RECOMMENDATIONS FOR EFFECTIVE PATIENT INVOLVEMENT IN THE ASSESSMENT OF MEDICAL DEVICES

HPR71

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CONTEXT

Patients are a key component of the healthcare system; however, their preferences, values, and experiences are not always considered in health technology assessments (HTS).

Nowadays, HTA is undergoing a significant regulatory transformation, offering a valuable opportunity to enhance patient participation. The new European HTA Regulation, set for gradual implementation from 2025, and the Spanish Royal Decree project on HTA aim to enhance the transparency, predictability and standardization of the process, and open the door to a model where patients' experiences and perspectives could enrich clinical and non-clinical assessments.

OBJECTIVE

The aim of the study was to analyze and improve the current process of patient participation in HTA in Europe and Spain, establishing recommendations that promote effective patient involvement in decisions on medical devices.

This approach not only seeks to meet the needs of patients, but also to align assessment processes with new regulatory frameworks, fostering a more inclusive, legitimate and effective healthcare system.

METHODS

The methodology consisted of three main phases:

1. **Literature review**: Current initiatives on patient involvement in the evaluation of medical devices in Spain and Europe were investigated.
2. **Expert Group:** A multidisciplinary advisory committee, composed of 8 experts from HTA agencies, patient associations and academia, held a face-to-face meeting to share experiences, discuss the challenges of patient engagement and propose recommendations. Prior to this session, the experts completed a diagnostic questionnaire on their perceptions and experiences.
3. **Results Report**: Based on the group's contributions, a report was prepared by Weber and reviewed by the members of the Advisory Committee.

RESULTS

The diagnostic questionnaire emphasized that **74% of the experts considered that patient participation in HTA processes in Spain could be improved**. The Advisory Committee identified the main actual issues or barriers for an effective patient participation at the HTA process of medical devices (Figure 1).

Then, they proposed both general and specific recommendations encompassing **participation spaces, patient profiles, levels and modes of involvement, training, and other critical topics such as recruitment, transparency, feedback, incentives, and resources** (Figure 2).

Figure 1. Main barriers for patient participation in HTA in the current situation

Figure 2. Main recommendations in the different areas addressed

General recommendations

- Patient participation strategy ensuring adequate planning
- Regulation for patient participation
- Harmonize patient participation at the regional and national level
- Establish standards derived from best practices

Profile of Participants

- Adapted according to the phase
- Include patient experts, representatives and citizens

Degree of Involvement

- Diversify levels of involvement
- Improved collaboration and coordination
- Avoid paternalism and foster trust

Education and Training

- Methodological and specific training programs
- Identify barriers
- Adapted information material

Transparency and Feedback

- Share annual list of topics to evaluate and times
- Publish all patient input
- Publish conflict of interests

Recruitment

- Updated and unified patient databases
- Specific recruiting role

Incentives and Resources

- Recognize participation as paid time and/or other incentives
- More human, economic and time resources

The committee underscored the essential role of patient involvement in all phases of the HTA process, as well as in the earlier phases of identification, prioritization, and development of technologies. They highlighted the need for tailored patient profiles, strategic planning, enhanced recruitment and communication methods, specialized training programs, effective expectation management, and more robust engagement reporting mechanisms. They also emphasized the importance of personalized engagement strategies, with adaptable engagement approaches based on patients' experience and knowledge.

In the European context, they recommended harmonization of stakeholder involvement methods, use of patient involvement as a quality indicator in HTA, the establishment of systematic feedback mechanisms, and participation in horizon scanning programs.

CONCLUSIONS

Patient participation brings significant value to the evaluation of medical devices, improving the quality of decisions, increasing transparency and facilitating greater alignment between the results of the evaluation and the real needs of patients. The proposed action recommendations across various domains could be key to incentivize, harmonize, plan, and regulate patient involvement in the HTA process of medical devices. It could also address and overcome the barriers for an effective participation at national and at the European level.

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