Medico-Legal Aspect of Patient Safety for Online Consultation and Telemedicine

Tia Maya Affrita[1,3], Sujari Solichin[2], Widyana Beta Arthanti[3]*

[1]Resident of Forensic Medicine and Medicolegal Specialist Program, Universitas Airlangga, Surabaya, Indonesia

[2]Departement of Forensic Medicine and Medicolegal, Universitas Airlangga, Surabaya, Indonesia

[3]Faculty of Medicine Universitas Pembangunan Nasional Veteran Jawa Timur, Surabaya, Indonesia

Correspondence author

Widyana Beta Arthanti

Faculty of Medicine Universitas Pembangunan Nasional Veteran Jawa Timur

Rungkut Madya Street Number 191, Rungkut Kidul, Rungkut District, Surabaya, Jawa Timur 60293

Tel/Fax: +628113111846

E-mail: widyana.beta.fk@upnjatim.ac.id

Abstract

COVID-19 is an infectious disease caused by SARS-CoV-2 and spread through droplet transmission which makes it easy to spreads fast, especially from human to human interaction. It means that doctor-patient interaction in healthcare settings also prone to be one of the transmission points. Telemedicine is used to decrease the transmission of COVID-19 in healthcare settings since health service will be done without a human on human contact during the process and replaced by online interaction instead. The changing between face to face examinations to the online examination will change the course of health services on how examination should be done and what kind of consideration to take when treating the patient. This raise a question on the legal aspect of safety and the quality issues of online examination. A literature review with the legal aspect of patient safety during online health care as the main focus. Based on the suggestion from the Indonesian Doctor Association, a review of standard operating procedures is needed for online health service. This new standard will be focusing on how to build a good clinical practice that maintains the aspect of patient safety of conventional practice while reducing the risk for COVID-19 transmission. A new standard

operating procedure which patient safety and quality of service become a priority is needed so telemedicine can be developed to be used as an alternative in the COVID-19 pandemic era

Keywords— COVID-19, telemedicine, patient safety, standard operational procedure, medico-legal

Introduction

At the end of 2019, a new type of pneumonia caused by a pathogen that has never been acknowledged before was reported in Wuhan, China. This newly reported virus has similarities with SARS-CoV and MERS-CoV which were caused an outbreak in 2003 and 2012 with enough different characteristics to own its new name. Phylogenetically, SARS-CoV 2 belongs to the Betacoronavirus genus which can infect humans, bats, and any other wild animal.[1] COVID-19 is transmitted by direct contact, droplet, and some journals stated that it can also be transmitted by airborne transmission. To reduce the transmission rate of the virus we have to break the chain of infection which means that we have to reduce direct contact from person to person.[1,2]

In every outbreak, there is a certain group of people being at higher risk than the other. For example, is people who work as a healthcare worker. As in the previous outbreaks, namely SARS and MERS, around 37%-63% of the severe cases were happened to healthcare workers. In the COVID-19 pandemic, 22% of the reported cases happened to healthcare workers. At the beginning of the pandemic, 24 Italian healthcare workers died and more than 5,000 healthcare workers suffered from COVID-19.[3] This high number of healthcare workers who suffered from COVID-19 means there will be fewer numbers who will fight in the front line while the number of COVID-19 cases is rising. In the end, this will lead to exhaustion and burn out, makes them more susceptible to the virus.[4,5]

The healthcare setting can also be the perfect source of transmission. At the outpatient service, inpatient service, and emergency room are locations where close contact is often unavoidable. The spread of infection between fellow healthcare workers and patients is very likely to happen. Patients can catch COVID-19 from other patients or the asymptomatic healthcare workers while attending their examination in healthcare settings, especially vulnerable patients group such as the elderly, children, and immunocompromised patients. Guidelines to reduce the transmission such as dividing work areas based on infectious levels, implementing new adapted workflows to reduce the number of infections, and using PPE according to the work area zone have been established and applied at any healthcare institution.[6] However, the high demand for PPE and healthy healthcare workers to handle the

epidemic appear to be an additional problem that must be resolved fast. Changing the healthcare settings from conventional face-to-face service to telemedicine seems to be the logical way to achieve this purpose.

The Utilization of The Telemedicine in Indonesia and Medico-Legal Aspect of Patient Safety

The Utilization of the Telemedicine in Indonesia

In early March 2020, on 2nd March to be exact, the President of Indonesia, Joko Widodo announced the first two cases of COVID-19 in Indonesia. Before the end of March, there were more than eight hundred cases of COVID-19 in Indonesia with a death rate of 78 cases. The government has made an effort to tackle the COVID-19 outbreak by forming a COVID-19 operational taskforce on March 13th, 2020. One of the policies made by the Government to reduce the transmission rate is to urge the public to implement social distancing and reduce activities outside the house.[7] To make "stay at home" movement and social distancing a success, the Indonesian Medical Council issued a regulation regarding the utilization of telemedicine as an effort to reduce the transmission of COVID-19 in healthcare settings.[8]

In Indonesian's Medical Council Regulation (Peraturan Konsil Kedokteran Indonesia) Number 74 the year of 2020, there are articles regarding the use of telemedicine during the COVID-19 pandemic, including in article 3 verse (1) which states that "Medical practice during the Corona Virus Disease 2019 (COVID-19) pandemic can be carried out by Doctors and Dentists by direct face-to-face and/or through electronic applications/systems in the form of Telemedicine with attention to effective communication. " In this article, Indonesian's Medical Council (Konsil Kedokteran Indonesia) provides an opportunity for doctors and dentists to use telemedicine in practice while paying attention to effective communication". This verse emphasizes the implementation of medical practice by taking into account the principles of effective communication. Why effective communication becomes a concern in telemedicine-based medical practice?[8] Telemedicine is a combination of information communication technology with medical expertise to provide health services without limited by space (remotely). Unlike conventional medical practice, telemedicine relies on technological advancement to connect doctors and patients or doctors with other healthcare workers, and this method is prone to creating communication barriers.[9]

The utilization of technology in medical practice has been known and carried out for a long time. Since the invention of electronic telecommunications, telemedicine has begun to develop. Give the example on the tele-stethoscope introduced by William Einthoven and the utilization of radio transmissions to provide health advice to seafarers who have minimal access

from health services. In World War II, the photos transmission technique was developed by the European military and this had inspired clinical photo mailing (of disease and disorder) from patients to doctors. Tele-consulting was developed in 1960 by the Nebraska Psychiatric Institute in the US. However, the progress of telemedicine is slowing down in the 1970s and this was caused by several obstacles, including information technology utilization's cost which at that time was still relatively high.[9]

Likewise in Indonesia, at a time when information technology was rapidly developed and cellphones can be found almost in any Indonesian household, telemedicine began to rise. Telemedicine then began to develop and be adopted as a new health trend. However, just like any other legal regulations which are always constructed later compared to its phenomenon, the laws and regulations regarding telemedicine in Indonesia are also set up late. These regulations are inadequately sufficient and have not been covering all telemedicine problem in Indonesia. Even though telemedicine is one of the examples of e-Health regulation strategy as part of Indonesia's health development, the implementation of telemedicine is still not well integrated.[10]

Medico-legal Aspect of Patient Safety

In contrast to conventional medical practice, telemedicine does not allow direct face-to-face contact between service providers and consumers and this will certainly generate problems. One of the problems is whether medical practice via telemedicine have equivalent quality compare to conventional practice. As stated in the Indonesian Code of Ethics Article 2 that "A doctor is obliged to always make professional decisions independently, and maintain professional behavior in the highest measure." In the elucidation section of this article, it is implied that in carrying out medical practice, a doctor is obliged to maintain professional standards and that professional decisions must be made after carrying out a thorough examination and evaluation of patients using standards practice/guidelines for medical services that have been legally recognized. There are several important points in this elucidation that are closely related to the implementation of telemedicine, namely professional standards and that decisions must be made based on careful assessment after a comprehensive examination which we know that this comprehensive examination can be such a challenge in telemedicine practice.[11]

In several previous studies, it was stated that with the limitations of telemedicine, the service quality of telemedicine is equivalent to conventional medical practice and so does its patient safety aspect. In a study by McConnochie, is shown that there is no significant discrepancy in acute illness diagnoses between conventional practice and telemedicine. In

another study, conducted by Lundberg showed that in ear-related illness that needed examination using otoscope, telemedicine gets higher accuracy than in conventional practice. This is possible because, in telemedicine practice, ear examination is carried out using a video otoscope which results can be played back and evaluated further compared to the manual otoscope used in conventional practice.[12] A similar result also stated by medical practice using tele-burn and tele-urology. In conclusion, the challenges of performing a physical examination in telemedicine practice do not necessarily reduce the outcome quality of the telemedicine practice.[13,14]

For telemedicine practice to thrive, a certain organization that regulates its existence is needed. In several countries, this organization for telemedicine and special regulations that discuss telemedicine in detail, have been established. For example, we have the American Telemedicine Association (ATA) which in charge of telemedicine systems development in the USA. ATA works in developing legal regulations regarding telemedicine and also in charge of developing rules and guidelines regarding the implementation of telemedicine itself. Currently, the ATA has issued more than twenty guidelines regarding telemedicine, including guidelines for telepathology, teleradiology, teleburn, and so on.[15-17] Meanwhile, in Indonesia, there is no such institution/organization and there is no adequate legal regulation regarding telemedicine. So far, there are three legal regulations about telemedicine in Indonesia, namely the Ministry of Health Regulation (Peraturan Kementerian Kesehatan) Number 46 the year of 2017, the Ministry of Health Regulation (Peraturan Kementerian Kesehatan) Number 20 the year of 2019, and Indonesian's Medical Council Regulation (Peraturan Konsil Kedokteran Indonesia) Number 74 the year of 2020, but all three do not discuss details about telemedicine in daily practices.[8,10,18]

ATA surveyed healthcare workers who downloaded the telemedicine guidelines that they have written. In the survey, several questions regarding telemedicine and the utilization of guidelines were asked, such as how they are planning to implement the guideline in their practices and how substantial for telemedicine these practice guidelines will be. As many as 97% of respondents answered that a specific guideline on the implementation of telemedicine in medical practice is needed, simply because the guidelines that have been used in healthcare settings in both public healthcare and private healthcare are not accommodating enough to be used in telemedicine practice. Even so, from the survey, it is also noticed that telemedicine guidelines have not been used evenly and not yet to be mandatorily implemented in each telemedicine settings because there is no official agreement regarding the guidelines for telemedicine.[19]

Three main components become benchmarks in the telemedicine guidelines developed

by the ATA, namely administrative guidelines, clinical guidelines, and technical guidelines. Administrative guidelines include the agreement of which institution is going supervise the implementation of telemedicine, which institution that develops telemedicine regulations, and the administrative part of healthcare settings that implement telemedicine (such as who is the healthcare workers that will do the examination and to whom the result supposed to be consulted, how the reimbursement system is used, etc.). The technical guidelines are more directed at what kind of technology will be used in the service, what is the minimum requirement of each infrastructure to be used, and how the data storage system and data storage security will be handled. Clinical guidelines emphasizing more on the process of medical practice itself which means that each guideline has its characteristic depending on what service is offered.[16,17] Of these three main guidelines, the technical and clinical guidelines have a larger portion in determining the quality of telemedicine services and whether these services can guarantee patient safety aspects of medical practice.

Several institutions and organizations need to be involved in the establishment process of the telemedicine guideline; therefore, it is better if a special institution was formed to develop telemedicine services in Indonesia and set the guidelines for telemedicine services. Comparable with ATA, which consists of not only of laws regulators but also from medical organizations (doctors, pharmacies, nurses. traditional medicine, medical academics) and non-medical workers such as the IT sector, and also technology and telecommunication company. Indonesian Medical Councils and Indonesian Medical Association then will coordinate to develop telemedicine guidelines by their respective fields of expertise. This guideline will then be adopted and adapted to each healthcare setting according to its capability and policy.[18] The supervision act will be carried out by the Health Ministry, National Public Health Department, Province Public Health Department, and Indonesian Medical Council.[18,20]

The next steps will be the dispersion of this guideline and appropriate training for its implementation to ensure each doctor/dentist and healthcare workers who will provide telemedicine services can adapt themselves to the new system. Another consideration, telemedicine is one of the regulation strategies of E-Health described in Ministry of Health Regulation No. 46 of the year 2017. It is implied that telemedicine advancement is imperative. Furthermore, telemedicine should be taught to medical students as prospective health workers to maintain the quality and safety of telemedicine practice.

Acknowledgment

We wish to express our deepest gratitude to our supervisor dr. Sudjari Solichin, Sp.FM for his guidance. His vast knowledge about journal writing and Indonesian Medicolegal system, is the

reason that could make this paper possible. And we also thankful for our colleagues and teachers, who we cannot state one by one for their endless support. The generosity and expertise of one and all have improved this study in innumerable ways and save me from many errors; those that inevitably remain are entirely my responsibility.

References

1. Rothan HA, Byrareddy SN. The epidemiology and pathogenesis of coronavirus disease (COVID-19) outbreak. J Autoimmun. 2020;109:102433.
2. Zhou B, She J, Wang Y, Ma X. Airborne or droplet precaution for health workers treating COVID-19. 2020;1–14.
3. Lan FY, Wei CF, Hsu YT, Christiani DC, Kales SN. Work-related COVID-19 transmission in six Asian countries/areas: A follow-up study. PLoS One. 2020;15(5):1–11.
4. Sim MR. The COVID-19 pandemic: Major risks to healthcare and other workers on the front line. Occup Environ Med. 2020;77(5):281–2.
5. Doshi A, Platt Y, Dressen JR, Mathews BK, Siy JC. Keep calm and log on: Telemedicine for COVID-19 pandemic response. J Hosp Med. 2020;15(5):302–4.
6. Gan WH. Preventing intra-hospital infection and transmission of Coronavirus Disease 2019 in healthcare workers. 2020;241–3.
7. World Health Organization. Coronavirus Disease 2019 (COVID-19) situation reports. WHO Situat Rep. 2020;72:1–19. Available from: https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200401-sitrep-72-covid-19.pdf.
8. Konsil Kedokteran Indonesia. Peraturan Konsil Kedokteran Indonesia Nomor 74 Tahun 2020 tentang kewenangan klinis dan praktik kedokteran melalui telemedicine pada masa pandemi Corona Virus Disease 2020 (COVID-19). Indonesia; 2020.
9. Ikatan Dokter Indonesia. Telemedisin - Rekomendasi Ikatan Dokter Indonesia untuk masa depan digitalisasi kesehatan di Indonesia. Indonesia; 2018.
10. Kementerian Kesehatan. Peraturan Menteri Kesehatan Republik Indonesia Nomor 46 Tahun 2017 tentang strategi E-Kesehatan Nasional. Indonesia; 2017.
11. Ikatan Dokter Indonesia. Kode Etik Kedokteran Indonesia. Jakarta: Ikatan Dokter Indonesia; 2012.
12. McConnochie KM, Wood NE, Alarie C, et al. Differences in diagnosis and treatment using telemedicine versus in-person evaluation of acute illness. Ambul Pediatr. 2006;6(4):187–95.
13. Monte Soldado A, Estevez Fernandez MJ, et al. Implementation and evaluation of

telemedicine in burn care: Study of clinical safety and technical feasibility in a single burn center. Burns. 2020.

14. Sherwood BG, Han Y, Nepple KG, Erickson BA. Evaluating the effectiveness, efficiency and safety of telemedicine for urological care in the male prisoner population. Urol Pract. 2018;5(1):44–51.
15. American Telemedicine Association. ATA telemedicine practice guidelines. Available from: https://www.americantelemed.org/.
16. Theurer L, Hussain T, et al. American Telemedicine Association guidelines for teleburn. Telemed E Health. 2017;23(5):365–75.
17. Krupinski EA, Burdick AE, Pak HS, et al. American Telemedicine Association's practice guidelines for teledermatology. Telemed e-Health. 2008;14(3):289–302.
18. Kementerian Kesehatan. Peraturan Menteri Kesehatan Republik Indonesia Nomor 20 Tahun 2019 tentang penyelenggaraan pelayanan. Indonesia; 2019.
19. Krupinski EA, Antoniotti N, Bernard J. Utilization of the American Telemedicine Association's clinical practice guidelines. Telemed E Health. 2013;19(11):846–51.
20. Dewan Perwakilan Rakyat RI, Presiden RI. Undang-Undang Republik Indonesia Nomor 29 Tahun 2004 tentang Praktik Kedokteran. Indonesia; 2004.