

Sustainable Development of the Health System through the Prism of Patient Participation in HTA in Bulgaria

Claudia I. Georgieva^a, Antonia Y. Yanakieva^b and Alexandrina Vodenicharova^c
Department of Health Technology Assessment, Faculty of Public Health, Medical University - Sofia, Bulgaria

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Abstract: Background: Several countries worldwide are developing policies aimed at patient participation in healthcare as a critical element for sustainable development in the field. HTA is an essential part of sustainable development strategies, and patient involvement as an expert is a mechanism for ensuring transparent, fair, and equitable healthcare. Aim: The study aims to determine the readiness of patients and patient organizations in Bulgaria to be included in the HTA process and outline the challenges for their implementation. Materials and Methods: The study was based on two questionnaires conducted from September 2019 - May 2020. They involved 563 patients and 53 patient organizations in the Republic of Bulgaria. Various analytical approaches have been applied for data processing. Results: Patients in Bulgaria are willing to participate in the HTA process. The survey proves that 67.1% of the respondents would participate in training organized for them. 64.2% would meet with representatives of the HTA institution. 61.2% are willing to assist in the preparation of HTA strategies and work plans. The main challenge for implementing patients in the process is the low level of competence in the field, which does not allow equal participation in HTA. For this purpose, it is necessary to conduct training campaigns and promote the process among patients in our country and allocate funds to support the inclusion of patients in HTA. Conclusions: Stimulating close cooperation between patients, HTA institutions, manufacturers, and users of health technologies is the basis for the modern health system's sustainable development.

1 INTRODUCTION

The sustainable development goals are now steering the global health and development agendas (Hone, 2018). There is an extensive body of literature available on sustainable development. Definitions vary, but in the main they draw out environmental, economic and social dimensions of the concept, emphasizing that progress to date has been achieved at huge cost. The 2005 UK sustainable development strategy sets out five principles (HM Government. Delivering sustainable development together: shared UK principles for sustainable development, 3 March 2021) which resonate strongly with the practice of public health:

- living within environmental limits;
- ensuring a strong healthy and just society;

- achieving a sustainable economy;
- promoting good governance;
- using sound science responsibly (Adshead, 2006).

Health status in general, as well as, the mortality rate at various stages of life in developed, developing, and least developed countries vary based on several factors. The government/health insurance/private funds (out-of-pocket, NGOs, private corporations) spending in health (health expenditures) are few of the factors that mortality rate varies greatly from country to country (OECD. Health spending (indicator), 3 February 2021).

Life expectancy, the morbidity of the population, quality of life are among the indicators that determine how effectively a health system functions (Department of the Environment, Food and Rural Affairs. Sustainable development indicators in your

^a <https://orcid.org/0000-0002-3738-6598>

^b <https://orcid.org/0000-0001-6418-2788>

^c <https://orcid.org/0000-0002-4133-0132>

pocket. London, 27 February 2021). Among the main goals of the National Health Strategy of Bulgaria is to reduce mortality and increase life expectancy while ensuring the sustainability of the implemented measures and policies, allowing 2025 Bulgaria to reach the current European average levels of demographics (National Health Strategy 2020, 3 March 2021). One of the plan's priority policies to achieve these objectives is to build and manage a fair, sustainable development, and efficient health system focused on quality and results (Ministry of Health of the Republic of Bulgaria Action Plan for implementation of the National Health Strategy 2020, 8 March 2021). One of the modern approaches for implementing the development strategy is the inclusion of the patient's experience and opinion in decision-making at different health policy levels. The process includes integrating patients' competencies at various decision-making levels and other state institutions, the National Health Insurance Fund, HTA institutions, professional organizations, and the non-governmental sector.

The concept of sustainable development health care is defined by elements, among which the patient occupies an important place, namely:

1. The health literacy of the population and the resulting choices for leading a healthy lifestyle, sharing responsibility for disease prevention, active participation of patients in treatment, shared with the professional skills and care of medical professionals, skills and readiness for taking care of personal health;

2. Awareness of the population and knowledge of the rights and obligations of patients;

3. Active participation of patients, which are also leading aspects for establishing the concept of sustainable development.

4. An adequate level of health literacy gives patients self-confidence and confidence in dealing with illness and making decisions concerning their health. Personal choice is a leading moral aspect for establishing the concept of sustainable development healthcare development.

Health Technology Assessment (HTA) plays an essential role in decision-making and the allocation of available resources in modern health systems. Health technology assessment (HTA) is the process of systematic evaluation of the properties and effects of health technology, focusing on its direct and expected impact and its indirect and unintended consequences (HTAGlossary, 27 February 2021). The goals of HTA are achieved by assessing health technologies against their clinical effectiveness, cost-effectiveness, safety, social and economic characteristics (EUR-ASSESS Steering Committee, 13 December 2020)

(Government of Australia. Review of Health Technology Assessment in Australia, 16 November 2020). HTA has evolved as a key element to support the distribution of healthcare budgets (Priftis, 2017). In this sense, the HTA process is an essential part of sustainable development strategies, and patient participation as an expert is a mechanism for ensuring transparent, fair, and equitable healthcare.

Specific practical benefits for the sustainable development of the health system through the prism of patient participation in HTA can be identified, namely:

- Fairness - the status of patients as an equal party in the HTA process, along with other stakeholders and access to strategies that allow effective engagement, would prove to the general public that the decisions taken regarding the evaluation and reimbursement of essential health technologies are a fair and just process;
- Equality - the participation of patients in HTA contributes to the equality of all those in need, understanding the specific health problems. In a balanced health system, resources are distributed fairly among all consumers;
- Legitimacy - patient participation in HTA contributes to greater transparency, accountability, and trust in healthcare decision-making;
- Capacity building - overcoming the barriers to patient participation in HTA and joint work between patients and HTA institutions would contribute to the sustainable development of the field based on capacity building of experts in HTA decision making (Guidance for patient involvement in HTA, 20 September 2020).

HTA contributes to the distribution and expenditure of financial resources in the health sector in growing consumption conditions. The main idea of the assessment is to give evidence-based point of view to policy-making (Georgiev, 2017). The inclusion of the patient as an equal party in HTA is essential for achieving a balanced health system and the sustainable development of health care in general. That is why the present study focuses on patients in Bulgaria. It is interesting to study their attitudes and real opportunities for inclusion in HTA.

2 METHODS

The study aims to show patients' attitudes to participate in the HTA process and the challenges before their implementation. Involving patients in the

process would encourage open communication between different stakeholders in HTA.

The object of this review is patients and patient organizations in the territory of the Republic of Bulgaria. The study is multicomponent and complex.

The first component includes research and analysis of information provided by patients about the HTA process in Bulgaria. We collected the data based on a questionnaire in open pharmacies. The survey questions were answered by 567 patients with various diseases, giving information about their level of awareness regarding HTA, their willingness to share experience and point of view, and to assist HTA institutions.

The second component includes a survey among patient organizations in Bulgaria on their point of view and position related to patients' inclusion in HTA. Based on 53 responding organizations, demographic characteristics, general knowledge, and interest in HTA, activity in training, preparation of reports, etc., were analyzed.

The survey was conducted in the period September 2019 to May 2020. Various analytical approaches have been applied for data processing. Descriptive statistics are mainly used. Quantitative variables are represented by the arithmetic mean (Mean) - a characteristic for estimating the central trend and a standard deviation (SD) - a characteristic for estimating the scattering. For categorical variables, the results are presented by absolute frequencies (n) - the number of units in a single group and relative frequencies (%) - the number of units in a single group relative to the total number of units in the population.

The Chi-square test or Fisher's Exact Test were also performed - to study the relationship between descriptive (category) data with two or more categories. The study established a connection between the survey's different questions by determining Spearman's rho rank correlation coefficient.

3 RESULTS

Surveyed patients were 567, of which 62.8% (356 patients) were men and 37.2% (211 patients) were women. The average age of men is 45.03 years, and women are 48.87 years (Table 1).

Table 1: Age and gender structure of the respondents (Mean - arithmetic mean, SD - standard deviation, Min - minimum value, Max - maximum value).

Gender	N	%	Age			
			Mean	SD	Min	Max
Male	356	62,8	45,03	12,89	22,00	81,00
Female	211	37,2	48,87	14,21	18,00	86,00
Total	567	100,0	46,46	13,51	18,00	86,00

The majority of respondents have higher education - 60.5%, 37.4% have primary, and 2.1% have secondary education (Figure 1).

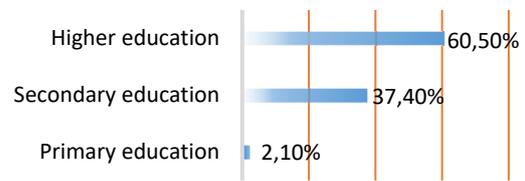


Figure 1: Educational status of the respondents.

The active patients who took part in the study were mainly aged between 41 and 60 years. These are people of active working age, carriers of the disease (acute or chronic), or disease symptoms. The study shows that patients with this profile would be most useful for the HTA process.

To be included in evaluation procedures, it is crucial to what extent the average patient is familiar with HTA. 43% of respondents show a complete lack of knowledge in the field, and 37.4% - "somewhat low" awareness. The data show that most respondents are not familiar with the concept of HTA (Figure 2).

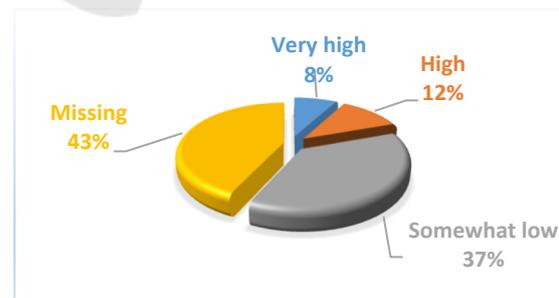


Figure 2: Level of knowledge of the concept of Health Technology Assessment.

Statistical analysis reveals a relationship between the level of competence in the field of HTA and the age of patients. The confidence interval $p < 0.001$ indicates the result's statistical significance (Table 2).

The respondents indicate the highest level of knowledge of the process under the age of 31. 14.9% state that they have knowledge at a "very high" and 18.4% in a "high" degree. With age, the percentage of patients who know the process to a more significant extent decreases. Younger patients have greater access to information technology and social

networks. This access allows easier finding of information and communication with various specialists, which is essential for higher competence. There is a tendency for the age group of patients to increase the percentage of respondents with "low" or "missing" awareness in the field of HTA.

Table 2: Relationship between the level of knowledge of the concept of HTA and the respondents' age group.

	Age group					p
	Up to 30 years	31-40 years	41-50 years	51-60 years	Over 60 years	
Very high	13 (14,9)	11 (8,7)	4 (2,9)	12 (9,4)	5 (5,8)	<0,001
High	16 (18,4)	23 (18,3)	7 (5,0)	11 (8,6)	9 (10,5)	
Somewhat low	20 (23,0)	41 (32,5)	56 (40,0)	67 (52,3)	28 (32,6)	
Missing	38 (43,7)	51 (40,5)	73 (52,1)	38 (29,7)	44 (51,2)	
Total	87 (100)	126 (100)	140 (100)	128 (100)	86 (100)	

The situation is similar with patient organizations. For most of them, the concept of HTA is relatively little known. 38% show "low" and 10% "very low" competence in the field (Figure 3).

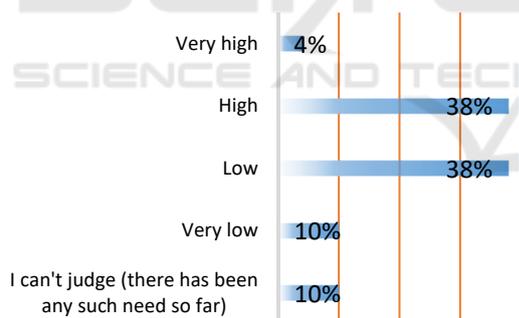


Figure 3: To what extent is your organization familiar with Health Technology Assessment?

The lack of knowledge and interest on the part of patient organizations is mainly due to the fact that they have not had contact or need so far to contact an HTA institution. 67% of the respondents have never participated or were not interested in HTA procedures, and 19% have taken part in such activities from 1 to 2 times (Figure 4).

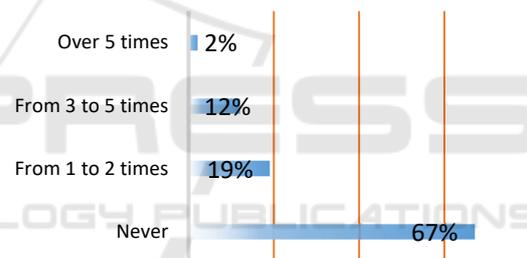


Figure 4: Has your organization been directly involved in making specific health technology assessments?

The results clearly show a low level of knowledge of the HTA process by patients and patient organizations in Bulgaria. The lack of information is also the first challenge for the implementation of patients in the process. It can overcome the Bulgarian patient's low factual competence by organizing training that will increase both their level of competence and society as a whole. Only in this way could the patient be an equal member of HTA committees in decision-making and contribute to sustainable development in the sector.

Several countries around the world are setting a positive example in this regard. The Center for Drug Evaluation (HTA) is the main body in Taiwan dealing with HTA procedures in which the patient is active. The institution organizes training seminars for patients, focused on the legislative framework and the rules for implementing HTA in the country. Part of

the initiatives to stimulate patient participation is the convening of an international conference discussing the global experience in HTA to support and promote patient activity in local HTA procedures (Center for Drug Evaluation (CDE), Taiwan, 20 September 2020).

The agency's main priority in Australia (Australian Department of Health and Aging) is to decide on the reimbursement of medical devices. The country's health system's sustainable development is linked to the profitable consumption of private health funds. The patient's inclusion guarantees the observance of public values and compliance with ethical, legal, and financial norms. The HTA institution finances a "Health Forum", where patient representatives (based on illness, membership in patient organizations) are selected to participate in the HTA process. "Health Forum" is a place where patients can exchange experiences with each other, raise their awareness in the field, and get acquainted with the methodology of HTA in an understandable and accessible language (Government of Australia, 16 November 2020).

Of interest for the study is the extent to which patients in Bulgaria have participated in decision-making affecting their own health statuses, such as upcoming manipulations, health activities, or choice of health technology (Figure 5). 25.7% have never faced such decisions, and 32.6% say they have met a selection of different alternatives to a "low" degree. 25.9% were patients who reported a "high" degree of participation in this type of activity.

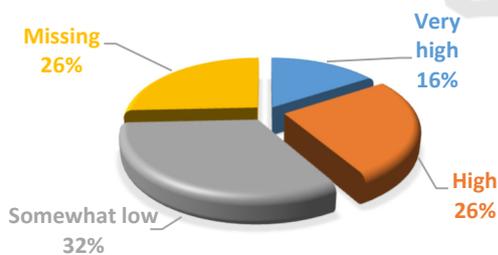


Figure 5: Degree of participation in decision-making concerning forthcoming manipulations or health activities (needs) related to the patient's own health condition.

The analyzes established a statistically significant relationship between the frequency with which patients participated in decision-making and their educational status (the level of statistical significance $p < 0.001$) (Table 3). Patients with the lowest education level most often made decisions in a "somewhat low" group - 75%. Among patients with higher education, "high" and "somewhat low" activity

is reported to approximately the same extent when participating in decision-making affecting their personal health - 29.2% and 29.4%, respectively. Patients with secondary education most often answer "lack" participation in such activities - 36.8%.

Table 3: To what extent have you been involved in decision-making concerning upcoming manipulations or health activities (needs) related to your health condition?

	Primary education n(%)	Secondary education n(%)	Higher education n(%)	p
Very high	2 (16,7)	13 (6,1)	74 (21,6)	<0,001
High	1 (8,3)	46 (21,7)	100 (29,2)	
Somewhat low	9 (75)	75 (35,4)	101 (29,4)	
Missing	0 (0)	78 (36,8)	68 (19,8)	
Total	12 (100)	212 (100)	343 (100)	

Trends show that the majority of patients have not been involved in making decisions about their health. The lack of such practices is dictated by established medical institutions' policies or passivity on the part of patients.

In order to be honored by experts in decision-making, the patient must be willing to share personal experiences and experiences gained in the course of a disease or care to a loved one with specific disease symptoms. 40% of patients state that they are fully prepared, and 37.9% have a "very high" degree of readiness to share their experience and opinion on issues affecting their health. (Figure 6). There is a willingness on the part of patients to openly share their experience in different approaches to treatment and therapy.

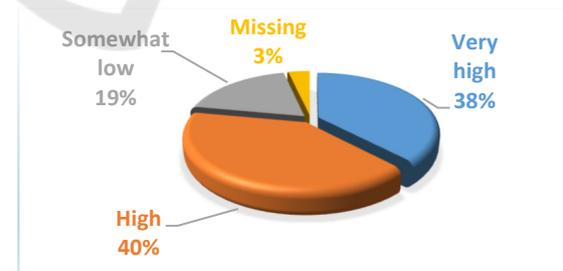


Figure 6: Willingness of patients to share experiences and opinions about their medication or therapy.

It has been proven that in order to achieve sustainable development in the field of healthcare with the active participation of patients, it is necessary to conduct training activities.

To the question "Do you want to participate in pieces of training or seminars organized by an HTA

institution?", 42.9% answered with a "high" degree of desire to participate, and 24.2% have a "very high" desire. "Somewhat low" and "no" willingness to participate indicate 22.2% and 10.8%, respectively (Figure 7). The majority of the surveyed patients would participate in pieces of training organized by an HTA institution. Patients today are open to new knowledge. They want to enrich their healthcare knowledge to more easily overcome the disease or disease symptoms with which they live.

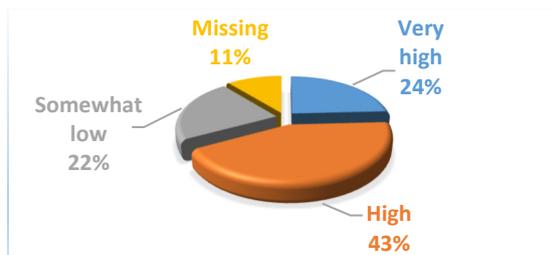


Figure 7: Patients' desire to participate in training or seminars organized by the HTA institution.

The survey proves that 67.1% of all respondents would participate in training organized for them, 64.2% would meet with representatives of the HTA institution, and 61.2% are willing to assist in preparing HTA strategies and work plans (Figure 8).

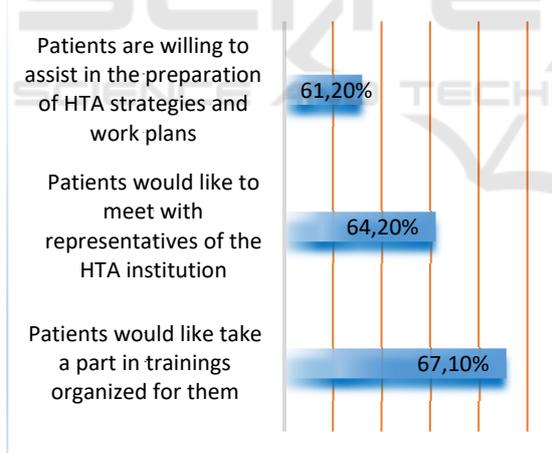


Figure 8: Willingness of patients to engage in activities related to HTA.

To the question "What is your attitude to participate in the Health Technology Assessment process? 46.4% of the respondents give a "high" answer. "Very high" is the attitude of 18.5% (Figure 9). The majority of respondents have a positive attitude to participate in the process and are ready to be involved as an active part in decision-making in HTA.

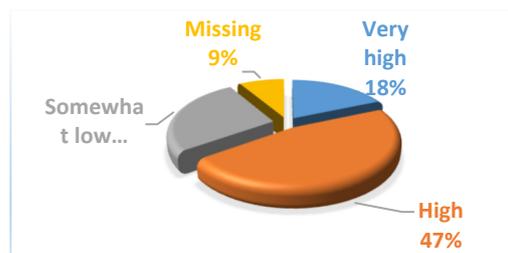


Figure 9: What is your attitude to participate in the Health Technology Assessment process?

The willingness of institutions to cooperate is largely linked to the patient's desire for his voice to be heard and contribute to the health sector's sustainable development. The general attitude is that the patient has the right to express their views on the therapy and to share any inconveniences, side effects, or unpleasant sensations during treatment. Patient participation in HTA would lead to active communication and dialogue with the specialist and selecting the best therapeutic approach. Such an attitude is precious for HTA institutions because the inclusion of the patient's point of view ensures open communication between stakeholders and ultimately the most rational decisions in the field.

One of the next challenges to the useful inclusion of patients in HTA is the lack of sufficient resources (tangible and intangible). Patient organizations were asked if they had the funds to fund staff to engage in the HTA process activities. 86% of them state that they do not have the financial means for such activities. Only 14% of the respondents have the necessary funds (Figure 10). Despite the availability of time, desire, and human resources (patients, members of the organization), this is not enough. Additional funds are needed to engage staff to plan and implement HTA methodologies in participation in the process. Additional funds are required both for a direct financial incentive for other staff and for increasing the knowledge and competence in HTA practices. Additional funding will allow participation in training, seminars, purchase of specialized literature, consulting, etc.

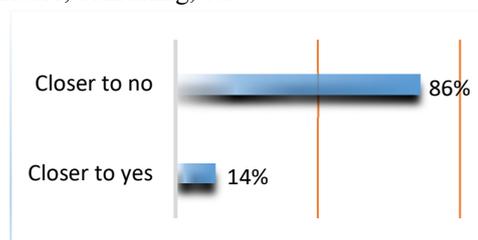


Figure 10: Does your organization have the resources to fund staff involved in coordinating and contributing to the Health Technology Assessment process?

In several countries, patient participation is financially supported by providing fees for seminars, transport costs, seat fees, hotel stays, etc. The Dutch Health Care Institute (the Dutch HTA agency) conducts an open and transparent process through collaboration between patients and professionals, ensuring the reimbursement of patient costs associated with their involvement in the process.

Patient organizations were asked what they see as a basic need in their organization for more effective involvement in HTA. 52% categorically stating "compiling registers of patients and their diseases"(Figure 11). 31% believe that one of the main needs of patient organizations to participate in HTA is "increasing knowledge and competence in HTA methodologies". Many believe that they need a "financial incentive from public authorities to provide information on HTA" - approximately 15%.

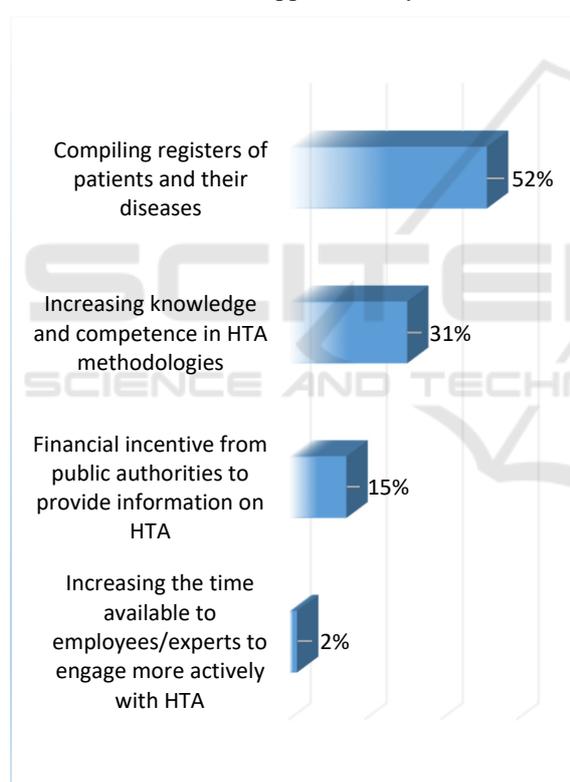


Figure 11: What do you see as your organization's basic needs for more effective involvement in HTA processes?

4 DISCUSSION

The main goal of the HTA process is to provide quality, safe and effective health technologies in the presence of limited resources. Decision-making in HTA must ensure optimal spending of the financial

resources available to a country's health system. At the same time, society's vital needs must be met, which will ensure the health, prosperity, and well-being of citizens, which is the basis for the sustainable development of health care in modern countries.

Involving the patient in the HTA process is key to achieving the principles of sustainable development in healthcare, namely fair distribution of health resources, equal access to health care, quality health technologies with optimal financial resources. The sustainable development of healthcare links the economic with the ecological efficiency of social production. It affirms the principle of equality and justice by increasing human possibilities and civic consciousness.

One of the main challenges to the sustainable development of healthcare is strengthening patients' participation and role in the care of their health by increasing health literacy, health responsibility, and public solidarity. The study shows that patients in Bulgaria desire and are willing to cooperate with institutions through their perspective and experience. Still, the main obstacle to this is the low competence and knowledge related to the methods of HTA. 43% of the respondents lack any knowledge in the field, and 37.4% have insufficient knowledge. At this level of competence, patients in Bulgaria would not be able to participate as a legitimate party in the process if they are not further trained for this purpose.

Patients show a willingness to increase their knowledge in the field, aware of their contribution to society, and the chance to help other patients with their personal experience. The analysis proves a positive attitude of patients to participate in the HTA process. In 46.6% of patients, the attitude to participation is "high", and in 18.5%, it is "very high". Against this data's background, 25.7% of Bulgaria patients have never participated in decision-making affecting their health, and 32.6% have participated in such activities to a somewhat low degree. The lack of experience on the part of patients in the choice of healthy alternatives can be another challenge for the health system and HTA institutions due to the impossibility of building patients' capacity with expert opinion.

The creation of registers is of paramount importance for patient organizations' work and their effective participation in HTA. To be of maximum benefit to the process, HTA institutions must target patients appropriately. When assessing a specific health technology, participants must have some "technical" knowledge. Usually, these are patients in the field they represent (orthopedics, urology, cardiovascular diseases), providing expert opinions

and advice from the patient's perspective living with the disease.

In summary, the contribution of patient participation in HTA to achieving sustainable development in the health sector requires several legislative changes to stimulate the consideration of the patient's point of view in his treatment. Changes are needed in the health policy of medical institutions and health institutions in the direction of active involvement of patients in the treatment process, choice of therapy, treatment specialists, procedures, and manipulations to become a legitimate participant in HTA.

5 CONCLUSION

The involvement of patients in healthcare and, in particular, in the general practice of development and evaluation of health technologies allows new and valuable products to be developed and to be directly addressed to patients and their unmet needs. Patients' participation in the HTA process is an initial step to be recognized as a key figure in revealing the evaluated health technologies' full value. Stimulating close cooperation between patients, HTA institutions, manufacturers, and users of health technologies is the basis for the modern health system's sustainable development.

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