the risk of false positive or false negative results. Some findings may potentially have serious medical, social

or financial consequences not only for the individuals, but for their relatives. In some cases the fact of having been screened or tested may itself have serious implications' (para 16.2.1).

The HPCSA has also issued COVID-19 guidelines for health practitioners on how to deal with the COVID-19 outbreak,<sup>[5]</sup> but they do not deal with informed consent. The guidelines, however, mention that practitioners should follow the professional guidelines for ethical decision-making as far as possible, including in emergencies, but acknowledge that the COVID-19 pandemic may mean that practitioners are 'required to depart from their established procedures, although this should be done responsibly, reasonably and in the best interest of patients' (para 2).

### What health practitioners should tell their patients

Ethically, in terms of the informed consent guidelines,<sup>[3]</sup> practitioners should explain clearly to their patients: (i) the purpose of any screening or test; (ii) the likelihood of positive or negative findings and the possibility of false positive or negative results; (iii) the uncertainties and risks attached to the screening or testing process; (iv) any significant medical, social or financial implications of screening or testing for the particular condition or predisposition; and (v) follow-up plans, including the availability of counselling and support services (paras 16.2.1 to 16.2.5).

Healthcare practitioners should also inform their patients that ethically, as far as is reasonably possible, they will not screen, test or treat their patients without their informed consent or that of their proxies, unless the law requires them to do so. Even then, in such circumstances they will observe their ethical duties regarding the information and assistance they are obliged to provide to their patients.

### The law regarding informed consent

The SA Constitution<sup>[6]</sup> provides that everyone has the right to bodily and psychological integrity, which includes the right to security in and control over their body (section 12(2)(b)), and the right not to be subjected to medical or scientific experiments without their informed consent (section 12(2)(c)). These rights may, however, be limited provided that it is reasonable and justifiable to do so (section 36(1)). For instance, a non-compliant extensively drug-resistant tuberculosis (XDR-TB) patient can be quarantined to ensure isolation and compliance with their medication, provided the isolation facilities are consistent with fundamental human rights.<sup>[7]</sup>

The National Health Act provides that healthcare providers must take all reasonable steps to obtain the patient's informed consent (section 7(2)), provided that the patient has legal capacity (section 7(3)). Health services may not be provided to a patient without the patient's informed consent (section 7(1)). However, if the patient is unable to give informed consent, proxy consent may be given by: (i) a person who has been mandated by the patient in writing to grant consent on their behalf; (ii) a person authorised to give such consent in terms of any law or court order; or (iii) where no person is mandated or authorised to give such consent, the spouse or partner of the patient or, in the absence of such spouse or partner, a parent, grandparent, adult child or a brother or a sister of the patient, in the

specific order as listed (section 7(1)). In addition, consent by a patient is not necessary where (i) the provision of a health service without informed consent is authorised in terms of any law or court order (e.g. as previously mentioned, a patient quarantined for XDR-TB non-compliance);<sup>[7]</sup> (ii) failure to treat the patient, or group of people that includes the patient, will result in a serious risk to public health; or (iii) any delay in the provision of the health service to the user might result in their death or irreversible damage to their health, and the user has not expressly, impliedly or by conduct refused that service (section 7(1)).

The National Health Act also requires the following information to be given to patients: (i) their 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; (ii) the range of diagnostic procedures and treatment options generally available to the user; (iii) the benefits, risks, costs and consequences generally associated with each option; and (iv) the user's right to refuse health services, and the implications, risks, obligations of such refusal (section 6(1)). Furthermore, the healthcare provider must, where possible, inform the patient of this information in a language that the patient understands and in a manner that takes into account their level of literacy (section 6(2)). Special provisions exist for consent by children in terms of the Children's Act,<sup>[8]</sup> and mentally disabled persons under the Mental Health Care Act No. 17 of 2002.<sup>[9]</sup>

The common law provides that before health practitioners treat patients, they must obtain informed consent, which means that a patient must: (i) have knowledge of the nature or extent of the harm or risk involved by being informed about 'material risks' that may affect their decision to consent; (ii) appreciate and understand the nature of the harm or risk; (iii) have consented to the harm or assumed the risk; and (iv) have provided a comprehensive consent that extends to the entire transaction, including its consequences.<sup>[10]</sup> In addition: (i) the patient must have given the consent freely and voluntarily; (ii) the patient must have the legal capacity to give consent – i.e. not be an incompetent child or mentally disabled person; and (iii) the consent must not be contrary to public policy<sup>[11]</sup> or law or medical ethics, as was so in the Michael Jackson case, where the singer died as result of consenting to the use of an anaesthetic at home to alleviate his insomnia when such anaesthetic should only be administered in a hospital environment.<sup>[12]</sup>

### What health practitioners should tell their patients

Health practitioners should inform their patients that certain statutes and the common law require them to obtain informed consent before treating patients, except where, inter alia, the provision of a health service without informed consent is authorised in terms of any law or a court order, or failure to treat the patient, or group of people that includes the patient, will result in a serious risk to public health. However, in all such cases the healthcare practitioner should assure the patient that even if (s)he does not consent, he or she will nonetheless be provided with the information required to be given in terms of National Health Act and the common law.

Health practitioners should also mention that the exceptions mentioned above are in line with some of the COVID-19 regulations

under the Disaster Management Act No. 57 of 2002<sup>[13]</sup> aimed at preventing the spread of COVID-19 in SA.

## The effect of the COVID-19 regulations on informed consent

The COVID-19 regulations<sup>[13]</sup> provide that any person who has been clinically (or by a laboratory) confirmed as having contracted COVID-19, or who is suspected of having contracted COVID-19, or who has been in contact with a person who is a carrier of COVID-19, may not refuse to consent to: (i) a medical examination, including the taking of any bodily samples; (ii) admission to a health establishment or a quarantine or isolation site; or (iii) submission to mandatory prophylaxis, treatment, isolation or quarantine in order to prevent transmission of the disease (regulation 6 (1)). If the person refuses to consent, (s)he may be quarantined for up to 48 hours until a court order for detention in isolation is obtained. (regulation 6(1)). Persons who refuse such prophylaxis, treatment, isolation or quarantine may also expose themselves to prosecution for intentionally exposing other persons to COVID-19, and convicted of assault, attempted murder or murder (regulation 14(3)). Although they do not have the direct intention to infect others, should they infect them, they could be regarded as having the 'eventual intention' to do so, and could therefore be prosecuted for intentionally exposing others to the risk of COVID-19 infection. 'Eventual intention' arises when a person subjectively foresees the possibility of death or serious bodily injury because of their conduct, but nonetheless proceeds with such conduct.<sup>[14]</sup>

The COVID-19 regulations<sup>[13]</sup> provide that if a doctor (or a laboratory) takes a sample from a patient for testing for COVID-19, the clinician (or laboratory) must record the patient's name, identity or passport number, residential address and cellular phone number, as well as obtain a copy or photograph of the passport, driver's licence, identity card or identity book of the patient tested, and promptly submit this information, along with any information regarding the likely contacts of the person tested, to the Director General of Health for inclusion in the COVID-19 tracing database established in terms of the regulations (regulation 8(6) and (7)). The information will be captured in the database and sent to the designated judge, who will ensure that it is used for the purposes of the COVID-19 regulations (regulation 8(14)).

There is no provision that patients must consent to this disclosure, but the regulations respect the confidentiality of patients by providing that such information remains confidential (regulation 8(4)), and may not be disclosed unless this is authorised in terms of the regulations, or the disclosure is necessary for addressing, preventing or combatting the spread of COVID-19 (regulation 8(5)).<sup>[15]</sup>

## What health practitioners should tell their patients

Health practitioners who send patients for COVID-19 testing and/or test patients who refuse to consent, should first counsel them by explaining that although they have to send personal information about their patients and copies of their patients' documents to the Director General of Health for inclusion in the COVID-19 tracing database, such information will be kept confidential. The information will be captured in the database and sent to the designated judge, who will ensure that it is used for the purposes of the COVID-19 regulations. Doctors should also tell their patients that any information mentioned during

their consultations that is not relevant to the COVID-19 preventive measures, or necessary to be disclosed in terms of any other law, will be kept confidential.<sup>[15]</sup>

Where patients refuse consent, health practitioners should counsel them on why they should comply with the precautions in COVID-19 regulations to halt the spread of the virus. They should explain the consequences of refusing to comply, including that it is a criminal offence to: (i) refuse to submit to a medical examination; (ii) refuse to go into isolation or quarantine in order to prevent endangering others; or (iii) fail to get tested if one thinks that one might have COVID-19. Furthermore, it must be explained that if patients refuse, they may be quarantined for up to 48 hours until a court order for their detention in isolation is obtained. In addition, doctors must state that by patients' not subjecting themselves to the necessary medical examination, isolation, quarantine or test, such a refusal or failure that results in infecting others may be regarded as recklessness, which could be interpreted to mean that patients have the 'eventual intention' to infect others, and could therefore be prosecuted for intentionally exposing others to the risk of COVID-19 infection.<sup>[15]</sup>

## May employers compel their employees to undergo testing for COVID-19?

The Constitution states that everyone has the right to an environment that is not harmful to their health or wellbeing (section 24(a)), while the Occupational Health and Safety Act No. 85 of 1993<sup>[16]</sup> provides that every employer shall provide and maintain, as far as is reasonably practicable, a working environment that is safe and without risk to the health of employees (section 8(1)). The Employment Equity Act No. 95 of 1998<sup>[17]</sup> prohibits the testing of employees unless this is permitted by legislation (which includes regulations under an Act), or the testing is justifiable in light of medical facts, employment conditions, social policy or the fair distribution of employee benefits, or necessary for the job requirements (section 7). Testing, when legally justified, however, must be done by a healthcare practitioner – not the employer.

It has been pointed out<sup>[18]</sup> that in terms of the National Health Act regulations relating to the surveillance and the control of notifiable medical conditions,<sup>[19]</sup> carriers or cases of notifiable medical conditions such as a 'respiratory disease caused by a novel respiratory pathogen' (annexure A, Table 1), which includes COVID-19, must be immediately reported, and such carriers must subject themselves to further medical examination. The regulations also require persons in contact with a carrier or case of a notifiable medical condition to subject themselves to a medical examination (regulation 14(3)).

It has also been suggested that the notifiable disease regulations<sup>[19]</sup> require such medical testing, and employers may compel their employees to undergo medical testing for COVID-19 where: (i) the employee has recently travelled to an area in which COVID-19 is prevalent; (ii) the employee has had recent contact with persons travelling from an area in which COVID-19 is prevalent; or (iii) the employee exhibits symptoms consistent with the known symptoms of COVID-19.<sup>[18]</sup> If an employee tests positive for the virus, in terms of the COVID-19 disaster management regulations (s)he may not refuse to consent to admission to a health establishment or a quarantine or isolation site, or to mandatory prophylaxis, treatment, isolation or quarantine in order to prevent transmission (regulation 6 (1)). In any event, employers are entitled to rely on their obligations in

terms of the Occupational Health and Safety Act to refuse entry to the workplace in order to protect other employees from COVID-19 contagion.<sup>[18]</sup> Failure to do so may result in the prosecution of such employers (section 38(1)(a)). In all cases, however, such testing must be done by a healthcare provider.

In the case of healthcare practitioners employed in a health establishment, there is a special duty on such establishments under the National Health Act to take steps to minimise: (i) injury or damage to the person and property of healthcare personnel working at the establishment; and (ii) disease transmission (section 20(3)).<sup>[20]</sup>

## What health practitioners should tell their patients

Health practitioners should tell their patients that employers may compel them to undergo medical testing for COVID-19, if the employee has recently travelled to an area in which COVID-19 is prevalent, or the employee has had recent contact with persons travelling from an area in which COVID-19 is prevalent, or the employee shows symptoms consistent with the symptoms of COVID-19. Employers are required to do this in terms of the Occupational Health and Safety Act, Employment Equity Act and National Health Act regulations dealing with notifiable diseases, because there is a duty on them to protect the health and safety of other employees and persons in the workplace. However, the testing must be done by a healthcare provider – not the employer.

Once they have tested positive, employees will be bound by the COVID-19 regulations, which require them not to refuse to consent to admission to a health establishment or a quarantine or isolation site, mandatory prophylaxis, treatment, isolation or quarantine in order to prevent transmission. Even if they refuse consent, they will still be quarantined until a court order is obtained. They may also be liable for criminal penalties for exposing other employees to COVID-19 if any other workers are infected by them. Employers may also be criminally liable if they do not take steps to prevent their employees from exposing others to COVID-19 infection.

## Conclusion

The HPCSA's ethical rules, the Constitution, statutory law and the common law all recognise a person's right to consent before being subjected to treatment or surgical operations. However, because of the dangers of spreading the potentially fatal COVID-19 virus, it has been necessary for the government to take steps to prevent transmission. As a result, patients may be compelled to be screened, tested and treated – sometimes without their consent. In such cases, healthcare professionals should try to counsel their patients to comply with extraordinary precautions in COVID-19 regulations to halt the spread of the virus. They should also give their patients the usual information that they are ethically and legally required to provide, and explain to them that, where necessary, the COVID-19 regulations may require them to screen, test or treat patients without informed consent. They should explain the consequences of refusing to comply with the regulations for both themselves and their patients. Likewise, if asked, they should mention that circumstances arise when employers

can compel their employees to undergo testing for COVID-19 without consent, failing which they may exclude them from the workplace. Such testing, however, must be done by a healthcare provider.

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