

## Medicine and the Law

# TELEMEDICINE

(PART 1) Text by Jansen Aw and Dr Alex Cheng Wei Ray

*This is the first of a two-part series. In this, the authors discuss issues where law and technology converge in the realm of telemedicine. In the next part, they explore the legal-technological aspects surrounding the use of telemedicine.*

One of the clearest lessons to emerge out of the COVID-19 maelstrom is that the way the world conducts its business must change. Amid global lockdowns, businesses have shifted towards remote or online services. The healthcare industry is no exception. Perhaps, now more than ever, there is greater impetus for medical practitioners to embark on telemedicine in delivering medical services.

Telemedicine refers to the provision of healthcare remotely through means such as information and communications technology (ICT).<sup>1</sup> Generally, telemedicine encompasses four distinct domains:<sup>2</sup>

- (a) **Teleconsultation or tele-treatment** comprises interactions between healthcare professionals, mainly doctors, and patients or their caregivers, for the purpose of providing direct clinical care resulting in diagnosis and treatment;
- (b) **Tele-collaboration** refers to interactions and discussions of a patient's case files between healthcare professionals for clinical purposes;
- (c) **Tele-monitoring** refers to the remote, ICT-enabled collection of data from patients for the purpose of health monitoring; and
- (d) **Tele-support** comprises the utilisation of online, ICT-enabled services for non-clinical purposes to support patients.

### The telemedicine climate in Singapore

Telemedicine is not new to Singapore. For example, WhiteCoat, which started in April 2018, was one of the earliest telemedicine providers under the Ministry of Health's (MOH) regulatory sandbox. However, even before that, Telecare, in which nurses provide follow-up consultations for chronic conditions, started as early as 2011 in SingHealth hospitals and polyclinics.<sup>2</sup>

Recently, MOH has proposed new regulations which will govern telemedicine in Singapore. This is a welcome development as there is a need to regulate the provision of such services, especially if they are being offered by companies operating out of offices (and sometimes out of jurisdiction) that may not be affiliated with medical clinics.<sup>3</sup> Chief among the objectives of the new regulations is to mitigate the risks of teleconsultation in the interests of patient safety. In particular, MOH has stipulated that all medical practitioners seeking to offer teleconsultation are required to obtain a licence in the future. This requirement will come into force in 2022 under the new Healthcare Services Act (HCSA).<sup>4</sup>

In the domains of tele-collaboration and tele-support, MOH will continue to monitor developments for the time being and may implement regulations where needed.<sup>5</sup>

In the past few years, although the total number of players has

increased,<sup>6</sup> telemedicine remains predominantly the province of private healthcare providers. COVID-19 changed this landscape. In the first half of 2020, with COVID-19 in full swing, various restructured hospitals<sup>7</sup> and government polyclinics have also jumped on to the teleconsultation bandwagon.<sup>8</sup> In recognition of the commercial potential, non-traditional healthcare providers like the Overseas-Chinese Banking Corporation have also teamed up with partners and entered the fray to provide value-added services to its customers by offering fixed-fee teleconsultation.<sup>9</sup>

Given the benefits that underlie telemedicine, MOH set up a Licensing Experimentation and Adaptation Programme regulatory sandbox in 2018 to review telemedicine practices with the aim of collaborating with industry stakeholders to develop the regulations that would govern the industry.<sup>10</sup>

In recognition that the fight against COVID-19 is likely to be long-drawn, the Government has also taken steps to encourage the development of telemedicine to reduce unnecessary travel and prevent another wave of infection. Among the various initiatives, the Government has expanded the scope of the Productivity Solutions Grant (PSG) to support healthcare providers in providing teleconsultation (video) solutions to patients. All eligible healthcare providers will be able to

receive up to 80% PSG support to incorporate these solutions into their existing business and can apply for it through the Business Grants Portal.<sup>11</sup>

### Current and future laws

Various disparate laws apply to telemedicine services in Singapore; however, there is no specific piece of legislation governing such services.

For a start, the common law would apply to certain aspects or activities of telemedicine, such as the contracts between the service provider and the patient. The law of tort will also continue to apply to the advice and treatment given to the patient. The law of confidentiality would also apply to a patient's confidential data that is obtained for the purposes and in the course of providing telemedicine services.

Additionally, doctors registered with the Singapore Medical Council (SMC) would also need to comply with the SMC Ethical Codes and Ethical Guidelines (ECEG). The ECEG states that doctors must endeavour to provide the same standard of medical care as they would in an in-person situation.<sup>12</sup> In addition, medical practitioners providing telemedicine should abide by the National Telemedicine Guidelines, which cover four domains: clinical standards and outcomes, human resources, organisational and technology, and equipment.<sup>2</sup> It is to be noted that these telemedicine guidelines are entirely honour-based and are premised on a professional and moral standard.

The Health Products Act (Cap. 122D) regulates telehealth products that may be used for the provision of telemedicine services. Generally, the Health Sciences Authority employs a rule-based approach to classify such medical devices or products, as set out in the relevant guidelines.<sup>13</sup>

The Personal Data Protection Act (No. 26 of 2012) would also apply to the personal data collected, used and disclosed for the purposes of providing the telemedicine service. Given that patient medical data is involved, which is considered "sensitive personal data", the service provider must take care in ensuring

that a higher standard of protection be accorded to safeguard such data.<sup>14</sup>

While there is no single piece of legislation governing telemedicine in Singapore, this is set to change once the HCSA comes into force in 2022.<sup>15</sup> The Healthcare Services Bill was passed on 6 January 2020 and is intended to repeal the outdated Private Hospitals and Medical Clinics Act (Cap. 248) which was enacted decades ago. The Bill modifies the regulatory regime for healthcare services from a "premises-based" to a "services-based" form of licensing. The Bill is expected to be implemented in three phases, starting from September 2021 and ending in March 2023. Telemedicine will be regulated in Phase 2, which is expected to take place in the second half of 2022.<sup>16</sup>

The HCSA will also allow for a more flexible and modular services-based licensing regime that caters to the licensing of different healthcare services, while enabling the development of new and innovative services. This form of healthcare licensing is similar to that practised by Malaysia<sup>17</sup> and the UK,<sup>18</sup> for example.

To ensure accountability, the HCSA will also introduce new "step-in" provisions to authorise MOH or an appointed "step-in" operator to temporarily take over the operations of a service provider that has violated the regulatory regime or is operating in a way that is detrimental to patients' interests.<sup>19</sup>

### The legal-technological considerations of telemedicine

#### On issues of negligence and breach of duty

The provision of telemedicine services is inherently limited by the state of technology and practical constraints in carrying out medical assessment and treatment remotely. For example, a telemedicine service may be constrained by technical limitations of an end user lacking reliable broadband access, or by practical limitations of carrying out a physical examination of the patient. Given these limitations, it is understandable for there to be concerns that a doctor may not be able to meet the standard

of care in treating or advising the patient, thereby setting up for the risk of negligence or breaching the doctor's duty to the patient.

In the recent judgement in an Indian case of *Deepa Sanjeev Pawaskar and Anr v State of Maharashtra*<sup>20</sup> the court found that the physician had prescribed treatment to the patient over telephone without an appropriate diagnosis which ultimately led to the patient's passing. The physician was found guilty of criminal negligence for the teleconsultation given to the patient. This judgement was interpreted by some Indian doctors as deeming the practice of telemedicine and teleconsultation itself illegal and has resulted in the Indian Medical Association seeking clearer guidelines from their own medical council to clarify the status of telemedicine in India. As a result, an amendment to the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 that gave statutory support and basis for the practice of telemedicine in India was subsequently published in March 2020.<sup>21</sup>

In Singapore, medical negligence is presently determined based on: (a) the Bolam-Bolitho test in respect of a patient's diagnosis and treatment,<sup>22</sup> and (b) the Modified Montgomery test espoused in *Hii Chii Kok v Ooi Peng Jin London Lucien*<sup>23</sup> in respect of the advice given to a patient. On 6 October 2020, the Singapore Parliament passed the Civil Law (Amendment) Bill which enacted a new section 37 that will come into effect soon to replace the current standard of care for medical advice. In the context of telemedicine, given the inherent risks and limitations underlying such services, it would be important for a doctor to pay special care and attention to these risks and limitations in seeking to meet the prescribed standard of care.

For example, in the case of upper respiratory tract infections (URTI), this usually presents with combinations of symptoms of runny nose, cough and sore throat. However, more serious conditions like asthma, pneumonia, tuberculosis and heart failure can also masquerade as various forms of cough.

If the patient is a poor historian then it is only likely through auscultation that a doctor can differentiate them with certainty. Since it is not feasible to auscultate by teleconsultation, it is likely that some of these more serious cases are misdiagnosed as URTI due to the limitations of physical examination in teleconsultation.

There is perhaps no silver bullet in overcoming these challenges in telemedicine services. However, with careful planning and consideration before rolling out the telemedicine service, the authors are of the view that the doctor can still provide the appropriate care and treatment to the patient, and mitigate the risks involved. Some of the considerations a telemedicine service provider should consider include:

- (a) What are the boundaries of the telemedicine services that I will provide?
- (b) What are my contingency plans if the remote means of providing diagnosis, treatment and advice are not feasible for a particular patient? (ie, emergency situations)
- (c) Have I done a risk assessment and testing of the system to ensure that there are sufficient safeguards in place?
- (d) Have I covered all the relevant guidelines in implementing the telemedicine services?
- (e) Does the telemedicine platform properly obtain express consent from the patient?
- (f) Do I have the relevant legal protections in place, such as a contract limiting liability on certain aspects of my telemedicine activities?
- (g) How often should I carry out a review of my system and processes in place to check for any weaknesses or flaws?
- (h) Have I obtained regular feedback in order to improve my system and processes?

By drawing the contours of what the telemedicine service can offer, and adopting the proper policies and processes, the telemedicine service provider is able to control its exposure to risk better. ♦

Jansen is a partner with the Litigation and Dispute Resolution Practice, and Technology and Data Protection Practice in one of the oldest law firms in Singapore, Donaldson & Burkinshaw LLP. Jansen is an advocate and solicitor of the Supreme Court of Singapore.



Dr Alex is a family physician who works as a locum medical doctor during his free time. He is currently pursuing a Master of Laws with the University of London. Aside from his medical qualifications, he also holds the degrees of Bachelor of Laws, Master of Professional Accounting and Master of Business Administration. He is an incoming practice trainee lawyer at Donaldson & Burkinshaw LLP.



### References

1. Singapore Medical Association. Introduction to telemedicine. Available at: <https://bit.ly/3dpfr2i>.
2. Ministry of Health. National telemedicine guidelines. Available at: <https://bit.ly/37nb7fU>.
3. SingHealth. Telecare. Available at: <https://bit.ly/3qxeEjs>.
4. Ministry of Health. Licensing Experimentation and Adaptation Programme (LEAP) – a MOH regulatory sandbox. Available at: <http://bit.ly/2ZqVWxv>.
5. Ministry of Health. FAQ on Healthcare Services Act (HCSA). Available at: <https://bit.ly/3pyWGLY>.
6. Today. Amid debate about telemedicine, 4 more providers join MOH regulatory initiative. Available at: <http://bit.ly/2LZv05e>.
7. Yeo KK. Tele-consultant pilot @ NHCS. National Heart Centre Singapore. Available at: <https://bit.ly/3bijFWy>.
8. Integrated Health Information Systems. Smart health video consultation. Available at: <https://bit.ly/3bhZ1Gc>.
9. Oversea-Chinese Banking Corporation, Limited. OCBC bank launches healthcare app with partners to provide access to the largest panel of telehealth doctors. Available at: <https://bit.ly/3axjilJ>.
10. Ministry of Health. MOH launches first regulatory sandbox to support development of telemedicine. Available at: <http://bit.ly/3qAbM5s>.
11. Enterprise Singapore. Productivity Solutions Grant (PSG). Available at: <http://bit.ly/3k1u9NS>.
12. Singapore Medical Council. Ethical Code and Ethical Guidelines 2016 edition. Available at: <https://bit.ly/3ubNYqq>.
13. Health Sciences Authority. Guidance documents for medical devices. Available at: <https://bit.ly/2Zt3oJ2>.
14. Personal Data Protection Commission Singapore. Advisory guidelines for the healthcare sector. Available at: <https://bit.ly/2NzqhrA>.
15. Healthcare Services Bill (Bill 37 of 2019). Available at: <https://bit.ly/3qsfAFz>.
16. Ministry of Health. Healthcare Services Act. Available at: <http://bit.ly/2M0JMIZ>.
17. The Commissioner of Law Revision, Malaysia. Laws of Malaysia Act 586 private healthcare facilities and services act 1998. Available at: <https://bit.ly/3qzZQAv>.
18. Legislation.gov.uk. Health and Social Care Act 2012. Available at: <http://bit.ly/3asYMsR>.
19. Channel News Asia. Healthcare Services Bill: MOH can temporarily take over operations of healthcare services in financial trouble. Available at: <http://bit.ly/3u8i665>.
20. Lexology. Indian perspective of telemedicine practice. Available at: <http://bit.ly/3arblzc>.
21. Lexology. India's new telemedicine guidelines – analysis and do's and don'ts for doctors offering teleconsultation. Available at: <http://bit.ly/3pxy8D0>.
22. Khoo James v Gunapathy d/o Muniandy [2001] 1 SLR(R) 1024.
23. Hii Chii Kok v Ooi Peng Jin London Lucien [2017] 2 SLR 492.