

Treating your virtual patient

What are your ethical and legal responsibilities?

This report is based on the webinar presented by Elizabeth de Stadler on the 21st of April 2021



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Learning objectives

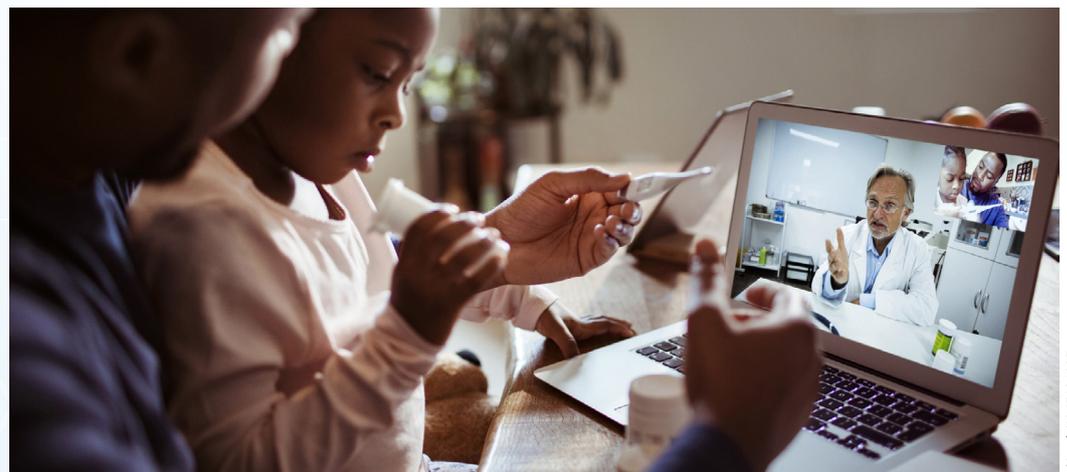
You will learn:

- The trend towards incorporating digital health services into daily clinical practice, particularly in the context of the COVID-19 pandemic
- Potential risks and opportunities associated with the practice of telehealth
- Guidelines and regulations, and their inadequacies, for the practice of telehealth
- Lessons from the ethics of affiliated industries.

Introduction

The adoption of new technology is always a tale of challenges and opportunities, 'the yin and yang' of innovation. Sub-Saharan Africa is considered to be the new breeding ground for global digital health, and there are many implications. Digital health innovations improve access to healthcare by vulnerable communities and offer new commercial opportunities for healthcare practitioners, healthcare service providers and healthcare companies.

The trend toward incorporating digital health services into daily clinical practice preceded the onset of the COVID-19 pandemic. However, circumstances during the past year have demanded considered and accelerated adoption of these innovations, which has highlighted certain challenges associated with the practice of telehealth. Access to digital health services can be hampered by many factors - while some communities have little or no access to electricity at all, the whole of South Africa is periodically subject to unreliable electricity provision; certain parts of the country have really patchy cellular network coverage; other parts of the country have poor internet speeds and, importantly, the cost of data for South Africans is among the most expensive in the world.

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The Health Professions Council of South Africa (HPCSA) has had to urgently review its regulations on telehealth, and the law has had to be reconsidered within the framework of the Disaster Management Act. This provides a unique opportunity to consider whether these changes are appropriate beyond the COVID-specific context and which of these changes should be made permanent. Elizabeth de Stadler shares her expertise in consumer law when considering the ethical and regulatory implications of the current and future practice of telehealth.

Telehealth trends – to infinity and beyond

The HPCSA created general ethical guidelines for good practice in telemedicine in 2014. In essence, these guidelines stated that all telemedicine services offered should involve a healthcare provider where there is an actual face-to-face consultation and physical examination of the patient in a clinical setting. Only some services could be remotely rendered, and always with a face-to-face component to that service.

The emergency setting of the COVID epidemic has highlighted the shortfalls and obstacles in the original guidelines, which have been updated to state that remote consultation should preferably be practised in circumstances where there is already an established practitioner-patient relationship. The concept of telemedicine or telehealth has also been broadened to providing a greater range of remote digital health services and consultation to the population while in the enforced isolation of hard lockdown. It is undoubtedly easier to have a virtual interaction with somebody already known to you, as there are certain micro-expressions and gestures that you will be able to interpret more effectively because of previous interactions with that person; it is considerably more difficult to do the same when interacting virtually with a stranger. Of note, however, is that provisions have been made for telepsychology and telepsychiatry, where strangers may be treated remotely; this is an interesting distinction in telehealth recommendations, highlighting an opportunity to discuss what we want for post-COVID regulations regarding the delivery of medical services.

What are the risks of telehealth?

Effective communication is key. Patients are not very good at describing their symptoms accurately and you might be consulting with a child, or a person who belongs to a different culture or for whom English, for instance, might be a second or third language. There is also the question of ‘social literacy’, beyond

The updated guidelines confirm that a fee can be charged for telehealth services. Stating the obvious is important in this case, because it must be remembered that remote consultation should always be in the best clinical interests of the patient. Telehealth decision-making was easier during hard lockdown, but now that we are in this in-between phase, it is trickier to decide when to see a patient in person and when to consult remotely. This grey area is not currently covered by the regulations and it is up to the clinician to navigate this decision by consistently thinking about the clinical interests of the patient.

Effective communication is paramount in the context of remote consultation, and the clinician needs to be a communication specialist. Factors that should be considered are detailed in Table 1.

Table 1. Communication factors to be considered

- How well do you know the patient?
- How articulate is the patient?
- Do you speak the same language?
- Do you belong to the same culture?

Useful resources for further information on the regulations and guidelines include the Medical Protection Society website <https://www.medicalprotection.org/southafrica>, which has an excellent set of FAQs and one can only assume that these will be updated as change occurs. Publicly available on the internet are some excellent write-ups by various lawyers on the regulatory changes.

how well a person speaks, reads or writes. Some people suffer from ‘social exclusion’, usually the result of poverty, which means that they simply do not have the same level of life experience as other patients and this can typically impact how well people can describe what is wrong with them. This divide needs

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to be bridged, irrespective of the mode of practice of medicine, and potential miscommunications can easily be amplified in the digital setting. Language barriers, the loss of non-verbal cues and the loss of the opportunity to actually examine patients can add to the risk of misdiagnosis or miscommunication between patient and doctor. There is also the risk, particularly in patients unknown to the clinician, of their over-exaggerating their symptoms or the possibility that the symptoms might not even exist. American literature on telehealth reports concerns as to whether it makes it easier for people to obtain opioids, for instance, when there is no clinical reason for them to take the drugs.

There are reports by doctors that they cannot charge as much for remote services as they would for face-to-face consultations and that

they are facing dramatic changes in their business model. Uncertainty about how much can be charged for telehealth services is therefore also problematic.

Other regulatory issues relevant to telehealth include privacy. What are the ethical conundrums that we face when we start using technology in an inherently private space? Important considerations in this regard are noted in Table 2.

Table 2. Important considerations when using technology

- How much clinical information are these platforms harvesting?
- What are they using that information for?
- Are they selling it to other service providers?

What opportunities does telehealth offer?

Clinicians report that telehealth is a way to render their services that it is much cheaper and more efficient for the patient from a time-saving perspective; it is also cheaper for the practice due to changing physical infrastructure needs. Telehealth also saves on valuable and scarce resources, such as personal protective equipment.

Traditionally, clinicians have been very wary of adopting new technologies to facilitate or to automate practice management. The use of telehealth platforms has facilitated the automation of other processes traditionally performed in a manual and costly manner. This 'digital transformation', where using or digitising one part of a business has a knock-on effect in respect of automating other aspects of the business, thereby lowering expenses and improving efficiency, can benefit the actual provision of medical care and advice.

There is a very strong argument that telehealth will enable better access to healthcare

for marginalised communities, be they rural communities or those with other forms of social exclusion such as poverty and low literacy. There are enormous opportunities to actually make healthcare available to more people. Telehealth also provides a growth opportunity to the clinician; a larger patient base implies that even though telehealth is cheaper, it does not necessarily mean that revenue will drop.

Very importantly, we cannot ignore the fact that it is extremely unlikely that COVID will be the last disaster that makes it difficult for us to venture outside of our houses. Whether it be the result of another pandemic or natural disasters and climate change, it is likely that we are going to see these kinds of disruptions again and again. We therefore need to think about the structures and the permanent regulatory changes that we could put in place in the future to improve our resilience to disaster in the practice of medicine.

What do the HPCSA guidelines and regulations say about the practice of telehealth?

The HPCSA states that in order to practise telehealth, you have to be a doctor. Ethical values and respect for human rights, whereby actions are in the best interest of the patient, with respect for privacy and dignity, informing patients and maintaining confidentiality, are still applicable when consulting remotely.

The doctor must decide the diagnosis, scope of care and treatment, with necessary medical evaluation, history-taking and informed consent. This should not be limited or influenced by non-clinical considerations of telemedicine technologies.

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Elements of these current guidelines are problematic, and were even prior to the COVID pandemic. For example, in this digital age many patients present to the consultation already knowing their diagnosis; so in the

digital setting, performing a proper medical examination and obtaining informed consent before proceeding to treatment become even more important.

Beyond the law – learning about ethics from other industries

The answers to conundrums in the healthcare setting on many occasions lie not in the regulations, but in ethics. When considering the multidisciplinary approach required for

effective telehealth, it is important to learn about ethics from other industries, particularly as medicine, innovation and technology increasingly overlap.

World Economic Forum ethical principles

The following World Economic Forum ethical principles were created in the context of COVID-19 tracking technology.

Bias and discrimination

Is there any bias or risk of discrimination in the tool, and if so, how can they be mitigated? While telehealth opens up the world and gives more people access to healthcare, we need to think about who these people are, because they are not necessarily the same as the patient population that one ordinarily treats. When thinking about technologies such as artificial intelligence and machine learning, it must be remembered that they are not neutral as they use existing data to learn and will have bias towards the characteristics of the creator. In order to practise telehealth in an inclusive manner, it is important to recognise inherent bias against those who do not speak our language and/or who are from a different culture, for example.

Accessibility

Is the tool accessible to anyone? If the practice of telehealth requires fantastic internet speeds and an uninterrupted supply of electricity, it may create new ways of excluding access to healthcare.

Proportionality

What are the trade-offs? Are the benefits proportional to the risks?

Privacy

Have we respected privacy by design? Is privacy a priority? What can we do to guard the privacy of our patients on these platforms?

Accountability

Who will guard the guardians? Who is accountable for how the technology works? If you are going to use a telehealth platform, it is part of your duty to the patient to understand exactly what the implications of using that particular platform are and to understand how the information flows, whether the information is still going to be confidential and who owns that information.

Risk prevention

How can we limit the fallout if something goes wrong?

Performance

Is the system accurate? How will it be assessed? Are the best available tools being used?

Right to information

Are users well informed? Consent is no longer only about the treatment, but also about rights to privacy when using telehealth platforms.

Consent

How do you ensure that users provide informed, explicit and free consent?

Guidance from the Institute for Ethical Machine Learning

The Institute for Ethical Machine Learning provides guidance for technologists to develop machine learning systems responsibly. Bias evaluation is one of the eight principles of this guidance, as is ‘explainability’, a term which could encompass the informed

consent requirements of clinical practice. ‘Data risk awareness’ and ‘trust by privacy’ are also features of machine learning and artificial intelligence common to the practice of medicine.

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Nuffield Bioethics principles

Principles subscribed to by Nuffield Bioethics include:

- Oversight by an inclusive and transparent advisory board (including the public)
- Agreement on and publication of ethical principles
- Guarantees of equity in respect of access and treatment
- A transparent and auditable algorithm
- Integrating evaluation and research to inform management of future outbreaks
- Careful oversight and effective protections around the use of data
- Sharing of knowledge with other countries, especially low- and middle-income ones
- Involving the minimum imposition possible

- Guidance by the three moral values of equal respect, fairness and the importance of reducing suffering.

These principles raise important questions. Do you as a physician know how these technologies work? Have you agreed with everybody else who helps you to provide these services in a way that follows ethical principles? Are there guarantees in place where you monitor and ensure equity of access and treatment, and do not create new ways to be biased against patients? Is the platform that you are using auditable? Telehealth platforms offer the potential for using data generated for research purposes and sharing of knowledge, while obviously always keeping in mind the privacy of the patient.

Future-proofing your practice

As healthcare providers we want to be telehealth or telemedicine pioneers, we want to be good doctors and we want to be efficient doctors, but we also want to be fair and to treat everybody equally. These goals require both honesty and transparency to inspire the trust of patients in both the healthcare services and the technology used to provide these. Healthcare providers must be deliberate in assessing all of the implications of changing the way in which healthcare is delivered, both by the industry and individual

practitioners, while weighing risk against benefit and opportunity.

An observation of the Human Rights Watch on the COVID pandemic is appropriate to the practice of telehealth:

‘The crisis offers an opportunity to demonstrate our shared humanity. We can take extraordinary efforts to fight this pandemic that are consistent with human rights standards and the rule of law.’



Key learnings

- Digital health innovations improve access to healthcare by vulnerable communities
- The COVID-19 pandemic has accelerated the adoption of telehealth in routine clinical practice
- The practice of telehealth may be compromised by lack of, or unpredictable, access to electricity, cellular network coverage and the internet
- The HPCSA has reviewed its regulations on telehealth within the framework of the Disaster Management Act; this provides the opportunity to consider appropriate guidance when looking towards a post-COVID future
- Risks of telehealth include an amplified risk of miscommunication and misdiagnosis, as well as a breach of privacy
- Opportunities of telehealth include access to cheaper healthcare by a larger patient base and also by marginalised communities, along with the positive knock-on effects of digital transformation in the management of clinical practice
- The ethical principles ascribed to by affiliated industries offer useful guidance when considering the future needs of telehealth regulation.

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