

MACHINE TRANSLATION

Reducing social inequalities in health through the use of telemedicine and e-health solutions – geriatrics

Telemedicine service design: a telemedicine model in the field of geriatrics – summary

Report from Stage 4 (final version of the document)

Report prepared within the project "Tackling social inequalities in health with the use of e-health and telemedicine solutions", co-financed by the Norwegian Financial Mechanism 2014-2021 and the Polish state budget

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Glossary

- **BMI** - body mass index, a ratio derived by dividing body weight [kg] by the square of height [m²]
- **FRAIL** - a form used to screen for frailty syndrome
- **FRA-MA-SARC** (FRA - frailty, MA - malnutrition, SARC - sarcopenia) - a platform to assess the prevalence of malnutrition, sarcopenia and frailty syndrome
- **IKP** - individual patient account
- **IT** (Information Technology) - an IT discipline and industry that deals with the application of technologies such as software and hardware to everyday life
- **POZ physician** - a primary care physician
- **Local Pilot Implementation and Evaluation Team** - a team of experts in geriatrics, public health, law and IT selected by the implementing center
- **MNA** (Mini Nutritional Assessment) - a form used to assess nutritional status
- **MNA-SF** (Mini Nutritional Assessment Short-Form) - a form used for screening for malnutrition
- **MZ** - Ministry of Health
- **NFZ** - National Health Fund
- **Malnutrition** - a condition resulting from a lack of absorption or lack of consumption of nutrients, leading to changes in body composition, and thus to impaired physical and mental activity of the body and adversely affecting the outcome of treatment of the underlying disease
- **Highly specialized care** - in this study it is geriatrician
- **Caregiver for the elderly** - a person who assists an elderly person in day-to-day functioning, this may be a formal caregiver (a person with paid position and experience in such care e.g. MOPS worker, community nurse) or an informal caregiver (usually a member of the person's family,) a friend or e.g. a neighbor
- **Patient organization/association/foundation** - an organization of patients, working for a chosen interest and not operating for profit, usually arising from personal experience of illness
- **Senior citizens' organisation/association/foundation** - an organisation serving a specific interest (senior citizens) and not-for-profit
- **External POZ** - a primary care provider recruited additionally by the lead (managing) POZ and participating in the program as a supporting partner
- **PR** - emergency ambulance service
- **MOPS employee** - an employee of the Municipal Social Welfare Centre
- **Pre-frailty** (English) - a risk of developing fully symptomatic frailty syndrome
- **Medical professional** - a person who is medically trained - in this study it is a primary care physician, geriatrician, physician of other specialization, community nurse, physiotherapist, dietician or other person of related competence
- **GDPR** - General Data Protection Regulation
- **Sarcopenia** - loss of muscle strength and mass primary to age or secondary to associated conditions
- **SARC-F** - Screening Assessment for Sarcopenia form
- **SOR** - Hospital Emergency Department
- **Teleconsultation** - a consultation between physicians (e.g. primary care physician - geriatrician) for the purpose of obtaining an opinion on the patient, carried out by means of distance communication, without the simultaneous physical presence of doctors

- **e-consultation** - provision of medical services aimed at improving health, performed with the use of means of distance communication, without the simultaneous physical presence of the patient and the doctor, understood as a consultation between the doctor and the patient
- **frailty** - a geriatric syndrome in which there is a state of increased susceptibility to various external and internal stressors as a result of decreased physiological reserves of the body

Introduction

This document presents the collected results of a team of experts working on the problem defined in the project: Development of telemedicine models in the fields of cardiology, geriatrics, psychiatry, obstetrics, diabetology, palliative care, chronic diseases under the project entitled: "Tackling social inequalities in health with the use of e-health and telemedicine solutions", financed by the Norwegian Financial Mechanism 2014-2021 and the Polish State budget.

1. Description of the problem - sample clinical scenarios

To illustrate the underlying problem, the following are sample clinical scenarios that experts believe are typical of health issues facing older adults in the project area. The scenarios include a description of the situation, the problem and a brief description of the tool that could be used to solve the problem or minimize the impact of the problem.

Clinical Scenario 1

Description:

Mr. Stanislaw, 78 years old, retired teacher, resident of a town of fifteen thousand inhabitants. He lives alone in a single-family house. He has two children living a few hundred meters away. He eats meals alone. Requires assistance with heavier errands. He uses the internet and pays bills electronically. Previously, he reported to his primary healthcare facility (POZ) every 3 months for prescriptions (treated chronically for hypertension and pre-diabetes). In the pandemic, he avoids seeing his doctor in person - he uses e-consultation. He noted that the restriction of going out of the house has led him to decrease physical exertion and thus, weakness. The patient has had two falls.

Issue:

Risk of progressive loss of muscle strength, malnutrition, and development of frailty syndrome.

Solution:

Repeated screening every 6 months for the above disorders.

Tool:

- The patient logs into their individual patient account and completes three surveys. The results of these surveys assign him to one of three groups (not at risk, at risk, burdened). Mr. Stanislaw's results indicate that he is at risk for each of the listed and related geriatric syndromes.
- The patient receives feedback from the IKP, receives basic recommendations, access to the education module, and a recommendation to contact his primary healthcare facility (POZ) physician.
- After the patient gives consent (once during the first use of the modality or during a stationary visit) for the data to be transferred to his/her POZ physician, the data are transferred to the gabinet.gov.pl website of his/her POZ physician.
- During the next visit the Primary Care Physician can verify the risk assessed by the Patient and give personalized recommendations.
- If the doctor finds it necessary, the Patient has a e-consultation with the POZ physician.
- The POZ physician can discuss the Patient's problems with a geriatrician by teleconsultation.
- A geriatrician may have a specialist e-consultation with selected Patients.

Repeated assessment will provide a history of the patient's changes that will help in planning physical activity, physiotherapy, nutritional intervention and monitoring the progress of treatment. The physician in the gabinet.gov.pl portal will receive a proposal for personalized recommendations for their patient. Additionally, if the patient reports falls, they will be flagged with information about the need to refer the patient to a social worker for an in-depth analysis of their needs, housing conditions and environmental risks.

Clinical Scenario 2

Description:

Mrs. Janina, age 82, with an armchair-bed lifestyle, occasionally moves with the aid of a walker. She lives in a large city (100-500,000 inhabitants) and does not use the Internet independently. She has multimorbidity and multiple medications. She eats monotonous meals. The patient is periodically visited by her daughter who lives in another city. She is self-dependent to a considerable degree. Due to mobility limitations, she has limited visits to her POZ physician and has been functioning on a e-consultation system for several months.

Issue:

At risk for progressive loss of muscle strength, malnutrition and development of frailty syndrome.

Solution:

Repeated screening every 3 months for the above disorders.

Tool:

- The authorized caregiver logs in to the patient's IKP or to an additional feature that can be created, "www.opiekun.gov.pl", where they make an assessment using the proposed scales. The information is forwarded to the POZ physician.
- The caregiver receives feedback in the form of simple universal recommendations with information on possible actions to be implemented.
- The primary care physician gets information about the patient who does not reach him. He can prepare recommendations and select patients for periodic home visits. He or she may also provide information to the community nurse. Making the above-mentioned deficits apparent may lead to a critical review of the medications used and discontinuation of some of them.
- It is possible to create an additional online opiekun.gov.pl - where after a simplified login a member of the patient's family, a MOPS worker (visits the patient daily for 2 hours), a physical therapist can conduct an assessment which is reported as above.

2. Sarcopenia, malnutrition, frailty syndrome - scale of the problem, risks, assessment possibilities, management

Population aging and multimorbidity, disability and dependence on third-party assistance in the elderly generate increasing socioeconomic costs. This creates the need for effective prevention, rapid identification and appropriate treatment of significant geriatric syndromes. Such syndromes include, among others, sarcopenia, malnutrition, and frailty syndrome. These three geriatric syndromes are intertwined. Malnutrition is a condition resulting from a failure to absorb or consume nutrients,

leading to altered body composition, thereby impairing the body's physical and mental activity and adversely affecting the outcome of the primary disease (Sobotka L, editor. Basics in clinical nutrition. 4th ed. St.Galen; 2012). Malnutrition promotes the development of sarcopenia, a loss of strength and muscle mass primary to age or secondary to associated medical conditions (Cruz-Jentoft et al, Ageing. 2019). In turn, sarcopenia through deterioration of functional capacity is one of the factors in the development of malnutrition and frailty syndrome, a state of increased vulnerability to various external and internal stressors as a result of a reduction in the physiological reserves of the body (Fried et al. 2001, Morley et al., 2016).

Despite significant medical advances, malnutrition remains a significant and widespread public health problem in developed countries. In Europe, it affects 28% of hospitalized patients, 17.5% of inpatients and 8.5% of outpatients. The prevalence of malnutrition increases in adults older than 80 years, in women, and in patients with at least one comorbid condition (Leij-Halferk et al, Maturitas 2019). Additionally, among people living in their own households, more than 30% are at risk of malnutrition (Kaiser et al. J Am Geriatr Soc. 2010). In Poland, according to 2006 data, 2.6% of people aged 60-69 years and 5.3% of people aged 70 years and older were underweight or severely underweight (GUS Central Statistical Office, 2006. Health status of the Polish population 2004, Warsaw). The prevalence of frailty syndrome ranges from 4.9-27.3% depending on the diagnostic tool used and the population studied (Choi et al, J Am Med Dir Assoc. 2015). In Poland, frailty syndrome is estimated to affect 6.7% of the elderly, including more than 30% of those aged 75-80 years and 50% over 80 years (Sokolowski et al. J Health Sciences. 2014). Sarcopenia is responsible for approximately 70% of frailty syndrome cases (Mijnarends et al J Am Med. Dir Assoc. 2015). Sarcopenia can also occur in overweight or obese individuals - sarcopenic obesity. Despite growing awareness among physicians, efforts to standardize the proposed diagnostic tools and simplify the diagnostic pathway, still many cases of malnutrition, sarcopenia and frailty syndrome remain undiagnosed.

Preliminary data from the PolSenior2 study show the estimated prevalence of the geriatric syndromes in question in the Polish population aged 60 and older (about 8.5 million people). The estimated prevalence of malnutrition is 3.2%, risk of malnutrition 23.6%, sarcopenia 11.9%, frailty 15.9% and risk of developing pre-frailty 55.8%. (Data were presented initially at modular conferences, <https://konferencjapolsenior2.pl/>) (Figure 1).

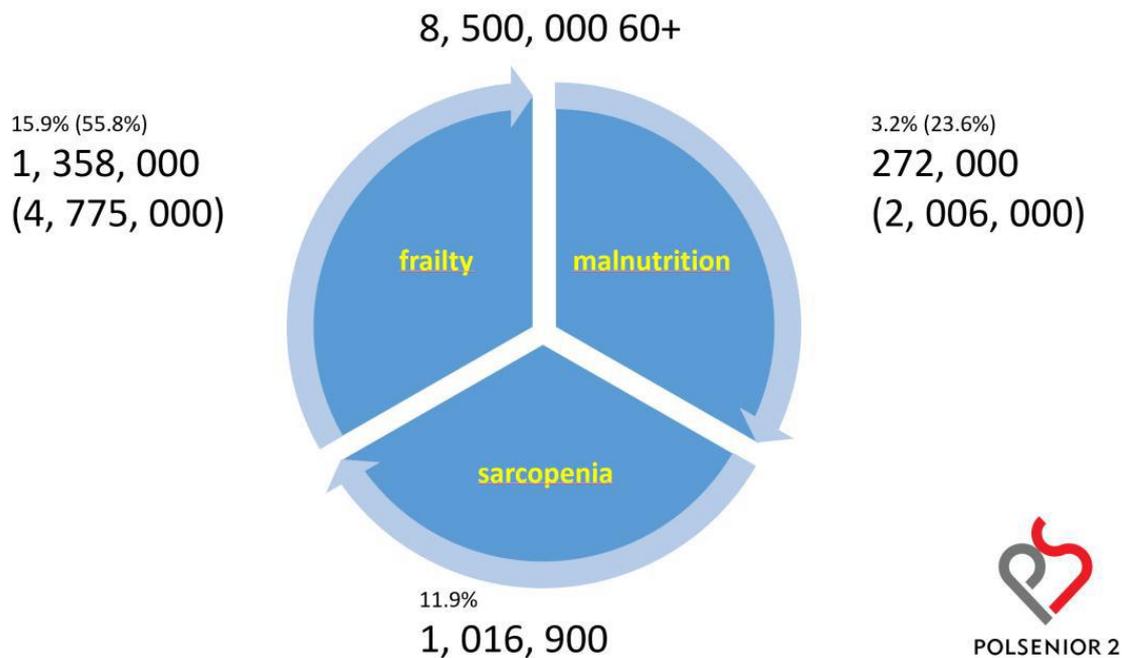


Figure 1. Estimated prevalence of malnutrition (risk of malnutrition), sarcopenia, frailty syndrome (risk of developing frailty syndrome) in the population of people 60+ in Poland. Preliminary data from the PolSenior2 study. Own modification.

In older patients, malnutrition, sarcopenia, and frailty syndrome increase the risk of complicated and more severe acute illnesses, exacerbations of chronic diseases, emergency and elective surgeries, and injuries and thus prolong hospitalization, worsen prognosis, and increase mortality. As a result of the risk of functional impairment, they promote the development of disability and increase the risk of dependence on third-party assistance. Consequently, they significantly worsen the quality of life of patients and their caregivers.

The screening diagnosis of the above-mentioned syndromes uses simple scales that can be self-administered by the patient or caregiver and that do not take much time to complete. Currently, an effective proposed tool to look for sarcopenia is the SARC-F form (Malmstrom J Am Med Dir Assoc. 2013), which has been validated in Poland in recent years (Piotrowicz 2021, Krzyżmińska 2020). It includes five simple questions about strength, walking assistance, getting up from a chair, climbing stairs, and occurrence of falls. The maximum score possible is 10 points, and a score of ≥ 4 points indicates suspected sarcopenia. The Mini Nutritional Assessment (MNA) scale, which takes approximately 10 minutes to complete (Kaiser, J Am Geriatr Soc 2011), is recommended for assessing the nutritional status of individuals >65 years of age due to its greatest sensitivity and specificity. Its screening portion, the MNA-SF (Mini Nutritional Assessment Short-Form) contains 6 questions instead of 18 allows the test to be completed in about 3 minutes and is equally effective in detecting malnutrition (Rubenstein et al, J Gerontol A Biol Sci Med Sci. 2001). It includes questions on food restriction and weight loss in the past 3 months, ability to move independently, presence of psychological stress or severe illness in the past 3 months, presence of neuropsychological disorders, and BMI (interchangeably calf circumference - when data on patient weight and height cannot be obtained). A maximum score of 14 points is possible; a score <12 points indicates suspicion of malnutrition and a need for further investigation. Validation in Poland of this scale was done in 2014 (Kostka J Nutr Health Aging. 2014). A generalized method for screening and diagnosis of frailty syndrome is still lacking. Currently, the results of a recent FRAILTOOLS study evaluating the usefulness

of different scales in detecting frailty syndrome in different clinical and social settings are being analyzed (Checa-López et al, FRAILTOOLS, BMC Geriatr. 2019). One of the scales is the FRAIL scale (Morley et al. 2016). The scale is undergoing Polish validation. The medical experts informed Prof. Morley about the planned use of the SARC-F and FRAIL scales in the project and obtained his approval (scales in Appendix).

Identification of the risk of sarcopenia, malnutrition or frailty syndrome by the patient or caregiver will allow for referral to a specialist (primary care physician/geriatrician), complete evaluation, early diagnosis and implementation of treatment. In the treatment of all three syndromes, appropriate dietary and rehabilitative intervention, including a complete diet with adequate protein and regular physical activity including resistance exercise, is of paramount importance. These are simple and effective measures that can be implemented at home with prior patient education. Thanks to them we can prevent malnutrition, slow down the development of sarcopenia and reduce the risk of frailty syndrome.

3. Benefits of implementing a solution addressing the three diagnosed deficits - a proposal of the FRA-MA-SARC model

The literature analysis carried out in the first stage of the project, as well as scientific and clinical experience of the experts, made it possible to identify important problems of old age in geriatrics. It was decided to work on a tool that addresses three geriatric problems described in earlier stages of the project: malnutrition, sarcopenia and frailty syndrome.

Earlier identification of malnutrition, sarcopenia, and frailty syndrome and appropriate intervention can help reverse or halt the developmental trajectories of these syndromes and their negative outcomes, thereby reducing socioeconomic costs:

1. Early remote identification of patients at risk for malnutrition/malnutrition, suspected sarcopenia, and frailty syndrome and the ability to alert the physician to the risk or presence of the geriatric syndromes in question. Ability to perform a complete assessment.
2. Once the diagnosis is confirmed, early opportunity to implement appropriate nutrition and rehabilitation intervention.
3. Prevent complications of hospital treatment for acute medical illness and medical interventions, injuries, and exacerbations of chronic disease resulting from malnutrition, sarcopenia, and frailty syndrome.
4. Reduce the risk of disability and the socioeconomic costs of reliance on third-party assistance.
5. Increase awareness and knowledge of geriatric syndromes such as malnutrition, sarcopenia, and frailty syndrome among older adults

Solutions that could contribute to the diagnosis of the health status of patients at risk of the above mentioned problems were proposed. The Steering Committee selected the solution recommended by the expert team to ultimately create functionalities on the existing e-health platforms under the responsibility of public authorities (www.pacjent.gov.pl and www.gabinet.gov.pl), the use of which will allow screening of the older population. As a result:

- 1) the above population is to receive:

- a) feedback on their health status (in relation to the above-mentioned problems),
- b) recommendations for further action,

2) Doctors and nurses of primary healthcare facility (POZ) shall receive:

- a) information on the health status of people under their care,
- b) possibility to consult the results with specialists [geriatricians],
- c) an opportunity to intervene with recommendations for nutrition, physical activity and rehabilitation.

As mentioned, it was assumed that the tool in question:

1) It should be:

- a) simple to use,
- b) Accessible to the public,
- c) free of charge for users,
- d) Validated (providing repeatable, valuable and reliable information),
- e) accessible for disabled persons, including visually impaired persons (compliant with current regulations concerning digital accessibility of websites and mobile applications of public entities),
- f) secure (communication will be via encrypted HTTPS protocol),
- g) Efficient (allowing for simultaneous use by multiple users).

2) Give the possibility, including the legal one, of integration with existing and developed in Poland e-health system.

For this purpose it is proposed to create a tool for identification of malnutrition, sarcopenia and frailty syndrome, named FRA-MA-SARC tool (FRA - frailty, MA - malnutrition, SARC - sarcopenia).

As the tools listed below are freely available / free / validated / with potential for integration, the use of:

- MNA-SF (Malnutrition and Malnutrition Risk; Mini-Nutritional Assessment, Short Form) questionnaire tool. MNA-SF: 6 simple questions, knowledge of current weight and height required; a version of the questionnaire is available which has been adapted as a self-completion tool by the patient; the tool is available free of charge (https://www.mna-elderly.com/forms/mini/mna_mini_polish.pdf); translation of the patient version will be done by experts: https://www.mna-elderly.com/forms/Self_MNA_English_Imperial.pdf); Polish validation of the tool is available
- SARC-F questionnaire tool (sarcopenia). SARC-F: 5 simple questions, self-completion questionnaire; tool available free of charge; Polish translation, clinical and cultural validation by Piotrowicz K, Gąsowski J and Klimek E, among others, who are experts of the project.
- FRAIL (frailty syndrome and frailty risk) questionnaire tool. FRAIL: 5 simple questions, self-completion questionnaire; tool freely available; Polish translation, clinical and cultural validation currently being carried out by Piotrowicz K, Gąsowski J and Klimek E, who constitute the expert group.

4. Existing national and international solutions of telemedicine models in relation to the subject matter of the project

In the last decade or so there has been a very strong development of different kinds of eHealth solutions. However, this development was not accompanied by a strong integration of these solutions. As a result, effects that could have been achieved were not obtained. From the very beginning, the solutions proposed within the framework of the present project assumed a strong integration with the existing possibilities provided by the platforms indicated at the earlier stages of the development of the document.

The work carried out in phases I-IIIa of this project has identified the lack of international comprehensive e-health solutions addressing the above mentioned issues. At the same time, a number of elements included in the existing partial solutions can be implemented and some are already in use. Therefore, it is possible to apply the philosophy behind them in the solutions proposed for adoption and create a new solution that could solve the problem of linking the above-mentioned deficits and allow obtaining comprehensive information about the health status of the elderly.

The model described in this paper implies the **implementation of a patient-centered approach and the use of the concept of integrating the involvement of different levels of health care, i.e., primary care and specialized health care, which should solve the problems of the elderly patient.**

In the course of the work, **no solution was found that was identical to the proposed FRA-MA-SARC solution.** It has to do with the **novelty of the approach proposed by the expert team**, which pointed out the need and possibility of **collecting (integrating) data on three problems, which are mainly described separately** - because of their separateness. However, these problems taken together are common and co-occurring.

Considering the arguments given above, it should be concluded that:

- **Currently, there is no solution addressing the problem of frailty syndrome, sarcopenia and malnutrition in a simple yet comprehensive manner - therefore there is no solution to be transferred directly to the Polish ground.**
- **However, the concept of integrating different activities / healthcare sectors / data that should address the patient's problems should be applied.**
- **It is necessary to apply a patient-centered model of care - for the population which is the focus of this project.**

5. Detailed description of the telemedicine service model

a. Substantive assumptions of the telemedicine service model

Target solution: Platform incorporated into existing and developed by MZ elements of the eHealth system in Poland (www.pacjent.gov.pl, www.gabinet.gov.pl).

FRA-MA-SARC is an e-Health model in the field of geriatrics aimed at improving awareness (education and prevention), screening and treatment (non-pharmacological recommendations) of the deficits of the elderly selected for the project, i.e. the above mentioned deficits: FRA - frailty syndrome, MA - malnutrition, SARC -sarcopenia.

For the implementation of the universal screening program (FRA-MA-SARC model) we will use three recommended questionnaire assessment tools in geriatrics presented in the previous stages of this work:

- MNA-SF: a questionnaire consisting of 6 single-choice questions to identify elderly people at risk of malnutrition or already suffering from malnutrition.
- SARC-F: questionnaire consisting of 5 simple one-choice questions to identify elderly people at risk of sarcopenia.
- FRAIL: a questionnaire consisting of 5 simple questions to identify older people at risk of frailty syndrome.

The Internet platform created for elderly patients, integrated with existing e-Health solutions (www.pacjent.gov.pl, www.gabinet.gov.pl), should enable medical data acquisition and management by medical professionals and provision of services (appointments, consultations, remote monitoring) financed by the public health insurance system. Its functioning is graphically presented in Figure 2.

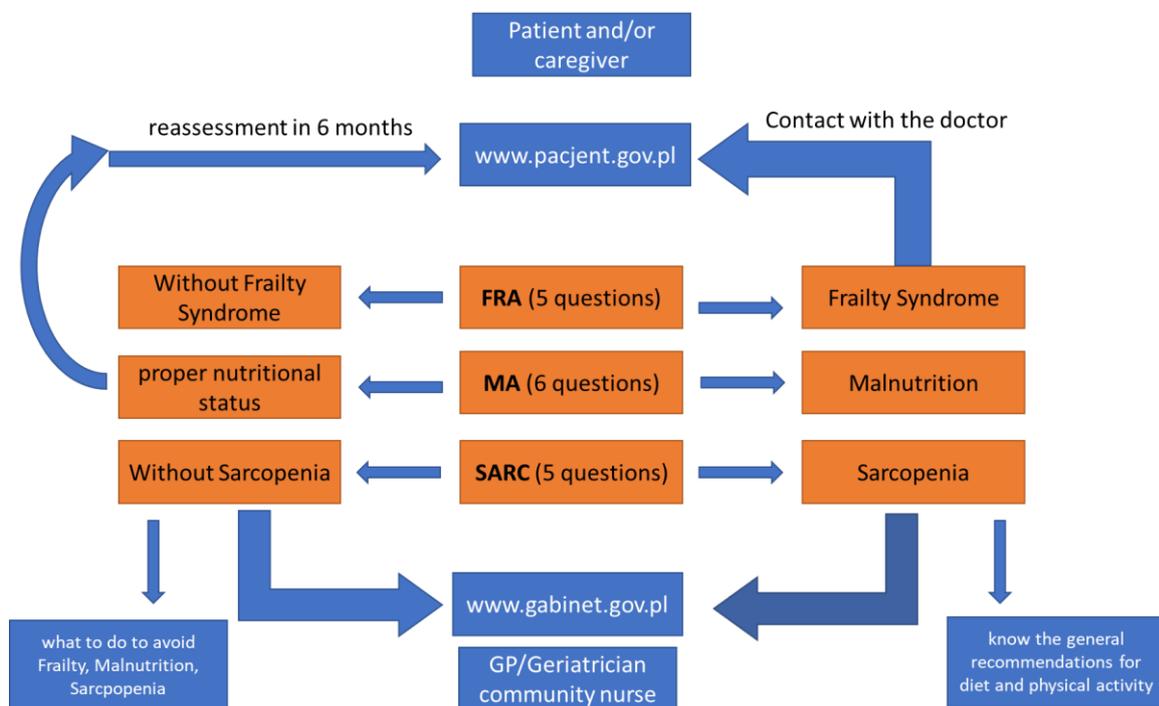


Figure 2: Telemedicine service proposal (schematic); author's study [detailed description is included in the Phase II report].

It is assumed that the above mentioned model can be developed in cooperation with partners that have different experience and competencies that allow to create the solution described in this document.

The above mentioned experience and competencies should include

- Knowledge of the functioning of the health care system, ability to navigate through it, knowledge of patient pathways, legal, management and financial conditions.
- Broadly understood IT area, working with such solutions, implementation of e-health projects.
- Clinical background for project implementation, including rapid response to emerging needs, especially those of patients requiring assistance.

- Understand the concept of patient-centeredness, implementing solutions that foster the concept of "patient centeredness".
- Ability to look at a problem from a different perspective, having international experience, critical thinking skills, pointing to other possible solutions.

In view of the above, it can be assumed that the pilot project promoter will have the above experiences and competencies or will be able to document the possibility of taking action in a consortium with business partners (IT companies), social partners (patient/senior citizen organizations) and a foreign partner representing a different perspective on the problem.

The implementation of the pilot 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 adapted both to the geographical area covered by the pilot, the target groups, as well as the type of information and the goals to be achieved.

The recommended prevention activities include: leaflets, posters for patients, the organisation of at least two one-day conferences (with content targeted at patients), the organisation of webinars to raise awareness and skills among medical staff on sarcopenia, malnutrition and frailty. The information and prevention activities aim to improve awareness on the importance of the problems addressed in the pilot.

The information and prevention activities, aimed at both professionals and patients, are intended to improve awareness of the problems addressed, as well as to enable the implementation of primary prevention measures.

One of the necessary functionalities of the website, in which the pilot platform will be embedded, is an educational tab for the patient, where information content related to prevention in the field of geriatrics will be placed, with particular emphasis on the issues covered by the model, as well as a tab for the doctor/nurse with appropriately adapted content.

Information channels to be used: telephone communication, leaflets for older people and their carers, posters, website.

Supporting materials planned to be used: printed training materials and information leaflets, short instructional videos, educational meetings for medical services providers via on-line system.

b. Technological assumptions of the telemedicine service model

The solutions proposed in the pilot concern the creation of an online platform that allows the patient to self-assess, the medical professional to monitor the patient's condition and consult with the patient and other medical professional, and the healthcare system to collect data on the health status of the population. This platform must meet the following conditions:

- Be accessible at a designated web address (to be determined).
- Have the ability to function as a website on a computer (PC/Mac), cell phone, tablet (Android / iOS version).
- Have an account creation and login mechanism that:
 - o Will be tailored to the needs and capabilities of an elderly person, that is:
 - Account creation and operation will be possible on any device equipped with a web browser, with Internet access (computer, tablet, phone).

- Creating an account will require entering a minimum amount of data and will be supported by an account creation wizard (step by step).
- User authorization will be possible by entering a code sent directly to the device (via e-mail/sms).
- For those who have problems with self-service there will be an elderly person's tutor support.
- The account creation and login screen will have a very simple design, with large icons and font, without additional links at this stage.
- More advanced functionalities for users proficient in multimedia devices will be available only after logging in, as optional.
- They will ensure:
 - Security of stored data regardless of its type.
 - Easy access regardless of the age of users.
- Contain basic information about malnutrition, sarcopenia, and frailty syndrome and their implications for health status for participants.
- Enable self-assessment of health status in the areas of malnutrition, sarcopenia, and frailty syndrome by the patient/caregiver by completing the aforementioned questionnaire tools. After completing the above-mentioned scales, the patient/caregiver and the primary care physician will receive feedback on any deficits or lack thereof in the areas of malnutrition, sarcopenia, and frailty syndrome.
- Include brief patient information on dietary and exercise recommendations in the case of suspected/diagnosed malnutrition, sarcopenia, and frailty syndrome.
- In the event that teleconsultation at a high-specialty geriatric outpatient clinic is necessary, allow the clinic physician access to the patient's/caregiver's self-assessment results.

c. Economic assumptions of the telemedicine service model

The proposed solution is to provide an opportunity to monitor the health status of the Polish population over 60 years of age. At the end of 2020, the population of Poland aged ≥ 60 years was 8.54 million people (Central Statistical Office, 2021, *Ludność. Stan i struktury oraz ruch naturalny w przekroju terytorialnym w 2020 r. Stan w dniu 31 XII*, Warsaw). It should not be assumed that all these people will be willing to make self-assessments, but the above value gives an idea about the target scale of demand for the size of the database that should be created and the software that would be able to handle it. It should also be taken into account that the population aged 60+ will significantly increase. Additionally, these will be people with more experience in using the Internet. All this will make it necessary to assume a gradual significant increase in the users of the proposed solution.

Cost calculation for the pilot phase of the project in the following areas is shown below:

- Costs related to IT, for the calculation of which the following assumptions were made:
 - Purchase for the duration of the pilot, the service consisting in making available for the project participants (medical staff, patients covered by the pilot) the platform used to operate or support the processes:
 - patient recruitment;
 - defining, sharing and filling in surveys
 - sending text messages, including automatic notifications;

- management of specialists' availability schedules with the possibility of arranging teleconsultations;
- establishing secure audio-video connections
- taking notes
- contextual data review
- run reports;

According to estimates, the cost of providing and operating the service for the full pilot period will amount to about 145 000 zł. which consists of: Provision by an external provider of a platform adapted to the needs of the project (**63 000 zł**); preparation and management of surveys (**17 000 zł**); provision of described communication tools (30 000 zł); management of graphics (**20 000 zł**); support service/assurance of constant availability of the platform (**15 000 zł**).

As part of anti-exclusion activities, purchase of **sets of tablets with modem, sim card and mobile Internet plan** for 5-10% of participants: people without computer equipment and own Internet access. Estimated **unit cost is 1 500 zł** (1 200 zł device, 300 zł mobile Internet). Before being handed over to the patients, the devices will be configured in such a way as to make connecting to the platform as easy as possible.

- **Purchase of computer equipment for participating POZ physicians - one set per primary healthcare facility (POZ), unit cost approx. 6 000 PLN.**

- o It is also necessary to provide for additional **costs related to IT** service in each of the participating primary healthcare facilities (POZ) (it is assumed that it may amount to about **10 000 zł gross per center**).

- o Creation of a **website** dedicated to the project (estimated cost is approx. **30 000 zł**)

- Cost of project promotion, educational and preventive activities, for the calculation of which it was assumed that patients will be included in primary healthcare (POZ), therefore the scope of the promotional campaign will be limited both in terms of geographical coverage and type of information and objectives to be achieved. The total cost of promotion during the pilot (including leaflets, posters for patients) is estimated at 30 000 zł. Related to this will be the cost of recruiting / notifying patients, encouraging them to participate in self-assessment, researching the need for this type of service (approx. 10 000 zł). It is recommended to conduct a series of conferences (at least two one-day conferences) and webinars to raise awareness and skills among medical staff on Sarcopenia, malnutrition and frailty. This is to improve awareness on the importance of the issues addressed in the pilot. In addition, a band aimed at patients should be included in the aforementioned conference. Both components (for professionals and for patients) are intended to improve awareness of the issues discussed, to enable the implementation of basic preventive measures. One of the necessary functionalities of the website in which the pilot platform will be embedded is an educational tab for the patient and separately for the doctor/nurse. The part dedicated to the patient should contain simple motivational content and enable the implementation of universal preventive actions. Estimated cost **160 000 zł**.
- **Medical staff salary cost**, which was calculated using the following assumptions: Primary Care Physician: 200 zł gross for visit "0" (recruitment), and 200 zł gross for e-consultation "1" and "3". Specialist doctor of geriatrics: 250 zł gross specialty e-consultation with the patient, 250 zł gross teleconsultation for the POZ physician.

- **Cost of user satisfaction survey (questionnaire)** for the designed solution. (about **6 000 zł**).
- **Cost of training materials** (printed training materials and information leaflets, short instructional videos, educational meetings for providers in the on-line system). estimated at about **35 000 zł**.
- **Salary cost** of members of the Local Pilot Implementation and Evaluation Team . The cost of remuneration for the members of the Local Team for the Implementation and Evaluation of the Pilot - based on a task-related principle, related to the training and supervision of POZ physicians, feasibility assessment of the implementation of the proposed e-health system on the Polish healthcare market, the cohesion of individual stages and elements of the system, with an option to re-evaluate the system structure after the pilot stage, the degree of satisfaction of beneficiaries and service providers involved in the model implementation, evaluation of selected health indicators in patients recruited for the pilot system, publication of preliminary results to show the project, promoting the idea (development of publications, webinar, materials for the website), legal and IT services, etc. estimated at **495 000 zł**.
- **Cost of additional examinations for 20% of patients** - total cost estimated on the basis of the commercial price list of the University Hospital in Kraków, for one patient 220 zł, the set of examinations includes:

blood count assessment:

Morphology (25 param. + reticulocytes) - 25.00

Renal function assessment:

urea - 8.00

creatinine - 8.00

uric acid - 8.00

General urine examination with sediment evaluation - 20.00

assessment of liver function:

ALAT - 8.00

ASPAT - 8.00

GGTP - 8.00

Albumin - 8.00

Na (sodium) - 8.00

K (potassium) - 8.00

Ca (calcium) - 8.00

vitamin D - 65.00

vitamin B12 - 30.00

Assuming that the research will be carried out in min. 100 patients (20% of the patients included in the project), the estimated total cost is **22 000 – 30 000 zł**

- **The cost of participation of patient organization** (organization of focus groups / in-depth interviews, contact with patients, presentation of opinions on the results obtained in the project, support of project activities) (about **80 000 zł**).
- **Cost of potential participation of a foreign partner** supporting and consulting the project implementation - about **100 000 zł**.
- **Cost of travel** of project participants (meetings with the foreign partner - approximately **50 000 zł**).
- **Cost of project management** - 10% of the total budget

To sum up: the implementation of the pilot program should not exceed approximately 2 140 000 zł. The above cost estimate is based on the cost analysis of projects implemented to date with a similar scope. The final costs may vary slightly depending on changing market prices and the number of patients. The cost of the pilot project should be between 200 000 and 675 000 EUR.

d. Requirements for legal issues of the telemedicine service model

- **Patient's consent to processing of personal data**

As part of the telemedicine model outlined, the patient's unambiguous and informed consent to the processing of personal data in the broadest sense, including health data, plays an important role. Due to the fact that the patient's consent is a necessary prerequisite for the processing of data of a sensitive nature, it will be necessary to obtain the patient's clear and unambiguous consent to the processing of personal data concerning him or her before proceeding to complete the form.

Recital 32 of the preamble of the GDPR indicates that consent may consist of checking a box when browsing a website, selecting technical settings for the use of information society services, or any other statement or conduct that clearly indicates that the data subject has accepted the proposed processing of his or her personal data.

However, in the case of the telemedicine model presented, for evidentiary purposes, **it is suggested that the patient's consent to the processing of personal data be given in writing**, in a properly prepared document. Alternatively, if the patient proceeds to complete the form electronically, the patient should consent to the processing of his or her personal data, including health data, **by explicitly checking a checkbox 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 and in accordance with the information clause attached to my consent.

I agree

- **Information obligation of the personal data controller**

Pursuant to Article 13 of the GDPR, if personal data of a data subject are collected from that data subject, the controller is obliged to provide a number of information specified in the aforementioned provision when collecting personal data. It follows from the above that the controller should make available an information clause containing a number of the information indicated below, the content of which should be provided to the user, before the user starts to fill in the questionnaire.

In the case of the telemedicine model presented, it is suggested **to include the information clause in a properly prepared document**, attached to the patient's written consent to the processing of personal data. Alternatively, if the patient proceeds to fill out the form electronically and will be giving his/her consent to the processing of personal data by explicitly checking a checkbox on the website, the **information clause may be located in the relevant tab on the website**.

The analysis of particular telemedicine solutions used in the European Union countries, the European Economic Area and the USA shows that the information clause is most often included on the website in a separate tab called "Privacy Policy". It is suggested that the information regarding the data processing be properly ordered and preceded by titles, instead of using a sequence of incomprehensible definitions and clauses referring to particular editorial units of the legal text. The primary goal is to **inform users**, i.e. seniors or guardians of the elderly most often lacking legal knowledge, **in an understandable and accessible way** about the purposes and scope of the processing of personal data concerning them.

- **Patient Consent for Examination and Health Care Provision**

Within the presented telemedicine model for people over 60 years of age, an important role is played by the informed consent for examination and provision of health services. Within the framework of patient autonomy, the principle of consent for health services is important. The capacity to give consent is a legal characteristic (qualification) of an individual, meaning the ability to decide independently whether to undergo an examination or other health service.

Pursuant to Article 32(1) of the Act of 5 December 1996 on the professions of doctor and dentist (Journal of Laws of 2021, item 790), a doctor may perform an examination or provide other health services, with exceptions provided for in the Act, after the patient gives his consent. The above provision corresponds to Article 17(1) of the Act of 6 November 2008 on Patient's Rights and Patient's Rights Ombudsman (Journal of Laws of 2020, item 849), according to which a patient has the right to give consent to conduct an examination or provide other health services. It follows from all the above regulations that full capacity to consent is granted **to adult natural persons who are not completely incapacitated and are capable of giving their informed consent**.

Consent may also be expressed verbally or through such conduct of the patient that undoubtedly indicates a willingness to submit to the actions proposed by a medical professional (see Article 32, paragraph 7 of the Act on professions of physician and dentist and Article 17, paragraph 4 of the Act on patient rights and patient rights ombudsman). However, in the case of the telemedicine model presented, for evidentiary purposes, **it is suggested that the patient's consent to the examination and provision of further medical services be given in writing, in a properly prepared document**.

The consent document should be accompanied by **written and accessible information for the patient** about the purpose of the examination, proposed and possible diagnostic and therapeutic methods, as well as foreseeable consequences of their application or omission. This information duty of a medical professional is set forth in Art. 31 (1) of the Act on professions of physician and dentist. The counterpart of the above obligation is the **patient's right to information** provided for in Article 9 (2) of the Act on Patient's Rights.

- **Guidance from the Supreme Medical Council for the delivery of telemedicine services**

On July 24, 2021. The Presidium of the Supreme Medical Council adopted Resolution No. 89/20/P-VIII on the adoption of guidelines for the provision of telemedicine services. These guidelines were

developed by the Supreme Medical Council's Telemedicine Team together with the Telemedicine Task Force and are intended to be applied to the provision of telemedicine services by physicians within the scope of their professional practice.

The guidelines consist of three documents that are appendices to the resolution:

- *Guidelines for the Provision of Telemedicine Services* - covering legal requirements for the processing of personal data under telemedicine (i.e., principles of legal liability of a physician providing telemedicine, catalog of physician's duties and patient's rights), practical issues (i.e., principles for ensuring confidentiality of telemedicine, verification of patient's identity, access to medical records), and technical and organizational aspects.
- Guidelines for telemedicine services taking into account ethical aspects - covering issues related to ethics of medical practice applicable to the provision of health services "at a distance".
- 10 steps of a telemedicine visit - describing important stages of providing health services in the form of telemedicine.

Within the framework of the presented telemedicine model, in the case of providing health services by a doctor (in particular providing e-consultation), **it is desirable to take into account the above guidelines within the framework of the designed teleinformatics tool.**

6. implementation and formal evaluation of the pilot implementation model

a. Assumptions regarding feasibility of piloting

In order to test the target model within the framework of the planned pilotage, it is proposed to use an external platform whose functionalities as well as the implementation process are described in detail later in this report. The project should be implemented in cooperation with a foreign partner whose role will be to support the Polish team, provide comments on the developed solutions, possibly participate in webinars etc.

The pilot program should be conducted by the center selected through a competitive process (supra-regional hospital or institute as a central unit) that at the time of the pilot program implementation has

- appropriate specialist facilities:
 - o a team of at least 3 geriatric specialists with access to outpatient and inpatient facilities, at least a senior physician
 - o employing at least 4 research staff, including:
 - i. 3 physicians, working at medical universities with at least a doctoral degree in medical sciences, including at least one with a habilitation degree, with experience in conducting scientific and applied projects requiring quality control of the clinical data collected. At least one of these individuals should be a geriatric specialist.
 - ii. a specialist in public health / health management with at least a PhD degree, who will be part of the Local Pilot Implementation and Evaluation Team
- **Adequate logistical facilities** - premises with the possibility to conduct training meetings, own IT team,

- experience in conducting projects in the area of health from public funds (at least three projects implemented from public funds in the competitive mode in the last 3 years - may be in progress).
- **academic background,**
- **experience** in the implementation of projects that involved external primary healthcare facilities (POZs),
- **experience** in realization of international projects concerning e-Health,
- **consent of a foreign partner** to cooperate in the project (if applicable) - a foreign partnership is advisable (foreign partner, e.g. Norwegian, with experience in conducting telemedicine projects, including broadly defined geriatrics, whose role will consist in consulting on building a detailed pilot protocol and discussing problems and assistance in solving them during the project)
- **consent of other primary healthcare facilities (POZs)** for cooperation in the project - it is necessary to include in the project at least three POZs (offices), including at least one taking care of digitally excluded people, preferably from rural areas (a minimum of 10% of patients for a given pilot project should come from the so-called excluded areas - towns far from large cities, taking into account the per capita income ratio at the county level in relation to the average income in the country),
- **Patient/senior organization's agreement** to cooperate in the project (if applicable) - it is advisable to partner with a senior or patient organization whose task would be to spread the idea of FRA-MA-SARC among its members, potential future users of the platform,

In addition to the above, it is strongly recommended:

- **own primary healthcare facility (POZ)**, which will allow to check the functioning of the model (however, this is not a limiting condition).

In the opinion of the expert group, in order to ensure coherence of the project and minimize the level of complication of the system, the project in the pilot phase should be implemented by a single center managing and responsible for performance of project tasks and quality of acquired data. However, for the purposes of realization of the Health Program it is allowed to carry out the pilot run by more than one center. Breaking up the contract and dividing the tasks into more centers carries a high risk of significant problems with co-ordination of activities, especially when - probably - there are strong constraints concerning the project implementation time and formulation of conclusions that can be drawn on the basis of multi-centre activities. However, the experience gained in this phase (1 leading center, several POZs cooperating) will be useful in the implementation of the model on a national scale.

b. Stages of implementation of the pilot project

- I. **Information campaign** aimed at promoting the project and the MZ initiative in medical and senior communities.

Information channels to be used: telephone communication, leaflets for the elderly and their carers, posters, website.

- II. **Involvement of external primary healthcare facilities (POZ)** (maximum 4) interested in participating in the pilot of the described e-health system.

Information and training meetings with POZ representatives interested in participating in the initiative.

Auxiliary materials planned for use: printed training materials and information leaflets, short instructional videos, educational meetings for providers in the on-line system.

III. **Recruitment of patients** from primary care practices to participate in the pilot. From the lists of POZ patients, 2000/5000* individuals will be selected, of whom at least 500 will be included in the FRA-MA-SARC self-assessment scheme.

**NOTE: it is assumed that at least 500 patients will be included in the further phase. For this purpose, 2000 patients will be recruited. Because some patients may refuse to participate or drop out of the study, it is assumed that recruitment may include a larger patient population, but not more than 5000 patients. If the recruitment goal is reached earlier (e.g., with the above 2,000 people), a survey will be conducted of the remaining patients regarding their need for this type of service. This will allow for more accurate identification of demand for the service described in this document. In the rest of the text we use the term: "2000/5000".*

IV. **Meetings with representatives of senior citizens, including elderly patients:** patient association(s) and 1 meeting / 1 POZ participating in the project. The manner of conducting the meeting will be adapted to the current epidemiological conditions of the region, focus research on the expectations and needs of elderly patients regarding e-health services (depending on the epidemiological situation, remote meetings will be possible).

V. **Implementation of the pilot** taking into account, as described in earlier sections of this paper, the participation of the beneficiaries of the presented e-health solution (geriatric patient, patient's caregiver) and the providers involved in the implementation of the model (primary care physician and, if possible, nurse employed in the primary care, geriatric specialist).

VI. **Evaluation of the proposed solution** with analysis of the feedback received from beneficiaries and involved providers:

- o evaluation of the implementation possibilities of the proposed e-health system on the Polish market of health services (feasibility assessment),
- o Detailed evaluation of coherence of individual stages and elements of the system, with the option of re-evaluation of the system structure after the pilot stage,
- o Evaluation of satisfaction of beneficiaries (patient, patient's caregiver) and service providers involved in the model implementation (primary care physician, primary care nurse, community health nurse, geriatric specialist) with the proposed solution
- o Evaluation of selected health indicators in patients recruited to the pilot system (frequency of hospitalization, frequency of SOR and PR use, institutionalization, falls, death).

NOTE: The work steps described above will be consulted with the foreign project partner. For the sake of clarity of the text, the aforementioned were not included in the description of individual stages.

The role of the foreign Partner, e.g. Norwegian, with experience in running e-health projects including in broadly defined geriatrics, will be to consult on building a detailed pilot protocol and to discuss problems and help in solving them during the project. The partner will provide substantive support to the Polish side in the implementation of the project by exchanging experience, sharing knowledge on e-health or prevention projects through consultations, meetings, conferences, webinars, as well as by participating in the development of information materials.

c. Detailed description of the primary healthcare facility (POZ) pathway

I. Application for participation in the piloting of the presented telemedicine model

- II. A training meeting with experts designated to implement the project, representatives of the entity implementing the project, aimed at standardization of project procedures.
- III. Recruitment of patients - will be carried out through the following paths:
 - a. **Telephone contact:** selected patients from the list (2000/5000 persons) will be contacted by a doctor, nurse or an employed person with information about the pilot program. Those who are willing to participate in the pilot will be invited to Visit 0 (see explanation below).
 - b. **Proposal from the POZ physician:** During a routine visit to the POZ, the POZ physician will suggest that the patient should participate in the pilot - once the patient agrees, Visit 0 will be scheduled and performed.
 - c. **Patient Proposal:** The patient, having read the information about the pilot (leaflet, poster, website) during a routine visit to the POZ, will himself ask the POZ physician about the possibility of participating in it - the physician will propose a date for the performance of Visit 0.
- IV. Examination of senior patients:
 - a. **the recruitment visit (referred to herein as "Visit 0" - is performed separately from the POZ visit):**
 - o provide the patient and/or caregiver of the elderly patient with information about the project being conducted,
 - o Collecting a document of informed consent to participate in the project and a document for the protection of personal data of the project participant,
 - o Training in the use of the implemented web-based platform, if needed,
 - o Supervision and support during initial self-assessment by patient (and/or patient's caregiver) using the platform.
 - o Providing feedback to the patient regarding current health status with respect to deficits/or lack thereof (in terms of sarcopenia, malnutrition and frailty syndrome) with additional information including further management.
 - b. **follow-up e-consultation after a period of 30 days \pm 5 days (referred to as "Visit 1" in this document):**
 - o standard physician e-consultation with assessment of the occurrence of previously indicated adverse events, supervision and support while the patient (and/or patient's caregiver) performs a follow-up self-assessment using the platform (if required),
 - o Identification of patients who will require extended evaluation (including no less than 20% of patients ordering additional laboratory tests - evaluation of blood count, renal function, liver function, albumin, sodium, potassium, calcium, vitamin D, vitamin B12) with discussion of the patient's case during specialist teleconsultation (consultation with a geriatrician)*.
 - c. **Final e-consultation at the third month of the patient's inclusion (referred to as "Visit 3" in this document)**
 - o a standard medical e-consultation with assessment of the occurrence of the adverse events and endpoints indicated earlier,

- o Assessment of satisfaction with the solution used (beneficiary and provider),
- o Formulation of final recommendations for the patient*.

* In justified cases (for pre-determined scores obtained by patients on geriatric scales used in the project) and at the request of the POZ provider, the project provides teleconsultation/specialist advice:

- o the results of selected (minimum** 10%) recruited patients will be discussed within the teleconsultation POZ physician - geriatrician,
- o selected (at least** 5%) patients will have a specialist teleconsultation with a geriatrician.

****NOTE:** We assume that this number of patients will hold teleconsultations/specialty e-consultations. If the above indicator would not be fully achieved (e.g. 9.5%, 4.5%) due to lack of patients who would require this type of service, it should not be treated as an error or failure to achieve the assumed results.

A diagram describing the patient selection process is shown in Figure 3.

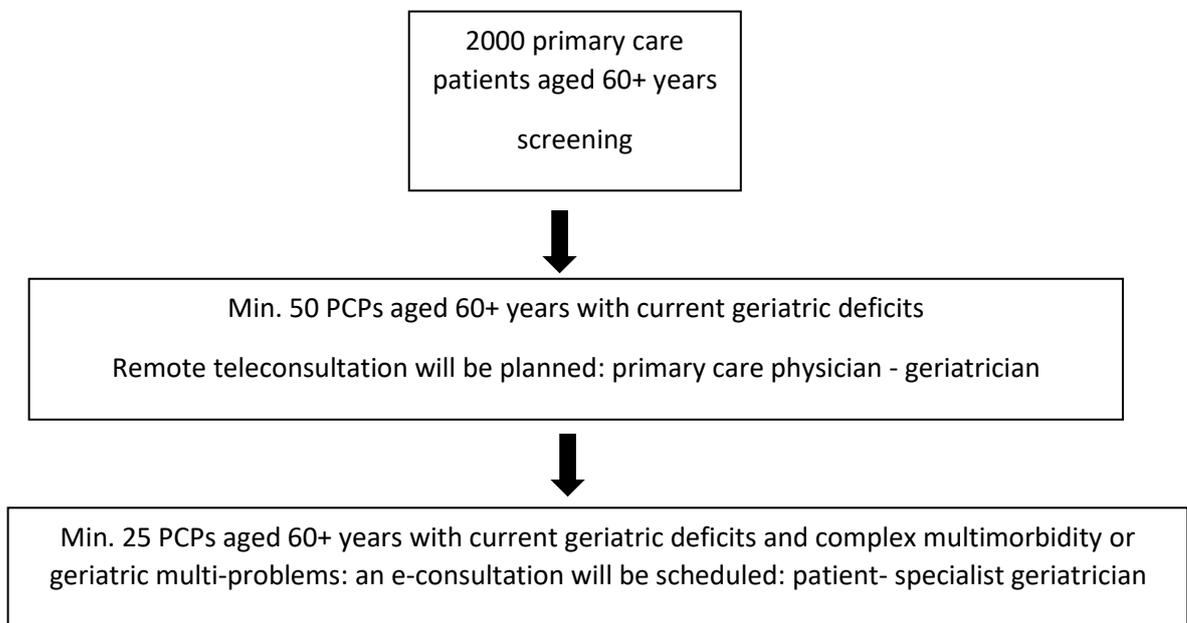


Figure 3: Patient selection scheme for teleconsultation and specialty e-consultation; author's study.

d. Criteria for patient inclusion in the project

Patient inclusion in the project will be based on the following criteria:

- age \geq 60 years,
- Informed consent to participate in the project expressed in writing or electronically, in accordance with legal conditions.

It is allowed for the caregiver to assist in the use of the Internet platform and to participate with the patient in training on the use of the platform and educational training, assuming that the patient is able to give informed consent for participation in the study. In order to minimize the risk of exclusion from the project of digitally excluded elderly people (who do not have their own computer or Internet network), system support was provided consisting in the purchase of 10 sets

of tablets with modem, sim card, mobile Internet plan, intended for people who do not have computer equipment and their own Internet access. Estimated unit cost is 1500 PLN (1200 PLN device, 300 PLN mobile Internet). Before handing over to the patients, the devices will be configured in a way that makes connecting to the platform as easy as possible.

Technical parameters of the tablets:

- Screen - minimum 10"
- RAM and hard drive - minimum 3 GB RAM + hard drive minimum 32 GB
- Wireless connectivity Bluetooth 5.0, WiFi 802.11 ac, 4G/LTE modem
- There are no criteria for excluding the patient from the project other than age <60 years and lack of informed consent - one of the basic assumptions of the implemented e-health model is the universality of the model and availability of applications for all elderly people.

e. Define the roles and activities of the various entities involved in the project

1. patient/caregiver

- a. Is recruited within the POZ. It is not required that this is a patient enrolled in the POZ, it can also be a person from outside the given institution who, as a result of promotional activities, received information about the possibility of joining the project.
- b. After consenting in the presence of the POZ physician to participate in the pilot, the patient/caregiver **receives training** in the use of the Internet platform for the pilot (**Visit 0**).
- c. **Completion of a self-assessment** that includes completion of forms for screening assessment for sarcopenia, malnutrition, and frailty syndrome uploaded on the web-based platform. Activity completed three times at **Visits 0, 1, 3**.
- d. After the self-assessment, the patient/caregiver receives feedback from the POZ physician regarding:
 - 1) current health status with respect to deficits/or lack thereof (regarding sarcopenia, malnutrition, and frailty syndrome) along with:
 - 2) current health status with respect to deficits/deficits (in terms of sarcopenia, malnutrition and frailty syndrome) along with: 2) additional information including further management, i.e., discussion of dietary and exercise recommendations attached on the online platform, referral for a e-consultation at a highly specialized - geriatric clinic.

The above is done as part of the e-consultation (**Visit 1, 3**).

2. Primary healthcare facility (POZ)

- a. Selection (2000/5000) and recruitment (min. 500) of patients/patient caregivers for the pilot including:
 - 1) contacting potential participants (patients),
 - 2) presenting information about the project,
 - 3) encouraging participation in the project.
- b. Conducting **Visit 0** which includes:

- 1) providing information about the pilot,
 - 2) obtaining patient/caregiver consent to participate in the pilot,
 - 3) providing training on how to access and use the web-based platform for the pilot with feedback to the patient on current health status with respect to deficits and/or lack thereof (in terms of sarcopenia, malnutrition, and frailty syndrome) with additional information including follow-up.
- c. Analyze the results of the self-assessment completed by the patient/caregiver and recorded on the online platform and provide feedback to the patient/caregiver regarding further management, within the framework of the e-consultation (Visit 1, 3). The above will include:
- 1) discussion of dietary recommendations,
 - 2) discussion of exercise recommendations, optional:
 - 3) referral for e-consultation to a highly specialized clinic - geriatric.
- d. In the case of abnormal results of self-assessment (MNA-SF <12 points or SARC-F \geq 4 points or FRAIL \geq 1) after prior teleconsultation of the POZ physician with a physician of a highly specialized geriatric clinic, referral of patients for specialist e-consultation in the above-mentioned clinic. It is assumed that for these patients, the e-consultation with the POZ will take place within a week and the e-consultation with the geriatrician within 28 days.
- e. In the event of abnormal (alarming) self-assessment results ie: MNA-SF <7 or SARC-F >5 or FRAIL \geq 3, expedited contact with the patient for further diagnosis and referral to a highly specialized outpatient clinic - geriatric. For these patients, it is assumed that e-consultation with the primary healthcare facility (POZ) will occur within three days and e-consultation with the geriatrician within 14 days.
- f. Cooperation with physicians of the highly specialized - geriatric outpatient clinic: referring selected patients with abnormal self-assessment results to the highly specialized - geriatric outpatient clinic for e-consultation with prior notification by phone or email.
- g. Collaborate with the IT specialist when patients report problems in using the online platform.

3. highly specialised outpatient geriatric clinic

- a. Teleconsultation of patients' cases with a POZ physician (on the basis of incorrect results - as in point 2) (applies to a minimum of 10% of patients)
- b. Specialist teleconsultation of selected patients referred by the POZ physician with abnormal (alarming) self-assessment results (as in point 2) (applies to a minimum of 5% of patients in the above group).

4. the Local Pilot Implementation and Evaluation Team (selected by the re-launching center)

- a. Training and supervision of primary care physicians and geriatric outpatient clinicians in the field of:
 - 1) conducting the pilot study and the principles of cooperation between doctors of primary care and doctors of highly specialised outpatient clinics - geriatric,
 - 2) operation of the Internet platform,

- 3) definition and diagnosis of malnutrition, sarcopenia and frailty syndrome (range of abnormal results and abnormal alarms)
- 4) discussion of dietary and physical activity recommendations for malnutrition, sarcopenia, and frailty syndrome, with particular emphasis on those attached to the online platform.
- b. Conduct a user needs survey for the designed solution.
- c. Conducting a user satisfaction survey for the designed solution.
- d. Assessing the feasibility of implementing the proposed e-Health system on the Polish healthcare market,
- e. Performing a detailed evaluation of the cohesion of individual stages and elements of the system, with an option to re-evaluate the system structure after the piloting stage.
- f. Evaluation of selected health indicators in patients recruited for the pilot system.
- g. Publicizing preliminary results, demonstrating the project, promoting the idea (development of publications, webinar, materials for the website).
- h. Legal services.
- i. IT support.
- j. Consulting solutions with a foreign partner, exchanging experiences and transferring them to the Polish ground.
- k. Perform other activities necessary for the implementation of the project.

5. foreign partner

It is advisable to have a foreign partner (foreign partner, e.g. Norwegian, with experience in conducting telemedicine projects including in widely understood geriatrics, whose role will consist in consulting on building a detailed pilot protocol and discussing problems and providing assistance in solving them during the project implementation.

The partner will provide substantive support to the Polish side in the implementation of the project by exchanging experience, sharing knowledge in the field of telemedicine or prevention projects through consultations, meetings, conferences, webinars, as well as through participation in the development of information materials.

- a. Supporting the Polish project promoter.
- b. To present a different view on analyzed problems.
- c. Providing comments on the solutions worked out
- d. Participating in webinars.

f. Detailed rules of cooperation between particular entities

1. organizational meeting (stationary or remote) of Local Team for conducting and evaluation of the pilot program with physicians of primary care (1 for each included center) in order to train them in the following areas

- a. discussing the principles of conducting the pilot study and discussing the principles of cooperation with physicians of the highly specialized outpatient clinic - geriatrics,
 - b. using the Internet platform,
 - c. definition and diagnosis of malnutrition, sarcopenia and frailty syndrome (abnormal results and abnormal alarms)
 - d. discuss dietary and physical activity recommendations for malnutrition, sarcopenia and frailty syndrome, with particular emphasis on those attached to the online platform.
2. organizational meeting (at least one stationary or remote) of the Local Pilot Implementation and Evaluation Team with physicians of highly-specialized outpatient clinics - geriatric in order to train them in the following areas
 - a. discussing the principles of conducting the pilot and discussing the principles of cooperation with primary care physicians,
 - b. using the Internet platform,
 - c. definition and diagnosis of malnutrition, sarcopenia and frailty syndrome (abnormal and alarming results)
 - d. to discuss the dietary and physical activity recommendations in case of malnutrition, sarcopenia and frailty syndrome, with particular attention to those attached to the Internet platform.
3. monitoring meetings (stationary or remote, at least 4) of the Local Pilot Implementation and Evaluation Team with the primary care physicians and with the physicians of the high-specialist clinic - geriatricians during the project in order to:
 - a. discuss the results and progress of recruitment,
 - b. discuss any problems arising during the pilot study e.g. related to the operation of the Internet platform, analysis of the results obtained in the self-assessment.
4. contact between the primary care physician and the specialist clinic in order to:
 - a. teleconsultation of abnormal (alarm) self-assessment results,
 - b. to provide information on patients referred for teleconsultation in the geriatric outpatient clinic.
5. possible regular contact with the IT specialist in case of technical problems with the operation of the Internet platform.
6. contact between the Local Pilot Implementation and Evaluation Team and the patient/senior organization to:
 - a. identify requirements for the designed solution (user needs),
 - b. analyze the results obtained in the project,
 - c. use the contacts of these organizations to disseminate information about the project.
7. contact between the Local Pilot Implementation and Evaluation Team and the foreign partner in order to exchange experiences, consultations and solutions.

g. Technical and organizational requirements of the pilot project

1. access to a stationary computer/laptop/tablet/smartphone with access to broadband Internet is required (by the patient/caregiver, primary care physician, physician of the highly specialized geriatric clinic) with the possibility of teleconsultation/e-consultation (in video mode if possible)
2. in the absence of the above, it is possible to rent a tablet with Internet connection to patients as part of the pilot program (5-10% of patients)
3. office of the primary care physician for **Visit 0** (signing the consent and training in using the Internet platform),
4. teleconsultation platform for e-consultation by the primary care physician within **Visits 1, 3** and specialist e-consultation by the geriatrician,
5. teleconsultation platform for teleconsultation of a POZ physician with a highly-specialized doctor - geriatrician
6. e-consultation point within the general practitioner/geriatrician office - an area enabling e-consultation (room equipped with a comfortable computer workstation)
7. e-consultation point within the primary care office or other dedicated place in the health care facility (e.g., pharmacy) - a e-consultation area designed to provide equal opportunities for patients with lower e-health literacy - a room equipped with a comfortable computer workstation with an additional chair for a trained staff member responsible for supporting an elderly person during e-consultation.

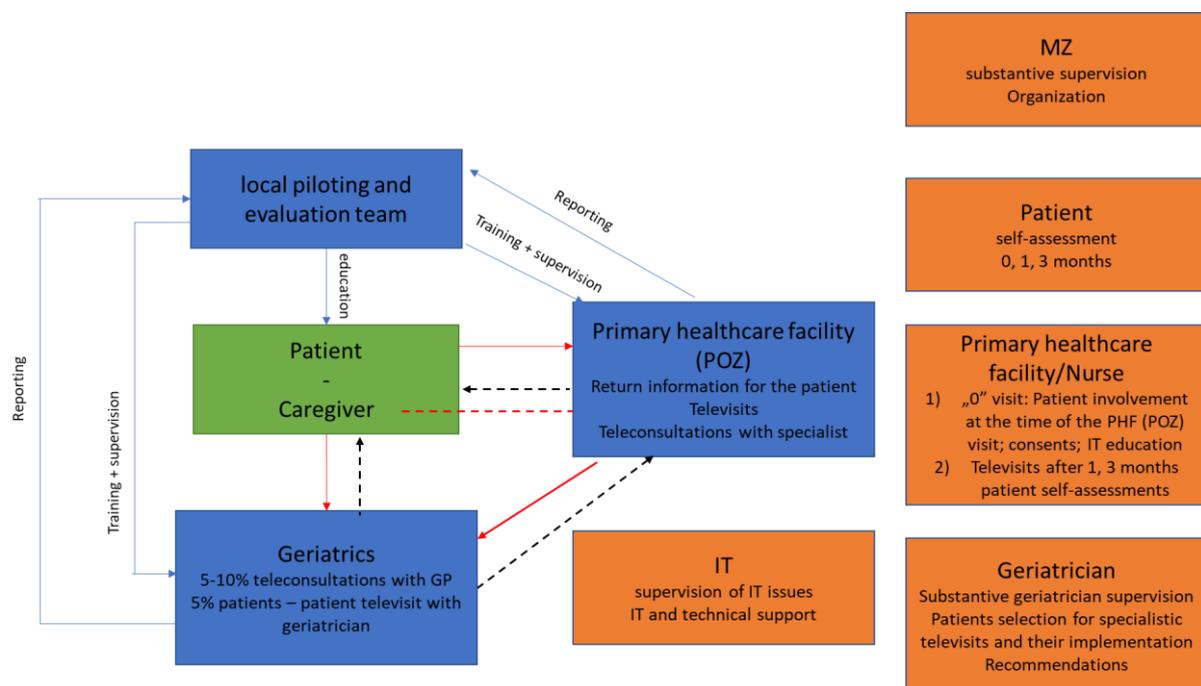


Figure 4: Graphical representation of the principles of operation of the model for senior patients in the Polish health care system (pilot model); own elaboration.

Legend:

→ denote VISITS i.e. - Visits 0, 1, 3 within the POZ, teleconsultation of the doctor POZ and geriatrician teleconsultation and patient's teleconsultation/visit to geriatrician.

---→ denote the RETURN INFORMATION the patient receives from the POZ physician during Visit 0, 1, 3, the POZ physician from the geriatrician during the teleconsultation, the patient from the geriatrician during a teleconsultation/visit.

----- denote the CENTRE of the pilot model, i.e. constant contact of the patient with the POZ physician and geriatrician during Visit 0, 1, 3 with feedback on health status

7. Risks and problems associated with implementation of the model

1. Risks related to motivation and competence issues

• Lack of sufficient incentives to implement the model

The proposed model assumes cooperation between units at different levels of the health care system (POZ - specialist). As far as some organizational linkages currently exist, they can be described as loose. In practice, they are limited to routing patients between the above levels. With the introduction of the model, there will be a need to seek partners, to create linkages that would enable the system to become operational. Given the current system of paying for health services and work overload - health care units are not motivated to cooperate. It is therefore necessary to create incentive mechanisms that will encourage them to change their ways.

Suggested mitigation/prevention tools:

- Conduct an information campaign by MZ/NFZ targeting health care units regarding the new service delivery model.
 - Reliable valuation of services [it is also suggested that a higher valuation of services be used for centers which will implement the model].
 - Providing POZ units with computer equipment enabling teleconsultation
 - Financing laboratory tests for at least 20% of patients (100 persons) included in the project
- #### • Patients' reluctance to use new technological solutions

Reluctance to change, increasing with age, may make a relatively large group of recipients reluctant to use the services offered in this model.

Suggested mitigation/prevention tools:

- Conduct an information campaign by MZ/NFZ targeting older people about the new service delivery model.
- **Older people's distrust of information obtained by telephone**

Suggested mitigation/prevention tools:

- Telephone information about the model should be provided by trusted persons (doctor, nurse, person hired for this purpose, whose affiliation with the POZ, however, can be verified).
- Providing a possibility of telephone contact with the caregiver who will find it easier to verify the information obtained by contacting the POZ facility or accessing information on the website.
- Wide information campaign conducted in POZ in the form of direct information from the POZ doctor/nurse during a visit, leaflets, posters or website (*applies to pilot stage*).
- **Lack of sufficient competence to freely access online resources and the FRA-MA-SARC platform**

Suggested mitigation/prevention tools:

- Maximum facilitated access to the platform: account creation and login mechanism that will be adapted to the needs and abilities of the elderly person.
- Caregiver participation, supervision and support when the patient performs self-assessment using the platform.
- To be considered: initial training on how to use the platform and ongoing support from IT staff in case of any difficulties (help-desk).
- **Concerns about giving out personal information and health information online**

Suggested mitigation/prevention tools:

- Providing the possibility of contact (help-desk) with the state institution / POZ in order to clarify doubts related to the entry of personal data by the patient.
- An appropriate (nationwide) information campaign to promote the project.
- Prominent data security information on the web site, providing contact numbers / other means of contact to clarify doubts related to the patient's input of personal data

2 Risks related to organizational issues

- **Limited number of older people to be reached with information about the model**

The elderly often lead "armchair-bed" lifestyles with limited access to medical services (problems with access to in-patient services). They also do not use the Internet, and so will have limited access to information about the model.

Suggested mitigation/prevention tools:

- An appropriate outreach campaign to promote the project in the medical and senior living communities.
- Information channels planned to be used: telephone communication, leaflets for older people and their carers, posters, website.
- Inclusion of elderly caregivers in the model, giving them a greater opportunity to learn more about the telemedicine model through contact with the POZ, the ability to obtain a flyer, read a poster, or obtain information about the model on the Internet.
- **Problems of "baby age" of the project in the start-up phase**

It should be assumed that - as in any new venture - at the model introduction stage there will be "standard" problems associated with project initiation. This will probably include gaps in information, different interpretation of received information and records, unfamiliarity with software used to provide services, etc.

Suggested mitigation/prevention tools:

- Preparation of simple instructions on how to use the system for all its participants: patients/caregivers, employees of POZ, employees of specialized centers, employees of NFZ. The above concerns both the software itself (intuitiveness and simplicity) and additional information placed on the website.
- Launching a help-desk system, including both chat/ mailing and **telephone, which is particularly important for the elderly,**
- **Problems of cooperation between units: the start-up phase**

The discussed model assumes collaboration between different participants of the system, which is currently not common and finding pairs of POZ - highly specialized centers, which may be a problem due to the small number of people with appropriate competencies (mentioned at earlier stages of the work the small number of geriatricians).

Suggested mitigation/prevention measures:

- Assist MZ/NFZ in the search for partners - in view of the small number of highly specialized centers, as well as the remote mode of work, it can be assumed that the selection of partners would not have geographical limitations - by publishing lists of specialized centers (with their prior consent).

NOTE: the problem of shortage of geriatricians will become more apparent as the interest in the discussed project increases.

- **Problems of cooperation between entities: the action phase of the project**

This closer cooperation between the various participants in the system is a major organizational and financial challenge, as the current funding model does not promote such cooperation and coordination. It is therefore necessary to change the philosophy of paying for medical services. In this matter, the discussed project could be a good example of how the idea of cooperation/coordination could be realized.

Suggested mitigation/prevention tools:

- Preparation of model solutions (model contracts) between participants (POZ/specialist center).
- Communicate (make public) information about good practices.
- A campaign promoting the model, explaining the role of individual participants.
- Establish a financial system to promote cooperation (see below - risks concerning financial issues).

3 Risks related to legal issues

- **The manner and form in which the patient consents to the examination and provision of health care services**

The basic principle of Polish law, consistent with the directive to respect patient autonomy, is the rule that consent to medical services should be given individually by an adult natural person who is capable of making a conscious statement of will. The proper expression of consent for a medical procedure is a legal condition for the legality of medical procedures. In addition, a patient who gives informed consent takes the risk of possible complications resulting from the medical procedure upon himself.

The patient should be provided with full and comprehensible information about the state of his or her health, the diagnosis made, the proposed methods of treatment and the foreseeable consequences of the treatment. There are no specific requirements concerning the form of such information. For evidentiary purposes, it is desirable that the medical professional provides full information to the patient in writing (with an indication of possible risks and complications) and additionally discusses the indicated issues verbally and answers all questions and doubts of the patient. This is particularly important both for the patient, who should have full information regarding the medical services provided, and for the doctor himself, who frees himself from a charge of illegal action. The provision of verbal explanations is important because physicians appearing in medical trials in which patients challenge the fact of informed consent indicate that a very small percentage of patients actually read the information provided to them in written form.

Suggested Mitigation/Prevention tools:

- Develop written templates that include the required information. Information prepared in a written form should be sent to the patient via e-mail or be downloadable from a website so that the patient has access to it and has time to read it in convenient conditions. On the other hand, explanations provided by a medical professional in addition to the written information may be provided via ICT systems (telephone, video calls).

After obtaining the above-mentioned information, the patient should give his/her consent to provide the health care service. The current regulations do not require consent to be given in a specific form. Consent for health care services that do not pose an increased risk to the patient may be effectively given verbally as well as implicitly.

Suggested mitigation/prevention tools:

- Although there is no legal requirement for a specific form of consent and for consent to be given in the presence of witnesses, it is postulated that, for evidentiary purposes, consent should be given in writing, bear the patient's handwritten signature, and be included in the patient's medical record. Thus, it makes sense to develop written templates that include a patient consent form. For these reasons, Visit 0 should take place in person to collect written consent from the patient. Alternatively, the patient consent form should be sent to the patient via email or downloadable from a website, and the patient, after completing the form, should return the signed form in the original via mail for inclusion in the medical record.

- **Obtaining the patient's consent for the processing of personal data**

Since the patient's consent is a condition for the lawfulness of processing data of a sensitive nature, it is necessary to obtain the patient's explicit and unambiguous consent to the processing of personal data concerning him or her. In particular, this applies to personal data entered into the questionnaire form.

Before obtaining the patient's consent to the processing of personal data, the data controller is obliged to provide a range of information regarding the purpose, scope and manner of processing the users' data. Experience shows that patients - particularly the elderly - are reluctant to read complex and extensive legal clauses that are written in language they do not understand. Thus, it is important to inform users, i.e. seniors or caregivers of elderly people usually without appropriate legal knowledge, in a clear and accessible way about the purposes and scope of the processing of personal data concerning them.

Suggested mitigation/prevention tools:

- Develop an information clause containing the content provided for in Article 13 of the GDPR, written in language accessible to the patient, sequenced and preceded by understandable titles. The information prepared in a written form should be sent to the patient via e-mail or be downloadable from the website (e.g. under the tab named "Privacy Policy") so that the patient has access to it and has time to read it at his/her convenience.

In the case of personal data entered into the questionnaire form, the patient should give clear and unambiguous consent to the processing of his/her personal data, in particular sensitive data concerning his/her health. The law does not provide for the necessity of written consent to the processing of personal data, however, the burden of proof is on the personal data controller to

demonstrate that the patient has given such consent. In the case of the telemedicine model presented herein, for evidentiary purposes, it is suggested that the patient's consent to the processing of personal data be given in writing, in a properly prepared document, and bear the patient's handwritten signature. Alternatively, if the patient proceeds to complete the form electronically, the patient should consent to the processing of his or her personal information, including health information, by explicitly checking a checkbox on the website.

Suggested mitigation/prevention tools:

- Develop written templates that include a consent form for processing patient data. The patient consent form should be sent to the patient via e-mail or downloadable from the website, which the patient should then send back in the original by post. However, given that the questionnaire will be accessible via ICT tools, it seems more convenient to obtain the patient's consent to the processing of personal data in electronic form by explicitly ticking a box on the website.

With regard to the provision of health services that prove necessary due to the patient's medical condition disclosed in the questionnaire, it may be necessary to collect the patient's separate consent to the processing of personal data (in addition to the consent already given for the provision of health services).

Suggested mitigation/prevention tools:

- However, the law allows to waive obtaining the patient's consent for the processing of sensitive personal data if the conditions provided for in Article 9(2)(h) of the GDPR are met. According to the cited regulation, in the case of the provision of health services, if the processing is necessary for "medical diagnosis, the provision of health care or social security, treatment or the management of health care or social security systems and services". Personal data may be processed for the above purposes if they are processed by - or under the responsibility of - a person subject to the obligation of professional secrecy.

- **The need to verify the identity of the patient**

Suggested mitigation/prevention tools:

- If health services will be provided via an ICT system, verification will take place after the patient logs in with a given login and password. Otherwise, it is necessary to establish the patient's identity, preferably by asking control questions about the personal data contained in the medical records. The Personal Data Protection Office also suggests the possibility to perform verification by asking additional questions regarding the reason for the medical visit, date and time of the visit. In addition, in order to confirm eligibility for benefits, it is necessary to determine the patient's PESEL number and verify its accuracy with the medical records. If the patient is a first-time patient, it is necessary to determine the complete set of data needed to establish the medical record. If the e-consultation is done via video call, the patient may be asked to show ID to the camera.

- **Ensuring confidentiality of the e-consultation**

Suggested mitigation/prevention tools:

- The health care provider should be in a location that ensures the confidentiality of the call due to the fact that sensitive patient health information is being transmitted. No one else should be in the room where the health care practitioner is providing the telehealth care except for those involved in providing the telehealth care.

- **Security of personal data**

Suggested mitigation/prevention tools:

A security policy should be developed in a health care unit that provides health care services and allows for effective and comprehensive management of information security. All employees of the health care unit or persons employed on the basis of civil law contracts should have appropriate authorizations to process personal data. If it is necessary to transfer personal data to an external entity (such as an ICT system provider), it is necessary to conclude a personal data processing entrustment agreement between the data controller and the external entity.

4 Risks related to financial issues

- **Incorrect valuation of the service by the public payer**

The service, which is to be introduced as a result of the implementation of the discussed project, requires coordination of activities of the POZ employee (not only the doctor, certain duties can also be performed by other medical professions, e.g., nurses, physiotherapists, dieticians), the specialist unit (geriatrician), and also the functioning of IT technology. The role of a doctor in primary care will not only consist in admitting patients or having telemedicine sessions with them, but also in controlling the patient's condition. The burden of care will shift from contact with the patient to monitoring selected indicators of the patient's condition. Much of the monitoring will be done automatically by the system, but ultimately the responsibility for the patient will rest on the doctor. Watching over the patient must therefore also be valued and included in the price of the service.

Suggested mitigation/prevention tools:

- Reliable valuation of all costs and benefits associated with the introduction of the model.
- A clear delineation of roles and responsibilities of individual users (understood here also as health care professionals) and the adoption of a philosophy of fair "profit sharing" resulting from the benefits of the implemented model.
- The payment system should take into account not only bonuses for the analysis of the patient's condition, but also for maintaining the patient in good health, improving patient outcomes, etc.

NOTE: with such a significant shortage of geriatricians, one should consider the possibility of including into the system of care people with the competences of nutritionists, who could partly relieve doctors in matters of malnutrition, or physiotherapists, who could support patients in their efforts to improve physical fitness.

- **Problems with payments due to large number of users**

The introduction of this model will need to be financed. Although it should be expected that it will bring the benefits described in earlier stages and below in this document, they will not appear immediately and will not be directly linked to expenditures. The NFZ may be faced with the problem

of funding services that are essential (life and health saving) and those that make it unnecessary for patients to use expensive services (remote health monitoring). A large number of patients using such services will therefore be a heavy burden on the system, but it is assumed that prevention of adverse conditions, their early detection and early intervention will still be more cost-effective than not taking the above measures.

Suggested mitigation/prevention tools:

- Robust calculation of all costs and benefits associated with model implementation.

5 Risks related to technological issues

- **Group of risks associated with the development, implementation and operation of central system components**
- **Risk group related to access to technology and digital competences of senior citizens**

In the target model it is planned to use already existing central solutions and to extend them with required functionalities. Thus, there is no risk associated with ensuring an adequate level of security of the system and data processed in it, because such mechanisms are already in place. There is, however, the issue of the necessity to plan the development of the patient.gov.pl and gabinet.gov.pl applications and in this case both the issue of the central approval itself and the set potential deadline for implementation should be taken into account. In this case, both the issue of acceptance itself at the central level and a potential deadline for implementation should be taken into account.

In relation to the user, the risk concerning the senior patient is the same as in the pilot study [see below] (*attention should be paid to the problem of lack of access to the Internet and to the devices that can connect to the Internet and operate network applications. Another risk is the lack of digital competence of a significant part of patients to whom the project is addressed. Some of them have never used such devices, and some of them may have problems with operating touch screens on their own or going through the registration/user verification process*).

Suggested mitigation/prevention tools:

- Prior to the start of the pilot program, initial arrangements should be made with the institutions responsible for the development of central applications, i.e. the Ministry of Health and the Center for e-Health (CEZ). The design and detailed analytical work should begin at the beginning of the pilot program, so that a plan for implementation of the piloted functionalities in central systems can be developed immediately after its completion.
- In relation to the user, the remedial measure at the level of equipment and Internet access will be the same as in the case of the pilot [cf. below] (*the project should provide for free provision of equipment to senior patients in the form of tablets with a modem and SIM card to connect to the Internet. It should be estimated that the problem of lack of access may concern about 5-10% of the group covered by the project*).
- In order to counteract the factor of lack of digital competence, it seems reasonable to develop available countermeasures and, in addition to making available instructional materials and introducing the function of a tutor in the application, which could be performed both by a family member or another person authorized by the patient and a representative of the health care system, launching a toll-free hotline, whose employees would specialize in helping to solve basic problems related to access and use of central platforms.

6 Risks related to clinical issues

- Geriatric deficits (such as hearing loss) hindering telephone contact and thus the ability to obtain information on the model.

Suggested mitigation/prevention tools:

- Ability to contact caregiver by phone.
- Information campaign to promote the model (nationwide).
- Possibility to obtain direct information from the POZ physician/nurse during the visit.
- **Incorrect data entered by patients during questionnaire completion in the FRA-MA-SARC platform**

It is reasonable to assume that some self-assessment questionnaires will contain inaccurate data as a result of operational problems, errors due to limitations of the patient's health status (e.g., incorrectly pressed key), or lack of skills in using the application.

Suggested mitigation/prevention tools:

- Brief information on malnutrition, sarcopenia, and frailty syndrome provided on the FRA-MA-SARC platform to increase knowledge and awareness of the above deficits.
- Supervision and support of the caregiver during survey completion.
- Feedback given to the patient by the primary care physician after completing the questionnaires with the possibility of verifying the data obtained.

- **Doubts of the primary care physician about further management of the patient in case of abnormal and/or alarming results in completed questionnaires.**

Suggested mitigating/preventive tools:

- Opportunity for the POZ physician to discuss the patient's case via teleconsultation with the geriatrician to obtain support and clarify concerns and to identify those patients who will require extended evaluation with possible in-person consultation at the geriatrician's office

- **Deterioration of the patient's general condition**

Suggested mitigation/prevention tools:

- By detecting the risk of geriatric deficits (malnutrition, sarcopenia and frailty syndrome) the possibility of implementing appropriate dietary and rehabilitation prevention and improving the patient's condition.
- Through the detection of existing geriatric deficits (malnutrition, sarcopenia and frailty syndrome) the possibility of implementing appropriate treatment and referring the patient to specialized care (geriatrician) and the potential possibility of improving the patient's condition.

7 Risks concerning the pilot phase

- **Participation of healthy individuals excluding those most likely to benefit from self-assessment to identify geriatric deficits**

Suggested mitigation/prevention tools:

- A broad information campaign to promote the project and the MZ initiative in the medical and senior communities.
 - No exclusion criteria except age ≥ 60 years and the need to provide informed consent to participate in the pilot.
 - Inclusion in the pilot program of a limited number of POZ with the need to reach as many elderly people as possible, which will allow to include in the pilot program also those with the above-mentioned geriatric deficits. Emphasizing the quality of the pilot program, not the number of people who participated in it.
 - Involving caregivers of older adults will allow older adults with deficits to participate in the pilot.
- **Lack of device (computer/tablet/smartphone) and internet access**

Suggested mitigation/prevention tools:

- The opportunity to equip the patient/caregiver with a tablet with internet access will create an opportunity to participate in the pilot and thus become familiar with the platform and its benefits.

NOTE: the risks discussed above also apply to the full implementation phase. However, in case of covering the whole country with the model, the suggested mitigation/prevention tools are beyond the capabilities of the health care system

- **Inability of the primary care physician to recruit an adequate number of patients**

Suggested mitigation/prevention tools:

- Extensive information campaign to promote the project and the MZ initiative in the medical and senior communities.
 - Possibility of including other POZ facilities in the pilot.
 - Limited exclusion criteria - every patient over 60 years of age who can give informed consent can participate in the pilot.
- **Possibility to integrate with the application that would simulate the future solution implemented in central systems.**

The application must be complete in terms of functionality while maintaining the high level of security required for access to patients' personal and medical data. The risk in this area includes the problem of creating the application, because the customer is not able to fully predict the course of the tender procedure or its outcome. This entails the risk of delay in delivery and implementation of the application, as well as receiving a product that literally meets the provisions of the contract, while lacking the required ergonomics of use. Such provisions, which are often defined more by the feelings of use than by the availability of functionality itself, are practically impossible to include in the description of the subject of the contract. It is also necessary to take into account the need to ensure an appropriate balance which, on the one hand, will properly protect users and their data and, on the other hand, will not excessively complicate access to the application.

- **With respect to the user - the senior patient:**

- o Lack of accessibility both to the Internet and to devices that can connect to the Internet and operate networked applications.
- o Lack of digital competences of a significant part of patients for whom the project is directed (some of them have never used such devices and some of them may have problems with independent operation of touch screens or passing the registration/user verification process).

Suggested mitigation/prevention tools:

- The tender procedure should include all the necessary provisions, not only functional, but also those concerning security. It is important to clearly indicate the standards to be met by the delivered product. The conditions of participation should include provisions referring to the experience in similar projects and also require providing examples of solutions that were produced earlier before the tender was awarded, in order to eliminate unreliable suppliers already at this stage. In the description of the subject of the contract, in order to ensure appropriate ergonomics, the process of moving around the application should be clearly described, with precise indication of the number and type of steps required to perform specific operations.
- As far as the user is concerned, the project should envisage the possibility of providing senior patients with free of charge equipment in the form of tablets together with a modem and a SIM card enabling Internet connection. It should be estimated that the problem of lack of access may concern about 5-10% of the group covered by the project.
- The application should include the function of "caregiver", who could operate the account of senior patient with authorization and prepare high-quality information materials and instructions.

As it is shown above, in the course of work numerous risks were defined, which concern wide spectrum of issues. Some of them can be relatively easily mitigated or prevented. Others will require a significant investment of time and resources. Certainly it is necessary to:

- test the model in the pilot phase, to learn from it.
- Creating a support system in the initial stage of project implementation on a pan-Polish scale, which will allow for its relatively easy implementation.

8. Benefits resulting from the implementation model

According to experts, the recommended FRA-MA-SARC e-health care system will enable effective, real-time communication between the POZ office and the specialist, providing the basis for the implementation of the coordinated care model. Currently, there are no systemic solutions enabling such coordinated medical care for senior patients.

When a senior patient is referred to a specialist clinic from primary care, he or she has a long way to go to a geriatrician. By the term "long" we mean that:

- the average waiting time for an appointment with a geriatric specialist can be several months;
- a small number of geriatric specialists in Poland results in a lack of local accessibility to specialist geriatric clinics, in particular for patients living in villages and small towns.

According to the Polish National Chamber of Physicians, only 517 geriatricians are professionally active in Poland. Feedback from the specialist and recommendations for further management are forwarded to the primary care physician in the form of written recommendations given to the patient on paper.

Many times the patient forgets to provide the result of the consultation to the referring POZ, which results in the lack of therapeutic intervention or prolongs its duration while decreasing its effectiveness / efficiency.

The identified potential benefits of implementing the FRA-MA-SARC model in Poland are presented below. They are given in the following terms:

- title / brief description of the activity / area / activity,
- explanation / extended description, detailing (as appropriate),
- indication of potential benefits.

For the sake of clarity of the argumentation, in selected cases the potential benefits were described in the form of more detailed sections - indicating several of the above-mentioned benefits derived from one activity (cf. e.g. point 1 below).

1. Optimization of cooperation with POZ and use of available resources of geriatric specialists in Poland.

The primary care physician identifies the patient who requires a geriatric consultation. Thus, only patients who, in the opinion of the primary care physician, require a geriatric consultation/therapy are referred to the specialist. Cases that are less questionable are consulted by the primary care physician independently during teleconsultation with a geriatric specialist.

Benefits:

- **implementation of the system of teleconsultation POZ physician - geriatrician, allows to improve the accuracy of selection of patients who require teleconsultation of a specialist (patient - geriatrician),**
- **use of the teleconsultation system POZ physician - geriatrician allows to increase the number of specialist medical consultations per time unit / 1 geriatrician.**

The POZ physician in the teleconsultation system has the opportunity to discuss the medical problems of his patients with a specialist, which in the long term will contribute to improving his competence in the field of geriatrics (discussion of doubts and acquisition of new diagnostic and therapeutic skills by the POZ physician is not possible when he receives only the result of the geriatric consultation issued to the patient in writing).

Benefit:

- **Increasing the geriatric competence of the POZ physicians collaborating in the FRA-MA-SARC platform.**

The geriatric patient and primary care physician receive consultation support and specialist advice without the need for personal contact with the specialist. This makes the possibility of using the services independent of the distance to the specialist's office. The proposed model of teleconsultation based on the FRA-MA-SARC platform enables to equalize social inequalities in access to specialist care and geriatric consultation for senior patients living in villages and small towns. This also applies to equalizing opportunities to access services for patients living in regions (voivodships) where there is a large deficit of geriatric specialists. Such facilitation is particularly important in the case of elderly patients who, due to commonly occurring diseases of the locomotor system, fitness and independence

deficits, or financial constraints, are unable to travel to a specialist consultation. This model makes the possibility of obtaining the service independent of the prevailing epidemiological situation.

Benefit:

- **Equalization of social inequalities in access to specialist care and geriatric consultations for senior patients living in villages and small towns / regions with high deficits of geriatric specialists.**

The primary care physician receives specialist support in real mode. The use of the FRA-MA-SARC platform is expected to contribute to the reduction of the number of special-listed consultations, the result of which is provided to the primary care physician with a significant delay or is not provided at all. This is particularly important in the case of elderly patients suffering from multimorbidity and multiple deficits, who often require multi-specialist care. For these patients, lack of coordinated communication between the specialists caring for the patient can contribute to life-threatening medication errors (e.g., prescribing drugs with potentially dangerous drug interactions), duplication of diagnostic procedures, hospitalizations, and ultimately death.

Benefits:

- **reduction of specialist medical consultations, the results of which are not used by the consulting primary care physician,**
- **Reduction of the risk of medication errors or unnecessary diagnostic and treatment procedures resulting from a lack of effective communication between healthcare professionals.**

2. The "*patient-centered*" model of geriatric care, which should ultimately involve all providers of medical services for the elderly patient.

The functioning of the "*patient-centered*" model of e-health for elderly patients in the Polish healthcare system (implementation model) is graphically presented in Fig. 4 (based on what was developed in the report IIIb).

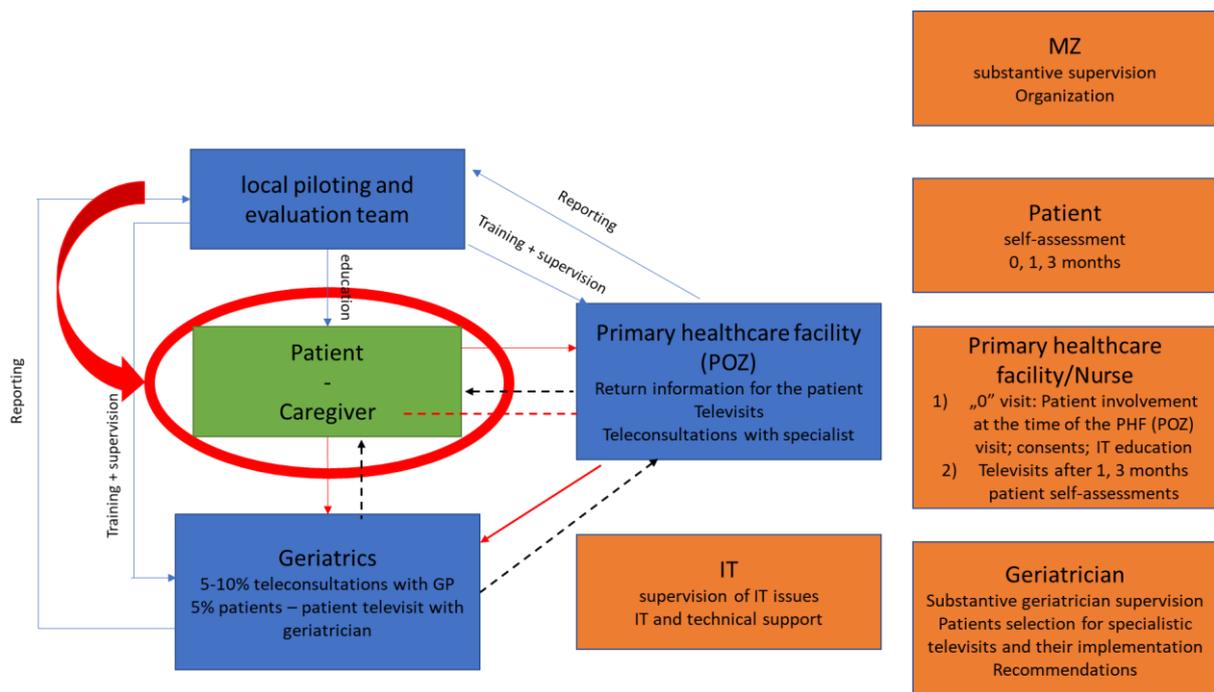


Figure 4a. Graphical representation of the principles of the senior patient model in the Polish health care system (pilot model); modification of Figure 4.

The construction of a patient-centered care model is in line with global recommendations on how to deliver medical care to elderly patients (National Institute for Health and Care Excellence, NICE, European Union of Geriatric Medicine Society, EuGMS). According to the recommendations of international scientific societies, medical care dedicated to the oldest patients should be closely coordinated, individualized according to the needs and deficits of the patient and their caregiver, taking into account the complex medical, psychological and social needs of the patient.

Benefit:

- **The implementation of the FRA-MA-SARC platform will be a step towards a paradigm of integrated, patient-centered medical care provided to senior patients.**

Common access for healthcare workers to the e-health platform resources (individual for a given patient) will improve their knowledge about the patient and the effectiveness of performed actions. The implementation of the platform will enable effective multi-specialist use of knowledge already collected about the patient, reduce duplicate medical procedures, increase accuracy of diagnosis and treatment.

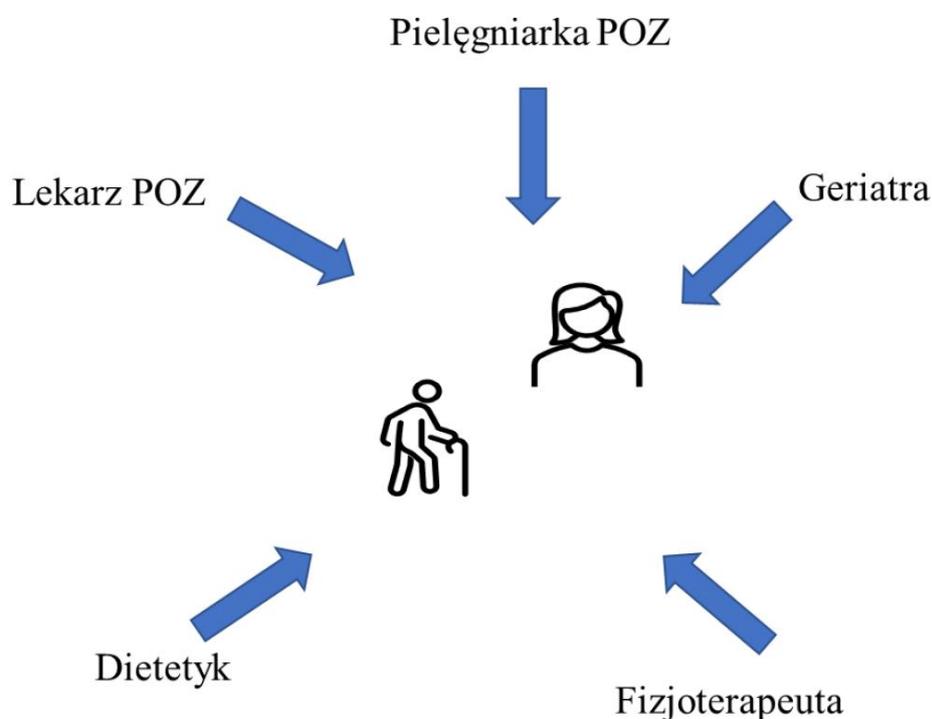


Figure 5: A coordinated, multi-specialty model of patient and caregiver centered health care (*patient-centered care*). A dietician and a physiotherapist are planned to participate in the development of publicly available recommendations for patients on the Platform.

Benefits:

- **To engage all professionals providing care to the geriatric patient in teamwork,**
- **improve the appropriateness of diagnostic and interventional procedures ordered for the patient.**

The inclusion of the elderly caregiver in the eHealth platform dedicated to the elderly patient will significantly increase the participation of older people with cognitive deficits, sensory deficits or motor limitations in the proposed systemic telemedicine solutions. Moreover, the elderly caregiver can play the role of coordinator of medical care provided for the close relative, verify information provided by the elderly patient to the doctor, and, properly instructed, supervise the process of the patient's compliance with medical recommendations. Incorporating a caregiver for an elderly person into the process of caring for a senior patient may also improve the caregiver's sense of empowerment, thereby reducing the risk of developing caregiver burnout syndrome.

Benefit:

- **To redress social inequalities in access to specialized care and geriatric consultations for patients with complex and advanced deficits of old age.**
3. **collecting reliable medical data** on the elderly patient population in order to **forecast the demand** for medical, rehabilitation and care services in this age group.

Benefit:

- **integration, acquisition and analysis of medical data on health status, medical, rehabilitation, care or finally, economic needs of elderly patients will allow to accurately predict and allocate financial resources for preventive and therapeutic procedures in geriatrics.**
- **The collected high-quality epidemiological data will be used in scientific gerontological research describing the state of health of the Polish population.**

4. **development of existing e-health platforms**, which will contribute to improving accessibility and quality of medical care, as well as reducing the need for personal medical visits, which seems particularly important in view of the current epidemiological threats of the SARS-CoV-2 pandemic.

5. **To increase awareness and knowledge of selected geriatric deficits** (sarcopenia, malnutrition, frailty syndrome) among patients, caregivers and physicians.

Discussion of selected geriatric deficits on the platform and self-assessment questionnaires will provide reliable information on sarcopenia, malnutrition, and frailty syndrome and criteria for their diagnosis. Increased awareness and knowledge of these deficits may contribute to increased recognition rates.

6. Reducing medical expenses for the elderly through prevention

Early diagnosis of sarcopenia, malnutrition, and frailty syndrome, especially detection of the risk of their occurrence among the elderly, provides an opportunity to implement appropriate dietary and rehabilitation intervention. In this way it is possible to improve the health of elderly patients and thus prevent the occurrence of complications, hospitalizations and falls with subsequent injuries. These conditions, causing deterioration of the functional status of the elderly, lead to dependence on third-

party assistance and subsequent institutionalization, situations that significantly contribute to the need for increased financial outlays for the treatment of the elderly.

7. increasing competence and skills in the use of Internet resources among older people

The need to use the platform to complete self-assessment questionnaires will allow elderly patients and their caregivers to become familiar with the opportunities created by access to digital resources and thus pave the way for a wider and bolder exploration of new technology products. It is possible that this will increase the number of elderly people using Internet resources.

8. development of e-health systems in the country

The implementation of the e-health system forces a change in the organization, which must lead (if the system is going to work) to a number of phenomena, beneficial from the point of view of its participants and the system itself.

The role and importance of the patient, who becomes a more active participant of the system, the creator of the data, increases. This leads to his empowerment.

Benefit:

- **Patient empowerment.**

In order for the system described in this document to work, it is necessary to improve the collaboration between the various participants in the system, the exchange of information, the aforementioned more active participation of the patient, etc. This exchange of information allows for more transparency in the system.

Benefit:

- **Improved cooperation between system participants,**
- **Increase of the level of transparency of the system.**

Compliance of the benefits with those described by the European Commission

The benefits of implementation of the proposed telemedicine model correspond with the assumptions formulated by the European Commission in its Communication on telemedicine for the benefit of patients, healthcare systems and society. In its Communication of 4 November 2008, COM(2008)689, addressed to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, the European Commission highlighted the benefits of telemedicine for patients, healthcare systems and society.

The Commission pointed out, in particular, such benefits as:

- facilitating access to specialist medical care for inhabitants of small towns and rural areas,
- support for specialist services and consultations for smaller medical centers,

- improvement of health care in isolated or remote areas
- rapid diagnosis and medical assistance,
- easier access to medical assistance in serious emergencies,
- reduced hospitalizations and the need for patients to commute,
- reduced overall costs of treatment and healthcare in the Member State,
- Increased opportunities for upskilling of medical staff, especially in the provinces,
- savings resulting from administrative improvements,
- Enabling scientific research, so far requiring labor-intensive travel and data consolidation scattered across various health care units,
- reduction of barriers in communication between health care centers.

Summarizing the above considerations, one can indicate a wide range of benefits that will be associated with the introduction of the model discussed in this study. In case of proper implementation of the project and reduction or elimination of the risks described earlier, all the participants of the system (which are affected by the project) should experience significant improvement in their functioning.

9. Summary

The work conducted during the project phases has allowed us to:

- Identify areas where change is required and possible (3 deficits relating to the health of geriatric patients: malnutrition, frailty syndrome and sarcopenia).
- Identify the need for services addressing these deficits.
- Identify the lack of tools in the solution market to address the mass screening of the above deficits.
- To propose a simple tool for mass screening based on the following assumptions:
 - o The tool is based on a patient-centric model of care.
 - o The tool is easy to use.
 - o It is possible to pilot the tool in a relatively short period of time.
 - o The level of complexity of the proposed model is low (it assumes the participation of relatively few shareholders and the relationships between them are simple).

The above actions were consulted with Norwegian partners and received their approval. These partners agreed with the general concept of the project, making comments and suggestions in the course of work, which allowed for the creation of a better quality solution.

Considering the above, it can be assumed that the proposal submitted within the framework of this project is feasible and, according to the authors, should bring real benefits on many levels:

Patient:

- access to knowledge about health problems that may affect her/him,
- possibility of self-diagnosis,
- System support,
- Increased awareness of lifestyle,
- Higher quality of life,
- coverage for care when health needs arise,

POZ center:

- More efficient acquisition of health data for those under care,
- Better communication with patients,

- Opportunity to receive support from a specialist center, High-Specialty Center:
- quicker information on emerging health problems in the area of interest of the center,
- establishing contact with POZ, creating cooperation network and its improvement,

MZ/NFZ

- reliable data on population health,
- more effective care of the elderly,
- creation of inter-centre cooperation network.

Synopsis - boundary conditions for project implementation

- Value of each pilot project: between 200 000 – 675 000 EUR, of which:
- max 37% for equipment of which unit expenditure cannot exceed 10 000 zł,
- max 10% for administrative service.

1) Service process

Step I: Self-assessment by the patient. Based on the individual result, after completing the self-assessment scales, the patient receives one of e.g., 9 possible pre-designed feedbacks, including a few sentence description and interpretation of the result and basic lifestyle recommendations. In case of alarming results (indicating the presence of frailty syndrome, malnutrition or sarcopenia), the patient is advised to contact a physician urgently.

The result of the self-assessment will be transmitted in the system to the primary care physician.

Stage II: The primary care physician will perform a telehealth assessment and provide feedback to the patient. The doctor will make an appointment with the patient for the e-consultation during which the patient/caregiver will receive feedback on further management (including discussion of dietary recommendations, exercise recommendations, and possible referral to specialist teleconsultation). On the basis of the e-consultation, in no less than 20% of patients, the physician will be able to order laboratory tests: evaluation of blood morphology, renal function, liver function, albumin, Na (sodium), K (potassium), Ca (calcium), vitamin D, vitamin B12.

Stage III: Results of patients referred for in-depth evaluation discussed by the POZ physician with a geriatric specialist (via teleconsultation).

Stage IV: Selection by the primary care physician of patients for specialist e-consultation based on teleconsultation.

Based on the above selection, the geriatrician will be able to provide an electronic information mode consultation to the POZ physician and will be able to make preliminary recommendations for the patient. In order to level the playing field for patients with lower e-health literacy, each POZ running the program will create at least one teleconsultation point equipped with appropriate computer equipment. This point will be staffed by a trained staff member responsible for supporting the elderly person. Min. 10% of participating patients will be provided with the opportunity to borrow telehealth equipment.

2) Requirements for a unit entering the program

- a. Required: Supra-regional hospital or institute as a central unit.

- b. Indicated (strongly recommended): Own primary care practice (but this is not a limiting condition).
- c. Required: Inclusion in the project of at least three POZ establishments (offices), including at least one having under care digitally excluded people, preferentially from rural areas (a minimum of 10% of patients for a given pilot project should come from so-called excluded areas - localities far from large cities, taking into account the per capita income ratio at the county level in relation to the average income in the country).
- d. Required: hire 3 specialists, at least a senior physician.
- e. Required: 3 projects implemented with public funds on a competitive basis within the last 3 years (may be in progress).
- f. Required: Employing at least 4 research staff, including:
 - i. 3 physicians, working at medical universities with at least a doctoral degree in medical sciences, including at least one with a habilitation degree, with experience in conducting scientific and applied projects requiring quality control of collected clinical data. At least one of these individuals should be a geriatric specialist.
 - ii. 1 specialist in public health/health management with at least a PhD degree, who will be part of the Local Pilot Implementation and Evaluation Team
- g. Required: Screening (telephone and documentation) of 2000/5000 people aged 60+, of which at least 500 people will be included in the e-consultation program.
- h. The facilitator of each project will be responsible for developing, based on recommendations and within the budget received, an online platform for the FRA-MA-SARC assessment
- i. Recommended: Foreign partnership (a foreign partner, e.g. Norwegian, with experience in running telemedicine projects including in broadly defined geriatrics, whose role will be to consult on building a detailed pilot protocol and to discuss problems and help solve them during the project)
- j. Recommended: Partnership of a senior or patient organization whose role would be to spread the idea of FRA-MA-SARC to its members, potential future users of the platform.

3) Hardware requirements (minimum)

- a. Senior User: Computer/laptop/tablet/smartphone with broadband internet access, capable of e-consultation handling in video mode.
- b. Primary care office: computer with broadband internet access capable of providing teleprompting. www.pacjent.gov.pl
- c. A e-consultation point within the POZ's office/geriatrician's office- an area that allows for e-consultation (a room equipped with a convenient computer station),
- d. A e-consultation point within a POZ's office or other dedicated location within a health care facility (e.g., pharmacy) - a e-consultation area designed to level the playing field for patients with lower e-health literacy (competences to use e-health services) - a room equipped with a comfortable computer workstation with an additional chair for a trained staff member responsible for supporting an elderly person during e-consultation,

- e. Geriatric office: computer with broadband Internet access to provide teleconsultation and specialty e-consultation.

10. Bibliography

This study is based on expert knowledge, consultation with the Norwegian partner, and analysis of the literature. The key literature items are listed below.

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