ORGANIZATION AND MANAGEMENT SERIES NO. 168

COORDINATED MEDICINE - ASSUMPTIONS FOR A MODEL OF MEDICAL FACILITY MANAGEMENT

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Purpose: The main purpose of the paper is to provide an introduction to the issues of the coordinated medicine model and the management of the medical facility. Due to the comprehensiveness of the topic, the paper is only a theoretical introduction to a further, more detailed publication series encompassing research assumptions.

Design/methodology/approach: The paper is based on a theoretical analysis and literature review.

Findings: The paper describes the theoretical assumptions of the model setting the directions for further research.

Research limitations/implications: The content presented is an outline of the further research area

Practical implications: The considerations presented and references to international experience provide a basis for further research to identify possible impacts on improving the availability and quality of health service provision in Poland.

Social implications: Undertaking research based on the theoretical assumptions of the model described should improve the health of the population and make more rational use of resources to improve access to services.

Originality/value: The paper is primarily addressed to health care managers, as well as economists and government employees dealing with management issues in health care and public health.

Keywords: management, quality management, coordinated medicine, medical facility, healthcare system.

Category of the paper: General review.

1. Introduction

The development of health care systems in Poland and worldwide is taking place in two major directions. The dynamic growth of medical knowledge and technological progress result in increasing specialisation both within the medical professions and in the ways in which health

services are organised. This makes it possible to provide medical services based on the latest available diagnostic and therapeutic technologies, but also requires cost-intensive maintenance of complex organisational structures and multidisciplinary human resources. A side effect of the specialisation process within the health care system has been the weakening of organisational ties between individual providers. This phenomenon is exploited by some patients who skip the primary care level and go directly to specialists, both in outpatient and inpatient care. This leads to the over-consumption of expensive specialist services, causing a rapidly progressive increase in the operating costs of the entire health care system, without, however, translating into adequate results in terms of length and quality of life. Excessive specialisation also leads to an increase in inequality in access to services, as specialised services, which are individually expensive and limited, are addressed to a relatively small group of patients (Zapaśnik, Skłucki, Tumasz, Szynkiewicz, Jędrzejczyk, Popowski, 2016).

It is important to emphasise that, in parallel with increasing specialisation, highly developed countries provide citizens with free access to primary health care (PHC). Strong primary health care, due to its universal accessibility, has a significant positive impact on public health (Shi, 1994; Starfield, Shi, Macinko, 2005). By the same token, it must be added that other countries, including highly developed countries, which have consistently developed primary health care, have achieved significant improvements in the health of their populations (Macinko, Starfield, Shi, 2003). In Poland, there has been a discussion for many years about the need to increase the scope of competence of primary care and to transfer to the primary level some of the services hitherto performed only in specialist clinics, thus increasing its organisational complexity. However, in order to limit the adverse effects of progressive specialisation, there is a need to strengthen the role of the primary care physician as an effective coordinator of the entire treatment process (Suominen-Taipale, Koskinen, Martelin, Holmen, Johnsen, 2004).

The Polish health care system has a mixed financing system: capitation - in primary care and per service - for all other types of services. In many countries, where outpatient care (OPC) billing for services based on so-called unit products was introduced earlier than in Poland, this system has been heavily criticised as economically inefficient and unfriendly to the patient. In particular, opponents pointed out that billed points become more important than the real health needs of the patient (Kozierkiewicz, 2016).

Currently, changes have been initiated in Poland with the aim of creating a public payer financing system for health services provided as part of comprehensive care. Attempts of this type of action, with currently unknown results, may be: comprehensive care for women and children, combining invasive cardiology and orthopaedic services with rehabilitation, or the announced projects for reform of psychiatric care. However, the above changes in the way funding is provided are limited in scope and focus on particular health problems of limited patient groups. They do not, however, solve the fundamental problems facing health care in Poland, such as: limiting the negative effects of civilisation diseases, ensuring continuous preventive care for entire local populations, transferring diagnostic, therapeutic and

rehabilitation competencies to the lowest effective level of care, control and optimisation of costs. These challenges can only be met by a far-reaching change in the services provision process in outpatient healthcare.

2. Review of definitions

An alternative to the contemporary management of healthcare facilities at the level of primary care and OPC is the coordinated care model. This term is the most commonly used Polish translation of the English term *managed healthcare* or *managed care*. Other terms, less commonly used in Poland, are oriented care', 'comprehensive health care' or 'integrated health care'. All these terms attempt to encapsulate both the purpose and the approach to healthcare in the name. It should be emphasised that management plays a key role in it, and in turn both the coordination and integration of different levels of medical care providing a broad complex of health services and the way they are financed are important (Kowalska, Kalbarczyk, 2013).

The concept of coordinated medicine was born in the United States and is deeply rooted in American culture. It has proved so accurate that, transformed into business practice over several decades, it has resulted in the creation of many organisations guided by its principles, which in turn has helped to revolutionise the functioning of the US healthcare sector. It is worth mentioning that coordinated medicine is widespread in the United States, but it cannot be identified solely with this country, as elements of it can be found in many health care systems (the United Kingdom, Germany, Spain, Switzerland, Hungary, Australia or the countries of South-East Asia). Certainly, however, this expansion has been made possible by the success that the concept of healthcare management has had in the USA (Skowron, 2014).

According to the definition prepared by the WHO Regional Office for Europe (2016), coordinated care is "the concept of services related to diagnosis, treatment, care, rehabilitation and health promotion in terms of inputs, delivery and organisation of services and management". Coordinated healthcare leads to improvements in the availability, quality and efficiency of care, as well as patient satisfaction. From a practical perspective, an integrated delivery system can be described as a close working relationship between different services and services, such as hospitals, police, home care, public health, social care and other health-related services. Co-ordinated care is not an end result, but an important factor in improving the quality of care. There is extensive research outlining the different elements and definitions of such care, revealing different perspectives that influence the design and shape of the change process (AHRQ, 2007).

According to D. Kodner and C. Spreeuwenberg, coordination is a coherent set of methods and models at the funding, administrative, organisational, service delivery and clinical levels, designed to create connectivity, unify and stimulate collaboration within and between the

treatment and care sectors. The aim of these methods and models is to improve quality of care and life, patient satisfaction and system efficiency (...). Where such multi-faceted efforts to promote integration lead to benefits for recipients, the result can be referred to as coordinated care" (Kodner, Spreeuwenberg, 2002).

Of course, one can also encounter other functioning terms, for example: patient's centred care, integrated care, shared care, collaborative care (Kozieł, Kononiuk, Wiktorzak, 2017). However, it should be noted that some of these terms are used interchangeably, even though they do not always mean exactly the same thing. Co-ordinated (or integrated) care is also: methods and ways of organising care that make it possible to provide preventive and curative services of high quality and, at the same time, cost-effectiveness, ensuring continuity and coordination of treatment for patients with the greatest health needs (Øvretveit, 1998); a system that combines health care (emergency, primary and specialist) with social/environmental care (long-term care, home care, education) to improve system efficiency and patient outcomes (Leutz, 1999); a system that binds together inputs, staff, etc.; necessary for the system design, provision of services, organisation and management of care related to disease diagnosis, treatment, rehabilitation and health promotion to increase accessibility and quality of care, patient satisfaction and system performance (Gröne, Garcia-Barbero, 2001); models of payment, system organisation, delivery and professional pathways for health professionals that foster collaboration, coherence and consolidation of linkages between levels of care contributing to increased quality of care and patient life and system performance (Kozieł, Kononiuk, Wiktorzak, 2017).

The classification of coordinated care can also be presented through the following functions (Nolte, McKee, 2008; Fulop, Mowlem, Edwards, 2005; Shortell, Gillies, Anderson, Morgan, Mitchell, 2000): functional integration, i.e. coordination at a level not directly related to the provision of services (financing, information, management); organisational integration, i.e. coordination of care between institutions; interdisciplinary integration, understood as the creation of interdisciplinary teams; service integration, i.e. coordination of services within a single therapeutic process; normative integration, i.e. the definition of common norms and values and their orientation in the provision of services; systemic integration as the alignment of strategies and incentive systems at the organisational level. It should be added here that care coordination - to be effective and long-lasting - must take place at all levels of the system.

In a way, this can be confirmed by the rainbow model developed in 2000 by the team of P.P. Valentijn, S.M. Schepman, W. Opheij and M.A. Bruijnzeels (Valentijn, Schepman, Opheij, Bruijnzeels, 2000), i.e. a graphical elaboration of a definition representing the mechanisms and dimensions of coordinated care. While it is true that this model only considers coordinated care in the context of primary health care in the Netherlands, the model is still a useful tool to analyse the different levels of the health care system and to identify what needs to be changed, combined or coordinated to achieve better outcomes. Furthermore, the team of P.P. Valentijn, I.C. Boesveld, D.M. van der Klauw, D. Ruwaard, J.N. Struijs, J.J.W. Molema, M.A. Bruijnzeels

and H.J.M. Vrijhoef argue that coordination at all levels (clinical, specialist, organisational and systemic) ultimately results in a system of care that focuses on the needs of the service recipient and the population.

In contrast, D. Kodner and C.K. Kyriacou write about coordination at the level of: funding, understood as the consolidation of funds at different levels; administration, as the consolidation of tasks; institutions, as the planning and management of budgets within a group of providers; services provided, i.e. the coordination of treatment; and evaluation, understood as uniform and comprehensive evaluation procedures (Kodner, Kyriacou, 2000).

Following W.N. Leutz, it is possible in turn to present degrees of coordination based on three levels: as little change as possible - ad hoc cooperation; coordination within existing structures - defining mechanisms to facilitate communication and information exchange between different actors; full coordination - the creation of a new institution, encompassing all tasks, resources and funding (Leutz, 1999).

It is worth noting that a key feature of coordinated care is that it varies according to the level of activity and the degree of integration. Although coordinated care can take different forms in different health systems, a common feature is that gaps in integration at one level can have a negative impact on integration at other levels.

Despite the lack of a clear definition, the vast majority of coordinated care programmes have the same aim - to support chronically ill people. The result of these programmes is very often a reduction in hospitalisations (by up to 19%) and an increase in patient satisfaction (Dorling, Founaine, McKenna, Suresh, 2015).

In conclusion, it is worth being aware that the concept of "coordinated medicine" cannot currently be described as homogeneous. Over the decades, its development, depending on conditions, needs and opportunities, as well as the management mechanisms in place, has taken different organisational forms in practice.

In the most general terms, for the purposes of this paper, 'coordinated medicine' will be defined as a network of healthcare providers working together, formed by managers assuming financial and organisational responsibility for providing access to a relatively wide range of healthcare services, coordinating the care of their patients, ensuring continuity of treatment and internal supervision of its quality. Thus, it is a certain system in which the institution of a 'patient care coordinator' is created, i.e. a person or entity who would act as an agent. This agent could be an autonomously operating PHC, a primary or multispecialist outpatient healthcare facility, a network of facilities that includes primary healthcare within its scope, a hospital or an organisation of an administrative and organisational nature.

From the point of view of the management of a medical facility in the context of the principles of coordinated medicine, based on international experience, it is possible to identify the main objectives that significantly change the ways in which they have been managed to date. These include:

- improving the design and delivery of patient-centred healthcare,
- improving the quality of services for the elderly, chronically ill and disabled,
- reducing fragmentation, closing the gap and removing surplus/increasing efficiency in the use of existing resources,
- ensuring continuity and coordination of treatment,
- prevention of medical errors,
- increasing public satisfaction with the healthcare system and treatment processes,
- increasing the cost-effectiveness of ongoing processes,
- greater freedom in the selection of partners and subcontractors,
- more efficient management.

3. Diagnosis of the Polish health care system in the context of coordinated medicine

Issues related to the functioning of health care arouse great emotion around the world. In Poland, these discussions are most focused on a few persistent problems. Citizens regularly hear in the media about difficulties in accessing health care services, the exhaustion of limits on services, contracts that are too low in relation to hospitals' capacity to fulfil them, or the failure to provide needed services in a timely and sufficient manner. The problem of hospital indebtedness and the discussion on how to solve it has been growing louder in recent months.

If the overall level of outlays on health care, the number of consultations or hospitalisations, as well as the level of outlays on the treatment of patients within the framework of highly specialised treatment or drug programmes for rare and very serious diseases are taken as the measure of fulfilment of the health care needs of Poles, then certainly in this area enormous progress should be emphasised. Looking only at the level of public spending on health between 1999 and 2011, there has been an increase of almost 170 per cent. Public outlays increased from PLN 25 to 67 billion. In the same period, private expenditure on health rose from PLN 14 to 33 billion. As a society, more than PLN 100 billion is spent on health, which is approximately 7% of Poland's GDP. However, taking the level of the percentage of public expenditure on health as a measure of accessibility to benefits in the public sector, Poland, with the current level of wealth of its citizens and a 67% share of public expenditure on health, would be classified as a country with a problem of accessibility and equity in access to publicly funded benefits under WHO assessments. Thus, the bulk of private expenditure on benefits is due to unavailable (or far from adequate) access to publicly funded services.

An attempt is made below to indicate the essence of the problem to be tackled on a systemic basis, assuming the implementation of the coordinated medicine model.

First of all, it is important to note that effective treatment requires getting to the causes and making an effort to eliminate them, rather than just dealing with the prevailing symptoms. In this respect, the Polish system of publicly financed health care has, admittedly, undergone significant transformations over the last twenty years, but the reason for its inefficiency and low effectiveness is the lack of sufficient cohesion of the "contractual" relationship with the organisation of the health care system. Competition dominates the cooperation between healthcare providers, and the lack of incentives to promote the coordination of investment and the use of resources, as well as the continuity of patient care, mean that the system is constantly struggling financially. This creates an atmosphere full of mutual accusations and an almost permanent conflict between the public payer and the healthcare providers, with patients becoming a bargaining chip.

The second element is the problem of waiting queues. In the Polish health care system, the contract has a hugely important function in moving away from the safe world of guaranteeing money to maintain the resources of health care institutions without any particular analysis of their use, costs and results to providing - within the available resources - those services that are needed by sick people at a given time.

It is worth noting that, while at the beginning of their operation, both the health insurance funds and the branches of the National Health Fund did not have information precise enough to be able to correctly determine the structure of the health needs of the insured, subsequent years allowed for a process of "learning by experience". The needs of the insured were gradually better recognised, but in the absence of coordination of health policy and tools for their implementation both at the state and regional level, the public payer is unable to meet them. In such a situation, with financial constraints on the part of the payer, the main tool for limiting demand for services has become the rationing of access through the institution of the 'limit' - the creation of a waiting queue. The limit, on the other hand, contradicts the idea of universal accessibility to healthcare and is a solution unaccepted by society and the medical community.

Another element worth pointing out is cost shifting. The institution of the limit, although it has helped the health insurance funds and now the branches of the National Health Fund to balance revenues and expenditures, has not, however, protected the system from cost shifting. Incentives for cost shifting are hidden in the ways in which services are financed, and those who were susceptible to them were primarily those managing primary health care (PHC), which is financed using simple capitation techniques. PHC providers received funding in the form of a capitation rate to pay for the costs of providing primary care services. With rates set for narrow ranges of services, in the absence of appropriate standards of medical conduct, poor supervision of contract performance and, above all, the possibility of retaining surpluses due to 'frugal' management of funds, there is a strong incentive to refer patients for more expensive treatment in institutions with a so-called higher reference level. On the other hand, the forms of remuneration of individual GPs are important. If GPs do not manage budgets and do not also perform ownership functions, and if their remuneration systems are not linked to the number of

patients and do not use capitation techniques (usually a salary is the form of remuneration), then there are hidden motivations to refer patients to specialist treatment, linked to the reduction in the scope of responsibility and the amount of work in the PHC. These motivations, stemming from the way in which the services of the PHC are financed and related to the scope of responsibility and the intensity of the work performed, were reinforced by implicit incentives in the ways in which specialised services are financed, according to the *fee-for-service* individual payment rule. Lacking in the funding model for primary care physicians are incentives to provide better care in the form of payment for expected outcomes or to take on the role of a real coordinator of patient care, resulting in costs being passed on to higher levels of care, 'getting rid' of troublesome patients by referring them to specialists and generally poor quality healthcare in the public perception. In a solution to improve and relieve the burden on higher levels of care, including hospitals, it would be advisable to use arrangements similar to the UK - whether *GP-fundholding* or more advanced pay-for-performance.

The next handicap of the system is the decomposition of structures and fragmentation of medical care. The problem of cost shifting, mentioned earlier, is also strongly linked to the phenomenon of quality deterioration - the fragmentation of medical care and the weakness of incentives to oversee the standard of medical services. The problem of fragmentation of medical care is present in most health care systems, but is sometimes more acute where GPs work with a high degree of autonomy while suffering no financial consequences for their therapeutic decisions. Another consequence of such freedom of action may also be an increasing variation in the approach to identical health problems (small area variation), resulting from different styles of patient care. The disadvantage of the new allocation mechanisms in the universal insurance system at the health insurance fund stage was undoubtedly the unit contracts, which encouraged the decomposition of integrated structures (primary care, outpatient and inpatient care and ambulance services in one organisation covering a large population with care). Some structures were weak, but in many cases valuable bonds of cooperation between doctors of different specialities (formal and informal networks) were destroyed. These ties are very important for maintaining continuity of treatment and coordinating patient care. The problem of the dispersion of primary care providers, outpatient specialised care and hospitals, with the lack of financial incentives to consolidate and coordinate medical care, only reinforces the inefficient structure of health care in Poland. It seemed that the changes introduced in the scope of obligations of creating entities by the Healthcare Institutions Act of 15 April 2011 were to bring the desired results in a few years' perspective and, as a result of consolidation and restructuring processes related to the commercialisation of healthcare entities, bring about the adjustment of the number and type of healthcare entities to the real health needs of Poles. Improvements in efficiency in this respect should be attributed to the key elements of coordinated healthcare - appropriateness and substitution of treatment, as well as disease management and quality management tools.

Another element in the diagnosis of the health care system in Poland is the role of the general practitioner. An important change that was implemented in 1999 was to grant the patient the right to freely choose his or her general practitioner (as well as a nurse and a midwife), while at the same time being able to receive specialist services dependent on referrals issued by GP. The idea was that the doctor would become the patient's 'guide' through the healthcare system. However, this objective of the reform was not reflected in the designed institutions. The allocation mechanisms created meant that the *gatekeeper* function of the system was strengthened above all. Due to the incentive structure, which is inconsistent with the philosophy of family medicine, the actual responsibility of GPs has been limited to a narrowly defined scope of primary care, including diagnostic tests allocated within the capitation rate to primary care physicians. As a result, few people provide information about test results and appointments with other doctors to their GP. In turn, there is no legally enforceable obligation on the specialists to whom GPs send their patients to send back information on the diagnosis and recommended treatment. The result of all this is that there is no real possibility of coordinating the patient pathway in the healthcare system. This problem is clearly visible in Poland (Skowron, 2014).

One of the final elements is the issue of information. A peculiar feature of the healthcare sector is the uncertainty between doctor and patient related to the patient's illness. The strong asymmetry of information between patient and doctor is the most characteristic feature of the healthcare sector. The doctor usually has adequate expertise information to make a diagnosis and recommend the optimal therapy, while the patient is aware that he or she is not qualified to make rational choices. As a result of the asymmetry of information, a relationship of agency is created between the doctor and the patient, in which the doctor becomes an advocate for the patient's interests. In the Polish medical care system, the problem of inequality in access to information is additionally caused by the scarcity of information and the lack of mechanisms and tools for collecting and transmitting it. This problem concerns both the National Health Fund and, above all, medical entities at all levels of care. It is also compounded by the discrepancy between provinces in reporting on epidemiological parameters such as incidence, prevalence and causes of death. This results in a lack of data on the basis of which adequate health care can be planned, its delivery coordinated and its quality monitored. It should be added that in the Polish health care system, computerisation still stands at a relatively low level of development, and the IT integration of various health care entities in terms of access to information is also difficult and costly. An additional obstacle to the unification of these standards and the exchange of information is the fragmentation of the system and the multiplicity of creating entities.

A final element worth noting is the importance of contracting health services. Designing a functional and efficient healthcare system is a very complicated task - as it must take into account the economic specificities of the healthcare sector. The incompleteness and lack of symmetry of information between economic actors is the cause of market failures that prevent

the achievement of equilibrium states. Therefore, in order to eliminate or weaken the negative effects of such imbalances, assistance is sought in the sphere of institutional solutions that constrain the Polish health care system. Nevertheless, it has been assumed that the contract, together with the entire 'auxiliary apparatus', is considered the most serious instrument, with the proviso that the process of constructing contracts should be preceded by an analysis of the behaviour and relations between the subjects of economic activity. Such a research perspective sets the horizon for the increasingly frequent analyses undertaken today. They allow us to focus not on the outcome, but on the mechanisms that determined the final decisions on the allocation of financial resources. A contract between an insurer and a health care provider, which is part of the concept of coordinated health care, should (Kowalska, Kalbarczyk, 2013):

- be based on the principles of capital funding and its modification in certain spheres of benefits,
- whose implementation is guided by the 2S principles of appropriateness and substitution,
- allow for the management of the healthcare process and mechanisms in areas such as access to and quality of healthcare services,
- whose evaluation criterion is a measurable effect about which information is available to patients,

This is an opportunity to improve the situation that the Polish health care system needs at the moment.

4. Current problems for the management of medical facilities

The results of the Supreme Audit Office inspections, carried out periodically in recent years, indicate the need for urgent changes, both in terms of financing and organisation of the health care system. The system is not patient-friendly, does not ensure the efficient use of public funds, and creates problems for the managers of treatment entities and the staff employed in them. Among the main scopes, concerning the management of treatment facilities, five basic ones can be identified, the elements of which translate into problems related to the management of treatment facilities. These are (SAO, 2019):

In terms of organisation and resources:

- lack of a target vision for the system and a strategy for state policy in key areas of health system functioning,
- uneven distribution of healthcare providers, inadequate for the health needs of the population
- disparities between regions and between rural and urban areas,
- limited coordination between the different actors in the health system,
- lack of sufficient staff.

- decapitalisation of assets, failure to meet current building and equipment standards,
- indebtedness of healthcare entities.

In terms of funding the system:

- low public funding for health care. High share of patients in the financing of Benefits,
- financial flows incompatible with the health needs of the population,
- inefficient use of resources, including those caused by a flawed structure of expenditure on health services,
- payment for a benefit and not for its effect,
- inadequate pricing of services. Significant price spreads of contracted benefits,
- shortcomings of the contracting the services,
- control and systems for verifying the accounts sent by treatment providers,

In terms of benefit availability:

- limited and territorially differentiated access to services,
- lack of security of access to selected benefits,
- limited coverage of coordinated healthcare, fragmentation of care,
- access to selected benefits,
- lack of access to innovative medicines and treatments,

In terms of patient rights and safety:

- disrespect for the dignity and intimacy of patients and the right to pain treatment,
- failure to respect patients' rights when it comes to nutrition and conditions of stay in hospitals,
- lack of organisational standards for most types of benefits,
- poor quality of services provided,
- ineffective system of supervision of entities operating in the health system,
- an ineffective system of out-of-court redress for patients,

In terms of information resources of the system:

- lack of a coherent concept for the development of health care information systems,
- no data exchange between distributed registers,
- incomparability of data contained in dispersed registers,
- unreliability of the data contained in the scattered registers and the underestimation of the role and importance of medical registers,
- unreliability of the data contained in the medical records.

Of course, the scopes indicated above are very general and only show the most important problems to be solved in the health care system, which in turn is necessary to ensure that citizens realise their constitutional right to health care. One such direction could be the introduction of a well-designed model of coordinated medicine.

The impairments mentioned above will form the basis for the Author's research in this area.

5. Summary

Coordinated care can be a solution to the problems of Polish health care. It will not only improve the quality of patient care, but also increase its effectiveness. At the moment, the issue of introducing such a model of health care system management faces many challenges, which may hinder its introduction or discourage further expansion to new groups of patients. When deciding on such a management model, it should be emphasised that a prerequisite for this model is information sharing, so it is important to connect different IT systems (or build new dedicated solutions) - doctors must have full information about their patients (both administrative and medical data) delivered in a timely and usable manner. Finances and economic pressures on healthcare systems can also be a significant impediment to integrative care projects. It takes several years to implement a project and a short-term approach to efficiency gains can overshadow the benefits of long-term, systematic improvements. Another major challenge is overcoming a lack of understanding on the part of the patient and physician about the needs of the evolving system. Integrated care prioritises the needs of the patient, focusing on managing health with the help of information and assistive technologies. It is also worth bearing in mind that the governance model under discussion raises concerns for both doctors (due to the change in the way funding is directed - there is a greater focus on the outcomes of treatment rather than the delivery of the service itself, as in the traditional model) and other system staff working with the doctor (there is an issue of independence and subordination of individuals and processes within the redefined model). In addition to the above challenges, there are also issues of different types of integration (coordination) and differences in the priorities of different groups caring for the patient, e.g. medical staff or social workers, who have their own standards and regulations.

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