

Legal Preparedness for Incorporating Telemedicine into the Post Pandemic Health Care Ecosystem: Taiwan Experience

Meng-Chen Tsou

Ph.D. Candidate, Institute of Public Health
National Yang-Ming Chiao-Tung University
Taipei, Taiwan
nina.mc.tsou@gmail.com

Hsiu-Yi Yang

Professor of Law, Institution of Public Health
National Yang-Ming Chiao-Tung University
Taipei, Taiwan
hsiuiyang@nycu.edu.tw

Abstract—While the COVID pandemic is coming to an end, will the telemedicine surged during the pandemic fade away or become a “new normal”? This paper reviews the application of Taiwan’s digital technology in the pandemic, discusses the suitable scenarios for telemedicine, and introduces the responding legal/regulatory amendments. The authors argue that telemedicine has a potential to solve the care scarcity problem in an aging society, and the law should be more proactive in regulating telemedicine from a wider perspective aiming to better facilitating decentralization, resource-integration, and precision care.

Keywords—*legal preparedness; Taiwan; Telemedicine; Telehealth; COVID; pandemic.*

I. INTRODUCTION

Taiwan's National Health Insurance (NHI) system is known for its high quality and low cost. In 2019, NHI provided 23 million residents with comprehensive medical services at a rate of 6.54% of GDP. A significant portion of this success can be attributed to the effective use of information technology. Since 2004, the NHI IC card has been in use, which integrates the cardholder's basic information, insurance information, medical information, and health administrative information. During the COVID pandemic, a simple card swipe can determine a cardholder's travel history and implement necessary quarantine measures. In 2014, NHI further introduced the "NHI MediCloud" system, which integrates patients' medical records from different hospitals on a single platform, allowing medical professionals to better understand the patient's medical history. When a COVID-positive patient needs to use Paxlovid, an oral medication, also known as nirmatrelvir/ritonavir, used to treat COVID-19, Taiwan's doctors can use this system to check for potential drug interactions. In addition, through digital contact tracing, electronic fencing, and digital monitoring of individual or population mobility flows, Taiwan was able to keep its number of confirmed COVID cases to only 800 by the end of 2020, when the global total exceeded 83 million.

While the COVID pandemic is coming to an end, will the telemedicine surged during the pandemic fade away or become a “new normal”? In Section II of this paper, we will discuss the legal restrictions in Taiwan regarding

telemedicine, as well as how the COVID-19 pandemic has led to greater openness towards it. Section III will outline the various legal adjustments made in Taiwan as a result, including the Telemedicine Rule, Regulations of Making and Management on Electronic Medical Records in Medical Care Institution, Medical Device Act, and Pharmacists Act. Finally, in Section IV, we will provide a summary of the impact of telemedicine on healthcare in times of care scarcity.

II.OMICRON AND TELEMEDICINE

Article 11 of Taiwan's Physicians' Act stipulates that doctors must treat patients “in person”, with a limited exception of remote and isolated areas or some special situation. That is, telemedicine is not allowed. However, in April 2022, the Omicron outbreak occurred in Taiwan, and given that vaccination in Taiwan has become quite widespread, the government adjusted the definition of COVID cases: anyone having a positive rapid screening result confirmed by medical staff would be immediately considered a confirmed case. This made it necessary for the medical system to respond to the outbreak through telemedicine, and during the period from May 15 to June 22, 2022, alone, the number of patients using telemedicine reached 1.85 million [1].

III. LEGAL/REGULATION AMENDMENTS IN TAIWAN

Telemedicine is a form of healthcare that involves real-time audio-video communication, as well as real-time audio and telephone communications. While the process may seem simple, it requires significant coordination, such as allowing for the reading and writing of medical records and the use of medical devices or equipment. Additionally, it is important to ensure information security and privacy throughout the process. After the telemedicine consultation, measures such as drug delivery and health insurance coverage must also be taken into consideration. To facilitate telemedicine during the pandemic, the Taiwanese authority issued necessary regulation amendments.

A. Rule of Medical Diagnosis and Treatment by Telecommunications (the Telemedicine Rule)

The Telemedicine Rule defines in detail the scope and situations of “remote areas” and “special circumstances and urgent situations”. When the criteria above are met, doctors may use telecommunications methods to inquire about illness, set diagnosis and issue prescriptions, and treatment may be dispensed by nursing or obstetrics personnel belonging to health organizations. The term “special circumstances” refers to (1) patients who require close monitoring within three months of acute hospitalization, (2) residents of long-term care facilities, (3) integrated care recipients of family doctors, (4) recipients of home health care integrated plans, and (5) international patients. As for “urgent situations,” it refers to situations where immediate medical treatment is required to save a life or to address an emergency [2].

In February 2020, Taiwan's health authorities clarified through an explanatory letter that patients who require immediate medical treatment or who need to see a doctor during home isolation or quarantine are considered to be in urgent situations. Chronic disease patients who are stable are considered to be in special circumstances [3][4]. Then in May 2021, the door to telemedicine was further opened, as long as the medical institution has been designated by the local health authorities, it can treat outpatients via telemedicine [5][6].

Currently, Taiwan is preparing to revise the Telemedicine Rule. In the draft, in addition to maintaining the existing framework, it is also planned to add the following five situations as special circumstances in which telemedicine can be used: long-term medication care for chronic diseases, end-of-life care, care for mobility-impaired patients, care for disasters, infectious diseases or other major changes, and other situations designated by the competent authorities [7]. From this, we can see that although telemedicine may be considered an exception to face-to-face medical treatment, these special types are all intended to increase the accessibility of medical care for those who have difficulty using general medical care.

B. Regulations of Making and Management on Electronic Medical Records in Medical Care Institutions

A key element of telemedicine is communication networks and other information and communication technologies or equipment. Studies have shown that the highest proportion of video software used for telemedicine consultations during the epidemic in Taiwan is Line (54%), followed by Zoom (39%) [8], and whether these software have sufficient protection for security and privacy is in question.

In July 2022, Taiwan announced a new version of the Regulations of Making and Management on Electronic Medical Records in Medical Care Institutions. In response to information and communication security, it added the use

of encryption mechanisms that comply with international standards and also made relevant regulations for the electronic medical record exchange format to increase interoperability. These all help to improve the protection of information and communication security [9]. In addition, Article 18, Paragraph 2 of the draft of Telemedicine Rule also added a provision regarding “the information system used for telemedicine, involving the transmission, exchange, storage or issuance of prescription, examination, or test results, shall have personal identity verification and comply with the international standard organization's common data transmission encryption mechanism, and shall comply with the relevant regulations of the electronic medical record production and management regulations for medical institutions” [7]. Although there are no clear regulations for the equipment or software used in telemedicine, there is further protection for the storage and upload of medical record-related information.

C. Medical Devices Act

In the process of telemedicine, in addition to the software used for video, many medical equipment and even AI can assist patients in obtaining physiological data or tracking and monitoring diseases. For medical device hardware, there are already laws and regulations for medical devices to ensure safety and quality, however, for software, due to the characteristics is different from hardware [10], and for AI-based deep/machine learning products, the same regulatory approach may not be appropriate [11]. How to regulate software is challenging many countries. Taiwan implemented the Medical Devices Act on May 1, 2021, in which the design of medical device software is included as part of the manufacturers' responsibilities to be managed [12]. Additionally, guidelines for medical device software and AI products have been released to provide a basis for compliance within the existing legal framework.

D. Pharmacists Act

Many telemedicine services require a prescription from a doctor. In the past, telemedicine in Taiwan also followed this principle. However, although Taiwan has implemented a separation of prescribing and dispensing of drugs, in practice, most medical institutions have attached pharmacies and drug revenue is also a source of hospital income[13][14], so the proportion of prescriptions issued is not high. In the past, patients usually had to go to the hospital to pick up their medication after telemedicine consultation, but this became inconvenient during the pandemic. Therefore, the Ministry of Health and Welfare, citing a meeting record from November 30, 2017, stated that pharmacists can personally deliver medication to homes, but only within the county or city where they are registered to practice, which is compliance with the Pharmacists Act [15].

The Taiwan Association of Young Pharmacists also advocated for the use of electronic prescriptions as a support for telemedicine during the pandemic to reduce the risk of infection. In response to this call, the draft Telemedicine Rule have also included provisions for electronic prescriptions [16].

As for the types of medications that can be prescribed, there were no restrictions in the past, but the new draft regulations have added a provision that generally prohibits the prescription of controlled drugs, similar to many states in the US.

IV. TELEMEDICINE AND CARE SCARCITY: CLOSING REMARKS

The problem of aging and low birth rate in Taiwan is quite serious. In 2021, the population over 65 years old accounted for 14%, while the number of newborns was only around 150,000, setting the world record of low birth rate. The problem of care scarcity is imminent, and many elderly people living alone in cities can benefit from telemedicine. Taiwan's laws are clearly aware of this problem, so they are deliberately turning telemedicine from an exception to a new normal. Although there are still many challenges to overcome, increasing the scope of telemedicine and enhancing the requirements for information and communication security, as well as setting up new electronic prescriptions, can make telemedicine both convenient and safe. Additionally, through regulations on AI, medical software, etc., manufacturers have the opportunity to better understand the regulatory framework, so that future telemedicine can provide more comprehensive care. And with the coverage of the National Health Insurance, telemedicine can not only ensure the medical accessibility of the people, but also make it affordable.

Even as the pandemic comes to an end, the widespread use of telemedicine is expected to change the medical system. Currently, telemedicine in Taiwan is still mainly based on synchronous telemedicine as defined by the AMA. However, in the era of digital health, our research team has also proposed the concept of the digital health era: the DIP model, which shifts healthcare services from large hospitals to home care (“Decentralization”); by “Integrating” health information collected by different sources, we hope to provide more “Precision” care for the public. This approach may also require the use of asynchronous telemedicine to achieve. Currently, the NHI Administration in Taiwan is also actively using existing databases to assist the development of AI and precision medicine in the biomedicine industry, while ensuring individual privacy, with the goal of improving the quality of healthcare services in the future [17].

The development of telemedicine has brought numerous benefits to healthcare, but it also requires infrastructure development and policy considerations to ensure that resources are allocated to the most in-need populations and

that information security and privacy are safeguarded. Additionally, the development of medical device software and AI cannot be overlooked, and product safety, efficacy, and reliability must rely on proper regulatory design. In particular, as AI is advancing rapidly, ethical issues must also be further addressed. Therefore, as technology develops, policies and laws should also continue to be updated and discussed in order to respond to changing needs.

ACKNOWLEDGMENT

The authors would like to express their sincere gratitude to the National Science and Technology Council of Taiwan for providing the funding for this research (MOST 110-2420-H-037-003: THE IMPLEMENTATION OF NEW HEALTHCARE MODELS IN THE POST-PANDEMIC ERA IN TAIWAN: OPPORTUNITY AND CHALLENGES). Their support has been instrumental in allowing us to conduct this study and achieve the results that we present in this paper.

We would also like to extend our sincerest thanks to Professor Tsuen-Chiuan Tsai for her exceptional leadership and guidance throughout this project. Her unwavering commitment and dedication to this research have been a constant source of inspiration, and her contributions to this study have been invaluable.

Finally, we would like to acknowledge the hard work and efforts of all team members involved in this project. Their support and collaboration have been essential to the success of this research, and we are grateful to have had the opportunity to work with such talented individuals.

REFERENCES

- [1] N. Y. Shu, “Video Medical Consultation and Clinical Processes No Longer Disconnected: Taiwan's Telemedicine Care Chain Completely Linked” *DIGITIMES*, Jan. 7th, 2022. [Online]. Available from: https://www.digitimes.com.tw/iot/article.asp?cat=&id=0000640375_UBZ4S1RY68YID463YOGFX (last visit: Apr. 10th, 2023).
- [2] Rules of Medical Diagnosis and Treatment by Telecommunications of Taiwan, 2018
- [3] Ministry of Health and Welfare, Wei-Bu-Yi No. 1091660661, Feb. 10th, 2020.
- [4] Ministry of Health and Welfare, Wei-Bu-Yi No. 1091661115, Feb. 19th, 2020.
- [5] Ministry of Health and Welfare, Wei-Bu-Yi No. 1101663341, May 15th, 2021.
- [6] Ministry of Health and Welfare, Wei-Bu-Yi No. 1101663760, May 17th, 2021.
- [7] Draft of Rules of Medical Diagnosis and Treatment by Telecommunications of Taiwan, Nov. 24th, 2022.
- [8] M. K. Huang, H. C. Fang, H. Y. Hsu, M. C. Yeh, and C. H. Lee, “Discussion on the application of telemedicine in Taiwan in response to COVID-19”-vol 54:1, pp. 15–23, March, 2021.
- [9] Regulations of Making and Management on Electronic Medical Records in Medical Care Institutions of Taiwan, 2022.

- [10] K. Kadakia, B. Patel and A. Shah, “Advancing digital health: FDA innovation during COVID-19”, *npj Digital Medicine*, vol.3, pp. 1-3, Dec., 2020, doi: 10.1038/s41746-020-00371-7.
- [11] “Fostering Medical Innovation: A Plan for Digital Health Devices; Software Precertification Pilot Program”. Food and Drug Administration, pp. 35216–35218, July 28th, 2017, [Online]. Available from: <https://www.federalregister.gov/documents/2017/07/28/2017-15891/fostering-medical-innovation-a-plan-for-digital-health-devices-software-precertification-pilot>. (last visit: Apr. 10th, 2023.)
- [12] Medical Devices Act of Taiwan, 2021.
- [13] H.H. Fan and L. K. Lin, “Single Track System of Separation of Prescribing and Dispensing: South Korea’s Experiences”, *The Journal of Taiwan Pharmacy*, vol. 32, pp 22-28, 2016.
- [14] Y. C. Huang, “How Hospitals Make Profits through Non-Core Revenues? Revealing the Secrets Hidden in Hospital Financial Reports.” In-news, Taiwan Public Television Services, 2023, available from: <https://innews.pts.org.tw/column/MTU0> (last visited Apr. 10th, 2023)
- [15] Ministry of Health and Welfare, Wei-Bu-Yi No.1061669199, Dec. 14th, 2017.
- [16] Young Pharmacists’ Group, e-prescription should be the supporting measure for telemedicine to reduce people’s risk from infection. Taiwan Young Pharmacists’ Group| Facebook, May 24th, 2021. [Online]. Available from: <https://www.facebook.com/TaiwanYPG/posts/3895945330504822/> (last visit: Apr. 10th, 2023).
- [17] P.-C. Lee, J. T.-H. Wang, T.-Y. Chen and C. Peng, *Digital Health Care in Taiwan: Innovations of National Health Insurance*. Cham: Springer International Publishing, 2022.