Health technology assessment in Italy

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Objectives: The aim of this study was to review the history of health technology assessment (HTA) in Italy.
Methods: Founded in 1978, the Italian National Health Service (NHS) has been strongly regionalized mainly after a constitutional reform, which started a devolution process. HTA started in the 1980s at the National Institute of Health and in a few University Hospitals, with a focus on big ticket technology: that process was driven by clinical engineers.
Results: In recent years, HTA is becoming an important tool for decision-making processes at central, regional, and local levels. In particular, the National Agency for Regional Health Services (AGENAS) and five regions (of twenty-one) are strongly committed to develop HTA initiatives connected with the planning process.
Conclusions: At the local level, the hospital-based HTA activity is probably the most important peculiarity of the country and the real driver of the HTA movement.

Keywords: Health technology assessment, History, Health policy, Evidence based medicine, Decision making

THE ITALIAN HEALTHCARE SYSTEM

Overview

Italy's healthcare system is a regionally based National Health Service, founded in 1978, that provides universal coverage free of charge at the point of service. However, changes introduced in a devolution reform (2001) have resulted in the nineteen Italian regions and the two autonomous provinces exercising their autonomy very differently (15).

The system is organized across three levels: national, regional, and local. The national level is responsible for ensuring the general objectives and fundamental principles of the national healthcare system. Regional governments are responsible for ensuring the delivery of a benefit package through Local Health Care Trusts, as well as public and private hospitals (8;18).

The Italian National Health Service is largely funded through national and regional taxation, supplemented by co-payments. Decentralization of the healthcare system has led to regions having substantial legislative, administrative, and regulatory powers (1;2;13;16).

The 1999 reform devolves new management powers to the regions and softens the previous shift to the market and competition, promoting cooperation among healthcare providers and partnerships with local authorities for health promotion and community care. This reform is linked to the process of regional devolution.

The evolving system of fiscal devolution was substantially strengthened by the 2001 constitutional reforms, and now the organization of health care falls into the remit of the regions and autonomous provinces.

In the Italian National Health Service, care is granted to every Italian as a constitutional right. In 1998, Italy was the first country to extend these rights to illegal migrants.

PUBLIC POLICIES

System of Financing and Coverage

A progressive fiscal devolution started in 1997, and regional taxes finance most healthcare expenditures, with general taxation playing a complementary role. Central funding is intended to be used primarily to redistribute resources to the regions with a narrower tax base.

Healthcare benefits and rationing

The 1978 reform introduced the principle of a common package of benefits available to all citizens irrespective of age, social condition, or income. However, a positive list has only been developed for outpatient services and drugs (3).

HEALTHCARE DELIVERY SYSTEM

Primary Care

Primary care is provided by general practitioners (GPs) and pediatricians who are independent contractors paid by capitation fee. GPs and pediatricians act as gatekeepers for access to secondary care. The 1999 reform introduced significant changes in primary healthcare services by reinforcing group practice.

Public Health Services

A compulsory vaccination program protects all children under 24 months against diphtheria, poliomyelitis, tetanus, and hepatitis B. Other recommended childhood vaccinations protect children from whooping cough, measles, and rubella. No national screening program exists, as regions are responsible for disease prevention activities.

Starting in 2001, some procedures aimed at early diagnosis of cancer would be delivered free of charge: mammography every 2 years for women aged between 45 and 69 years; pap test every 3 years for women aged between 25 and 65 years; and fecal blood every 2 years for people between 50 and 69. However, several regions developed screening programs in these three areas.

Ambulatory Care

Specialized ambulatory services, including visits and diagnostic and curative activities, are provided either by local health trust or by accredited public and private facilities. A co-payment with a maximum of €36 is required as an additional source of financing and in an attempt to moderate the use of specialist ambulatory care, with exemptions for chronic conditions and low income people.

Hospital Care

With the 1992 reform, university hospitals and highly specialized and nationally relevant hospitals were given the status of a trust, with considerable financial independence as well as full responsibility for their budget, financing, management, and technical functioning.

For inpatient care, patients are classified according to the diagnosis-related group scheme, whereas for outpatient care, diagnostic services, and specialist treatments, reimbursement should be based on fees for services. The only two forms of treatment for which a bed-day rate should still apply are for rehabilitation and long-term care.

Emergency wards, spinal cord units, burn units, organ transplant centers (transport, donor, and receiver support and transplant activity co-ordination), AIDS centers, home-based care, training activities, and teaching and research activities, receive additional funding from the regional governments. The 1999 reform strengthened the principle of a prospective payment system based on diagnosis-related group.

Payment of Healthcare Professionals

GPs and pediatricians delivering primary care and preventive medicine are mainly paid on a capitation basis, whereas hospital physicians delivering secondary care earn a monthly salary.

In addition, GPs who set up a joint medical practice get an incentive and, in addition, they are paid fees for services for specific treatments, including minor surgery, preventive activities, therapies, and postsurgery follow-up.

The basic wage of hospital physicians is determined by the level in the hierarchical structure, taking into account duties, responsibilities, and training profile. A seniority allowance is also usually included as is an allowance for specific duties requested.

Productivity rewards are part of the more general incentive scheme that ties a portion of the wage to the results achieved by the employee.

EVALUATION AND ASSESSMENT

Introduction of Health Technology Assessment in Italy

In the 1980s, health technology assessment (HTA) began in Italy at the National Institute of Health: the focus was on big ticket technologies and on safety issues. The process was led by clinical engineers (9).

Some hospital experience began in a few university hospitals across the country. In 1993, the International Society

of Technology in Health Care (ISTAHC) held in Sorrento its annual meeting, attended by 338 people.

Early Developments

In the second part of the 1990s, several regions started dealing with big ticket biomedical technologies, focusing on technical issues, with the objective of keeping prices under scrutiny. In 1998, the Autonomous Province of Bolzano and the San Matteo Hospital in Pavia started a project to experiment with hospital-based technology assessment.

A similar project made it possible to establish the Technology Assessment Unit at the "A. Gemelli" University Hospital, which is the first national example of "*hospital based HTA*" (4).

The Mario Negri Institute in Milan focused on the development and spreading of methods and synthesis tools of evidence to facilitate the transfer of research results into practice. The Italian Cochrane Center, the use of TRIPPS programs (i.e., getting research into practice) and the start of the National Guidelines Program sped up the spreading of the culture of evidence-based medicine.

The Health Care Trust of the Autonomous Province of Trento also supported the diffusion of HTA in Italy, promoting since 2002 several workshops, where different perspectives of the technology assessment approach have been investigated (6).

The Master in Administration and Management of Health Services of Emilia Romagna greatly contributed to raising awareness on HTA. The International Master Program in Health Technology and Management, with the participation of several Universities (McGill, Montreal, Ottawa, Toronto, Barcelona, and the Catholic University of Rome) is contributing to an international approach (14).

The Emilia Romagna region, through its Regional Healthcare Agency, boosted clinical governance, the first Italian example of institutional production of HTA reports supporting clinical practice and decisions in healthcare policies.

Since 2002, grants of the national Ministry of Health for health research have been dedicated to HTA initiatives and the promotion of multidisciplinary competencies in HTA.

In 2003, a grant of the Ministry allowed for the birth of an Italian *Health Technology Assessment Network*, grouping together all those who gathered experience with HTA in Italy in the years 1998 to 2002 (5;7;17).

In 2005, these activities led to confirm the presence of Italy in the HTA field on an international level with the third *Health Technology Assessment International* (HTAi) annual meeting at the Catholic University of Sacred Heart in Rome.

In 2006, a consensus paper named "Carta di Trento on HTA" was approved; thereafter, the Italian Society of HTA (SIHTA) was founded and organized the first annual meeting in Rome, February 2008.

The regions of Veneto and Emilia Romagna and the Catholic University entered the EUNETHTA project, aimed at building the HTA European network, which gathers all the fruits of previous projects, such as EUROASSESS and ECHTA-ECAHI, which had seen the participation of avant-garde Italian colleagues between 1994 and 2003.

HTA INSTITUTIONALIZATION IN ITALY

The National Level

HTA is mentioned for the first time in a national policy document in the 2006–2008 National Healthcare Plan: "...it is necessary for HTA to be recognized as a priority also in Italy, as it is necessary to promote the use of HTA tools, gathering all knowledge on the subject, some of which already exists in a number of regions and Trusts..."

Following this statement, the Standing Conference between state, regions, and autonomous provinces gave the National Agency for Regional Healthcare Services (AGE-NAS) the task of supporting the regions for the development of current HTA, in connection to the national Ministry of Health.

AGENAS started the production of HTA reports for the General Directorate of Medical Devices of the Ministry, through an ad hoc working group. In addition, AGENAS began a project to create a monitoring system of emerging technologies, linked with the EUROSCAN program. The COTE project (Observation Center for Emerging Biomedical Technologies) is under way and looking to activate a national "alert" network that involves regions, universities, research centers, healthcare and hospital trusts, and scientific bodies.

Another initiative is the "Green Paper on the Future of Welfare," published by the national Ministry of Welfare, where HTA is quoted as a tool for rational decision making.

The Regional Level

The progressive taking up of political, administrative, organizational and financial responsibilities by the regions makes it possible a HTA development (10–12).

In a survey carried out in 2004 by the Italian *Health Technology Assessment Network*, only 9 of 21 answered the survey, and reported some HTA activities. To limit public pharmaceutical costs, regions now show an intense assessment activity on drugs, and edit therapeutical reference books, even though an explicit HTA approach is often lacking.

A survey carried out in July to October 2008 described organization and methods adopted by the regions to support to the technological innovation governance. The survey is based on a documental analysis, interviews, and a structured questionnaire, to understand the spreading of the HTA approach in the Italian regions.

HTA activities have undergone different development phases. Emilia Romagna and Veneto have carried out activities of healthcare technology prioritization, research, assessment, and spreading. Apart from Emilia Romagna and Veneto, another three regions (Piemonte, Lombardia, and Toscana), have recently started programs to include HTA in regional decision-making processes.

These regional experiences have been monitored within a common framework, highlighting HTA programs, responsibilities, and tools and including four phases: (i) clarifying the process for identification of study priorities; (ii) research and assessment; (iii) analysis of results for allocating and applying decisions; and (iv) spreading of results.

Table 1 shows a comparative analysis of HTA processes in these five regions. Regions generally adopt a wide concept of technology, including drugs, devices, procedures, organizational models, and sometimes focusing on some issues (i.e., drugs in Veneto).

Regions have not made clear when and how the main *stakeholders* were involved, that is, industry and patients. Only the Piemonte program provides for the consultation of patients within an HTA Council. The participation of the industry is not provided for. In Emilia Romagna, the industry is involved in participating to the funding of the PRIER program (Emilia-Romagna Research and Innovation Program).

As far as the governance of the HTA process is concerned (priorities, research, assessment, decision, spreading), the situation seems heterogeneous. The experiences in Emilia Romagna and Veneto show that defining priorities is a very complex process whereby political and technical functions hold different roles and different degrees of action. In the case of Piemonte, for example, a Working Group is responsible for defining priorities. The Group is located at the Regional Healthcare Unit, which obtains assessment proposals from the system, especially through the HTA Council.

As far as research is concerned (appraisal and in particular translational), Emilia Romagna, Veneto, and Piemonte have funded specific programs. The two research programs of Emilia Romagna seem to be those more oriented toward assessment needs.

The assessment phase, that is, the synthesis of evidence for the production of documents or information useful for decision making, is managed quite differently. In recent regional regulations in Lombardia, Toscana, and Piemonte, there is a clear identification of responsibilities, which is based on appraisal. In the case of Veneto, it seems possible to identify two functions and two different structures: one is for drugs and devices and the other one for all other technologies. Responsibilities and tasks are not yet sufficiently clear.

All regions provide for a link with decision making. In the case of Emilia Romagna, for instance, assessment impact on the healthcare unit system mainly through the Clinical Governance Committee, where the decision on the use of medical technology (adoption, conditioned adoption, rejection) stems from a shared process that involves user companies. In the case of Veneto, mainly as far as drugs are concerned, the link is on a regional level and appears to be tighter. The assessment phase serves the decisions of the committee responsible for editing regional pharmacological reference books. In the case of the other regions, it is not possible to assess and monitor the impact that assessment processes will have on the actual decisions.

In the cases of Emilia Romagna and Veneto there are mechanisms in defense of the spreading of scientific evidence produced and of the information related to technologies in the regional system.

Currently, Emilia Romagna is the only region to have started a Horizon Scanning system (early detection of technological innovation).

As far as financing and available resources are concerned, the regions already committed in HTA have significant resources in bodies that coordinate research and the assessment phase (see Table 2). In general, it is possible to categorize necessary resources and competencies in two main groups: those in support of research activities, distributed in the area, and those necessary for the governance of assessment programs.

Another structural factor is the level of concentration of competencies, that is, the number of bodies involved in the HTA process. Whereas the other four regions show a tendency of concentration of competencies of the governance of the process (apart from the decision-making phase), Veneto has at least three different institutions relevant to this field (Regional Plan Management, Regional Reference Center for Drugs, Regional Healthcare Unit).

The impact of the HTA assessment process on the healthcare system greatly depends on the integration between the appraisal and the decision making. If the process is highly integrated, the decision maker also has to be able to define the agenda of the evaluator who is asked for support. Should that not be the case, the evaluator's level of independence ("agencies") will be higher. In the regions studied, the consultations of Toscana and Lombardia and the Implementation Regulation in Piemonte show a tendency toward a high level of integration between assessment and decision. In Emilia Romagna, the regional agency guarantees an assessment activity partially disconnected from political decisions. The assessment takes the shape of a transmission chain—characterized by independence—that connects research to decisions taken on a regional or on a corporate level, in the Board of Directors and in the Management.

In Veneto, the experience with drug assessment and the tight link to the Committee for the Determination of Pharmaceutical Reference Books (UVEF – HTA Unit for Drugs) seem to lay out a strong overlap between appraisal and decision making. In the case of the PRIHTA (Program for Research, Innovation, and HTA), appraisal seems to be independent from the decision-making process.

Table 1. Comparative Analysis of HTA Processes in Five Regions

	Emilia Romagna	Veneto	Piemonte	Lombardia	Toscana
Experience with HTA	>10	>5	Starting	Starting	Starting
Field of implementation	Wide meaning of Health Technologies	Initially drug	Wide meaning of Health Technologies	Wide meaning of Health Technologies	Wide meaning of Health Technologies
Role of the industry	Finances Research (PRIER)	Not clarified	Not clarified	Not clarified	Not clarified
Role of patients	Not clarified	Not clarified	Planned (Council for HTA)	Not clarified	Not clarified
Multidisciplinary actions	YES	NO (UVEF, HTA Unit for Drugs) YES (PRIHTA, HTA Research Innovation Program)	YES	YES	Not assessed
Defining priorities (responsibilities)	Explicit and spread (single programs)	Explicit and spread (single programs and functions)	Explicit and concentrated (Planning Group with support of HTA Council)	Explicit and concentrated (Priorities and conflicts of interest assessment group)	Explicit and concentrated (Regional HTA Center)
Research (instruments)	Financing research (PRIER, Emilia-Romagna Research and Innovation Program) (PRU – Region- University Research Program)	Financing research (PRIHTA)	Regional oriented research (not specific appraisal)	Not assessed	Not assessed
Appraisal (instruments and responsibilities)	Clinical governance councils (ASSR)	UVEF PRIHTA (future)	ARESS (Regional Agency in Health Care, Technical Group)	Expert assessment (Technical Assembly of healthcare technology assessment)	Regional HTA Center
Adoption of decisions (responsibilities)	Council office, regional and corporate committees for clinical governance	PTORV (therapeutical reference books) Committee CRITE (Regional Committee for technology and building investment) CTRDM (Technical Commission for Regional Medical Devices References Book)(underway of establishment) Healthcare council office	Regional Management 20 Healthcare units	Healthcare Management	Healthcare council office
Spreading (instruments)	Dossier	Bulletin ARSS books	Not assessed	Not assessed	Not assessed
Horizon scanning	YES (ORI)	NO	NO	NO	NO
Process integration (priorities-research-appraisal-decision)	AVERAGE	AVERAGE	Not assessed	HIGH	HIGH
Financing	€30 mil for research (3 years)	€120.000 for star up (PRIHTA) €2.6 mil for research (2008)	Regional Oriented Research	€200.000 for start up	€36.000 for start up (Regional responsibility)
Centralization (number of bodies involved in the process)	HIGH 1 (ASR)	LOW 3 (Management of programs and plans, Regional Drug Reference Center, Regional Unit)	HIGH 1 (ARESS)	HIGH 1 (Healthcare Management)	HIGH 1 (HTA Regional Center)
HTA hospital or wide range functions	YES	YES	YES	YES	YES

Table 2. Web Resources

http://www.sihta.it
http://www.who.int/en/
http://www.ministerosalute.it/
http://www.agenziafarmaco.it/section8983.html
http://www.assr.it
http://www.ministerosalute.it/dispositivi/dispomed.jsp
http://www.sifoweb.it/
http://www.ceveas.it/flex/cm/pages/ServeBLOB.php/L/IT/
  IDPagina/1
http://www.uvef.it/web/index.php
http://www.hcta.it/
http://asr.regione.emilia-romagna.it/asr/index.htm
http://www.sanita.regione.lombardia.it/
http://www.regione.veneto.it/Servizi+alla+Persona/Sanita/
http://www.arssveneto.it/html_pages/index.php
http://www.regione.lazio.it/web2/contents/sanita/
http://www.regione.piemonte.it/sanita/index.htm
http://www.regione.toscana.it//salute//index.html
http://www.regione.abruzzo.it/portale/index.asp
http://opt1.area.trieste.it/
http://www.policlinicogemelli.it/area/?s=206

In all regions there, are experiences in hospital-based HTA. If, however, in Emilia Romagna, and partly in Veneto, these experiences followed the regional initiative, in other regions such as Lombardia (S. Matteo Policlinico Hospital in Pavia) and Toscana (Asl 10 in Florence), "corporate" HTA activities are pre-existent to the regional coordination initiative.

The regions of Lazio, Friuli Venezia Giulia and, more recently, Basilicata have established working groups oriented toward technology assessment activities. Currently, however, the level of institutionalization and clarification of such practices does not allow for a systematic analysis of the HTA process in these regions.

Within the Scientific Management of Laziosanità (already Regional Healthcare Unit) for instance, Lazio has established a Health Technology Assessment Laboratory with epidemiological-statistical competencies (four staff units), which produces "Quick HTA Reports," that is, documents for rapid responses to requests by political decision makers on issues related to biomedical technology. To date, there is no explicit prioritization defining in appraisal activities that are often carried out with research financing from the Ministry of Health. Research activities are mainly focused on screening and vaccination.

The region of Friuli Venezia Giulia also has long started an assessment procedure on biomedical technologies. It has mainly focused on electro-medical technologies with the support of the Observatory of Prices and Technology (OPT), established on an experimental basis in Friuli Venezia Giulia in 1996, then taken over by the National Agency (AGENAS).

DISCUSSION

The general trend in Italy shows progressive institutionalization of HTA processes, both at national and regional level.

For the purpose of HTA, regions are using all their possible autonomy to design institutional solutions appropriate for the management of technology assessment, with a view to producing useful evidence for the decisions regarding the adoption and spreading of biomedical technologies. The survey showed that the five regions studied are adopting deeply differentiated institutional processes and working methods. Two emerging issues are important. The first one concerns the possibility of finding methodological harmonizing solutions to make the evidence produced in different places applicable, so that it can be used throughout the country. The second issue concerns the need to find methodological support to initiate similar initiatives in the regions that are still lagging behind in the institutionalization process.

The Italian Society of Health Technology Assessment, founded in 2007 as scientific and multidisciplinary association of professionals and institutions dealing with HTA, could hopefully help to commit the most important stakeholders and strengthen the HTA movement in the next years.

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