

## SHORT COMMUNICATION

## TELEMEDICINE IN PRENATAL CARE

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## SUMMARY

Telemedicine, as a health service provided remotely, is increasingly becoming a common part of health care. Telemedicine is defined as “an umbrella term for health activities, services and systems operated remotely through information and communication technologies to promote global health, prevention and health care, as well as education, health management and health research”. It also describes telemedicine as “the provision of services where distance is a critical factor, using information and communication technologies to exchange valid information for the diagnosis, treatment and prevention of disease and injury, for research and evaluation, and for the continuing education of healthcare providers to improve the health of individuals and communities”. Both definitions imply that two of the hallmarks of telemedicine include the use of communication and information technologies to overcome distance as a critical factor, a factor that is well known to us, not least from the recent months of the COVID-19 pandemic. Distance medicine can thus act as a tool for improving access to health care and also complement health care itself in a very appropriate way.

**Key words:** telemedicine, prenatal care, pregnancy, e-health, pandemic, telemonitoring

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## INTRODUCTION

## Concept of e-Health

Telemedicine is gaining value especially at a time when speed and accessibility of medical care is particularly important for patients. We are convinced that the standard use of remote access in medicine may be a question of the near future, especially in cases of further epidemics. Among other things, telemedicine makes it desirable to maintain a sufficient distance or even to limit contact between persons altogether (1). The modern concepts of e-Health, referring to electronic health care, including projects such as ePrescription or eHealth, and m-Health, referring to mobile health care, include:

- telemonitoring – checking vital signs such as BP, SpO<sub>2</sub>;
- tele-education – making information available to the public or transferring information between professionals;
- teleintervention, which is understood as robotic medicine, where, for example, surgical procedures are performed without direct patient-doctor contact; and
- teleconsultation – using videoconferencing, a telephone connection without face-to-face contact (2).

## Benefits and Shortcomings of Telemedicine

The modernisation of healthcare in connection with the use of IT technologies brings several advantages, mainly in the form of fast and accessible contact with a healthcare professional, possible reduction of direct patient contact and thus reducing the risk of infection transmission, etc. In addition, the digitisation of health services enables the collection of huge amounts of data that can be analysed by experts and subsequently used in research. Case modelling and the use of artificial intelligence can help to catch diseases early and thus increase the chances of recovery for patients.

We believe that the introduction of telemedicine into routine practice can also relieve the Czech healthcare system economically. If a certain group of chronically ill patients with poor compliance do not attend regular dispensary check-ups, this increases the risk of hospitalisation, which entails increased costs for the provision of health services. At the same time, telemedicine seeks to save on often scarce commodities such as respirators, surgical drapes, disposable gloves, and disinfectants. On the other hand, it should be noted that the practice of telemedicine inherently requires the purchase of IT technology, not only hardware but also software, including the appropriate training of medical staff, which also entails significant economic costs.

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However, in order for telemedicine to become a normal part of the healthcare system, it is necessary to provide it with a stable basis at legislative level. Currently, a major problem in the Czech Republic is the lack of legal norms that would regulate telemedicine. For the time being, there are no clear boundaries, except for e-Vacation and e-Prescriptions, which are used in the Czech healthcare system.

Telemedicine brings possible pitfalls, for example in the area of personal data protection. Patients send a huge amount of personal data to medical staff via apps, which of course must be handled properly in accordance with the relevant national and EU legislation, in particular Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data (GDPR) (3). For integration of telemedicine to a mainstream part of health care, it is therefore necessary that the privacy and data protection of patients is sufficiently ensured to make telemedicine trustworthy for both patients and healthcare professionals.

### **Vision of the Ministry of Health of the Czech Republic, Legislation and Resources to Support Telemedicine in the Czech Republic**

Currently, a certain obstacle to the introduction of telemedicine in the Czech Republic into common practice is the legislation that regulates the provision of health services through remote access at the legal level in an uncoordinated, isolated manner without centrally established rules and without basic elements of infrastructure. The Ministry of Health of the Czech Republic is aware of this fact and therefore currently includes among its priorities:

- electronic health care and a central e-health infrastructure;
- ensuring cyber security throughout the entire Ministry of Health;
- organizational and personnel support for the coordination of the use of public funds for the digitalization of health care, including cybersecurity;
- developing standardisation of eHealth and interoperability of health records;
- supporting telemedicine; and
- digitisation of the Ministry itself.

Regarding the actual electronization of health care, without which telemedicine is hardly imaginable, the Ministry of Health of the Czech Republic prepared a draft law on the electronization of health care and submitted the draft to the Czech Government, which approved it on 15 February 2021. The Government's draft law on the electronization of health care went through the standard legislative process, being approved by the Chamber of Deputies in the third reading on 7 July 2021, and subsequently approved by the Senate on 18 August 2021. On 8 September 2021, the approved Act was published in the Collection of Laws in volume 143 under number 325/2021 Coll., with effect (in most parts) from 1 February 2022. In terms of content, the Act on the electronization of health care brings in particular an innovation in the form of the Integrated Data Interface, which is to represent the centralisation of the basic infrastructure, i.e., health registers, where tribal data on healthcare providers, healthcare workers and, of course, patients will be stored and made available.

According to the explanatory memorandum, Act No 325/2021 Coll. on the computerisation of health care is based, among other

things, on the principle of respect for established processes in health care, where no new, parallel type of health care is created, but it is “only” the computerisation of already established processes, and on the principle of respect for the set roles of institutions, where there is no change in the rules of interaction between the health service provider, health worker and patient; the current position of the Ministry of Health of the Czech Republic is respected and the role of health insurance companies is also unaffected. Last but not least, the law respects the necessary level of protection of patients' privacy and personal data, as the law corresponds not only to the GDPR but also, for example, to the OECD Council Recommendation on Health Data Management of 17 January 2017.

The law also represents some progress in building services that are interconnected and usable within the European Union. The National Contact Point for eHealth is connected to the Integrated Data Interface. This precedes the next phase in the development of international operability, which is the definition of standards that will allow standardised messages to be generated and shared internationally using trust building tools in accordance with Regulation (EU) of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market (eIDAS Regulation).

As far as the currently applicable and effective legislation is concerned, the main source of regulation of the provision of health care is Act No 372/2011 Coll., on health services and conditions of their provision (Health Services Act), which acts as a kind of health code. Section 2(2) of the Health Services Act defines health services under (a) not only as the health care itself provided by health professionals, but also under (b) as consultative services, the purpose of which is to assess the individual treatment procedure, or to propose its change or supplementation, and other consultations supporting the patient's decision-making regarding the provision of health services, carried out by another health service provider or a health professional chosen by the patient (so-called second opinion). The possibility of consultation is also mentioned in Section 7(2)(a) of the Health Services Act in the context of primary outpatient care. However, the fact that the place of provision of health services (i.e., both health care and consultations) is tied to the premises designated for the provision of health services remains an obstacle. According to Section 11(5) of the Health Services Act, “Health services may be provided only in healthcare facilities in places specified in the authorisation for the provision of health services.” The legislator is well aware of this problem, however, we are currently still waiting for a draft amendment to the Health Services Act that would address the situation outlined.

Despite this, there is a real development of telemedicine applications and virtual surgeries, i.e., applications for remote consultation with patients, including remote measurement of clinical data with advanced analysis of outputs (BigData and AI). These telemedicine applications are already being used for diabetes, heart failure patients and cancer dispensaries, and could prospectively be incorporated into other disciplines such as general practice or gynaecology (in the context of antenatal care) (4). The innovative model of telemedicine has been investigated mostly in gynaecologist care (5).

The National Telemedicine Centre (NTMC) of the University Hospital Olomouc is involved in research on the operational and economic model in the field of telemedicine. The aim of the NTMC is to research and propose appropriate operational and

economic models for the provision of telemedicine services in the Czech Republic, which would define how to develop telemedicine services and ensure their sustainability.

Another important concept for joint action to support the implementation of digital solutions in the provision of integrated healthcare is the Joint Action on implementation of digitally enabled integrated person – centred care (JADECARE), which is a project supported by the European Commission under the EU Health Programme 2014–2020.

The so-called “eHAction” – Joint Actions supporting the eHealth Network is a European Commission project providing support to the eHealth/mHealth network, which acts as a high-level network of representatives of national health authorities in the EU and as the highest EU-level authority on eHealth. The aim is to develop draft methodologies that will be submitted to the eHealth Network as guidance documents for national eHealth implementation.

In relation to the above-mentioned international interoperability, it is also worth mentioning the X-eHealth project – Exchanging Electronic Health Records in a common framework, which aims to support a faster and sustainable digital transformation of the EU. The X-eHealth project aims to create a single interoperable format for sharing health data or medical records for the exchange of discharge reports, orders and results of laboratory tests, orders and results of imaging complements, and to complement the existing European Patient Summary specification in the area of rare diseases.

## Czech Republic and Telemedicine, Prenatal Care in the Czech Republic

Since March 2020, the Czech healthcare system has been facing difficulties with the arrival of COVID-19, such as significant financial losses, extreme workload of health professionals or interdisciplinary transfers of personnel often not respecting the given specialties.

The COVID era, with its pitfalls of quarantines and various epidemiological constraints, in a way invites change and allows us to make telemedicine more part of the routine. GPs are a shining example of this, as they have adapted most of their agenda to dealing with it remotely, without losing any of the quality of the care they provide. It is essential to consider whether and how to implement this model in other fields. In the field of gynaecology and obstetrics, the introduction of telemedicine into antenatal care for women with physiological pregnancies and possibly also routine consultations in gynaecology could be considered (6, 7).

During pregnancy, pregnant women are selected according to the course of pregnancy into two (low risk/high risk) or three basic groups, and the prenatal care scheme is set up accordingly (8):

*Low risk pregnancy* – physiological pregnancy, no risk factors are observed in the patient’s medical history, the results of clinical and laboratory tests are normal, the pregnancy is described as physiological and the dispensary care can be described as basal/basic care – it can be provided by a private gynaecologist or in a type I inpatient unit.

Dispensary prenatal care is provided:

- up to and including the 36th gestational week at an interval of 4–6 weeks;
- from the 37th gestational week until the due date/until delivery once a week;

- after the delivery date, more frequently according to the current situation.

*Risky pregnancy* – pregnant women with intermediate risk: patients have an anamnestic burden of risk factors, the results of clinical and laboratory tests are normal but require repetition, dispensary care can be described as intermediate, such a facility allows hospitalization of light and intermediate pathologies, carries out in utero transport and premature births from the 33rd gestational week to the end of the 36th gestational week in the perinatal centre.

Dispensary antenatal care depends on the current state of the woman’s health. If there is an abnormality in clinical or laboratory tests at any time during pregnancy, the pregnant woman is reassigned to group C.

*High-risk pregnancy* – pathological pregnancies: they may or may not have a history of risk factors, pathological results of clinical and laboratory examinations, dispensary care is provided by perinatology centres, which concentrate significant pathologies, allow premature births from the 24th gestational week to the end of the 32nd gestational week (22 + 0–24 + 0, time frame requiring an individual approach).

Clinical and laboratory examinations in the provision of antenatal care can be classified as routine, which are carried out at each visit to the antenatal clinic, and irregular, which are specific to a given week of gestation. Routine examinations include:

- collecting and analysing anamnestic data and updating it;
- blood pressure test;
- the weight of the pregnant woman;
- chemical analysis of urine (urinalysis, urine test) – diagnostic strips;
- detection of signs of foetal vitality – by listening to foetal sound (Doppler monitoring, cardiotocography (CTG) monitoring, ultrasound);
- bimanual vaginal examination with determination of cervix score – frequency of examination depends on the doctor’s opinion.

## Telemedicine and Its Access to Pregnant Women in Other EU Countries During the COVID-19 Pandemic

As the EU countries are among the most affected countries in the world by COVID-19, it was necessary to adapt the care of pregnant women to minimize the transmission of the infection. Thus, with the increasing number of infected workers, the lack of protective work equipment (disposable gloves, respirators) and the use of healthcare workers within COVID units played a crucial role (9). The conservative solutions to the staff shortage also included calling in retired workers and medical students.

In the Netherlands, antenatal care was reorganised very soon after the pandemic started – after an initial face-to-face visit in the 10th–12th week of gestation, when blood tests and ultrasound examinations were performed, subsequent visits were already conducted at a distance. Physical contact of the doctor with the pregnant woman was only in case of problems after a previous teleconsultation.

Similarly, in France and the UK, most of the check-ups were replaced by online consultation, and in some regions of the UK, patients were even provided with a blood pressure monitor and HeptaPhan diagnostic strips for urine chemistry analysis.

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In Italy and Spain, access to telemedicine varied by region. In most countries, the presence of an attendant at the delivery was also limited to a maximum of 1 person, and only during the active management of labour. The approach to postnatal care for newborns and mothers in the six-week period is individual to the region, but in general all countries preferred a distant form to reduce contact and risk for both mother and newborn.

### **The Goal of Distance Medicine in the Field of Prenatal Care in the Czech Republic**

The use of telemedicine in prenatal care is possible mainly in regular examinations of low-risk pregnant women with physiological pregnancy, especially in the third trimester.

We assume that after the first “check in” check-up, the pregnant woman will be offered the possibility of further regular check-ups within the framework of distance care. If the patient agrees, an informed consent is signed and the procedure is also explained in detail and the necessary equipment is handed over – a tonometer, a mobile CTG and also enough diagnostic strips for urine testing. As instructed, the patient secures a free ready-to-use app that allows for self-distance monitoring and regular check-ups.

We are currently planning to conduct a pilot follow-up, with regular in-person and distance check-ups, to be able to set up the optimal functioning of the whole system. The antenatal clinic has set precise surgery hours when an obstetrician and midwife will be attached to check on patients who are booked in. Once all the parameters entered by the patient and the CTG record have been checked, the final report for that particular check is written and this can be printed, including all the data from the patient, in PDF format. Of course, if any of the data is not within the physiological range or if the patient indicates any health problem, she has the option of contacting the doctor or midwife immediately, via the application itself and, if it is an acute situation, by phone. This can be done in the other way around, where the obstetrician or midwife determines that additional data should be obtained, or the patient should be contacted by telephone or invited to attend a check-up at the maternity hospital.

As part of the overall monitoring, we use a blood pressure monitoring (Omron) that records blood pressure readings directly into the app. Similarly, the Pregnabit – a portable device with easy operation, which the pregnant woman places in the navel area using the app on her phone to guide her step-by-step, the foetal sounds can be sensed during a 20-minute recording, which is sent to her gynaecologist by entering the selected password in the mobile app for checking. The patient’s urine sample is diagnosed using standard dg strips and following a very simple assessment scheme, the patient enters the result into the app, similar to her weight.

If the distance check-up is uneventful and all readings are physiological, a follow-up appointment is scheduled for another in-person or distance visit as recommended. The physician creates a final report of the visit and adds everything to the documentation, including the CTG record.

### **Technical Specifications**

Distance health care will be provided in the upcoming pilot project through a solution developed by MEDDI hub a.s. This

platform, developed in the Czech Republic, allows the doctor/midwife and the pregnant patient to communicate securely in real time. This solution was chosen because it meets the highest requirements for data security, which was a top priority for us.

The application allows communication between medical staff (doctor or midwife) and patient in the form of chat, call and video call. All three communication methods are encrypted with a 2048-bit key. Patient registration with identity verification will be performed in the pilot project during the first personal physical examination by a healthcare professional. Subsequent login to the app uses biometric verification of the user’s identity if available on the smartphones. This variability was one of the requirements to offer this new way of delivering remote health care to as many patients as possible, regardless of the type of smartphone they own. Furthermore, this solution is also available on a computer in a web browser.

The app does not collect any data, including geolocation data, and is GDPR compliant. The company is ISO 16 001 certified, and its entire solution has been consulted with the National Institute for Cyber and Information Security whose requirements it meets. The process of obtaining ISO 13485:2016 certification, which specifies the requirements for a quality management system (QMS) for organizations involved in the manufacture and provision of medical devices that need to demonstrate their ability to consistently deliver the services and requirements of their customers in accordance with applicable regulatory mechanisms, is assured. The aim is to unify the different interpretations of laws relating to the regulation between EU member states, to facilitate the EU market and to ensure the same quality and safety across the EU.

If necessary, the doctor/midwife can contact the patient directly in the application, by starting the patient’s phone ringing as if he/she were calling her directly on the phone or sending a message, ePrescription or making an appointment for a physical examination. At the end of each telehealth appointment is a medical report that the doctor/midwife can create directly in the app. This medical report is then signed directly in the app with a qualified electronic signature and time stamp and sent to the doctor and patient.

In the future, it will be possible to send this electronic medical report directly to the hospital information system as the application works with the latest data standards used in the processing of medical records.

### **DISCUSSION**

This innovation brings several benefits for both the patient and the healthcare provider. In addition to the minimization of contact with infectious/risk persons and absolute freedom of movement without compromising the quality of care for pregnant women, there are also obvious positive economic implications for healthcare facilities and providers, respectively. For some patients, a visit to the doctor is still quite stressful and they prefer this distance option – here it can be noted that the influence of the so-called white coat syndrome, which can cause an acute increase in blood pressure, is eliminated and doctors often respond by recommending blood sampling and possibly an internal check-up, which are ultimately additional unnecessary examinations (10).

Another important benefit is the minimisation of complications with transport to the hospital/outpatient clinic, including financial costs. Many pregnant women see their gynaecologist or obstetrician in locations far from their home and spend most of their time travelling themselves or have to use a family member who is taking time off work.

## CONCLUSION

In our experience, there is a clear assumption that this form of distant care is suitable for the care of non-risk pregnancies in addition to the above-mentioned disciplines. We are convinced that if the application is of sufficient quality and error-free, user-friendly and simple, this method of communication between pregnant woman and medical staff (doctor or midwife) will be popular and frequently used. Of course, a professionally secured legal platform will be a safeguard for both the data entered into the app by the patient and the doctors and midwives in case any health complications arise. Given that obstetrics is generally one of the most “forensically affected” fields, this legal preparation is mandatory.

## Conflict of Interests

None declared

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