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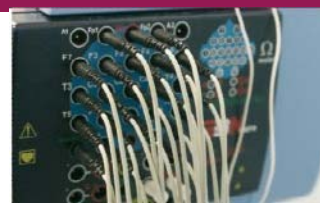
IER Inštitut za ekonomska raziskovanja
Institute for Economic Research



International Conference on Applied Health Economics and Mathematics

HTA in Italy
from a national perspective to hospital based HTA

Marco Marchetti
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Policlinico Universitario "Agostino Gemelli"
Università Cattolica del Sacro Cuore

Koper, May 2nd – 4th, 2010

Member of INAHTA

Policlinico Gemelli
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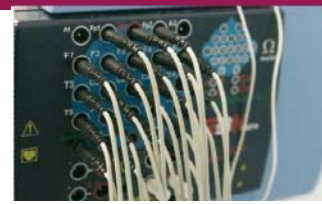
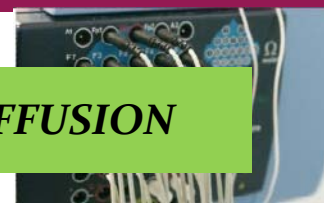


Agenda

- Background
  - Challenges in managing technological innovation
- Regulating technology innovation
- What is HTA?
- HTA and regulation
- One example: Italy
- HTA decentralization
- Future scenario



GENERATION	ADOPTION	DIFFUSION

Intellectual capital
Relational capital
Financial resources

Innovation Process → radical / incremental

Health Systems
International/National
Legislation

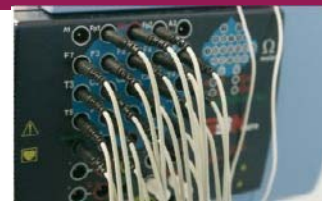
Regulation → safety / utility

Legislation
Social factors
Economic factors
Organizational factors
Ethical factors

Assessment → cost effectiveness

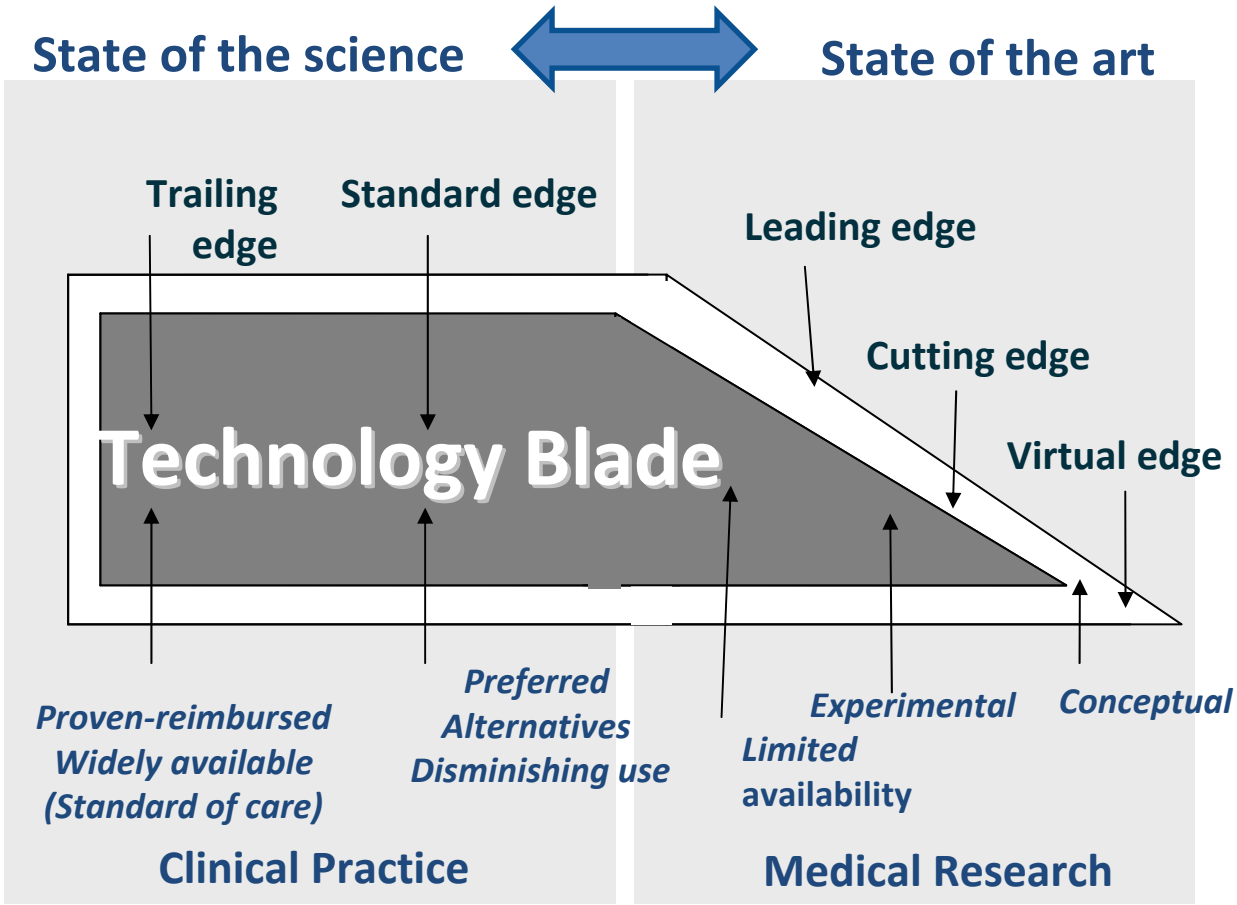
Impact on health

Adapted from The European-House Ambrosetti by A. Cicchetti, F. Leone, D. Mascia, "*Ricerca scientifica e trasferimento tecnologico*", 2007



Technology spectrum

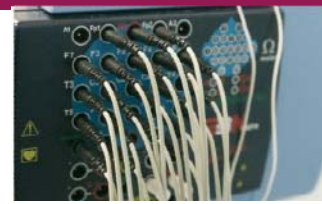
Source: Mikhail et al, 1999



Technology application

Technology development

Technology research



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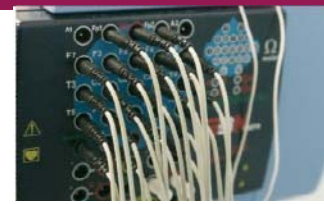
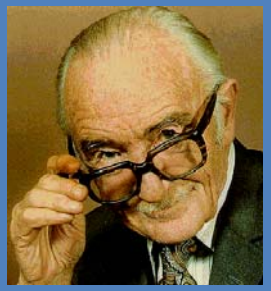


Decisions in health care systems



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

1990

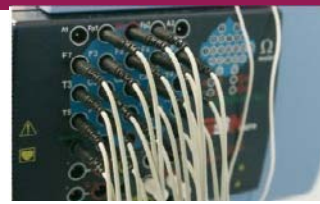
Cost containment health care reforms (Quasi-markets; DRGs; Trusts)

2000

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

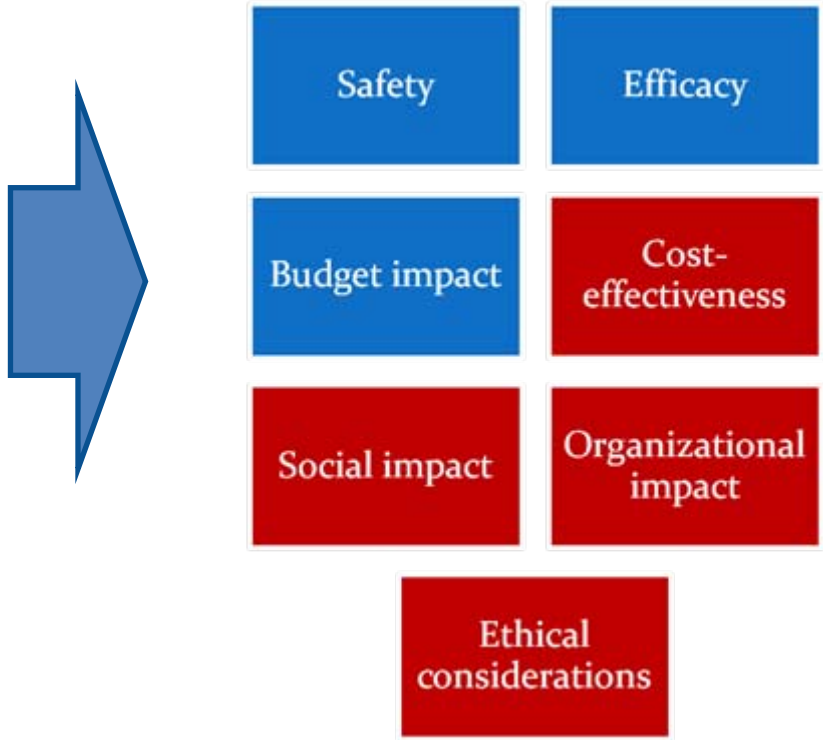
"All cost-effective treatments should be available to the population"
Alan Williams, 1997

Emerging needs = “advanced” regulation

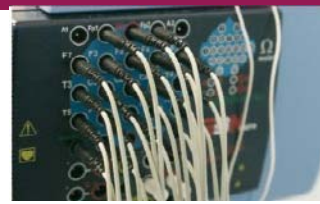


Mission: ***Ensure health care system sustainability***

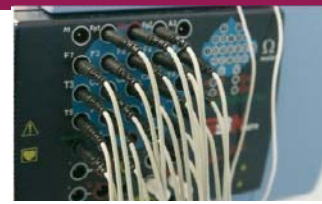
- Managing health care expenditures (opportunity cost – resource allocation)
- Societal value (ethical dilemmas, acceptability of treatments ...)
- Support to technological innovation (Lisbon Protocol)



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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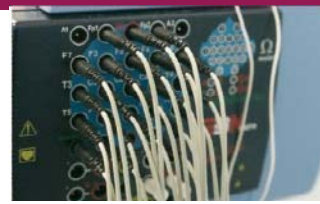
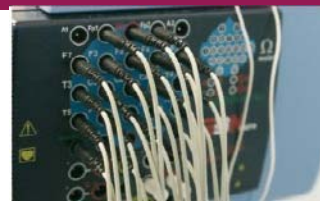
Definition



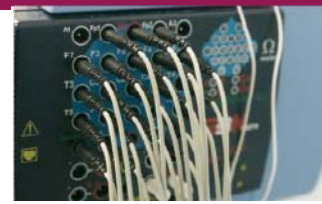
Health Technology Assessment

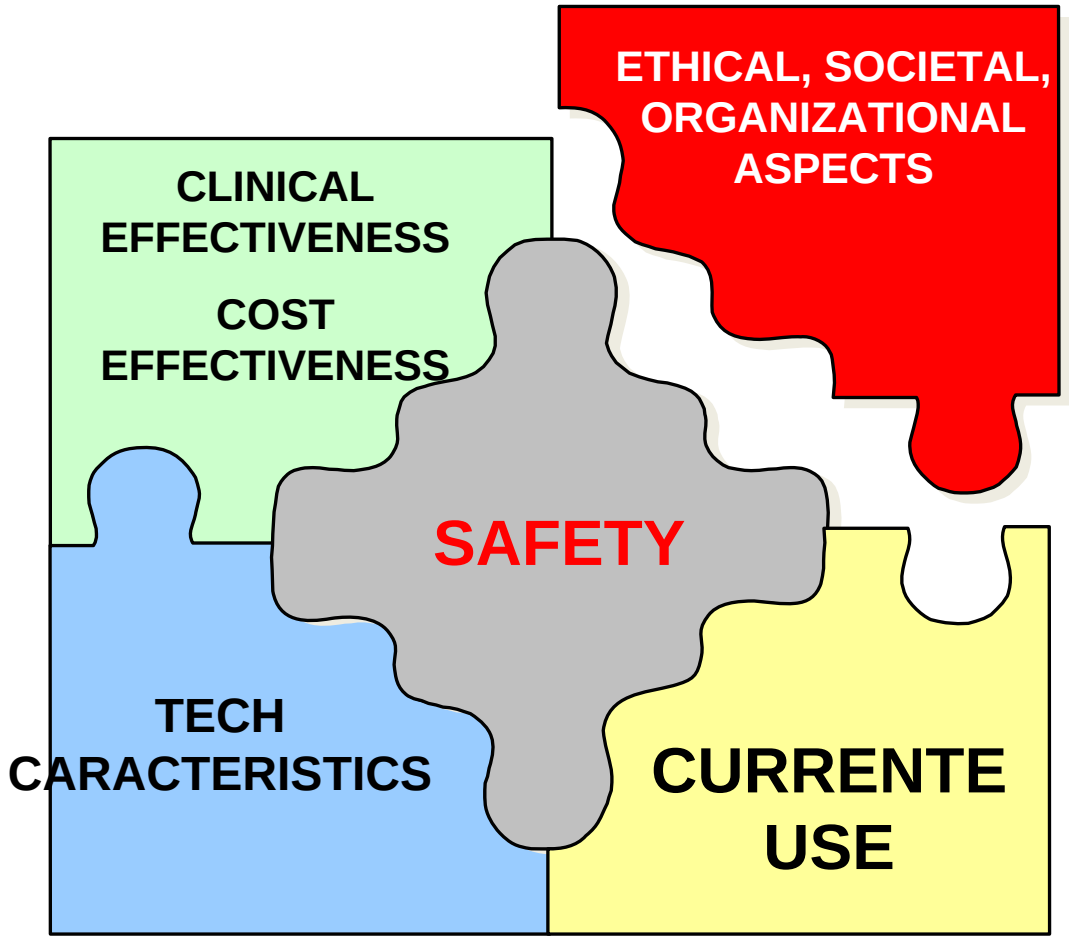
- "HTA is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient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



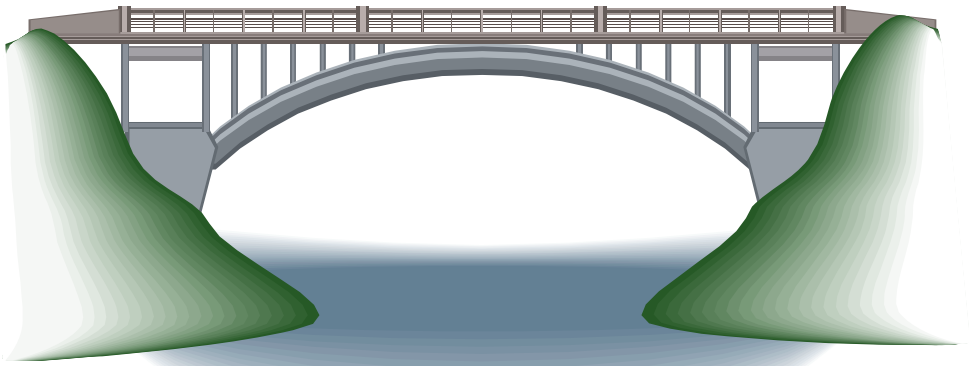
Pillars

- Policy oriented
- Transparent
- Science-based
- Evidence based
- Multidisciplinary
- Multistakeholder

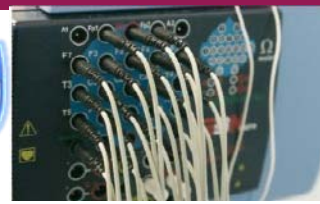



ETHICAL, SOCIETAL, ORGANIZATIONAL ASPECTS
CLINICAL EFFECTIVENESS
COST EFFECTIVENESS
SAFETY
TECH CARACTERISTICS
CURRENTE USE

Science



Decisions



DOMAINS

- Description and technical characteristics
- Current use
- Safety
- Clinical effectiveness
- Costs, economic evaluation
- Ethical aspects
- Organizational aspects
- Societal aspects
- Legal aspects

MACRO

- Coverage
- Reinbursement level
- Guidelines

MESO (HOSPITAL)

- Tech adoption

MICRO

- Clinical practice

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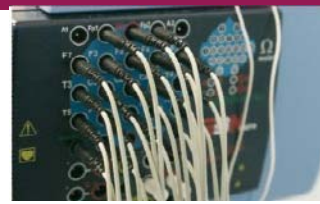
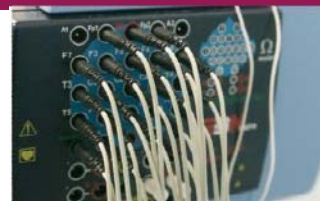
HTA's Domain

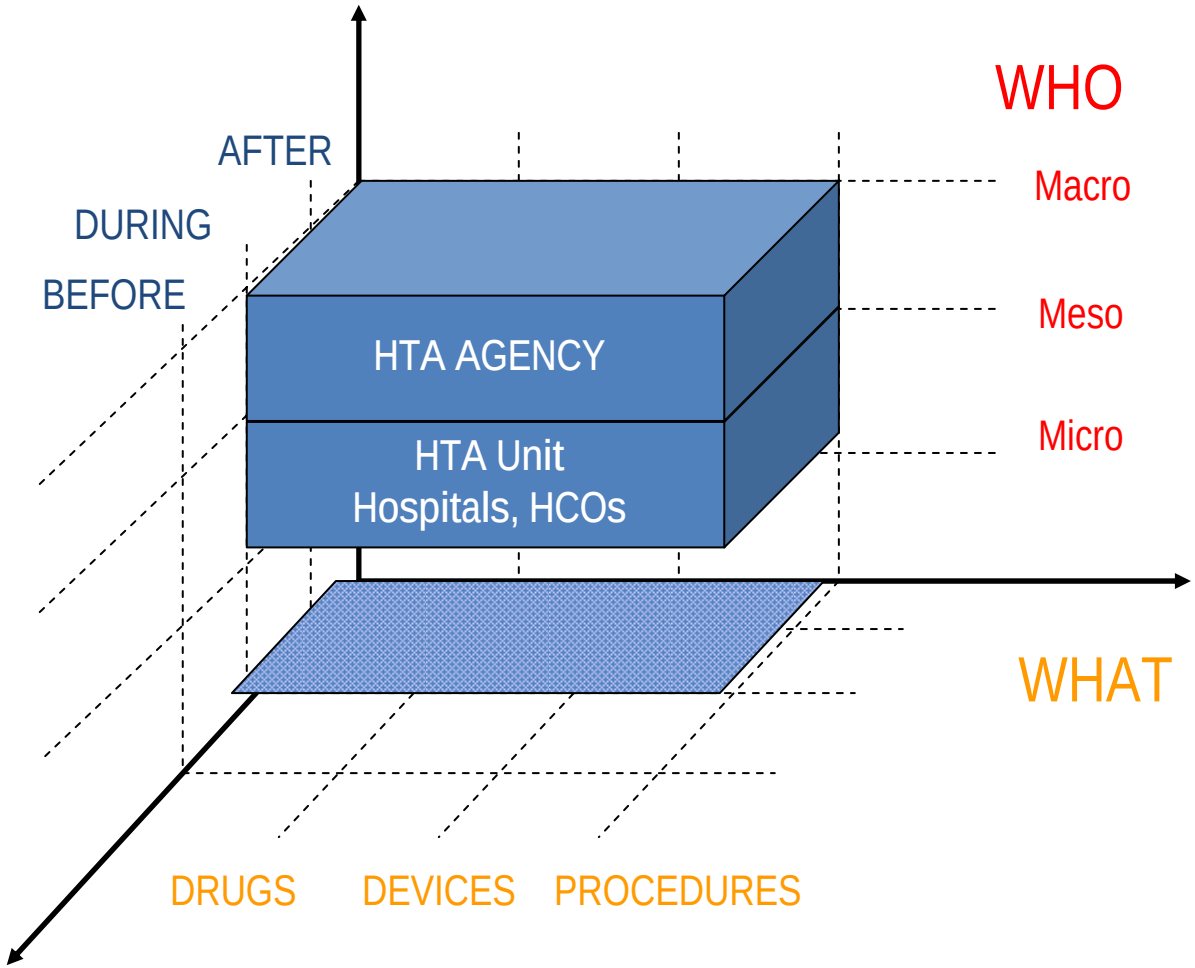


- Domains of HTA
  - Description and technical characteristics
  - Current use
  - Safety
  - Clinical effectiveness
  - Costs, economic evaluation
  - Ethical aspects
  - Organizational aspects
  - Societal aspects
  - Legal aspects

eunethta

HTA's Map




WHO
AFTER
Macro
DURING
BEFORE
HTA AGENCY
Meso
HTA Unit
Hospitals, HCOs
Micro
WHAT
DRUGS
DEVICES
PROCEDURES
WHEN

INAHTA

International Network of Agencies for Health Technology Assessment

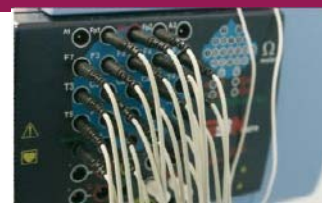
- 52 Agencies associated in INAHTA

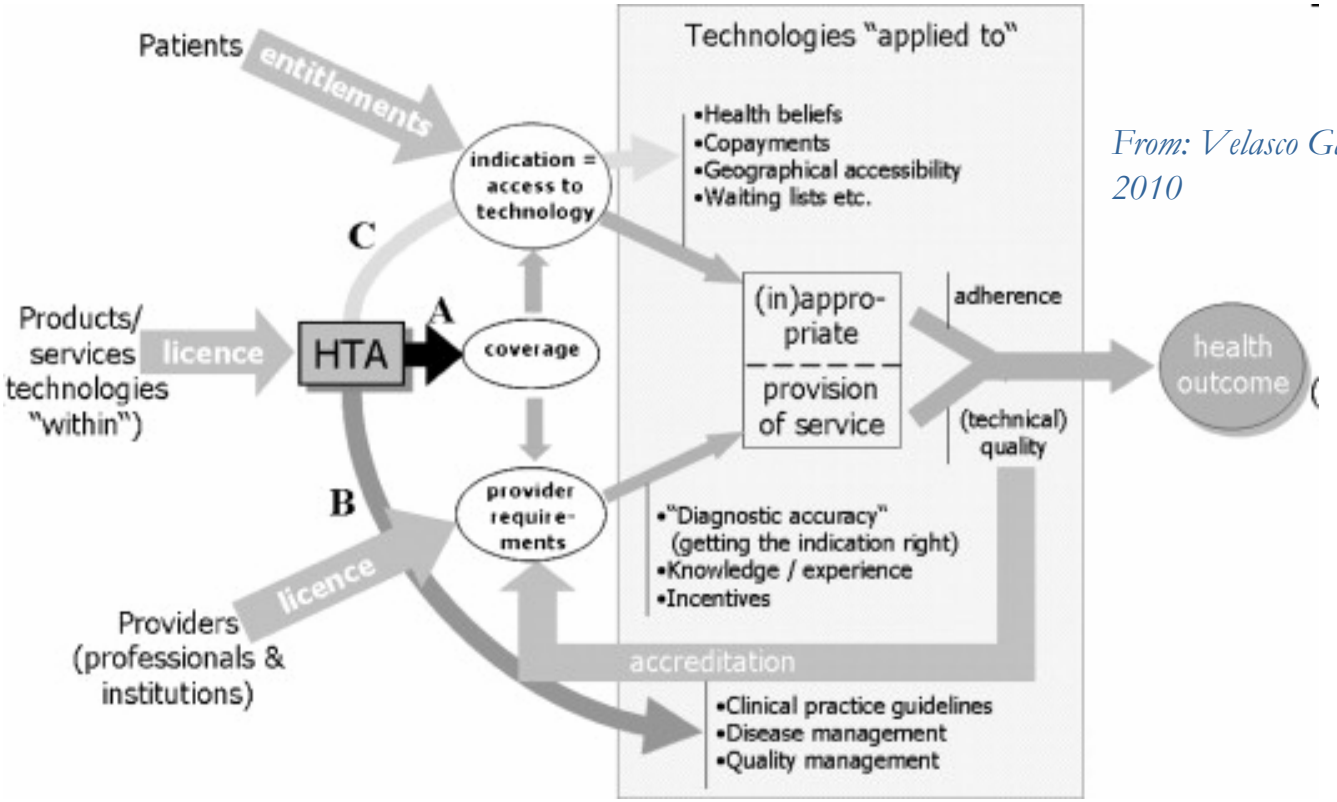
- UK (6)
- Spain (5)
- The Netherlands (4)
- Canada, USA (3)
- Sweden, Australia, France, Denmark, Italy (2)
- Israel, Finland, Switzerland, New Zealand, Lituania, Cuba, Belgium, Norway, Ungheria, Austria, Germany, Cile, Mexico

agena.s. AGENZIA NAZIONALE PER I SERVIZI SANITARI REGIONALI

Policlinico Gemelli IMPEGNO PER L'ECCELLENZA.

Health Care System and HTA

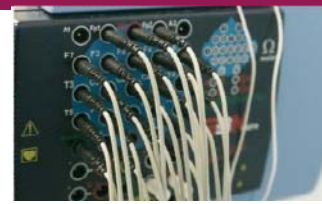




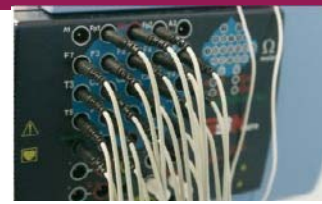
From: Velasco Garrido et al. 2010

"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



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



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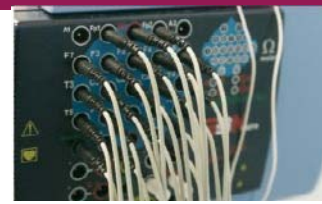
HTA in decision-making level (1/5)

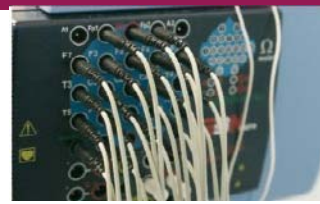


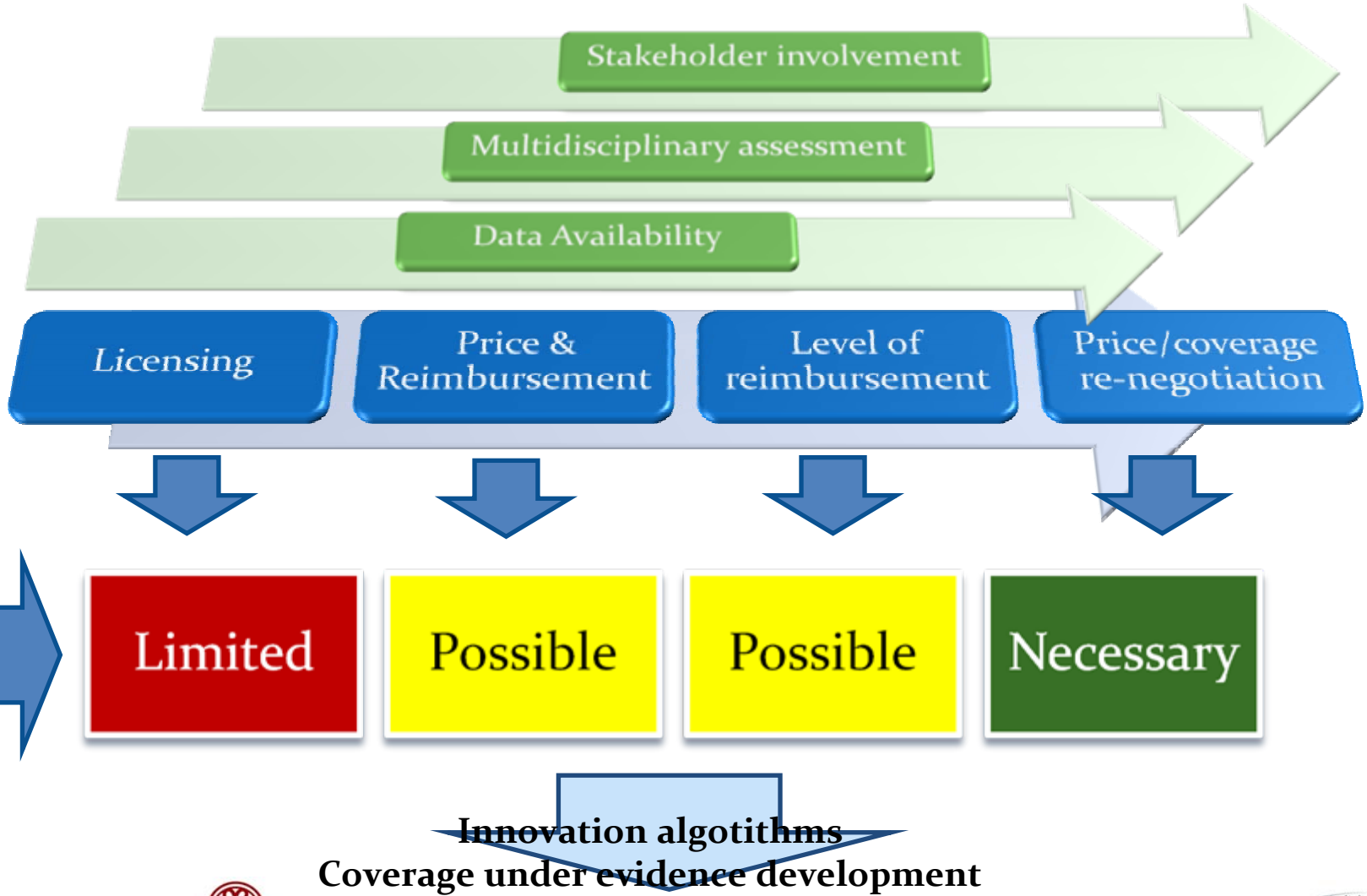
Key evidence used to support decision-making
✓ Health benefit (mortality, morbidity)
✓ Cost-effectiveness (cost per quality-adjusted life year- QALY)
✓ Necessity (e.g. disease burden, severity)
✓ Availability of treatment alternatives
✓ Public health impact
✓ Equity
✓ Innovative characteristics
✓ Budget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

Adapted from *Sorenson et al, 2008*

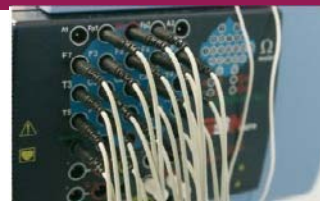
The case of Drugs regulation

Scope of application of HTA approach





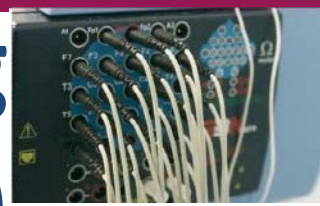
HTA in decision-making level (2/5)



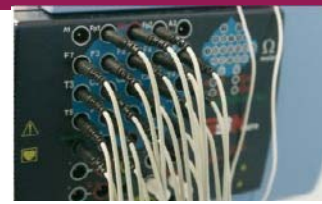
- The usage of HTA by decision makers is still restricted;
- Policies of pricing and reimbursement of technologies consider a limited range of factors in the assessment process (often clinical effects and budget impact).

"Consequently, HTA was not integrated with other mechanisms for resources allocation"
(Hutton et al. 2006)

HTA in decision-making level (3/5)



	Technologies appraised		
	Pharmaceuticals	**Devices**	**Procedures**
FULL HTA **• Canada/CCOHTA**		X	X
CEA/CUA **• Belgium/CRM** **• Denmark** **• Canada/CDR** **• England and Wales/NICE** **•Finland** **•Hungary/ESKI & TAB** **• Italy** **•Norway** **•Netherlands** **•Portugal** **•Sweden/LFN & SBU**	X X X X X X X X X X X X X	X	X
Budget Impact **• France** **• Spain/Spanish Agency**	X X		



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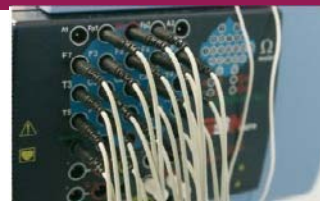
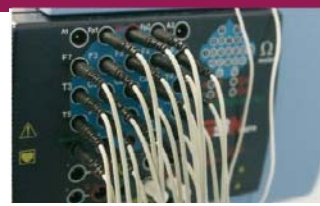
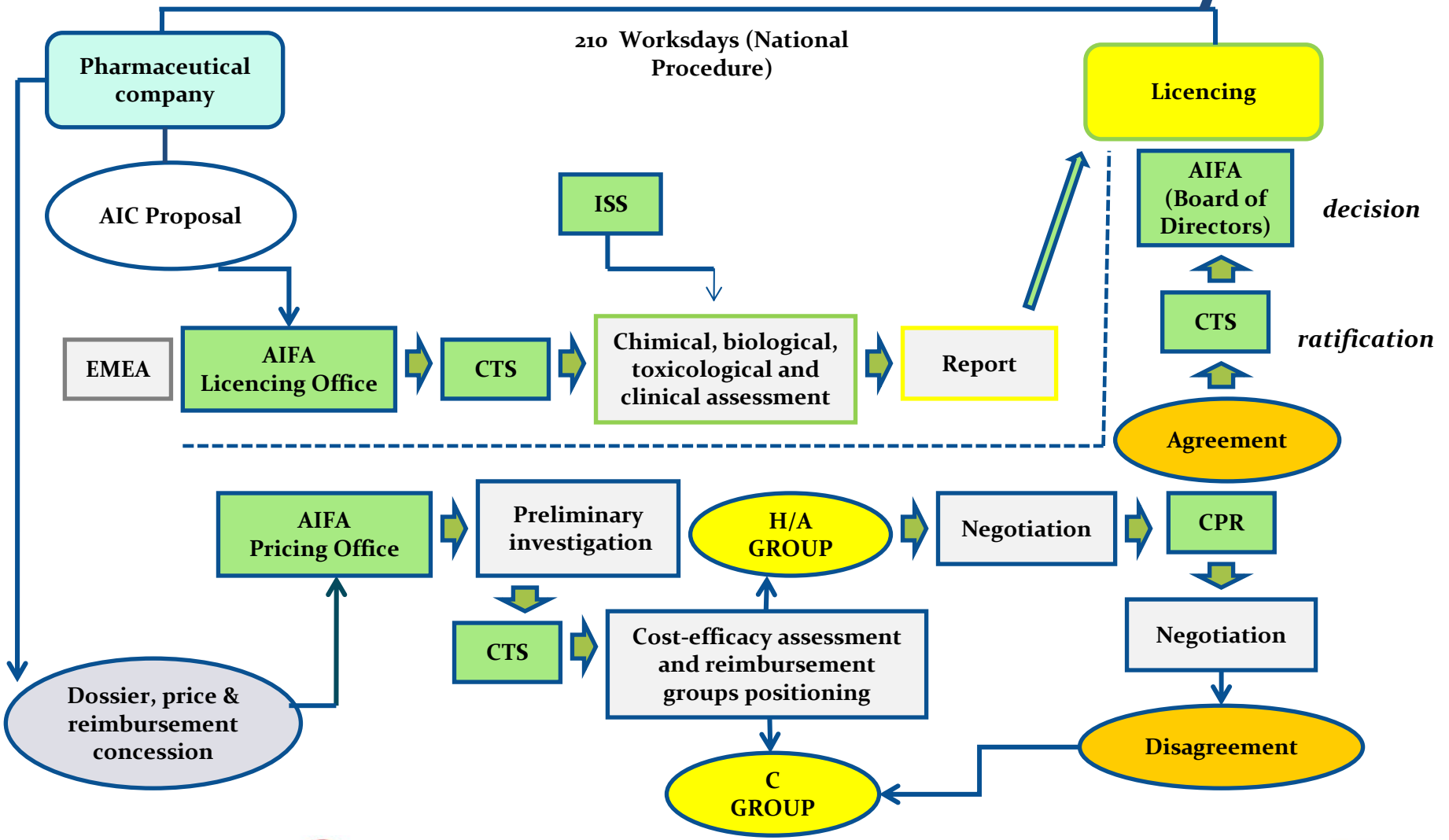
Drugs regulatory system Italy



- 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).*

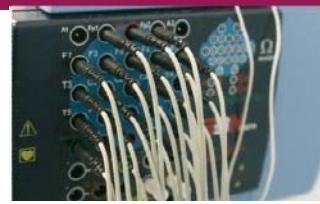
Drugs regulatory system Italy





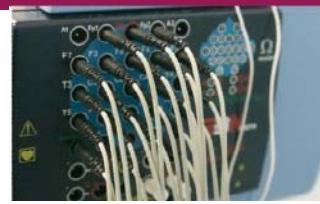
General scheme of Italian Procedure for pharmaceutical licencing, reimbursement and price negotiation, adapted from *Meridiano Sanità, 2008*

Medical Devices Italy

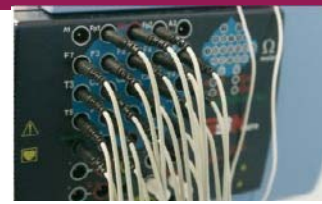


- No formal regulatory procedure has been established
- A National Medical Devices Commission has been established in 2002:
  - Define medical devices lists
  - HTA activities
  - Define referring pricing for class of medical devices (not for single Medical Devices)
- Regional Medical Devices Commission have been established in some Italian Regions

Medical Devices Italy

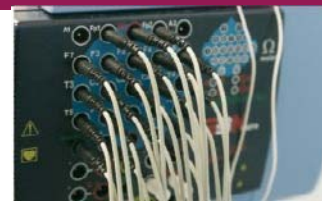


- A real HTA approach is needed
- Scenario is actually evolving toward a National Agency (AGENAS) able to coordinate Regional activities



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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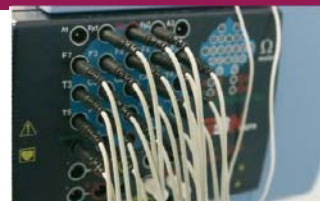
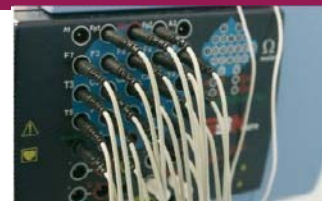


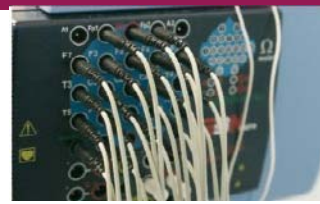
Decentralization process

- 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*
  - Catananti, Cicchetti e Marchetti, 2005. Italian Journal of Pub Health, 2(2): 23-29



Decentralization process

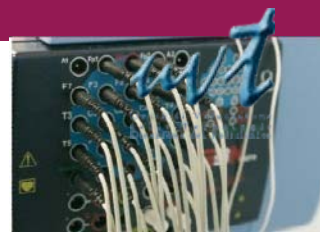
- …as a matter of fact:
- Available HTAs, centrally produced by Agencies are frequently:
  - Not relevant to hospital problems
  - Delivered too late to be useful (12-18 months)
  - Not user friendly for healthcare decision makers
  - Unable to incorporate local data
  - Produce policy advice that does not reflect local priorities and local values.

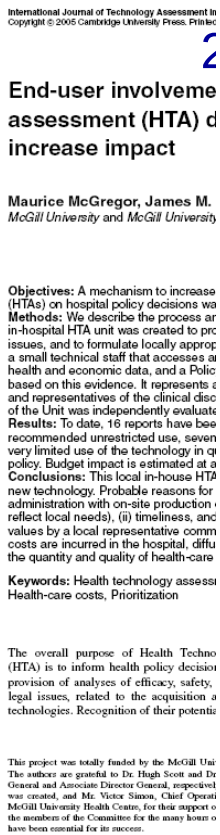


The role of Hb-HTA

- 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





Health Technology Assessment International

An International Society for the Promotion of Health Technology Assessment

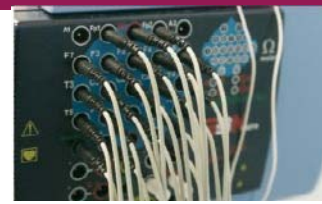
2008

Hospital Based Health Technology Assessment
World-Wide Survey

Hospital Based Health Technology Assessment Sub-Interest Group

Member of INAHTA

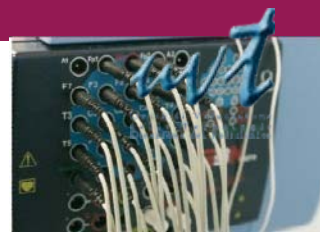
Policlinico Gemelli
IMPEGNO PER L'ECCELLENZA.



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



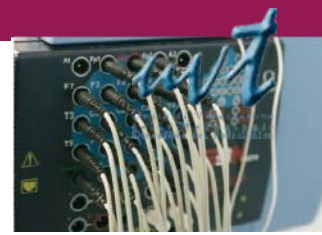
2008

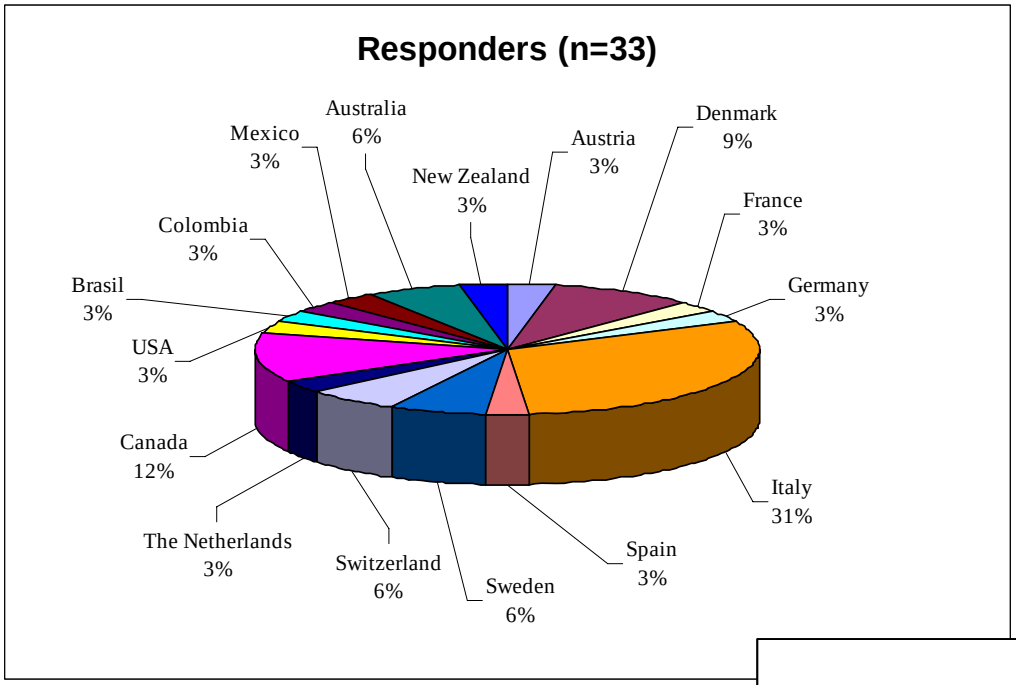
Hospital Based Health Technology Assessment
World-Wide Survey

Hospital Based Health Technology Assessment Sub-Interest Group

		Focus of Action	
		Clinical Practice	Managerial Decision making
Organizational Complexity	High (Team group unit)	Q3	Q4
		Internal Committee Model	HTA Unit model
	Low (individual)	Q1	Q2
		Ambassador model	Mini HTA model

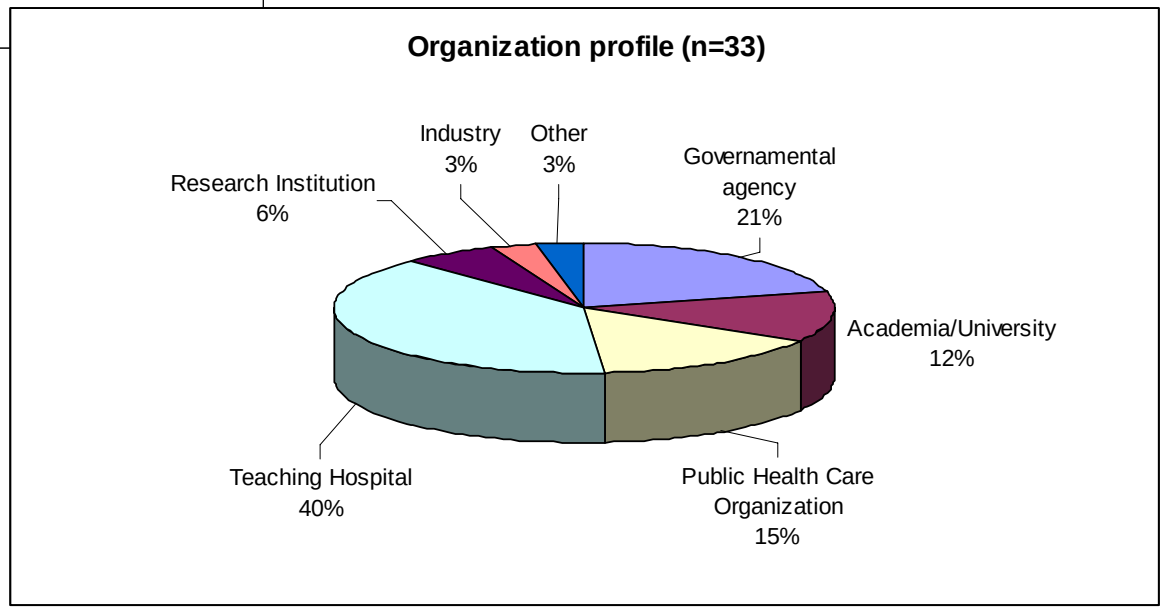
Results





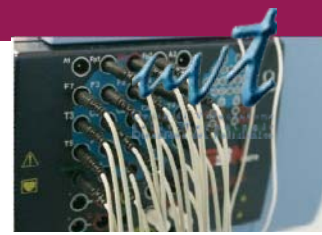
Responders per Countries

Profile of responders organization

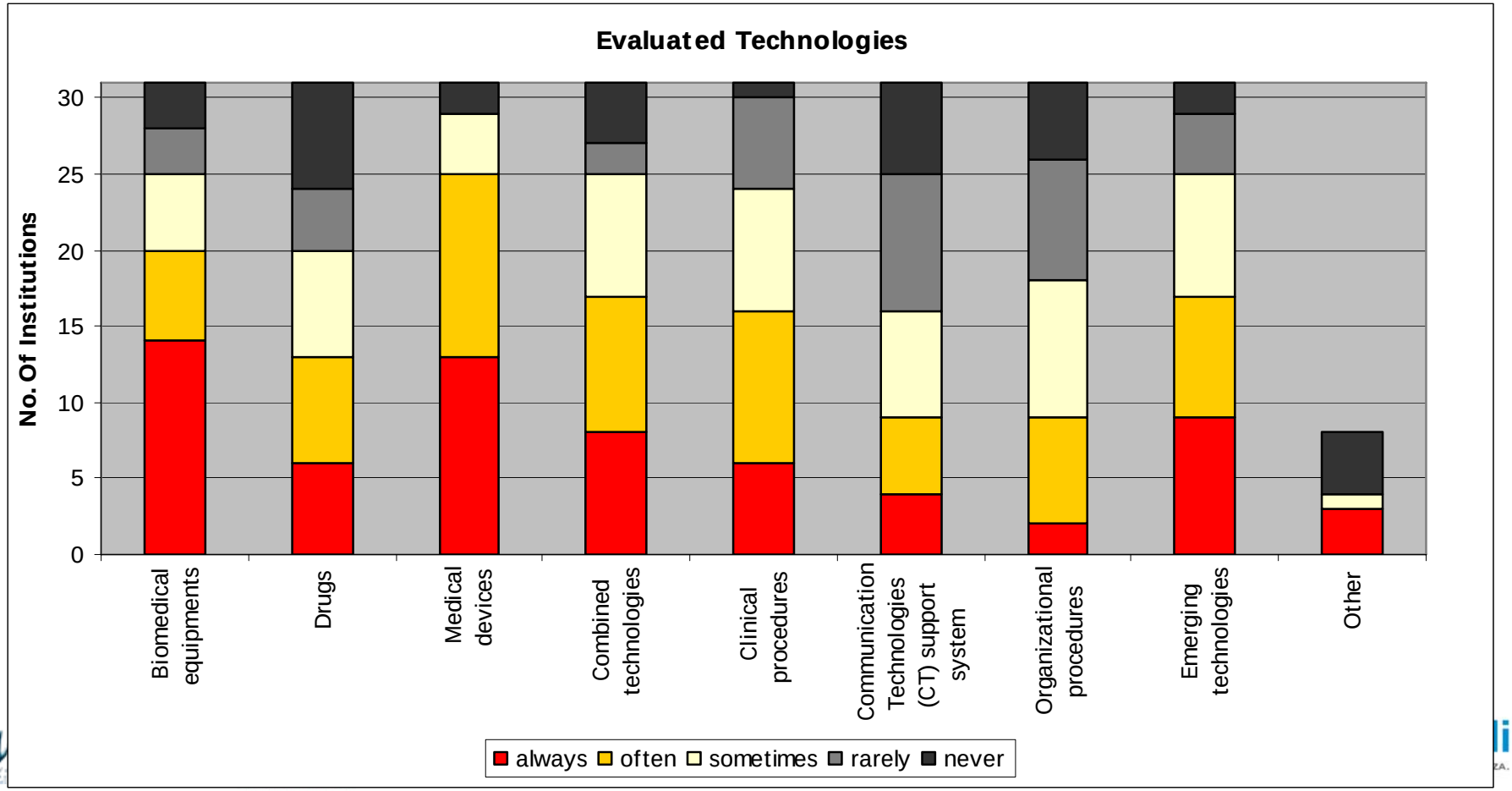


Member of INAHTA

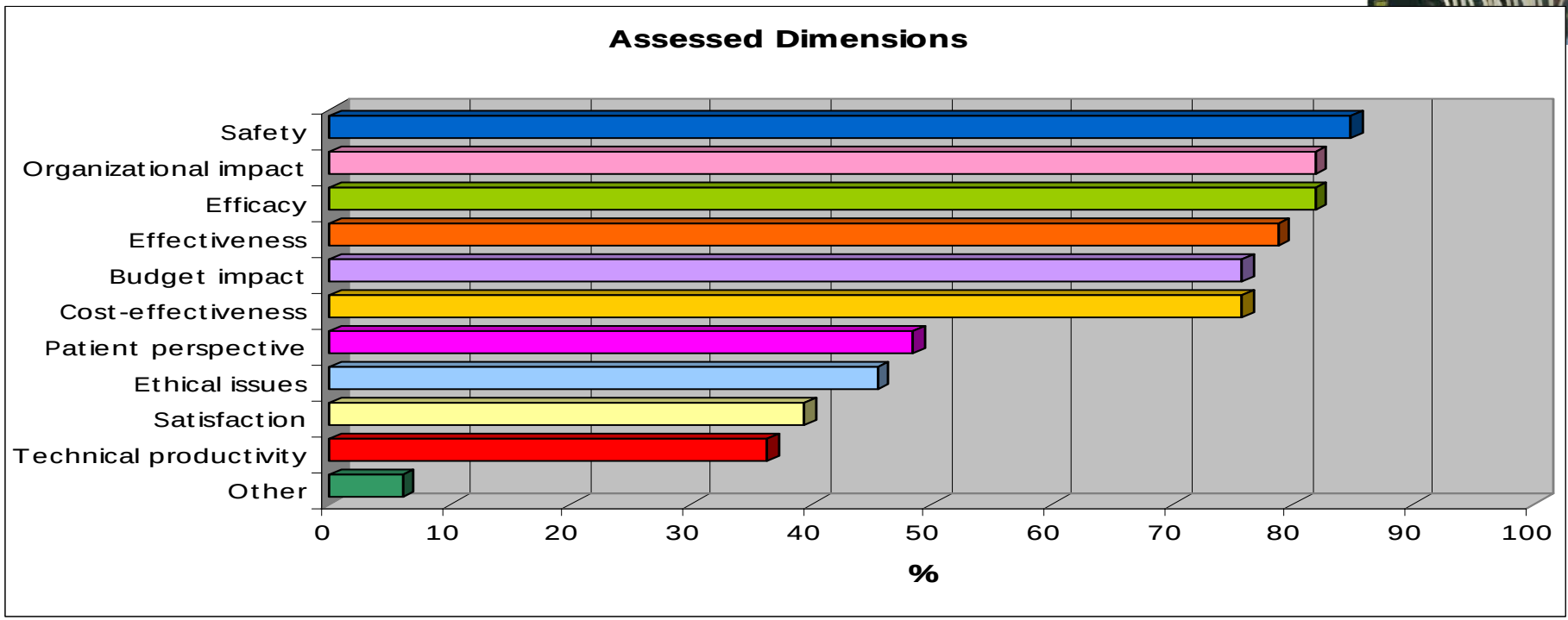
Results



Assessed technologies in Hb-HTA



Assessed dimensions



Prioritization criteria relevance

Criteria to prioritize HTA activities	Relevance (1=most relevant, 6=less relevant)		
	Median	25° percentile	75° percentile
Economic concern	2	1	3
Clinic relevance	1	1	1
Public health concern	2	1	3
Political concern	3	2	4
Public and media concern	4	3	5
Other	6	3	6

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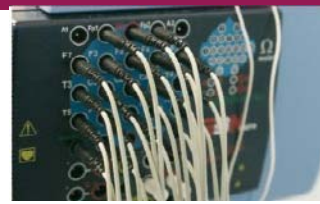


The experience of HTA Unit at “A.Gemelli” University hospital

HTA Unit Presentation Context

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

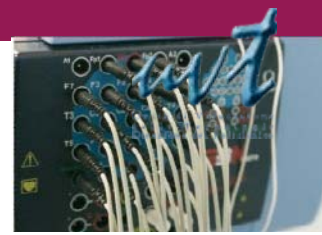
Physicians	962
Nurses	1,967
Total	4,634

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

Member of INAHTA

HTA Unit Presentation
Purpose and Structure



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.

Technology Assessment
- Medical devices
- Diagnostic test
- Medical equipment

R&D
- Internal R&D
- Economic evaluation

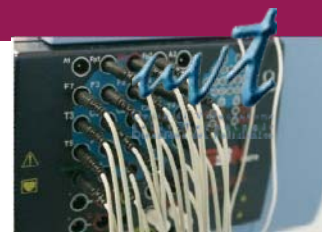
Communication
- Newsletter HTA unit

Clinical Governance
- Institutional Certification/ /Accreditation
- Risk management

Education
- International master Ulysses
- Courses in HTA

Staff

It employs multidisciplinary expertise:
- **1 clinician (in charge)**
- **2 biomedical engineers**
- **1 engineer expert in quality**
- **5 health economists**
- **1 statistician**



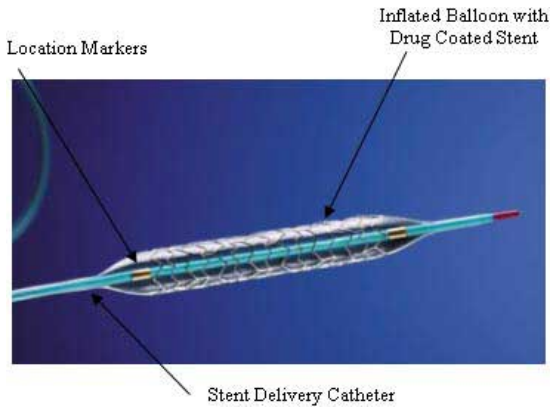
What kind of health technologies are assessed

- 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)

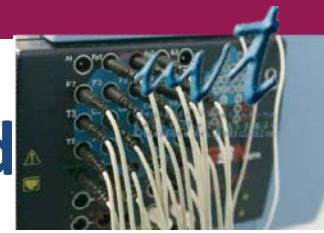
•Pain relief system

•Interspinous System

•Drug eluting •stent



What kind of health technologies are assessed



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

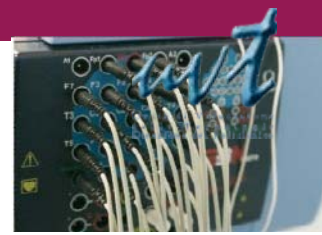
Proton therapy

Ablatherm HIFU

- Diagnostic Test
  - Innovative
  - high unit cost

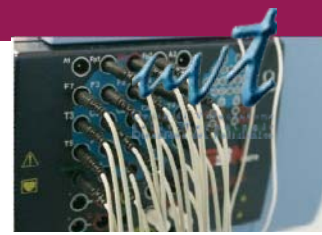
Genetic Test

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

Department 2

Department 1

Department 3

Purchase Unit

HTA unit

Health DIrectorate

Management & Control Unit

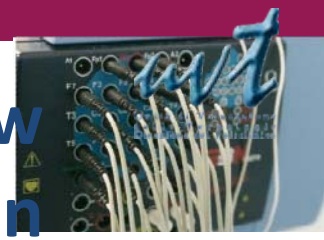
Department 4

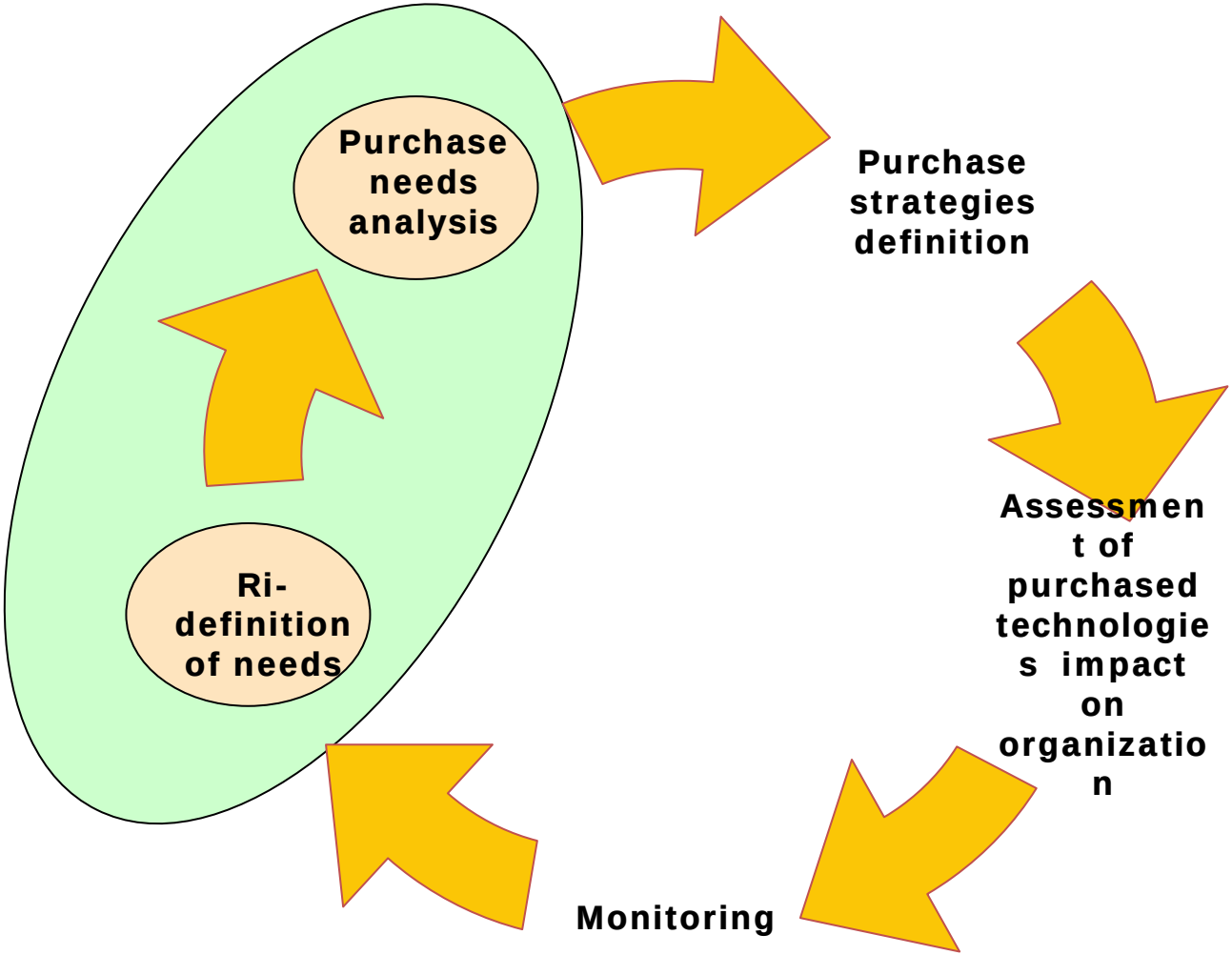
Department 5

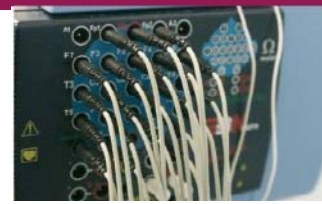
Member of INAHTA

Policlinico Gemelli
IMPEGNO PER L'ECCELLENZA.

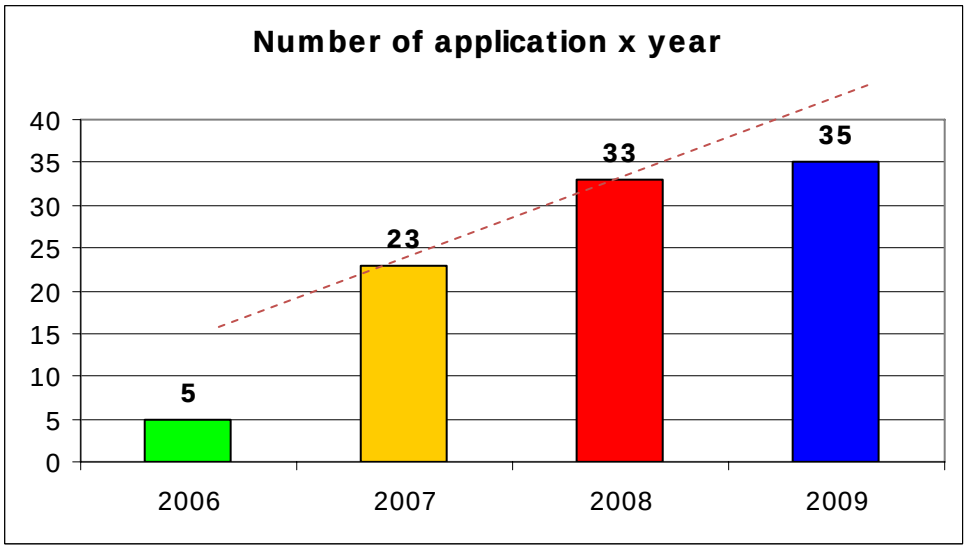
Virtuous Circle of the process of new technology introduction

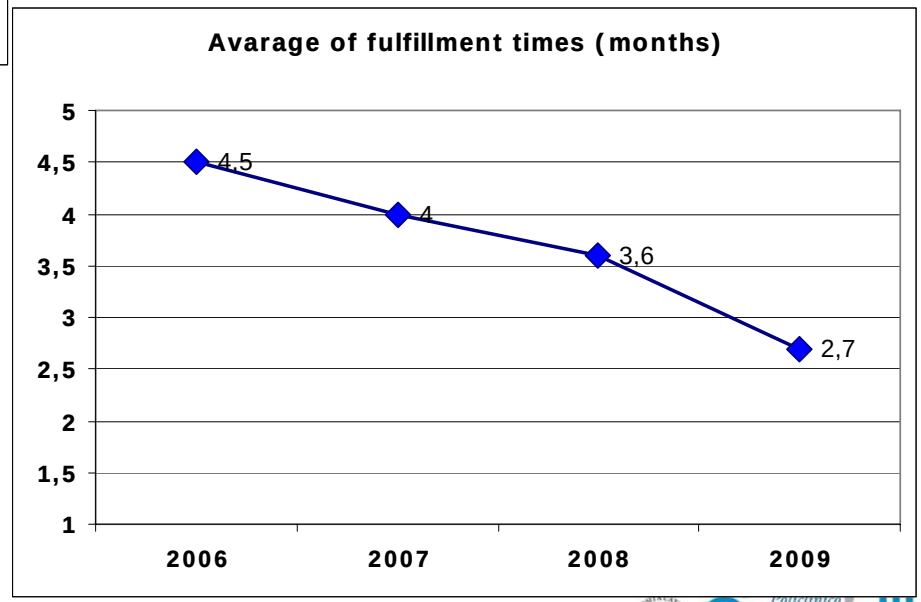


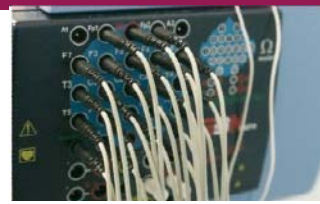




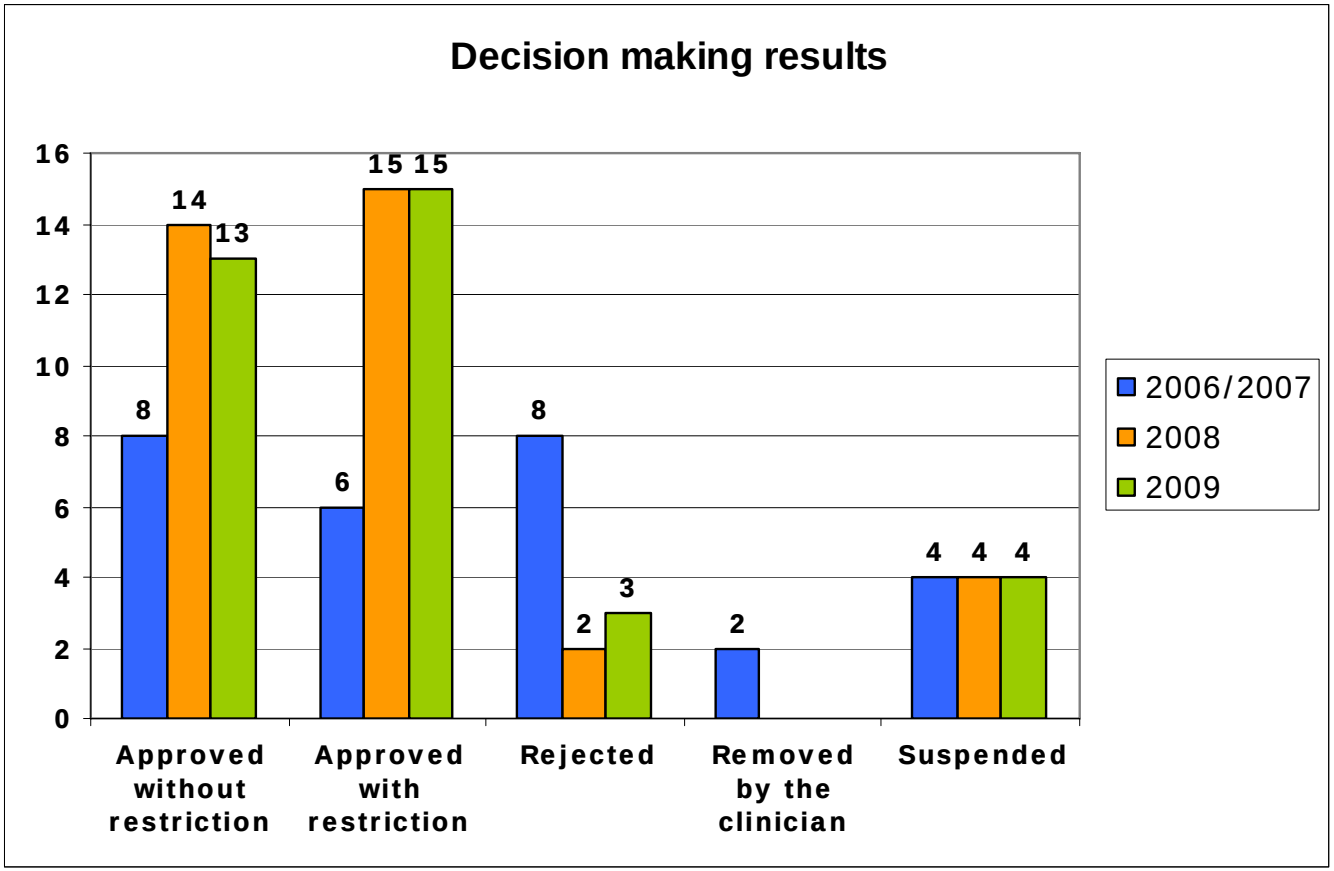
Medical Devices Activities



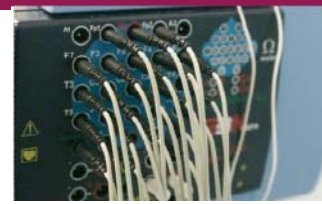




Medical Devices Activities



Medical Devices Activities



Case presentation on Approved device without restriction

Device

Prismocitrate (citrate solution)

Procedure

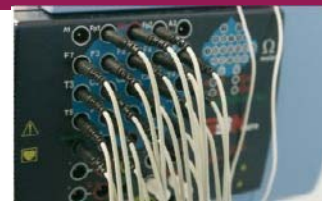
Regional Citrate Anticoagulation in Continuous Venovenous Hemodiafiltration

Patients target

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

Medical Devices Activities

Regulation



CE mark: OK

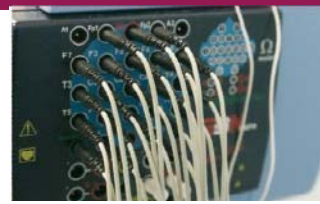
FDA: 510(k) Regulation Number 876.5820 (Hemodialysis system and accessories)

Rapid Literature review (February 2009)

Examined Database	Pubmed, Cinhal
Selected studies with key words: ***"Regional Citrate Anticoagulation"*** **AND** ***"Acute Renal Failure"*** **AND** ***"Critical Ill patient"***	**7 / 9 identified**
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

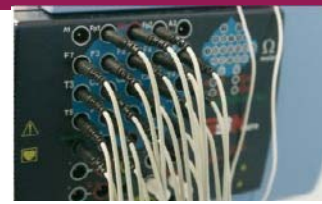
Farmaco-therapy final Decision (2009 February)

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

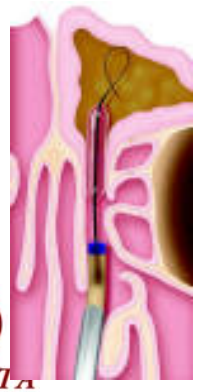
Patients with chronic sinusitis or chronic rhino-sinusitis not respondent to medical therapy (anti-inflammatory drugs)

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.

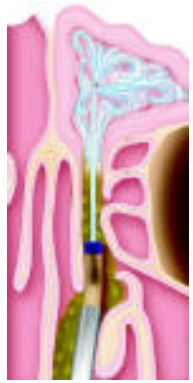
Step 1

Gain Access to the Sinus



Step 2

Inflate Balloon Across Ostium.

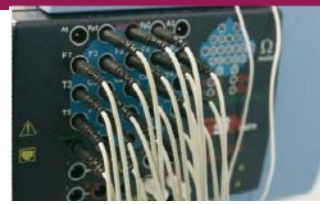


Step 3

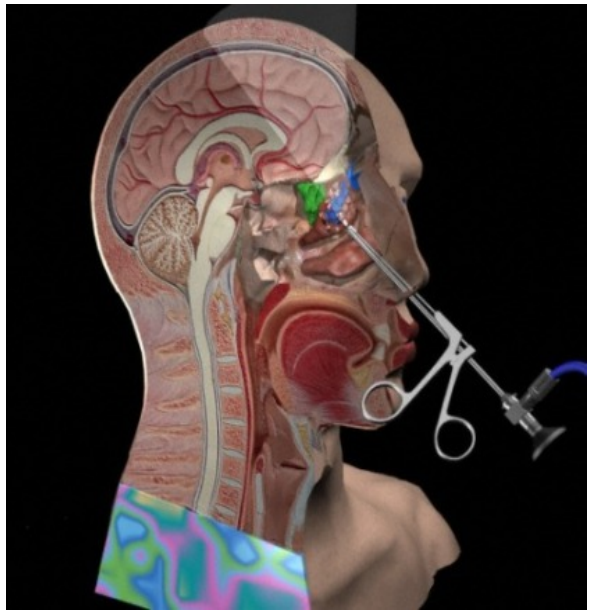
Sinus irrigation

Step 4

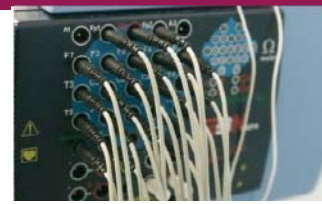
Deflate and Remove Balloon



Traditional Functional Endoscopic Sinus surgery (FESS)



Medical Devices Activities



Regulation

CE mark: ok

FDA: 510K Approval (substantial equivalence) K0053198 del 2005

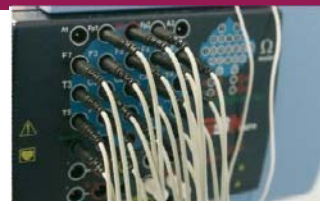
Rapid Literature review (June 2008)

Examined Database	Pubmed, Cinhal
Selected studies with key words: "Relieva" AND "Balloon Catheter" AND "Sinusitis""	**4 / 11 identified**
Studies design	▪ 1 multicentre RCT ▪ 2 high quality observational study ▪ 1 systematic review
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

•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)

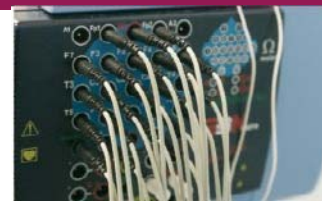
On the below data:

- 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

Medical Devices Activities



Monitoring results on 10 procedures

Surgical times

Functional Endoscopic sinus surgery	⇨	1 h
Balloon catheter sinusotomy	⇨	30 min

Post operative bleeding

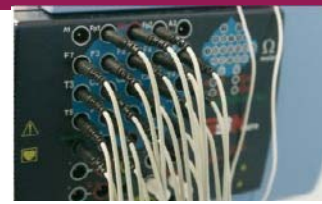
Functional Endoscopic sinus surgery	⇨	High post operative bleeding: tamp is needed
Balloon catheter sinusotomy	⇨	Low post operative bleeding: tamp is not needed

Days of hospitalization

Functional Endoscopic sinus surgery	⇨	48 h
Balloon catheter sinusotomy	⇨	24h

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

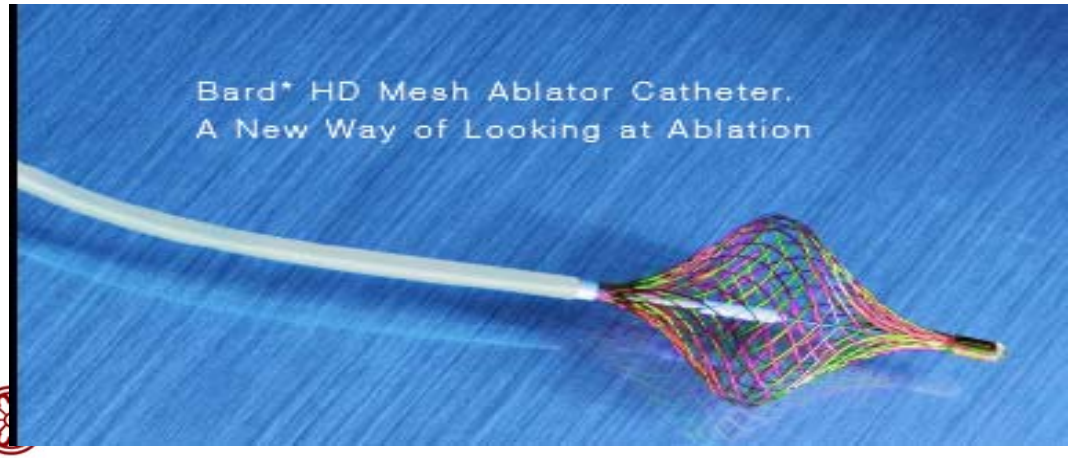
Mesh Ablator and Mapping Catheter

Procedure

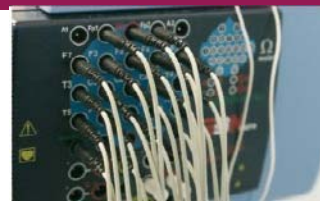
A 36 pole catheter which allows high density mapping and ablation of pulmonary vein potentials at the PV ostium, in a single device

Patients target

Patients with atrial fibrillation (AF).



Medical Devices Activities



Regulation

CE mark: ok (2006)

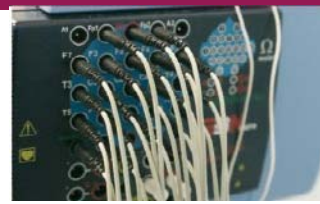
FDA: Not approved in US market

Rapid Literature review (May 2009)

Examined Database	Pubmed, Cinhal
Selected studies with key words: "*MESH*" AND "*paroxysmal atrial fibrillation*" AND "*pulmonary vein isolation*"	**6 / 6 identified**
Studies design	▪ 6 observational studies
Evidence level (GRADE System)	**Low** further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate

- 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

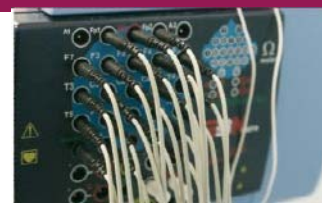
Pharmaco-therapy final Decision (2009 May)

On the below data:

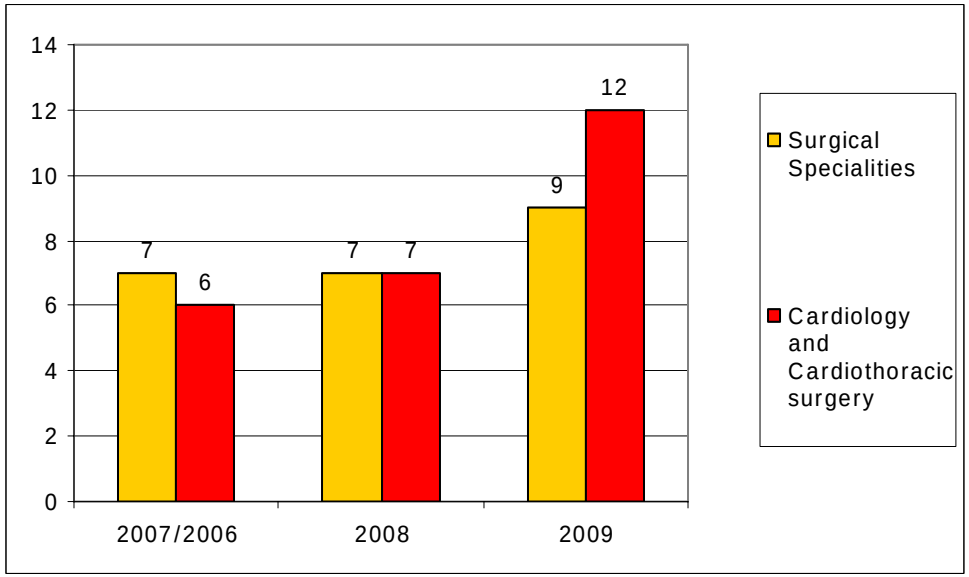
- Low evidence so any estimate of effect is very uncertain.
- Unsustainable costs in relation to reimbursement code

It was state the rejection of device introduction into clinical practice

Medical Devices Activities

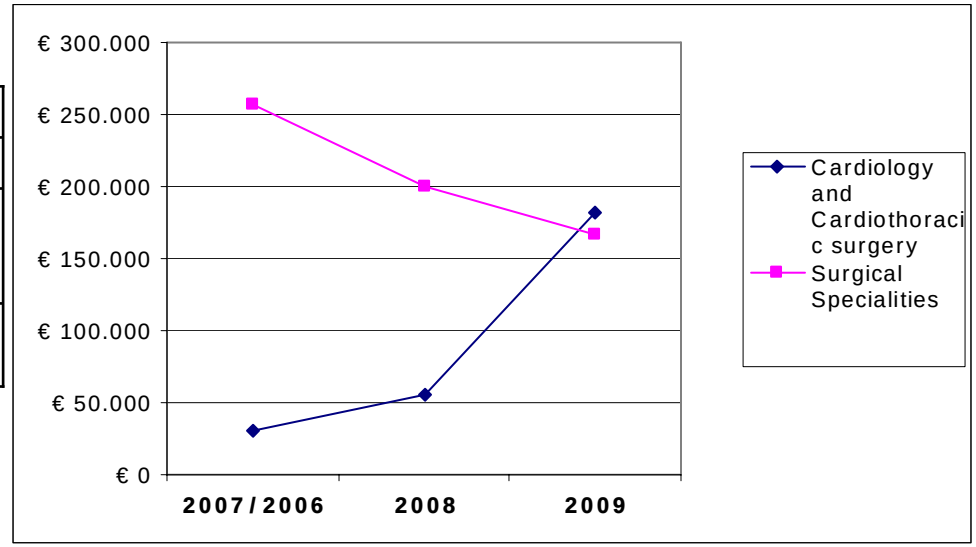


Growth in application x most applicant departments



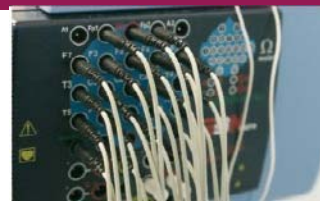
Total expenditure authorized trend			
	2007/2006	**2008**	**2009**
Cardiology and Cardiothoracic surgery	€ 31.150	€ 55.000	€ 182.000
Surgical Specialties	€ 257.000	€ 200.000	€ 166.000

Total expenditure authorized trend



Member of INAHTA

Medical Devices Activities



And all the rest…..

18 report on new diagnostic test completed

total estimated expenditure about € 300.000

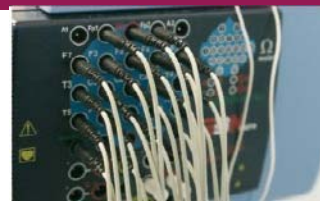
15 report on new medical equipment completed or still in course

Two strategic planning report

total estimated expenditure more than € 20.000.000

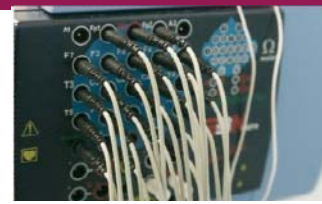
2009 Results

Biomedical Technology Investment Plan



	Highest	High	Medium	Low	Total costs (VAT
Initial request of clinicians	-	19.183.542	6.005.553	328.205	30.620.760
Requests after UVT assessment	**2.826.576**	**7.281.614**	**7.179.225**	**6.300.882**	**28.305.956**
out of order	1.671.000	813.621		1.000.000	4.181.545
% out of order	59,12%	11,17%		15,87%	14,77%

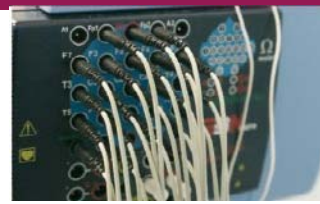
		Highest+High	Medium	Low	Total costs (IVA incl)
differenziale dopo attività UVT		**-66,92%**	**19,54%**	**1819,80%**	**-7,56%**
to buy	subito	I° anno	II° anno	III° anno	
(previa conferma valutazione)					



Agenda

- Background
  - Challenges in managing technological innovation
- Regulating technology innovation
- What is HTA?
- HTA and regulation
- One example: Italy
- HTA decentralization
- Future scenario

The netwok model



Macro Level
HTA

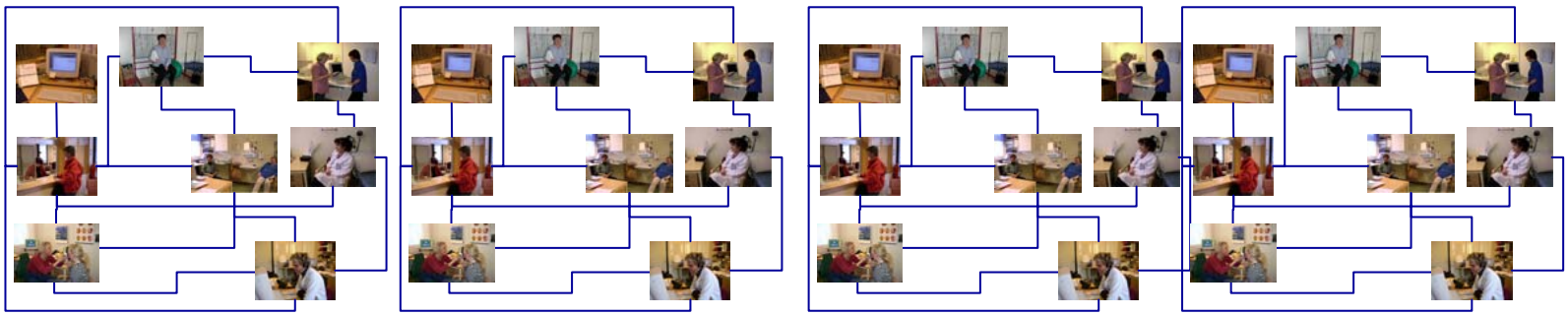
Evidence production

Meso Level
HB-HTA

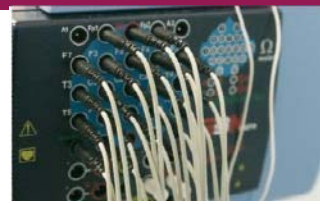
Evidence in context

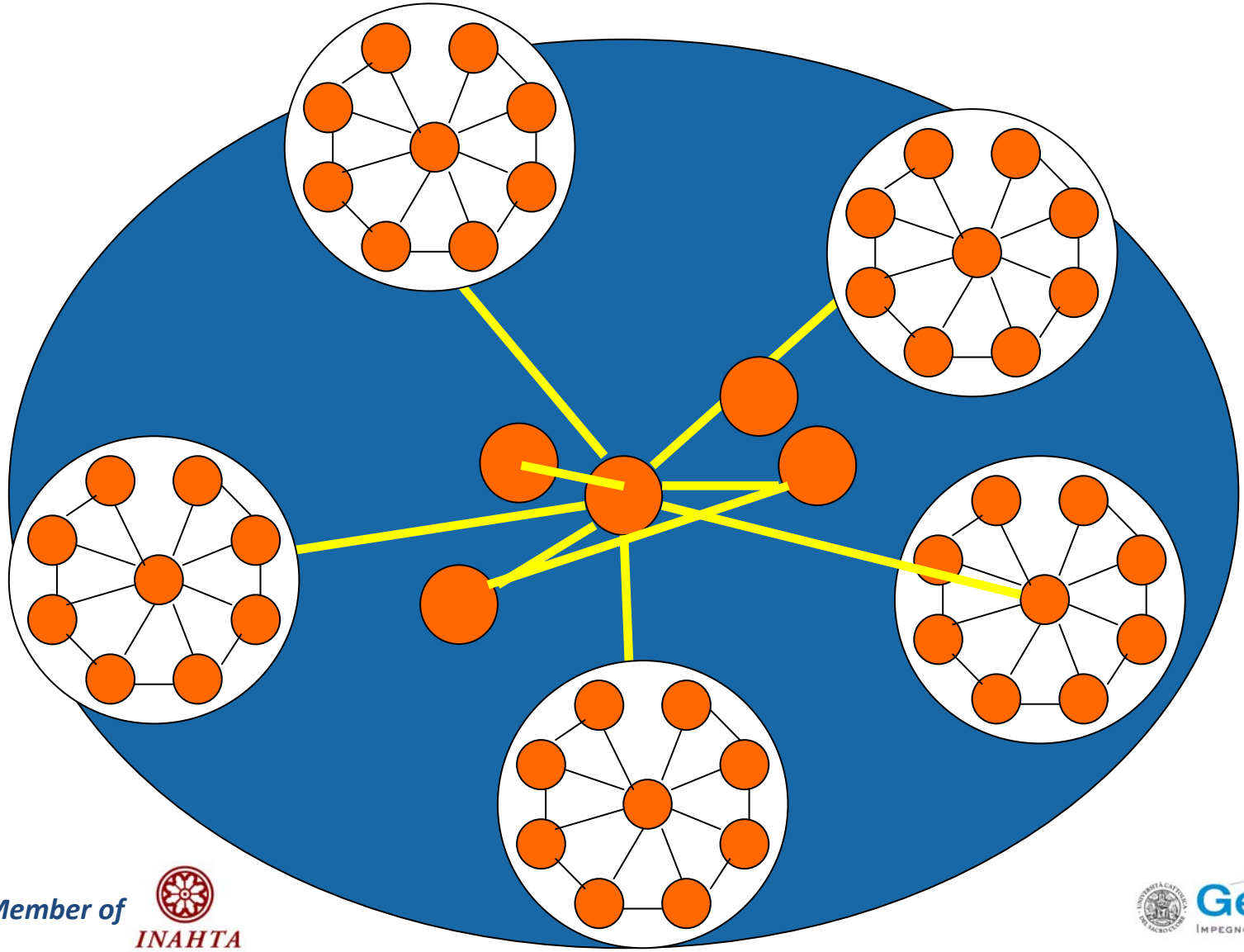
Micro Level
HB-HTA

Frontline

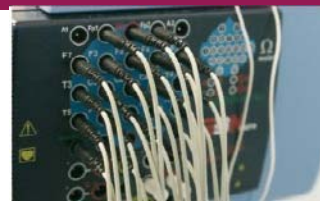


The netwok model: national and international prespective

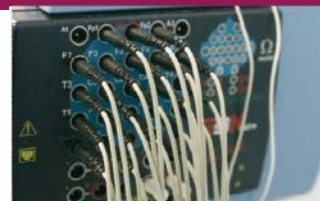




Conclusion



- 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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