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Legal Protection of Patients in Clinical Teleconsultation Service Practice

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Abstract: The development of digital technology is growing rapidly, as well as in the world of health. At first, Telemedicine was limited to only among Health Service Facilities as a solution to the challenge of the limited number of specialist/subspecialist doctors at Remote Hospitals in the country. However, after the COVID-19 Pandemic struck, the development of Telemedicine grew rapidly. This needs serious attention, especially in the aspect of legal protection. If the status of the COVID-19 Pandemic is revoked, how will the Legal Arrangements for Clinical Teleconsultation services be? How is Patient Legal Protection in the Practice of Clinical Teleconsultation Services? Methods This research uses a normative juridical method with an inductive conclusion approach. The result is that the existing legal regulation of Clinical Teleconsultation is only limited to the pandemic period and has many things that need to be addressed in its implementation and supervision, especially in terms of protection of patient rights in compliance with the rules and legislation that apply. The government needs to start drafting detailed regulations right away to ensure that patients using clinical teleconsultation services are protected by the law. Especially related to licensing and supervision.

Keyword: Clinical Teleconsultation, Patient's Legal Protection, Indonesia

Abstrak: Perkembangan teknologi digital semakin berkembang pesat, begitu pula dalam dunia kesehatan. Pada awalnya, Telemedicine terbatas hanya di kalangan Fasilitas Pelayanan Kesehatan sebagai solusi atas tantangan terbatasnya jumlah dokter spesialis/subspesialis di Rumah Sakit Terpencil di tanah air. Namun, setelah Pandemi COVID-19 melanda, perkembangan Telemedicine berkembang pesat. Hal ini perlu mendapat perhatian serius, terutama dalam aspek perlindungan hukum. Jika status Pandemi COVID-19 dicabut, bagaimana Pengaturan Hukum untuk layanan Telekonsultasi Klinis? Bagaimana Perlindungan Hukum Pasien dalam Praktik Layanan Telekonsultasi Klinis? Metode Penelitian Penelitian ini menggunakan metode yuridis normatif dengan pendekatan kesimpulan secara induktif. Hasil penelitian ini adalah pengaturan hukum Telekonsultasi Klinis yang ada saat ini hanya sebatas pada masa pandemi dan masih banyak yang perlu dibenahi dalam pelaksanaan dan pengawasannya, terutama dalam hal perlindungan hak-hak pasien agar sesuai dengan peraturan dan perundang-undangan yang berlaku. Pemerintah perlu segera mulai menyusun

peraturan yang lebih rinci untuk memastikan bahwa pasien yang menggunakan layanan telekonsultasi klinis terlindungi oleh hukum. Terutama terkait perizinan dan pengawasan.

Kata Kunci: Telekonsultasi Klinis, Perlindungan Hukum Pasien, Indonesia

INTRODUCTION

Technological development is currently progressing very rapidly, including in the field of healthcare. With the acceleration of the industrial revolution era, along with the increasing public demand for healthcare services and the various challenges that must be faced (PB.IDI, 2018: p.5). One of the main challenges is the limited access to healthcare in remote areas, which require expert support in diagnosis and treatment (WHO, 2010). Furthermore, in today's digital era 4.0, the demand for fast healthcare services is increasingly favored by the public.

In 2019, the development of telemedicine was initiated by the Government through the issuance of the Regulation of the Minister of Health on Telemedicine between Healthcare Facilities, which

includes services such as Tele-EKG, Tele-USG, Tele-Radiology, and Clinical Teleconsultation between healthcare workers (Permenkes, 2019). Prior to this, telemedicine had been piloted since 2017 in several hospitals across various regions to address the need for medical expertise.

In 2020, The COVID-19 pandemic caused a considerable acceleration in the development of telemedicine, especially clinical teleconsultation. Teleconsultations between physicians and patients who needed to be monitored while undergoing self-isolation were one direct application of telemedicine during the epidemic. Telemedicine also helped to slow the spread of the COVID-19 virus by reducing crowding and long lines at medical facilities for other disorders, particularly for people receiving treatment for chronic diseases.

In fulfilling patients' rights, it is essential to uphold the established standards, both in terms of licensing and supervision, to ensure the legal protection of patients. Based on existing theory, legal protection refers to the safeguarding of human dignity and the acknowledgment of human rights.

Legal protection is an effort to safeguard human rights as legal subjects by establishing legal instruments (Soekanto, 2007). Licensing is necessary to ensure that patients' rights are fulfilled by complying with all requirements and procedures, as healthcare services involve acts of state administrative law, which apply regulations to concrete situations based on specified requirements and procedures (Syahran Basah, 1995). Once these requirements and procedures are met, approval is granted by the authorities in accordance with applicable laws and regulations (Spelt & Ten Berg, 1992). Therefore, the issuance of a license removes any legal prohibitions, as the service is deemed appropriate for healthcare provision (1945 Constitution of the Republic of Indonesia, Article 34).

Legal Issues

Several Healthcare Facilities have developed various Telemedicine services, particularly Clinical Teleconsultation. Likewise, service platforms offering Clinical Teleconsultation have continued to grow. However, how is the legal regulation of healthcare service practices through clinical teleconsultation structured? And how is legal protection for patients ensured in the practice of such teleconsultation services?

In health services, the principles of legality, justice, and balance must be observed (Veronika Komalaty: 2002). There is a relationship between doctors, patients, health service facilities, and other personnel that must consider their respective rights and obligations as

regulated by legislation in order to achieve the highest possible degree of public health (Law No. 36/2004: Article 56). Regarding the protection of patients' rights, what must be observed are the rights to receive quality services, the right to receive an explanation about their illness, the right to refuse or accept treatment, the right to obtain a second opinion, the right to confidentiality of medical information, and the right to access medical records (Law No. 29/2004: Article 24). All patients' rights can be fulfilled if healthcare providers comply with all applicable laws and standards, namely service standards, operational standards, and professional standards. In carrying out health service practices, service providers are required to adhere to the established standards and obtain proper licensing. During the practice, implementation must be supervised to ensure service quality is maintained and patients' rights are protected (Law No. 36/2009: Articles 54 and 55).

Theory of Legal Protection

Philipus M. Hajon divides legal protection into two categories: based on means and based on preventative and repressive protection. He defines legal protection as the preservation of dignity and honor as well as the acknowledgment of human rights held by legal subjects based on legal provisions and authority. In order to avoid conflicts, preventive protection entails allowing society to voice its thoughts prior to decisions or legislation being adopted. The goal of repressive protection is to settle conflicts. Therefore, the state's assurance that each party can exercise their rights and legal interests in their role as legal subjects is known as legal protection.

According to Satjipto Rahardjo, legal protection is an endeavor to safeguard an individual's interests by granting human rights authority to act on those interests' behalf. Additionally, according to Soerjono Soekanto, legal protection is basically defense provided to legal subjects through legal instruments.

Theory of Licensing

According to Sjahran Basah, a license is a one-sided administrative legal act of the state that applies regulations in a concrete case according to the guidelines and protocols established by the relevant statutory regulations.

Meanwhile, according to Spelt and Ten Berg, A licence is an authority's approval based on laws or government regulations that permits a departure from the legislation's prohibitions in specific situations. Furthermore, according to Ateng Syafrudin's opinion, the purpose of a license is to eliminate prohibitions, turning what was forbidden into something permitted.

A licensing decision is made by a State Administrative Officer in compliance with Law Number 9 Year 2004's Article 1 Point 3, which states: "State Administrative Decisions are written determinations issued by a State Administrative Body or Officer that contain State Administrative legal actions which, based on applicable legislation, are concrete, individual, and final, and can cause legal consequences for a person or a civil legal entity."

According to the aforementioned viewpoints and in accordance with Law Number 9 of 2004's Article 1 Point 3 stipulations, the author can conclude that licensing is a form of government decree or decision containing permission or approval from the government to carry out something, whether previously prohibited or not, under certain procedures and requirements to obtain it.

In the implementation of health services with teleconsultation, which is a special part of telemedicine, specific regulations are needed in order to provide legal protection for patients, especially in fulfilling their rights as patients.

In this case, licensing is a form of State Administrative Decision that is enforced, but it is not intended to complicate the public in carrying out their desired activities. Rather, it aims to regulate, control, and supervise the behavior of the public, both individuals and groups, so

that the activities carried out do not cause unrest and harm to the community, the environment, and the state.

With the existence of licensing, it is expected to provide a sense of legal certainty and peace to the public. Every human behavior is supervised, and so are the actions of authorities or the government. If the authorities wish to carry out a plan or activity, including issuing a license, it should, as much as possible, have a legal basis and genuinely consider the interests of the public so that no one feels disadvantaged.

To issue a license, many things must be considered and taken into account because the license issued does not only affect the intended person (licensee) but also affects the people around the location where the license is issued or third parties.

Supervision Theory

According to P. Nicolai and colleagues, the means of enforcing administrative law include:

1. supervision to ensure that government organs can comply with or act based on the laws established in writing, and supervision over decisions that impose obligations on individuals; and
2. the application of governmental sanctioning authority.

The opinion expressed by Nicolai Hamper is in line with Ten Berg as cited by Philipus M. Hadjon, who states that the instruments for enforcing administrative law incorporate oversight and the application of penalties. While sanctions are a repressive method of enforcing compliance, supervision is a preventive strategy.

In a state with a rule of law, oversight of government operations is meant to make sure that, as a preventative measure, the government carries out its operations in accordance with the law, and it is also intended to restore situations to how they were before violations of legal norms occurred, as a repressive effort. In addition, and most importantly, this supervision is carried out as an effort to provide legal protection for the people. Supervision in terms of law and policy regarding government actions in administrative law is aimed at providing protection for the people.

The review of legal aspects concerning the enforcement of administrative law in resolving violations committed by members of the public is divided into:

1. theoretical aspects of administrative law; and
2. aspects of positive law.

The first aspect is intended to determine the theoretical framework for analyzing positive law. To define this aspect, the basic concepts of administrative law are explained, while the second aspect is approached and analyzed using positive law, which is the law currently in force and enacted by authorized officials.

The purpose of a nation's oversight of government operations is to make sure that government operations are conducted in compliance with the law, as a preventative measure, and to, as a repressive measure, return things to their pre-violation state. Furthermore, and perhaps most significantly, this oversight is done to give the public legal protection.

It has been stated that sanctions are a kind of law enforcement in addition to supervision. A crucial component of any legislative regulation is sanctions. Sanctions are actually regarded by J.B.J.M. Ten Berg as the foundation of administrative law enforcement.

The use of governmental power, which derives from both written and unwritten administrative legal regulations, is what administrative sanctions in administrative law are. In administrative law, sanctions are tools of public authority that the government can employ to address noncompliance with duties outlined in administrative legal standards.

METHOD

The type of research used in Legal Protection for Patients in the Practice of Clinical Teleconsultation Services is normative juridical, with research specifications in the form of descriptive-analytical and prescriptive-analytical. The approaches used are the statute approach (legislation), conceptual approach, and comparative approach, with inductive qualitative data analysis. The theoretical framework used includes the Theory of Legal Protection, Theory of Licensing, and Theory of Supervision.

The legal materials used are primary materials in the form of legislation, namely the Health Law, Medical Practice Law, Hospital Law, Health Worker Law, and Ministerial Regulations or Ministerial Decrees related to Telemedicine both before and during the COVID pandemic. Secondary materials are journals, theses, papers related to Telemedicine, as well as books about health services, legal protection, licensing, and supervision. Tertiary materials are dictionaries or other supplementary materials.

RESULT AND DISCUSSION

In Indonesia, the regulation of telemedicine currently only applies between health facilities and is still in the development stage, facing obstacles due to the high cost of equipment. However, telemedicine services such as Tele-ECG, Tele-Radiology, and Tele-Ultrasound can help overcome limitations in resources, especially in terms of expertise or skilled professionals, as regulated in Minister of Health Regulation Number 20 of 2019.

During the implementation of telemedicine, discretion was applied during the COVID-19 pandemic, with many relaxations — for instance, health services could be provided via teleconsultation using just a mobile phone. Previously, telemedicine required tools like Tele-ECG, Tele-Ultrasound, and Tele-Radiology. Yet, during the pandemic, doctors practicing at places like the Wisma Atlet only needed an assignment letter instead of a practice license. In a medical emergency situation, discretion was also applied regarding competency requirements.

In several countries, outside pandemic conditions, telemedicine platforms are used for follow-up patients, with services supported by devices and home care/home visit health workers. Ethical issues in telemedicine and telehealth services include fidelity — the existence of financial interests in providing services through certain platforms; competency — the ability of doctors to make diagnoses via a platform without direct physical examination; transparency and informed consent — patients must be informed about the strengths and limitations of doctor services through telemedicine platforms; issues related to second opinions; privacy and confidentiality — guarantees for the protection of personal and medical data, and access to and storage of medical records; and continuity of care — managing health conditions after service through the platform.

These provisions were only valid during the COVID-19 pandemic. So what happens when the pandemic ends? This requires urgent regulation. Consequently, the Minister of Health Decree Number 4829 of 2021 was issued regarding Guidelines for Healthcare Services Through Telemedicine During the COVID-19 Pandemic, which regulates the following matters:

1. Telemedicine providers are healthcare facilities (hospitals, community health centers, clinics, private practices, medical laboratories, pharmacies) that use applications developed by the healthcare facility itself or applications developed by the government or private sector.
2. Activities that can be carried out through the Telemedicine application include:
 - a. Consultation on communication, information, and education (CIE).
 - b. Clinical consultation: anamnesis, physical examination through audiovisual means, providing advice/suggestions, establishing a diagnosis, management/prescription writing, and the doctor is responsible for the prescription.

Doctors must be held accountable for prescriptions. The government needs to carefully address the issue that physical examinations conducted via audiovisual platforms must meet certain standards in order to establish accurate diagnoses. If such physical examinations are substandard, they may lead to diagnostic errors, which in turn carry the risk of treatment errors.

The development of telemedicine regulations in Indonesia began in 2016 with the issuance of the Decree of the Minister of Health Number HK.02.02/MENKES/409/2016 concerning Pilot Hospitals for the Telemedicine Program Based on Video Conference and Teleradiology. This was driven by the need to improve access to and quality of healthcare services, and due to the limited number of healthcare graduates in rural and remote areas. At that time, the distribution of radiology specialists was uneven—83% were located in western Indonesia, 15% in central regions, and only 2% in eastern Indonesia. The same issue applied to other specialist and subspecialist doctors. To address this disparity, the Ministry of Health designated the National Brain Center Hospital (RS PON) in Jakarta as the lead hospital for video conference services. Meanwhile, RSUP M. Djamil in Padang, RSUP Dr. M. Hoesin in Palembang, RSUP Dr. Wahidin Sudirohusodo in Makassar, and RS PON Jakarta were designated as lead hospitals for teleradiology (Ministry of Health, 2016).

The hospitals under the guidance of RS PON Jakarta include RSUD Besemah Pagar Alam and the National Stroke Hospital in Bukittinggi for both video conferencing and teleradiology. Hospitals under the guidance of RSUP M. Djamil Padang include RSUD Pasaman Barat, RSUD Zein Painan, RSUD Pariaman, RSUD Lubuk Sikaping, and RSUD Kepulauan Riau Meranti. Hospitals guided by RSUP Dr. M. Hoesin Palembang include RSUD Curup Rejang Lebong Bengkulu, RSUD Hasanuddin Damrah Manna Bengkulu, and RSUD Kotaagung Lampung. Meanwhile, RSUP Dr. Wahidin Sudirohusodo Makassar oversees RSUD Harapan Insan Sendawar in East Kalimantan (Ministry of Health, 2017).

A case of pneumonia in Wuhan City, Hubei Province, China, with an unclear etiology was reported by the WHO China Country Office on December 31, 2019. China classified the case as a novel coronavirus type on January 7, 2020. Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), a new coronavirus that had not yet been discovered in humans, is the cause of Coronavirus Disease 2019 (COVID-19).

The WHO designated the incident as a Public Health Emergency of International Concern (PHEIC) on January 30, 2020, and COVID-19 was formally designated as a pandemic on March 11, 2020.

Indonesia had previously put in place a number of legal frameworks pertaining to infectious disease epidemic response policies: Regulation Number 1501/Menkes/Per/X/2010 concerning Certain Types of Infectious Diseases That Can Cause Outbreaks and Response Measures, Government Regulation Number 40 of 1991 concerning Control of Outbreaks of Infectious Diseases, and Law Number 4 of 1984 concerning Outbreaks of Infectious Diseases.

The Minister of Health issued Decree of the Minister of Health Number HK.01.07/MENKES/104/2020 concerning the Designation of Novel Coronavirus Infection (2019-nCoV Infection) as a Disease Capable of Causing an Outbreak and Measures for Its Response in order to aid in the early containment of the COVID-19 outbreak. The WHO designation of the Novel Coronavirus (2019-nCoV Infection) as a Public Health Emergency of International Concern (PHEIC) served as the foundation for this decision. Furthermore, the extensive spread of COVID-19 to other nations and the possibility of its expansion to Indonesia as a result of population movement called for extensive reaction measures to combat the illness (Kemkes, 2020).

The Declaration of Public Health Emergency for Coronavirus Disease 2019 (COVID-19) was addressed in Presidential Decree Number 11 of 2020, which was published on March 31, 2020. The Non-Natural Disaster of the Spread of Coronavirus Disease 2019 (COVID-19)

was then designated as a National Disaster by Presidential Decree Number 12 of 2020 (Keppres, 2020).

The outbreak of the COVID-19 pandemic significantly strengthened the utilization of telemedicine as an alternative method for delivering healthcare services. COVID-19 is known to be transmissible from human to human through droplets. Those at the highest risk of contracting the disease are individuals in close contact with COVID-19 patients, including doctors and other healthcare workers providing direct medical services.

Individuals infected with COVID-19 may exhibit a range of symptoms—or none at all—yet all require laboratory testing, such as RT-PCR or a negative rapid test result, to be confirmed as not infected. Face-to-face interactions between patients as service recipients and physicians as healthcare providers increase the risk of infectious disease transmission, particularly COVID-19. This transmission can happen between patients and physicians or between asymptomatic physicians, often known as People Without Symptoms (OTG), and patients. Thus, limiting in-person healthcare services through the use of information and communication technology in the form of telemedicine is one of the steps that must be taken to stop the spread of COVID-19.

During the COVID-19 pandemic, the public in Indonesia was required to implement Community Activity Restrictions (PPKM). Currently, PPKM Level 4 was enforced for 5 days from July 20 to July 25, 2021, followed by an Emergency PPKM for 8 days from July 26 to August 2, 2021. This government policy led to the early closure of various public facilities. Consequently, the public was urged to stay at home and avoid visiting these public places to reduce the transmission of COVID-19 and restore stability to the situation. Therefore, telemedicine became a solution to meet the demand for easy and safe healthcare services.

To stop the spread of COVID-19, the Republic of Indonesia's Ministry of Health released Circular Letter Number HK.02.01/MENKES/303/2020 on the Use of Information and Communication Technology in Health Services on April 29, 2020. This circular regulates telemedicine services conducted between doctors and patients or between doctors, while ensuring the security of patient data. All consultations must be recorded in digital or manual medical records and confidentiality must be maintained. Doctors providing services through information and communication technology to diagnose, treat, prevent, and/or evaluate health conditions must act according to their competencies and authority, which are verified by their Registration Certificate (STR), while still maintaining the quality of service and patient safety (Kemkes, 2020).

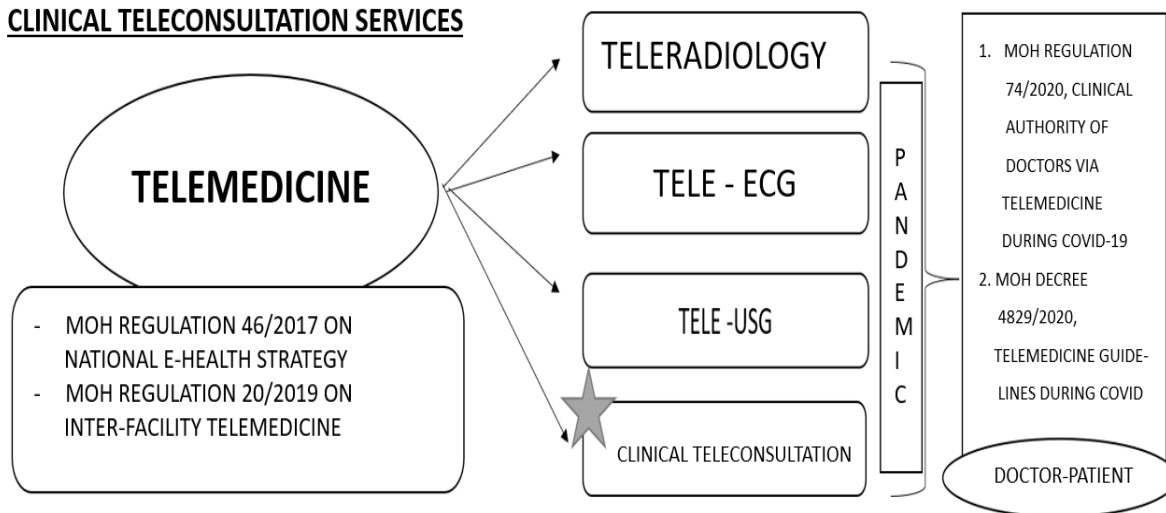
Regulation Number 74 Year 2020 concerning Clinical Authority and Medical Practice through Telemedicine during the COVID-19 pandemic in Indonesia was also issued in the context of telemedicine during the pandemic. It stipulates that medical practice during the pandemic may be carried out online or in person using electronic telemedicine applications and systems, with a focus on effective communication. Telemedicine must be conducted through Health Service Facilities and carried out by competent doctors/dentists who possess a Registration Certificate and Practice License. Doctors/dentists performing telemedicine must assess the patient's eligibility whether in an emergency condition or can be managed via telemedicine. If in an emergency condition, the patient must be immediately referred to a Health Facility accompanied by relevant information. Doctors must also create medical records, conduct supporting examinations, and provide prescriptions (KKI, 2020).

This was further strengthened by the Decree of the Medical Ethics Honorary Council (MKEK) of the Indonesian Medical Association Central Number 05 Year 2020 concerning the Telemedicine Fatwa, which urges to still pay attention to legal aspects, medical professional ethics, and communication ethics in the era of information technology as best as possible (MKEK, 2020).

In 2021, In addition to declaring the Circular Letter of the Minister of Health Number HK.02.01/MENKES/303/2020 repealed and no longer effective, the Minister of Health issued Decree Number HK.01.07/MENKES/4829/2021 about Guidelines for Health Services through Telemedicine during the COVID-19 Pandemic. (KMK, 2021)

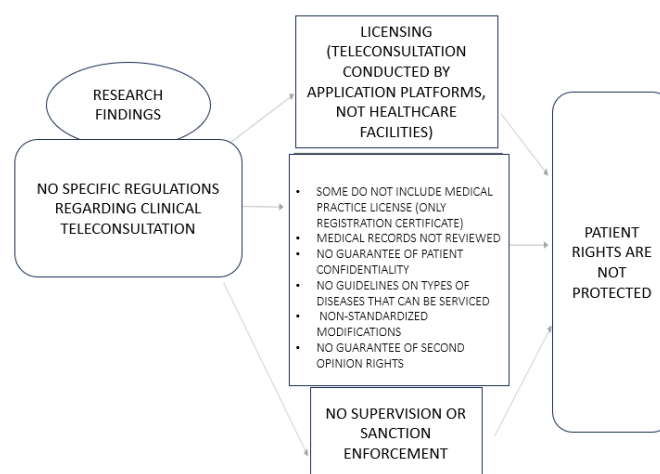
In Minister of Health Decree 4829, telemedicine with clinical consultation is regulated. Clinical consultation is a health service provided by doctors through telemedicine, including anamnesis, limited physical examination via audiovisual means, and management such as education/advice up to the provision of therapy with prescription medication.

CLINICAL TELECONSULTATION SERVICES



Legal Protection for Patients

In general health services, patients have the right to legal protection. The guarantee of legal protection for patients includes receiving proper health care, which is the responsibility of the government. Fulfilling patients' rights means receiving safe and quality services according to their needs. Patients have the right to receive explanations about the procedures to be performed, to obtain a second opinion, and to be assured of the confidentiality of their personal information and medical records.



From the results of research conducted, many aspects need to be carefully considered in the implementation of Teleconsultation related to the legal protection of patients.

Telemedicine services provided by healthcare facilities can make use of apps they have created or collaborate with other government or commercial sector applications.

In practice, many consultation service platforms are only platforms and not health facilities as regulated in the Ministerial Decree. This can pose risks to the legal protection of patients when receiving health services. Clinical Teleconsultation requires special regulations on this matter so that patients' rights are properly fulfilled.

Patients do not receive guarantees of medical confidentiality, medical records are not created in accordance with statutory regulations, and the organizers of clinical teleconsultation are not health service facilities but rather platforms that list various doctors from several Health Service Facilities. When prescribing, the logo on the prescription does not include the Health Service Facility where the doctor practices as stated in the application, but rather the platform's logo. There is no supervision regarding the implementation of Clinical Teleconsultation.

It cannot be denied that Clinical Teleconsultation greatly helps the community, but patients must also receive legal protection guarantees. Therefore, Clinical Teleconsultation must be further regulated within telemedicine regulations, as there is currently no law governing this, or at least a Government Regulation, since it involves matters beyond health, including patient data protection, information transparency, and consumer protection.

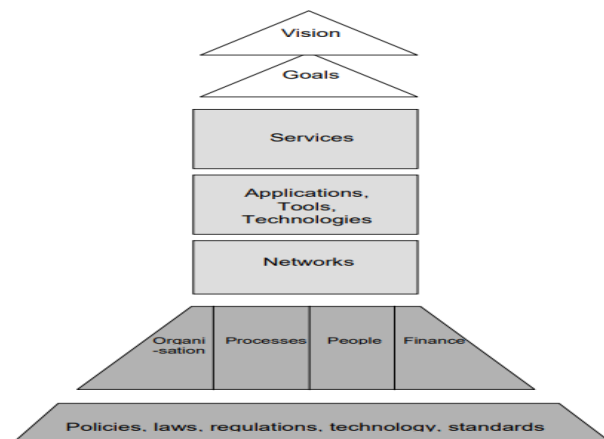
Discussion:

Legal protection for patients in the practice of Clinical Teleconsultation services requires strong regulation that underpins the implementation of telemedicine in general and teleconsultation in particular.

Looking at the best practice from the neighboring country Malaysia, which has prepared telemedicine since 1997 with the enactment of the Telemedicine Act and the Personal Data Protection Act.

In the Malaysian Government's Blueprint, there is a strong emphasis on the future health system that utilizes the power of information and multimedia technology as the main driver to provide a health service system that is easily accessible, integrated, high quality, affordable, and recognized as one of the best in the world.

As the main foundation of Telehealth in Malaysia, policies, laws, systems, and standards must be prepared. Then, organizations are established to carry out processes, human resources, and budgeting. Next, networks, applications, and technologies that support telemedicine are prepared, and services are provided to the public to achieve the goals and vision-mission of Malaysia's health sector (Malaysia Law, 1997).



Malaysian Telemedicine Flagship Application

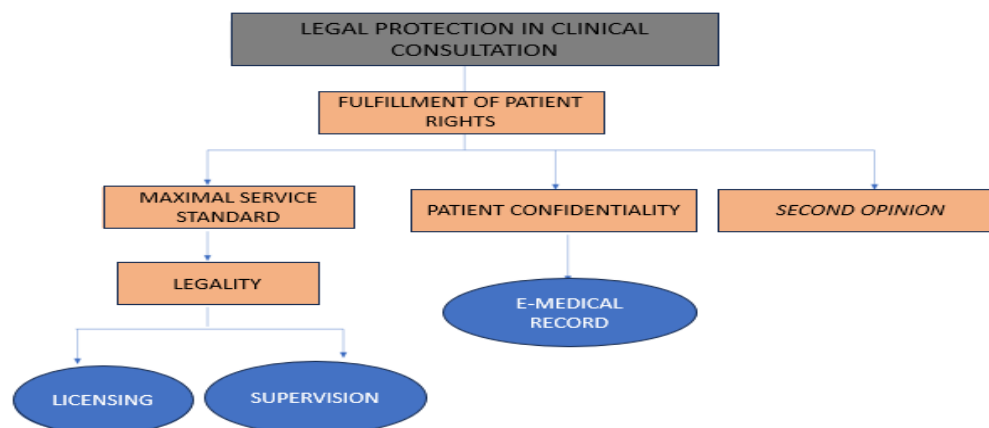
Telehealth in Malaysia has continuously developed. In 1997, there were 4 main components, which were restructured into 7 components in 2000, and then into 5 components in 2007. This process has taken about 25 years until now related to the development of telemedicine and teleconsultation, which then became part of the 5 main components that prioritize legal protection and ensure the sustainability of Telehealth with technological developments, namely: 1) Life Time Health Record (LHR) & Services, 2) Health Package, 3) Online Health, 4) Teleconsultation, 5) Continuing Professional Development (M.H. Mat Som).

Supervision is carried out by the Director General of the Ministry of Health. Anyone practicing telemedicine in violation of this section, even if they practice from outside Malaysia, shall be guilty of an offense and shall be punished with a fine not exceeding five hundred thousand ringgit or imprisonment for a term not exceeding five years, or both.

ASPECTS	MALAYSIA	INDONESIA
Regulation	1. Telemedicine Act 1997 2. Malaysian Personal Data Protection Act 2010 and other derivative regulations governing telemedicine and teleconsultation	1. Does not yet have a Telemedicine Law 2. Does not yet have a law on patient data protection Only regulated by Ministerial Regulation No. 20 of 2019 concerning Telemedicine between health facilities and regulations for telemedicine during the pandemic.
Service standards	- Doctors with fully registered and valid certificates - Must have a Telemedicine certificate for foreign doctors registered with the Malaysian Ministry / Council	Competency regulations for telemedicine service doctors do not yet exist, and there is no registration for telemedicine competency yet.
Legal protection of patients	Informed consent, confidentiality assurance, patient records regulated by law and its derivatives including sanctions	Only regulated at the Ministerial Regulation level concerning medical records

The application for a telemedicine practice certificate as referred to in paragraph 3(1)(b) must be made by a medical practitioner who is registered or licensed outside Malaysia as a fully registered medical practitioner to the Council in a certain manner or form and accompanied by the required documents, details, and fees as may be determined. The Council may issue to the applicant a certificate to practice telemedicine for a period not exceeding three years, subject to terms and conditions that may be determined by the Council in relation to the certificate. The Council may at any time amend the terms and conditions of the telemedicine practice certificate issued as referred to in the paragraph. The Council may at any time revoke a telemedicine practice certificate issued if the holder of the certificate breaches any terms or conditions specified in the certificate. Any person aggrieved by the Council's refusal to issue a certificate to practice telemedicine or by the revocation of a telemedicine practice certificate may appeal to the Minister whose decision shall be final.

In the implementation of Telemedicine, or specifically Clinical Teleconsultation in Indonesia, it must at least include aspects that ensure maximum service standards, second opinions, and guarantees of medical record confidentiality. As illustrated in the following diagram:



The minimally regulated concept is as follows:

a. Maximum Service Standards

The fulfillment of the right to Maximum Service Standards can be met if it is stated in the requirements and procedures, which are components that must be fulfilled in Licensing and Supervision. As illustrated in the following table:

No	General Health Service Standards	Clinical Teleconsultation Standards
	Licensing	
	Operational license for healthcare facilities must meet building, infrastructure, personnel, and SOP requirements.	It should be regulated that: <ol style="list-style-type: none"> 1. The operational license is attached to a healthcare facility that already holds an operational license as a physical facility, with buildings, infrastructure, personnel, and complete equipment. 2. If in the future there is an idea that existing online health consultation platforms can be recognized as online health facilities, then there must be regulations governing their legality and licensing standards to ensure legal protection for both patients and healthcare workers.
	<p>A doctor's practice license is limited to a maximum of 3 locations.</p> <p>Standard services related to infrastructure and facilities.</p>	It should be regulated that: <ol style="list-style-type: none"> 1. The doctor must have at least 2 years of experience in direct, face-to-face medical practice with patients 2. Doctors providing clinical teleconsultation must have specific competency standards in telemedicine communication. 3. Doctors providing clinical teleconsultation must be registered with a verified Indonesian domain email, authenticated by the Ministry of Health. 4. Doctors must have designated practice hours. Teleconsultation services must be provided during specific hours and may not be conducted simultaneously with in-person patient services. 1. Must maintain medical records in accordance with applicable laws and regulations. 2. Must have a dedicated system for clinical teleconsultation services, either through an in-house application or a third-party platform. 3. Must meet service standards that support accurate diagnosis. 4. Mechanisms for pharmaceutical therapy, prescriptions, and medication delivery must be regulated.
	Standard services for types of diseases	It should be regulated that: <ol style="list-style-type: none"> 1. Define patient status categories that may be served through teleconsultation (e.g., new patients or follow-up patients).

	handled based on facility level.	<ol style="list-style-type: none"> Clearly define the types of diseases that can and cannot be handled via clinical teleconsultation. Establish referral mechanisms and follow-up procedures within healthcare services.
	Supervision	
	Supervision of licensing, operational standards, and service procedures.	It should be regulated that: <ol style="list-style-type: none"> Doctors with telemedicine/teleconsultation capability must be registered with the Ministry of Health to facilitate supervision, with standardized national numbering. If online healthcare facilities become formalized, both doctors and facility licenses should be assigned specific numbers issued by the Ministry of Health. Credentialing must continue to be implemented for online teleconsultation services.
	Legal enforcement through sanctions according to regulations.	It must be stipulated that: <ol style="list-style-type: none"> Accountability of healthcare facilities and doctors providing teleconsultation services must be regulated. Internal audits and patient safety supervision are needed, especially regarding accurate diagnosis and appropriate therapy provision.

b. Confidentiality of Medical Records

One of the rights of patients in healthcare services is the confidentiality of their information, the completion of medical records, and the right to access the contents of those records. In the growing practice of Clinical Teleconsultation on the internet, such services are essentially Clinical Teleconsultation practices. However, the providers are not healthcare facilities but rather digital platforms related to health consultation that offer services including issuing prescriptions. There needs to be regulation regarding the security of patient confidentiality and the provision of medical records in accordance with applicable regulations.

According to the Regulation of the Minister of Health Number 24 of 2022, the implementation of medical records in Clinical Teleconsultation, as a part of telemedicine, refers to this regulation. Along with the development of the times, medical records in healthcare facilities offering telemedicine services are required to use Electronic Medical Records (E-Medical Records) (MoH, 2022).

A medical record created with an electronic system designed to implement medical records is known as an e-medical record. This electronic system is made up of a number of electronic machines and processes that work together to prepare, gather, process, analyze, store, display, publish, transmit, and/or distribute electronic information. It is one of the subsystems of the Health Service Facility Information System that is connected to other information subsystems in the health service facility and is operated by a dedicated working unit or adjusted based on the needs and capabilities of each healthcare facility.

This E-Medical Record system can be developed either by the Ministry of Health, by the Health Service Facilities themselves, or by other electronic system providers through cooperation. If the system used is from the Ministry, an application must be submitted. If it is the result of cooperation with a provider, then the provider must be registered as an electronic system operator in the health sector with the Ministry responsible for communication and informatics, in accordance with the prevailing laws and regulations. Electronic System registration must include the name, system documentation, available features/functions, data storage location, variables and metadata, and the list of Health Service Facilities using the Electronic System, if it is used by healthcare facilities.

E-Medical Records must be maintained from the time the patient enters the facility until the service is completed, the patient is referred, or passes away. Specifically for Clinical Teleconsultation, this process begins when the patient logs in and registers through the application or other means until the consultation is fully completed. It involves patient registration, distribution of electronic medical record data, entry of clinical information, information processing, input of data for financial claims, storage, quality assurance, and transfer of medical record contents performed by staff.

Filling in the Medical Records is the obligation of the Health Service Facility and is carried out by healthcare professionals. The specific requirements of the Medical Record are illustrated in the following table:

No	Activity	Provision	Personnel
1	Patient Registration	Must include at minimum: 1. Identity Data: – Name – Medical Record Number – National Identity Number (NIK) 2. Social Data: – Religion – Occupation – Education – Marital Status	Medical Records/Health Information Officer or other personnel trained in Electronic Medical Records (EMR)
2	Data Distribution	<i>(No additional provisions specified)</i>	Medical Records/Health Information Officer or other personnel trained in EMR
3	Clinical Information Entry	– Documentation of examination results– Treatment – Education/Other actions– Must include name, time, and signature of the healthcare provider – Must follow chronological order of services provided– In case of error, the healthcare provider may correct it – If multiple providers are involved, entries must be integrated in a single, chronologically ordered document – May include family data entry (family folder)	Healthcare Provider delivering the service
4	Information Processing	Includes: a. Coding with <i>International Statistical Classification of Disease and Related Health</i>	Medical Records/Health Information Officer or other personnel trained in EMR

		<i>Problems</i> b. Reporting: – Internal reporting – External reporting to the District Health Office, MOH, and other stakeholders c. Analysis (qualitative and quantitative)	
5	Data Entry for Financing Claims	Entry of disease classification codes based on diagnoses and procedures written by healthcare providers	Medical Records/Health Information Officer or other personnel trained in EMR
6	Medical Record Storage	a. Server b. Certified cloud computing system c. Other certified digital storage media d. Must have backup system stored separately from the healthcare facility and performed periodically e. Must be stated in SOP f. Must be connected to the data interoperability and integration platform managed by the MOH g. May collaborate with service providers under an integrity pact h. Stored for up to 25 (twenty-five) years from the last visit	Medical Records/Health Information Officer or other personnel trained in EMR
7	Quality Assurance	a. Conducted internally b. Internal audit by a team appointed by the healthcare facility leader c. May involve external parties as part of supervision and guidance	Medical Records/Health Information Officer or other personnel trained in EMR
8	Transfer of Medical Record Content	a. For referral purposes b. Done through the data interoperability and integration service platform managed by the MOH	Medical Records/Health Information Officer or other personnel trained in EMR

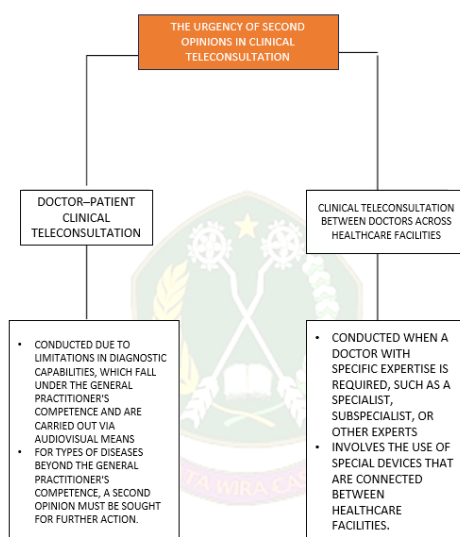
Second Opinion

A second opinion can involve visiting another doctor to obtain further information or to hear a different perspective (Kyle Beardsley, 2011). There are several reasons why obtaining a second opinion is important. These include situations where a doctor recommends surgery, when a doctor diagnoses a patient with a serious illness such as cancer, or when the doctor recommends a treatment plan that differs from what the patient believes is necessary. In cases

where a doctor recommends elective surgery, a second opinion may be required by the insurance plan. In other instances, insurance might not cover the cost of a second opinion (Chiosea, 2009). A second opinion is also sought when a patient believes they have been misdiagnosed or undiagnosed, or when the doctor themselves recommends seeking another opinion.

Obtaining a second opinion is a right of the patient and is protected by law. In the context of Clinical Teleconsultation Health Services, this second opinion can be provided or facilitated by the healthcare facility if the patient feels uncertain or if the doctor believes another expert's perspective is necessary.

In Clinical Teleconsultation, there are many limitations in establishing a diagnosis that relies solely on audiovisual means. Therefore, the right to a second opinion is particularly important, especially for patients who require direct, face-to-face treatment. In the context of Clinical Teleconsultation, providing a second opinion is essential. This is because the purpose of Clinical Teleconsultation is to facilitate access and provide initial assistance in the form of education and recommendations to patients in maintaining their health. However, Clinical Teleconsultation is inherently limited, and for that reason, the role of a second opinion is absolutely necessary.



CONCLUSION

Clinical Teleconsultation, which is a part of Telemedicine, has not yet been specifically regulated. Therefore, further regulation is required beyond the COVID-19 pandemic period, ideally through a law or at the very least a government regulation.

Legal protection for patients receiving Clinical Teleconsultation services from doctors or healthcare facilities must adhere to existing regulations already established in current legislation. This research found that patients undergoing clinical teleconsultation do not receive adequate legal protection, especially concerning elements such as service quality, medical records, medical confidentiality, and diagnostic and therapeutic accuracy. As a result, clinical teleconsultation services can generally be considered a failure in fulfilling patients' rights to attain the highest possible standard of health.

Patient protection in Clinical Teleconsultation is absolutely necessary, given the weak position of patients and the high potential for errors by doctors or healthcare professionals. It is recommended that to ensure sufficient legal protection for patients, Clinical Teleconsultation should only be conducted by licensed hospitals or healthcare facilities that are under comprehensive supervision.

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