Monitoring the HAS' Initiative on Patient Contribution to Rapid HTA

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INTRODUCTION

In November 2016, the French National Authority for Health (HAS) introduced a new procedure to include the patient perspective in rapid HTA on drugs and devices, which consists of written submissions from patient organizations (POs).

In order to gain insight on implementation, adoption, and continuous improvement needs, the HAS launched an examination of the entire process.

METHODS

Our monitoring protocol consists of a series of questions and indicators that inform the 3 categories of the Donabedian model:

- **structure**, which relates to the technical and human resources used;
- **process**, relating to the quantitative and qualitative aspects of the patient submission process and
- **outcomes**, relating to the scientific nature and democratic dimension of patient engagement in HTA.

RESULTS

Questions about structure (HAS organization)

Q1. Does the **internal information flow** function well? (Handling of files from firms, posting necessary information once a week about coming assessments, information to interested POs).

Q2. Are the **dedicated ways of contacting HAS** (email, phone number) used and what for?

Q3. What are **the resources (time, personnel)** required to accomplish this new process?

Questions about process

Q4. **Do firms accept** that HAS publishes information about future assessments online? (name of the product+ therapeutic indication) (this information reveals their request for coverage, an aspect of commercial secrecy).

Q5. To what extent **do POs participate** in this new activity?

Q6. Does the **submission template** meet HAS' and POs' needs?

Q7. Are the **explanations and documents** dedicated to POs (on HAS website) sufficient?

Q8. Do **POs have sufficient time** to contribute?

Q9. Are **the mechanisms for staff and committee members for accessing the content submitted by patients satisfactory?** (time to read, clarity of the submission, interest of a short presentation at the beginning of the committee discussion? Interest and possibility of asking PO for complementary information?)

Q10. Is there a need to supplement the **standard submission template** with additional specific questions or hearings?

Questions about outcomes

Q11. Are specific aspects of patient submissions **explicitly considered** in the appraisal committee deliberations?

Q12. Have POs gained a **greater understanding** of the decision-making process?

Q13. Do POs consider that their contribution to this procedure **will be of benefit to them** in other areas of their work?

Q14. Are POs **satisfied** with this procedure?

Q15. Does this new procedure provoke **reflections** about our current methods?

Indicators were also developed for each question

Different sources of information were defined to inform the indicators: patient written submissions, short questionnaires completed by POs following each assessment, Committee deliberations, and feedback discussions with members of the concerned HAS Appraisal Committees and Departments.

CONCLUSIONS

The first analysis will serve as a basis to discuss, with POs and other stakeholders, the early phases of the Patient Contribution to Rapid HTA initiative and how we may further build on our efforts (training sessions, tools). Results may also shed light on a need for additional follow-up, questions and indicators to stop, maintain or modify.

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