

MACHINE TRANSLATION

Telemedicine model in cardiology:

Telemonitoring of patients with heart failure

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Technological advances now make it possible to manage heart failure (HF) from remote to telemonitoring using non-invasive solutions or implantable devices. Today, it is possible to monitor parameters at home that can be recorded, stored and remotely communicated to physicians, allowing them to make decisions about modifying therapy, hospitalization or emergency room access. Independent systems equipped with self-intelligence are available and are able to acquire and process data that can inform the remote physician of impending decompensation before it causes additional complications. The development of miniature implantable devices that could measure hemodynamic variables and transmit them to a monitor outside the body gives the physician the ability to assess HF patients more frequently and the ability to incorporate this data into management decisions. The current challenge for telemedicine in the treatment of HF is to find a more appropriate biological parameter to monitor clinical status.

Research studies

A study conducted by Koehler F. et al. in Germany was designed to answer the question of whether continuous telemonitoring, telemedical treatment modification, and education of patients with heart failure could reduce the number of days lost due to unplanned hospital visits for disease exacerbations.

Participants in the study were given a home telemedicine unit with which they measured their baseline vital signs such as heart function, blood pressure, ECG, saturation, and a brief well-being questionnaire every day at home and sent them to the Telemedicine Center. The data was analyzed and patient risk profiles were created based on the data. Seeing the deteriorating condition of the patient, doctors and nurses working in the Center contacted the patient and modified their treatment accordingly.

The implementation of the solution yielded optimistic results. During the follow-up, patients who had telemedicine support were hospitalized less frequently and had lower mortality during the one-year follow-up. Thus, it seems that once the algorithms for identifying high-risk patients are improved, telemedicine may become a useful tool for preventing heart failure exacerbations that are costly to the healthcare system.

Technological advances have enabled increasingly sophisticated remote monitoring of heart failure. This should enable earlier identification of decompensation, better adherence to lifestyle changes, and the use of medications and interventions (such as diuretic dose changes) that reduce the need for hospitalization.

The conventional concept of a remote monitoring system in healthcare is often implemented using a telephone-based interactive voice response system. It usually collects patients' daily information such as related symptoms, feelings and habits by asking questions. The collected information is then reviewed by physicians. Chaudhry et al. created a telemonitoring system with 1653 included patients, where 826 were randomly assigned to undergo telemonitoring and 827 to receive usual care. The telemonitored patients were required to make daily phone calls for six months. During each call, patients were asked a series of questions about their general health and HF symptoms.

Suh et al. developed a system for remote monitoring of CHF patients that had a three-tiered architecture consisting of ubiquitous biosensors, a web server, and an internal database. Four health-related measurements were obtained: weight, blood pressure, physical activity, and the Heart Failure Somatic Awareness Scale (HFSAS), which reflect the most common physical and subjective symptoms of CHF.

Recommendations for monitoring patients with heart failure

Table 1: Guidelines on Remote Monitoring in Heart Failure

European Society of Cardiology (2016):⁸

"Telemedicine in HF, which is also termed remote patient management, has variable clinical trial results. Several meta-analyses suggest clinical benefits, but numerous prospectively initiated clinical trials including >3700 patients have not confirmed this."

- Monitoring of pulmonary artery pressures using a wireless implantable haemodynamic monitoring system (CardioMems) may be considered in symptomatic patients with HF with previous HF hospitalisation in order to reduce the risk of recurrent HF hospitalisation. (Class IIb, level B.)
- Multiparameter monitoring based on ICD (IN-TIME approach) may be considered in symptomatic patients with HFrEF (LVEF≤35%) in order to improve clinical outcomes. (Class IIb, level B.)

American College of Cardiology Foundation/American Heart Association Guideline (2013):⁹

Systems of Care to Promote Care Coordination for Patients With Chronic HF

"The quality of evidence is mixed for specific components of HF clinical management interventions, such as home-based care, disease management, and remote telemonitoring programs... Overall, very few specific interventions have been consistently identified and successfully applied in clinical practice."

Evidence Gaps and Future Research Directions

"What is critically needed is an evidence base that clearly identifies best processes of care, especially in the transition from hospital to home."

Heart Failure Society of America White Paper (2018):¹⁰

"Based on available evidence, routine use of external remote patient management devices is not recommended. Implanted devices that monitor pulmonary arterial pressure and/or other parameters may be beneficial in selected patients or when used in structured programs, but the value of these devices in routine care requires further study. Future research is also warranted to better understand the cost-effectiveness of these devices."

HF = heart failure; HFrEF = heart failure with reduced ejection fraction; LVEF = left ventricular ejection fraction, IN-TIME = Influence of Home Monitoring on The clinical Management of heart failureE patients with impaired left ventricular function.

<https://assets.radcliffecardiology.com/s3fs-public/article/2020-12/table1-guidelines-on-remote.png>

Best Practices

Telephone support

US Tele-HF system is an example - (1653 patients). One of the earliest adopted methods. Patients are called out by a member of the HF team to discuss symptoms and review adherence to lifestyle and drug treatment. Patients may be asked to weigh themselves, which they then report verbally, identify when their weight has risen above a set level, and contact the HF team for advice. These approaches have become a standard part of disease management programs, based on evidence from many relatively small studies showing that such programs reduce all-cause and HF mortality rates compared with usual care.

Telephone support for patients enrolled in an HF program remains central to the activities of many centers, but is generally targeted at more unstable patients, those who have recently returned home after being admitted to the hospital for HF or who live a considerable distance from an HF center.

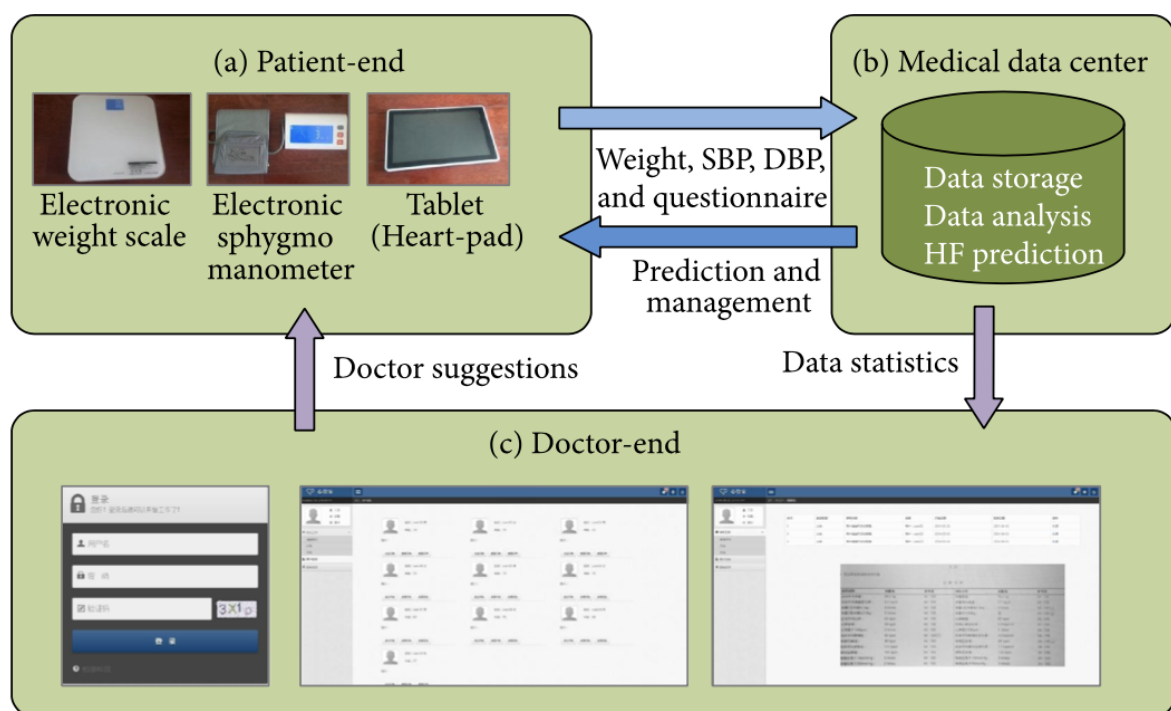
Stand-alone telemonitoring systems

Stand-alone systems allow patients, usually in their own homes, to send noninvasive data measurements to the health care team via telephone systems or the Internet. In many countries, Internet access is wireless and can be done via mobile telecommunications networks. The HF team reviews the data regularly (usually looking for trends over several days) or may receive an alert if any variable is outside a set limit. Data-driven actions may be taken at the discretion of the healthcare professional or there may be local guidelines or protocol to follow.

One of the earliest randomized trials was the Trans-European Network - Home-Care Management System (TEN-HMS) study. In this study, 426 patients with HF with reduced ejection fraction (HFrEF) from across Europe were recruited and randomly assigned in a 2: 2: 1 ratio to telemonitoring at home with a stand-alone system, telephone assistance from a nurse, or usual care. There was a reduction in hospital length of stay for the home telemonitoring group and lower mortality for patients with telephone support and telemonitoring compared with usual care. A meta-analysis with other (small) studies suggested mortality benefits and reduced hospitalizations for HF (but not for all causes)

Remote monitoring platform

The remote medical monitoring system for HF consists of three parts, as shown in the figure



<https://doi.org/10.1155/2015/406327>

The first part is for the patient and is used to collect data and send / receive feedback. It includes non-invasive sensors used to measure weight and systolic/diastolic blood pressure and a tablet with an "end-user" application used to collect questionnaire responses and interact with patients. The second part is the medical data center, to which data from the patient side is sent. The medical data center stores the collected data, performs statistical data analysis and HF prediction, and generates data statistics and patient reports that can be provided to physicians and patients. The third part is the medical part, through which patient reports are sent to physicians, who can then present interventions/suggestions to patients according to their (current and previous) statistics and reports. These three parts form a system so that the remote medical monitoring system can provide early

detection of HF and also provide timely interventions. The system has several noteworthy functions. First, it can assess a patient's condition by intelligently analyzing physiological data. Second, it provides a real-time platform for questions and answers between physicians and patients. Third, it offers historical tracking of patient heart health data and medical records. Below are more details related to the implementation of the system.

The system includes three hardware devices:

- An electronic scale that measures body weight (kg).
- An electronic blood pressure monitor that measures systolic blood pressure (SBP, mmHg) and diastolic blood pressure (DBP, mmHg).
- A tablet "Heart-pad" that is a platform between patients and the system/doctors with an Android operating system, including the functions of collecting physiological data from the other two devices, collecting questionnaire data from patients, asking questions to doctors (via patients), and sending feedback to patients (via the system/doctors). All three hardware devices are connected via built-in Bluetooth 4.0 modules.

Several different types of software have been implemented to predict the occurrence of HF.

- Tablet data collection software, which is used to control the acquisition of weight and blood pressure data and to automatically upload the data to a medical data center;
- Questionnaire generation software that automatically generates a certain number of questions for patients each day;
- prediction software, which uses data mining algorithms to analyze historical data and predict the future probability of HF, and then calculates a score indicating HF risk
- reporting software that visualizes certain data and generates reports delivered to patients, where each report includes, for example, questionnaire statistics, daily changes in body weight and blood pressure (SBP and DBP), variation in the HF risk score (HFRS), and suggestions from physicians and/or the system itself;
- a doctor-patient interaction software that provides a real-time platform for questions and answers between doctors and patients.

There are two graphical user interfaces (GUI) in the system, one for patients (patient side) and one for doctors (doctor side).

- Patient Graphical User Interface: On the home page, patients can see the different functions of the system and choose what they want to perform: for example, they can measure their weight and blood pressure by following voice instructions, answer online questions, or read a report with suggestions generated by the system or the doctor.
- Graphical user interface for the physician: physicians can log into the system via desktop, search for and manage patients, check in on patients, and communicate instantly with patients where they can receive messages from their patients.

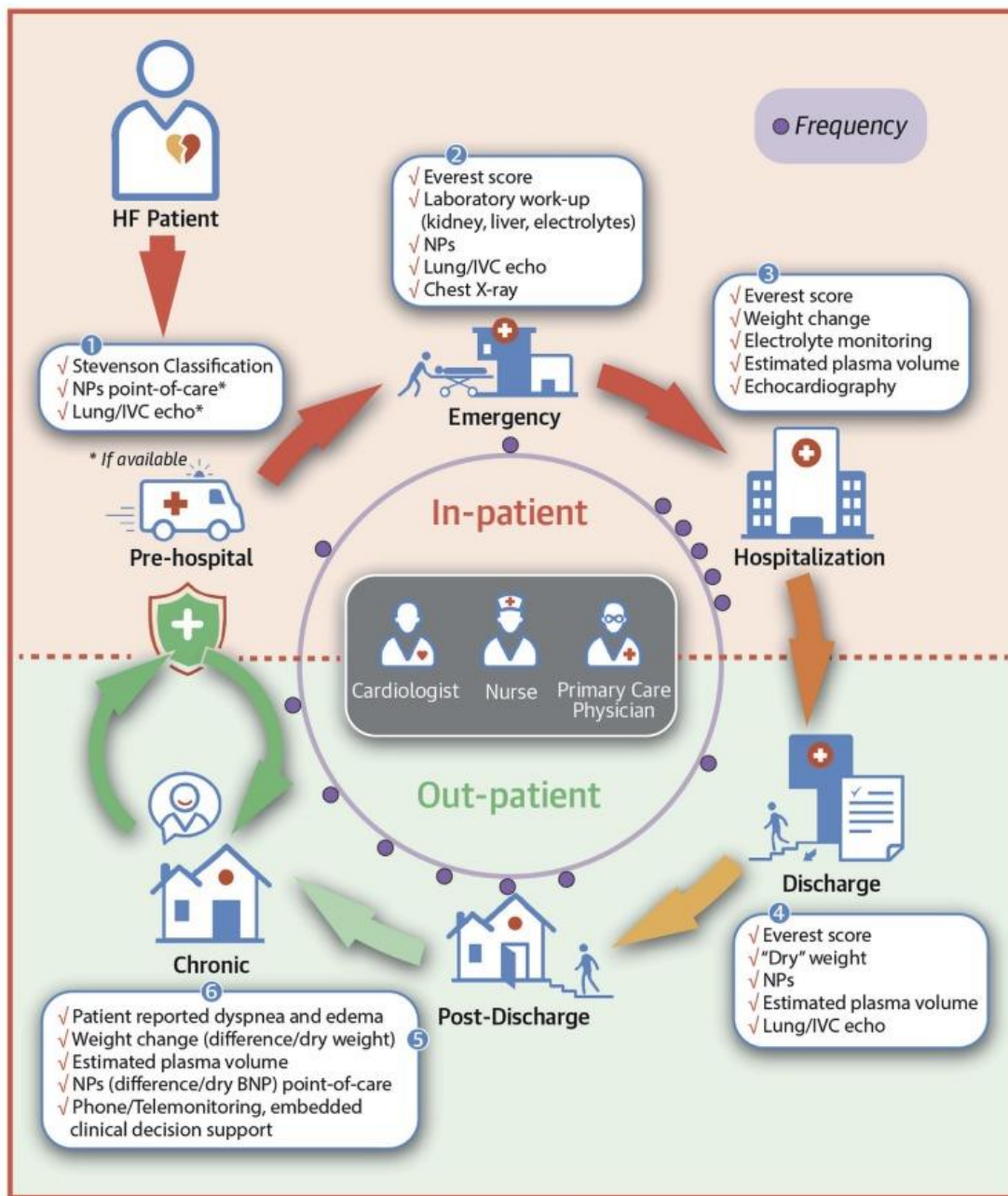
Recommendation

Based on previous studies, the literature review and the analysis presented above, we recommend the implementation in Polish conditions of a complete monitoring of patients with heart failure consisting of:

- Dedicated internet platform
- Medical support team
- Telephone consultation
- An interface for the patient - a website
- Interface for the physician - web page
- Medical devices communicating wirelessly: scale, blood pressure monitor with heart rate monitor.
- Algorithm for automatic evaluation of symptoms, reasoning and prognosis of symptom exacerbations

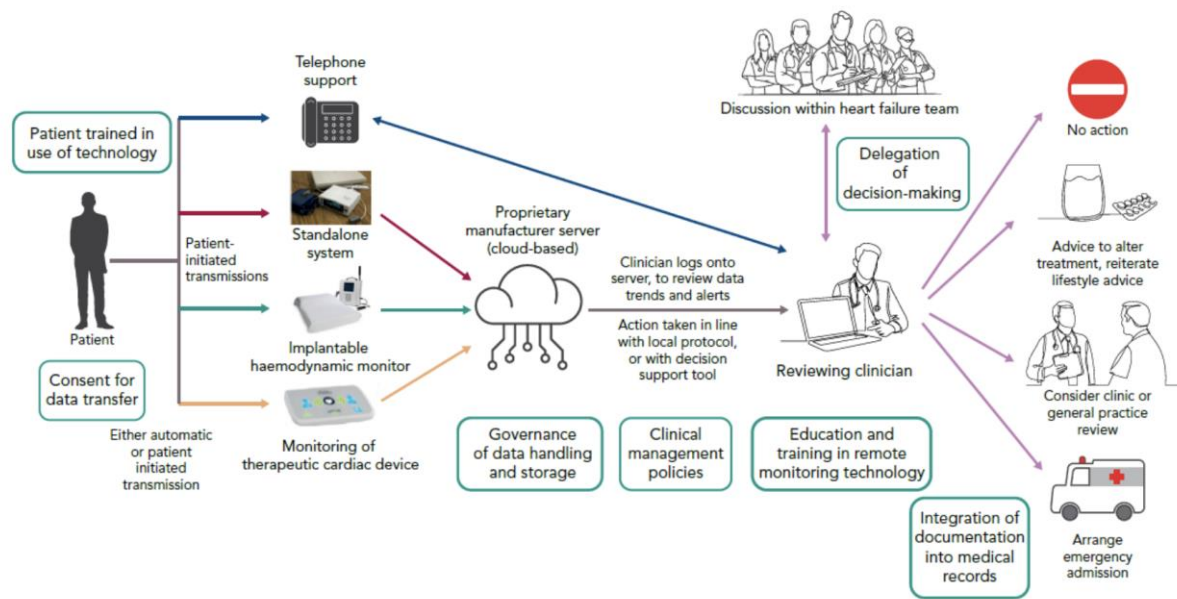
A complex scheme of functioning of the whole system can be based on the following example

CENTRAL ILLUSTRATION: Congestion Assessment in HF Patient Journey



Girerd, N. et al. J Am Coll Cardiol HF. 2018;6(4):273-85.

The mechanism for monitoring patients with heart failure can be based on the following scheme:

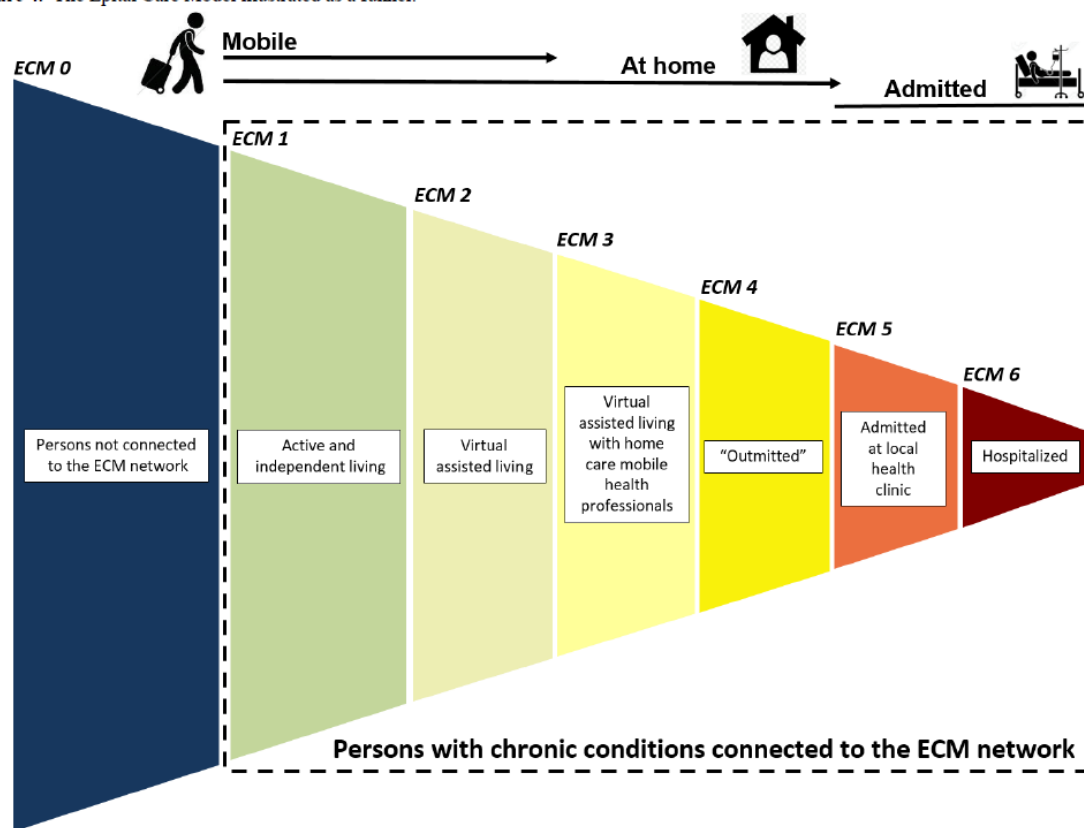


Source:

<https://assets.radcliffecardiology.com/s3fs-public/article/2020-12/figure1-schema-for-remote-monitoring.png>

A global effect is described in E-(hos)pital Care Model

Figure 4. The Epital Care Model illustrated as a funnel.



Source:

Phanareth K, Vingtoft S, Christensen AS, Nielsen JS, Svenstrup J, Berntsen GKR, et al. The Epital Care Model: A New Person-Centered Model of Technology-Enabled Integrated Care for People With Long Term Conditions JMIR Res Protoc 2017.

The content presented above included information on the epidemiology and challenges that heart failure patients and the healthcare system face. Based on the analysis of available scientific data, epidemiological reports, and experience from daily clinical work, the experts identified potential gaps in the framework of care for patients with heart failure, and which can be filled through telemedicine solutions. The reports indicate that there are a number of e-health solutions in the world relating to the topic of heart failure. It allows for selection and implementation of best practices from leading centers around the world. Therefore, there is a chance to create a systemic solution, based on scientific evidence, which, thanks to the payer's resources and experience, can be implemented on a wide scale and face the problems in the care of the aforementioned group of patients. The care model described below assumes comprehensive patient care with efficient use of medical resources. This model will be patient-centered, with a group of specialists working around the patient to improve the patient's prognosis and quality of life through the integration of inpatient care, outpatient specialty care, and primary care. Over the past two decades, the number of patients with heart failure has doubled globally. In Poland, it is estimated that as many as 1.24 million citizens have this diagnosis. Heart failure is a severe disease with poor prognosis. Moreover, the quality of life of this group of patients is significantly lower, and treatment is a huge challenge. In addition, these patients usually have many other conditions in addition to heart failure and are more often hospitalized, which, along with increased frequency of outpatient visits, imposes huge costs on the payer. Comprehensive care based

primarily on outpatient care, in our view, will reduce costs and improve the quality of life and prognosis of patients with heart failure. Proper treatment avoids unplanned hospitalizations associated with heart failure exacerbations, for example.

Treating these patients is a complex process, some of which can be done in the primary care setting (POZ). In the model described below, part of the treatment will take place in the primary care setting - e.g., appropriate patient education regarding recommendations for lifestyle changes, such as physical activity, diet, and use of stimulants. On the other hand, periodic support from a cardiologist specialist is necessary to optimally treat patients according to the latest regimens suggested by world scientific societies. Part of the contact with the healthcare system can be based on e-health solutions, e.g., e-consultations supplemented with data from the patient's weight and blood pressure monitor. Ultimately, some visits will take place in-person, as it is important to remember that telehealth has its limitations and that the physical examination remains a valuable tool in the hands of the physician.

Based on the available scientific data and the analysis of possible solutions, the working group working on the "Cardiology" solution has, in previous reports, proposed applications that could find their place in the conditions of the Polish healthcare system. In reference to the arrangements with the ordering party, this document discusses the pilot stage in a more detailed and complete way and refers to the stage of implementation on a national scale.

Model description

a. Substantive assumptions

We recommend that the target solution be a platform integrated with available and continuously developed by the Ministry of Health e-health elements in Poland (patient.gov.pl, gabinet.gov.pl). The aim of implementing the described care model is to prevent heart failure exacerbations and cardiovascular deaths. Through thorough care and an educational panel, emphasis will be placed on prevention. The pilot program will use a dedicated online platform to coordinate activities around the patient and as an educational tool for patients. It is intended that the platform will allow for the capture and management of medical data by physicians and nurses, as well as provide a tool for service delivery i.e., e-consultation, remote monitoring. According to our analysis, the model of care described in this document is possible to develop and implement with the cooperation of centers that have extensive experience in the management of patients with heart failure, as well as in employing world-class specialists. Staff competencies should relate to: knowledge of how the healthcare system works, knowledge of the pathways a patient takes, as well as legal and financial constraints. In addition, people involved in the pilot should be proficient in IT, preferably with experience within telemedicine applications. Individuals working on the project should also have the background necessary for the implementation of the project. The facilities include the ability to operate telemedicine tools and accommodation conditions that can be dedicated to these people. One of the requirements is availability and readiness to react in case of an urgent need for help. The value will also undoubtedly be the ability to benefit from international experience, so it will be easier to adopt solutions from outside the Polish health care system.

Taking into account the above requirements, it should be expected that the pilot project promoter will have adequate organizational experience and technical facilities. It is advised to document the possibility to act within a business consortium with partners from IT, social sector, partner

organizations, as well as to act in agreement with a partner from Norway, who will guarantee looking at the program from a different perspective.

The implementation of the pilot projects should be supported by prevention and information activities, both on the side of the specialist centre and of the primary healthcare facility (POZ). The scope and range of these activities should be adjusted to the geographic area covered by the pilot, target groups, as well as the type of information and goals to be achieved.

The recommended prevention activities include: leaflets, posters, advertising spots, organization of at least two conferences (including content addressed to patients), training materials, webinars, instructional videos, publications, educational meetings addressed to potential patients.

These types of activities are intended to raise awareness among both medical personnel and patients about heart failure-related diseases.

One of the elements of the pilot is an Internet platform - one of its necessary functionalities will be an educational tab for the patient, which should contain information related to the course of treatment, but also prevention of heart failure-related diseases, with particular emphasis on the issues to which the model is dedicated.

A dedicated website with a promotional panel should also contain informational and educational content as part of activities supporting prevention.

In addition, leaflets, posters and advertising spots will be created for the promotion and implementation of prevention and education activities. Their role will be to raise patient awareness of cardiovascular diseases and support patient recruitment.

Educational and promotional materials created for the programme (training materials, instructional videos, educational meetings aimed at potential patients) should also contain content related to prevention.

When publicising the results of the pilot through publications, webinars and materials for conferences and websites, aspects related to the broader prevention of heart disease should also be addressed.

Model description

b. Technological assumptions

The described pilot is a proposal of using an Internet platform that will allow the patient, doctor and nurses to coordinate the treatment process, patient's condition and consultations. The platform should be selected from market offers or created from scratch by the program leader. In addition, the platform will be a tool to collect data on the treatment process. All technical requirements will be elaborated during the project implementation phase. Nevertheless, most of the assumptions are presented in this document. In addition, it seems to be a good opportunity to collect data for population analyses and, based on this, further optimization of the healthcare system. The platform must have certain functionalities:

- Accessible through a web browser
- Adapted for use by mobile devices (creation of a dedicated mobile application or extension of available mObywatel applications etc. to be considered)
- A mechanism to enable registration and login with confirmation of patient identity. Alternatively, if it is integrated with the patient's account at www.pacjent.gov, there will be no need for it.
- The whole system should be supported by a dedicated tutorial so as to support older users in moving on

- The whole system should be extensive but at the same time as simple as possible so that users are able to use it. Large, clear fonts and limiting additional links are preferred. The system will be selected from the offers available on the market or created from scratch by the project leader.
- An "assistant/guide" function for people who have difficulty operating independently. This function consists in enabling access to specific data and the possibility of entering them for an authorized person - assistant/mentor.
- More advanced features should be available as optionals when you go to your account.
- Data security is a very important aspect - tests conducted by an external company specializing in this field will be required
- An educational panel should contain basic information about the pathophysiology, symptoms and treatment (including validity of treatment, diet, physical activity, etc.) of heart failure for patients.
- A panel where the patient will be able to add his or her parameters (weight, blood pressure, heart rate) or view also in the form of graphs the parameters that have been imported from dedicated devices
- Provide the ability to upload the patient's medical records, as well as notes from individual contacts with a representative of the health care system
- In the event that a consultation is needed with a primary care provider, an outpatient cardiologist, or a hospitalist, the physician and nurse must have access to the data on the platform

c. Economic assumptions

Currently there are about 1.5 million people with heart failure in Poland. According to the forecasts of specialists, this number will constantly increase. It is obvious that not every patient will be interested in participating in the presented project. Nevertheless, the number of people requiring care is undoubtedly enormous. It should not be overlooked that with the aging of the population and parallel advances in the management of heart attack patients, the number of patients with heart failure will increase. Moreover, more and more people will be able to benefit from telemedicine solutions. Given the above, a steady increase in the number of stakeholders in this program is expected. A sample cost calculation for the pilot is shown below:

- IT costs, including:
 - a. the duration of the project
 - b. the number of roles on the platform (doctor, nurse, patient)
 - c. the capabilities of the platform (including integration with weight and blood pressure monitors and automatic data transfer)
 - d. delivery of notifications and messages (organizational and educational)
 - e. management of schedules of individuals involved in the project
 - f. creation of notes after visits

g. possibility of audio-video communication

h. generating reports

- The cost of creating the service and making it available for the duration of the pilot will probably amount to 400 000 zł. The amount was estimated on the basis of experience and preliminary market research of the authors of this study. This amount includes the delivery of the platform by an external company, preparation of surveys for patients, graphic support, maintenance and support in case of problems with the platform.
- Given that not every patient has a computer/tablet with internet access, some funds should be allocated to ensure that they can participate in the pilot by having access to such a device. We estimate that such a need will arise in the case of about 50 patients. This estimate is based on the clinical experience of the authors of the present study. The cost per patient is 2000 zł, so the total cost will be 100 000 zł.
- Another expense will be the purchase of computers for primary care doctors, cardiologists and nurses. The cost of one computer is 6000 zł. Number of required devices: 15 (approximate quantity, may change). Total cost: 90 000 zł. Please note that the purchase of equipment may constitute up to 37% of the project value.
- In addition, it will be necessary to purchase 500 dedicated scales and pressure gauges. The price of the set will amount to 250 zł. The total cost: 125 000 zł.
- You also need to take into account the costs of implementing the solution - about 10 000 zł per each primary healthcare facility (POZ). The implementation costs include the installation of equipment, organizational and training meetings.
- The project requires a dedicated website with a promotional panel and its regular management - estimated cost is 30 000 zł.
- In addition, leaflets, posters and advertising spots will be created for promotion and implementation of preventive and educational activities. Thanks to this, patient recruitment should run smoothly and patients should be eager to join the program. The total cost of will amount to about 60 000 zł.
- Costs related to the provision of medical services are as follows:
 1. cardiologist – 250 zł per visit
 2. primary care physician – 200 zł per visit
 3. a nurse - 150 zł per visit
- Under the program, a patient will have 1 visit to a cardiologist, 2 visits to a primary care physician and 1 visit to a nurse - total cost of visits per patient is therefore PLN 800. With the suggested number of patients equal to 500, the total cost of medical visits will amount to: 400 000 zł.
- As part of the project, patient satisfaction will be assessed - the cost of the forms and their conduct is approximately 6000 zł.
- Educational and promotional materials will be created for the program (training materials, instructional videos, educational meetings) - the estimated cost of this task is 40 000 zł.
- Remuneration for persons comprising the Pilotage Management and Evaluation Group - task-based remuneration. Tasks will include e.g. training of primary healthcare facility (POZ) physicians, nurses, cardiologists, assessment of the feasibility of implementing the program on a wider scale, assessment of the coherence of the described project, assessment of the level of satisfaction of individual users, publication of the obtained results (publications, webinars,

materials for conferences and websites), legal and IT support, etc. Among the members of this group there will be several cardiologists who will supervise the project, conduct trainings, be responsible for legal support - the estimated cost is PLN 600 000. The estimated amount may eventually be less. At this stage precise calculations are not possible. Each expense will have to be conscientiously recorded and accepted by the payer.

- Cost of participation of patient organizations - support in implementation and improvement of the program - PLN 80,000.
- Optional: cost of participation of the Norwegian partner who will support the Polish side, consult and advise on the project - PLN 100,000.
- Optional cost of travel of project participants (meetings with the Norwegian partner) - approximately PLN 50,000
- Cost of project management - 10% of the total budget

In summary: the project cost should be approx: 2 200 000 zł (the value of the pilot project may range from 200 000 - 675 000 EUR). The final value of the project depends on the number of examined persons, the number of cooperating primary healthcare facilities (POZ) and the scope of cooperation with the partner and patient organization.

d. Legal requirements

- Patient's consent to the processing of personal data

Participation in the described project involving the use of a telemedicine system to coordinate and support the care of patients with heart failure requires that the patient give their unambiguous and informed consent to the processing of personal data in a broad sense, including health information. Obtaining informed and explicit consent from the patient will mandatorily be the first step of care. According to recital 32 of the preamble of the GDPR, it is indicated that consent can be given by "(...) ticking a checkbox while browsing a website, selecting a technical setting, or any other statement that indicates without doubt that the patient has accepted the proposed broad processing of personal data (...)". Nonetheless, we propose that the patient's consent to the processing of personal data and to participate in the pilot be expressed in writing, in a dedicated document prepared in advance. Alternatively, in exceptional circumstances it may be possible to give consent by ticking a box on the website as shown below:

I consent to the processing of my personal data regarding ..., for the purpose of ..., in accordance with 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 and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation) - GDPR and in accordance with the information clause attached to my consent.

I consent

Date and signature of the patient

- Information obligation of the controller of personal data

According to Article 13 of the GDPR, "if the personal data of the citizen to whom it relates are collected directly from that person, the controller, when collecting the personal data, is obliged to provide the information enumerated in the aforementioned provision. It follows that the controller should make available an information clause which will contain the information specified in the

content of Article 13(1)(a-f) of the GDPR. Their content should be provided to the user before they complete the questionnaire. In the described pilot program, it is suggested to include the information clause in a dedicated document that will be attached to the patient's written consent to the processing of personal data. Alternatively, if the patient proceeds to complete the form via the website and gives consent to the processing of personal data by ticking a box, then it is possible to include the information clause in the relevant tab on the website. The analysis of used, similar solutions globally indicates that the information clause is most often included on the website, in a dedicated tab with the proposed name "privacy policy". We suggest that information about data processing be properly segregated and titled instead of placing an incomprehensible string of definitions and clauses referring to individual pieces of legislation. The final version of the document will be prepared by the Pilot Management and Evaluation Group. It is important to remember that the overriding goal is to provide accessible and understandable information to users (i.e., mainly elderly people, often not familiar with intricate legal issues).

- Patient consent for examination and other health services

Given that probably most of the participants in the pilot will be seniors, it is very important to give informed and consent for the examination and provision of health services. Given the fact of patient autonomy, the principle of consent for health services is very important. The capacity to consent means the ability to decide for oneself whether to undergo or refuse a health service. Pursuant to Article 32(1) of the Act of 5 December 1996 on the professions of physician and dentist (i.e. Journal of Laws of 2021, item 790), "a physician may perform an examination or provide other health services, subject to exceptions provided for in the Act, after the patient gives his/her consent". An analogous provision has been included in Article 17(1) of the Act of 6 November 2008 on Patient's Rights and Patient's Rights Ombudsman (i.e. Journal of Laws of 2020, item 849), according to which a patient has the right to express consent or objection to an examination and provision of other health services - including medical treatment. It should be emphasized that the full capacity to consent and/or object is held by adults who are not incapacitated by a court judgment and at the time of consent or objection have the actual capacity to make an invalid declaration of will. If health care services are of ordinary risk nature, the consent for health care services may be given orally or conclusively - i.e. through conduct that does not raise doubts as to the content of the will (cf. Art. 32 par. 7 of the Physician and Dentist Professions Act). In the case of services of higher risk, the consent must be expressed in a specific form - i.e. by submitting a written statement (Art. 34 par. 1 of the Physician and Dentist Professions Act). At the same time it should be emphasized that the law does not define the catalogue of ordinary and increased risk activities, which means that the classification of activities to the appropriate group depends on the doctor's decision each time. In the described telemedicine model, the consent should take the form of a document signed by the patient. The consent should contain information about the examination, its specifics, planned medical services, as well as benefits and risks for the patient resulting from taking or not taking the planned actions. The patient should receive both a copy of the consent and a document describing the planned procedure. The duty to inform, as mentioned above, results directly from the content of Article 31, section 1 of the Physician and Dentist Professions Act and Article 9, section 2 of the Patient's Rights Act.

- Guidelines of the Supreme Medical Council for providing telemedicine services

Resolution No. 89/20/P-VIII adopting guidelines for the provision of telemedicine services was adopted on July 24, 2020. The document was prepared by a team of experts from the Supreme Medical Council on Telemedicine in conjunction with the Telemedicine Task Force and was created to provide support to physicians when providing telemedicine services. The resolution has an appendix consisting of three parts. The Guidelines relating to the provision of telemedicine services is the part that addresses legal

requirements related to the processing of personal data, teleprompting and televising, practical issues, as well as technical and organizational aspects. Furthermore, the appendix addresses the ethical aspects of providing health services in a form other than in-person. Finally, the 10 steps of a telemedicine visit are also presented, where the individual stages of services provided with the use of telemedicine are described. It should be emphasized that the resolution adopted by the NRL does not constitute a source of law, however, it has the character of a scheme of practical conduct in the case of health services provided with the use of ICT or other communication systems.

In the case of the discussed model of care with the use of ICT, it is necessary to take into account the above-mentioned normative acts, including the Act on professions of physician and dentist and the Act on patients' rights (...), as well as the guidelines included in the resolution of the NRL, in order to proceed both in accordance with the letter of the law and good clinical practice.

Implementation and formal evaluation of the pilot model

a. Assumptions

In order to implement the described program on a large scale, it is advisable to perform a pilot program to evaluate performance and functionality on a smaller population. The authors of the study suggest using an external platform, whose functions and capabilities are described below, and costs in a previous paragraph. The project can be implemented in close cooperation with the Norwegian partner, who will support the Polish side, provide comments and participate in meetings. Participation of primary healthcare facilities (POZ) in the project is obligatory. The pilot study should be conducted in a unit selected through a competition. The requirements include:

- Specialist facilities (a team of experienced cardiologists - about 10 1 cardiologist per 50 patients) with access to outpatient and inpatient care, as well as space to provide care to a specific group of patients, conduct meetings and trainings
- It is advisable to have experience in conducting publicly funded projects in the area of health
- Academic background would be an asset
- Closely cooperating primary healthcare facility (POZ), under the care of which patients are placed after hospitalization. There is no upper limit of the number of primary healthcare facility (POZ) offices. More offices will translate into broader promotion of the project. The minimum number of POZ offices is four.
- Experience in projects with primary healthcare facilities (POZs) will be desirable
- Experience in international projects, especially with telemedicine solutions

According to the authors of the presented analysis, in order to ensure consistency, simplification and facilitation of the project management, the pilot program should, but does not have to be implemented by a single center that will be responsible for performing the project tasks and for the quality of data obtained for further studies. Around the main center there should be a large primary healthcare facility (POZ) or several smaller centers (at least 4), with which cooperation will be established. The described model will allow efficient extension of the program on a national scale, where each hospital/institute (project leader) will cooperate with several primary healthcare facilities (POZ).

b. Implementation stages

- The pilot should be supported by an information campaign aimed at promoting the project and the initiative in medical circles and among patients. The campaign should be based on dedicated, personalized telephone advertising, social-media advertising, leaflets in primary healthcare facilities (POZ) and hospitals and through a dedicated website.
- Selecting, through a competition, a hospital/institute (project leader) that will cooperate in the organization of patient care with primary care units. It is necessary to establish cooperation with external primary healthcare facilities (POZ) that will be interested in participating in the pilot of the presented study. Non-urban and excluded areas should also be taken into consideration in order to provide care not only to patients in large cities. Ultimately, at least 10% of patients will come from deprived areas. Telemedicine solutions allow to overcome geographical barriers. This stage will include informational meetings and trainings with people from primary healthcare facilities (POZ), who will be interested in taking part in the pilot. To conduct this stage effectively, it will be advisable to use educational and training materials, information leaflets, instructional videos and meetings to discuss the exact issues of the project and potential difficulties. Training must be conducted by individuals knowledgeable and experienced in telemedicine and technical solutions. Optimally, trainings should be conducted by physicians who use telemedicine solutions on a daily basis.
- The next step will be to begin patient recruitment. Recruitment will take place in both inpatient and outpatient settings following a diagnosis of heart failure. Recruitment will also be done in deprived areas and among patients with limited access to day-to-day medical services. The authors expect that most patients will be enrolled in the study during hospitalization for an exacerbation of chronic heart failure or a de novo diagnosis of heart failure. The planned population initially includes 500 patients. Based on experience, the authors of this study estimate that approximately 1,500 patients will need to be screened to recruit 500 patients, keeping in mind that the final decision to participate in the project rests with the patient.
- This will be followed by meetings with patients' representatives (3 meetings) and meetings with centers that care for patients (1 meeting with each center). The subject of the meetings will be the expectations and observations of patients and discussion on solutions that can potentially be applied. Each meeting will include a presentation of the program to date, the major benefits perceived, as well as objections. Each objection will be discussed separately and together the meeting participants will try to work out a solution. The exact course of the meeting depends on the difficulties encountered, so at this stage the description of this subsection remains descriptive. It is the task of the management group to remain flexible and responsive, so no detailed meeting agenda is presented.
- Finally, an evaluation and analysis of the implemented solution will be conducted. Patients' quality of life, prognosis, control of cardiovascular risk factors and cost analysis will be taken into account.
- Finally, the feasibility of applying this solution on a large, national scale will be analyzed, provided the results of previous analyses are positive. The Norwegian side will be asked to assist, if a cooperation with the Norwegian partner can be established. The Norwegian partner will be asked to look at the topic from a different perspective and identify potential strengths and weaknesses of the implemented project. Then, on the basis of the developed results, it will propose a scheme for implementing the solution on a large scale. Please note that if you do not find a Norwegian partner, the project must be implemented without its support. That is why the partner's participation in this project is described as an advisory body and not as a main contractor. If necessary, it may be necessary to analyze for possible changes in the project depending on the progress of the project and taking into account the possibility of changes specified by the regulations of the Norwegian Financial Mechanism 2014-2021.

c. Detailed description of the pathway

The care of patients with heart failure requires a coordinated inpatient and outpatient approach. The goal of this approach is to improve the prognosis of patients, improve their quality of life and reduce hospitalizations. An appropriately designed scheme of care will save funds, as hospital visits are the most expensive method of medical service delivery. In order to enable the realization of the above assumptions, a multimedia platform is needed, which enables the cooperation of many specialists, but most of all brings the patient closer to the therapeutic process. On this platform, the following roles should be created: patient, nurse, primary healthcare facility (POZ) physician, cardiologist (both outpatient and in-hospital). Each person has specific tasks and capabilities within the platform regarding the treatment process of a patient with heart failure. The role of each member of the overall process will be discussed below.

1. enrol facilities willing to participate in the pilot.
2. training of centers on the planned procedure
3. recruitment of patients for the study.

Cardiologist

In the Hospital

The vast majority of patients with heart failure end up in the hospital, where they present mainly because of shortness of breath, weight gain, swelling and reduced physical capacity. During hospitalization, physicians seek to determine the cause of the failure to treat. Causal and symptomatic treatment is implemented. In some patients, coronary angiography and revascularization of atherosclerotic coronary arteries is performed. Individually tailored pharmacotherapy is implemented in each patient taking into account concomitant diseases. Treatment regimens for heart failure developed by international scientific societies include low-dose drug initiation followed by periodic dose escalation every 2 weeks up to the maximum tolerated dose. In this way, optimal treatment should be established. However, heart failure is a progressive and dynamic condition, making regular adjustments and changes in pharmacotherapy required. Patients with heart failure sometimes require hospitalization, e.g., for implantation of a subcutaneous defibrillator-cardioverter-defibrillator device or resynchronization therapy, which cannot take place in an outpatient setting. The role of the physician managing a patient with heart failure in the cardiology department will be to enter the patient's discharge card into the platform, with attached test results and recommended pharmacotherapy. A note for the coordinating cardiologist should also be added to the platform so that the patient is managed according to a single regimen. For example - recommended repeat echocardiogram in 3 months to assess valve function and indications for possible intervention. The patient will have access to the recommendations through their account on the platform.

In addition, in the group of patients with an implanted cardiac pacing system with telemonitoring capabilities, it is usually the laboratory in the hospital that handles the parameter readings. Based on

these, information will be able to be transmitted to the patient and to the attending cardiologist that an expedited visit is indicated, for example, to start anticoagulation treatment. Another option is to call the patient directly to the hospital, e.g., after a life-threatening cardiac arrhythmia.

In summary, the role of the cardiologist in the hospital is to stabilize the patient's condition and to set the course of the therapeutic and diagnostic process, which the patient will mostly be able to perform in the outpatient setting. In addition, the hospital laboratory will be responsible for monitoring the implantable device. However, it is important to remember that not every patient with heart failure has an implantable system.

In the outpatient specialty care setting

The second person involved in the care of a patient with heart failure will be a cardiologist who works in outpatient specialty care. It is this physician who will be the person guiding the patient. The idea is that he or she should follow the plan offered at the hospital, but may also modify it depending on the results of subsequent tests and the patient's condition. There will be two options available for the patient to contact the cardiologist: e-consultation and an in-person visit. For patients in a stable condition with no complaints, e-consultation seems to be a sufficient form of contact. In addition, the patient will report their weight, blood pressure, and heart rate through dedicated devices. Thus, e-consultation will not be limited to just talking to the patient. In case of rapid weight gain (>3kg for 2 days), abnormal blood pressure or heart rate values, contact will be initiated by the cardiologist and recommendations will be made to intensify pharmacotherapy, report for an in-person visit or hospitalization. During the physician-designated interval, the patient will come in for in-person visits for examination of the patient and reassessment regarding indications for given medications and their dosages.

The outpatient cardiologist's role will be to post notes from each visit to the platform, which will include the patient's current condition, short-term recommendations, as well as potential future plans (e.g., consideration of indications for cardioverter-defibrillator implantation). Recommendations will also be available to the patient as well as to the POZ physician, who is expected to have the most contact with the patient. A message will be sent directly to the POZ physician with a brief summary of treatment to date and regarding further diagnostic and therapeutic plans.

Despite the fact that most patients with heart failure are sooner or later hospitalized for this reason, there is also a group of patients who have not been hospitalized before. In these patients, the diagnosis has been made in outpatient care and has been optimally treated up to now. The starting point for such a patient would then be the first visit to the cardiologist under the described regimen. The remaining stages of care are the same.

Patient recruitment will proceed as follows:

- **During hospitalization:** during a hospital stay for an exacerbation of heart failure or a de novo diagnosis of heart failure, the attending physician will offer the patient participation and take appropriate consents.

- **During an outpatient visit to the cardiologist:** Some (although a minority) of heart failure diagnoses are made in the outpatient setting and the cardiologist will also have the opportunity to offer the patient participation in the study.
 - **Telephone contact:** This contact will be dedicated to patients who are registered with a primary care provider and who have already been diagnosed with heart failure. The call will consist of an offer to participate and a presentation of the potential benefits of participation.
 - **During an outpatient POZ physician visit:** Similar to the scenarios suggested above, the primary healthcare facility (POZ) physician will also have the opportunity to engage the patient in the project.
 - **After obtaining consent, the patient will be offered a visit 0**
 - **Alternatively, on the basis of promotional materials, the patient will ask the primary care physician to participate in the pilot.** In this case the role of the primary care physician will be to carefully check the inclusion and exclusion criteria and collect the appropriate documents from the patient.
- Recruitment visit (referred to as "Visit 0" in the following document) - takes place within the scenarios proposed above - optimally with a cardiologist, otherwise a cardiology consultation to develop a treatment plan for the patient by a specialist is indicated), during it:
 - Accurate communication of information regarding the pilot, potential benefits and possible risks.
 - Collection of relevant consents
 - Brief training on the use of the platform and how to use the dedicated tutorial, or where to seek help in case of technical problems
 - Supervise the patient during the first sample measurements of body weight, blood pressure and heart rate.
 - Inform the patient of his/her current condition, risks, prospects and plans for further management.
 - This will be followed by Visit 1 in the primary healthcare facility (POZ) setting after one month \pm 5 days
 - This visit will be a typical medical e-consultation, during which the patient's reported vital signs, symptoms will be assessed. At the end of the visit a note will be posted on the platform with further recommendations for the patient.
 - If there are any alarming symptoms, the patient will be referred for an expedited cardiology consultation or directly to the hospital emergency room depending on the patient's condition.

Primary Care Physician

The primary care physician will follow up on the recommendations provided by the cardiologist upon discharge from the hospital or the cardiologist working in the outpatient specialty care setting. The role of the primary care physician will be to care for the patient's health, periodic checkups and tele-visits to complement specialty care. The POZ physician, as part of his or her activity, will be able to change medication dosages or add or discontinue individual medications. It is important to note that the cardiologist will be the attending physician, however. The primary healthcare facility (POZ)

physician will also assist the patient with prescriptions. If there is a gradual, steady deterioration in the patient's health, the physician will be able to request an expedited visit from the cardiologist or hospitalization, as appropriate.

It is important to remember that the role of the primary care physician is not limited to treating only cardiovascular disease. The primary care physician must care for patients' health in general and look at it from a broader perspective. Therefore, the primary care physician coordinates treatment with other specialists (e.g., pulmonologists, oncologists, gastroenterologists, etc.). Patients with heart failure are usually patients with multiple burdens, and patient care should not be limited to just one disease entity. The platform will also include information about other, parallel treatment processes, so that the cardiologist will take into account, for example, oncological treatment and related planned hospitalizations,

The primary care physician will also be able to access the platform with reports prepared by the patient regarding their blood pressure control and weight, which is expected to facilitate patient care.

Nurse

The nurse consultation will take place 2 months after the start of the pilot. In Poland, the role of nurses in coordinated care programs is neglected, despite the fact that such support has proven its effectiveness in clinical trials conducted in our country and around the world. The role of the nurse as the person who completes the whole program is very important. Nurses as contact persons mainly by telephone interview the patient according to a previously prepared form. Simple algorithms are used to assess whether the patient requires urgent outpatient or inpatient care. In addition to making sure the patient is not currently experiencing alarming symptoms, a very important role of nurses is patient education. Regular and meaningful education has been proven to improve patient prognosis. This is because patients with a better understanding of their disease are more likely to follow their doctor's orders, take their medications more regularly, and avoid factors that can exacerbate chronic heart failure. Therefore, after completing the form, the second part of the nursing televideo will be patient education. Information for the patient should be individually tailored based on the patient's burdens and comorbidities. For example, a patient who smokes cigarettes should be told that nicotine is very harmful to the cardiovascular system. On the other hand, a patient without diabetes does not require information on maintaining a blood glucose profile. The final step in the conversation should be advice on the patient's nutrition, also adjusted according to the presence of other diseases. Thanks to such a visit, which will be recorded on the platform, the patient will remain under constant medical care, will receive a series of educational messages and will have a sense of active participation in the healing process. After each e-consultation, the nurse will post an entry on the platform with information about what the conversation was about, what the patient was educated on, and the result of the prepared form along with a conclusion (e.g. patient referred to a cardiologist on an elective basis/patient does not require an expedited visit/patient referred to the hospital emergency room)

- Finally, there will be a final e-consultation to the primary healthcare facility (POZ) physician (visit 3) 3 months after the start of the pilot.
 - It will be a typical e-consultation with assessment of reported parameters and patient's condition. The patient will receive detailed recommendations for further treatment.

During this visit endpoints of the project will be assessed including quality of life, prognosis, frequency of unplanned hospitalizations.

d. Inclusion criteria

Patients who meet the following criteria will be included in the project:

- Age \geq 18 years
- Written or electronic informed consent to participate (in accordance with applicable law)
- Diagnosis of heart failure

It is important to consider that heart failure patients are typically seniors and their ability to use the web platform/mobile app varies. Given this fact, it will be acceptable to support a caregiver (e.g., son/daughter/wife/husband, etc.) in using the platform and assisting with training on how to use the platform, as well as with educational training. Of course, the above scenario should take place with the informed consent of the study participant. In order to minimize the risk of excluding some patients without a technical background, the project provides the possibility of lending a computer/tablet to the patients and providing access to the Internet. As the project assumes its universality and possibility of extrapolation to the general population, the exclusion criteria were not described in the project. The intention is to target as large a group of heart failure patients as possible.

e. Defining the roles/activities of the various entities involved in the project

1. patient +/- caregiver

The patient remains the most important person in the whole treatment and diagnostic process. It is the patient around whom the whole comprehensive care program will be built, but also how he or she uses it will determine his or her prognosis. The aim of the project is to use telemedicine solutions to bring the patient and the healthcare system represented by nurses, primary care physicians and cardiologists closer together.

Most patients will begin the care program with hospitalization for heart failure. In their case, medical recommendations will be placed on the platform so that the patient can access them at all times. Already during hospitalization, they will be informed about the suggestion of regular measurements of blood pressure, heart rate and weight from the first days after hospitalization. The parameters will be entered into the platform automatically - after synchronization with blood pressure monitors and scales or will be entered manually - depending on the equipment provided by the payer. By the time a patient is seen by an outpatient cardiologist, the cardiologist will have monitored the reported parameters to minimize the risk of another heart failure exacerbation between hospital discharge and the first outpatient visit to the specialist. Alternatively, if the diagnosis is made on an outpatient basis, without hospitalization, the patient will receive all information in the outpatient clinic. The patient will be instructed on the roles of specific members of the team caring for him or her. As a result, he or she will know who to contact with a particular problem. For example, basic educational issues can be addressed by the nurse. For prescription renewals, the patient will be referred to a primary care physician, and with results of specialized lab tests to a cardiologist.

Educational materials will be placed on the platform so that the patient can find out information on their own from a reliable source, which can then be clarified during the visit. In addition, to increase patient engagement, quizzes based on the available materials may be considered to encourage patients to read the materials thoroughly.

The premise of the entire program is to surround the patient with care so that they will accurately follow the doctor's recommendations, adhere to healthy lifestyle principles, and understand why the steps are so important. There is ample scientific evidence to show that a better informed patient is more engaged in the treatment process, which directly translates into patient behavior.

- The patient is recruited at the hospital or by an outpatient cardiologist, or possibly by a primary care physician. Patients are not recruited on a district basis - they may be treated in a facility that is not closest to their place of residence
- After obtaining the patient's consent, the recruiting doctor conducts training on the use of the Internet platform, goals and objectives of the project
- The patient is advised to take regular vital signs measurements and report them to the platform.
- The patient is advised to use the platform especially for education
- The patient can find on the platform dedicated medical recommendations

2. PRIMARY HEALTH CARE (POZ)

1. role of primary care will be screening and recruiting patients and providing care to a group of patients recruited by cardiologists

2. contact with potential participants (patients), provide information about the project

- Conducting the **Initial Visit** includes:
 1. referral to a cardiologist in the absence of previous contact with a specialist
 2. follow up of recommendations given by hospital or outpatient cardiologist
 3. to be informed of the objectives of the project
 4. obtain informed consent
 5. Provide training in the use of the platform
 6. provide general lifestyle recommendations: including diet, physical activity, stimulants, etc.
 7. monitoring of reported vital signs, checking alerts (the system will alert the physician when critical values are reached (e.g. very low blood pressure). If necessary, the POZ physician will be the first person to intervene by modifying pharmacotherapy or referring the patient to a cardiologist or hospital emergency room. Cardiology consultation should take place within 48h of the indication for intervention.
 8. mediate between patients and IT staff when there are problems with the platform.

3. Highly specialised outpatient cardiology consultation

1. develop a management plan for the patient. Treatment of heart failure is a dynamic process that requires constant adjustment of medication doses. Once a treatment regimen is established, it can be referred to the POZ physician for implementation and continuation.
2. 2scheduling of specialist check-ups.
3. 3consultation of patients whose problem requires specialist consultation, i.e. patients referred by the POZ physician
4. 4consultation with the POZ physician of results about which the POZ physician is not sure, but which do not require specialist consultation.
5. on the basis of the available data, the cardiologist decides whether the visit can take place by e-consultation or whether the patient should attend an inpatient appointment.

4. Management and evaluation of the pilot (chosen by the implementing center)

Provide training and supervision to the POZ physicians, cardiology clinic and hospital on:

- Lead the program, including consideration of collaboration between units. Being a coordinator and mediator between units.
- Utilizing and maintaining the online platform. Remaining responsive to make any changes during the course of the program.
- Lead the treatment process for patients with heart failure
- Conduct surveys to assess the needs of users (patients, nurses, and patients) with respect to the proposed platform
- Assessing user satisfaction with the pilot through regular surveys
- Assessing the feasibility of applying the tested solution on a wide, nationwide scale based on the analyses performed
- Evaluate the consistency of subsequent stages and seek opportunities to optimize the project in organizational, health and financial terms
- Summarize the prognosis and perspectives of patients participating in the pilot with respect to the use of the care model, its cost-effectiveness and benefits for patients
- Promoting the project by publishing encouraging results, posting information about the project on social media, as well as in scientific journals, thus giving the project credibility in the eyes of experts
- Legal support - being ready for potential challenges in the form of constantly changing legal regulations in Poland and the European Union. Being ready for potential lawsuits from dissatisfied patients.
- IT support - responding on an ongoing basis to the problems of patients as well as nurses and physicians through both ad hoc actions and targeted changes in the system
- Regular (at least every 6 weeks) consultations with the Norwegian partner (if applicable) in order to optimize the piloting and regularly improve the implemented solutions
- Norwegian partner - optional participation
- Substantive support of the Polish side in the project implementation
- Different perspective will allow for optimal management of challenges that will arise during project implementation
- Regular provision of comments and objections to the Polish side activities
- Active participation in online meetings
- Identify benefits and risks of the final implementation plan

- Identify potential areas for optimization
- Indication of potential actions improving prognosis of patients within the developed model of care
- Develop an independent cost-effectiveness analysis

f. Detailed rules of cooperation between particular entities

- o Conducting organizational meetings (the form of the meeting depends on the epidemiological situation) of the Pilot Management and Evaluation Group with physicians from the hospital. The following issues will be addressed during the meeting:
 - Discussing the methodology and assumptions of the project
 - Presentation of the principles of cooperation between different parties in the project
 - Introduction to the use of the web platform, around which the project will be run
 - Summary of the principles of care for patients with heart failure with particular emphasis on activities that improve prognosis and quality of life of patients
- o Conduct an organizational meeting (format dependent on the epidemiological situation) of the Pilot Management and Evaluation Group with POZ physicians
 - Discussing the methodology and assumptions of the project
 - Presenting the principles of cooperation between individual parties in the project
 - Introduction to the use of the www platform, around which the project will be conducted
 - Summary of the assumptions of care for patients with heart failure with particular emphasis on activities that improve prognosis and quality of life
- o Conduct an organizational meeting (format dependent on epidemiological situation) of the Pilot Management and Evaluation Group with outpatient cardiologists
 - Discuss the methodology and objectives of the project
 - Presentation of the principles of cooperation between the various parties in the project
 - Introduction to the use of the web platform, around which the project will be conducted
 - Summary of the objectives of care for patients with heart failure with particular emphasis on activities that improve prognosis and quality of life
- o Conduct an organizational meeting (format dependent on the epidemiological situation) of the pilot management and evaluation group with nurses
 - Discuss the methodology and objectives of the project
 - Presentation of the principles of cooperation between the different parties in the project
 - Introduction to the use of a web-based platform around which the project will be run
 - Summary of heart failure care with a focus on interventions that improve prognosis and quality of life for patients
- o Management and evaluation group meetings for the pilot with hospitalists, outpatient cardiologists, PCOZ physicians and nurses (meetings +/- once a month) to assess performance to date and any difficulties encountered
 - Discuss the patient recruitment process
 - Discuss the benefits and difficulties of using the web platform
 - Presentation of potential solutions for encountered problems
- o Collaboration between POZ physicians and outpatient cardiologists to:

- Discuss results of concern to the POZ physician
- Present patients who have already been referred to a cardiologist
- Presentation to the primary care physician by the cardiologist of the patient's treatment goals and guidelines for their implementation

o Cooperation of nurses with physicians

- With physicians of primary care - in the case of patients with a specific result in the form of evaluation of patient's symptoms, where it is advisable to consult the doctor of primary care
- With cardiologists - in the case of patients with a specific result in the form evaluating patient's symptoms, where the consultation of a cardiologist is indicated

o It is advisable for nurses and physicians to contact the IT site when encountering problems or difficulties reported by patients. A platform should be created for error reporting, where IT will present the progress of the task so far. In case of urgent problems (e.g. system does not work at all) the possibility to contact IT representative by phone is advisable.

o Possible ongoing collaboration between the pilot management and evaluation group and patient representatives (patient organization) to:

- Accurately understand the needs and requirements of patients entering the program
- Jointly analyze the results obtained by the project
- Work with patient organizations to publicize and promote the project and its results.
- To make the program as patient-centered as possible. The aim of the project will be to improve the quality of care in all areas, therefore the recommendation to collaborate with the patient organization is emphasized.

o Cooperation between the pilot management and evaluation group and the Norwegian partner in order to consult and exchange on the developed and implemented solutions within the project

g. Technical and organizational requirements

- All project members (doctors, nurses, patients) should have a computer/tablet with permanent internet access
- If it is not possible to meet the above requirements, it is possible to borrow the device free of charge within the framework of the pilot study
- Borrowing free of charge for patients a scale and a blood pressure monitor, whose measurements will be synchronized with the platform, or the patient will manually transfer the results to the platform
- A web-based platform for e-consultation, uploading of patient health notes, storage of vital signs from the scale and blood pressure monitor, as well as consultations between different representatives of the healthcare system.

Given the assumptions presented, the authors of this study assume that the pilot is feasible and will be associated with numerous benefits for study participants.

Patient:

- Facilitated access to educational materials

- Greater patient engagement in the treatment process translates into better adherence to medical recommendations and improved prognosis
- Real systemic support for seriously ill patients
- Increased self-awareness, especially with regard to heart failure
- Improved quality of life
- Comprehensive care for patients with heart failure
- Efficient acquisition of data for subsequent analyses enabling scientific publications as well as optimization of the solution
- Bringing the patient closer to the healthcare system
- Networking between primary care physicians, specialist clinics and hospitals
- Developing international care

The above-described coordinated care program is based on close cooperation between numerous specialists and, above all, the patient. The tool for this cooperation should be a dedicated platform that is comprehensive and powerful on the one hand, but also simple and transparent. Patients with heart failure tend to be elderly and have varying degrees of coping. Despite this, seniors are usually not closed off to new solutions, even more so if they have a direct impact on their health and lives. Additionally, more and more young people who use computers and mobile devices on a daily basis suffer from heart failure. It seems that the potential use of telemedicine solution to support and coordinate the treatment process of the discussed group of patients is a solution that meets the needs and possibilities of the Polish health care system.

The Web platform described earlier will be a model in the field of cardiology, which will help in educating patients, coordinating their treatment and strengthening the contact between representatives of the health care system with the use of modern solutions. Implemented solutions have proven their effectiveness in large clinical trials.

As previously mentioned, according to the authors of the study, the target solution should be a telemedicine platform that would be integrated and developed together with the systems developed by the Ministry of Health (e.g. www.pacjent.gov.pl, www.gabinet.gov.pl). The platform should be used to manage medical data in an optimal way by dedicated staff. The platform would support the provision of services envisioned under the universal health insurance system. The pilot study was developed as an attempt to implement a solution using a dedicated tool on a smaller scale.

The described project will constitute a proposal to change the model of care for patients with heart failure. Any intervention of this type, is associated with the possibility of failure, but on the other hand the potential benefits of the program certainly outweigh the risk of possible failures. It should be emphasized that the advantage of a pilot study is that in a smaller, more controlled setting, potential steps that need improvement can be caught and appropriate steps can be taken when the project is applied nationwide. The pilot is intended to be coordinated by a single, specialized unit that will collaborate with the POZ offices. Thanks to the above mentioned, comfortable conditions for testing the telemedicine solution will be created. It seems that at this stage all potential problems can be faced.

In the future the benefits of the solution are expected to be felt throughout the country, but during the pilot implementation the effect will be marked locally and present only in given centers.

Before discussing the benefits in more detail, however, it should be emphasized how the described model is an alternative approach to the model of care, because so far similar solutions have not been implemented in Poland.

1. The system is based largely on the provision of services using telemedicine tools, which translates into:
 - a. Elimination of geographical barriers (e-consultation can take place regardless of the location of the doctor, nurse and patient). This will allow patients to be under constant care regardless of where they are at any given time. Also, the distance between the specialist and the POZ physician will not matter, and their consultations will be easier to carry out.
 - b. However, it is important to remember that a significant proportion of heart failure patients are elderly and may have difficulty using remote communication methods.
2. The project emphasizes coordination to improve patient prognosis and quality of life. Collaboration between units will pose a major organizational challenge. So far similar systems have not been implemented on a large scale.
3. The presented model significantly changes the role of individual users of the treatment process
 - a. The patient will be encouraged to take a more active part in the treatment process by constant contact with the doctor or nurse, taking vital signs measurements and using the www platform.
 - b. The primary care physician will become a kind of 'monitor' of the patient's health status and a person who will alert about its deterioration. Interventions taken by the primary care physician will be based on observations of patient's parameters as well as reported symptoms. Nevertheless, the POZ physician should be in constant contact with the patient even when there are no overt signs of exacerbation of chronic heart failure.
 - c. It is worth paying attention to the automation of processes - the constant permeation of systems from IT and everyday medical practice seems to be inevitable.
 - d. It is required to analyze the costs incurred by the payer and cost-effectiveness of the described solution at the pilot stage and at the stage of wider application. The model will include a change in the way services are paid for. The remuneration will be given for the monitoring of the health condition itself and not only for the intervention, which is supposed to prevent the condition requiring strong intervention.

The above points should be analyzed during the implementation of the pilot study. Nevertheless, the proposed model of care is simple and involves relatively few people (cardiologist, primary care physician, patient, nurse), so it should be relatively easy in terms of organization and finances. Consequently, according to the authors of the study, the pilot study will be a good testing ground to start changes in the health care system and implementation of telemedicine systems.

Risks associated with the implementation of the model

The risks that are associated with the implementation of the pilot study should be divided into several categories listed below:

- motivational and competency-based,
- organizational,
- legal,
- financial,
- technological,

- clinical,
- pilot phase.

The individual risks are discussed in detail below, with suggestions for managing potential problems.

1. Risks related to incentive and competency issues

- Insufficient incentives to implement the model

The described care proposal is based on cooperation between primary care units, specialist offices and hospitals. Currently, these relationships also exist but they are much looser and less organized. The practice shows that patients are simply redirected between different levels of care. When implementing a telemedicine solution, there will be a need to establish defined relationships on which the cooperation will be based. There is a lack of motivation for this type of cooperation, as both primary care units and specialist offices are overburdened and do not want to commit to further tasks. Given the above, there is a need to develop motivational mechanisms to encourage this cooperation.

Suggested measures to solve the above problem:

- Widespread information and promotion campaign signed by the Ministry of Health and/or the National Health Fund, which will be directed to health care units
- Conscientious pricing of services (to consider bonuses for a given procedure - e.g. for the first patients to complete the program)
- Reluctance of seniors to change and use new technology - some people are reluctant to use new solutions. On the other hand, nowadays even seniors are eager for alternative methods that will provide them with better care and improve their prognosis.
- A large-scale information and promotion campaign signed by the Ministry of Health and/or the National Health Fund, which will target potential patients.
- A large-scale information-promotion campaign signed by MoH and/or NHF, which will be conducted in POZ, so that the information will be credible.

Lack of necessary skills to operate and freely navigate the WWW platform

Suggested mitigation/prevention measures:

- Simplified scheme for account creation and login
- Access to a tutorial to help with account creation and operation
- Allowed participation of a mentor who can assist in using the platform
- Instructional videos for patients
- Ongoing access to support from IT, should technical issues arise.

Patients are likely to have concerns about sharing their personal and health information online

Suggested mitigation/prevention measures:

- Ability to contact the data controller at all times to clarify concerns about submitting their personal information
- A broad information campaign to increase trust in the project
- Access to email addresses and phone numbers of people who can clarify concerns about the management of personal and health data on an ongoing basis

2. Risks related to organizational issues

- Limited information about the project among seniors

Seniors often lead sedentary lifestyles and have limited access to medical services (difficulty using telemedicine tools). In addition, less frequent use of the internet means that seniors will have information about the project.

Suggested mitigation/prevention measures:

- Conduct a promotional campaign among the target audience - in the medical and senior communities
- Promote the project through: phone calls, flyers, posters, website
- Include caregivers in promotional channels
- Potential initial problems of the project at the start-up stage

Typical challenges that can be called "baby-age" problems of the program are to be expected in connection with the implementation of a large undertaking. Among these are likely to be differences in interpreting the information received, handling the software, or project assumptions.

Suggested mitigation/prevention measures:

Prepare uncomplicated instructions showing system operation for all roles envisioned in the project.

- Organize help-desk systems with chat and telephone capabilities, which are often more valuable for older people
- Challenges in cooperation between units during project start-up

The presented project is an example of a new approach to cooperation between POZ physicians and specialists, which has not been popular in the health care system in Poland so far. Due to the need to establish new contacts, support will be required in organizing a network of cooperating units and health care system representatives.

Suggested mitigation/prevention measures:

- Support from MoH and NHF in searching for partners - possible identification of potentially interested centers. It is also worth noting that in view of the busy workload of both primary care physicians and cardiologists, finding enough physicians to support the project may be a challenge.
- The challenge of cooperation between units during the project

Collaboration between the various parties in the project should be considered in the category of a financial and organizational challenge, as such collaboration is not promoted in the current system of billing for services. It would be beneficial to change the approach to pricing procedures to include paying for preventive activities and rewarding collaboration between the aforementioned parties.

Suggested mitigation/prevention measures:

- Development of a model for cooperation between centers (model contracts between partners)
- Transfer of developed schemes which have been proven to work in practice between centers
- Carry out a campaign and training on the best available model of cooperation
- Proposing a change in the valuation of the cooperation in question, taking into consideration rewarding cooperation and prevention

3. Legal risks

- Patient's consent to medical examination and health services

One of the fundamental principles of Polish law is to take into account the autonomy of the patient to give consent or domination for the provision of health care services in the case of adults who are not incapacitated. Adequate consent for a medical procedure is a legal condition for the legality of medical treatments. Furthermore, the patient, by giving informed and informed consent, takes the risk of possible adverse events resulting from the medical procedure upon himself. That is why the patient should be given full and accessible information about his/her condition, treatment options and the consequences related to each of them. However, there are no unambiguous requirements concerning the form in which such information should be provided. Optimally, full information should be provided to the patient in writing by a medical professional, and it is advisable to discuss any concerns the patient may have. This is an important element that causes the patient to make an informed decision and also an element that releases the physician from a charge of illegal action. Oral explanation is very important because, as practice shows, only a small percentage of patients read and familiarize themselves with the information provided to them in writing.

Suggested mitigation/prevention measures:

- Prepare templates that will contain the information in question. The patient will receive it as an email, or will download the document from the website. This will give him/her time and conditions to read the contents of the file. Contact with a medical professional will be used to supplement the information about which the patient is unsure or has additional questions.
 - After receiving the information described above, the patient should give his consent or lack of consent for the provision of health care services. According to the current regulations, consent for the provision of medical services may also be given verbally.
 - Despite this, there will be an emphasis on receiving consent in writing, so a consent document should be prepared for the patient. One copy will be given to the patient and the other copy will be kept at the facility. Signing the consent in person does not seem to be a problem, as the first initiation visit will be an inpatient visit, not a telehealth visit.
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- Obtaining patient consent for the processing of personal data

Given that the patient's consent is essential for the lawful processing of sensitive data, it is necessary to obtain consent for the processing of personal data with particular emphasis on the data entered on the questionnaire form. Before obtaining the consent, the patient should be informed about the way in which the data is collected, processed and the purpose for which it is collected. It is important that consent is kept as simple as possible and that any concerns are explained to the patient at the beginning of the program.

Suggested mitigation/prevention measures:

- Prepare consents containing all necessary clauses in as accessible a manner as possible. The documents will be available on the website, can be emailed to the patient or preferably handed over during the first visit with time for the patient to read it.
- The patient should give clear and unambiguous consent to the processing of personal data, including sensitive data. Preferentially, this consent should also be physically signed, to reduce the risk of being accused of not providing all the information to the patient.
- However, it is possible to waive obtaining the patient's consent for the processing of sensitive personal data provided that the points in Article 9.2lit. H GDPR. According to the cited provision, if for "medical diagnosis, provision of health care or social security, treatment or management of health care or social security systems and services", then personal data may be processed for the above purposes if it is processed by - or under the responsibility of - a person subject to the obligation of professional secrecy.
- Verification of patient identity

Suggested mitigation/prevention measures:

- If medical services are received via an ICT system, then identity confirmation will take place when logging into the system. In other cases, the identification of identity will be done on the basis of the identity document presented. In the case of first visits, it will be advisable to collect all data necessary for further treatment (e.g. PESEL number). During e-consultation, the patient may be asked to show his/her ID to the camera.
- Caring for the confidentiality of the e-consultation

Suggested mitigation/prevention measures:

- Any medical service should take place in a comfortable place where confidentiality is assured. There should be no other persons in the room from which the e-consultation is provided other than those necessary for the provision of the medical service.
- Keeping personal information secure

Suggested mitigation/prevention measures:

- Each entity should have security policies in place to effectively manage data security. Each employee of the entity should have appropriate authority to manage personal data. If it is necessary to transfer data to an external company, it is advisable to conclude an agreement between the data controller and the entity to which the data is entrusted.

4 Risks related to financial issues

- Incorrect pricing of the service by the payer

The service involves the introduction of the discussed assumption requires the cooperation of many people (nurses, patients, doctors, IT specialists, coordinators, etc.). It is very important to define appropriate roles in the project so that everyone can fulfill their responsibilities. Some services will probably not have to be performed by physicians, and for others there will be an indication that a physician should perform it. Therefore, there may be discrepancies between the original estimate and the final cost of the project.

Suggested mitigation/prevention measures:

- Accurate pricing of all costs that are associated with implementing the model.
 - Carefully define the roles and responsibilities of the various project participants.
 - The funding system should reward prevention and patient retention
 - It is worth noting that some of the education can be provided by a nurse, potentially reducing costs to some extent.
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- Difficulties in the implementation of payments due to the large group covered by the project

The described project requires a carefully designed financing system. It is important to recognize that the benefits will not come immediately, and savings will have to be sought from a broader perspective. Each time the payer carefully analyzes the balance of benefits and costs before financing the solution. In the absence of more detailed and thorough analysis, it may seem that the whole project does not make sense and is an example of wasteful spending of public funds.

Suggested mitigation/prevention measures:

- A very conscientious and thorough calculation of all costs, risks, and benefits of the preventive measure in the model under discussion should be conducted.

5 Risks related to technological issues

- Risks related to the production, implementation and use of the developed system
- Risks in terms of access to technology and digital literacy for heart failure patients

Ultimately, existing solutions will be used and expanded based on requirements. Consequently, data security should be ensured as these mechanisms are already in place. An important issue is the development of existing services, e.g. patient.gov.pl with the necessary functionalities. One should remember about the necessity of central approval and technical capabilities of such a solution. In addition, some patients do not have the appropriate equipment to operate the system or do not have the skills to use the proposed solutions.

Suggested mitigation/prevention measures:

- Arrangements for expansion of existing applications should be established with relevant institutions prior to the pilot so that widespread use can begin immediately after the pilot.
- The design should make provision for making appropriate devices available to those who do not have them, A very thorough patient tutorial should be created. It is acceptable to have a tutor to support in using the systems.
- A hotline should be set up to provide technical support to patients if they experience problems with the service.

6 Risks related to clinical issues

- Deficits Difficult contact due to e.g. hearing impairment or lack of platform skills, potentially making it difficult to televise

Suggested mitigation/prevention measures:

- Enabling contact with the patient's caregiver

- Thorough tutorials and a helpline with technical support for patients
- Possibility of an in-person visit if telehealth is not possible due to the aforementioned limitations.

- Incorrect information entered into the system

The purpose of the platform is to support the treatment process. Some of the questionnaires will be completed by patients who may, of course, make mistakes, which should be taken into account when making an intervention.

- Suggested mitigation/prevention measures:
- A thorough clinical assessment each time to verify the data provided
- Supervision by the caregiver

Feedback from the physician to the patient with possible suggestions of where errors may have crept in.

- Doubts of the primary care physician regarding the management and intervention of the patient after receiving the alert results of the completed questionnaires

Suggested mitigation/prevention measures:

- Opportunity to connect and obtain more accurate information and ascertain the veracity of the data provided. Talking with the patient and clarifying areas where errors may have crept in when completing the form.
- Problems with platform operation
- Suggested mitigation/prevention measures:
- Access to ongoing IT support when difficulties arise
- Tutor support
- A maximally simplified system and a powerful and intuitive tutorial tailored to the needs of seniors.

- Disease exacerbation

Suggested mitigation/prevention measures:

- By detecting the signs of a heart failure exacerbation (weight gain) early, there will be an opportunity to institute appropriate prophylaxis for these patients and anticipate adverse consequences.
- Early detection of an impending exacerbation means that there will be more time to arrange contact with the physician and implement the action needed for the patient.

7 Risks related to the pilot phase

- Risks related to the proposal of a new organization of cooperation between centers
- Suggested mitigation/prevention measures:
- Accurately establish the responsibilities of each facility and define their roles
- The training on the principles of the pilotage should be carried out so that the whole project can be organised and carried out efficiently.

- An information campaign to encourage the centers to participate
- In the initial stage, to select the best-performing facilities, which will be able to organize appropriate care for patients and set an example for other units.
- Lack of device (computer/tablet/smartphone) and/or internet access

Suggested mitigation/prevention measures:

- Possibility of lending equipment to the patient or caregiver
- Encourage patients through information campaigns that with such devices their treatment process can be optimized, which should indirectly encourage them to purchase.
- Insufficient/slow patient recruitment to the study

Suggested mitigation/prevention measures:

- Conduct an outreach campaign to promote the project with a NHF/MoH banner to patients and units potentially able to recruit patients
- Allowing more units to be included in the pilot study
- Virtually no exclusion criteria for patients from the program
- Simplicity of the program and clear presentation of benefits should encourage patients to participate
- Development of a tailor-made application compatible with central solutions

The system in question must be a complete tool which, apart from its functionality, will be characterized by high security. The risk is the very creation of the solution, because the ordering party is not able to predict the winner of the tender or its course. As a result, there is a risk of delay in the project implementation, as well as production of a product that does not meet all the assumptions. Moreover, ease of use is very subjective and difficult to define in the contract.

Suggested mitigation/prevention measures:

- Conscientiously and accurately describe the requirements in the procurement. The procurement should also include information to data security highlighting specific standards. Samples of solutions will be required to avoid unreliable suppliers.
- Provision should be made for the possibility of giving patients access to devices with internet access.
- The system should include a tutor to support the patient in the treatment process.
- After the piloting it is advisable to analyze the system and look for potential areas of improvement.
- Preparation of training (videos, leaflets) for users, so that they can use the solution more easily and effectively.

The above presented issues present potential risks and possible solutions to the problems. There is no doubt that piloting is an appropriate form of introducing the solution on a wider scale, so that there will be an opportunity to improve the flawed stages. It is undoubtedly advisable:

- Conducting a well-planned pilot
- Creation of a good system as a basis for the whole project
- Adequate information campaign to promote the whole project

Benefits of the model

According to the authors of the study, the recommended system of care for patients with heart failure will facilitate effective, efficient and cost-effective care that will improve their prognosis. Currently we do not have similar tools and even less systemic solutions to coordinate the treatment process and to organize cooperation between treatment units from different levels of care. Patients enrolled in the program are provided with comprehensive care, and their treatment process is organized and focused on a specific goal. Waiting times to specialists are clearly reduced by providing access to physicians. Despite the large number of cardiologists in Poland, the constantly growing number of patients with cardiovascular diseases means that their waiting time is very valuable and should be used in an appropriate manner.

Below we have listed the benefits of the platform and its implementation.

- Optimization of cooperation between POZ and specialist units with effective use of doctors' working time.
- Supporting a telemedicine tool that is recommended according to current guidelines and available scientific data confirms the benefits of such solutions.
- Providing the patient with a comprehensive care, thus improving his prognosis
- Support of telemedicine systems helps to identify patients who require an in-person visit and provides the rest of the patients with a telemedicine contact with a medical professional.
- Optimization of doctors' working time allows to help more patients with the best quality of provided services.
- Increasing the role of primary care physicians in the treatment process of patients with heart failure.
- Removing geographic barriers by allowing e-consultation. This will allow even those living in an area without a specialized unit to receive professional care.
- Adequate care translates into a reduced risk of heart failure exacerbation, and hospitalizations for this reason are very costly. Consequently, it seems that the proposed solution will be cost-effective.
- Availability of telemedicine solutions makes the treatment process independent of the epidemiological situation in the country - consultations can still take place regardless of the existing restrictions and limitations.
- Equalization of social inequalities in access to specialists between rural and urban residents.
- Reduction of unnecessary procedures resulting from ineffective cooperation between primary care physicians and specialists or resulting from the lack of cooperation. This translates into more efficient management of available funds.
- Reduction of errors resulting from the inability to obtain a specialist's consultation. Less medical errors translate into improved patient prognosis.
- Implementation of a project in which the patient is the most important link. It is around the patient that the program is implemented, which can be adjusted according to the expressed needs of the patient. This is in line with the recommendations of scientific societies, and is associated with tangible benefits for patients.
- Improve the care of heart failure patients with a state-of-the-art solution to their needs and capabilities.

- To organize the work of medical professionals in the form of teamwork with a single goal of improving the health of patients and fulfilling their health wishes to the extent possible.
- Improving the appropriateness of the procedures ordered for the patient - optimizing the management of funds.
- The involvement of the caregiver can improve the relationship between the caregiver and the patient by working together with a single goal of improving the patient's health.
- By removing geographic barriers, there will be no social inequities in access to medical services and procedures described in this program.
- Opportunity to collect a wealth of data for further analysis, scientific publication and optimization of the treatment process.
- Optimization of expenditure management - greater emphasis on prevention and the beginning of a trend in pricing and accounting for prevention activities, especially those that bring the desired effect.
- Expansion of existing telemedicine solutions, so that patients have easier access to medical care.
- Increase patient awareness of their diseases through an educational panel on the platform.
- Reducing costs associated with reduced hospitalizations due to heart failure exacerbations.
- Engaging patients and caregivers in active participation in the treatment process and increasing their competence in the use of telemedicine solutions.
- Development of e-health systems on a national scale taking into account the patient as the most important person in the whole process.
- Improvement of cooperation between the doctor and the patient thanks to facilitated contact.
- Transparency of the treatment process due to the assumptions for the next months of care placed on the platform.
- Improved medical access in case of chronic disease exacerbation.
- Increasing competence of medical professionals through thoughtful and systematic implementation of telemedicine solutions.
- Enabling scientific research to be conducted without a geographical barrier.

To sum up, it should be emphasized that the list of benefits is very extensive and potential threats seem to be solvable at this stage. With proper implementation of the program and taking care of the risks, all program participants should be beneficiaries. Of course, the priority is the health status and quality of life of the patient, which will guide both the authors of the project and the pilot project promoters.