

Short Communication

Giving patients a voice in Health Technology Assessment decision-making in Greece: a patient advocacy group consensus analysis

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Abstract

Objective This analysis aimed to assess patient advocacy groups' (PAGs) perspectives on patients' and PAGs' potential role in Health Technology Assessment (HTA) decision-making in Greece.

Methods In total, 22 representatives of PAGs participated in a consensus panel meeting. Participants' views were elicited via a consensus panel meeting, through a televoting procedure, based on a structured questionnaire with close-ended questions. Voting was anonymous, to avoid the influence of the dominant personality. After voting, the results were presented to the participants and televoting was repeated to achieve consensus.

Key findings The majority of participants (94.8%) believe that valid information on the developments regarding HTA in Greece is not conveyed to them by the official national regulatory sources. Key sources of valid information on developments regarding HTA were: conferences (95.2%), international PAGs (85.7%) and HTA experts/scientists (76.2%). About 76.2% of participants evaluated PAGs' competence to participate in policy-making concerning HTA scheme formation as moderate or higher. Regarding patients' effective participation in HTA decision-making, greater importance (points 4 and 5 on a 5-point scale) was given to their education on treatment effects in terms of quality of life (100.0%), basic principles of health economics and pharmaceutical policy (95.5%) and ethical aspects of HTA (95.0%). About 55.0% strongly agree that patients should formally express their opinion on HTA issues, while 72.7% believe that patients' opinions on HTA issues should be expressed through participation in the process and right to vote.

Conclusions The participation of patients in HTA decision-making is an issue not only of justice but also of essence. For a productive participation, PAGs training is essential.

Keywords: HTA; health technology assessment; patients; patient advocacy groups; decision-making; participation

Introduction

Universal health coverage has become a primary goal for most of the countries worldwide, making the decision on which health technologies will be reimbursed of utmost importance, especially in the context of finite resources.^[1] Health Technology Assessment

(HTA) is a systematic approach to assess the consequences of health technologies and interventions^[2] and is widely utilized in decision-making on new health technologies' pricing and reimbursement internationally.

HTA agencies around the world have started to involve patients and the general public in their decision-making process.^[3] The framework of this involvement is highly country specific,^[4] and representatives of patient advocacy groups (PAGs) are those generally involved.^[5]

Greece is among the late-comers in HTA implementation and, currently, in the process of establishing a national HTA system. In this context, the aim of this study was to assess the views of PAGs in Greece regarding their potential involvement in HTA decision-making.

Methods

In total, 22 representatives of 10 PAGs operating in Greece participated in a consensus meeting held in August 2019. National PAGs in disease areas for which marketed/under development pharmacotherapies have (or are expected to have) high budget impact, and, thus, to be subject to evaluation, were invited.

To elicit PAGs' perceptions on patients' and PAGs' potential inclusion in HTA processes and decision-making, a consensus panel meeting was held, where elements from the Delphi methodology were applied, namely the use of a structured questionnaire, anonymity of responses, iteration and a feedback process. Data elicitation was based on a close-ended questionnaire, which consisted of questions on participants' sources of information on HTA aspects

and on their perspectives concerning their potential role in HTA processes and decision-making.

Following an introduction about the purpose, scope and process of the meeting, the representatives were given the questionnaire (in paper form). Each of the participant's answers to each of the questionnaire items was given through a televoting procedure. Answers to the questions were fully anonymized, for reasons of data protection as well as the avoidance of dominant personality or strategic voting.^[6] After each voting, the results were presented to the participants on a wall screen as percentages and mean values. Upon completion of the first voting on the questionnaire, voting was repeated to achieve consensus.

Consensus on Likert-scale questions was defined as the achievement of at least 50% agreement on a category or 60% on two contiguous categories.^[7] For dichotomous questions, consensus was defined as the achievement of simple majority (at least 51% agreement on a category). The primary data were analysed on Excel and are presented in the form of descriptive statistics.

Results

Regarding the dissemination of information about the current process and future changes of HTA institutionalization in Greece, the vast majority of participants (94.8%) considered having little or no valid information from official regulatory sources (Table 1).

Table 1 Perceptions of PAGs' representatives on the process of HTA institutionalization in Greece

	N	%
Do you consider that you have valid information on developments regarding HTA from official national regulatory sources?		
Not at all	9	47.4
A little	9	47.4
Moderately	1	5.2
A lot	0	0.0
Extremely	0	0.0
Total	19	100.0
Do you have valid information on developments regarding HTA from other sources of information?		
Yes	16	84.2
No	3	15.8
Which are your main sources of valid information on developments regarding HTA? (multiple choice)		
The media	7	35.0
International PAGs	18	85.7
Conferences	20	95.2
Websites of various institutions, scientific associations and universities	10	52.6
International literature	14	70.0
Scientists/Experts	16	76.2
How much institutional capacity do you believe there is in Greece for the establishment of an HTA process?		
Not at all	5	24.0
A little	12	57.0
Quite	3	14.0
A lot	1	5.0
Very much	0	0.0
DK	0	0.0
Total	21	100.0
Do you believe that the currently implemented system is in place to fulfil the key resource allocation criteria of effectiveness, efficiency and equity?		
Not at all	9	45.0
A little	9	45.0
Quite	2	10.0
A lot	0	0.0
Very much	0	0.0
DK	0	0.0
Total	20	100.0

DK, Don't know; HTA, Health Technology Assessment; PAG, Patient Advocacy Group.

Table 2 Perceptions on patients' and PAGs' involvement in HTA in Greece

	N	%
How do you evaluate the PAGs' competence to participate in decision-making concerning an HTA scheme formation?		
None	0	0.0
Low	5	23.8
Moderate	10	47.6
High	5	23.8
Very high	1	4.8
DK	0	0.0
Total	21	100.0
How would you rate the value of educating patients on each of the following, in view of their potential participation in HTA decision-making? (1 = Not at all important, 5 = Very important) ¹		
Basic principles of HTA	21	90.5
Basic principles of comparative clinical assessment	21	90.5
Basic principles of economic evaluation	22	81.8
Treatment effects in terms of quality of life	22	100.0
Literature searching techniques	22	68.2
Intervention and negotiation techniques	22	81.8
Basic principles of health economics and pharmaceutical policy	22	95.5
Ethical aspects of HTA	20	95.0
Who do you think should participate in HTA decision-making? (multiple choice)		
Pharmaceutical industry representatives	8	44.4
Representatives of competent governmental institutions	15	68.2
Public sector health services providers	16	80.0
Experts (epidemiologists, health economists)	20	95.2
Physicians' representatives	14	70.0
Pharmacists' representatives	10	47.6
Patients	11	50.0
Patients' representatives	19	86.4
Representatives of the general public	9	40.9
To what extent do you agree or disagree that patients should formally express their opinion on HTA issues?		
Strongly disagree	0	0.0
Disagree	0	0.0
Neither agree nor disagree	2	10.0
Agree	7	35.0
Strongly agree	11	55.0
Total	20	100.0
How should patients' opinions on HTA be expressed?		
Through formal information	0	0.0
Through a deliberation procedure	0	0.0
Through a memorandum	0	0.0
Through a hearing process	0	0.0
Through participation in the process	1	4.6
Through participation in the process with a right to vote	16	72.7
Through a consensus process	0	0.0
Through participation in the process with a right of veto	5	22.7
DK	0	0.0
Total	22	100.0

DK, Don't know; HTA, Health Technology Assessment; PAG, Patient Advocacy Group.

¹Cumulative percentage of responses 4 = Important and 5 = Very important.

Nevertheless, it appears that PAGs actively search for information regarding the current status of HTA in general, mostly through conferences (95.2%), international PAGs (85.7%), scientists/experts (76.2%) and international literature (70.0%). About 84.2% states that this information is considered valid.

Most respondents (81.0%) consider that there is lack of institutional capacity regarding HTA in Greece and that the currently implemented system is not able to fulfil the key resource allocation criteria of effectiveness, efficiency and equity (90%).

Regarding Greek PAGs' competency to participate in decision-making on the development of an HTA system in Greece, 47.6% of respondents view PAGs' competency as moderate, while 23.8% as low and another 23.8% as high (Table 2).

Nevertheless, respondents feel that there is a need to further educate patients to efficiently participate in HTA decision-making. In particular, on a 5-point scale (1 = not at all important, 5 = very important), greater importance (points 4 and 5) was given to patients' education on treatment effects in terms of quality of life (100.0%), basic principles of health economics and pharmaceutical policy (95.5%) and ethical aspects of HTA (95.0%).

Almost all participants agreed that patients should be able to formally express opinions during the HTA process. Most PAG representatives (72.7%) believe that this opinion should be expressed through participating in the decision-making process with a right to vote, whereas another 22.7% believe that patients should have the right of veto in an HTA decision.

Discussion

Patient participation in HTA is important, as patients may provide insights regarding their experience with their health condition, the currently available health technologies and the corresponding health benefits and risks and their unmet healthcare needs.^[3,8] Patients may also add new dimensions that are usually overlooked by traditional treatment endpoint measures.^[8] Thus, patients may inform benefit-risk assessments by regulatory authorities and reimbursement decisions by third-party payers.^[9] On the other hand, it has been argued that there may be ethical challenges in patients' participation in HTA processes,^[10] highlighting the need for protection measures against ethical violations.

Patient representatives or PAGs are involved in different stages of HTA by providing submissions, participating in meetings or providing statements in public meetings, being members of HTA committees, drafting or commenting on recommendations and participating in hearings.^[3] Study participants also believe that patients should be able to formally express their opinion on HTA issues through their involvement in the process with a right to vote.

Patient organizations operating in Europe view their competence in various aspects of HTA such as knowledge of basic HTA concepts, evidence-based medicine and understanding of HTA methodology as highly/moderately important.^[5] Patient representatives who are involved in HTA are usually offered training and capacity building *ad hoc* or yearly, general training on HTA, training through courses or webinars and/or training provided by official organizations.^[3] However, there is still a need for education and training programmes to facilitate patient involvement.^[5] Participants in this study also highlighted the significance of patients' and PAGs' education. Educational programmes and material could prepare patients and their representatives for their effective participation in HTA.

Given that patients can have a significant contribution to HTA, their active involvement in the HTA process in Greece and expression of their viewpoints is important. Key prerequisites for the efficient participation of patients in HTA decision-making in Greece are their training on HTA aspects and the development of well-defined patient involvement processes which will also incorporate strict measures for protection against ethical violations.

Conclusions

This study aimed to assess the views of Greek PAGs regarding their potential involvement in HTA decision-making and suggested that patient involvement is an issue not only of justice but also of essence. Training is a key variable for their efficient participation in HTA decision-making.

Author Contributions

Kostas Athanasakis: Study design, data collection, data interpretation, manuscript revision, final approval of the version to be published. Vasiliki Naoum: Data analysis, manuscript writing and revision, final approval of the version

to be published. Eleftheria Karampli: Data interpretation, manuscript writing and revision, final approval of the version to be published. Panagiota Naoum: Data analysis, manuscript writing, final approval of the version to be published. Elpidia Pavi: Project conceptualization, study design, manuscript revision, final approval of the version to be published. John Kyriopoulos: Project conceptualization, data collection, manuscript revision, supervision, final approval of the version to be published. All authors take full responsibility for the integrity of the work and the accuracy of the data analysis.

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Conflict of Interest

The authors have no other potential conflict of interest to declare.

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