

Hospital-based Health Technology Assessment: the experience of Agostino Gemelli University Hospital's HTA Unit

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Abstract

The Italian National Health Care Service, as many other industrialised countries', has to cope with increasing health care needs in spite of the limited resources available.

Therefore, it is necessary to assess diagnostic-therapeutic procedures, technologies and organizational standards, in order to allocate the available resources appropriately.

Methodologies developed by the area of research known as Health Technology Assessment, provide scientific support for the policies that all countries have adopted in order to rationalize, and sometimes to ration, health care services.

Within this context Health Technology Assessment plays a key role in establishing appropriate health care policy decisions.

If in the past Health Technology Assessment's areas of applications have involved mainly macro health care policies, HTA's methods are now becoming imperative also on an organizational level, as a valuable tool to support managerial decisions.

This article outlines the 4 year - experience of A. Gemelli University Hospital of applying HTA methodologies.

Key words: quality of care, management, Health Technology Assessment

Introduction

As many industrialised countries', the Italian National Health Care Service has been facing, in the last decade, the problem of guaranteeing health care services to all citizens within the resources available.

Between '80 and '90 many countries adopted policies oriented at rationalizing resources, while trying at the same time to increase health care organization's efficiency by introducing elements of competition between producers.

The international community has recently started to address this problem, by defining priorities, in order to ration the essential services through public financing. This process implies the possibility of evaluating different diagnostic-therapeutic protocols, in relation both to the population involved and to the services' cost.

Also Italy has adopted policies oriented at defining essential levels of health care assistance, especially those that must be guaranteed by the National Health Care Service: to define such levels is the first step of a rationing process, based on explicit criteria (priorities) and shared in "a social solidarity health care pact".

The scientific evidence for the effectiveness and appropriateness of interventions is not only one

of the main inspiring principles of the National Health Care Service, but it is also a key condition to address its resources.

Within these principles an area of international multidisciplinary research has developed, known as Health Technology Assessment (HTA).

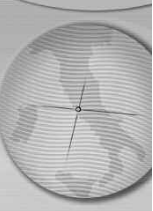
By producing information on the clinical, economic, organizational, social and ethical impact of each topic, HTA becomes a valuable tool to support decision makers in decision making processes.

HTA can be applied on three levels: *macro*, *meso* and *micro* level.

The *macro level* is the most popular HTA's area of application worldwide: scientific information directly aims to address health care policies (Nations, Regions, Local Health Units).

On a *meso* and *micro* level HTA is still in its early stages.

The Health Technology Assessment Unit (HTA-U), established in 2001 as part of A. Gemelli's University Medical Directorate, has been created with this special scope: to introduce to management processes a dedicated tool which is able to provide all of the information required to manage hospital structures.



After briefly introducing HTA's general features, this article outlines the main principles of its application at an institutional level (meso level) and describes its application according to the experience of A. Gemelli University Hospital's *Health Technology Assessment Unit (HTA-U)*.

Healthcare Technology Assessment: definition, principles and areas of activity

Health care policies, which are often highly expensive, impose a choice between which of the different technologies to employ (laparoscopy versus traditional surgery, morphologic imaging versus functional).

The most appropriate choice, in this case, presumes complete technical knowledge not only for the options available, but also for the clinical, economic and organizational, social and ethical consequences of each diagnostic-therapy. This knowledge is not always available to decision makers. The main aim of HTA is to provide useful information that they can use [1].

It is not easy to specify HTA's areas of application: what does exactly HTA apply to, and what does "technology" mean?

These questions, apparently simple and immediate, are in fact open to different interpretations. The same definition of "technology" is extensive and generic.

Health care technology is the complete group of technical and procedural tools offered by science and research to health care operators to decide on prevention, diagnosis, care and rehabilitation.

The broad concept of technology involves, therefore, not only electric and electro-medical devices employed in medical practice, but also health and pharmaceutical aids which support healthcare professionals to obtain the best results in care.

Health care technology is, consequently, all of the work necessary to realise the prevention, care and rehabilitation of people, on both an individual and community level.

Another one of HTA's distinctive characteristics is its multidisciplinary approach: by assessing

technologies on many different levels - clinical, organizational, economic, social, ethical, etc., it anticipates for decision makers the possible consequences of an action.

HTA's areas of application: the meso level

Health Technology Assessment's evolution has been strongly affected by the same conditions which fostered its advancement. HTA was created in 1970 in the United States Congress, as a tool to support political decisions for "...enabling technology to make the maximum contribution to our society's welfare" [2].

Meant, therefore, to support policy makers' decisions, Health Technology Assessment has always been, since the beginning, policy-oriented.

As a consequence, agencies have been established in different countries to exclusively work on Health Technology Assessment, in order to provide scientific support for policy decisions. These agencies, created on a national level (e.g. Swedish SBU) or sub-national level (e.g. HTA Catalan Agency or Quebec Health Technology Assessment Council), and operating more or less independently, are meant to provide solutions at a more general health care service level [3,4].

Even though Technology Assessment has developed to meet a more centralised need for policy making, (need which is emphasised by the creation of agencies and organizations depending on federal and regional governments), there is world-wide an increasing need for decentralisation.

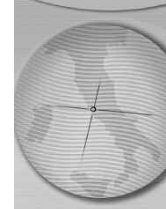
Decentralization is not due to a decrease in HTA's policy activity, which is increasing, but to the growing economic and social pressures on health care structures.

This situation, which is still evolving, can be explained with the absence of HTA's development standards dedicated to single health care organizations.

Even if with some exceptions, up to now HTA's operative aspect has been neglected on an international level, because a related scientific literature is still unavailable. In fact, a scientific

Table 1. Health Technology Assessment's main features

Aims	To produce information and support health care policy makers in the decision making processes.
Areas of application	Health care technologies. It widens the meaning of Technology. Technology means the complete group of tools, techniques and procedures, which support health care activities. Therefore this definition includes not only biomedical devices, but also health and pharmacological aids and organizational tools used in the health care system.
Methods of work	Multidisciplinary approach which makes possible to assess technologies and modes of intervention in health care on different levels (scientific, economic, organizational, ethical, sociological...).
Special notes	A decision making tool for the final allocation of resources. It uses information synthesis methods to produce reports which health care decision makers can easily interpret and utilise.



production about HTA's methodologies' application on a meso level does not exist yet.

One of the few useful documents has been produced in 2003 by the Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) [5], which outlines some of the possible organizational solutions to introduce Health Technology Assessment functions into health care structures, particularly into university hospitals.

The solutions proposed highlight two different organizational standards:

1. HTA's function focuses on producing information to be utilised for managerial purposes, while remaining independent of the management structure.
2. HTA's function focuses mainly on management research themes, and its structure is incorporated by the Centre of Research.

Both solutions imply advantages and disadvantages, but up to now practical applications of these have still to be realised.

Even if with different forms and areas of applications, also in the United States HTA method has been experienced, particularly by hospitals, Health Maintenance Organization and Third-Party Payers.

Hospitals are more focused on traditional financial analyses ("prudent purchasing"), which means that HTA is used almost exclusively as a means to control expenditures. Decisions are based on financial assessment with little or no formal evaluation of changes in patient outcomes or medical practice pattern.

HMOs and insurers conduct outcome assessments for coverage of expensive or controversial technologies but exclude economics. HTOs use technology assessment to determine what procedures are safe and effective to become standard medical care, while insurers (third party payers) use HTA to primarily ensure that the insured receives high quality and clinically appropriate care and to provide information for the basis of coverage decisions.

Another important experience of Health Technology Assessment that must be mentioned is the case of A. Gemelli University Hospital - Health Technology Assessment Unit - in Italy, where HTA' role becomes crucial in resources allocation decision making.

The Health Technology Assessment Unit (HTA-U)

Main principles

Health care organizations become increasingly expensive and technologically advanced.

Big hospitals, particularly university hospitals, are focused on care, research and training

activities which must be supported by appropriate management processes.

An appropriate management process is comprised of four phases:

1. strategic planning
2. annual or intra-annual operative planning
3. planning implementation
4. verifying planned and implemented processes by making comparisons with standards and initial expectations, in order to test the appropriateness of the performances.

In its conception, the HTA-U uses technology assessment method not only in the first phase (strategic planning), but also in the second (annual and intra annual operative planning) and in the third/final phase (verifying planned and implemented processes by making comparisons with standards and initial expectations, in order to test the appropriateness of the performances) [6,7].

This implies a new role of Technology Assessment, which becomes more management-oriented, compared to the traditional HTA's applications worldwide [8].

"A. Gemelli" University Hospital's HTA-U was created after a time of analysis and reflection on both a national and international level: in 1999 during the planning of the hospital technology investment in order to cope with important changes in the institutional scenarios, it was felt that it was crucial for the decision making processes to be supported by new effective tools.

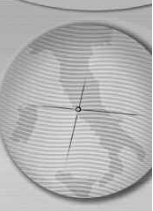
In 1995 hospital financing systems dramatically changed because in Italy a new system of *payment for performance* was introduced. In 1999 the situation became even more delicate: as except for funds earned by care performances, A.Gemelli University Hospital didn't have any ad hoc regional funds to meet clinicians' requests for technology.

Therefore in 2000 the HTA-U was made operative as part of the Medical Directorate.

Aims

As reported in the document of activation, HTA-U started in January 2001 in order to:

- "...assess technologies and quality within the hospital and the structures related to it, by supporting both the Directorate and the departments involved in technological choices, so that they (the choices) will be aligned with the specific institutional needs and objectives, respectful of the economical bonds and also able to foster performances' quality and appropriateness."
- "...perform research and teaching activities, in the specific areas of interest and in



collaboration with other national and international institutions.”

This definition sums up all of Technology Assessment’s main features mentioned in the introduction.

In the first 4 years of activities our objectives have undoubtedly been achieved, thanks to technology assessment activities, which have involved the application of a scientific methodology in order to evaluate the clinical, economical and organisational effects of introducing medical technologies into the hospital, that is to say, by producing information to support the hospital’s management choices.

HTA-U’s works on 5 main HTA macro-areas: drugs therapies, electro-medical devices, medical procedures, supporting systems, organisation and management systems.

Within these areas, HTA-U aims to:

- harmonize clinical and management problems in an academic context, where medical, research and training needs coexist
- optimize new technologies’ choice and use, clinical practices’ effectiveness, appropriateness and efficiency, and to start a constant quality improvement process
- make accurate forecasts on the clinical, economical and organizational impacts of newly introduced biomedical technologies.

Furthermore, the HTA-U is credited with having started a fruitful collaboration with industries of different and specific competences, aiming to study phenomena of innovation technology and to identify governance standards.

Structure and methodology

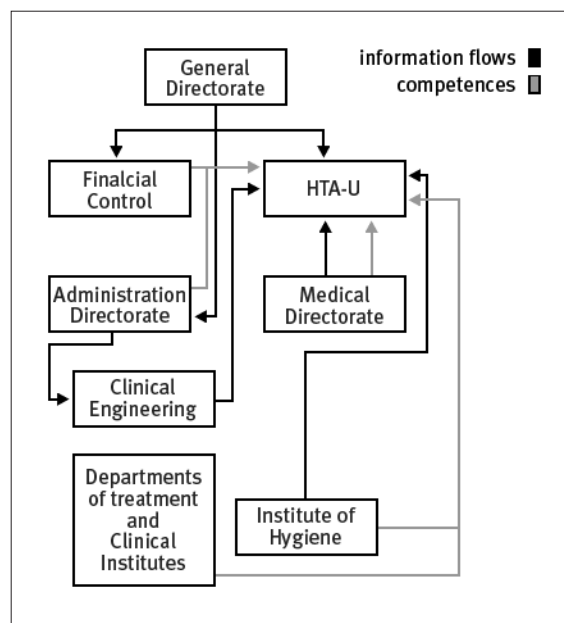
The HTA-U is part of the Medical Directorate and is directly supervised by the Medical Director.

The Unit employs multidisciplinary expertises from both the Medical Directorate and the A. Gemelli Faculty of Medicine and Surgery’s Institute of Hygiene. Regular collaborators are a clinician of the Medical Directorate, two biomedical engineers (specialised respectively in health technology assessment and certification/accreditation processes), a health economist, and a secretarial support, expert of international public relations and operative activities coordination.

The Unit is also supported by the Institute of Hygiene’s Health Economics Laboratory, for economic evaluations and organizational impact studies.

Moreover, with respect to the assessment of hospital activity, the HTA-U works conjointly with all of the hospital’s professionals and offices.

Figure 1. The Health Technology Assessment Unit and Gemelli University Hospital’s Organization



Picture 1 outlines HTA-U’s general framework. Information and competences’ flows have been schematised.

An HTA project, still in progress, involves also clinicians, each for their own areas of competences.

This project is supervised by an international Committee of Experts, made up of clinicians, HTA and Public Health experts, with the scope to address HTA-U’ s scientific and operative advancement.

The HTA-U’ s activities are based on the following principles:

- Clinical/organizational appropriateness
- Internal coherence of the activities/technologies assessed
- Activities/technologies’ alignment with the Organization’s aims
- Services and activities’ efficiency.

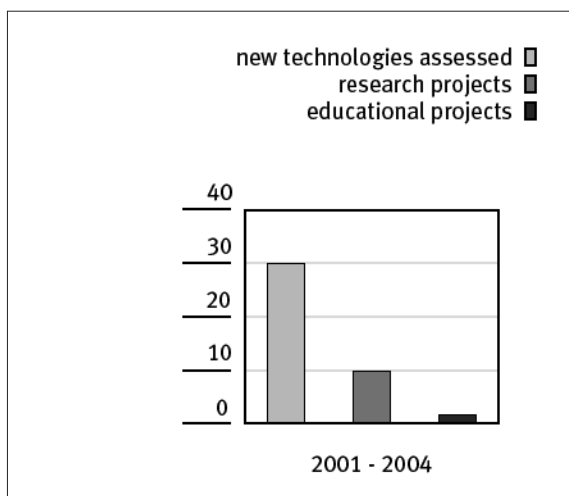
The HTA-U’ s methodology consists on a process of analysis which starts from the definition of the clinical need (which generates the request for technology) to assess the more appropriate technologies to satisfy it.

Areas of activity

The HTA-U has two main areas of activity: high-level management support activities and clinical support activities (Figure 2). High-level management support activities are:

- Investment planning
- New technologies and service assessment
- The assessment of health care services organisational evolution

Figure 2. Activities performed by HTA-Unit between 2001 and 2004



- Research and development activities
- Clinical support activities are:
- Clinical Governance
- Quality improvement activities.

With respect to Quality Improvement activities, in these first three years the HTA-U focused on institutional accreditation for services and Operative Units' excellence, such as: the Clinical-Chemistry Service, the Radiotherapy Service, the Microbiology Service, Domiciliary Therapy for Infectious Diseases, Centres of Performances for Pre-clinical Research, etc.

Clinical Governance activities and Risk Management programmes are still being developed.

Amongst technology assessment activities, there have been 40 cases of high-impact technologies: technologies for the new operating rooms and diagnostic imaging, highly innovating technologies and surgical aids.

HTA-U is presently engaged in supporting high-level management in the realisation of A. Gemelli University Hospital's 2004-2006 Investment Plan.

Many research projects are carried out in collaboration with the Institute of Hygiene and are mainly focused on health care organisation themes.

The last project financed in 2003 was the foundation of an HTA Italian Network, entirely coordinated, both in Italy and world-wide, by the Catholic University of the Sacred Heart of Rome.

The HTA-U also participates in partnerships with biomedical industries, in order to produce new technological innovation standards, and to create technological innovation, rather than only to study the effects of introducing technologies in health care structures.

In addition, training projects have been organised in collaboration with the Institute of Hygiene.

The main training projects realised are:

1. The International Master Program in Health Technology Assessment and Management - Ulysses Project
2. HTA Distance Learning Course.

The International Master Program in Health Technology Assessment and Management - Ulysses Project, started in 2001, financed by EU, Canadian Government (Eu-Canada Collaboration High Education Project) and The Ministry of Education, University and Scientific Research, MIUR, (High Education Internationalisation Projects).

Ulysses Project aspires to create professionals who are able to assess and manage health care technologies. It achieves this by providing them with all of the necessary tools to examine the medical, economic, ethical, legal and social effects of the application of specific procedures, services and techniques in health care.

Currently 30 students, coming from 20 different countries and enrolled in the 5 Universities partner, have attended the International Master.

Additionally, HTA Distance Learning Course is the first HTA interactive distance learning course in the world. It will be distributed in early 2005 in Italian by the Catholic University of the Sacred Heart.

Conclusions

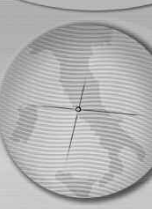
Activities carried out in the last three years are today producing important results: their impact is visible now both in our Hospital and University.

Our work has definitely increased the interest of the international scientific community in HTA's application on a meso level, (institutional, to support managerial decisions in health care structures).

Furthermore, A.Gemelli University Hospital's HTA-U represents at the moment one of the few models in the world of HTA's application on a managerial-organisational level.

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