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MECHANISMS FOR ALLOCATION OF LIMITED RESOURCES IN BULGARIA'S HEALTHCARE SYSTEM





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FOREWORD

On the fair allocation of limited health resources

You are the head of the emergency department, and you have ten equipped intensive care beds, all of which are currently occupied. Two patients, recently operated on after a severe accident, are brought in for admission. Their survival depends on whether you admit them. The survival of each of the already admitted patients is also at risk. What will you do? Will you discharge the driver who, drunk and on drugs, killed a child on the road yesterday? Or the notorious gangster who was shot the day before? Or the committed alcoholic? Or perhaps you will discharge the two oldest patients? Or the two most hopeless, with the lowest life expectancy? Or will you discharge the two relatively healthiest, who are also at risk of dying if discharged?

Welcome to the issue of fair allocation of limited healthcare resources. Do not say that the problem is simply the lack of enough equipped emergency care beds. Because in every distribution situation – whether at the scale of a hospital, a disease, a health insurance plan, or a country – resources are limited. Even when sufficient, they still come at a cost. Should a medication be used, which is 20 times more expensive but 30 times safer than another for the same purpose?

Globally, the costs of healthcare, medicines, equipment and other resources continue to rise due to growing investments in research. However, the healthcare needs of people are also increasing, and new needs arise. For instance, when a new treatment becomes available that previously did not exist, the demand for it appears. It is true that there is a difference between needs. But if the choice between a facelift and heart surgery seems clear-cut, how should we choose between purchasing an extraordinarily expensive treatment for advanced cancer on a national scale and working on obesity prevention in children? For Bulgaria, it is of critical importance what priorities are set for what is covered by the National Health Insurance Fund, and what is not.

The process of setting priorities in the distribution of limited healthcare resources is known as "healthcare rationing." The term is controversial partly because it is alarming to think that it could resemble a coupon system, and partly because many of the stakeholders pretend that such a problem does not exist. Health is not a commodity, it does not have a price, etc., they'd say. Indeed. healthcare services and

products are not ordinary commodities, but they do have a price, and when limited, their distribution is inevitable. For us, citizens, the rationing is largely invisible, whether it is explicit (written down in a document) or implicit (unwritten, applied by default).

In our country, there is no effective public oversight of rationing, and those who make rationing decisions rarely bear responsibility for the consequences. Since in a democratic society transparency is a prerequisite for justice, invisible allocation by default is unjust.

However, if we want to make rationing visible in the eyes of the public, the critical question is, of course, who should be the one making decisions about it - the market, the politicians, administrative bodies, medical commissions, the patients, the courts, the public, or some combination of them all?

If rationing were solely a medical issue – or more broadly, an expert issue – it would boil down to fighting for a fair and transparent process conducted by experts (doctors, pharmacists, economists, lawyers...) with oversight by the civil society. But the issue is that rationing, while based on expert information, is not merely an expert question, as there are no, nor should there be, experts in values, on which the choices for allocation of healthcare resources are based. These would be values of deeply philosophical, existential, religious, and moral nature, involving life, justice, humanity, personal autonomy... In short, we do not want experts in the meaning of life.

Nevertheless, such values do underpin decisions, such as – if we must choose – whether we want to provide better equipment for premature babies or to broaden the number of kidney patients receiving dialysis. Even within the scope of one disease, if a very expensive medication helps all patients with a given diagnosis, but due to its immense cost, only some can receive it, should those be the most critically ill, with the most advanced degrees of damage, or those who would experience the greatest relative improvement? This was the case with fingolimod, for example, a medicine for treating multiple sclerosis. When it was first introduced in Europe from the U.S. around 2010, each country that could afford to purchase some quantities of it had to decide how to distribute them.

The problem of criteria for allocation – such as therapeutic effect, economic efficiency, social justice, and others – is very complex because different criteria could be in conflict with each other, for instance prolonging life and minimizing suffering.

Even the seemingly indisputable criterion of not allowing discrimination leads to complex dilemmas. Should meeting religious needs in hospitals (such as special diets or expensive medications) be covered by public funds, or should it be the responsibility of the individuals concerned? It is even harder to determine what would be considered discrimination in the context of healthcare based on disability or age. As early as 1984, Aaron and Schwartz exposed that within the UK National Health Service, there was an unofficial unwritten rule for rationing dialysis: an "understanding" that patients over 65

years old would not be given dialysis, nor would patients over 55 years old whose kidney failure was linked to heart disease and diabetes. Can we say this is age discrimination? If we take a more extreme example, does a person in a persistent vegetative state or a person in the fourth stage of Alzheimer's disease, at risk of fatal arrhythmia, have an equal right to an implantable cardiac defibrillator costing \$40,000? Or would denying such a procedure be discrimination based on disability?

From the perspective of the general principles of democracy and human rights, the most appealing approach to rationing seems to be entrusting the process to a representative sample of the public through forms of democratic deliberation, as recommended by leading scholars on rationing, Norman Daniels and Lenard Fleck. But they also point out the risks of democratic voting.

There are many other issues related to the rationing of resources: Should genetic predisposition matter, and if so, how? Is it acceptable to sanction irresponsible behavior and lifestyle choices that led to illness? What should be done with the so-called bottomless pits – patients with multiple sufferings, who may require a disproportionately large number of expensive interventions over a long period of time? And given the immense importance and inevitability of healthcare rationing for equality, the most striking question is why there is so little public discussion on this issue.

This study gives us an initial understanding of the legal, moral, and political complexities associated with the question of fair allocation of healthcare resources.

Its goal is to spark public interest in this field, encouraging researchers and practitioners from diverse perspectives — health policymakers, medical professionals, philosophers, lawyers, economists, political scientists, — and, hopefully, ordinary citizens — to engage with it in the future.

Dr. Dimitrina Petrova

Executive Director BOLD Foundation

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INTRODUCTION

Research context and objectives

Globally, the allocation of scarce health care resources is a key challenge, driven by increased demand for health services, increased sophistication of medical technologies and constraints in health systems' budgets. In Bulgaria, this problem is particularly acute due to limited public resources, imbalances in the territorial distribution of medical services, significant socio-economic disparities and, in recent years, the political climate. This study focuses on the identification of practices and mechanisms for the allocation of scarce health resources in the country, as well as an assessment of the extent to which the existing regulatory framework ensures equity, transparency and efficiency.

The theoretical review covers implicit and explicit models of health resource allocation based on principles such

as utilitarianism, egalitarianism, prioritization of vulnerable groups and medical efficiency criteria. Explicit models, dominant in countries such as Sweden and Norway, emphasise the importance of transparency and public participation in decision-making.

The working hypothesis of the field study is based on publicly available data on decision-making practices for allocating scarce resources in health care. It suggests that implicit allocation is more common in Bulgaria due to inefficiencies in explicit mechanisms, including insufficient accountability and ineffective management of available resources, without commenting on the extent of their scarcity at this stage.

The study has the following main objectives:

- to determine which resource allocation practices respondents recognize as "popular" in the Bulgarian healthcare system;
- assess whether the existing regulatory framework practically ensures the fair participation of all stakeholders in decision-making;
- analyse possible barriers to mechanisms for equitable distribution of limited health resources;
- to provide a basis for in-depth dialogue between all stakeholders to develop more equitable mechanisms for the allocation of available resources in the health system.

Methodology

The study is based on a combination of desk study and empirical methods. The first stage involves an analysis of the legal framework and best practices identified in the international literature and national doctrine. The second stage comprises semi-structured interviews and focus group discussions conducted with representatives of the following stakeholders:

- politicians and experts in the health administration;
- doctors and medical directors;
- patient organisations and health mediators;
- NGO representatives.

Expected results

Through the combined approach, the study aims to provide:

- Objective analysis of the actual practice of health resource allocation in Bulgaria;
- Identify key gaps in the regulatory framework to ensure transparency and efficiency;
- a basis for more effective advocacy and the development of mechanisms for equitable distribution of scarce resources in health care
- This research seeks to be evidence-based, transparent and grounded in social justice principles.

Limitations of the study

The selection of participants

The study uses a small sample of participants for indepth interviews and focus groups, which allows for in-depth exploration of the interrelationships between influencing factors, but also risks skewing the data. When resource allocation is primarily implicit and based on subjective factors, the limited sample size may lead to underrepresentation of broader or alternative perspectives. This makes the results of the analysis susceptible to exaggeration or underestimation of certain issues and trends.

Time restrictions

The fixed timeframes for completion of the study limit both its scope and the depth of the analysis. Lack of time may have affected the ability to conduct more interviews, collect additional data, or test hypotheses in depth. This may have left some aspects of resource allocation unexplored or led to hasty generalisations.

Possible bias of the reasearchers

As with any qualitative research, the interpretation of data is susceptible to the personal or professional views of the researchers. These can influence the way questions are framed, the choice of participants, and the analysis of results.

ALLOCATION OF LIMITED (SCARCE) HEALTH RESOURCES

Globally, demand for health services is growing, but resources (financial, technological and human) are limited. Ageing populations, expensive medical equipment and increasing public demand are a challenge for developed countries. Developing countries, in turn, face a growing gap between health needs and the resources available to meet them; a lack of systematic and formal decision-making processes; multiple barriers to implementation, such as insufficient reliable information; an inadequately developed social sector, weak institutions, and corresponding social inequalities^[1] (Costanzo 2020). The problem of allocating limited health resources is exacerbated during economic recessions and public spending cuts, and during the COVID-19 pandemic it became a key issue for countries to address^[2]

¹Caterina Di Costanzo, "Healthcare Resource Allocation and Priority-Setting. A European Challenge," *European Journal of Health Law* 27, no. 2 (2020): 93-114. https://doi.org/10.1163/15718093-12271448.

²Jakub Berezowski et al, "Rationing in Healthcare-a Scoping Review," *Frontiers in Public Health* 11 (June 2023): 1160691. https://doi.org/10.3389/FPUBH.2023.1160691/BIBTEX

(Berezowski et al. 2023). This puts the issue in the spotlight and raises questions about the ethics and transparency of decision—making and the search for approaches to allocate limited health resources in a rational, equitable and cost-effective manner.

Scarcity, resource constraint, and exclusion are three concepts that are present in the allocation of limited health resources^[3] (Keliddar et al. 2017). For this reason, the term is usually used with a negative connotation as it is associated with scarcity, deprivation and forced choice. Prioritization, on the other hand, has a positive connotation as it refers to knowing the alternatives and making an informed decision that is in the best interest of society. In fact, the two concepts are closely linked. The allocation of scarce resources in health care is the action, and priority setting is the instrument through which this is accomplished. We will examine the two concepts and related issues.

What is health resource allocation?

The concept of allocating scarce health resources, as the name implies, refers to the distribution of scarce resources among many people, which also implies denying potentially beneficial treatment to certain individuals or groups. In practice, certain health services are deliberately and systematically denied, even when they are known to be

³Iman Keliddar, Ali Mohammad Mosadeghrad, and Mehdi Jafari-Sirizi, "Rationing in Health Systems: A Critical Review," *Medical Journal of the Islamic Republic of Iran* 31, no. 1 (2017): 47. https://doi.org/10.14196/MJIRI.31.47.

beneficial, simply because they are judged to be too expensive, and this raises controversy about the mechanisms by which rationing takes place.

Implicit distribution

Implicit rationing relies on implicit norms and rules set mainly by health care providers and health care contractors, such as physicians. The public is not involved in resource allocation decisions and is therefore also defined as *covert allocation*. The implicit process is characterized by a lack of clarity regarding priorities, an inability to objectively identify strategies, and a lack of public accountability for decisions. Its' proponents argue that explicit priority principles limit health care providers from responding in a sensitive and timely manner to a complex and dynamic situation. However, implicit processes have come to be viewed under increasing criticism and have been described as arbitrary, unfair and lacking transparency and accountability^[4] (Costanzo 2020).

A study of physicians in Norway, Italy, Switzerland and the United Kingdom found that allocation of resources by the physician over the course of treatment is prevalent in the countries studied and varied according to physician attitudes and resource availability. The most frequently mentioned decision criteria were small expected benefit (82.3%), low chance of success (79.8%), intervention intended to prolong life when quality of life is low (70.6%), and patient over 85

⁴Costanzo, "Healthcare Resource Allocation and Priority-Setting. A European Challenge."

years of age (70%)^[5] (Hurst *et al.* 2006). The lack of a framework for allocating resources for health services at the policy level can lead to unchecked decision-making power by medical professionals^[6] (Keliddar *et al.* 2017).

Implicit allocation includes practices such as^[7] (Tragakes 1998):

- refusal health care providers turn patients away on the grounds that their needs are not urgent enough;
- selection only patients who are most likely to benefit from an intervention are accepted;
- diversion potential patients are referred to other programs or services;
- discouragement instead of an outright refusal, access to a service is made more difficult (e.g. with long waits, lack of information about the service, incomprehensible forms, etc.), thus discouraging patients;
- delay demand is discouraged by imposing long waiting periods;
- reduction services are still available, but the range of services is reduced, so that everyone still has access to them but receives limited care or service;

⁵ Samia A. Hurst et al, "Prevalence and Determinants of Physician Bedside Rationing: Data from Europe," *Journal of General Internal Medicine* 21, no. 11 (November 2006): 1138. https://doi.org/10.1111/J.1525-1497.2006.00551.X.

⁶Keliddar, Mosadeghrad, and Jafari-Sirizi, "Rationing in Health Systems: A Critical Review."

⁷Ellie Tragakes and Mikko Vienonen, "Key Issues in Rationing and Priority Setting for Health Care Services" (World Health Organization. Regional Office for Europe, 1998). https://iris.who.int/handle/10665/348006.

 termination - the time limit for a treatment or intervention is shortened (e.g. premature discharge from hospital or termination of treatment).

Explicit distribution

Explicit allocation is based on systematic, predefined rules and is therefore also referred to as overt allocation. As an approach, it was introduced in the 1980s and depends on a pre-established policy framework. It allows society to establish precise and transparent rules defining the circumstances under which individuals can request specific medical services. This is done after a public debate about the important organisational, ethical and social principles on which decisions about resource allocation are based. Explicit allocation focuses on principles, norms and values (e.g. need, efficiency, cost-effectiveness, equity, solidarity) as criteria to guide decisions (e.g. thoughtful, transparent, inclusive and accountable [8] Costanzo 2020). The advantage of this approach is that it ensures transparency and legitimacy regarding allocation decisions. In this way, health authorities strike a balance between increasing costs and demands and maximising benefits.

Both covert and overt allocation of resources have advantages and disadvantages. It is recommended that all decisions that have societal and ethical implications be made public as far as possible. At the same time, it remains important that clinicians have the widest possible freedom to

⁸Costanzo, "Healthcare Resource Allocation and Priority-Setting. A European Challenge."

choose the best treatment for the individual patient, with interventions undertaken in accordance with the policy framework outlined (i.e. within the explicit allocation framework). In turn, the policy framework is based on predefined priorities.

Principles of allocation of scarce resources

Before deciding on the principles according to which resources will be allocated, a transparent and stable framework must be established. There are four considerations to take into account: transparency (all stakeholders, such as the public and health professionals, are informed), consistency (guidelines are implemented consistently, without any form of prejudice or bias), inclusiveness (allowing people to challenge or possibly change the guidelines over time or as the situation changes), and accountability (the trust placed in people that they will carry out these actions according to the guidelines and remain true to justice in different situations)^[9] (Yip *et al.* 2022).

A major difficulty in moving from implicit to explicit approaches to resource allocation is determining principles on which to base the allocation. There are several principles that apply:

⁹Yuk Chiu Yip, Ka Huen Yip, and Wai King Tsui, "When Rationing Becomes Inevitable in a Pandemic: A Discussion on the Ethical Considerations from a Public Health Perspective," *Public Health in Practice (Oxford, England)* 4 (December 2022). https://doi.org/10.1016/J.PUHIP.2022.100294.

Utilitarian principle

According to the utilitarian principle, the action that brings the greatest benefit to the widest range of people is chosen. In resource allocation in health care, this principle aims to maximize utility with available resources. According to this view, collective benefits take priority over individual benefits. There are various approaches to quantifying health-related benefits, with quality-adjusted life years (QALYs) identified as the best indicator^[10] (Scheunemann and White 2011), despite the limitations of the approach.

Egalitarian principle

Egalitarianism stresses the equal moral status of individuals and the resulting equal right to the possession of basic goods. Resources are shared as equitably as possible. The aim is to reduce inequality so that the more privileged and disadvantaged can get a fair share. Fairness implies treating equals equally and unequals unequally, but in proportion to their relative differences. Under this approach, people with greater or lesser needs receive treatment that is proportional to their needs.

¹⁰Leslie P. Scheunemann and Douglas B. White, "The Ethics and Reality of Rationing in Medicine," Chest 140, no. 6 (2011): 1625-32. https://doi.org/10.1378/CHEST.11-0622.

Priority principle

This principle gives priority to the most disadvantaged, i.e. those who are most vulnerable, such as the elderly, the homeless, the poorest, etc. They have priority in the allocation of resources. The disadvantage of this approach is that it completely ignores the need or severity of symptoms of individuals^[11] (Yip *et al.* 2022).

According to merit

Under this principle, people with certain characteristics receive special attention and more health services. The approach was typical in Eastern Europe^[12] (Tragakes 1998). For example, the disabled, veterans, pensioners, military, members of a particular political party, etc. had privileges in the area of health care.

Principle of rescue

This principle is about trying to save those facing death, no matter how expensive the treatment or how small the chance of success^[13] (Scheunemann and White 2011).

¹¹Yip, Yip, and Tsui, "When Rationing Becomes Inevitable in a Pandemic: A Discussion on the Ethical Considerations from a Public Health Perspective."

¹²Tragakes and Vienonen, "Key Issues in Rationing and Priority Setting for Health Care Services."

¹³Scheunemann and White, "The Ethics and Reality of Rationing in Medicine."

Principle of urgent need

In this case, the allocation of resources is directed to the people who need them the most^[14] (Yip *et al.* 2022).

Each of these principles has its own logic and set of rules, and when they are applied selectively, the result - the priorities set and the allocations made - can appear arbitrary and unfair. Each principle has practical limitations and it is important to apply it after a social consensus on the particular concept of fairness that is chosen. In pluralistic societies, people may fail to agree on which principles should guide the allocation of resources. In such situations, the use of a fair decision-making process is of great importance. The following present five characteristics of fair processes related to allocation^[15] (Scheunemann and White 2011):

- supervision by a legitimate institution;
- transparent decision-making;
- debate in accordance with information and principles that all can accept as relevant;
- appeal and review procedures for individual decisions;
- public engagement.

¹⁴Yip, Yip, and Tsui, "When Rationing Becomes Inevitable in a Pandemic: A Discussion on the Ethical Considerations from a Public Health Perspective."

¹⁵Scheunemann and White, "The Ethics and Reality of Rationing in Medicine."

Decision-making levels for health resource allocation

Decisions about resource allocation for health services are made at four levels^[16] (Keliddar *et al.* 2017):

- 1. Patient individual patient needs and preferences can lead to self-limitation. For example, a sick person without health insurance benefits may refuse to continue receiving services if they cannot afford them or assess the costs as outweighing the benefits.
- 2. Medical executive most often refers to physicians who make resource allocation decisions depending on the patient's situation. They may use clinical protocols in selecting diagnostic, surgical and therapeutic services, hospital stays, etc. Despite a commitment to overt allocation of health services in theory, clinicians may also use covert methods in practice. The patient and the health care provider make decisions on a micro level.
- 3. Organisational level (hospital, clinic, nursing home) infrastructure and necessary resources are provided at the mid-level to support the implementers of medical activities. Organizations allocate resources among the various contractors.
- 4. Policy level policymakers and health insurers at the macro level set rules and regulations on health budgets, coverage of services and cost-sharing mechanisms, taking into account political, economic, social and technological factors. Through budgets, benefit packages and payment mechanisms, they control the behaviour of organisations and medical contractors and limit the possibility that many inappropriate health services will be provided. The budget influences the behaviour of contractors and causes them to reallocate healthcare resources or even ration some medical services. This can lead to covert rationing for

¹⁶Keliddar, Mosadeghrad, and Jafari-Sirizi, "Rationing in Health Systems: A Critical Review."

example, there is evidence that limited budgets lead to patients over a certain age being denied dialysis and heart surgery.

Coverage of health services is sometimes limited by a minimum package. Accordingly, some health services outside this package will not be available to all patients. The allocation of resources also depends on the sources of funding for the healthcare system. While in tax-based healthcare systems, government authorities might retain responsibility for the allocation of health resources, in wage- and premium-based healthcare systems, social or private insurance companies assume responsibility.

Defining a minimum or basic package of health services

The World Health Organization (WHO) emphasizes that the allocation of scarce health resources is a prerequisite for universal health coverage^[17] (Tragakes 1998). Typically, this coverage is secured by a package of health services guaranteed by law that includes broader categories and does not specify everything in detail. In practice, this leaves a degree of discretion to clinicians and decision-makers about specific treatments. Thus an implicit allocation of resources is realised, but within the existing policy framework.

¹⁷Tragakes and Vienonen, "Key Issues in Rationing and Priority Setting for Health Care Services."

In terms of the basic package, there are four ways for the state to set priorities explicitly^[18] (Tragakes 1998):

- Limiting the basic package to a strictly defined set of services, defining who does or does not receive a given service and in what case. All possible interventions are listed in order of priority and the budget sets a framework for the interventions that can be included. In the US, this approach has been used in the state of Oregon, where the package includes a detailed listing of over 500 specific interventions. A disadvantage of the approach is that it does not allow any freedom to clinicians, who are usually involved in micro-level allocation.
- Define a set of core services contained in the basic package. Regulatory and/or technical criteria shall be used to define priority areas. In this case, within the core services, there is an option for further prioritisation and allocation to determine the order in which the service will be received and who will receive it. This provides a varying degree of discretion for doctors, social security funds (in the case of socially funded systems) or health authorities. In other words, different actors have discretion to make allocation or prioritization decisions. This option allows more freedom to clinicians, which varies according to the specific package. The Netherlands implements this type of basic health package.
- A package of even more broadly defined service categories, allowing an even greater degree of freedom on the part of the responsible entities.
- Broad areas of priorities are defined (Finland, Spain, Sweden) or plans to purchase services are made on behalf of citizens (UK), which are constrained by technical and regulatory rules.

¹⁸Tragakes and Vienonen.

Resource allocation during the COVID-19 pandemic

Health resources, especially during a pandemic, are limited even in developed countries, as the health system would collapse trying to meet all the demands. Allocation of health resources is paramount in times of crisis and scarce resources need to be distributed to as many people as possible, which raises a number of ethical issues. The COVID-19 pandemic has triggered a major health crisis worldwide and has brought to the fore the allocation of scarce health resources in terms of prevention, controlling the spread of the disease and providing medical care to infected persons with severe symptoms.

WHO recommended that health professionals take the initiative to adopt and implement existing distribution frameworks in their respective contexts. During a pandemic, allocation of health services in some systems involves prioritizing patients who are considered to have a better response to treatment. Patients found to have only short-term benefit are excluded. These include people with terminal illnesses, the elderly and those who have underlying conditions that prevent full recovery. This provokes a serious ethical dilemma, as vulnerable groups are not protected and are placed at an extreme disadvantage^[19] (Yip *et al.* 2022).

¹⁹Yip, Yip, and Tsui, "When Rationing Becomes Inevitable in a Pandemic: A Discussion on the Ethical Considerations from a Public Health Perspective."

In a study of the ethical and legal implications of countries' behaviour in allocating health resources during the pandemic, Italy and the United Kingdom are considered, respectively the first country in Europe to face uncontrolled spread of the virus and the country with the highest mortality rate in Europe in the first year of the pandemic^[20] (Pulvirenti and Diver 2021). A utilitarian approach to resource allocation has been adopted by both countries. The rules put in place aim to maximise benefits for the greatest number of people, regardless of the potential violation of the rights of those at risk from the disease. Guidelines in both countries prioritize and protect those with a higher chance of survival.

The long-term ethical and human rights impacts of the global pandemic cannot yet be accurately or fully predicted.

 $^{^{20}}$ Rossella Pulvirenti and Alice Diver, "Covid-19 Health Crises and Human Rights in Italy and the UK: Is an Ethical Rationing of Healthcare Resources Possible?," in *L'éthique à l'épreuve de La Crise* (Epitoge, 2021), 15.

PRIORITISATION AND ALLOCATION OF HEALTH RESOURCES

The growing resource deficit in health care is putting pressure to provide the best care or service with the money that is available. This suggests that health authorities should choose strategies that would help to balance costs and benefits. Achieving such a balance is critical to providing affordable, patient-centered care with the best outcomes^[21] (Berezowski et al. 2023).

Approaches to setting priorities

The concept of allocation of scarce resources is related to the idea of priority setting, a process of comparing alternative healthcare programs and services based on regulatory and technical rules^[22] (Tragakes 1998, Berezowski *et al.* 2023). There are three approaches to priority setting that

²¹Berezowski et al, "Rationing in Healthcare-a Scoping Review"

²²Tragakes and Vienonen, "Key Issues in Rationing and Priority Setting for Health Care Services"; Berezowski et al, "Rationing in Healthcare-a Scoping Review."

are used: epidemiological, economic, and evidence-based medicine^[23] (Tragakes 1998).

Epidemiological approach

Epidemiological studies are used to determine and rank relative health care needs. Epidemiology analyses patterns of morbidity and mortality by age and social groups and accumulates information on the relative burden of disease and the major causes of death and disability. Based on this information, health service needs are assessed, then prioritized based on their relative importance to society, and finally resources are allocated based on priorities. As there are different ways of measuring the burden of disease and treatment needs, there is no single approach to prioritisation. Several criteria are therefore used on which to base the development of priorities. One commonly used is the impact of disease on mortality. Other criteria include: the impact of the disease on overall health in the future; combining morbidity and mortality criteria to produce a disability-adjusted life year (DALY) measure; the potential for a disease to develop into a major cause of morbidity or mortality in the absence of preventive action (e.g., infectious diseases and AIDS)[24] (Tragakes 1998).

²³Tragakes and Vienonen, "Key Issues in Rationing and Priority Setting for Health Care Services."

²⁴Tragakes and Vienonen.

Depending on the criterion chosen, different priorities are set and this is a major limitation of epidemiological assessment. It is therefore advisable to combine this approach with the other two - economic evaluation and evidence-based medicine.

Economic approach

Economic evaluation is an important component of healthcare decision-making because it helps to identify, compare and evaluate the costs and outcomes of different policies and programmes. One of the following four evaluation methods is most commonly applied^[25] (ALMesned et al., 2021):

- 1. Cost minimization analysis. This method includes the cheapest alternative interventions under the assumption that the outcome is the same. For example, it is useful when comparing two drugs after a randomised controlled trial that examines their effects. The disadvantage of the method is that the outcome is not always comparable.
- 2. Cost effectiveness analysis. This method calculates the cost and effect of different interventions for the same condition. It looks at clinical outcomes such as number of years of life gained or symptom-free period due to treatment. A major drawback is the inability to compare different diseases. However, since it is currently the most commonly used economic method, the WHO has published a guide for its application. It is primarily used to inform future decisions without taking into account whether interventions currently offered in a particular setting are good value for money.
- 3. Cost-utility analysis. This method focuses on quality of

²⁵Sulaman ALMesned et al, "Healthcare Rationing and Economic Evaluation in Health Care," *Journal of Environmental Science and Public Health* 5, no. 4 (n.d.): 536-43.

life, not just the number of years gained as a result of health interventions, and takes into account additional quality-adjusted life years.

4. Cost-benefit analysis. This method determines the costs and benefits of a specific health service in monetary terms. It is used less frequently in clinical settings because of difficulties in monetizing benefits.

Some of the limitations of economic analysis are:

- smaller or larger groups of people differ significantly from the averages being worked with;
- different people respond differently to the same treatment;
- lack of knowledge about the effectiveness of different treatments, etc.

It is therefore recommended that economic analysis should only be a tool in outlining resource allocation policies^[26] (Tragakes 1998).

Evidence-based medicine

Evidence-based clinical protocols are one approach to prioritizing and therefore allocating scarce health resources. New medical knowledge that provides information on the effectiveness of various interventions helps in two ways in allocating scarce resources:

 Elimination - when certain interventions are ineffective or less effective than others, they can be removed from the list of eligible interventions in the

²⁶Tragakes and Vienonen, "Key Issues in Rationing and Priority Setting for Health Care Services."

healthcare system. This eliminates waste and frees up additional resources to use more effective interventions. Another plus is that in this way new treatments are not implemented broadly before there is evidence of their impact.

• Supporting economic analysis - new medical knowledge to assess and measure the benefits of an intervention is important for economic analysis.

However, new evidence is not always used effectively and can even be ignored in medical practice when doctors refuse to change their usual practices, regardless of new evidence. To overcome this risk, evidence-based medicine is used in resource allocation policies. Thus, ineffective interventions are removed from the legal provisions. In this way, a shift from implicit to explicit resource allocation is made.

However, the point remains that not all clinical interventions can be supported by sound scientific evidence^[27] (Tragakes 1998). Research, in the process of which new medical knowledge is accumulated, needs significant resources, such as time, money and specialists. Also, new interventions that are more effective in terms of outcomes may also be more expensive. The development and implementation of new technologies in recent decades is partly responsible for the rising costs in health care^[28] (Tragakes 1998). Because it is not possible to assess in advance whether innovations will reduce or increase costs, evidence on the effectiveness of

²⁷Tragakes and Vienonen.

²⁸Tragakes and Vienonen.

medical practices is only one element in prioritizing and allocating resources.

While evidence-based clinical protocols offer an approach to prioritizing and implementing explicit allocation, there are concerns that they can also be used as tools for unwarranted and covert resource allocation under the guise of expert recommendations^[29] (Norheim 1999). Another issue that has been raised regarding protocols is their legitimacy^[30] (Guerra-Farfan 2023). If used in resource allocation, it is important that they have undergone public discussion.

Public participation in setting priorities

As this is usually a public resource, it is important to involve the public in developing protocols for allocating scarce health resources in order to understand public priorities and avoid conflicts. There are two main arguments for involving the public in the prioritization process - it increases public accountability and ensures broader representation of interests so that conflicts can be explored and addressed^[31] (Norheim 1999).

²⁹Ole Frithjof Norheim, "Healthcare Rationing-Are Additional Criteria Needed for Assessing Evidence Based Clinical Practice Guidelines?," BMJ: *British Medical Journal* 319, no. 7222 (November 1999): 1426. https://doi.org/10.1136/BMJ.319.7222.1426.

³⁰Guerra Farfan, E., *Clinical practice guidelines: the good, the bad, and the ugly.* https://www.sciencedirect.com/science/article/abs/pii/S0020138322000778

³¹Norheim.

In the UK, the debate about the need for the public to be involved in resource allocation and priority setting dates back to the early 1990s. The comprehensive exploration of alternatives needed to set clear priorities in healthcare requires consideration of the clinical effectiveness of treatment, the costs involved, and the values on which choices will be based^[32] (Mossialos and King 1999). Engaging the public helps to educate them about the issues involved and leads to more transparent decision making in healthcare.

However, there are serious limitations to public participation in priority-setting:

- First and foremost, the lack of specific knowledge needed to make healthcare decisions. Basic information needs to be provided to participants to help them understand the issues involved.
- Second, the presence of bias, driven for example by emotional media content. Although biases are unlikely to be eliminated, it is advisable to minimize their effect by providing clear and timely information.
- Third, there is the issue of public engagement and willingness to engage in the debate on setting priorities in health.
- Fourth is the impartiality of people who are expected to think in terms of the good of society as a whole and not in terms of their self-interest.

³²Elias Mossialos and Derek King, "Citizens and Rationing: Analysis of a European Survey," *Health Policy (Amsterdam, Netherlands)* 49, no. 1-2 (1999): 75-135. https://doi.org/10.1016/S0168-8510(99)00044-5.

Several factors are thought to influence the opinions formed by the public. In addition to personal and attitudinal characteristics such as age, educational achievement and political ideology, other influences include the media, national, cultural and political context. There is little evidence to suggest that the public's opinions are the result of self-interest. Attempting to establish principles acceptable to the general population is fraught with difficulties^[33] (Scheunemann & White, 2011).

However, experience has shown that the public can be involved in decision-making in different ways, either through broad participation or through public representatives who represent key groups within the public. The inclusion or exclusion of some groups can have a significant effect on the range of attitudes and values expressed.

Experience in a number of European countries shows that opinion polling can be carried out by mail, interviews, focus groups, community groups and public meetings. The first multinational survey of public attitudes to priority setting and resource allocation was undertaken by the International Social Justice Project in 1991 in 13 countries^[34] (Mossialos and King 1999). The experience gained over the past three decades provides a good basis for planning public debate on resource allocation and priority setting.

³³Scheunemann and White, "The Ethics and Reality of Rationing in Medicine."

³⁴Mossialos and King, "Citizens and Rationing: Analysis of a European Survey."

Allocation of scarce health resources in Europe

The resilience of European healthcare systems has been put to the test by the COVID-19 pandemic and the economic crisis. Ageing populations and the ever-increasing costs of new technologies and medicines are leading to a progressive increase in healthcare costs in a context of scarce resources^[35] (Costanzo 2020).

States have full autonomy over the allocation of resources for health. In the health sector, the EU has an ancillary function but has shown a high degree of commitment in this area since 2011^[36] (Costanzo 2020). The European Commission's Health Programme is the main instrument for funding joint action to support public health in Europe. The current programme, which runs from 2021 to 2027, has an unprecedented budget of €5.3 billion (EU Health Programme (2021-2027). For comparison, the 2014 - 2020 programme had a budget of € 449.4 million^[37] (Final Evaluation of the 3rd Health Programme 2014-2020 - European Commission).

At a national level, there are significant differences in resource allocation and priority setting frameworks across Europe. Sweden, Norway, the United Kingdom, the Netherlands and Denmark have made significant progress in

³⁵Costanzo, "Healthcare Resource Allocation and Priority-Setting. A European Challenge."

³⁶Costanzo.

³⁷"Open Public Consultation - Final Evaluation of the 3rd Health Programme 2014-2020 - European Commission," n.d. https://hadea.ec.europa.eu/news/open-public-consultation-final-evaluation-3rd-health-programme-2014-2020-2022-03-22_en.

this respect. They are developing a public debate on resource allocation and priority-setting and on transparency and accountability in decision-making. In countries such as Italy and Spain, such a public debate has not yet developed and implicit allocation is applied in an attempt to maintain a balance between scarcer resources for healthcare and increasing demand for services. France, Germany and Switzerland have achieved a medium degree of transparency and accountability and are placed in the middle between implicit and explicit allocation. Eastern European countries such as Poland and Romania are still undergoing major changes. In these countries, transparency and accountability processes are not good enough and point to structural deficiencies of the healthcare system^[38] (Costanzo 2020).

In all the Western Balkan countries, healthcare packages are very broad and therefore very expensive. This leads to an implicit distribution of health care, which in turn is inefficient and inequitable. It is recommended to align the services provided with the available resources after reviewing the size and scope of the package and considering national demographic and epidemiological characteristics, expected future revenue flow and current international practices^[39] (Bredenkamp *et al.* 2008).

³⁸ Costanzo, "Healthcare Resource Allocation and Priority-Setting. A European Challenge."

³⁹ Caryn Bredenkamp, Vedad Ramljak, and Michele Gragnolati, "Enhancing Efficiency and Equity: Challenges and Reform Opportunities Facing Health and Pension Systems in the Western Balkans" (2008). https://microdata.worldbank.org/index.php/citations/2366.

An analysis of healthcare financing in eight Central and Eastern European countries (Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Slovakia and Slovenia) shows that there is low public health spending and tension between needs and available resources^[40] (Tambor *et al.* 2021). Countries that stand out positively are the Czech Republic and Slovenia.

The positive example of the Czech Republic and Slovenia

Both countries have high healthcare costs and extensive population coverage. In addition, out-of-pocket payments for medical services in these countries represent a relatively low share of health expenditure. In the Czech Republic this result has been achieved through the high priority given to healthcare and the significant, albeit declining over the years, participation of the government in covering healthcare costs. There, there is extensive coverage of health services and a correspondingly low co-payment (cost-sharing) rate in publicly funded health care. In Slovenia, the role of the government in health financing is smaller and cost sharing is usually applied. However, voluntary health insurance, which is usually signed by Slovenians, largely takes care of co-payment obligations, which

⁴⁰ Marzena Tambor, Jacek Klich, and Alicja Domagała, "Financing Healthcare in Central and Eastern European Countries: How Far Are We from Universal Health Coverage?," *International Journal of Environmental Research and Public Health* 18, no. 4 (February 2021): 1-26. https://doi.org/10.3390/IJERPH18041382.

removes the need for private payment (out-of-pocket)^[41] (Tambor *et al.* 2021).

Czech Republic

A review of health in the Czech Republic (OECD and European Observatory on Health Systems and Policies 2023a) reveals the significant progress the country has made in its health reform. The health system is based on a Social Health Insurance Scheme (SHIS) with universal coverage, a generous benefits package and a strong regulatory role for the Ministry of Health. The main institutional features of the healthcare system have remained stable since its establishment in the 1990s. The Ministry of Health is the main administrative and regulatory body, while the seven self-managed semi-public the health insurance funds administer collection contributions and purchase services on behalf of the insured.

The mandatory SHIS system provides a broad benefit package (including inpatient and outpatient care, prescription drugs, some dental procedures and over-the-counter drugs when prescribed by a physician, rehabilitation, and balneotherapy under certain conditions) and near-universal population coverage. Apart from the economically inactive population, whose health insurance contributions are paid directly by the state, all other citizens are required to make

⁴¹ Tambor, Klich, and Domagala.

⁴²OECD/European Observatory on Health Systems and Policies, "Czechia: Country Health Profile 2023," in *State of Health in the EU* (OECD Publishing, 2023). https://doi.org/10.1787/24a9401e-en.

monthly advance contributions. There is limited competition between the funds, but they can offer additional benefits to their members, such as vaccinations not covered by the SHIS. The Ministry of Health is the main regulatory body responsible for establishing health policy and overseeing the system. Outpatient care contractors are mostly privately owned, while many inpatient care contractors are owned by the state (including most university hospitals and specialist centres), regions and municipalities.

The Czech Republic spends less on healthcare than the EU average, but the share of public funding is the highest in the EU. In 2021, public funding represented 86.4% of total health spending in the Czech Republic, the highest level in the EU (the EU average is 81.1%). Out-of-pocket payments have been decreasing over the years and in 2021 account for 12.7% of health spending. A system of prescription drug co-payment limits stratified by age, economic and health status has been introduced.

By comparison, public funding for health care in Bulgaria is among the lowest in the EU at 65%, and private payments (out-of-pocket payments) are the highest at 34%^[43] (OECD and European Observatory on Health Systems and Policies 2023b).

Due to the broad package of statutory benefits covered by the SHIS, voluntary health insurance plays a minor role in

⁴³ OECD, European Observatory on Health Systems, and Policies, "Bulgaria: Country Health Profile 2023," in *State of Health in the EU* (OECD Publishing, 2023). https://doi.org/10.1787/8D90F882-EN.

the Czech health system (less than 1%). At the same time, citizens self-report low unmet medical care needs (only 0.2%) due to excessive costs, need to travel or waiting time, and this percentage is much lower than the EU average (2.2%).

Slovenia

According to a 2023 report^[44] (OECD and European Observatory on Health Systems and Policies 2023c), Slovenia's social and health insurance system provides almost universal coverage. The healthcare system is relatively centralised and health insurance covers more than 99% of permanent residents. In addition, supplementary health insurance, contributions for which are fixed and mandatory since 2024, covers about 95% of the population. The state commits to cover the supplementary health contributions of those who receive social benefits. Primary health care is mainly provided by municipal health centres, while hospital care is mainly provided by government facilities.

Spending for healthcare remains relatively low despite record growth in 2021. It remains lower than the EU average, but out-of-pocket payments are among the lowest in the EU (14.5%). Public sources cover 73.7% of current healthcare spending in 2021, while private sources cover the remaining 26.3% (half of which is covered by supplementary health insurance).

⁴⁴ OECD/European Observatory on Health Systems and Policies, "Slovenia: Country Health Profile 2023," in *State of Health in the EU* (OECD Publishing, 2023). https://doi.org/10.1787/0EB17A30-EN.

The number of services that are fully financially covered by social health insurance is decreasing. Co-payments of between 10% and 90% apply to most services and goods in the basic package, except for specific conditions. The low personal out-of-pocket contributions have been largely constant since 2005 and are below the EU average. The cost burden of co-payments for health services is mitigated by the widespread use of voluntary supplementary health insurance.

The widespread use of supplementary health insurance, a generous public benefits package and strong financial protection measures contribute to low personal healthcare costs. Due to a sharp rise in contributions, supplementary health insurance was abolished in 2023 and replaced by a fixed mandatory rate in 2024.

The examples of the Czech Republic and Slovenia present different ways of providing universal health coverage and allocating scarce health resources. On the one hand, by prioritising the budget and mobilising more public resources for health, and on the other hand, by creating conditions for private insurance to take a more significant role in health financing. The first measure requires strong political will and remains a challenge for less wealthy countries where competition for scarce resources is greater. The availability of private insurers requires capacity on the part of the government to control and mitigate adverse effects, such as the

inability of poorer and sicker individuals to purchase insurance^[45] (Tambor *et al.* 2021).

The tailoring of solutions to the national context, broad public engagement and the will to create a political framework are prerequisites for a successful solution to the problem of prioritization and allocation of scarce health resources.

⁴⁵ Tambor, Klich, and Domagała, "Financing Healthcare in Central and Eastern European Countries: How Far Are We from Universal Health Coverage?"

RIGHT OF ACCESS TO MEDICAL CARE AND CONDITIONS FOR LAWFUL RESTRICTION OF ACCESS - LEGAL ANALYSIS

Right to health - concept and international legal framework

The right to health is a fundamental human right that is guaranteed by a number of international legal instruments. It should be made clear that the right to health should not be understood as a right to be healthy. The WHO Constitution^[46], adopted in 1946, defines the right to the **highest attainable standard of good health** as a fundamental right of everyone. ^[47] Its preamble states that the right to health is "a state of complete physical, mental and social well-being, and not merely the absence of disease". According to the WHO, this standard can be achieved through the provision of quality health care, perceived as health care that increases the

⁴⁶ Constitution of the World Health Organization, https://www.who.int/about/governance/constitution

⁴⁷ Ibid. The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being (...)

likelihood of achieving desired outcomes^[48]. The right to health can therefore be achieved through the provision of quality medical care. It must meet a number of requirements - it must be safe, timely and effective.

In 1948, the Universal Declaration of Human Rights was adopted, Article 25 of which recognises the right to health as part of the right to an adequate standard of living.

- 1. "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.
- 2. Motherhood and childhood are entitled to special care and assistance. All children, whether born in or out of wedlock, shall enjoy the same social protection."

The right of everyone to the enjoyment of the highest attainable standard of physical and mental health is also guaranteed in Article 12 of the International Covenant on Economic, Social and Cultural Rights, and is clarified in General Comment No. 14 from the year 2000 by the Committee on Economic, Social and Cultural Rights^[49]. The General Comment also clarifies the nature of this fundamental human right. It

⁴⁸ Quality of care, https://www.who.int/health-topics/quality-of-care#tab= tab_1, accessed 11.07.2023

⁴⁹ General comment no. 14 (2000), The right to the highest attainable standard of health (article 12 of the International Covenant on Economic, Social and Cultural Rights). https://digitallibrary.un.org/record/425041.

encompasses a number of freedoms, including the right of every patient to be treated based on his or her explicit consent, without being subjected to coercive treatment, and the right to not be tortured or subjected to torturous or degrading treatment.

General Comment No. 14 clarifies what requirements medical services must meet. It is accepted that a core element of the right to health is the so-called 3AQ model, which guarantees the availability, accessibility, acceptability, and quality of medical care. This model is not explicitly contained in the Covenant, but has been consistently interpreted by the Committee in General Comment No. 14 as a core concept ensuring the effective enjoyment of the right to health^[50]. According to this interpretation, health services should be accessible, available, acceptable and meet the requirements of good quality. Services should be evidence-based appropriate, provided by trained personnel, medicinal products and medical equipment should be scientifically approved and fit for use, and adequate hygiene should be ensured. [51]

The right to health is also guaranteed by numerous other international legal instruments - Article 24 of the Convention on the Rights of the Child (1989), Article 5 of the International Convention on the Elimination of All Forms of Racial

 $^{^{50}}$ Riedel, E. The Human Right to Health: Conceptual Foundations. In Realizing the Right to Health, edited by Andrew Clapham and Mary Robinson, Zurich. Ruffer and Rub, 2009, 21-39

⁵¹ The Right to Health, factsheet№ 31, WHO, Office of the United Nations High Commissioner for Human Rights. https://www.refworld.org/reference/themreport/ohchr/2008/en/58915

Discrimination (1965), Articles 11, 12 and 14 of the Convention on the Elimination of All Forms of Discrimination against Women (1979), Article 25 of the Convention on the Rights of Persons with Disabilities (2006), etc.

Also Article 2 of the European Charter on Patients' Rights^[52] explicitly states:

"Every individual has the right of access to the health services that his or her health needs require. The health services must guarantee equal access to everyone, without discriminating on the basis of financial resources, place of residence, kind of illness or time of access to services."

Affordable care in the context of the right to health

The analysis of the international legal framework of the right to health shows that this fundamental human right cannot be realized without the provision of accessible medical care.

Accessibility is one of the most important aspects of both the right to health and the right of patients to benefit from the advances of science that are set out in **the International Covenant on Economic, Social and Cultural Rights (CESCR)**. There is a general obligation of States to provide equal access

⁵² European Charter on Patients' Rights. https://svetaekaterina.eu/?page_id=9684

to all economic, social and cultural rights (CESCR General Comment No. 25, paragraph 37). [53]

Article 12 of the Covenant^[54] stresses that everyone has the right "to the enjoyment of the highest attainable standard of physical and mental health", to which "states must take steps to achieve the full realization of this right", including "the establishment of conditions that would guarantee medical care and medical assistance in the event of illness to all" (similarly Article 25 of the Universal Declaration of Human Rights). The Covenant recognizes the right of everyone "to enjoy the benefits of scientific progress and its applications" and requires States to take steps to achieve the full realization of the right, including those necessary for the dissemination of science. UN human rights treaties also provide for accessibility of health care with respect for specific protected (or vulnerable) groups, underlining the understanding that equal access means access without discrimination on any grounds.

For example, the UN Convention on the Rights of Persons with Disabilities imposes an obligation on states to "provide persons with disabilities with the same range, quality and standard of free or accessible health care and programmes as provided to others, including in the area of sexual and

⁵³ General comment No. 25 (2020) on science and economic, social and cultural rights (article 15 (1) (b), (2), (3) and (4) of the International Covenant on Economic, Social and Cultural Rights). https://docstore.ohchr.org/SelfServices/FilesHandler.ashx? enc=4slQ6QSmlBEDzFEovLCuW1a0Szab0oXTdImnsJZZVQdxONLLLJiul8wRmVtR5Kxx73i OUz0k13FeZiqChAWHKFuBqp%2B4RaxfUzqSAfyZYAR%2Fq7sqC7AHRa48PPRRALHB

⁵⁴ International Covenant on Economic, Social and Cultural Rights | OHCHR. https://www.ohchr.org/en/instruments-mechanisms/instruments/international-covenant-economic-social-and-cultural-rights

reproductive health and population-based public health programmes" and to "provide these health services as close as possible to the communities of the people, including in rural areas" (UN Convention on the Rights of Persons with Disabilities

These primary sources of international human rights law indicate a general consensus that accessibility means equal access to health care without discrimination on any basis.

According to the International Covenant on Economic, Social and Cultural Rights (CESCR), the principle of progressive realization should be applied in creating conditions that ensure medical care and attention to all in the event of illness. The UN Convention on the Rights of Persons with Disabilities is one of the most progressive instruments to demand not just equal but especially free and accessible medical services. Progressive realization requires the progressive expansion of access to different types of medical services, taking into account the capacities of individual countries. When restricting access, it is necessary to follow certain standards, in the absence of which restrictions are deemed to violate the right to health.

According to General Comment No. 14, cited above, on the application of the right to health to the Covenant, accessibility has four dimensions:

▶ Non-discrimination: health facilities, goods and services must be accessible to all, especially the most vulnerable or marginalised segments of the population, in law

and in fact, without discrimination on any of the prohibited grounds.

- ▶ Physical accessibility: health facilities, goods and services must be safe and reach all segments of the population, especially vulnerable or marginalized groups such as ethnic minorities and indigenous peoples, women, children, adolescents, the elderly, people with disabilities and people living with HIV/AIDS.
- ► Economic accessibility: health facilities, goods and services must be accessible to all. Payment for health services, as well as for services related to basic determinants of health, should be based on the principle of equity, ensuring that these services, whether provided privately or publicly, are accessible to all, including socially disadvantaged groups.
- ► Accessibility of information: accessibility includes the right to seek, receive and impart health-related information.

The commentary further clarifies that accessibility includes both equal and timely access to "essential preventive, curative, rehabilitative health services." It imposes a specific obligation on States "to provide those who lack sufficient resources with the necessary health insurance and health facilities and to prevent any discrimination on internationally prohibited grounds in the provision of health care and health services, especially with regard to the fundamental obligations of the State to realize the right to health" (paras. 17 and 19 of General Comment No. 14 to the Covenant).

Affordable medical care in the positive legal framework in Bulgaria

Accessible medical care in Bulgaria is regulated in Article 82, paragraph 2, item 1 of the Health Act. According to the dictionary^[55], "accessible" means "available to someone, which can be reached or made easily without great effort".

According to Article 81, paragraph 2, item 1 of the Health Act, accessible care shall be provided in compliance with the principles of timeliness, sufficiency and quality. The linguistic interpretation leads to the conclusion that medical care should, in the first place, be physically accessible^[56]. This means that there should be sufficient medical facilities and medical professionals available to provide sufficient (within the required volume) and timely (within the required range of time) medical care to any patient who needs it. In order to be physically accessible, healthcare facilities should also have an accessible environment and infrastructure.

Secondly, for medical care to be accessible, it must be feasible, i.e. the patient must have real access to this care - including the economic possibility of access, i.e. being able to afford the treatment.

Therefore, accessible medical care is available and feasible when it can be provided in the required scope and

⁵⁵ Dictionary of the Bulgarian language. Sofia. Lyubomir Andreichin, 1977 - 2014.

⁵⁶ This thesis is supported by Zinovieva, D. Medical Law, Sofia. 178

within the optimal time frame. The understanding of the concept of "accessible medical care" that is embodied in Decision No. 32/1998 in Case No. 29/1998 of the Constitutional Court of the Republic of Bulgaria is also essential. According to the interpretation of the Constitutional Court, "accessible medical care" is understood as "the possibility of medical treatment for all citizens in case of illness and equal conditions and equal opportunities to benefit from the treatment".

In the context of the introduction of absolute *apriori* prohibitions that restrict access to medical care for groups of patients, the **Constitutional Court** has ruled in **Case No. 15/2023**. In this sense, the reasoning of the judgment should also be taken into account: the CC obliges the State to apply the principle of proportionality when regulating public resources for the provision of medical care: 'According to this principle, a legal provision which restricts fundamental rights must be, in addition to being necessary, appropriate. A statutory provision is appropriate if it is capable of achieving the result sought".

Resource allocation - international legal standards

The human rights standards of equality and non-discrimination are closely linked to the accessibility standard discussed above. The main differences are in the emphasis on prohibiting discrimination on the basis of specific

characteristics or in relation to specific groups, and in the scope of the standard, which goes beyond access.

Equality and non-discrimination are increasingly interpreted as requiring not only legal and formal equality, but also substantive equality in relation to healthcare (**General Comment No. 22, para. 24**).^[57]

According to General Comment No. 14, "the Covenant proscribes any discrimination in access to health care and underlying determinants of health, as well as to means and entitlements for their procurement, on the grounds of race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth, physical or mental disability, health status (including HIV/AIDS), sexual orientation and civil, political, social or other status, which has the intention or effect of nullifying or impairing the equal enjoyment or exercise of the right to health."

The Commentary further emphasizes that "States have a special obligation to provide those who do not have sufficient means with the necessary health insurance and health-care facilities, and to prevent any discrimination on internationally prohibited grounds in the provision of health care and health services, especially with respect to the core obligations of the right to health."

Misallocation of health resources can lead to discrimination that may not be overt. For example,

⁵⁷ General comment No. 22 (2016) on the right to sexual and reproductive health (article 12 of the International Covenant on Economic, Social and Cultural Rights).

"investments should not disproportionately favour expensive curative health services which are often accessible only to a small, privileged fraction of the population, rather than primary and preventive health care benefiting a far larger part of the population" (General Comment No. 14, para. 19).

According to **General Comment No. 3**^[58], paragraph 12 on the nature of States Parties' obligations under the Covenant, even in times of severe resource constraints, vulnerable members of society must be protected from the adoption of low-cost targeted programmes that limit access to quality health care.

General Comment No. 25, paragraph 25, on the right to the benefits of science emphasizes that "[s]tates parties to the Covenant are under an immediate obligation to eliminate all forms of discrimination against individuals and groups in the enjoyment of economic, social and cultural rights. This obligation is particularly important in relation to the right to participate in and enjoy the benefits of scientific progress and its applications, since this is where serious inequalities exist".

The UN Convention on the Rights of Persons with Disabilities requires States to prevent discriminatory denial of health care or health services on the basis of disability (Article 25).

According to the current Recommendation of the Committee of Ministers of the Council of Europe CM/

⁵⁸ General Comment No. 3: The Nature of States Parties' Obligations (Art. 2, Para. 1, of the Covenant).

Rec(2023)1^[59] for equal access to medicinal products and medical equipment in case of shortages, the following basic principles defined in Articles 4 and 5 should be taken into account:

- Non-discrimination in their allocation discrimination in the allocation of the medicinal products referred to and the apriori exclusion of patients is prohibited (Article 4).
- Specific attention to vulnerable and disadvantaged patients (Art. 5) and use of medical criteria in resource allocation (severity of condition, expected effectiveness, possible therapeutic alternatives, health consequences of lack of access for the person deprived of medicines or equipment).

According to these criteria, the initial exclusion of a group of patients from access to medicinal products for lack of funds and resources on general grounds (age, disability) without the introduction of medical criteria constitutes discrimination.

That Recommendation also introduces procedural requirements for the constraints put in place - policies and decisions should be made on the basis of clear and accurate evidence based on real, clear, measurable criteria (Article 10 of CM/Rec(2023)1). General Comment No. 20^[60] to the Covenant also requires the introduction of objective and reasonable criteria when introducing restrictions that treat patients differently.

⁵⁹ https://search.coe.int/cm#{%22CoEldentifier%22:[%220900001680aa0476%22], %22sort%22:[%22CoEValidationDate%20Descending%22

⁶⁰ General comment No. 20: Non-discrimination in economic, social and cultural rights (art. 2, para. 2, of the International Covenant on Economic, Social and Cultural Rights). https://www.refworld.org/legal/general/cescr/2009/en/68520

Several conclusions can be drawn from what has been said so far:

- International legal instruments do not explicitly prohibit the restriction of access to a range of health services, and lack of access to certain services does not constitute a violation of the right to health per se.
- However, the restriction of access should be carried out in compliance with certain principles, which include non-discrimination, the use of objective and clear criteria and the prioritisation of vulnerable and disadvantaged groups.
- It should be noted that the requirement of progressive realization of the right to health is violated when access to medical care is restricted in the following cases:
- —In no way can the restriction of so-called core obligations be justified and perceived as being in line with international law, therefore access to basic, essential medical services and medicinal products cannot be restricted on any grounds.
- With regard to restrictions on access to medical care and services outside the core obligations, the following circumstances shall be assessed: 1) the restriction should be justified; 2) possible alternatives should be well explored; 3) the groups affected by the restriction should have been involved in the examination of the measures and their alternatives; 4) whether the restriction results in direct or indirect discrimination; 5) whether the restriction will have an impact on the realisation of the right to health and will result in an individual patient or group of patients being restricted from accessing^[61].

⁶¹ Den Exter, André (2017). The Right to Healthcare under European Law. Diametros 51:173-195.

Conclusion

Given the above, it should be pointed out that Bulgaria is a party to the above-mentioned sources of international law, which makes them directly applicable and part of positive law. Therefore, our country is obliged to respect the principle of progressive realization of the right to health by ensuring unrestricted access to basic medical services within the so-called *core obligations*. Despite some disputes in scholarship and practice as to what is included in these core obligations, it is certain that the analysis of General Comment No. 3 to the ICESCR refers to "essential primary medical care." It includes at least the following: provision of clean water and food, child and maternal health care, health promotion and health education, promotion and treatment of common diseases, and provision of essential medicines.

Undoubtedly, the right to health includes the provision of accessible healthcare, which should be physically, economically and informationally accessible with priority for vulnerable groups and with respect for the principle of equality and non-discrimination. Restrictions on access to medical care and services should be exceptional and subject to certain rules and criteria.

MECHANISMS FOR ALLOCATION OF SCARCE HEALTH RESOURCES -A SURVEY OF PRACTICES

Quality and effectiveness of the regulatory framework

The regulatory framework for health care in Bulgaria provides basic mechanisms for resource allocation, but the general impression of the different actors in the system is that these mechanisms are often inefficient, unevenly applied and purely bureaucratic.

Different stakeholders have minor differences of opinion regarding the reasons for inefficiencies in spending the available resources - most often they relate them to the lack of transparency, coordination, adequate funding and practically Stakeholders applicable mechanisms. note that while regulations exist and in theory provide a framework for action, in practice they are often disregarded or remain ineffective due insufficient institutions, to communication between bureaucratic obstacles, lack of accountability and impartial oversight.

While the summarized conclusions are similar, respondents reached them through different empirical routes. With regard to mechanisms for creating equitable public healthcare policies that ensure respect for the rights of all stakeholders, one criticism relates to the lack of a normative requirement for adequate data, analysis and models on which to base resource allocation decisions, leading to their waste. It is noteworthy that the criticism comes from experts who hold and have held high positions in the system, in response to an open question about equity in the system. According to them, resource management should be based on real data of needs and necessities, which would lead to a more efficient and equitable distribution of resources for medical devices, medical care, medicinal products and medical assistance devices for people with disabilities.

"We are one of the top countries in terms of mortality and morbidity from cardiovascular disease, but we have not identified which people develop cardiovascular disease, at what point, we have not targeted these people long before they develop the disease. That is why we have the same drugs that are available in the European Union, but we are not using them effectively as other countries with access to the same drugs" (former minister).

Another problem is the complexity, lack of coordination or the imposition of insurmountable requirements in the implementation of regulations. Different respondents shared varied experiences with this problem. One striking example relates to ensuring access to treatment for socially vulnerable

patients. It indicates that some of the existing mechanisms aimed at achieving equitable distribution of resources to the most disadvantaged groups do not actually work.

"The main document that mediators work with when it comes to vulnerable groups is Decree 17/2007^{[62]62} of the Council of Ministers, which provides for certain groups of patients to be able to be hospitalized with funding from the state. But not all hospitals respect it... And there are a number of requirements that do not make it easily applicable" (health mediator).

The situation is similar with regard to the mechanisms envisaged for the correction of regional disparities and the uneven territorial distribution of resources - these mechanisms exist in some form in the legal framework, but they are unworkable and therefore - ineffective at a systemic level.

"In smaller settlements, the lack of hospitals and pharmacies significantly hampers access to health services. In Sofia, for example, there is a surplus of pharmacies, but in Yambol people travel miles to buy medicines. This shows that the system does not work for equal distribution" (politician).

None of the respondents were asked in specifics about "clinical pathways" as a mechanism for the distribution of financial resources in hospital care, but nevertheless some of them pointed them out as a factor leading to unfair or at least unbalanced behavior of the medical institutions and the people working in them. On one hand, the medical institutions have an

⁶² Decree No.17 of 31 January 2007, https://www.mlsp.government.bg/zakonodatelstvo-3

interest in "selecting patients according to the pathways that would bring them the most money", even when this does not serve the best interest of the patient. Moreover, this system leads to unprofitability of severe cases and incentivizes medical facilities to "perform more and more activity" in order to provide the staff's salaries. On the other hand, "it is a problem that there is no consistent logic in fund allocation to the pathways", and resource allocation is the result of the fact that "different specialties over the years have managed to lobby for more". A medical focus group participant said:

"... I want a person to be seen as a person first, not as a walking clinical pathway and revenue stream for the hospital. This is very important and at the moment there is no way".

In addition to criticism about resource allocation mechanisms, some respondents shared a similarly critical sentiment regarding the norms that ensure the representation of different stakeholders in decision-making at all levels - from public policy making to the treatment of each individual patient. It should be particularly noted that within research interviews both rank-and-file physicians and experts at the managerial level acknowledged that the mechanisms for including diverse societal groups in decision-making processes are merely formal. The weight of the opinion of patients and patient representatives as well as other public groups is again ultimately determined by the representatives of the system - at

the political level those are the healthcare institutions, and at the individual level they are individual medical professionals.

"At a meeting of the Public Council for Patients' Rights we presented the problem (...). Documents were submitted, translated with our own funds, but since then we have received no response. At the meeting itself, the professional associations' representatives behaved vulgarly and the patient was not at all the leader of the conversation" (focus group with patients).

At the institutional level, 'citizen participation' most often refers to the involvement of a specific group of directly affected patients and/or their representatives. Their role is perceived primarily as that of 'system control', much less often as participation in creating the rules by which the system is to operate. One possible reason for this is that the citizens do not have direct influence over the management of the funds that they necessarily allocate to healthcare. These resources are managed on their behalf by the Ministry of Health and the National Health Insurance Fund, but the individual citizen has no instrument either to sanction them or to withdraw his contribution if he is not satisfied.

"The citizen is absolutely missing, he is nowhere. He's not represented, he's not catered to, he's not chased by some people offering him things to buy. When a patient enters a hospital, he is treated as if he were some kind of burden. (...) They have no incentive to cure him, the outcome depends entirely on the personal qualities of the particular medical professional" (economist).

On a micro level, the various physicians and medical professionals involved share diametrically opposed beliefs on the issue. While some advocate that "patients do not have the necessary knowledge base to make a decision and the doctor must apply his intuition to guide them to the right decision", others are convinced that "the time to talk to patients is scarce, but no less important than treatment". Which factors shape and determine one position or the other among clinicians would be the subject of further research.

The inconsistent experiences of different respondents indicate that in the Bulgarian healthcare system the participation of different stakeholders in decision-making is unsystematic and unequal, often based on subjective decisions and anecdotal practices.

This applies not only to the inclusion of different societal groups, but also to the unequal participation of different medical professions. Physicians, especially those with specialties and those appointed in high administrative positions, are the main figures influencing decisions at the national and local level, and the research shows an awareness that this leads to imbalances. "Key medical professionals are not always included in working groups to make healthcare policies," says one respondent with a high management profile. Other professionals, such as nurses, paramedics and health care assistants, often remain on the periphery and are poorly represented in strategic processes, leading to neglect and underestimation of their role in these processes and hindering effective health service delivery. In order to achieve a balance,

it is necessary to create mechanisms for the integration and representation, alongside citizen participation, of all medical subspecialties in the decision-making process. At present, such mechanisms exist locally at a facility level, but again depend entirely on the management of any given hospital or medical centre, with no guarantee of autonomous initiative.

Ethical considerations in the allocation of limited health resources

Ethical principles in health care are poorly institutionalized and most often reduced to the personal beliefs of the participants.

"In some places there are just some individuals who have taken on like donkeys everything they can carry, and they work, and they act, and they have pretty good ethics" (health mediator).

The findings of the study suggest that, as a result, participants in the system remain highly reticent about the weight and effectiveness of ethical principles. They seem to represent more of a good wish that everyone shares, but no one is applying in practice. A high degree of consensus emerged among respondents that health resource allocation decisions at public policy level are not only not always based on equity or patient care, but in many cases are also the result of lobbying, vested interests, ambition or a desire to minimise costs.

"The moral commitment to evidence-based resourcing, equity and inclusion is not embedded in the system. There is no culture of transparency or a long-term vision for equity" (former Minister).

"There is a lot of lobbying going on in the negotiations for funding from the NHIF, and the focus is not the patient. The quality of the treatment is not guaranteed by the NHIF, but by the goodwill of the specialist with whom they will end up" (economist).

This creates conditions for tensions to arise in the executive segment of the system - between medical staff and administrative representatives, between medical staff and patients, between patients and administrators, etc. Within the study, medical professionals reported that they face administrative pressure to reduce costs, which may be contrary to the best interests of the patient. At the same time, patients identify as unethical and subjective decisions not to authorize or undertake a treatment due to the patient's unfavorable prognosis.

"I advised the mother to call, not to stop. But in the end they told her that if anybody was going to go to the States, it wasn't going to be N. because she was hopeless, you know? And I couldn't fight for this child. (...) And what I wanted to say is that this kind of selection of who should go or who should get state funding for treatment, or who should be bought, for example, medical assistance devices and so on, is done at the individual level, including at the hospital level, including at the level of the person who in this case has the power to stop or move something" (patient advocate).

Medical professionals themselves highlight the lack of specialized training in medical ethics, empathy and patient communication as a serious gap that hinders their work. Overtime work and subsequently burnout are also seen as risk factors for maintaining a high ethical environment.

"We are so overwhelmed that we can't give the proper attention to the patient as a person. We see them as a case, as a diagnosis, because otherwise we wouldn't be able to function. This is not only a problem of the profession, but also of ethics" (nurse).

Ethical considerations with regards to medical staff as a specific resource were not mentioned by respondents without explicitly addressing the topic. We found no spontaneous understanding of the relationship between the quantity of staff and the quality of the medical care provided in terms of an ethical issue. The topic is mainly considered through the prism of medical standards and the requirements of the National Health Insurance Fund.

Equitable access of vulnerable groups to limited health resources

In the context of healthcare, vulnerable groups are communities or individuals who are at greater risk of health problems due to social, economic, geographical, cultural or other factors. They often face barriers in accessing medical care, treatment or preventive services. Vulnerable groups may include people with low incomes, the uninsured, migrants, the

elderly, children, people with chronic diseases, rare diseases or disabilities, and members of minority ethnic communities. These groups are often disadvantaged in the health system due to lack of adequate support, discrimination or ineffective targeting of resources to their needs. In Bulgaria, people without health insurance have limited access to publicly funded health services. Different, in some cases opposing views emerged regarding the balance between the right of vulnerable persons to receive medical care and their contribution to the system.

Some of the opinions presented indicate that members of vulnerable groups in Bulgaria rather lack equitable access to health resources. There is also a lack of effective mechanisms to ensure their participation in decision-making in the health participation in decision-making in the health provides opportunities for the benefit of these groups, they often remain unused or unenforced in practice.

"It's very difficult to get an exam under Regulation 26/2007^[63], unless pregnant women from vulnerable groups are referred through some kind of social worker or through a health mediator, because you have to launch a minor advocacy campaign in every place to get that woman accepted" (health mediator).

Vulnerable groups' access to healthcare resources often depends on the individual initiative and commitment of supportive professionals or healthcare facilities that make

⁶³ Ordinance No 26 of 14 June 2007 https://lex.bg/laws/ldoc/2135556407

efforts to compensate for systemic deficiencies. In this regard, the professionals who commented on the topic through their personal experience with it defended the view that vulnerable groups are likely to access medical care when they need it. One of the arguments in this direction is the "misuse" of emergency care for health needs that are not characterized by emergency, or even urgency, as a means of entry into the healthcare Some professionals referred to their personal system. willingness to serve patients of different socioeconomic status or to particular effective solutions at the facility level that significant potential for demonstrated even implementation. Analysis of the responses suggests that these examples are based on the initiative and goodwill of medical teams and hospital administrations, rather than systematically organized or centrally managed mechanisms operating at the national level. This leads to a lack of equity and sustainability, with a significant proportion of vulnerable groups remaining outside the scope of the medical care they are legally entitled to, while individual cases of patients from vulnerable groups manage to receive a higher level of care in situations where their health condition does not necessarily require it. Cases in which members of vulnerable groups have access to the highest level of care remain anecdotal.

"I'll never forget, they recently transported a minority child overseas for a liver transplant, we used an Air Force resource. The comments under the announcement said that it must have been the child of a government official, that this is obtainable only for a select few, which it really isn't. Any child for whom we

have raised indications has access to this resource, which is actually quite expensive" (physician).

According to patients and patient representatives, one of the reasons for this inequality is rooted in the limited and often formal participation of representatives of vulnerable groups in decision making on the allocation of healthcare resources. This is particularly true for the uninsured, insofar as NGOs and patient organizations are at least formally represented on the NHIF governing body.

Of particular concern, however, are signs of increasing acceptance of discriminatory practices and targeting or restricting resources solely on the basis of vulnerability.

"It is becoming easier and easier to articulate some views that are quite cynical, downright fascist. To comment that it would be nice to have programmes to limit the birth rate in the Roma community... This is being said by people who work in a hospital where most patients are from such communities" (health mediator).

"It matters whether it's children or adults. The ethnic background matters. Social status matters, but not only. Italsomatterswhetheryouhaveagoodchanceorpotential as a patient, because in those with severe disabilities, thosewhosepotentialismuchmorelimited, nobodywould want to invest at the institutional level" (patient representative).

CONCLUSION

The distribution of healthcare resources in Bulgaria is constrained by systemic deficiencies that lead to imbalances and unequal access, with vulnerable groups most severely affected. Findings from the field study point to the need for a more transparent, data-driven and ethically oriented resource management system. The main issues identified are:

Limited and unequal access to healthcare resources

In Bulgaria, the allocation of limited health resources is hampered by territorial imbalances, lack of adequate coordination between institutions and significant socioeconomic disparities. Vulnerable groups are often marginalised, and their access to resources depends more on the individual commitment of healthcare professionals and hospitals than on systemic mechanisms.

Fragmented regulatory framework

While the regulations provide for resource allocation mechanisms, their implementation is hindered by bureaucratic obstacles, lack of coordination and effective monitoring.

Unequal participation of stakeholders

The regulatory framework provides mechanisms for the participation of civil society and patient organisations in decision-making, but these often remain formal and ineffective. Citizens, patients and especially some vulnerable groups are poorly represented and their views are rarely taken into account in resource allocation.

Insufficient transparency and reliable data

One of the main problems is the lack of data and analysis to guide the processes of resource allocation. This leads to inefficiency and waste amidst limited resources and a high proportion of unmet healthcare needs.

Ethical challenges

Ethical principles in healthcare are poorly institutionalized. Resource allocation decisions are influenced by factors incompatible with ethical doctrine - lobbying at the macro level, as well as subjective medical decisions and factors such as social status, ethnicity, or an assessment of the patient's "promisingness" at the micro level. Collectively, these create conditions for discrimination, inequity and inefficiency in resource allocation.

CONCLUSIONS AND RECOMMENDATIONS

Conclusions

The analysis shows that the practices for allocation of limited health resources in Bulgaria are based mainly on implicit models, which is associated with a lack of transparency, accountability and systematicity.

While there is a normative basis for explicit resource allocation, in practice it is applied only to a limited extent, calling into question the fairness of the process and the ability of the system to respond to the needs of different stakeholder groups.

Regulations and international requirements

The regulatory framework in Bulgaria follows key international legal principles such as equality, non-discrimination and progressive realisation. However, there is a lack of clear mechanisms for their implementation in daily

practice, especially regarding the involvement of patients and other stakeholders.

The lack of integrated processes based on objective medical criteria limits the effectiveness and sustainability of healthcare decisions.

Practices against the regulatory framework

Allocation practices often diverge from the regulatory framework, which requires transparency and fairness. Denying access to socially vulnerable patients or applying subjective selection criteria are examples of the shortcomings.

The gap between regulatory requirements and practical implementation is the result of insufficient coordination, lack of capacity and ineffective resource management.

Recommendations

In view of the conclusions and limitations of the present study, it is necessary to conduct in-depth studies on the impact of implicit models on different stakeholders and identify objective criteria for explicit distribution. Special focus should fall on the practice of financing hospital care through clinical pathways and their impact on the equitable distribution of resources in the system.

Systematic and transparent resource allocation mechanisms based on data, evidence, clear medical criteria and public dialogue should be introduced in legislation and

practice, strengthening the participation of citizens, patients, vulnerable groups and different professional groups in decision-making processes.

The long-term goal is to ensure progressive realization of the right to health through a more efficient and equitable allocation of scarce resources in the system.

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