SPECIAL REPORT

Comprehensive Heart Failure Care pilot study: starting point and expected developments

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Introduction Heart failure (HF) is a health problem characteristic of aging populations with cardiovascular diseases.¹ It is estimated that in Poland the number of people with HF exceeds 750 000. Recent data from the Polish National Health Fund (Narodowy Fundusz Zdrowia [NFZ]) show that the public healthcare sector treats 650 000 people a year (Nessler J, Kozierkiewicz A, Gackowski A, et al. Heart failure treatment in Poland in 2010–2017. Unpublished data, 2019). It is anticipated that the number of patients with HF will increase by almost 25%, which will create a significant burden to society.²

The current state of care for patients with HF and resulting challenges have been analyzed by numerous academic institutions and think tanks in the recent years.²⁻⁴ Among the most serious of the identified problems were shortcomings in prehospital care (which translate to both late diagnosis and absence of appropriate medical supervision). Inadequate optimization of treatment, in particular, leads to worsening of the condition and hospitalization. This is of particular importance for patients released from the hospital after acute decompensated HF, for whom the risk of repeated exacerbation is very high but could be prevented by optimizing treatment. Also noticeable is the lack of coordination between medical units providing care to patients, including limited communication, leading to repeated examinations and suboptimal therapeutic decisions. The fact that certain services are unavailable as one-day procedures or without hospitalization, on the other hand, leads to unnecessary hospital admissions. Limitations persist after hospitalization, mainly in terms of access to advanced therapy—caused by a budget ceiling—which lengthens the waiting time for some procedures (such as ablation, implantation of devices like pacemakers or implantable cardioverter-defibrillators and some valve procedures). This has significant implications for patient survival rates, especially

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in those with advanced stages of illness. Patients do not have sufficient knowledge about HF, especially concerning the need for a systematic administration of medication and avoidance of risk factors.⁵ They are also ill-prepared to self-test for symptoms, even though, as for acute decompensated HF, these could be spotted with relative ease by monitoring body weight, heart rate, and blood pressure.⁵ Repeated acute decompensated HF leads to gradual worsening of heart function as well as of the condition of other organs, which in turn lowers the survival rates of patients with HF.³

The aforementioned problems together with the increasing number of patients with HF as well as difficulties in providing treatment have prompted the Polish Cardiac Society (Polskie Towarzystwo Kardiologiczne [PTK]) to propose a care model for patients with HF, namely, the comprehensive heart failure care (Polish, Kompleksowa Opieka nad Osobami z Niewydolnością Serca – KONS) model. It is a coordinated care system, designed for patients with high risk HF, who have been diagnosed with stable HF and discharged from the hospital due to disease exacerbation (acute decompensation). It aims to deliver a comprehensive scope of care by combining outpatient care, pharmacology, interventional treatment (invasive cardiology, electrotherapy, cardiac surgery), and rehabilitation. The proposed model of care will offer multidisciplinary, continuous, and coordinated care, aiming to engage the patient in his or her treatment. This will enable obtaining appropriate services within an acceptable time frame. The KONS will complement the cardiological healthcare that is currently offered (Polish, Kompleksowa Opieka nad Pacjentem po Zawale Serca),⁷ and improve the system of coordinated care within primary healthcare (Polish, podstawowa opieka zdrowotna – POZ).⁷ The PTK initiative was approved by the Minister of Health and qualified for implementation as a pilot study.⁸

The principles of the KONS, which have been accepted as the policy basis in an ordinance by the Minister of Health and in a bylaw by the President of the NFZ, will be presented below.

KONS principles of patient care The ordinance published by the Minister of Health has defined the main goal and specific objectives of the KONS. The main goal is to "limit the occurrence of consequences of HF," while the specific objectives are as follows: early discovery of HF and determination of its etiology, inhibiting disease progression, optimizing the use of health-care resources in HF care, improving lives and longevity of patients with HF as well as limiting the exacerbation of the disease.⁹⁻¹²

Aims of the KONS are focused on removing the existing problems and improving the effectiveness of HF treatment. An early diagnosis of HF can be made possible by widening the scope of diagnostic possibilities available within POZ and introducing, for example, natriuretic peptide concentration markers, which would allow to rule out HF. This would also limit the number of patients directed to outpatient care to confirm HF.

Identifying patients with HF and including them in the KONS program will require additional funding for procedures necessary for pinpointing the causes of the illness and selecting treatment in line with the valid standards. This care model assumes optimal use of resources by relying on preferential financing of outpatient and 1-day services (as opposed to inpatient care). Outpatient care of patients with HF will also be promoted, both for patients who have been diagnosed but are awaiting treatment optimization as well as patients recently discharged from the hospital. POZ will perform these services and in the event of exacerbation of the disease, depending on their needs, patients will be directed to day wards. If their condition worsens and their prospects of recovery remain limited, they will be referred further to inpatient care.

Introducing well-functioning outpatient care, based on the cooperation of a cardiologist with other specialists and a general practitioner should improve the quality of care and of patients' lives. Ongoing active supervision of patients with stable HF conducted by general practitioners and education of patients about self-care carried out by nurses should translate to a lower number of acute decompensated HF episodes and, consequently, slower the progression of the disease. Possibly, advanced treatment strategies, combined with proper supervision and rehabilitation will eventually lead to improved quality of life and longevity in patients with HF.

Methods of financing Currently, POZ is financed primarily from capitation fees, which are differentiated according to age rather than health status of the patient. As part of the KONS, from the moment of including the patient in the program, it will be possible to obtain additional funding for the POZ medical unit as well as services that were so far unavailable, such as natriuretic peptide concentration marking (Btype natriuretic peptide, N-terminal fragment of the prohormone brain natriuretic peptide), echocardiography, consultations with a cardiologist, and education by a nurse with appropriate training. Patients will be able to access these services at the KONS group medial units or POZ medical units, which will be refunded from the POZ fundhold budget. It should be noted that the refunding is based on the diagnosis of stage II HF or higher according to the New York Heart Association and the patient's consent to participate in the program. Because of this, the services preceding the diagnosis have to be financed from

capitation fees of the medical unit or the lump sum of the hospital, where the diagnosis was made. The authors of the KONS assume that in the future, the B-type natriuretic peptide / N-terminal fragment of the prohormone brain natriuretic peptide test, too, will be available even to patients not yet qualified for the KONS to further improve diagnostic workup.

The continuation of the diagnostic workup (particularly determining the disease's etiology and aggravation) will be funded as part of the KONS. The KONS medical units will have the opportunity to perform certain services, especially diagnostic, without limit, as long as they will be performed in outpatient or 1-day modes. Services for patients included in the KONS will also be treated as continuation of their treatment and so, appointments will be set on the basis of clinical need, rather than on a first-come-firstserved basis.¹³ That way, the KONS medical units will be motivated to perform certain services by settling them outside of the lump sum of the national hospital network.¹⁴

Hospitalizations, with the exception of hospitalization required to perform highly-specialized services, will not be additionally funded, which means that they will be settled as part of existing lump sum of the national hospital network. This will promote diagnostic workup in outpatient or 1-day modes rather than during hospitalization.

The selected highly-specialized services, from coronary angiography and coronaropathy, through ablation, to implantation of devices like pacemakers or implantable cardioverter-defibrillators, will also be available to patients included in the KONS since there is special financial support. Further, the KONS medical facilities will have to offer the necessary rehabilitation. To preclude the possibility of overutilization of services, the absence of numerical limit for services will be compensated by an ongoing analysis of data and public presentations (*benchmark*) of indices characterizing the treatment patterns in the KONS units.

The valuation of currently offered services for settlement purposes will not change. The services performed in outpatient or 1-day modes, which are necessary for the diagnostic and therapeutic processes, but are not settled separately, have been identified and their valuation was made on the basis of their market value. Moreover, the NFZ will introduce predicators that should raise the valuation of certain services, especially for patients who have not used hospital services for the period of 6 months. In this way, outpatient and 1-day care is clearly prioritized.

Organizational structure In order to care for patients with HF in a coordinated manner, it was decided that the KONS groups should be established. These would include a few medical units.

Their hierarchy will resemble a pyramid, where POZ facilities would be the foundation, vertically integrated with hospitals of various reference levels (FIGURE 1). This kind of integration is functional, though it is not impossible that certain POZ facilities may operate within broader structures, similar to those that functioned in the past—as integrated specialist healthcare teams.¹⁵ A facility of the highest reference level would be at the top of the pyramid, fully competent to treat complicated cases of HF, which will serve as educational support for other units in the group.

The hospitals of lower reference levels will be placed between POZ facilities and the facility at the top of the pyramid. These hospitals should have at their disposal an internal disease department or a coronary care unit and an emergency department, and day-care services should be available. Higher reference level hospitals should perform coronary angiography and angioplasty, as well as electrocardiology, interventional cardiology, and cardiac surgery, including extracorporeal membrane oxygenation.

Patients with less severe HF will remain under the care of teams of POZ doctors and nurses, who will be continuously supported by consultant-cardiologists and nurses whose specialty is HF and who work in the KONS hospitals. As a result, POZ teams will be responsible for treating patients with HF whose condition is stable. These teams will provide the necessary services: medical care, nursing care, education, drugs administration as well as monitoring of patient compliance with physicians' advice. Consultant-cardiologists will offer ongoing support to general practitioners in diagnosing and treating patients with HF, but will not replace them. One innovation is that in their cooperation with POZ, cardiologists will offer consultations to their colleagues, general practitioners, where they will discuss clinical decisions via phone or other means of communication.

The detailed terms of this cooperation as part of the KONS will be developed at a local level, in response to diverse conditions. In larger agglomerations, it is possible and likely that some facilities will function as 2 or even 3 reference levels. Due to geographical concerns, in smaller towns, it may be necessary for local hospitals to adjust their activity to the proposed model to provide appropriate care.

Cooperation agreement A medical unit's participation in a KONS group is voluntary and should grant it a competitive advantage in the eyes of patients with HF. Facilities belonging to a KONS group will function as a consortium and will be bound by a cooperation agreement that, as a civil contract, could be altered freely by the group's members. Such contracts would determine the units' role in the group, ways of providing treatment, directing patients to particular

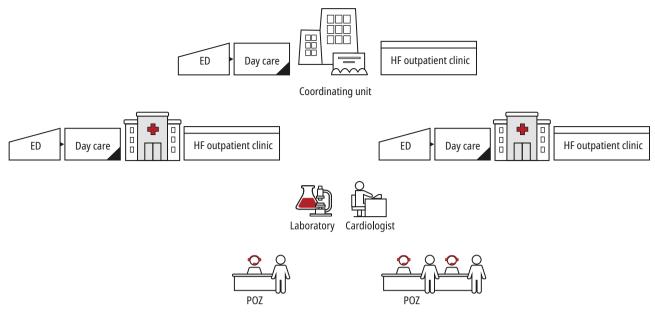


FIGURE 1 Organization of a KONS group

Abbreviations: ED, emergency department; POZ, primary healthcare in Poland (Polish, podstawowa opieka zdrowotna)

hospitals to obtain planned services as well as processing patient data. Furthermore, the crucial point of the agreement is to create a sense of community with shared goals. It is assumed that the facilities which do not perform will be properly incentivized or (if that does not help) eventually excluded from the group.

Clinical guidelines and monitoring of the quality of services The KONS facilities should implement the clinical guidelines by the European Society of Cardiology appropriate for the diagnostic workup and treatment of HF.^{12,16-18} It is also planned that prerogatives created by article 11 of the Act of August 27, 2004⁸ should be utilized, and the guidelines will be published in the form of a notice by the Minister of Health. The coordinating facility will be responsible for supporting good diagnostic and therapeutic practices, training the personnel, and overseeing the quality of services.

The KONS facilities will be encouraged to implement the treatment protocols for treating patients with HF, especially in emergency intervention as well as cooperation with other facilities to educate and plan the care regimen for patients suggested by the KONS group (which will remain open to modification). Furthermore, an individual medical care plan will be introduced to serve as a formal guideline for a patient and medical staff treating him or her.

A quality monitoring system will also run during the pilot stage, and the minimal range of quality indicators (TABLE 1) has been selected by the Minister of Health, allowing for a high level of flexibility for more specific quality monitoring. These indicators, by design, can be generated based on data collected by the NFZ for financial settlement purposes. Other possible indicators would require more elaborate data registration.

Information system The collection and flow of information about the patients, the course and effects of treatment, is a very important part of the KONS model. The information system will consist of a few parts, making the most of the already existing and available resources and tools of the NFZ and the Center of Information Systems for Health Care.

The main data set will be comprised of data collected for reimbursement purposes on the basis of the XML SWIAD communication protocol. This data set is necessary for accounting purposes and can be launched immediately, as all sides already have the required software for inputting information and transferring it to the NFZ. This data set will be supplemented with selected clinical data registered after performing certain services. It will allow to monitor the key clinical parameters to track the tempo of the disease's progression or remission.

A tool for exchanging medical documentation will also be introduced. For the moment, only a limited set of documents specified in the ordinance by the Minister of Health has been indicated and it includes referrals for examination or consultation and its result as well as hospital discharge card.¹⁹

Collecting data that portrays the state of health from the perspective of the patient will be a novelty in the Polish system.²⁰ As part of patient-reported outcome measure, short questionnaires comprising of a few questions (eg,

TABLE 1 Quality and effect indicators for the quality monitoring system in KONS facilities

| No | Indicator |
|-----|---|
| No. | |
| 1a | Ratio of patients admitted by a GP, with HF or suspected HF, in the GP captive population |
| 1b | Standardized ratio of patients admitted by a GP, with HF or suspected HF, in the GP captive population |
| 2 | Ratio of patients enrolled to the KONS, in the GP captive population with HF |
| 3 | Ratio of cardiology consultations provided to the population of patients enrolled to the KONS |
| 4 | Ratio of unique patients with exacerbation of HF who require emergency health intervention in the population of patients enrolled to the KONS |
| 5 | Ratio of unique patients with exacerbation of HF who require hospital admission in the population of patients enrolled to the KONS |
| 6 | Ratio of unique patients admitted to the hospital in the population of patients enrolled to the KONS |
| 7 | Ratio of unique patients admitted to the hospital because of HF in the population of patients enrolled to the KONS |
| 8 | Ratio of unique patients admitted to the hospital ED because of HF in the population of patients enrolled to the KONS |
| 9 | Ratio of patients admitted to HF outpatient clinic in the population of patients enrolled to the KONS |
| 10 | Ratio of patient visits to HF outpatient clinic in the population of patients enrolled to the KONS |
| 11 | Ratio of consultations of HF outpatient clinic to the GPs in the population of patients enrolled to the KONS |
| 12 | Ratio of patient visits to HF outpatient clinic after discharge from the hospital in the population of patients enrolled to the KONS discharging hospital |
| 13 | Ratio of patients treated by a GP with medicines from at least 2 from following groups: ACEI, ARB, BB, MRA, in the GP captive population |
| 14 | Ratio of patients treated by a GP, with medicines from at least 2 from following groups: ACEI, ARB, BB, MRA, in patients admitted by the given KONS medical unit |
| 15 | Ratio of patients provided with rehabilitation services after discharge from the hospital in the population of patients enrolled to the KONS discharging hospital |
| 16 | Ratio of patients who died within 30 days after discharge from hospital in the population of patients enrolled to the KONS discharging hospital |
| 17 | Ratio of patients readmitted within 30 days after discharge from the hospital in the population of patients enrolled to the KONS discharging hospital |
| 18 | Ratio of procedures (listed in Annex 1 to the ordinance by the Minister of Health) provided to unique patients with exacerbation of HF who require emergency health intervention in the population of patients enrolled to the KONS |

Abbreviations: ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker, sartans; BB, β-blocker; ED, emergency department; GP, general practice (-tioner); HF, heart failure; KONS, comprehensive heart failure care; MRA, mineralocorticoid receptor

> regarding the ability to walk up the stairs, weight gain, swelling of ankles) will be an aid in following the state of health and quality of life of a patient as well as in shaping the care he or she will receive. This tool will also function in a simplified manner as a mobile application, where information, such as medicine use, current weight and heart rate, can be reported.

> Eventually, the aforementioned data streams will become integrated. This can be done by combining records regarding particular persons on the basis of their patient ID (eg, national personal identification number, PESEL). This, however, will require setting terms in line with personal data protection laws (such as the General Data Protection Regulation). Integration could also be achieved by creating a Registry of Heart Failure (Krajowy Rejestr Niewydolności Serca) by feeding it the data from the sources mentioned above.

> **Expected results** The KONS model has been designed so as to halt the progress of the disease, maintain optimal life quality, prolong lives of patients with HF as well as limit the number of hospitalizations.

Patient care will be focused on the following:

1 Appropriate patient education conducted by a trained educator (eg, a nurse) and focusing on cooperation with doctors and clinical self-assessment. This will allow for self-monitoring of symptoms and modification of diuretic treatment.

2 Active surveillance of the course of illness, especially after discharge from hospital.

3 Easier access to care during episodes of acute decompensated HF.

4 Optimizing pharmacotherapy.

5 Optimal employment of revascularization, electrotherapy, cardiac surgery and minimally invasive structural procedures.

6 Providing psychosocial support for patients, their families and/or caregivers.

7 Quality monitoring and improvement measures.

Conclusion The Comprehensive Heart Failure Care model is a form of disease management program based on vertically coordinated structure of medical facilities. The KONS model implements the idea of coordinated care, a system in which every medical procedure follows from the preceding one and is planned (or at least anticipated) and facilities that arrange them understand their own role in the diagnostic and therapeutic processes. It offers continuous care, which ensures that the patient's condition is optimal and stable for as long as it is possible. Care offered as part of the KONS is active and patient-centered. In an organized manner, medical units will seek to respond to, and frequently to anticipate, his or her needs. The proposed model of care for patients with HF is another example of disease management, following the coordinated care program for patients with Acute Coronary Syndromes, introduced in 2017 and numerous programs introduced by the NFZ in relation to rare or particularly costly diseases (eg, hemophilia).

Due to its complexity, the KONS model will first be implemented as a pilot study. If it proves successful, it will gradually be expanded to encompass the whole country. Optimal use of the healthcare system's resources, particularly working time of doctors and nurses, will be emphasized during the pilot stage as well as later. This will be done by concentrating on proven and justified procedures and delegating certain tasks to other personnel.

The goal of all of the undertaken procedures is to lengthen and improve the lives of patients with HF as much as possible. The expected optimization of the functioning of the system is necessary due to the increasing occurrence of HF in the Polish aging population.

ARTICLE INFORMATION

CONFLICT OF INTEREST None declared.

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