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MACHINE TRANSLATION

Telemedicine Model in Diabetology

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1. Definition of the problem: diabetes - scale of the problem and possibilities of telemedicine solutions

1.1 Epidemiological data on diabetes worldwide and in Poland

Diabetes is a common and still unresolved health problem worldwide, and according to the World Health Organization (WHO), it is the first non-communicable epidemic disease due to the dramatic increase in the number of cases observed in recent decades. Characteristic for the course of this disease is the occurrence of chronic vascular complications of micro- and macroangiopathy nature, often already at the time of diagnosis, which significantly worsens the quality of life of patients, leading to disability and increased mortality, especially from cardiovascular causes (8th leading cause of death in both genders and 5th cause of death in women).

According to the definition, diabetes is a group of metabolic diseases whose characteristic and common feature is elevated blood glucose levels. These disorders are caused by abnormalities in the secretion or action of insulin produced by the beta cells of the pancreas. Since 90-95% of all diabetes cases are type 2 diabetes associated with obesity, its prevalence or incidence rates may refer to the entire population of people with diabetes. The systematic increase in the incidence of type 2 diabetes is associated with improved daily living conditions, easy access to food, a sedentary lifestyle and lack of physical activity, all of which are prevalent in civilisationally developed societies, leading to an

epidemic of obesity. At the same time, as the average survival rate of diabetes patients increases, the costs of treating the ageing population, especially those burdened with complications and co-morbidities, are rising.

Since 1980, there has been a fourfold increase in the incidence and in 2017 the number of patients worldwide was already 425 million. It is predicted that by 2045, around 693 million people will have diabetes. Many people are unaware of the disease and do not treat it.

Usually it takes 5-6 years before type 2 diabetes is diagnosed and this is an additional problem, because when it runs asymptomatically it can already cause complications, such as diabetic retinopathy.

According to epidemiological data, in 2018 there were 2.9 million adults with diabetes in Poland, which corresponds to 9.1% of the adult population, and about 22 thousand people under 18 years of age. (3.17 ‰ of the underage population - an increase of 2.5% compared to 2013). There were 1.3 million adult men with diabetes (8.6% of the adult male population), and 1.6 million adult women (9.5% of the adult female population). Compared to 2013, the number of adult patients increased by 379,000 (up 15.2%), translating into a 1.2 pp. increase in the percentage of the adult diabetes population (from 7.9% to 9.1%). There was an increase in the age- and sex-standardised prevalence rate per 100 adults between 2013 and 2018, indicating that factors other than a change in the demographic structure of the population were responsible for the increase in the number of adult patients. Among adults, those aged 65 to 74 years were the largest group of diabetes patients in 2018. The proportion of patients with diabetes, regardless of gender, increased significantly with age (up to 85 years of age) and was highest in the group between 75 and 84 years of age. - 30% for women and 28.1% for men, respectively.

Moreover, in 2018, the highest prevalence rates per 1,000 inhabitants were in the Silesian (103) and Łódź (101.4) voivodeships, while the lowest were in the Podlaskie (78.5) and Podkarpackie (79.5) voivodeships. Standardised against the national sex and age group structure, the prevalence rate in 2018 reached the highest value in Śląskie (99.0) and Wielkopolskie (97.0), and the lowest in Podlaskie (78.5) and Podkarpackie (83.1).

Each year, between 2013 and 2018, nearly 300,000 new cases of diabetes among adults were recorded in the public system. Incidence rates increased for almost every age group and for age groups above 45 years were higher in men than in women. Additionally, with the diagnosis of diabetes, other cardiovascular diseases coexist, among which the most common are hypertension (NT, I10-I14 according to ICD-10), lipid disorders (E78 according to ICD-10), obesity (E66 according to ICD-10) and ischemic heart disease (CHNS, I20-I25 according to ICD-10).

1.2 Clinical consequences of diabetes

A major problem in modern diabetology is the asymptomatic course of type 2 diabetes, with the result that one in three diabetic patients is unaware of their disease and is unaware of developing complications. At the time of diagnosis of diabetes, more than half of patients already have at least one chronic vascular complication The risk of ischaemic heart disease is 2-4 times higher in the diabetic population than in the non-diabetic population and it is also the leading cause of death in this group. Several studies have documented that the prevalence of retinopathy, the main cause of sight loss in developed countries, at the time of diabetes diagnosis ranges from 21% to 37%. Untreated diabetes causes deacreased quality of life, multimorbidity and premature death. Broad population-based screening for early diagnosis of diabetes and its complications, targeting those at risk, as well as multifactorial early therapeutic management, are the only solutions to improve public health.

1.3 Diabetes according to National Health Fund (NFZ) data

The estimated total costs of diabetes incurred by the National Health Fund in 2017 were 6,073 million zł, consisting of the costs of diagnosis and treatment -2,825 million zł and the costs of diagnosis and treatment of other comorbidities - 3248 million zł.

According to NFZ data, in 2018, services with a diagnosis of diabetes (main or comorbid) were provided to 2.18 million adult patients - 14.2% more than in 2013. Among people with diabetes in 2015, 50% of them of them had a treatment for ischemic heart disease at least once between 2015 and 2018. About 12% of people with diabetes in 2015 had a treatment for chronic renal failure at least once, 6% for stroke and 5.5% for diabetic retinopathy between 2015 and 2018.

1.4 The role of the family doctor

In Poland, it is mainly family doctors who treat patients with diabetes. The family doctor provides holistic care for the patient and his or her family in addition to acute illnesses of an infectious and traumatic nature, an increasing proportion of consultations are chronic diseases, of which hypertension, diabetes, osteoarticular diseases, and cardiovascular diseases predominate (Bujanowska et al.) The family doctor does not have the same specialist knowledge as the diabetologist and is not able to manage some patients. In practice, because of the large number of patients, the family physician often cannot devote enough time to educating the diabetic patient. There can be up to 2500 patients, and there may be several family doctors working in one centre. GPs are also unable to fully assess complications such as diabetic retinopathy and therefore have to refer patients to ophthalmologists. Access to ophthalmological examinations can be restricted, for example by queues to specialists or transport problems.

The family doctor is a valuable partner in telemedicine solutions. The COVID-19 pandemic seems to have significantly changed the attitude of family doctors and patients towards e-visits, which are now one of the most common forms in the therapeutic process. GPs should also be prepared to take charge of patients who will be diagnosed through telemedicine screening.

1.5 Access to specialist treatment in Poland

However, diabetes as a multi-organ disease generates a huge demand for specialist treatment, which is not sufficiently met. One of the reasons for this is the insufficient number of adequately trained doctors. For example, according to the National Chamber of Physicians, in 2020, the number of practising diabetologists in Poland was 1518, and ophthalmologists practising in Poland was 4719. This indicates that there may be many hundreds of patients per one specialist, for example, there are 1169 patients per 1 diabetologist. In addition, specialists dealing with diabetes tend to be concentrated in large university or city centres, while patients in rural areas, or those distant from specialist centres, face problems of limited access to doctors and specialist treatment. It should be recalled that many voivodeships and regions are still struggling with communication exclusion. At the same time, social expectations as regards the quality and availability of treatment are very high. Long queues, difficult access in rural areas and the need for referrals to specialists are particularly worrying. Lack of specialist treatment and allowing serious complications to develop may contribute to increased death and disability in diabetes patients and have negative health and economic consequences across the country.

1.6 Diabetes as a priority for WHO and the Ministry of Health

Given the as yet unresolved public health issues related to diabetes, the WHO NCD6 Global Action Plan 2013-2020 (NCD - noncommunicable diseases) recommends, among others: Strengthen the health

care response to diabetes, especially at the primary, first-line level; Legally establish policies and programs to ensure equitable access for people with diabetes to essential technologies used to treat and control diabetes; Strengthen national capacity to collect, analyze, and use the statistical and epidemiological data collected on the risks associated with the onset of diabetes, as well as diabetes itself and its treatment. This problem has been recognized by the Ministry of Health, which in a regulation dated 27.02.2018 recognized the reduction of incidence and premature mortality due to diabetes as one of the applicable health priorities. It is worth mentioning that currently implemented by the Ministry of Health and the National Health Fund, Drug Program for the treatment of diabetic macular edema, which is a real breakthrough in the treatment of this condition.

1.7 The need for systemic solutions based on telemedicine

The answer to the presented problem and social demand is the development and introduction of new, innovative forms of diagnostic and treatment visits in diabetology, based on telemedicine. The Covid-19 pandemic has influenced the structural transformation of the diabetes care system, causing an exponential increase in the scale of telemedicine solutions and, more broadly, digital technologies and solutions, particularly those based on the use of intelligent algorithmic methods ("Artificial Intelligence"). Remote forms of care are increasingly important in ensuring continuity of care, individualised approaches to patients and the integration of data from different sources, which is of particular importance in systemic diseases such as diabetes. The role of so-called self-care, which increases patient involvement in the therapeutic process, is also emphasised. However, until now, no systemic telemedicine solutions have been developed in diabetology, which are already successful in our country, for example in the field of cardiology.

Treatment and approach to diabetes have changed significantly in recent years. This was necessitated by social changes, the introduction of new forms of therapy and monitoring, as well as a different perspective on the role of the patient in the treatment process. Telemedicine should become more and more important in prevention, diagnosis, monitoring, consultation, treatment and education of patients with diabetes, complementing traditional medicine. There are several important reasons for this. The first of these is the continuous increase in the number of people with diabetes, which is not accompanied by a commensurate increase in the number of medical staff. The access to the doctor is facilitated by remote visits during which the obtained parameters of glycaemic control can be analysed and the therapy can be modified. As yet unpublished experience of diabetologists in our country indicates that during the COVID-19 pandemic, thanks to e-visits, good metabolic control was maintained in many patients. On the other hand, patients who did not have such an opportunity developed various complications (including severe cases of diabetic retinopathy requiring surgical treatment).

Telemedicine solutions are addressed especially to those people who cannot independently benefit from a specialist consultation in the field of diabetology due to, among others, age, communication problems, unequal access to specialists, as well as diabetological problems related to pregnancy (gestational diabetes, diabetes in pregnancy - advanced pregnancy, gynaecological advice against travelling). These features of telemedicine make it possible to effectively combat social inequality, which is particularly dangerous for diabetes patients.

Another argument in favour of the possibility of telemedicine solutions in diabetes is the easy availability of more and more intelligent solutions, e.g. modern glucose meters, continuous glucose monitoring systems or personal insulin pumps. Some of these devices already have the ability to upload data to the Internet cloud via special mobile applications and software, e.g. LibreView

(FreeStyle Libre system) and CareLink (Enlite/Guardian), i.e. they are potentially ready to be included in telecare. As the Delphi study showed, the highest rated criteria by patients for evaluating and recommending digital diabetes self-management tools were "Usability" and "Quality of information", respectively.

The e-health tools are intended to support the patient's new role of taking responsibility for their own treatment by regularly monitoring blood glucose levels, eating mindfully, and administering insulin injections and blood glucose-lowering tablets. It is expected that patients will be able to self-administer the correct dose to achieve the desired blood glucose level. The Norwegian Ministry of Health, emphasises the importance of self-motivation and knowledge about one's disease. Therefore, managing diabetes requires an approach in which the patient is at the centre of their own treatment (Feste and Anderson, 1995). Instead of talking about 'compliance' and 'adherence' to a predetermined care plan, the latest diabetes care systems require a more smoother approach to insulin regulation (Anderson and Funnel, 2000). For this, a telemedicine system is needed, which also through education increases the safety of the therapy in which patients actively participate.

It was already stated in 2009 that telemedicine programmes can have an impact on various aspects of diabetes care, including informational, clinical, behavioural, structural and economic. Informational impact is a better quality of information than enrolment handwritten records, which may be incomplete or inadvertently left at home by the patient, on the day of the visit. The clinical impact is more frequent provision of information and instructions, which may lead to improved treatment outcomes through lower HbA1C levels or fewer adverse consequences. The behavioural impact is more frequent treatment adjustments and reminders, leading to better patient education. The structural impact is usually time savings for patients, who may need to see a physician for fewer visits; however, the physician's workload of regularly reviewing messages and updated data may actually increase (Klonoff, 2009).

We now know that telediabetes, to be effective, should be implemented systemically. Hence the need for regional digital diabetes centres (as components of digital medicine centres, with virtualisation options). The requirements for the infrastructure of such centres, their logistics and functional scope, including ensuring interoperability, should be presented. There is a need to support automated procedures for prevention, pre-diagnosis and personalised monitoring. It should be noted that current IT and legal possibilities make it possible to develop telemedicine systems that could be supported by artificial intelligence.

Non-medical (nursing) staff should play an important role in telediabetology and could form the core of mobile forms of telediabetology. Mobile teams can perform the main tasks of prevention and early diagnosis. This will counteract the stratification of society ("digital divide") in terms of access to specialist medical care in patients with diabetes, especially in rural areas.

The Telemedicine Foundation Working Group (2020) emphasises that telemedicine increases the availability of health services, represents savings for providers and recipients, promotes optimisation of treatment processes, overcomes geographical barriers, reduces the risk of COVID-19, shortens waiting times to see a specialist and has an educational aspect. This is particularly important in view of the fact that the knowledge of the population about diabetes and its prevention is not high. One in five Poles has never carried out a blood glucose test, and only 26% of respondents declare that they carry out this test annually. In addition, every third adult Pole has never been to an ophthalmologist. Polish

research has shown that up to 25% of people with diabetes may be depressed, which makes cooperation between doctor and patient difficult.

The current recommendations of the Polish Diabetes Association for 2021 provide information on remote visits (telehealth) as part of diabetes care. Patients should be encouraged to use hardware technology and apps to facilitate remote medical visits. Remote medical visits for people with diabetes can be both part of ongoing diabetes care and used, for example, in an epidemiological emergency.

In summary, telediabetology should include: teleconsultation, telemonitoring, including telemonitoring of implantable devices, telerehabilitation, telecare and teleeducation. At the same time, the security of data and its processing, as well as personal data protection, should be preserved. Wider introduction of telemedicine will cause system changes and changes in the reimbursement system of specified medical procedures, which will allow for rational management of human and material resources.

1.8 Existing international solutions in the field of telediabetes

Telemedicine systems for diabetes care are now operating in many countries. The increase in interest in telemedicine has been particularly noticeable in the last 10 years. For example, typing the keywords "telemedicine, diabetes" into a browser and the PubMed database reveals that 78 papers were published on the topic in 2010, rising to 530 papers in 2020. During this time, different groups have been formed and different telemedicine systems have been tested, either of a local or broader nature, such as regional or national. Often, telemedicine programmes are constructed with rural communities in mind, which have health care problems even in the richest countries in the world.

Many reports come from within the USA. One example is the Catalina Island Telemedicine Center established to help residents of Santa Catalina Island, off the coast of California, access specialist medical care electronically. Some of the telemedicine services offered include diabetes education and eye screening. To help residents access specialists, the telemedicine centre has partnered with Loma Linda University Medical Center and the Los Angeles County Department of Mental Health.

Project ECHO offers programs to manage complex conditions, including diabetes. The model extends care to rural patients through video conferencing and is being used in communities across the country.

Mississippi Diabetes Telehealth Network is a program of the Telehealth Center owned by the University of Mississippi Medical Center. The program was launched in 2014 to improve diabetes care in the Mississippi Delta region. Among other things, the program provides remote patient monitoring and treatment, health education, and coaching. The evaluation conducted showed that providing remote patient monitoring through telehealth is effective in managing diabetes in rural areas.

The University of Virginia's Diabetes Tele-Education Program uses videoconferencing technology to provide diabetes education for people who have diabetes or are at high risk for developing diabetes. Diabetes education courses cover the basics of diabetes, nutrition, self-management and lifestyle changes. https://www.ruralhealthinfo.org/toolkits/rural-toolkit

An interesting solution is the innovative digital system "Joslin HOME", which is a virtual clinic connected to patients through telemedicine and mobile health. It encompasses 5 pillars of diabetes interaction: short, 5-15 minute visits conducted via telehealth, more frequent visits with a multidisciplinary team (including an exercise physiologist and behavioural therapist), electronic scheduling of visits at times convenient for the patient and team, short documentation and easy, one-step billing. (Al-Badri M, Therapeutic Advances in Endocrinology and Metabolism, 2020).

The largest telemedicine study ever conducted was the Informatics for Diabetes Education and Telemedicine project. This study in 1,665 Medicare patients compared the outcomes of using a telemedicine system based on a combination of an Internet network and video connection with primary therapy without a telemedicine system. In those who received telemedicine, improvements in glycaemic control, blood pressure, and total cholesterol and low-density lipoprotein cholesterol levels were observed at 1-year follow-up.

Klonoff presented the basic principles of telemedicine systems (Using Telemedicine to Improve Outcomes in Diabetes-An Emerging Technology Journal of Diabetes Science and Technology Volume 3, Issue 4, July 2009). These systems were developed to organize six types of transmitted objective and subjective data relevant to diabetes management, including: (1) patient-collected physiological data such as blood glucose, continuous glucose, and blood pressure; (2) laboratory data such as haemoglobin A1c (A1C) or lipid levels; (3) behavioural information such as diet and exercise patterns; (4) medication dosage, allergies, and other history data; (5) subjective symptoms of hypoglycemia or other complaints; (6) relevant event data such as emergency room visits, hospitalizations, scheduled eye visits, vaccines, and missed visits; and (7) photographs of the retina, wounds, or other structures. The information can be analysed using decision support software. This allows the doctor to contact the patient either on a regular, scheduled basis if the situation is safe, or on an, immediate, as needed basis. Images from retinal examinations or foot wounds can be transmitted by healthcare professionals to a specialist in a remote, central location. In some cases, foot images for remote transmission may even be taken at home by patients themselves. These images can be assessed either in real time by the doctor performing the imaging or shortly afterwards by a specialist consultant at a remote, central location.

1.9 Parameters to assess the effectiveness of telemedicine models

1.9.1 HbA1C level

One of the main metrics to assess the effectiveness of telemedicine is its effect on glycated haemoglobin levels. Studies have shown that of all telemedicine strategies, teleconsultation with a clinician is the most effective strategy in reducing glycated haemoglobin levels. This is especially true for older adults, who said they would prefer to have experts show them how to use the technology. (Patient Preference and Adherence 2021:15 283-298)

1.9.2 Satisfaction (through health education)

Another parameter is patient satisfaction and the ability to meet health needs. For people with type 2 diabetes, diabetes education was the main factor influencing satisfaction with treatment. Most patients were satisfied with the consistent and personalised education provided by healthcare professionals. The study by Lopez et al. found that information provided by healthcare professionals played a key role in patients' ability to self-manage their blood glucose levels. Desired changes in self-care behaviour were occurring through telemedicine. Similarly, topics on diabetes complications, side effects of medications, as well as recent discoveries and innovations in diabetes treatment were well received (Patient Preference and Adherence 2021:15 283-298).

1.9.3 Patient expectations: the individual approach

Younger patients expressed a preference for the telemedicine team to consist of knowledgeable staff who were also friendly, empathetic and caring. Health professionals should also be reassuring and supportive. Some patients preferred support groups because they felt that learning and sharing the successes of others in managing their diabetes motivated them. However, this preference was not

consistently expressed by all patients, suggesting the need for an individualised approach Patient Preference and Adherence 2021:15 283-298 Young people like health issues to be communicated in an appealing form e.g. videos, iconographics. Similarly, appealing to positive emotions elicited greater user engagement than, for example, discouraging information.

1.10 The role of social media

Social media are "a group of web-based applications that build on the ideological and technological foundations of Web 2.0 and that enable the creation and sharing of user-generated content". Among the most popular are Facebook, Twitter and WhatsApp. The proliferation of social media applications is made possible by the widespread access to mobile phones and the internet, especially among young and educated people. Social media have great potential in health education because of their huge reach, the constant contact between users and the free flow of information, which spreads in a "viral" way (rapid spread and no control of content), as well as minimal costs. Patients can form support groups that raise awareness among themselves and other users. The media are an important source of information and inspiration, e.g. encouraging screening tests e.g. eye tests or lifestyle changes. A study conducted by AlQarni et al in Arab and Islamic countries assessed the sharing of diabetes-related health information on the social media platform Facebook. A total of 1551 Facebook posts from 22 countries were analysed in this study. The main focus of posts was sharing personal experiences of diabetes (n=423, 27.3%), followed by posts supporting patients and caregivers (n=220, 14.2%), raising awareness of the disease (n=210, 3.5%), providing spiritual support (n=162, 10.4%), sharing the latest research (n=147, 9.5%) and providing education (n=110, 7.1%) about diabetes. A large proportion entries by people aged 40 to 60 years were related to seeking diagnosis-related information due to limited access to healthcare in their home countries. These findings support the increasing pace of sharing information on social media to improve public health Turki Alanzi Role of Social Media in Diabetes Management in the Middle East Region: Systematic Review J Med Internet Res 2018 Feb 13;20(2):e58.

One study on patients' social media activity was conducted on Twitter. Patients focused on improving social connections, feeling better about themselves, strengthening self-management skills, overcoming stigma, encouraging involvement in their healthcare and dealing with barriers. In addition, patients noted that many people judge diabetics, including some healthcare professionals, diabetics feel compelled to educate others about the condition and proactive patient-doctor teams are important. Hence, social media is also a vast information base for educators, health promoters and those responsible for wider health policy. Much data can be used to predict future trends (Gomez-Galvez P, Suarez Mejias C, Fernandez-Luque L. Social media for empowering people with diabetes:Current status and future trends. Conf Proc IEEE Eng Med Biol Soc. 2015;2015:2135-8)

1.11 Useful apps that are recommended on social media

An interesting example is SocialDiabetes.com where monitoring features are complemented by the ability to share tips with other app users. SocialDiabetes is certified as a medical device in the European Community.

In the Middle East, among the social applications that facilitate diabetes management from the patient's perspective were the SANAD and DIAR systems. The SANAD system consists of 3 main components: (1) a mobile diabetes management module, (2) a social networking module, and (3) a cognitive behavioural therapy module for addressing behaviour change. The DIAR system consists of 2 main components: (1) a mobile blood glucose self-monitoring system and (2) a remote Web interface and health management system. Other social networking tools consisted of mobile phones and social

media such as Facebook. (Turki Alanzi Role of Social Media in Diabetes Management in the Middle East Region: Systematic Review J Med Internet Res 2018 Feb 13;20(2):e58).

1.12 "Wearables" and other technological "gadgets"

These are wearable devices that are increasingly integrated with diabetes applications. They can use social networks to motivate users. These include:

- Integrated insulin pumps and continuous glucose monitoring systems (artificial pancreas)
- Pens that record the number of insulin units injected
- Step counters to monitor physical activity, which is an important aspect of diabetes management (SenseWear Armband)
- Google Glass glasses that help patients with treatment, awareness, education, blood glucose measurement, send reminders and alerts for diabetes control
- Continuous monitoring device manufacturer Dexcom, has released a mobile app that allows you to report your glucose levels in real time to others (e.g., parents).
- There are also smartwatch apps for diabetes control. These provide a more user-friendly approach to data entry and educational messages.

1.13 The role of eye examinations in telediabetes

1.13.1 Examples of solutions used worldwide

Teleophthalmology can be used in diabetology because diabetes is closely associated with retinal disorders and diabetic retinopathy, (DR- diabetic retinopathy) occurs in 30% of diabetic patients. Almost all patients with type 1 diabetes and about 60% of patients with type 2 diabetes will develop retinopathy during the first 20 years after diabetes. According to the recommendations of the Polish Diabetes Association (as well as other European and American scientific societies), adults with diabetes should have their first ophthalmologic examination immediately after the diagnosis of type 2 diabetes and up to 5 years after the diagnosis of type 1 diabetes. Subsequently, ophthalmologic examinations should be performed once a year or more often if the retinopathy is more advanced and requires closer control (e.g. during pregnancy, in uncompensated diabetes) or specialized treatment. It should be emphasized that DR is a complication that progresses extremely insidiously and asymptomatic for the patient.

A fundus examination allows a quick, non-invasive and simple assessment of the small vessels in the retina that are damaged by hyperglycaemia (microangiopathy). It causes characteristic changes in the retina: haemorrhages, microaneurysms, lipid exudates, oedema, ischaemia or proliferation of new abnormal vessels, which are referred to as DR. Nowadays we have very advanced technological devices that accurately visualise all these changes (including retinal thickness). This allows for qualitative and quantitative assessment of the changes and determination of DR severity on an appropriate scale. Such digital images can also be easily transmitted remotely and analysed by artificial intelligence. This is the basis of telemedicine systems used in many countries, which have become a necessity due to the insufficient number of ophthalmologists. In the US, for example, in 2011 only half of patients with diabetes attended the required annual eye screening. Today, screening for both diabetes and its complications, especially diabetic retinopathy, combined with timely referral and treatment, is a widely accepted strategy to prevent blindness worldwide. This is because current treatments are 90% successful in preventing vision loss due to DR. Screening can also detect undiagnosed cases of diabetes. Telemedicine programmes for the detection of diabetic retinopathy (DR) have been clinically validated and are successfully implemented worldwide. They can provide high sensitivity and specificity for DR

screening, while improving patient access to eye examination in a cost-effective manner. The American Telemedicine Association Validation Level defines 4 levels of validation for telemedicine DR screening programmes. For example, Ophdiat (France) , EyePacs (USA) and Digiscope (USA) were in the lower first category, Eye Check (Netherlands), NHS Diabetic Eye Screening (UK) in the second category and Joslin Vision Network (USA), Alberta Screening Program (Canada) in the third category.

The following is a description of the UK Diabetes Screening Programme (NDESP) within the NHS, which was the first large-scale screening programme introduced at government level. It has been in operation for over 15 years. The first stage is to take a fundus photograph and then a trained person determines whether diabetic retinopathy is present. If any degree of diabetic retinopathy is found, the images are assessed by a second classifier, blinded to the results of the first assessor. In addition, 10% of all images assessed as 'no retinopathy' by the first classifier are checked by the second classifier for quality assurance. If there is a disagreement, the case is resolved by a third classifier, who is an ophthalmologist The NDESP classification scheme defines four levels of retinopathy (R0 to R3) and 2 types of macular oedema and, depending on the severity, the patient is referred as an urgent or stable case to an ophthalmologist or, in the case of minor changes, invited for another telemedicine examination in a year's time. In 2012, almost 2 million people were screened for DR under this programme. In 2013, around 74,000 people were referred to an eye specialist and around 4,600 people received treatment. Researchers have praised this programme for reducing the rate of vision loss due to diabetes. Following the introduction of the NDESP by the UK, DR was no longer the leading cause of blindness in England and Wales for the first time in five decades (Tozer et al. 2015 Telemedicine and Diabetic Retinopathy: Review of Published Screening Programs. Journal of Endocrinology and Diabetes) One of the earliest countries to use telescreening is the UK. It has been conducted there systematically for over 15 years, which has resulted in the fact that diabetic complications are no longer the main cause of blindness in people of working age. Similar solutions are being introduced by other countries, e.g. France (e.g. the 'Ophdiat' system) and other EU countries, Australia, the USA or Bahrain. In the latter country, a DR screening programme was introduced in 2003. From 2003 to 2009, six DR screening teams were established in which a total of 17 490 diabetic patients were screened. Of these, 20.4 % were diagnosed and diagnosed with DR (Teleophthalmology in Preventive Medicine. Editor Georg Michelson ISBN 978-3-662-44974-5 DOI 10.1007/978-3-662-44975-2 Springer Berlin Heidelberg New York Dordrecht London).

1.13.2 The role of artificial intelligence

Artificial intelligence (AI)-based algorithms for detecting DR from retinal images are likely to replace retinal image assessors in the future Recent advances incorporating machine learning into algorithms have led to greater diagnostic accuracy.

Based on these results, the FDA has approved one AI system for use by healthcare professionals to detect more than mild DR and diabetic macular oedema, potentially helping to prevent vision loss in thousands of people with diabetes each year.

AI's analysis of fundus images was able to predict gender, refractive error, blood pressure and stroke risk. refractive error, blood pressure and stroke risk with remarkable accuracy. Optical coherence tomography imaging can even help identify undiagnosed cases of dementia. Thus, fundus images may enable us to diagnose many systemic diseases, not just conditions such as diabetes, hypertension and haematological conditions.

AI is likely to have a significant direct impact on access to care, monitoring and treatment of chronic diseases, as well as on the design of clinical trials. AI can identify common vision-threatening diseases with sensitivity and specificity comparable to experienced clinicians. AI can even predict the progression of diabetic retinopathy. If routine screening could be performed outside of doctors' offices, then ophthalmologists could spend more time treating rather than screening patients (Zarbin M Artificial Intelligence: Quo Vadis? Translational Vision Science & Technology 2020 9(2):1).

1.13.3 The situation of screening for diabetic retinopathy in Poland

Unfortunately, there is no universal screening programme for diabetic retinopathy in Poland and patients cannot self-refer to an ophthalmologist. A referral from a family doctor or a diabetologist, who has a contract with the National Health Fund, is necessary. There is also the possibility of a private visit to the ophthalmologist, which, depending on the centre, ranges from 100 to 300 zł (plus possible costs of additional examinations). It is worth noting that diabetic patients are usually in a worse financial situation than healthy people and such an expense is a big burden for them. In 2019, there were 226,942 eye examinations reimbursed by the National Health Fund, which is only a few percent of the necessary visits (about 3 million per year).

After receiving a referral from the family doctor, the patient usually chooses the nearest eye clinic. They can sign up in person or by phone. According to NFZ data for December 2019, a stable case waits on average 95 days for an appointment, and an urgent case 42 days. The longest (142 days) wait for a stable patient is in the Malopolska voivodeship, and the longest wait for an urgent case (62 days) is in the Silesian voivodeship. At present, due to the COVID-19 pandemic, this time could be even longer.

In addition, there are large differences in the number of ophthalmologists between voivodeships. For example, in 2016 , in the Mazowieckie voivodeship there were 151 ophthalmologists per 1 million inhabitants, and the least in the Podkarpackie voivodeship: 75 per 1 million inhabitants, which results in unequal access to health care. When complications are diagnosed, the patient is referred to institutions performing injections into the vitreous lens, laser treatments or vitrectomies, which also involves waiting for the examination and queuing for the surgery. Therefore, the time to proper diagnosis and treatment is greatly increased. The result is a large number of severe complications, whose treatment is very expensive and sometimes ineffective. However, it should be emphasised that screening by ophthalmologists in person is impractical and impossible to carry out, given the pandemic size of the diabetic patient population.

Fig. 1 Example of fundus photography under field conditions by a technician

Figure 2 Example of detection of non-proliferative diabetic retinopathy by fundus photography (left). However, only OCT examination shows retinal oedema (cystoid spaces in the retina filled with fluid) (right). Images from monitors of ophthalmic devices. For the purposes of the programme, images will be exported from the devices in digital form.

1.13.4 Major ocular complications of diabetes and their impact on management

Patients with diabetes have an approximately 25-30 times higher risk of vision loss than people of a similar age without diabetes. The most dangerous forms of DR are diabetic macular edema (DME diabetic macular edema) (in Poland an estimated 165,000 patients or 6.8-7.5% of diabetics), which is considered the most common cause of blindness in people of working age, and proliferative retinopathy (less common). DR if not treated properly can cause irreversible loss of vision at any stage of diabetes. Loss of vision is a profound disability because the sense of sight provides more than 80% of the information about the world around us. It causes profound disability, followed by social and economic exclusion, particularly acute for young people. The ocular complications of diabetes have a negative economic impact on the whole country. For example, indirect costs of DME treatment (loss of productivity, unproduced income, benefits, etc.) in Poland are 12 times higher than direct costs and amount to 92 million PLN and 1 billion 92 million respectively (0.059 % of GDP), "Assessment of economic costs and social burden of retinal disorders, with particular emphasis on DME and AMD". Institute for Innovative Economy, Ed. Prof. Ewelina Najszewska Warsaw May 2018 Whereas, in Poland, no register is kept of people who have been declared disabled due to ocular complications of diabetes.

1.14 Telemedicine - the legal basis

On November 5, 2019, the Regulation came into effect of 31 October 2019 amending the Regulation on guaranteed treatment in the field of primary health care came into force. This regulation regulates the legal issues of providing telemedicine services. The basis for the provision of telemedicine is Article 3(1) of the Act of 15 April 2011 on medical activity and Article 2(4) of the Act of 5 December 1996 on the professions of doctor and dentist. Pursuant to these provisions health services and activities involving the medical and dental professions may also be provided via ICT systems or communication systems. Thus, currently in Poland there is a legal possibility to conduct televisits (eVisits), during which it is possible to decide on the patient's state of health, modify treatment, refer for diagnostic tests, issue prescriptions and orders for medical products. However, not every service can be provided remotely. Therefore, it is assumed that telemedicine is admissible when a doctor, from the point of view of modern medicine, determines that he is able to help the patient in this way. Currently, remote verification of identity based on a patient's statement is permitted. Such a possibility was included in the Regulation of the Council of Ministers of 10 April 2020 on establishing certain restrictions, orders and prohibitions in connection with the outbreak of an epidemic. Identity is confirmed on the basis of data provided by the healthcare provider via an ICT system or a communication system - including by telephone. A remote visit must fulfil two conditions. First, the person who provides such a service must assess whether he or she has the appropriate knowledge, skills and capacity. Secondly, all requirements for ensuring security during such a visit must be met. This includes personal data, the transfer of medical records and medical confidentiality. A phone, smartphone, computer or other device with internet access may be used to contact the patient. The doctor may also use online chat. Special attention must be paid to the security of the software used and the modern technological infrastructure. It is worth mentioning that in the case of POZ, the purchase of systems for providing telemedicine services can be subsidised from public funds. Remote patient care of a systemic nature requires the implementation of a dedicated telemedicine system. Such a solution guarantees confidentiality and security (https://medidesk.pl/telemedycyna-a-prawo-co-o-zdalnych-wizytach-mowia-przepisy/).

1.15 Information society in Poland - selected aspects

In Poland, there are opportunities to expand remote care based on Internet connections. According to Eurostat data, in 2019 almost 90% of households in Poland had access to the Internet (an increase of

10 percentage points compared to 2014 was recorded). In comparison, this is 10% less than in Norway where 98% of households have internet. In 2020, 81.4% of people aged 16-74 in Poland used the Internet regularly (at least once a week) (compared to 78.3% in the previous year), of which almost 90% use it daily. The groups least frequently using the Internet in 2020 were pensioners, economically inactive people and farmers (50 and 60% respectively). The most frequent Internet users were pupils and students as well as employed people (90-100%). Interestingly, the percentage of people using the Internet is inversely proportional to age. For example, in the group over 65 years of age only 40% use the Internet, and up to 24 years of age as many as 99.8%. Most often the Internet is used by inhabitants of big cities, then smaller towns and the least often in rural areas. Internet use is dominated by people with higher education (almost 100%), while the percentage of Internet use among people with primary or secondary education oscillates around 70%. People, who regularly use the Internet, are least in eastern Poland and more in western and central Poland. It is worth noticing, that in older age groups a much lower percentage of people has the so-called digital skills. The above data was taken from the GUS 2020 report (Warsaw, Szczecin) "Information society in Poland in 2020", which interestingly does not provide any information on the use of e-health services. Hence, this area is still poorly monitored.

The presented data indicate significant disproportions that may limit the possibilities of remote communication. They indirectly testify to social inequality. It may be suspected that the use of the Internet in a way reflects the readiness of the society for digital services. Hence, there is a need to take measures facilitating online contact for seniors, people living in rural areas and those involved in agriculture. This is part of the so-called "smart villages" strategy, which is one of the priorities of the regional policy of the European Union, whose aim is to equalise the quality of life in urbanised areas and rural areas, as well as to prevent depopulation of the latter. In the case of telemedicine, friendly software and education, or even facilitate the purchase of appropriate electronic devices, will be important. Such undertakings should be preceded by public consultations, e.g. using social media or patient organizations.

1.16 Summary

In Poland, there is an urgent need for systemic solutions based on telemedicine for comprehensive care of patients with diabetes. The nature of diabetes, its multiple organs and chronicity make it a very good candidate for telecare. The examination of the fundus of the eye can greatly facilitate diagnosis and be the subject of artificial intelligence analysis. Very many countries have introduced such solutions with good results, which have translated into improved health of the population and reduced costs of diagnosis and treatment. The COVID-19 pandemic seems to have accelerated this inevitable transition process. Polish society is more ready for such solutions than before.

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2. Target groups

2.1 Rural communities - why is diabetes a problem for them?

The programme will be carried out mainly for people living in areas remote from large cities (mainly rural), taking into account the per capita income ratio at county level in relation to the average income in the country from so-called excluded areas. This will contribute to levelling social inequalities and counteracting exclusion, which affects many people living in rural areas.

Currently, according to many publications and reports, there is a very clear trend towards an increase in the number of obese and diabetic people in rural regions. This increase is more rapid than for people living in urban areas. This represents a reversal of the previously existing situation.

According to the Centers for Disease Control and Prevention's National Diabetes Statistics Report, in 2016 in the United States, 12.6% of the population was diagnosed with diabetes in non-metropolitan counties, compared to 9.9% in metropolitan counties. Studies in Poland also indicate a higher proportion of diabetes in people living in rural areas. (Zatońska, K., Połtyn-Zaradna, K., Einhorn, J. et al. Differences in prevalence of diabetes type 2 and impaired fasting glucose between urban and rural areas according to PURE Poland substudy. Int J Diabetes Dev Ctries 37, 305-312 (2017). https://doi.org/10.1007/s13410-016-0523-4

Rural areas also have higher rates of obesity, which increases the likelihood of developing diabetes. Based on an analysis of 112 million adults between 1985 and 2017, it was found that obesity now affects those living in rural areas to a greater extent. Where low- and middle-income people live, the percentage of overweight people is even over 80%. This is due to civilisational changes involving improved rural infrastructure, mechanisation and the frequent use of cars. There has been an improvement in the comfort of life, accompanied by a decrease in physical activity. At the same time, villagers could buy more food, but it was usually of low quality (Majid Ezzati Imperial Collegr London Nature).

In most European countries, people with lower levels of education are now the most likely to be overweight or obese. Increasing levels of socio-economic development have been associated with the emergence of inequalities among men and the persistence of these inequalities among women. Int J Epidemiol Albert-Jan R Roskam et al *Comparative appraisal of educational inequalities in overweight and obesity among adults in 19 European countries* Int J Epidemiol 2010 Apr;39(2):392-404. doi: 10.1093/ije/dyp329. Epub 2009 Nov 19.

In Poland the rural population is characterised by lower education than the urban population, which is a consequence of a smaller number of public schools in rural areas, high costs of education in the city and underestimation of the role of education by the rural population (Wojnar J.: *Wykształcenie ludności na obszarach wiejskich a stopień wykorzystania nowoczesnych technologii informacyjnych .*

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Rural communities also have worse access to a variety of services, including medical services. There is a smaller number of health care providers and a shortage of professional health care workers, i.e. specialist doctors, including endocrinologists and dieticians. This worsens the possibilities for, among other things, diabetes education. Lower income makes it difficult for rural residents to cover the costs of private medical visits, medicines and medical devices. Limited access to transport in rural areas makes it difficult for people with diabetes to travel to medical appointments.

In addition, the **rural population is ageing - 25% are post-working age, which should also be considered as one of the factors increasing the risk of type 2 diabetes**. The ageing of the rural population is most evident in the periphery in the Podlaskie and Lubelskie voivodeships and in the outskirts of the Mazowieckie, Świętokrzyskie and Łódzkie voivodeships (Foundation for the Development of Polish Agriculture).

An additional problem is the prevalence of undiagnosed diabetes among Polish seniors. The prevalence of undiagnosed diabetes is significantly higher among rural than urban residents (4.8% vs. 3.5%, p = 0.033). (Monika Puzianowska-Kuźnicka, Joanna Januszkiewicz-Caulier, Alina Kuryłowicz, Małgorzata Mossakowska, Tomasz Zdrojewski, Aleksandra Szybalska, Anna Skalska, Jerzy Chudek, Edward Franek Prevalence and socioeconomic predictors of diagnosed and undiagnosed diabetes in oldest-old and Endocrinologia Polska 2021 doi 10.5603/EP.a2021.0029)

Despite improved access to the internet and digital devices, statistically, rural areas have the highest number of people who do not use the internet and have low digital skills (digital literacy), which can hinder education and be another cause of social inequality.

2.2 Groups of patients qualified for the study

Approximately 1000 persons in the pilot study, adult women and men, insured in the National Health Fund:

1. patients with diagnosed diabetes (diabetes type 1, 2, with or without vascular complications) in order to assess the degree of metabolic compensation and possible proposal for correction of treatment (especially persons with declared disability).

2. Patients without diabetes, but with risk factors for type 2 diabetes, for early diagnosis of diabetes, as well as education and integrated preventive interventions (in particular persons with certified disability). Membership of risk groups was determined according to the following recommendations of the Polish Diabetes Association:

- in every person over 45 years of age (glycemia determination orders once every 3 years)
- regardless of age, diabetes screening every year in persons from the following risk groups:
  - overweight (BMI ≥ 25 kg/m2)
  - with a family history of diabetes (parents or siblings)
  - not very physically active
  - from an environmental group at higher risk of diabetes

- with a previous history of abnormal fasting blood glucose (>100mg%) or glucose intolerance
- have a history of gestational diabetes
- women who have given birth to a child weighing > 4kg
- with hypertension (≥140/90mmHg)
- with hyperlipidaemia (HDL<40mg% and/or TG >250mg%)
- polycystic ovary syndrome
- with cardiovascular disease.

2.3 Place of survey

Minimum 5 selected outpatient clinics of family medicine/primary health care (POZ) in towns distant from large cities, taking into account the ratio of income per capita at the county level to the average income in the country from the so-called excluded areas (10% of patients must meet these criteria)

References

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3. Clinical Case Descriptions

We present examples of two clinical cases that illustrate a possible course of action within the proposed telemedicine system

In each case, we include a description of the situation, the patient's main problem, and the solution.

Patient #1

Description:

Mr. Christopher, 52 years old, owns a family-run country store. He considers himself healthy and does not attend regular visits to his family doctor. He is obese, eats irregularly and does not follow a healthy diet. He has easy access to cheap food products. He does most errands by driving, physical activity is poor and irregular. The scenario depicts a situation in which the pilot study would be extended e.g. to 6 months

Problem:

Risk of diabetes and hypertension.

Solution:

Repeated screening for diabetes every 6 months as part of the Mobile Diagnostic Team (MZD) at a POZ center.

Tool:

- The patient, after being informed of the screening opportunity, visits his/her POZ where his/her weight, height, waist circumference blood pressure is tested and HbA1C level is done from capillary blood taken from a finger prick. He completes a questionnaire about his diabetes risk factors. His or her results are recorded on the Regional Center for Digital Medicine (RCMC) telemedicine online platform

- HbA1C and RR score are normal and no further diagnostic or treatment steps are taken.

- During the same visit, the patient receives educational materials on the principles of diabetes prevention, the principles of proper diet and the need for weight reduction.

- Fills out a diabetes knowledge quiz. Receives recommendations on the principles of proper nutrition. Is informed about the possibility of a follow-up health assessment during the next visit of the Mobile Team at their primary care center.

- The patient receives information about the possibility of free education and preventive measures via the account created by IT on Facebook.

- Patient is notified about the next visit via SMS if he/she agrees

- At the next visit (in 6 months), his or her weight, height, waist circumference blood pressure is reexamined and HbA1C levels are performed from capillary blood drawn from a finger prick. He completes a questionnaire on diabetes risk factors. His results are recorded on RCMC's telemedicine online platform. Adherence to previous recommendations is verified.

- The results show an HbA1C of 6.7% and an abnormal RR. The patient's BMI has not decreased

- The patient is scheduled for a fundus photograph and retinal OCT examination as part of the Mobile Diagnostic Team visit to the POZ center, and the results are evaluated by an ophthalmologist and diabetologist after being sent to the Regional Center for Digital Medicine. The results of these consultations will be available on RCMC's telemedicine web platform.

- The evaluation by the ophthalmologist showed no changes in the fundus, but a full eye examination after pupil dilation is necessary because according to PTD recommendations, such an examination must take place as soon as type 2 diabetes is diagnosed. Further, the patient is referred to an

ophthalmologist via e-referral, which is issued by the GP after receiving prior information from the RCMC telemedicine web platform.

- During the examination conducted by the Mobile Team, a date for the e-consultation with a diabetologist and recommendation for verification of the diagnosis of diabetes within the POZ is also set.

- After confirming the diagnosis of diabetes, glucometer with the option of data transmission by the primary care physician is issued, and the patient is trained in this field in the form of stationary or remote.

- During the e-consultation, the current treatment is adjusted, therapeutic goals are set and the date of the next e-consultation is set in order to assess the realization of therapeutic goals.

- The patient continues to be cared for by the POZ if the therapeutic goals are achieved.

- If the therapeutic goals are not achieved in spite of treatment adjustments or in case of deterioration of metabolic control, the patient receives an e-referral to the diabetes clinic during the e-consultation by a consultant diabetologist.

With the monitoring and treatment of diabetes and comorbidities by the family physician supported by RCMC specialists, the effectiveness of treatment will improve. The patient will gain more knowledge about diabetes as well as support from others through social media. Through e-visits, he will become more responsible for his health condition.

Patient #2

Description:

Mrs. Margaret, age 72, a retired overweight farmer suffers from type 2 diabetes and has a low income. She lives alone in a small, modest single-family house. She does not use the Internet. Telephone communication is possible. She does not have a car. Her town is poorly connected. No bus service. Due to the COVID-19 pandemic, she has limited visits to her primary care physician and has been functioning on a e-consultation system for several months. Recently, she has noticed a deterioration in her vision, but has difficulty getting to an ophthalmologist who accepts in a town 50 km away (she has to hire a driver with a car).

Problem:

Risk of metabolic disorders and multi-organ complications of diabetes

Solution:

Scheduling diabetes e-consultation and ophthalmology management.

Tool:

- The patient, after being informed of the screening opportunity, visits her primary care provider, where her weight, height, waist circumference blood pressure is checked and HbA1C levels are performed from capillary blood drawn from her finger. He or she completes a questionnaire on diabetes risk factors. His or her results are recorded on RCMC's telemedicine online platform

- Results: HbA1C >8% and RR >140/80

- During the same visit, the patient receives educational materials on the principles of diabetes treatment, the principles of proper diet and the need for weight reduction.

- Fills out a diabetes knowledge quiz. Receives recommendations on proper nutrition.

- Primary care provider glucose meter with data transmission option, trains patient, or arranges nurse from POZ visit for assistance with glucose meter data transmission prior to scheduled e-consultation.

- The patient is scheduled for fundus photography and retinal OCT as part of the Mobile Diagnostic Team visit at the POZ center, and the results are evaluated by an ophthalmologist and diabetologist after being sent to RCMC.

- Ophthalmologist:
  - Evaluation by an ophthalmologist revealed nonproliferative diabetic retinopathy and diabetic macular edema (DME) in both eyes

    The patient is referred to the Department of Ophthalmology for treatment of diabetic macular edema (e-referral) on an urgent basis . The patient is further referred to the ophthalmologist via e-referral, which is issued by the patient's primary care physician after receiving prior information from RCMC's online telemedicine platform.

- - Diabetologist:
  - The patient selects an e-consultation with a diabetologist. During the e-consultation, the current diabetes treatment is adjusted, therapeutic goals are established taking into account the scheduled treatment at the Ophthalmology Clinic and the date of the next e-consultation to evaluate the achievement of the therapeutic goals.
  - The patient remains under the care of primary health care if the therapeutic goals are achieved. If the therapeutic goals are not achieved despite the introduced treatment adjustments or in case of deterioration of the metabolic control of diabetes, the patient receives an e- referral to the diabetes unit or diabetes clinic.

Thanks to the examination, macular edema, which is one of the most frequent causes of the vision loss, is detected. Urgent treatment in a specialized center will help to preserve and even improve the visual acuity of the patient, who was not aware that she might go blind. This, in turn, would result in a total loss of her independence and the need for her to be cared for by other people or to live in a nursing home, which is located several dozen kilometers from her place of residence. For a patient accustomed to her own home and environment, this would be a major shock.

In addition, the patient will learn that her blood glucose levels are abnormal and that she needs to change her diet, take different medications, or modify the dosage of existing medications.

4. Description of the process and indication of the entities involved in its implementation with the division of duties and activities

4.1 Main assumptions for the national solution:

- Establish a telemedicine system consisting of a Regional Center for Digital Medicine (RCMC) and several mobile diagnostic teams (MZDs)
- MZDs work closely with the RCMC and send the collected data to it in digital form through secure telemedicine systems

- Examinations take place in GP practices, in smaller towns. i.e. MZDs commute to GP practices where they will rent a room to perform the examinations.
- MZD (staff and equipment) stay at the GP practice for a few days longer depending on the amount of eye examinations needed
- After 4-6 months, MZD returns to the given POZ for further examinations

4.2 Definitions and role of individual entities

Regional Centre for Digital Medicine (RCMC) is by definition a center for medical data acquisition and processing that meets the criteria described earlier (including security). It consists of staff with appropriate systems for communicating with patients, storing and analyzing data (including artificial intelligence). RCMC provides remote advice under contract with the National Health Fund. RCMC trains professionals accordingly to communicate with patients remotely. In addition, the Center educates how to use digital diabetes self-management tools such as apps, sensors, websites and social media. The RCMC is established on the basis of a teaching hospital or other large city or voivodeship hospital with experience in treating diabetes and its complications and employing diabetologists. The RCMC will be established by the Medical University/Clinical Hospital. It is not an independent entity. Ultimately, the RCMC is intended to operate for a longer period of time i.e. not just for piloting purposes. This center has experience in implementing projects with public funds. The Director of the Hospital is responsible for the RCMC. Medical and non-medical personnel meeting the required criteria are recruited to RCMC and are contracted by RCMC. RCMC seeks approval from the Local Bioethics Committee to conduct the study and insures the study. The consent of the Bioethics Committee concerns, among other things, the inclusion of patients in the study according to the presented model in accordance with the proposed study protocol; the processing of personal data used during the study (GDPR). The insurance depends on the decision of the Bioethics Committee, which may consider the proposed model as a cognitive research experiment (OC). RCMC organizes scientific conferences at the beginning and end of the pilot study. Conducts promotional and educational activities through social media and/or websites, among other means. Informs family physician practices about the pilot study and its rules and signs contracts with POZs. Makes necessary purchases, leases and manages the operation of the MZD. Coordinates the pilot study and is responsible for the proper conduct of the study and responds on an ongoing basis to various hazards and malfunctions in an effort to correct them.

A diabetes specialist from RCMC (at least 5 people): The diabetologist reviews the documentation contained in the patient's virtual account. Decides to contact the patient in the manner preferred by the patient and the family physician and ophthalmologist as needed. Sets appointment for televisit. Performs televisit and schedules next televisit. If necessary, refers to hospital

Ophthalmic specialist from RCMC (at least 2 people): Ophthalmologist analyzes the results of the fundus photograph and optical coherence tomography (OCT) examination of the retina. If diabetic macular edema, proliferative retinopathy (and its complications) are found, the patient is immediately referred to a specialized eye care center for treatment. In doubtful cases, the patient is referred for a complete eye examination. If necessary, teleconsultation with a family doctor and diabetologist.

Staff of MZD: (minimum 2 professional health workers i.e. nurses or paramedics) is a team performing diagnostic tests with the help of equipment transported by mini-van. The MZD travels between villages, getting to the vicinity of where patients live. As a result, patients do not have to commute to larger centers. The equipment is moved to predetermined locations-family physician practices. MZD delivers, prepares and collects diagnostic equipment from the POZ, collaborates with POZ staff.

Performs ophthalmological examinations (fundus photos and OCT examinations) in POZ and attaches them to the virtual patient account. Transmits results in a secure manner to RCMC. Gives educational materials to patients. Reports to the RCMC Medical Team Leader. The number of MZDs and the plan to visit each location, as well as how the population is notified, must be tailored to the needs of the region. These parameters should be the subject of a separate study. We propose that the MZD return to a given location in 4-6 months to deepen collaboration with patients and to complete tests that are not possible via telemedicine. For the purposes of this pilot, we propose 1 MZD.

IT staff: develop virtual patient account and tablet apps. Develop a system and notify patients via text messages, emails, phone calls. Ensure security of transmitted and stored data. Technical preparation of televisits, video consultations. Ensuring continuity of data flow. Creation and administration of project account set up in social media e.g. Facebook. Reporting to the RCMC IT Manager.

POZ (family doctor and staff)

Each POZ center joining the screening program will determine the declared number of patients, examinations and consultations performed, adequate to the size of the given patient population.

Family physician: after signing contract with RCMC, prepares room/office for screening, separates waiting rooms and nurses for pilot study. Select a group of patients who meet the criteria from those in his/her practice and invites patients to the study. Establishes study dates, informs local community of study opportunity and promotes project through social media announcement (e.g., POZs Facebook, phone calls, emails, posted notices and flyers . Takes informed consent given on the appropriate form and GDPR information (secures paper documentation). Based on the HbA1C result, makes a split into a group that requires no further testing and a group that will have a fundus photo and optical coherence tomography (OCT) scan. Makes an appointment for MZD at his practice and recommends scheduling patients. He reviews the results of the study. He receives payment for doing so. Treats patients with newly diagnosed cases of diabetes. Has remote teleconsultation with a diabetologist from RCMC via a digital link received. Gives educational materials to patients.

POZ staff (nurses delegated by the family doctor): directs patient traffic, provides information, contacts patients on the recommendation of the family doctor, sets up virtual patient account, enters personal data into the tablet, helps with questionnaires on the tablet, measures and weighs patients, measures RR and enters personal data into the tablet. performs HbA1C test from capillary blood taken from the finger and enters its value into the tablet. Schedules patients for ophthalmologic examination (fundus photography and OCT). Together with the patient, determines the preferred form of contact by collecting the contact telephone number or e-mail address.

Norwegian partner (optional): gives consultations, shares knowledge, especially on the use of social media and mobile applications. Visits the work of MZD in the field and RCMC specialists, coming to Poland or remotely. Participates in the preparation of scientific publications and congress speeches.

Patient organizations (optional): inform and encourage patients about telemedicine trials. Convince of their effectiveness. Cooperate in the education of patients, including the use of modern applications. Create support groups on social media providing reliable knowledge (participation of professional moderators)

Social media: will be used to inform about the possibility of tests and their dates, popularize the idea of telemedicine in diabetology, educate with the help of professional educators

4.3 Prevention activities

During the project there will be ongoing prevention activities involving RCMC staff, MZD, family doctor and POZ staff to encourage screening for diabetes, healthy eating, promotion of physical activity and prevention of obesity. They will consist of distribution of leaflets and information materials by the staff of POZ and MZD and education in the form of quiz on the knowledge of risk factors for diabetes. There will be lectures organized for citizens of different villages (in fire stations and schools) by RCMC. They will be attended by diabetes educators, psychologist, dietician and medical specialists. The activities will be open to the public. In addition, a conference will be held to open and close the project and a webinar with foreign experts from Norway and other countries will be held to train family doctors in telemedicine and diabetes prevention.

4.4 Conduct of the Pilot Study

Regional Center for Digital Medicine (RCMC) - sends information about the screening program to **Family Medicine/Primary Health Care (POZ) Clinics**, selected from among those most distant from Diabetes Specialty Clinics or Hospitals, with a view to counteracting population stratification in access to specialized diabetes care. After selecting at least 5 POZ declaring willingness to cooperate, a contract will be signed with them.

Each POZ participating in the screening program will determine the number of patients, tests and consultations performed, according to the size of the patient population. After consultations with family doctors, it was agreed that this number roughly corresponds to about 10% of the total number of POZ practice. The POZ will be provided with sets for HbA1c determination from capillary blood.

Provision of the following technological tools will be made to the POZ centers from the funds of the pilot study (if they do not have their own equipment):

1. a widescreen monitor and good quality headphones/microphone, taking care of optimal lighting and room setting.

2. Video software compatible with the technology being used

3. diabetes software in the form of an application for viewing data from diabetes devices

POZ - On the part of the Center remains (family doctor + nurse practitioner) :

1. to select diabetic patients and patients at risk from the population under the care of the center according to the following recommendations of the Polish Diabetes Association:

   o in every person over 45 years of age (orders for glycemic determination once every 3 years)

   o regardless of age, testing for diabetes annually in individuals in the following risk groups:

   overweight (BMI ≥ 25 kg/m2)

   - With a family history of diabetes (parents or siblings)
   - Not very physically active
   - from an environmental group more likely to have diabetes
   - with a previous history of abnormal fasting blood glucose (>100mg%) or glucose intolerance
   - with a history of pregnancy diabetes
   - women who have given birth to a child weighing > 4kg

- with hypertension (≥140/90mmHg)
- with hyperlipidemia (HDL<40mg% and/or TG >250mg%)
- polycystic ovary syndrome
- with cardiovascular disease

2. inform patients of the date and purpose of the study

3. establishing a list of patients with designated time of appearance, 15-20 minutes for a patient)

4. delegate a nurse assistant to pilot individuals -assist in completing the questionnaire,

-measurement of selected parameters,

-sampling of capillary blood and determination of glycated hemoglobin (HbA1c)

-further division of patients into groups according to the percentage of HbA1C and further piloting to ophthalmological examination (equipment for measurements and analyzer for HbA1C examination are purchased and provided by RCMC)

5. provision of premises (office for examination of patients, waiting room, sanitary facilities).

Patients will be informed about the date of examination by means of social media, announcements on the Internet with participation of local authorities, patient associations.

Creation of patient account, questionnaire, measurements of weight, height, waist circumference and HbA1C will be carried out by the POZ team even before the arrival of MZD. If the HbA1C level is abnormal, the family doctor will make an appointment for a group of patients (30-50 people) to be examined by MZD after ordering the arrival of MZD in advance (people with normal HbA1C will not show up during the arrival of MZD). In this way, MZD time will be optimally utilized.

We anticipate that ultimately (but not in the proposed pilot) the MZD will return every 6 months to a given POZ to repeat testing in selected and new patients.

4.4.1 The course of examination in POZ

Every adult insured citizen, referred by a family doctor, will be able to undergo the examination. After filling out consent for the examination and processing of personal data, an individual account will be created on the basis of data from the system of Electronic Verification of Beneficiary Entitlements (e-WUŚ).

- **Then the patient will fill out a short survey based on closed questions using a touch screen electronic device (tablet or other).**

The patient will complete the survey independently or with the assistance of an assistant.

Survey questions:

Do you smoke cigarettes?

o YES

o NO

Are you being treated for hypertension?

o YES

o NO

o Do not know

Are you being treated for high cholesterol/triglycerides?

o YES

o NO

o No idea

How much physical activity do you do per week?

o < 4 hours

o > 4 hours

Do you eat fruit and vegetables every day?

o YES

o NO

o Don't know

Was diabetes diagnosed in your family (parents, siblings, grandparents)?

o YES

o NO

o Don't know

Have you been diagnosed with diabetes?

o YES

o NO

o I don't know

If YES :

What type of diabetes do you have?

o 1

o 2

o Don't know

How long have you had diabetes?

o Up to 5 years

o 5-10 years

o > 10 years

What medications are you taking for your diabetes?

o Oral medication

o Insulin

o Oral medication and insulin

Have you received ophthalmologic treatment for diabetes?

o YES

o NO

o Don't know

Have you been treated with cardiology (heart attack, stents)?

o YES

o NO

o No o Don't know

What blood glucose monitoring system do you use (please select one of the following?

o Contour Plus (Ascensia Diabetes Care) Contour™Diabetes app

o Accu-Check Instant (Roche Diagnostics)

o Abra (Diagnosis)

o One Touch Select Plus (Lifescan)

Continuous Glucose Monitoring (CGM) System

o Medtronic CGM

o Eversense (Ascensia Diabetes Care)

o CGM Dexcom G6

Scanning/Flesh blood glucose monitoring

o FreeStyle Libre (Abbott) FreeStyle LibreLink application

Are you interested in a blood glucose monitoring device that sends information to your doctor?

o Yes

o No

o Don't know

Do you have one of the following eye diseases?

o Cataract

o Glaucoma

o Diabetic retinopathy

o Age-related macular degeneration

Have you had any ophthalmic procedures?

o Yes

o No

o Don't know

Your last visit to an ophthalmologist was:

o Less than 6 months ago

o Approx. 1 year ago

o I have not been to an ophthalmologist for more than 5 years

The automatic survey data will be stored in the patient's individual account.

- **The next step is anthropometric testing**, i.e., body weight, height, waist circumference measurement (calculation of body mass index - BMI), and blood pressure and heart rate measurement, which will also be entered into the patient's online account
- **Next, capillary blood will be drawn** from a finger for HbA1c screening (POCT analyzer). This will provide an initial split between patients without diabetes (HbA1c<6.5%) and those with suspected or diagnosed diabetes (HbA1c>6.5%).
- **Patients with normal HbA1c results** will receive a printout of their results in the form of recommendations. If the BMI or RR score calculated by the system is abnormal, the patient will be referred for an educational visit to address risk factors for t.2 diabetes with their family physician or a tele-education visit at RCMC (Patient will also receive educational materials).
- **Patients with elevated HbA1c>6.5%** are referred for fundus photography and OCT testing. Results from the equipment, in the form of images will be directly recorded on the patient's account. According to the current recommendations of the Polish Diabetes Association, the diagnosis of diabetes can be confirmed by an HbA1C test performed using a method certified according to the NGSP (National Glycohemoglobin Standardization Program), therefore, people without a diagnosis of diabetes, but with an HbA1C result > 6.5% on the POCT analyzer, will be referred to a family doctor for a repeat of the HbA1C test using a method certified according to the NGSP and possible additional tests such as; lipidogram and renal function parameters (creatinine, urea, uric acid).
- Patients with diabetes and HbA1c <7.0% can remain under the care of their General Practitioner, who also has the option of teleconsultation with the RCMC specialist
- Patients with diabetes mellitus and HbA1c 7.0-8.0 % may remain under the care of a family physician and/or diabetes specialist who also has the option of teleconsultation with an RCMC specialist
- Patients with diabetes and an HbA1c of 8.0-10.0 % should be urgently referred to a diabetes specialist or have the option of teleconsultation with an RCMC specialist
- Patients with diabetes and HbA1c >10.0 % should be urgently referred to a Diabetes Specialist Hospital or have teleconsultation with an RCMC specialist

The results will be recorded on the patient's account and will be interpreted by an RCMC specialist.

Course of Ophthalmic Examination:

The examination will be performed by a trained MZD staff member without the need for pupil dilation, in a room with dim light. The equipment should not be placed directly near the window to avoid pupil constriction. During examination of one eye, the patient will be asked to cover the other eye to reduce pupil constriction. The examination will take place in a sitting position. A digital fundus photograph of the right and left eye will be taken first, followed by OCT examinations of both eyes. These examinations will be attached to the patient's virtual account and sent to the RCMC ophthalmologist for evaluation. If poor quality exams are obtained that cannot be corrected by repeating the exam, a full eye exam by a specialist after pupil dilation will be recommended. A referral to an ophthalmologist will be made by the family physician.

A complete set of each patient's data, recorded in their account, is then sent to the RCMC, which decides on further action. The information for the patient can be given directly by the doctor working at the RCMC after analysis of the sent results or in the future can be assisted by artificial intelligence.

Further treatment - depending on the case (division into stable, urgent).

In stable cases, it will be a decision on referral or further treatment within the practice of the family doctor. In cases requiring urgent diabetes consultation, if the patient agrees he/she will be able to be treated within the diabetes care guaranteed by RCMC or an e-referral will be made to the nearest diabetes clinic integrated into the system. In cases requiring urgent hospitalization, an e-referral will also be issued to the patient. The RCMC ophthalmologist will analyze the results and decide on an immediate referral for ophthalmic treatment (diabetic macular edema, proliferative retinopathy) to a hospital or eye clinic. In doubtful cases, the patient will be referred to an ophthalmologist. In the case of diabetic retinopathy that does not require treatment but only observation, the patient will be informed when to see an ophthalmologist. This information will be given to the family doctor.

RCMC offer if patient wishes to continue telemedicine care

- Establishing the route of telemedicine communication with the patient - at the patient's choice - teleconsultation, video-consultation. Setting an appointment for tele/video consultation with a specialist.
- Prior to the teleconsultation appointment information will be sent to the patient in the form of SMS / e-mail reminding about the date and expected medical information necessary to be prepared by the patient.
- On the appointed day and time a teleconsultation / video-consultation with a diabetes specialist will take place
- Ability to obtain data from blood glucose meters and continuous glucose monitoring systems uploaded to the Internet cloud via mobile applications and computer programs.
    - o Conduct patient education and training - establish rules for capturing self-monitoring data in the future (ability to use mobile glucose meter apps/software).
    - o Obtaining data from a patient who already has self-monitoring skills - entering that data into the telemedicine system.
- Access to educational information - forms, leaflets, assistance in installing mobile applications, computer programs - teleeducation
- Collection and processing of databases for better use of human and financial resources
- Determination of further form of contact / appointment for patients requiring further telemedicine support - individual teleconsultation / video-consultation - as part of "counteracting the stratification of society ("digital divide") in terms of access to specialized medical/diabetes care"
- Referral of patients to the Diabetes Clinic as needed

Televisit scheme

Preparation within RCMC for televisit/video visit

- Complete data of each patient, stored in his/her account is analyzed at RCMC.
- Documentation prepared for specialist physician.

- Designated specialist physician for the patient.
- Physician review of prepared medical records.
- Reminder information about the teleconsultation appointment on the day or days before the appointment in the form of SMS / e-Mail. Personal data of the doctor appointed for the consultation provided. A request for medical data to be prepared by the patient (results of blood glucose measurements, if they have not been sent via the application, information on medications used, etc).
- Establishing consultative contact with the Patient in an agreed manner (phone/Internet connection, computer - with the option of a video-consultation camera), on an appointed day and time.

Preparation of the Patient for the tele-/video-visit

Open telecommunications connection telephone / or computer with the option of a video-consultation camera

- Uploading of data from blood glucose meters and continuous glucose monitoring systems to the internet cloud using mobile applications and software programs - prior access allowed for RCMC to patient's account on mobile application system.
- Prepare data - glycemic measurements from a predetermined schedule> daily glycemic profile / half glycemic profile - in a readable version during teleconsultation.
- Arrangement of time and place for teleconsultation to be conducted freely and conveniently on a given day and time.

Televisit / video visit

Establishing consultative contact with the Patient by a designated Consultant / Physician Specialist in an agreed manner (telephone / Internet connection, computer - with the option of a video-consultation camera), on an agreed date and time.

- Introduce oneself, including personal details of the Consultant
- Identification of the Patient with whom the consultation is about to begin (personal data, it is also possible to establish the Patient's individual identification number)
- Getting Patient acquainted with hitherto obtained medical data (information from the examination in MZD) and the resulting preliminary medical assessment.
- Obtaining current medical data from the Patient - subjective health status, test results from self-monitoring (if they were not sent by mobile application), information about medications, etc.
- Summary of the patient's medical data obtained. Establishing the diagnosis. Discussing medical issues related to the diagnosis and health problems reported by the patient.
- Determine the patient's education and training needs -.
    - o Establish principles for obtaining self-monitoring data in the future (ability to use mobile glucometer applications / software),
    - o education on healthy nutrition and physical activity.
    - o referral to educational clinic / referral to e/education (possibility of establishing further teleconsultation contact as part of further educational counselling)

- Summary of the consultation. Suggestions for possible therapeutic changes. Discussing them with the patient.
    - o If accepted - adjustment of the current treatment / referral to hospital / determining the need for the patient to visit the AOS or POZ unit.
    - o If the Patient categorically refuses the proposed changes in therapy - an urgent personal visit in a primary care or AOS facility or referral to hospital.
- Issuing e-referrals, e-prescriptions, issuing written post-consultation recommendations that will be sent to the Patient via e-mail and, with his/her consent, also to the POZ unit.
- Establishing further form of contact / appointment for patients requiring further telemedical support - individual teleconsultation / video-consultation - within the framework of "counteracting the digital divide" in terms of access to specialist medical / diabetes care. Especially for patients who cannot independently take advantage of specialist consultation in the field of diabetology due to, inter alia, age, communication problems, women with gestational diabetes (advanced pregnancy, gynecological advice against traveling), etc.
- Referral to AOS if patient does not require further consultative support via telemedicine system / or prefers personal contact with attending physician.
- Termination of the teleconsultation / video-consultation.
- Information from the teleconsultation is recorded in the RCMC computer system and transmitted to the POZ.

5. Description of Information Circulation

- Information about telemedicine testing opportunities will be provided by RCMC
- Contact between RCMC and family doctors will be established
- Family doctors will declare their willingness to join the pilot and give an approximate number of patients to be tested and will be in contact with RCMC on organizational matters
- Family doctors will address the local community
- The results of the tests performed at the POZ will be placed in a virtual patient account that can be accessed by the RCMC diabetologist and ophthalmologist as well as the family physician
- Patient will be advised by the POZ to continue further testing or will be sent home (with normal anthropometric and HbA1C results
- A diabetologist and an ophthalmologist (in patients with abnormal HbA1C levels) will perform the evaluation and the results will be available in the patient's account, which will be visible to the family doctor.
- Based on this, your GP will make e-referrals to appropriate specialists if necessary
- A remote visit by an RCMC diabetologist will be able to take place without a referral. The result will be recorded in the patient's account.
- Through the patient's account, information (notification) will be provided that further treatment (once the patient's condition has leveled off) can take place in the POZ. At the same time, recommendations from a diabetologist or ophthalmologist will be recorded in the patient's account.

- The family doctor will be able to contact the RCMC again in case of any doubts related to the management of the patient and, for example, ask for reinstatement of the teleconsultation system or, on the basis of obtained recommendations, will continue treatment within the POZ.

6. Description of the solution from the technological side

6.1 Introduction

The development of information infrastructure expands the possibilities in the design, implementation and operation of information systems. This theorem also applies to telediagnostic and medical teleconsultation systems. The possibilities of development are conditioned by the continuous progress in hardware and software development technologies. It has become possible to build scalable open telemedicine systems that integrate teleconferencing, transmission of high quality radiological images and access to medical databases within one tele-diagnostic service.

The creation of such advanced systems requires the proper selection of hardware, system software architecture and the development of scenarios for the implementation of applications and their exploitation in medical practice.

6.2 Technological assumptions

Due to the intensive implementation of eHealth solutions on a large scale in the Republic of Poland (e-prescription, e-recall, e-prescribing, Electronic Medical Records, www.pacjent.gov.pl, www.gabinet.gov.pl), the target solution will be a platform integrated with the existing and continuously developed eHealth platform systems in Poland by the Central Administration.

In addition, there is a number of HIS (Hospital Information System) systems, such as AMMS by Asseco, OptiMED and e-Care by Comarch, CLININET by CompGroup Medical, ESKULAP by Nexus Polska, which offer comprehensive services for medical entities and enable the execution of treatment processes.

The piloting of the solution will use a specially created for this purpose Internet platform, which is a health area in the field of diabetology, serving to improve awareness (educational aspect), screening diagnostics and treatment. Of course, the use of the telediabetology platform does not eliminate the possibility of using an already implemented HIS-type system for patient contact. It is desirable to make comprehensive use of already existing tools in order to extend patient care. Assuming that all systems will be integrated with P1 Platform, this will enable data flow.

Internet platform created for patients, integrated with the currently existing solutions for e-health, must enable the acquisition of medical data, its management by medical staff, providing services (appointment scheduling, consultations, remote monitoring) financed by the public health insurance system.

Designed and implemented telemedicine system, will provide a common space for medical staff, patients and administrative staff.

Members of each of the three groups will be able to perform activities in accordance with the assigned rights and roles.

The architecture of the system will include the central part and interfaces providing communication with physicians, patients, administrative staff and other systems, with which communication will be necessary or desirable.

As part of the piloting of the solution, we propose to create a platform that will enable each group to perform activities:

- Medical staff to monitor the patient's health status and consult with the patient and other specialists,
- The patient to communicate with the doctor,
- The health care system for collecting data on the health status of the population

The platform will meet the following conditions:

- Availability through a web browser at a specific web address (to be defined at the implementation stage)
- Web interface for display on PC/Mac and mobile devices such as Android/iOS tablets and smartphones
- Mechanism enabling registration and logging in with confirmation of the patient's identity (optimally integrated with the patient's account at www.pacjent.gov.pl)
- Creation of a virtual patient account and its operation will be possible on any device equipped with a web browser
- Will maintain the security of stored data due to its special nature. Required cybersecurity testing by an external company specializing in ICT security.
- Accessibility and ease of use for users with varying levels of knowledge and experience in using web technologies.

The platform will have specific features:

- The system will be supported by a dedicated tutorial,
- An "assistant/tutor" function for those who have difficulty operating it on their own,
- Enhanced features available only after going to your account,
- Educational panel with treatment information for patients
- Possibility of adding comments, additional information, answers, filling in questionnaires by the patient
- Visualization in the form of graphs of parameters that can and should be presented in a graphical mode
- Access to data on the platform by appropriate medical personnel in the context of a single patient
- Additional confirmation of patient identity through the use of a telecode (authorization code), which will be used for patient authorization during telephone conversations with medical personnel

The design and implementation of the model will be possible through the cooperation of partners with different experience and competencies that allow the creation of the solution described in this document. The partners may include, among others, Norwegian partners, patient organisations, primary healthcare facilities.

The required experience and competencies should be in the areas of knowledge of the functioning of the health care system, broadly understood IT area, clinical background allowing the implementation of the project.

6.3 Architecture of the solution

It is assumed that the telemedicine system will have a layered architecture.

6.4 Client Layer

Client layer enables using functionalities provided by presentation layer. It provides working environment for the user (medical staff, administrative staff, patient), presents data and receives commands from the user given using Graphical User Interface (GUI) components. Active, dynamic web pages were chosen as a way of communication with the user. This solution translates into high ease and availability of use of the system due to the fact that commonly used operating systems (Microsoft Windows, Linux, macOS) have built-in web browsers (Mozilla Firefox, Google Chrome, Microsoft Edge, Safari). This means no need to install additional software on client devices to use the telemedicine system. It was assumed that the graphical interface will be primarily functional, while keeping advanced functionalities to a minimum, so as to maintain its accessibility and ease of use for people with varying degrees of proficiency in using modern technologies.

6.5 Data presentation layer

The use of a browser in the client layer is possible if HTTP server-side software is used. The data presentation layer will be a server farm providing HTTPS services. The servers will send the correct information to the browser. An integral part of the presentation layer is the load balancing layer which will spread the load between multiple servers and lead to an even load. This approach will ensure high availability of the telemedicine system and stability in accessing resources.

6.6 General Assumptions of the Web Interface

The interface will be made using web technologies and accessible through a web browser.

The website will be created using the RWD method and will smoothly adjust to the resolution of the device on which it will be displayed. Screen elements, i.e. photos, graphics, fonts, buttons, will be arranged appropriately to screen size. In case of devices with lower resolution, some elements of the interface will also change in order to optimally arrange the content for users.

The prepared website will be optimized for laptop PC and tablet devices.

All web interfaces available in the system will be made according to general assumptions, but they will differ in functionality, according to users' roles in the system.

GP interface

Functionally, the web interface provides:

- allows text and numeric data entry, with validation,
- interview information
- upload scanned medical examinations (if necessary)
- patient visit history,
- visualization of time variation in test parameters,
- schedule of visits,
- providing answers to patient questions asked in electronic form

POZ staff interface

Functionally, the web interface allows:

- patient account management
- patient recruitment
- arranging teleconsultation
- Allows entering text and numerical data, together with their validation,

MZD personnel interface

Functionally, the interface enables:

- patient account management
- Entering GDPR information
- Diagnostic equipment management
- Define, share and fill in questionnaires

Specialist physician interface

Functionally, the interface allows:

- allows the entry of text and numerical data, with their validation,
- consultations of patients within the specialization
- review of treatment history (documentation)
- treatment recommendations
- visualization of variability of examination parameters over time,
- management of specialists' availability schedules,
- defining, sharing and filling in surveys

Patient interface

Functionally, the interface allows:

- Conduct a medical interview (answers to questions within the web form)
- Review of visit history (recommendations, treatment)
- Visualization of time variation in test parameters,
- Scheduling a visit
- Ask a question to a specialist
- Uploading medical examination results

Administrative staff interface

Functionally, the interface allows:

- Generate predefined reports
- Definition and generation of ad-hoc reports
- Statistical summary of visits in different criteria

6.7 Data processing layer

The data processing layer focuses on the logic of system operation. Because of its key role in the operation of the system, it is the most complex and modularly built. It is the central element of the system and is built as a set of rules that strictly describes how the different layers of the system and its modules communicate with each other.

In a telemedicine system, the client layer through the data presentation layer communicates with the data processing layer. Then the data processing layer communicates with the data storage layer. Communication is possible after authentication and authorization in the context of medical staff or patient. API implementation is a set of procedures and protocols that enable software components to communicate with each other according to established convention. The use of data processing layer increases the system security by limiting the interaction between the layers and creating built-in control and scaling mechanisms. Moreover, it introduces mechanisms of authentication, authorization, confidentiality and non-repudiation of the telemedicine services implementation. The API will be implemented as a set of microservices, in a scalable container service.

6.8 Data Storage Layer

The data storage layer will consist of three primary subsystems.

The first is the relational database management system (RDBMS). The system will use two database instances that contain complementary information to each other. The first database instance will contain staff and patient data to enable authentication and authorization in the system. It will store permissions to the modules of the data processing layer. The second instance of the database will store the results of diagnostic tests, diagnosed disease entities, applied medical procedures. The relational repository will store a structured view of the medical case. Each instance will satisfy the ACID condition. The key connecting the data from two databases will be a unique identifier. It will be necessary to design an appropriate data model. Application of such approach will contribute to increase of security level of the whole system.

The second system will be a non-relational NoSQL database, providing mechanisms for storing and retrieving data modeled in ways other than tabular relations. The key-value and document models will store interview/survey descriptions.

The third data storage layer system is object storage. It provides a method of non-hierarchical data storage. It does not use a directory tree but objects (separate data units) existing at the same level in the storage pool. Each object has a unique identifier used by the application to access the object. Objects will be accessed from the system using the API rather than from the user interface. Entities that are scans of test results and diagnostic imaging will be stored as objects in the system.

6.9 Communication

Data transfer between the user interface (web interface) and the central telemedicine system will be carried out using encrypted communication in accordance with the SSL standard. It is a network protocol used for secure Internet connections. It has been adopted as a standard for encrypting Web

pages. SSL certificate ensures the confidentiality of data transmitted over the Internet. It also ensures the credibility of the website and the whole organization (it is possible to carry out a comprehensive verification of the entity applying for the certificate). The intention of SSL developers was to design a universal protocol so that it can be used by application protocols.

7. Detailed description of the path from POZ to teleconsultation

1. enrolling the POZ to participate in the pilot telemedicine model presented by RCMC and signing the agreement.
2. provision of analyzers for HbA1C level testing, scales, height and waist circumference measurement, blood pressure monitor, educational materials (quizzes and others), tablet rental.
3. training POZ team in the rules of cooperation and using the equipment Establish ways and criteria of patient recruitment.
4. recruitment of patients by POZ - preceded by dissemination of information through local media, media information, phone from POZ. People who meet the criteria and agree to participate in the program will be invited to visit the POZ on a previously set date
5. the POZ examination- providing the patient with information about the study, obtaining informed consent to participate in the study and the participant's personal data protection document.

- Create a patient account with a unique number.
- Conduct a survey on a tablet with the support of the POZ staff.
- taking RR, weight, height, waist circumference, HbA1C test and entering the results on the tablet by the primary care nurse
- Dividing patients according to their HbA1C level:

- **Patients with an elevated HbA1c>6.5%** are referred for fundus photography and OCT testing. The results from the equipment, in the form of images will be directly recorded on the patient's account. According to the current recommendations of the Polish Diabetes Association, the diagnosis of diabetes can be confirmed by an HbA1C test performed using a method certified according to the NGSP (National Glycohemoglobin Standardization Program), therefore, people without a diagnosis of diabetes, but with an HbA1C result > 6.5% on the POCT analyzer, will be referred to a family doctor for a repeat of the HbA1C test using a method certified according to the NGSP and possible additional tests such as; lipidogram and renal function parameters (creatinine, urea, uric acid).
- Patients with diabetes and HbA1c <7.0% can remain under the care of their General Practitioner, who also has the option of teleconsultation with the RCMC specialist
- Patients with diabetes and HbA1c 7.0-8.0 % may remain under the care of a family physician and/or diabetes specialist who also has the option of teleconsultation with an RCMC specialist
- Patients with diabetes and an HbA1c of 8.0-10.0 % should be urgently referred to a diabetes specialist or have the option of teleconsultation with an RCMC specialist
- Patients with diabetes and HbA1c >10.0 % should be urgently referred to a specialist diabetes hospital or have teleconsultation with a specialist at RCMC

- Patients with normal HbA1C levels are sent home after completing a diabetes risk factor knowledge quiz and providing patients with information on healthy eating habits and diabetes-related problems.
    - Setting up teleconsultation appointments for patients selected as requiring this form of support.
    - Training of willing patients in the use of blood glucose meters/ CGM systems with the ability to transmit data to the Internet. 6,

6. visit of the Mobile Team at POZ center

Takes place during the POZ after prior appointment. Patient after signing informed consent form has fundus photography and retinal OCT examination done by MZD. The digital results are posted to a patient account created by RCMC. The results are evaluated by an ophthalmologist to decide the need for therapy/observation/complete eye examination.

7. Teleconsultation at a time designated for the patient

Medical teleconsultation - correction of current treatment is made, therapeutic goals are established, and a decision is made on further direction of the patient's treatment:

- continuation of the teleconsultation - setting a date for the next meeting
- Referral to diabetes clinic
- Referral to hospital - diabetes unit
- Referral for further treatment in POZ

8. Medical and technical qualifications of team members

Medical team:

The medical team should include:

- Team leader:
- MZD staff
- Specialist diabetologist RCMC
- Specialist ophthalmologist RCMC

MZD Staff: (at least 2 professional health workers i.e. nurses or paramedics): Has the ability to transport, install and operate a fundus imaging machine and an optical coherence tomography (OCT) retinal imaging machine.

Basic skills in operating computer equipment and remote communication applications will be required, as well as the ability to behave in random and emergency situations. Preparedness for constant changes in test location and movement. Availability. Personnel shall be licensed and authorized to drive the vehicle in which the MZD will travel.

Diabetes specialist physician with RCMC (at least 5 persons): has a specialty in diabetes, clinical practice, currently practicing in accordance with his/her specialty and in has basic skills in operating computer equipment and remote communication applications, has basic experience in providing telehealth.

Ophthalmology specialist from RCMC (at least 2 persons) : has a specialty in ophthalmology, clinical practice in the diagnosis and treatment of retinal diseases with particular emphasis on diabetic retinopathy. He/she is currently practicing according to his/her specialization and in possession of basic skills in operating computer devices and applications for remote communication.

Team Leader: Medical doctor with specialization in diabetology with at least 5 years of diabetology practice

IT Team:

The web platform implementation team should include at least:

- Solution Coordinator / Team Leader
- DevOps Engineer
- Developer (front-end, back-end, integrator)
- Software tester
- Computer graphic designer
- Social media marketing specialist
- Teleconsultation coordinator

The scope of work related to the creation and availability of the Internet platform for the duration of the pilot will include all administrative work (installation, configuration, software implementation) and programming, related to the launch of the platform and its maintenance during the pilot, as well as working with medical and administrative staff.

Competencies of staff of a technical nature should relate to: knowledge of the functioning of the healthcare system, proficient in IT, having experience within telemedicine applications. These people should have competencies within their field of specialization that enable them to implement the project. Availability and readiness to react in case of an urgent need of help will be a value.

Implementation of the project will require coordination (solution coordinator / IT team leader) of all technical activities, with particular emphasis on the coherence of the work performed. A special task of the technical coordinator will be to work closely with the medical coordinator to create the highest quality system possible.

The DevOps Engineer prepares and maintains the server and network part for hosting the Platform during the pilot period, works with the development team on the implementation and deployment of the system. Performs platform support and availability services.

Developer (front-end, back-end, integrator) - responsible for creating Telediabetology Internet Platform (WWW portal) and communication interfaces with m-health central systems.

Software tester - verifies the correctness of the implemented program, whether the created program meets the requirements. He participates in creating requirements specification and test scenarios.

Graphic designer - creates graphic designs, visualizations, logotypes, flyers, posters, co-creates advertising campaign. Together with social media marketing specialist creates advertising campaign.

Social Media Marketing Specialist - the person who takes care of the digital image of the pilot stage of the project by running a social media outreach campaign. Will be responsible for setting up and administering pages in selected social media and maintaining them as an active channel of

communication with patients. Consults with medical specialists on content posted on the site, prepares promotional materials, and conducts ongoing outreach campaign. Responsible for patient communication. In the case of nationwide implementation, it is recommended to extend the promotion of the project by creating a website dedicated to the project (estimated cost approx. 30,000 zł).

Teleconsultation coordinator - a dedicated person to coordinate during the pilot stage of teleconsultation with specialist doctors (arranging teleconsultations, potential date changes). It is advisable to have medical education in order to competently undertake conversation with the patient. Responsible for research (survey) on the satisfaction of users of the designed solution.

9. proposed model of integration with existing e-Health architecture in Poland

The implemented system puts the patient at the center by using the concept of integration of involvement of different levels of health care, i.e. primary health care and specialized health care.

The system will be integrated with the electronic platform of public health services - P1 Platform (Electronic Platform for Collection, Analysis and Sharing of Digital Resources on Medical Events). Integration with the P1 Platform enables the exchange of medical information between institutions. All medical events are sent to the P1 Platform in real time, so that it is possible to build an electronic platform of public services in the field of healthcare, which enables collection, analysis and sharing of digital resources on medical events in accordance with the Act of 28 April 2011 on the information system in healthcare.

The P1 system is available for service providers and regional systems registered with CSIOZ only through standard Web Services interfaces. The integration of the telediabetes platform with the P1 Platform will be implemented according to the guidelines contained in the available technical documentation.

10. Defining risks associated with the implementation of a given telemedicine model and possible ways to mitigate them

10.1 Risks associated with the technical background of the project

One of the most important issues related to the implementation of the proposed telemedicine model is information security. Data leakage (accidental or intentional) may result in unauthorized access to patients' personal data, questionnaire results and medical examination results. It may occur that someone unauthorised impersonates a consultant or patient during a telephone call.

This can result in legal consequences, as well as serious reputational damage and loss of public confidence. Reducing the risk can be achieved by using current standards, good practices for designing and securing ICT systems (also in terms of verifying the identity of the person receiving the call). There is also a need to modify the existing infrastructure and develop and implement an Information Security Policy. There should be systematic risk assessment and monitoring, implementation of control procedures, staff training, introduction of quality systems, evaluation of external service providers,

legal safeguards for the performance of contracts and other preventive, prescriptive, corrective and detection mechanisms. It is also necessary to inform patients which mistakes they should avoid during telemedicine visits (e.g. which data no one should ask about) and how they can properly verify the doctor. Additionally, in order to identify the patient - a request for an identification number established for contact with the patient, such as a prescription number. The patient, as a participant in the teleconsultation, should be aware of the legal consequences in case of disclosure of its content in any form. An obligatory statement in the patient's account that he is aware of the legal responsibility for disclosure of the contents of the tele-transfer can be used.

An important risk is **downtime in the availability of system environments** due to low availability of production environments. Prevention of this risk will consist in administration and supervision of the IT infrastructure by IT personnel being a part of the project team.

Slightly smaller consequences may be caused by the **use of outdated technology or an unproven solution leading** to problems with scalability and stability of the built system. Maintaining such an unfavourable environment may require a large number of on-going administrative tasks, which is excessively resource-intensive. This risk is mitigated by selecting technology on the basis of an up-to-date review of solutions addressing particular areas of the system under development, and by applying good design practices.

Equally dangerous is **data loss** due to failure. This will result in loss of data integrity, lack of application availability, inability to fully assess the patient (e.g. loss of ophthalmic examinations) image losses and legal problems and the need to repeat the patient encounter. To prevent data loss, system environments should be backed up regularly. Hardware and software data protection techniques are required, as well as the use of source code versioning tools.

A lesser risk is the **inappropriate choice of IT tools**, resulting in an increasing number of errors and time-consuming fixes. As a result, schedules may be delayed. The proposed solution is to review the administrative and development tools used.

If **equipment** (tablets, glycated haemoglobin analysers, fundus photography equipment and retinal optical coherence tomography OCT) **is damaged** during a patient visit, the study cannot continue as planned. In the case of tablets and analysers, spare equipment is possible. It is necessary to train the mobile diagnostic team (MZD) in the use and proper transportation of ophthalmic equipment.

Breakdown of the means of transport (minivan) or **adverse weather conditions**: problem with arrival at the agreed time. The solution is to organise a substitute means of transport and/or postpone the examination by MZD to another date.

Lack of internet access may cause disruption in sending data to the Regional Centre for Digital Medicine (RCMC). How to minimise the risk: mobile units using dedicated cars should be equipped with a local WLAN access point connected via a router with at least two GPRS (LTE) modems making connections to networks of different operators. Attention should be paid to the power requirements of computer and network equipment and the electrical installation of the vehicle should be modified accordingly (e.g. additional battery to be charged while driving or by means of a dedicated station at the home parking place - vide https://www.udt.gov.pl/systemy-ladowania) The provision of possible buffering of files before sending to the central system should be realized within an application providing an interface for entering and reading data of the tele-medical diagnostics system. Access to

a company mobile phone should be provided for the mobile team, independent of WLAN communication.

In conclusion, it can be stated that it is a good solution to **transfer the risk** by transferring it to other entities through e.g. insurance: against random events, databases, IT equipment, project, etc.

10.2 Risks associated with the proper conduct of the processes described

The biggest risk that cannot be excluded is a **total lockdown** related to the next wave of COVID-19 or due to other epidemiological reasons. It will cause a temporary inability to conduct the pilot study as planned. An alternative might be to send HbA1C analysers (as was the case with pulse oximeters) to patients' homes and limit the procedures to televisit or visiting the patient's home, if necessary.

Insufficient cooperation with the GP and his/her POZ may result in a certain number of patients not being qualified for testing by the RCMC (e.g. failure of the doctor to send information about the test, failure to perform glycated inhiboglobin levels, anthropometric measurements, careless execution of the questionnaire, lack of preparation of the premises, insufficient contact with the RCMC specialists). To reduce this risk, it is necessary to explain in detail to the GP the principles of cooperation, to sign a contract with the RCMC in which the duties of the RCMC (and possible penalties) are strictly defined, and to carry out a visit to the centre in advance.

Low quality of received ophthalmic examination results resulting in lower sensitivity and specificity of telemedicine examination. This factor can be reduced by adequate training and continuous monitoring of the quality of the imaging studies received by the RCMC ophthalmologist.

Inadequate skills of RCMC doctors may result in incorrect therapeutic decisions. Diabetes physicians should have practice in conducting e-visits. Ophthalmologists should correctly interpret fundus images and retinal OCT. This risk can be eliminated or significantly reduced by appropriate recruitment rules for medical staff (including the need for specialisation in the field, ability to use digital devices, relevant clinical experience and current work in the profession).

Lack of agreement with patients on the choice of the preferred method of e-visit, forgetting about e-visit, random situations on the side of the patient and the doctor. This can result in the interruption of the telemedicine care system. In order to reduce this risk, telephone notifications, text messages, e-mails reminding about the consultation can be sent. In case of a missed appointment, a new appointment should be scheduled. More than 1 specialist should be recruited for the position and a substitution system (contingency plan) should be developed.

10.3 Other human factors

A risk is the **lack of acceptance of teleconsultation** due to previous habits. Patients may associate teleconsultations with pandemic times and therefore consider them as "second-class" visits. Elderly people in particular may not believe that a teleconsultation can in many cases successfully replace a personal visit to the doctor. Patients from smaller towns may also be eager for interpersonal contacts that used to take place during visits to a primary care centre or a specialist. The solution to this problem may be education and convincing patients that remote visits are effective. People of public trust can

play an important role here, e.g. a local family doctor, nurses, a priest, a village leader, who will encourage patients to participate in pilot examinations, e.g. by personally taking part in them or by becoming their patron. The GP can announce the pilot in advance e.g. on the GP surgery Facebook page, put up posters in the clinic, pharmacy or shop. The village leader can distribute leaflets to residents. Surveys can be preceded by information campaigns on television, radio, newspapers, the internet and social media. The benefits of teleconsultation should be emphasised, such as no risk of infection, time saving, no travel costs, better access to specialists, smaller queues. It is necessary to build trust and explain that such remote visits are already standard in many countries of the world. Moreover, it is necessary to strengthen the belief that the e-health system will continue to develop and changes in the existing care are inevitable.

Inability to use appropriate applications on a smartphone or computer in the community, due to lack of information and education. Patients may fear that they will not be able to use the different applications correctly. In this case, it is better to suggest contact through a phone call. One can also ask younger household members to help seniors.

Poor patient understanding of the screening process - the patient should be thoroughly informed about the rules of the study, e.g. that screening tests cannot fully replace a personal visit to the doctor and how to properly prepare for a remote visit in order not to waste time or forget the most important issues. The patient should know that during a remote visit he will be able to receive an e-prescription or e-referral. He should prepare something to write down the relevant numbers.

Low interest of POZ physicians due to low valuation of services, fear of "outflow" of patients", lack of equipment or low number of staff. This risk can be mitigated by adequate funding and education, and by providing adequate resources for teleconsultation and communication with the RCMC specialist team. Nurses should receive additional compensation for tests performed during the pilot study, education and promotion of telemedicine.

Appendices:

Table 1.

Table 2.

11. Analysis of potential benefits

The proposed telemedicine programme will increase the availability of health services, will save time and money for providers and recipients. It will be possible to optimise treatment processes, reduce waiting times to see a specialist and overcome geographical barriers. The risk of COVID-19 will be reduced. The programme has an educational aspect. It will contribute to building a health care system in which the patient takes an active part in therapy and is co-responsible for it. The clinical impact will be more frequent provision of relevant information and instructions, which may lead to improved treatment outcomes through lower HbA1C levels or fewer complications. A potential benefit will be increased patient satisfaction due to the individualised approach and safeguarding the patient's health needs. In addition, the patient may start to use social media more for better diabetes control and support. Early detection of diabetic retinopathy and diabetic macular oedema, which can lead to blindness and loss of independence, is very important. These complications are very common but with appropriate early treatment, good vision can be maintained. Unfortunately, due to their long

asymptomatic course, these complications are diagnosed very late. Then the effectiveness of treatment is very limited. It should be mentioned that the treatment of patients with diabetic macular oedema is possible within the "Drug Programme for the Treatment of Diabetic Macular Oedema". Preventive measures for people with risk factors for diabetes will be important. Education on healthy nutrition, maintaining a healthy body weight will contribute to the reduction of the incidence of type 2 diabetes in people with risk factors. The social inequalities faced by people in rural areas (e.g. poorer access to health services, poorer education and material status), which are responsible for a higher proportion of people with diabetes than in urban areas, will be reduced. In the future, the option of other, additional tests and artificial intelligence may be introduced into the system.

12. Economic analysis

1000 patients will be examined in 5 primary care centres

Insurance costs: the insurance costs of the study are not known at this stage.

12.1 Management costs

The management costs of the pilot project must not exceed 10% of the project value.

Remuneration:

-Project substantive coordinator: 5,000 PLN x 6 months x 2 persons = 60,000 PLN

-Project administrative coordinator: PLN 5,000 x 6 months = PLN 30,000

-Project accountant: PLN 4,000 x 6 months = PLN 24,000

-Project administrative support: PLN 3,000 x 6 months x 2 persons = PLN 36,000

The total cost of salaries related to project management: **PLN 150,000**

12.2 Purchasing equipment

The purchase of equipment (it is not possible to purchase so-called fixed assets) may constitute **up to 37% of the project value".**

- Purchase of tablets - 6 x 1,200 (**7,200 zł**) to connect to the platform.
- Purchase of a GSM mobile router, two SIM cards with mobile internet plan - 4,500 + 2 x 300 x 6 months= **8100 zł**
- Purchase of mobile workstations - 6x 6,000 **(36,000 zł)**
- Purchase of mobile phones for the needs of arranging and carrying out teleassistance calls with a card - 6 x 1200 + 6 x 30= **7380 zł**
- Purchase of analyzers for HbA1C determination from capillary blood: 50 analysers (20 determinations each, unit price 600 zł) for 1000 patients - total cost 30,000 zł plus 5 spare analysers 5 x 600zł =3000 zł; total cost **33,000 zł.**
- The purchase of an upper arm blood pressure monitor with a set of cuffs, with the ability to detect irregular heart rate - approx. 250 zł x5 pieces= **1250 zł**

- A purchase of a class III legalized medical column scale with a height meter, (load max 300 kg, BMI and BSA measurement and transmission of the parameters to a computer) - approx. 1300 zł x 5 pieces = **6500 zł**
- A purchase of a measure tape for measuring waist circumference - **5 units, 300 zł**
- Purchase of a laser printer with maintenance materials (1000-2500 zł) 2 items= **5,000 zł**

The total cost in this category is: 104,730 zł

12.3 Equipment rental costs:

Due to the limitations of the specific value of the pilot projects (200,000-675,000 EUR) adopted in the "Health" Programme, equipment rental is necessary for the implementation of the pilot. In case of nationwide implementation, it is ultimately recommended to purchase it.

- Mini-van for transportation of equipment and personnel (monthly rental cost varies from 9,000 to 11,000 zł gross per month plus fuel costs of approx. 1,000 zł per month; expected usage time 3-4 months). Total cost: approx. 40,000-**45,000 zł**
- Camera for fundus photography and OCT/angioOCT camera (monthly lease cost of a specialist camera for fundus examination, e.g. Canon OCT-A1 and fundus camera CR-2 AF with full equipment costs 14,760 zł gross (assuming at least 3-month lease period) or SOCT iScan + funduscamera NFC-700, - 9,000 zł/m or SOCT AngioVue + funduscamera NFC, - 14,500 zł). Expected usage period 3-4 months= **14760 zł**
- **Total cost of equipment rental: 59,040 zł**

12.4 Remuneration:

- Salaries for the POZ physician for recruitment of the declared number of patients, provision of rooms for the pilot (including the equipment brought by RCMC), promotion of the project, medical security during the study and covering costs of electricity, internet and cleaning - 100 zł per patient (1000x100 zł=**100,000 zł**)
- Salary for a primary care nurse for making appointments, anthropometric and blood pressure measurements, HbA1C measurements, entering data into a tablet, assistance in conducting a survey and educating patients with the use of diabetes knowledge quiz and information materials, directing patients' movement in primary care - 60 zł per patient (1000 x 60 zł= **60,000 zł**)
- Remuneration of MZD members 2 persons x 6,000 x 3 months= **36,000 zł**
- Remuneration of diabetologists 100 zł for teleconsultation x 1000 patients= **100,000 zł**
- Remuneration of ophthalmologists 100 zł for the evaluation of fundus photos and OCT of both eyes x 1000= **100,000 zł**
- RCMC team leader - 1 x 14,000 x 6 months (**84,000 zł**)

Creation and maintenance of the Telediabetes Internet Platform (WWW portal) at the pilot stage:

- Solution Coordinator / IT Team Leader - 1 x 14,000 x 6 months (**84,000 zł**)
- DevOps Engineer - 2 x 11,500 x 6 months (**138,000 zł**)
- Developer - 1 x 7,000 x 4 months + 2 x 11,000 x 4 months (**116,000 zł**)
- Software tester - 1 x 6,500 x 4 months (**26,000 zł**)
- Computer graphic designer - 1 x 4,500 x 6 months (**27,000 zł**)

- Tele-consultation coordinator - 1 x 4,000 x 4 months (**16,000 zł**)
- Total cost of remuneration in this category: **887,000 zł**

12.5 Promotion costs

- Running a campaign profile on Facebook: 1,500 zł per month x 6 months = 90,000 zł
- Ads on Facebook promoting the campaign targeted at audiences in Poland of unlimited age category within 6 months, total cost: **5,000 zł**
- Content marketing - sponsored articles with nationwide coverage: 5 articles within 6 months: 15,000 zł x 5 = **75,000 zł.**
- Conference opening and closing the project (including: costs of the room, catering, speakers' speeches) 25,000 zł x 2 = **50,000 zł**
- Printing leaflets, posters **5,000 zł**
- **Total cost** of the marketing campaign: **225,000 zł**

12.6 Other costs:

- Providing a platform for the project by an external provider - 80 000
- Development of Information Security Policy - 5 500
- Cost of courier mail (delivery of HbA1C analysers, educational materials, to POZ practices, etc.) - **5000 zł**
- Educational materials (publications, tutorials) **10,000 zł**
- Office supplies **10,000 zł**
- Development of the Project Risk Prevention Policy – **5500 zł**

Total cost of this category: **116,000 zł**

12.7 SUMMARY OF COSTS

150,000 zł - project management costs

104,730 zł - costs of purchasing equipment

59,040 pln - costs of hiring equipment

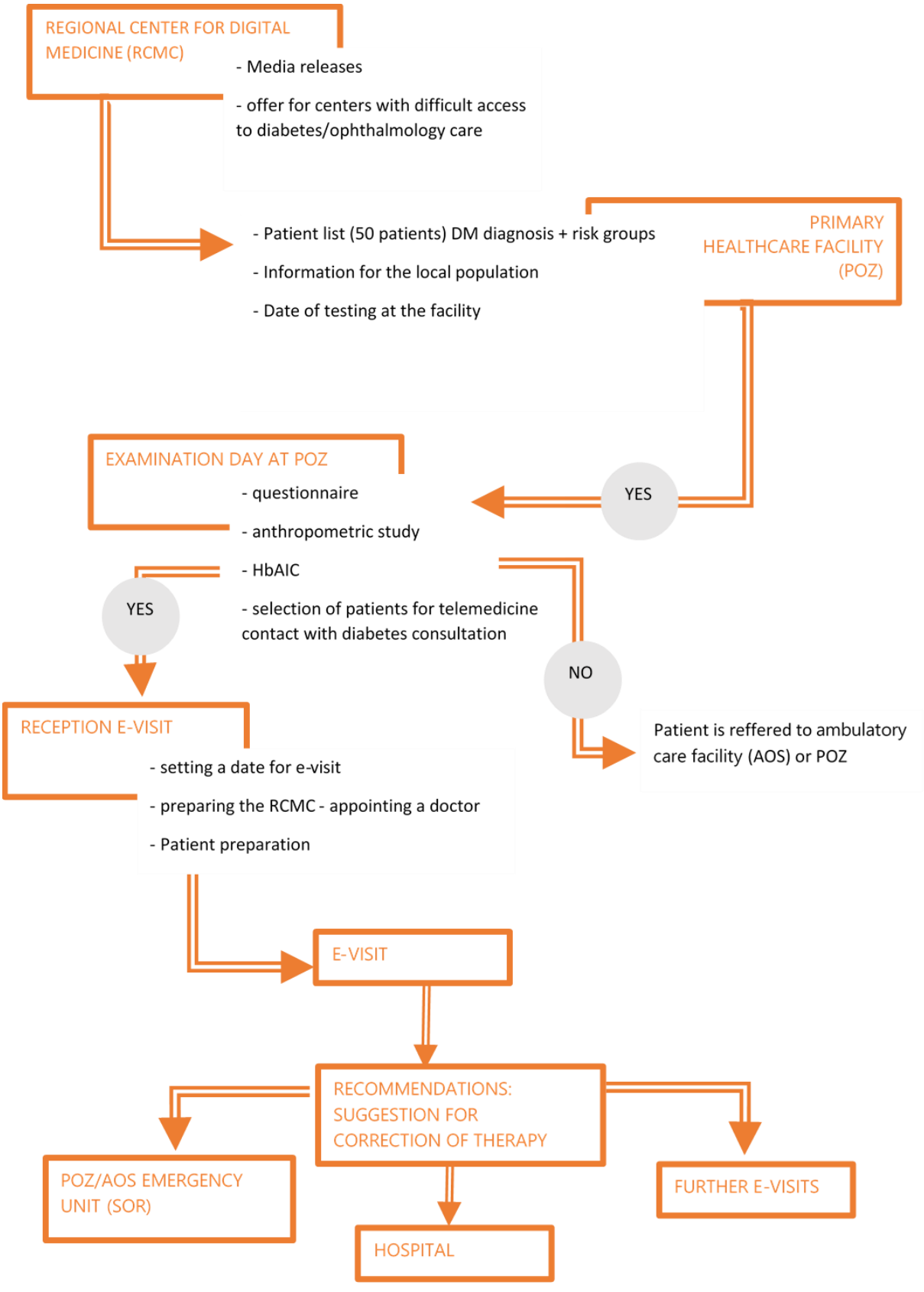
plN 887,000 - salary costs

225,000 pln - costs of the project promotion campaign

116,000 pln - other costs

Total cost: 1,541,770 zł

The proposed estimated cost calculation has been presented on the basis of the analysis of the costs of undertakings implemented to date with a similar scope. The final costs may vary slightly depending on changing market prices. Also, the final duration of project activities will depend on the date of signing the grant agreements.


REGIONAL CENTER FOR DIGITAL MEDICINE (RCMC)
- Media releases
- offer for centers with difficult access to diabetes/ophthalmology care
- Patient list (50 patients) DM diagnosis + risk groups
- Information for the local population
- Date of testing at the facility
PRIMARY HEALTHCARE FACILITY (POZ)
YES
EXAMINATION DAY AT POZ
- questionnaire
- anthropometric study
- HbAIC
- selection of patients for telemedicine contact with diabetes consultation
YES
NO
Patient is reffered to ambulatory care facility (AOS) or POZ
RECEPTION E-VISIT
- setting a date for e-visit
- preparing the RCMC - appointing a doctor
- Patient preparation
E-VISIT
RECOMMENDATIONS: SUGGESTION FOR CORRECTION OF THERAPY
POZ/AOS EMERGENCY UNIT (SOR)
HOSPITAL
FURTHER E-VISITS

Attachments

Table 1.

Probability (Loss frequency)	HIGH	Risks that are very common and result in relatively low losses • Availability of manufacturing environments	Risks that are very common and cause quite high losses • Information security	Critical Risks, Occurs with high frequency and causes fairly high losses- threatens achievement of objectives
	MEDIUM	A risk that occurs fairly systematically and causes low losses • Patient disregard for medical advice, resulting from insufficient information about obligations • Use of outdated technology or unproven solution	Risks that occur fairly systematically and result in fairly high losses • Loss of data due to failure	Risks that occur fairly systematically and result in fairly high losses
	LOW	Risks that are rare and result in low losses • Lack of informed consent of the patient for particular procedures (misinterpretation of patient's intentions) • Damage to equipment (tablet) during patient visit • Coexisting diseases - hospitalization • Teleconsultation does not take place - patient does not answer	Risks that are rare and cause quite high losses • Total lockdown for epidemiological reasons • Loss of data collected by the Mobile Team due to system failure • Mobile Team does not arrive at the agreed meeting place with Patients random situation, traffic accident,	Risks that are rare but result in high losses • Lack of professional qualifications of medical personnel: knowledge, skills, experience • Telephone conversation with a consultant is conducted by a person impersonating a patient

			meteorological conditions • Patients do not have an opportunity to come to an agreed meeting with the Mobile Team - e.g. adverse weather conditions • The teleconsultation does not take place - the Consultant does not make the call, random situation, indisposition of the Consultant • Inappropriate selection of IT tools	
		LOW	MEDIUM	HIGH
Consequences (level of losses)				

Table 2.

Groups/risk areas	Specific risks/threats and actions or inactions related to....	Risk mitigation / avoidance proposals
1. risks associated with the technical background of the project	a) Damage to the equipment (tablet) during the patient's visit b) The teleconsultation does not take place - patient does not answer c) The teleconsultation does not take place - Consultant does not call, random situation, Consultant's indisposition	(a) Spare equipment. Equipment insurance. Guaranteeing a proper place for the examination (table top, table), instruction in the use of the equipment, etc. b) Reminder SMS, e-mail. Telephone notification c) Organisation of work in the Centre Substitution system. Quick information about the reasons for delayed consultation given to the patient.

	d) Inappropriate choice of IT tools	d) Verification of administrative and development tools used
	e) Use of outdated technology or unproven solution	e) Selection of technology on the basis of current review of solutions addressing particular areas of the created system. Use of good design practices.
	f) Information security	f) Application of current standards and good practices for designing and securing ICT systems. The need to modify the existing infrastructure. Developing and implementing Information Security Policy.
	g) Availability of production environments	g) IT infrastructure administered and supervised by IT personnel being a part of the project team.
	h) Loss of data due to failure	h) Regularly performed backup copies of the system environments. Use of hardware and software data protection techniques. Use of source code versioning tools.
2 Risks associated with the proper conduct of the described processes	a) Lack of conscious consent of the Patient for performing particular procedures (wrong interpretation of his/her intentions)	a) Re-education of the patient on the objectives of the study
	b) Lack of professional qualifications of the medical personnel: knowledge, skills, experience	b) Staff selection, training.
	c) Mobile Team does not arrive at the agreed meeting place with Patients - random situation, traffic accident, meteorological conditions	c) Proper logistics of organizing the meeting. In case of a random situation, prompt information provided to patients. Information about an alternative date of the meeting.
	d) Patients are unable to come to the agreed meeting with the Mobile Team - e.g. adverse weather conditions	d) Meeting place that guarantees safety of Patients. Prior analysis of the weather forecast. Providing an alternative date for the meeting.

3.others	a) Total lockdown for epidemiological reasons b) Disregard for medical recommendations by the patient, resulting from insufficient information on obligations c) Coexisting diseases - hospitalization d) Telephone conversation with a consultant is conducted by a person impersonating the patient	(a) Limiting examination procedures to teleconsultation or visiting the patient's home (b) Re-education of the Patient regarding responsibilities. (c) Deferring the performance of examination procedures d) Application of current standards and best practices for verification of the call taker. Develop and implement an Information Security Policy.