

Teleconsultation – Legal Aspects

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Abstract

In the context of the recently adopted law, teleconsultation is a new solution for mutual communication between the doctor and the patient. The introduced legal provisions are to improve contact with the doctor and his or her availability for the patient as a person in need of help. Such form of advice, or consultation is right now a health service provided by the doctor over distance using electronic communication channels (online, telephone). The epidemic safety means and the recommendations concerning caution in contacts with others during the ongoing COVID – 19 pandemic are key. The doctor, owing to the specific nature of the profession, is particularly exposed to the risk of infection from the patients or the places where he or she must stay. In order to counteract the COVID – 19 pandemic, new legislation has been introduced such as the Act of 2 March 2020 on special solutions related to preventing, counteracting and combating COVID-19, other infectious diseases and crisis situations caused by them and its later amendment of 31 March 2020, as well as the Regulation of the Minister Health of 12 August 2020 on the organizational standard of a teleconsultation within primary health care. The legal provisions included in these acts are related to the principles of providing health services by doctors in the form of a teleconsultation. The act determines and clarifies what a teleconsultation is, as a form of a mutual communication channel between the doctor and the patient, and the regulation applies to health services provided in this way within primary health care (POZ, family doctors), by POZ doctors. For the doctor, the changes introduced in the law are important, because they determine the new formula of providing health services, the way they are provided and the manner this fact is recorded in the medical documentation.

Introduction

Telemedicine, understood as a teleconsultation (consultation over the phone), an on-line consultation, video-conference, instant messaging (IM) or e-mail is currently the most common form of doctor - patient communication. This technological development has been applied in Europe and the States for a long period of time (decades even); in Poland it was only the Covid-19 pandemic that forced its implementation and practical application. What should be emphasized, apart from the obvious pragmatics and easiness of use, it is safe in terms of the doctor patient direct contact, which in the times of pandemic is of pivotal importance.

The dynamic COVID-19 pandemic has caused big changes in the functioning of the medical area. Consultations given by a doctor over distance via electronic means (on-line, telephone) have become a fact. This form of contact was differently treated before the pandemic, however, presently, safety measures and caution in contacts with other persons are a priority.

Undoubtedly, medicine recommends limiting direct contacts to those required by the patient's health condition and the need for a specific medical intervention. In other cases, the use of electronic devices to obtain medical aid is currently a standard and, what should be emphasized, is safe for both sides; the doctor and the patient, as well as their family members and friends. In exercising his or her profession, the doctor is particularly exposed to the risk of patient-derived infection. Teleconsultation, namely a health service provided over distance by means of various communication systems, is a compromise between the doctor's work safety and his or her accessibility to patients and the possibility to offer consultations to them. Currently, telephone or on-line consultations are used not only in many European countries but all around the world.^[1] In countries such as Great Britain, Denmark, Switzerland, USA, this form of communication has started to be implemented as an alternative to the form of direct doctor-patient contact, and now its use has become a fact. The system of electronic or telephone forms of communication is accessible and easy to use.^[2] Especially in the era of a pandemic, the possibility of treating patients with telemedicine increases significantly. However, it is necessary to undertake harmonized actions, i.e. centrally coordinate reporting and communication systems that facilitate crisis management.^[3] In Denmark, telemedicine system has proved flexible in adapting to new challenges. Hospitals have been fully computerized with on-line medical records of patients and a digital mechanism for submitting prescriptions to pharmacies.^[4] Telephone consultations in Great Britain are a part of the universal health system. In Australia, telemedicine is currently

available through the Medicare Benefits Schedule for specialist services and disease management through video-conferences held by doctors of various specialties (psychiatrists, occupational medicine physicians, and palliative medicine specialists). Telemedicine as a form of a segregating system facilitates the assessment of patient's health condition and his/her referral to an appropriate doctor and is important in responding to emergencies by providing access to care for patients in remote locations.^[5,6] In some situations, due to the lack of appropriate technological solutions, doctors use private devices, e.g. in South Africa, doctors use their own cell phones to care for their patients. In this context, the use of mobile phones increased the availability of primary healthcare services.^[7] Physicians use these electronic devices to register patients, track their health status, make decisions as to further treatment, and to communicate. The challenges that doctors face included poor connection and poor access to electronic communication channels.^[8] The problem with the implementation of telemedicine is noted in low and middle income countries. There is no large scale apps or services and the most frequently documented method of communication was the use of one – way text messages and telephone reminders on the date of follow-up visits. Large-scale applications and services are missing and the most frequently documented use of this form of communication was one-way text messages and telephone reminders about the dates of follow-up visits.^[9] Consultations and prescriptions via mobile phones are extremely common in pediatric offices. However, there is a need for proper oversight of these regulations and the involvement of those at interest i.e. as pediatricians and pharmacists.^[10] Online consultations in Canada are becoming more common and have the potential to modernize the way healthcare is delivered. Here, too, various contexts are analyzed including the ethical one. The need to implement measures to reduce the risks to which the patient may be exposed is noted.^[11] Telemedicine can also prove convenient to patients with discrete health problems and relieve general practitioners.^[12] The current situation has contributed to the popularization and direct use of this form of contact, i.e. in Poland. However, until recently it has been argued that deontological records create a traditional form of doctor- patient contact and diagnosis and advice provided at a distance is to be given in exceptional situations. Undoubtedly, this form of contact is new to Polish doctors. Once established, it can be the subject of research and comparison to the systems of other countries that introduced telemedicine much earlier.

What is more, it will also be possible to determine its quality in comparison to traditional treatment methods.

In order to counteract the COVID – 19 pandemic, new legislation has been introduced. These include the *Act of 2 March 2020 on special solutions related to preventing,*

counteracting and combating COVID-19, other infectious diseases and crisis situations caused by them and its later amendment of 31 March 2020 (hereinafter referred to as the Act), as well as the *Regulation of the Minister Health of 12 August 2020 on the organizational standard of a teleconsultation within primary health care* (hereinafter referred to as the Regulation). These acts define the principles of granting health services in the form of a teleconsultation.^[13] The Regulation introduced in August this year applies to providing health services within primary health care as defined in the *Act of 27 October 2017 on primary health care*.^[14] For the doctor, the changes introduced in the law are very important, because they bring into play a new formula of providing health services and new elements of consulting procedure.

Formal Basis for Conduct of a Doctor Providing a Teleconsultation

The solutions introduced to the Polish law, intended to counteract the pandemic caused by the SARS-CoV-2 virus, are included in the quoted Act.^[15,16] This legal act sets out the rights and obligations of service providers (doctors, hospitals, medical entities) in the scope of preventing and combating infectious diseases caused by this virus. Teleconsultation means a health service provided over distance by an authorized person (a doctor) using data communication systems (the Internet) or communication systems (telephone). Teleconsultations may be granted by entities involved in medical operations, as well as by doctors (and dentists) using the data communication system provided by the entity competent in the scope of health care information systems. Then, it is necessary for the doctor to keep simplified medical documentation in the form of a teleconsultation card containing:

- designation of the patient: name and surname, PESEL number (in case of its absence, the series and number of another document confirming identity), date of birth, sex, e-mail address, contact telephone number.
- designation of the person providing the teleconsultation: first and last name, occupational title, number of the license to exercise the regulated profession.
- information about the patient's health condition and the recommended diagnostic and therapeutic process, identification of the disease or health problem, recommendations.
- information about any issued certificates, recipes or referrals, other information significant for the treatment process.

Requirements and standards of Teleconsultation

The provision of health services in the form of a teleconsultation is a new formula of mutual relations between the doctor and the patient, which is naturally still being developed and particularized at the present stage, in terms of the area and the scope of the service provided in this way.^[17,18] It is worth adding that, on the basis of Article 22, item 3b of the *Act of 15 April 2011 on therapeutic operations*, the Competent Minister for health, in consultation with the Competent Minister for IT development, has determined, in the *Regulation*, the requirements which should be fulfilled by rooms and devices, as well as data communication systems or communication systems of the entity involved in medical operations providing only ambulatory health services using data communication systems or communication systems.^[19] The Regulation of the Minister of Health of 12 August 2020 applies to the standard and the organizational principles of the so-called teleconsultation within primary health care (POZ, family doctors).^[13] Such advice may be given by a doctor in a primary health care entity mentioned in Article 9 section 1 of the *Act on primary health care*.^[20] Primary health care is the place of the first contact of the beneficiary (the patient) with the health care system, except for situations when the beneficiary is in a condition of a sudden health hazard or any services are provided to them where access to preventive, diagnostic, medical, nursing, as well as rehabilitation health care services financed from public funds is ensured.^[20] The implementation of effective communication between the patient and the doctor requires a definition of the components, such as the organizational standard and the principles of a teleconsultation provided under POZ. Such elements include the obligation to notify the parties involved about the details and the conditions of providing teleconsultations. This obligation is to be fulfilled by posting an announcement at the place of performing the services by the POZ entity, on its website and by phone (if necessary). The information is to specify the data communication systems or communication systems by means of which the service provider conducts teleconsultations (e.g. online, email, phone, audio-video system, Zoom) and the method of setting the date of a teleconsultation. Through legislation, there is a specified way for the doctor to initiate contact with the patient in order to provide a teleconsultation and a specified way to provide it. At a specific time, including the day and the hour, the doctor makes him/herself available for the patient using a particular communication device. This can be an audio (telephone) or an audio and video (e.g. video messenger such as Zoom) communication device, and a teleconsultation may be granted in the form of a phone consultation, a video chat, and, in justified cases, also by e-mail (electronic mail). The person providing the teleconsultation should precisely specify to the public the possibilities and the ways of performing such a service,

along with the phone numbers, e-mail addresses, login data, or video chat access codes. In a situation when there is no contact with the patient at the agreed time, the notification is canceled. However, before that, the doctor is obliged to make an attempt, at least three times, to contact the patient, for no less than 5 minutes.^[20] It should be emphasized that, in the event that, due to the patient's health condition, the health service cannot be offered in the form of a teleconsultation, the patient is informed about the possibility to use a health care service that involves direct contact with the doctor. Naturally, such a procedure needs to be agreed with the patient or his or her statutory supervisor (if the patient is in the legal situation of care).

Teleconsultation is to inform the patient about methods of filling an e-prescription, e-referral and e-order for medical products, methods of filling the order for additional (laboratory, imaging) tests. Patients can set up an Patient's online account (IKP) on the server of the Ministry of Health – pacjent.gov.pl.^[21] Persons registered IKP can receive e-prescription or/and e-referral at the provided telephone number or e-mail address, and can share with a relative personal information about their health condition and the history of prescribed drugs. In this way, he or she can also check e.g. coronavirus test results. Moreover, a relative or a legally appointed person (statutory representative) can be authorized to access the account. The service provider is obliged to notify the National Health Fund about the phone number(s) under which teleconsultations are provided.

The course of teleconsultation – patient's identification

A doctor providing a teleconsultation, prior to granting it, is obliged to confirm the patient's identity on the basis of the data mentioned in Art. 25 sect. 1 item 1 of the *Act of 6 November 2008 on the patient's rights and the Patients Ombudsman*.^[22] In Article 25, the Act enumerates the components of the medical documentation that are used in this case to confirm the patient's identity. These include: surname and first name (names), date of birth, sex, address of the place of residence, PESEL number (in the case of a newborn – mother's PESEL number, and for any persons who have no PESEL number assigned – type and number of the identity-confirming document). In specific cases when the patient is a minor, a completely incapacitated person or a person incapable of expressing consent deliberately, it is necessary to verify the statutory representative's surname and first name, along with the address of his or her place of residence.^[22] This information should be transferred by the patient using data communication systems or communication systems (e.g. scan, picture, e-mail attachment). Information confirming the patient's personal data can also be obtained on the basis of information from the medical documen-

tation, if the doctor has such documentation, from the statement on doctor selection, as well as upon presentation of an identity-confirming document while providing the service in the form of a video consultation (a document presented to the video camera).

The course of teleconsultation – providing healthcare services

The person providing a teleconsultation is obliged to conduct it in the circumstances that guarantee confidentiality (no access of persons unauthorized to access the information communicated in this way). Based on the subjective test and after analysis of the patient's available medical documentation, the service provider should determine whether the health service granted in the form of a teleconsultation is sufficient for the health problem being its subject matter. This last is an important task of the doctor providing a teleconsultation. If the nature of the current health problem prevents a health service from being provided in the form of a teleconsultation, the doctor is obliged to notify the patient about the need to gain such service via direct contact, for example, during a traditional visit, also mutually agreed with regard to day and time.

The course of teleconsultation – medical documentation

After the end of a teleconsultation, the doctor should generate a memo to be placed within the medical documentation (kept in the form of a teleconsultation) about the provided health service. Naturally, in the event that any information concerning the patient's health condition is transferred, the data communication systems and the technical and organizational solutions used by the service provider should ensure integrity, safety and protection of any data transferred electronically. Furthermore, all data collected (e.g. included in the medical documentation) must be protected against destruction, loss, unlawful disclosure or utilization. This applies to transmission of electronic documents in graphic and text form. In the event of (if any) destruction, loss, illegal disclosure or utilization of data, we will usually be dealing with the so-called personal data protection violation. Such a breach may result in material or immaterial damage for the person who has deposited the data. In practice, this can relate to data theft, falsified identity, financial loss, personal damages (discrimination, stalking, damage to reputation), as well as business damages. The provisions of GDPR, along with their solutions, already have relevance in this regard.^[23] It should be emphasized that this act and the sanctions it has introduced apply mainly to the failure to observe the obligation to duly protect data (and not any effects of such failure) and offer a possibility to impose monetary administrative fines in a fixed amount to the personal data controller in a specific medical entity.

Discussion

In order to counteract the effects of the SARS-CoV-2 virus, special solutions have been introduced that are legally stipulated. In the discussed case, due to the epidemiologic safety and more effective availability of doctors than in the traditionally contact form, the possibility has been introduced to offer a teleconsultation using electronic means and distance communication.

Not a lot of time has passed since teleconsultation was introduced into the polish medical reality, therefore it is difficult to find research based on an objective assessment of the current situation. Information gathered on patient forums vary; from positive to negative. Out of 40 000 complains made to the Patient's Ombudsman from the end of June 2020, 1 175 were made in connection to teleconsultations. Doctors' views on telemedicine differ and the previously cited studies show that they are usually positive with a lot of hope for pragmatic innovations. This form of doctor-patient communication has its limitations and specificity. It concerns the specialization of doctors providing teleconsultation and the scope of such a medical service. Primary care physicians talk differently with their patient, same as pediatricians talks differently with mothers of a small children, and a specialist who has to plan treatment based on provided data will also have to adopt a different approach. In this case, it must be based on data such as the results of diagnostic tests or a precisely described health condition, which may be difficult in case of the used communication channel. Currently, as is also noted in research conducted around the world, the limitation of the effectiveness of teleconsultation is dictated by the specificity of the patient's health. Difficult the diagnosis, hindered contact with the patient or inadequate/ insufficient data may cause the advice to be imprecise or faulty. Also, typical surgical medical specializations expect different information from the patient than, for example, a doctor who provides general advice.^[24] Teleporting seems appropriate to be used in specific cases, i.e. first contact doctors, general advice, treatment continuity, prescription or general diagnosis. The doctors' possible liability for providing a teleconsultation that would be a misadvice and cause negative consequences for the patient's health is also worth considering. An approximation of such a situation are the circumstances of a diagnostic error that had come about through incorrect description and assessment of the patient's health condition, and, based on that, specific medical activities being conducted. In the present situation of pandemic, the possibilities are seriously being considered not to punish doctors for any decisions made in connection with providing health services in the case of persons infected with the SARS-CoV-2 virus. Naturally, such a solution must be well-considered in the implementation

so as not to result in mere ordinary impunity. However, in the current situation, a doctor incorrectly providing teleconsultation may result, first of all, in the termination of the POZ services agreement with the medical entity and, second, the doctor may be subject to typical professional and civil liability (liability for damages). Having this in mind, doctors must hold themselves to high standards of professional conduct while providing a teleconsultation. Such standards are described in *the Act on the doctor's and the dentist's professions*.^[25] Therefore, it is worth remembering here that a teleconsultation should also be provided according to the principle of due diligence and the principle of up-to-date medical knowledge.

Authors declare none potential conflicts of interest.

Conclusion

Legal sanctioning of teleconsultation as a new form of providing remote health services is important to both doctors and patients because of personal safety and much greater availability of this form of advice compared to visits in the traditional form in the times of pandemic. New technological solution for the doctor-patient relationship in the form of teleconsultation (and its various types) should aim to improve the effectiveness of healthcare services. However, it is a dynamic and constantly improving field, and its consolidation in medical practice will be a process that is primarily intended to effectively treat patients.

References

- Downes, M.J., Mervin, M.C., Byrnes, J.M. et al. Telephone consultations for general practice: a systematic review. *Syst Rev* 6, 128 (2017). <https://doi.org/10.1186/s13643-017-0529-0>
- Blozik E, Wildeisen IE, Fueglistaler P, von Overbeck J. Telemedicine can help to ensure that patients receive timely medical care. *Journal of Telemedicine and Telecare*. 2012;18(2):119-121
- Verhagen LM, de Groot R, Lawrence CA, Taljaard J, Cotton MF, Rabie H. COVID-19 response in low- and middle-income countries: Don't overlook the role of mobile phone communication. *Int J Infect Dis*. 2020 Oct;99:334-337. doi: 10.1016/j.ijid.2020.07.069. Epub 2020 Aug 4. PMID: 32763447; PMCID: PMC7402274.
- Pedersen KM Andersen JS Søndergaard J. General Practice and Primary Health Care in Denmark. *The Journal of the American Board of Family Medicine* Mar 2012, 25 (Suppl 1) S34-S38; DOI:10.3122/jabfm.2012.02.110216
- Bunn F, Byrne G, Kendall S. The effects of telephone consultation and triage on healthcare use and patient satisfaction: a systematic review *British Journal of General Practice* vol. 2005; 55: 956–61.
- Bryan L. Burke, R. W. Hall and the SECTION ON TELEHEALTH CARE Telemedicine: Pediatric Applications. *Pediatrics* July 2015, 136 (1) e293-e308; DOI: <https://doi.org/10.1542/peds.2015-1517>
- Anstey Watkins JOT, Goudge J, Gómez-Olivé FX, Griffiths F. Mobile phone use among patients and health workers to enhance primary healthcare: A qualitative study in rural South Africa. *Soc Sci Med*. 2018 Feb;198:139-147. doi: 10.1016/j.socscimed.2018.01.011. Epub 2018 Jan 10. PMID: 29335160.
- Odendaal WA, Anstey Watkins J, Leon N, Goudge J, Griffiths F, Tomlinson M, Daniels K. Health workers' perceptions and experiences of using mHealth technologies to deliver primary healthcare services: a qualitative evidence synthesis. *Cochrane Database Syst Rev*. 2020 Mar 26;3(3):CD011942. doi: 10.1002/14651858.CD011942.pub2. PMID: 32216074; PMCID: PMC7098082.
- Källander K, Tibenderana JK, Akpogheneta OJ, Strachan DL, Hill Z, ten Asbroek AH, Conteh L, Kirkwood BR, Meek SR. Mobile health (mHealth) approaches and lessons for increased performance and retention of community health workers in low- and middle-income countries: a review. *J Med Internet Res*. 2013 Jan 25;15(1):e17. doi: 10.2196/jmir.2130. PMID: 23353680; PMCID: PMC3636306.
- Haddad RN, Sakr C, Khabbaz L, Azouri H and Eid B (2020) Telephone Consultation and Prescription in Pediatrics: Contributing Factors and Impact on Clinical Outcomes. *Front. Pediatr*. 7:515. doi: 10.3389/fped.2019.00515
- Kobewka D, Forster AJ. On-line doctors: A disruptive innovation? *Healthcare Management Forum*. 2018;31(4):160-162. doi:10.1177/0840470418780022
- Casey M. Shaw S. Swinglehurst D. Experiences with online consultation systems in primary care: case study of one early adopter site. *British Journal of General Practice* 2017; 67 (664): e736-e743. DOI: 10.3399/bjgp17X693137
- Rozporządzenie Ministra Zdrowia z dnia 12 sierpnia 2020 r. w sprawie standardu organizacyjnego teleporady w ramach podstawowej opieki zdrowotnej. *Dz.U* 2020 poz. 1395
- Ustawa o podstawowej opiece zdrowotnej. *tj. Dz.U.*

2020 poz. 172

15. Ustawa z dnia 2 marca 2020 r. o szczególnych rozwiązaniach związanych z zapobieganiem, przeciwdziałaniem i zwalczaniem COVID-19, innych chorób zakaźnych oraz wywołanych nimi sytuacji kryzysowych Dz.U. 2020 poz. 374
16. Ustawa z dnia 31 marca 2020 r. o zmianie ustawy o szczególnych rozwiązaniach związanych z zapobieganiem, przeciwdziałaniem i zwalczaniem COVID-19, innych chorób zakaźnych oraz wywołanych nimi sytuacji kryzysowych oraz niektórych innych ustaw Dz.U. 2020 poz. 568
17. Olszanecka-Glinianowicz M. Dudek D. Filipiak KJ., Krzystanek M., Markuszewski L. Ruchała M. Tomiak E. Leczenie nadwagi i otyłości w czasie i po pandemii. Nie czekajmy na rozwój powikłań – nowe wytyczne dla lekarzy. <https://insulinoopornosc.com/wp-content/uploads/2020/08/wytyczne-dla-lekarzy-leczenie-otylosci-i-nadwagi.pdf>
18. Rostkowska, J., Wojewódzka, D. (2020). Teleporady logopedyczne w czasie pandemii COVID-19 dedykowane dorosłym użytkownikom implantu ślimakowego. *Nowa Audiofonologia*, 9(1), 45-50. <https://ojs.academicon.pl/na/article/view/3479>
19. Ustawa z dnia 15 kwietnia 2011 r. o działalności leczniczej. t.j. Dz.U. z 2020 r., poz. 295
20. Ustawa z dnia 27 października 2017 r. o podstawowej opiece zdrowotnej t.j. Dz. U. z 2020 r. poz. 172
21. Ustawa z dnia 17 lutego 2005 r. o informatyzacji działalności podmiotów realizujących zadania publiczne Dz. U. z 2020 r. poz. 346, 568 i 695
22. Ustawa z dnia 6 listopada 2008 r. o prawach pacjenta i Rzeczniku Praw Pacjenta.t.j. Dz.U. 2020 poz. 849
23. Rozporządzenie Parlamentu Europejskiego i Rady (UE) 2016/679 z dnia 27 kwietnia 2016 r. w sprawie ochrony osób fizycznych w związku z przetwarzaniem danych osobowych i w sprawie swobodnego przepływu takich danych oraz uchylenia dyrektywy 95/46/WE (ogólne rozporządzenie o ochronie danych) <https://uodo.gov.pl/pl/404/224>
24. Prus K. Teleporada lekarska zawiodła. Miał być liszaj, grzyb a to była borelioza. <https://www.dziennikwschodni.pl/zdrowie/teleporada-lekarska-zawiodla-liszaj-grzyb-a-to-byla-borelioza,n,1000272240.htm>
25. Ustawa z dnia 5 grudnia 1996 r. o zawodach lekarza i lekarza dentysty tj. Dz. U. z 2020 r., poz. 514, 567.