HTA in Italy
from a national perspective to hospital based HTA

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Koper, May 2nd – 4th, 2010
Agenda

• Background
  – Challenges in managing technological innovation
• Regulating technology innovation
• What is HTA?
• HTA and regulation
• One example: Italy
• HTA decentralization
• Future scenario
Adapted from The European-House Ambrosetti by A. Cicchetti, F. Leone, D. Mascia, “Ricerca scientifica e trasferimento tecnologico”, 2007
Technology spectrum

Source: Mikhail et al, 1999

State of the science  ↔  State of the art

Technology Blade

- Leading edge
- Cutting edge
- Virtual edge
- Conceptual
- Experimental
- Limited availability
- Preferred Alternatives
- Widely available (Standard of care)
- Disrupting use
- Proven-reimbursed

Clinical Practice  ↔  Medical Research

- Technology application
- Technology development
- Technology research

Member of
INAHTA
• Background
  – Challenges in managing technological innovation

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Decisions in health care systems

“All effective treatments should be available to the population”
Archibald Cochrane, 1971

Cost containment health care reforms (Quasi-markets; DRGs; Trusts)

Health care reforms oriented to appropriateness, quality, risk management (Clinical governance, )

“All cost-effective treatments should be available to the population”
Alan Williams, 1997
Emerging needs = “advanced” regulation

Mission: *Ensure health care system sustainability*

- Managing health care expenditures (opportunity cost – resource allocation)
- Societal value (ethical dilemmas, acceptability of treatments ...)
- Support to technological innovation (Lisbon Protocol)
Health care system and HTA

• Governments current strategies intend to:
  – Reduce economic costs,
  – Reinforce efficiency through regulation,
  – Ensure quality of health performance through technological empowerment (Sorenson, 2009, Harzt et al., 2009).

• HTA represents a tool in supporting coverage and in the case of drugs for pricing decisions:
  – Determining “value for money” of a new technology;
  – Promoting useful information for patients and providers (Sorenson, 2009).
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Health Technology Assessment

• “HTA is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value” (EUNETHTA)
Pillars

- Policy oriented
- Transparent
- Science-based
- Evidence based
- Multidisciplinary
- Multistakeholder
DOMAINS
• Description and technical characteristics
• Current use
• Safety
• Clinical effectiveness
• Costs, economic evaluation
• Ethical aspects
• Organizational aspects
• Societal aspects
• Legal aspects

MACRO
• Coverage
• Reimbursement level
• Guidelines

MESO (HOSPITAL)
• Tech adoption

MICRO
• Clinical practice

Member of INAHTA
HTA’s Domain

- Domains of HTA
  - Description and technical characteristics
  - Current use
  - Safety
  - Clinical effectiveness
  - Costs, economic evaluation
  - Ethical aspects
  - Organizational aspects
  - Societal aspects
  - Legal aspects
52 Agencies associated in INAHTA

- UK (6)
- Spain (5)
- The Netherlands (4)
- Canada, USA (3)
- Sweden, Australia, France, Denmark, Italy (2)
- Israel, Finland, Switzerland, New Zealand, Lithuania, Cuba, Belgium, Norway, Ungheria, Austria, Germany, Cile, Mexico
“For regardless of differences in definition and application, it is clear that HTA brings together public and private interests in a process in which there are potentially winners and losers, and the perception of outcome is highly contingent on each party’s point of view” (O’Donnel).
# Health Care System and HTA

<table>
<thead>
<tr>
<th>Model</th>
<th>Characteristics</th>
<th>Countries/ Regions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Integrated</td>
<td>One or more agencies operating in a national framework integrated within the decision making process</td>
<td>UK, France, Germany, Denmark, Sweden,</td>
</tr>
<tr>
<td>Integrated</td>
<td>One or more agencies producing scientific HTA reports and appraisals to support decision making without explicit integration in decision making process</td>
<td>Norway, The Netherlands, Finland, Belgium, Australia</td>
</tr>
<tr>
<td>Federal</td>
<td>Different agencies operating at National, Regional or Provincial level</td>
<td>Spagna, Canada</td>
</tr>
<tr>
<td>Network</td>
<td>Different agencies co-operating at National, Regional, Provincial level and Local (Organizational level) with a multilevel framework</td>
<td>Canada (Quebec), Denmark, <strong>Italy</strong></td>
</tr>
</tbody>
</table>
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### Key evidence used to support decision-making

- ✓ Health benefit (mortality, morbidity)
- ✓ Cost-effectiveness (cost per quality-adjusted life year- QALY)
- ✓ Necessity (e.g. disease burden, severity)
- ✓ Availability of treatment alternatives
- ✓ Public health impact
- ✓ Equity
- ✓ Innovative characteristics
- ✓ Budget Impact
- ✓ Ethical/legal considerations
- ✓ Feasibility of decision/guidance implementation
- ✓ Projected uptake/utilization

Adapted from Sorenson et al, 2008
The case of Drugs regulation

Scope of application of HTA approach

Use of HTA

- Limited
- Possible
- Possible
- Necessary

Innovation algorithms
Coverage under evidence development
Managed entry schemes

Stakeholder involvement
Multidisciplinary assessment
Data Availability
Licensing
Price & Reimbursement
Level of reimbursement
Price/coverage re-negotiation
HTA in decision-making level (2/5)

• The usage of HTA by decision makers is still restricted;
• Policies of pricing and reimbursement of technologies consider a limited range of factors in the assessment process (often clinical effects and budget impact).

“Consequently, HTA was not integrated with other mechanisms for resources allocation”
(Hutton et al. 2006)
### HTA in decision-making level (3/5)

<table>
<thead>
<tr>
<th>Technologies appraised</th>
<th>Pharmaceuticals</th>
<th>Devices</th>
<th>Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>FULL HTA</td>
<td></td>
<td></td>
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<tr>
<td>- Canada/CCOHTA</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>CEA/CUA</td>
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<tr>
<td>- Belgium/CRM</td>
<td>X</td>
<td></td>
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<tr>
<td>- Denmark</td>
<td>X</td>
<td></td>
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<tr>
<td>- Canada/CDR</td>
<td>X</td>
<td></td>
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</tr>
<tr>
<td>- England and Wales/NICE</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Finland</td>
<td>X</td>
<td></td>
<td>X</td>
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<tr>
<td>- Hungary/ESKI &amp; TAB</td>
<td>X</td>
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<td>- Italy</td>
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<td>- Norway</td>
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<td>- Netherlands</td>
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<tr>
<td>- Portugal</td>
<td>X</td>
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<tr>
<td>- Sweden/LFN &amp; SBU</td>
<td>X</td>
<td></td>
<td>X</td>
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<tr>
<td>Budget Impact</td>
<td></td>
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<tr>
<td>- France</td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td>- Spain/Spanish Agency</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

Adapted from Hutton et al., 2006
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Drugs regulatory system

Italy

• AIFA (Agenzia Italiana del Farmaco):
  – Technical and Scientific Committee (Commissione Tecnico-Scientifica, CTS):
    • Provides an advice and decides around reimbursement and classification of drugs;
    • Reviews of Pharmaceutic Handbook (Prontuario Farmaceutico);
    • Analyses pharmaceutical company dossiers (comprehensive of costs, benefits, available alternatives, use and specific indications);
  – Pricing and Reimbursement Committee (Commissione Prezzi e Rimborsi, CPR):
    • It is involved into negotiation activity for price definition and reimbursement (Meridiano Sanità 2008).
General scheme of Italian Procedure for pharmaceutical licencing, reimbursement and price negotiation, adapted from *Meridiano Sanità, 2008*
• No formal regulatory procedure has been established
• A National Medical Devices Commission has been established in 2002:
  – Define medical devices lists
  – HTA activities
  – Define referring pricing for class of medical devices (not for single Medical Devices)
• Regional Medical Devices Commission have been established in some Italian Regions
Medical Devices

Italy

- A real HTA approach is needed
- Scenario is actually evolving toward a National Agency (AGENAS) able to coordinate Regional activities
HTA and regulation

- HTA in regulation is
  - increasingly applied ...
  - ... to manage technological innovation and to ensure health care systems sustainability ...
  - ... but also to reduce discretionarily of “expert based” decision making ...
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Decentralization process

• Even though Technology Assessment developed to meet central policies’ needs, the advancements in health care systems have raised worldwide the necessity of an HTA’s progressive *decentralization*
  
...as a matter of fact:

Available HTAs, centrally produced by Agencies are frequently:

– Not relevant to hospital problems
– Delivered too late to be useful (12-18 months)
– Not user friendly for healthcare decision makers
– Unable to incorporate local data
– Produce policy advice that does not reflect local priorities and local values.
The role of Hb-HTA

- The diffusion of the use of HTA logic in HCOs,
  - can be considered as a way for hospital managers to respond to three different environmental “pressures”
  - to improve the level of efficiency and effectiveness
  - (micro-economic efficiency) as a key to improve the efficiency of the entire system (macro-economic efficiency)
  - the progressive acknowledgement of the relevance of the "context" factor
  - to the diffusion of “evidence based medicine culture
The beginning of Hospital Based HTA Experience reporting

Dan Greenberg  
Joseph S. Pilskin  
Yitzhak Peterburg  
Bar-Ilan University of the

Abstract
Objectives: This preliminary study aims to assess the impact of new guidelines on patient care and decision-making processes. The study investigated the adoption and implementation of new technologies on patient outcomes and decision-making processes.

Background: The adoption of new medical technologies has been rapid and widespread, raising questions about their impact on patient care and decision-making processes. The study aimed to assess the impact of new guidelines on patient care and decision-making processes.

Methods: A cross-sectional study was conducted to assess the impact of new guidelines on patient care and decision-making processes. The study included patients treated at a hospital in a rural setting.

Results: The study found that the adoption of new guidelines had a significant impact on patient care and decision-making processes. The implementation of new guidelines was associated with improved patient outcomes.

Conclusions: The adoption of new guidelines had a significant impact on patient care and decision-making processes. The results of this study highlight the importance of ongoing evaluation and monitoring of new guidelines to ensure their effective implementation.

Keywords: New guidelines, patient care, decision-making processes.
Experiences of HB-HTA

- Canada (Mc Gregor & Brophy, 2005),
- Denmark (Ehlers, 2006)
- Italy (Catananti et al. 2005)
- Andalucia (Briones et al., 2005)
- Austria (Wild, 2005)
- Sweden (Rehnqvist, 2005)
- France (Baffert et al. 2005)
- Switzerland (Wasserfallen; Zuellig, 2005)
- Australia (Maddern, 2005).
# HB-HTA models

<table>
<thead>
<tr>
<th>Organizational Complexity</th>
<th>Clinical Practice</th>
<th>Managerial Decision making</th>
</tr>
</thead>
<tbody>
<tr>
<td>High (Team group unit)</td>
<td>Q3</td>
<td>Q4</td>
</tr>
<tr>
<td></td>
<td>Internal Committee Model</td>
<td>HTA Unit model</td>
</tr>
<tr>
<td>Low (individual)</td>
<td>Q1</td>
<td>Q2</td>
</tr>
<tr>
<td></td>
<td>Ambassador model</td>
<td>Mini HTA model</td>
</tr>
</tbody>
</table>
Results

Responders (n=33)

<table>
<thead>
<tr>
<th>Country</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Italy</td>
<td>31%</td>
</tr>
<tr>
<td>USA</td>
<td>3%</td>
</tr>
<tr>
<td>Brasil</td>
<td>3%</td>
</tr>
<tr>
<td>Canada</td>
<td>12%</td>
</tr>
<tr>
<td>The Netherlands</td>
<td>3%</td>
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<td>Switzerland</td>
<td>6%</td>
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<td>Australia</td>
<td>6%</td>
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<tr>
<td>Mexico</td>
<td>3%</td>
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<tr>
<td>Colombia</td>
<td>3%</td>
</tr>
<tr>
<td>Germany</td>
<td>3%</td>
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<tr>
<td>France</td>
<td>3%</td>
</tr>
<tr>
<td>Denmark</td>
<td>9%</td>
</tr>
<tr>
<td>Spain</td>
<td>3%</td>
</tr>
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<td>Denmark</td>
<td>9%</td>
</tr>
<tr>
<td>Spain</td>
<td>3%</td>
</tr>
</tbody>
</table>

Organization profile (n=33)

- Academia/University: 12%
- Public Health Care Organization: 15%
- Teaching Hospital: 40%
- Governmental agency: 21%
- Research Institution: 6%
- Industry: 3%
- Other: 3%

Profile of responders organization
Results

Assessed technologies in Hb-HTA

Evaluations Technologies

- Biomedical equipments
- Drugs
- Medical devices
- Combined technologies
- Clinical procedures
- Communication Technologies (CT) support system
- Organizational procedures
- Emerging technologies
- Other

No. Of Institutions

- always
- often
- sometimes
- rarely
- never
Assessed dimensions

**Prioritization criteria relevance**

<table>
<thead>
<tr>
<th>Criteria to prioritize HTA activities</th>
<th>Relevance (1=most relevant, 6=less relevant)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Median</td>
</tr>
<tr>
<td>Economic concern</td>
<td>2</td>
</tr>
<tr>
<td>Clinic relevance</td>
<td>1</td>
</tr>
<tr>
<td>Public health concern</td>
<td>2</td>
</tr>
<tr>
<td>Political concern</td>
<td>3</td>
</tr>
<tr>
<td>Public and media concern</td>
<td>4</td>
</tr>
<tr>
<td>Other</td>
<td>6</td>
</tr>
</tbody>
</table>
The experience of HTA Unit at “A.Gemelli” University hospital
Regulation context

**Italian National Health Care System (NHCS)**
- NHS provides universal coverage and comprehensive health care, free of cost or at a nominal charge upon delivery.
- NHS is defined as a public system financed by taxes.
- Public hospitals funding system is based on DRGs system for hospitalized patients and on outpatients fee for the other patients.

Organization context

Agostino Gemelli University Hospital

**Employees**
- Physicians 962
- Nurses 1,967
- Total 4,634

**Beds**
- Acute ordinary beds 1,425
- Rehabilitation beds 82
- Day hospital beds 192
- Number of discharges 57,156
- Number of outpatients treatments 1,920,145
**Mission**
The HTA unit is part of the General Directorate which is supervised by the General Director. Its purpose is to counsel top management in decisions making on resource allocation, using transparent, fair and consistent evaluation process.

<table>
<thead>
<tr>
<th>Technology Assessment</th>
<th>Clinical Governance</th>
<th>R&amp;D</th>
<th>Education</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical devices</td>
<td>Institutional Certification/ Accreditation</td>
<td>Internal R&amp;D</td>
<td>International master Ulysses</td>
</tr>
<tr>
<td>Diagnostic test</td>
<td>Risk management</td>
<td>Economic evaluation</td>
<td>Courses in HTA</td>
</tr>
<tr>
<td>Medical equipment</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Communication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Newsletter HTA unit</td>
</tr>
</tbody>
</table>

**Staff**
It employs multidisciplinary expertise:
- 1 clinician (in charge)
- 2 biomedical engineers
- 1 engineer expert in quality
- 5 health economists
- 1 statistician
What kind of health technologies are assessed

- **New Medical Device**
  - A device available on the market but not still used at Gemelli University Hospital

- **Innovative MD**

- **High unit cost**

- **Implantable MD (mainly)**
  - **Pain relief system**
  - **Interspinous System**
  - **Drug eluting stent**
What kind of health technologies are assessed?

• Medical equipment
  ➢ Innovative
  ➢ high impact (on patient safety, economic, organizational)

• Diagnostic Test
  ➢ Innovative
  ➢ high unit cost
Rationale of the Assessment

• Guarantee the introduction of health technologies really Appropriates for the hospital using an evaluation process founded on evidence based medicine

• Assess all implication linked to the possible technologies introduction. Particularly it is take into account the following dimensions:
  ✓ safety
  ✓ regulatory status
  ✓ economic issues
  ✓ organizational impact
Assessment Process

The work flow

**Application of Technology**
Elaborated by clinicians with administrative department manager and pharmacy service support, and approved by department director.

**HTA Unit**
Writing of assessment report

- Clinicians
- Management control unit
- Health directorate
- Purchase Unit
- Intern pharmacy service

**Final approval by COFT**
(Pharmaco-therapy Commission) based on assessment report information
Virtuous Circle of the process of new technology introduction:

1. Purchase needs analysis
2. Purchase strategies definition
3. Assessment of purchased technologies impact on organization
4. Monitoring
5. Re-definition of needs
Medical Devices Activities

Number of application x year

Avarage of fulfillment times (months)
Medical Devices Activities

Decision making results

- Approved without restriction
  - 2006/2007: 8
  - 2008: 14
  - 2009: 13

- Approved with restriction
  - 2006/2007: 6
  - 2008: 15
  - 2009: 15

- Rejected
  - 2006/2007: 2
  - 2008: 3
  - 2009: 2

- Removed by the clinician
  - 2006/2007: 4
  - 2008: 4
  - 2009: 4

- Suspended
  - 2006/2007: 0
  - 2008: 0
  - 2009: 0
Medical Devices Activities

Case presentation on Approved device without restriction

Device
Prismocitrate (citrate solution)

Procedure
Regional Citrate Anticoagulation in Continuous Venovenous Hemodiafiltration

Patients target
Critically ill patients with acute renal failure requiring continuous renal replacement therapy

The Prismaflex system
Prismocitrate
Medical Devices Activities

Regulation

**CE mark:** OK

**FDA:** 510(k) Regulation Number 876.5820 (Hemodialysis system and accessories)

### Rapid Literature review (February 2009)

<table>
<thead>
<tr>
<th>Examined Database</th>
<th>Pubmed, Cinhal</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Selected studies with key words:</strong> &quot;Regional Citrate Anticoagulation&quot; AND &quot;Acute Renal Failure&quot; AND &quot;Critical Ill patient&quot;</td>
<td>7/9 identified</td>
</tr>
</tbody>
</table>
| **Studies design** | 1 guideline  
2 RCT  
3 prospective observational studies  
1 retrospective cohort study |
| **Evidence level (GRADE System)** | **Moderate**  
Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate |

- The selected studies agree that the Regional Citrate Anticoagulation in Continuous Venovenous Hemodiafiltration reduces the risk of blood bleeding vs the traditional system (systemic heparin)
- Several studies verified the increase in filter duration (consequently a reduction of hospital costs)
Medical Devices Activities
Organizational and economics issues

**Number of treatments forsaken:** 70 per year (3.676 units of prismocitrate)

**Overall Costs:** about € 100.000

**Reimbursement code:** DRG 316 “renal insufficiency”
fee € 3.965

**Farmaco-therapy final Decision (2009 February)**

Under these data:

- Moderate level of evidence that determines advantages for the patients in terms of reduction of bleeding risk
- Sustainable costs in relation to reimbursement code

Authorization of introduction of the devices into clinical practice
**Medical Devices Activities**

**Case presentation on Approved device with restriction**

**Device**
Sinus Balloons  E Sinus Guide Catheters.

**Pazienti target**
Patients with chronic sinusitis or chronic rhino-sinusitis not respondent to medical therapy (anti-inflammatory drugs)

**Procedure**

*Balloon catheter sinusotomy* describe the use of a sinus balloon catheter to surgically repair the sinus ostia during a Functional Endoscopic Sinus Surgery (FESS) procedure.

**Step 1**
Gain Access to the Sinus

**Step 2**
Inflate Balloon Across Ostium.

**Step 3**
Sinus irrigation

**Step 4**
Deflate and Remove Balloon
Traditional Functional Endoscopic Sinus surgery (FESS)
Clinical studies have indicated that using Balloon Sinuplasty™ technology is safe and effective in dilating sinus openings (max follow up 2 year).

- the system is minimally invasive, less invasive than traditional FESS.
Medical Devices Activities

Organizational and economics issues

**Number of treatments forsaken:** 20 per year (1/3 of overall surgical procedures for sinusitis)

**Overall Costs:** about € 42.000

**Unit cost**

about € 2.100

**Reimbursement code:** DRG 53 “sinus and mastoid procedures”, fee € 2.236

**Pharmaco-therapy final Decision (2008 June)**

On the below data:

- Moderate level of evidence on effectiveness and safety of the device
- Low economic sustainability in relation to reimbursement code

It was propose the introduction of 10 Sinus Balloon and it was require to the clinician the monitoring of subsequently outcome measures:

- Surgical times
- Post operative bleeding
- Day of hospitalization

Member of INAHTA
Monitoring results on 10 procedures

**Surgical times**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functional Endoscopic sinus surgery</td>
<td>1 h</td>
</tr>
<tr>
<td>Balloon catheter sinusotomy</td>
<td>30 min</td>
</tr>
</tbody>
</table>

**Post operative bleeding**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Bleeding Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functional Endoscopic sinus surgery</td>
<td>High post operative bleeding: tamp is needed</td>
</tr>
<tr>
<td>Balloon catheter sinusotomy</td>
<td>Low post operative bleeding: tamp is not needed</td>
</tr>
</tbody>
</table>

**Days of hospitalization**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functional Endoscopic sinus surgery</td>
<td>48 h</td>
</tr>
<tr>
<td>Balloon catheter sinusotomy</td>
<td>24h</td>
</tr>
</tbody>
</table>

Moreover Balloon catheter sinusotomy allows:

- Reduction of pain relief drugs therapy
- Headache absence six mounts after intervention
Medical Devices Activities

Case presentation on Rejected device

Device
Mesh Ablator and Mapping Catheter

Procedure
A 36 pole catheter which allows high density mapping and ablation of pulmonary vein potentials at the PV ostium, in a single device

Patients target
Patients with atrial fibrillation (AF).
Medical Devices Activities

Regulation

**CE mark:**  ok (2006)

**FDA:**  Not approved in US market

---

**Rapid Literature review (May 2009)**

<table>
<thead>
<tr>
<th>Examined Database</th>
<th>Pubmed, Cinhal</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Selected studies with key words: “MESH” AND “paroxysmal atrial fibrillation” AND “pulmonary vein isolation”</strong></td>
<td>6/6 identified</td>
</tr>
<tr>
<td><strong>Studies design</strong></td>
<td>6 observational studies</td>
</tr>
<tr>
<td><strong>Evidence level (GRADE System)</strong></td>
<td>Low</td>
</tr>
</tbody>
</table>

- The selected studies agree that the mesh ablator is safe and effective.
- The selected studies are limited in design (retrospective observational studies) and in number of enrolled population (max 26).
Medical Devices Activities

Organizational and economics issues

**Number of treatments forsaken:** 30 per year

**Overall Costs:** about € 171,000

**Unit cost** about € 5700

**Reimbursement code:** DRG 518 “intervention on cardiovascular system”, fee € 4,848

**Pharmaco-therapy final Decision (2009 May)**

On the below data:

- Low evidence so any estimate of effect is very uncertain.
- Unsustainable costs in relation to reimbursement code

It was state the rejection of device introduction into clinical practice
Medical Devices Activities

Growth in application x most applicant departments

<table>
<thead>
<tr>
<th>Total expenditure authorized trend</th>
<th>2007/2006</th>
<th>2008</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiology and Cardiothoracic surgery</td>
<td>€ 31,150</td>
<td>€ 55,000</td>
<td>€ 182,000</td>
</tr>
<tr>
<td>Surgical Specialties</td>
<td>€ 257,000</td>
<td>€ 200,000</td>
<td>€ 166,000</td>
</tr>
</tbody>
</table>
Medical Devices Activities

And all the rest.....

18 report on new diagnostic test completed
   total estimated expenditure about € 300,000

15 report on new medical equipment completed or still in course

Two strategic planning report

   total estimated expenditure more than € 20,000,000

2009 Results
## Biomedical Technology Investment Plan

<table>
<thead>
<tr>
<th></th>
<th>Highest</th>
<th>High</th>
<th>Medium</th>
<th>Low</th>
<th>Total costs (VAT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial request of clinicians</td>
<td>-</td>
<td>19.183.542</td>
<td>6.005.553</td>
<td>328.205</td>
<td>30.620.760</td>
</tr>
<tr>
<td></td>
<td>out of order</td>
<td>813.621</td>
<td></td>
<td>1.000.000</td>
<td>4.181.545</td>
</tr>
<tr>
<td>% out of order</td>
<td>59,12%</td>
<td>11,17%</td>
<td></td>
<td>15,87%</td>
<td>14,77%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>differenziale dopo attività UVT</th>
<th>Highest+High</th>
<th>Medium</th>
<th>Low</th>
<th>Total costs (IVA incl)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-66,92%</td>
<td>19,54%</td>
<td>1819,80%</td>
<td>-7,56%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>to buy</th>
<th>subito</th>
<th>I° anno</th>
<th>II° anno</th>
<th>III° anno</th>
</tr>
</thead>
<tbody>
<tr>
<td>(previa conferma valutazione)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Agenda

• Background
  – Challenges in managing technological innovation
• Regulating technology innovation
• What is HTA?
• HTA and regulation
• One example: Italy
• HTA decentralization
• Future scenario
The network model

Macro Level
HTA

Meso Level
HB-HTA

Micro Level
HB-HTA

Evidence production

Evidence in context

Frontline

Member of
INAHTA
The network model: national and international perspective
Conclusion

• A multilevel networking approach, nationally and internationally seems to be necessary in order:
  – enhance HTA productivity
  – Increase HTA impact on national and regional context

• Competences represents and information “the” key-point for HTA diffusion
Thank you for your attention

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