HTA in Hospital
The HTA Unit of the University Hospital Agostino Gemelli
Università Cattolica del Sacro Cuore

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Italian National Institute for Health

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Bilbao, October 24th 2017

25th anniversary. Osteba

Health technologies life cycle
From Investment to Disinvestment

OSTEBA. Basque Office for HTA
Ministry for Health
Basque Government

October 24th and 25th, 2017

In collaboration with:
Outline

• Introduction
  – Healthcare in Italy
  – HTA in Italy

• Hospital based HTA at University Hospital Agostino Gemelli
  – Acquisition of Topics
  – The HTA process
  – Results and impact
  – Future direction
The Italian health care system

The system is funded mainly through direct and indirect regional taxes

<table>
<thead>
<tr>
<th>System</th>
</tr>
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<tbody>
<tr>
<td>The Italian National Health care System (Servizio Sanitario Nazionale – SSN) is a comprehensive system which assures health care services to all citizens</td>
</tr>
<tr>
<td>Citizens can choose the professionals and the places of treatment they prefer between public structures and private accredited (publicly funded) structures</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Funding</th>
</tr>
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<tbody>
<tr>
<td>The SSN is funded through the general taxation system, especially through direct and indirect regional taxes and a transfer from the equalization fund</td>
</tr>
<tr>
<td>Local health care units (Aziende Sanitarie Locali, ASL) also have direct revenues coming from services provided privately and from direct co-payments from patients</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Organization</th>
</tr>
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<tbody>
<tr>
<td>The SSN is formed by different levels of responsibility and governance:</td>
</tr>
<tr>
<td>- National or central level: Ensures citizens’ rights, the Essential Levels of Health care (LEA), a strong system of guarantees</td>
</tr>
<tr>
<td>- Regional level: manages expenditure to achieve the stated health objectives</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Overview/budget</th>
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</thead>
<tbody>
<tr>
<td><strong>National or central level</strong>: Defines the Essential Levels of Health care (LEA)</td>
</tr>
<tr>
<td><strong>Regional level</strong>: Controls health care expenditure in order to achieve the established LEA</td>
</tr>
<tr>
<td>–Has the authority to regulate and organize health services/activities and funding of ASL</td>
</tr>
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</table>
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

While HTA was originally developed to meet central policy needs, changing secular trends in the pace of technologic innovation and limited resource availability suggest that the traditional HTA mission needs to adopt a new integrated model that guarantees implementation of central policy at the local level. For this reason there has been recent interest in decentralising HTA to increase relevance and impact at the local level, such as within the hospital or local regional setting.
Health Technology Assessment in Italy

Hospital’s origins, the management and network approach

Health Technology Assessment’s Italian Network: origins, aims and advancement

Walter Ricciardi¹, Americo Cicchetti², Marco Marchetti³
Representing Health Technology Assessment Italian Network Partners

Abstract

The Italian National Health Care Service, as many other industrialised countries’, has to cope with increasing health care needs in spite of limited resources available. Therefore, it is necessary to assess diagnostic-therapeutic procedures, technologies and organizational standards, in order to allocate the available resources appropriately. Health Technology Assessment provide scientific support to the policies that all countries have adopted in order to rationalize, and sometimes to ration, health care services. Since in Italy dissemination and utilisation of HTA as means to support health care policies are still limited, in 2003 The Ministry of Health Care, within the development of Special funding Programmes – art.12 bis, comma 6, Law 229/99n. –, financed the establishment of an HTA Italian network, in order to foster the application of principles of technologies’ management in health care organisations.

Key words: network, Health Technology Assessment, standards

http://ijphjournal.it/article/view/5981
Region of Molise, Health Care Council
Catholic University of Sacred Heart of Rome, “A. Gemelli” University Hospital
Local Health Care Unit n.17, Medical Directorate, Monselice, Veneto
IRCCS University Hospital “S. Matteo” of Pavia, Clinical Engineering Service
District Unit for Health Care Services of Trento, General Directorate
“G. D’Annunzio” University of Chieti - Pescara, Epidemiology and Public Health – Department of Medicine and Geriatrics
Higher Institute of Health Care, Department of Biomedical Technologies
Agency for Regional Health Care Services, Department of Innovation, Experimentation and Development
IRCCS Casa Sollievo della Sofferenza, Opera Padre Pio, Clinical Engineering Service
Lombardia Region, Health Care General Directorate
Hospital Trust of Padova, Medical Directorate

Partner joined the network later
Project Partners
The University Hospital «A. Gemelli» in numbers (2015)

94,805 Admitted patients
I PAZIENTI DIMESSI

46,080 Surgical Intervention
GLI INTERVENTI CHIRURGICI

1,547 Beds
I POSTI LETTO

92% Occupancy Rate
IL TASSO DI OCCUPAZIONE LETTI IN DEGENZA ORDINARIA

Spending one day at the University Hospital «A. Gemelli»

- **Born children**: 11
- **Patients in the Emergency**: 220
- **Surgical interventions**: 126
- **Outpatients procedures**: 9,604
- **Patients admitted**: 262
- **Referrals**: 350
- **Procedures administrative di accettazione**: 4,200
- **3,100 Pasti Erogati**: 3,100
- **3100 meals delivered**: 3,100
University Hospital Agostino Gemelli – Università Cattolica del Sacro Cuore

Physicians: 975
Nurses: 2,045
OTA, Ausiliaris, OSS: 754
Technici Sanitari Altri Sanitari: 461
Personale Amministrativo E Altre: 953
Total Staff: 5,188

Administrative Staff: 76
Corsi di Alta Formazione: 31
Corsi di Perfezionamento: 108
Corsi di Alta Formazione: 76
Corsi di Perfezionamento: 41
Corsi di Laurea: 138
Corsi di Laurea Triennale: 13
Corsi di Laurea Magistrale: 3
Corsi di Laurea Triennale: 1

Students: 5,036

Comunità Lavorativa
University Hospital Agostino Gemelli – Università Cattolica del Sacro Cuore

GLI ASSET DELLA FONDAZIONE

Value of production and other revenues

National Center for HTA
HTA Unit – University Hospital A. Gemelli

Original mission and Vision

Activities to support the directorate

Research and training activities

• “…technology assessment and quality within the Hospital… in order to support technology innovation on decision making process ….to increase appropriateness and according to economic constraints

• “…research and training in specific fields of interest carried out in liaison with other Italian and foreign institutions…”

[Minutes of the Governing Board, 01/11/2000]

✓ Agostino Gemelli University Hospital in Rome established Italy’s first Health Technology Assessment Unit in the year 2000 named Unità di Valutazione delle Tecnologie (UVT).

✓ Since 2006 HTA Unit has also played an integral role in the process of introducing new technologies (included drugs and medical devices) to this teaching hospital.
A successful story?

- **Some positive aspects**
  - An extensive and formal HTA approach to managing the company's technology strategy
  - Continuity in commitment by the Management since its starting in 2001
  - A progressive continuous involvement of professionals
Technological strategy in the technology lifecycle
Management and promotion of technological innovation at the University Hospital A. Gemelli

HTA Unit activities evolution 2001 2015

Phase 1 - Creating Innovation
Phase 2 - Introduction to Clinical Practice
HB-HTA
Phase 3 - Rationalization / Disinvestment
HB-HTA
HTA activities

Using technology in clinical practice
Development of technology

National Center for HTA
Member of INAHTA
HTA Unit – University Hospital A. Gemelli
The HTA process

The current situation

A complete integration into the operating streams of the structure (from planning to purchase)

Priority setting
The critical issue/the urgency of the evaluation (i.e. when a device previously used is withdrawn from the market and thus it must be replaced with a new one);
The chronological order of request (the "first in first out" criterion);
The assessment of all the technologies required by a single department, which gives an overall view of what is required from each organizational unit within the hospital;
The input coming from the Medical Department or the General Direction, for strategic issues.
Production

- HTA Report (medical devices and drugs)
- Positive and negative List for drugs formulary
- List of technologies to disinvest
Main aspects of the evaluation process

- Identify the health technology, type of request and its motivation
- Details of the health technology & its National negotiation profile
- Comparative approach vs. available alternatives
- Impact on organization (staff requirement or education needs)
  - For Medical device
- Awareness of clinicians of the impact on their budget
- Declaration of non fungible device
  - For Medical device
The impact
Drugs Evaluation May 2013-may 2016

<table>
<thead>
<tr>
<th>Evaluation of pharmaceuticals (Novembre 2013 – Maggio 2016)</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved</td>
<td>23</td>
<td>27%</td>
</tr>
<tr>
<td>Approved with limitation</td>
<td>21</td>
<td>25%</td>
</tr>
<tr>
<td>Not approved</td>
<td>17</td>
<td>20%</td>
</tr>
<tr>
<td>Suspended decision</td>
<td>24</td>
<td>28%</td>
</tr>
<tr>
<td>Total</td>
<td>85</td>
<td>100%</td>
</tr>
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</table>
October 2006- may 2016 experience – Device

Impact of approved expenditure on total expenditure

<table>
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<tr>
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</thead>
<tbody>
<tr>
<td>Valore richiesto</td>
<td>€ 685.811</td>
<td>€ 752.262</td>
<td>€ 1.213.921</td>
<td>€ 709.545</td>
<td>€ 870.070</td>
<td>€ 753.610</td>
<td>€ 947.340</td>
<td>€ 2.037.377</td>
<td>€ 2.054.529</td>
<td>€ 844.975</td>
</tr>
<tr>
<td>Valore approvato</td>
<td>€ 387.331</td>
<td>€ 332.329</td>
<td>€ 550.948</td>
<td>€ 251.493</td>
<td>€ 427.570</td>
<td>€ 316.095</td>
<td>€ 571.860</td>
<td>€ 504.705</td>
<td>€ 717.361</td>
<td>€ 717.361</td>
</tr>
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</table>
UVT Experience – Device

Number of applications per year

<table>
<thead>
<tr>
<th>Year</th>
<th>Approvazione condizionata</th>
<th>Non approvazione o sospensione</th>
<th>Approvazione</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006/2007</td>
<td>4</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>2008</td>
<td>23</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>2009</td>
<td>15</td>
<td>14</td>
<td>2</td>
</tr>
<tr>
<td>2010</td>
<td>13</td>
<td>11</td>
<td>2</td>
</tr>
<tr>
<td>2011</td>
<td>7</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>2012</td>
<td>7</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>2013</td>
<td>2</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>2014</td>
<td>11</td>
<td>28</td>
<td>11</td>
</tr>
<tr>
<td>2015</td>
<td>19</td>
<td>16</td>
<td>16</td>
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<tr>
<td>2016</td>
<td>15</td>
<td>7</td>
<td>7</td>
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<td></td>
<td></td>
<td></td>
<td>3</td>
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<td>(gen-mag)</td>
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</table>
## Drivers of decision on introduction on denial of medical device in the hospital

<table>
<thead>
<tr>
<th>Driver</th>
<th>Favorable</th>
<th>Unfavorable</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Effectiveness</strong></td>
<td>• Good evidence that they brought substantial health benefits</td>
<td>• Insufficient proof of benefit or insufficient quantity of health benefit to justify the costs</td>
</tr>
<tr>
<td><strong>Economic issues</strong></td>
<td>• Relatively lower cost respect internal comparator with same effectiveness</td>
<td>• Relatively higher cost respect internal comparator with same effectiveness</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Cost not sustainable respect to budget in spite weak proof of evidence</td>
</tr>
<tr>
<td><strong>Organizational issues</strong></td>
<td>• Medical device that could be used by several departments that entail a rationalization in the area</td>
<td>• Needs of increasing in staff not sustainable</td>
</tr>
<tr>
<td></td>
<td>• Change of setting of care (eg. From normal operative theatre to day surgery theatre)</td>
<td>• Needs of additional physical area</td>
</tr>
<tr>
<td><strong>Strategic issues</strong></td>
<td>• Device with sufficient proof of health benefit to be used in a strategic area of the hospital even if an increasing in costs</td>
<td></td>
</tr>
</tbody>
</table>
Drivers of decision on introduction on denial of medical device in the hospital

**Denied**
- Insufficient proof of benefit or insufficient quantity of health benefit to justify the costs (6)
- Costs too higher respect to internal comparator (4)
- Organizational issues (3)

**Approved**
- Good evidence that they brought substantial health benefits (10)
- Relatively lower cost respect internal comparator with same effectiveness (4)
- Strategic (2)

**Suspended**
- The MD will be used in a ward to be implemented (eg. Pelvic floor disease) (7)
- The number of MD required seems overestimate (2)
- Waiting for budget negotiating (5)

**Restricted use**
- It is suggested to implement a register of patient to monitor specified clinical outcomes not well demonstrated (8)
- The number of required MDs have to be confirmed by a monitoring activity (2)
Dissemination of results

– Report are not public but accessibile by the community of the hospital (*in the future this policy could change*)

– Impact is visible

– HTA approach is mandatory

– Increasing impact and increasing reaction from some leader clinicians

– Monitoring impact of raccomandation is still limited
HTA Unit 2.0

Future Direction

• Maintain the high impact of the HTA activity
• Development of HTA activities also in the phase of creating innovation
• Increase the creation of consensus on the theme of HTA among clinicians
  – Bring them on board
• Improve collaboration with national anche regional institutions and industries on the subject of .
  – Evaluation, education, sharing activities
  – Evidence generation
Thanks for your attention

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