

## Health Technology Assessment: a flexible approach? Experiences in Lombardy

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### Abstract

Italy is dealing with an early stage of Health Technology Assessment diffusion. In our opinion, there are at least three important dimensions related to Health Technology Assessment (strategy, inter-organisational relationships and governance) that are able to affect it, at each level, systemic and operating-unit related. Although Health Technology Assessment may have originated as a centralised function conducted by federal government agencies or other national/regional organisations, it is an increasingly decentralised activity. In Italy this decentralisation process is now reaching a peak because of the almost total assignment of health responsibilities to regional authorities. Moreover, Health Technology Assessment is interdisciplinary and it is interdependent with innovation processes. The context seems to be very complex: in our opinion a flexible approach is advisable. The following describes this new approach and the experiences in Lombardy where various solutions have been adopted to support and improve Health Technology Assessment processes.

*Key words: Health Technology Assessment, innovation, clinical engineering, flexibility, Lombardy*

### Introduction

Definitions of Health Technology Assessment (HTA) concern an multidisciplinary approach to support policy-making in health systems [1], as reported in Table 1.

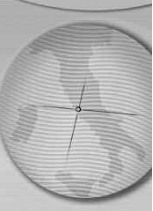
The criteria for technologies considered by HTA are broad ranging. It concerns medical technologies in a strict sense (such as electro-medical equipment and electronic tools), aids and drugs, as well as, organisational and procedural instruments [7]. Therefore the concept of technology, as used in HTA, is very wide: it is comprised of physical components, found in objects, such as instruments, systems and material resources in general, and knowledge components, relative to given activities [8,9], to transform inputs (resources, competences and knowledge) into outputs.

Therefore, innovation in the field of health (in particular, healthcare organisations) becomes important in respect to two dimensions: the *technology driven* one (and the related development of new activities) and the *knowledge based* one which is linked to the professional growth of the participants, (that is the ongoing reconfiguration of the portfolio of competences and available knowledge).

HTA is multidisciplinary by nature because it uses information related to technical properties, feasibility, practical and theoretical efficacy, safety of health interventions and their efficiency, as well as social and ethical considerations. The inter-organisational nature is clear because technology assessment and innovation processes in the field of health are interdependent, due to the interaction between the user (the clinician) and the producer of technology [10]. Clinicians play a fundamental role in both the innovation and technology assessment processes, as well as in industrial research and development, taking advantage of the relationship between universities and healthcare organisations.

### Dimensions and levels of the HTA processes: the Italian experience

In our opinion, the overlapping and interdependence of such different areas of competence are highly complex and require a flexible approach. The present process of convergence between health technology and ICT (Information and Communication Technologies) is enigmatic; highlighting the need for enhancing competencies for HTA processes. Moreover [11], research and development often originates from

**Table 1. Exemples of definitions of HTA [2].**

“We shall use the term assessment of a medical technology to denote any process of examining and reporting properties of a medical technology used in health care, such as safety, efficacy, feasibility, and indications for use, cost, and cost-effectiveness, as well as social, economic, and ethical consequences, whether intended or unintended” [3].
“The term Health Technology Assessment (HTA) is used to describe the assessment of the costs, effectiveness and broader impact of all methods used by health professionals to promote health, prevent and treat disease and improve rehabilitation and long term care” [4].
“Health Technology Assessment [...] is a structured analysis of a health technology, a set of related technologies, or a technology-related issue that is performed for the purpose of providing input to a policy decision” [5].
“Health Technology Assessment is the evaluation of medical technologies, including procedures, equipment and drugs. An assessment requires an interdisciplinary approach which encompasses analyses of safety, costs, effectiveness, efficacy, ethics, and quality of life measures” [6].

networks and communities of independent organisations whose members operate through complex and spontaneous relationships.

Administrative and technical processes of HTA, harmonised at a global level, can be used to manage and reduce the complexity of HTA. In Italy, there are at least at two decisional levels related to the governance of healthcare system and the management of expenditure: the systemic one, i.e. national and regional, and the operating-unit related one, which refers to individual organisations supplying health assistance services (for example, hospitals). Both levels are supported by HTA processes because of the relationship between technology and healthcare costs [12-14]. Three important dimensions of HTA at the systemic and operating-unit related levels are:

- strategy;
- inter-organisational relationships;
- governance.

Although the approach of evidence-based medicine [15-18] favours the subsequent diffusion of HTA processes at a systemic level, there is still heterogeneity between different countries and sometimes between regions in the same national health system. This lack of homogeneity affects the efficacy of communication processes between participants in the health system, as well as efficiency, for example, cost reductions associated with the assessment of technologies [19]. Italy is in the early stages of health technology assessment diffusion [20] and an institutional organisation specially dedicated to HTA (as in other European countries and in the USA) has yet to be established. The interdependence between innovation and assessment of health technologies leads to the issue of governance for research collaboration processes. This means a correct balance between institutionalisation of relationships between health systems and industry and the management of inter-organisational relationships to select strategic areas of cooperation; an appropriate degree of flexibility and freedom granted to individual participants to

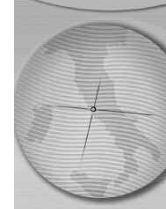
favour innovation processes is also needed. Regardless, excessive fragmentation can make a health system vulnerable with respect to the actual contractual power held by the industrial system; therefore, it seems appropriate to support networks and communities of organisations and to provide them with an adequate portfolio of competences and knowledge. This is a chance to define a sufficiently flexible pathway towards more dynamic and agile (inter)organisational network, as illustrated in the case of the Italian HTA Network. It involves various Italian institutions and operating units (regions, universities, health organisations, etc.) whilst being open and “sensitive” even to foreign experiences. This project is a co-planned process based on distinct steps of organisational design, negotiation, implementation and redefinition, involving the dynamic interaction of its participants. This is consistent with the subsidiary approach related to the gradual increase of responsibilities of regional authorities concerning Welfare policies; it is also consistent with the need for autonomy in the various network nodes, which entails that coordination cannot be done in a hierarchical or authoritative manner but rather it must be done by all participants [21].

The main objectives of the network project are as follows [22]:

1. to identify an organisational model for HTA methodologies that can be used in each Italian health organisation;
2. to encourage the extension of HTA knowledge to managers and health operators in health organisations.

More specifically this means:

1. encouraging the diffusion of HTA principles and methodologies to manage health technologies in all national health care system organisations;
2. integrating the methodological and organisational approaches;
3. bringing together the best Italian HTA local experiences, to compare them with each other and with international benchmarks;



4. designing a single model to be tested within the project itself and to be proposed at a national level as an organisational and management standard;
5. creating a meta-model for professional training of operators involved in HTA activities;
6. assessing technologies in order to encourage the correct transmission (from a scientific point of view) of HTA principles and tools within the national health care system.

A flexible approach can be proposed in a similar manner for health service providers at an individual organisational level. Firstly, the strategic and governance dimensions are connected to the delicate management of conflicts of interest and the equilibrium between the organisation needs as a whole and the individual ones. This is important in order to avoid wasting resources to satisfy particular local needs. It is therefore necessary to connect the governance of HTA processes through the direct involvement of upper-level management and the exploitation of local knowledge and competences, according to a resource-based view approach [23-27]. This also means balancing a top-down approach (“deliberate strategy”) with a bottom-up approach (“emerging strategy”) [28]. Finally, the inter-organisational dimension is due to the interdependence between technology assessment, innovation processes and the relationships between collaborators (industry, universities, health organisations, professional associations, scientific organisations, etc.).

In our opinion, the systemic regional level falls within the scope of HTA for different reasons. First of all, the European Union has recently promoted the decentralisation of social policies - vertical and horizontal subsidiarity [29]-; this is due to an awareness that centralised welfare policies are unsustainable. Countries with a strong tradition of centralisation have undertaken important and sometimes even radical reforms towards decentralisation (France, UK), where as countries which are already “decentralised” have increased the level of local independence (Germany, Italy, Spain). Although technology assessment may have originated as a centralised function, conducted by federal government agencies or other national/regional organisations, HTA is becoming an increasingly decentralised activity conducted by a large variety of organisations, who make technology-related policy decisions, in both the public and private sectors [30]. The growth in decentralised HTA activity has not arisen from a reduction in the

level of centralised activity but from the increased economic and social pressures placed upon healthcare organisations.

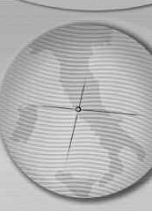
Secondly, in Italy, since the first health system reform in 1978, there has been a gradual increase in the responsibilities of regional authorities in regards to welfare policies. During the past twenty-five years the Italian health system has faced different reforms, with subsequent changes to institutional and organisational structures. These changes are likely to support the drive towards federalism. The decentralisation process is now reaching its peak with almost all of the health responsibilities being allocated to regional authorities. Finally, the payment system based on hospitalisation-events means that regional authorities have to set down tariffs which must be voted upon by their regional boards. Therefore, the DRG (Diagnosis Related Groups) system is very important as the cost of the whole system is no longer funded on the basis of the historic cost but on the value of the services provided; these are classified according to their DRG. The configuration of diagnostic groups uses an *iso-resources* approach. In such systems patients are classified according to how complex the consumed health care services and resources are; funding to health organisations and hospitals is correlated to specific types of clinical cases.

More specifically there are three ways of setting down tariffs within each region:

1. Using national tariffs: in this case the value published in the ministerial decree for each DRG will be adopted.
2. Setting regional tariffs using a dual method:
  - reducing/increasing the national tariffs by a given percentage;
  - using the relative weight system in the ministerial decree and setting their own Adjusted Standardised National Payment (ASNP) rate; the value of each DRG is obtained by the product between the relative weight of each DRG and the base tariff adopted as the unit of payment.
3. Calculating the regional tariffs: in this case regions calculate their production costs for every DRG on the basis of a representative sample of hospitals.

Moreover, regions are able to differentiate between tariffs by subdividing health care organisations into different classes in terms of service complexity.

The hospitalisation-event financing model related to the DRG system can have a dual role: a method to control costs and as a potential tool to



“reward” some technologies with respect to others. The value of the reimbursement affects the number of health care services performed by a specific organisation; it also affects the purchasing process of technology and the frequency of its utilisation. Therefore, the role of each region is actually between the systemic national level and that of a single operating-unit.

**Experiences in Lombardy**

In this context Lombardy has adopted various solutions to support HTA methodologies and to propose financing and tariff adjustments related to new technologies. These are as follows:

- a committee to assess new health technologies;
- regional guidelines which define roles and competences in HTA processes to support the Lombardy health organisations;
- a guideline to support the implementation of “UNI EN ISO 9001 : 2000” which aims to check and to improve processes; this guideline describe all the phases of the macro-process related to health technology management;
- a feasibility study for a regional unit of technology assessment.

Health organisations, scientific organisations and professional associations are able to submit proposals for financial adjustments [31], related to emerging health technologies; moreover, a scientific committee undertakes an evaluation in order to support the above mentioned decisional process and to perform the following tasks:

- to carry out the first selection of proposals presented to the Lombardy general health care board;
- an assessment of the scientific evidence submitted within each proposal or a request for an experimentation project to supply the scientific evidence;
- establishing the best way to support the diffusion of the health technology assessed (i.e. changing the value of reimbursement, financing an experimentation project, etc.).

The Lombard HTA process also includes processes similar to those performed by agencies around the world, such as:

1. Identifying assessment topics, priorities and parameters.
2. Specifying the assessment problem.
3. Identifying the assessment committee.
4. Retrieving evidence.
5. Collecting primary data and generating new data and studies.
6. Interpreting the evidence collected.
7. Synthesizing evidence.
8. Formulating findings and recommendations.
9. Disseminating findings and recommendations.
10. Provides follow-up and monitors impact.

Due to the diversity of the impacts addressed and the range of methods used, a variety of different experts are needed. In response to this Lombardy has involved different professionals in their committee: clinical engineers, health economists, clinicians, epidemiologists, radiology technicians and oncologists [32]. The committee has always used a questionnaire to assess the impacts, the conceptual and technological innovation, security related issues, as well as, the cost-efficacy and effectiveness of health technologies (Table 2).

The committee has filled in more than thirty questionnaires during its first year. Examples of the different health technologies assessed are: devices including drug eluting stents and more complex technologies such as brachithery and percutaneous radiofrequency ablation for the treatment of tumors.

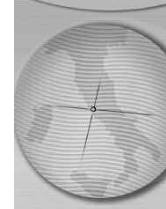
The committee’s professionals are grouped according to the technology that needs to be assessed; for example, during the first year the committee was divided into three groups: cardiology, oncology and radiology and each group included at least one economist, an epidemiologist and a clinical engineer.

In January 2004, the Lombardy general health care board incorporated an internal committee

**Table 2. The questionnaire (in short) used in HTA process in Lombardy.**

Health impact	How technology can influence global indicators of health (such as mortality, morbidity, etc.) taking efficacy and epidemiologic perspectives into account?
Conceptual innovation	How much innovative is technology compared with standard technologies from a conceptual point of view (action mechanism, biological assumption, etc.)?
Technological innovation	How much innovative is technology compared with standard technologies from a technological point of view?
Feasibility	How many organisational and logistic changes does technology involve?
Quality of life	How does technology influence patients’ quality of life ?
Reimbursement	What changes are contemplated in the reimbursement system?
Efficacy	Does efficacy and effectiveness of technology support its adoption in clinical use?
Literature	What evidence is highlighted by l efficacy, cost-efficacy and safety literature?





within its organisational structure to perform the following tasks:

- to evaluate the effect of the technological innovation and its impact on diagnostic and treatment methodologies;
- to assess the economic impact of new health technologies;
- to evaluate potential experiments (number of cases to be treated, financing issues, etc.).

The Lombardy guidelines defines the roles and competences for HTA processes in order to support its healthcare organisations [33]. Clinical engineers have an important coordination role in technology-related issues, in that they support high-level management decisions (strategy, management, planning, procurement and maintenance); they also have an important role in HTA processes, the diffusion of information and communication technologies and the undertaking of research activities.

Specifically, the guidelines for the application of UNI EN ISO 9001 : 2000 [34], combined with the management of technologies within the healthcare structure and the economic processes, lead to an important co-ordination role [35]. In cases where technology is a fundamental issue, the role of the co-ordinator can be carried out by a clinical engineer.

A feasibility study for the development of a regional technology assessment unit, that will utilise those professionals with specific HTA skills and competences, is underway. This unit could service the Lombardy General Health Care Board and would be able to co-ordinate a panel of clinicians depending upon the kind of technology to be assessed.

The Italian and Lombard experiences demonstrate a twofold interpretation of HTA's approach. The scopes are both operating and strategic, as shown below:

- to increase adequate skills, competences and knowledge about HTA and to share these not only at a local level (among the Health care organisations of the Region Lombardy) but also at a national level (through the participation of the Italian Network of HTA.). The Lombardy model could also be tested in other organisational contexts within the network and be integrated with other Italian experiences with the aim of creating and disseminating a shared model to all national healthcare organisations;
- to ensure an appropriate degree of flexibility that is inherent within HTA processes, according to the heterogeneity of the health technologies and the specific skills needed in different assessment processes.

The first requirement also addresses the concepts of process and routine, connected to more repetitive and frequent activities, which are often managed by set procedures and assists in reducing complex procedures. The second one also reiterates the concept that a project includes all of the activities to innovate or to change, i.e. the activities are characterised by different levels of interdependence in order to co-ordinate and obtain an innovative result.

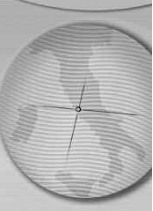
Finally, the search for the right degree of flexibility is coherent within the vision of HTA as a bridge between the worlds of research and that of decision-making and in particular, policy-making [1]. A rigid definition of HTA boundaries would result in no results being produced by the organisations involved, since the normally weak boundary is negotiated according to each technology being assessed.

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