MACHINE TRANSLATION

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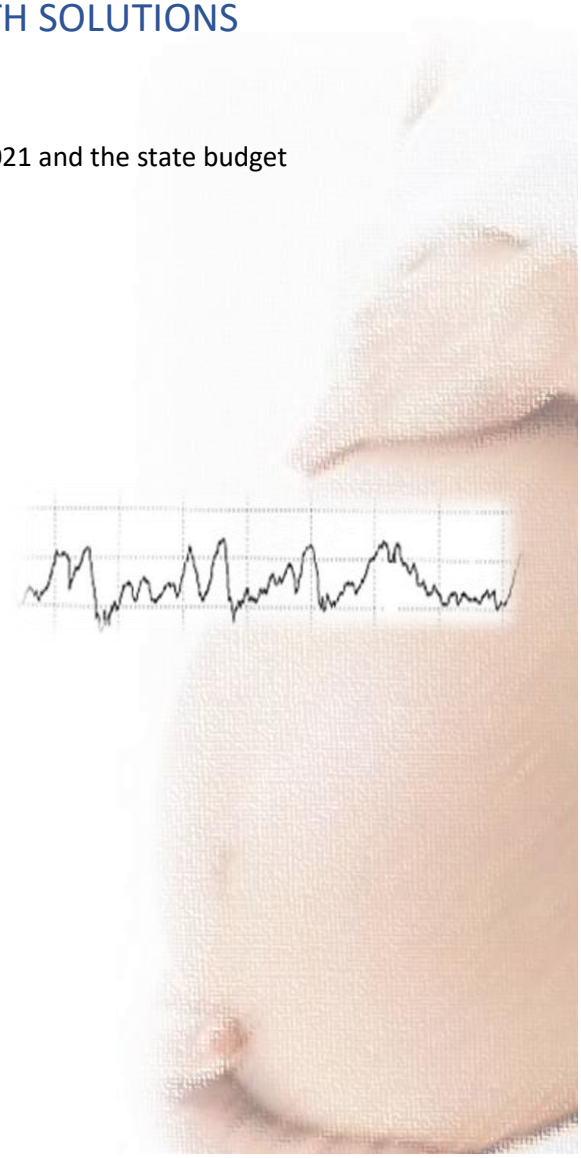
# TACKLING SOCIAL INEQUALITIES IN HEALTH WITH THE USE OF TELEMEDICINE AND E-HEALTH SOLUTIONS



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DEVELOPMENT OF MODELS

TELEMEDICINE MODELS IN OBSTETRICS

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**Tackling social inequalities in health with the use of telemedicine and e-health solutions - obstetrics**

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# 1. DEFINITION OF THE PROBLEM - PERINATAL CARE IN POLAND AND WORLDWIDE

The last three decades there has been a huge breakthrough in perinatal care in Poland. It was undoubtedly influenced by the launch of the National Programme for the Improvement of Perinatal Care in 1993, which aimed to prevent the incidence of complications resulting from prematurity. Undertaking the activities specified in the programme led to a decrease in perinatal mortality, a decrease in the number of preterm deliveries, a reduction of adverse effects of diseases of mothers and children. As a result of the undertaken works, the indicators of perinatal mortality of women and children have dramatically decreased. In 1990, 1.6 deaths per 10,000 population were recorded due to conditions beginning in the perinatal period; in 2013, the rate was 0.2. In contrast, the perinatal mortality rate decreased from 19.2 in 1990 to 5.6 in 2019.

Progress in medical knowledge, the development of technology facilitating diagnosis and treatment, and improvements in the organisation of care have all contributed to improving the quality of perinatal care. The improvement in the quality of care for women during pregnancy, labour and puerperium is also undeniably influenced by legal regulations that have come into force in recent years. In 2012, the Standard of medical procedure in the provision of health care services in the field of perinatal care provided to a woman during a physiological pregnancy, physiological delivery, puerperium and care of the newborn was developed and implemented (Journal of Laws of 2016, item 1132), which has been evaluated and is in force since 1. January 2019 as the Standard of organizational health care in entities performing medical activity providing health care services in the field of perinatal care (Journal of Laws 2018, item 1756). It comprehensively covers the organisation of care provided to a woman during pregnancy, delivery, puerperium and the newborn. This standard applies to all entities that perform therapeutic activities, provide health services in relation to perinatal care, regardless of the source of funding for these services. These regulations oblige both commercial health care units and health care providers contracted under the National Health Fund (NFZ) to comply with them. In Poland, a pregnant woman is cared for by a gynaecologist-obstetrician and, if the course of the pregnancy is normal and the woman and her baby are healthy, the care of a pregnant woman may be provided by a midwife. In Poland, there are 8,580 registered doctors with obstetrics and gynaecology specialisation, including 7,926 practising doctors, and 39,792 registered midwives, while 28,231 midwives are employed.

## 1.1. PRINCIPLES OF PERINATAL CARE FOR WOMEN IN POLAND

The Constitution of the Republic of Poland guarantees a woman during pregnancy and in the perinatal period care by the state, while the process of caring for a woman in this period is determined by the assumptions of the above-mentioned Standard. The provisions contained therein regulate in detail the scope of preventive, educational, diagnostic and consultative services in the prenatal period; they also indicate the need to identify risk factors for complications in the perinatal period. They also implement changes in preventive services and health promotion activities as well as diagnostic tests and medical consultations for women during pregnancy. They also draw particular attention to the need for antenatal and postnatal education. They present the principles of conduct in each period of labour, draw attention to limiting the medicalisation of this period and suggest the need to relieve labour pain.

The guidelines of the standard oblige the healthcare entities providing health services in the field of perinatal care to define indicators of perinatal care and their monitoring, at least once a year, guided in particular by the reduction of medical interventions and the assessment of satisfaction of women covered by care, in order to assess the effectiveness of planned and undertaken activities. They are

supposed to contribute to reducing the number of medical interventions that are not medically indicated, including the rate of caesarean sections. These regulations guarantee a proper and unified organisation of work, utilising the full potential of the staff in the most efficient way, while guaranteeing patient safety. In addition, they unify the approach of all health professionals, regardless of the place where health services are provided. In addition, the regulations guarantee women during pregnancy, childbirth and the puerperium subjective treatment, dialogue and respect for their rights. They make it easier to take the best decisions as regards health-promoting behaviour during pregnancy, choice method and of the place of delivery and the care of the newborn child. The regulation also sets out a framework programme for antenatal education, which makes it possible to standardise the content provided to pregnant women and their partners. This guarantees the right quality of education, optimal preparation for childbirth, and reduces fear of childbirth and childcare.

The standard also aims to raise awareness of the needs of the patients and indicates the principles of proper organisation of care for women in special situations, such as: diagnosis during pregnancy of a serious illness or defect of the child, miscarriage, giving birth to a stillborn child, incapacitated, sick or with congenital defects. It also indicates the principles of care for mother and child in the maternity ward in the "mother and child" system and the necessity of ensuring optimal organisation and conditions for the correct process of lactation and nutrition of the newborn.

The organisational standard of perinatal care indicates and sets models of behaviour for medical personnel and formulates guidelines in accordance with current medical knowledge and professional deontology. Patients, on the other hand, can find in the text of the Standards a list and schedule of a number of activities which should be performed by every woman during pregnancy, labour and puerperium, or which should be expected from medical personnel.

**TABLE 1.** Scope of preventive services and health promotion activities, as well as diagnostic tests and medical consultations, performed on women during pregnancy, together with their time periods.

| EXAMINATION DATE | PREVENTIVE SERVICES AND HEALTH PROMOTION ACTIVITIES | DIAGNOSTIC EXAMINATIONS AND MEDICAL CONSULTATIONS |
|---|---|---|
| **By the 10th week of pregnancy or at the time of first notification** | 1. subjective and physical examination<br>2. blood pressure measurement<br>3. examination of the mammary glands<br>4. determination of height, weight and BMI<br>5. pregnancy risk assessment<br>6. promotion of a healthy lifestyle<br>7. information about testing for genetically determined diseases<br>8. mandatory consultation of an obstetrician for midwife-led care<br>9. Collection of data on healthy lifestyle and eating habits, including use of alcohol and other drugs | 1. blood group and Rh group determination if the pregnant woman does not have an adequately documented blood group test<br>2. antibodies to red cell antigens<br>3. blood morphology<br>4. general urinary examination<br>5 Cytological examination, if not performed within the last 6 months<br>6. fasting blood glucose, or OGTT in women with risk factors for GDM<br>7 VDRL test<br>8. recommendation for dental check-up<br>9. HIV and HCV testing<br>10. Test for toxoplasmosis (IgG, IgM) in the absence of evidence of pre-pregnancy IgG antibodies<br>11. rubella test (IgG, IgM), when pregnant woman has not had the disease or vaccination or if no information is available |

| EXAMINATION DATE | PREVENTIVE SERVICES AND HEALTH PROMOTION ACTIVITIES | DIAGNOSTIC EXAMINATIONS AND MEDICAL CONSULTATIONS |
|---|---|---|
| | | 12. TSH determination |
| **11-14th week of pregnancy** | 1. subjective and physical examination<br>2. blood pressure measurement<br>3. weight measurement<br>4. pregnancy risk assessment<br>Assessment of risk and severity of depressive symptoms<br>6. promotion of healthy lifestyle | Ultrasound examination in accordance with the recommendations of the Polish Society of Gynaecologists and Obstetricians (PTGiP) |
| **15-20th week of pregnancy** | 1. subjective and physical examination<br>2. blood pressure measurement<br>3. weight measurement<br>4. pregnancy risk assessment<br>5. promotion of healthy lifestyle | 1. blood morphology<br>2. general urinary examination |
| **18-22th week of pregnancy** | | Ultrasound examination in accordance with the recommendations of the Polish Society of Gynaecologists and Obstetricians |
| **21-26th week of pregnancy** | STARTING PREGNANCY EDUCATION - referral to the family midwife<br>Educational meetings with the midwife should be held once a week from the 21st to the 31st week of pregnancy, and twice a week from the 32nd week of pregnancy until delivery | |
| **21-26th week of pregnancy** | 1. subjective and physical examination<br>2. assessment of foetal heart function<br>3. blood pressure measurement<br>4. weight measurement<br>5. pregnancy risk assessment<br>6. promotion of a healthy lifestyle<br>7. in the case of care provided by a midwife, consultation with an obstetrician (24-26 weeks' duration of pregnancy) | 1. blood glucose test following oral administration of 75 g of glucose (at 24-26 weeks' duration of pregnancy) - three-point glucose determination: before glucose administration (fasting), 1 and 2 hours after glucose administration<br>2. general urine examination<br>3. anti-D antibodies in Rh (-) women<br>4. in women with negative results in the first trimester - test for toxoplasmosis (IgM) |
| **27-32th week of pregnancy** | 1. subjective and physical examination<br>2. assessment of foetal heart function<br>3. blood pressure measurement<br>4. weight measurement<br>5. pregnancy risk assessment<br>6. promotion of healthy lifestyle | 1. blood morphology<br>2. general urinary examination<br>3. anti-D antibodies in Rh (-) women<br>4. ultrasound examination according to PTGiP recommendations<br>5. if indicated - administration of anti-D immunoglobulin (28-30 weeks of pregnancy) |
| **33-37th week of pregnancy** | 1. subjective and physical examination<br>2. obstetric examination<br>3. assessment of pelvic dimensions<br>4. fetal heart function assessment<br>5. blood pressure measurement<br>6. assessment of fetal movements<br>7. examination of the mammary glands<br>8. weight measurement | 1. blood morphology<br>2. general urinary examination<br>3 HBs antigen test<br>4. HIV examination<br>5. vaginal and rectal cultures for B-haemolytic streptococci (35-37 weeks' gestation) |

| EXAMINATION DATE | PREVENTIVE SERVICES AND HEALTH PROMOTION ACTIVITIES | DIAGNOSTIC EXAMINATIONS AND MEDICAL CONSULTATIONS |
|---|---|---|
| | 9. pregnancy risk assessment<br>10. assessing the risk and severity of depression symptoms<br>11. promotion of healthy lifestyles | 6. VDRL, HCV in women with increased population or individual risk of infection |
| **38-39th week of pregnancy** | 1. subjective and physical examination<br>2. obstetric examination<br>3. assessment of fetal movements<br>4. assessment of fetal heart rate<br>5. blood pressure measurement<br>6. weight measurement<br>7. pregnancy risk assessment<br>8. promotion of a healthy lifestyle<br>9. in the case of care provided by a midwife, consultation with an obstetrician | 1. general urinary examination<br>2. blood morphology |
| **Immediately after the 40th week of pregnancy** | 1. subjective and physical examination<br>2. obstetric examination<br>3. assessment of foetal movements<br>4. blood pressure measurement<br>5. weight measurement<br>6. pregnancy risk assessment<br>7. with normal results of CTG and ultrasound and with normal feeling of fetal movements - another examination in 7 days, with another ECG and ultrasound - during this visit a date of hospitalization should be determined, so that the birth takes place before the end of the 42nd week. In the case of deviations from the norm - individualisation of the management | 1. CTG examination<br>2. ultrasound examination in accordance with PTGiP recommendations |

The organisational standard of perinatal care which has been developed and implemented assumes that the woman during pregnancy prepares a document in the form of a birth plan with the support of the caregiver. It is a detailed list of aspects of perinatal care in relation to each stage of childbirth. The birthing plan includes all elements of the medical management of the birth and the identification of the place of delivery; it is attached to the pregnant woman's individual medical record. During the course of care, it is adapted to the pregnant woman's health situation and current needs and expectations. Its main purpose is to facilitate communication in the delivery room between the parturient and the members of the therapeutic team.

The perinatal period is characterised by numerous biological, emotional and social changes occurring simultaneously. It requires considerable personal and interpersonal adaptation from the woman. During this time she is particularly vulnerable to the emergence of mental disorders. The World Health Organization (WHO) report shows that 80% of women experience a set of emotionally difficult experiences after childbirth, the so-called baby blues. The magnitude of postnatal depressive disorders in mothers is estimated at 7-19%, making it the most common postnatal complication. In 2018, there were 388,000 live births in Poland, so the estimated number of women affected by postnatal

depression in one year is approximately 50,000. However, these disorders often go unrecognised and the actual incidence rate is much higher. The negative consequences of perinatal depression can have a long-lasting impact on the bond between mother and child or the family and cause difficulties in forming a proper maternal role. Untreated depression is associated with a higher number of pregnancy complications (preterm birth, low birth weight of the newborn) and anxiety disorders are considered one of the factors responsible for preterm birth. Despite abundant evidence of the effectiveness of treatment for postnatal depression, the disorder is still too often unrecognised. The main problem lies not in the lack of treatment options, but in the insufficient ability to diagnose depression among medical personnel involved in caring for women during pregnancy and after childbirth. In Poland, these needs are met by the recommendations included in the above-mentioned standard of care, according to which the assessment of the risk and severity of depression symptoms of a woman in the perinatal period should take place twice during pregnancy (between the 11th and 14th week of pregnancy and between the 33rd and 37th week of pregnancy) and once during a patronage visit in the place of residence or stay of the mother and her child. The person conducting the pregnancy uses screening tools in relation to the assessment of the risk of depression, in accordance with current recommendations and medical knowledge, e.g: Edinburgh Postnatal Depression Scale, recommended by the Agency for Health Technology Assessment and Tarification. The assessment and conclusions should be recorded in the medical records. If the assessment of the woman's mental state indicates that she is at risk of depression, she should be provided with psychological assistance and informed about possible forms of family support and institutions providing it.

## 1.2. ANTENATAL EDUCATION AS PART OF OPTIMAL PERINATAL CARE

According to the Regulation of the Minister of Health of 16 August 2018 on the organisational standard of perinatal care (Journal of Laws 2018, item 1756), if the person providing care is not a primary care midwife, he or she shall inform the woman of the possibility of receiving care from such a midwife and refer her to her between the completed 21st and 26th week of pregnancy for antenatal education and care provided for her and the child in the place where they will stay after delivery. Antenatal education can be provided in an individual or group format. The condition for women to participate in free antenatal education classes is a current declaration of choice of a primary care midwife submitted to the unit where antenatal education visits are carried out. It is important that the fact that a pregnant woman has been referred to the care of a primary care midwife is recorded in her medical records by the person providing care. The primary care midwife confirms that the woman is being cared for during pregnancy by entering her data or the data of the primary care healthcare provider in the antenatal care plan and the pregnancy chart. From that point on, the primary care midwife is responsible for providing antenatal education services in the form of individual or group meetings. Until the woman is covered by the POZ midwife, antenatal education is carried out by the person carrying out the pregnancy.

The preventive visits of the primary care midwife include: the diagnosis of health problems, as well as planning and implementing, within the scope of their competence, preventive services and health promotion. Preventive activities are carried out by POZ midwives primarily in the form of antenatal education visits, which are provided on the basis of an educational programme. Education should also be provided to women with high-risk pregnancies. The education plan, the number of hours and the form of provision (individual/group) should be individually adapted to the needs and knowledge of the pregnant woman.

The antenatal education framework programme for women during pregnancy covers the prenatal period (pregnancy), the delivery period, the postpartum period, as well as support for the woman and her family during the postnatal period.

The antenatal education framework programme on the prenatal period (pregnancy) covers in particular:

- the course of pregnancy and child development from the beginning of pregnancy to birth,
- prenatal care - available forms of medical care and antenatal care plan,
- lifestyle during pregnancy - diet, stimulants, addictions and their effects on the development of pregnancy and the child, occupational activity, physical activity, behaviour and actions considered dangerous for women during pregnancy
- pregnancy ailments and how to deal with them,
- prevention of infectious diseases during the perinatal period, including preventive vaccinations
- psychological and emotional problems of a woman and her family during pregnancy, childbirth and the puerperium
- legal issues concerning regulations, standards, patient rights, medical care in the perinatal period, family legislation, legal protection of pregnant women, mothers.

The antenatal education framework programme on childbirth includes in particular:

- preparation for labour and the birth plan, including the preferences and expectations of the parturient,
- birth warning factors, onset of labour, including emergencies requiring rapid hospitalisation,
- physiology of labour, active labour, family labour,
- positions used in the 1st and 2nd periods of labour (vertical positions) and equipment helpful during labour
- labour pain relief (non-pharmacological and pharmacological),
- skin-to-skin contact between mother and child, including initiation of breastfeeding,
- caesarean section - benefits and risks for mother and baby, early and late complications after caesarean section
- information on the possibility of postnatal tissue deposition, including cord blood, umbilical cord for stem cell collection.

The antenatal education framework programme for the postnatal period (puerperium) includes in particular

- care during the postpartum period - the course of postpartum, return of fertility after childbirth and psychological aspects of postpartum,
- breastfeeding and lactation support, including resolution of lactation problems
- care of the newborn and then the infant, including management of the newborn after birth, preventive measures for the newborn and infant, care of the child, information and recommendations for parents on how to manage the child at home, and ensuring the child's safety in the home environment.

The antenatal education programme should also include issues concerning social support: emotional, informational, instrumental and material in the perinatal period. The content provided ensures the

right quality of education, better preparation for childbirth and reduces fear and anxiety before childbirth and childcare.

## 1.3. HEALTH PROMOTION AND PREVENTION AS AN ESSENTIAL PART OF OPTIMAL CARE FOR THE PREGNANT WOMAN

In 2017, the "Health Behaviours in Pregnant Women" report was published, based on a survey of 3,451 women from across Poland. Compared to the first edition (in 2013) of the study, a decrease in the number of behaviours harmful to the health of mother and child, i.e. drinking alcohol and smoking cigarettes, was observed. There was also a significant decrease in the number of women exposed to passive smoking at home and at work. This indicates that awareness of the harmfulness of dangerous substances to the health of the mother and child influences their use. Less awareness of the risks of drinking or smoking definitely increases the likelihood of using stimulants during pregnancy. Knowledge about the harmfulness of drinking alcohol during pregnancy is widespread, yet it appears that myths are still circulating, e.g. about the low harmfulness of drinking moderate amounts of alcohol during pregnancy. As the above-mentioned report shows that the majority of doctors did not inform the respondents about the harmfulness and potential adverse effects of drinking alcohol during pregnancy, this topic should be addressed as prevention of Foetal Alcohol Syndrome (FAS).

The diet of women during pregnancy is very important. Dietary mistakes can be the cause of many pregnancy disorders and even increase the risk of diseases for both mother and child. The respondents changed their diet during pregnancy, enriching it with vegetables, fruits and dairy products. The vast majority of pregnant women also supplemented their diet, including enriching it with folic acid. The prevalence of obesity (BMI >30 kg/m2) amongst women has increased significantly in recent years. Approximately 8% of women now fall into the group with extreme (pathological) obesity, defined as BMI ≥40 kg/m2. The prevalence of obesity amongst women worldwide is projected to exceed 21% by 2025. Obesity in pregnancy poses a risk to both mother and foetus and contributes significantly to health care costs due to its impact on the occurrence of obstetric pathologies. According to the European Perinatal Health Report, the lowest percentage of overweight and obese pregnant women is in Poland (25.6%), France (27.2%) and Slovenia (27.8%). More and more attention is being paid to the so-called fetal metabolic programming - already during pregnancy it is possible to influence the increased or reduced risk of developing civilisation diseases, including obesity, type 2 diabetes, hypertension, coronary heart disease, osteoporosis and certain cancers in the child. Because of the growing obesity epidemic, pregnant women should be offered nutritional counselling and encouraged to be physically active.

A cytological examination is one of the examinations which, according to the recommendations contained in the Organisational Standard of Perinatal Care, should already be performed at the first visit of a pregnant woman. The report "Health Behaviour in Pregnant Women" shows that although most women had a cytological examination, they declared that they had a deficit of knowledge regarding cervical cancer risk factors. It is worrying that most of the respondents did not regularly perform breast and lymph node self-examination, despite the fact that they declared that in their opinion self-examination is a very good tool for early detection of breast cancer at their age.

A very important element of correct hygienic habits during pregnancy is taking care of the oral cavity. During this period, many factors occur which can adversely affect the state of her health, and the

consequences of a lack of knowledge or negligence in this area can affect the health of the child. It is alarming that almost half of the respondents did not visit a dentist during pregnancy.

Most of the respondents were physically active to a greater or lesser extent, although they felt there was a lack of information on sports recommended for pregnant women. To inform pregnant women about safe forms of activity and possible limitations.

The above information clearly indicates the need for educational activities, which is why special attention has been paid to them in the standard of perinatal care. At this point, it is important to mention that already in 2015 the World Health Organization (WHO) guidelines on health promotion interventions for maternal and newborn health were published. They indicate a series of interrelated actions to improve access to and use of skilled care during pregnancy, childbirth and after delivery.

Health promotion and prevention activities for women during pregnancy are the simplest form of care for good health during this period and for the prenatal development of the child. The basic form of promoting women's health during pregnancy is undertaking educational activities.

Priority is given to the promotion of health-enhancing behaviour and prevention, and therefore comprehensive information should be provided during pregnancy on:

- an optimal diet (both in terms of quantity and quality and the regularity of meals eaten);
- the elimination of known teratogenic factors with a brief explanation of their influence on the development of the pregnancy and ways of avoiding them (at work, in the environment);
- the risk and severity of depressive symptoms (according to current recommendations and medical knowledge, e.g. using the Edinburgh Postnatal Depression Rating Scale),
- quitting addictions (smoking, drinking alcohol, drugs, abused medicines, psychoactive substances);
- the beneficial effects of sleep and rest on the body;
- principles of body and mouth hygiene (including dental checks) during pregnancy
- physical activity appropriate to the woman's condition (walking, exercise);
- explaining the psychological conditions that characterise this period.

As far as women during pregnancy are concerned, preventative measures aimed at early diagnosis of cervical cancer and cancer of the mammary gland and the prevention of inflammatory conditions of the reproductive organs are very important.

The situation of the Covid-19 pandemic also enforces the need to make pregnant women aware of the legitimacy of vaccination, also during pregnancy. This is evident from the Polish Society of Gynaecologists and Obstetricians' April 26, 2021 statement that COVID-19 vaccines should be offered to pregnant and lactating women. Pregnant women are a group at increased risk of severe SARS-CoV-2 infection, which justifies the implementation of prevention of this disease in the form of vaccination.

The above-described activities, which make pregnant women aware of the need for self-control of their health, elimination of factors adversely affecting health and the course of pregnancy, regular use of prophylactic tests and vaccinations, can be carried out using information technology in the form of teleeducation.

## 1.4 LIMITATIONS ON ACCESS TO PERINATAL CARE IN POLAND

A sustainable and equitable health care system should ensure equal access to health care regardless of health needs, financial resources or place of residence. Thus, for example, the fact of living in a rural

area should not affect one's ability to access health care services. However, research conducted by the World Health Organisation (WHO) indicates that there are differences between urban and rural areas not only in terms of the socio-economic status of the inhabitants, but also in terms of access to healthcare. The main problems in this area are related to the lack of skilled workers, distance from major medical centres, limited access to specialised health services, prevention and health promotion, financial barriers related to lower income and additional costs resulting from peripheral location (transport costs). In this context, ensuring equal access to health care has been a major objective of the WHO for many years.

Similar difficulties are confirmed by the results of the report of the Supreme Chamber of Control (NIK) in Poland "Availability of publicly financed gynaecological and obstetric services in rural areas". The report shows that women living in rural areas have limited access to gynaecological and obstetric medical care according to current standards, performed in outpatient conditions.

Not only access to specialist gynaecological and obstetric care is limited in rural areas, but also education on preparation for childbirth, postpartum, breastfeeding and parenthood. Pregnant women are not educated in practical and theoretical preparation for childbirth, puerperium, breastfeeding and parenthood, despite the fact that, according to the guidelines of the organizational standard of perinatal care, this should take place during each visit, starting from the 21st week of pregnancy until delivery. The results of the analysis also showed that rural women were not provided with equal access to outpatient gynaecological and obstetric services financed from public funds. Outpatient clinics located in rural municipalities accounted for a negligible percentage of the total number of such clinics; there were up to 27,000 women per one gynaecological clinic in rural areas, which in extreme cases had 50 km to reach the clinic.

## 1.5 PERINATAL CARE FROM A EUROPEAN PERSPECTIVE

Poland is one of the few countries in Europe where standards of perinatal care have been developed. Similar documents have been developed in Norway, while in the United Kingdom and Spain, for example, they concern only the course of childbirth and do not define the course of care for the pregnant woman. The Polish Standard of Perinatal Care does not differ significantly from the recommendations valid in European countries with a much higher development index, measured by GDP per capita. For example, a comparison of the level of care in Poland and in Switzerland, Norway, Germany and the United Kingdom shows that: in Poland each patient should have four ultrasound examinations, in Germany - three, and in Switzerland, Norway and the UK - two examinations during pregnancy. In Poland, a patient usually has eight visits to a pregnancy attendant during her pregnancy, in Germany - 15, in the UK - 10, in Norway - nine, and in Switzerland - 10 for the first child and seven for the next. Pregnancy care in European countries is provided by a midwife or doctor. In Switzerland, for example, according to a study conducted by the Swiss Federation of Midwives, 7% of women with their first pregnancy were mainly cared for by midwives, with 11% with their second and 21% with their third. At the same time, 54% of pregnant women assumed to switch exclusively to a model of care provided by a midwife. Since January 2017, care for pregnant women in Poland can also be provided by a midwife, if the course of the pregnancy is physiological. Similarly, in Norway, maternity care is mainly provided by midwives, which care for pregnant women with low risk factors. As in Poland, all pregnant women in Norway have the right to free maternity care. This includes free courses to prepare the mother-to-be and her partner for the birth.

In Switzerland, a prototype of an electronic pregnancy record system has been developed to improve access to standardised pregnancy data. In England, there is a system for both paper and electronic

record keeping. The possibility of keeping an electronic pregnancy record enjoys good reviews among both medical staff and pregnant women, who emphasise the rapid access to up-to-date data. Nevertheless, in many countries, as in Poland, the course of pregnancy is documented in a paper version of the pregnancy chart.

## 1.6 THE NEED FOR SYSTEMIC SOLUTIONS BASED ON TELEMEDICINE

Contemporary achievements in the development of modern telemedicine technologies open up new possibilities of using them for the benefit of patients, health care workers and the health care system. These are solutions which make it easier for patients to contact medical staff and reduce waiting times for specialist consultations. Telemedicine, as the newest form of medicine and health care, thanks to the use of new technologies, allows to break geographical barriers, enabling the exchange of information at a distance, which is particularly important in perinatal care. In Poland, the branch of telemedicine has been developing for more than a dozen years, although the law introduced relevant regulations only in the Act on the Information System in Health Care of 2015 (Journal of Laws 2015, item 1991, as amended), according to which it was possible to provide health services not only during face-to-face visits, but also by means of communication and ICT systems, which gave a real basis for the implementation of information and communication technologies into clinical practice.

The development of telemedicine-related technology makes it possible to improve the level of care provided to patients, particularly in areas remote from units providing advice by specialists, by making it easier for them to communicate with each other. Research shows that telemedicine is being used in low- and middle-income countries, especially in rural communities where access to antenatal care is difficult. As technologies develop and the cost of their implementation decreases, the opportunities and reach of their use continue to increase. Telemedicine in obstetrics can be used for prevention, monitoring, consultation, education, diagnosis and treatment, while maintaining the provision of essential health services, as outlined in the Organisational Standard for Perinatal Care.

Teleconsultation brings savings due to, among other things, reduced transport and optimised use of medical staff time. One of the solutions for telehealth is the use of synchronous and asynchronous consultations. Synchronous or real-time interventions include audiovisual consultations that allow the doctor to give advice remotely instead of an in-person visit. Asynchronous or store-and-forward communication, on the other hand, involves remote monitoring of patient-generated data such as maternal weight gain, blood glucose levels, screening results obtained from questionnaires or medical examinations. Modern equipment used, for example, in perinatal care: CTG machines, UDT machines, pulse oximeters, etc. reduces the number of unwarranted medical interventions and thus contributes to improving the quality of care.

Interventions related to the use of telemedicine and telehealth are gaining popularity during pregnancy to treat complications such as gestational diabetes and hypertension. For women with high-risk pregnancies who have a chronic disease (e.g. diabetes, hypertension), systematic measurement (of blood glucose levels, blood pressure) is an important part of their care. In this case, it is possible to use an application developed for diabetics that allows wireless sending of blood glucose measurements, to which the persons carrying out the pregnancy (diabetologist and gynaecologist) have permanent access, but also the possibility to contact the doctor in case of alarming results or lack of an adequate reaction to the applied medicines.

Another possibility is a remote cardiotocographic examination - CTG, i.e. simultaneous monitoring of the fetal heart rate and uterine muscle activity. During the examination, a pregnant woman is fitted

with a wrist band for monitoring her heart rate and two probes on her abdomen, then the woman lies down comfortably and after about 30 minutes the apparatus is removed. The result is sent to the Monitoring Centre and interpreted, and the test results are sent back via SMS.

Apart from e-visits, telemedicine services also include programmes or applications that help patients (e.g. chronically ill patients) in self-control and self-observation and, when their condition becomes worrying, in quicker contact with the attending doctor. Telehealth facilitates consultations with specialists in maternal-fetal medicine, and can also be used in the postnatal period when it is necessary to solve problems related to lactation, to support women during this period or to assess the risk of postnatal depression.

There have been a number of different studies on the use of telemedicine over the years, most of which have shown its importance and positive impact on the process of caring for patients in the perinatal period. As technologies develop and the costs of their implementation decrease, the possibilities and scope of their use continue to increase. The use of telemedicine in perinatal care has been greatly intensified in the wake of the pandemic caused by the SARS-CoV-2 coronavirus, and the experience of recent months suggests that telehealth support technologies will continue to play an important role in obstetric care in the future.

## 1.7 INTERNATIONAL DEVELOPMENTS IN THE FIELD OF TELE-OBSTETRICS

Telemedicine as a dynamically developing aspect of modern patient care combines elements of medicine, IT and telecommunications and significantly improves the quality of medical services. In recent years, many different studies have been carried out on the use of telemedicine in obstetrics. The results obtained confirm the influence of this type of solution on the optimisation of care provided to women in the perinatal period.

Interest in telemedicine in obstetric care has been particularly evident in recent years. Currently, browsing the online database PubMed after entering the words "pregnancy, telemedicine" one can find 1100 papers (2021), in 2015 there were 331 papers published, while in 2011 there were only 177. The development of telemedicine services in the world gained momentum during the SARS-CoV-2 pandemic. During this period, e-visits to a gynecologist/midwife are one of the primary and most frequently chosen forms of contact with the specialist carrying out the pregnancy. In the first month of the pandemic, the New York University Health System recorded more than 8,000 video consultations per day. A study by Ferrag and Medwely (2016) found that the introduction of telemedicine elements into perinatal care resulted in increased adherence to follow-up appointments. Teleconsultation can take place through the use of popular communication apps. Pflugeisen et al (2017) showed that pregnant women who used video conferencing using an instant messenger were more satisfied with their visit than respondents who consulted with a doctor/midwife during an office visit.

The authors of a number of studies (Marko 2019, Moyo 2020, Pflugigisen 2017, Greiner 2017) point out the important role of using messaging apps in the care of pregnant women. For example, Marko et al (2019) conducted a study among 88 US pregnant women. 47 patients used mobile apps to support pregnancy management, the control group consisted of 41 women who did not choose this model of communication with their doctor/midwife. The use of mobile apps during prenatal care was associated with a reduction in the number of in-person visits, while recipient and provider satisfaction were at similar levels in both groups of women studied.

UNITED STATES

In the United States, clinics where patient care is based primarily on telemedicine, using video conferencing, communication apps and text messages, are becoming increasingly popular. This type of option can be used by pregnant women up to the 36th week of pregnancy, who are 18-36 years old, who do not report coexisting diseases, complications in previous pregnancies, and who are not pregnant with twins. The doctor qualifies the patient for telecare. During the first visit (8-12 weeks of pregnancy) in the office, the doctor performs ultrasound examination to confirm the pregnancy, collects detailed medical history and presents e-visit plan. Every 4 weeks the patient has contact (in the office or remotely) with the attending physician. Office visits take place at 12, 20, 28, 36 and 39 weeks of pregnancy, during which the patient can obtain referrals for laboratory tests, fetal heart rate monitoring, ultrasound. Before the appointment, the pregnant woman must weigh herself, regularly measure her blood pressure (the clinics rent blood pressure monitors and fetal heart rate detectors). In addition, the patient outside the scheduled appointment has a chat room where she can talk to the doctor or midwife.

The Covid-19 pandemic has imposed unprecedented challenges on the entire healthcare system, leading to a previously unimaginable acceleration of digital transformation processes. According to the US Center for Disease Control and Prevention, large-scale use of e-health ICT platforms should be introduced wherever possible, and this particularly applies to all pre- and post-natal care. Markwei M. and Goje O. 2021, point out how important the large-scale introduction of telemedicine procedures is in counteracting the broad data-based threat of an observed increase in stillbirths not only resulting from Covid-19 infection, but also from the fear of reporting in person to medical facilities. Telemedicine solutions, far beyond teleconsultation, are a way not only to relieve the burden on the current healthcare system, but initiate a fundamental transformation of its traditional paradigms, leading to a new, radically higher level of quality of medical services.

CANADA

In Canada, patients like to use a helpline with midwives and nurses on duty 24 hours a day. The service is available in 300 languages, 7 days a week. After a short interview, the person on duty is able to advise the patient on further treatment, referral to a specific specialist.

The results of a study published by Butler et al (2019) indicate that female patients using the classic appointments and teleconsulation (OB Nest programme) are more satisfied with their care than women covered by a routine system based only on checks at the doctor's/midwife's office.

NORWAY

In Norway, specialists from different centres consult the results of individual patients via videoconferencing. At the meetings, the patient's care pathway is discussed in detail (e.g. assessment of the risk of comorbidities with pregnancy), division of tasks between members of the treatment team. Since 1 March 2017, all Norwegian residents have had access to Kjerne journal, an electronic health diary. This is a database of patient health information that can be accessed by the patient and health care professionals. Kjerne journal was created specifically so that data about the patient is immediately available to medical staff in the event of an emergency regardless of where it happened. The data contained in the electronic service can be retrieved from any healthcare facility: hospitals, medical centres, registers, medical facilities operating outside normal opening hours. What is more, the patient himself can complete the data on his health - he only needs to log on to nahelsenorge.no. This form of transmission and collection of information is extremely useful in maternity care, gives continuity of information about the patient and allows a quick response in case of complications.

UK

Another project on the use of telemedicine among pregnant women was a study conducted by Oxford University Hospital in 2012-2013, which included pregnant women not eligible for drug treatment after a week of blood glucose measurements. Blood glucose measurements taken at home by patients were uploaded to a system managed by a diabetes doctor or midwife. If the results were abnormal, the medical staff contacted the pregnant woman (or vice versa) by voice or text message. Respondents were very satisfied with such care and considered it a great convenience for those for whom the hospital is far from home or who have more children. The relationship with the medical team was also rated highly by the women surveyed.

OTHER

In recent years, devices have become available to measure blood glucose levels without the need for punctures. The system communicates with the patient's mobile phone via bluetooth. The device vibrates when blood glucose levels reach alarm levels. The blood glucose monitoring system provides a simple way to scan glucose levels and analyse trends in blood glucose throughout the day. Previous clinical studies and data collected from diabetes patients have shown that patients who use this system improve their blood glucose values within a few months.

Patients who cannot attend a stationary birthing school are more and more willing to choose courses available on the Internet. At an online birthing school, pregnant women have the opportunity to listen to lectures by an obstetrician, midwife, nutritionist and psychologist. An increasing number of birthing schools offer to conduct part of the course remotely using communication platforms such as Zoom, Microsoft Teams or Cisco Webex.

All over the world, professionals are looking for telemedicine solutions to support perinatal care. Israel recently developed GynTool, an artificial intelligence-based diagnostic tool for collecting vaginal secretions and a scanning device that can be used in gynaecological clinics to provide rapid diagnostic solutions. The company has also developed a home use kit for diagnosing reproductive tract infections.

## 1.8 MOBILE APPLICATIONS IN OBSTETRICS

Mobile health apps (mHealth apps) can serve as a useful tool to complement and reinforce the information provided by healthcare providers to patients. Mobile apps used in midwifery can be divided, among other things, according to the user group they are aimed at. There are two main categories: apps for patients and apps for medical staff.

Nowadays, pregnancy apps are a vademecum of knowledge about the baby's development week by week. In addition, they have such useful functions as the organisation of a calendar of visits to the gynaecologist or laboratory tests. These apps are extremely popular among moms-to-be. Depending on your personal preferences, you can choose from Polish apps such as: Asystent Ciążowy (Pregnancy Assistant), Preglife or other renowned English-language programs. Among the latter, the free applications Sprout and The Bump - the latter including the possibility of consultation with experts and

other pregnant women - or the paid Pregnancy ++, offering high-quality videos simulating the development of the foetus, are very popular.

Asystent Ciążowy (Pregnancy Assistant) is a free app that accompanies women throughout their pregnancy. It contains articles and information tailored to the current week of pregnancy. The pregnant woman can use a convenient and simple layette list, name ranking, calculator of correct weight during pregnancy, blood pressure diary.

The Preglife app includes a calendar and pregnancy calculator, instructional videos, tips for pregnant women, as well as information on the youngest children. Users can follow their child's development from the prenatal period to the age of two. Pregnancy weight gain is illustrated in a graph, and the patient also has the option of monitoring weight loss after birth. If data from more than one pregnancy are stored in the app, it is possible to compare individual graphs. The Preglife app also includes a vaccination table and percentile grids. The latest version of the app has been enhanced with the ability to keep a diary, attach photos that can be shared via email on Facebook, Instagram and Twitter.

Pregnancy Sprout - this app stands out from others with its very realistic 3D visualisations of what the baby looks like at a given stage of pregnancy. Thanks to Pregnancy Sprout, pregnant women can complete their appointment schedules, create to-do lists or shopping or hospital lists, monitor weight gain, count foetal movements and contractions.

DIABETES PROBLEMS IN PREGNANCY

In Europe, gestational diabetes mellitus (GDM) affects nearly 13% of pregnant women and represents the majority of diabetes complicating pregnancy. Recently, continuous glycaemic monitoring has gained the status of a therapeutic tool. It has been observed that its use improving glycaemic parameters on its own. The continuous glucose monitoring system by scanning (isCGM or FGM) was developed to replace glucometers. Glucose is measured in the intratissue fluid. The system is also suitable for use by pregnant women. The device consists of two components: a sensor and a reader, and an application that can be installed on mobile devices. The system takes the glucose reading at the moment of scanning, i.e. when the reader is brought close to the sensor. The measurement is painless, takes one second, and can be done through clothing.

For example, in Poland, a popular app dedicated to women with diabetes is Sweet Pregna. The application helps to control blood sugar levels (by using a glucometer connected to the application, all the measurements can be automatically downloaded and saved); to control the correct weight gain of a pregnant woman; to determine the appropriate calorific needs, to eat healthy thanks to sample menus; in the appropriate composition of meals, calculating the calorific value, glycaemic load and nutritional value of a given product and meal; to measure physical activity using a calories burn calculator. The programme also includes sample exercises suitable for the second and third trimester of pregnancy.

RISK OF PRETERM BIRTH

WISH - Wearable Integrated System for Early Detection of Preterm Labour is a modern technology, developed in Belgium, used to analyse risk factors and identify the onset of preterm labour. The device consists of a sensor placed on the pregnant woman's abdomen at the level of the fundus of the uterus, which is connected with an application that sends data to the system. The data obtained is automatically stored in the cloud, the platform allows it to be read and analysed by the attending doctor of the pregnancy. With the WISH system, specialists can estimate the risk of developing preterm

labour in real time. This method of pregnancy monitoring, which can be used by patients during their daily activities, significantly improves the quality of perinatal care.

APPLICATIONS FOR MEDICAL STAFF

An application frequently chosen by doctors and midwives in charge of pregnancy is *kółko położnicze* (‘obstetrics group’). The system allows to mark the date of the last menstrual period, date of conception, end of the first trimester, end of the second trimester of pregnancy, probable/planned date of delivery, week of fetal life. When one of these dates is entered, the others are calculated. Changing the date of the test allows the determination of the week of pregnancy for the selected date. The application works on the basis of Naegele's rule used to calculate the date of delivery - the probable date of delivery falls exactly 280 days after the date of the last menstrual period.

In order to meet the needs and expectations of medical staff, applications offering capabilities adapted to the statutory requirements for the digitisation of the healthcare system have appeared on the market. A characteristic example of such applications is *Gabinet drWidget*. It ensures comfortable work when the doctor has no access to a computer (e.g., during home visits). The application allows to manage work schedule, conduct visits, complete, review and send documentation, as well as issue e-prescriptions. The application includes modules:

DrWidget Drug Database - the application contains comprehensive descriptions of medicinal products, dietary supplements and dermocosmetics available in Polish pharmacies.

DrWidget Interactions - this application provides a quick and easy way to find information on the effects of one substance on the activity of another when administered simultaneously.

DrWidget ICD-10 is a code base for the International Statistical Classification of Diseases and Related Health Problems. The application also presents drugs and active substances along with the routes of administration in the given disease entities.

DrWidget Standards and Scales - the application contains over 200 medical standards and scales, from about 20 categories.

Mobile apps in obstetrics are a promising strategy for women's health care, not only in the pre-conceptual, perinatal and postnatal periods, but also at every stage of a woman's life.

## 1.9 ARTIFICIAL INTELLIGENCE IN OBSTETRICS

Artificial intelligence (AI) and modern technologies are increasingly becoming an integral part of the healthcare system. The development of artificial intelligence is playing an ever-growing role in the analysis, diagnosis and monitoring of patient treatment. According to a report by Grand View Research, the global market for AI in medicine will grow at an average annual rate of around 42% between 2021 and 2028. The national AI policy and the financial perspective for 2021-2027 allow us to expect a systematic increase in spending on AI research and development in Poland, including in the healthcare sector.

Digitisation and analysis of health data provides measurable benefits for the health care system and for beneficiaries. The main purpose of AI techniques used in medicine is to predict, detect abnormalities or classify disease, and then provide healthcare and monitor the health of patients. Efforts to use AI in clinical care include clinical decision support systems and mobile health applications.

AI can be used in high-risk pregnancy diagnosis and assessment in situations such as gestational diabetes, fetal stunting, hypertensive spectrum disorders, intrahepatic cholestasis, preterm birth, fetal structural abnormalities, genetic defects (e.g. Down syndrome, Turner syndrome, Edwards syndrome) and others. Sensors based on artificial intelligence can be used to monitor blood glucose levels, blood pressure by pregnant women, or assist medical staff in interpreting an CTG records. This relates to one of the most promising application areas for AI, mobile health (mHealth).

The development of prognostic models and effective methods of screening for abnormal pregnancy can improve diagnostic and therapeutic decision-making. It seems that in the future almost every predictive value of a diagnostic method will be enhanced by artificial neural networks.

## 1.10 USE OF INFORMATION AND COMMUNICATION TECHNOLOGIES (ICT) IN POLAND

The pace of change in many areas of life observed in recent years has been influenced by, inter alia, the development of information and communication technologies (ICT). It has resulted in the formation of the information society, for which access to computers, the Internet and online information is of great importance. According to the CSO data, in 2020 in Poland 90.4% of households had access to the Internet at home. This percentage was 3.7 p.p. higher than in the previous year. The level of this indicator varied depending on the type of household, degree of urbanisation, place of residence and region. This percentage was slightly higher in large than in medium-sized towns and in rural areas, as well as in central Poland compared to other regions. Households with children were much more likely to have Internet access at home than households without children. In Poland, in 2020, 81.4% of people aged 16-74 used the Internet on a regular basis, but even here the differences can be observed - depending on age, economic activity, education level and place of residence. The highest percentage of regular users was noted among people aged 16-24 (99.2%), pupils and students (99.8%), people with higher education (98.2%), and residents of large cities (89.2%). In the European Union countries, the proportion of people using the Internet was 84%. The highest share of regular internet users was recorded in Norway (98%), Denmark, the Netherlands, Sweden and the United Kingdom (95% each), and the lowest - in Bulgaria (67%).

The technological advances and access to the internet have also had an impact on health care. It has resulted in solutions used also by telemedicine and e-health, which are developing very dynamically. In the meantime, the Internet is one of the places to look for information on pregnancy, childbirth and the postpartum period. In recent years, the number of users of parenting websites has increased twelvefold - from 659,000 to 8 million, and the number of websites themselves is also growing very fast - in November 2006 there were 18, and in October 2016. - 75 (in the Gemius/PBI study). The growing popularity of online forums and information websites dedicated to motherhood is evidence of the need for such contacts.

## 1.11 TELEMEDICINE - LEGAL ASPECTS

Polish law provides for and allows the provision of telemedicine services, calling them health benefits provided via teleinformation or communication systems. The beginnings of telemedicine in Poland date back to 2001, when the Telemedicine Section of the Polish Medical Association was established. However, the possibility of providing telemedicine advice was initiated in 2015, when the amended Article 3(1) of the Act of 15 April 2011 on medical activity was amended to: "Curative activity consists in providing health services. These benefits may be provided via ICT systems or communication systems". This provision unambiguously implies the possibility of providing health services in the form

of teleconsultation. By the regulation proposed by the legislator, telemedicine advice has been made equal to that given through personal contact with the patient. In 2020, a regulation appeared standardising the service of teleconsultation, which was amended in 2021.

The amended Act on the professions of doctor and dentist provides for the possibility to practice the profession of doctor and dentist via ICT systems or communication systems, similarly to the Act on the professions of nurse and midwife. Pursuant to these, health services and activities consisting in the practice of the profession of doctor and dentist may also be provided via ICT systems or communication systems. Hence, currently in Poland there is a legal possibility to conduct televisits (eVisits), during which the patient's state of health can be assessed, treatment can be modified, diagnostic tests can be carried out, prescriptions and orders for medical products can be issued. However, not every service can be provided remotely. Similar regulations, which organise the remote provision of health services, can also be found in other health legislation. Similarly, the Act on professions of nurse and midwife contains provisions that a nurse and midwife perform their profession with due diligence, in accordance with the principles of professional ethics, respect for patient rights, care for patient safety, using indications of current medical knowledge and the intermediation of ICT systems or communication systems.

On the other hand, on 5. November 2019, the Regulation of the Minister of Health of 31. October 2019 came into force, which amended the guidelines on guaranteed benefits in primary health care. This Regulation regulates the legal issues of providing telemedicine services. Therefore, it is assumed that telemedicine is permissible when the doctor/nurse/midwife, from the point of view of modern medicine, determines that they are able to help the patient in this way.

Currently, remote verification of identity based on a patient's statement is permitted. Such a possibility has been included in the Regulation of the Council of Ministers of 10 April 2020 on the establishment of certain restrictions, orders and prohibitions in connection with the occurrence of an epidemic state. Identity shall be 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 meet two conditions. First, the person who provides such a service must assess whether he or she has the optimal knowledge, skills and capacity. Secondly, all requirements for ensuring security during such a visit must be met. This includes personal data, transfer of medical records, and professional confidentiality. A phone, smartphone, computer or other device with internet access may be used to contact the patient. The doctor/midwife may also use online chat. Particular attention should be paid to the security of the software used and the modern technological infrastructure. Telemedicine services should not be provided via free messengers on social networking sites that are intended for private use, nor should they be provided via tools that do not ensure a high level of security and confidentiality of the conversation.

Providing healthcare services via ICT or communication systems involves the processing of personal data, including sensitive health data within the meaning of the GDPR. If a doctor, midwife acts as a data controller within the scope of their professional practice, they should take care to meet all the conditions arising from the GDPR, including, among others, sign a data processing entrustment agreement with the provider of the system for communication with the patient.

The purchase of appropriate systems may be financed from public funds. The Order of the President of the NFZ of 12 March 2020 expanded the catalogue of IT devices, software and services covered by co-financing to include expenses incurred by an eligible healthcare provider to purchase IT devices, software and services that enable remote provision of medical advice in outpatient conditions using

ICT systems or communication systems. However, the possibility of obtaining co-financing in this mode applies only to primary health care institutions.

The aforementioned legal acts confirm that telemedicine is nowadays a legal form of practicing the profession of a doctor and a midwife, as it is a standard procedure in many situations in accordance with the current state of medical knowledge.

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# 2 TARGET GROUPS

The programme will be implemented for women of reproductive age who are pregnant and live at a distance from large cities, mainly in villages, taking into account the ratio of income per capita at county level to the average income in the country from the so-called excluded areas. People living in rural areas face many health disparities compared to urban residents, which are influenced by, among other things, low income and poorer access to health care. According to the Centers for Disease Control and Prevention, female residents of rural areas have higher rates of premature births and infant mortality. Lack of or difficult access to antenatal care for pregnant women is one of the key barriers to reducing maternal mortality and morbidity. Properly administered antenatal care has been shown to be one of the best indicators of positive pregnancy outcomes.

In 2019, 88.82% of the population of Poland's population was enrolled in health care entities that provide POZ services. In addition, a regional analysis of accessibility showed that in 59 municipalities (2.38% of the total) there was not a single health care provider providing POZ services. These were mainly rural-circling municipalities, i.e. separate municipalities surrounding a city.

According to data from the Central Statistical Office as of 31 December 2020, there were 7,704,690 women living in rural areas in Poland (38.98% of the total 19,762,772 women). There were 8,866,560 women of reproductive age 15-49 (in the statistical practice of the Central Statistical Office, the reproductive age for the temperate climate zone in which Poland is located is assumed to be 15-49), of whom 3,633,702 lived in rural areas (40.98%). In 2020 Poland were born 355,309 children, of which 147,174 in rural areas (41.4% of births). At the end of 2020, there were 21.5 thousand outpatient clinics in Poland, in which 156.2 million consultations were provided in primary care, 100.5 million - consultations in specialist care, of which 11.3% were consultations provided in gynaecological-obstetric clinics. In 2020, 56.8 million medical consultations in primary care and 16.3 million in specialised care were delivered by telehealth.

The analysis of the Supreme Chamber of Control (NIK) has shown that women living in rural areas have limited access to gynaecological and obstetric care provided under outpatient conditions in accordance with current standards. The majority of outpatient clinics with which the NFZ has concluded contracts for the provision of outpatient gynaecological and obstetric care are located in large cities. Data from the National Health Fund show that in many rural municipalities there were no gynaecological-obstetrics outpatient clinics at all. This can be a barrier to proper care during pregnancy, as well as to access to preventive examinations, including those specified in perinatal care standards. The package of services recommended by perinatal care standards is the minimum that should be provided during pregnancy.

Although the standard of perinatal care defines individual elements of the organisation of care aimed at ensuring good health of the mother and child, some gynaecological clinics located in rural areas do not fully implement them. Hence the need to take action to minimise socio-economic and technological inequalities in access to care.

## 2.1 STUDY SITE AND ELIGIBLE PATIENTS

The programme should be implemented in primary health care units and outpatient specialist care units in places distant from large cities. Outpatient clinics located in places where patients have difficult access to 24-hour prenatal care (distance criterion) are recommended. A minimum of 10% of patients

for a given pilot project should come from the so-called excluded areas. The eligibility criterion for the project is the age of majority of the women.

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# 3 DESCRIPTION OF THE CLINICAL CASE

The following is a clinical case example that illustrates a possible course of action within the proposed systems using telemedicine, in the context of the analysis conducted earlier.

PREGNANT WOMAN, PATHWAY 1.

Description:

Ms Anna aged 27, a hairdresser by profession. She reported to her gynaecologist because she took a pregnancy test, which came out positive. She lives in a house in the countryside with her husband and parents, in a place about 40 km from the dispensary and clinic. The woman's husband does not work permanently, he goes abroad for seasonal work.

Issue:

Limited access to obstetric care in pregnancy, in line with current standards.

Objective:

To extend care to the pregnant woman in line with the standard of perinatal care using telemedicine and e-health capabilities.

Procedure:

- After confirming the pregnancy, the woman reports to her obstetrician-gynaecologist or midwife. The obstetrician-gynaecologist taking care of the woman establishes her Pregnancy Card and the Virtual Account of the pregnant woman created for this purpose by the Centre for Digital Medicine, to which the following will be attached: Organisational standard of perinatal care, Questionnaire to assess the risk and severity of depression symptoms, e.g.: Edinburgh Postnatal Depression Scale, Birth plan.
- Thanks to direct access to the Organisational Standard of Perinatal Care (the part concerning care during pregnancy), a pregnant woman will have information on all prophylactic services, diagnostic tests, medical consultations, health promotion and education activities, together with the periods of their performance.
- The person carrying out the pregnancy (obstetrician-gynaecologist or midwife) shall assess the presence of risk factors identified during pregnancy on the basis of the history and examination. If risk factors are identified, the pregnant woman shall remain under the care of the obstetrician.
- During all visits, the person in charge of the pregnancy performs preventive services and health promotion activities and orders diagnostic tests and medical consultations on a face-to-face basis, in accordance with the timetable set out in the Organisational Standard for Perinatal Care.
- The results of the examinations are entered in the pregnancy chart.
- The patient is informed of the possibility of 3 additional teleconsultations with the person carrying out the pregnancy, the date of which is mutually agreed.
- During the visits, the woman is informed about the possibility of using applications available on the market intended for pregnant women, which will contain information on management of pregnancy disorders, lifestyle, legal aspects related to maternity, offering videos simulating foetal development in particular weeks of pregnancy, Cards for assessment of foetal movements, etc.

- If the pregnancy is managed by a doctor, the pregnant woman between 21 and 26 weeks of pregnancy is referred to the family midwife, who starts educational meetings with her. These meetings can be face-to-face or online in the form of teleeducation. Teleeducation takes place once a week from the 21st to the 31st week and twice a week from the 32nd week of pregnancy until delivery.
- The educational activities will cover the course of pregnancy, childbirth, postpartum, lactation problems and care of the newborn child.
- The Pregnancy Practitioner will develop a Birth Plan together with the pregnant woman, attached to the Patient Account. The Birth Plan may be modified during subsequent visits.
- Between the 11th and 14th week of pregnancy and between the 33rd and 37th week of pregnancy, using the application attached to the Virtual Account of a Pregnant Woman, the pregnant woman performs a preventive survey aimed at identifying women at risk of depression. The data obtained from the questionnaire are interpreted by dedicated artificial intelligence algorithms and the results of the analysis appear on the patient's Virtual Account. If a pregnant woman is found to be at increased risk of depression, the person taking care of the patient will refer her for consultation with a psychologist or psychiatrist.
- At the time of delivery, the woman will have the opportunity to borrow a mobile CTG - the recording of the results will be sent to the Medical Telemonitoring Centre (service provided by the provider of the remote CTG solution) and interpreted. If the record is incorrect, appropriate medical procedures will be initiated to protect the health of the pregnant woman and her baby.
- A pregnant woman, after being instructed by her doctor or midwife on how to perform the test, monitors fetal activity using a fetal movement counting application. The results will be analysed by the system and interpreted. If there are any doubtful results, the pregnant woman will contact her doctor or midwife.

# 4 DESCRIPTION OF THE PROCESS AND INDICATION OF THE INVOLVEMENT OF ENTITIES IN ITS IMPLEMENTATION WITH A DISTRIBUTION OF RESPONSIBILITIES AND ACTIVITIES

## 4.1 ENTITIES INVOLVED IN PROJECT IMPLEMENTATION

Establishment of a regional telecare system for pregnant women is an activity which is part of a broader program of development of a coherent, integrated system of telemedicine and e-health. To ensure rationality and effectiveness of telemedicine solutions it is necessary for them to be interoperable, both horizontally, covering various departments of medical care and geospatially, meaning the possibility of data exchange between various entities in a regional system, as well as vertically, where local and regional solutions are compatible with the national system.

Due to the dynamics of the development of telemedicine and e-health solutions, strongly intensified by the scale of the pandemic challenges, each decision on the direction of the creation of regional telemedicine systems should be coordinated with the ongoing national programmes, but also, and particularly importantly, with the plans for such actions.

At the stage of the programme pilot implementation, a CENTRE FOR DIGITAL MEDICINE (CMC) - the project leader - should be established, which would ensure the integrated development and operation of domain-specific telemedicine systems. The Centre should be established at a domain-specific institute or clinical centre with supra-regional/national range of influence. In relation to tele-obstetrics, it should be a centre with perinatology departments. The medical issues should be separated from the target technical and organisational solutions concerning the ICT infrastructure, which should guarantee the implementation of the assumptions of the "Health" Programme. At the level guaranteeing digital security of the system, as well as operational efficiency and economic rationality, the latter infrastructure can be built within a joint, multidisciplinary undertaking; the issues of decisions in this respect are beyond the scope of the current project (they should be made jointly for the entire tele-care system and, more broadly, health care).

The CMC (project leader) will provide technical and IT support for the gynaecologist/midwife when providing outpatient care to pregnant women in primary health care and specialist outpatient care.

CMC performs functionalities in the broadly understood scope of obtaining and processing medical data relating to the course of pregnancy. It should be emphasized that the aforementioned functionalities are performed both online (in real time), which refers to the current monitoring, and offline, where retrospective analyses can be performed based on the collected archival data, as well as comparative analyses using the available data, e.g. from medical registers.

CMC provides processes for communication (both interactive and one-way) with pregnant women, analysing and storing data (including procedures using artificial intelligence methods). The CMC trains instructors to communicate with patients using tools that allow them to receive care remotely, which is particularly important for non-urbanised regions distant from centres offering direct specialist care. In addition, the Centre's staff educate medical staff in the use of:

- digital tools to assess the risk and severity of depressive symptoms of perinatal women,
- applications for monitoring foetal movements,
- birth plan,
- mobile CTG (cardiotocograph),

- websites and social media available on mobile devices.

In view of the broad multidisciplinary spectrum of tasks to be entrusted, CMC should employ both medical and non-medical staff.

The highly specialised centre, which is the leader of the pilot, must have experience in the implementation of projects in the area of health financed with public funds, at least three projects carried out with public funds in the last 5 years (may be in the ongoing stage).

**TASKS OF THE CMC (PROJECT LEADER):**

- conducts a promotional and educational campaign using, among others, social media and/or websites;
- supervises the development and preparation of leaflets, posters informing about the project;
- organises scientific conferences at the beginning and end of the pilot study;
- informs entities providing services under contract with the National Health Fund over a pregnant woman in this project about its principles and signs contracts with POZ and AOS;
- purchases equipment necessary for the implementation of the project by local healthcare facilities and individual equipment for women under telecare
- coordinates the course of the study and responds directly to various risks and emergencies.

The ICT SPECIALIST TEAM will carry out tasks related to:

- Development of the Pregnant Woman's Virtual Account (WKKC) and inclusion of:
- Organisational Standard of Perinatal Care (Part II: Scope of preventive services and health promotion activities, as well as diagnostic tests and medical consultations, performed on women during pregnancy, together with the periods of their performance),
- a questionnaire for assessing the risk and severity of depressive symptoms,
- birth plan,
- applications for assessing foetal movements,
- and relevant smartphone applications.

**The ICT team is required to:**

- develop the overall system for communication and notification of pregnant women through sms messages, emails, telephone contact;
- ensure the security of the data transmitted and stored;
- make the technical preparation of the tele- and video-consultations;
- ensuring continuity of data flow;
- creation and administration of a project account on a wide range of social media.

**TASKS OF THE MEDICAL TEAM**

SPECIALIST GINEKOLOGIST-OBSTETRICIAN from AOS - establishes the WKKC of a pregnant woman, manages the pregnancy according to the guidelines of the Organisational Standard of Perinatal Care, conducts teleconsultation in accordance with the guidelines of the Organisational Standard of Perinatal Care, orders examinations, analyses and interprets their results, collects lifestyle data, informs about the possibility of additional teleconsultations, informs about the need to contact the midwife in order for her to conduct the process of education / tele-education after the 21st week of pregnancy, draws up a birth plan, arranges further appointments. Informs about the possibility of borrowing equipment and performing an CTG examination at home on the due date. In the event of abnormalities in the course of pregnancy, the gynaecologist-obstetrician refers the pregnant woman

for specialist examinations or makes a referral to hospital. Takes informed consent given on the appropriate form and information about GDPR.

MIDWIFE, FAMILY MIDWIFE (primary healthcare facility – POZ) - establishes the WKKC for a pregnant woman, in the case of pregnancy guidance: carries out the pregnancy according to the guidelines of the Organisational Standard of Perinatal Care, conducts teleconsultation according to the guidelines of the Organisational Standard of Perinatal Care, orders examinations, analyses and interprets their results, collects lifestyle data, informs about the possibility of additional teleconsultation, informs about the schedule of teleeducation, draws up an education plan, including practical and theoretical preparation for labour, puerperium, breastfeeding, parenting and preventive measures. After the 21st week of pregnancy, conducts antenatal education/tele-education, draws up a birth plan, schedules subsequent visits. Three times during pregnancy refers pregnant women for obligatory consultations with an obstetrician-gynaecologist. Informs about the possibility of borrowing equipment and performing an CTG examination at home on the due date. If abnormalities are found during pregnancy, the midwife shall refer the pregnant woman to the care of an obstetrician-gynaecologist. She takes informed consent given on the appropriate form and information on GDPR.

POZ / AOS MANAGER - Signs a contract with the CMC (highly specialised centre, leader of the pilot), provides information on the objectives of the project, informs the local community about the possibility of participating in the project, inform women about services to be provided during pregnancy in accordance with the Organisational Standard of Perinatal Care.

NORWEGIAN PARTNER - the pilot project may be implemented in international partnership, e.g. with Norwegian partner having experience in the implementation of similar projects in the field of obstetrics. The partner's role will be mainly to provide substantive support to the Polish side, through experience exchange, sharing knowledge in the field of telemedicine or preventive projects by means of consultations, meetings, conferences, as well as participation in the development of information and training materials. Participates in a scientific conference aimed at sharing experiences in telemedicine and e-health. Provides substantive support to the head of the CMC (gynaecologist) - a highly specialised centre, the pilot leader.

SCIENTIFIC ASSOCIATIONS, ORGANISATIONAL UNITS OF PROFESSIONAL SELF-GOVERNMENTS (optional) - including the Polish Society of Gynaecologists and Obstetricians, the Polish Society of Midwives, the National Association of Family Midwives, Chambers of Physicians, District Chambers of Nurses and Midwives - inform about the project in their websites, encourage pregnant women to participate in the project.

SOCIAL MEDIA - inform and encourage pregnant women to participate in the project, cooperate in the education of pregnant women, health preventive measures during pregnancy, popularisation of women's rights resulting from the provisions of the Organisational Standard of Perinatal Care.

## 4.2 PREVENTION AND INFORMATION ACTIVITIES

The implementation of the pilot should be supported by prevention and information activities, both on the part of specialist centres and primary care centres. The scope and range of these activities should be adapted both to the geographical area covered by the pilot project and to the target groups - pregnant women from the so-called excluded areas, living in rural areas.

The planned preventive activities should include: organisation of at least two subject-related conferences and preparation of leaflets, posters and advertising spots addressed to target groups - pregnant women. These activities will aim to raise awareness among both medical personnel and patients on the care of pregnant women based on the assumptions of the organisational standard of perinatal care.

Educational and promotional materials created for the programme (leaflets, posters) should also contain content related to health prevention during pregnancy, including topics related to lifestyle during pregnancy, health behaviours and prevention of emotional disorders in pregnancy.

## 4.3 DESCRIPTION OF THE PROJECT PROCESS INCLUDING THE PREGNANT WOMAN'S VISITS

- The Centre for Digital Medicine (CMC) (highly specialised centre, project leader) provides information about the pilot Care of pregnant women with the use of telemedicine and e-health to primary healthcare facilities (POZ) and ambulatory care units (AOS) (optional), located in rural areas, far from large cities.
- After submitting a declaration of willingness to participate in the programme, a contract will be signed with gynaecologists-obstetricians and POZ/family midwives. This pilot will be open to 300 pregnant women.
- Train the POZ/AOS team (gynaecologist-obstetrician/midwife) on the principles of collaboration, use of equipment, transfer of information. Establish ways and criteria for recruiting pregnant women (the stage running in parallel with the following point).
- Recruitment of patients by POZ/AOS - preceded by dissemination of information through local media, media information. Pregnant women who meet the criteria and give informed consent for participation in the programme will be invited to visit the POZ/AOS on a previously set date.
- It is necessary to plan the purchase of equipment (project leader) to equip the dispensary (POZ/AOS) to purchase the necessary equipment, technological tools from the programme funds: mobile workstations with software to operate the Virtual Account of a Pregnant Woman (WKKC), smartphones for the person taking care of the pregnant woman and for pregnant women, mobile data cards.
- The WKKC will include: Organisational standard of perinatal care, questionnaire to assess risk and severity of depressive symptoms, birth plan, available apps for pregnant women.
- Training of the patient on how to use the WKKC and the communicator. If the woman does not have a smartphone supporting the above-mentioned applications, lending her the equipment - signing a contract.
- The gynaecologist-obstetrician/midwife carries out preventive services, health promotion activities, diagnostic tests and medical consultations for the pregnant woman, in accordance with the guidelines of the Organisational Standard of Perinatal Care.
- The work and consultation schedule of the gynaecologist-obstetrician/midwife is available at the WKKC.

- The person carrying out the pregnancy informs the woman about the possibility of using pregnancy apps. On the basis of the interview, after analysing the individual needs of the patient, he/she helps her to choose the appropriate app.
- The obstetrician-gynaecologist and the midwife caring for the pregnant woman have access to the WKKC and can enter information/data.
- The pregnant woman, through the use of the WKKC, will have information on the services she will receive during subsequent visits.
- Each teleconsultation will be concluded with a summary, explanation of test results, issuance of e-referrals for tests, possible e-prescriptions and further recommendations.
- The obstetrician-gynecologist/midwife informs the pregnant woman to assess the risk and severity of depressive symptoms between the 11th and 14th week of pregnancy and between the 33rd and 37th week of pregnancy by completing an appropriate questionnaire. The data obtained from the questionnaire are interpreted by dedicated artificial intelligence algorithms and the results of the analysis appear on the WKKC. The completion of the assessment and its outcome are marked on the WKKC, along with any further recommendations if a risk of depression is identified. The outcome of the assessment and any further recommendations are discussed with the patient.
- If the pregnancy is carried out by a doctor, he or she informs the woman of the possibility of receiving care from a primary care midwife and refers her between the 21st and 26th week of pregnancy for antenatal tele-education and care for her and the baby in the place where they will stay after the birth.
- The doctor shall record on the WKKC the fact of referral for care by a primary care midwife.
- From the 21st to the 31st week of pregnancy, online educational meetings with the midwife should take place once a week, and from the 32nd week of pregnancy until termination - twice a week.
- The primary health care midwife confirms the woman's coverage of care during pregnancy by entering her data or the data of the entity providing treatment in the field of primary health care, including: contact telephone number and fax number or e-mail address, into the antenatal care plan on the WKKC.
- The community midwife carries out the antenatal tele-education programme in accordance with the guidelines contained in the Organisational Standard for Perinatal Care.
- The provision of tele-education is confirmed by an entry on the WKKC.
- The pregnant woman is informed about the possibility of participating in the Virtual Birthing School by providing her with a link to the learning platform.
- The gynaecologist-obstetrician/midwife develops with the pregnant woman a Birth Plan attached to the WKKC. The Birth Plan can be modified during the pregnancy.
- A pregnant woman who is about to give birth is informed about the possibility of borrowing a mobile CTG free of charge, she will be instructed by the gynaecologist-obstetrician or by the midwife on how to use the equipment and how the system works. The test results will be sent to the Mobile Telemonitoring Centre (MCT) (the company renting the equipment) and interpreted by artificial intelligence. In the event of any abnormalities, medical staff from the MCT will contact the pregnant woman and give advice on how to proceed.

# 5 DESCRIPTION OF THE INFORMATION FLOW

INFORMATION FLOW:

- Information about the project will be given by the CMC (project leader) in social media, leaflets will be prepared and delivered to health care facilities that have expressed their willingness to participate in the project.
- CMC (project leader) will make contact with obstetrician-gynecologists and primary healthcare facility (POZ) manager and POZ/family midwives.
- Primary healthcare facility (POZ) manager, doctors, midwife confirm willingness to join the project.
- Signature of contract with those joining the project.
- Training of medical staff on project details and use of equipment and applications.
- The doctor, midwife contact the CMC (project leader) in organisational matters.
- Primary healthcare facility (POZ) manager, gynaecologist-obstetrician, midwife inform the local community about the possibility of participation in the project, provide women with information on benefits due to them during pregnancy, resulting from the standard of care.
- CMC staff set up a WKKC on a computer/laptop in the clinic, which will be accessible to the obstetrician-gynaecologist and midwife.
- CMC staff will set up the WKKC on pregnant women's smartphones.
- The WKKC will be accompanied by: Organisational standard of perinatal care, questionnaire to assess risk and severity of depression symptoms, birth plan, available apps for pregnant women.
- The results of the assessment of the risk and severity of depressive symptoms, the results from the Fetal Movement Chart, the results from the mobile CTG will be posted on the WKKC.
- The pregnancy manager informs the pregnant woman about the possibility of additional teleconsultation and teleeducation.
- Establishment of a teleconsultation and teleeducation calendar at the WKKC.
- The work and consultation schedule of the gynaecologist-obstetrician/midwife is available on the WKKC.
- A pregnant woman, through the WKKC, will have information on all preventive services, diagnostic tests, medical consultations, health promotion and education activities.
- The pregnant woman, through the information contained in the Organisational Standard of Perinatal Care, will have information on the services she will have at her next visit.
- The person in charge of the pregnancy develops with the pregnant woman the Birth Plan attached to the WKKC.
- If there are problems with the operation of the WKKC, the obstetrician-gynaecologist / midwife asks the IT staff to help resolve the problem.

# 6 DESCRIPTION OF THE TECHNOLOGICAL ASPECTS OF THE SOLUTION

The development of ICT and digital technologies expands the possibilities of designing, implementing and operating telemedicine systems. Applicable solutions that fit into the Internet of Things (IoT) model are becoming present practically everywhere, and their functionalities are mastering all spheres of social and economic life, which was given an additional boost to accelerate the processes of digital transformation by the state of the COVID-19 pandemic.

Such an acceleration naturally applies in particular to medicine and healthcare systems as a whole. One area of particularly intensive development has become telemedicine and e-health systems. Thanks to the development of digital technologies, it has become possible to build scalable open telemedicine systems integrating teleconferencing, transmission of high quality radiological images and access to medical databases within a single tele-diagnostic service. The inefficiency of the health care system caused by the COVID-19 pandemic has spread to all areas, therefore the only way to restore its efficiency is the widespread introduction of new structural solutions based on the use of digital technologies, in particular ICT. New system approaches using telemedicine solutions is one of the most important elements of such transformation.

## 6.1 TECHNOLOGICAL ASSUMPTIONS

Due to the intensive implementation of eHealth solutions on a large scale in Poland (e.g. e-prescription, e-medical sick leave, e-referral, e-prescription, Electronic Health Record, www.pacjent.gov.pl, www.gabinet.gov.pl), it is advisable that the target solution will be a platform included in the existing and continuously developed eHealth systems in Poland at the central level. These systems are created on the basis of the P1 platform, which is operated by the e-Health Centre operating at the Ministry of Health and Social Welfare. In addition, there is a number of hospital information systems of the HIS (Hospital Information System) type, such as AMMS by Asseco, OptiMED and e-Care by Comarch, CLININET by CompGroupMedical, ESKULAP by Nexus Poland, which offer comprehensive services for medical entities and enable the implementation of the treatment process. A separate problem of the Polish healthcare system is the issue of compatibility of individual products, which often results in their lack of interoperability.

It is recommended that, in the pilot version of the proposed solution, a dedicated Internet platform should be created to support the area of care during pregnancy. The platform, in addition to directly operational medical functionalities, should support the implementation of tasks aimed at raising social awareness of health (educational aspect). Of course, the use of the tele-obstetrics platform itself will only extend the scope of utility of the independently implemented HIS-type system for contact with patients, which will primarily concern situations requiring extended specialist medical care.

The IT system for pregnancy care oriented at the needs of the whole group of women, after integration with the currently existing e-health solutions, should allow to obtain medical data, manage them by the medical personnel, provide services (appointment scheduling, consultations, remote monitoring) financed by the public health insurance system.

It is recommended that the designed and implemented telemedicine system, is a common space for medical staff, patients and administrative staff. Members of each of the three groups should be able to perform activities in accordance with the assigned rights and roles.

It is advisable that the system is built from a central part, performing operational functions, related to full data handling, and from dedicated interfaces, ensuring communication with physicians/midwives

on different levels of health care organization structure, patients, administrative staff, as well as with other systems, with which communication will be necessary or desirable.

As part of the pilot stage of the implementation of the tele-midwifery system, it is proposed to create a platform that will enable each of the groups listed below to carry out the activities assigned to them:

- health personnel: monitoring the health of the pregnant woman and consultation with the patient;
- pregnant woman: communication with doctor/midwife, health education.

The platform should meet the following conditions:

- Availability through a web browser at a specific web address (to be defined during the implementation phase).
- Web interface for display on PC/Mac and mobile devices such as Android/iOS smartphones.
- Mechanism enabling registration and log-in with confirmation of the patient's identity (for security guarantees, integrated with the patient's account at www.pacjent.gov.pl).
- Creation of a virtual patient account and its operation should be possible on any device supporting a web browser.
- With the protection mechanisms in place, the security of the stored data should be ensured due to its specific nature and sensitivity. It is also recommended to pass cyber security tests conducted by a certified external company specialising in ICT security.
- It is advisable to ensure accessibility and user-friendliness for users with different levels of knowledge and experience in using internet technologies, including those with very limited background.

In particular, the platform should provide the functions listed below:

- Support of the system by a dedicated tutorial;
- Availability of an "assistant/tutor" function for people who have problems operating the system on their own;
- Multi-level accessibility to functionalities: extended functions should be available only after going to an individual account;
- It is recommended to include an educational panel, providing information on the perinatal period;
- Provide the possibility to add comments, enter additional information, give answers, fill in questionnaires by the pregnant woman;
- Ensure access to data on the platform by medical personnel appropriate to the individual patient;
- It is recommended that to ensure an increased level of digital security, additional confirmation of the patient's identity is required, in particular through the use of telecode (authorization code), which was used to authorize the patient during telephone conversations with medical staff.

The development of the project and implementation of the system model at the pilot stage will only be possible through cooperation of partners with different experience and complementary competencies, allowing the creation of the solution described in the current report. It is also a natural derivative of the contracting authorities' expectation to use as much as possible the IT solutions existing on the market. The required experience and competencies should be in the

areas of knowledge of the functioning of the health care system, widely understood ICT area, as well as clinical facilities involved in the project.

## 6.2 SOLUTION ARCHITECTURE

The basic assumption adopted throughout the current report is the requirement that the created ICT system for tele-midwifery should be characterized by layered architecture and modular layout. In this way it is possible to ensure easy adaptability of the system to emerging new requirements and at the same time to achieve a high level of its reliability and security.

## 6.3 CUSTOMER LAYER

The client layer enables using the functionalities made available by the presentation layer. It constitutes the work environment for the user (medical personnel, administrative staff, patient), presents data and receives commands from the user issued with the use of Graphical User Interface (GUI) components. As a method of communication with the user, it was decided to use active, dynamic web pages. Such a solution ensures high ease of use and accessibility 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). As a result, using the telemedicine system does not require installing any additional software on client devices. We assume that the introduced graphic interfaces will be functional, with all advanced functionalities limited to a necessary minimum, so as to maintain its accessibility and ease of use for people with different levels of proficiency in using modern information technologies, especially mobile ones.

## 6.4 DATA PRESENTATION LAYER

The use of a browser in the client layer is possible as long as appropriate software is used on the HTTP server side. We recommend that the data presentation layer is handled by a set of servers implementing HTTPS services. These servers will send properly addressed information to the browser. An integral part of the presentation layer is the load balancing layer, which will distribute the load among multiple servers and lead to their even usage. Such an approach will ensure high availability of the telemedicine system and stability of access to its resources. It is required that through the use of specialised solutions ensuring data archiving redundancy, an increased level of security is ensured.

## 6.5 GENERAL PRINCIPLES OF THE WEB INTERFACE

It is recommended that the interface is created using web technologies and is accessible through a web browser. The website should be created using the RWD method and will smoothly adjust to the resolution of the device on which it will be displayed. The layout of screen elements such as video content, photos, graphics, fonts, buttons should be automatically adjusted to the screen size. In the case of devices with lower resolution, some interface elements should also change in order to optimally arrange the content for users. It is recommended that the prepared website is optimized for devices such as PC/mac (including laptops), tablets and smartphones.

All web interfaces available in the system should be made according to unified general assumptions, they may differ in functionality according to the roles of users in the system.

GYNAECOLOGIST-OBSTETRICIAN/MIDWIFE INTERFACE

Functionally, the web interface allows:

- entry of textual and numerical data, their modification and validation,
- entry of history information,
- upload scanned medical examination results,
- visualisation of the time variation of test parameters,
- entering a schedule of visits,
- documenting the patient's visit history,
- recording recommendations for further treatment,
- entering personal information in a form guaranteeing compliance with the requirements of the GDPR Act.

THE PREGNANT WOMAN PATIENT INTERFACE:

Functionally, the interface allows in this case:

- conduct an interview (answers to questions within the web form),
- an overview of the visit history (including recommendations, treatment),
- visualise variation in test parameters over time,
- scheduling a visit,
- asking a question to a specialist,
- upload medical test results.

THE ADMINISTRATIVE STAFF INTERFACE:

Functionally, this interface allows:

- generate reports in a predefined form,
- definition and generation of ad-hoc reports,
- statistical summary of the visits made according to various criteria.

## 6.6 DATA PROCESSING LAYER

The data processing layer focuses on the logic of the system operation. Due to its key role in the operation of the system, it has the most complexed structure and is built in a modular layout. This layer is the central element of the system and is built as a strictly defined set of rules, describing the interlayer and intermodule communication in the system.

In the ICT system being developed, the client layer should communicate with the data processing layer through the data presentation layer. On the next level, the data processing layer should communicate with the data storage layer. It is recommended that all communication is possible only after authentication and authorisation, both on the part of the medical personnel and the patient.

API (Applications Programming Interface) implementation is a set of procedures and protocols enabling mutual communication of software components according to the introduced convention. Separation of the data processing layer increases system security by limiting direct interaction

between the layers and by introducing built-in control and scaling mechanisms. Moreover, in this way, mechanisms of authentication, authorization, confidentiality and non-repudiation of the telemedical services implementation are introduced. It is recommended that the API be implemented as a set of microservices, in a scalable container service.

## 6.7 DATA STORAGE LAYER

It is recommended that the data storage layer consists of three basic subsystems.

- The first is a relational database management system (RDBMS). The system will use two database instances containing mutually complementary information. The first database instance should contain staff and patient data to enable authentication and authorisation in the system. It is recommended that the instance stores authorisations to modules of the data processing layer. In the other hand, the second database instance should store in particular the results of a questionnaire for assessing the risk of severity of symptoms and onset of depression. The relational repository should store a structured view of the medical case. The key linking the data from the two databases should be a unique identifier. It will also be necessary to design an appropriate data model. The use of such an approach will contribute to increasing the security level of the whole system.
- The second system should be a non-relational NoSQL database, providing mechanisms for storing and retrieving data modelled in ways other than tabular relationships. The key-value and document models will store interview/survey descriptions.
- The third data storage layer system is object storage. It implements the method of non-hierarchical data storage, whereby it does not use a directory tree, but the objects themselves (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. Access to objects from within the system should be through an API and not from the user interface. Units that are scans of test results and diagnostic imaging should be stored as objects in the system.

## 6.8 COMMUNICATION

It is recommended that data transmission between the user interface (web interface) and the central IT system is carried out via encrypted communication, in accordance with the accepted SSL standard. It is a network protocol used for secure internet connections. It has been adopted as a standard for encryption on websites. An SSL certificate ensures the confidentiality of data transmitted over the Internet. It also ensures the credibility of the website and the whole organisation (it is possible to carry out a comprehensive verification of the entity applying for the certificate). The intention of SSL creators was to design a universal protocol, so that application protocols could use it.

# 7 MEDICAL AND TECHNICAL SKILLS OF TEAM MEMBERS

**MEDICAL TEAM**

COMPOSITION OF THE MEDICAL TEAM AT CMC (PROJECT LEADER):

- team leader,
- specialist gynaecologist-obstetrician,
- midwife.

QUALIFICATIONS REQUIRED:

TEAM MANAGER - gynaecologist-obstetrician with specialisation and at least 5 years of professional experience after specialisation.

OBSTETRICS AND GYNAECOLOGY SPECIALIST from CMC (1 person) - has specialisation in obstetrics and gynaecology, clinical practice, currently practising in accordance with his/her specialisation. Has at least 5 years of professional experience. Has the ability to use computer equipment and applications for remote communication.

ENVIRONMENTAL / FAMILY MIDWIFE from CMC (1 person) - Has the qualifications of a primary care midwife as defined in the Act of 27 October 2017 on Primary Health Care (Journal of Laws 2017, item 2217). Has at least 5 years of professional experience. Is skilled in the use of computer equipment and remote communication applications.

**ICT TEAM**

MINIMUM COMPOSITION:

The web platform implementation team shall include at least (some functions may be performed by one person):

- Solution Coordinator / Team Leader.
- DevOpsEngineer.
- Developer (front-end, back-end, integrator).
- Software tester.
- Computer graphic designer.
- Social media specialist.
- Teleconsultation and telemonitoring coordinator.

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

The competences of staff of a technical nature should refer to: knowledge of the functioning of the healthcare system, proficiency in ICT, experience within telemedicine applications. These persons, within their field of specialization, should have competences enabling the realization of the project assumptions. Availability and readiness to react in case of an urgent need for help will be a required value.

The implementation of the project will require coordination (solution coordinator / ICT team leader) of all technical activities, with particular attention to the coherence of the work carried out. A special task of the technical coordinator will be to work closely with the medical coordinator to create a high quality system.

DevOpsEngineer - prepares and maintains the server and network part for hosting the Platform during the piloting period, cooperates with the team of developers on the implementation and deployment of the system. Performs platform support and availability services.

DEVELOPER (front-end, back-end, integrator) - is responsible for the creation of the tele-obstetrician Internet Platform (WWW portal) and communication interfaces with e-Health central systems.

SOFTWARE TESTER - verifies the correctness of operation of the implemented software against the requirements set. It participates in the development of the requirements specification and test scenarios.

COMPUTER GRAPHIC DESIGNER - creates graphic designs, visuals, logos, flyers, posters, co-creates advertising campaign. Together with a social media specialist creates an advertising campaign.

SOCIAL MEDIA SPECIALIST - a person taking care of the digital image of the pilot stage of the project by running an information campaign in social media. He/she will be responsible for setting up and administering pages in selected social media and maintaining them as an active channel of communication with patients. Consult with obstetrics and gynaecology specialists / midwives on the content of the website, prepare promotional materials, run the ongoing information campaign. Responsible for communication with patients.

TELECONSULTATION AND TELEMONITORING COORDINATOR - a person dedicated to coordinating during the pilot stage of teleconsultations with obstetrics specialists / gynaecologists / midwives (arranging teleconsultations, potential rescheduling). It is advisable to have a medical background in order to competently undertake the conversation with the patient. He/she is responsible for the survey (questionnaire) on the satisfaction of the users of the designed solution.

# 8 THE PROPOSED MODEL OF INTEGRATION WITH THE EXISTING mHEALTH ARCHITECTURE IN POLAND

The system of telemedicine solutions should be built in a coherent way, ensuring a wide level of interoperability of its individual domain components, and at the same time rationalizing the use of ICT infrastructure resources. Therefore, it would be unjustified to create separate physical infrastructures for individual healthcare areas, and the principle of integration and synergy of infrastructural resources should be formulated as an overriding recommendation, with preservation of an appropriate graphical structure, mapping mutual relationships of various system functionalities.

In relation to telemedicine solutions for pregnancy and perinatal care, it is recommended to integrate the system with the electronic platform of public services in healthcare - P1 Platform (Electronic Platform for Collection, Analysis and Sharing of digital Medical Records). Integration with the P1 Platform will enable the exchange of medical information between institutions. All medical events will be sent to the P1 Platform in real time, so that it will be possible to build an electronic platform of public services in healthcare, which will enable integrated collection, analysis and sharing of digital resources on medical events, within the scope consistent with the Act of 28th April 2011 on the information system in healthcare. In order to determine the operational scope of the P1 platform in the pilot project, it should be emphasized that it is available for the systems of service providers and regional systems registered in the e-Health Centre, only through standard Web Services interfaces. Integration of the tele-obstetrics system with the P1 Platform will be performed vertically, in accordance with the guidelines included in the technical documentation prepared at an appropriate stage. There is a possibility of implementing a part of telemedicine solutions for perinatal care initially only within a dedicated sectoral system and only in subsequent stages introducing them to the integrated central platform P1.

The proposed model assumes that the implemented tele-obstetrics system puts the pregnant woman at the centre by using the concept of integrating the involvement of different levels of health care, i.e. primary health care and specialist health care. The telemedicine services within this system will be delivered both online and offline, thus providing a wide spectrum of functionality, from real-time to analytical procedures using archived data (e.g. on previous pregnancies or other health events).

The potential of the application of telemedicine and the multitude of solutions it offers allow for the use of telemedicine services in a number of different operational models. In the pilot project, a distinction will be made according to the method of medical data transmission (communication):

- real-time - the doctor, the midwife providing the medical services and the pregnant woman will communicate via online tele- or video-conferencing,
- remote monitoring - the well-being of the foetus will be monitored using a system that collects data from monitoring devices and transmits it to an external centre, from where healthcare professionals monitor its health status (using cardiotocography during pregnancy).

The way data are transmitted has an important impact on the organisation of the provision of services, technical requirements and requirements related to the protection of medical data. It can thus be used to create standards and good practices for the provision of services, as well as generally applicable laws (e.g. regulations specifying minimum requirements for the provision of telemedicine services).

The recommendation, resulting in particular from the U.S. experience for the solutions of the presented problems proposed in the pilot project, is the need to ensure the necessary redundancy of technical solutions, protecting against unannounced interruptions in the availability of remote

services, which could violate the confidence in the reliability of the offered system; its availability in the 24x7 mode should be guaranteed at a high level of confidence. The actual technical (IT) and personnel solutions will have to result from the geospatial layout of the telemedicine care system, introducing components and back-up procedures prepared for various emergency situations. The system will be characterised by a distributed structure with a hierarchical arrangement of functionalities, thus ensuring its flexibility and, at the same time, its reliability and security.

Telemedicine solutions are, above all, continuous monitoring of the pregnancy and the patient's condition, awareness and education, and finally multilateral information rather than just teleconsultations. In addition to the online mode (real-time activities), offline functionalities (outside of real time) will play an important role, including the availability of archived data and their algorithmic processing (artificial intelligence approaches), e.g. allowing early prognosis of potential pregnancy risks.

An additional dimension of the opportunities of telemedicine, related to the use of smart technologies: the development of smart wearable technologies enables a new type of remote non-invasive diagnostics, thus improving healthcare itself. For example, monitoring blood pressure levels via this route can be more objective than measurements taken in person by a pregnant woman.

One of the proposals of additional activities in the field of telemedicine and e-health in Poland could be the establishment of the status of "Telecare Leaders", awarded to hospitals or other healthcare system facilities in recognition of the good practices introduced and applied by them. Such centres will be able to serve, among others, as training venues or educational workshops.

# 9 DEFINING RISKS RELATED TO IMPLEMENTATION OF A GIVEN TELEMEDICINE MODEL AND POSSIBLE WAYS OF THEIR MITIGATION

## 9.1 RISKS ASSOCIATED WITH THE TECHNICAL BACKGROUND OF THE PROJECT

The implementation of telemedicine solutions is connected with a number of non-medical problems, in particular with the issues of data protection against unauthorised interventions and, as a result, against the breach of data security. These are threats of general nature, resulting from the nature of ICT systems and computer data processing. Counteraction to such threats is undertaken in all areas of introducing digital technologies, and especially focuses on securing the integrity and security of processing infrastructures and data resources. Since, also in the case of the tele-obstetrics system, it will be developed in conjunction with the wider digital infrastructures of telemedicine and e-health, such procedures will be implemented in its case.

Therefore, the description below will concern not only general recommendations in the area of counteracting the threats of breaching the security of ICT systems, but also the indications of specific rules of conduct in the specific context of tele-obstetrics systems. First of all, it is necessary to ensure multi-level protection of medical and personal data by introducing adequate technical solutions, but also procedures defining precisely the scope of persons and institutions entitled to access such data. In the case of tele-obstetrics, this is data with a particular level of vulnerability, so it is necessary to adopt precise operational rules in order to avoid potential legal risks.

It should be very strongly emphasised that the implications of any data breaches from this system may include not only legal consequences, but also significant damage of image and loss of public trust in the whole system. A reduction of the risk can be achieved by using current international and national standards for data management security, good practices for designing and securing ICT systems (also in terms of verifying the identity of the person receiving the call).

If there are any concerns, protective action should be taken immediately, which may include the need to modify existing infrastructure and implementing appropriate adjustments to the Information Security Policy. There should be carried out:

- systematic risk assessment and monitoring of the whole system and its individual components,
- implementation of control procedures,
- additional staff training,
- introduction of quality systems adapted to the situation,
- evaluation of external service providers,
- legal security for the fulfilment of contracts,
- as well as other preventing, prescribing, correcting and detecting mechanisms.

It is also necessary to preventively inform patients about mistakes they should avoid during telemedicine visits (e.g. which data should not be transmitted remotely and no one should request them) and how they can correctly verify the identity of the consultant (doctor/midwife, ...). Similarly, in the other direction, the identification of the patient's identity should be done in a multilevel way (e.g. by providing a one-time access code or a digital signature). The patient, as a participant in the teleconsultation, should be aware of the legal consequences in the event of disclosure of its contents

in any form. A mandatory statement that the patient is aware of the scope and legal liability consequences of disclosure of the contents of the teleconsultation must be entered into the patient's account.

**TECHNICAL AND SYSTEM THREATS:**

On the technical side, an important risk is **downtime in the availability of system environments** due to low availability of generation environments. Prevention of this risk will rely on the administration and supervision of the ICT infrastructure by technical-systems personnel who are part of the project team.

While this is not always the primary issue, it is worth noting the possible consequences resulting from the use of outdated technology (operated for too long, insufficiently serviced, using outdated, not updated versions of system or application software) or untested solutions (without appropriate guarantees or, in justified cases, security certificates), which may lead to problems not only with the stability and scaling of the built system, but also directly with the level of its operational security. Maintaining such an unfavourable system environment may additionally require a large number of redundant ongoing administrative tasks, which excessively engages forces and resources, simultaneously lowering the quality of the entire system. Reducing this risk requires the selection of technology based on an ongoing review of solutions addressing particular areas of the system under development and the application of good design practices.

In addition to intentional risks, **data loss** due to technical failures is equally dangerous. This will result in:

- loss of data integrity,
- lack of availability of applications,
- inability to fully assess the patient (e.g. loss of medical examinations),
- image losses,
- legal problems
- and the need to repeat (tele-)meetings with patients.

To prevent data loss, data should be backed up regularly and system environments should be backed up. Hardware and software data protection techniques are required, as well as the use of source code versioning tools. Although this is an overarching ICT infrastructure problem, it is important to recall here the need for a back-up data processing and storage centre, without which it would not be possible to fulfil the basic requirements of cyber security certification.

We also draw attention here to the often underestimated risk due to the inadequate selection of IT tools for the system's tasks, which may result in lower operational efficiency of the system through an increasing number of errors and time-consuming their removal, as well as its effectively lower scalability. As a result, delays in the execution of time-critical system functions may occur. The proposed solution is a regular, periodic verification of the administrative and development tools used.

Damage to equipment (including mobile workstations in the POZ, dedicated smartphones) during a patient visit will result in the inability to continue the examination in the standard, planned way. Maintenance and the availability of spare equipment should be guaranteed as part of the system.

The provision of possible buffering of files before sending to the central system should be realised within the application providing an interface for entering and reading data of the medical tele-diagnosis system. Access to a company mobile phone should be provided for the mobile team, independent of WLAN communication.

A critical risk is possible local disruption or complete lack of internet access. A backup solution is to provide alternate connectivity via the mobile network, which requires appropriate instructions for both medical staff and patients.

Irrespective of all technical, procedural and legal safeguards against possible risks, attention should be paid to the need for various insurances: in particular against random events, data and their resources, IT equipment or, finally, the system itself.

## 9.2 THE RISKS ASSOCIATED WITH THE PROPER FUNCTIONING OF THE DESCRIBED PROCESSES

- LACK OF INTEREST OF DOCTORS AND MIDWIVES IN THE PROJECT, due to the need to allocate additional time for teleconsultation and analysis of the results obtained. In order to reduce this risk associated with the implementation of the telemedicine model, it is necessary to educate those involved in the project and to introduce appropriate funding for them. Those involved in the promotion process will also receive additional remuneration.
- LACK OF WILLINGNESS TO CONTINUE COOPERATION ON THE PART OF MEDICAL PERSONNEL: DOCTORS, MIDWIVES may cause interruption of the project, therefore it is necessary to organise prior meetings with the persons involved in the project in order to familiarise them with the project, train them in the use of the equipment used and deal with any irregularities found. In order to reduce this risk it is necessary to prepare the scope of responsibilities for the doctor and midwife as well as for the medical entities - POZ, including, among others, in the contract the description of consequences, which will be in force in the case of failure to meet the agreements.
- LIMITED INTERNET ACCESS IN RURAL AREAS AND NO SMARTPHONES TO CONTACT WITH MEDICAL STAFF - lending pregnant women mobile phone data equipment for the duration of the project to ensure contact with medical staff.
- CONCERNS OF PREGNANT WOMEN AS TO WHETHER THE CURRENT OF THE PREGNANCY IS RIGHTLY MONITORED may make them reluctant to take advantage of telemedicine solutions. To reduce this risk, it is important to explain to women at the recruitment stage that they will use telemedicine services during pregnancy, while maintaining the provision of basic health services as per the guidelines in the Standard of Perinatal Care for Care during pregnancy. It should also be emphasised that all pregnant women will be included in the pre-natal education programme included in the above-mentioned standard. Adequate guarantees of security and privacy of the data collected and archived should also be provided.
- CONCERNS OF PREGNANT WOMEN ABOUT HAVING TO DEAL WITH DIFFERENT PEOPLE DURING THE TELECONSULTATION, WHICH MAY CAUSE DISTRUST IN MEDICAL STAFF. During the recruitment process for the programme, pregnant women should be assured that they will be under the care of the same doctor/midwife (barring random situations), also medical staff will be informed of the need to maintain continuity of care for patients.
- LACK OF SKILLS TO USE TELECONSULTATION AND TELEEDUCATION SOFTWARE AND DEVICES can be an obstacle for both women and providers. Before starting the programme, medical staff should be trained in the use of the equipment and software used during the call, and

technical instructions should be given to female patients on how to properly use the equipment and access the information. There should be pages / links on clinic websites with access to tutorials instructing about the programme and how to operate and use it.

- FORGOTTING of TELECONSULTATION / TELEEDUCATION BY PREGNANT WOMEN - such a situation can be prevented by sending reminders in the form of text messages. In the event of a missed appointment, another appointment must be scheduled.
- NOTICE OF A LOCKDOWN CAUSED BY A PANDEMIC SITUATION, CURRENTLY CAUSED BY COVID-19, BUT OTHER REASONS MAY APPEAR IN THE FUTURE, should not affect the implementation of projects already started, but MAY MAKE IT DIFFICULT TO INCLUDE NEW PATIENTS IN THE PROJECT, due to lack of dissemination of the telemedicine model in obstetrics. The solution to the problem may be to advertise the functioning of the programme in the form of information posters, leaflets, in clinics, on the website of the clinic or municipality offices, in social media. The initiative should also be publicised on local television and in the press. It is important to emphasize that the proposed solutions are complementary to traditional care, but also allow for faster response in case of complications, especially when a pregnant woman lives far from a clinic. The information campaign should also include the provision of information to women on the benefits due to them during pregnancy, resulting from the standards of perinatal care.
- OCCURRENCE OF MISCARRIAGE OR PREMATURE BIRTH - these are situations that can occur at any stage of pregnancy that cannot be prevented; however, when a threatened miscarriage or threatened premature birth occurs and hospitalization is required, the pregnant woman will still be eligible for the program.

Providers need to know and overcome potential barriers to adopting a telemedicine programme, such as connectivity, licensing, legal, authentication requirements to ensure quality and safe providing of telehealth. It is also recommended to conduct a risk analysis before introducing a project.

# 10 ANALYSIS OF THE POTENTIAL BENEFITS ASSOCIATED WITH THE IMPLEMENTATION OF THE TELEMEDICINE MODEL IN OBSTETRICS

The increasing pace of life, the mobility of society, building patient trust in telemedicine solutions and improving patient satisfaction all have an impact on the increasing use of telemedicine. The proposed telemedicine programme - a model in the field of obstetrics - will bring benefits both for pregnant women, their children and health care institutions. It should be emphasized that telemedicine in obstetrics will not compete with traditional medicine in the course of providing care to a pregnant woman; it will be a tool supporting the work of medical personnel and acting for the benefit of beneficiaries.

One of the undoubted benefits will be limiting the problem of unequal access to health services between the inhabitants of cities and rural regions, and thus improving access to health care in places, where access is difficult or there is a lack of specialists. Failure to provide services resulting from the standard of perinatal care constitutes a violation of one of the basic patient rights - the right to health services corresponding to the requirements of the current medical knowledge and provided with due diligence. Thanks to hybrid care for women in the perinatal period, women living in rural areas will have better access to health care. Virtual consultations (tele-consultations and tele-education) will be associated with time savings and lower costs related to visits for women. The proposed solution will not compete with traditional medicine, it will be a tool supporting the work of medical personnel and working in favour of beneficiaries.

An additional advantage is that the project is in line with the National Transformation Plan for 2022-2026 (Announcement of the Minister of Health of 15 October 2021 on the National Transformation Plan (item 80)), which speaks of the most important health needs and challenges of the organization of the health care system, including: Activity 2.4.5 Strengthening of health care in rural areas to secure areas not covered by primary healthcare; Activity 2.4.6 Strengthening of preventive actions in primary healthcare and creation of health balances; Activity 2.4.8 Development and dissemination of modern forms of providing health care services combining elements of telecommunications, IT and medicine (telemedicine) at the level of POZ.

It should be assumed that all women in the programme will have an online preventive screening to identify women at risk of depression. If a pregnant or postpartum woman is found to be at increased risk of depression, the person caring for the patient will refer her for consultation with a psychologist or psychiatrist. These actions are consistent not only with the guidelines contained in the standard of perinatal care, but also with the recommendations of the President of the Agency for Health Technology Assessment and Tarification on recommended medical technologies, actions carried out as part of health policy programmes and the conditions for implementing these programmes, regarding the health problem of postnatal depression.

A significant role will be played by telemedicine in relation to educational activities carried out in relation to pregnant women. Through e-learning platforms, it will be possible to reach the woman at the optimum time for her and the person providing care, and to conduct individualised educational activities. Educational activities will concern the course of pregnancy, childbirth, puerperium, problems related to lactation, care of the newborn child and health prevention.

If a mobile CTG is used, the recording of the results will be sent for interpretation by specialists, using a wireless network. The interpretation of the results will be performed by qualified medical personnel who will inform the patient of the test results. If the reading is incorrect, appropriate medical

procedures will be initiated to protect the health of the pregnant woman and her baby. All results will be available to the doctor and midwife caring for the patient at the same time.

Other benefits will include improved safety for pregnant women and their babies thanks to additional easy and quick contact with medical personnel, comfort and convenience of tests in the home environment, no need to register at a medical facility and thus wait in a queue.

More frequent contact with the doctor/midwife will increase the effectiveness of care during pregnancy, which in turn will improve the reputation and image of medical facilities.

Another benefit will also be the emotional aspect. Pregnancy is a special period in a woman's life. Innovative telehealth applications will allow pregnant women to experience the joy of pregnancy while ensuring that the objectives of prenatal care (prevention, detection, treatment and mitigation of complications when they arise) remain a priority.

The introduction of the programme will also allow monitoring the implementation of the provisions of the Organisational Standard of Perinatal Care and even a rational health policy. The optimal procedure would be to continue the project in the postnatal period, as well as in the next pregnancy, which would allow to ensure continuity of care for the woman and her child.

The events of recent months have shown that having a functional telemedicine infrastructure that can be used in times of pandemic or other emergencies will be crucial to ensuring continuous, safe and professional care in the perinatal period.

The introduction of telemedicine in obstetrics will have an impact on the organisation of telemedicine provision in the future, and may thus be used to develop standards and good practice in the provision of services, as well as legislation of general application, e.g. regulations defining minimum requirements for the provision of telemedicine services.

# 11 AN ESTIMATE LEVEL OF THE COSTS OF THE PROPOSED SOLUTIONS

**ECONOMIC ASSUMPTIONS**

The project should include 300 pregnant women. Minimum number of cooperating primary healthcare facilities (POZ) - 5 (obligatory condition) and 5 ambulatory care units (AOS) (optional) (units providing perinatal care)

| | |
|---|---|
| **MANAGEMENT COSTS**<br>*The management costs of the pilot project may not exceed 10% of the project value.* | |
| • CMC team leader - PLN 4,000 x 18 months | **PLN 72,000** |
| • Project coordinator PLN 2,000 x 18 months x 2 persons (doctor and midwife - ½ time job) | **PLN 72,000** |
| • Project administrative coordinator: PLN 2,800 x 18 months | **PLN 50,400** |
| • Project accountant: PLN 2,000 x 18 months | **PLN 36,000** |
| **Total costs** | **PLN 230,400** |
| **PURCHASE OF EQUIPMENT**<br>*Purchase of equipment (no possibility to purchase so-called fixed assets) may constitute up to 37% of the project value.* | |
| • Mobile workstations (POZ + AOS + CMC) – 11 pcs. x PLN 5,000<br>*(example parameters: screen 15,6'', 1920 x 1080 pixels 144 Hz, Processor Intel Core i5, 11300H 3,1-4,4 GHZ, Memory 16 GB DDR4 RAM, Graphic card NVIDIA GeForce RTX 3050 + Intel UHD Graphics, Disc 512 GB SSD)* | **PLN 55,000** |
| • Mobile phones for appointments and teleconsultations with cards (4 pcs. AOS/POZ ( 2 pcs. staff + 2 pcs. patients) - (40 pcs. x PLN 1,100) + (40 pcs. x PLN 30) = PLN 44,000 + PLN 1,200 | **PLN 45,200** |
| • Mobile phone in CMC with card – PLN 1,100 + PLN 100 | **PLN 1,200** |
| • Earphones with microphone (POZ + AOS + CMS) – 11 pcs. x PLN 150 | **PLN 1,650** |
| **Total costs** | **PLN 103,050** |
| **COSTS FOR RENTING EQUIPMENT**<br>*Due to the limitations of the specific value of pilot projects (EUR 200,000-675,000) adopted by the "Health" Programme, equipment rental is necessary for the implementation of the pilot. In the case of nationwide implementation, its purchase is ultimately recommended.* | |
| • Rental of a mobile CTG (price for its rental per week: approx. PLN 150/week), i.e. approx. PLN 300/2 weeks; 300 (no. of patients) x PLN 300<br>*Recommended technical parameters of CTG: frequency: 1 MHz, pulse doppler PW + DSP system, FHR measurement range: 50~210 BPM , accuracy: ±2 BPM, TOCO Measurement range: 0-100% , accuracy: <10%, movable alphanumeric LED 7" screen, low and high heart rate alarm functions, end of paper, etc., built-in thermal printer 110 mm, power supply: AC 100V-240V 50/60 Hz, built-in battery.* | **PLN 90,000** |
| **TELEMEDICINE SERVICE COST** | |
| • Remuneration for AOS doctor/primary care midwife for recruiting a declared number of patients - PLN 100 per patient (300 x PLN 100)<br>• Remuneration for gynaecologist-obstetrician / midwife who carry out the pregnancy: PLN 100 per teleconsultation x 300 patients (maximum 3 teleconsultations during pregnancy) = 300 x (PLN 100 x 3) = 300 x | **PLN 30,000** |

| | |
|---|---|
| PLN 300 | **PLN 90,000** |
| • POZ manager: PLN 1000 when signing the contract x 5 | **PLN 5,000** |
| • AOS manager: PLN 1000 when signing the contract x 5 | **PLN 5,000** |
| • Remuneration for midwife for teleeducation (60 min): PLN 100 x 300 patients (number of consultations consistent with the guidelines of standard: 28) = 300 x (PLN 100 x 28) = 300 x PLN 2,800 | **PLN 840,000** |
| • Midwife consultations with CMC doctor: 300 x PLN 100 | **PLN 30,000** |
| **Total costs** | **PLN 1,000,000** |
| **TELEMEDICINE PLATFORM SERVICE COST** | |
| • Solution Coordinator / IT Team Leader - 1 x 14,000 x 18 months | **PLN 252,000** |
| • DevOps Engineer - 2 x 12,000 x 18 months | **PLN 432,000** |
| • Developer - 1 x 8,000 x 18 months | **PLN 144,000** |
| • Software tester - 1 x 6,000 x 18 months | **PLN 108,000** |
| • Computer graphic designer 1 x 4,500 x 3 months | **PLN 13,500** |
| • Tele-consultation coordinator - 1 x 4,000 x 18 months | **PLN 72,000** |
| **Total costs** | **PLN 1,021,500** |
| **COSTS OF PROMOTION, INFORMATION AND PREVENTIVE ACTIVITIES** | |
| • Maintenance of information profile in social media: PLN 1000/month x 18 months | **PLN 18,000** |
| • Ads and information in social media, promoting pilotage project, addressed to public in Poland during 18 months: PLN 500/month x 18 months | **PLN 9,000** |
| • Content marketing - sponsored articles with nationwide reach: 3 articles within 18 months: 3 x PLN 15,000 | **PLN 45,000** |
| • Conference opening and closing the project (including: costs of the room, catering, speakers' speeches) 2 x PLN 30,000 | **PLN 60,000** |
| • Printing leaflets, posters | **PLN 20,000** |
| **Total costs** | **PLN 152,000** |
| **OTHER COSTS** | |
| • Provision of a platform for the project by an external provider | **PLN 80,000** |
| • Development of Information Security Policy | **PLN 6,000** |
| • Cost of courier shipments (delivery of equipment, educational materials to POZ practices, AOS, etc.) | **PLN 10,000** |
| • Educational materials (publications, handbooks), e.g. on prevention | **PLN 20,000** |
| • Office supplies | **PLN 10,000** |
| • Development of the Project Risk Prevention Policy | **PLN 6,000** |
| **Total cost of this category:** | **PLN 132,000** |

**SUMMARY COST**

| | |
|---|---|
| Project management cost | **PLN 230,400** |
| Equipment purchase cost | **PLN 103,050** |
| Renting equipment cost | **PLN 90,000** |
| Telemedicine service cost | **PLN 1,000,000** |

| | |
|---|---|
| Telemedicine platform service cost | **PLN 1,021,500** |
| Promotion, information and preventive activities cost | **PLN 152,000** |
| Other cost | **PLN 132,000** |
| **Total costs** | **PLN 2,728,950** |

NOTES:

- Estimated costing has been provided on the basis of cost analysis of past projects of similar scope.
- Final costs may vary slightly depending on changing market prices.
- The final implementation of the project activities will depend on the date of signing the grant agreements.
- In addition to the above-mentioned visits, in order to provide adequate care to the pregnant woman, standard services should be implemented, in accordance with the standard of perinatal care (within the framework of the National Health Fund),
- The cost analysis does not take into account possible changes due to rising inflation.
- The analysis does not take into account the costs of project insurance.

CMC

**MEDIA INFORMATION**

**AOS/POZ OFFER (VILLAGES)**

PREGNANT WOMEN RECRUITMENT (AOS/POZ)

OBSTETRICIAN-GYNAECOLOGIST/MIDWIFE
FIRST VISIT, INTERVIEW, CONFIRMATION OF PREGNANCY, GENERAL AND GYNAECOLOGICAL EXAMINATION, RISK ASSESSMENT, ESTABLISHING DOCUMENTATION

**CREATION OF A PREGNANT WOMAN'S VIRTUAL ACCOUNT (WKKC)**

PERINATAL CARE ORGANIZATIONAL STANDARD

DEPRESSION SCALE (11-14 Hbd and 33-37 Hbd)

BIRTH PLAN

FETAL MOVEMENTS APPLICATION

OBSTETRICIAN-GYNAECOLOGIST

MIDWIFE

**PREGNANT WOMAN**
CONDUCTING THE PREGNANCY VISITS + TELECONSULTATION
BIRTH DATE (CTG)

21-26 Hbd

**PREGNANT WOMAN**
CONDUCTING THE PREGNANCY VISITS + TELECONSULTATION
TELEEDUCATION
BIRTH DATE (CTG)

**BIRTH**