Possible role of European collaborative assessments in national reimbursement processes

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Agenda

- Background
- Recent evolutions of Italian NHS
- HTA framework in Italian NHS
- Relevant experiences
- Italian participation in EUNetHTA
- A way forward
To govern technological innovation health care systems need to align different processes:

- clinical research programmes, to produce evidence
- health technology assessment, to synthesize evidence
- appraisal, to consider evidence from different stakeholders perspective
- decision making, for market regulation, resource allocation, management of health care organizations

To manage these processes specific competencies, robust experience and relevant resources are needed;

Collaboration at international, national and local levels can be useful for effective division of work, to create economies (of scale and scope), to share critical and rare knowledge;
Recent evolution of the Italian NHS

- Italy’s health care system is a regionally based national health service (Servizio Sanitario Nazionale (SSN) that provides universal coverage almost free of charge at the point of service.

- More than 70% of healthcare expenditures is ensured by the Italian National Health Service.

- It is a federal system where Regions are obliged to offer a core benefit package to all population using legislative, financial, administrative and organizational autonomy.

**Fact Sheet**
- 21 Regional health authorities
- 102 Mld € public health care expenditure
- 130 Mld€ total health care expenditure
- 2\textsuperscript{nd} Oldest population in the world
- Highest indicators worldwide for life expectancy at birth, among lowest infant mortality rate

**HTA Process**

- **Drugs**
  - National framework managed by the National Drug Agency (Aifa)

- **Devices and procedures**
  - Assessed both at a Regional and National level
  - Coordination ensured by the National Agency for Regional Health Care Services (AGENAS)
Population needs

Ministry of health (Priority Setting)

Health technology Assessment framework

- Core benefit package (public coverage)
- Standart costs of services (Drug prices, DRGs, etc.)
- Estimation of financial resources needed for NHS yearly
- Other benefits
  - Private insurance funds, out of pocket

Adapted from Cicchetti and Marchetti, 2010 (Handbook of Health Technology Assessment)
Health technology assessment framework in Italy

Priority setting

Assessment

Appraisal

Coverage decision

MDs and procedures
MoH*(Regions)
Agenas/Regions/Universities (RIHTA)
Regions
Regions
Drugs
MoH (Regions)
AIFA (CTS)
AIFA (CTS-CPR)
AIFA Regions

* (Drug and MDs Directorate)
The institution of the Italian Network for Health Technology Assessment - RIHTA

Objectives

In 2009 Italy’s Regions and Agenas created the Italian Network for HTA (RIHTA) coordinated by Agenas and composed by regional representatives. RIHTA’s main objectives are the spread of HTA awareness across Italy, the establishment HTA programmes in Regions that do not yet have them, and the improvement of HTA in Regions that already have established HTA programs. RIHTA aims at facilitating collaboration and communication among Regions on common topics and technologies within a structured and agreed framework.

Methods

The agreement is based on a non-hierarchic structure with a coordination board composed by all regional representatives and a technical board managed by Agenas. Working groups, meetings and ad hoc workshops for regional representatives are organized by Agenas.
ASR ABRUZZO
REGIONE BASILICATA
REGIONE CALABRIA
ASSR EMILIA ROMAGNA
LAZIOSANITA’ ASP
ARESS PIEMONTE
ARES PUGLIA
REGIONE SICILIA
REGIONE UMBRIA
P.A. BOLZANO
P.A. TRENTO
REGIONE VENETO
REGIONE LIGURIA
REGIONE LOMBARDIA
The agreed RIHTA program

- Capacity building activities: analysis of training needs, gaps in the availability of HTA professional profiles and exchange of personnel to share expertise;

- Creation of an *ad hoc* web-based resource to facilitate documentation and dissemination of reports produced by international and national agencies and to host a forum aimed at facilitating exchange of regional HTA know-how;

- Sharing topics of regional interest with a view to possible HTA development;

- Collaborative research and trials on assessing the appropriateness of adopting technologies and how to implement them and evaluate their effects.
Health Technology Assessment

La possibilità di consultazione di database rappresenta una delle principali opportunità di cui può fruire la comunità scientifica: medici, sia clinici che ricercatori, decisori della sanità e policy makers, amministratori. La letteratura prodotta in esito a studi valutativi sull'efficienza ed efficacia degli interventi di politica sanitaria, in particolare sulla loro costo-efficacia, è in continua crescita. Tale documentazione, tuttavia, non sempre è di buona qualità scientifica e non è facilmente reperibile per quanti non abbiano adeguate competenze di ricerca documentale.

Inoltre, risulta ancora più difficile valutazione critica da parte di utenti che non abbiano accesso a specifici strumenti di valutazione delle metodologie usate per lo svolgimento degli studi.

La sezione del sito dell'AGENAS rappresenta quindi un'importante fonte di informazione per coloro che operano in sanità, supportandoli nel lavoro di identificazione del report di Health Technology Assessment disponibili al livello nazionale. Allo stesso tempo, il sito indirizza l'utenza anche alla ricerca di documentazione utile prodotta a livello internazionale.

Il database Agenas è utilizzato dal network del Progetto di ricerca finalizzata, programma strategico Hr&i Transfer, fomentando informazioni a carattere generale, e quindi non di natura qualitativa, riguardo gli studi inclusi nella banca dati.
Better definition of the prioritization process within the Ministry of Health
  - Increasing stakeholder involvement (Policy Forum SIHTA)

Enhance collaboration among Regions through AIFA (Drugs) and AGENAS-RIHTA (MDs and procedures)
  - Shared Methodological framework
  - Shared information (RIHTA Platform)

AIFA: increasing use of HTA approach to support coverage decisions and drugs price re-negotiation (post marketing HTAs)

Enhance appraisal process
Pharmaceutical context shows an evident contradiction:

While the authorization procedures are based on a well defined and shared mechanism

price and reimbursement procedures, based on national responsibility, are usually developed in a non-shared way, using different methodologies and sometimes with contradictory results.
The efficacy and effectiveness gap

HTA approach in the current system

AIFA uses HTA for:

- Evaluating the real impact of medicine on a specific area;
- Defining the best place in therapy for new drugs;
- Operating the necessary re-evaluations both of the place in therapy and pricing setting.
AIFA Post marketing assessments

Arrangement of specific assessment report

• Product’s characteristics;
• Disease involved;
• Current place in therapy;
• Place in therapy of medicines positioned in the class;
• Pricing analysis in EU countries;

• Analysis of data collected with the Registers;
  • Relative effectiveness analysis:
  • Re-evaluation of the place in therapy taking into account the new clinical evidences and treatments;
  • Identification of target population;
  • Cost effectiveness evaluation;
  • Budget impact analysis;

• Literature analysis;
• Analysis of further more clinical studies in progress.
• Is post marketing strategy sufficient to solve the sustainability of the system?
In a context characterized by scarcity of economic and structural resources, the need to define specific parameters for evaluating the value of new “technologies” is highly shared.

Parameters have to be:
- Indipendent
- Shared
- Public
- User-friendly

Parameters that allow to make clear choices on the prioritization in the use of resources.
The debate on innovation

Equal access for patients to new therapies, technologies and diagnostic tests.

Resources optimization
Future challenge for targeting innovation

- Pharmaceutical innovation have to demonstrate incremental clinical benefit to satisfy regulators and payers requirements.

- **Pharmaceutical innovation** have to respond to the needs of broader conditions of safety, efficacy, selectivity, and utility.
Future challenge for targeting innovation: AIFA commitment

Promoting a *scientific advice* model in the process of R&D shared by the Regulator and the Payer.

Design together authorizative trials to obtain homogenous and forecasting decisions.
Networking and collaboration world-wide in HTA: Italian Involvement

- Research and evidence production
  - International
    - Cochrane collaboration,
    - Guidelines International Network (GIN)
- HTA and Horizon Scanning
  - International
    - INAHTA, International Network of Agencies of Health Technology Assessment (Agenas, UCSC)
  - European
    - EUNetHTA, European Network of Health Technology Assessment,
    - EUROScan, European Network of Horizon Scanning)
EUnetHTA

European Network for Health Technology Assessment (EUnetHTA) starts as a Project financed by European Commission in 2006.

Italy has been present since the beginning:
• AIFA and Agenas (AP)
• Veneto (AP) and Emilia Romagna Regions (CP)
• Università Cattolica del S. Cuore (CP)
Italy and EuNetHTA Joint Action 2

- The Italian participants
  - MoH (Supervision)
  - AIFA, AGENAS, Emilia Romagna and Veneto Regions (AP)
  - Università Cattolica del Sacro Cuore (CP)
  - Others (TBD)
Italy and EuNetHTA Joint Action 2

What Italy can do for (and in) Eunehta

1. Ensure “advanced collaboration”
2. To enhance the presence of professional resources in EUNetHTA JA2
3. To experiment the use of the Core Model as a key element in designing national HTAs
Italy and EuNetHTA
Joint Action 2

What EUNetHTA can do for Italian NHS

1. To help to quickly upscale the learning curve in HTA participating in training activities

2. To share knowledge, professional competencies and technical solutions
Establishment of a National HTA framework in which national agencies (Agenas and AIFA), regional agencies and hospital HTA units can collaborate, share priorities, methodologies and resources
Conclusions

Thank you for the attention