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IN THIS ISSUE

Featured Article

In this month's newsletter, Associate Professor Dr Tay Pek San discusses the remit of the Telemedicine Act 1997 and the legal challenges in implementing telemedicine in Malaysia.

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News

Congratulations to our members on the following publications:

Articles

Ainee Adam (2020). Pricing and proofing in copyright: introducing an Islamic perspective. Queen Mary Journal of Intellectual Property, vol 10, issue 2.

Sharon Kaur Gurmukh Singh. Peer Review Report For: Social, ethical and behavioural aspects of COVID-19 [version 1; peer review: 1 approved, 1 approved with reservations]. Wellcome Open Res 2020, 5:90 (https://doi.org/10.21956/wellcomeopenres.17341.r38676).

Tay Pek San (2020). Predictions from data analytics: Does Malaysian data protection law apply? Information & Communications Technology Law, doi: 10.1080/13600834.2020.1759276.

Chapter in books

Sherin Kunhibava & Aishath Muneeza (2020).
Regulating FinTech Businesses: The Malaysian Experience. In N. Naifar. (Ed.), Impact of Financial Technology (FinTech) on Islamic Finance and Financial Stability, pp. 149-173. Hershey, PA: IGI Global. doi:10.4018/978-1-7998-0039-2.

Mohammad Ershadul Karim (2020).
Functionalised Nanomaterials: Selected Legal and Regulatory Issues in Handbook of Functionalized Nanomaterials for Industrial Applications, Chapter 30, pp. 983-994, Elsevier. ISBN: 9780128167878. https://www.elsevier.com/books/handbook-of-functionalized-nanomaterials-for-industrial-applications/mustansar-hussain/978-0-12-816787-8.

Mohammad Ershadul Karim (2020).
Functionalised Nanomaterials: Selected Occupational Health and Safety Concerns. In Handbook of Functionalized Nanomaterials for Industrial Applications, Chapter 31, pp. 995-1006, Elsevier. ISBN: 9780128167878. https://www.elsevier.com/books/handbook-of-functionalized-nanomaterials-for-industrial-applications/mustansar-hussain/978-0-12-816787-8.

Mohammad Firdaus Abdul Aziz, Muhamad Shakirin Bin Mispan & Febri Doni (2020).
Regulatory Issues in Organic Food Safety in the Asia Pacific. Organic Food Policy and Regulation in Malaysia: Development and Challenges, In Bee Chen GOH, Rohan Price (Eds), Springer. Advanced Online Publication. doi: 10.1007/978-981-15-3580-2.

Appointments

Mohammad Ershadul Karim. Appointed as Member of the Technical Advisory Committee, 1st International Conference of Advanced Research on Renewable Energy for Universal Sustainability 2021 (27-28 March 2021), Arus Infiniti Sdn Bhd and Razak Faculty of Technology and Informatics, Universiti Teknologi Malaysia, Malaysia.

Sharon Kaur Gurmukh Singh. Appointed as Member of the Planning Committee of the Global Forum for Bioethics in Research 2020.

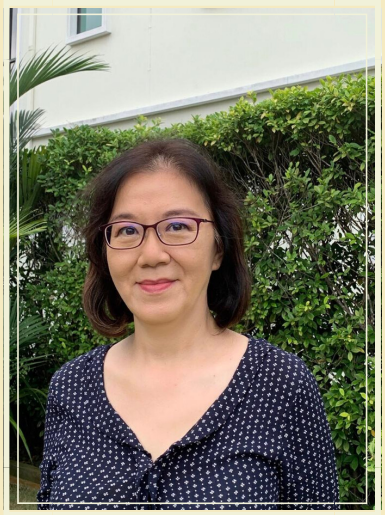
Sharon Kaur Gurmukh Singh. Appointed as Member of the Data Sharing Working Group for the COVID-19 Clinical Research Coalition (https://covid19crc.org).

Sik Cheng Peng. Appointed as Member of the Policy Working Group on Malaysia Open Science Platform by Malaysian Open Science Alliance.

Events

- **28 May 2020**

Sharon Kaur Gurmukh Singh spoke at the expert seminar on "Human Rights and Authoritarianism in the time of Covid-19" organised by SHAPE SEA (Strengthening Human Rights and Peace Research and Education in ASEAN/Southeast Asia).



Embracing Telemedicine in the New Normal: The Legal Challenges

By Associate Professor Dr Tay Pek San
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Author's Biography

Dr Tay Pek San is an Associate Professor at the Faculty of Law, University of Malaya. She teaches Contract Law and Intellectual Property Law at undergraduate level and Trade Mark Law at postgraduate level. She is the Director of the Centre for Law and Ethics in Science and Technology, which is a research centre at the Faculty of Law. Her areas of interest are Intellectual Property Law, Cyberlaw and Data Protection Law. She has written six books and many book chapters. Dr Tay has also published widely in peer-reviewed local and international journals.

Introduction

The Covid-19 pandemic has forced us to limit face-to-face interaction with others as a way of curbing the spread of the disease. This has brought telemedicine into a new light. In the current pandemic situation, the healthcare system is faced with the need to provide continued medical care for patients and to ensure that the patients' risk of exposure to the coronavirus is minimized. The difficulty is more acute for public hospitals which are Covid-19 centres. Frontline healthcare workers put their lives at risk every day because of physical contact with affected patients. In view of the risks of transmission and depending on the circumstances they are in, they might need to shift from their usual method of delivering medical care.

These hospitals face the dilemma on how to sustain the capacity to provide medical care to Covid-19 and other non-communicable disease patients. Some of these hospitals have to reschedule medical appointments with their patients to a later date. While this may be acceptable in respect of routine or elective medical appointments, the same cannot be said for patients suffering from life-threatening diseases, such as heart attack, stroke, diabetes, cancer and the like.

Telemedicine is an ideal way of bridging the gap for patients to have access to their doctors in the comfort of their homes and minimize their risk of infection. As with many other technology-driven innovations, the legal and regulatory response to the implementation of telemedicine is slower than its clinical adoption.

Currently, there is no law that is in force in our country which regulates telemedicine in the healthcare industry. Understandably, there are also no local court decisions on telemedicine to serve as legal precedents to guide its adoption and development. The Telemedicine Act 1997, which was enacted to provide for the regulation and control of the practice of telemedicine, has not been enforced despite being more than two decades old.

The absence of a legal framework that regulates telemedicine represents a major challenge to its widespread adoption. Given this legal vacuum, the Malaysian Medical Council has recently issued an advisory on virtual consultation that is applicable during the Covid-19 pandemic. [1]

The advisory covers a range of matters which doctors must follow, exercise or ensure when adopting telemedicine. It also states that a doctor can only have virtual consultation with a person who is already his patient. In other words, telemedicine is to be used only as a continuation of care or follow-up and not for diagnosis or treatment purposes.

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This note provides an overview of the major legal challenges of telemedicine. One of the most significant legal challenges is the protection of patients' privacy and confidentiality in the digital environment. This was aptly dealt with in the previous issue of this newsletter (CELEST Newsletter, May 2020 Issue 2) by Dr Mohammad Firdaus Abdul Aziz and, hence, will not be revisited here.

This note focuses on patients' informed consent, liability for telemedicine malpractice, insurance, and cross-border practice of telemedicine. Before addressing these issues, this note will discuss the scope of the Telemedicine Act 1997 in order to acquaint readers with Parliament's stance on telemedicine during its enactment in 1997.

Telemedicine Act 1997

The Telemedicine Act 1997 covers two important aspects of telemedicine. The first deals with the categories of individuals who are permitted to practise telemedicine in Malaysia. The categories are: [2]

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- A fully registered doctor under the Medical Act 1971 holding a valid practising certificate
- A doctor who is registered outside Malaysia and holds a certificate to practise telemedicine issued by the Malaysian Medical Council. In addition, the doctor must practise telemedicine from outside Malaysia through a fully registered doctor holding a valid practising certificate under the Medical Act 1971
- A provisionally registered doctor, a registered medical assistant, a registered nurse, a registered midwife or any person providing healthcare who works under the supervision, control and authority of a fully registered doctor and is permitted by the Director-General of Health, Malaysia to practise telemedicine

Individuals who practise telemedicine but do not fall within any of the above categories commit an offence, which is punishable with a fine and/or imprisonment.

The second aspect deals with the patient's consent to the use of telemedicine. A doctor is required to obtain the written consent of his patient before practising telemedicine in relation to him. [3] To constitute a valid consent, the Act requires the doctor to first inform the patient of several matters. These are:

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- He is free to withdraw his consent at any time without affecting his right to future care or treatment
- He knows of the potential risks, consequences and benefits of telemedicine

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- He is aware that all existing confidentiality protection apply to any information about him which is obtained or disclosed in the course of the telemedicine interaction
- He understands that any image or information resulting from the telemedicine interaction will not be disseminated to any person without his consent

The written consent must contain a statement signed by the patient indicating that he understands the information provided above and that he has discussed that information with his doctor. These will become part of the patient's medical records. The failure by the doctor to obtain the patient's written consent or to inform him of the above matters before obtaining his consent is an offence.

The doctrine of informed consent requires doctors to provide their patients with sufficient information so that the patients can assent to or withhold consent from a medical treatment...Other matters which a doctor needs to discuss with his patients are spelt out in the Telemedicine Act 1997...

The Act confers on the Minister the power to make regulations on a wide range of matters. These include prescribing the minimum standards of any facilities used in telemedicine and providing for acceptable quality assurance and quality control in respect of telemedicine services.

Legal challenges of telemedicine

Informed consent

The doctrine of informed consent requires doctors to provide their patients with sufficient information so that the patients can assent to or withhold consent from a medical treatment. A patient needs to be informed of telemedicine's risks, benefits and limitations.

Thus, a doctor should discuss with his patient the risks or limitations affecting medical examination and, consequently, medical advice. It is also important to notify the patient of technical risks associated with electronic transmissions that could cause distortions in images, unauthorized interception of electronic communications or illegal access to the patient's electronic medical records. [4]

Where the doctor intends to audio or video record the consultation, he should inform the patient and seek his consent. Other matters which a doctor needs to discuss with his patients are spelt out in the Telemedicine Act 1997 and have been noted above.

The Act requires that the consent from the patient be in a written form. It also requires that the consent be accompanied by a signed statement from the patient stating that he understands the information which the doctor discussed with him.

The consent to participate in telemedicine extends only to the doctor attending to the patient and any assistants deemed necessary for the consultation. [5] Thus, specific consent will have to be obtained from the patient if there are others present during the consultation. This may mean that in public hospitals where different junior doctors under the supervision of a senior doctor attend to patients on different occasions, a separate written consent is needed for each telemedicine consultation. This obviously creates a ridiculous situation where the patient has to be physically present to give a written consent on each occasion, in which case the patient would be better off seeing the junior doctor face-to-face. It is suggested that the written consent which is obtained by the senior doctor on the first occasion should be widely-framed to include future attendance by junior doctors under that senior doctor's supervision. However, this situation does not arise in private hospitals where a patient is attended to solely by one doctor.

While it cannot be denied that the gold standard is to obtain a written consent from patients specifically for telemedicine, the exigencies of particular situations may necessitate a relaxation of the requirement for patients' written consent. This is particularly so since the Telemedicine Act 1997 has not yet come into force and, in the absence of a legislative mandate, there is currently no law in this country that demands that written consent must be obtained from patients to participate in telemedicine.

While it cannot be denied that the gold standard is to obtain a written consent from patients specifically for telemedicine, the exigencies of particular situations may necessitate a relaxation of the requirement for patients' written consent.

For instance, the Covid-19 emergency that has befallen the country within a matter of weeks has left little or no time for many public hospitals to obtain the prior written consent of their existing patients to the use of telemedicine. Several Covid-19 designated hospitals have temporarily suspended outpatient clinics and are out of bounds for most non-Covid-19 patients. For these hospitals, there is no possibility for their existing patients to go to the hospitals to sign any written consent. Yet, some of these patients need close medical attention.

During this emergency, it is suggested that a modified form of consent be considered instead. An electronic consent, such as through e-mails or WhatsApp messages, or even a recorded verbal consent is arguably sufficient. This is a temporary response during the duration of the emergency and not a permanent policy shift away from a written consent.

Malpractice

The elements of negligence in the traditional mode of healthcare delivery, namely, duty of care owed by the doctor to the patient, breach of that duty of care and causation or consequential damage to the patient, are equally relevant in telemedicine malpractice. [6]

Unlike the traditional setting where the doctor and patient are in the same consultation room, the inherent feature of telemedicine is that both parties are separated by distance. This would usually not create added difficulties in establishing a doctor-patient relationship except in the case of cross-border telemedicine.

Under the Telemedicine Act 1997, cross-border telemedicine can only be carried out through a local registered doctor. On the assumption that this remains the position when a legislative telemedicine framework is eventually enforced, it is foreseeable that difficulties could arise in determining who the parties are in the doctor-patient relationship.

In so far as the standard of care is concerned, questions arise as to the requisite standard of care in telemedicine. Where the telemedicine procedures are identical to the traditional procedures, such as a telemedicine practitioner reading an X-ray, the standard of care should be the same. [7] Prior to 2007, the doctor's standard of care in relation to his patient was governed by the Bolam test that was laid down in the English case of *Bolam v Friern Hospital Management Committee*. [8]

According to the test, the doctor is required to act in accordance with 'a practice accepted as proper by a responsible body of medical men skilled in that medical act'. In other words, the courts need to rely on the expert opinions of medical practitioners to determine whether negligence has occurred. However, in 2007, our Federal Court departed from the Bolam test in *Foo Fio Na v Dr Soo Fook Mun & Anor*. [9] The court decided that the Bolam test has no relevance to the duty and standard of care in providing advice to a patient.

Instead, the court adopted the test in the Australian case of *Rogers v Whitaker*. [10] In that case, the Australian High Court made a distinction between, on the one hand, the doctor's duty of treatment and diagnosis and, on the other hand, the duty to advise of material risks. In *Zulhasnimar Hasan Basri v Dr Kuppu Velumani P*, [11] the Federal Court further provided a clearer legal position with regard to the distinction. In the context of diagnosis and treatment, the Bolam test will apply since the courts are not equipped with the expertise and skills to decide whether there is negligence in the matter. However, as patients have the right of self-determination, the court will decide whether a patient has been properly advised before consent is obtained from the patient.

In situations where telemedicine practice is less effective than the traditional mode of healthcare delivery, such as where full medical examination or touch cannot be carried out, questions arise as to how this may affect the standard of care. The challenges faced by doctors in observing the informed consent requirement and how these would affect their duty to advise of material risks are unclear.

Insurance

Combining rapidly changing communications technology with the complexities of healthcare delivery carries with it the possibility of new or increased risks of medical malpractice. Doctors need to ensure that their professional indemnity insurance extend to cover healthcare services rendered through telemedicine.

Currently, there is no set standard for private health insurance providers regarding telemedicine and thus, it behooves doctors to discuss this with their insurance providers. Alternatively, the medical industry could pursue this with the relevant medical indemnity provider.

Cross-border liability

While national boundaries do not per se pose any obstacle in the world of telemedicine, jurisdictional issues will inevitably arise where there is telemedicine malpractice. This is because cross-border telemedicine services span across different jurisdictions.

In malpractice cases, it is necessary to ascertain where the practice of medicine occurred, which country's laws apply and which court has jurisdiction to hear the dispute. Additional complexity can arise where countries have differing standards and requirements of medical care. Such uncertainties call for legal uniformity in addressing international telemedicine disputes. [12]

Conclusion

Telemedicine is a step forward in our healthcare system as underscored by the Covid-19 pandemic. However, its development depends on the existence of a suitable regulatory framework that provides certainty to all stakeholders involved in this mode of healthcare delivery. The absence of such regulatory framework in our country necessitates urgent action to be taken by the relevant authorities.

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Additional complexity can arise where countries have differing standards and requirements of medical care. Such uncertainties call for legal uniformity in addressing international telemedicine disputes.

References

1. Malaysian Medical Council Advisory on Virtual Consultation (during the Covid-19 pandemic), available at https://mmc.gov.my/wp-content/uploads/2020/04/MMC_virtualconsultationADVISORY.pdf.

2. Telemedicine Act 1997, section 3(1).

3. Ibid, section 5(1).

4. Poe, K, 'Telemedicine Liability: Texas and other States Delve into the Uncertainties of Health Care Delivery via Advanced Communications Technology', (2001) 20 Review of Litigation 681.

5. Ibid.

6. E-medicine in Malaysia: Legal and Ethical Challenges, [2009] The Law Review 21.

7. Supra n4.

8. [1957] 2 All ER 118.

9. [2007] 1 MLJ 593.

10. (1992) 175 CLR 479.

11. [2017] 8 CLJ 605.

12. See Raposo, VL, 'Telemedicine: The legal framework (or the lack of it) in Europe', (2016) GMS Health Technology Assessment, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4987488/.

Editor:
Dr Mohammad Firdaus Bin Abdul Aziz