

Article

The patient at the center of the HTA evaluation process: research protocol

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Abstract. *Background:* HTA is a multidisciplinary evaluation process that examines the short and long term consequences of using new or existing health technologies.

The subjects directly involved in the evaluation are the patients, the only ones who live with the disease and who know deeply treatments, undesirable effects and benefits of drugs and technologies. The evidence provided by patients (EBP) is based on direct experience and this makes it essential in the evaluation process, especially when comparing technologies that achieve the same clinical outcomes.

Objectives: several studies have shown that the assessment by regional administrations is more oriented towards a rationalization and management of economic resources than all the introduction of new technologies that meet appropriateness criteria. Furthermore, the research highlighted a lack of interest in the impact of technology and a low level of involvement of patients and, more generally, of stakeholders in the evaluation process. The aim of the project is to develop, through the tools, a plan for involving patients, their associations and health professionals, to build hta reports.

Methods/design: the methodology will mainly focus on the opinions of the patients and will refer to the "outcomes reported by the patient", ie structured questionnaires concerning the effects of a treatment and / or benefits and advantages of drugs and technologies, through targeted questions on the state of greeting, on the quality of life and on more specific aspects such as the perception of pain.

Conclusion: the quantitative investigation of the structured questionnaires will be accompanied by the tools of the qualitative methodology such as interview, focus group and social media analysis

which will constitute the completion of the feedback analysis of the three recipients identified for the purposes of the project.

Keywords: HTA, patient involvement, patient-based evidence (EBP), patient-reported outcomes-PRO.

Background

HTA is a multidisciplinary assessment process that examines the short and long term consequences of the use of new or existing health technologies.

Health technology is a broad term that includes all aspects of health care, from prevention programmes, medical devices, drugs, medical and surgical procedures to organisational, economic, social and ethical aspects related to the care provided.¹

The HTA process has a direct impact on health policy choices, enabling the provision of appropriate and effective services, containment of expenses and improvement in the quality of medical care.

The evaluation is carried out through the involvement of stakeholders: policy makers, doctors and healthcare professionals, manufacturers, patients, patient associations and all the people who care for the patient (caregivers).²

Among these, those who are directly involved in the evaluation process are the patients, the only ones who live with the disease and who know deeply treatments, undesirable effects and benefits of drugs and technologies. The evidence provided by patients (EBP) is based on direct experience and this makes it essential in the evaluation process, especially when comparing technologies that achieve the same clinical outcomes.³

Over the past 15 years, a long way has been made in defining a methodology that could combine scientific research with the participation of patients and their associations.

In 2017, a theoretical-practical manual was published, Patient involvement in HTA, which was attended by more than 50 authors who come from academic backgrounds and important HTA agencies belonging to the five continents.⁴

A survey reported in 2013 by the International Network of Agencies for Health Technology Assessment (INHTA) showed that 67% of 33 HTA agencies that responded to the surveys, entered HTA programs that involve patient participation.

Despite the gradual increase in patient involvement in the HTA process, confirmed by various experiences in many countries, current research shows that the elements most taken into consideration in the assessment are those related to the consequences of care.

In Italy there has been a national HTA system for some time: however, in a study presented in October 2016 by the National Agency for Regional Health Services (AGENAS)⁵ and by the Italian Society of Health Technology Assessment (SIHTA)⁶ it emerged that the HTA assessment by the regional administrations is more oriented towards rationalization and management of economic resources which introduce new technologies that meet appropriateness criteria. In addition, the

research highlighted a lack of interest in the impact of technology and a low level of involvement of patients and, more generally, of stakeholders in the assessment process.

In the current perspective, the patient's involvement on the methodological level develops through two main strands:

- Scientific research, with the systematic review of the literature, which produces patient-based evidence (EBP);
- The use of techniques that draw on social research using both qualitative methods (interviews, focus groups and social media analysis) and quantitative methods such as standardized questionnaires and other methodologies that measure outcomes that have a specific relevance for patients.^{7,8}

Objectives

Patient involvement in the HTA process is currently a highly discussed topic in the field of public health policies in many countries of the world.

The economic crisis, and the consequent reduction of resources to be used in new health technologies, have led decision-makers to seek a comparison with the community and with those who have direct experience of the disease, to be able to manage certain choices that become always more complex.

The patient engagement involves the use of specific methodologies to obtain information regarding the use of a health technology such as efficacy, quality of life, economic impact, costs and benefits of a treatment. Despite the extensive literature existing on the different experiences of some countries such as Australia, Canada and the United Kingdom, many difficulties and barriers to the real and concrete participation of patients in HTA are currently emerging.

The aim of this project is to develop, through specific tools, a plan for involving patients, their associations and health professionals, to build HTA reports.

For this purpose, qualitative and quantitative methodologies will be used to incorporate patients' perspective and "input" and to encourage their involvement in many other phases of the HTA process, including those concerning the definition of priorities.⁷

Methods/design

Within this project, the plan to involve patients in the HTA process includes the development of three separate surveys with participants:

- Patients
- Patients' associations
- Healthcare Professionals

Healthcare professionals, together with patients and their associations, are the recipients most interested in understanding and making the best use of HTA tools to ensure appropriate treatment and to achieve the greatest benefit for the patient.

The questionnaire that will be used will be the same for all participants and will be constructed on the basis of information in the scientific literature. The methodology will mainly focus on patients' opinions and will refer to "patient-reported outcomes-PRO", i.e. structured questionnaires that are used to understand the effects of a treatment and/or benefits and advantages of drugs and technologies, through targeted questions on health status, quality of life and more specific aspects such as pain perception.^{9,10}

The quantitative investigation of the structured questionnaires will be accompanied by the qualitative methodology tools such as interviews, focus groups and social media analysis which will complete the analysis of the feedback of the three recipients identified for the purposes of the project.

Conclusion

The patient must be at the centre of health care systems and research investigations as the essential knowledge about the condition and burden of the disease, the costs and benefits of treatment, and the impact of certain choices on quality of life is derived from it. Feedback from this participation is essential to identify needs, requirements and gaps in health care and to provide a comprehensive view of the consequences of health technology assessment and its social, economic and ethical impact.

The present project aims to improve the doctor-patient dialogue by building, thanks to the tools provided by the scientific literature and social research, new solid methodologies that facilitate and foster greater patient participation in HTA processes, especially in phases where such involvement is still insufficient.

The creation of a clear systematization of the methodology that incorporates the perspective and "input" of patients, their associations and health professionals involved will increase its effectiveness when combined with improved understanding of HTA through the support of training and communication tools.

References

1. Favaretti C, Torri E. Che cos'è l'Health Technology Assessment. RIMeL / IJLaM 2007; 3 (Suppl.): 25-28.
2. Ricciardi W, La Torre G (Eds.). Health Technology Assessment. Principi, dimensioni e strumenti. SEEd, Torino 2010.
3. La Torre G, Monteduro A, Kheiraoui F. Comprendere l'Health Technology Assessment. Health Equality Europe. 2009.)

4. Facey KM, Hansen HP, Single ANV (eds.). Patient involvement in health technology assessment. Singapore: Springer Nature, 2017.
5. https://www.agenas.gov.it/images/agenas/hta/Manuale_delle_procedure_HTA_def_20.9.2018_full.pdf
6. <https://www.sihta.it/web/>
7. Lo Scalzo A. Il coinvolgimento del paziente nell'HTA tra ricerca orientata al paziente e partecipazione diretta: concetti, metodi ed esperienze. *GIHTAD*, 2017, 10: 5.
8. FAQ For Patient Groups And Individual Patients. Available at: <https://htai.org/interest-groups/pcig/resources/for-patients-and-patient-groups/faq/>
9. Haywood KL, De Wit M, Staniszewska S, et al. Developing Patient-Reported and Relevant Outcome Measures. In: Facey KM, Hansen HP, Single ANV (eds.). Patient Involvement in HTA. Singapore: Springer, 2017.
10. <http://www.fsk.it/le-pubblicazioni/tendenze-nuove/numero-1-2014/i-patient-reported-outcomes-pros>.