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Legal aspects of teleservices in oncology

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The use of teleinformatic tools and other means of communication in specialist care, including oncological care, is completely admissible and in accordance with currently binding law. Key legal acts on principles of providing health services, including the Act on the Profession of Doctor and Dentist and the Act on Medical Activity, allow adjudicating on a patient's health status and providing all activities of a health service nature with the use of teleinformatic means and other communication systems. No organizational standards on televisits in specialist care have been established to date, imposing *per analogiam* use of the regulations on organizational standards of teleservices in primary health care. However, such a solution should be considered temporary and imprecise, therefore the regulation dedicated to providing televisits within specialist care, including its specificity areas, is essential. Simultaneously, it is necessary to eliminate the use of announcements and guidelines of the National Health Fund which refer to the admissibility of televisits as a binding legal form. Announcements, guidelines, recommendations and positions may only serve as advice for proceeding with special care and this should be eventually reflected in the current law.

Key words: telemedicine, teleconsultation, distance services, teleoncology, e-health

Introduction

Telemedicine is one of the novel forms to provide health services, replacing on many levels classic diagnostic and therapeutic process involving physician's and patient's personal contact. In the literature there are many terms defining telemedicine. In the 90s, P.F. Granade, J.H. Sander [1], among others, attempted to define telemedicine, being the first authors to refer to the issue of responsibility for damages related to health services "at a distance". According to the WHO, telemedicine is "the delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies (ICT) for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities" [2].

Communication from the Commission to the European Parliament defines telemedicine as "the provision of healthcare services, through use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients" [3]. Furthermore, the communication emphasizes that advantages of ICT use in health care include, among others, specialist care access improvement in areas with hindered access to health care or with insufficient number of specialists. In case of numerous services, including for example teleradiology, teleconsultations may contribute

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to waiting lists reduction, resource use optimization and efficiency gain [4].

Telemedicine is undoubtedly immanent component of e-health concept which involves the use of technologies for medicine in the health sector. There is no doubt that telemedicine tools have been supporting both the process of diagnosis and consultation, and the process of monitoring the state of health of chronically ill patients for many years [5–8].

Material and methods

The materials used in this paper are the provisions of Polish law directly referring to providing health services with the use of ICT or other means of communication. The additional material comprised content of current Polish Court Case Law as well as positions grounded in the doctrine. The authors used method of analysis for reviewing and interpreting binding provisions, positions of the doctrine and judicature.

The main objective of the paper is to assess the admissibility of teleinformatic communication means or other means of communication (ICT) used to initiate and continue health services in oncology, including the diagnosis, treatment and monitoring of patients' health. An additional objective is to analyze the scope of duties of medical professionals performing health services "at a distance".

Admissibility of health services with the use of information and communications technology

Before the act from 9.10.2015 on the amendment of the act on information systems in health care (…) came into force on 12.12.2015, only single legal regulations and documents on ethics and medical deontology referred to the use of ICT for health services [9]. Direct admissibility of the use of teleinformatic tools in the treatment process was foreseen by the Medical Code of Ethics whose art. 9 states that a physician can only initiate treatment after examining the patient, excluding cases in which medical advice can only be provided at a distance [10]. Even though the Medical Code of Ethics is not a normative act but a set of ethical principles, the literature emphasizes that "ethical norms can be incorporated by the legal acts into the binding legal system. The Act on Medical Chambers made such incorporated of the Medical Code of Ethics' norms. The norms of this code specified the content of legal norms included in the Act on Medical Chambers (…)" [11]. Therefore, applying the provisions of the Medical Code of Ethics in the context of providing health services that exclude personal contact with a patient is justified in exceptional cases whose assessment depends each time on a physician's individual decision. Although telemedicine was the subject of residual legal regulations, these issues were analyzed in literature from the last decade, among others, in the context of teleconsultations in cases of severe poisoning, cardiac rehabilitation and also the monitoring of health status in diabetic patient [12–14].

According to revised art. 42 section 2 of the Act on the Profession of Doctor and Dentist of 5.12.1996 "a physician adjudicates on the health state of a particular person after examination of this person performed in-person or examining this person performed with the use of teleinformatic systems or communication systems" [15]. The term "a physician adjudicates" should be identified twofold. Firstly, this term refers to the possibility of performing an assessment of the state of health, to diagnose, which constitutes a formal statement on health status and the potential need for treatment. Secondly, the above term stands for issuing an opinion or a certificate in the form of a document – i.e. "adjudication" in the material sense [16].

Before the revision of the Act on the Profession of Doctor and Dentist (…) [15] provisions, there were statements in judicature claiming that the use of telemedicine tools should not be identified with health care services. The Voivodship Administrative Court in Krakow, in a judgement from 23.06.2015, emphasized that [17]:

"telemedicine services provided with the use of the Internet are in fact provision of advice, lectures, constitute recommendations on performing exercises, their assessment and monitoring, as well as consultations in health education. These activities cannot be deemed as medical care (…)". Taking into consideration the current wording of art. 42 section 1 of the Act on the Profession of Doctor and Dentist it should be deemed that the use of teleinformatic means during the provision of health services unquestionably constitutes executing a form of medical care activity whose purpose can be diagnosis, treatment, monitoring process, as well as constant monitoring of a patient.

When analyzing providing health services "at a distance", the difference between the notions: "personal contact" and "direct contact" should be emphasized. The ICT used by a physician to contact a patient does not prevent direct contact, but only personal contact understood as physical people meeting at the same place and time. Proper comprehension of the notion of "direct contact" has a major impact pursuant to, among others, the Act of 25.06.1999 on cash social insurance benefits in the event of sickness and maternity [18]. According to art. 55 section 4 point 1 of the act cited above "deciding on temporary incapacity for work due to illness, hospitalization (…) or on the need to provide care to an ill family member follows a direct examination of the state of health of the insured person or ill family member".

Direct examination cannot be identified with personal examination performed as a result of initiating physical contact of a physician with a patient, but only with the need for a heath state assessment, e.g. remotely or with the use of ICT. An exception that allows the use of teleinformatic means in the patient's health state decision process, determines art. 11 section 1 of the Mental Health Protection Act [19] which states that "decision on the state of health of a person with mental disorders, opinion or referral to another physician or psycho-

logist or healthcare entity may only be issued by a physician based on a previous personal examination of this person". The literal wording of art. 11 section 1 of the Mental Health Protection Act results in necessary requires an obligatory personal examination in order to assess the patient's state of health or issue referral to further treatment.

General ICT use admissibility is foreseen by art. 3 section 1 of the Act on Medical Activity of 15.04.2011 stating that "medical activity involves providing medical services. These services may be provided through teleinformatic systems or communication systems" [20]. It should be mentioned that the wording of art. 2 section 1 point 10 of the Act on Medical Activity defines the notion of health services as "(…) activities aimed to maintain, rescue, regain or improve health, and all other medical activities related to the process of medical treatment or separate regulations on the principles for performing these activities" [20]. The definition indicates that health services are any activities performed by medical professionals aimed at enhancing, sustaining or improving health regardless of the specificity, scope and specialization of provided services.

Undoubtedly health services "at a distance" gained popularity during the COVID-19 pandemic, nevertheless this form of delivering services was already present before the epidemiological threat manifested. For the purpose of this paper, delivering health services "at a distance" is identified with the televisit which should be clearly distinguished from teleadvice. The latter should be identified with a service provided through teleinformatic systems or other communication systems due to suspicion of, or infection with SARS-CoV-2 or a COVID-19 case. According to no longer binding art. 7 section 4 of the COVID Act [21]: "a physician's and dentist's (…) may provide health services in relation to COVID-19 prevention through teleinformatic systems provided by a unit subordinated to the minister competent for matters of health, appropriate in the field of information systems in health care, further called 'teleadvice' (…)". All services provided by healthcare professionals using ICT, which are related to other health problems, should be cataloged as a televisit, i.e. health services provided without personal contact between the medical personnel and the patient.

It should be emphasized that all legal regulations referring to providing health services using ICT concern publicly funded services. The above, however, does not exclude proper application of these regulations to commercially provided services. Currently, the law refers directly to ICT means used for providing primary health care services as well as certain specialist services.

In March 2020, the Central Office of the National Health Fund (NHF) issued an announcement indicating possible "execution and settlement of specialist advice provided under the contracts for providing health care services within outpatient specialist services with the use of teleinformatic systems or other communication systems" excluding services listed in appendix 1a and c to the resolution of 31.12.2019 no 182/2019/DSOZ of the President of the National Health Fund on specifying the conditions of conclusion and implementation of the contracts for providing outpatient specialist services [22]. At the same time the announcement emphasized that televisits can be provided "only in a situation when a health state assessment and scope of the necessary activities to be provided for a patient does not require the personal presence of healthcare professionals" [23]. It should be emphasized that appendix no 1a to the resolution no 182/2019/DSOZ of the President of the NHF enumerates, among others, services within oncology which are provided by specialist clinics, including, among others, gynecologic oncology clinic, oncology clinic, chemotherapy clinic and radiotherapy clinic [22].

Considering the above, it should be deemed that the NHF announcements of March 2020 excluded possible use of ICT tools for provision of outpatient oncological services. At the same time, no legal regulations allowing providing health services with the use of ICT were established as the above-mentioned art. 42 section 1 of the Act on the Profession of Doctor and Dentist [15] and art. 3 section 1 of the Act on Medical Activity [20], both allowing providing health services "at a distance", were still in force.

The issue of providing remote services was also referred to by the announcements of the NHF which allowed ICT use in home parenteral nutrition and home enteral nutrition when it concerns:

1. previously planned follow-up visits,
2. patients in a stable state [23].

On 24.03.2020, the National Health Fund also issued an announcement on the execution and settlement of health teleservices in the form of hospital treatment – drug programs and chemotherapy hospital treatment [23]. The announcement emphasized that teleconsultation is only possible in patients continuing treatment, in line with the specified therapeutic plan, accordingly to the current patient's clinical state. According to recommendations included in the announcement, follow-up visits for patients in a stable state may be performed by phone consultation with the use of teleinformatic systems or other communication systems. A patient's medical record should include appropriate notation on the way the service was provided. Furthermore, the provider is obliged to report on data in line with the provisions of the regulation on principles of settlement for services of a given type. Subsequent updates of the ICD-9 dictionary include reporting codes with their effective dates – i.e. code 89.0099 – medical advice through teleinformatic systems or communication systems (since 1.03.2020) and code 94.483 – a consultation with the use of teleinformatic systems (since 17.03.2020).

Since 17.04.2020, providing advice and visits with the use of teleinformatic systems or other communication systems was approved in home hospice care, provided that such form does not constitute a risk to the patient's health[23]. According to the

announcement of the Central Office of the NHF of 17.03.2020, remote services can be provided within:

- the order no 45/2018/DSOZ of the President of the NHF of 30.05.2018 on specifying conditions of conclusion and implementation of contracts in care and nursing allowance within long term care,
- long term home care for mechanically ventilated patients,
- long term home care for mechanically ventilated children,
- long term home nursing care,
- the order no 74/2018/DSOZ of the President of the NHF of 31.07.2018 on specifying conditions of conclusion and implementation of contracts in palliative and hospice care,
- home hospice services,
- pediatric home hospice services.

It should be emphasized that all NHF announcements on ICT admissibility were issued due to the need to minimize risk of COVID-19 infection transmission through limiting personal contact with patients. Therefore, communication refers to exceptional situations and does not apply to treatment processes provided in conditions unrelated to the COVID-19 pandemic.

It should be noted that the announcements issued by the NHF are not normative in nature and therefore are only an indication of proceedings whose eventual application treatment depends on the decision of the health care entity. Obligatory proceedings were included in the legal acts on ICT use in the process of providing health care services.

When analyzing the law on ICT use in health care services, it is necessary to indicate the regulation of the Minister of Health of 06.04.2020 amending the regulation on guaranteed services in outpatient specialist care [24], under which the possible use of teleinformatic systems or communication systems in providing services by dialysis unit physicians was added. The list of services which can be provided with the use of teleinformatic systems include, among others, peritoneal dialysis, dialysis with 24-hour care and hemodiafiltration (HDF).

On 9.04.2021, the regulation amended the regulation on guaranteed services in outpatient specialist care came into force [25] allowing the use of teleinformatic systems in diagnostics and monitoring in complex oncological care in patients with colorectal cancer. ICT tools can also be used for cooperation with the colorectal cancer treatment center which guarantees: the possibility to schedule or reschedule routine checkups and to utilize specialist consultations or advice.

Organizational standards of televisits

Although the pandemic led to the increased use of televisits, only limited provisions of the law referring to implementation and reporting standards for such visits were established. It should be emphasized that the Act on Medical Activity includes authorization for the Minister of Health to issue organizational standards in particular fields of medicine or in the case of the implementation of precisely specified services. According to art. 22 section 5 of the Act on Medical Activity [20]: "the minister competent for health issues can specify, through a regulation, health care organizational standards in chosen fields of medicine or in specified medical entities, following the need to ensure appropriate quality of health services". Organizational standards issued in the form of a regulation are strictly binding and mandatory as a result of their normative character. A medical entity is obliged to apply organizational standards in health care in providing health services, if they were issued based on art. 22 section 5 for the field of medicine covered by the scope of health services provided in this medical entity, or for the type of medical activity performed.

Until now, standards of proceedings in providing services within telemedicine were specified in the regulation of the Minister of Health on organizational standards in radiology and diagnostic imaging performed with the use of teleinformatic systems [26]. On 29.08.2020, organizational standards for a primary health care televisit came into force [27]. Based on art. 22 section 5 of the Act on Medical Activity [20], however, no provisions for the televisit within specialist health care were established. Taking into consideration the lack of provisions directly dedicated to televisits within specialist health care, the authors indicate that it is necessary to apply the provisions pertaining to the televisit in primary health care to specialist teleconsultation.

Organizational standards refer to formal aspects related to the implementation of the televisit and these are undoubtedly common for primary and specialist health care services. The common denominator applies to: principles concerning qualification to distant services, a mode in which a televisit is performed, verification of a patient's identity, cancellation of the appointment as well as medical entity's responsibility for the damage related to delivered service.

When analyzing the fundamental principles for implementation of the televisit, it is necessary to indicate the need to confirm the patient's identity in line with the principles specified in art. 50 section 2–2b of the Act on Healthcare Benefits Financed from Public Funds. The patient's identity can be confirmed by presenting an identity card, passport, driving license, school card or with the use of electronic document by presenting the document on the screen of the mobile device to the person confirming identity, or based on data transferred by the patient through the teleinformatic systems used to deliver the service. A patient may confirm his identity and declare eligibility for health care services through the electronic patient health account created as a result of personally confirmed identification or by the use of electronic identification means issued in the electronic identification system.

Another issue concerns verification of eligibility to health care services financed from public funds. In the case of "at a distance" services, verbal verification of eligibility to services is possible through a patient's verbal statement during the televisit. According to art. 50 section 7 of the Act on Health

Care Services Financed from Public Funds [28], a patient should make the following statement: "I am entitled to use health care services financed from public funds". Information on a patient's statement of eligibility to services financed from public funds should be reported in the individual medical record which should also include annotations, among others, on:

- the fact that the service was provided through teleinformatic systems or other communication systems,
- the fact that the patient was informed about the limitations related to teleconsultation,
- indication that providing a service through teleconsultation does not constitute a risk to the patient's health and the scope of the performed activities does not require the physical presence of medical personnel,
- postponement of an examination (for example diagnostic) with an explanation stating that it applies to a patient in a stable state in whom no need for such an examination was determined,
- informing a patient on the need to report to the physician or emergency room in person in case of a deterioration in their state of health or a change in the nature of the reported ailment,
- visit cancellation due to inability to connect with a patient despite 3 attempts to connect at intervals no shorter than 5 minutes,
- giving instructions on the use of the e-prescription and e-referral service, performing activities comprising provided health services, including the determination that a televisit is sufficient for the health problem that is the subject of the visit or informing the patient on the need to provide health service in personal contact with a doctor.

It should be emphasized that one of the changes introduced into the organizational standards of a televisit in primary health care [29] was limiting remote services provided to children under the age of 6, with the exclusion of routine services resulting from previously initiated treatment. Using the analogy on formal aspects of providing remote services in primary care and specialist care, it should be acknowledged that teleoncology services should only apply to patients aged 6 and older, excluding cases in which the televisit aims at monitoring the treatment plan or initiating routine activities affecting the quality of implemented procedure.

At the same time, in line with analogy to the regulation of 5.03.2021 [27], a teleservice in specialist care should not be provided in cases where:

- a patient or a patient's statutory representative does not consent to service "at a distance",
- the medical visit aims at obtaining a certificate (a document),
- a visit concerns a chronically ill patient experiencing worsening or changing symptoms.

It should be stressed that the entity providing the televisit is obliged to keep medical records in line with the principles specified in the regulations on type, scope and format of medical records and method of their processing [30] and archive it for the period of time indicated in art. 29 section 1 points 1–4 of the Act on Patients' Rights and Patients' Spokesman Rights [31], depending on the type of produced document. As a side note, it is worth reiterating that recording audio and vision during teleadvice does not replace a medical record whose scope and management was specified in the regulation indicated above.

Conclusions

The research papers developed several years ago already emphasized that the use of teleinformatic means in the process of treatment directly impacts the inclusion of financial and organizational efficiency criteria, hence a reduction in the health care cost [32, 33]. The papers published during the pandemic indicate the significant role of telemedicine in the reduction of SARS-CoV-2 transmission and the increased safety of the oncological patient [34]. At the same time, numerous authors indicate that teleoncology, which developed during the pandemic, will soon be introduced into the everyday clinical practice scheme [35]. The literature emphasizes that ICT tools provide a source of preliminary selection of oncological patients, including identifying those for whom visits "at a distance" may be more beneficial due to the limited need for physical examination [36, 37].

The authors engaged in the area of teleoncology indicate not only the positive aspects of ICT tool implementation for diagnostics and consultations, but also the drawbacks resulting from the use of this solution [38]. Among the negative aspects, the researchers indicate the unstable regulatory situation, problems related to settlement of services and the risk of diagnostic errors due to the lack of personal contact with the patient.

Taking into consideration the analysis of the regulatory environment of telemedicine in Poland, it should be emphasized that the use of ICT in specialist care, including oncology, is completely admissible and in accordance with currently binding law. It is becoming crucial that both the Act on Medical Activity and the Act on the Profession of Doctor and Dentist allow for assessing patients' state of health and providing any activities characterized as health services within the meaning of art. 2 section 1 point 10 of the Act on Medical Activity [20] with the use of teleinformatic means and other communication systems.

At the same time, it should be stressed that until now no organizational standards for televisits within specialist care were established, which necessitates the application of the provisions referring to organizational standards in teleservices within primary health care in this respect. This solution, however, should be deemed temporary and imprecise. The authors indicate that the regulation dedicated to providing televisits within specialist care, including its specificity areas, is necessary. Simultaneously, it is essential to eliminate the use of announcements and guidelines as a binding legal form. Announcements, guidelines, recommendations and positions may only serve as advice for

proceeding, which should be eventually reflected in the current law. Regardless of the announcements on the admissibility of televisits within oncology issued by the NHF, such activities are completely justified and in accordance with the provisions on the general principles of providing health care services.

In conclusion, it should be reiterated that services with the use of ICT in oncology are admissible in light of the law and thereby can be provided with the use of such tools in every case where the patient's health state and the specificity of the service allow replacing personal contact with remote contact. Furthermore, the use of ICT tools may lead to a reduction in the number of patients waiting lists for consultation.

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