

## Telemedicine: International Law Comparison

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### ABSTRACT

The main problems in telemedicine include the lack of uniformity in international regulations, limited technological infrastructure in some countries, and data protection and patient privacy. Additionally, legal responsibilities and malpractice risks have not been standardized. Gaps in access to services, especially in remote areas, and ethical challenges and quality standards are also obstacles. The purpose of this research is to find out international legal considerations regarding the use of Telemedicine and find solutions to overcome Telemedicine legal issues. This research uses a normative juridical approach with an emphasis on comparative studies. The results of the research were then analyzed qualitatively. Based on research results, show that Telemedicine is regulated differently in various countries. In Indonesia, it is regulated by Minister of Health Regulation Number 20 of 2019 for diagnosis, treatment, and continuing education with service costs borne by the health facility. Malaysia has a Telemedicine Act 1997, focused on follow-up care and drug prescriptions, growing rapidly in the private sector during the COVID-19 pandemic. Argentina published telehealth guidelines in 2019 and 2022, requiring health insurance companies to adopt teleconsultation platforms. Austria through the TeleHealth Commission since 2013 regulates telemonitoring, teletherapy, teleconciliation, and teleconferencing with strict data protection laws. Mexico integrates telehealth in general health services, regulated by IMSS and ISSSTE, while Russia regulates through the Health Protection Law with strict IT requirements. International telemedicine legal solutions require harmonization of regulations, personal data protection, information security standards, recognition of professional licenses, dispute resolution mechanisms, and legal liability regulations. Education and public awareness are essential to overcome these challenges, supported by international cooperation that strengthens the global legal infrastructure of telemedicine.

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## 1. INTRODUCTION

The world of health has experienced quite rapid progress recently. Indonesia, as one of the developing countries in Southeast Asia, is trying to keep up with the development of health services following the Industrial Revolution 4.0 era, including telemedicine which uses many advances in information and communication technology [1]. E-health represents one of the most exciting technological innovations, combining telecommunications, audio/visual technology, and computers in a variety of ways from providing medical information to diagnosis and treatment. Like many other new information-based technologies, the appropriate applications and impacts of Telemedicine are only beginning to be appreciated [2].

Telemedicine is the provision of health care services, clinical information, and education in all specialties through a variety of technologies including the Internet, mobile phones, and electronic medical records. Telemedicine continues to grow due to expanding broadband infrastructure and decreasing technology costs. The use of technology in healthcare settings is also increasingly recognized and used in managing changing healthcare conditions and their challenges [3]. Telemedicine allows treatment in remote areas and at lower costs for patients, and in the current situation, can reduce the number of infections as well as the use of beds in health facilities, but telemedicine also faces limitations, especially due to current legislation [4]. Telemedicine is diverse and can be provided both in regional care in rural areas or across countries as well as in specialized care of rare diseases or by specialists not available everywhere. Especially in the wake of the coronavirus pandemic, telemedicine has increased in importance [5].

For the first time, in developed and developing countries, proven, reliable, and cost-effective telemedicine and telehealth services are available on a large scale. Therefore, thanks to a strong technological infrastructure, the great promise of telemedicine is finally being realized. Instead

of transferring patients to clinical specialists, it is now commonplace to harness the power of technology to deliver specialist knowledge directly to patients who need it. These progressive changes in health care could open new doors in legal, ethical, and regulatory issues and have a major impact on policymaking by health authorities.

New international e-health law principles will not be helpful if created in a vacuum, even though the law in this area is influenced by existing entities such as the World Trade Organization (WTO) and current international agreements that underlie the legal structure and operations of the sector trade, telecommunications, and the provision of health services [6].

E-Health licensing and regulation standards have not been implemented in many countries at the regional or state level. Professional licensing, unapproved health alternatives and practices, conflicting fraudulent practices misleading claims, regulation, and legal jurisdiction issues nationally and internationally are major regulatory and quality assurance issues in today's climate [7].

The Korean Health Law in 2002 was the beginning of a legal system that supports telemedicine. Until the revision of the health law in 2013, there was no national telemedicine program. So telemedicine is not popular enough in Korea, namely only 0.1% based on research conducted in 2013-2014, but in the end in July 2015, Korea provided telemedicine for areas with low health services. In contrast to South Korea, Indonesia, as a member of the Asia Pacific Association for Medical Informatics (APAMI), is still lagging in terms of telemedicine, even now signal access in the interior is still minimal. Communication between doctors in remote areas and doctors in big cities can only be done via email. Telemedicine technology in Indonesia continued to develop until 2010, telemedicine was included as part of biomedical techniques, one of which is the existence of a medical station that facilitates

telemedicine both in real-time teleconsultation and in store and forward.<sup>1</sup>

The use of telemedicine in Malaysia is also no less advanced. Malaysia is a country that has received a lot of praise from various parties, one of which is Leonard R. Graziplene, President of The Center For Rural Resurgence, Inc. Malaysia also now has a fully operational telemedicine network from cities to remote areas. In Malaysia, telemedicine was built into the first virtual private network of its kind in the world with nationwide coverage. This network allows patients to access care from 37 service points (clinics, health centers, and district hospitals) connected to four major hospitals. Malaysia already has a law related to telemedicine, namely Malaysia's Telemedicine Blueprint 1997 (Telemedicine Act 1997) [8].

The use of telemedicine has the potential to provide healthcare services to people, for example in America who are uninsured and who live in poverty. Studies conducted by Paul Spradley, show the United States Census Bureau estimates that 50.7 million Americans were uninsured in 2009, and 91.2 million received Medicaid or Medicare. Telemedicine has the potential to provide an affordable way to diagnose and treat common conditions, as well as identify more serious symptoms. For those who already have internet service at home, many services can be provided without having to leave the house. For those without internet service, public medical facilities can provide needed services, without long wait times or a staff of doctors. Telemedicine could also help reduce the costs of government-subsidized health services, which have become an increasing burden on countries [9].

A study conducted by Vera Lucia Raposo, described within the framework of European law, that telemedicine is simultaneously a health service and an information service (a service usually provided for remuneration, remotely and by electronic means at the request of an individual). In the European Union, there is still a lack of uniform regulation, especially in

the domain of medical liability and medical artist leges. The European Union to date does not have a common set of norms on civil and criminal liability, let alone specific legal norms on medical liability. This void could endanger the true European internal market in healthcare and hinder the development of telemedicine in the Eurozone [10].

Telemedicine is a broad subject, but to date data regarding the clinical effectiveness and cost-effectiveness of most telemedicine applications is limited. As a result, objective information regarding the benefits and drawbacks of telemedicine is also limited [11].

Telemedicine still has its pros and cons. For example, misdiagnosis can occur in both face-to-face and virtual interactions, but face-to-face interactions have detailed mechanisms from patient complaints to investigations and compliance standards. The rapid growth of telemedicine may result in future cost savings, however, the risk of misdiagnosis is greater, and legal clauses are not standardized or universal. This often leads to varying standards and coverage offered by service providers, including the danger of reducing the quality of handling ethical and legal issues to outperform the competition [12].

The cost of telemedicine services is practically the same as services performed in face-to-face interactions. There is no guarantee of payment parity between in-person and telemedicine healthcare providers. On the other hand, legal liability and potential issues such as negligence and malpractice will also impact telemedicine.<sup>2</sup>

Currently, there is no uniform and internationally accepted legal framework to regulate telemedicine. Each country has different regulations regarding data protection and privacy, which may affect the practice of telemedicine, especially when it comes to the exchange of patient medical information. In addition, not all countries have adequate infrastructure and technology to support telemedicine, which can affect the quality of medical services provided.

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<sup>1</sup>Kuntardjo, C., Op. Cit.

<sup>2</sup>Ibid.

Telemedicine provides several benefits such as increased access and rapid patient engagement at lower costs, but ethical and legal challenges need to be taken into account when implementing a telemedicine program. For example, some states have established prerequisites for obtaining informed consent, especially for telemedicine, to ensure patients are aware of the privacy risks and important techniques of telemedicine. Regulations in telemedicine training policies for patients can vary from verbal explanation of the policy to written consent. Resolving legal issues in telemedicine can be a long and complicated process; however, this is not impossible to understand. To make progress, it is first important to know the current status.<sup>3</sup>

Consideration of telemedicine in international law is expected to offer a comprehensive and detailed analysis of telemedicine regulation in various countries, including legal comparisons, regulatory challenges, and policy recommendations. This international legal approach provides an in-depth understanding of how various jurisdictions address legal issues in telemedicine, which has not been done so thoroughly. Therefore, in-depth research is urgently needed to identify and develop a legal framework that can be adopted internationally, which makes it easier to practice telemedicine across borders without violating local laws.

### Formulation of the problem

Based on the background above, the problem formulation in this research is as follows:

1. How does international law compare to the use of Telemedicine?
2. What is the solution to overcome Telemedicine legal issues?

## 2. RESEARCH METHODS

This research uses a normative approach to analyze various aspects of international law related to the application of

telemedicine [13]. A normative approach was chosen to understand in-depth and comprehensively the various legal issues that arise in the context of telemedicine. This research focuses on comparative studies of legal regulations in various countries. This research began with an extensive literature study, in which relevant literature from international legal sources, such as regulations, policies, and guidelines issued by international organizations such as the WHO and the European Union, was collected and analyzed. In addition, scientific journals, books, and articles related to telemedicine and law were also analyzed in depth. The data collected was then analyzed using content analysis methods to identify main themes related to legal considerations in telemedicine. In this analysis, applicable legal regulations and guidelines in various jurisdictions are compared to understand the differences and similarities in legal approaches to telemedicine. By focusing on a normative approach, this research aims to provide a comprehensive insight into the existing legal framework and how this framework can be applied to regulate and facilitate the development of telemedicine. It is hoped that the results of this research will provide a strong basis for policymakers, legal practitioners, and health service providers in understanding and overcoming the legal challenges associated with telemedicine at the international level.

## 3. DISCUSSION

### 3.1 Comparison of International Laws on the Use of Telemedicine

The following are legal considerations from several countries regarding the use of telemedicine:

#### a. Indonesia

Telemedicine is regulated in the Regulation of the Minister of Health of the Republic of Indonesia Number 20 of 2019. This includes the exchange of information regarding diagnosis, treatment, disease prevention,

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<sup>3</sup>Ibid.

research, evaluation, and continuing education for health service providers. Telemedicine services include tele-radiology, tele-electrocardiography, tele-ultrasound, and tele-consultation clinics to assist with diagnosis and provide clinical opinions, which can be done via writing, voice, or video with written notes following applicable regulations. Based on Article 15 of the Regulation of the Minister of Health of the Republic of Indonesia Number 20 of 2019 concerning the Organization of Telemedicine Services through Health Service Facilities: The costs of telemedicine services are borne by the health facility requesting the consultation, including determining costs for the health insurance program determined by the Minister, as well as the possibility of determining other costs through collaboration between health facilities and based on cost guidelines regulated by the Minister

b. Malaysia

Malaysia has Act 564 Telemedicine Act 1997. This law covers methods of practicing medicine using audio, visual, and data communications. The practice of medicine in Malaysia is regulated by the Medical Act of 1971, as well as the Malaysian Medical Council's Code of Professional Ethics. There is also the Telemedicine Act of 1997, which was promulgated in 1977, but has not yet been enacted. Although the Telemedicine Act 1997 has not yet come into force, the Malaysian Medical Council (MMC) has advised that doctors can only conduct virtual consultations with patients who are already their patients, which

is seen as a continuation of care. Additionally, digital healthcare products or medical devices are regulated primarily by the Malaysian Medical Devices Act, of 2012. Under this act, the definition of 'medical device' is very broad, so electronic equipment that can be used to diagnose patients in telemedicine can also fall within the scope of the Malaysian Medical Devices Act. Telemedicine in Malaysia is largely limited to follow-up care and simple medication prescriptions that can be completed without a physical examination. However, public health systems have not yet adopted telemedicine and continue to operate in brick-and-mortar settings. Patient-doctor remote medical services have increased in the private sector in Malaysia, which has grown rapidly during the COVID-19 pandemic. However, neither patient-doctor nor doctor-doctor remote medical services have been explicitly regulated by specific laws or regulations at this time. Telemedicine is generally not available in the public health system in Malaysia at present. Health workers must be fully registered medical practitioners and have a valid practicing certificate. Foreign doctors must have a certificate to practice telemedicine issued by the MMC or practice telemedicine through a fully registered medical practitioner with a valid practicing certificate. There are no specific requirements applicable to regulating telemedicine platforms in Malaysia. However, if the telemedicine service provider is a legal entity regulated under the Personal Data Protection Act 2010 (PDPA),

they must ensure that the platform is built securely to protect patients' data following the PDPA. The 2019 Good Medical Guidelines state that patients have the right to choose treatment, obtain adequate information, and give informed consent. Therefore, it can be concluded that patient consent is required to engage in telehealth. When personal data is collected to exploit a market, the provisions of the PDPA will apply if the data collected can be used to identify the individual concerned in some form. Therefore, it is important to ensure that the data collected is anonymized and individuals are identified to exclude the collected data from the scope of the PDPA. The Economic Planning Unit of the Department of the Prime Minister of Malaysia published the Malaysian Digital Economy Blueprint, which sets out a national initiative to develop a framework for the adoption of rapidly emerging technologies for healthcare-related products and accelerated use of the Malaysian Health Data Warehouse, with the inclusion of blockchain technology.

c. Argentina

In 2019, the Argentine Ministry of Health published a guideline of recommendations for the use of 'telehealth' (Disposition No. 21/2019). The guideline entitled "Recommendations for the use of telehealth: meetings between health professionals and patients using real-time ICT" was prepared by a group of healthcare providers under the coordination of the Ministry of Health. The goal is to establish guidelines for the safe, efficient, and ethical provision of telehealth services.

Based on General Resolution No. 282/2020 of the Superintendency of Health Services ("Superintendencia de Servicios de Salud"), all private health insurance companies are required to adopt and promote the use of teleconsultation platforms to provide health care. They must guarantee the protection of patient data and information collected through the platform following the Personal Data Protection Law no. 25,326. Additionally, these telehealth platforms are also subject to subsequent audits conducted by the Health Services Superintendency. Furthermore, the Argentine Ministry of Health issued new guidelines in the field of telehealth through General Resolution No. 581/2022: "Recommendations for the use of telehealth and good practices for healthcare providers."

d. Austria

In 2013, the Minister of Health established the TeleHealth Commission (Telegesundheitsdienste-Kommission) which continues to work to increase telehealth coverage. The commission also adopted resolutions and submitted reports to the competent Ministry of Health. According to the TeleHealth Commission, the concept of telehealth includes a variety of services that include but are not limited to telemonitoring to medically monitor a patient's health condition, teletherapy for active intervention in a patient's treatment, teleconciliation to obtain a second opinion from another doctor, and teleconferencing to involve a second doctor in medical treatment ongoing.

Telemonitoring is one of the more advanced and widely applied areas of telehealth, especially for patients with diabetes, heart failure, and unstable high blood pressure. In Austria, there is no official list of the types of health services available via telehealth. Decisions regarding the telehealth services offered are up to each clinician, taking into account direct and personal principles and meeting data protection requirements. In addition to popular applications such as Skype or Zoom that can be used for telehealth services (subject to meeting data protection requirements), such services can also be provided through special e-health applications that can be certified by TELEMED Austria. For example, the application "eDoctors-App" has been officially certified since April 2020 by TELEMED Austria, which also maintains a register of certified telehealth service providers. In addition to the general applicability of the GDPR and the Austrian Data Protection Act, some specific personal data protection laws also apply to certain limited data applications, such as data transfers between doctors or hospitals, which are regulated by the *Gesundheitstelematikgesetz* (Federal Health Telemedicine Act) and *Gesundheitstelematikverordnung* (Health Telemedicine Regulations). In addition, there are also several data protection provisions included in the Federal Doctors Act, Federal Dentist Act, Federal Pharmacy Act, etc., which essentially do not exceed the requirements set out by the GDPR. Special emphasis is

placed on secure technical solutions, such as the use of encryption, to maintain the security of data handled in the context of telemedicine.

e. Mexico

After the initial project from December 2015 to April 27, 2018, which was the Mexican Official Standard "PROY-NOM-036-SSA3-2015 for the regulation of remote medical services" ("NOM Project"), which established the regulation of procedures for health personnel in the performance of health services distance, the Mexican Government takes the approach that telehealth is an integrated activity in health services. Therefore, laws and regulations (such as the General Health Law and the General Health Law Regulations regarding the Provision of Health Services) that apply to general health services, also apply to telehealth. Currently, telehealth is available for various types of health services as long as they comply with the regulatory framework applicable to health services in general, and if necessary, the regulatory framework specific to each sector and/or activity in the health sector. Mexican law does not specify the type of platform that must be used in the provision of telehealth services. However, NOM-024-SSA3-2012 (discussed below) regulates the exchange of information between electronic medical record information systems ("SIREs"), which are information systems that enable the retrieval, management, and exchange of structured and integrated information from patient clinical records, as well as geographic, social, financial, infrastructure and other

information documenting medical care. SIREs must obtain certification by NOM-024-SSA3-2012. The Mexican Institute of Social Security ("IMSS") and the Institute of Social Security and Services for State Workers ("ISSSTE") provide telehealth services. However, the service is limited to patients coming from hard-to-reach areas of the Mexican Republic who require medical attention in certain specialties. The service is part of social security for Mexican workers.

f. Russia

In Russia, the rules regarding telehealth were adopted in 2017. On July 29, 2017, Article 36.2., which regulates telemedicine, was added to the Federal Law "On the Basics of Protection of Citizens' Health in Russia" No. 323-FZ of November 21, 2011 (known as the "Health Protection Law"). On November 30, 2017, the Russian Health Authorities also adopted Order No. 965n "On Approval of the Rules for the Provision of Medical Assistance with the Assistance of Telemedicine Technology" (known as the "Order") which establishes requirements regarding the provision of medical services via telehealth technology. Telehealth is regulated primarily as a medical service in Russian law. Russian law refers to telehealth as involving "telemedicine technology". "Telemedicine technology" is defined in the Health Protection Act as information technology that enables remote interaction between health professionals and patients (or minor patient's legal representatives) related to the implementation of medical

consultations and observations of patients. Thus, telehealth is understood as the provision of medical services remotely. Telehealth services are not limited to doctors or clinics conducting initial consultations or examinations. Neither the Health Protection Act nor the Order provides an explicit requirement for patients to remain with the same doctor or clinic after an initial in-person consultation or examination. Therefore, patients can start with one doctor or clinic and continue through telehealth services after that. There are also some technical requirements for telehealth services in Russia. Telehealth services can only be provided using state-approved IT systems that allow proper identification and verification of both the health care provider (clinic or health professional) and the patient. In particular, a single identification and authentication system ("ESIA") must be used. ESIA is regulated by Russian Government Decree No. 977 of 28 November 2011. In brief, it is a state-run system used for official interactions between state officials, or between state officials and citizens, and ensures the identification and authentication of all users based on enhanced electronic signatures. Some in the industry have indicated that these systems are somewhat bulky and uncomfortable to use, especially for patients, which may impact the acceptability of using telehealth services.

### 3.2 Solutions to Overcome Telemedicine Legal Issues

Overcoming legal issues in telemedicine internationally is a complex challenge because it involves various legal, regulatory, and policy aspects from different countries.



However, several solutions can be considered to face these challenges effectively and ensure that telemedicine can develop safely and sustainably at a global level. The following are some of the main solutions that can be implemented:

**a. Harmonization of International Regulations**

One of the main approaches to overcoming telemedicine legal issues is to encourage the harmonization of regulations at the international level. This is important because regulatory variations between countries can create barriers to the development and implementation of cross-border telemedicine. Steps that can be taken include:

1. **Global Guidelines Development**

International organizations such as the World Health Organization (WHO) or the International Telecommunication Union (ITU) could lead efforts to develop global guidelines governing the practice of telemedicine. These guidelines should cover aspects such as clinical standards, data protection, medical ethics, and licensing requirements.

2. **International Agreement**

Countries can collaborate to reach international agreement on minimum standards for telemedicine practice. This can be done through bilateral or multilateral agreements governing licensing recognition, data protection, and medical practice requirements.

**b. Personal Data Protection and Information Security**

Personal data protection is a crucial issue in telemedicine because it involves the transfer and storage of sensitive patient information across national borders. Solutions to this problem include:

1. **Adopt a Data Protection Framework**

Countries must adopt a strong and comprehensive data protection framework, such as the European Union's General Data Protection Regulation (GDPR). This framework should regulate how health data is processed, stored, and protected from unauthorized access.

2. **Information Security Standards**

The development of international standards for information security in the context of telemedicine is essential. This includes data encryption, network security, and strict data access and use policies.

**c. Professional Licenses and Credentials**

Issues related to licensing and professional credentials are also something to consider in telemedicine. Possible solutions include:

1. **International License Recognition**

Countries could explore mechanisms to recognize cross-border professional licensure, thereby allowing healthcare practitioners to provide telemedicine services in other countries without having to undergo lengthy and expensive licensing processes.

2. Certification and Training  
International standardization in certification and training for telemedicine practitioners can improve trust and quality of care. International organizations and universities can work together to develop comprehensive training programs.

**d. Dispute Resolution and Legal Responsibility**

Legal liability in telemedicine is an important issue that needs to be addressed. Solutions to this problem include:

1. International Dispute Regulations

Development of effective and fair dispute resolution mechanisms for problems that may arise in the context of cross-border telemedicine.

2. Insurance and Professional Liability

States may develop regulations to regulate insurance and professional liability for telemedicine practitioners. This includes protection against malpractice claims or losses that may arise from telemedicine services.

**e. Education, Ethics, and Public Awareness**

Education, ethics, and public awareness are also important in dealing with telemedicine legal issues. Solutions include

1. Education and Training Program

Improve education and training for healthcare practitioners on ethics, data security, and best practices in telemedicine.

2. Public Awareness Campaign  
Educate the public about the benefits of telemedicine, their rights in protecting personal data, and ethics in using technology in health services.

**f. Cooperation and Collaboration Between Countries**

Cooperation and collaboration between countries are very important to address telemedicine legal issues effectively. Countries can share best experiences, adopt practices proven to work and build a strong legal infrastructure to support the global development of telemedicine.

#### 4. CONCLUSION

That Telemedicine is regulated differently in various countries. In Indonesia, it is regulated by Minister of Health Regulation Number 20 of 2019, covering diagnosis, treatment, and continuing education, with service costs borne by the health facility requesting the consultation. Malaysia has a Telemedicine Act of 1997 that has not yet been enforced, with telemedicine used primarily for follow-up care and simple drug prescriptions and has grown rapidly in the private sector during the Covid-19 pandemic. Argentina published telehealth guidelines in 2019 and 2022 for safe and efficient use, with an obligation for health insurance companies to adopt teleconsultation platforms. Austria has a TeleHealth Commission that has increased the scope of services since 2013, with telemonitoring, teletherapy, teleconciliation, and teleconferencing regulated by strict data protection laws and certification requirements by TELEMED Austria. In Mexico, telehealth is integrated into public health services and regulated by applicable regulations, with services provided by IMSS and ISSSTE for hard-to-reach areas. Russia regulates telehealth through the Health Protection Law, which covers telemedicine technology and

requires a state-approved IT system for proper identification and verification.

The solution to overcome telemedicine legal issues internationally is through a comprehensive and collaborative approach from various related parties. Harmonization of regulations is the main key to creating legal clarity and reducing cross-border barriers in telemedicine practice. Strong personal data protection and high standards of information security are also needed to maintain public trust and prevent data misuse. International recognition of professional licensure and certification can facilitate the mobility of health practitioners across countries without compromising service quality standards. In addition, the development of effective dispute resolution mechanisms and clear regulations regarding legal responsibilities is very important to minimize the risk of malpractice and increase consumer protection. Better education of health practitioners and increased public awareness about the benefits and risks of telemedicine are also crucial steps in addressing this challenge. Closer international cooperation in sharing

experiences and best practices will strengthen the global legal infrastructure that supports the safe and sustainable growth of telemedicine around the world.

The advice offered by researchers in this research is that a comprehensive and collaborative approach between countries is needed. Harmonization of regulations is important to create cross-border legal clarity and secure data protection and information security. International recognition of professional licensure and certification can facilitate the mobility of healthcare practitioners without compromising service quality standards. Effective dispute resolution mechanisms and clear regulations on legal responsibilities are needed to reduce the risk of malpractice and increase consumer protection. Better education for health practitioners and increased public awareness of the benefits and risks of telemedicine are also essential. Finally, close international cooperation in sharing experiences and best practices will strengthen the global legal infrastructure that supports the safe and sustainable growth of telemedicine worldwide.

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