

Hospital-Based Health Technology Assessment in Italy: Lombardy Region

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Italian NHS

“Italy as one nation—still a work in progress”
(Ricciardi and Tarricone, 2021, page 1294)

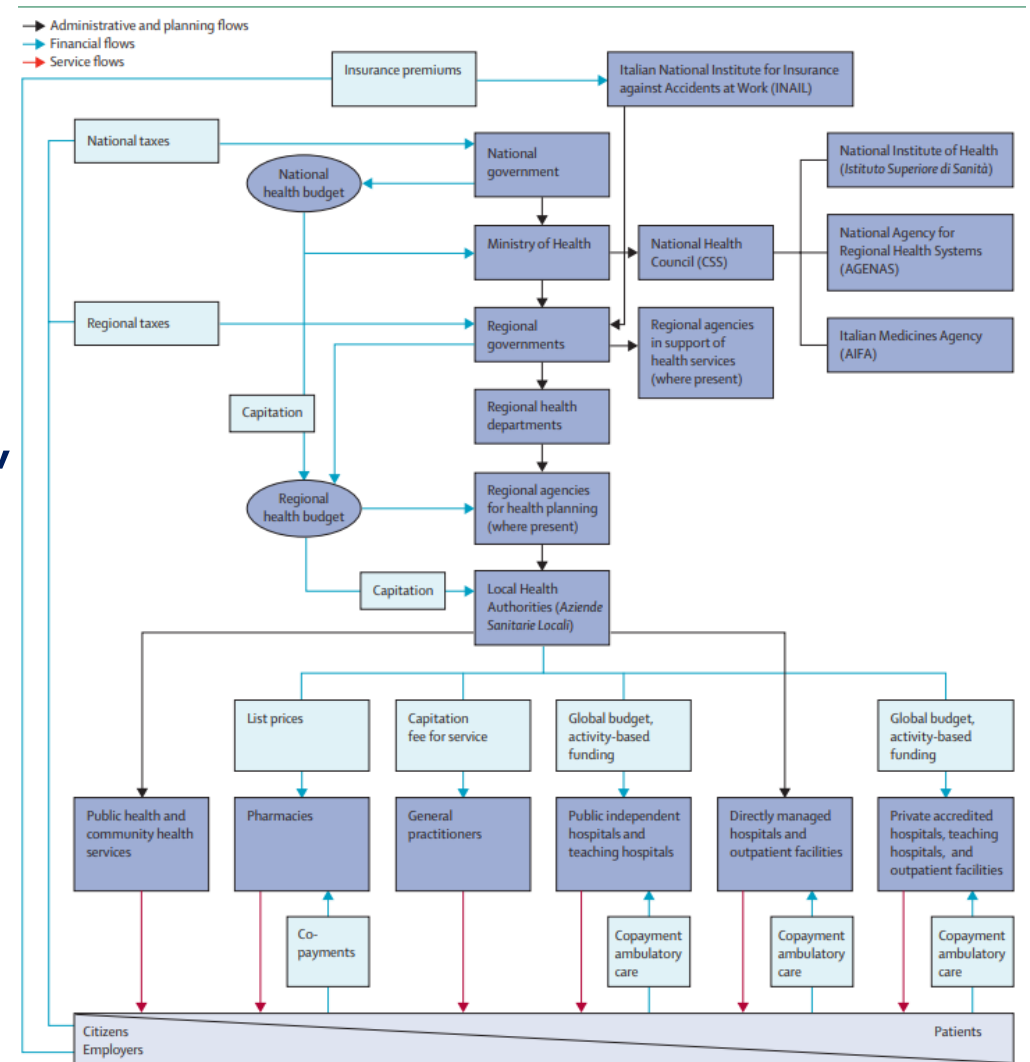


Figure: The Italian National Health Service (Servizio Sanitario Nazionale): current structure and governance
Adapted from France et al. and Ferré et al.

Source: Ricciardi, W., & Tarricone, R. (2021). The evolution of the Italian National Health Service. *The Lancet*, 398(10317), 2193-2206.

Current challenges: the perfect storm

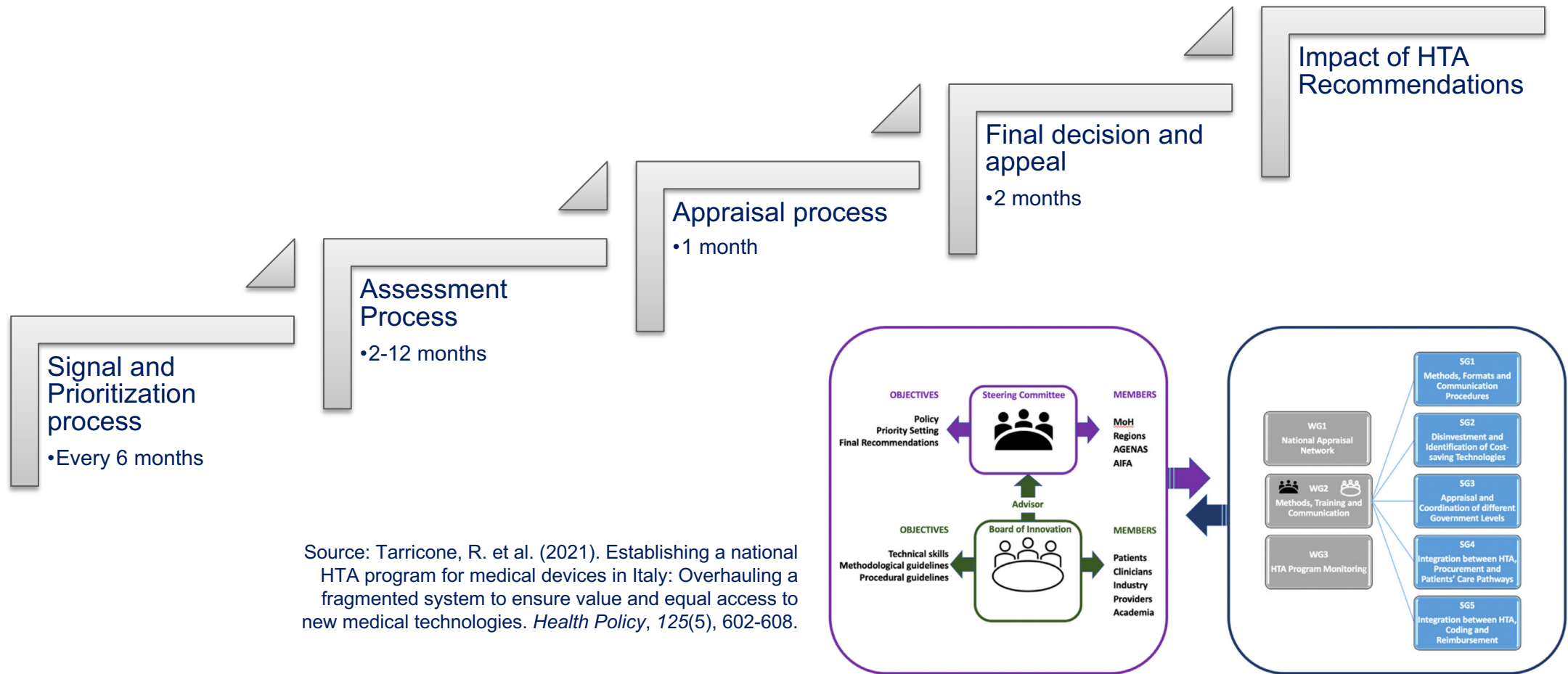
- Ageing and the increase of chronic conditions
- Socio-economic situation
- New technologies

HTA in Italy

The general objectives and the fundamental principles that should be guaranteed by the healthcare system are provided by the **national level**, the delivery of the services is ensured by the **regional level**, through the **local level** (Local Health and Social Authorities, and public and private hospitals) (Taroni, 1999; Donatini et al., 2001).

National Agency for Regional Health Services (AGENAS)	Italian Drugs Agency (AIFA)	Italian Network for HTA (RiHTA)	Italian Society of HTA (SIHTA)	National Centre for HTA
Support and coordination of regional and local HTA activities Disseminate national HTA results	Undertake HTA activities related to drugs	Support for the systematic production of HTA reports Favor the development of a decentralized culture of HTA	Share mission and objectives of the HTAi Promote training activities at different levels	Improve the quality, standards and the value for money by integrating HTA in the programming of health services

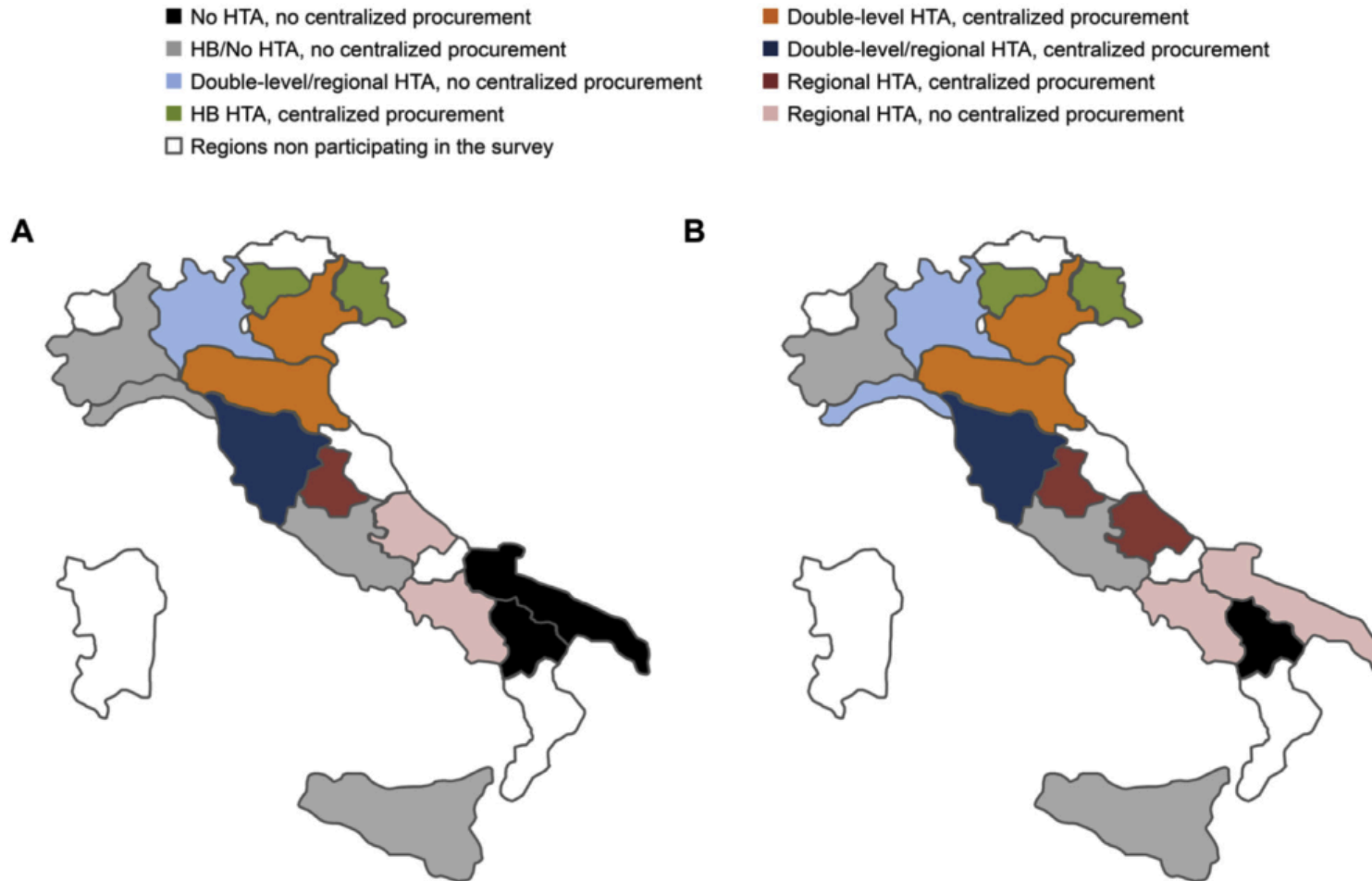
HTA in Italy – National Level



Source: Tarricone, R. et al. (2021). Establishing a national HTA program for medical devices in Italy: Overhauling a fragmented system to ensure value and equal access to new medical technologies. *Health Policy*, 125(5), 602-608.

Fig. 1. Governance and Methodology of the Italian National Program of HTA for Medical Devices (PNHTADM).

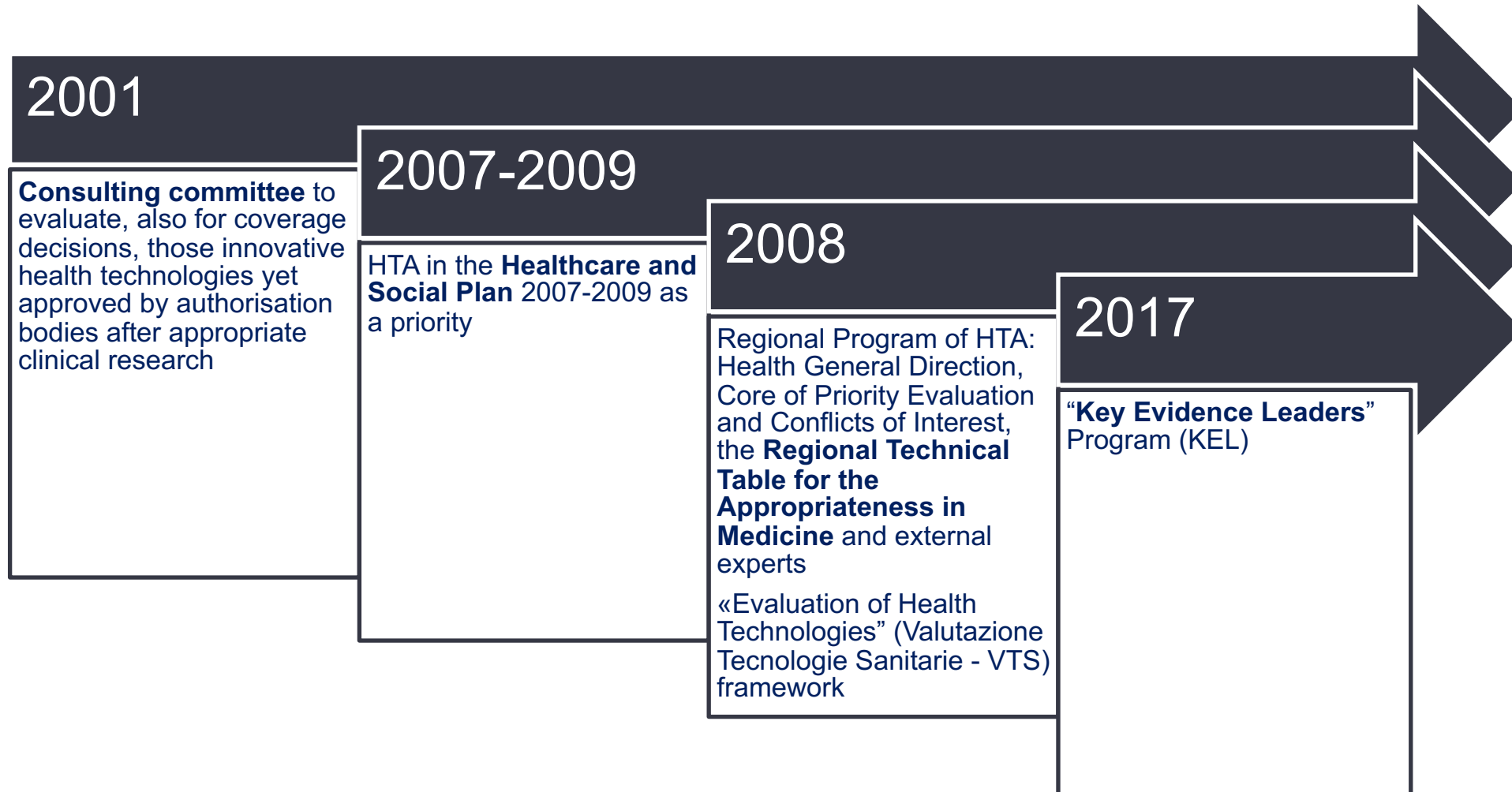
HTA – Regional level



Source: Callea, G., Armeni, P., Marsilio, M., Jommi, C., & Tarricone, R. (2017). The impact of HTA and procurement practices on the selection and prices of medical devices. *Social Science & Medicine*, 174, 89-95.

Fig. 1. HTA governance models and procurement practices implemented in Italy in 2008–2009 Combination of HTA governance models (regional, hospital-based, double-level, and no HTA) and centralized procurement in the hospitals participating in the survey in 2008 (1a) and 2009 (1b).

Regional HTA - Lombardia



Regional HTA - Lombardia

QUANTITATIVE	
Dimension	Criterium
D1 – Health problem relevance	C01– Disease severity
	C02 – Size of affected population
D2 – Technology solution relevance	C03 – Type of preventive benefit
	C04 – Type of therapeutic benefit
	C05 – Quality of evidence
D3 - Safety	C06 – Comparative safety / tolerability
D4 - Effectiveness	C07 – Efficacy and effectiveness advantages
	C08 – Patient reported outcomes advantages
	C09 – Unmet needs
	C10 – Clinical practice guidelines and regulatory state
D5 – Financial aspects	C11 – Direct financial impact on health care budget
	C12 – Cost consequences on other medical costs
	C13 – Cost consequences on non-medical costs
D6 – Organizational aspects	C14 – System capacity and requisites for appropriate use
QUALITATIVE	
D7 – Ethical aspects	C15 – Equitable opportunities for access and use
D8 – Social aspects	C16 – Pressures and difficulties of stakeholders
D9 – Legal aspects	C17 – Mandate and scope of National Healthcare System

Methodology:
Multiple criteria decision analysis (MCDA), in collaboration with EVIDEM.

HB-HTA in Regione Lombardia

OBJECTIVES:

Facilitate the dissemination in clinical practice of the most effective, safe and efficient technologies in replacement of less effective, safe and efficient technologies, in a responsible, shared, transparent, monitorable and verifiable manner, in compliance with the provision of the Essential Levels of Assistance

Operational implementation of the indications of the Regional Health Technology Assessment Program and of the National HTA Medical Devices Program

Considering the **level of uncertainty of information** on health technologies and **transferability of the assessments** produced in other national and international contexts to the Lombard Health Service

Production of **technical reports on technologies not prioritized** at national level and of regional strategic interest on the basis of the indications of the D.G. Welfare

Support for the regional network of **contact people for the technical assessment** of health technologies at the Lombard social and health companies

Promotion of the **culture of evaluation** and the use of comparative effectiveness documentation in health planning and clinical practice in Lombardy;

Assurance of the **separation between the technical evaluation phase** and the **formulation of recommendations (appraisal) for the appropriate use of health technologies**

HB-HTA: San Matteo Hospital, Pavia

- One of the oldest and largest teaching hospitals in Italy.
- Scientific Institute for Research, Hospitalization and Health Care (IRCCS) - biomedical institutions of relevant national interest, which drive clinical assistance in strong relation to research activities.
- More than 1,000 ordinary beds



HB-HTA: San Matteo Hospital, Pavia

Commissione Health Technology Assessment (CHTA), that is a technical-scientific body that operates, in support of the Strategic Management, in order to:

- achieve **controlled and sustainable adoption** of new medical devices to be introduced and, where necessary, allow the **disposal of obsolete ones**;
- carry out **technology assessment activities**, so that the choices are consistent with the needs and specific institutional purposes as well as respectful of economic constraints;
- promote the **quality and appropriateness of services**.

• Dimensions:

- technical innovation and clinical-assistance innovation
- proven clinical efficacy attested by adequate documentation in terms of quality and quantity,
- security (surveillance),
- economy (cost/effectiveness),
- homogeneity of use in the various Structures,
- periodic analysis of consumption,
- any infungibility and exclusivity.

HB-HTA: Papa Giovanni XXIII, Bergamo

- Among the largest Italian hospitals with all clinical and surgical specialties.
- Active since December 2012, it is a modern hospital with a high level of technology.
- 1,024 ordinary beds



HB-HTA: Papa Giovanni XXIII, Bergamo

- Commissione Health Technology Assessment:
Description of the functioning in the
Strategic Plan
- **Coordinator:** Clinical Director

- Main duties:
 - carry out analyzes on the **introduction of technologies** (equipment, medical devices, drugs, etc...) that have a **significant clinical, organizational or economic impact** whose assessment is **required** by national/regional legislation;
 - carry out analyzes on the introduction of **innovative technologies** (equipment, medical devices, drugs, PDTA, etc) for which the **Company Management** deems necessary to acquire specific insights, regardless of the impact economic.

HB-HTA: Niguarda Hospital

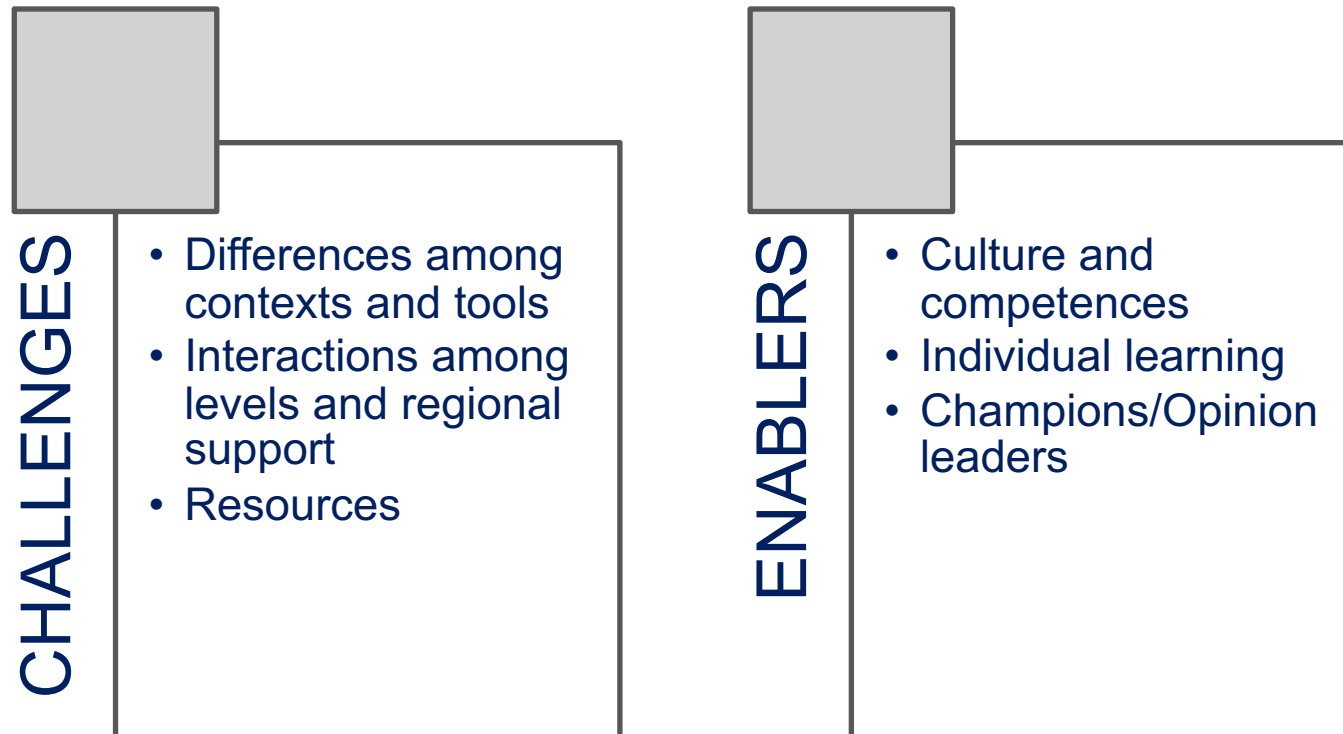
- Large metropolitan hospital with social and health skills for territorial care.
- Its orientation: integrating specialist care with territorial social and health care, in synergy with all the actors involved in protecting the health of the citizen.
- 1,167 ordinary beds



HB-HTA: Niguarda Hospital

- Commission Health Technologies (CTS): technical-scientific body that operates for the **promotion of efficient, efficacy, rational and safe use** of the **biomedical technologies, drugs, medical devices and health procedures**.
 - The proponent of the evaluation can be the **end user** or the Strategic Director.
 - Coordinator: Clinical Director
 - Three different bodies:
 - **Members by right:**
 - decision-making and validation function.
 - **Core Team:**
 - Multidisciplinary team aimed at providing evaluation of the introduction/use/disinvestment of health technologies. Leadership function.
 - **Working group:**
 - HTA experts and specialists identified on the basis of the health technology under evaluation. Coordination function.
- **Dimensions:**
 - Technology framework
 - Literature Review
 - Efficacy and safety
 - Organizational impact
 - Economic impact

Conclusions





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Thank you
