La valutazione delle tecnologie in sanità

Focus sulla cardiologia

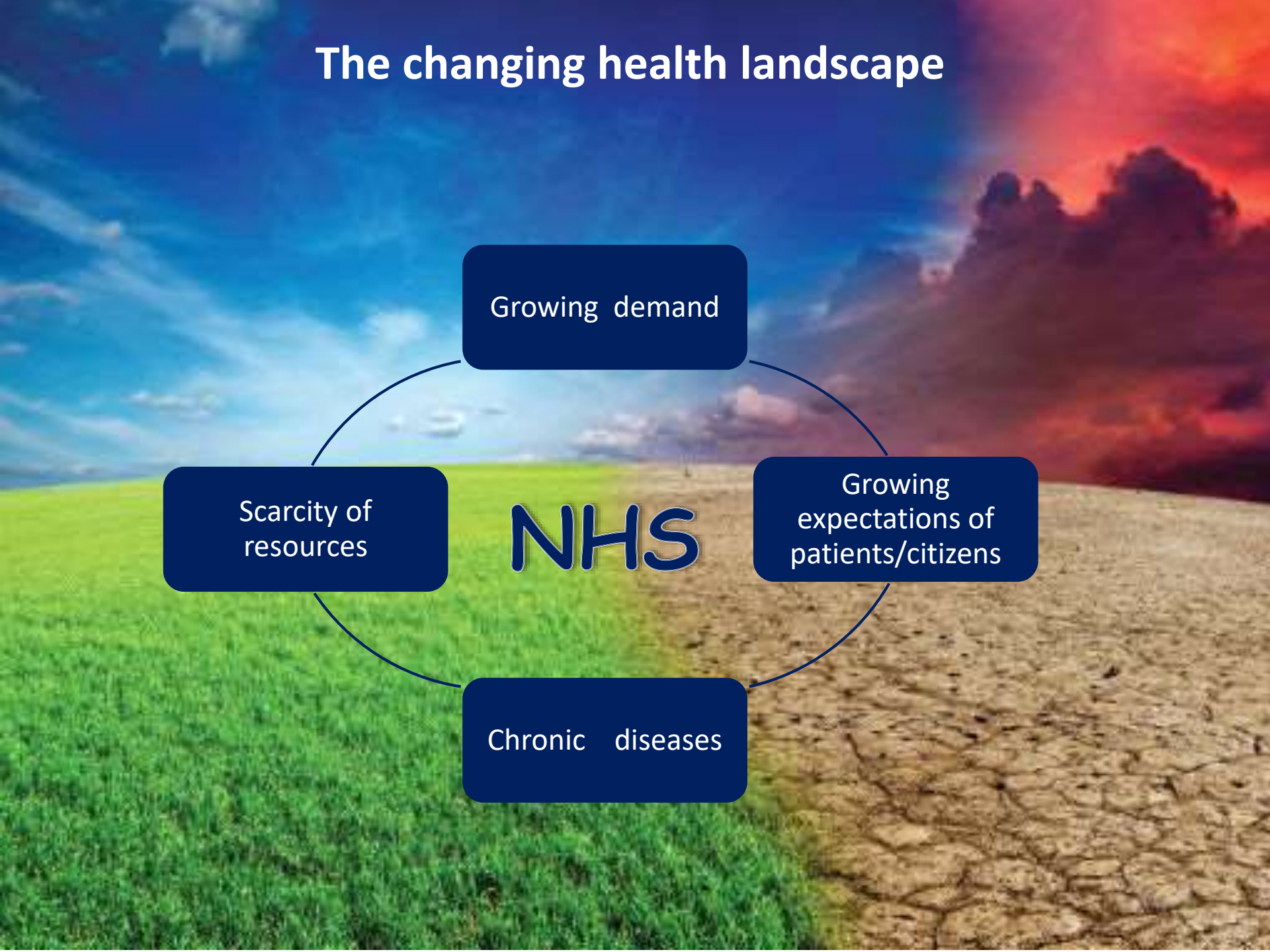
Prof. Walter Ricciardi
Presidente
Istituto Superiore di Sanità

La Sanità che cambia: L'innovazione a supporto dell'appropriatezza
Napoli, 17 febbraio 2017

Agenda

- Il mutato scenario della salute
- L'innovazione in sanità (e le tecnologie)
- La Valutazione delle tecnologie in sanità (HTA)
- HTA in cardiologia

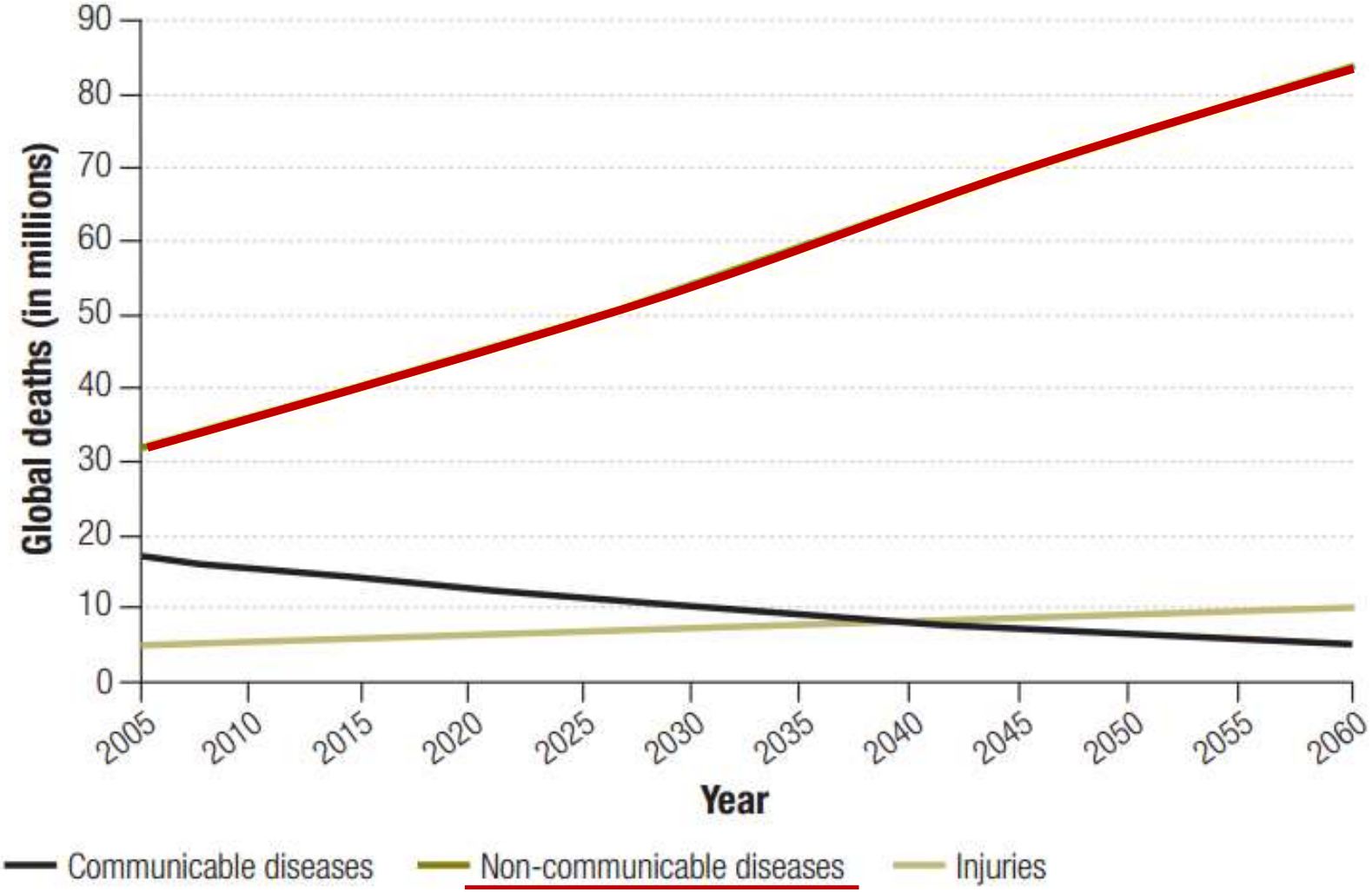
The changing health landscape



70s

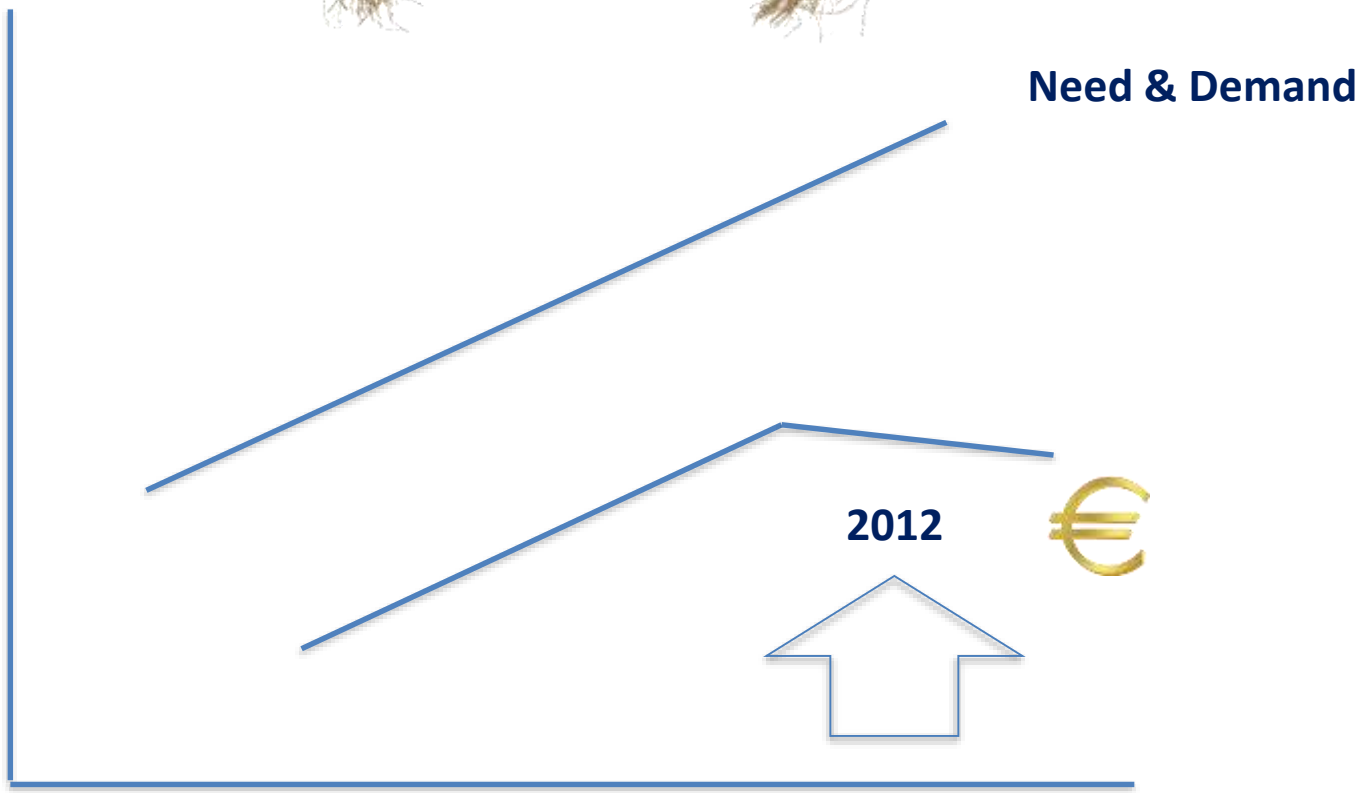
2016

Chronic diseases

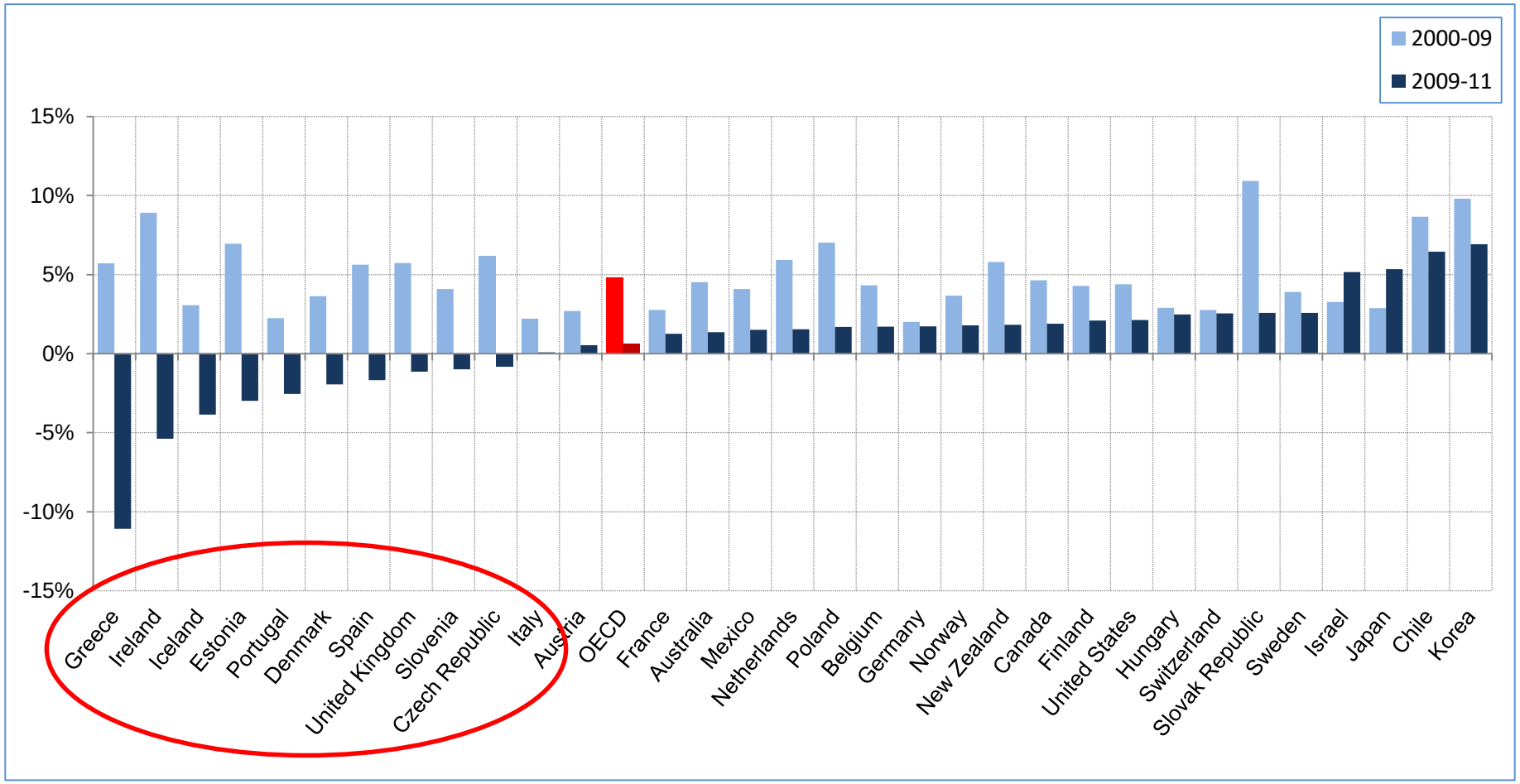


Source: Projections of global health outcomes from 2005 to 2060 using the International Futures integrated forecasting model. WHO bullettin 2011.

Scarcity of resources



Health expenditures



Fonte: OECD Health Data 2013

A complex challenge

As seen, health care providers are currently faced with an extremely complex challenge characterised by rising demand, increasing cost and insufficient funding.

Never as much as today have health care systems been interested and involved with the **potential benefits deriving from innovations**

Innovation is a key feature that organisations have to incorporate as a condition to offer sustainable and efficient solutions

Innovation

≠

INVENTION

Innovation refers to the use of a better and, as a result, novel idea or method

whereas

invention refers more directly to the creation of the idea or method itself

IMPROVEMENT

Innovation refers to the notion of doing something different

rather than

rather than doing the same thing better

Types of innovation

SUSTAINING	**An innovation that does not affect existing markets**	
	Continuous	An innovation that improves a product in an existing market in ways that customers are expecting.
	Discontinuous	An innovation that is unexpected, but nevertheless does not affect existing markets.

DISRUPTIVE	**An innovation that creates a new market or expands an existing market by applying a different set of values, which ultimately (and unexpectedly) overtakes an existing market**	
	Main features are:	a) improved health outcomes b) create new professional culture c) serve new groups or have new products/services (“create new markets”) d) create new players e) disorders old systems

Disruptive innovation in health care

The EXPH understands disruptive innovation in health care as:

“a type of innovation that creates new networks and new organisations based on a new set of values, involving new players, which makes it possible to health improve outcomes and other valuable goals, such as equity and efficiency. This innovation displaces older systems and ways of doing things”.

Tecnologie sanitarie

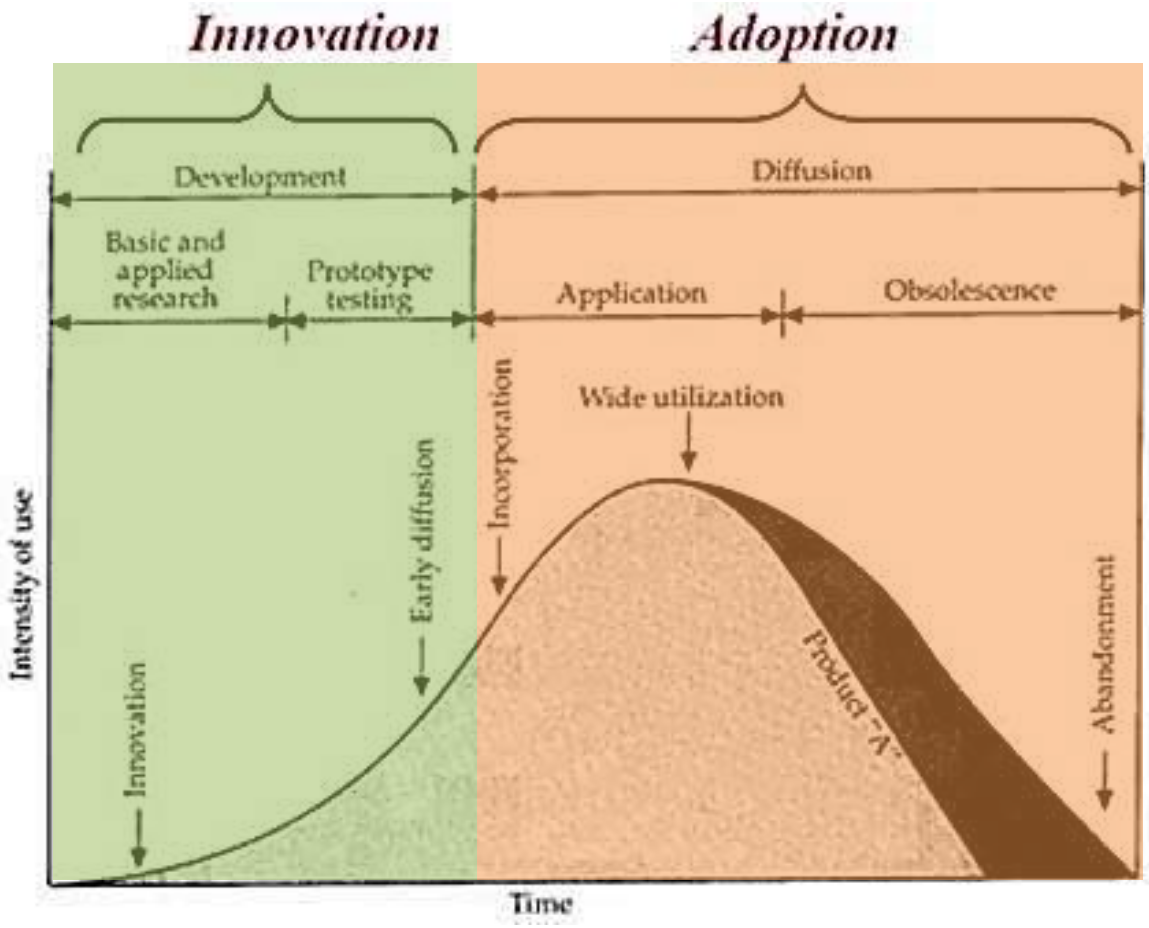
Una tecnologia sanitaria consiste nell'applicazione di conoscenze e competenze per risolvere un problema di salute e migliorare la qualità della vita. (World Health Organization-WHO)

Questa ampia categoria include:

1. Whole range of *interventions* which can be provided *within* the health-care system as it delivers health services. **Farmaci, dispositivi, strumenti diagnostici, procedure, percorsi clinici, …**
2. *Interventions applied* to the health-care system in order to organize service delivery, access, payment of providers, etc. **Interventi organizzativi, meccanismi di finanziamento…**
3. *Tools* for promoting and protecting health outside the health-care system – i.e. in the broader health system. **Politiche pubbliche in sanità, interventi di sanità pubblica, …**

Fonte: ***European Observatory on Health Systems and Policies.*** *Health Technology Assessment and Health Policy-Making in Europe, 2008.*

Ciclo di vita delle tecnologie sanitarie



PAHO WHO – Virtual campus for public health

Decisioni relative alle tecnologie sanitarie

Technology area	Decision types
Health-care interventions – interventions provided within the health-care system	Market approval Coverage Managing/organizing
Health-care reform – interventions applied to the health-care system	Managing/organizing
Health interventions – interventions outside the health-care system but in the broader health system	Public health decisions

APPROPRIATEZZA

European Observatory on Health Systems and Policies. Health Technology Assessment and Health Policy-Making in Europe, 2008.

L'innovazione e il processo decisionale *value-based*

Rapido sv
farmaci,
procedur

ITARIO

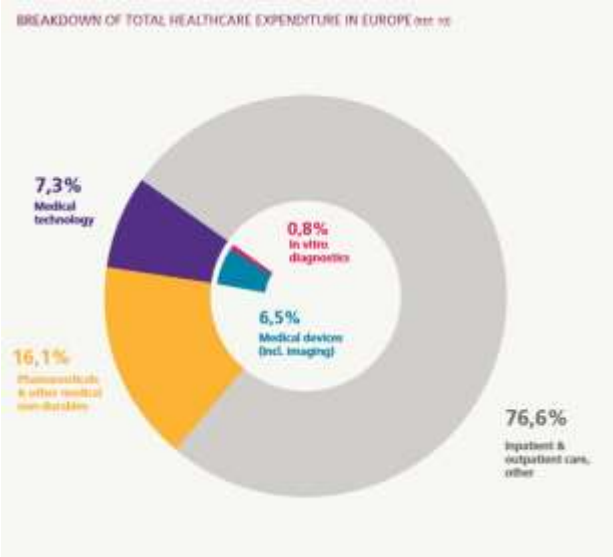
ili limitate

Diventa prioritario identificare il «VALORE» di ogni innovazione
così come il corrispondente rapporto costo-beneficio

MASSIMIZZARE I BENEFICI con il finanziamento disponibile

L'innovazione in sanità in Europa nel 2015

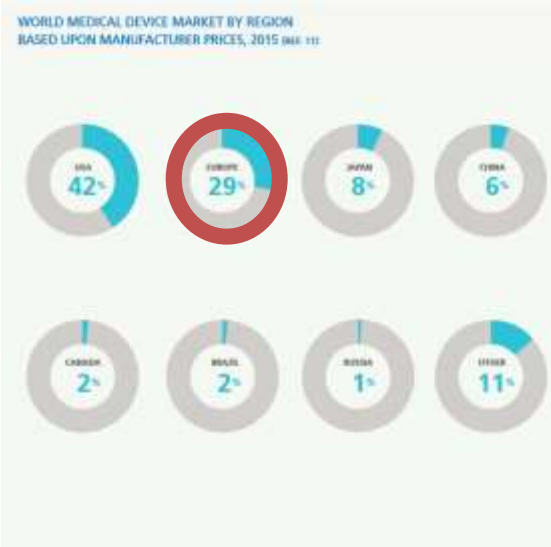
(esclusi i farmaci)

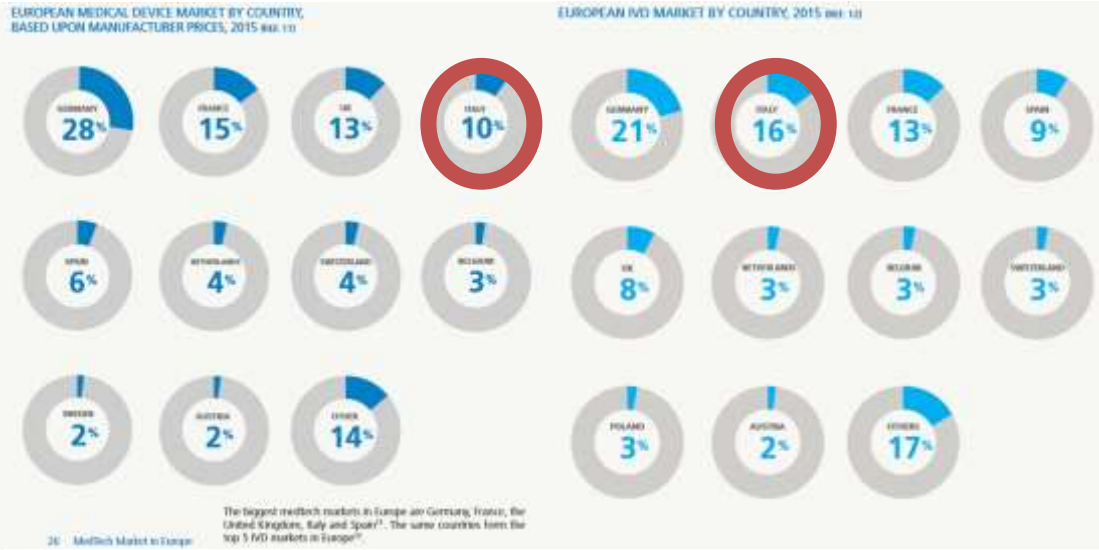


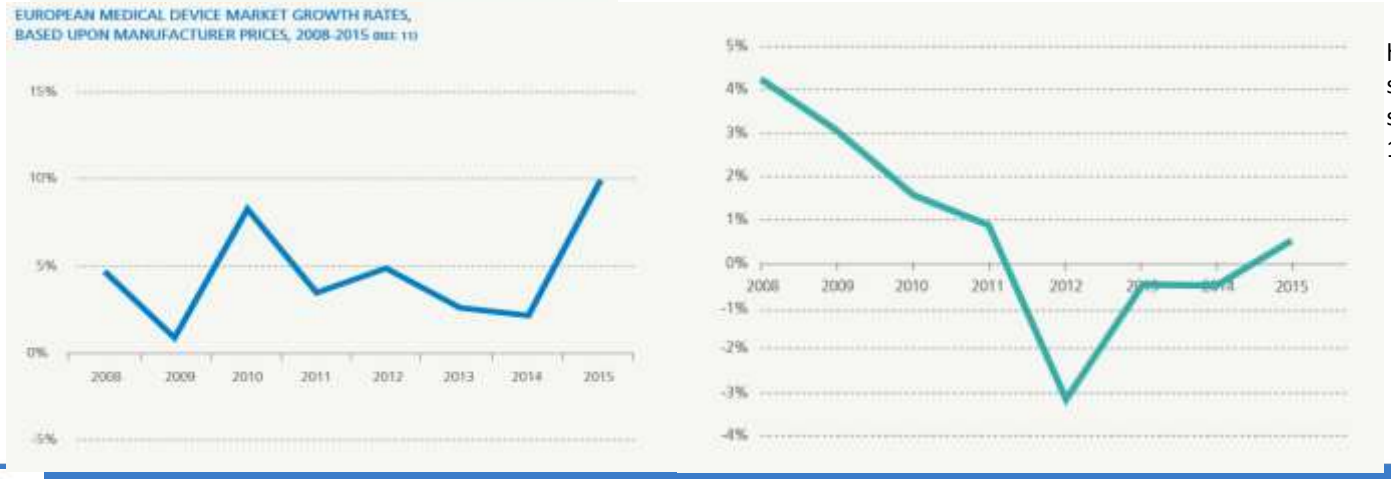
http://www.medtecheurope.org/sites/default/files/resource_items/files/MedTech_FactsFigures_2016.pdf

L'innovazione in sanità in Europa nel 2015

(esclusi i farmaci)

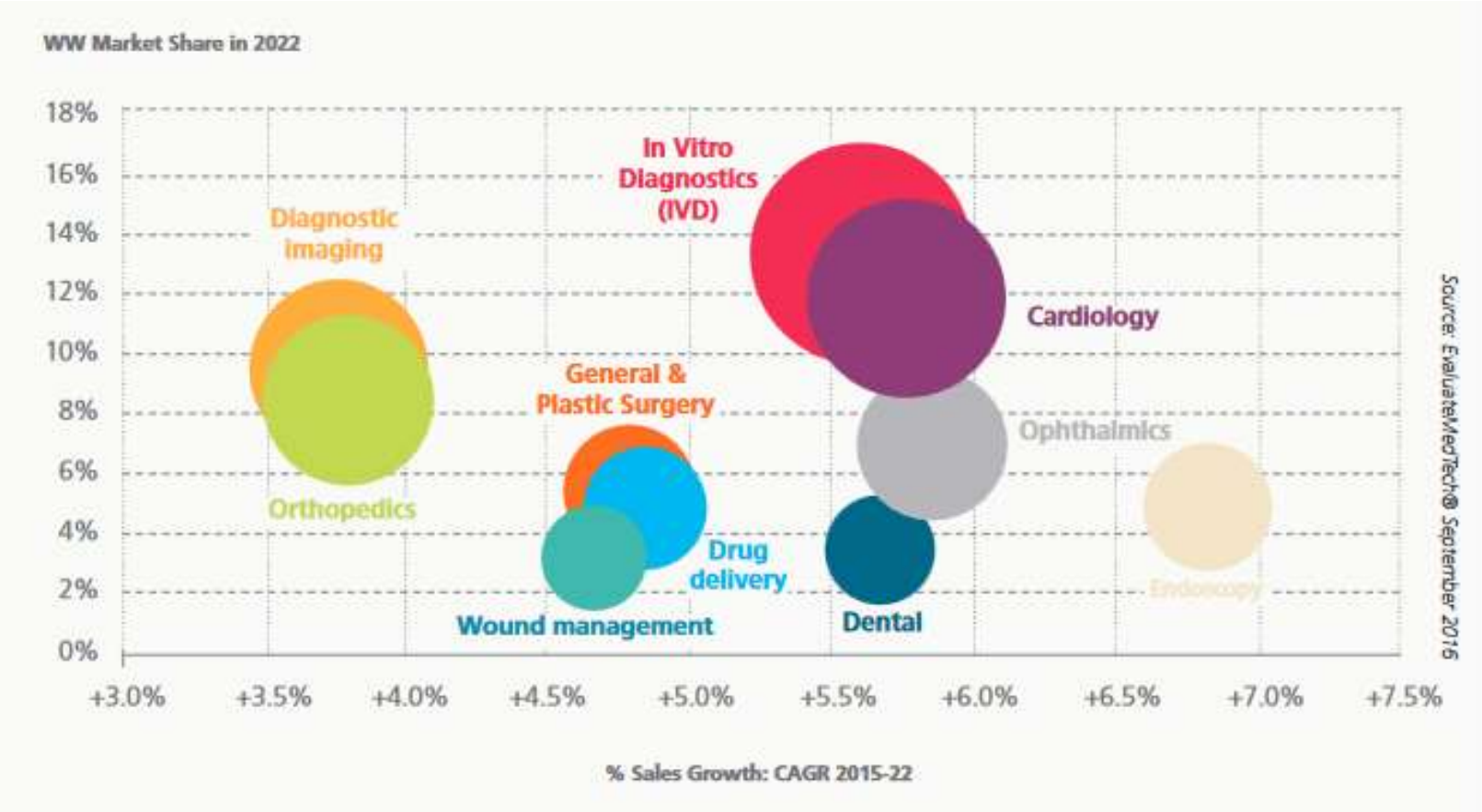






http://www.medtecheurope.org/sites/default/files/resource_items/files/MedTech_FactsFigures_2016.pdf

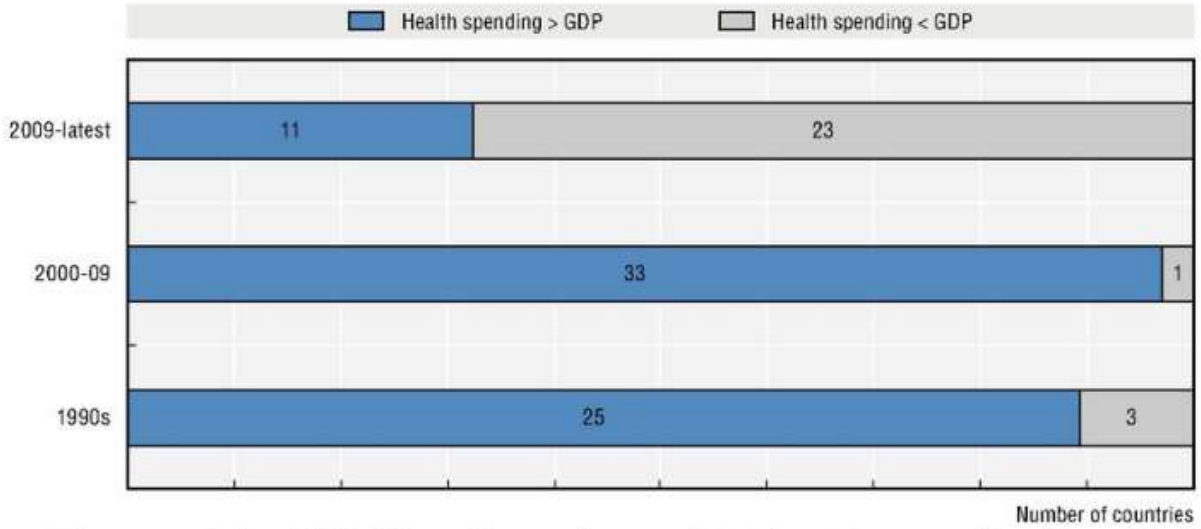
World Medical Technology market by area and sales growth, 2015-2022



EvaluateMedTech® World Preview 2016, Outlook to 2022 (October 2016)
http://www.evaluategroup.com

Crescita della spesa sanitaria e sostenibilità

Figure 1.3. **Growth in health spending as compared with GDP**



Note: The 11 countries in which health spending growth outpaced GDP since 2009 are Australia, Belgium, Finland, France, Hungary, Israel, Japan, Korea, Netherlands, New Zealand and Switzerland.

Source: OECD Health Statistics, http://dx.doi.org/10.1787/health-data-en.

Fonte: OECD (2015). *Fiscal Sustainability of Health Systems: Bridging Health and Finance Perspectives, OECD Publishing, Paris. DOI: http://dx.doi.org/10.1787/9789264233386-en*

Sostenibilità del Sistema Sanitario

OECD (2015). Fiscal Sustainability of Health Systems: Bridging Health and Finance Perspectives, OECD Publishing, Paris. *DOI: http://dx.doi.org/10.1787/9789264233386-en*

Fiscal Sustainability of Health Systems

BRIDGING HEALTH AND FINANCE PERSPECTIVES

continued to exceed inflation levels for decades. Four broad factors are commonly cited as determinants of health expenditure: new health technologies, changing demography, rising incomes and institutional characteristics of health systems (Gerdtham and Jonsson, 2000; Oxley and Morgan, 2009; Smith et al., 2009; IMF, 2010; Chernew and Newhouse, 2011; EC, 2012; De La Maisonneuve and Oliveira Martins, 2013a).

New health technologies extend the scope, range and quality of medical services. This increases health care costs, by offering better but more expensive care for complex illnesses, including those that may not have been previously treatable. The range of health interventions is extended and deepened, thereby increasing the use of health services overall. Conversely, new technologies can reduce costs through shortened morbidities or less costly treatment inputs.

OECD

OECD (2015). Fiscal Sustainability of Health Systems: Bridging Health and Finance Perspectives, OECD Publishing, Paris. *DOI: http://dx.doi.org/10.1787/9789264233386-en*

I problemi valore delle tecnologie e del loro utilizzo appropriato

«…This report estimates that from 20% to 40% of all health spending is currently wasted through inefficiency, and points to 10 specific areas where better policies and practices could increase the impact of expenditures, sometimes dramatically. Investing these resources more wisely can help countries move much closer to universal coverage without increasing spending…»

– Dr Margaret Chan, Director-General, World Health Organization, The World Report , 2010

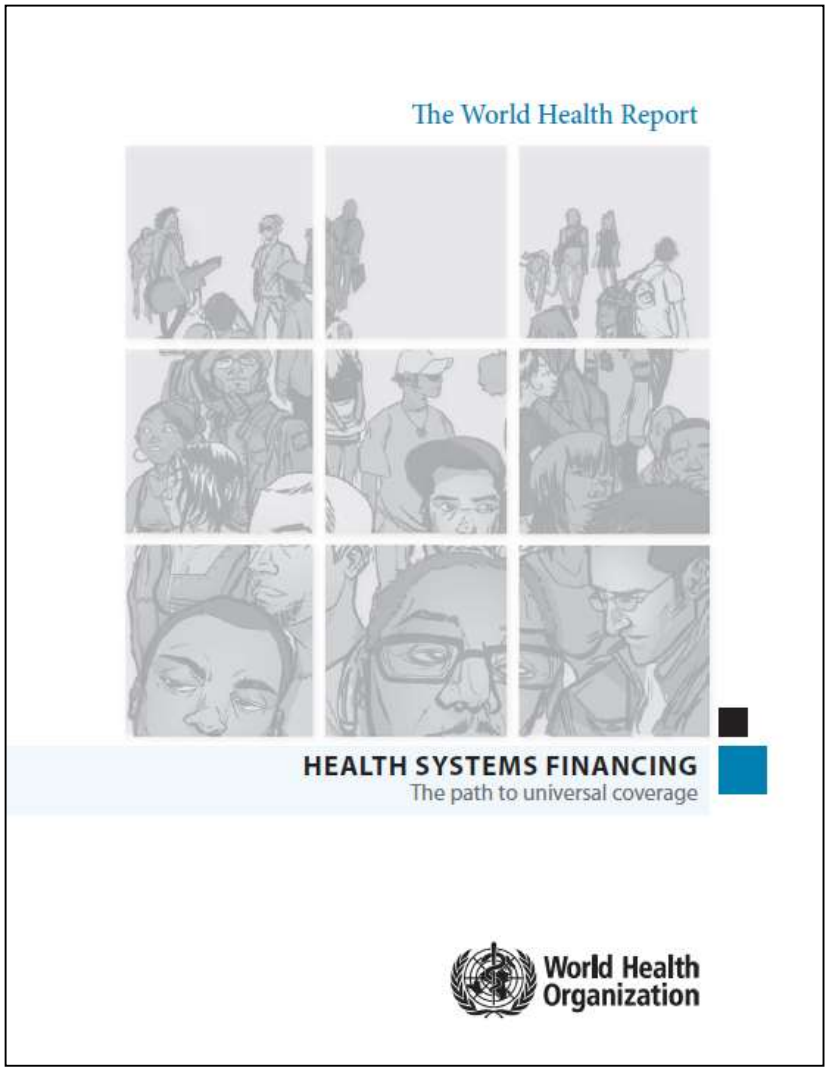


Table 4.1. **Ten leading sources of inefficiency**

Source of inefficiency	Common reasons for inefficiency	Ways to address inefficiency
1. Medicines: underuse of generics and higher than necessary prices for medicines	Inadequate controls on supply-chain agents, prescribers and dispensers; lower perceived efficacy/safety of generic medicines; historical prescribing patterns and inefficient procurement/distribution systems; taxes and duties on medicines; excessive mark-ups.	Improve prescribing guidance, information, training and practice. Require, permit or offer incentives for generic substitution. Develop active purchasing based on assessment of costs and benefits of alternatives. Ensure transparency in purchasing and tenders. Remove taxes and duties. Control excessive mark-ups. Monitor and publicize medicine prices.
2. Medicines: use of substandard and counterfeit medicines	Inadequate pharmaceutical regulatory structures/mechanisms; weak procurement systems.	Strengthen enforcement of quality standards in the manufacture of medicines; carry out product testing; enhance procurement systems with pre-qualification of suppliers.
3. Medicines: inappropriate and ineffective use	Inappropriate prescriber incentives and unethical promotion practices; consumer demand/expectations; limited knowledge about therapeutic effects; inadequate regulatory frameworks.	Separate prescribing and dispensing functions; regulate promotional activities; improve prescribing guidance, information, training and practice; disseminate public information.
4. Health-care products and services: overuse or supply of equipment, investigations and procedures	Supplier-induced demand; fee-for-service payment mechanisms; fear of litigation (defensive medicine).	Reform incentive and payment structures (e.g. capitation or diagnosis-related group); develop and implement clinical guidelines.
5. Health workers: inappropriate or costly staff mix, unmotivated workers	Conformity with pre-determined human resource policies and procedures; resistance by medical profession; fixed/inflexible contracts; inadequate salaries; recruitment based on favouritism.	Undertake needs-based assessment and training; revise remuneration policies; introduce flexible contracts and/or performance-related pay; implement task-shifting and other ways of matching skills to needs.
6. Health-care services: inappropriate hospital admissions and length of stay	Lack of alternative care arrangements; insufficient incentives to discharge; limited knowledge of best practice.	Provide alternative care (e.g. day care); alter incentives to hospital providers; raise knowledge about efficient admission practice.
7. Health-care services: inappropriate hospital size (low use of infrastructure)	Inappropriate level of managerial resources for coordination and control; too many hospitals and inpatient beds in some areas, not enough in others. Often this reflects a lack of planning for health service infrastructure development.	Incorporate inputs and output estimation into hospital planning; match managerial capacity to size; reduce excess capacity to raise occupancy rate to 80–90% (while controlling length of stay).
8. Health-care services: medical errors and suboptimal quality of care	Insufficient knowledge or application of clinical-care standards and protocols; lack of guidelines; inadequate supervision.	Improve hygiene standards in hospitals; provide more continuity of care; undertake more clinical audits; monitor hospital performance.
9. Health system leakages: waste, corruption and fraud	Unclear resource allocation guidance; lack of transparency; poor accountability and governance mechanisms; low salaries.	Improve regulation/governance, including strong sanction mechanisms; assess transparency/vulnerability to corruption; undertake public spending tracking surveys; promote codes of conduct.
10. Health interventions: inefficient mix/inappropriate level of strategies	Funding high-cost, low-effect interventions when low-cost, high-impact options are unfunded. Inappropriate balance between levels of care, and/or between prevention, promotion and treatment.	Regular evaluation and incorporation into policy of evidence on the costs and impact of interventions, technologies, medicines, and policy options.

Evidence-based decision making

Figure. Domains that influence evidence-based decision making. Source: Satterfield JM et al (2).

La valutazione delle tecnologie sanitarie svolge un ruolo fondamentale nel conformare le condizioni per l'implementazione dell'innovazione nei sistemi sanitari

World Health Organization. Health technology assessment of medical devices; 2011.

Agenda

- Tecnologie sanitarie e innovazione in sanità
- Valutazione delle tecnologie in sanità (HTA)
- HTA in cardiologia

Valutazione delle Tecnologie Sanitarie (Health Technology Assessment - HTA)

- Ricerca multidimensionale mirata ad informare il processo decisionale
- Valutazione sistematica delle proprietà e degli effetti di una tecnologia sanitaria
- Affronta gli effetti diretti e desiderati della tecnologia, così come le rispettive conseguenze indirette e indesiderate
- Condotta da gruppi interdisciplinari

Fonte; Health Technology Assessment International (HTAi) - INAHTA

La valutazione multidimensionale dell'HTA

Informazioni

Research

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

Decisions

MACRO
- Reimbursement
- Guidelines

MESO (HOSPITAL)
- Tech adoption

MICRO
- Clinical practice

Valore

Perché è importante il supporto dell'HTA nei processi decisionali

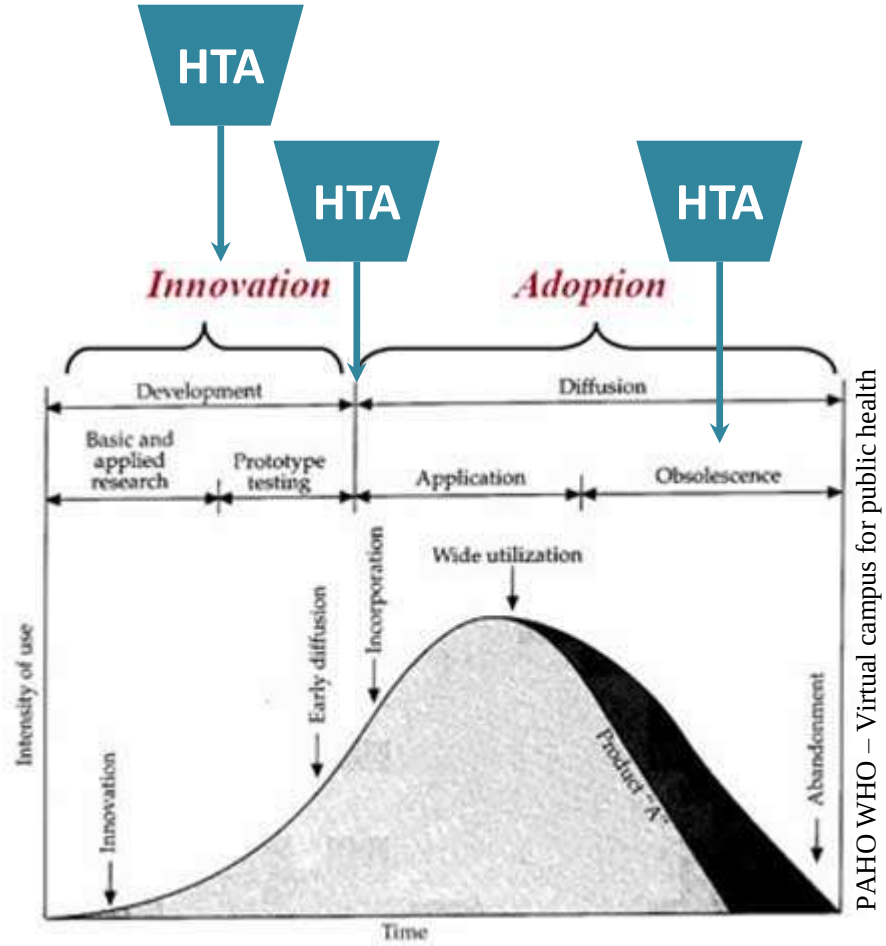
- Favorisce :
  - Ottimizzazione / trasparenza / legittimità del processo decisionale
  - Contestualizzazione delle conoscenze scientifiche
  - Equilibrio accesso / qualità / sostenibilità
  - Diffusione delle innovazioni efficacie rispondenti ai fabbisogno della popolazione

Making Decisions Transparent
https://leadershipmatters1213.wordpress.com/2015/06/22/making-decisions-transparent/

http://content.healthaffairs.org/content/24/1/151.long

HTA e innovazione

- L'HTA storicamente nasce per valutare l'innovazione tecnologica in ingresso ed ora anche in uscita dalla pratica clinica
- Una sempre maggiore tendenza è quella di anticipare il momento della valutazione per meglio governare l'introduzione dell'innovazione nel sistema sanitario



PAHO WHO – Virtual campus for public health

The Domains of the HTA Core Model®

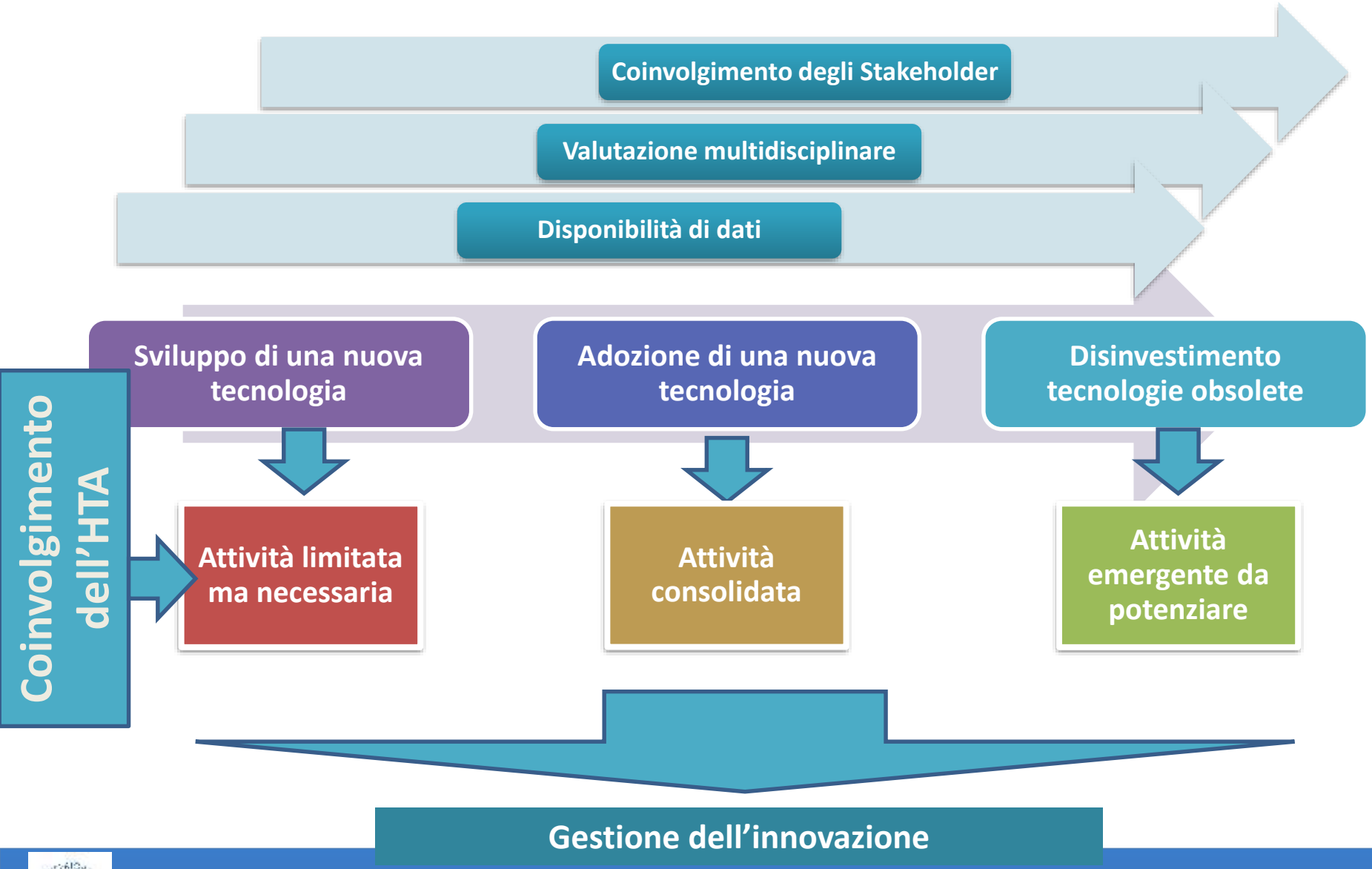
Su quale dominio impatta la tecnologia innovativa?

15

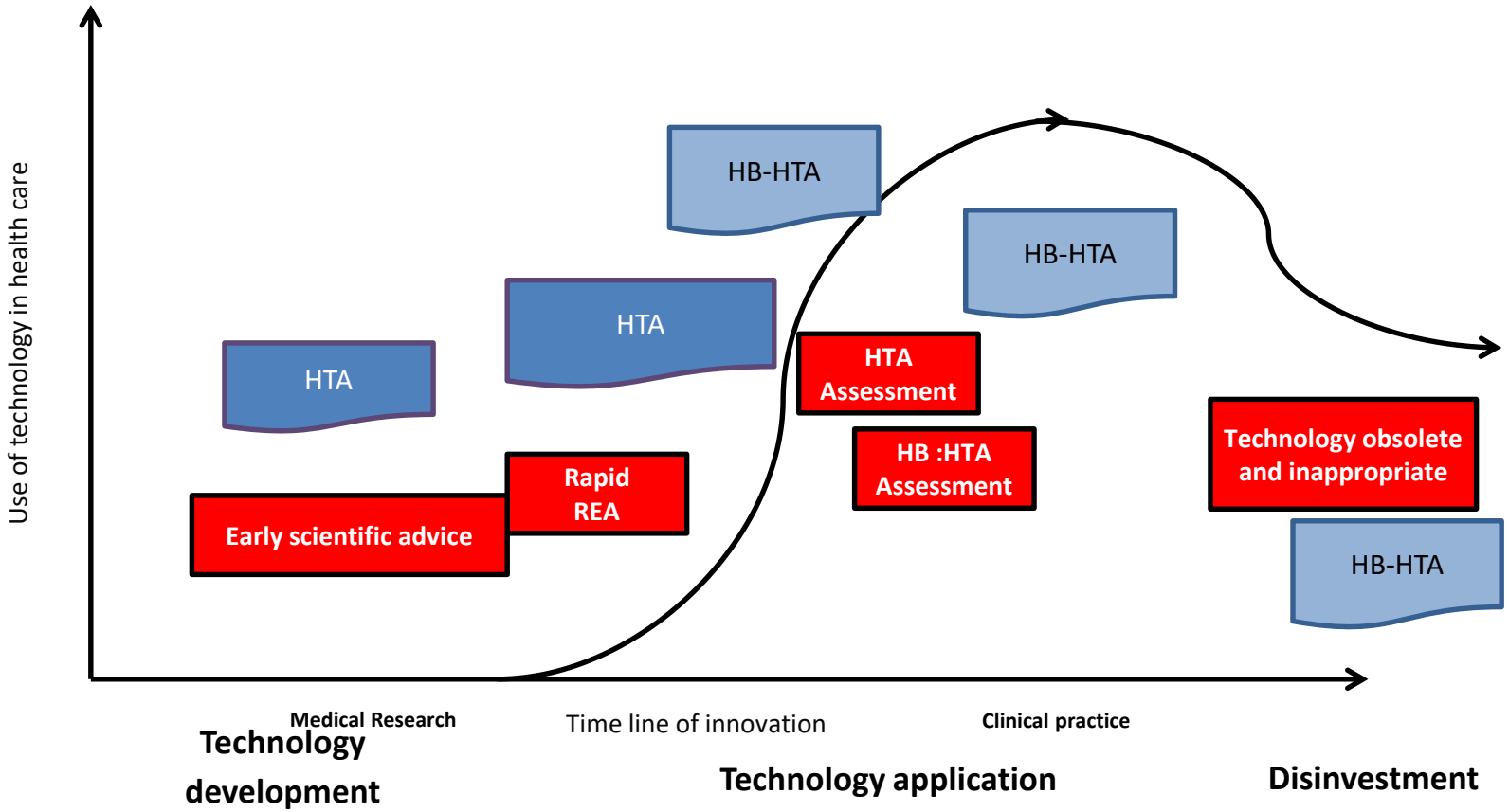
European network for Health Technology Assessment | JA2 2012-2015 | www.eunetha.eu

Al momento dell'immissione in commercio e quindi della disponibilità della tecnologia innovativa, già dovrebbe essere noto il corrispondente «valore»

Ambiti di applicazione dell'HTA



Health Technology Life-cycle & Assessment



Un processo continuo senza interruzione

HTA e Sistemi Sanitari

World Health Organization

EXECUTIVE BOARD
134th session
Agenda item 9.6

EB134/CONF./9
22 January 2014

Health intervention and technology assessment in support of universal health coverage

Draft resolution proposed by Malaysia and Maldives

The Executive Board,

Having considered the report on health intervention and technology assessment in support of universal health coverage,[1]

RECOMMENDS to the Sixty-seventh World Health Assembly the adoption of the following resolution:

The Sixty-seventh World Health Assembly,

PP1 Recalling World Health Assembly resolutions WHA52.19 on revised drug strategy, WHA58.33 on sustainable health financing, universal coverage and social health insurance, WHA60.16 on progress in the rational use of medicines, WHA60.29 on health technologies, WHA63.21 on WHO's role and responsibilities in health research, and WHA64.9 on sustainable health financing structures and universal coverage;

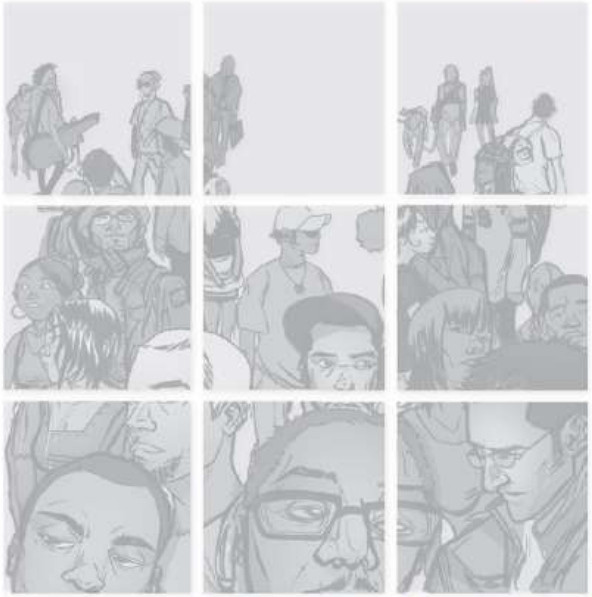
PP2 Recognizing the importance of evidence-based policy development and decision-making in health systems, including decisions on resource allocation, service system designs and translation of policies into practice, as well as reaffirming the roles and responsibilities of the World Health Organization in provision of support to strengthen information systems and health research capacity, and their utilization in Member States;

PP3 Noting that the efficient use of resources is a crucial factor in the sustainability of health systems' performance, especially when significant increases in access to essential medicines, including generic medicines, to medical devices and procedures, and to other healthcare interventions for prevention, diagnosis and treatment, rehabilitation and palliative care are pursued by Member States, as they move towards universal health coverage;

[1] Document EB134/30.

World Health Organization

The World Health Report



HEALTH SYSTEMS FINANCING
The path to universal coverage

World Health Organization

Applicare l'HTA in tutti i livelli organizzativi del Sistema Sanitario

"…AdHopHTA will support an adequate ecosystem where formal coordination among existing hospital-based HTA initiatives is fostered and liaison with national and regional HTA agencies can flourish…"

http://www.adhophta.eu/

http://cordis.europa.eu/result/rcn/184859_it.html

http://meeting.htai.org/events/htai-rome-2017/custom-136-1c2301d261504d679c3b63c233b5033a.aspx

L' HTA nel mondo

http://www.htai.org/

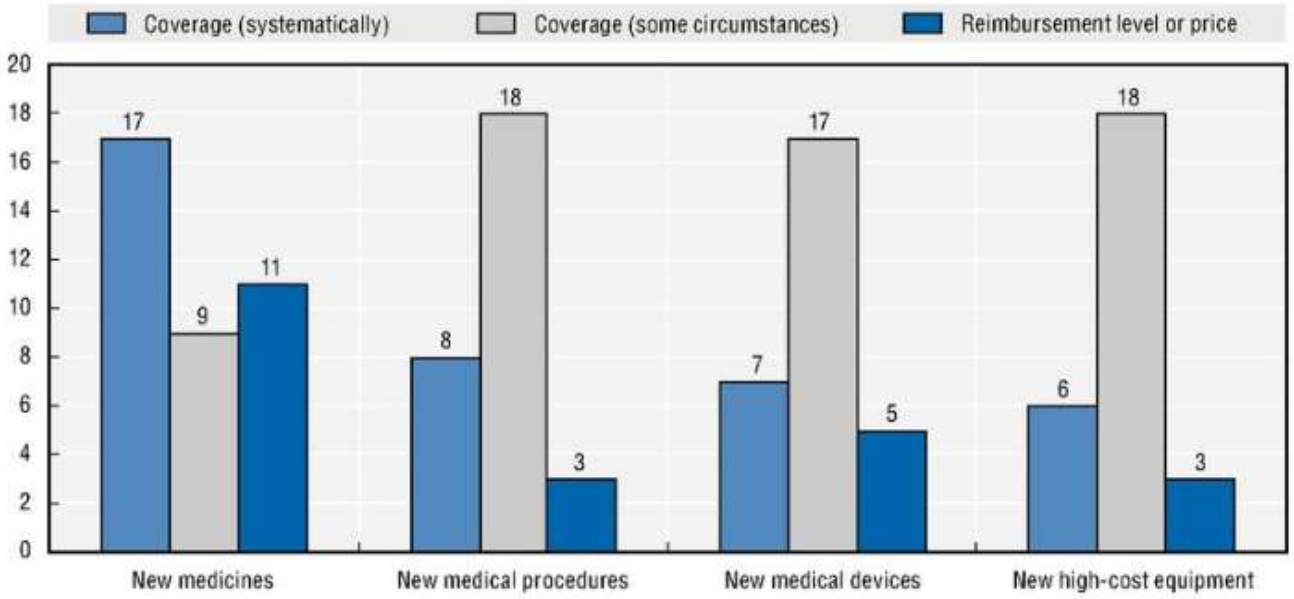
http://www.inahta.org/members/

The International Network of Agencies for Health Technology Assessment
Health care decision making requires the right evidence at the right time. Every day there are new health technologies available that can improve patient outcomes and refine health system efficiency. Health technology assessment (HTA) is a tool to review technologies and provide evidence of the value these technologies can deliver to patients and their families, health system stakeholders, and to society more broadly.
INAHTA is a network of 52 HTA agencies that support health system decision making that affects over 1 billion people in 33 countries around the globe. *With more than 2,100 staff and consultants working in the INAHTA network, there are clear benefits to connecting these agencies together to cooperate and share information about producing and disseminating HTA reports for evidence based decision making.*
INAHTA serves this purpose.

" Health Technology Assessment international (HTAi) is the global scientific and professional society for all those who produce, use, or encounter HTA. ***HTAi has members from over 65 countries and embraces all stakeholders, including researchers, agencies, policy makers, industry, academia, health service providers, and patients/consumers.*** *We are the neutral forum for collaboration and the sharing of leading information and expertise…"*

HTA come strumento per le decisioni di *coverage* e rimborsabilità

Figure 1.11. **Number of countries using HTA to make coverage decisions or set reimbursements**



HTA: Health technology assessment.

Source: OECD Health Systems Characteristics Survey, 2012.

StatLink http://dx.doi.org/10.1787/888933218655

OECD (2015). Fiscal Sustainability of Health Systems: Bridging Health and Finance Perspectives, OECD Publishing, Paris. *DOI: http://dx.doi.org/10.1787/9789264233386-en*

HTA come strumento per le decisioni di *coverage* e rimborsabilità

Institut national d'excellence en santé et en services sociaux Québec

NICE National Institute for Health and Care Excellence

Canadian Agency for Drugs and Technologies in Health — Agence canadienne des médicaments et des technologies de la santé

HTA in Europa (2011-2020)

La direttiva 2011/24/UE concernente l'applicazione dei diritti dei pazienti relativi all'assistenza sanitaria transfrontaliera prevede (art. 15) la realizzazione di una **rete europea per l'HTA**.

eunethta

HTA in Europa

The Domains of the HTA Core Model®

eunethta

SCOPE	DOMAINS
Rapid	1. Health problem and current use of technology
Rapid	2. Description and technical characteristics
Rapid	3. Safety
Rapid	4. Clinical effectiveness
Full	5. Costs and economic evaluation
Full	6. Ethical analysis
Full	7. Organisational aspects
Full	8. Social aspects
Full	9. Legal aspects

HTA in Europa (*timeline*)

Health Programme

- **2005** Call for project proposals
- **2009** Call for joint action
- **20011** Call for joint action
- **2014-2020** Financial support HTA

Advance-HTA

MedtechHTA — Methods for Health Technology Assessment of Medical Devices: a European Perspective

INTEGRATE-HTA

AdHopHTA

- **2012-2015** Other HTA Projects
- .....

eunethta

- **2006-2008** EUnetHTA Project
- **2009** EUnetHTA Collaboration
- **2010-2012** EUnetHTA JA1
- **2012-2015** EUnetHTA JA2
- **2016-2020** EUnetHTA Scientific and technical cooperation

Synergy

Legislation

- **2008-2011** Draft Cross Border Healthcare Directive. Article 15 on HTA network
- **2011-12** CBHC Directive now decided
- **2013** EU Cooperation on HTA Implementing Decision
- **2013+** HTA Network

DG R&I

- 2011 FP7-Health
- 2012-Innovation-1
- New methodologies for HTA
- Horizon 2020
- Calls
- Health Care

EU-HTA2020

HTA in Europa (2020-…)

Il futuro dell'HTA in Europa…la Commissione Europea progetta il futuro

Options:

1. **The status quo** – Voluntary cooperation (Joint Action) until 2020;
2. **Long-term voluntary cooperation** (financed by the EU beyond 2020);
3. **Cooperation on collection, sharing and use of common tools and data;**
4. **Cooperation on production of joint REA reports and their uptake** (cooperation on clinical/medical matters);
5. **Cooperation on production of joint Full HTA reports and their uptake** (cooperation on cost-effectiveness).

Period of consultation
From 21/10/2016 to 20/01/2017

HTA in Italia

http://www.tesoro.it/doc-finanza-pubblica/def/2013/documenti/NOTA_AGG_DEL_DEF_8-10-2013.pdf

- Patto per la Salute 2014-2016 (art. 26)
  - Articolo 26 Creazione di un modello istituzionale di HTA dei dispositivi medici
  - Articolo 27 Valutazione nazionale dei medicinali secondo la metodologia dell'Health Technology Asses
  - Articolo 28 - Cabina di regia per il monitoraggio del patto

- Aggiornamento Documento di Economia e Finanza DEF 2013
  - l sistema sanitario dovrà cioè essere sempre più 'selettivo', occorrendo in particolare ridisegnare il perimetro dei LEA e adottare l'approccio del c.d. Health Technology Assessment (HTA), al fine di identificare le opzioni assistenziali dimostratesi non solo maggiormente costo - efficaci ma anche preferite da pazienti e cittadini, in modo da assicurare, a parità di risorse disponibili, il massimo valore possibile in termini di salute.
- LEGGE 23 dicembre 2014, n. 190 - Disposizioni per la formazione del bilancio annuale e pluriennale dello Stato (Legge di stabilità 2015)
  - Art. 587. In attuazione delle disposizioni contenute nella direttiva 2011/24/UE del Parlamento europeo e del Consiglio, del 9 marzo 2011, e per promuovere il razionale uso dei dispositivi medici sulla base del principio costo-efficacia, il Ministero della salute, avvalendosi dell'Agenzia nazionale per i servizi sanitari regionali (AGENAS) e dell'Agenzia italiana del farmaco (AIFA), per gli aspetti di relativa competenza, al fine di garantire l'azione coordinata dei livelli nazionale, regionali e delle aziende accreditate del Servizio sanitario nazionale per il governo dei consumi dei dispositivi medici, a tutela dell'unitarietà del sistema, della sicurezza nell'uso della tecnologia e della salute dei cittadini, con proprio decreto, provvede, senza nuovi o maggiori oneri per la finanza pubblica:
  - a) definire, attraverso l'istituzione di una Cabina di regia, con il coinvolgimento delle regioni, dell'AGENAS e dell'AIFA, sentiti i rappresentanti dei pazienti, dei cittadini e dell'industria, anche in conformità alle indicazioni del Piano sanitario nazionale, le priorità ai fini assistenziali;
  - b) individuare, per la predisposizione dei capitolati di gara, i requisiti indispensabili per l'acquisizione dei dispositivi medici a livello nazionale, regionale, intra-regionale o aziendale, e indicare gli elementi per la classificazione dei dispositivi medici in categorie omogenee, garantendo, al fine delle esigenze terapeutiche, più tipologie per i presidi utilizzati per la terapia domiciliare delle patologie croniche adattabili ai diversi tipi di pazienti, fatto salvo il principio della valutazione costo-efficacia, e per l'individuazione dei prezzi di riferimento;
  - c) istituire una rete nazionale, coordinata dall'AGENAS, di collaborazione tra le regioni per la definizione e per l'utilizzo di strumenti per il governo dei dispositivi medici e per Health Technology Assessment (HTA), denominato «Programma nazionale di HTA dei dispositivi medici».
  - Art. 588. Per garantire un equo e omogeneo accesso dei pazienti a tutti i medicinali, con particolare riguardo ai medicinali innovativi o di eccezionale rilevanza terapeutica, l'AIFA predispone, a supporto del Ministero della salute e delle regioni, valutazioni di HTA volte a caratterizzare e individuare i percorsi farmaco-terapeutici in grado di garantire l'impiego efficiente e costo-efficace delle risorse disponibili. La funzione di cui al primo periodo si inserisce nell'ambito delle attività previste ai fini dell'attuazione della direttiva 2011/24/UE del Parlamento europeo e del Consiglio, del 9 marzo 2011, attraverso il Network permanente per l'Health Technology Assessment (HTA Network), anche, per quanto concerne i medicinali, nel perseguimento degli obiettivi previsti dalla medesima direttiva, a supporto della Cabina di regia istituita presso il Ministero della salute e delle indicazioni del Piano sanitario nazionale.

http://www.governo.it/sites/governo.it/files/Conferenza_SR.pdf

LEGGE 23 dicembre 2014, n. 190

Disposizioni per la formazione del bilancio annuale e pluriennale dello Stato (legge di stabilita' 2015). (14G00203) (GU Serie Generale n.300 del 29-12-2014 - Suppl. Ordinario n. 99)

note: Entrata in vigore del provvedimento: 1/1/2015, ad eccezione della disposizione di cui al comma 16 che entra in vigore l'1/7/2015, delle disposizioni di cui ai commi 281, 282, 283, 395, 408, 409, 410, 411, 412, 413, 487, 513, 514, 515, 516, 517, 518, 519, 520, 521, 522, 523 che entrano in vigore il 29/12/2014, dal comma 503 che entra in vigore il 29/12/2014 e dai commi 692, 693, 694, 695, 696, 697, 698, 699 e 700 che entrano in vigore il 30/12/2014

HTA in Italia

- **Legge di stabilità 2015** (art. 256-257) in attuazione delle disposizioni contenute nella direttiva 2011/24/UE

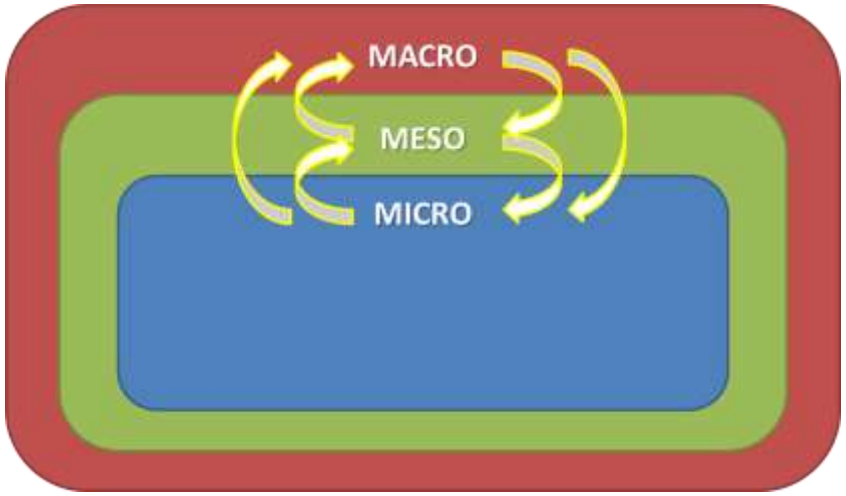
  a) **Cabina di regia per l'HTA**, con il coinvolgimento di tutti gli *stakeholder*, per definire le priorità ai fini assistenziali;

  b) Individuazione di requisiti per l'acquisizione dei dispositivi medici a livello nazionale, regionale, intra-regionale o aziendale; classificazione dei dispositivi medici; individuazione dei prezzi di riferimento;

  c) Rete nazionale di collaborazione tra le regioni: «**Programma nazionale di HTA dei dispositivi medici**».

HTA in Italia

Un sistema in costruzione e da perfezionare per avere un reale impatto sui processi decisionali a tutti i livelli e sulla pratica clinica



agenas

Agenzia Italiana del Farmaco
AIFA

ISTITUTO SUPERIORE DI SANITÀ

sihta
società italiana di health technology assessment

Agenda

- Tecnologie sanitarie e innovazione in sanità
- Valutazione delle tecnologie in sanità (HTA)
- HTA in cardiologia

Perché applicare le logiche dell'HTA anche in cardiologia?

- Dal punto di vista epidemiologico, le malattie cardiovascolari sono **la principale causa di mortalità** in quasi tutti gli Stati membri della UE.

- Queste malattie rappresentano circa il 40% dei decessi nell'UE nel 2013 (seguite dal cancro, 26%).

OECD. Health at a Glance: Europe **2016**, OECD Publishing. *dx.doi.org/10.1787/9789264265592-en*

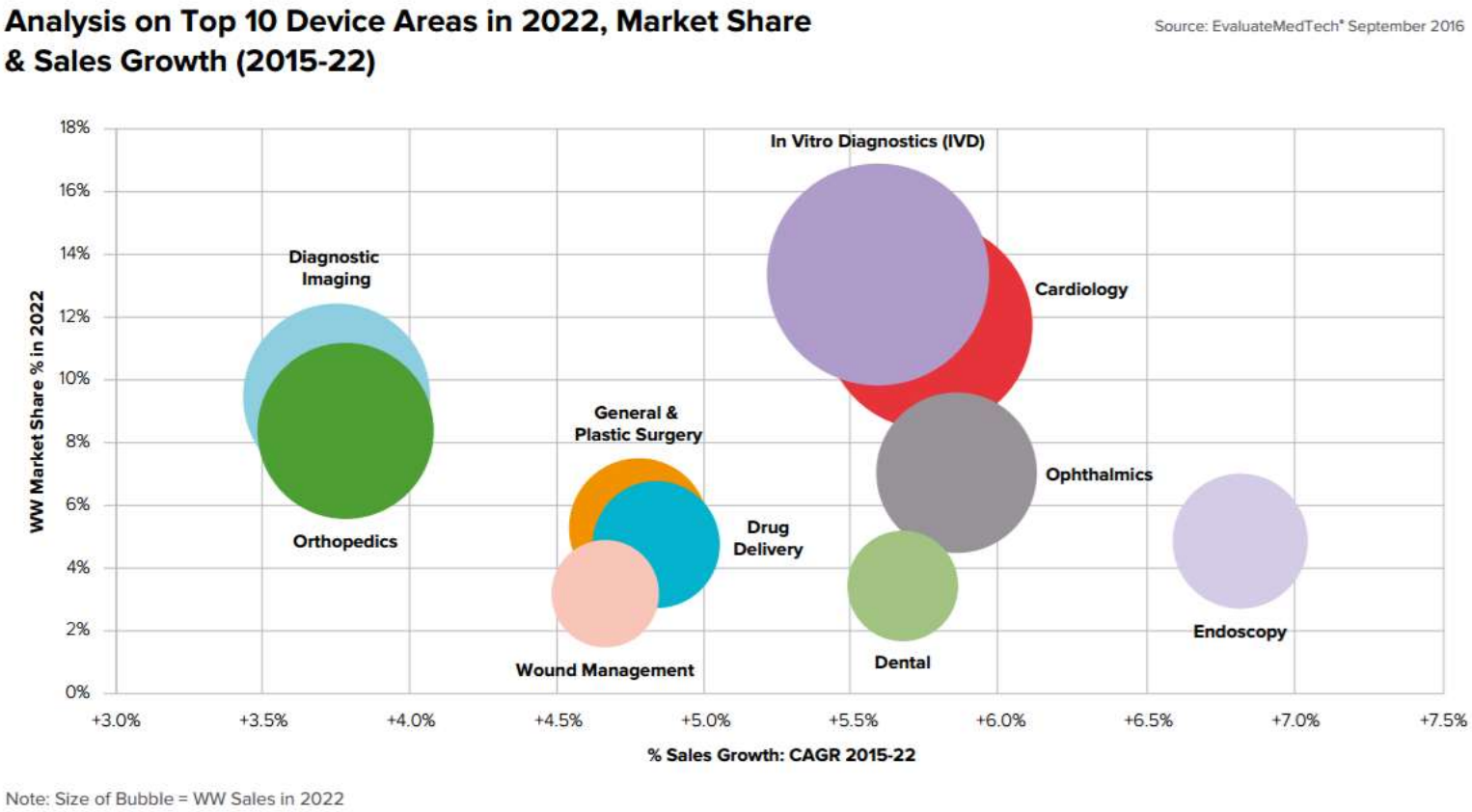
Costo delle malattie cardiovascolari, coronariche e cerebrovascolari

Table 12.1 Total cost of CVD, CHD and cerebrovascular diseases, 2009, EU

	CVD		CHD		Cerebrovascular disease	
	€ thousands	% of total	€ thousands	% of total	€ thousands	% of total
Direct health care costs	106,156,940	54%	19,867,875	33%	19,102,868	50%
Productivity loss due to mortality	26,963,326	14%	12,014,249	20%	4,812,409	13%
Productivity loss due to morbidity	18,873,665	10%	5,530,552	9%	3,329,282	9%
Informal care costs	43,560,202	22%	22,812,144	38%	11,115,782	29%
Total	**195,554,133**		**60,224,820**		**38,360,340**	

European Heart Network and European Society of Cardiology.
European Cardiovascular Disease Statistics, 2012 Edition.

Proporzione della spesa (dispositivi medici)



EvaluateMedTech. World Preview 2016, Outlook to 2022. 2016.

HTA in cardiologia

Esempi delle diverse tecnologie valutabili tramite strumenti di HTA:

Specific technology (tool)	Area	Type
Aspirin, lipid-lowering drugs, ACE inhibitors	Intervention provided in health-care services	Drug
Stent/stenting Coronary artery bypass grafting (CABG)	Intervention provided in health-care services	Device/ procedure
Rehabilitation programme Educational interventions	Intervention provided in health-care services	Multifaceted intervention
Disease management programme for CVD	Intervention applied to the health-care system (organization of service provision)	Multifaceted intervention
Pay for performance (e.g. targeting higher prescription of aspirin for CVD)	Intervention applied to the health-care system (payment of providers)	Policy
Smoking ban	Intervention outside health-care system	Policy

European Observatory on Health Systems and Policies. Health Technology Assessment and Health Policy-Making in Europe, 2008.

Determinare il «valore» delle tecnologie sanitarie in cardiologia

Cosa deve essere nei LEA? Cosa deve essere garantito? Come rendere il Servizio Sanitario Sostenibile?

	Biomonitor 2	Medtronic Reveal LINQ	Medtronic Reveal® XT	St. Jude Confirm
Size (Dimension)	88,4 x 15,2x 6,2mm	44,8 x 7,2 x 4 mm	62 x 19 x 8 mm	56.3 x 18.5 x 8 mm
Size (Volume)	5 cc	1 cc	9 cc	6,5 cc
10,1	26 g	2,5 g	15 g	12 g
Arrhythmia Detection	Asystole, bradyarrhythmia VT/FVT, AT/AF	Asystole, bradyarrhythmia VT/FVT, AT/AF	Asystole, bradyarrhythmia VT/FVT, AT/AF	Asystole, bradyarrhythmia VT/FVT
Insertion	Iniettabile	Iniettabile	Creazione tasca e incisione cutanea di 2 cm	Creazione tasca e incisione cutanea di 2 cm
R-wave Sensing	Tracking threshold, noise reversion, over range detector reduce the number of sensed P-waves and T-waves	Tracking threshold, noise reversion, over range detector reduce the number of sensed P-waves and T-waves	Tracking threshold, noise reversion, over range detector	Tracking threshold, noise inhibition -Sense Ability
Extended Diagnostics	AT/AF burden, HRV, Patient Activity, Day/Night HR, Cardiac Compass	AT/AF burden, HRV, Patient Activity, Day/Night HR, Cardiac Compass	AT/AF burden, HRV, Patient Activity, Day/Night HR, Cardiac Compass	n.a.
Longevity	4 years	3 years	3 years	3 years
Event Storage (Memoria totale)	35,8 min	57 minutes	49.5 minutes	48 minutes
Loop Storage (Memoria loop - attivazione manuale)	7,5 min per evento: • 7 min prima dell'attivazione • 0,5 min dopo l'attivazione	7,5 – 15 min pre	7,5 min per evento: • 6,5 min prima dell'attivazione • 1 min dopo l'attivazione per eventi auto attivati	1-4 min pre + 1 min post
Patient Assistant	Marking symptoms and query collect and trend data continuously and wirelessly	Marking symptoms and query collect and trend data continuously and wirelessly.	Marking symptoms and query	Marking symptoms
Remote monitoring	Home monotoring daily transmission	Carelink home monitoring	Carelink home monitoring	transTelephonic monitoring

- Incremento di costo rispetto allo standard di circa 800-1200 Euro
- Rimborso previsto per procedura DRG 517 Euro 1562

Sulla base delle considerazioni di cui sopra risultano evidenti i seguenti punti:

- gli studi clinici non evidenziano differenze in termini di outcome clinici;
- il …… è tra i loop recorder quello con dimensioni minori

«Valore» delle tecnologie sanitarie in cardiologia

Table 2: Accounting for the Decline in U.S. Deaths from Coronary Disease: 1980-2000

Number of Deaths Prevented/ Postponed	Percent of Total Mortality Decline	Type of Medical/Surgical Treatment or Risk Factor Change
209,000	61.2%	Health risk reduction: Declines in prevalence of smoking, hypertension, cholesterol, physical inactivity
-59,370	-17.4%	Health risk increase: Rise in prevalence of body-mass index (BMI) and diabetes
149,630	***43.8%***	***Subtotal: Deaths prevented or postponed because of health risk factors***
83,285	21.9 %	Category I: Aspirin, heparin, warfarin, anti-hypertensives, β-blockers, diuretics
45,225	13.2%	Category I+: Statins, ACE Inhibitors, IIb/IIIa antagonists, thrombolytics
30,830	11.5%	Category II: Angioplasty/stents, bypass surgery (CABG), cardio-pulmonary resuscitation, cardiac rehabilitation
159,340	***46.6%***	***Subtotal: Deaths prevented or postponed by medical/surgical treatments***
32,775	9.6%	Unexplained by model
341,745	***100.0%***	***Total deaths prevented or postponed***

Source: Ford, et al., 2007.

HTA in cardiologia

Valvular heart disease

openheart

Conceptual model for early health technology assessment of current and novel heart valve interventions

Simone A Huygens,[1,2,3] Maureen P M H
Ad J J C Bogers,[1] Carlijn V C Bouten,[4] S
Peter P T de Jaegere,[6] Arie Pieter Kappe
Nicolas M D A van Mieghem,[6] Michel I M
Johanna J M Takkenberg[1]

- Emerging technological advances in the field of heart valve interventions are often accompanied with high research and development costs. To avoid unsuccessful implementation of new technologies in clinical practice, it is essential to investigate the potential cost-effectiveness of new technologies before implementation in clinical practice using early health technology assessment (HTA) techniques. Early HTA investigating particular requirements for novel heart valve interventions to become cost-effective in the future is not yet available.
- An example of an emerging technological advance is tissue-engineered heart valves. In

Fonte: Huygens SA et al. Conceptual model for early health technology assessment of current and novel heart valve interventions. Open Heart. 2016 Oct 14;3(2):e000500. eCollection 2016.

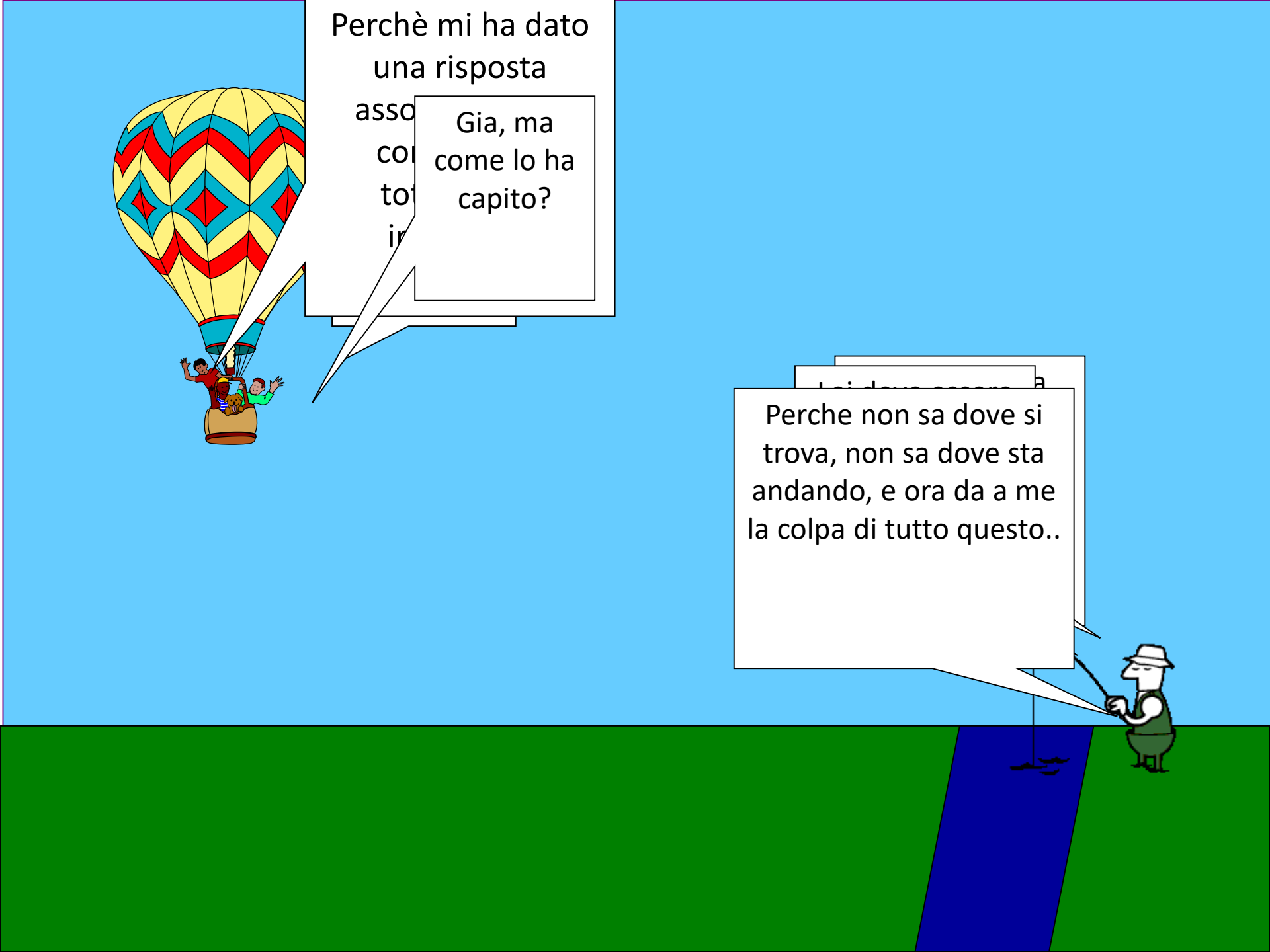
Conclusioni

- La sfida è quella di assicurare che ogni aumento della spesa contribuisca alla sostenibilità e offra un buon rapporto costo-beneficio

Conclusioni

- L'HTA mira a informare i decisori collegando innovazione, fabbisogno di salute, sostenibilità ed equità.
- L'HTA può contribuire al processo decisionale in tutti i livelli organizzativi del Sistema Sanitario.
- È fondamentale creare un «ecosistema di HTA» che permetta l'integrazione adeguata di tutti i livelli (internazionale, nazionale, regionale, locale, individuale) per ottimizzare l'impatto dell'HTA.

Una sfida per il nostro Paese se non vuole rinunciare ai principi di universalità ed equità per garantire il Diritto alla Salute sancito dalla Costituzione


Perchè mi ha dato una risposta asso
co
to
ir
Gia, ma come lo ha capito?
Perche non sa dove si trova, non sa dove sta andando, e ora da a me la colpa di tutto questo..

Grazie per l’attenzione