The added value of the EUnetHTA experience in the Italian context

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BACKGROUND

- EUnetHTA is a collaborative European-wide network on HTA involving nearly 70 HTA national and regional agencies. One of the main objectives of the network is the promotion of collaboration between HTA agencies.
- Agenas is an active partner of the EUnetHTA network and is Lead Partner of the WorkPackage 4 (WP4). The main objective of the WP4 is the collaborative production of Core HTA information.
- Agenas, as technical-scientific Agency of the Italian National Health Services (NHS), is promoter of the collaboration at different levels of the Italian NHS. For HTA, Agenas promotes the creation of the Italian Network for HTA (RIHTA).
- The experience of Agenas in the EUnetHTA network is being replicated in the Italian context within the RIHTA Network; this includes the testing of procedures, models and management activities similar to the one used at the European level.

OBJECTIVES

- To transfer the experience of the EUnetHTA collaborative production of HTA information in the Italian context.
- To improve the proficiency and expertise of regional agencies in HTA production.
- To test procedures and management activities from the EUnetHTA experience linked to the HTA collaborative production activities.

METHODS (Continues)

HTA Core Model for the assessment

- The HTA Core Model is a methodological framework for shared production and sharing of HTA information. Its purpose is to enable production of high quality HTA information in a structured format to support the production of local (national or regional) HTAs and reuse of existing information.
- The Assessment element is the basic unit of the model: It defines a piece of information that describes the technology or the consequences or implications of its use, or any other aspect relevant for the assessment, such as the patients and the disease for which it is applied. Each assessment element contains an "issue", which is a question that should be answered in an HTA.
- The HTA Core Model employs a multidisciplinary view of HTA. Any technology that is being assessed is considered through 9 domains, each of which provides a wide framework for the analysis.

Composition and Management of the teams

- Each domain of the full Core HTA is managed by a Domain Team formed by 1 Primary Investigators (to coordinate the work and interact with Coordinator of the Project), at least 2 investigators (to develop the work and interact with PI), plus a number of Reviewers (to review the document produced by each domain team).

Stakeholders Involvement and Conflict of Interest

- In the EUnetHTA network a Stakeholder is "Groups or organisations which provide considerable insight into views of the groups they represent, and which will be affected by, or have an interest in, and may in a consultative role contribute to the actions or aims of an HTA organisation, project or policy direction".
- Four types of stakeholder groups have been identified as particularly important for the EUnetHTA Joint Action to interact with.
- EUnetHTA Joint Action Stakeholder Policy was developed to facilitate a transparent, responsible, accountable, participative and responsive stakeholder involvement process.
- Conflict of interest is managed accordingly a specific procedure developed by a Conflict of Interest Task Force set-up during the Joint Action 2 and composed by representatives of some of the EUnetHTA Work-Packages.

EUnetHTA

EUnetHTA

EUnetHTA

BACKGROUND

- 16 members
eunethta

METHODS

- 9 domains

Stakeholders

METODOS

- Topic selection and prioritization
  - In the EUnetHTA WorkPackage 4, topic notification and selection procedure is based on an electronic form (webform) that WP4 partners, WP4 Stakeholders (Manufacturers, Patients associations, etc.) and DG SANCO can use for notify and select a topic of common interest for the assessment.
  - A multiple-round vote system is used for selection of the topic among the list of notified technologies.
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RESULTS

Topic selection and prioritization

• The topic selection procedure for the Italian HTA reports (Full, Rapid or other) is similar to the one used in the EUnetHTA network. The procedure is based on an electronic form for expressing the topics of interest for the assessment. The form is available both in Italian and English.
• Stakeholders (Ministry of Health, Regional Agencies, clinicians, manufacturers, patients, scientific society, etc.) can use the web-form and indicate a need for the assessment.
• The notified technologies are then prioritized by a specific Commission (Prioritization Committee) formed by Agenas members, Ministry of Health representative and RIHTA representatives.

Composition and Management of the teams

• Each working team is coordinated by a member of the Agenas and includes at least 2 investigators from the Agenas and the members of RIHTA Network.
• The notifier of technology under assessment is usually involved in the working group (if possible).
• A number of reviewers are recruited within the RIHTA network (Internal reviewers); Experts and Clinicians are recruited as external reviewers.
• This structure is influenced by the structure of the Domain Teams used in the collaborative production of Core HTA in the EUnetHTA network.

Stakeholders Involvement and Conflict of Interest

• Procedures and methods for Stakeholder involvement developed in the EUnetHTA network has been adapted and applied to the Italian context and currently used in the RIHTA Network, just as the Conflict of Interest procedure (based on a declaration form collected for every researchers involved in a project).

Stakeholders Involvement and Conflict of Interest

• Specific procedure for involvement of Manufacturers, Patients associations and Citizens has been developed and are included in the Methodological Manual for HTA production the Agenas.
• Conflict of Interest disclosure and Confidentiality agreement has been also developed and used in the RIHTA Network.

HTA Core Model for the assessment

• The structure of Core Model is being tested for the production of full national reports in Italy.
• Researchers use the Core Model and its Assessment Elements as a checklist for preparing the full HTA report. The structure of the report is the one already used for the Agenas products, but references to the Assessment Elements are added to the relative paragraph in the text.
• Five HTA projects have been committed to Agenas-RIHTA for 2015 and are currently ongoing. The full report will be produced using the Core Model structure.

• All documents will be available at www.agenas.it

CONCLUSIONS

• The EUnetHTA networking experience has allowed Agenas to implement in the national context terminology, methodologies and organisational models for collaborative production of HTA with regions participating in the national HTA network (RIHTA).
• Further implementation of tools and methods are being discussed for the future.