THEME ISSUE - HEALTH TECHNOLOGY ASSESSMENT
HTA in Italy: Past Experiences and Perspectives

ABSTRACT

Health Technology Assessment (HTA) is a multidisciplinary field of research that provides information based on scientific criteria to support health policy decisions at different levels: national institutions, health organizations, and clinical practice. In the field of HTA the term 'technology' is very comprehensive and includes, among others, evaluating equipment, intervention protocols, computer science applications, organizational systems and managerial tasks. The aim of this article is to present the areas of application, the methods and the main experiences of HTA in Italy. In particular, it will illustrate the nation-wide project named OPT (Osservatorio dei Prezzi e delle Tecnologie - Technology and Expenditures Observatory) and the constitution of a network among ten representative Italian institutions, including the Istituto Superiore di Sanità. Finally, we will discuss the so called *Carta di Trento,* a programmatic agreement among the members of the above mentioned network covering the main principles of the health technology assessment in Italy.

Health Technology Assessment, introduced in the late 70's in the United States, aims at estimating the effectiveness and the efficiency of biomedical technologies: this concept is very comprehensive and includes, among others, evaluating equipment, intervention protocols, computer science applications, organizational systems and managerial tasks.

The importance of HTA has been lately recognized by the European Commission ([1],[2],[3]) and in 2004 a pilot project was co-financed (EUnetHTA, European Network for Health Technology Assessment[4]) to coordinate the efforts of 35 European partner organizations:

To establish an effective and sustainable European Network for Health Technology Assessment that informs policy decisions.

In Italy one of the first nation-wide experience on health technology evaluation has been carried out since 1996 by the Friuli-Venezia Giulia Region, under a project named OPT (Osservatorio dei Prezzi e delle Tecnologie - Technology and Expenditures Observatory) funded by the Ministry of Health. This project had considerable success, and its operation was subsequently taken over in 2005 by the ASSR (Agenzia per i Servizi Sanitari Regionali - the Government Agency for the coordination of regional health services)

Among the main tasks, OPT developed and kept up-to-date a Technology Data Base (named BDTB, Banca Dati Tecnologie Biomediche) that can be accessed through the Web (**http://opt1.area.trieste.it**) by all the National Health Services hospitals and branches. The BDTB containing bulletins & detailed technical reviews on a number of medical devices and technologies, and several purchase information (on prices, accessories, consumables) based on the yearly survey of tender purchasing events on participating hospitals.

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All biomedical technologies are classified by an encoding system called CIVAB, the use of which has been widespread in Italy since its introduction in the late 80's, made up of an 8-character coded string (XXX JJJ YY) the meaning of which is:
1.   class of technology (XXX). Example: ECT = ecotomograph;
2.   manufacturer (JJJ);
3.   the specific model (YY).

As an example, the following table shows the number of products in the database (as of March, 2005)

Table 1. Number of products in the HTA database

Technology group	Class	Manufacturer	Models
Biomedical Equipment	825	3,114	47,981
Reagents for analytical instruments	459	785	52,982
Angiographic catheters	41	22	4,904
Dialysis filters	1	24	737
Radiographic films	46	13	5,203
PaceMakers	1	14	662
Implantable defibrillators	1	7	100
Orthopedic prostheses	17	65	3,933
TOTAL	1,391	4,044	116,502

This database is one of the most widespread available in Europe in its kind, and every year a *yearbook* is released for each Technology Group in the table, containing an organized list of makes, models and characteristics.

In the last two years a project has been funded by the Italian Ministry of Health ("Promozione di un network di collaborazione per la diffusione delle metodologie di Health Technology Assessment per la gestione delle tecnologie nelle aziende sanitarie") to promote the development of a nation-wide HTA network with the aim of spreading the use of technology assessment and developing a sustainable national reference model. Players in this network are research institutions, hospitals and universities with previous experience in HTA (see Table 2).

Comparing this network, in which the Istituto Superiore di Sanità has an active involvement, with those already existing in Europe (e.g. Swiss and Austrian networks), the Italian one is more committed on the use of Health Technology Assessment as a management support tool, both on a decision makers level and on hospital manager's perspective.

A short-term effect of the birth of the Italian network has been an increased visibility, on the international scenario, of HTA activities carried on in Italy: in 2005 the Second International

Table 2. Research institutions, hospitals and universities participating in the Italian HTA network

U.O.	ISTITUZIONE	STRUTTURA
UO 1	Regione Molise, Assessorato alla Sanità	Osservatorio Regionale per le Tecnologie biomediche
UO 2	Università Cattolica del Sacro Cuore Roma	Policlinico universitario "A. Gemelli" - Unità di Valutazione delle Tecnologie
UO 3	Azienda Socio Sanitaria n. 2 Isontina	Direzione Sanitaria
UO 4	IRCCS Policlinico "S. Matteo" di Pavia	Servizio di ingegneria clinica
UO 5	Azienda Provinciale per i Servizi Sanitari di Trento	Direzione Generale
UO 6	Università "G. 'Annunzio" di Chieti	Sezione di Epidemiologia e Sanità Pubblica, Dip. Di Medicina e Scienze dell'Invecchiamento
UO 7	Istituto Superiore di Sanità	Dipartimento delle Tecnologie Biomediche
UO 8	Agenzia per i Servizi Sanitari Regionali	Sezione Innovazione, Sperimentazione e Sviluppo
UO 9	IRCCS Casa Sollievo della Sofferenza, Opera Padre Pio	Servizio di Ingegneria Clinica
UO 10	Regione Lombardia	Direzione Generale Sanità

Meeting of HTAi (Health Technology Assessment international) was held in Rome, where the ISS (Istituto Superiore di Sanità, which is the main technical-scientific organ of the Italian National Health Service) presented research on the structure and the organization of 24 leading HTA Agencies in Europe, Americas and Australia [5].

More recently, during the First Italian Forum on Health Technologies (held in Trento, January 19-21, 2006) the network summarized on a paper named Carta di Trento a programmatic agreement covering the main principles of health technology assessment in Italy:

1. Technology Assessment should involve all the parties involved in health care delivery *(Who)*
2. The assessment should be carried on all the elements and topics involved in the health care delivery process *(What)*
3. Health Technology Assessment should involve and affect all managerial levels and structures involved in the health care delivery process *(Where)*
4. Health technologies should be assessed throughout their entire lifecycle, i.e. before, during and after their introduction in real practice *(When)*
5. Health Technology Assessment is both an opportunity and a need for the integrated governance of health care systems and of the structures they are built of *(Why)*

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6. Health Technology Assessment is an inherently multidisciplinary process, and should be carried on coherently with other processes (medical, technical, administrative) running in the health care systems and of the structures they are built of *(How)*

Even more recently, the activities carried on by the Italian Network received an implicit acknowledgement with the publication by the Ministry of Health of the 2006-2008 National Health Plan [6], which recognizes Health Technology Assessment as a strategic tool for the evaluation of the technological and scientific progress, stating:

> *… [HTA] aims to inform the decision makers on the technological choices, using the best available scientific evidence on the impact and the medical, social, economical and ethical implications on health expenditures and investments. Those methodologies are indispensable for the assessment of high technologies, their related high costs and management issues, their rational distribution over the country, and to avoid unnecessary duplication or serious deficiency on health care investments.*

In Italy, health is constitutionally recognized as a right of the individual and a collective wealth, and the health care system is almost totally financed with public funds. The low growth of the gross domestic product in the last ten years has threatened the sustainability of the growth of national health expenditure, which is consistent with other OECD (Organisation for Economic Co-operation and Development) member countries data, but in excess to the life cost increase in the same years. This situation is not sustainable in the long term, and can be dealt both with a managed increase in the national health expenditure and using tools designed to increase efficiency in resource utilization. Health Technology Assessment is a promising tool in this field, and we look forward to its widespread utilization in Italy.

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References
[1] Commissioner Markos, Kyprianou Member of the European Commission, responsible for Health and Consumer Protection. The new European Healthcare Agenda. The European Voice conference Healthcare: Is Europe getting better? Brussels, 20 January 2005, p. 3
[2] Markos Kyprianou European Commissioner for Health and Consumer Protection. Growing inequalities, stronger partnerships European Health Forum Gastein - Session: European Health and partnership challenges. The widening health divide in Europe. Partnerships between the state and its citizens, health reforms and patients safety. Gastein, 7 October 2005, p. 3
[3] Decision No 1786/2002/Ec of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008)
[4] Available from: http://www.eunethta.net
[5] Martelli F, La Torre G, Di Ghionno E, Staniscia T, Neroni M, Cicchetti A, Ricciardi W. Health Technology Assessment Agencies: an international comparison. Ital J Public Health 2005; 3 (2):130
[6] Ministero della Salute. Piano Sanitario Nazionale 2006-2008, 28 marzo 2006