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ORIGINAL ARTICLE

Project of the Health Policy Program: Access to Vessels in Renal Replacement Therapy – Fistula First/Catheter Last

Authors' Contribution:
A – Study Design
B – Data Collection
C – Statistical Analysis
D – Data Interpretation
E – Manuscript Preparation
F – Literature Search
G – Funds Collection

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ABSTRACT:

Introduction: The number of patients with end-stage renal failure (ESRF) that require inclusion in the renal replacement therapy program (RRT) is steadily increasing. This fact caused an increase in vascular operations involving the production of vascular access. According to the current guidelines, the best and safest option for a patient with chronic kidney disease (CKD) is the early creation of arteriovenous fistula (AVF). An efficient vascular access to haemodialysis determines the procedure and directly affects the quality of life of a patient with CKD.

Aim: The aim of this paper is to present the author's project of the health policy program „Vascular access in renal replacement therapy – fistula first/catheter last", the essence of which is to assess the practical effectiveness and develop an optimal model of CKD patient care organization qualified for the chronic RRT program.

Material and methods: The target population of the program consists of all patients diagnosed with CKD, qualified for the RRT program. The basic measures of the program's effectiveness include: (1) reduction in the number of re-hospitalizations related to vascular access, (2) reduction in the number of complications associated with haemofiltration surgery, (3) reduction in general mortality among patients undergoing dialysis in a 12-month perspective, (4) increasing knowledge in the field of self-care and self-care of arteriovenous anastomosis, and (5) creating a register of vascular access in Poland.

Conclusions: To sum up, health policy programme "Vascular access in renal replacement therapy – fistula first/catheter last" covering health care services provided in the scope and on the conditions specified in the regulations issued on the basis of article 31d of the Act of 27 August 2004 on health care benefits financed from public funds, is to check whether planned changes in the organization and delivery of services will improve the situation of patients with CKD eligible for chronic RRT and whether it will be effective the point of view of the health care system.

KEYWORDS: chronic kidney disease, comprehensive care, dialysis vascular access, haemodialysis, improvement of effectiveness, renal replacement therapy

ABBREVIATIONS

AVF – arteriovenous fistula
CKD – chronic kidney disease
EBPG – European Best Practice Guidelines
eGFR – estimated glomerular filtration rate
ESRF – end-stage renal failure
HFD – high-flux dialysis
KDIGO – Kidney Disease Improving Global Outcome
KDOQ – Kidney Disease Outcome Quality Initiative
LFD – low-dialysis
NHF – National Health Fund
QOL – quality of life
RRT – renal replacement therapy

BACKGROUND

Among modern civilization-related diseases, apart from common cardiovascular diseases, hypertension, obesity and diabetes, chronic kidney disease (CKD) has recently been mentioned as well [1]. The number of CKD patients, and in particular end-stage renal failure patients (ESRF), requiring inclusion in a renal replacement program (RRT), is constantly increasing [2].

This situation is becoming a challenge for clinical nephrology by the increasing number of patients requiring RRT, resulting in an increase in vascular operations involving the production of vascular access [3]. According to the recommendations of European Best Practice Guidelines (EBPG) the best and safest option for a patient with CKD is early production of an arteriovenous fistula (AVF) [4]. An efficient vascular access to haemodialysis determines the haemodialysis procedure and directly affects the quality of life (QOL) of the patient with CKD [5].

Chronic kidney disease

Referring to the guidelines of the American working group Kidney Disease Outcome Quality Initiative (KDOQ) [6] and international experts from Kidney Disease Improving Global Outcome (KDIGO) [7], CKD is defined as a multi-symptom syndrome formed as a result of permanent damage or reduction in the number of active nephrons destroyed by various disease processes ongoing in the kidney parenchyma [8]. In other words, it is an irreversible decline in glomerular filtration associated with the progressive disappearance of active renal parenchyma [9].

From a practical point of view, CKDs were divided into 5 stages that closely correlate with the degree of kidney function measured by the estimated glomerular filtration rate (eGFR) and the pres-

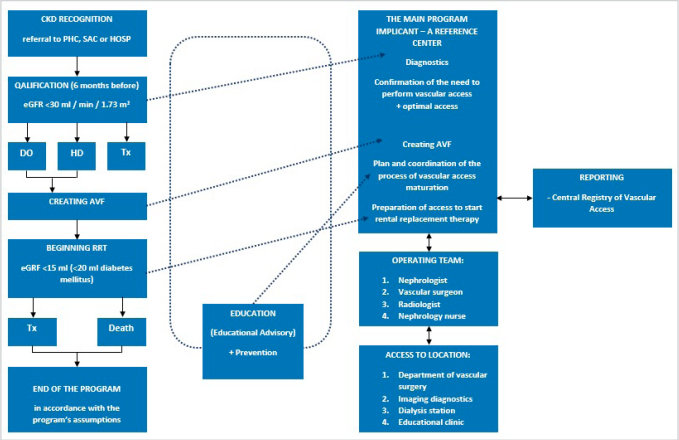

Fig. 1. Scheme of the program „Vascular access in renal replacement therapy – fistula first/catheter last".

Abbreviations: **CKD** – chronic kidney disease; **SAC** – specialist ambulatory care; **PHC** – primary health care; **HOSP** – hospital care; **DO** – peritoneal dialysis; **HD** – hemodialysis; **TX** – kidney transplantation; **RRT** – renal replacement therapy; **eGFR** – estimated glomerular filtration rate; **AVF** – arteriovenous fistula.

Fig. 2. Stages of the program together with detailed actions taken in the next program modules.

Abbreviations: **AVF** – arteriovenous fistula; **RRT** – renal replacement therapy.

ence of kidney damage features in the examinations. The criterion for diagnosing V stage CKD is permanent eGFR <15 ml/min / 1.73 m^2 or RRT (dialysis) [10]. Among the causes of ESRF, diabetic nephropathy is found predominantly in about 30% of patients included in the RRT program, glomerulonephritis in about 20%, and hypertensive nephropathy in about 15% [11].

The introduction of a new definition and classification of CKD in 2002 in the opinion of specialists has significantly influenced the breakthrough in clinical nephrology. Epidemiological studies conducted on the basis of this study show that kidney diseases affect more than 10% of the world's population [12]. As results from the presented data obtained in the POLNEF epidemiological pilotage [13], the incidence of CKD varies between 9–15% of the population studied. Taking into account albuminuria, which was the decisive indicator in this study, CKD was diagnosed in 11.9% of people. Considering other symptoms, the percentage of people increases to 18%. This is particularly important in the context of modern civilization diseases, such as hypertension, obesity or diabetes.

According to data from the National Health Fund (NHF) of Poland in 2018, the program of chronic RRT (haemodialysis) covered 24496 patients, including those diagnosed according to the ICD-10 classification: N18.0 End-stage renal failure 21951, N18.8 Other chronic renal failure: 898 and N18.9 Chronic renal failure, unspecified [14].

Renal replacement therapy

The consequence of the loss of renal function is the increase in the concentration of unperturbed compounds in the extracellular space, including plasma [15]. The retention of protein catabolism products, purines and pyrimidines is of particular importance. Accumulation of uremic toxins leads to non-respiratory acidosis, oedema, water-electrolyte disturbances and secondary hyperparathyroidism [16].

The minimum goal of renal replacement therapy (RRT) in patients with ESRF is to prevent the arbitrarily set values of selected uraemic toxaemia parameters from being exceeded, which is to ensure survival and QOL similar to that in the period preceding dialysis [17, 18]. The mortality of hemodialyzed patients is assessed as high and the number of organ related complications is high [19].

The two basic types of dialysis are haemodialysis (extracorporeal dialysis) and peritoneal dialysis (intracorporeal dialysis), whereas in Poland >90% of patients are haemodialysed. The purpose of RRT is to provide the patient with the length and quality of life similar to normal kidney function, by maintaining the correct composition and volume of body fluids – such results can be achieved after kidney transplantation and probably also using daily haemodialysis [20].

The classic haemodialysis treatment involves simultaneous implementation of two processes, i.e. diffusion and ultrafiltration. It is a procedure commonly used in patients with an extreme form of CKD. A single treatment lasts 4–5 hours (usually 240 minutes) and is usually repeated three times a week [21]. Variations are also possible due to the time interval (>3 days per week) and the duration of a single treatment (extended, short, ultra-short). Due to the size of the ultrafiltration coefficient of the dialyzer, the division into low- (LFD) and high-flux dialysis (HFD) is used [22].

HFD is currently the preferred technique in European clinical practice guidelines, especially in patients at high risk of complications, but both methods are used in Polish centres, thus representing Polish clinical practice. In order to improve the adequacy (effectiveness) of haemodialysis in selected patients, the treatment time is extended (e.g. up to 5 hours) or the weekly number of treatments is increased (e.g. up to 4 weeks) [23, 24].

Vascular access

A characteristic feature of CKD is its slow course and persistent for a long time mediocre symptoms. However, over time, the disease undergoes a gradual (sometimes very dynamic) exacerbation. Then it is necessary to make a decision about choosing the optimal RRT for the patient [25, 26].

It is considered that RRT should be switched on optimally early. The patient included in the RRT program must be fully aware that the ability to perform effective haemodialysis depends on his/her involvement

Tab. I. Structure of the implementation of medical procedures related to the production of vascular access in renal replacement therapy in 2017.

GROUP CODE	PROCEDURE CODE	PROCEDURE NAME (ACCORDING TO ICD-9)	NO. OF HOSPITALIZATIONS	MEDIAN TIME OF HOSPITALIZATION
Q51	39.275	Creation of AVR on the arm using vascular prostheses	210	2
	39.425	AVR reconstruction using a vascular prosthesis	110	2
	39.273	Creating AVR on the forearm with the use of vascular prostheses	40	2
Q52	38.952	Insertion of permanent dialysis catheter	3233	2
	39.272	Creating AVR from own vessels on the forearm	2837	1
	39.274	Creation of AVR from own vessels on the shoulder	1555	2
	38.951	Insertion of a dialysis time catheter	1382	3

Source: own study based on: National Health Fund. JGP statistics. Accessed on February 13, 2019. Internet source: https://prog.nfz.gov.pl/app-jgp/Start.aspx
Abbreviations: AVF – arteriovenous fistula; **ICD-9** – International Classification of Diseases-9th Revision.

in self-care and self-care of arteriovenous malformation [27]. According to EBPG recommendations, the best and safest option for a patient with CKD is early AVF. An efficient vascular access to haemodialysis determines the procedure and directly affects the QOL of the patient with CKD [28].

AVF is a subcutaneous artery anastomosis with a vein adjacent to it. It is the most secure and long-lasting, permanent vascular access. The precondition for primary AVF formation on the forearm is proper arterial blood supply to the limb, undamaged superficial veins and free venous outflow [29]. The advantages of this anastomosis include very good blood flow and a low rate of complications such as infection or stenosis. Among the defects of AVF should be pointed out for a long time from its creation until its use [30].

In the modern world, the clinical problem is not to provide vascular access to haemodialysis, but above all to maintain its patency. Making it out of patients' own vessels and maintaining a permeability of vascular access is a big challenge for specialists in the field of vascular surgery. According to observations, in the first year after AVF production, one of the main reasons for repeated hospitalization is the problem of maintaining the fistula patency [31].

Some problems may be due to technical problems or poor patient qualification. Other most commonly occurring later include those associated directly with the haemodialysis procedure itself (decrease in pressure after dialysis, coagulation disorders, inappropriate technique of AVF puncturing by nursing staff) and resulting from non-compliance by the patient with AVF self-care principles. It should be emphasized that complications related to vascular access are today one of the most important causes determining mortality in patients undergoing dialysis [32, 33].

Types of permanent vascular access in RRT: AVF produced from the patient's own vessels, AVF produced using vascular prostheses, vascular catheters placed in large vessels using tunnelling [34].

Current proceedings

Complications associated with vascular access are a significant cause of hospitalization of patients qualified for chronic RRT. The most common cause of malfunctioning of AVF is partial or complete lack of blood flow through the fistula associated with vasoconstriction or thrombosis in the vascular access [35]. Favourable factors are: the degree of primary damage to the patient's own vessels, slow blood flow and strains damaging the vessel wall, previous vascular diseases, systemic factors [36]. The age of the patient, sex, smoking, diabetes, fistula localization, blood pressure, anaemia, disturbances in mineral and bone metabolism and malnutrition also play an important role [37, 38].

Due to the fact that patients with RRT are dialyzed on average 3–4 times a week, it can be assumed that they are in fact one of the most controlled groups of patients in the outpatient specialist care system [39]. Importantly, the inability to carry out an effective haemodialysis operation unambiguously allows assessing the occurrence of complications within the vascular access. As we know, demographic and clinical factors influence the correct function of the anastomosis, but it is extremely important that the anastomoses are produced in an optimal and safe way for the patient. This also applies to vascular catheters used with RRT [40].

Before the creation of AVF, an important role is played by: (1) a primary care physician (CKD diagnosis time); (2) nephrologist (optimal qualification for RRT, decision to produce AVF in advance; (3) vascular surgeon (determines the place of production and type of RRT – own vessels, vascular prosthesis, catheter) and (4) nurse (saving superficial venous vessels, education in the field of self-care and self-care) [41].

As already mentioned, due to the nature of the service, in the decision-making process related to the treatment of RRT complications and/or malfunctioning AVF, the main role is played by: (1) the interview collected from the patient (self-observation, e.g. the patient does not feel murmuring, feverish, see pain and redness in the AVF area); (2) nurse of the dialysis centre (problems with puncture and fistula functioning during hemodiafiltration); (3) doctor of the dialysis centre (initial assessment, contact with a surgeon, radiologist) and (4) a vascular surgeon (decision about the necessity to perform a repair procedure or the creation of a new AVF) [42, 43].

Epidemiological data

According to NHF data [14], in 2017, the number of hospitalizations related to vascular access in RRT with the use of vascular prostheses (group Q51) was 360 (346 patients), while the amount of hospitalization associated with vascular access in RRT (group Q52) was 10590 (related to 7944 patients). Analyzing the previous years, the number of procedures (hospitalizations) associated with the creation of vascular access remains at a similar level.

The detailed structure of the implementation of medical procedures (according to ICD-9 classification) together with the number of

Tab. II. The structure of availability of renal replacement therapy services in individual provinces in Poland in 2019.

PROVINCIAL BRANCH OF THE NHF	NO. OF SERVICE PROVIDERS	NO. OF DIALYSIS STATIONS
Lower Silesian	20	389
Kuyavian-Pomeranian	11	264
Lublin	18	263
Lubusz	8	130
Łódź	9	334
Laser Poland	22	380
Masovian	36	599
Opole	9	137
Subcarpathian	15	245
Podlaske	9	129
Pomeranian	15	273
Silesian	38	563
Świętokrzyskie	10	137
Warmian-Masurian	7	193
Greater Poland	15	455
West Pomeranian	13	246

Source: own study based on data provided by the National Health Fund as of February 5, 2019.
Abbreviations: NHF – National Health Fund.

hospitalizations directly connected with the creation of vascular access (AVF from own vessels, anastomosis with vascular prosthesis, establishment of a dialysis catheter) are presented in Tab. I.

The author draws attention to the number of vascular access created using the dialysis permanent catheter (3233), compared to the AVFs created from the patient's own vessels (4392). Analyzing the median time of hospitalization associated with the procedure, it should be clearly indicated that only the creation of AVF from the vessels on the forearm allows one-day hospitalization of the patient (median duration of stay equal to 1).

In turn, services in the field of RRT (haemodialysis, peritoneal dialysis and, as a result of recent hemodiafiltration) in accordance with the Regulation of the Minister of Health of November 6, 2013 on guaranteed services in the field of outpatient specialist care are included in the list of guaranteed services and are financed from public funds [44]. The structure of accessibility to RRT benefits in 2019 is presented in Tab. II.

AIM OF THE STUDY

Presentation of the original project of health policy program entitled „Vascular access in renal replacement therapy – fistula first/catheter last". The essence of the prepared program is the assessment of practical effectiveness and the development of an optimal model of organization of care for a patient with CKD qualified for a chronic RRT program.

PROGRAMME DESCRIPTION

The project of health policy program „Vascular access in renal replacement therapy – fistula first/catheter last" provides for the coordination of all activities related to comprehensive care of a patient with CKD in the field of vascular access within a maximum period of 12 months from the time of vascular access. The draft program was prepared in accordance with the requirements of the Act of 27 August 2004 on healthcare services financed from public funds.

The main objectives of the program

The main purposes include: (1) increasing the availability of high-quality vascular surgery services consisting in the production of AVF from patients' own vessels; (2) increase in the proportion of patients in whom AVF was developed from their own vessels and (3) reduction of complications related to the use of AVF.

Detailed objectives of the program

The detailed objectives include: (1) developing a uniform standard for dealing with patients qualified for the RRT program, excluding patients with acute glomerular filtration loss requiring a time-limited haemodialysis program; (2) selection of reference centres, among service providers implementing procedures related to the creation of AVF, specializing in these procedures. Creating a standard, under the supervision of a national consultant in the field of vascular surgery and a national consultant in the field of nephrology, which will effectively affect the quality of services provided (performed). An additional goal, unique on a European scale, is: (3) to create a central register of vascular access.

Effectiveness of the program implementation

The basic measures of the effectiveness of the program include: (1) reduction in the number of re-hospitalizations regarding complications related to the production of vascular access; (2) reduction in the number of complications associated with haemofiltration surgery; (3) reduction of general mortality among patients undergoing dialysis in a 12-month perspective; (4) increasing knowledge in self-care and self-care of AVF and (5) creating a register of vascular access in Poland.

POPULATION CHARACTERISTICS

Target population

The target population of the program consists of all patients diagnosed with CKD, eligible for a chronic renal replacement program.

Eligibility criteria

Criteria for inclusion in the program: (1) diagnosed CKD, (2) eGFR <15 ml/min / 1.73 m^2, (3) consent of the patient to participate in the program and (4) qualification of the vascular surgeon to create AVF from patient's own vessels. Additional criteria were: (1) clinical manifestations of uremia, (2) refractory hypertension, (3) hyperkalemia not responding to pharmacological treatment, (4) high hyperphosphatemia, (5) anaemia disproportionately high in relation to the degree of renal failure, (6) severe metabolic acidosis and (7) hyperhydration.

Exclusion criteria from participation in the program: (1) acute glomerular filtration loss requiring a temporary haemodialysis program, (2) lack of patient's consent to participate in the program,

(3) disqualification of a vascular surgeon to produce AVF from patient's own vessels.

Planned interventions

Planned interventions include: (1) diagnosis of CKD; (2) qualification for production of AVF from own vessels for 6 months before inclusion in the chronic RRT program; (3) diagnostics (Main Program Implementator) in the scope of confirming the necessity of AVF implementation together with the determination of the optimal solution (own vessels, vascular prosthesis, dialysis catheter); (4) creation of AVF (Main Program Implementator); (5) education at the Educational Outpatient Clinic run by a nephrological nurse – defining a plan for the process of vascular access maturation along with education in the field of self-care related to the possession of vascular access; (6) commencement of a chronic RRT program in a dialysis centre selected by the patient – detailed preparation of vascular access for commencement of treatment/observation for complications; (7) ending the program – organ transplantation/death of the patient covered by the program; and (8) program evaluation.

Ending participation in the program

The ending of the participation in the program may include: (1) organ transplantation (desirable and optimal), (2) death of the patient, (3) resignation from participation in the program (undesirable) and (4) each time recording the end of participation in the program in the central vascular access register.

PROGRAM ORGANIZATION

Program scheme

Details of the health policy program schedule „Vascular access in renal replacement therapy – fistula first/catheter last" are shown in Fig. 1.

Stages and modules of the program

The program has been divided into five consecutive stages, containing individual modules that guarantee the complexity of the service provided. It is worth noting that the education of the patient covered by the program occurs at every stage of the program. Details of the stages and modules of the program are presented in Fig. 2.

Organization of services provision

Taking into account the specificity of the planned program (preventive services, diagnostics, treatment, secondary prevention, vascular surgery, access to RRT, education during each contact), it should be clearly stated that all procedures characteristic of the program are guaranteed services in accordance with the Act of 27 August 2004 on healthcare services financed from public funds [45]. The designed compilation of procedures aims to harmonize the standard of provision, which will obviously affect the cost-effectiveness of the service and unequivocally improve access to highly specialized centres specializing in the management of patients with CKD.

Detailed conditions for the provision of services (formal requirements, requirements for: doctors, nurses, organization of providing services – outpatient specialist care/hospital treatment, equipment and medical equipment) in relation to the educational outpatient clinic, nephrology clinic, vascular surgery clinic, vascular surgery department, nephrology department and dialysis centre were determined by the minister competent for health and the President of the NHF in:

1. Regulation of the Minister of Health of November 6, 2013 on guaranteed services in the field of outpatient specialist care [44];

2. Regulation of the Minister of Health of 22 November 2013 on guaranteed services in the field of hospital treatment [46];

3. Order No. 22/2018 / DSOZ of the President of the NHF of March 14, 2018 on defining the terms of concluding and implementing contracts in the form of outpatient specialist care [47];

4. Regulation No. 66/2018 / DSOZ of the President of the NHF of 29 June 2018 determining the conditions for concluding and implementing contracts, such as hospital treatment and hospital treatment – highly specialized services [48];

5. Regulation No. 73/2016 / DSOZ of the President of the NHF of 30 June 2016 on determining the conditions for the conclusion and implementation of contracts, such as health services contracted separately [49].

MONITORING AND EVALUATION OF THE PROGRAM

Monitoring

Monitoring of program implementation will take place on the basis of data provided by the program implementer in the field of program effectiveness indicators: (1) reduction in the number of repeated hospitalizations regarding complications related to the production of AVF; (2) reduction in the number of complications associated with haemofiltration surgery; (3) reduction of general mortality among patients undergoing dialysis in a 12-month perspective; (4) increase the knowledge on self-care and self-care regarding AVF and (5) creating a register of vascular access in Poland.

Evaluation

A retrospective evaluation of the program regarding the effectiveness of the practical model of organization of patient care with CKD qualified for the RRT program will be possible after the end of the 12-month period of its duration. All data provided by service providers will be subject to a detailed analysis.

Evaluation parameters

The program assumes the creation of an Internet application (ICT system) that is the Central Register of Vascular Accessions made in patients with CKD qualified for RRT. The data administrator will be the President of the NHF/Centres of Information Systems for Health Care (a solution analogous to the currently applicable registers). The basis for creating the register is the Act of 28 April 2011 on the information system in health care [50].

The register processes data and identifiers including:

1. patient's personal data (name and surname, PESEL number, sex, citizenship, place of birth, address of the place of residence, date and cause of death);

2. unitary medical data: (2a) main diagnosis (duration of CKD), co-morbid diagnosis (diabetes, atherosclerosis, cardiovascular diseases, vein and deep vein thrombosis, obesity), number of days of hospitalization, information on benefits provided the scope of outpatient specialist care/hospital treatment, dialysis centre identification, (2b) the date of the anastomosis procedure, type of anastomosis (own vessels, vascular prosthesis, dialysis catheter), limb identification (dominant);

3. personal data of the physician qualifying for the creation of the anastomosis: the service provider's identification, the number of professional licence (NPL), the proposed site of anastomosis formation, information on diagnostic tests performed (ultrasound, venography, arteriography, computed tomography, magnetic resonance);

4. personal data of the physician performing the anastomosis: identification of the service provider, NPL;

5. personal details of the nurse educating the patient: identification of the service provider, NPL;

6. medical data on the performed vascular access: (6a) time and place of production, (6b) information about the procedure performed: limb (upper, lower, torso), side (left, right), anastomosis (first, second, subsequent), anastomosis (native, prosthesis, allograft), type of anastomosis (end to end, end to side, side to side), postoperative complications (bleeding, blood clot, limb ischemia, lymphectomy, infection, fistula dysfunction, limb oedema), information on reoperation (yes, no), information on failure (necessity to set up a dialysis catheter);

7. data on the follow-up appointment: (7a) date, provider's identification, (7b) whether the anastomosis is working correctly (yes, no): presence of murmur (yes, no), ultrasound imaging (yes, no), (7c) information on education: whether the patient needs further education (yes, no), deficit (what);

8. data on the decision on the use of dialysis anastomosis: (8a) date, care provider identification, (8b) Doctor's designation: NPL, specialization (8c) indication whether the anastomosis works correctly according to the qualified doctor (yes, no);

9. data on the first fistula puncture: (9a) date, care provider identification, (9b) nurse designation, NPL, specialization (9c) obtained flow (in ml/min), complications at the first puncture (yes, no);

10. Data regarding the follow-up visit after the first month of use of the anastomosis: (10a) date, provider's identification, (10b) doctor's mark, NPL, specialization, (10c) whether the anastomosis is working correctly (yes, no): presence of murmur (yes, no), ultrasound imaging (yes, no), (10d) whether there is a need for correction within the operating fistula (yes, no), did the referral (yes, no), (10d) information about education: does it require further education (yes, no), deficit found (what).

FINANCING THE PROGRAM

The program implementer can be a provider performing a contract with the NHF for the provision of healthcare services in the form of ambulatory specialist care/hospital treatment/health services contracted separately. The program implementer is obliged to provide data necessary to finance and settle program costs and prepare reports on the implementation of the program for the Polish NHF.

SUMMARY

Health policy program „Vascular access in renal replacement therapy – fistula first / catheter last" covering health care services provided in the scope and on the conditions specified in the regulations issued on the basis of art. 31d of the Act of 27 August 2004 on health care benefits financed from public funds, is to check whether planned changes in the organization and delivery of services will improve the situation of patients with CKD eligible for chronic RRT and whether they will be effective the point of view of the health care system. In the author's opinion, taking into account the target population (all patients diagnosed with CKD, qualified for the RRT chronic program), the program must have a nationwide coverage.

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