

- Lo scenario
- L'HTA
- La teoria
- La pratica
- Il rischio
- Le proposte

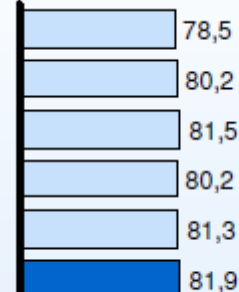
Il sistema sanitario italiano produce buoni risultati di salute a fronte di limitata soddisfazione dei pazienti e bassa protezione finanziaria



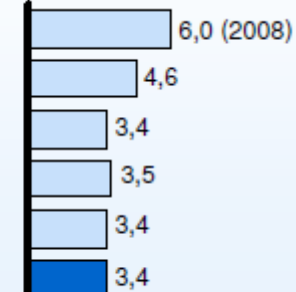
Health Status

2011

Aspettativa di vita
alla nascita
Anni



Mortalità infantile
Per 1.000 nati vivi



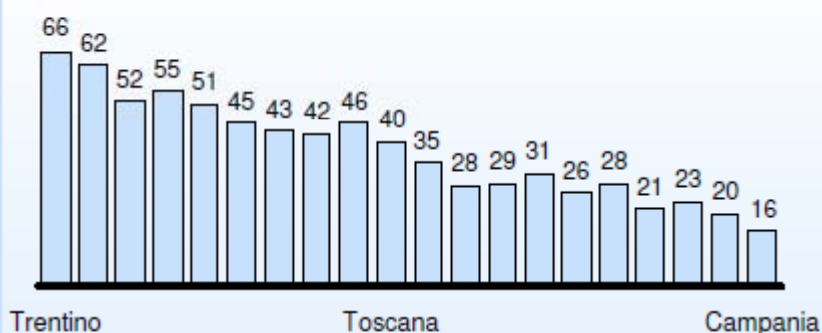
1 Media di persone molto soddisfatte di assistenza medica, infermieristica e servizi igienici



Soddisfazione pazienti



Media di assistenza medica e servizi igienici¹, 2010

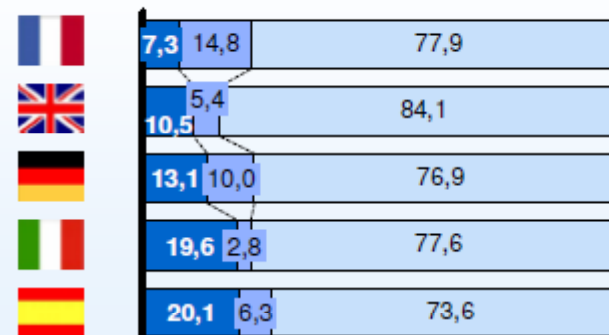


Protezione finanziaria

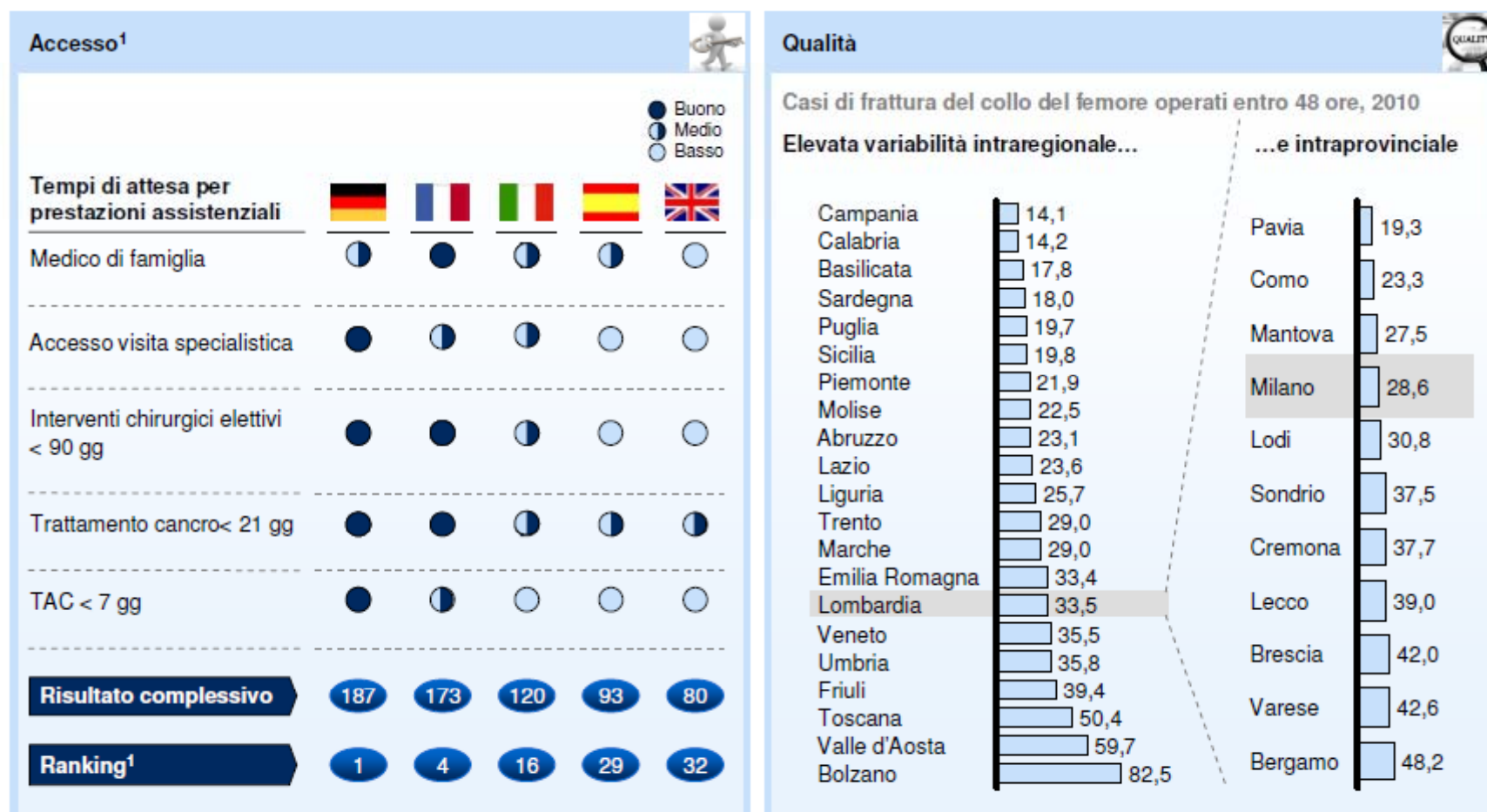


2009

■ OOP ■ Fondi ed assicurazioni ■ Spesa pubblica



Le condizioni di accesso, non in linea con le migliori esperienze internazionali, e la qualità soffrono di elevata variabilità

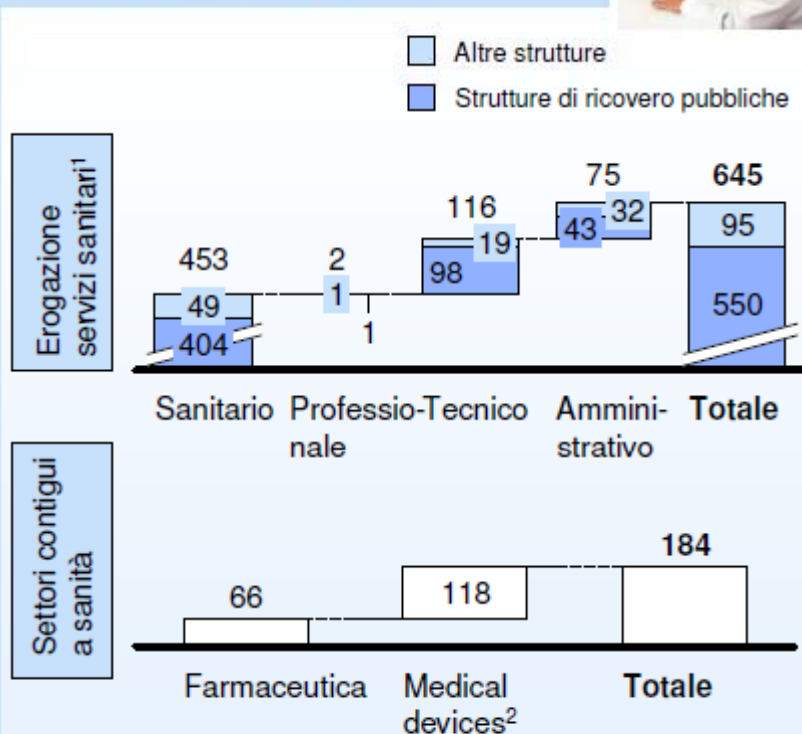


¹ Oltre 33 Paesi europei monitorati da Health Consumer Powerhouse

Il comparto sanità in senso lato impiega un elevato numero di risorse, in particolare nell'erogazione dei servizi sanitari e alloca ~9,5% del PIL

Numero di dipendenti (migliaia), 2009

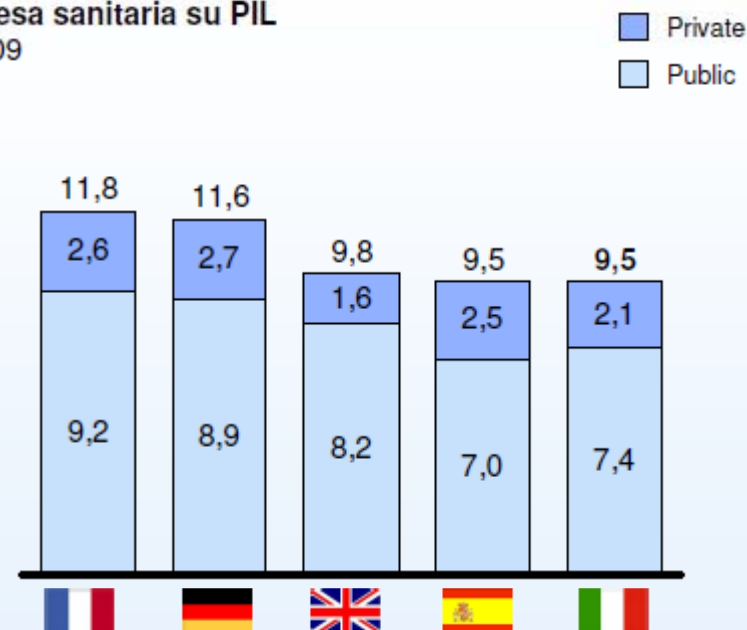
Risorse impiegate nel settore



Incidenza della spesa



Spesa sanitaria su PIL 2009



¹ Include i dipendenti del SSN (i.e., i dipendenti pubblici di aziende sanitarie locali, aziende ospedaliere e aziende ospedaliere integrate con università)

² Include anche fabbricazione di prodotti di elettronica e ottica, apparecchi di misurazione e orologi

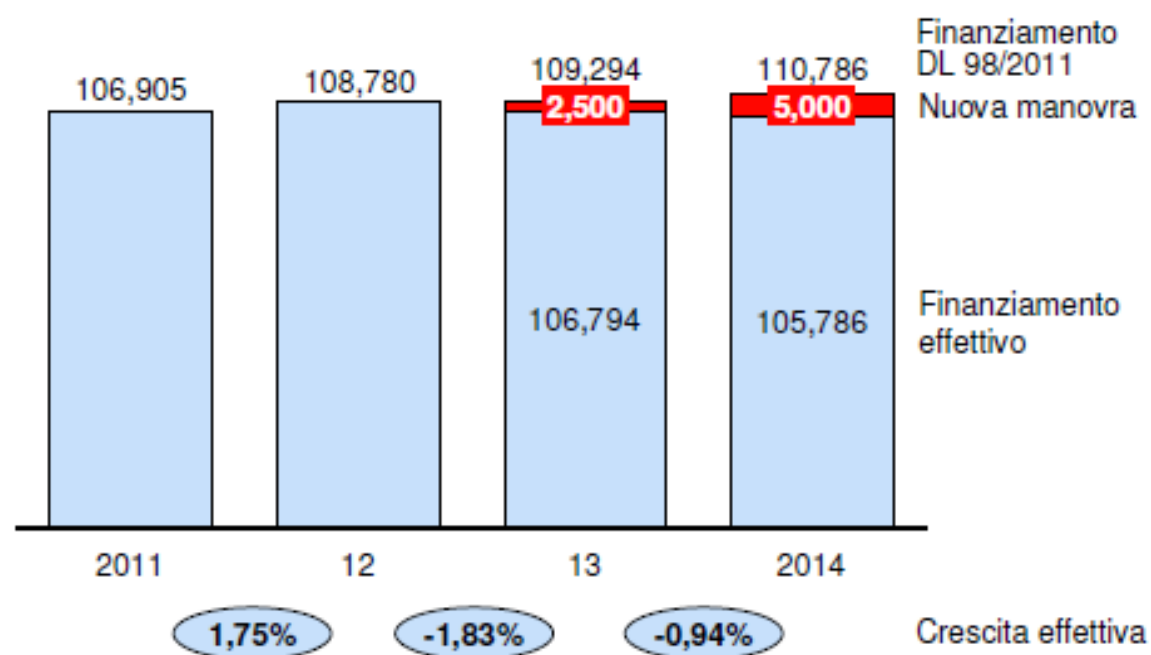
La sanità come motore di crescita

Nel contesto attuale, i decisori nazionali e regionali vedono quasi sempre la sanità prevalentemente, se non esclusivamente, come una voce di costo. E' invece evidente anche l'effetto volano che un sistema sanitario ben gestito può svolgere per la crescita economica.

Quello biomedico, insieme a quello della tecnologia dell'informazione, è il settore in più rapido sviluppo e può generare enormi margini di crescita nella ricchezza e nell'occupazione del Paese. Concentrarsi solo sui tagli determinerà non solo riduzione dei servizi, ma anche impoverimento economico e industriale e la marginalizzazione del Paese nella competizione internazionale.

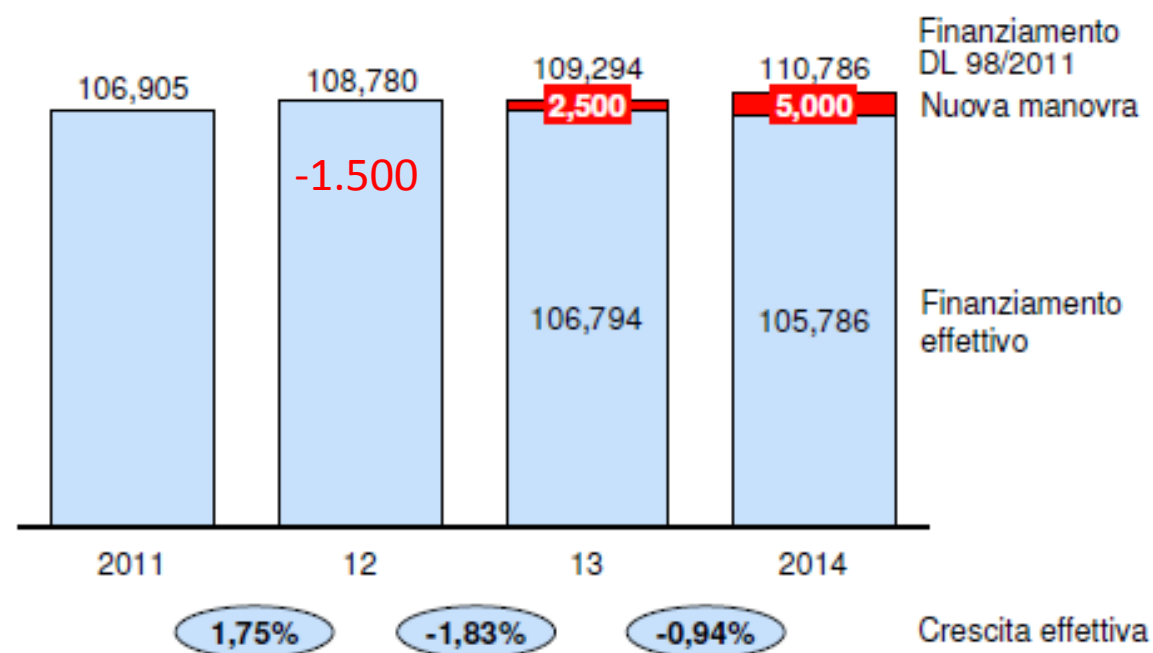
Il Governo Monti ha definito il quadro del finanziamento del SSN fino al 2014 ...

Finanziamento del SSN, ex DL 98/2011; Miliardi di Euro



Il Governo Monti ha definito il quadro del finanziamento del SSN fino al 2014 ...

Finanziamento del SSN, ex DL 98/2011; Miliardi di Euro



DL disposizioni urgenti in materia sanitaria

- Art 1 tutela brevettuale dei farmaci
- Art 2 tutela dell'innovatività terapeutica
- Art 3 medicinali sperimentali
- Art 5 impiego razionale ed economicamente compatibile dei medicinali
- Art 6 procedure concernenti i medicinali
- Art 7 emoderivati
- Art 8 razionalizzazione e contenimento spesa
- Art 9 misure di risparmio
- Art 10 farmacie
- Art 11 professioni sanitarie

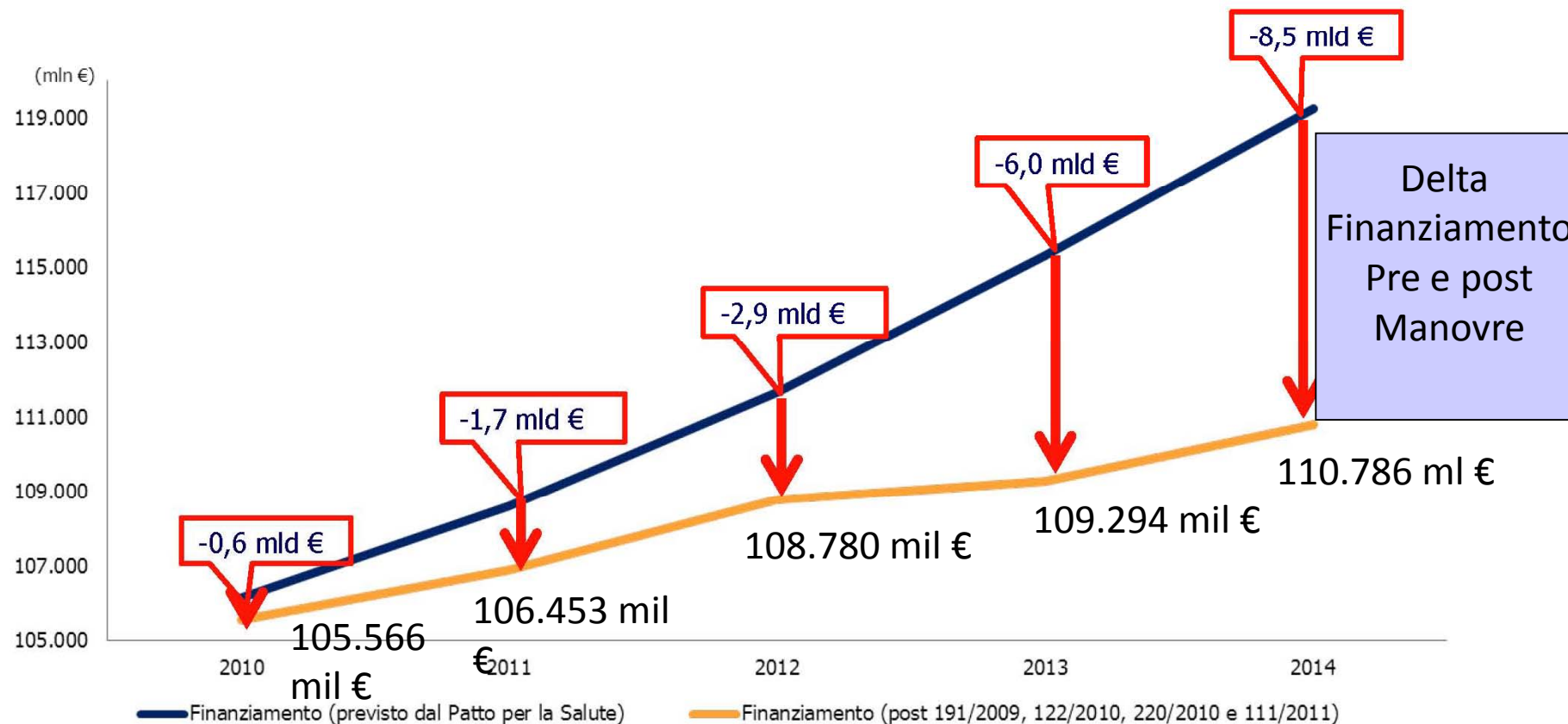
Misure che emergono

- ridimensionamento degli attuali livelli di finanziamento dell'assistenza sanitaria già dal 2012;
- tagli drastici nei trasferimenti alle Regioni
- introduzione di ulteriori ticket;

non toccano concretamente dimensioni come la riduzione dell' inappropriatezza, l'implementazione della “clinical governance” (attraverso cure più sicure, l'Evidence Based Health Care, il rafforzamento dei sistemi informativi), né altre importanti dimensioni “core” o rilevanti dell'assistenza sanitaria (liste d'attesa, continuità della cura, integrazione socio-sanitaria, centralità del paziente).

L'impatto delle manovre 2009-2011 sul finanziamento della sanità è nettamente restrittivo

Tagli al Finanziamento previsto del FSN



Che cosa possiamo aspettarci per la salute dalla crisi in corso?

- In breve:
 - Aumento suicidi
 - Diminuzione incidenti stradali
 - Problemi alcol-correlati: dipende dalla disponibilità
 - Malattie infettive: pressochè impossibile da predire

OPEN ACCESS Freely available online

PLOS ONE

The Impact of Economic Crises on Communicable Disease Transmission and Control: A Systematic Review of the Evidence

Marc Suhrcke¹, David Stuckler², Jonathan E. Suk³, Monika Desai⁴, Michaela Senek¹, Martin McKee⁴, Svetla Tsolova⁵, Sanjay Basu⁶, Ibrahim Abubakar¹, Paul Hunter¹, Boika Rechel¹, Jan C. Semenza^{2*}

¹ Norwich School of Medicine, University of East Anglia, Norwich, United Kingdom, ² Harvard School of Public Health, Boston, Massachusetts, United States of America, ³ Future Threats and Determinants Section, Scientific Advice Unit, European Centre for Disease Prevention and Control (ECDC), Stockholm, Sweden, ⁴ London School of Hygiene and Tropical Medicine, London, United Kingdom, ⁵ Department of Medicine, University of California San Francisco, San Francisco, California, United States of America

Abstract

There is concern among public health professionals that the current economic downturn, initiated by the financial crisis that started in 2007, could precipitate the transmission of infectious diseases while also limiting capacity for control. Although studies have reviewed the potential effects of economic downturns on overall health, to our knowledge such an analysis has yet to be done focusing on infectious diseases. We performed a systematic literature review of studies examining changes in infectious disease burden subsequent to periods of crisis. The review identified 230 studies of which 37 met our inclusion criteria. Of these, 30 found evidence of worse infectious disease outcomes during recession, often resulting from higher rates of infectious contact under poorer living circumstances, worsened access to therapy, or poorer retention in treatment. The remaining studies found either reductions in infectious disease or no significant effect. Using the paradigm of the "SIR" (susceptible-infected-recovered) model of infectious disease transmission, we examined the implications of these findings for infectious disease transmission and control. Key susceptible groups include infants and the elderly. We identified certain high-risk groups, including migrants, homeless persons, and prison populations, as particularly vulnerable conduits of epidemics during situations of economic duress. We also observed that the long-term impacts of crises on infectious disease are not inevitable: considerable evidence suggests that the magnitude of effect depends critically on budgetary responses by governments. Like other emergencies and natural disasters, preparedness for financial crises should include consideration of consequences for communicable disease control.

Citation: Suhrcke M, Stuckler D, Suk JE, Desai M, Senek M, et al. (2011) The Impact of Economic Crises on Communicable Disease Transmission and Control: A Systematic Review of the Evidence. PLOS ONE 6(6): e20724. doi:10.1371/journal.pone.0020724

Editor: Jos H. Verbeek, Finnish Institute of Occupational Health, Finland

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Funding: This work was conducted by the European Centre for Disease Prevention and Control and contractors hired to support data collection and analysis. ECDC is an international public health agency, similar to CDC in Atlanta, and the authors have no financial interests in the outcome of the studies. No funding bodies had any role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Competing Interests: The authors have declared that no competing interests exist.

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Introduction

Analyzing the complicated and myriad pathways through which economic crises may have impacted infectious disease transmission is fraught with difficulty. The global economic downturn of the past few years is the result of a financial crisis whose scale is unprecedented in the post-war period. With its proximal origins in overly complex credit instruments [1], the crisis initially led to a tightening of private sector credit, and ultimately the collapse of several financial institutions, sharp increases in public sector debt and declines in global trade, markedly lower and in some cases negative GDP growth, and rising unemployment in many industrialised countries [2].

Although the early signs suggest that a fragile recovery is underway [3], it is clear that recent economic damage, principally inflicted during 2008–2009, has led to severe economic hardship for many governments and citizens across the world. The effects of the financial crisis will almost certainly linger beyond any economic recovery. Inevitably, therefore, concerns have been

raised that control of infectious diseases could have been and will continue to be adversely affected by budgetary constraints as well as the social effects of recession [4,5,6]. For example, some countries have cut budgets for infectious disease control, risking disruption of treatment and/or the exacerbation of drug-resistance [7]. Pharmaceutical companies report declines in sales of prescription drugs, especially in countries with high reliance on out-of-pocket spending [8]. Workers have been reluctant to take sick days, fearing unemployment while increasing the risk of disease transmission at work [9].

Marked rises in infectious disease incidence during previous economic crises and downturns raise concerns about the current situation. During the 1990s, countries of the former Soviet Union (FSU) and Eastern Europe experienced a devastating economic crisis, as GDP fell by one-third on average. Concurrently, the incidence, prevalence and mortality of tuberculosis rose markedly, and worsening treatment led to the emergence of drug-resistant strains [10,11]. HIV also increased from relatively low pre-crisis levels; outbreaks of diphtheria [12] and tick-borne encephalitis

ISS: la mortalità materna italiana è diventata la più alta d'Europa (+ 63% rispetto a Francia e Germania)

CEIS: 42.000 famiglie a rischio impoverimento con i nuovi ticket

CENSIS: 9 milioni di italiani hanno rinunciato totalmente o parzialmente alle cure

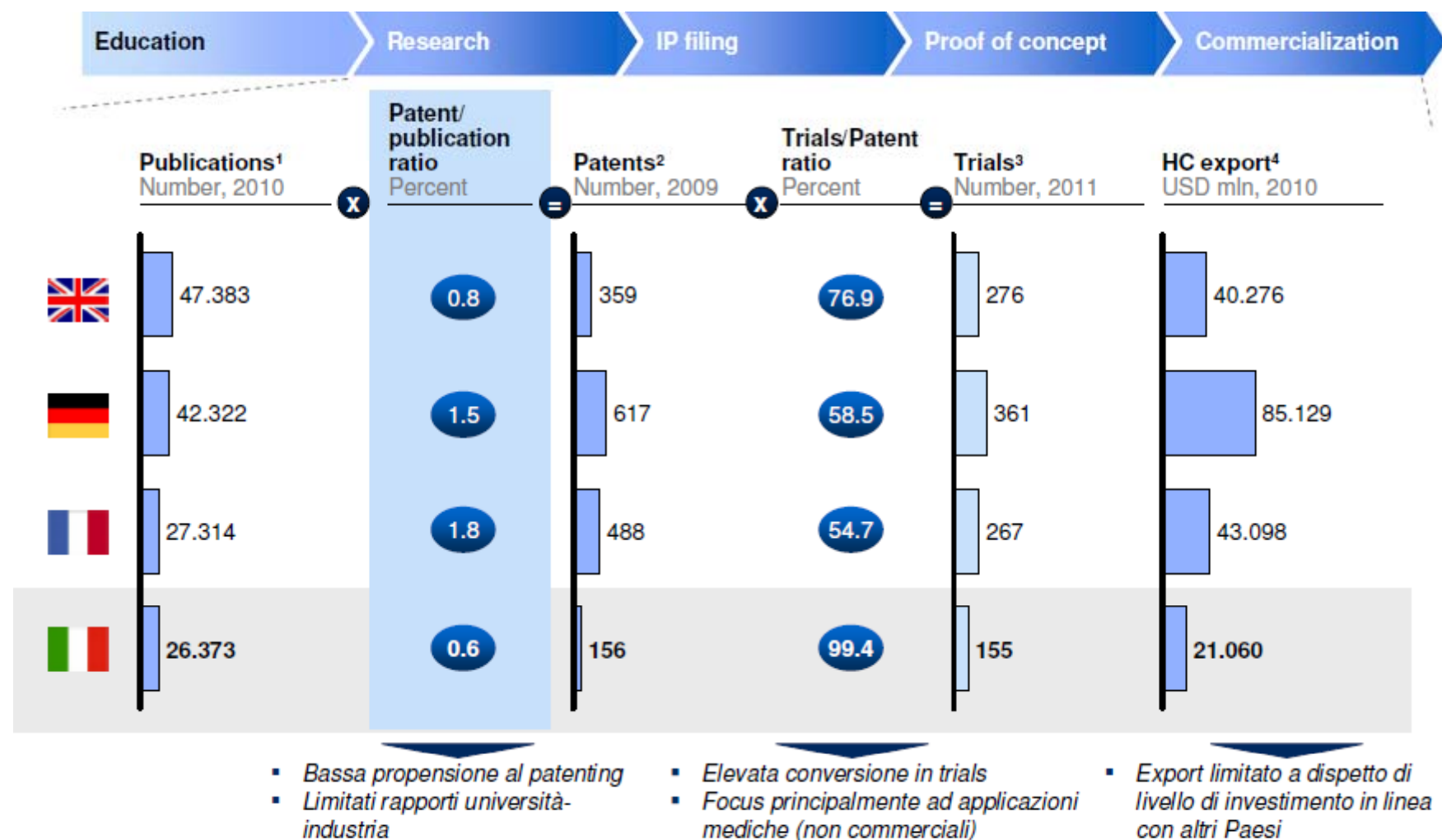
2.4 milioni di anziani, il resto coppie con figli

Agenas: calo dei consumi in sanità in Italia simile a quello in Grecia

CENSIS: 18% popolazione si fa già curare fuori regione, ma il 71% pensa che in caso di necessità lo farà (e non sanno ancora della direttiva CE 24/2011)

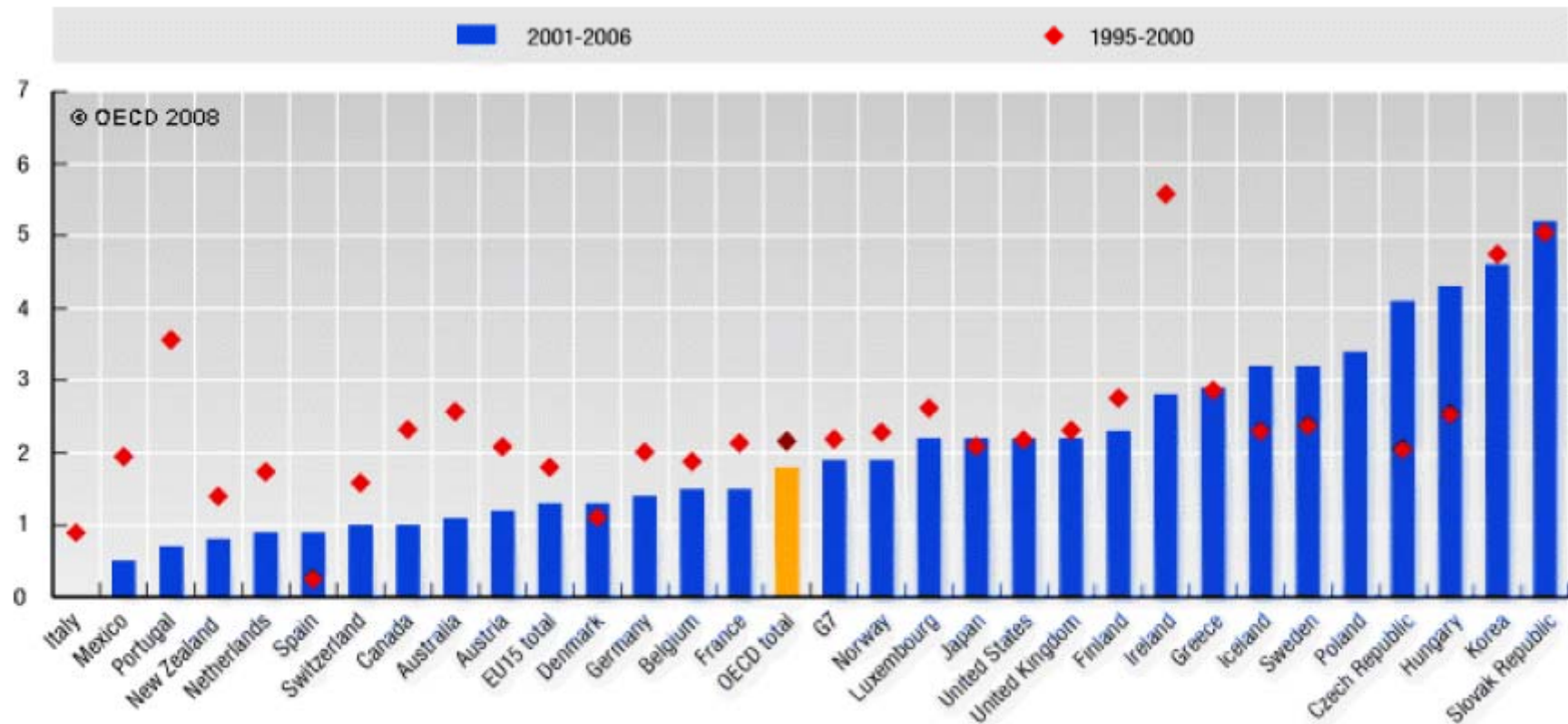
Corte dei Conti: nel 2011 tagli superiori all'attesa per 2.9 miliardi

OCSE: Italia spende il 26.1% in meno rispetto a Francia e Germania



¹ Sum of citable documents in Medicine and Biochemistry, Genetics and Molecular Biology; ² Biotechnology patent applications under the Patent Cooperation treaty; ³ Includes phase I/II trials; ⁴ Pharma and Medical Devices

Crescita media annua % del PIL per ora lavorata nei paesi OECD



http://lvsander.sourceoecd.org/vl=10619687/cl=16/nw=1/rpsv/fact2008/cru/bin/csp08.htm?var=labprodqdp_t1

Fonte: OECD, 2009

Innovation Gap: R&D Investments Vs New Drug Approvals

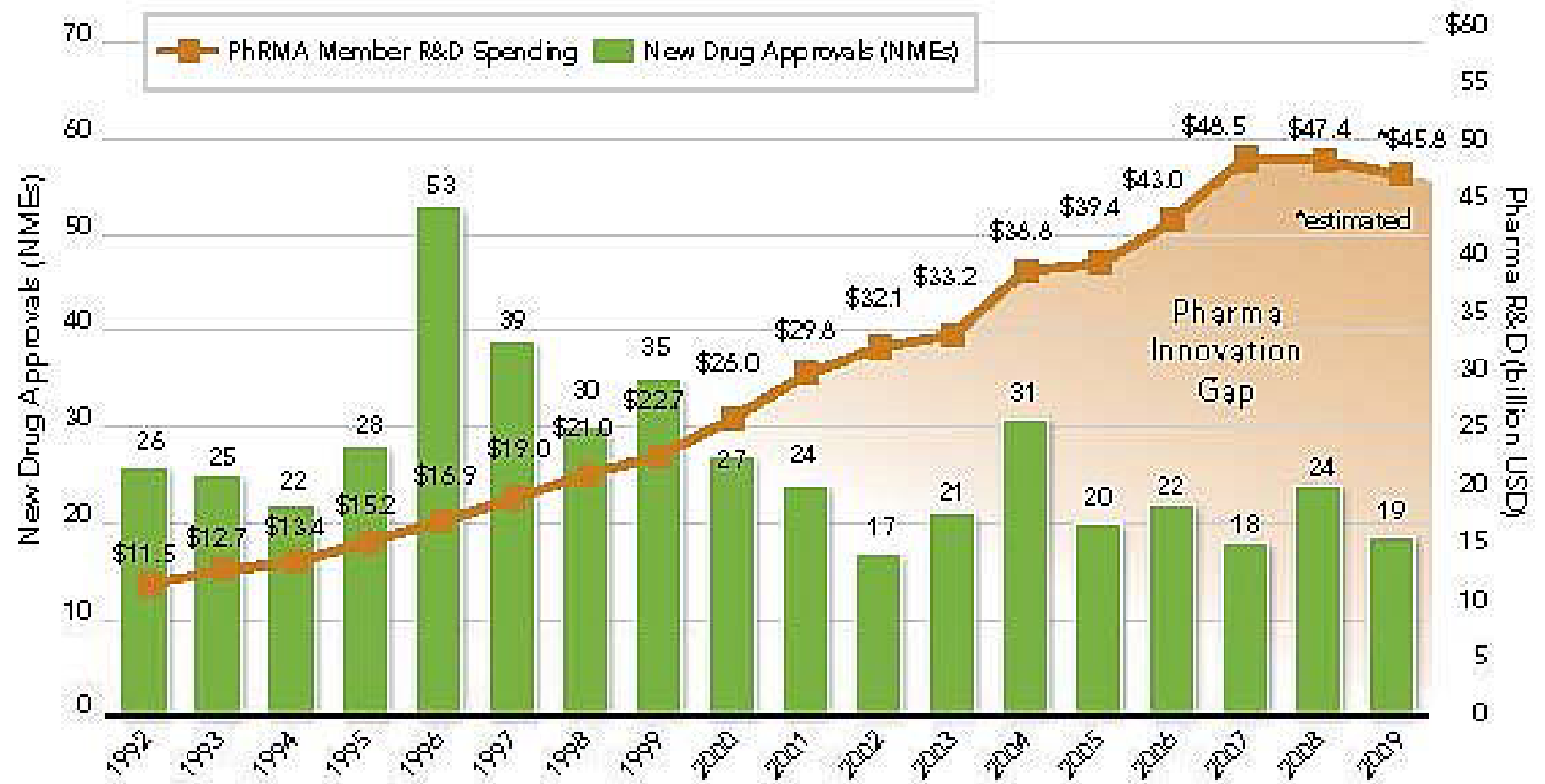
Current industry

Time for change

Diversification

Rise of biotechnology

R&D in transition



The Cost of Developing a New Drug Has Greatly Increased

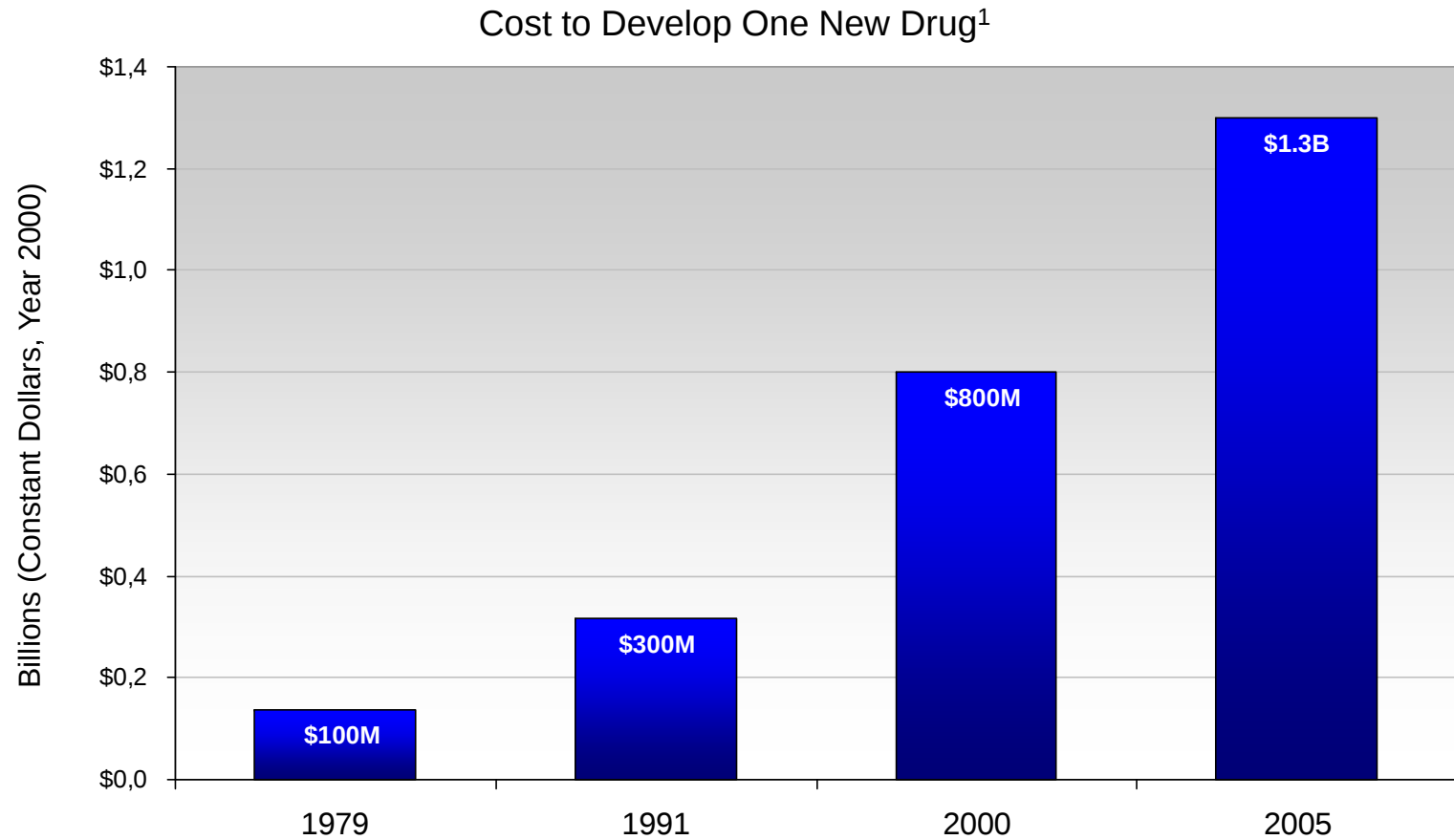
Current industry

Time for change

Diversification

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R&D in transition



Sources: ¹J. DiMasi and H. Grabowski, "The Cost of Biopharmaceutical R&D: Is Biotech Different?," *Managerial and Decision Economics*, 2007; J. DiMasi et al., "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics*, 2003.

Just 2 in 10 Approved Medicines Recoup R&D Costs

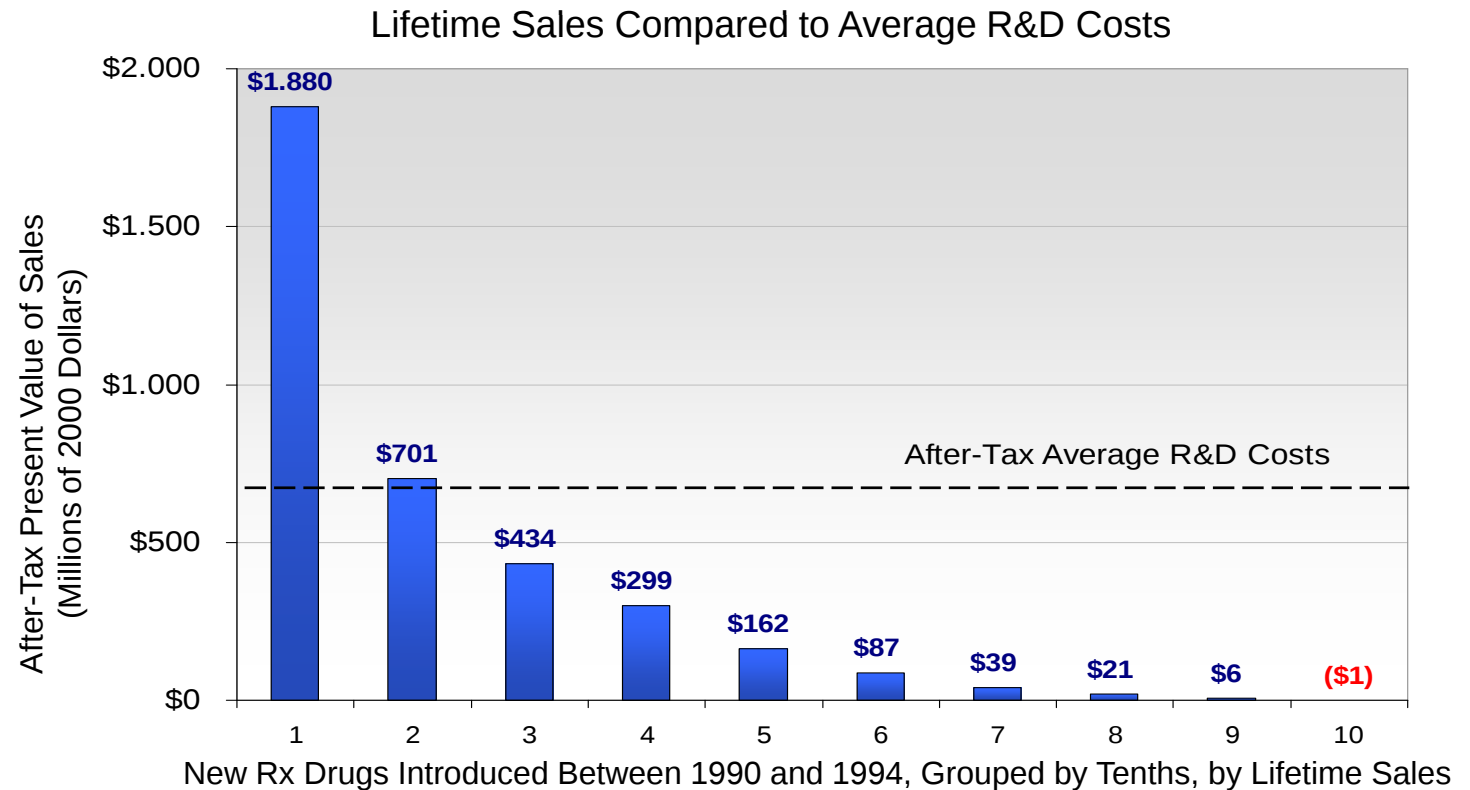
Current industry

Time for change

Diversification

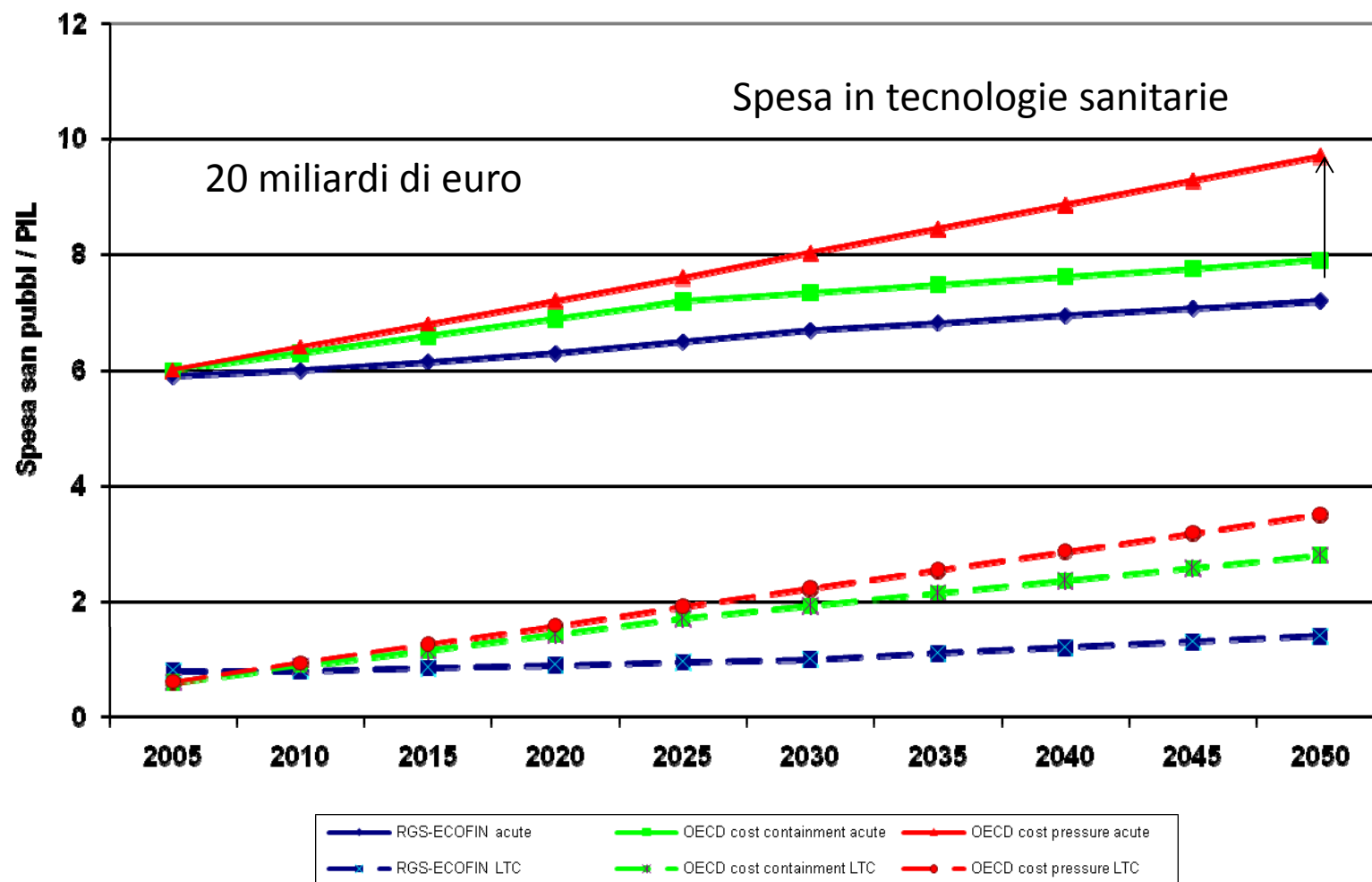
Rise of biotechnology

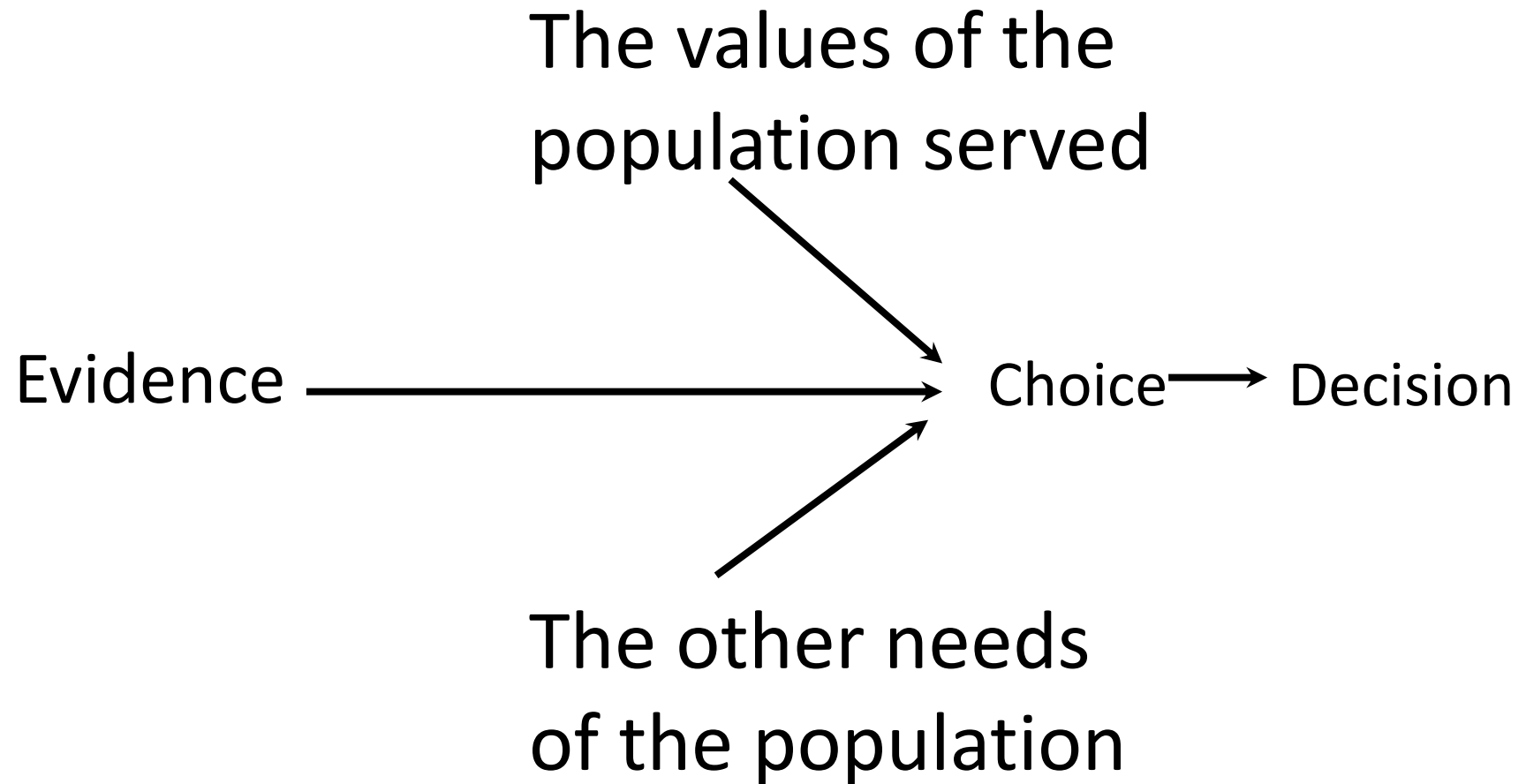
R&D in transition

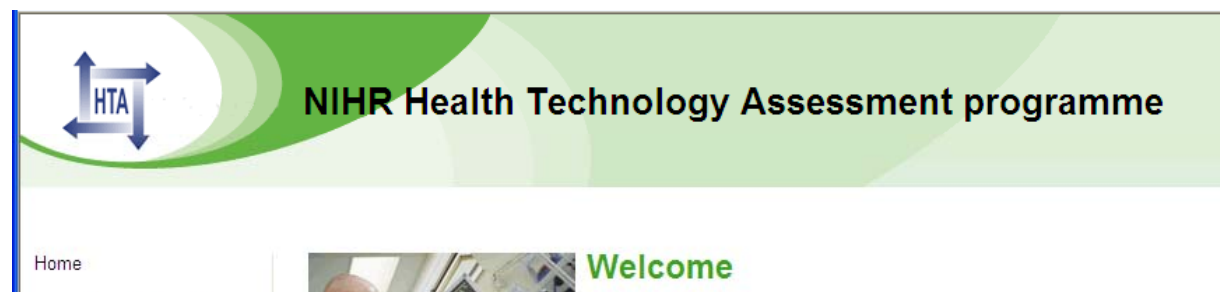


Sources: J. A. Vernon, J. H. Golec, and J.A. DiMasi, "Drug development costs when financial risk is measured using the Fama-French three-factor model." Health Economics, (2009). ; J. DiMasi and H. Grabowski, "The Cost of Biopharmaceutical R&D: Is Biotech Different?," Managerial and Decision Economics, 2007.

Le prospettive di medio-lungo periodo







- **HTA Definition**
- **Health technology** is the application of scientific knowledge in health care and prevention.
- **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.

Despite its policy goals, HTA must always be firmly rooted in research and the scientific method.

HTA Definition

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National Institute for Health Research (NIHR). It provides information on the costs and broader impact of healthcare treatment



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D.G.R. 7856 / 2008

Programma regionale di Valutazione delle Tecnologie Sanitarie

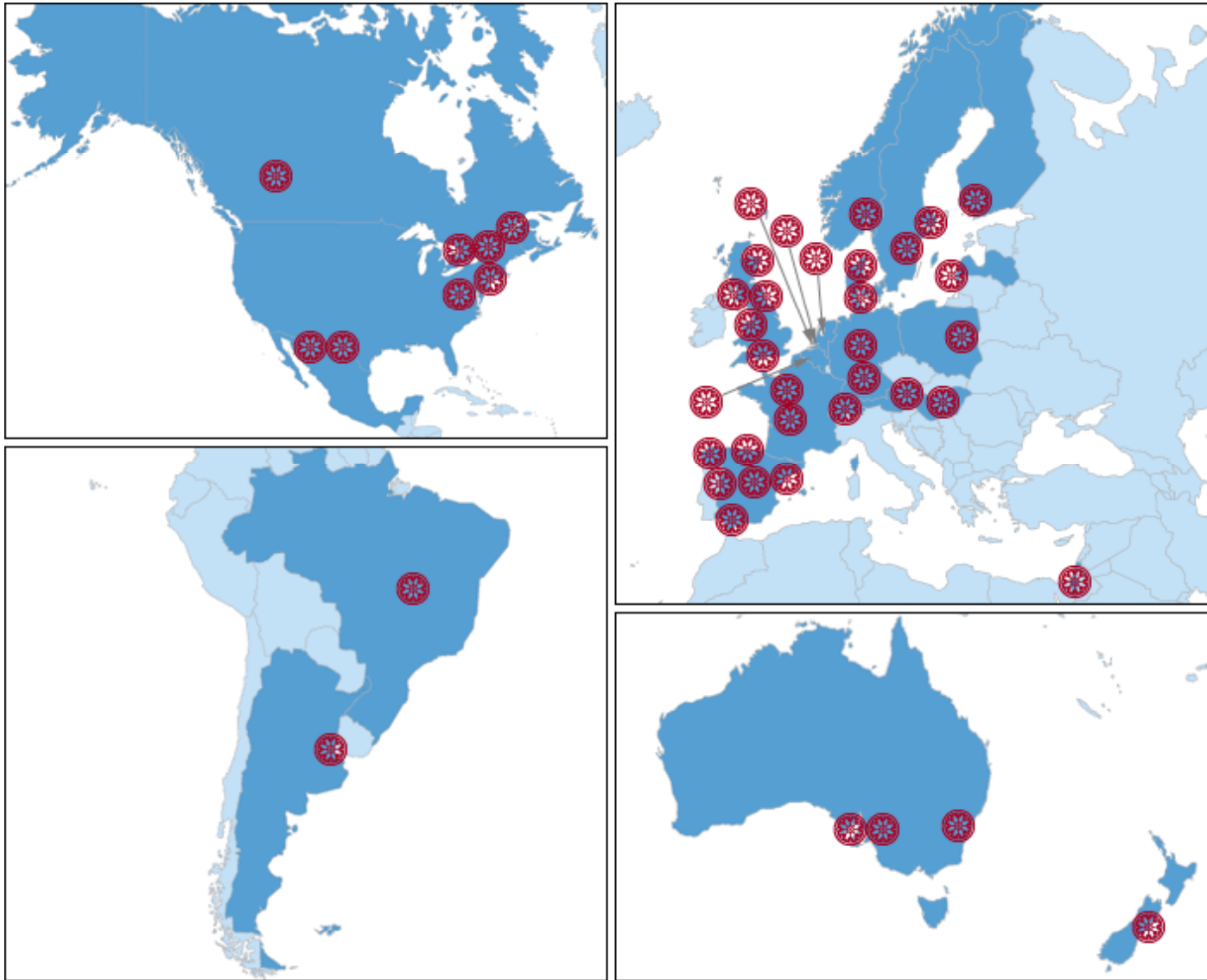
Health Technology Assessment

(VTS-HTA)



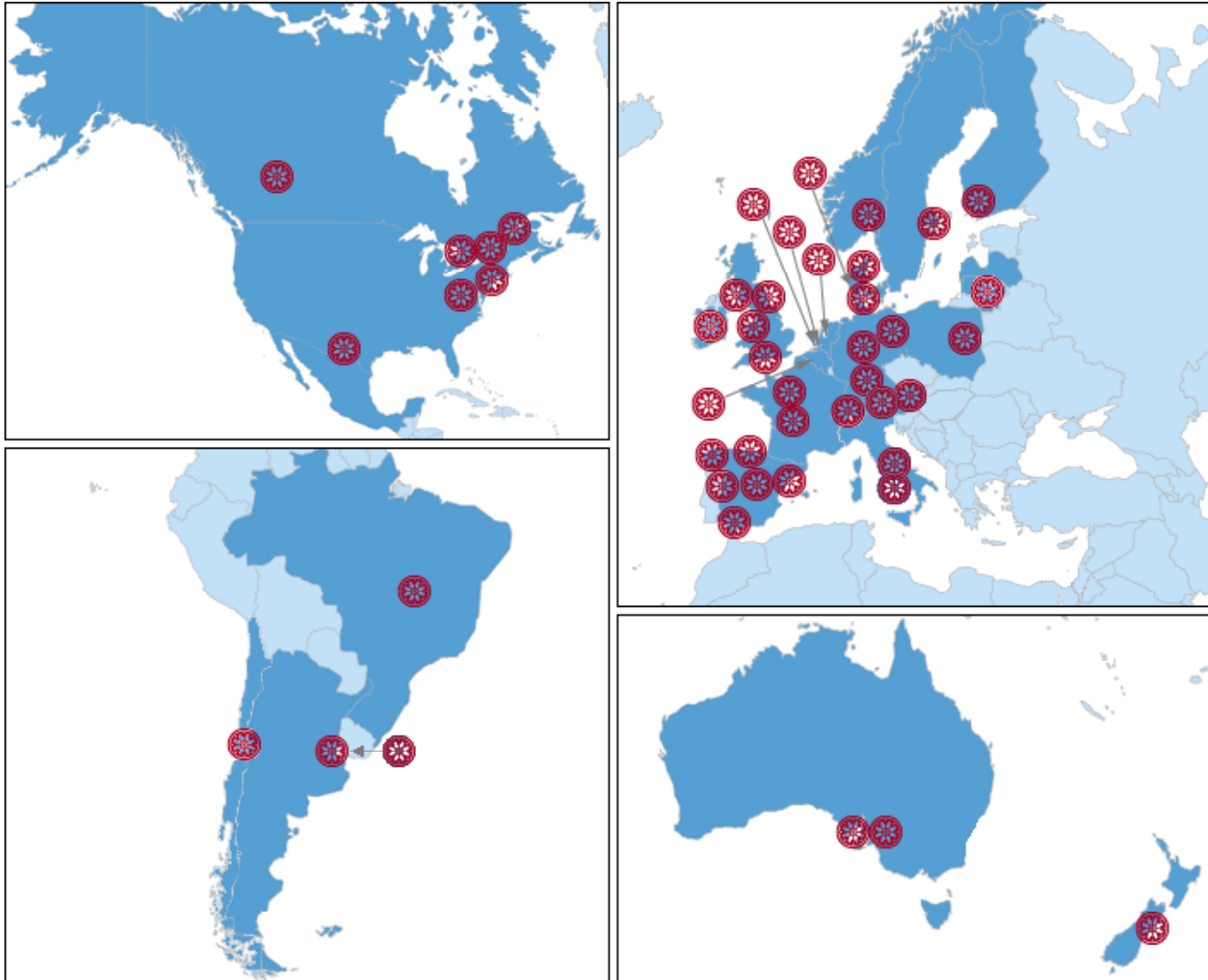
CDEC FINAL RECOMMENDATION

INAHTA Member Map



Fino al 2009

INAHTA Member Map



Dopo il 2009

European – national – regional – local HTAs

Is the process adding **value** or only **complexity** to decision making ?

How to contribute to improve a **consistent** and **valuable** assessment of technologies?

How to reduce **complexity** and increase **efficiency**?

HTA : open issues

- Capacity building for agencies
- Competencies and methodology development
- Data availability for non regulatory data (QoL, Costs, effectiveness..)
- Quality of involvement for stakeholders
- Coordination between regulatory and HTA
- Prioritization and scoping for assessment
- Disinvestments – sustainability - innovation
- Multiplicity of assessors – consistency of assessments
- HTA and decision making
- Networking across agencies at national and european level

Optimizing HTA in a complex environment:

Enablers

Insitutions/levels	Scientific community & Accademia	Professionals
•Collaborate and create joint initiatives •Clarify accountability •Share common goals and KPIs	•Guarantee evolution in core curricula •Share knowledge •Adapt methodology •Facilitate research and access to data •Educate professionals •Collaborate with institutions/Professional s •Build public-private collaborations	•Be prepared •Create networks •Be proactive

Non ci saranno più risorse,
bisogna spenderle meglio

FUNZIONANO MEGLIO LE RIFORME
CHE AGISCONO SUL VERSANTE
DELLA RAZIONALIZZAZIONE
DELL'OFFERTA CHE SU QUELLI DEL
FINANZIAMENTO
R. SALTMANN

- Dare credibilità e fiducia al SSN ed ai suoi operatori
- Dare certezza ai meccanismi di programmazione
- Aumentare la produttività e l'efficienza

- L'organizzazione
- Il funzionamento
- La valutazione e la trasparenza
- Il coinvolgimento dei cittadini

National

NHS
National Institute for
Health and Clinical Excellence

Scottish Medicines Consortium **NHS**
SCOTLAND

 Australian Government
Department of Health and Ageing
Pharmaceutical Benefits Advisory Committee

 Canadian Agency for
Drugs and Technologies
in Health

IQWiG Institute for Quality
and Efficiency in Health Care

HAS
HAUTE AUTORITÉ DE SANTÉ

CVZ College voor zorgverzekeringen

 **AIFA**
Agenzia Italiana del Farmaco

TLV
TANDVÅRDS- OCH
LÄKEMEDELSFÖRMÅNSVERKET

Regional

 Generalitat de Catalunya
www.gencat.cat
Catalan Agency for Health Information, Assessment and Quality

Private payer

 BlueCross BlueShield
Association
Technology Evaluation Center **TEC**

Networks

 eunetha

INAHTA 

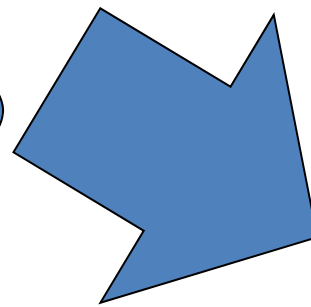
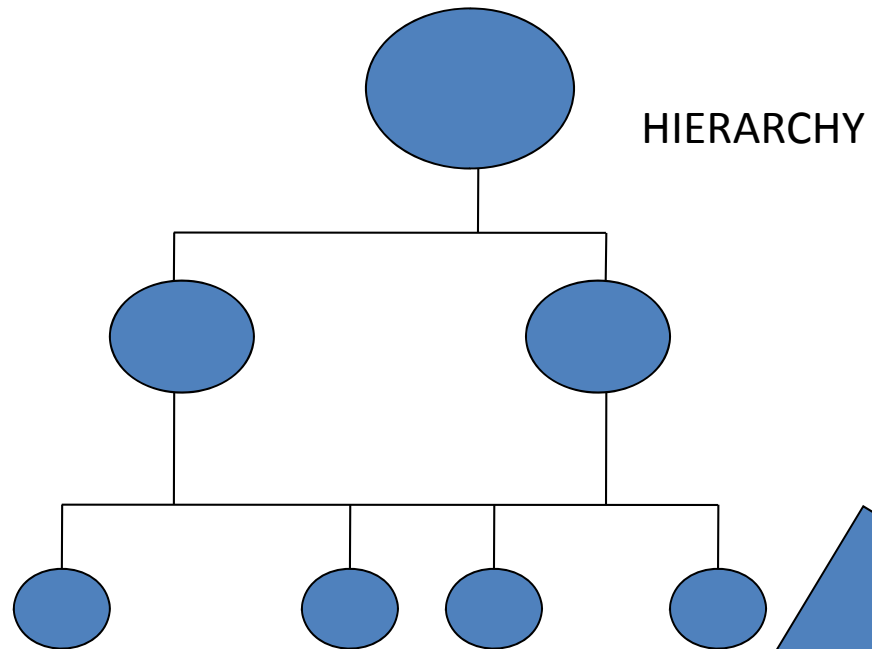
 **HTAi**

Advisory-academic

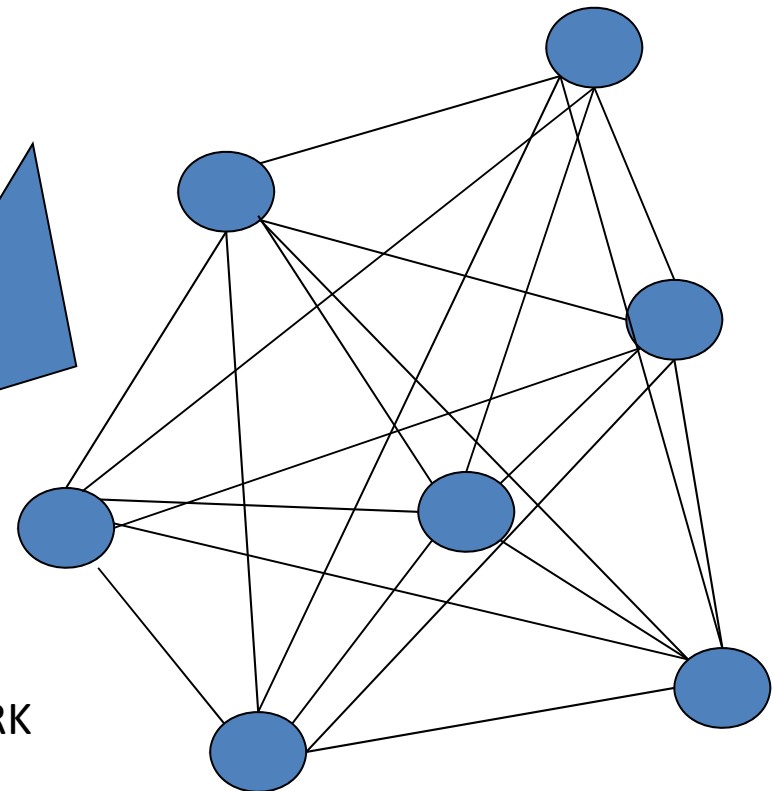
 **SBU**

SBU Kunskapscentrum för hälso- och sjukvården

 **HTA** Health
Technology
Assessment
NIHR Health Technology Assessment
programme New to this



NETWORK





Response to meet HTA requirements

'Evidence' building blocks

Unmet need

Safety, Efficacy

Effectiveness

Cost-effectiveness

Financial impact

Access, service impact

Internal resource
(dossier, toolkit)

**Evidence
synthesis**

**Adaptation &
dissemination**

'Evidence' translation

Reg

HTA

Reg

Submission

HTA

Reg

Submission

HTA

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Submission

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Submission

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Submission

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Submission

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Submission

Input: local evidence requirements



Principles

Consistency and transparency of process (HTA/reimbursement)

Consistency and transparency of judgement of evidence (quality, relevance...)

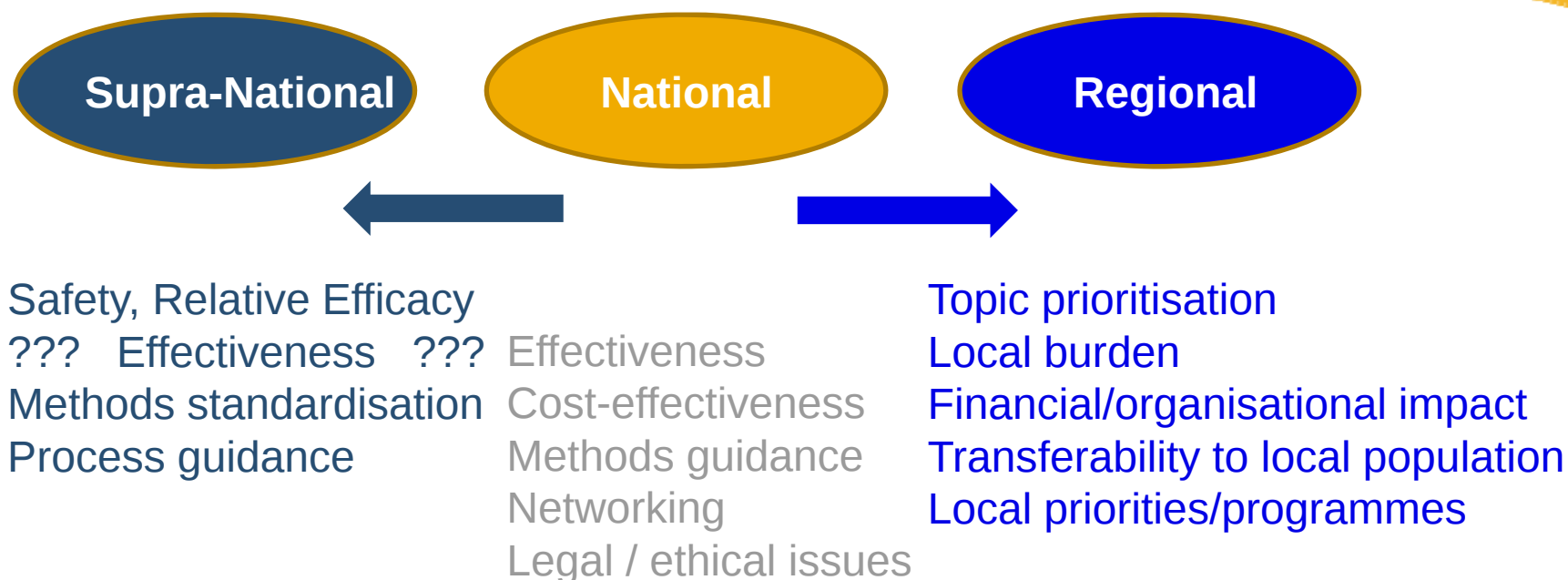
Efficiency: sharing appropriate elements of assessment, xRegional studies

Efficiency: coverage with evidence generation/managed access

Collaboration: evidence generation, address organisational, ethical issues

Equity: how to handle different access levels across Regions?

Widening spread of HTA responsibility



Emerging issues

- Broadening scope of HTA – ‘care pathways’
- ‘Real world’ evidence generation
- Supporting local access initiatives (Regional HEOR)