

Patient Involvement in Health Technology Assessment in Europe

Results of the EPF Survey



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Executive Summary

Patient involvement in Health Technology Assessment (HTA) is still in its infancy, although several efforts have been initiated in recent years. In the course of EPF's HTA Seminar in 2010, many patient organisations called for support for them to be meaningfully involved in HTA processes.

This is the integrated report of the main findings obtained from the HTA Survey with HTA agencies, decision-makers and patient organisations in Europe which EPF conducted between the end of 2010 and the autumn of 2011. The research aimed to assess the current state of patient involvement in HTA in Europe as well as contribute to the knowledge on the topic by producing a comprehensive report of the results. To this end, responses were collected from 40 HTA agencies, 18 decision-makers and 23 patient organisations through online questionnaires.

The type and level of patient involvement varies widely, which is a reflection of the different rationale, motivation and approach applied in each country. Very few HTA agencies and decision-making bodies currently involve and integrate patients' perspectives in their reports and conduct formal evaluation of the impact of patient involvement in HTA. Apart from financial resource constraints, the main challenges are perceived to be the lack of capacity, time and good methodologies to involve patients. Above all, the question of the exact stage of HTA where patient engagement is needed or is most useful is still being debated. HTA agencies and decision-makers mainly use easy-to-read HTA summaries to facilitate patient involvement, but they need to improve other means of facilitation, such as education and training programmes and holding public conferences, seminars and workshops.

The report ends with a list of recommendations to HTA agencies, decision-makers and patient organisations in order to foster patient involvement in HTA. These recommendations are the HTA agencies' and decision-makers' recommendations to patients, and patients' recommendations to HTA agencies and decision-makers. All stakeholders suggest that patients would need to start by first understanding the principles of HTA and then being pro-active to identify ways and means to get involved. Above all patient organisations have to be vigilant and flexible to emerging opportunities.

The findings clearly support the need for EPF to continue advocating for patient involvement in HTA. Despite the fact that involving patients is in general considered beneficial there are not many HTA agencies and bodies/institutions in charge of decision making on health technologies that do this. Moreover, when there is some form of patient involvement this is often not done in a systematic, comprehensive and meaningful way.

1 Introduction

Health Technology Assessment is a multidisciplinary approach that ideally should involve patients' perspectives; however, in reality, there is still a long way to go in achieving meaningful patient involvement in HTA. The existing material on patient involvement in HTA, though not extensive, includes literature, surveys and tools (e.g. literature in IJTAHC, INAHTA surveys and HTAi Glossary for Consumers and Patients). It has been produced to either directly support or to inform and initiate discussion on involving patients, patient organisations, citizens, informal carers and/or consumers in HTA. Despite doing some good groundwork, patient organisations are still struggling to gain a foothold in the HTA process, as was highlighted in EPF's HTA Seminar¹ held in May 2010. The need to follow up on the seminar, during which the patient organisations clearly called for support to be meaningfully involved in HTA processes, led EPF to conduct this research to further explore and address some of the issues around patient involvement in HTA.

The research was conducted in three stages and involved collecting primary data through surveys with three main stakeholder groups: HTA agencies (first stage), HTA appraisal committees/policy makers (second stage) and patient organisations (third stage). One report for each stage of the survey has been drafted and is accessible at EPF website.

The purpose of this document is to offer a comprehensive overview regarding patient involvement in HTA from the three stakeholder groups' perspectives in order to inform and shape patient involvement in HTA in Europe. This report integrates the main findings from all three stages, gives recommendations to HTA agencies, decision-makers and patient organisations for meaningful patient involvement in HTA processes, and provides some examples of good practices collected through the survey.

1.1 AIM OF EPF HTA SURVEY

The aim of the research was two-fold:

- I. To identify the current situation, good practices in place and the challenges related to patient involvement in HTA in Europe
- II. To contribute this knowledge to the process of informing and building the capacity of patient organisations, HTA agencies and HTA appraisal committees and decision-makers in Europe, by producing a comprehensive report.

¹ The seminar report is available at: <http://www.eu-patient.eu/Documents/Publications/ConferenceSeminarReports/hta-seminar-2010-brussels-report.pdf>.

1.2 AIM OF THIS REPORT

Three reports detailing the results of the three stages of the stages were prepared and publicly shared in 2012 in EPF's website. This report aims to present the results of all three stages of EPF HTA Survey in one comprehensive document in order to compare the perspectives of all three stakeholders that participated in the research. Although it includes all the topics discussed in the previous reports, this document rather summarises the results. For this reason, readers who are interested in more detailed information are invited to consult the stakeholder-specific reports².

² The reports are accessible here: <http://www.eu-patient.eu/Initiatives-Policy/Initiatives/>

2 Methodology

2.1 DATA COLLECTION METHOD

The survey was conducted between the end of 2010 and the autumn of 2011. An online questionnaire was prepared for each stakeholder group where many questions were common in order to ensure comparability of perspectives. On the other hand, each group was asked additional questions in order to gain more insight on their specific views.

The questionnaire comprised multiple-choice questions as well as both open- and closed-ended questions. The Survey Monkey online tool was used to conduct the survey and the questionnaire was sent electronically to the participants' official email addresses. Incomplete surveys were excluded from analysis of the results. Confidentiality of information was ensured through prior consent from respondents.

The scope of patient involvement in the survey was intended to comprise three levels and types of involvement:

Involvement at organisational level:

1. Patient organisations through their representatives

Involvement at individual level:

2. Lay patients
3. Informal carers (relatives and friends)

Note that the term "patient" used throughout the text is meant to cover all three above-mentioned categories.

2.1.1 HTA AGENCIES

HTA agencies were identified through both European and international HTA networks (EUnetHTA, INAHTA, EuroScan and ISPOR member lists), but the survey focused on Europe. The survey used purposive and snowball sampling to identify and invite participants from HTA agencies (a total of 50). The sampling was done independent of the agencies' current status regarding patient involvement in HTA. Both formally established HTA agencies and, in their absence, national/regional bodies that are responsible for HTA were included in the research. The questionnaire was piloted with two HTA agencies in Spain and Lithuania and the questions were modified based on their input. The online questionnaire was sent electronically to participants' official email addresses. A formal request was sent to EUnetHTA Secretariat and EuroScan Vice-Chair to encourage participation of their members in the survey.

2.1.2 DECISION-MAKERS

The first step in preparation for the survey was to identify the relevant decision-makers across Europe. It took a month to identify possible participants, establish communication with them and get their consent to take part in the survey. For this, we contacted HTA agencies across Europe and asked for their support to identify key decision-makers in Europe. 28 decision-makers were identified as a result of this approach. We obtained the contact details of 17 more decision-makers by contacting the relevant national institution(s). 18 out of 45 decision makers from 13 European countries completed the survey. During the follow up with decision makers who did not respond to the survey it was found that the reason for the low response rate was primarily due to lack of time.

2.1.3 PATIENT ORGANISATIONS

The survey was piloted with two patient organisations and the questions were modified based on their input. The first step to conduct the survey was to contact patient organisations across Europe. The following channels were used for this: (1) with their agreement to take part, the survey was sent to all participants of Patient Involved in NICE (PIN) group that includes patient organisations that give their input to HTA, (2) EPF members, and (3) EPF directory of patient organisations in Europe.

2.2 RESPONDENTS

It is important to mention that the conclusions are formulated based on a limited number of responses (see *Table 1*).

Out of 50 HTA agencies invited to participate in the study, 40 completed the survey.

Out of the 18 decision-makers who responded, the great majority were public officials (16) and half of them (nine) were national health insurance board members. Moreover, two-thirds of the respondents are from national institutes and the remaining ones operate at regional level.

Despite several hundred patient organisations receiving the survey and several follow-ups, only 23 patient organisations completed the survey. The patient organisations that participated operate at different levels: national level (22), European level (2), regional level (2), and local level (1).

Table 1: Distribution of respondents across European countries

Country	HTA agencies	Decision-makers	Patient organisations
EU-15			
Austria	3	2	-
Belgium	1	1	-
Denmark	4	1	1
Finland	1	-	1
France	1	-	-
Germany	-	-	1
Greece	1	-	2

Ireland	1	-	1
Italy	4	1	-
Netherlands	1	1	1
Portugal	-	-	2
Spain	6	4	1
Sweden	1	1	1
United Kingdom	4	1	1
<i>EU-12</i>			
Czech Republic	1	-	-
Estonia	1	2	2
Hungary	3	1	1
Latvia	1	1	3
Lithuania	1	-	1
Malta	1	-	-
Poland	1	-	1
Romania	-	-	1
Slovenia	1	1	2
<i>EU candidate</i>			
Croatia	1	1	-
<i>EFTA</i>			
Norway	1	-	-
TOTAL	40	18	23

3 Main Outcomes

3.1 CURRENT PATIENT INVOLVEMENT IN HTA

Out of the 40 HTA agencies that responded, nearly half of them (18) involve patients in HTA. The situation regarding is quite different in EU-15, EU-12, EU candidate and EFTA countries, with only EU-15 member states having an equal number of agencies that involve and do not involve patients in HTA. EU-12, EU-candidate and EFTA countries have a higher proportion of agencies with no patient involvement.

Out of the 23 patient organisations that completed the questionnaire, 10 indicated that their organisations have been involved in HTA. Respondents listed HTA agencies, national health insurance agencies, national health services, and ministries of health as the HTA agencies they interact. They also listed national organisations of pharmaceutical and medicinal products, national health insurance, ministries of health, and national health services as the decision-making bodies/HTA appraisal committees that their organisation interacts with.

Out of 18 decision-makers, four stated that they are planning to involve patients in decision-making for health technologies and three said that they already involve patients. On the other hand, five respondents stated that they do not intend to involve patients in the future and the remaining six either stated that they did not know or did not respond to the question.

3.1.1 SPAN OF PATIENT INVOLVEMENT

The beginning of patient involvement in HTA differs across the HTA agencies in Europe. Those that have established it in the past 5-10 years are from the EU-15 whereas those that established it in the past 1-5 years comprise a mixture of EU-12 and EU-15 member states, though consisting more of the former.

We also observed that the patient organisations that are involved in HTA started contributing patient perspectives to HTA at different time periods. Two of them have been involved for more than 10 years, one has been contributing for 5-10 years and five of them for 3-5 years.

3.1.2 PROVIDERS OF PATIENTS' PERSPECTIVE

For those HTA agencies that involve patients, the interlocutors providing patients' perspectives are mainly patient representatives from patient organisations. Most HTA agencies that involve patients have cooperated with at least three patient organisations. In some countries HTA agencies also involve lay patients and/or informal carers. Out of the 18 HTA agencies that involve patients in HTA, 14 of them actually integrate those perspectives (needs, preferences, patient evidence) in their HTA reports.

Similar to HTA agencies, the survey with decision-makers revealed that the main interlocutor from the patient community giving views to decision-making on health technologies are the representatives of formally established patient organisations. While the involvement of lay patients

and representatives of informal patient groups is negligible, informal carers are not involved at all in decision-making processes. Other interlocutors include representatives of consumers and representatives from health insurance organisations.

Two thirds of the decision-makers who responded stated that there is an appraisal committee at national level that makes decisions on health technologies. The majority of stakeholders that contribute a patient perspective in appraisal committees were indicated to be doctors, patient organisations, and healthcare managers. Lay patient and nurse representation is moderately low, while ethicists and citizens are the least represented stakeholder groups on appraisal committees. Informal carers are not represented at all.

When we look at patient organisations, we see that out of the eight organisations that responded to the specific questions regarding their involvement in HTA, five were represented by staff members who contributed an organisational perspective to HTA, two were represented by lay patient members of the organisation who contributed an organisational perspective, and one was represented by a lay patient member of the organisation who contributed an individual experience. Only three respondents indicated that their perspective was being integrated into HTA reports, while five respondents indicated that patients’ perspective was integrated in decisions made.

3.1.3 TYPES AND LEVELS OF PATIENT INVOLVEMENT

All three stakeholder groups were asked to rate the level of patient involvement on in various stages of HTA. While HTA agencies were asked in which stages of HTA patient involvement occur while the decision-makers were asked how this involvement took place. Finally the patient organisations were asked to provide their experience on both aspects.

Patient involvement in various stages of HTA

According to the responses from the HTA agencies, high to moderate involvement is mainly seen in the phases of diffusion and dissemination, assessment, production of information, and external review. Low to no involvement is seen in the phases of identification, filtration, and prioritisation.

The patient organisations that responded to the survey provided similar feedback stating that they were highly to moderately involved in phases such as diffusion and dissemination, external review, and assessment. On the other hand, different from the responses from HTA agencies, patient organisations declared to be rather lowly or not involved in the stage of producing information. The majority of respondents from patient organisations were lowly or not involved in HTA stages such as production of information, internal review, identification, filtration, and prioritisation.

Table 2: Level of patient involvement in various stages of HTA

Stages of HTA	HTA agencies (n=18)			Patient organisations (n=8)		
	High to moderate involvement	Low to no involvement	Don't know	High to moderate involvement	Low to no involvement	Don't know
Identification	4	12	1	2	3	3
Filtration	2	13	2	2	3	3

Prioritisation	5	13	-	3	4	1
Assessment	8	9	1	4	3	1
Produce information	8	7	2	3	5	-
Internal review	5	9	1	3	5	-
External review	8	7	2	5	2	1
Diffusion and dissemination	9	7	-	6	2	-

Forms of patient involvement in in decision-making processes based on HTA

According to the decision-makers' responses, patients are most involved in decision-making in relation to health technologies through appeals against the final recommendations of the decision makers. The survey with decision-makers reveals that patient involvement and non-involvement are even for each form of involvement. On the other hand, patient organisations that responded to the survey stated that they are involved mainly through public consultations, in providing patient evidence and in appeals against decisions. Note that according to both patients and decision-makers, patients are least involved in HTA in terms of prioritising research topics, topic selection, or scoping.

Table 3: Forms of patient involvement in decision-making based on HTA

Forms of patient involvement in decision-making based on HTA	Decision-makers (n=18)			Patient organisations (n=8)		
	High to moderate involvement	Low to no involvement	Don't know	High to moderate involvement	Low to no involvement	Don't know
Possibility of appeal for patients/patient organisations against the final recommendations of the decision makers	10	7	1	5	2	1
Involvement through public consultations	9	9	-	5	2	1
Involvement in appraisal committees	8	10	-	3	5	-
Patient evidence provided through HTA has been weighted in the decision and is clearly included in public reports and communications	8	8	2	5	2	1
Involvement in prioritising the research topics/topic selection/scoping	4	11	3	2	6	-

3.1.4 REASONS BEHIND PATIENT INVOLVEMENT

The main reason for initiating patient involvement for HTA agencies is the agency's own initiative. Other reasons such as observation of other agencies' experiences, demand from patient organisations and suggestions by HTA networks were found to be less frequent.

Similarly, most respondents from patient organisations stated that they got involved in HTA upon their own initiative and interest, which is followed by the demand from the members of the organisation and policy-makers’/decision-makers’ initiative. The other reasons were HTA agencies’ initiative, observation of experiences or good practices from other patient organisations.

3.1.5 COMPETENCIES REQUIRED TO PARTICIPATE IN HTA

HTA agencies and patient organisations that participated in the survey were asked about the knowledge and skills required by patients/patient organisations/informal carers to be involved in HTA. The vast majority of patient organisations claimed that patients need to be highly to moderately competent in all areas listed. On the other hand, the HTA agencies asking for high to moderate competence and the ones that claim that competence is unnecessary are proportionally almost equal. Note that the “knowledge to interpret standard clinical research” is regarded as an area that needs least competence level according to the HTA agencies.

Table 4: Competencies that a patient organisation/representative should have to be involved in HTA

	HTA agencies (n=18)			Patient organisations (n=8)		
	High to moderate importance	Low to no importance	Don't know	High to moderate importance	Low to no importance	Don't know
Knowledge of Evidence Based Medicine and HTA and basic concepts	7	9	-	7	1	-
Understanding of HTA methodology	8	8	1	7	1	-
In depth knowledge of disease condition	9	8	1	7	1	-
Practical knowledge of how and when to contribute evidence	8	7	2	7	-	-
Knowledge to interpret standard clinical research	3	12	1	7	-	1

3.1.6 IMPACT OF PATIENT INVOLVEMENT

With regard to the impact of patient involvement in HTA on both HTA agencies and patient organisations, the surveys show that patient organisations draw a rather pessimistic picture compared to the HTA agencies. This is not surprising given that most patient organisations either do not know whether their contributions are taken into account or think their contributions are not taken into account (see section **Error! Reference source not found.**). On the other hand, both HTA agencies and patient organisations agree on the areas where patients have the most and the least impact on.

Both groups agree that patient involvement has the highest impact on ‘understanding of the impact of technologies in a real-life context’ (e.g. barriers to complying with current therapy, side-effects, the patient’s ability to pay, etc.), ‘understanding of the quality of life aspects’, ‘accuracy in measuring needs and preferences of patients’, and ‘quality of assessment and comprehensive information’.

Whilst the majority of HTA agencies stated that patient involvement has a high to moderate impact on the reliability and relevance of reports to the local context, patient organisations are rather sceptic about this. The lowest impact of patient involvement was indicated in relation to reducing the costs of HTA reports and improving the timeliness in producing them.

Table 5: Impact of patient involvement in HTA

	<i>HTA agencies (n=18)</i>			<i>Patient organisations (n=8)</i>		
	High to moderate impact	Low to no impact	Don't know	High to moderate impact	Low to no impact	Don't know
Better quality of assessment and comprehensive information	10	4	4	4	3	1
Better understanding of technology impact in real life context (e.g. barriers to comply to current therapy, side effects, patient capacity to pay, etc.)	16	1	1	5	3	-
Better understanding of the quality of life aspects	13	4	1	5	3	-
Higher accuracy in measuring needs and preferences of patients	15	2		4	3	1
Higher reliability and relevance of reports to the local context	10	6	2	2	4	2
Increased timeliness in producing information	4	7	3	2	5	1
Lower costs for producing reports	-	8	6	-	5	3

Similarly, both decision-makers and patient organisations were asked about the impact of patient involvement on decision-making regarding health technologies. Here, the decision-makers painted an even better picture than HTA agencies with regard to patient involvement stating that patient involvement had high to moderate impact in all areas except for ‘increased timeliness in making decisions’.

On the other hand, patient organisations responded in an almost completely opposite way and stated that patient involvement had merely low to no impact on decision-making regarding health technologies except for ‘decisions made meeting patients’ needs in terms of quality of life and patient expected outcomes’. In terms of ‘increased timeliness in making decisions’, the vast majority of patient organisations claimed that patient involvement had low to no impact at all as opposed to equal proportions of decision-makers stating high to moderate and low to no impact.

Table 6: Impact of patient involvement in decision-making for health technologies

	<i>Decision-makers (n=18)</i>			<i>Patient organisations (n=8)</i>		
	High to moderate impact	Less to no impact	Don't know	High to moderate impact	Less to no impact	Don't know
Increased transparency and accountability of decision-making	15	2	1	3	5	-
Decisions that meet patients’ needs in terms of quality of life and patient expected outcomes	14	3	1	5	3	-

Addressing unmet medical needs of patient groups	14	3	1	3	5	-
Higher reliability and relevance of decisions (e.g. which treatment and care should be available)	14	2	2	3	4	1
Decisions will be more consensus-driven	13	2	2	2	5	1
Patient centred health expenditures	11	4	3	3	5	-
Increased timeliness in making decisions	7	7	3	1	7	-

3.2 ENABLERS AND CHALLENGES FOR PATIENT INVOLVEMENT IN HTA

3.2.1 ENABLERS OF PATIENT INVOLVEMENT IN HTA

The HTA agencies, decision-makers and patient organisations were asked about how the decision-making entity/institution facilitates patient involvement in HTA-based decision-making. According to all groups, ‘easy access to key reports/guides/protocols on HTA’ is used the most. This is followed by ‘easy to read HTA summaries in HTA reports that can be understood by patients/patients’ organisations/ informal carers’. However, these items are rather moderately used according to the patient organisations.

While ‘public documents that describe transparent mechanism in how patient views influence decision-making’ was rated as moderately used by decision-makers and HTA agencies whereas patient organisations clearly stated that this is rarely or never used. On the other hand, both HTA agencies and patient organisations agree that ‘easy accessibility to journals’ is the approach the least used.

Table 7: Facilitators of patient involvement in HTA

	HTA agencies (n=18)			Decision-makers (n=18)			Patient organisations (n=8)		
	Often/sometime s used	Rarely/never used	Don't know	Often/sometime s used	Rarely/never used	Don't know	Often/sometime s used	Rarely/never used	Don't know
Easy, understandable and timely accessibility of information on HTA and how to contribute	8	7	1	10	5	2	3	5	-
Easy to read HTA summaries	13	-	3	8	6	3	4	4	-
Education and training courses to patients/informal carers/patient organisations	9	6	1	6	7	4	3	5	-
Public documents that describe the transparent mechanism in how patient views influence decision-making	9	5	3	7	7	3	-	7	1
Easy access to key	13	2	1	12	3	2	4	3	1

reports/guides/protocols on HTA									
Regular distribution of newsletters	8	6	1			2	5	1	
Easy accessibility to journals	5	7	3			1	6	1	
Workshops, seminars, conferences	11	5	-			3	5	-	
Dedicated websites and forums	9	7	-			3	5	-	

When asked how patient organisations themselves facilitate the involvement of their representatives in HTA, we found out that the “easy, understandable and timely accessibility of information on HTA and how to contribute” is the approach mostly used while “organising workshops, seminars, conferences” and ‘easy access to reports/guides/protocols’ are quite low in the list.

3.2.2 CHALLENGES FOR PATIENT INVOLVEMENT IN HTA

HTA agencies, decision-makers and patient organisations strongly agree or agree that ‘lack of agreed and good method to obtain/provide patient evidence’, ‘knowing the stage at which patient engagement is needed or most useful’, and the important time investment required are major challenges for patient involvement in HTA.

It is interesting to note that all three stakeholder groups indicated lacking capacity from their side to implement the involvement of patients in HTA. All believe as well that the lack of financial resources is a significant challenge. Also the view on the commitment of the other parties to enable patient involvement appears as an important matter.

With regard to other aspects the three parties seem to have different views. Even within each group there are at times no conclusive views. It is worth noting that both patient organisations and decision-makers consider the ‘credibility of patient evidence’ an issue.

Table 8: Challenges for patient involvement in HTA

	HTA agencies (n=40)			Decision-makers (n=18)			Patient organisations (n=23)		
	Strongly agree /agree	Strongly disagree /disagree	Don't know	Strongly agree /agree	Strongly disagree /disagree	Don't know	Strongly agree /agree	Strongly disagree /disagree	Don't know
Lack of agreed and good method to obtain/provide patient evidence	19	13	5	14	2	2	12	2	8
Knowing the stage at which patient engagement is needed or most useful	20	11	7	12	3	3	14	2	5
Credibility of patient evidence	14	17	5	13	2	3	13	2	6
Commitment from patients/informal	9	16	10	11	3	4	11	8	3

carers/ patient organisations									
Technical and language difficulties	11	16	8	6	10	2	14	5	3
Time intensive	25	6	3	11	3	4	13	4	5
Lack of financial affordability	15	11	7	8	3	7	13	2	6
Conflict of interest	5	20	6	10	5	3	7	5	9
Lack of capacity of the HTA agency to involve patients	26	7	3				12	2	8
Lack of interest of HTA agency	1	26	5				13	3	6
Lack of commitment from HTA staff	6	19	8				9	3	9
Lack of capacity of decision-making organisation				14	2	2			
Lack of commitment from my institution				8	7	3			
Lack of capacity of the patient organisations							12	9	1

In addition to the common challenges identified, patient organisations were also asked about the main challenges for patient organisations to be meaningfully involved in decision-making on health technologies. Two major challenges are clearly identified as ‘lack of commitment from decision-makers’ and ‘lack of legal or policy framework for patient involvement in HTA decision-making’.

Table 9: Challenges for patients to being meaningfully involved in decision-making on health technologies

Challenges	Strongly agree or agree	Strongly disagree or disagree	Don't know
Understanding who/which institution makes the decisions	14	7	1
Finding an interlocutor within the decision-making body/institution	13	4	5
Understanding the decision-making process	13	7	2
Lack of commitment from decision-makers	17	2	3
Lack of legal or policy framework for patient involvement in HTA decision-making	16	4	2

3.3 IDEAL SCENARIO FOR PATIENT INVOLVEMENT IN HTA

After assessing the current situation of patient involvement in HTA, we then explored with HTA agencies and patient organisations their views on the ideal type and level of patient involvement. The results show a stark difference between real and ideal situations. Both HTA agencies and patient organisations agree that patients need to be moderately or highly involved in HTA stages such as identification, prioritisation, assessment, external review, and dissemination. On the other hand,

HTA agencies were rather sceptical on the need for patient involvement in filtration and internal review, while patient organisations claimed that a rather high involvement is needed also there.

Table 10: Ideal types and level of patient involvement in HTA stages when working with HTA agencies

	<i>HTA agencies (n=40)</i>			<i>Patient organisations (n=23)</i>		
	High to moderate involvement	Low to no involvement	Don't know	High to moderate involvement	Low to no involvement	Don't know
Identification	24	9	5	16	3	4
Filtration	13	14	-	11	5	6
Prioritisation	25	8	5	19	3	1
Assessment	20	11	7	17	1	5
Internal review	10	19	7	15	4	4
External review	26	8	5	16	1	4
Diffusion and dissemination	33	1	4	18	1	4

Besides the stages of HTA, patient organisations were also asked for their ideal scenario of involvement in decision-making on health technologies. The two options with highest rank were ‘public consultations’ and ‘providing patient evidence that has been included in HTA reports used by decision-makers’. However, the remaining options have just one point of difference in scores; we can therefore say that from a patient perspective all aspects proposed should be part of the picture.

Table 11: The ideal type and level of patient involvement in decision-making on health technologies

Involvement in HTA stages through	High to moderate involvement	Low to no involvement	Don't know
Appraisal committees	17	3	2
Public consultations	20	2	1
Provide patient evidence that has been included in HTA reports used by decision-makers	18	1	4
Appeals against the final recommendations of the decision makers	16	1	5
Involvement in prioritising HTA research topics/topic selection/scoping	16	2	4

3.4 GOOD PRACTICES ON PATIENT INVOLVEMENT IN HTA

HTA agencies cited good practices in involving patients in HTA either based on their own or other agencies’ experiences. The main good practices indicated were:

- Involving public contributors to review research articles and full grant applications, and in prioritisation panels and commissioning boards;

- A public involvement unit within the agency which gives advice on appropriate patient groups/organisations to involve in HTAs, and convenes a public involvement network involving representatives from a range of patient organisations as a conduit for sharing good practice;
- A dedicated team of permanent staff in the agency who are completely focussed on and responsible for patient, carer and public involvement across all of the agency's work on patient and public involvement programmes. Availability of formal and informal support and contact details - email, phone, face to face meetings etc.;
- A formal patient, carer and public involvement policy made available on the website of the agency, which sets out the mission, values and commitment to this work and the principles that are followed;
- Offering payment for lay involvement - attendance fees for lay committee members, one-off payments to patient organisations per topic they participate in. Travel and food expenses covered - also carers and childcare costs if needed - to attend meetings, workshops and training;
- Setting up an advisory committee of lay people including patients;
- Using a reviewer form specially designed for patients to review the HTA grant applications;
- Writing a handbook with all the different roles patient representatives may take;
- Organising HTA events specially related to patient participation, where patient representatives are asked to think about relevant issues regarding research.

When decision makers of health technologies were asked to give feedback on existing good practices of patient involvement in decision-making for health technologies, very little evidence of good practice was indicated. A possible reason for this could be that there are only a few good practices known by decision-makers themselves.

Finally, patient organisations described good practices supporting patient involvement in HTA from their or other organisations' experience as involvement in appraisal committees, participation in evaluation of the critical trial process for the development of a new drug, ongoing collaboration with the HTA agency/institution.

4 Conclusions

4.1 KEY FINDINGS

4.1.1 CURRENT STATUS OF PATIENT INVOLVEMENT AND TRENDS

In both aspects of HTA and decision-making patient organisations are poorly or not involved in stages like identification, filtration, and prioritisation where decisions are made about which treatments to assess and what aspects. Without this early involvement there is a serious risk that treatments made available do not respond to patients' needs and that crucial needs remain unmet. In terms of forms of involvement with regard to decision-making, the possibility to appeal against decisions scored highest. Public consultations are also quite used. However, this study did not explore to what extent those influence the decisions made.

It is not very encouraging to see that out of the 18 decision-maker respondents five do not intend to involve patients in the future and six did not reply or did not know. Moreover, where respondents said that patient involvement had reached a proper level it would be important to understand what that means in concrete.

4.1.2 CAPACITY-RELATED ISSUES

There are four main challenges according to all three stakeholders to involve patients in HTA: (1) lack of an agreed and good method to obtain/provide patient evidence, (2) not knowing the stage at which patient engagement is needed and most useful, (3) patient involvement process being time intensive, and (4) lack of capacity (HTA agencies, decision-making bodies, patient organisations). These themes represent all different forms of capacity that need to be in place for a meaningful patient involvement in HTA.

The need for capacity building for HTA agencies, decision-making bodies, as well as patient organisations is a crucial one. On the other hand, the main tools used to support capacity are 'informational' type of tools like reports, summaries, guides, etc. As a complex subject, HTA requires much more than information to enable patients to contribute actively and relevant education and training programmes, particularly at national level are still scarce.

4.1.3 PROVIDERS OF THE PATIENTS' PERSPECTIVE

The main providers of patients' perspectives in HTA are representatives of patient organisations rather than lay patients and informal carers for both HTA agencies and decision-makers. However, with regard to decision-making, it is quite surprising to see that doctors are those mainly providing a patient perspective in appraisal committees while patient organisations are under-represented, whereas we would argue patient organisations and/or lay patients are those best placed to express patients' views. It is also not reassuring that in many countries there is not a transparent selection process for selecting members of these committees.

4.1.4 TRANSPARENCY

In most countries there are laws, regulations, guidelines that support decision-making on health technologies and HTA was indicated by respondents as highly impacting the transparency of decisions in a positive way. However, transparency of decisions remains one of the key concerns for patient organisations and therefore this aspect requires significant further investigation. It is important to also note that public documents describing a transparent mechanism on how patient perspective influences decision-making is rarely or never used according to patient organisations as an enabler for patient involvement in HTA.

4.1.5 IMPACT OF PATIENT INVOLVEMENT

Respondents clearly think that patient organisations can have a high impact in helping HTA agencies and decision-makers to better understand technologies' impact in real life context and also the quality of life aspects' and thus, leading to decisions that meet patients' needs. The downside is however coming from the fact that patient involvement does not necessarily lead to the integration and weighing of the patient perspective in HTA reports and decision-making. There seems to be quite a 'tokenistic' approach that discourages the involvement of patients. Moreover, very few HTA agencies have carried out a formal evaluation of the impact of patient involvement in HTA; therefore there is little evidence of the learning coming from those experiences.

4.1.6 COMMITMENT TO PARTNERSHIP

The survey indicates the need for all parties to bring a real commitment for equal partnership. Currently there seems to be some distrust on the real willingness of other parties to work together. Respondents from the patient organisations expressed the feeling of not being given a place at the table. This seems to be supported by the fact that less than half of the patient organisations involved in HTA indicated that their perspective was being integrated into HTA reports. This might be due to the debated credibility of patient evidence, but also brings about the question whether HTA agencies and decision-makers are really committed in making patients' perspectives part of the game or not.

4.1.7 GOOD PRACTICES

Although a number of good practices have been identified by some HTA agencies and patient organisations, very few examples were provided by decision-makers, which points to a need to improve sharing of those good practices that are available. For HTA agencies these mainly include having dedicated staff or a separate unit to address patient involvement within the agency, developing a special policy to facilitate patient involvement, producing handbooks, financial incentives, and organising HTA events to promote patient involvement. For patient organisations the described good practices are involvement in appraisal committees, participation in evaluation of the critical trial process for the development of a new drug, and ongoing collaboration with the HTA agency/institution.

4.2 RECOMMENDATIONS FOR MEANINGFUL PATIENT INVOLVEMENT IN HTA

In this section some recommendations are listed for HTA agencies, decision-makers and patient organisations based on the outcomes of the survey. Since the recommendations from the patients for both HTA agencies and decision-makers were quite similar, we present them together. On the other hand, since both decision-makers and HTA agencies have recommendations for patients from their perspectives, we present them separately.

4.2.1 RECOMMENDATIONS TO HTA AGENCIES AND DECISION-MAKERS

Better and timely communication with patient organisations is needed. Patients state that they need to be involved in a timely fashion, and not to be asked to comment on reports within a week. They should be involved in setting the outcome measures and criteria for assessing added therapeutic value and effectiveness, not only in the end in the review and assessment phase, but much earlier when drafting the studies in order to prepare the reports.

Capacity Building HTA agencies and decision-making bodies should help patients gain the competencies to contribute to HTA. By just providing access to information without a real skills-building, it is hard to imagine that a meaningful patient involvement can take place. Comprehensive coaching is necessary to ensure that patients are trained in the required areas, and this could be provided by the HTA agencies themselves or other stakeholders with the relevant expertise. Moreover, resources can be pooled from different stakeholders e.g. appraisal committees, national/regional health systems, academic institutions, patient organisations/umbrella organisations that may bring in their expertise, financial and mentoring support. Capacity building for patient involvement in HTA should not just entail educational or training activities; attention must be given to other factors that can affect patient engagement. In the context of capacity building, these are: organisational development, workforce development, partnership working, leadership and resources allocation.

Transparency The process of HTA should be more transparent and explained step-by-step to patients. This would motivate patients who have never contributed to engage in the process and would support further participation of those who contributed already

Policies and Guidelines on patient involvement in HTA are a useful tool to frame patient involvement in HTA in terms of opportunities, roles, methodologies and processes. Most countries do not have a clear framework for involving patients in HTA and we would urge them to establish it, whereas in countries where some sort of framework is available in the form of regulations, policies, etc. a better dissemination to all relevant parties could be done.

Partnership, there is clearly a call from patient organisations to be considered credible actors that can bring value to HTA. This relates to both the process of involvement as well as the outcome. Patients' perspectives should be integrated in HTA reports and decision-making procedures after they are collected. It is very important for patients who have devoted their time and experience to see that their input is valued and integrated into the actual results. If this does not happen, it will result in frustration and lack of motivation to be involved again; the very rationale behind the involvement would then have to be questioned.

The impact of patient involvement should be assessed in a structured way. Integrating a structured assessment of the contribution of patients to HTA could help improve both patient involvement as well as the HTA reports and decision-making process. Moreover, the learning could be beneficial for other actors that want to work towards involving patients in HTA.

4.2.2 RECOMMENDATIONS TO PATIENT ORGANISATIONS

Recommendations for getting involved in the work of HTA agencies

In order to get more involved into HTA agencies' activities, patients are recommended to:

- Educate the organisation's representatives so that they have a basic understanding of Evidence Based Medicine (EBM) and HTA. This covers two things: a broad-based understanding of the nature of HTA and its role in the allocation of healthcare resources and in decision-making should be understood; increasingly, some of the more scientific aspects and cost-effectiveness issues should be understood, and the organisations' representatives should be trained in these aspects.
- Approach the HTA agency pro-actively to ask for involvement and respond to invitations to participate in HTA activities. Following up on information about health technologies and the work of HTA agency would help organisations stay pro-active.
- Engage in different HTA forums where the producers meet and suggest how patient involvement can be achieved in HTA through clear proposals and comments on existing HTA. Provide input to the identification of relevant assessment topics.
- Meet with staff from the agency (ideally someone whose job is to support patient organisation involvement) to learn about the processes and how best to get involved (who to send to meetings, what to put on forms, what type of evidence is most useful).
- Understand the processes of the HTA agency. There are often very clearly defined methods and processes that have to be followed and strict timelines that must be adhered to.
- If the agency has a glossary, ask for it, and use that to better understand the language/jargon/acronyms the agency uses.
- Contact other patient organisations that are experienced in engaging with the agency's work and see whether you can learn from them.
- Demonstrate independence by diversifying the organisation's financial support and having a transparent framework for cooperating with industry. This will help support one of the core principles of HTA, i.e. to remain transparent.

Recommendations for getting involved in the decision-making processes on the introduction of health technologies

In order to get more involved in decision-making processes based on HTA, patients are recommended to:

- Ensure that there are two lay representative members of the group in the planning and decision-making processes of health service boards.
- Stay in contact and build links with decision-makers and ask for more accountable and transparent decisions. Cooperate in building the rules for transparency. This can also be achieved by calling for more transparency in decision processes, using the media, and demanding the legal regulation of patient involvement.
- Lay people or citizens should also represent the views, beliefs and opinions of patients and carers affected by the condition. They should also champion the evidence sent in by the patient organisations, and make sure it is raised in the decision-making discussions.
- Ask for payment and relevant training that is tailored to needs and backgrounds. Lay members should have equal status on the committee and have full-voting rights, as all other committee members do. There should always be at least two lay members on a group, to ensure the patient and public voice is a real one and it is not just tokenistic, or a box-ticking exercise to have them there.
- Participate in review processes of HTA reports and ask for a version that is understandable by patients/patients' groups/patient organisations where applicable.
- Be a member of hearing boards at any local hospital and do lobby work in the national health department.
- Try to have a representative participate in one of the committees that judge the value of HTA research.
- Actively initiate and participate in public debates on introduction of technologies.

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