NO MORE WAITING ROOM: REGULATING TELEHEALTH IN SOUTH AFRICA

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South Africa's telehealth guidelines, which were in place up until July 2022, were temporarily relaxed during the pandemic to allow health care workers to use telehealth more extensively. The most pivotal change was related to regulations around when telehealth services can be offered. Before COVID-19, telehealth could not be used for first time consultations between patients and healthcare professionals. This hampered the use of telehealth as it required an established relationship or a doubling up of providers (one in the room, and one digital). This temporary relaxation has since been made permanent, an important step toward improving access to telehealth. However, there is still room to grow. This paper makes the case for using "regulatory sandboxes" to incentivize innovation while still protecting patients and providers as the seek, and deliver, quality healthcare.

01
INTRODUCTION

The COVID-19 pandemic brought about a new set of challenges for public health systems for high- and low-income countries alike. Whereas health systems are generally reliant on patients coming to them, there was a need for a more remote-access option during the hard "lockdowns" of the pandemic. This article provides a summary of the work done by Percept entitled "No More Waiting Room," wherein we examined the impact of COVID-19 on telehealth (in practice and in regulation) in South Africa. The work was done in 2021 and has been updated to reflect more recent regulatory changes.

The first paper in the series provided an overview of the South African telehealth sector and the changes brought on by COVID-19. The second paper used five South African telehealth providers as case studies to showcase how telehealth can be utilized to increase access to quality healthcare. The third paper built on the first two and was a deeper reflection on how telehealth can contribute practically to help achieve Universal Health Coverage ("UHC") and improved access to quality affordable healthcare.[2] This third paper also examined the potential implications of a poorly regulated telehealth market and proposed policy recommendations to promote a more robust and ethical telehealth sector.

Telehealth is not new to South Africa. In July 1998, the National Department of Health ("NDoH") convened a task team to coordinate the phased introduction of telehealth into healthcare service delivery in South Africa, and to develop the National Telehealth Strategy. Despite the project's bold and noble ambitions, the provision of equipment, and buy-in at the highest level within the NDoH, it wasn't successfully implemented at provincial level. This was primarily due to a lack of technical expertise at the local level and unreliable funding for the ongoing support and maintenance required.[3]

But, South Africa has come a long way since the early 2000s and there are now many examples of telehealth being successfully used in the South African public and private health sectors. This includes South Africa's flagship mobile health ("mHealth") application "MomConnect,"[4] which aims to improve antenatal care and maternal and child health outcomes through an SMS/WhatsApp messaging service.

Despite the false start in 1998, telehealth has remained part of the NDoH's strategy. The NDoH has moved from the language of mobile health to electronic health and now to digital health in its latest 2019-2024 strategy.[5] The 2019-2024 digital health strategy defines digital health as "*the use of information and communication technology (ICT) for health to, for an example, treat patients, pursue research, educate students, track disease and monitor public health.*"[6] Although this definition is very broad, the strategy explicitly states the importance of maximizing telehealth to achieve the NDoH's strategic aim of "a better life for all" and the National Development Plan ("NDP") 2030 goals of an interconnected and dynamic "information society."[7]

02
THE IMPACT OF COVID-19 ON TELEHEALTH REGULATIONS

Innovation in the health sector is tricky. There is a need to balance the professional and ethical obligation to protect the rights of clients; the need to indemnify doctors from potential unnecessary legal action; and the need to create room and incentivize innovation. While this combination of factors is daunting, sound regulation can support safe innovation that is patient-centered and high quality.

Prior to the COVID-19 pandemic, most of the more mature digital health innovations were only taking place in the pri-

2 Percept Actuaries and Consultants. Unlocking health innovation through balanced regulation [Internet]. Percept Actuaries and Consultants; 2021 Jun [cited 2023 Jul 25]. ("No more waiting room"). Available from: https://percept.co.za/wp-content/uploads/2021/07/Percept_UnlockingHealthInnovationThroughBalancedRegulation-2.pdf.

3 Gulube S, Wynchank S. Telemedicine in South Africa: Success or Failure? J Telemed Telecare. 2001 Feb 1;7 Suppl 2:47–9.

4 MomConnect – National Department of Health [Internet]. [cited 2023 Jul 25]. Available from: https://www.health.gov.za/momconnect/.

5 National Department of Health: South Africa. National digital strategy for South Africa: 2019-2024 [Internet]. Pretoria, South Africa: National Department of Health; 2019 [cited 2023 Jul 25]. Available from: https://www.health.gov.za/wp-content/uploads/2020/11/national-digital-strategy-for-south-africa-2019-2024-b.pdf.

6 *Id*.

7 South African Government. National Development Plan 2030 [Internet]. Pretoria, South Africa; 2011 [cited 2022 Nov 16]. Available from: https://www.gov.za/issues/national-development-plan-2030.

vate health sector and on a small scale. But, with the onset of the pandemic this quickly changed as the whole health system re-oriented itself for mass vaccinations and for providing more remote access.

The Health Professions Council of South Africa ("HPCSA") is a statutory body established to regulate the education, training, and registration of practicing health professionals. Its objective and function are to develop strategic policies in this regard, and in accordance with national health policy as determined by the Minister of Health. In addition to this, the HPCSA's role is to protect patients from any potential abuse, and to defend and provide guidance to healthcare practitioners.

The HPCSA's telehealth guidelines, which were in place up until July 2022, were temporarily relaxed during the pandemic to allow health care workers to use telehealth more extensively. The most pivotal change was related to regulations around when telehealth services can be offered. Before COVID-19, the HPCSA guidelines did not allow first time consultations between patients and healthcare professionals through teleconsultations unless a healthcare professional was present with the patient to consult on behalf of the patient. This hampered the use of telehealth as it required an established relationship or a doubling up of providers (one in the room, and one digital). One provider interviewed stated that the regulation led to "defensive innovation," meaning that innovators were not designing for optimal outcomes for clients or health systems, but instead confined innovations to what was permissible by regulation.

This relaxation of the guidelines allowed for a myriad of COVID-19 related digital health solutions to proliferate and since 2021 many providers in the space have been lobbying the HPCSA to update the official guidelines to reflect this new way of working. This was achieved in August 2022- where the HPCSA changed the name of the guideline from telemedicine to telehealth (to reflect a broader ambit) and gave their support for the use of telehealth solutions irrespective of the longevity of the relationship between patient and provider.[8]

However, even with these new guidelines there is some confusion over whether these must be followed as policy or as recommendations. This lack of clarity poses a potential risk to providers and patients alike and there is a need to promulgate the telehealth guidelines into enforceable and clear policy.

03

ISSUES REGARDING REIMBURSEMENT FOR TELEHEALTH IN THE PRIVATE HEALTH SECTOR

Reimbursement models are a major factor in private healthcare workers' ("HCW") uptake of telehealth solutions. This is not material in the public sector currently, given that staff are salaried, but it may become pertinent as the country shifts towards its National Health Insurance ("NHI") where providers will be remunerated through global fees and the like to care for their patients.

To date, telehealth consultations are broadly reimbursed at lower rates than face-to-face consults. When this rate is too low, HCWs or telehealth providers may choose to not provide these services, preventing access to remote care for patients who cannot present at a facility (for whatever reason) or where there are insufficient human resources for health ("HRH") for the catchment area. According to the telehealth providers interviewed, some medical schemes will only reimburse doctors at the telephonic consultation rate, which is 55 percent of the face-to-face rate. This dampens telehealth innovation not only for the private health sector but for the total South African health sector as well.

Several providers are unhappy with this arrangement.[9] While telephonic consultations used to be short and light, telehealth interventions aim to provide a more comprehensive consultation that can take as long as, or longer than, the face-to-face alternative. However, this landscape is changing with one funder stating (in 2021) that they had created new reimbursement codes which refund doctors at 60-75 percent of their standard consultation fees.

There are signs that some challenges are being addressed and that progress is being made towards more appropriate remuneration. Nevertheless, a glaring challenge remains – the lack of funder support for nurse-delivered telehealth. Given the scarcity of medical doctors in South Africa, and the need to reduce the high cost of health care, nurse-driven interventions are critical for delivering more efficient care.

8 Affairs HC. HPCSA. 2022 [cited 2023 Jul 25]. HPCSA Telehealth Guidelines. Available from: https://www.hpcsa-blogs.co.za/hpcsa-telehealth-guidelines/.

9 Percept Actuaries and Consultants. Unlocking health innovation through balanced regulation [Internet]. Percept Actuaries and Consultants; 2021 Jun [cited 2023 Jul 25]. ("No more waiting room"). Available from: https://percept.co.za/wp-content/uploads/2021/07/Percept_UnlockingHealthInnovationThroughBalancedRegulation-2.pdf.

04

REGULATORY SANDBOXES: LESSONS FROM THE FINANCIAL SECTOR

Regulatory sandboxes have their origins in the financial sector. After the 2008 global recession, regulators encouraged rapid innovation in the financial services market, while managing the need for increased regulatory oversight following the financial crisis.[10]

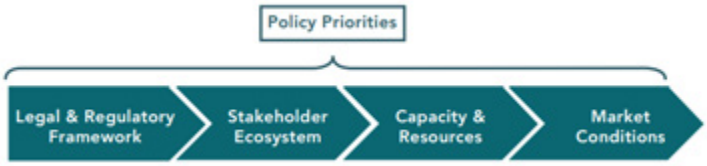
A regulatory sandbox is described by Jenik & Lauer (2017) as a framework established by a regulator that enables, *"… smallscale live testing of innovations by private firms in a controlled environment [operating under a special exemption, allowance, or other limited, time-bound exception] under a regulator's supervision."*[11]

The term was coined by the United Kingdom's Financial Conduct Authority, the financial services regulator in the UK, to develop a framework for regulation that supported innovation and competition in the financial services market. The ultimate aim was to improve the quality and variety of financial services available to UK consumers. In essence, this approach to regulating for innovation creates a controlled environment in which service providers can test or pilot their innovations.[12] Regulators can limit the number of clients providers have access to and, where necessary, create regulatory exemptions to observe how innovations work and identify potential risks they may pose to consumers or the market. It's also an opportunity for service providers to tweak their products to address any concerns the regulator may have.

In the financial sector, particularly following the 2008 financial crisis, regulators often try to provide protection against the systemic risk that poorly regulated financial services and products pose to the financial system. In the health sector, regulators are often more concerned with the risk posed to individual patients if their rights are violated, or their health is compromised by the health service provided. In the case of infectious diseases, the inadequate provision of healthcare may also have system- or population- level consequences. Even though the types of risks may differ, the regulator's mandate is the same – to protect users of the system and by extension, the population at large.

In many sectors, particularly in this technology driven age, regulators are often playing catch-up with innovators. Given that regulators' mandate is mainly to mitigate risk rather than enabling innovation, their response is often to shut down or limit the innovations they don't fully understand or which do not it in the current regulatory envelope**. Regulatory sandboxes allow for a more collaborative approach to regulating innovation.** There's no one-size-fits-all approach to implementing regulatory sandboxes. Regulatory sandboxes have been applied in over 50 countries, mainly in financial services, with varying approaches. Before implementing the sandbox approach, Jenik & Lauer(7) propose the following decision-making process (see Figure 1).

Figure 1: Decision making process for establishing a regulatory sandbox



Firstly, regulators need to consider whether the legal and regulatory framework supports the sandbox approach. It should be clear whether the regulator has the authority to issue waivers or temporary exemptions. Sandboxes are most useful in *"…jurisdictions that have complex regulatory frameworks or highly prescriptive rules, each of which can present obstacles to innovation."*[13] In the case of South Africa, both conditions hold. The HPCSA can issue temporary waivers, as they did during the pandemic.

Secondly, the stakeholder ecosystem needs to be considered. There's often an overlap of different regulations and regulators that need to be considered when implementing a regulatory sandbox. For example, although the HPCSA has drafted the telehealth guidelines, the nature of telehealth means that patient and provider information is shared and stored electronically. Therefore, the Protection of Personal Information ("POPI") Act and the Electronic Communications and Transactions ("ECT") Act should also be taken into consideration. There are likely other regulations that also impact telehealth providers and this ecosystem needs to be considered when implementing a sandbox.

Thirdly, the regulator needs to consider their capacity in terms of staff, funding, and time to implement regulatory sandboxes. Where resources are low, processes that are

10 Jenik I, Lauer K. Regulatory Sandboxes and Financial Inclusion. Washington, DC: CGAP; 2017 Oct. (Working Paper).

11 *Id*.

12 Bhatia A, Matthan R, Khanna T, Balsari S. Regulatory Sandboxes: A Cure for mHealth Pilotitis? J Med Internet Res. 2020 Sep 15;22(9):e21276.

13 Jenik I, Lauer K. Regulatory Sandboxes and Financial Inclusion. Washington, DC: CGAP; 2017 Oct. (Working Paper).

lower cost, such as improving communication between innovators and regulators, should be considered.

Lastly, the conditions of the market need to be taken into account, such as the number of innovations in the market, the quality of these innovations, the level of competition, the market's growth rate, and the level of development of the supporting infrastructure.[14]

In making the case for sandboxes in the telehealth space, Bhatia et al (2020) argue that *"Medicine is after all the original home of randomized controlled trials … The profession has, for decades, strived to make the practice evidence based. It is time to apply the same vigilance to digital health implementation, even during the pandemic. Regulatory sandboxes may present an effective mechanism to do so."*[15]

05
RECOMMENDATIONS

There are ways to design regulations to protect consumers and support market development.

As the ultimate regulator of the health sector, the NDoH should deliberately collect learnings from telehealth interventions used during the pandemic and since. These learnings can guide future policy, help to regulate the industry, and support improved healthcare.

Uptake of telehealth by both HCWs and patients will require a change in behavior. Although COVID-19 has created an impetus to use these services, their uptake will not happen entirely organically. For HCWs there needs to be appropriate training, change management, and a technological support structure that can make learning and transitioning into a new way of delivering care less daunting. Telehealth must be embedded in healthcare professionals' training and best practice guidelines should be developed for teleconsultation services and virtual care.

Regulations also need to be clearly communicated to HCWs to ensure that they know the risks posed to both patients and HCWs if they fail to uphold ethical standards and/or protect the privacy of patient data. Providing clear guidelines on what can and cannot be treated virtually will empower HCWs to work confidently and mitigate the risk of them operating at their own discretion. This could, for example, restrict the use of virtual consultations to a defined list of conditions. It will protect HCWs acting within the confines of the regulation and give them peace of mind against undue legal backlash if they're operating in a patient's best interests. This will support innovation that is patient-centered and responsive to current health system challenges.

A recognized industry association should be established to allow for a degree of self-regulation, but also greater collaboration in how guidelines are developed so that the needs of the telehealth industry are represented. South Africa has a Digital Health Association ("DHA") which aims to bring together a diverse group of industry participants who are passionate about the potential for telehealth to significantly increase access to high quality and affordable healthcare for all South Africans.

06
CONCLUSION

The way in which the HPCSA frames the existing telehealth guidelines makes it seem as if there's a trade-off between less restriction in the telehealth sector and protecting healthcare workers and patients. However, this is a false dichotomy; regulations can be drafted in a way that supports innovation and protects the rights of healthcare workers and patients.

South African healthcare regulators need to leverage the existing window of opportunity for innovation and observe what's currently happening in the telehealth market. They also need to design guidelines and policies that are evidence-based and create a conducive environment for telehealth innovation to thrive. Consideration of regulatory sandboxes for telehealth interventions could propel the South African health system forward.

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14 Jenik I, Lauer K. Regulatory Sandboxes and Financial Inclusion. Washington, DC: CGAP; 2017 Oct. (Working Paper).

15 Bhatia A, Matthan R, Khanna T, Balsari S. Regulatory Sandboxes: A Cure for mHealth Pilotitis? J Med Internet Res. 2020 Sep 15;22(9):e21276.

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