

25<sup>th</sup> anniversary. Osteba



Health technologies life cycle  
From Investment to Disinvestment

OSTEBA. Basque Office for HTA  
Ministry for Health  
Basque Government

October 24<sup>th</sup> and 25<sup>th</sup>, 2017

EuroScan  
International Network



In collaboration with:

National Center for HTA



# HTA in Hospital

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

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Bilbao, October 24<sup>th</sup> 2017



HTA Unit – University Hospital A.  
Gemelli

# 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

## System

- The Italian National Health care System (*Servizio Sanitario Nazionale* – SSN) is a comprehensive system which assures health care services to all citizens
- Citizens can choose the professionals and the places of treatment they prefer between public structures and private accredited (publicly funded) structures

## Funding

- The SSN is funded through the general taxation system, especially through direct and indirect regional taxes and a transfer from the equalization fund
- Local health care units (*Aziende Sanitarie Locali*, ASL) also have direct revenues coming from services provided privately and from direct co-payments from patients

## Organization

- The SSN is formed by different levels of responsibility and governance:
  - National or central level: Ensures citizens' rights, the Essential Levels of Health care (LEA), a strong system of guarantees
  - Regional level: manages expenditure to achieve the stated health objectives



## Overview/budget

- **National or central level:** Defines the Essential Levels of Health care (LEA)
- **Regional level:** Controls health care expenditure in order to achieve the established LEA
  - Has the authority to regulate and organize health services/activities and funding of ASL

Source: ISTAT Italia in cifre 2012; Agenzia Italiana del Farmaco (AIFA), Rapporto Nazionale OSMED 2011

National Center for HTA



Gemelli



HTA Unit –University Hospital A. Gemelli

# Health Technology Assessment in Italy

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**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 Ricciardi<sup>1</sup>, Americo Cicchetti<sup>2</sup>, Marco Marchetti<sup>3</sup>

Representing Health Technology Assessment Italian Network Partners



[Home](#) > [Vol 2, No 2 \(2005\)](#)

### 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>

# HTA Italian Network (2003)

- 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



# The University Hospital «A. Gemelli» in numbers (2015)

**94.805**

Admited patients

I PAZIENTI DIMESSI

Surgical

Intervention

**46.080**

GLI INTERVENTI CHIRURGICI

**1.547**

Beds

I POSTI LETTO

Occupancy Rate

**92%**

IL TASSO DI OCCUPAZIONE  
LETTI IN DEGENZA ORDINARIA



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

## UNA GIORNATA AL GEMELLI

CHI SIAMO

Born children

**11** BAMBINI NATI

**220**

PERSONE CHE ACCEDONO AL PRONTO SOCCORSO

**Patients in the Emergency**

**7**

PERSONE CHE ACCEDONO AL PRONTO SOCCORSO IN CODICE ROSSO



**4.200**

PROCEDURE AMMINISTRATIVE DI ACCETTAZIONE

4.888  
PERSONE CHE MUOIONO

**126**  
INTERVENTI CHIRURGICI

**Surgical interventions**

**9.604**

PRESTAZIONI AMBULATORIALI PER PAZIENTI NON RICOVERATI



**Outpatients procedures**



**130**  
RICHIESTE DI PRENOTAZIONE VISITE ONLINE

**262**

PAZIENTI RICOVERATI

**Patients admitted**

**350**

REFERTI  
MEDICI CONSEGNATI

OLTRE  
**3.100**  
PASTI EROGATI



A PAZIENTI E PERSONALE

**3100 meals delivered**



# University Hospital Agostino Gemelli – Università Cattolica del Sacro Cuore

OFFERTA FORMATIVA

Students



**5.036**

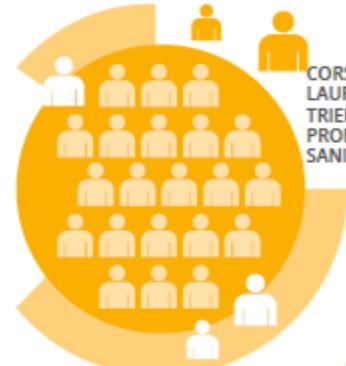
STUDENTI DI CORSI DI LAUREA,  
SPECIALIZZAZIONI E MASTER

**13**

CORSI DI LAUREA  
TRIENNALE IN  
PROFESSIONI SANITARIE

**3**

CORSI DI LAUREA  
MAGISTRALE A  
CICLO UNICO  
IN MEDICINA E  
CHIRURGIA, DI  
CUI 1 IN LINGUA  
INGLESE



**1**

CORSO DI LAUREA  
TRIENNALE DI AREA  
BIOTECNOLOGICA

**3**

CORSI DI LAUREA  
TRIENNALE  
IN ECONOMIA E  
GESTIONE DEI SERVIZI

**1**

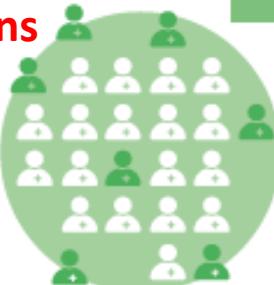
CORSO DI LAUREA MAGISTRALE  
DELLE PROFESSIONI SANITARIE



**975**

PERSONALE MEDICO

**Physicians**



**2.045**

PERSONALE INFERMIERISTICO

**Nurses**



**754**

OTA, AUSILIARI, OSS

**461**

TECNICI SANITARI  
ALTRI SANITARI



**953**

PERSONALE  
AMMINISTRATIVO  
E ALTRO

**5.188**  
**TOTALE**  
**Total staff**

**administrative staff**

ALTEMS 2013 - 2015

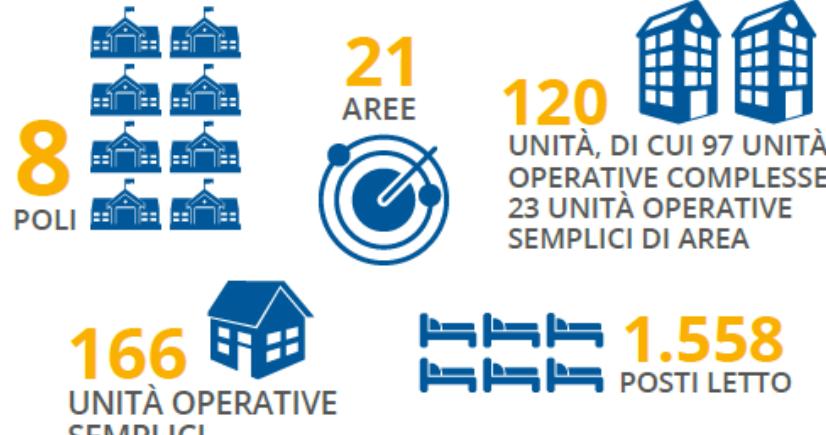


# University Hospital Agostino Gemelli – Università Cattolica del Sacro Cuore

## GLI ASSET DELLA FONDAZIONE



IL POLICLINICO È ORGANIZZATO IN DUE PRESIDI OSPEDALIERI: GEMELLI E COLUMBUS



## DISTRIBUZIONE DEL VALORE AGGIUNTO\*

**Value of production and other revenues**

### DETERMINAZIONE DEL VALORE AGGIUNTO

Million Euro

Valore della produzione e altre entrate	620.828
Costi intermedi della produzione	- 266.054
Valore aggiunto caratteristico lordo	354.774
Componenti accessorie e straordinarie	- 24.383

**330.391**  
VALORE AGGIUNTO GLOBALE NETTO

### RIPARTO DEL VALORE AGGIUNTO

Remunerazione del personale <sup>1</sup>	277.718
Remunerazione della pubblica amministrazione <sup>2</sup>	50.699
Remunerazione del capitale di credito <sup>3</sup>	12.846
Remunerazione della Collettività / Ambiente <sup>4</sup>	6.321
Sistema ente <sup>5</sup>	- 17.193

# 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?

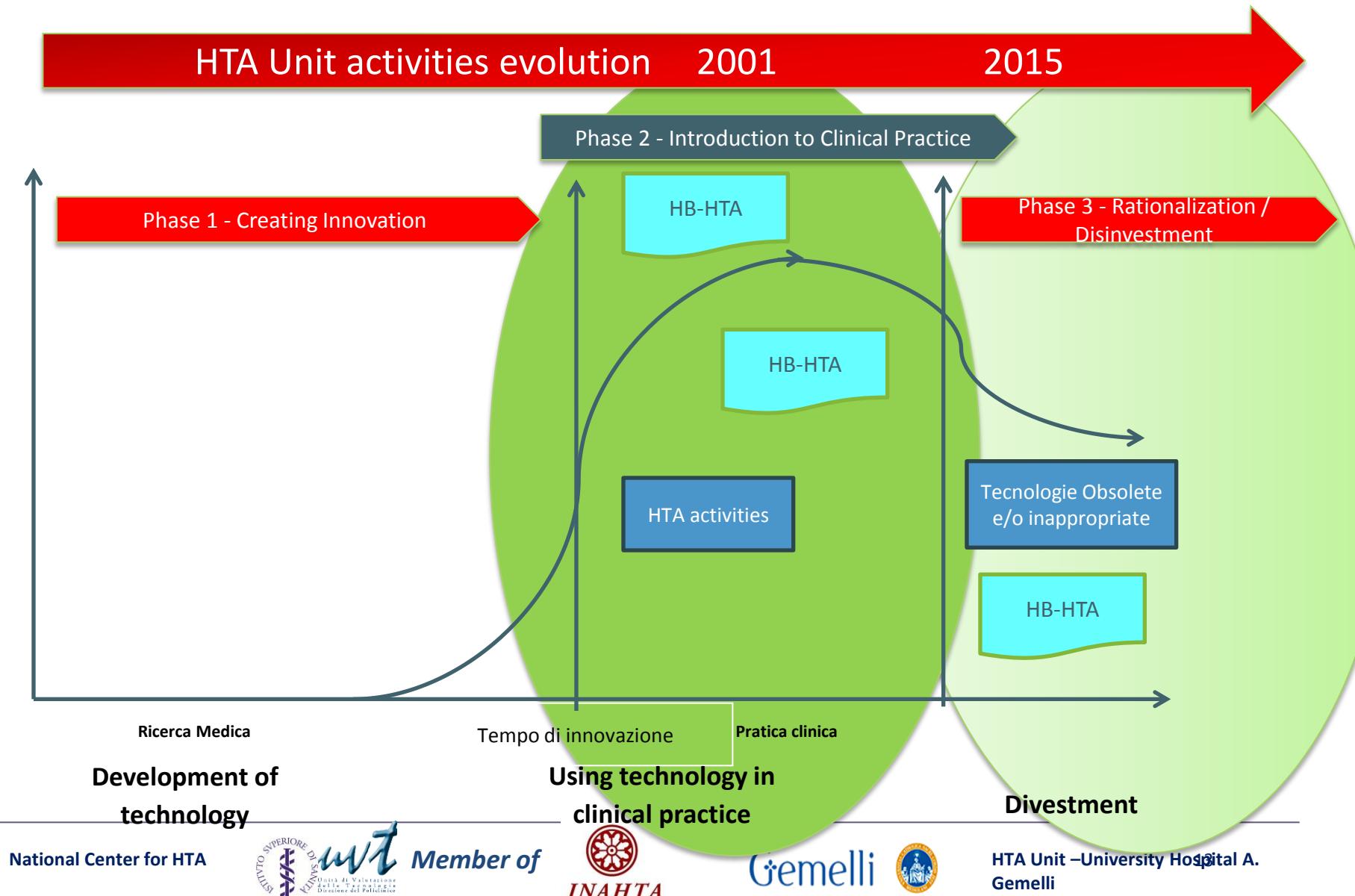
- **Some positive aspects**

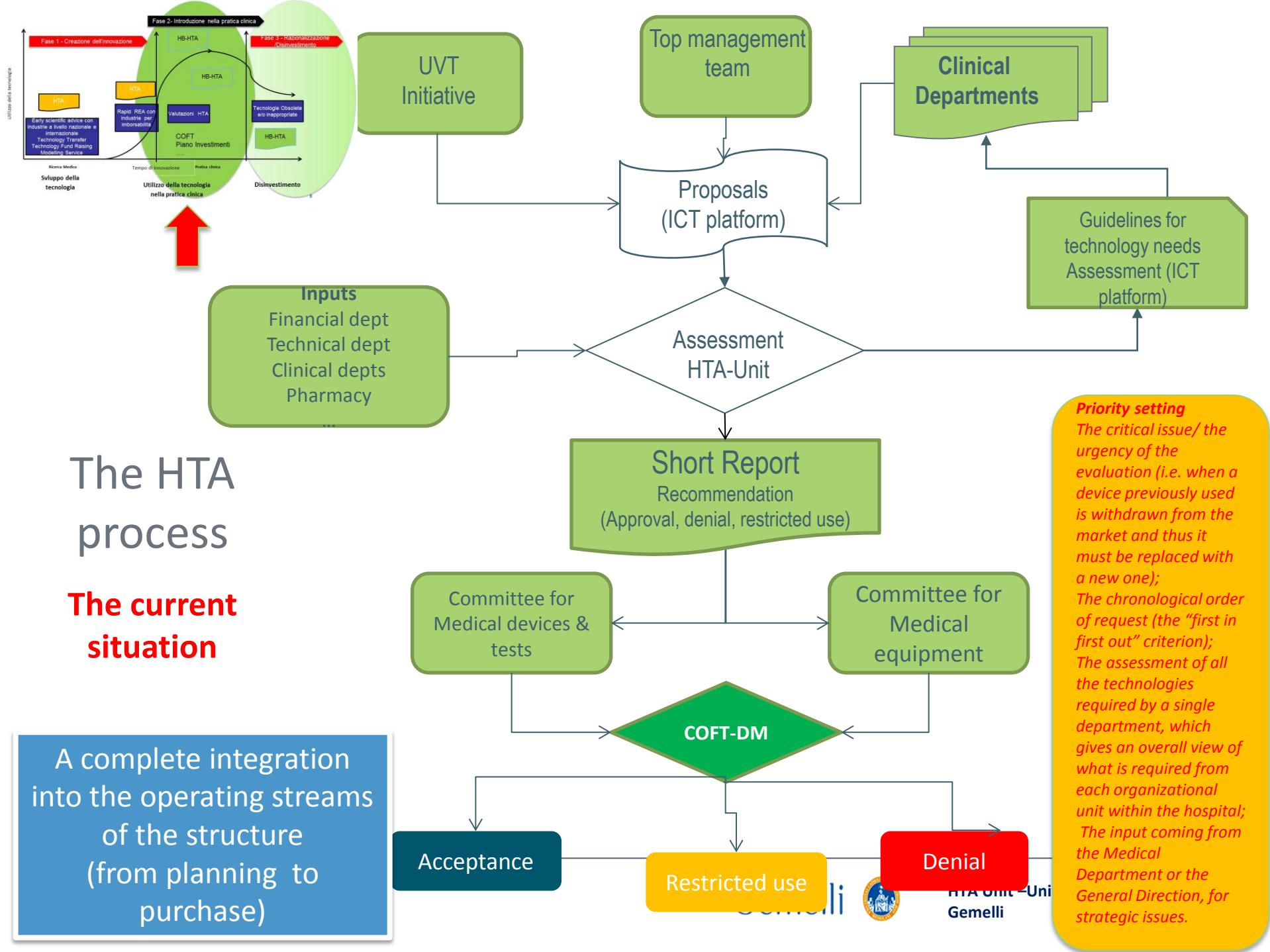
- An extensive and formal HTA approach to managing the company's technology strategy
- Continuity in commitment by the Management since its starting in 2001
- A progressive continuous involvement of professionals



# Technological strategy in the technology lifecycle

*Management and promotion of technological innovation at the University Hospital A. Gemelli*





# Production

- HTA Report (medical devices and drugs)
- Positive and negative List for drugs formulary
- List of technologies to disinvest

Category of technologies	Applicant	Type of recommendations	Product	Role and responsibilities
Pharmaceuticals	Any hospital doctor through formal application approved by referred Department	Adoption	HTA report	The Unit is the only responsible for the assessment of request of introduction of new pharmaceuticals in the hospital formulary. It verifies the regulatory status, the effectiveness and reimbursement. For these activities collaborate with Hospital Pharmacy.. The report contains a recommendation on the introduction, the denial or the introduction with restriction of assessed drug. The Responsible of the Unit is permanent member of Commission on Drugs and Medical Devices.
	Directions	Disinvestment	List of pharmaceuticals to withdraw	Periodically a stable working group revised the hospital formulary in order to update the list of pharmaceuticals. An employer of the unit takes part to the working group. Other Unit involved are Pharmacy and Purchase Unit.
Medical Devices	Any hospital doctor through formal application approved by referred Department	Adoption	HTA report	The Unit is the only responsible for the assessment of request of introduction of new medical devices in the hospital list. It conducts an evaluation considering the following dimensions: current use of medical device, regulatory status, effectiveness, impact on organization, economic considerations (budget impact analysis and adequacy of reimbursement). For these activities collaborate with Pharmacy Unit, Purchase Unit and Management and controlling Unit. The report contains a recommendation on the introduction, the denial or the introduction with restriction of assessed medical device. The Responsible of the Unit is permanent member of Commission on Drugs and Medical Devices.
	Directions	Disinvestment	List of medical devices or medical procedures to withdraw	Periodically a stable working group revised the hospital list of medical devices, in order to update the list of medical devices and the patient paths. An employer of the Unit takes part to the working group. Other Unit involved are Pharmacy and Purchase Unit.
Medical equipment	Clinical Departments	Investment	Investment plan	The Unit is responsible for collecting technology needs of medical departments, prioritizing the request with an explicit method and providing the plan of the investment. For these activities collaborate with Hospital Technical Services Department, Clinical Engineering, Purchase Unit and Management and controlling Unit.
Diagnostic tests	Laboratory	Adoption	Structured advice	The Unit is a permanent member of Commission on diagnostic test introduction and is responsible for the evaluation on organizational and technical dimensions. The Unit provides information on: clinical and patients benefit for new diagnostic tests, existence of any technical or organizational difficulties for introducing the test.

# 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

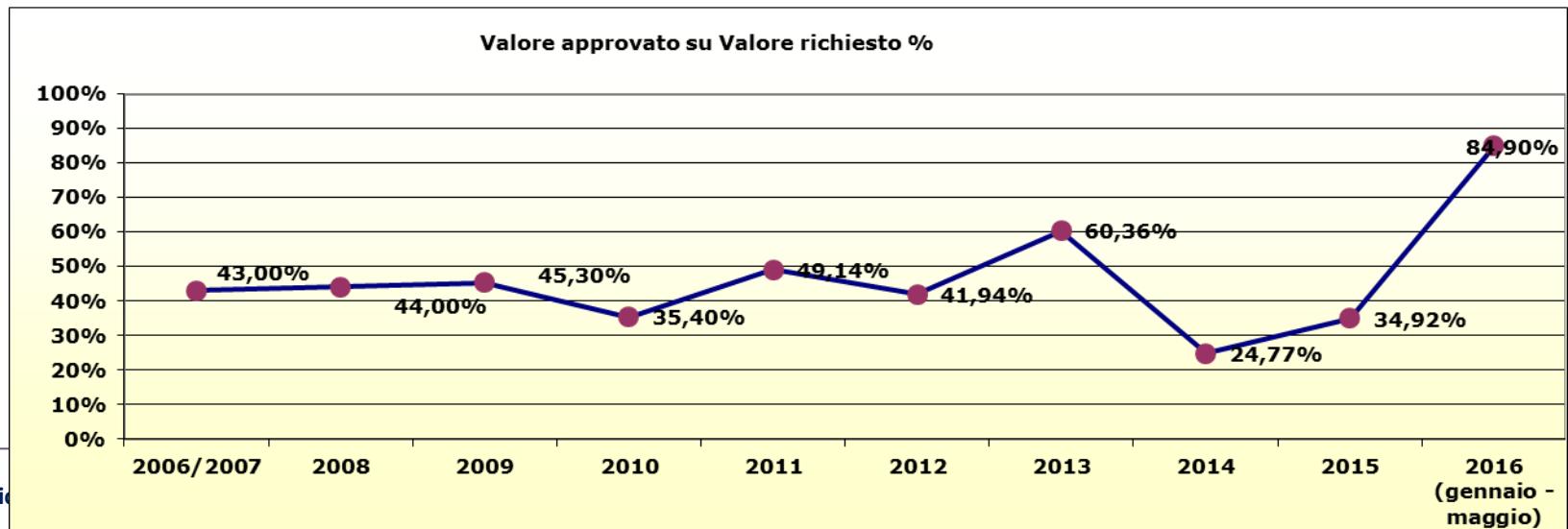
## *Drugs Evaluation May 2013-may 2016*

Evaluation of pharmaceuticals (Novembre 2013 – Maggio 2016)	Number	%
Approved	23	27%
Approved with limitation	21	25%
Not approved	17	20%
Suspended decision	24	28%
<b>Total</b>	<b>85</b>	<b>100%</b>

# October 2006- may 2016 experience – Device

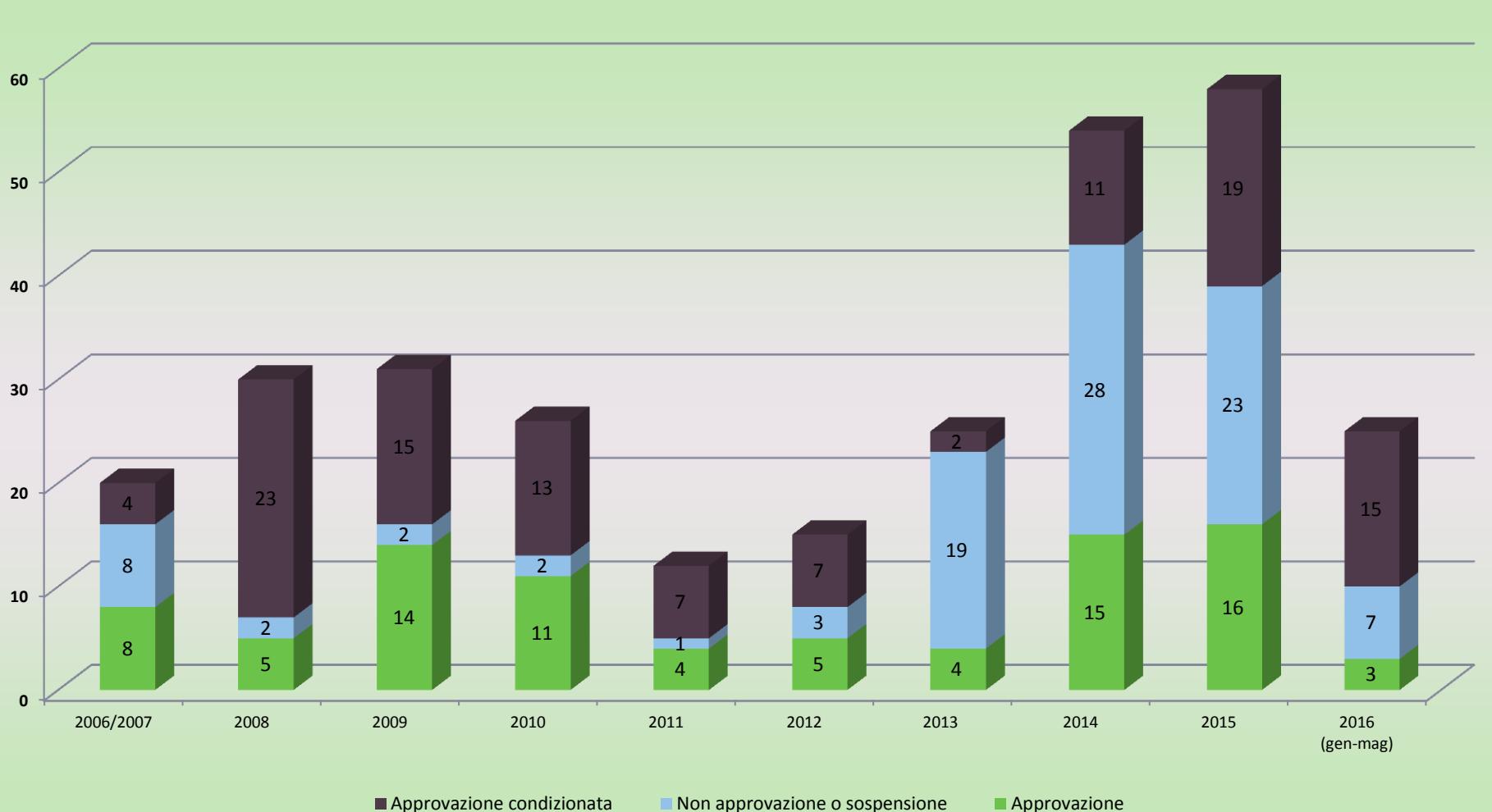
## *Impact of approved expenditure on total expenditure*

	2006/2007	2008	2009	2010	2011	2012	2013	2014	2015	2016 (gennaio - maggio)
Valore richiesto	€ 685.811	€ 752.262	€ 1.213.921	€ 709.545	€ 870.070	€ 753.610	€ 947.340	€ 2.037.377	€ 2.054.529	€ 844.975
Valore approvato	€ 387.331	€ 332.329	€ 550.948	€ 251.493	€ 427.570	€ 316.095	€ 571.860	€ 504.705	€ 717.361	€ 717.361
Δ = Approvato - richiesto	-€ 298.480	-€ 419.933	-€ 638.973	-€ 458.052	-€ 442.500	-€ 437.515	-€ 375.480	-€ 1.532.672	-€ 1.337.169	-€ 127.615



# UVT Experience – Device

## *Number of applications per year*

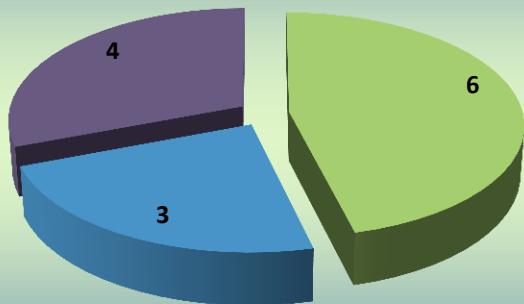


# Drivers of decision on introduction on denial of medical device in the hospital

Driver	Favorable	Unfavorable	
Effectiveness	<ul style="list-style-type: none"><li>Good evidence that they brought substantial health benefits</li></ul>	<ul style="list-style-type: none"><li>Insufficient proof of benefit or insufficient quantity of health benefit to justify the costs</li></ul>	35%
Economic issues	<ul style="list-style-type: none"><li>Relatively lower cost respect internal comparator with same effectiveness</li></ul>	<ul style="list-style-type: none"><li>Relatively higher cost respect internal comparator with same effectiveness</li><li>Cost not sustainable respect to budget in spite weak proof of evidence</li></ul>	19%
Organizational issues	<ul style="list-style-type: none"><li>Medical device that could be used by several departments that entail a rationalization in the area</li><li>Change of setting of care (eg. From normal operative theatre to day surgery theatre)</li></ul>	<ul style="list-style-type: none"><li>Needs of increasing in staff not sustainable</li><li>Needs of additional physical area</li></ul>	31%
Strategic issues	<ul style="list-style-type: none"><li>Device with sufficient proof of health benefit to be used in a strategic area of the hospital even if an increasing in costs</li></ul>		15 %

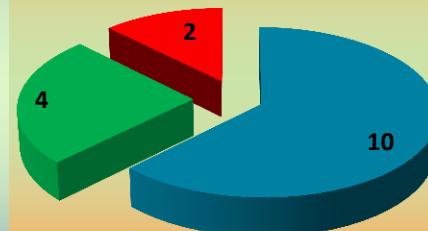
# Drivers of decision on introduction on denial of medical device in the hospital

## Denied



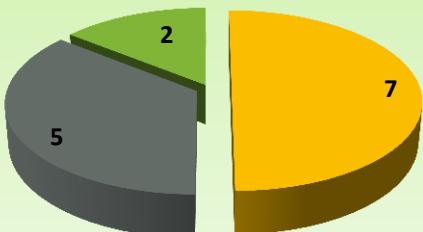
- Insufficient proof of benefit or insufficient quantity of health benefit to justify the costs
- Costs too higher respect to internal comparator
- Organizational issues

## Approved



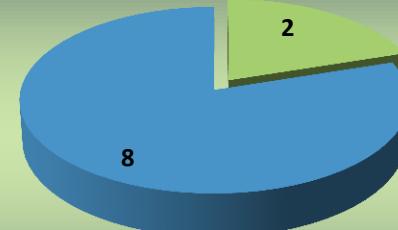
- Good evidence that they brought substantial health benefits
- Relatively lower cost respect internal comparator with same effectiveness
- Strategic

## Suspended



- The MD will be used in a ward to be implemented (eg. Pelvic floor disease)
- The number of MD required seems overestimate
- waiting for budget negotiating

## Restricted use



- It is suggested to implement a register of patient to monitor specified clinical outcomes not well demonstrated
- The number of required MDs have to be confirmed by a monitoring activity

# Dissemination of results

- Report are not public but accessible 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 recommendation 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 you attention

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