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 electromedical 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...
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;

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

<table>
<thead>
<tr>
<th>Definition</th>
<th>Source</th>
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<tr>
<td>“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”</td>
<td>[3]</td>
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<td>“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”</td>
<td>[4]</td>
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<tr>
<td>“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”</td>
<td>[5]</td>
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<tr>
<td>“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”</td>
<td>[6]</td>
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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.
Firstly, 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 brachitherapy 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.

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

Acknowledgement section

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