

ENGAGEMENT OF TEST PERSONS AND CONSIDERATION OF LEGAL ASPECTS



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1. Introduction

This document describes the process of involving the elderly and health and care services professionals to act as testers for the Care for Frail platform. In the project, we count on the involvement of 10 people - the frailty elderly, who will use the Care for frail platform for solving home care after discharge from the hospital. For these purposes, cooperation is ensured with two providers of home nursing health care, one provider of social home care and the social department of University Hospital Olomouc. Due to the situation with Covid-19, access to patients in the hospital is very demanding, in the first half of the year was almost impossible. In addition, due to covid pandemic, there were no planned operations after which platform testing could be planned for frail elderly.

The period when access to patients was not possible was used to create documents for the ethics committee and its approval of testing, to create documents for patients, including informed consent and consent to participate in the project, all in accordance with GDPR rules. In addition, UX testing was performed by senior volunteers. The platform was modified so that it could be used for frail elderly, but without the direct use of frail elderly - so that it could be used by entities in its interest on the basis of its possibility. Furthermore, employees of the social department of UHO, nursing care and home social care were trained in the use of the platform.

2. Consideration of legal aspects and approval of the ethics committee

2.1. Legal aspects of telemedicine

2.1.1. Introduction into legal aspects of telemedicine

From a legal point of view, the institute of telemedicine can be perceived as a set of means and procedures enabling remote monitoring of the patient's health condition and the possibility of consultation with a healthcare professional in order to improve patient care. From the application point of view, telemedicine is a set of technical measures and procedures, with the aim of implementing electronic healthcare. Therefore, it is necessary to establish a legal framework for the technical issues of telemedicine implementation and to specify specific legal regulations that legally allow the implementation of telemedicine.

2.1.2. EU legislation

Extensive discussions on telemedicine have been taking place at EU level for many years, such as the EU Commission's strategy paper, which adopted on 10 April 2014 a code COM (2014) 219 - Green Paper on Mobile Health ("mHealth") however, European legislation does not yet exist.

2.1.3. Czech Republic legislation

The barrier to the performance of telemedicine is the insufficient legal regulation in the field of electronic healthcare, to which the institute of telemedicine belongs. Telemedicine is thus in the "gray zone". It is not explicitly legally allowed, nor is it prohibited, but in the prevailing opinion of the

professional legal community, support for the performance of telemedicine can be found in existing legislation, which is in particular Act No. 372/2011 Coll., On health services ("ZoZS").), Act No. 373/2011 Coll., on specific health services (hereinafter referred to as "ZoSZS") and Decree of the Ministry of Health No. 134/1998 Coll., which issues a list of health procedures with point values, as amended.

2.1.3.1. Bill on electronic healthcare

The government's bill on electronic healthcare is essential for the legal regulation of telemedicine and its provision. It should introduce a legal definition of e-health and its means and enable the creation of an e-health portal. The portal should include an offer of services provided within e-health and a catalog of web and mobile applications, including the conditions of their operation. It can be deduced from the above that only those telemedicine solutions that will meet the specified conditions and that will be able to be listed in the e-health portal will be legally approved for use in the provision of health care. Although the institute of the legal concept of telemedicine is not mentioned in the government bill, there is no doubt that the means and procedures of telemedicine can be subordinated to the mentioned services, applications and especially to the concept of electronic health care.

2.1.3.2. ZoZS

ZoZS does not contain specific legal regulation of telemedicine and its provision. Despite the absence of explicit legislation, however, the basis for the implementation of telemedicine can be found in the provisions of the Emergency Medical Service, especially in Sections 5 to 10 of the Emergency Medical Service, which stipulate the types and forms of health care. It is necessary to mention in particular section 6 ZoZS, which defines the form of health care provided in the patient's own social environment. It is the patient's own social environment where telemedicine can be used. In current legal and medical practice, health services can be provided outside the health facility through remote access. The determination of more detailed conditions for the performance of telemedicine within the so-called distance care is to be the subject of an amendment to the Health Services Act. At the same time, however, it should be noted that telemedicine should be used mainly for consultation purposes and should not replace standard doctor-patient contact if such contact is necessary. In view of the above, it can be concluded that telemedicine and the means used in it fall under the provision of health care and thus find support in ZoZS.

2.1.3.3. ZoSZS

Although the means and procedures of telemedicine are not explicitly regulated within the ZoSZS, from the point of view of the specific, even experimental, nature of telemedicine services, according to some experts it is possible to classify the institute of telemedicine under section 33 as a treatment/care, that have not yet been fully implemented in clinical practice. However, telemedicine does not find specific legal support within the ZoSZS.

2.1.4. Legal protection of personal data

In connection with telemedicine, it is necessary to mention the area of personal data protection, especially in connection with the requirements set by the general GDPR Regulation (hereinafter "GDPR") and Act No. 110/2019 Coll., On personal data processing (hereinafter "ZOÚ"). Telemedicine involves the collection of a significant amount of personal data and their simultaneous processing, and for this reason

it is necessary to ensure a sufficient system of protection and processing of personal data, even beyond the applicable legislation. A healthcare professional using telemedicine should be sufficiently familiar with the obligations they must comply with when handling personal data. In addition to existing legislation, this issue should be further regulated in the proposed wording of the Act on Electronic Health Care.

2.1.5. Conclusion

The issue of legal aspects of telemedicine can be summarized as follows. Currently valid legislation does not explicitly allow the provision of telemedicine services and their payment by health insurance companies. At the same time, however, the provision of telemedicine services and their payment are not prohibited, and according to current practice and the opinion of the professional legal community, the provision of telemedicine can be implemented despite the absence of legislation. However, this does not change the fact that telemedicine and its payment remain a "gray zone" with absent legislation, so it will be necessary to adopt the necessary legislation in the Czech legal environment.

2.2. Approval of UHO Ethics Committee

Given that the project mainly collects personal and health data, the legislation of the General EU Data Protection Regulation (GDPR) needs to be addressed in particular. For this reason, the following documents were prepared together with the legal department of University Hospital Olomouc:

- Declaration of consent under the Data Protection Act

This document obtains the written consent of the participants to the storage and further use of the obtained health and other data. In addition, it provides information on appeals that is possible at any time. Signature will be obtained during the initial meeting.

- Informed consent

This document contains all information about the project, the pilot and the protection of personal data and informs the participants about the important articles of the general regulation on personal data protection in connection with the project.

- Syllabus of a research project for an ethics committee

Basis for the ethics committee, on the basis of which it can decide on approval or disapproval. It contains information about the project and the pilot verification.

The Ethics Committee of University Hospital Olomouc met on June 7, 2021 and, on the basis of the submitted documents, approved the pilot testing of the Care for Frail tool and documents for participants.

3. UIX testing

UIX testing is described in separate deliverable D.T.3.8.3.

4. Modifying the platform

Based on the results of UIX testing, we made the following changes in the platform

- Allowing the possibility of using the platform for patients discharged from hospital only by social care and nursing institutions without the intervention of the frailty elderly.
- Adding a chat and possibility to order medication and health aids
- Adding a feature - Monitoring Grid (developed at Burgenland Austria by PP8)

5. Involvement of nursing care and social home care

In the preparatory phase of testing, only some parties in the care model that our tool addresses can be prepared in advance. Our tool connects frail elderly, family members, hospitals, nursing care providers, social home care and general practitioner. Due to the fact that there are so many individual parties and these parties contain dozens of individuals, it is not possible to prepare all the parties involved in the project in advance. We therefore chose an approach where partners from the discharging hospital (UHO social department) , two nursing care providers (out of five providing care in Olomouc in the current moment) and two social home care providers (home care and personal assistance) are involved and prepared for the pilot in advance. These involved partners - UHO social department, Charita Olomouc - Nursing Home care, Charita Olomouc - Social Home Care and Pomadol Olomouc home nursing care - were acquainted with the platform and were trained in its use.

6. Involvement of frail elderly and general practitioners - planned procedure

For the group of frail elderly and general practitioners, we are ready for them to participate in the project, install the tool and learn with the platform immediately after frail elderly finds himself in a situation of discharge from the hospital, meets the rules for involvement in the project and shows interest.

Criteria for involving frail elderly in the pilot:

- Age Above 65
- Discharged from University Hospital Olomouc
- Need a subsequent home health care - prescribed by his hospital doctor or general practitioner

Installation of tool is very easy, as well as using the platform. Thanks to detailed UX testing and subsequent modifications to the platform, we are sure that it is senior user friendly. The platform manual and the National Telemedicine Center staff on the phone will also serve as support.

General practitioner of Frail elderly will be contacted after frail elderly expressions of interest in joining pilot testing. The meeting with general practitioner will be conducted by an employee of the National Telemedicine Center, and if you are interested in participating in the project, they will immediately install the platform in the doctor's IT equipment and explain the use of the platform.

7. Conclusion

For the pilot testing of the Care for Frail tool, a consultation of legal aspects was performed and approved by the ethics committee of the University Hospital Olomouc. Two key parties of the participants in the pilot, ie the dismissal hospital and the home health care provider, were prepared for the other two parties - frail elderly and general practitioners.

In the group of seniors, extensive UX testing was performed so that the communication platform was senior user friendly. Based on this testing, the platform was slightly modified in terms of appearance and some functionalities were added, such as chat and ordering medical devices or the possibility of using the platform for frail seniors by other partners in his interest without his personal involvement.