Patient-MedTech Dialogue Workshop:
HTA and medical technologies

24 May 2018, Brussels

Summary

HTA explores the value of a new health technology compared to existing products

HTA is performed on <1% of medical technologies; industry views EU HTA cooperation as part of a value-based healthcare model

A new European Commission proposal calls for common rules for clinical assessment of health technologies

Patients voices should have a meaningful impact on decision-making

Greater transparency is needed on how patient involvement translates into action

Barriers to greater patient involvement include lack of training and funding

Background

Dialogue between patients and the medical technology (medtech) industry can help foster greater understanding between those who develop new healthcare solutions and those who use them. The patient-medtech dialogue was devised by the European Patients' Forum (EPF) and MedTech Europe as a forum for regular interaction on topics of mutual interest.

On 24 May 2018, representatives of national and European patient organisations joined medical technology companies and national associations to discuss Health Technology Assessment (HTA). The meeting was held against the backdrop of a new legislative proposal on HTA from the European Commission.

HTA explores the value of a new health technologies compared to existing products. As a multidisciplinary process, HTA should involve patients' perspectives. Knowledge of the process and of medical technologies can maximise the impact of patient engagement in HTA.

Only a minority (approximately 1%) of medical devices are currently subject to HTA[1]. Medical technologies include diagnostic tests, monitoring tools, implantable devices and eHealth systems. These broad range of products differ from pharmaceuticals and require a different approach to development, regulation and evaluation. For example, clinical outcomes can vary depending on how medical technologies interact with users such as patients and surgeons.

Participant expectations

Opening the discussion, Nicola Bedlington, EPF Secretary General and Tanja Valentin, Director of External Affairs at MedTech Europe asked participants what they hoped to learn during the dialogue. For patients, the opportunity to learn about HTA and its role in medtech was a priority, along with discussing practical measures for bringing patients into HTA discussions. Some patient representatives said they had contributed to HTA on new medicines

[1] Synergus: https://synergus.com/; Repertorio (Italian Device Registration) : http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=395&area=dispositivi-medici&menu=vuoto

but had much less experience in devices and diagnostics. Industry representatives saw the meeting as an opportunity to hear from patients to explore developments at national and EU levels. Patients and medtech representatives highlighted the benefits to both parties of working together towards improving patient outcomes and delivering value to health systems.

Patient involvement in HTA

Neil Bertelsen, Chair of the HTAi Interest Group on Patient and Citizen Involvement in HTA outlined the purpose and impact of HTA. Less than 1% of medtech products undergo HTA at national level. However, a growing number of hospitals and regional authorities are undertaking local HTA, often as part of procurement processes. There are a variety of approaches taken across Europe: some look at cost-effectiveness, some focus on clinical effectiveness, while a minority also consider the social and ethical impact of new technologies.

"HTA is a bridge between scientific evidence and decision making," Mr Bertelsen said. "It can help society to make difficult decisions about whether and how to use a new technology." He noted that stakeholder views are often sought from clinicians, industry and the research community, but that patients should also have a voice.

What is HTA?

HTA is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective health policies that are patient focused and seek to achieve best value. *(EUnetHTA definition)*

What is a health technology?

A "health technology" is any intervention that may be used to promote health, to prevent, diagnose or treat disease, or for rehabilitation or long-term care.

Patients and carers can help to define meaningful benefits and desired outcomes of healthcare; to highlight local variations and explain real-world pathways of care; and to inform discussion on who will benefit from technologies and their long-term impact.

Patient perspectives can illuminate HTA by:

- Clarifying burden of disease on patients and health systems
- Identifying important outcomes
- Highlighting areas of unmet need
- Describing real added value of new technologies

Several guides are available from HTAi to support patient groups in making HTA submissions. Separate advice has been developed for medicinal and non-medicinal products.

Discussion

Participants agreed that patients should be more involved in the HTA process as they can help decision-makers to understand the burden of disease and impact of interventions. However, some speakers noted that there is currently very little transparency or feedback on how patient input translates into decisions. It was suggested that patients could have a 'vote' when authorities are assessing new technologies.

Training patients to make impactful submissions will lead to more patient-centric HTA decisions, it was argued. At present, a small cohort of patient voices are making the bulk of submission but this can be time-consuming. Initiatives such as the EUPATI Patient Academy are helping to create a critical mass of informed and trained patients who can engage in the process as equals.

EU HTA proposal

Ioana Raluca Siska, Policy Officer for Health Technology Assessment, DG Sante, European Commission, outlined the new legislative proposal for strengthening EU cooperation on HTA which was adopted by the European Commission in January 2018. The proposal is currently being discussed in the European Council and the European Parliament. The proposal followed more than a decade of collaboration between national HTA bodies through EUnetHTA and other EU-funded projects. While new tools and databases were developed, and joint assessments have been piloted during the three Joint Actions (JAs), uptake of joint work has been low. As a result, duplication of effort continues and differences in HTA methodologies remain. Significant funding was dedicated to EUnetHTA JAs (e.g. €20 million has been devoted to the third JA) which are merely intended to kick-start cooperation rather than becoming a permanent support structure.

Ms Siska drew a distinction between regulatory assessments and HTA. Regulatory approval ensures that products conform to safety and efficacy standards. For medical technologies, approved products receive a CE mark. HTA, in contrast, is a comparative process: it examines whether a product is safer or more effective than alternative treatment options. "The Commission's proposal does not interfere with the regulatory step," she noted.

The focus of the new proposal will be limited to cooperation on clinical aspects of HTA. Clinical domains, it was argued, include objective information and are essentially the same across Europe. In contrast, context-specific issues – such as economic, organisational, social or ethical considerations – are difficult to assess jointly at EU level. Therefore, they should continue to be assessed at national levels. She briefly introduced the key elements of the Commission proposal, clarifying the choice of medical devices covered by the proposal (i.e. high-risk medical devices), the flexible timeline for performing joint clinical assessments (i.e. at or after, market launch, to be decided by the Member States), the involvement of patients at strategic and technical level (i.e. in the Stakeholder Network and joint assessments, respectively) and the phase-in approach which would allow the implementation of the proposed European HTA system after the full implementation of the new Medical Devices Regulation.

Closer EU cooperation on HTA will deliver long-term savings for health systems by pooling expertise, greater transparency and engagement for patients, and improved efficiency and predictability for industry.

Objectives of the new EU HTA proposal

- Promote convergence in HTA tools, procedures and methodologies
- Reduce duplication of efforts for HTA bodies and industry
- Ensure uptake of joint outputs in Member States
- Ensure the long-term sustainability of EU cooperation

Medtech perspective

Yves Verboven, Director Market Access and Economic Policies, MedTech Europe, set out the industry position on HTA. Broadly speaking, MedTech Europe supports assessing the value of their technologies with the appropriate tools and is leading a number of initiatives in this area. The industry has detailed its view on HTA cooperation in a paper published last year. Mr Verboven shared some of the key elements of the industry's position:

- Currently, approximately 1% of medical technologies are subject to an HTA[2] and only in a certain number of Member States, therefore there is no duplication of efforts.
- In countries where an HTA process is in place (France), we see significant delays in patient access to innovative technologies[3].
- In order to have meaningful cooperation on HTA for medtech, we see the following enabling conditions which need to be met:
    - To maximise the uptake of joint clinical assessments, the governance of the HTA collaboration should: a) let those Member State representatives, that have decision making power on the funding and use of medical technologies, define the questions of a joint assessment, and b) let those Member States with a similar need (less than 28) collaborate on a voluntary basis;
    - Appropriate rules and methodologies should be used for assessing medical technologies;
    - There should be a clear separation of the regulatory approval (CE marking) and the HTA assessment processes, since they serve two different purposes. The safety of a medical technology is already assessed prior to market entry (through the CE mark), there is therefore no need to duplicate this process.
- Patients should have an active role in all phases of the HTA process: from preparation of the assessment (which products to choose, which questions to answer) through the actual process all the way until uptake).

Patient perspective

Valentina Strammiello, Programme Manager, EPF, outlined the patient view on the Commission proposal before discussing barriers to greater patient involvement in HTA. EPF actively advocates for greater patient input in HTA and has conducted a study, produced factsheets and position papers, and delivered webinars and briefings on this topic.

Overall, EPF welcomes the Commission proposal which responds to a clear need from the patient community to reduce the discriminatory effects of variation in how HTA is used across Europe. The Commission has struck the right balance by focusing on clinical aspects of HTA. EPF favours mandatory uptake of joint clinical assessment, leaving Member States scope to assess economic, social and legal aspects.

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[3] MedTech Europe internal data collection

Ms Strammiello said there still is some room for improvement in how patients are represented. Actions to address this issue include:

- A clear distinction between patient involvement in the governance and in the assessments;
- Involvement of patient representatives on the Coordination Group;
- Strengthen the way the Stakeholder Network feeds into decision-making.

Patients can also play a stronger role in prioritisation of technologies, in horizon scanning and in identifying unmet patient needs. Access to lay language HTA summary reports and greater transparency in HTA decision-making remain priorities for EPF.

On a practical note, Ms Strammiello said guidelines and funding will be required to ensure appropriately-resourced patient involvement – a call echoed by several other patient representatives.

Discussion

Several participants welcomed the trend towards more patient engagement in HTA, clinical trials, guideline development and regulation but said support for training would be needed to create a larger pool of patients with the skills and knowhow to engage with other professional stakeholders.

Contributors also asked the Commission to be more explicit about patient involvement in the section of the proposal covering clinical aspects of HTA. Patient input on how medical devices are used is particularly relevant in the medtech sphere, it was noted.

The Commission representative said the Coordination Group would be a forum for sharing the views of Member States, stakeholder networks and patient organisations – allowing patients to shape discussions on unmet needs. The European Medicines Agency (EMA) model for patient engagement, where a large database of registered patients with various levels of expertise is used, is being explored. The Commission may seek to develop its own database, with input from patient organisations.

Barriers and opportunities for meaningful patient involvement in HTA

Participants were split into four groups to explore barriers and opportunities to patient input on HTA. To stimulate the discussion, participants were asked to consider the following questions:

- How can we facilitate the involvement of patients in the assessment of medical devices?
- Can you identify criteria for patient involvement?
- What are the opportunities for meaningful involvement?
- What type of patient involvement in HTA can foster access to medical technologies?

Each group reported back at the end of the session, with several common points emerging from the discussions:

- Heterogeneity and scarcity of HTA processes that include patient views
- Challenges identifying and engaging patients/users of medtech

    - Need to minimise bias and select patient advocates who represent a wider community
    - Training and funding are needed for patient representatives; patients treated as equals
    - Patients should be equipped with the emotional capacity to handle the process of providing advice/input
    - Guidelines on conflicts of interest are needed
    - ICHOM standard sets could be used as objective patient-centred outcome measures
    - Patients should define unmet need, helping medtech companies deliver value through innovation
- Education of decision-makers and other stakeholders on the value of patient input for all players

Conclusions & next steps

A productive meeting closed with a brief review of the presentations and discussion. Tanja Valentin, MedTech Europe, expressed surprise that many of the issues raised during the meeting were new – illustrating the value of patient-industry engagement. Nicola Bedlington, EPF, reflected positively on an illuminating discussion, noting some of the challenges that lie ahead while remaining optimistic about the scope for future dialogue.