7 novembre

Introduzione all'Health Technology Assessment

Primiano Iannone
Direttore DEA
Ospedali del Tigullio
ASL4 Chiavarese (GE) Italy

Cos'è l'HTA

complessiva e sistematica valutazione multidisciplinare delle conseguenze assistenziali, economiche, sociali, etiche provocate in modo diretto e indiretto, nel breve e nel lungo periodo, dalle tecnologie sanitarie esistenti e da quelle di nuova introduzione. Tradizionalmente essa rappresenta il ponte fra il mondo tecnico scientifico e quello dei decisori (Carta di Trento, NI-HTA, 2003)

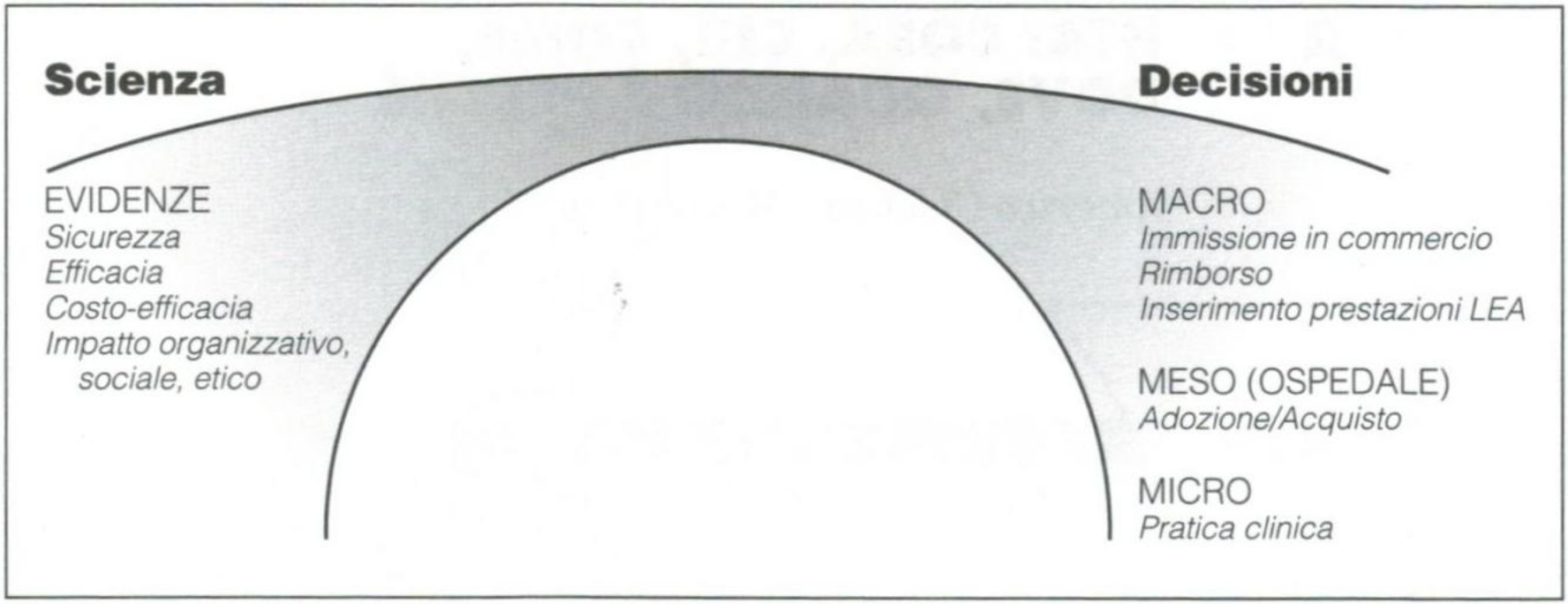


Figura 2.1 • L'Health Technology Assessment: il ponte tra scienza e decisione
(Da: Battista, 1994)

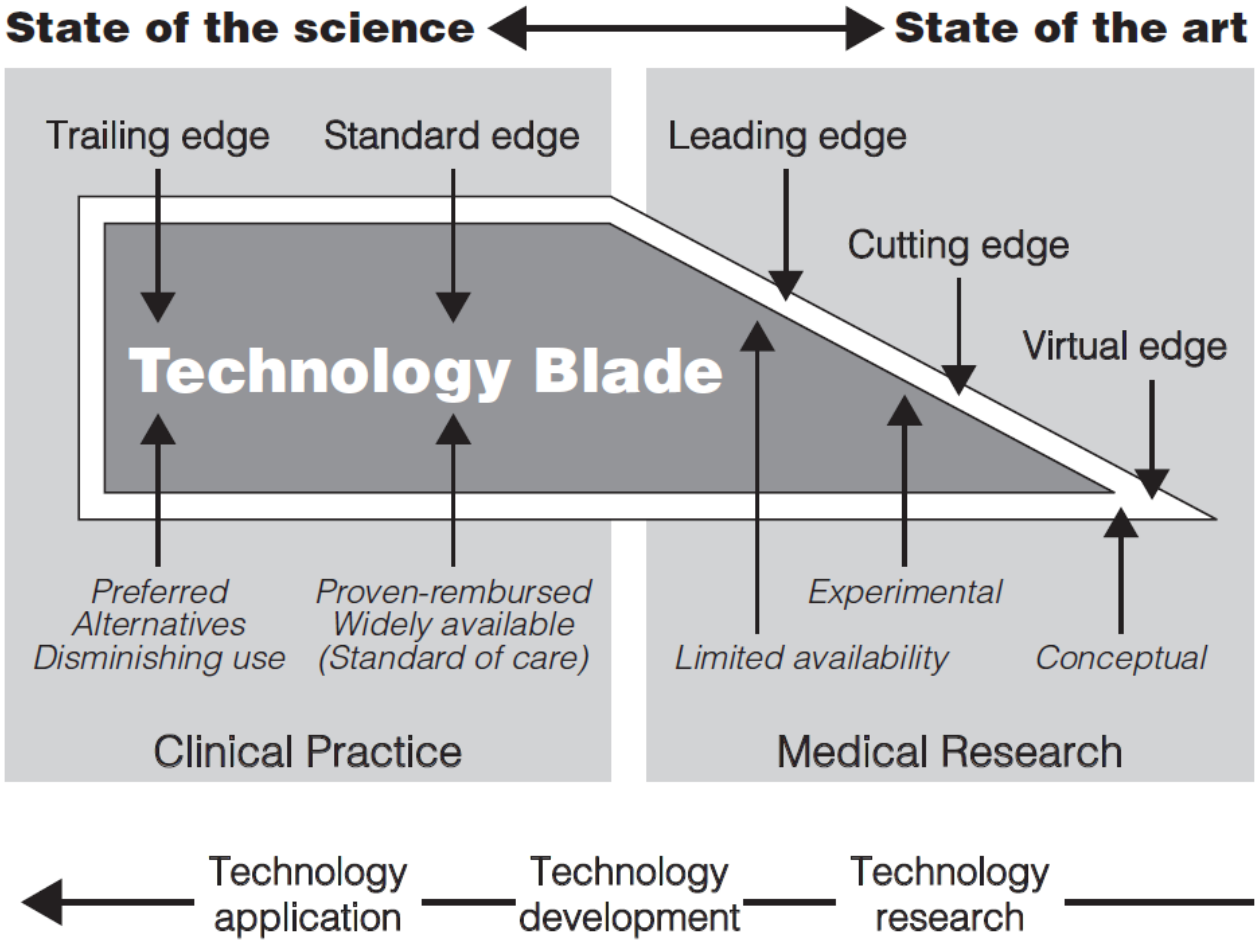


Figura 1.1 • Il *technology spectrum* (Da: Mikhail et al., 1999)

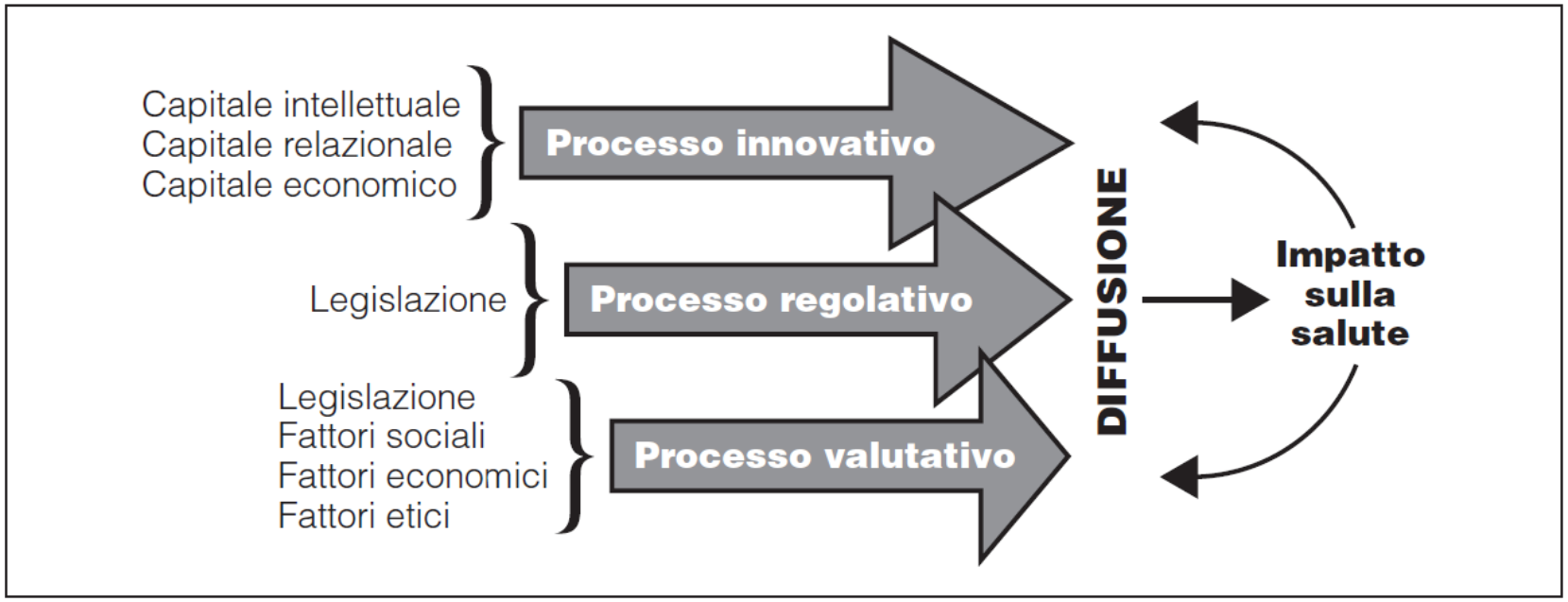
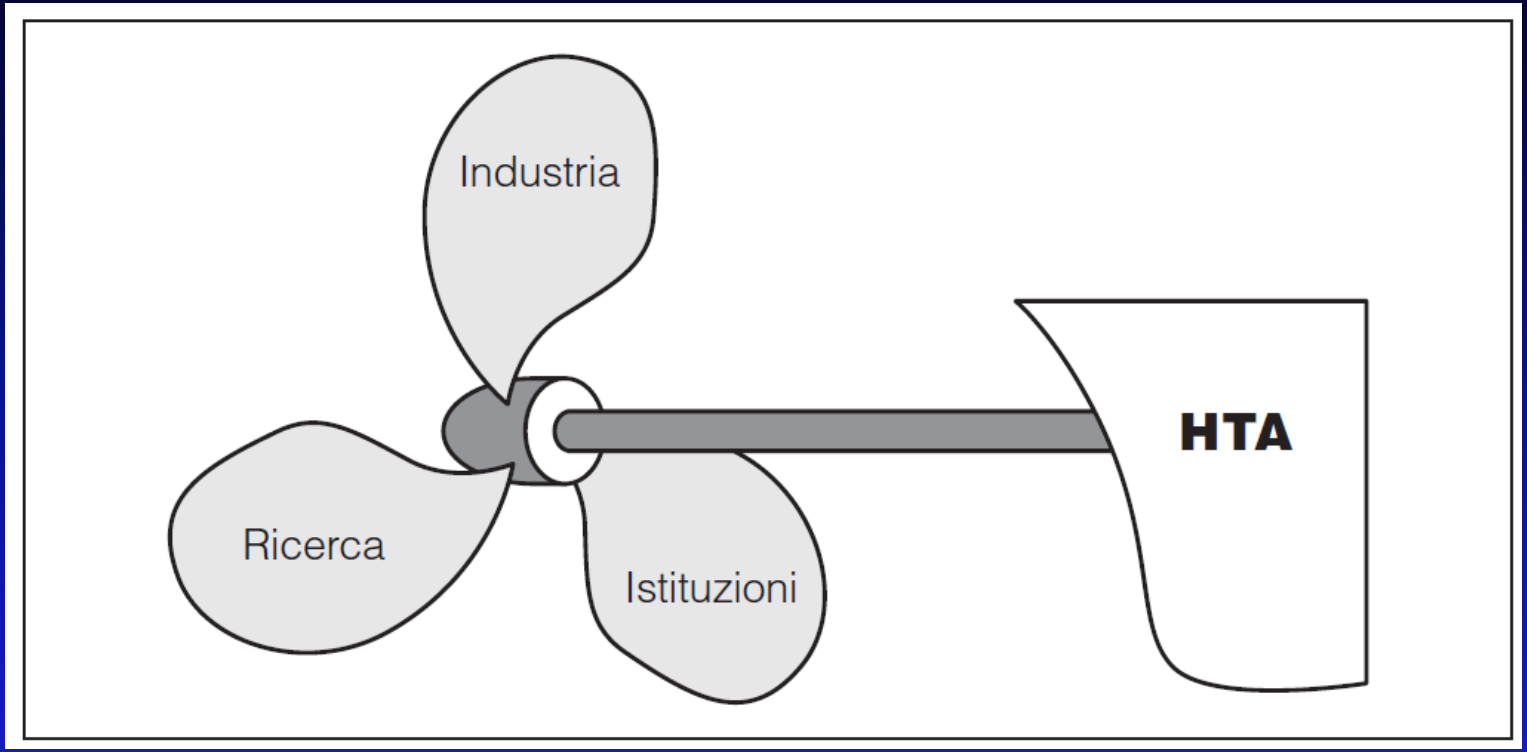


Figura 1.2 • Il "percorso dell'innovazione" (Da: Cicchetti et al., 2007)



Cicchetti, 2008

Tecnologia sanitaria: una definizione (ristretta)

"l'insieme di farmaci, strumenti, procedure mediche e chirurgiche utilizzate per la prevenzione, la diagnosi, il trattamento e la riabilitazione della malattia" (Jonsson & Banta, 1999)

Tecnologia nell'emergenza territoriale ed ospedaliera

Dispositivi medici (devices) secondo la direttiva 2007/47/EC

- cannula di Guedel → ventilazione non invasiva
- siringa → stent medicato
- ecografo portatile → Angio-TC
- bisturi →robotic surgery
- elettrocardiografo → defibrillatore → ICD,
- saturimetro→ emogasanalizzatore
- Tele-medicina
- Information & communication technology
- Test diagnostici
- Software di supporto decisionale
- …

Tecnologia sanitaria: una definizione (estesa)

"l'insieme di farmaci, strumenti, procedure mediche e chirurgiche utilizzate per la prevenzione, la diagnosi, il trattamento e la riabilitazione della malattia" (Jonsson & Banta, 1999)

+

Sistemi organizzativi e di supporto attraverso i quali l'assistenza sanitaria viene fornita (Office of Technology Assessment)

Tecnologia nell'emergenza territoriale ed ospedaliera

- Triage
- Percorsi «fast track»
- Medicina d'osservazione
- Gestione dell'affollamento (overcrowding) e posti letto (bed system management)
- Percorsi clinico assistenziali
- ….
- Sistema dell'emergenza territoriale 118
- Trauma center
- Rete degli ospedali e dei piani regionali dedicati all' emergenza

Le dimensioni valutative dell'HTA

progetto EUnetHTA core model (WP4)

- **Problema di salute e utilizzo attuale della tecnologia**
- **Caratteristiche della tecnologia**
- **Sicurezza**
- **Efficacia clinica (effectiveness)**
- **Costi e valutazione economica**
- **Aspetti etici**
- **Aspetti organizzativi**
- **Aspetti sociali**
- **Aspetti legali**

Dove agisce l'HTA

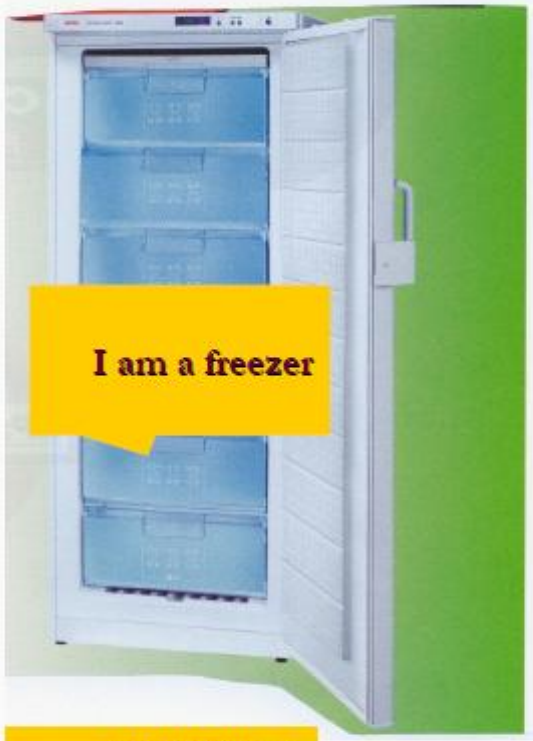
- Macro: decisioni di politica sanitaria nazionale/regionale
  - Rimborso di prestazioni (LEA)
  - Designazione di un trauma center
  - Allocazione delle (grandi) tecnologie sul territorio
- Meso: ospedale
  - Adozione acquisto di nuove tecnologie
  - Costituzione di nuovi servizi e percorsi assistenziali
- Micro: professionisti singoli / team
  - Scelte su singoli pazienti di adozione di determinate tecnologie diagnostiche o terapeutiche

HTA : finalità valutative

What do we need ??

I am a freezer
with
a plasma TV incorporated !

SFr.6'000 ca.



I am a freezer

Sfr.1'500 ca.

HTA : finalità regolatorie

BMJ

BMJ 2011;342:d2748 doi: 10.1136/bmj.d2748

MEDICAL DEVICES

Europeans are left to their own devices

When it comes to medical devices, Europeans seem to get a worse deal than US patients. **Deborah Cohen** and **Matthew Billingsley** compare the regulatory systems

Editorial

Health technology assessment and public health: a time for convergence

Renaldo N. Battista, Louise Lafortune

European Journal of Public Health, Vol. 19, No. 3, 227

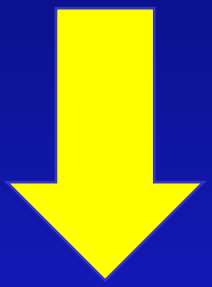
2009

- **approccio interdisciplinare**
- **Knowledge translation**

- **Come prioritizzare gli interventi di prevenzione diagnosi e trattamento delle malattie ?**
- **Come valutare le conseguenze etiche e sociali di interventi sempre più complessi e costosi ?**
- **Come scegliere le metodologie di studio più adeguate per valutare tali interventi ?**
- **Come usare le evidenze se non ci sono prove certe di efficacia (RCTs) ?**

Ampliamento degli orizzonti dell'HTA

Valutazione di tecnologie sanitarie ad alto costo



Health services research

Caso 1

Arresto cardiaco sul territorio (OHCA)
come aumentare la sopravvivenza ?

più tecnologia → migliori risultati ?

ALS più “tecnologico” del BLS-D, quindi preferibile al BLS-D

Tempi di soccorso inversamente proporzionali alla probabilità di sopravvivenza, quindi ridurre i tempi di arrivo del 118 medicalizzato sull’OHCA

ORIGINAL ARTICLE

Advanced Cardiac Life Support in Out-of-Hospital Cardiac Arrest

Ian G. Stiell, M.D., George A. Wells, Ph.D., Brian Field, A.C.P., M.B.A., Daniel W. Spaite, M.D., Lisa P. Nesbitt, M.H.A., Valerie J. De Maio, M.D., Graham Nichol, M.D., M.P.H., Donna Cousineau, B.Sc.N., Josée Blackburn, B.Sc., Doug Munkley, M.D., Lorraine Luinstra-Toohey, B.Sc.N., M.H.A., Tony Campeau, M.Ed., Eugene Dagnone, M.D., and Marion Lyver, M.D., for the Ontario Prehospital Advanced Life Support Study Group

N Engl J Med 2004;351:647-56.

L'aggiunta di interventi ALS non ha migliorato il tasso di sopravvivenza in un sistema già ottimizzato per la defibrillazione precoce. Per salvare più vite, i policymakers dovrebbero rendere la RCP da parte dei laici e la defibrillazione precoce una priorità per i sistemi di emergenza territoriale

Ryynänen et al. Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine 2010, 18:62
http://www.sjtrem.com/content/18/1/62

SCANDINAVIAN JOURNAL OF
trauma, resuscitation
& emergency medicine

REVIEW Open Access

Is advanced life support better than basic life support in prehospital care? A systematic review

Olli-Pekka Ryynänen[1,2], Timo Iirola[3], Janne Reitala[4], Heikki Pälve[5], Antti Malmivaara[6*]

In the prehospital care of sudden cardiac arrest early defibrillation and cardiopulmonary resuscitation are still essential; further ALS interventions have not been able to demonstrate increased survival. Prehospitally initiated

EDITOR'S CHOICE

Role of ambulance response times in the survival of patients with out-of-hospital cardiac arrest

Colin O'Keeffe,[1] Jon Nicholl,[1] Janette Turner,[1] Steve Goodacre[2]

Emerg Med J 2011;**28**:703–706.

Concentrating resources on reducing response times across the board to improve survival for those patients already in arrest is unlikely to be a cost-effective option to the UK National Health Service.

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 AUGUST 12, 2004 VOL. 351 NO. 7

Public-Access Defibrillation and Survival after Out-of-Hospital Cardiac Arrest

The Public Access Defibrillation Trial Investigators*

CONCLUSIONS

Training and equipping volunteers to attempt early defibrillation within a structured response system can increase the number of survivors to hospital discharge after out-of-hospital cardiac arrest in public locations. Trained laypersons can use AEDs safely and effectively.

Journal of the American College of Cardiology
© 2010 by the American College of Cardiology Foundation
Published by Elsevier Inc.

Vol. 55, No. 16, 2010
ISSN 0735-1097/10/$36.00
doi:10.1016/j.jacc.2009.11.077

Survival After Application of Automatic External Defibrillators Before Arrival of the Emergency Medical System

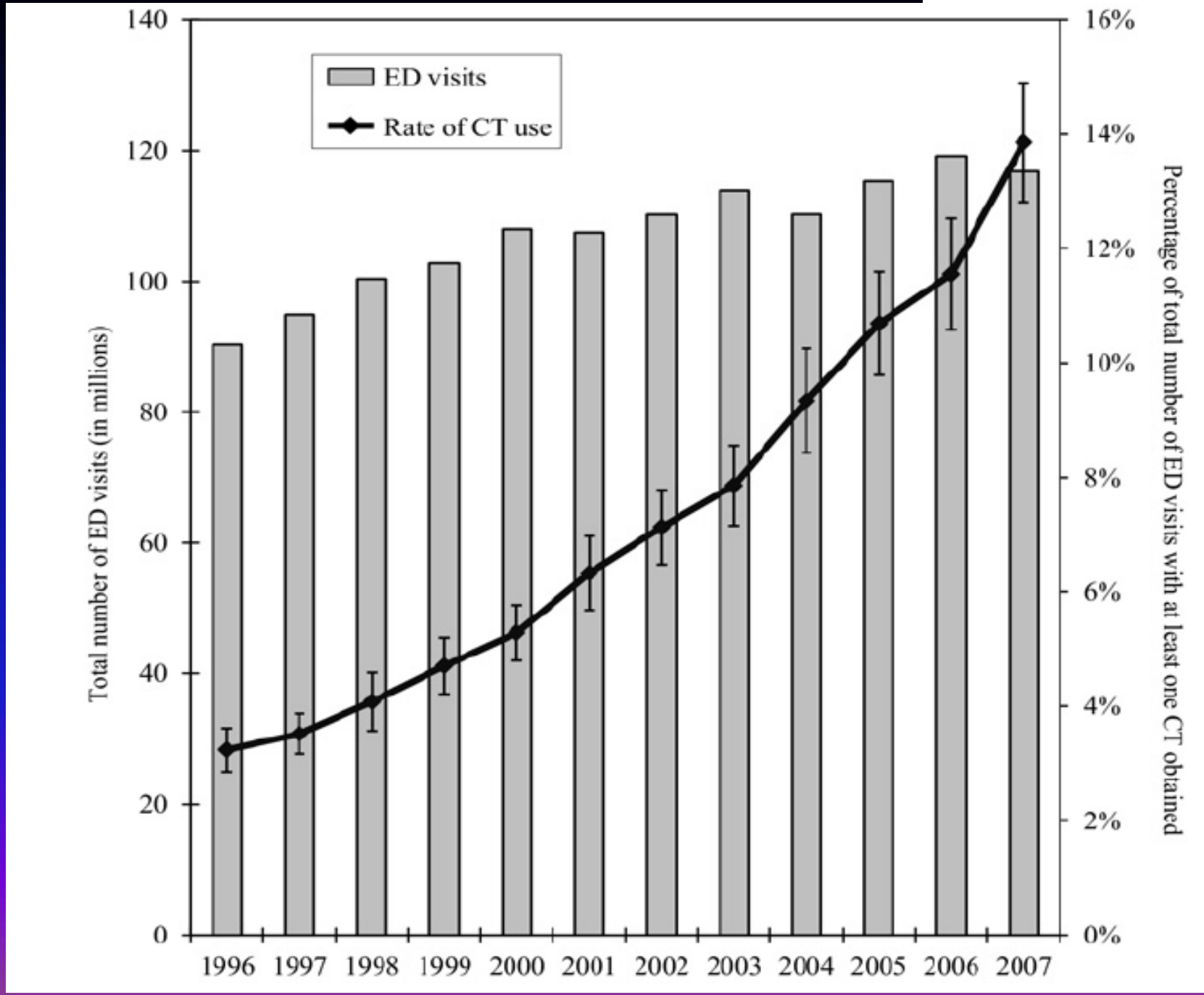
Evaluation in the Resuscitation Outcomes Consortium Population of 21 Million

Application of an AED in communities is associated with nearly a doubling of survival after out-of-hospital cardiac arrest. These results reinforce the importance of strategically expanding community-based AED programs. (J Am Coll Cardiol 2010;55:1713–20)

Caso 2: l'aumentato ricorso alla TC in Pronto Soccorso .

Più tecnologia, più salute ?

[Ann Emerg Med. 2011;58:452-462.]

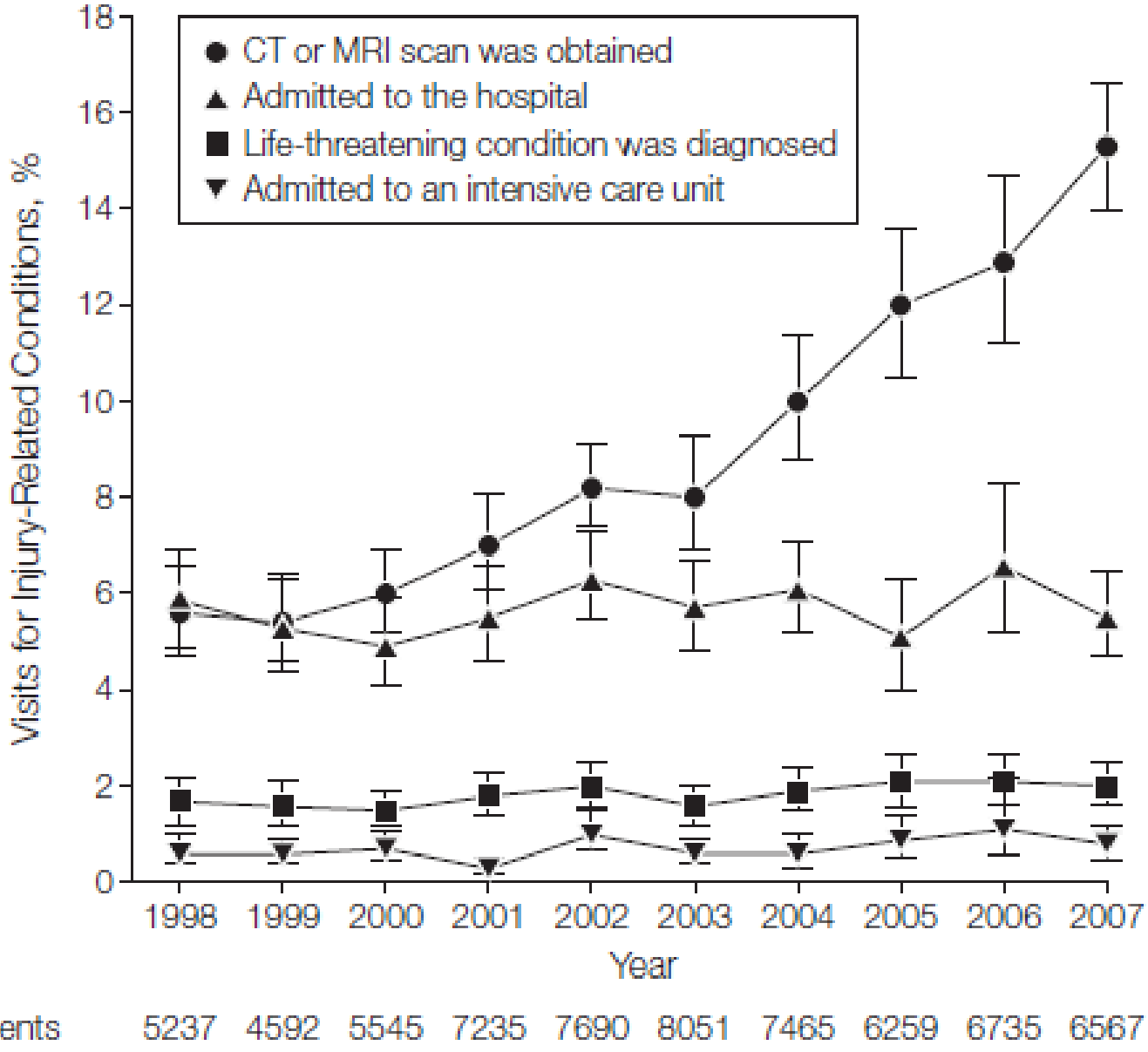


CT use is increasing; it remains to be determined whether outcomes are sufficiently improved to justify the harms and costs.

Use of Advanced Radiology During Visits to US Emergency Departments for Injury-Related Conditions, 1998-2007

JAMA. 2010;304(13):1465-1471

Frederick Kofi Korley, MD
Julius Cuong Pham, MD, PhD
Thomas Dean Kirsch, MD, MPH



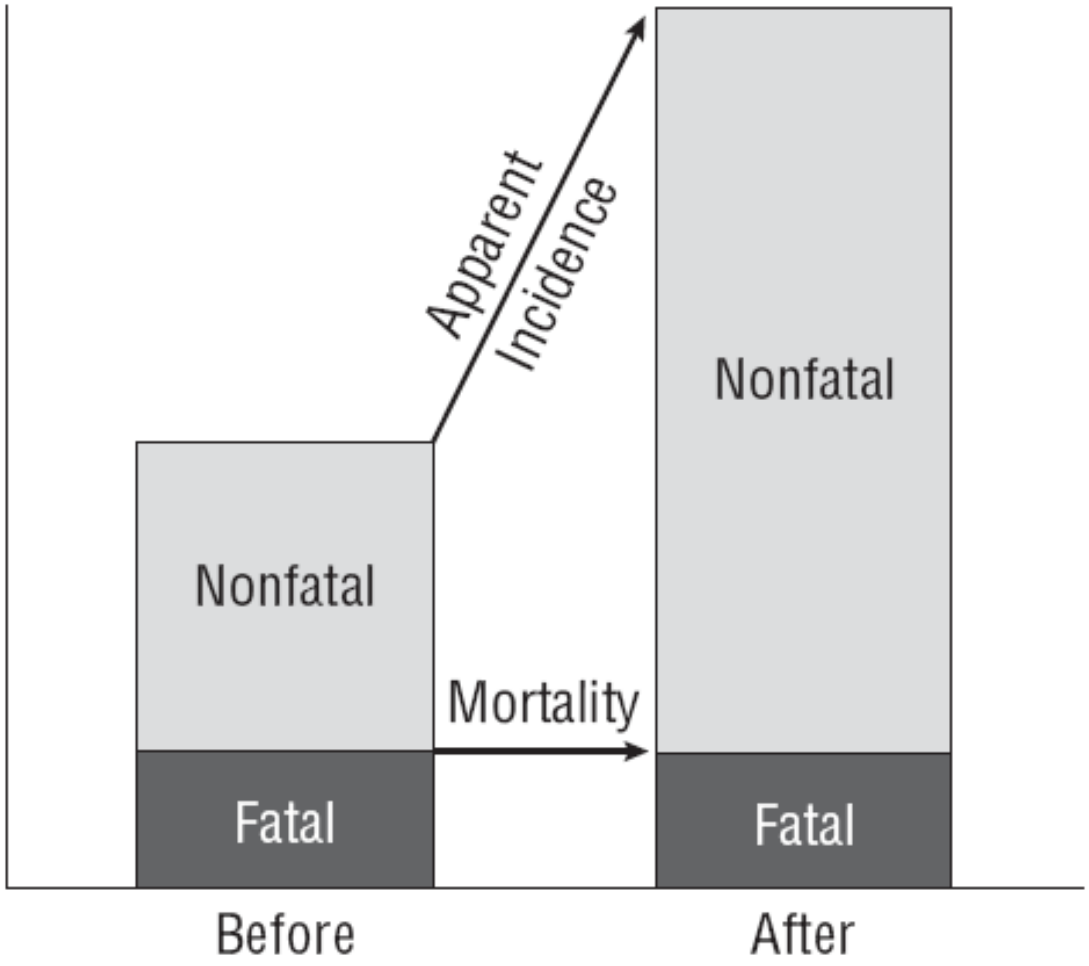
LESS IS MORE

Time Trends in Pulmonary Embolism in the United States

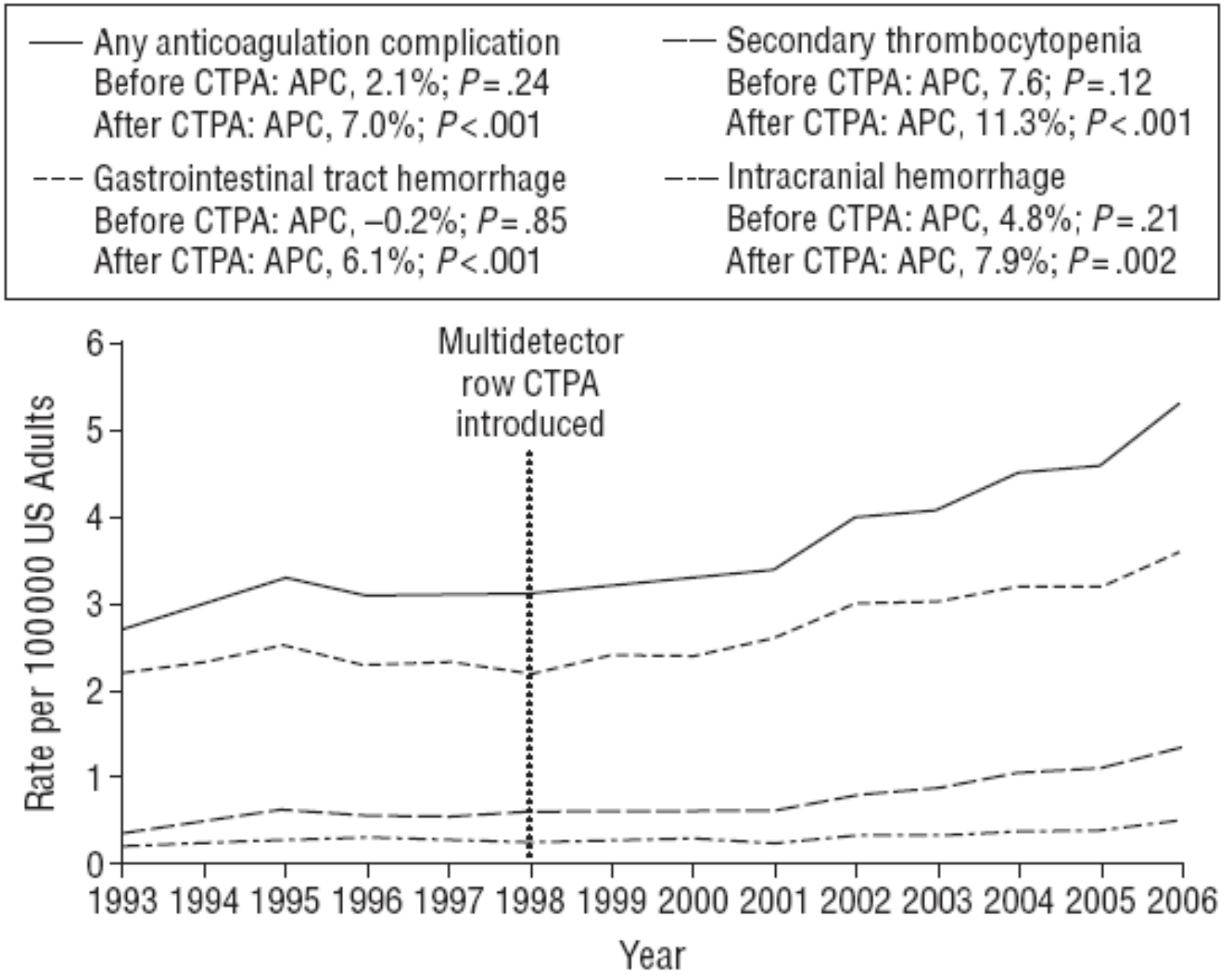
Evidence of Overdiagnosis

Renda Soylemez Wiener, MD, MPH; Lisa M. Schwartz, MD, MS; Steven Woloshin, MD, MS

Arch Intern Med. 2011;171(9):831-837



More sensitive test detects more pulmonary emboli, and new cases do not benefit from treatment (mild disease).


Any anticoagulation complication
Before CTPA: APC, 2.1%; P = .24
After CTPA: APC, 7.0%; P < .001
Secondary thrombocytopenia
Before CTPA: APC, 7.6; P = .12
After CTPA: APC, 11.3%; P < .001
Gastrointestinal tract hemorrhage
Before CTPA: APC, –0.2%; P = .85
After CTPA: APC, 6.1%; P < .001
Intracranial hemorrhage
Before CTPA: APC, 4.8%; P = .21
After CTPA: APC, 7.9%; P = .002
Multidetector row CTPA introduced
Rate per 100000 US Adults
0
1
2
3
4
5
6
1993 1994 1995 1996 1997 1998 1999 2000 2001 2002 2003 2004 2005 2006
Year

The Uncritical Use of High-Tech Medical Imaging

Bruce J. Hillman, M.D., and Jeff C. Goldsmith, Ph.D.

N ENGL J MED 363;1 NEJM.ORG JULY 1, 2010

- Fastest growing medical expenditure
- Evidence base inconsistent
- Regulatory approval but limited testing of new tests for their contribution to improving health
- Direct patient advertising, lay press and WEB pressures underplaying risks and costs
- Overweight of small risks, and liability for underuse much more than for overuse
- Additional tests from interpreters to reduce uncertainty
- Shotgun approach
- Needless exposure to downstream tests and treatment due to overdiagnosis

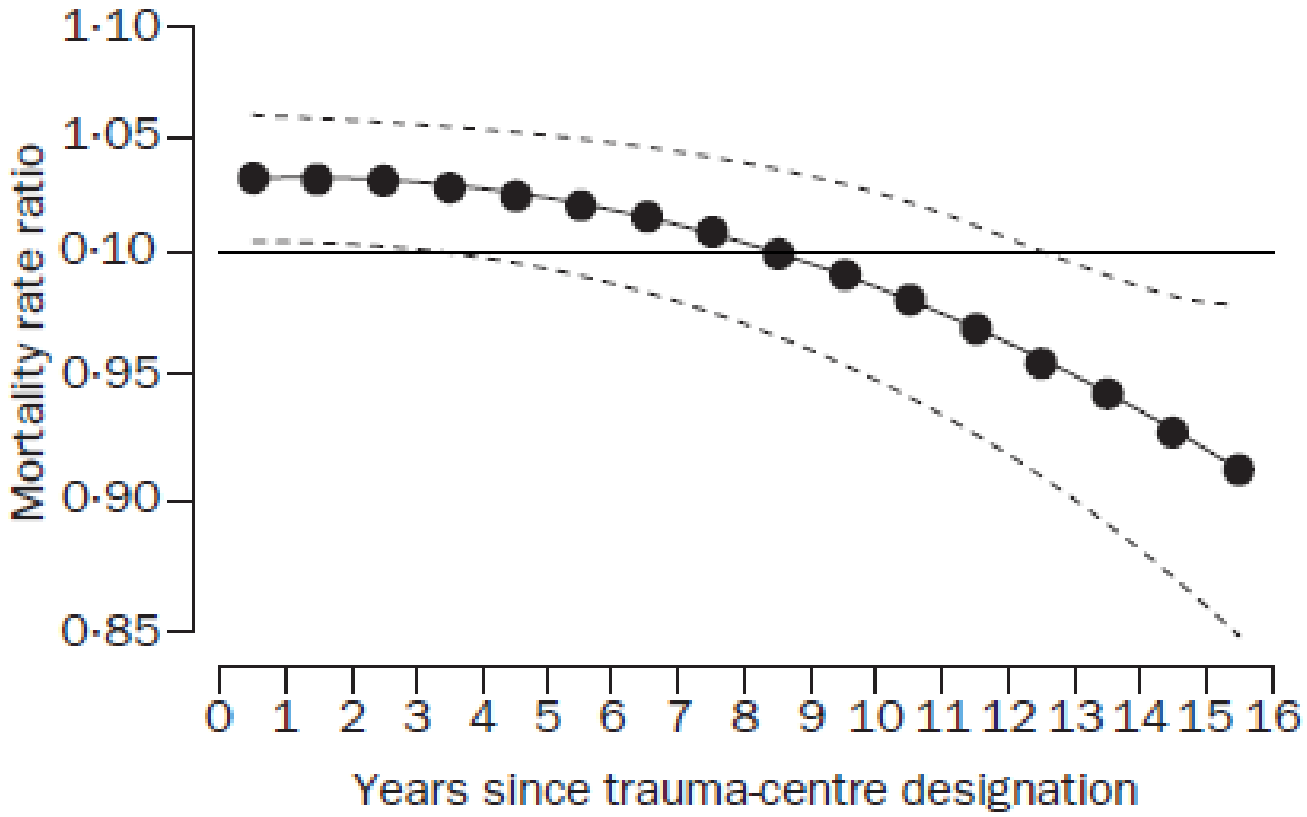
Caso 3
HTA per la rete dell'emergenza

HTA e rete dell'emergenza

- Organizzazione e gestione percorsi clinici interaziendali e regionali (tempo e/o volume dipendenti)
  - Trauma maggiore
  - STEMI
  - Stroke
  - Cardiochirurgia, neurochirurgia
  - Aneurisma aorta addominale

HTA e rete dell'emergenza

- Distribuzione e utilizzo ottimale risorse strutturali e di trasporto
  - *Walk-in centers, minor injury units*
  - PPI, PS, DEA (1° e 2° liv) Trauma centers
  - Ground based & Helicopter Emergency Medical Services



Mortality from motor-vehicle accidents as a function of time from first trauma-centre designation

Avery B Nathens, Fabrice P Brunet, Ronald V Maier

Lancet 2004; **363:** 1794–801

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

A National Evaluation of the Effect of Trauma-Center Care on Mortality

Ellen J. MacKenzie, Ph.D., Frederick P. Rivara, M.D., M.P.H., Gregory J. Jurkovich, M.D., Avery B. Nathens, M.D., Ph.D., Katherine P. Frey, M.P.H., Brian L. Egleston, M.P.P., David S. Salkever, Ph.D., and Daniel O. Scharfstein, Sc.D.

CONCLUSIONS

Our findings show that the risk of death is significantly lower when care is provided in a trauma center than in a non–trauma center and argue for continued efforts at regionalization.

N Engl J Med 2006;354:366-78.

HTA e rete dell'emergenza

Is it the H or the EMS in HEMS that has an impact on trauma patient mortality? A systematic review of the evidence

Daniel P Butler, Imran Anwar, Keith Willett

Emerg Med J 2010;**27**:692–701. doi:10.1136/emj.2009.087486

Conclusions The role and structure of HEMS in a modern trauma service is a debate that is likely to continue. Prehospital care design should be specific to critical incident frequency, geographical arrangements of hospital facilities and travel times within each trauma network. It is also important to consider the benefits and capabilities of the emergency medical team separately from the transport method being considered. An effective helicopter EMS will ultimately depend on effective operating procedures and tasking protocols, clinical governance, and auditing of the helicopter EMS activity.

Helicopter emergency medical services for adults with major trauma (Review)

Galvagno Jr SM, Thomas S, Stephens C, Haut ER, Hirshon JM, Floccare D, Pronovost P

THE COCHRANE COLLABORATION®

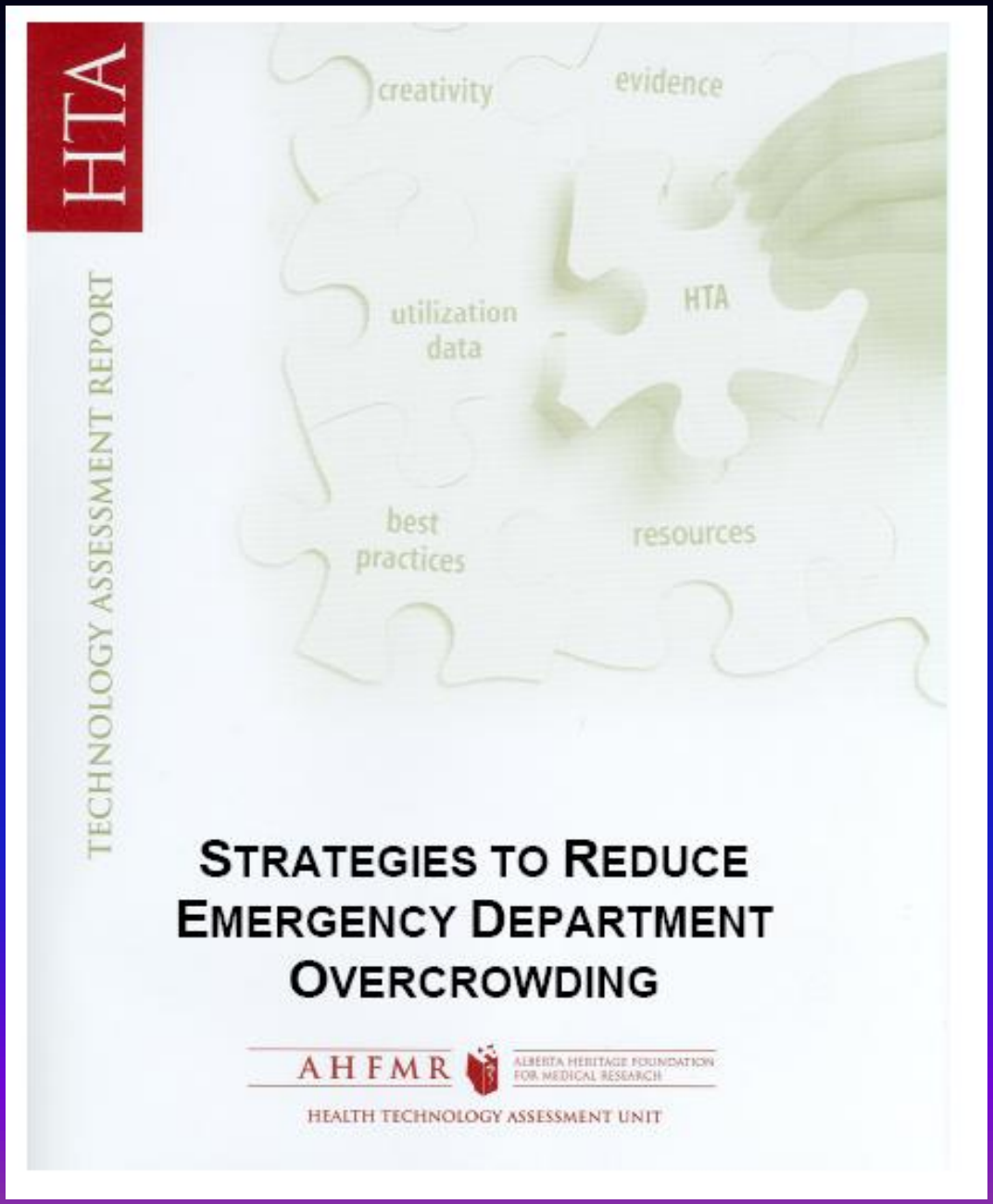
This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2013, Issue 3

Helicopter emergency medical services compared with ground emergency medical services for adults with major trauma

Patient or population: adults (age>15) with major trauma (ISS>15)
Settings: Multinational
Intervention: Transportation to a trauma centre by helicopter emergency medical services (HEMS)
Comparison: Transportation to a trauma centre by ground emergency medical services (GEMS)

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	GEMS	HEMS				
Overall unadjusted mortality	Low risk population		**RR 1.00** (0.76 to 1.30)	163,748	⊕○○○ **very low**	Results could not be reliably combined for meta-analysis due to considerable heterogeneity. The relative effect calculated here reflects *unadjusted mortality* only for studies that reported data enabling the calculation of a risk ratio. See text and Figure 3 (Analysis 1.1) for details
	--	--				
	Medium risk population					
	--	--				
	High risk population					
	--	--				
Quality-adjusted life years (QALY)	--	--	--	--	--	No studies examining QALY as an outcome met the inclusion criteria for this review
Disability-adjusted life years (DALY)	--	--	--	--	--	No studies examining DALY as an outcome met the inclusion criteria for this review

Esempi di HTA nell'emergenza territoriale e ospedaliera



Advanced training in trauma life support for ambulance crews (Review)

Jayaraman S, Sethi D, Wong R

THE COCHRANE COLLABORATION®

This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2014, Issue 8

http://www.thecochranelibrary.com

BMJ 2014;349:g5538 doi: 10.1136/bmj.g5538 (Published 23 September 2014)

VIEWS & REVIEWS

PERSONAL VIEW

Preventing hospital admission: we need evidence based policy rather than "policy based evidence"

Politicians push for evidence that supports whatever initiative they back, but formal evaluation often shows such initiatives to have failed, writes former older people czar **David Oliver**

BMJ

BMJ 2012;345:e6017 doi: 10.1136/bmj.e6017 (Published 18 September 2012)

ANALYSIS

Reducing emergency admissions: are we on the right track?

Most attempts to reduce emergency hospital admissions are focused on people at high risk. **Martin Roland** and **Gary Abel** highlight the misconceptions behind this approach and suggest what to do about them

Overestimating the importance of frequent fliers

Ignoring regression to the mean

Assuming that all interventions are beneficial

Ignoring the possibility of supply induced demand

Forgetting that substantial amounts of variation can be due to chance

Table 2| **Variation in number of referrals or admissions that would occur if variation was due solely to chance (assuming a Poisson distribution)**

	Expected range. % of time that results would fall outside range by chance alone:		
Expected No of events	**50%**	**10%**	**5%**
5	3-6	2-9	1-9
10	8-12	5-15	4-16
25	22-28	17-33	16-35
50	45-54	38-61	37-64
100	93-106	84-116	81-120
200	190-209	177-223	173-228
500	485-515	463-536	457-544
1000	979-1021	948-1052	939-1062

Table 1| **Percentage reduction in admissions in each risk group alone required to meet overall targets for reductions in emergency admissions**

	% reduction required in risk group			
Target overall reduction (%):	Very high risk (0.5% of population)	High risk (0.5-5% of population)	Moderate risk (6-20% of population)	Low risk (80% of population)
1	10.8	4.0	3.9	2.5
2	21.5	8.1	7.8	5.0
3	32.3	12.1	11.8	7.5
4	43.0	16.2	15.7	10.0
5	53.8	20.2	19.6	12.5
10	107.5	40.4	39.2	25.0

VIEWPOINT

Engineering a Better Health Care System
A Report From the President's Council of Advisors on Science and Technology

JAMA August 27, 2014

Christine K. Cassel, MD
National Quality Forum, Washington, DC.

Robert S. Saunders, PhD
National Quality Forum, Washington, DC.

Accelerate Alignment of Payment Systems With the Desired Outcomes

Increase Access to Relevant Health Data and Analytics

Involve Communities in Improving Health Care Delivery

Share Lessons Learned From Successful Improvement Efforts

Train Health Professionals in New Skills and Approaches

SPECIAL ARTICLE

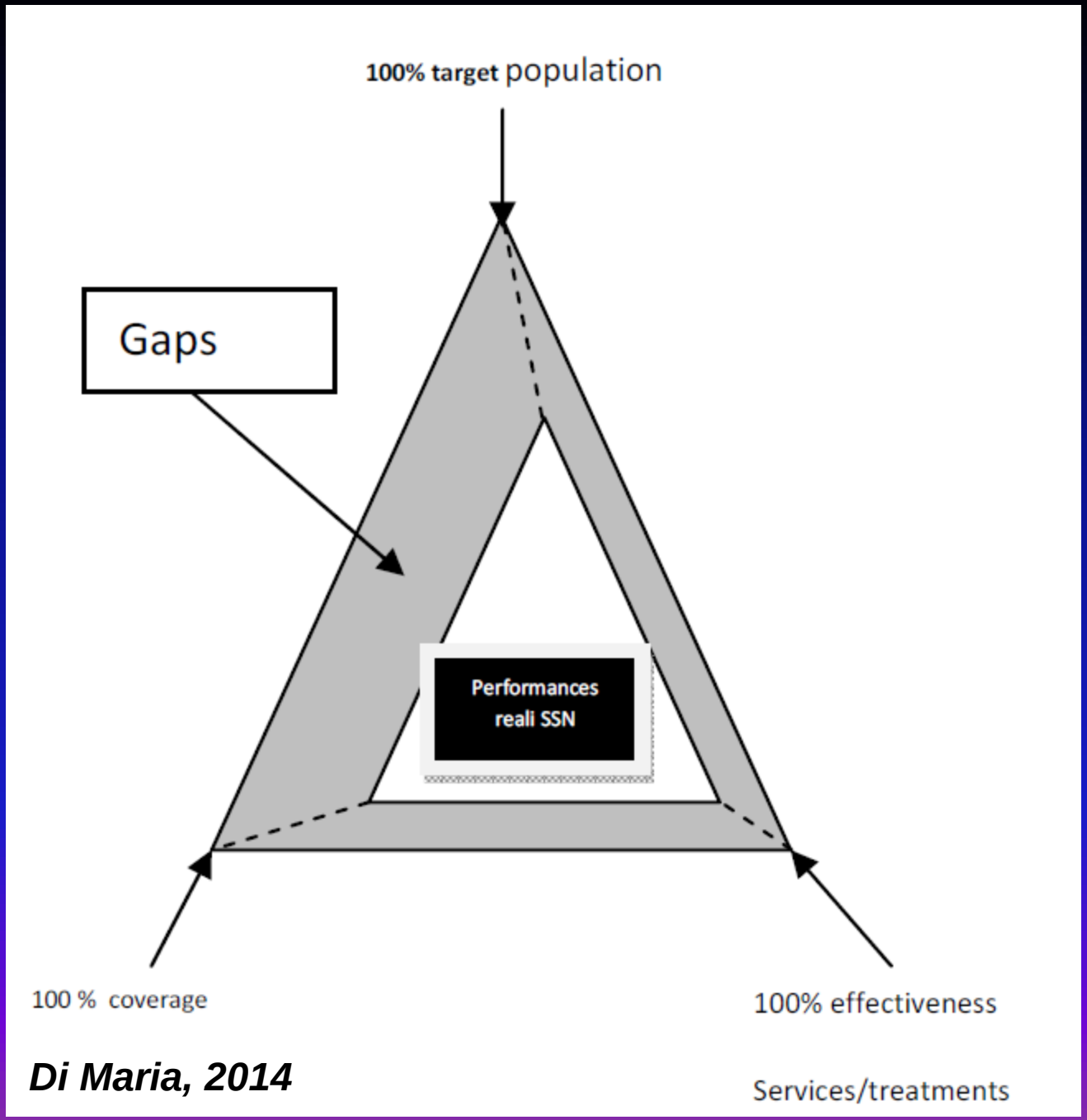
ONLINE FIRST | LESS IS MORE

"Less Is More" in Critically Ill Patients

Not Too Intensive

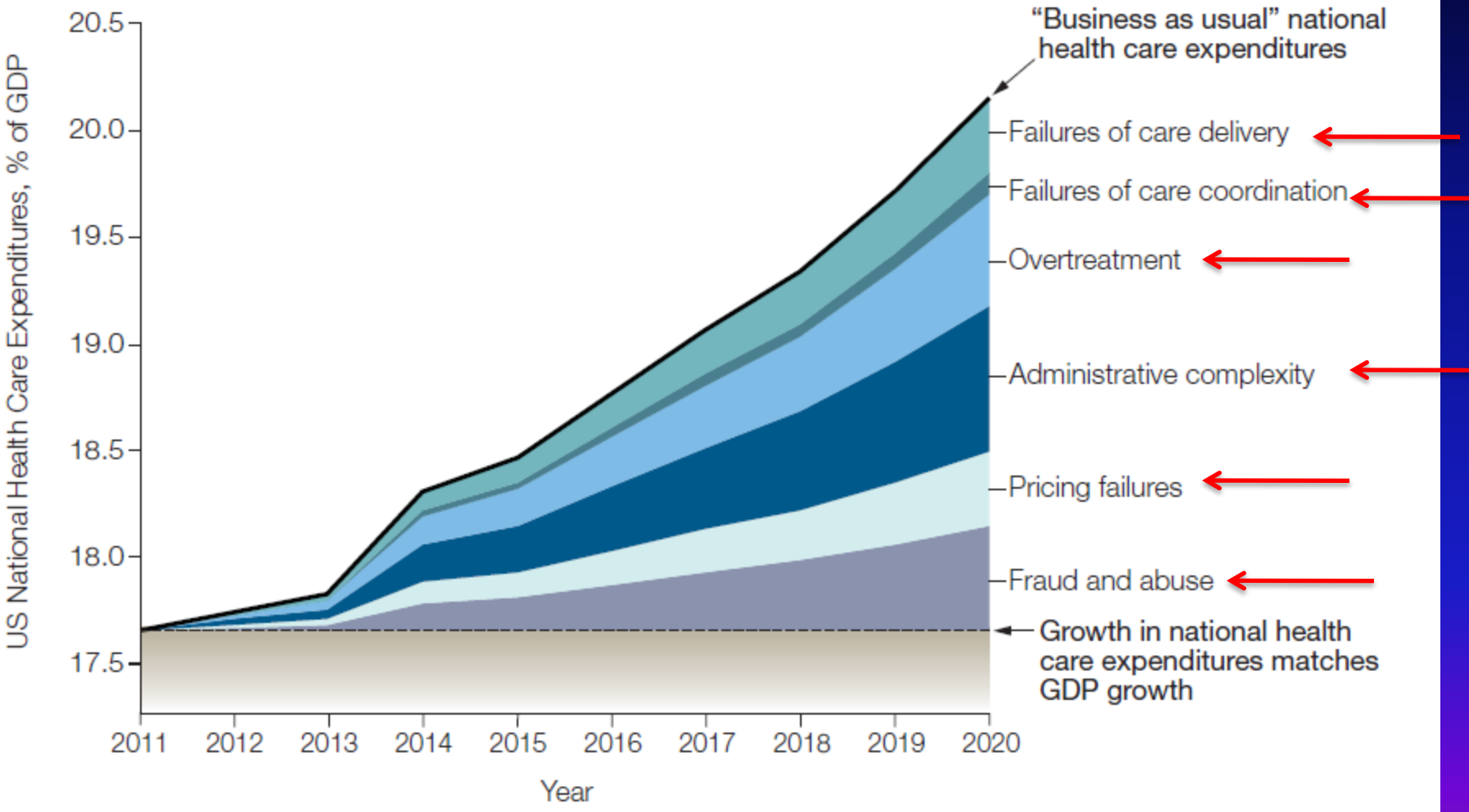
Matthijs Kox, PhD; Peter Pickkers, MD, PhD

JAMA Intern Med.
Published online June 10, 2013.
doi:10.1001/jamainternmed.2013.6702



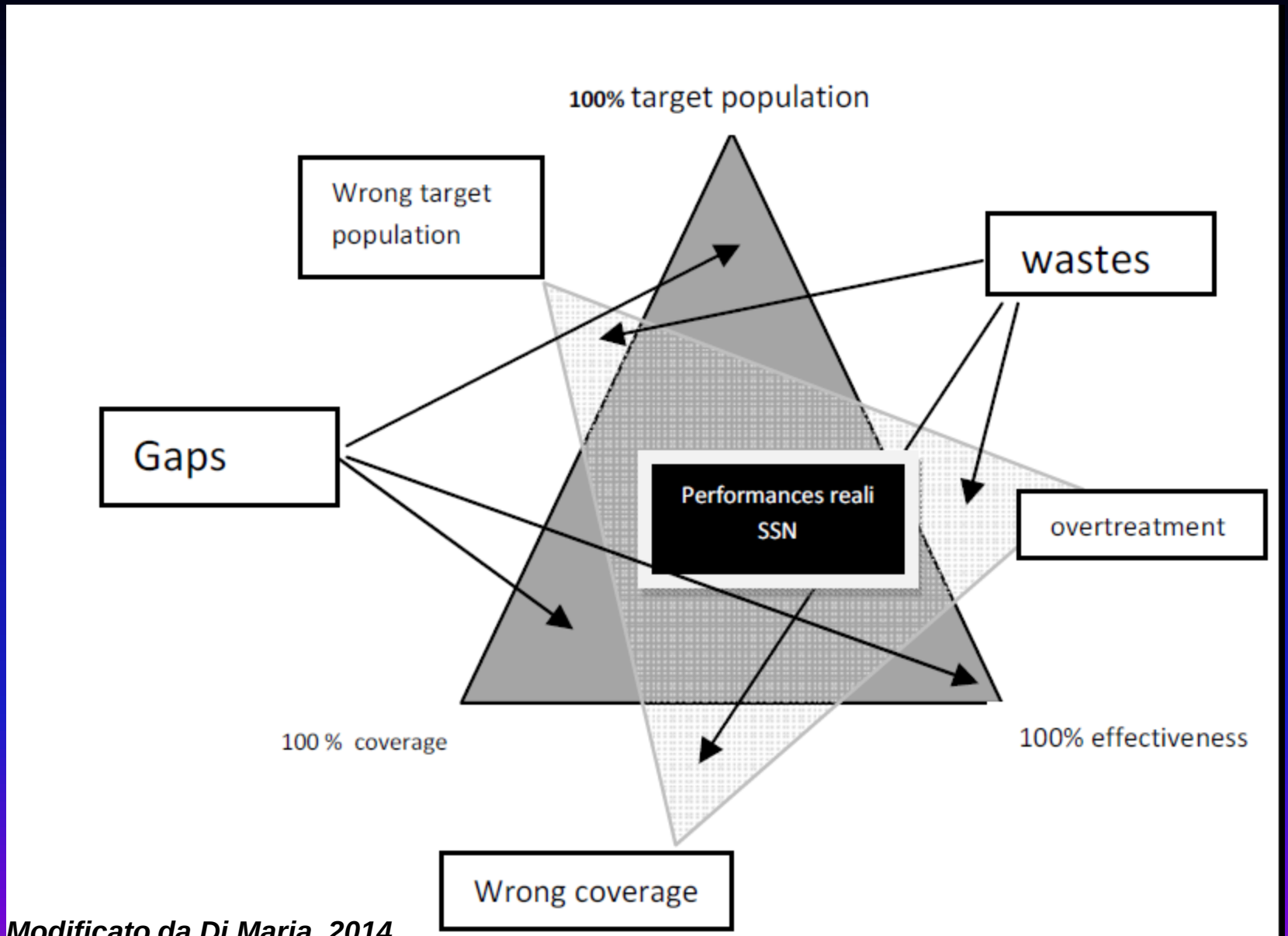
Di Maria, 2014

Figure. Proposed "Wedges" Model for US Health Care, With Theoretical Spending Reduction Targets for 6 Categories of Waste



Berwick et al

JAMA. 2012;307(14):1513-1516



Modificato da Di Maria, 2014

Le dimensioni della qualità in sanità (IOM, 2001)

- **S**afety
- **T**imeliness
- **E**fficacy (Effectiveness)
- **E**quity
- **E**fficiency
- **P**atient centeredness