

Telemedicine Model in Chronic Diseases:

Chronic Obstructive Pulmonary Disease

prof. Marcin Grabowski, dr hab. Paweł Balsam, dr hab. Justyna Zajdel, prof. Grzegorz Opolski

Report prepared by MP MED Sp. z o.o. experts 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

Table of content:

Best practices	2
Recommendation	6
Description of the model.....	11
Implementation and formal evaluation of the pilot model	18

Chronic obstructive pulmonary disease (COPD) is a progressive lung disease with a high prevalence and an extraordinary socio-economic impact on patients and healthcare systems. Early detection of exacerbations could reduce adverse health outcomes for patients and lower costs for patients with COPD.

Best practices

iTrain

Pulmonary rehabilitation is an effective intervention for the treatment of people with chronic obstructive pulmonary disease (COPD). However, available resources are often limited and many patients suffer from poor accessibility to programmes. Maintaining the benefits associated with PR and regular exercise over the long term is difficult without any exercise maintenance strategy. In contrast to traditional centre-based PR programmes, telerehabilitation can promote more effective integration of exercise into daily life in the long term and broaden its use and accessibility. Several studies have shown promising results in telerehabilitation, but mainly with short-term interventions (doi: 10.1186/s12890-016-0288-z.)

An international, multicentre, randomised trial with a control group, conducted at centres in three countries, will recruit 120 patients with chronic obstructive pulmonary disease (COPD). Participants will be randomly allocated to telerehabilitation, treadmill and control and followed up for 2 years. The telerehabilitation intervention consists of individualised physical training at home on a treadmill, telemonitoring by a physiotherapist via video conferencing using a tablet, and self-management via a customised website. Patients in the treadmill arm have a treadmill only for unsupervised exercise at home. Patients in the control arm are offered standard care. The primary outcome is the total number of hospitalisations and emergency department presentations. Secondary outcomes include changes in health status, quality of life, anxiety and depression, self-efficacy, subjective impression of change, physical performance, physical activity level and personal experience of telerehabilitation.



<https://pubmed.ncbi.nlm.nih.gov/27549782/>

Assessed physical activity among people with COPD in two Scandinavian countries and Australia

Seasons and weather conditions can influence physical activity and contribute to differences between countries. The present study aimed to investigate whether there are differences in physical activity levels between Norwegians, Danes and Australians with chronic obstructive pulmonary disease (COPD) and to determine whether any differences in physical activity can be attributed to the seasons. A cross-sectional study in which participants were people with COPD who had participated in two separate clinical trials: the iTrain study (Norway, Denmark and Australia) and the HomeBase study (Australia). Physical activity was assessed objectively using an activity monitor; variables were total energy expenditure, number of daily steps, sedentary wakefulness, light and moderate to heavy physical activity. Differences in physical activity between countries and seasons were compared, taking into account disease severity.

In this cross-sectional study, time spent in sedentary wakefulness was longer in participants from Denmark compared to participants from Norway and Australia after accounting for disease severity. The number of steps in all patients was highest in summer and lower in spring, winter and autumn, regardless of geographical location. In particular, the overall difference between summer and winter exceeded the minimal clinically relevant difference in daily step count after pulmonary rehabilitation. Weather conditions and seasonal variations may affect results in clinical trials and health registers measuring physical activity over time, regardless of the interventions provided, and should be taken into account when interpreting results.

<https://www.dovepress.com/seasonal-variations-in-objectively-assessed-physical-activity-among-peer-reviewed-fulltext-article-COPD>

USECARE

USECARE focuses on ICT solutions for people with chronic or non-communicable diseases (NCDs) such as heart failure, early diagnosis of type 2 diabetes and COPD Gold 1, as well as for informal caregivers (family, neighbours, friends). The USECARE project aims to show how current ICT can support the flow of information between the patient and informal caregivers, sensitize the public as the ultimate stakeholder for adequate remuneration, and add a solution to reduce stress for both patients and caregivers.

SENACA's current solution is technically based on the 2net platform, a robust cloud-based system designed to be universally interoperable with various medical devices and applications, enabling end-to-end wireless connectivity, while allowing medical device users and their doctors or caregivers easy access to biometric data. In collaboration, a pilot network has been established with a further 2 sites located in Norway (senaca.no) and Israel (senaca.il). In each of the 3 participating countries a group of patients will be recruited, provided with and trained in the prototype self-management system.

Further development of the current prototype of the SENACA 2.0 self-management system (for SENior Health ACAdemy) to enable caregivers to remotely control critical patient biomarkers, treatment adherence (medication and lifestyle), information aggregation and social interaction.

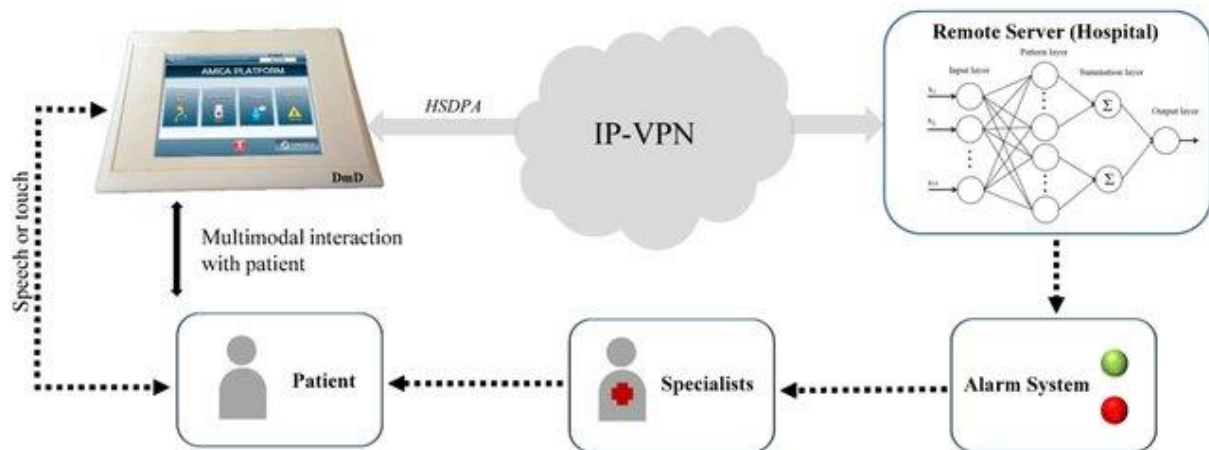
<https://ehealthresearch.no/en/projects/usecare>

AMICA: Autonomy, Motivation & Individual Self-Management for COPD Patients

Automatic prediction of chronic obstructive pulmonary disease exacerbations by telemonitoring of symptoms at home.

A group of patients were telemonitored at home using a novel electronic daily symptom questionnaire during a 6-month study. The recorded data were used to train and validate a probabilistic neural network (PNN) classifier to enable automatic prediction of exacerbations. The proposed system was able to predict COPD exacerbations early with a margin of 4.8 ± 1.8 days (mean \pm SD). The detection accuracy was 80.5% (33 out of 41 exacerbations were detected early); 78.8% (26 of 33) of those detected also had an exacerbation, and 87.5% (7 of 8) were unreported episodes. The proposed

questionnaire and the designed automatic classifier may help in the early detection of COPD exacerbations to the benefit of both clinicians and patients.



https://www.researchgate.net/publication/265734167_Automatic_prediction_of_chronic_obstructive_pulmonary_disease_exacerbations_through_home_telemonitoring_of_symptoms

United4Health (U4H) project - [UNI](#)versal solutions in [Telemedicine](#) [Deployment](#) [FOR](#) European [HEALTH](#) care

The United4Health (U4H) 2 project has tested telehealth services for COPD. The aim is to provide an alternative way to support self-treatment by providing an appropriate level of tele-monitoring that is flexible and can respond to fluctuations in their condition and thus avoid future emergency hospital admissions for COPD exacerbations. The duration of intervention and follow-up for an individual patient is up to 12 months.

A COPD care pathway that included telemedicine services and would operate at different levels of management was established in the Agder region of southern Norway as part of the European United4Health (U4H) project. (<http://www.united4health.no/>). The project started in 2012 and ended in 2015. The telemedicine service was established as a municipal service (Gallefoss et al., 2012), while in the other project regions it was a service organised within hospitals (Kidholm, 2016). Three telemedicine centres (TMCs) were established; each was to cover a group of surrounding municipalities.

U4H comprises 3 phases, corresponding to three levels of tele-monitoring intensity. A patient admitted with an exacerbation of COPD is discharged from hospital and provided with a tele-monitoring package including videoconferencing and a pulse oximeter. In the first phase (High Level TMon) there is a daily teleconsultation with the GP nurse (by video-consultation or by telephone if this is not possible). The patient answers questions about symptom management and records pulse oximetry readings, which

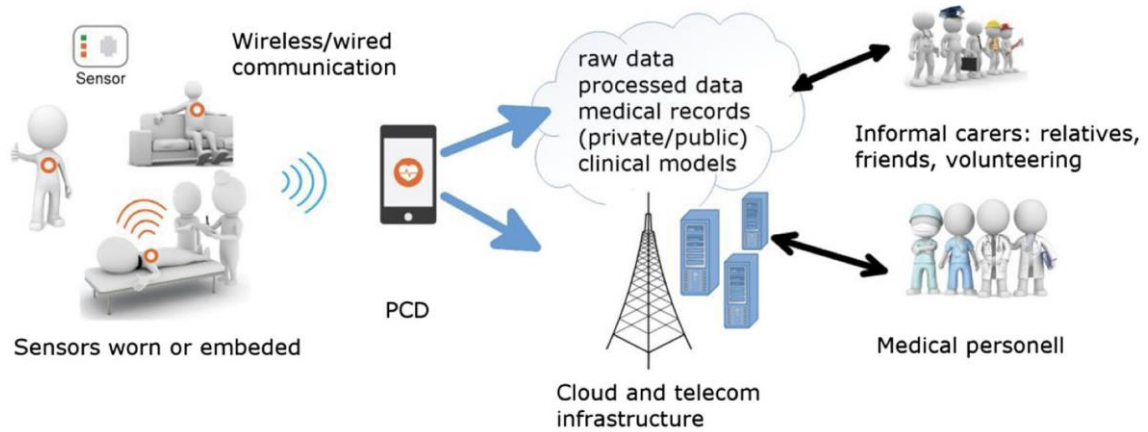
are sent prior to the teleconsultation. This phase is expected to last approximately 10 working days, but may last between 5 and 30 days, depending on the doctor's decision. In addition, if there are worrisome clinical symptoms, the patient may be referred for a medical examination and, depending on the condition, referred back to hospital. In this case they remain in the study and are discharged again from High Level TMon. At moderate level patients update pulse oximetry and symptom questions daily for up to 12 weeks (minimum 4 weeks) after discharge from hospital. The GP nurse receives this data and responds to any alerts and seeks advice from the GP and hospital specialists if necessary. Finally, low-level telemonitoring includes optional symptom management questions and behavioural text reminders or links to websites sent to a mobile phone for up to 12 months after discharge from hospital. Overall, the intervention and duration of follow-up (including the three levels of tele-monitoring intensity) for an individual patient can be up to 12 months (and a minimum of three), depending on the recommendation of the treating physician.

The evaluation was conducted using the MAST multidimensional assessment methodology (Kidholm et al., 2012). The study had an observational design, with intervention and comparison groups. The comparison group consisted of patients, distinct from those in the intervention group, who met the eligibility criteria and had been treated and observed for at least one year prior to the telehealth service, from the same health facilities as the intervention group. Patients in the comparison group received usual care. Usual care is managed by the patients themselves, supported mainly by a GP and a GP nurse, who make home visits depending on the patient's condition. Clinical information is recorded in the EHR provided. Patients may have scheduled appointments to review their treatment plan and self-manage. They may be referred to medical and nursing specialists in COPD if necessary. Eight indicators of success were assessed: hospital admissions, emergency room access, physician consultations, total cost of treatment, acceptance, organisational changes, reasons for non-participation and differences in clinical outcomes. The intervention is now in routine use as SERGAS has integrated tele-monitoring as one of the treatments available after discharge.

Recommendation

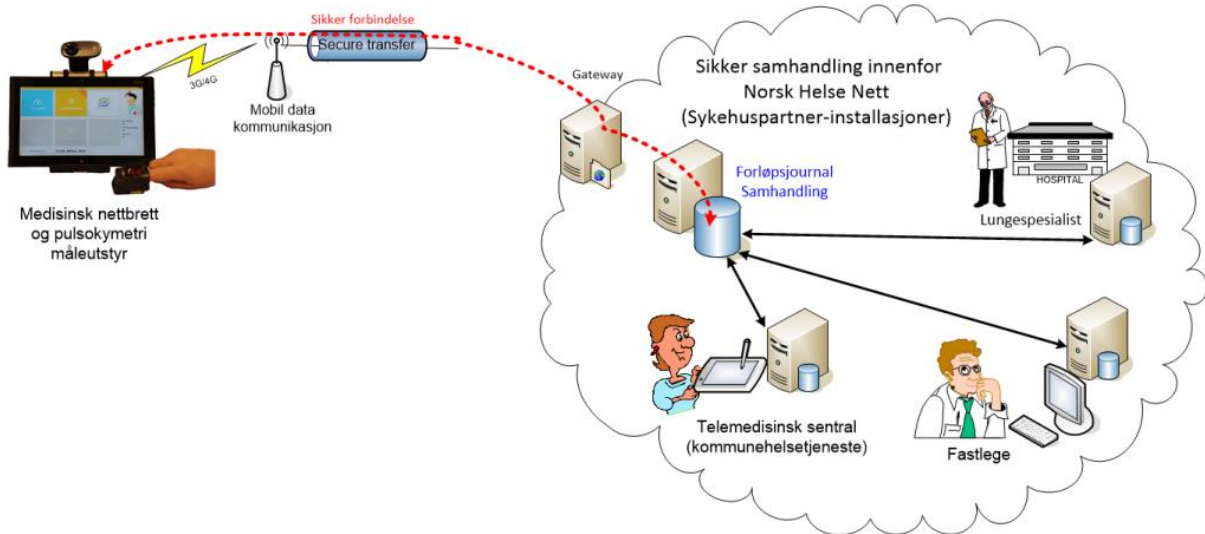
Based on previous studies, the literature review and the analysis presented above, we recommend that the United4Health (U4H) project be implemented in Poland as a whole to monitor patients with COPD.

Overall architecture of the monitoring system



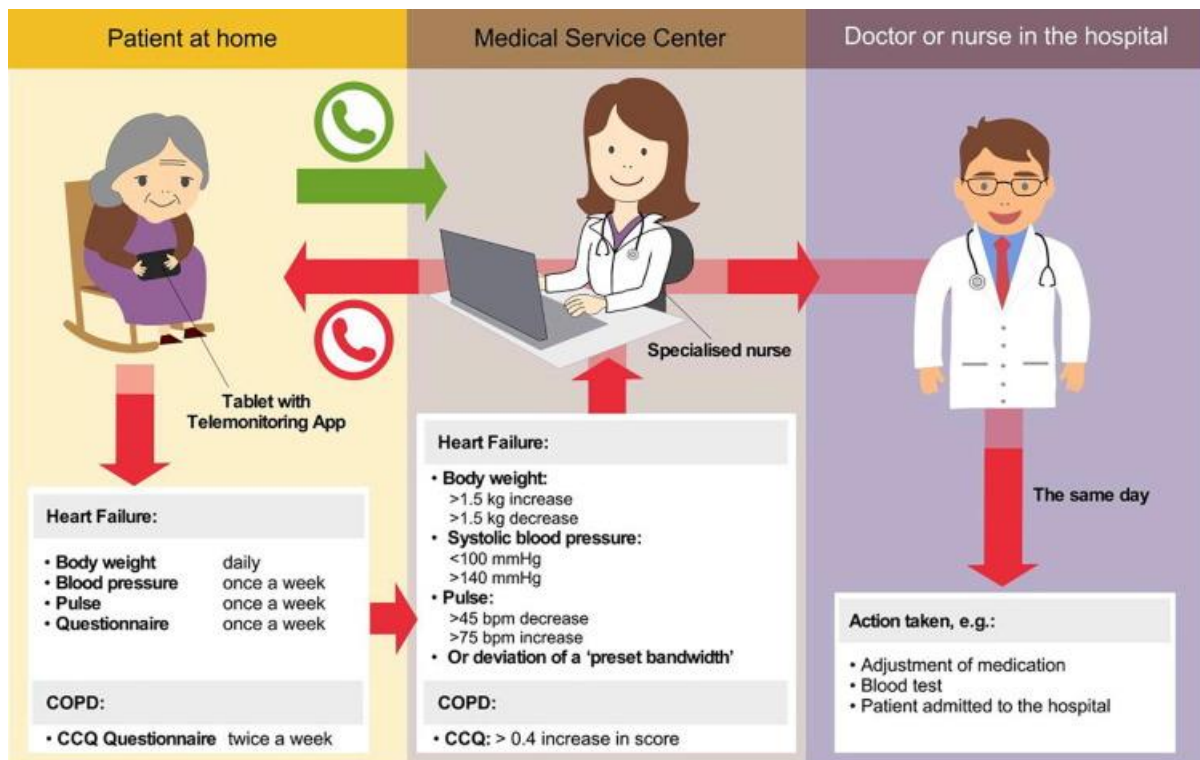
<https://link.springer.com/content/pdf/10.1007/s11517-018-1798-z.pdf>

A comprehensive scheme of how the entire system works can be based on the following example



<http://www.united4health.eu>

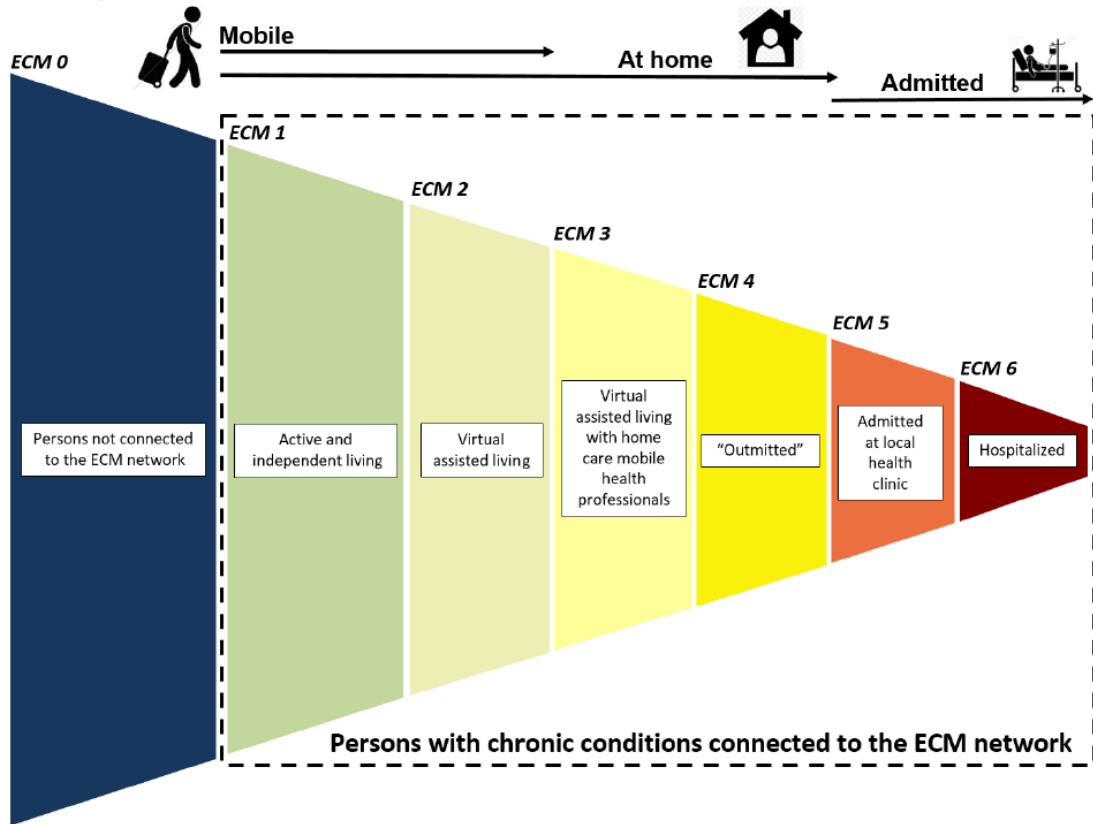
Monitored parameters and response system



<https://www.sciencedirect.com/science/article/pii/S2588914120300071>

The global effect describes E-(hos)pital Care Model

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



Source:

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

The materials provided above presented information on the prevalence of chronic obstructive pulmonary disease (COPD) and patients' challenges during treatment. Based on available scientific data, epidemiological reports and the authors' clinical work experience, areas in the care of patients with COPD that can be improved were identified. Telemedicine solutions seem ideal for improving care. A number of solutions used worldwide are outlined above. There appears to be an opportunity to develop a systemic solution that is based on scientific data. The presented model of care for patients with COPD is based on comprehensive care with effective use of human and technological resources.

It is noteworthy that the entire model will focus on the patient, their needs and the challenges they face in their daily functioning. In addition, each patient will be treated individually, and individual

specialists should always balance their decisions with the patient's best interests. A patient with appropriate, comprehensive, multidirectional care will benefit by improving their prognosis.

The number of patients with COPD is increasing - in the United States COPD is already the 3rd cause of death nationwide.

In Poland, it is estimated that such a diagnosis can be made in more than 2 million citizens. COPD is a severe disease requiring chronic treatment. Moreover, the quality of life of this group of patients is significantly lower and treatment is a huge challenge. In addition, these patients usually have many other burdens in addition to COPD, are more often hospitalised, which, together with an increased frequency of outpatient visits, entails huge costs for the payer. According to the authors of the study, comprehensive care based mainly on outpatient care will reduce costs and improve the quality of life and prognosis of patients with COPD. Correct treatment allows to avoid e.g. unplanned hospitalisations related to exacerbation of COPD.

The treatment of these patients is a complex process, part of which may take place in the primary healthcare centre (POZ). In the model described below, it is in primary care that part of the treatment will take place - e.g. appropriate patient education regarding recommendations for lifestyle changes, i.e. stopping smoking, physical activity, diet, use of stimulants. On the other hand, periodic support from a lung disease specialist is necessary to optimally treat patients according to the latest patterns suggested by global scientific societies. Part of the contact with the healthcare system can be based on e-health solutions, e.g. teleconsultations supplemented by data from a mobile spirometer with which the patient takes measurements at home. Eventually, some appointments will be made on site, as it must be remembered that telehealth has its limitations and that direct contact and physical examination remains a valuable tool in the hands of the doctor.

Based on the available scientific data and the analysis of possible solutions, the working group working on the solution of the model "Chronic Obstructive Pulmonary Disease" in the reports of the earlier stages presented a proposal of applications that could find a place in the conditions of the Polish health care system. In reference to the arrangements with the Employer, this paper discusses the pilot phase in more detail and in a complete manner and refers to the nationwide implementation phase.

Description of the model

a. Substantive assumptions

We recommend that the final targeted solution is a platform integrated with the available and continuously developed by the Ministry of Health elements of e-health in Poland (patient.gov.pl, gabinet.gov.pl). The pilot programme will use a dedicated web platform, which will serve to coordinate activities around the patient and as an educational tool for patients. It is intended that the platform will enable the acquisition of medical data and their management by doctors and nurses, as well as being a tool for providing services, i.e. teleconsultation, remote monitoring. This is a modern approach to the prevention of exacerbations of the disease and deaths due to it. According to our analysis, the care model described in this document is possible to develop and implement with the cooperation of centres that have extensive experience in managing patients with COPD, as well as in employing world-class specialists. Acquisition/leasing of the platform will be the responsibility of the centre that undertakes the pilot. We recommend that integration with government platforms should take place in the next stage, after the pilot has been completed and the effectiveness and safety of the platform has been confirmed. Among the competences of the team members should be the knowledge of the functioning of the health care system in Poland with particular emphasis on the path that the patient goes through during treatment. Team members should be aware of organizational, financial and legal constraints. It is advisable to be fluent in IT, with preferred experience in telemedicine applications. It is desirable that people working on the project have project management skills and preferably be a past leader of a similar project on an international scale. Availability and responsiveness in case of an emergency is required. Experience in international projects will be an additional asset, which will translate into easier adoption of solutions from outside the Polish healthcare system.

Given the requirements outlined above, it is expected that the project promoter will have experience in implementing similar projects. Technical and organisational background will be an asset. Moreover, experience in the implementation of European programmes will be a benefit. An added value, but not an indispensable requirement, will be documenting the possibility of acting within a business consortium with partners from the IT sector, social sector, patient organisations. In addition, cooperation with a partner from Norway remains an option, which will allow to look at all assumptions and solutions from a broader perspective.

The implementation of the pilot should be supported by prevention and information activities, both on the side of the specialist centre and of the POZ. The scope and range of these activities should be adapted both to the geographical area covered by the pilotage, target groups, as well as the type of information and goals to be achieved.

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

Information and prevention activities are aimed at improving awareness of the importance of the problems addressed in the pilot, taking into account the broadly understood prevention of lung diseases.

It should be emphasized that in the described model, it is the primary care centre that will provide part of the treatment supported by relevant educational and preventive activities raising patients' awareness - e.g. appropriate education of patients on recommendations to change their lifestyle, i.e. stop smoking, physical activity, diet, use of stimulants.

An educational panel should also be created within the Internet platform, which should contain basic information on pathophysiology, symptoms and treatment (including validity of treatment, influence of smoking, diet, physical activity etc.) of COPD for patients.

In addition, the educational panel should also contain basic information on diseases other than COPD - for example, hypertension, the most common cancers, etc.

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

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

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

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

b. Technological assumptions

The presented project is a proposal of using a web platform that allows the patient, doctor and nurses to cooperate and coordinate the treatment process, assess the patient's health condition and have consultations. The platform will collect data on the treatment process. The described project will provide an opportunity to collect extensive population analysis, which will serve as a basis for further optimization processes of the health care system. The platform should have the following functionalities:

- Accessible via a web browser

- Adapted for use by smartphones and tablets with a possible dedicated mobile application

- Have the ability to register and log in taking into account legal requirements for confirming patient identity. If possible, the platform should be integrated with the patient's account on the patient.gov.pl portal
- In order to support and facilitate moving around the platform, a tutorial should be created, which will help to go through the subsequent stages of platform operation
- Despite the multitude of options, the system should be simple to use, but offer a range of options. It is intended that large, clear fonts will be used and additional links will be limited.
- An "assistant/support person" function will be available for people who are not proficient in this type of solution. The support person would assist in operating the platform and its full use.
- Attention should be paid to data security - it will be advisable to conduct security tests by an external company that specialises in this area
- Adding further functionalities on the basis of patient consultation and taking their needs into account
- An educational panel should contain basic information on pathophysiology, symptoms and treatment (including validity of treatment, impact of smoking, diet, physical activity, etc.) of COPD for patients.
- An educational panel containing basic information on diseases other than COPD. For example, hypertension, the most common cancers, etc.
- The panel may integrate measurements from spirometry performed using a dedicated device such as AioCare. In addition to the parameters from spirometry, the device also measures blood saturation. In case of alarming results, the system itself alerts the user and the attending physician, who should then intervene.
- Provide the possibility to upload the patient's medical records, as well as notes from individual contacts with the healthcare system representative.
- If a consultation in the primary care, with a pulmonologist on an outpatient basis or in the hospital is necessary, the doctor and the nurse must have access to the data on the platform
- A summary of the patient's past and planned treatment process, so that the consulting specialist can take a broader perspective on subsequent events, taking into account the patient's subsequent visits
- The platform should be accessible to patients, doctors caring for the patient within the described programme, as well as other specialists treating other conditions.

c. Economic assumptions

Currently, there are over 2 million people with COPD in Poland. According to specialists' forecasts, this number will continue to grow. It is obvious that not every patient will be interested in participating in the presented project. Nevertheless, the number of people requiring care is undoubtedly huge. It should not be overlooked that with the ageing of the population, the number of patients with COPD will increase. Moreover, more and more people will be able to benefit from telemedicine solutions. Given the above, a steady increase in the number of people interested in this programme is to be expected. A sample cost calculation for the pilot is shown below:

- IT costs, taking into account:
 - a. the duration of the project
 - b. the number of roles on the platform (doctor, nurse, patient)
 - c. the capabilities of the platform (including integration with spirometer and automatic data transfer)
 - d. transmission of notifications and messages (organisational and educational)
 - e. management of schedules of individual persons involved in the project
 - f. making notes after visits
 - g. possibility of audio-video communication
 - h. generation of reports
- The cost of creating and providing the service for the duration of the pilot is likely to be around 600,000 PLN. This amount includes the delivery of the platform by an external company, preparation of patient surveys, graphic support, maintenance and support in case of problems with the platform. The cost was estimated based on the market analysis and experience of the authors of the study.
- The rental cost of the mobile spirometer from the manufacturer and data transfer from it is 1000 PLN/patient. The cost refers to the rental of the equipment for 3 months - the entire period of patient participation in the project. Assuming 500 patients are included in the pilot, the cost will amount to 500,000 PLN.
- Taking into account that not every patient has a computer/tablet/smartphone with Internet access, some funds should be allocated to provide them with the opportunity to participate in the pilot by having access to such a device. We estimate that this need will occur for

approximately 50 patients. The cost per patient is 2000 PLN, so the total cost will be 100,000 PLN.

- Another expense will be the purchase of computers for primary care doctors, pulmonologists and nurses. The cost of one computer is 6000 PLN. Number of required devices: 15 (approximate quantity, may change). Total cost: 90 000 PLN. Please note that the purchase of equipment may constitute up to 37% of the project value.
- It is also necessary to take into account the costs of implementing the solution - approx. 10,000 PLN per each primary healthcare facility (POZ). The final cost depends on the number of POZ that will participate in the project. Minimum number of POZ: 3, maximum: 10 Total cost is about 70,000 PLN.
- The project requires a dedicated website with a promotional panel and its regular management - the estimated cost is 30,000 PLN.
- In addition, leaflets, posters and advertising spots will be created for the promotion and implementation of preventive and educational activities. Thanks to this, patient recruitment should run smoothly and patients should be willing to join the programme. The total cost will amount to approximately 60,000 PLN.
- The costs associated with the provision of medical services are as follows:
 1. pulmonologist - 250 PLN per visit
 2. primary care physician – 200 PLN per visit
 3. nurse – 150 PLN per visit
- Within the program, a patient will have 1 visit to a pulmonologist, 2 visits to a POZ physician and 1 visit to a nurse - the total cost of visits per patient is therefore 800 PLN. With the suggested number of patients equal to 500, the total cost of medical visits will amount to 400,000 PLN.
- As part of the project, patient satisfaction will be assessed - the cost of the forms and their conduct is approximately 6000 PLN.
- Educational and promotional materials will be created for the programme (training materials, instructional videos, educational meetings addressed to potential patients) - the estimated cost of this task is 40,000 PLN.
- Remuneration for persons comprising the group for management and evaluation of the pilot - remuneration based on tasks. Tasks will include e.g. training of primary care physicians, nurses, pulmonologists, conducting an assessment of the feasibility of implementing the programme on a wider scale, assessing the coherence of the described project, assessing the level of

satisfaction of individual users, publicizing the results obtained (publications, webinars, materials for conferences and websites), legal and IT support, etc. Among the members of this group will be several pulmonologists who will oversee the project, provide training, be responsible for legal collateral. The estimated amount may eventually be less. Exact calculations are not possible at this stage. Each expense will have to be conscientiously recorded and accepted by the payer - the estimated cost is 500 000 PLN.

- Potential cost of participation of patient organisations - support in implementation and improvement of the programme - 80,000 PLN.
- Potential cost of participation of the Norwegian partner, who will support the Polish side, consult and advise within the described project - 100,000 PLN. The cost includes substantive support to the Polish side in the implementation of the project through exchange of experience, knowledge sharing through consultations, meetings, conferences, webinars as well as through participation in the development of information and training materials. Cost estimated on the basis of similar projects.
- Travel costs of project participants (meetings with the Norwegian partner) in case of cooperation - approximately 50,000 PLN
- Cost of project management - 10% of the total budget

To sum up: the cost of the project should amount to approx: 2 700 000 PLN (the value of the pilot project may range from 200 000 - 675 000 EUR). The final value of the project depends, among others, on the number of examined persons, the number of cooperating primary healthcare facilities (POZ) and the scope of cooperation with the partner and patient organisation.

d. Legal requirements

- Patient's consent to processing of personal data

Participation in the described project involving the use of a telemedicine system to coordinate and support the care of patients with COPD requires the patient's unambiguous and informed consent to the processing of personal data in the broad sense, including health information. Obtaining informed and explicit consent from the patient will obligatorily be the first stage of care. According to recital 32 of the preamble of the GDPR, it is indicated that consent can be given by ticking a box when browsing a website, selecting a technical setting, or any other statement that indicates without doubt that the

patient has accepted the proposed broad processing of personal data. Nonetheless, we propose that the patient's consent to process personal data and to participate in the pilot be expressed in writing, in a dedicated document prepared in advance. Alternatively, in exceptional circumstances it may be possible to give consent by ticking a box on the website as shown below:

I consent to the processing of my personal data in respect of ..., 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 the personal data of a concerned citizen are collected directly from that person, the controller is obliged to provide a number of information described in the cited provision when collecting the personal data. It follows that the controller should make available an information clause which will contain a number of information indicated below. Their content should be communicated to the user before he/she fills in the questionnaire. In the described pilot program it is suggested to include the information clause in a dedicated document, which will be attached to the patient's written consent to the processing of personal data. Alternatively, if the patient proceeds to complete the form via the website and consents to the processing of personal data by ticking a box, then it is possible to include the information clause in the relevant tab on the website. The analysis of similar solutions used globally indicates that the information clause is most often included on the website, in a dedicated tab with the proposed name "privacy policy". We suggest that information about data processing be properly segregated and titled instead of placing an incomprehensible sequence of definitions and clauses referring to individual pieces of legislation. It should be remembered that the overriding aim is to inform users (i.e. mainly elderly people, often not familiar with complex legal issues) in an accessible and understandable way.

- Patient consent for the examination and the provision of health services

Given the fact that most of the participants in the pilot will probably be seniors, it is very important to give informed and consent to the examination and provision of health services. Given the fact of patient autonomy, the principle of consent for health services is very important. Capability to consent means the ability to decide independently whether or not to undergo a 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 examine the patient or provide health services, subject to exceptions provided for in the Act, after the patient has given his/her consent. On the other hand, there is also

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 the patient has the right to give consent or lack of consent for the examination and provision of other health services - including therapeutic ones. Taking into account the above-mentioned legal acts, it should be deduced that full capacity to consent is held by adults who are not completely incapacitated and are capable and able to give informed consent. Consent is given verbally, by signing a document or by a patient's behaviour that does not raise doubts about the patient's willingness to undergo a medical service (cf. Article 32(7) of the Act on Physician and Dentist Professions and Article 17(4) of the Act on Patient Rights and Patient Ombudsman). In the described telemedicine model, it seems that the best method of giving consent will be a document signed by the patient himself. The consent should include information about the examination, the planned health services and the benefits and risks for the patient. The patient should receive both a copy of the consent and a document describing the planned procedure. This obligation arises from Article 31(1) of the Act on professions of doctor and dentist. On the other hand, the patient's right to information is described in Article 9(2) of the Act on Patients' Rights.

- Guidelines of the Supreme Medical Council for the provision of telemedicine services

Resolution No. 89/20/P-VIII concerning the adoption of guidelines for the provision of telemedicine services was adopted on 24 July 2020. The document was prepared by a team of experts from the Supreme Medical Council for telemedicine together with the Telemedicine Working Group and was created to provide support to physicians during the provision of telemedicine services. The resolution has an appendix consisting of three annexes. The Guidelines for the Provision of Telemedicine Services is the part that covers legal requirements related to the processing of personal data related to telemedicine, practical issues as well as technical and organisational aspects. In addition, guidelines with ethical aspects regarding the provision of services in a form other than in-person are discussed. Finally, the 10 steps of a telemedicine visit are also presented, where the individual steps of the services during a teleconsultation are described. For this telemedicine model of care, it is essential to take into account the above-mentioned documents in order to follow both the letter of the law and the best available medical practice.

Implementation and formal evaluation of the pilot implementation model

a. Assumptions

In order to implement the described programme on a large scale, it is advisable to carry out a pilot programme to assess the performance and functionality on a smaller population. The authors of the

study suggest using an external platform, whose functions and possibilities are described below, and whose costs are described in a previous paragraph. It is suggested that the project should be implemented in close cooperation with the Norwegian partner, who will support the Polish side, provide comments and participate in meetings. The pilot study should be carried out in a unit selected through a competition. The requirements includes:

- Specialist facilities (a team of experienced lung disease specialists approximately 10 → 1 specialist per 50 patients) with access to outpatient and inpatient care, as well as the capacity to provide care to a specific group of patients, conduct meetings and trainings
- It is advisable to have experience in conducting projects in the area of health, which are financed from public funds - to demonstrate the implementation of at least one such project
- Academic background will be an asset
- Closely cooperating primary healthcare facilities (POZ), under the care of which patients are placed after hospitalization (minimum 3, maximum 10). It should be remembered that the care should also include patients from deprived areas, who will constitute at least 10% of the population covered by the pilot project.
- Experience in projects with primary healthcare facilities (POZ) - documented implementation of at least one project based on cooperation between a hospital and a POZ.
- Experience in the implementation of international projects, especially including telemedicine solutions will be an asset, but is not mandatory
- Patients' organisations' agreement to cooperate in the implementation of the project - advisable but not necessary.
- At least 10% of patients should be people from deprived areas with difficult access to regular medical care

According to the authors of the presented analysis, in order to ensure consistency, maximal simplification and facilitation of the project management, the pilot study can be carried out by the centre, which will be responsible for carrying out the project tasks and for the quality of data obtained for further studies. However, it is also possible to coordinate the project by several centres in parallel. Around the main centre there should be a large primary healthcare facility (POZ) and several smaller centres with which cooperation will be established. There should be at least one primary healthcare facility (POZ) within the cooperating POZs to care for patients from deprived areas. As indicated above, ultimately such patients will constitute at least 10% of the population covered by the project. The

described model will allow smooth expansion of the programme on a national scale, in which each hospital/institute will cooperate with several POZ. It is also possible to start the pilot simultaneously in several institutions.

b. Implementation stages

- The pilot should be supported by an information campaign aimed at promoting the project and the initiative in medical circles and among patients. The campaign should be based on telephone advertising, advertising in social-media, leaflets in primary healthcare facility (POZ) and hospitals and through a dedicated website.
- In the competition, in accordance with the assumptions of the programme, supra-regional hospitals and institutes may apply for funding for the pilot project, and they will be the applicants who will select cooperating primary healthcare facilities (POZ). The institutions do not have to be in a similar region, because thanks to the development of telemedicine, geographical barriers are no longer relevant. Moreover, at least 10% of the patients will be people from excluded areas. In this phase, information and training meetings will be held with persons from primary healthcare facility (POZ) who will be interested in participating in the pilot. To carry out this stage effectively it will be advisable to use training materials, information leaflets, instructional videos and meetings to discuss the exact issues of the project and potential difficulties.
- The next stage will be to start recruiting patients. Recruitment will take place in both inpatient and outpatient settings following a diagnosis of COPD. The authors expect that some patients will be enrolled in the study during hospitalisation for an exacerbation of COPD or a de novo diagnosis of COPD. The planned population initially includes 500 patients. Based on experience, the authors of this study estimate that in order to recruit 500 patients, screening should be performed on approximately 1500 patients, bearing in mind that the final decision on participation in the project is up to the patient.
- This will be followed by meetings with patients' representatives (1 every 3 months) and meetings with centres caring for patients (1 every 4 months for each centre). These meetings will focus on the expectations and perceptions of the patients and discuss potential solutions. This is an important aspect of the project which takes into account the views and needs of the patients around whom the programme is being developed. It will enable those developing care policies to accurately consider the needs of patients and support them in the challenges they face on a daily basis.

- At the end, there will be an evaluation and analysis of the implemented solution. Patients' quality of life, prognosis and control of the underlying disease will be taken into account, as well as a cost analysis of the whole exercise. The evaluation will be based on two pillars: 1) qualitative data: Observations and interviews with participants regarding their expectations and experiences during the project. To observe unexpected events and challenges that may support or threaten the project. 2) Quantitative data on the expected outcomes of the project. Process: data should be recorded: who carried out the consultation, how long it lasted, costs of personnel and equipment involved, etc. 3) Outcomes: Patient experience and opinion. Outcomes should be assessed on dedicated scales to evaluate the different elements.
- Finally, a study will be carried out on the feasibility of applying this solution on a large, national scale, provided that the results of the previous studies are positive. The Norwegian side will be invited to assist, if cooperation with the Norwegian partner can be established. The Norwegian partner will be asked to look at the topic from a different perspective and identify potential strengths and weaknesses of the implemented project. Then, on the basis of the developed results, it will propose a scheme to implement the solution on a large scale. One should bear in mind the possibility to not find the Norwegian partner, in which case the project must be implemented without its support. This is why the partner's participation in the project is described as an advisory body and not as the main contractor. If required, it may be necessary to analyse for possible changes in the project depending on the progress of the project and taking into account the possibility of changes specified by the regulations of the Norwegian Financial Mechanism 2014-2021.

c. Detailed description of the proceedings pathway

The care of patients with COPD requires a coordinated approach between inpatient and outpatient settings. The aim is to improve patients' prognosis, improve their quality of life and reduce hospitalisations. A properly designed care scheme will save funds, as hospital visits are the most expensive method of delivering medical services. In order to make the above assumptions possible, a multimedia platform is needed, which enables cooperation between many specialists, but above all brings the patient closer to the treatment process. On this platform, roles should be created: patient, nurse, POZ physician, pulmonologist (both outpatient and in-hospital). Each person has specific tasks

and opportunities within the platform regarding the therapeutic process of a patient with COPD. The role of each member of the overall process will be discussed below.

Registration of centres willing to participate in the pilot.

1. Training of centres on the planned procedure.
2. Recruitment of patients for the study.

Pulmonologist

In hospital

A significant number of patients with COPD are admitted to hospital, where they present mainly because of shortness of breath, cough and reduced physical capacity. During hospitalisation, doctors aim to establish stabilisation of the condition and implement optimal treatment to reduce the patient's symptoms and improve their prognosis. In some patients, spirometry and other imaging tests are performed, among other things. Each patient has an individually adapted pharmacotherapy, taking into account concomitant diseases. Nevertheless, COPD is a progressive and dynamic condition, which requires regular adjustments and changes in pharmacotherapy. The role of the doctor managing a patient with COPD in a pulmonary ward will be to enter the patient's discharge record into the platform, with test results and recommended pharmacotherapy attached. A note for the coordinating pulmonologist should also be added to the platform so that the patient is managed according to a single pattern. For example - recommended repeat cardiopulmonary exercise test using treadmill or cycloergometer in 3 months to assess respiratory function and indications for possible intervention. The patient will have access to the recommendations through their account on the platform.

In summary, the role of the pulmonologist in the hospital is to stabilise the patient's condition and to set the course for the therapeutic and diagnostic process, which the patient will mostly be able to follow in the outpatient care setting.

In outpatient specialist care

The second person involved in the care of a patient with COPD will be a pulmonologist working within the outpatient specialist care service. It is this doctor who will be the person to guide the patient. The idea is that he or she should follow the plan proposed in the hospital, but may also modify it depending on the results of subsequent tests and the patient's condition. There will be two possibilities for the patient to contact the pulmonologist: a teleconsultation and an in-person visit. For

patients in a stable condition, without complaints, teleconsultation seems to be a sufficient form of contact. Based on the spirometry and saturation measurements taken from the mobile spirometer, the results will be transmitted to the platform. In this way, the teleconsultation will not be limited to just talking to the patient. In case of alarms from the system or self-observed abnormalities in the reported tests, the pulmonologist will initiate contact and recommend intensification of pharmacotherapy, an in-person visit or hospitalization. In the interval designated by the physician, the patient will come for personal visits for examination and reassessment regarding indications for given medications and their doses.

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

Despite the fact that a large proportion of patients with COPD are sooner or later hospitalised for this reason, there is also a group of patients who have not been hospitalised before. In these patients, the diagnosis has been made in the context of outpatient care and has so far been treated optimally. The starting point for such a patient would then be the first visit to a pulmonologist within the framework of the described scheme. The other stages of care are the same.

Patient recruitment will proceed as follows:

- **During hospitalization:** during a hospital stay due to an exacerbation of COPD or a de novo diagnosis of COPD, the attending physician will propose participation to the patient and obtain appropriate consents.
- **During an outpatient visit to a pulmonologist:** some diagnoses of COPD are made in the outpatient setting, in which case the pulmonologist will also have the opportunity to propose participation to the patient.
- **Telephone contact:** this form of contact will be dedicated to patients registered in a given primary healthcare facility (POZ) who already have a diagnosis of COPD. The call will consist of an offer of participation and a presentation of the potential benefits of participation.

- **During an outpatient visit at GP:** similarly to the scenarios proposed above, the POZ physician will also have the opportunity to involve the patient in the project.
 - **After obtaining the consent, the patient will be offered a visit 0**
 - **Alternatively, on the basis of promotional materials, the patient will independently ask the primary care physician to participate in the pilot.** In this case the role of the POZ physician will be to carefully check the inclusion and exclusion criteria and collect relevant documents from the patient.
- an enrolment visit (referred to as "Visit 0" in the following document) - takes place within the scenarios proposed above - optimally with a pulmonologist, otherwise advisable pulmonology consultation to develop a treatment plan for the patient by a specialist), during it:
 - Accurate communication of information regarding the pilot, potential benefits and possible risks.
 - Collection of relevant consents
 - Brief training on the use of the platform and how to use the dedicated tutorial, or where to seek help in case of technical problems
 - Supervision of the patient during the initial sample spirometry and saturation assessments.
 - As part of a patient-centred approach, it is very important to identify the patient's needs and include this in the care plan. Moreover, the patient should be strongly involved in the whole care process taking into account their expectations and everyday problems. Furthermore, the whole programme should be adapted to the patient's life and plans in such a way that it is feasible. The plan should take into account the patient's private and professional plans. This approach is a challenge for the application described. It is certainly not an easy task, but putting the patient at the centre of the whole process is one of the main objectives of the whole project.
 - Informing the patient about his/her current state of health, risks, perspectives and plans for further management.
 - Then after one month \pm 5 days there will be visit 1 in the POZ setting
 - This visit will be a typical medical tele-visit during which the reported vital signs, symptoms of the patient will be assessed. At the end of the visit a note of the visit and

information with further recommendations for the patient will be posted on the platform.

- If there are any alarming symptoms, the patient will be referred for an accelerated pulmonology consultation or directly to the hospital emergency room depending on the patient's condition.

POZ physician

The primary care physician will follow up the recommendations given by the pulmonologist after discharge from hospital or the pulmonologist working in the outpatient specialist care. The role of the primary care physician will be to take care of the patient's health, periodic examinations and tele-visits to complement the specialist care. As part of his or her activity, the POZ physician will be able to change the dosage of medicines or add or discontinue individual medicines. It is important to remember that the pulmonologist will be the attending physician, however. The GP will also support the patient with prescriptions. If there is a gradual, steady deterioration in the patient's condition, the doctor will be able to ask the pulmonologist for an expedited visit or, if necessary, hospitalisation.

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

The GP will also be able to access a platform with reports prepared by the patient on their saturation and spirometry results to facilitate patient care.

Nurse

Nursing consultation will take place 2 months after the start of the pilot. In Poland, the role of nurses in coordinated care programmes is neglected, despite the fact that such support has proven its effectiveness in clinical trials conducted in our country and in the world. The role of the nurse as a complement to the whole programme is very important. Nurses as the contact persons with the

patient mainly by telephone interview the patient according to a previously prepared form. Simple algorithms make it possible to assess whether the patient requires urgent contact with a doctor in outpatient or inpatient care. Besides making sure that the patient does not currently have worrisome symptoms, a very important role of nurses is to educate patients. Regular and meaningful education has been proven to improve patient prognosis. This is because patients with a better understanding of their disease are more likely to follow their doctor's instructions, take their medication more regularly and avoid factors that may exacerbate COPD. Therefore, after completing the form, the second part of the nursing televisit will be patient education. Information for the patient should be individually tailored based on the patient's burdens and associated diseases. For example, a patient who smokes cigarettes should receive information that nicotine is very harmful to the respiratory and cardiovascular systems. On the other hand, a patient without diabetes does not require information on maintaining a glycaemic profile. The final stage of the conversation should be advice on the patient's diet, also adapted according to the presence of other diseases. Thanks to this visit, which will be recorded on the platform, the patient will remain under constant medical care, will receive a series of educational messages and will have the feeling of active participation in the treatment process. After each teleconsultation, the nurse will place an entry on the platform with information on what the conversation was about, what the patient was educated on, and the result of the prepared form along with a conclusion (e.g. patient referred to a pulmonologist on an elective basis/patient does not require an expedited visit/patient referred to the hospital emergency room).

- Finally, there will be a final teleconsultation to the primary care physician (visit 3) 3 months after the start of the pilot.
 - It will be a typical teleconsultation with assessment of reported parameters and the patient's condition. The patient will receive detailed recommendations for further management. During the teleconsultation the endpoints of the project will be evaluated, including quality of life, prognosis, frequency of unplanned hospitalizations.
 - Among other things, the model of care based on constant telemonitoring of patient parameters will be innovative. Thanks to the use of telemedicine, it will also be possible to intervene in real time, without the unnecessary delay required for a traditional appointment.

d. Criteria for patient inclusion in the project

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

- Age \geq 18 years
- Informed consent to participate expressed in writing or electronically (according to the applicable letter of the law)
- Diagnosis of chronic obstructive pulmonary disease
- At least 10% of patients will come from excluded areas with limited access to day-to-day medical care.

It should be taken into account that patients with COPD are often seniors and their ability to operate the web platform/mobile application varies. Considering this fact, it will be acceptable to support the caregiver (e.g., son/daughter/wife/husband, etc.) in the use of the platform and to assist during training in the use of the platform, as well as in educational training. Of course, the above scenario should take place with the informed consent of the study participant. In order to minimise the risk of excluding some patients without a technical background, the pilot project foresees the possibility of lending a computer/tablet/smartphone to the patients and providing access to the Internet. As the project is intended to be universal and can be extrapolated to the general population, no exclusion criteria were described in the project. The intention is to target as large group of patients with COPD as possible. There is a risk that more than 50 patients will need to rent equipment, in which case it will be the responsibility of the project leader to arrange for additional equipment. As described in other parts of the project it will be possible to engage a caregiver/assistant to support patients in using the platform and spirometer.

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

1. Patient +/- caregiver

The patient remains the most important person in the entire treatment and diagnosis process. It is around them that the whole comprehensive care programme will be built, but also their prognosis will depend on how they use it. The aim of the whole project is to bring the patient and the healthcare system represented by nurses, primary care physicians and pulmonologists closer together by means of telemedicine solutions.

Some patients will start their care programme with a hospitalisation due to COPD. In their case, the medical recommendations will be placed on the platform so that the patient has constant access

to them. Already during hospitalization, the patient will be informed about the suggestion to perform regular spirometry and saturation tests. The parameters will be transferred to the platform automatically - after synchronisation with the device. By the time the patient reaches the outpatient pulmonologist, he or she will have monitored the reported parameters to maximally reduce the risk of another COPD exacerbation between hospital discharge and the first outpatient visit to the specialist. Alternatively, if the diagnosis is made on an outpatient basis, without hospitalisation, the patient will receive all information in the outpatient clinic. The patient will be instructed on the roles of specific members of the team caring for them. This way, he or she will know who to approach with a particular problem. For example, basic educational issues can be addressed by the nurse. For prescription renewals, the patient will be referred to a primary care physician, and with results of specialized laboratory tests to a pulmonologist.

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

The premise of the whole programme is to surround the patient with care so that they follow the doctor's recommendations accurately, adhere to healthy lifestyle principles and understand why the steps are so important. There is ample scientific evidence to show that a better informed patient is more engaged in the treatment process, which has a direct impact on their behaviour:

- The patient is recruited in the hospital or by a pulmonologist working on an outpatient basis, possibly by a GP. In the case of recruitment, there is no regionalization of patients - they can be treated in an institution which is not closest to their place of residence
- After obtaining the patient's consent, the recruiting doctor conducts training on the use of the Internet platform, goals and objectives of the project
- The patient is informed about the recommendation to regularly measure their vital signs and report them to the platform.
- Patient is advised to use the platform especially for education
- The patient can find on the platform dedicated medical recommendations

2. POZ

1. role of the POZ will be to screen and recruit patients and provide care for the group of patients recruited by the pulmonologists

2. Contact with potential participants (patients), presenting information about the project

- Conducting the **Initial Visit** includes:

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

3. Highly specialised outpatient clinic - pulmonology

1. develop a management plan for the patient. Treatment of COPD is a dynamic process that requires constant adjustment of drug doses. Once a treatment regimen has been established, it can be referred to the GP for implementation and continuation.
2. scheduling of specialist check-ups.
3. consultation of patients whose problem requires specialist consultation, i.e. patients referred by the GP
4. consultation with the primary care physician of results about which the primary care physician is not sure, but which do not require specialist consultation.

5. On the basis of the available data, the pulmonologist decides whether the visit can take place by teleconsultation or whether the patient should attend an in-patient appointment.

4. pilot management and evaluation group (selected by implementing centre)

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

- Running the programme, including consideration of collaboration between the different units.
- Use and operation of the internet platform
- Conducting the treatment process of patients with COPD
- Conducting surveys to assess the needs of users (doctors, nurses and patients) in relation to the proposed platform
- Assessment of user satisfaction with the pilot run
- Assessment of the possibility of applying the tested solution on a wide, national scale
- Assessment of the consistency of subsequent stages and search for opportunities to optimise the project in organisational, health and financial terms
- Summary of prognosis and perspectives of patients participating in the pilot
- Promotion of the project by publishing encouraging results, posting information about the project in social media as well as scientific journals
- Legal support
- IT support - responding on an ongoing basis to problems of both patients and nurses and doctors
- Regular consultations with the Norwegian partner (if applicable) to optimise the pilot and regularly improve the implemented solutions

5. Norwegian partner - optional participation

- Substantive support for the Polish side in the project implementation
- A different perspective will allow for optimal management of challenges that will occur during project implementation
- Regular provision of comments and objections to the Polish side activities
- Active participation in online meetings
- Identify benefits and risks of the final implementation plan
- Identify potential areas for optimisation

- Indication of potential measures to improve patient prognosis within the developed care model
- Develop an independent cost-effectiveness analysis

f. Detailed rules of cooperation of individual entities

- Conducting organisational meetings (the form of the meeting depends on the epidemiological situation) of the pilot management and evaluation group with doctors from the hospital. The following issues will be addressed during the meeting:
 - Discussing the methodology and assumptions of the project
 - Presentation of the principles of cooperation between the various parties in the project
 - Introduction to the operation of the web platform around which the project will be conducted COPD with particular emphasis on activities improving the prognosis and quality of life of patients
- Conduct an organisational meeting (format dependent on the epidemiological situation) of the Pilot Management and Evaluation Group with the POZ physicians
 - Discussing the methodology and assumptions of the project
 - Presentation of the principles of cooperation between individual parties in the project
 - Introduction to the use of the www platform, around which the project will be conducted
 - Summary of the assumptions of care for patients with COPD with particular emphasis on activities that improve prognosis and quality of life of patients
- Conduct an organisational meeting (format dependent on epidemiological situation) of the Pilot Management and Evaluation Group with outpatient pulmonary physicians
 - Discussion of the methodology and objectives of the project
 - Presentation of the principles of cooperation between individual parties in the project
 - Introduction to the use of the web platform, around which the project will be conducted
 - Summary of the objectives of care for patients with COPD with particular emphasis on activities that improve prognosis and quality of life
- Conduct an organisational meeting (format depending on the epidemiological situation) of the pilot management and evaluation group with the nurses
 - Discussing the methodology and the objectives of the project
 - Presentation of the principles of cooperation between the different parties in the project
 - Introduction to the use of the web platform, around which the project will be conducted

- Summary of the objectives of care for patients with COPD with particular emphasis on activities that improve prognosis and quality of life
- Meetings of the pilot management and evaluation group with doctors from the hospital, pulmonologists working in the outpatient clinics, GPs and nurses (meetings +/- once a month) to evaluate the operation so far and the difficulties encountered
 - Discuss the patient recruitment process
 - Discuss the benefits and difficulties of using the web platform
 - Discuss potential solutions to problems encountered
- Collaboration between GPs and outpatient pulmonologists to:
 - Discussing results that concern to the primary care physician
 - Presentation of patients already referred to a pulmonologist
 - Presentation by the pulmonologist to the primary care physician of the patient's therapeutic goals and guidelines for their implementation
- Cooperation of the nurse with doctors
 - With primary care physicians - in the case of patients with a specific outcome in the patient's symptom assessment form, where a consultation with a primary care physician is indicated
 - With pulmonary physicians - in the case of patients with a specific outcome in the patient's symptom evaluation form, where a pulmonary physician's consultation is indicated
- It is advisable for nurses and doctors to liaise with the IT site when encountering problems or difficulties reported by patients. A platform should be created for error reporting, where IT staff will report on the progress of the task to date. In case of urgent problems (e.g. the system does not work at all), it is advisable to contact the IT representative by phone.
- Ongoing collaboration between the pilot management and evaluation group and patient representatives (patient organisation) to:
 - Accurately understand the needs and requirements of patients entering the programme
 - Jointly analyse the results obtained in the project
 - Collaborate with the patient organisation on publicising and promoting the project and its results.
- Cooperation between the Pilot Management and Evaluation Group and the Norwegian partner for consultation and exchange of views on the developed and implemented solutions within the project

g. Technical and organisational requirements

- All project members (doctors, nurses, patients) should have a computer/tablet/smartphone with permanent internet access. The final number of specialists depends on the number of primary healthcare facilities (POZ) that join the cooperation - the target is 1/2 computers per institution.
- If it is not possible to meet the above point, it is possible to lend the device free of charge as part of the pilot project
- Free lending to patients of a mobile spirometer, the measurements of which will be synchronized with the platform
- A web platform for teleconsultation, patient health notes, storage of vital signs from the spirometer, as well as consultations between different health care professionals.

The above-described coordinated care programme is based on close cooperation between specialists and, above all, the patient. As described earlier, the tool for this cooperation should be a dedicated platform, which on the one hand is comprehensive and extensive, but also simple and transparent. Despite the fact that patients with COPD are of different ages, they are not usually closed to new solutions, especially if they have a direct impact on their health and life. Additionally, more and more young people, who use computers and mobile devices on a daily basis, are suffering from COPD. It seems that the potential use of telemedicine solutions to support and coordinate the treatment process of the discussed group of patients is a solution that meets the needs and possibilities of the Polish health care system.

The previously described web platform and dedicated tool for home spirometry will be a model in the field of pulmonology, which will help to educate patients, coordinate their treatment, as well as strengthen contact between health care system representatives using modern solutions. The implemented solutions have proven their effectiveness in large clinical trials.

According to the authors of the study, the target solution should be a telemedicine platform integrated with a mobile spirometer, which would be integrated and developed together with systems developed by the Ministry of Health (e.g. www.pacjent.gov.pl, www.gabinet.gov.pl). The platform is intended to be used for management of medical data in an optimal way by persons dedicated to this task. The platform would support the provision of services envisaged under the universal health

insurance system. The pilot was developed as an attempt to implement a solution using a dedicated tool on a smaller scale.

The described project will constitute a proposal for changing the model of care for patients with COPD. Any intervention of this type is associated with the possibility of failure, but on the other hand, the potential benefits of the programme certainly outweigh the risk of possible failures. It should be stressed that the advantage of piloting is that in a smaller, more controlled setting, potential steps that need improvement can be caught and appropriate steps can be applied at the stage of applying the project nationwide. The pilot is intended to be coordinated by a single, specialised unit (the project leader), which will collaborate with the primary healthcare facilities (POZ). Thanks to the aforementioned, comfortable conditions for testing the telemedicine solution will be created. It seems that all potential problems can be faced at this stage.

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

However, before discussing the benefits in more detail, it is important to emphasize how the described model is an alternative approach to the care model, as so far similar solutions have not been implemented in Poland.

Risks associated with the implementation of the model

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

- motivational and competence-related,
- organisational,
- legal
- financial,
- technological,
- clinical,
- the pilot phase.

The individual risks are discussed in detail below, and with them are suggestions for managing possible problems.

1. Risks related to motivation and competence issues

- Insufficient incentives to implement the model

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

Suggested measures to solve the above problem:

- Widespread information and promotion campaign signed by MoH and/or NFZ, which will be directed to health care units
- Conscientious pricing of services (to consider bonuses for a given procedure - e.g. for the first patients who complete the programme)
- Reluctance to change and use new technologies by seniors - some people do not want to use new solutions. On the other hand, nowadays even seniors are eager for alternative methods that will provide them with better care and improve their prognosis.
- A broad information and promotion campaign signed by the Ministry of Health and/or the National Health Fund, which will target potential patients.
- A large-scale information and promotion campaign signed by MoH and/or NFZ, which will be conducted in primary healthcare facility (POZ), so that the information provided is credible.

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

Suggested mitigation/prevention measures:

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

Patients are likely to have concerns about sharing their personal data and health information over the internet

Suggested mitigation/prevention measures:

- Ability to contact the data controller at all times to clarify concerns about providing their personal data
- A broad information campaign to increase trust in the project
- Access to e-mail addresses and telephone numbers of persons able to clarify concerns about the management of personal and health data on an ongoing basis

Risks related to organisational issues

- Limited information on the project among seniors

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

Suggested mitigation/prevention measures:

- Conduct a promotional campaign among the target audience - in the medical and senior communities
- Promote the project through: phone calls, flyers, posters, website
- Include caregivers in promotional channels

- Potential initial problems of the project in the start-up phase

In connection with the implementation of a large-scale project, typical challenges are to be expected, which may be called "childhood" problems of the programme. These are likely to include differences in the interpretation of the information received, the use of the software, the spirometer, or the project assumptions.

Suggested mitigation/prevention measures:

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

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

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

Suggested mitigating/preventive measures:

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

Collaboration between the different parties in a project should be considered in the category of a financial and organisational challenge, as in the current system of accounting for services such collaboration is not promoted. It would be beneficial to change the approach to pricing of procedures, including paying for preventive activities and rewarding cooperation between the mentioned parties.

Suggested mitigation/prevention measures:

- Development of a model for cooperation between centres (model contracts between partners)
- Transfer of successful schemes between centres
- Carry out a campaign and training on the best available model of cooperation
- Propose a change in the valuation of the cooperation in question with a view to rewarding cooperation and prevention

3 Risks related to legal issues

- Patient's consent to examination and provision of health services

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

Suggested mitigation/prevention measures:

- Prepare templates that will contain the information in question. The patient will receive them as an e-mail, or will download the document from the website. This will give him/her the time and conditions to read the content of the file. Contact with a medical professional will be used to supplement the information about which patient is unsure or have additional questions.
 - Having received the information described above, the patient should give his consent or lack of consent for the provision of the healthcare service. According to the current legislation, consent to provide medical services may also be given verbally.
 - Nevertheless, there will be an insistence that consent should be given in writing, so a document with the consent should be prepared for the patient. One copy will be given to the patient and a second copy will be kept at the centre. Signing the consent in person does not seem to be a problem, as the first initiation visit will be an in-patient visit and not a teleconsultation visit.
-
- Obtaining patient consent for the processing of personal data

Given that the patient's consent is essential for the lawful processing of sensitive data, it is necessary to obtain consent for the processing of personal data with particular emphasis on data entered on the

questionnaire form. Before obtaining consent, the patient should be informed about how the data is collected, processed and the purpose for which it is collected. It is important that consent is kept as simple as possible and any doubts explained to the patient at the start of the programme.

Suggested mitigation/prevention measures:

- Prepare consents containing all necessary clauses in as accessible a way as possible. The documents will be available on the website, can be emailed to the patient or preferably handed over during the first visit with time for the patient to read it.
- The patient should give clear and unambiguous consent to the processing of personal data, including sensitive data. Preferably this consent should also be physically signed, to reduce the risk of being accused of not providing all the information to the patient.
- However, it is possible to waive obtaining patient consent for the processing of sensitive personal data, provided that the points in Article 9(2)(H) GDPR. According to the cited provision, if for "medical diagnosis, the provision of health care or social security, treatment or management of health care or social security systems and services", personal data may be processed for the above purposes if it is processed by - or under the responsibility of - a person subject to the obligation of professional secrecy.
- Verification of patient identity

Suggested mitigation/prevention measures:

- In the case of receiving medical services via an ICT system, this identity confirmation will take place when logging into the system. In other cases, the identity will be identified on the basis of the identity document presented. In the case of first visits, it will be advisable to collect all data necessary for further treatment (e.g. PESEL number). During teleconsultation, the patient may be asked to show proof of identity to the camera.
- Maintaining the confidentiality of the teleconsultation

Suggested mitigation/prevention measures:

- Any medical service should take place in a comfortable place where conditions of confidentiality are ensured. There should be no other persons in the room from which the tele-treatment is given than those necessary for the medical service.

- Keeping personal data secure

Suggested mitigation/prevention measures:

- Each entity should have security policies in place to effectively manage data security. Each employee of the entity should have the appropriate authority to manage personal data. In case data has to be transferred to an external company, it is advisable to conclude a contract between the data controller and the entity to which the data is entrusted.

4 Risks related to financial issues

- Incorrect valuation of the service by the payer

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

Suggested mitigation/prevention measures:

- Accurate pricing of all costs that are associated with the introduction of the model.
- Careful definition of roles and responsibilities of individual project participants.
- The funding system should reward prevention and patient retention.
- It is worth noting that part of the education can be provided by a nurse, potentially reducing costs to some extent.

- Difficulties in the implementation of payments due to the large group covered by the project

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

Suggested mitigation/prevention measures:

- A very conscientious and reliable calculation of all the costs, risks and benefits of the preventive measure in the discussed model should be carried out.

5 Risks related to technological issues

- Risks related to the production, implementation and use of the developed system
- Risks in terms of access to technology and digital literacy, including mobile spirometer, by COPD patients

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

Suggested mitigation/prevention measures:

- Arrangements for the expansion of existing applications should be agreed with the relevant institutions before the start of the pilot, so that widespread use can begin immediately after the pilot.
- Provision should be made in the design to make appropriate devices available to those who do not have them. A very thorough patient tutorial should be created. It is acceptable to have a tutor to support the use of the systems.
- A helpline should be set up to provide technical support to patients in the event of problems with operation.

6 Risks related to clinical issues

- Deficits Impaired contact due to e.g. hearing impairment or lack of platform skills, potentially making televising difficult

Suggested mitigation/prevention measures:

- Enabling contact with the patient's caregiver
- Thorough tutorials and a helpline with technical support for patients

- Possibility of an in-person visit if telehealth is not possible due to the aforementioned limitations.
- Incorrect information entered into the system

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

Suggested mitigation/prevention measures:

- Careful clinical assessment each time to verify the data provided
- Supervision by the caregiver
- Feedback from the doctor to the patient with a possible suggestion of where an error may have crept in.
- Doubts of the primary care physician regarding the management and intervention of the patient after receiving the alarming results of the completed questionnaires

Suggested mitigation/prevention measures:

- Opportunity to call and obtain more accurate information and make sure that the information's provided are accurate. Talking to the patient and explaining where mistakes may have crept in when completing the form.
- Problems with using the platform

Suggested mitigation/prevention measures:

- Access to ongoing IT support when difficulties arise
- Tutor support
- A maximally simplified system and a powerful and intuitive tutorial tailored to the needs of seniors.
- Aggravation of illness

Suggested mitigation/prevention measures:

- By early detection of symptoms of exacerbation of chronic obstructive pulmonary disease (weight gain) it will be possible to introduce appropriate prevention for these patients and to anticipate adverse consequences.

- Early detection of an impending exacerbation means that there will be more time to organise contact with the doctor and implement the action needed for the patient.

7 Risks related to the pilot phase

- Risks related to the proposal for a new organisation of cooperation between centres

Suggested mitigation/prevention measures:

- Accurately establish the responsibilities of the different centres and define their roles
- The piloting process should be organised in such a way that the whole project can be efficiently organised and carried out.
- An information campaign to encourage the centres concerned to participate
- In an initial stage, to select the best-performing facilities, which will be able to organise appropriate care for patients and set an example for future facilities.

- Lack of device (computer/tablet/smartphone) and/or internet access

Suggested mitigation/prevention measures:

- Possibility to lend equipment to the patient or caregiver
- Encourage patients through information campaigns that with such devices their treatment process can be optimised, which should indirectly encourage them to purchase.

- Insufficient/slow recruitment of patients for the study

Suggested mitigation/prevention measures:

- Conduct an information campaign to promote the project with a NFZ/MoH banner among patients and units potentially able to recruit patients
- Allowing more units to be included in the pilot study
- Virtually no criteria for exclusion of patients from the programme
- Simplicity of the programme and clear presentation of benefits should encourage patients to participate

- Development of a tailor-made application compatible with central solutions

Discussed system must be a complete tool, which in addition to its functionalities will be characterised by high security. The risk is the development of the solution itself, as the contracting authority is not able to predict the winner of the tender or its course. As a result, there is a risk of delay in the implementation of the project, as well as the production of a product that does not meet all the assumptions. Furthermore, ease of use is very subjective and difficult to define in the contract.

Suggested mitigation/prevention measures:

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

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

- To carry out a well-planned pilot
- Development of a good system as a basis for the whole project
- Adequate information campaign to promote the whole project

Benefits resulting from the introduction of the model

According to the authors of the study, the recommended system of care for patients with COPD will facilitate effective, efficient and cost-effective care that will improve their prognosis. Currently we do not have similar tools, let alone systemic solutions to coordinate the treatment process and to organise cooperation between treatment units at different levels of care. A patient included in the programme is provided with comprehensive care, and his/her treatment process is organised and focused on a

specific goal. Waiting times to specialists are clearly reduced by ensuring access to doctors. Despite the large number of pulmonologists in Poland, the constantly growing number of patients with lung diseases means that their working time is very valuable and should be used appropriately.

Below we list the benefits of the platform and its implementation.

- Optimisation of cooperation between primary healthcare facility (POZ) and specialist units with effective use of doctors' working time.
- Supporting the telemedicine tool, which is recommended according to current guidelines and available scientific data confirms the benefits from such solutions.
- Providing the patient with comprehensive care, thus improving his prognosis
- The support of telemedicine systems helps to identify patients who require an in-person visit and provides the rest of the patients with a telemedicine contact with a medical professional.
- Optimisation of doctors' working time makes it possible to help more patients with the best quality of provided services.
- Increasing the role of GPs in the treatment process of patients with COPD.
- Elimination of geographical barriers through the possibility of teleconsultation. Thanks to this, even people living in an area without a specialist unit will be able to receive professional care.
- Appropriate care translates into a reduced risk of exacerbation of chronic obstructive pulmonary disease, and hospitalisations for this reason are very costly. Consequently, it seems that the proposed solution will be cost-effective.
- The availability of telemedicine solutions makes the treatment process independent of the epidemiological situation in the country - consultations can still take place regardless of the restrictions and limitations in force.
- Equalization of social inequalities in access to specialists between rural and urban residents.
- Reduction of unnecessary procedures resulting from ineffective cooperation between primary care physicians and specialists or resulting from the lack of cooperation. The above translates into more effective management of available funds.
- Reduction of errors resulting from failure to obtain a specialist consultation. Fewer medical errors translate into improved patient prognosis.
- Implementation of a project in which the patient is the most important link. It is around the patient that the programme is implemented, which can be adapted according to the expressed needs of the patient. This is in line with the recommendations of scientific societies, and is associated with tangible benefits for patients.

- Improving care for patients with COPD with a modern solution to meet their needs and capabilities.
- To organise the work of medical professionals in the form of group work with a single goal of improving the health of the patient and fulfilling his or her health wishes as far as possible.
- Improving the desirability of commissioned procedures for the patient - optimising fund management.
- The involvement of the caregiver can translate into an improved relationship between the caregiver and the patient by working together with a single goal of improving the patient's health.
- By removing geographical barriers, there will be no social inequalities in access to medical services and procedures described in this programme.
- Opportunity to collect a wealth of data for further analysis, scientific publication and optimisation of the treatment process.
- Optimisation of expenditure management - greater emphasis on prevention and the start of a trend in pricing and accounting for prevention activities, especially those that have the desired effect.
- Expansion of existing telemedicine solutions, thanks to which patients will have easier access to medical care.
- Increase patient awareness of their diseases through an educational panel on the platform.
- Reducing costs associated with reduced hospitalisation due to exacerbation of COPD.
- Engaging patients and caregivers in active participation in the treatment process and increasing their competence in the use of telemedicine solutions.
- Development of e-health systems on a national scale, considering the patient as the most important person in the whole process.
- Improving doctor-patient cooperation by facilitating contact.
- Transparency of the treatment process thanks to the assumptions for the following months of care placed on the platform.
- Improved medical access in case of exacerbation of a chronic disease
- Increasing the competence of medical professionals through thoughtful and systematic implementation of telemedicine solutions.
- Enabling research without the geographical barrier.

In conclusion, it should be emphasized that the list of benefits is very extensive and potential threats seem to be solvable at this stage. With proper implementation of the programme and taking care of potential risks, all participants in the programme should be beneficiaries. Of course, the priority is the

health status and quality of life of the patient, which will guide both the authors of the project and the pilot project promoters.