

**LA PREVENZIONE VACCINALE
UNO STRUMENTO DI SOSTENIBILITÀ**

2019 MOTORE
SANITÀ
Gestire il Cambiamento

Investire in prevenzione, aumentare il value for money

Nino Cartabellotta
Fondazione GIMBE

ROMA

SALA ATTI PARLAMENTARI
BIBLIOTECA DEL SENATO
"GIOVANNI SPADOLINI"

Piazza della Minerva, 38

11 DICEMBRE 2019

Disclosure

- La Fondazione GIMBE, di cui sono Presidente, eroga attività di formazione e coaching su alcuni temi trattati dalla mia relazione
- Per la presente relazione non ho ricevuto alcun compenso



Outline

1. Value in healthcare
2. Value for money
3. Value of preventive care



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1. Value in healthcare
2. Value for money
3. Value of preventive care



What Is Value in Health Care?

Michael E. Porter, Ph.D.

N ENGL J MED 363;26 NEJM.ORG DECEMBER 23, 2010

Value

=

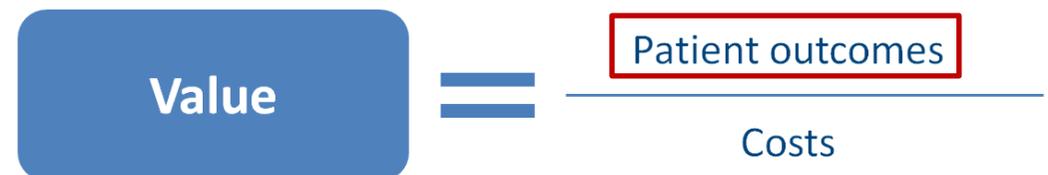
Patient outcomes

Costs

Quali outcome?

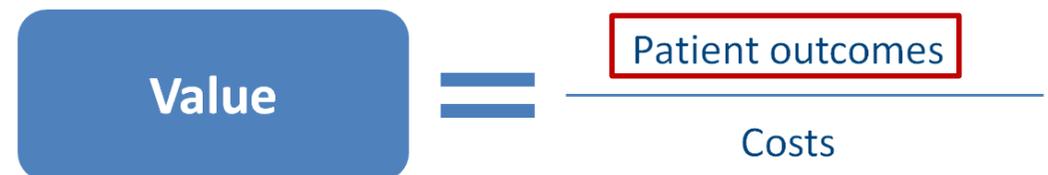
Nella sua originale formulazione il concetto di outcome include esclusivamente esiti rilevanti per il paziente:

- riduzione della mortalità e delle complicanze
- miglioramento della prognosi di malattia
- riduzione dei sintomi e del dolore
- miglioramento della qualità di vita e della funzionalità
- riduzione degli effetti avversi



Quali outcome?

- Produttori di farmaci e tecnologie vogliono estendere i “criteri di inclusione” del numeratore, considerando outcome non strettamente correlati alla salute del paziente
- Governi e Istituzioni espandono i “criteri di inclusione del denominatore”, includendo non solo i costi diretti, ma anche quelli indiretti, inclusi quelli ambientali





2013 Policy Forum

**HTA and Value:
Assessing value, making value-based decisions,
and sustaining innovation**

3 – 5 February 2013
Hotel Miramar Barcelona
Barcelona, Spain

Stakeholders

- Patient and/or group of patients
- Caregivers/families
- At-risk/vulnerable populations
- Clinicians
- Professional associations
- Health delivery organizations
- Health system
- HTA bodies/systems
- Academia/Researchers
- Payers (national/regional health authority, health plan, insurance company)
- Government
- Regulators
- Technology developers (device and pharmaceutical industry)
- Generic manufacturers
- Public/society
- Non-health sector stakeholders & programs (employers, workforce, EI, pensions, taxes, penal system, education system, etc.)

Whose perspective counts?

Which criteria count?

Examples of Value Measures

Health outcomes (population and individual health outcomes)

- Increased effectiveness, including level of certainty of outcome or heterogeneity of treatment effect.
- Increased safety

Other patient, caregiver and/or population health benefits

- Reduction of uncertainty (e.g. following diagnosis)
- Reduced caregiver burden/early return to normal activities and work (productivity)
- Technology meets unmet need
- Greater treatment choice
- Improved access to service
- Greater equity

Health system benefits

- Decreased net cost of delivery per patient
- Lesser budget impact
- Fewer sunk and other costs (e.g., operating costs)
- Greater economies of scale or scope
- Greater ease of incorporating technology into current system (and ease of future disinvestment)
- Improved administration/delivery

Benefits beyond the health system

- Decreased costs to other areas of government (e.g., education, penal system)
- Greater political acceptability
- Positive social impact (e.g., increased societal productivity, more environmentally friendly "greener")

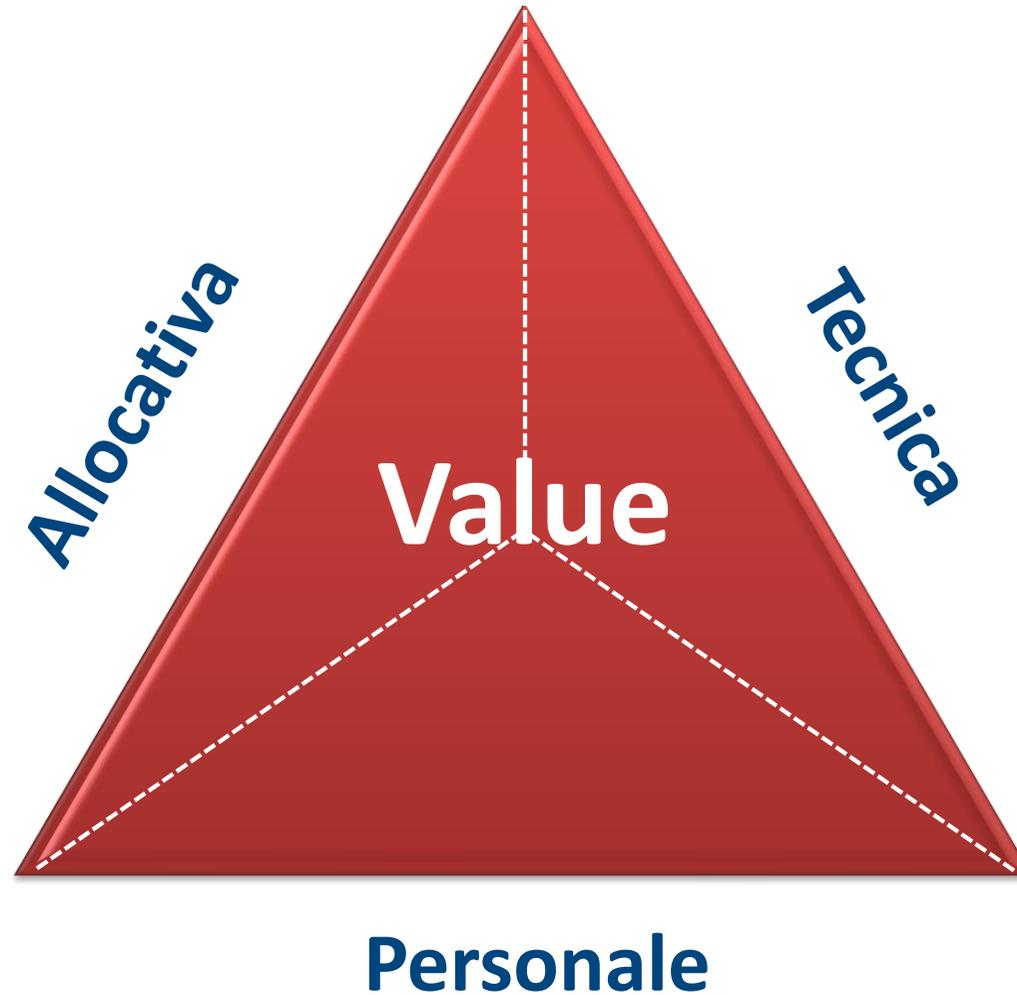
	Australia	Canada	France	Germany	Netherlands	Sweden	UK
	PBAC	CADTH	HAS	IQWiG	Health Care Insur. Bd., CHF	TLV	NICE
Types of technologies/interventions assessed							
• Drugs	✓	✓	✓	✓	✓	✓	✓
• Devices		✓	✓				✓
• Procedures, diagnostics, tests, surgeries			✓				✓
• Public health interventions			✓				✓
• Systems/services/delivery		✓					
Information requirements		Clinical benefit; health economic information required to establish value for money. Other evidence on equity, public health, and budget impacts may be submitted.	Clinical benefit; health economic information recommended, but not required, to establish value for money. Other evidence on public health impact, innovative characteristics, and budget impact may be submitted.	Clinical benefit; health economic information only considered when a manufacturer and the GKV-SV cannot reach agreement regarding price, at which time IQWiG may conduct an economic assessment. Other required information includes additional benefit in relation to appropriate comparator therapy and budget impact.	Clinical benefit; health economic information required to establish value for money. Other evidence on innovative characteristics and budget impact may be submitted.	Clinical benefit; health economic information required to establish value for money. Other evidence on disease burden/severity and equity impacts may be submitted.	Clinical benefit; health economic information required to establish value for money. Other evidence on societal preferences, equity impacts, innovative characteristics, and budget impact may be submitted.
Assessment of therapeutic value (preferred/required approach)							
• QALY	✓	✓			✓	✓	✓
• SMR/ASMR			✓				
• Benefit assessment categorization				✓			
Assessment of economic value (preferred/required approach)							
• CUA	✓	✓			✓	✓	✓
• CEA	In some cases	✓	✓		In some cases	In some cases	In some cases

Promoting Triple Value Healthcare in Countries with Universal Healthcare

Anant Jani and Muir Gray

Healthcare Papers 2016;15:42-48

Triple Value Healthcare





TRIPLE VALUE

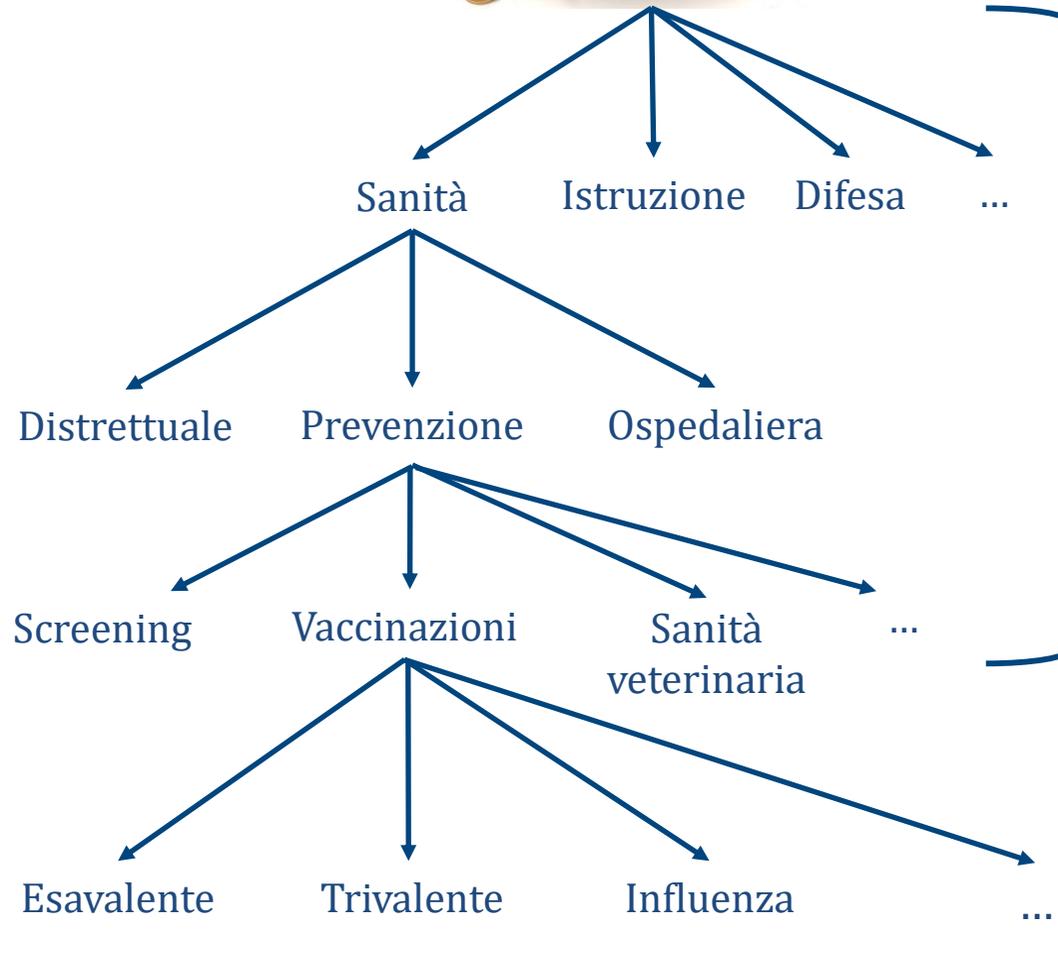
STAKEHOLDER

Governo

**Governo
Regioni**

**Regioni,
Aziende**

**Aziende
Medici
Pazienti**



DIMENSIONI

Allocativa

Tecnica

Personale



TRIPLE VALUE



STAKEHOLDER

DIMENSIONI

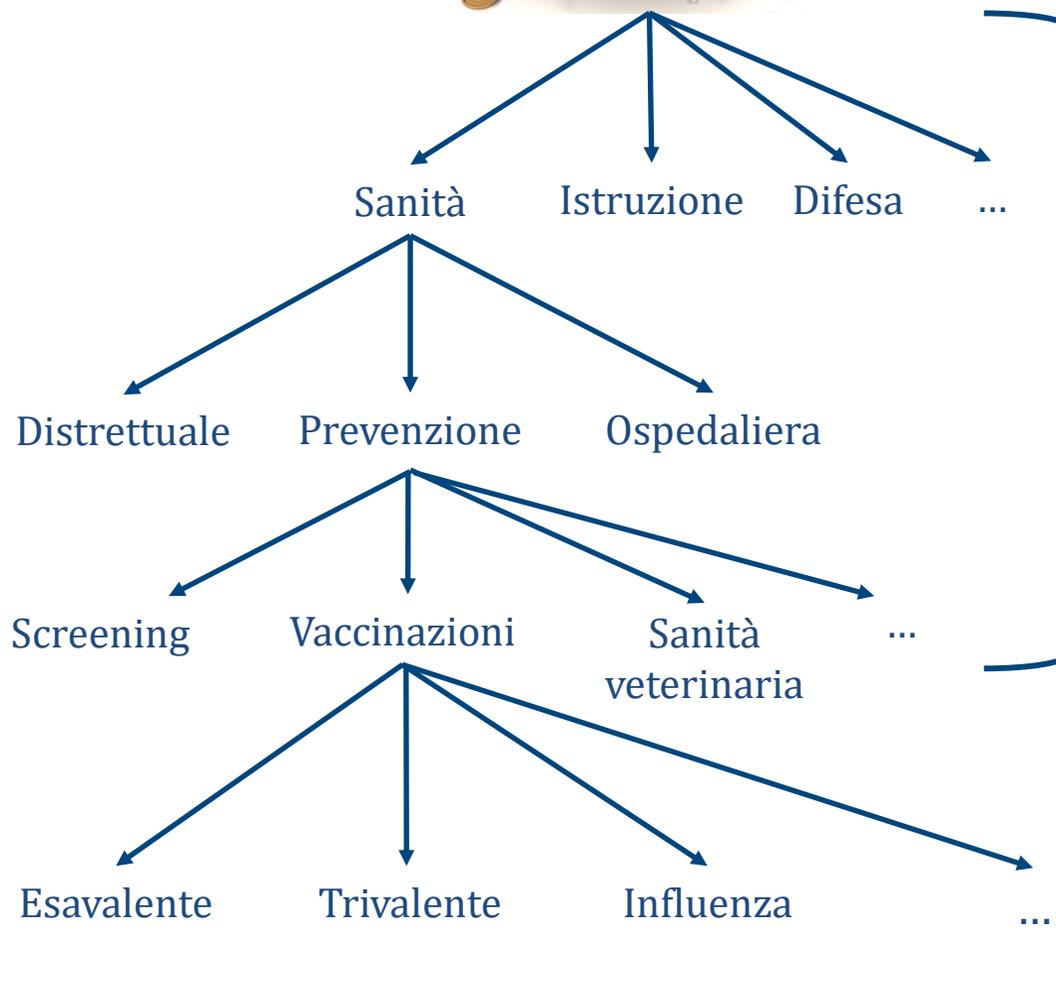
Stakeholder
Governo

Stakeholder
Governo
Regioni

Stakeholder
Regioni,
Aziende

Stakeholder
Aziende
Medici
Pazienti

**Programmi
reti
percorsi**



Dimensioni
Allocativa

Dimensioni
Tecnica

Dimensioni
Personale

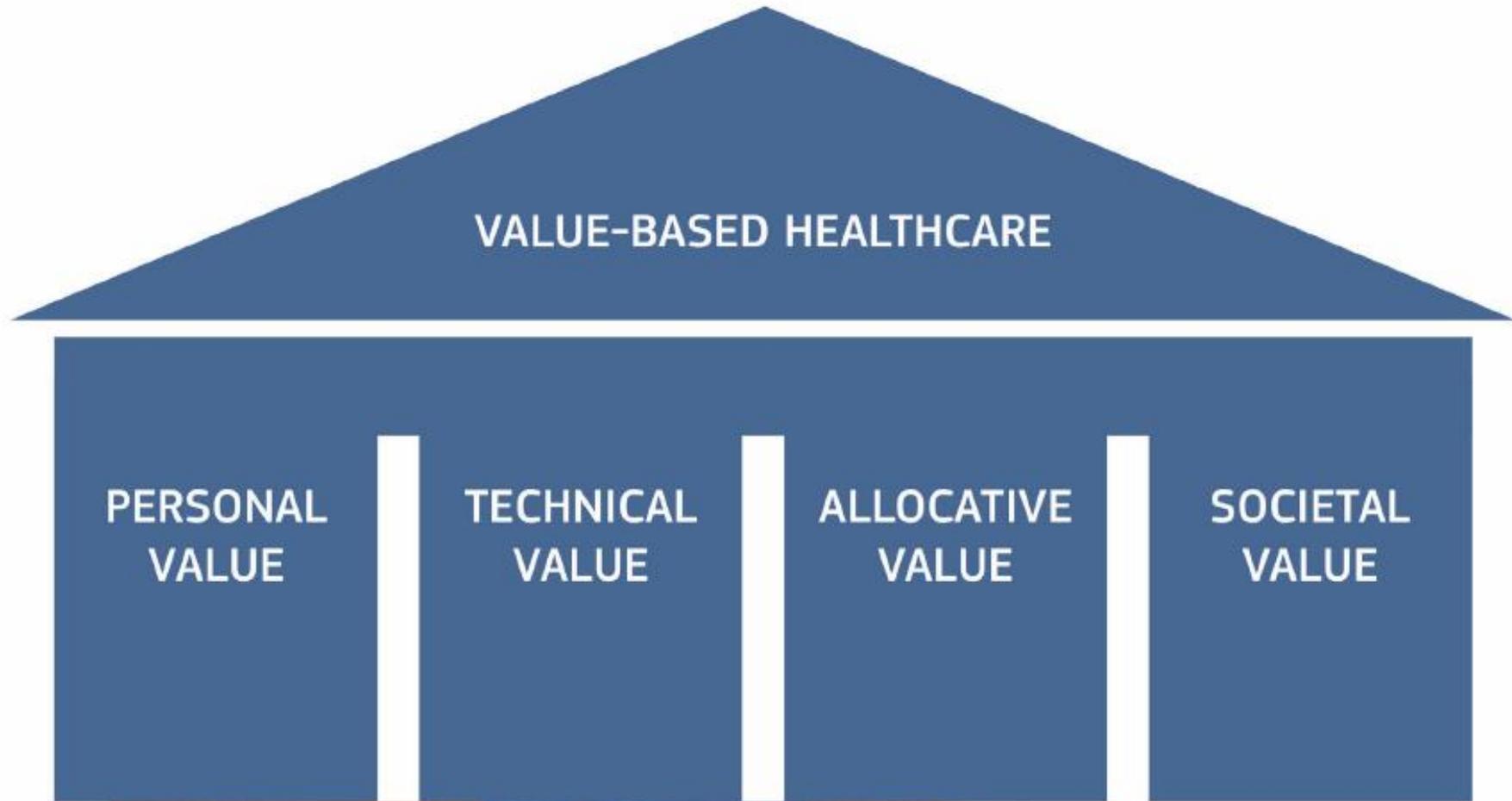


DEFINING VALUE IN “VALUE-BASED HEALTHCARE”

Report of the
**Expert Panel on effective ways of
investing in Health (EXPH)**

26 June 2019

Quadruple Value Model



Quadruple Value Model

- **Personal value:** appropriate care to achieve patients' personal goals
- **Technical value:** achievement of best possible outcomes with available resources
- **Allocative value:** equitable resource distribution across all patient groups
- **Societal value:** contribution of healthcare to social participation and connectedness

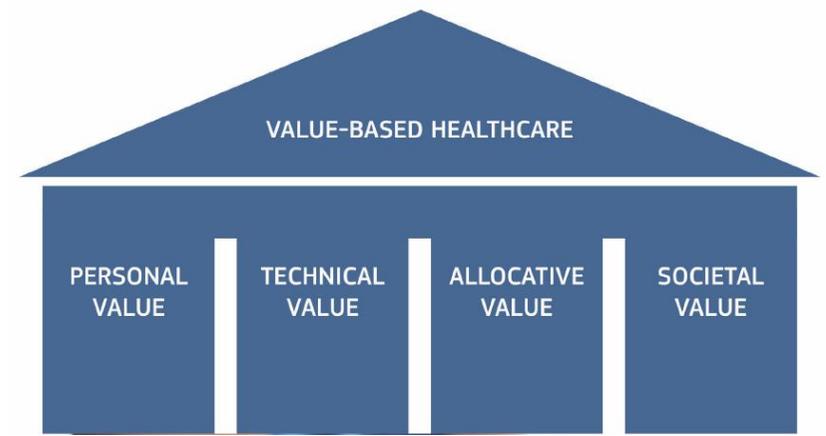
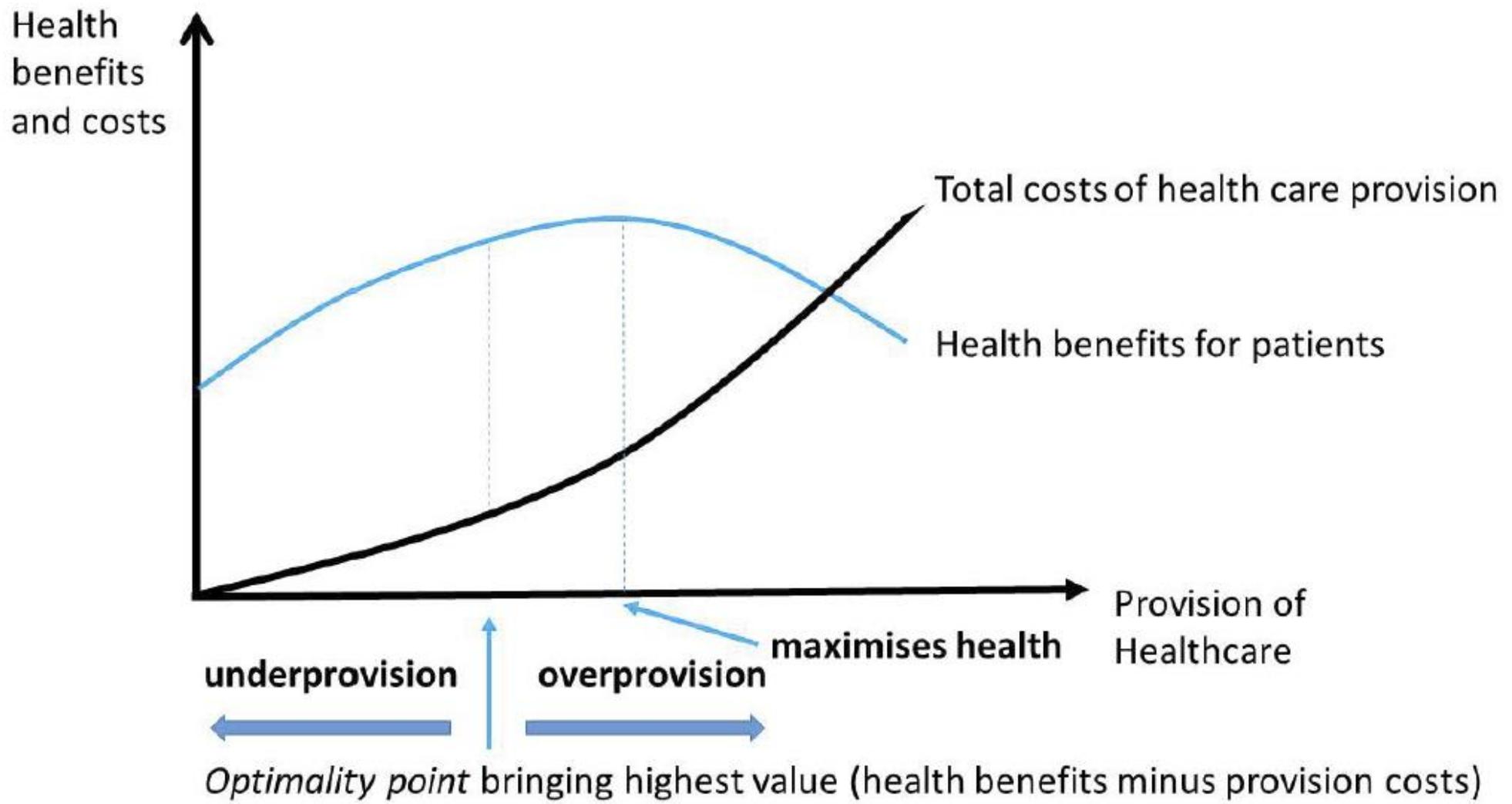


Figure 2: (Theoretical) illustration of the relation between healthcare provision, health benefits and costs of provision

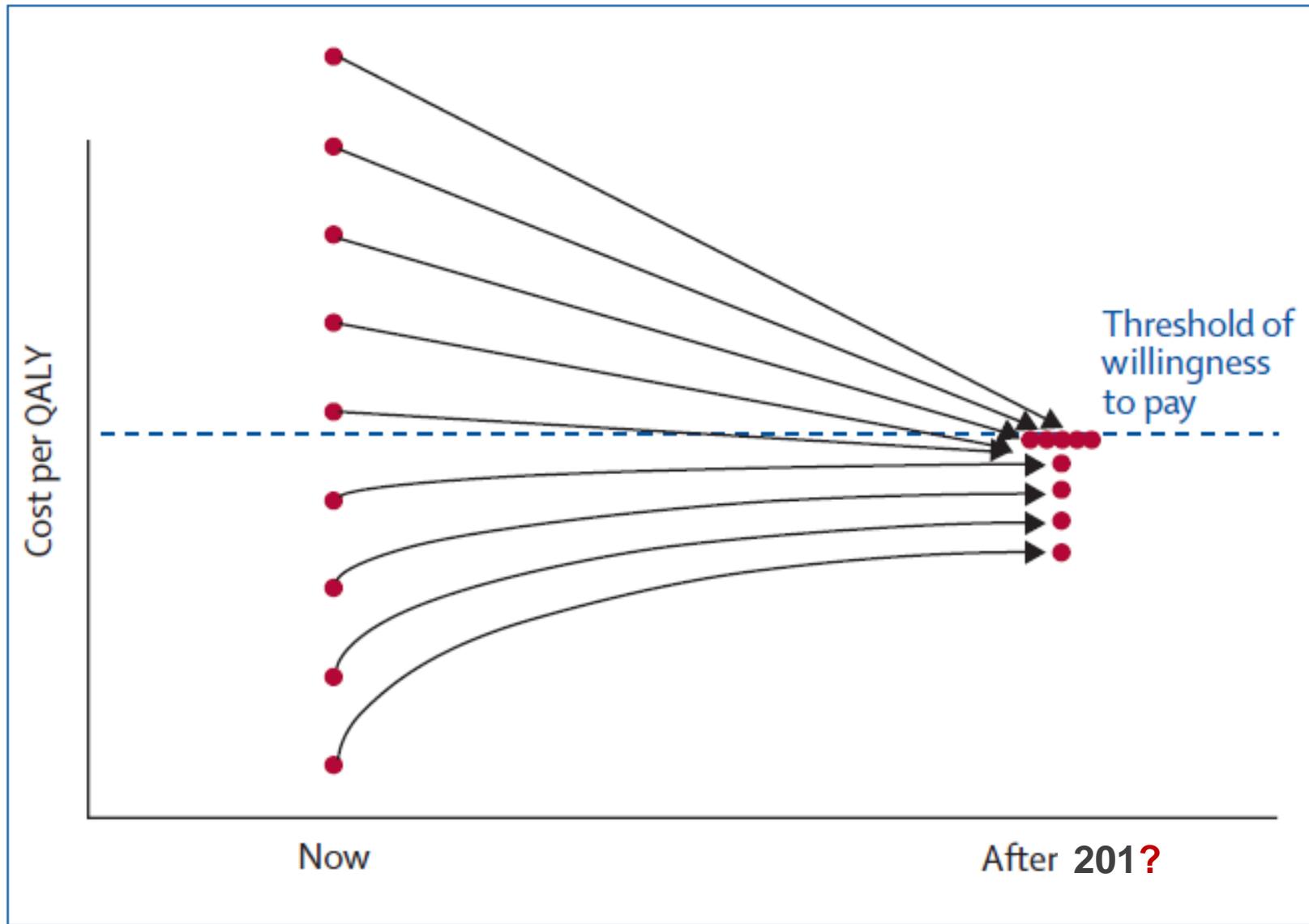


Value-based pricing of drugs in the UK

**David J Webb, Andrew Walker*

Clinical Pharmacology Unit, Queen's Medical Research Institute,
Edinburgh EH16 4TJ, UK (DJW); and Robertson Centre for
Biostatistics, University of Glasgow, Glasgow, UK (AW)

www.thelancet.com Vol 369 April 28, 2007



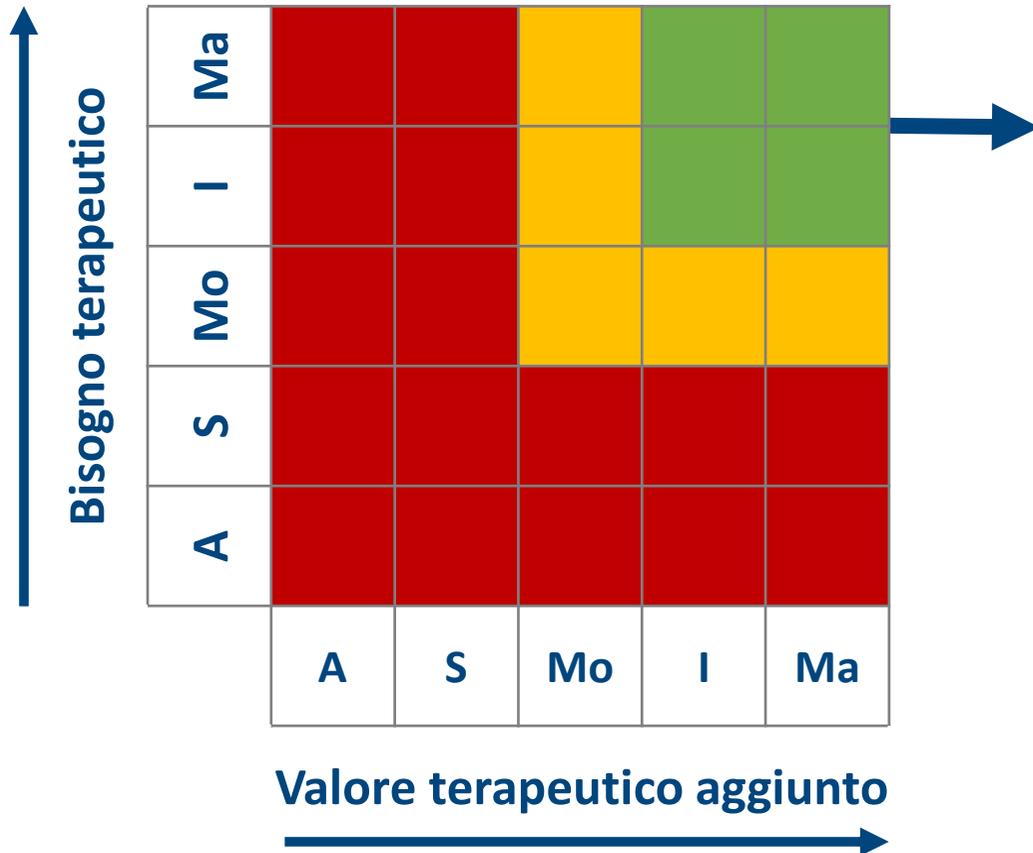


Agenzia Italiana del Farmaco

AIFA

IL DIRETTORE GENERALE

OGGETTO: Criteri per la classificazione dei farmaci innovativi e dei farmaci oncologici innovativi ai sensi dell'articolo 1, comma 402 della legge 11 dicembre 2016, n. 232.



Ma: massimo
I: importante
Mo: moderato
S: scarso
A: assente

Modificato dal grafico ideato da Giuseppe Recchia
 In: Di Marzio S. *AboutPharma* 2017 n.148:28-30

Value-based pricing

- Rispetto alla formula del *value* :
 - Commissione Tecnico Scientifica (CTS): valuta il numeratore
 - Comitato Prezzi e Rimborso (CPR): "negozia" con l'azienda il denominatore
- Le due fasi dovrebbero essere integrate in quanto la valutazione separata non concretizza l'applicazione del *value-based pricing*:
 - un farmaco a innovatività condizionata potrebbe aumentare il proprio *value* se il produttore accetta di ridurre il prezzo
 - un farmaco innovativo potrebbe avere un *value* moderato o, addirittura basso, se prezzo è molto elevato

Outline

1. Value in healthcare
- 2. Value for money**
3. Value of preventive care



2019



4° Rapporto sulla sostenibilità del Servizio Sanitario Nazionale

www.rapportogimbe.it

Presentato a Roma, 11 giugno 2019
Sala Capitolare, Chiostro del Convento
di Santa Maria sopra Minerva
Senato della Repubblica



#salviamoSSN

Prestazioni sanitarie

Evidence & Value

Value elevato

Benefici adeguati rispetto a costi e alternative
Liste positive, finanziamento pubblico

Value basso

Benefici minimi rispetto a costi e alternative
Spesa privata, partecipazione

Value incerto

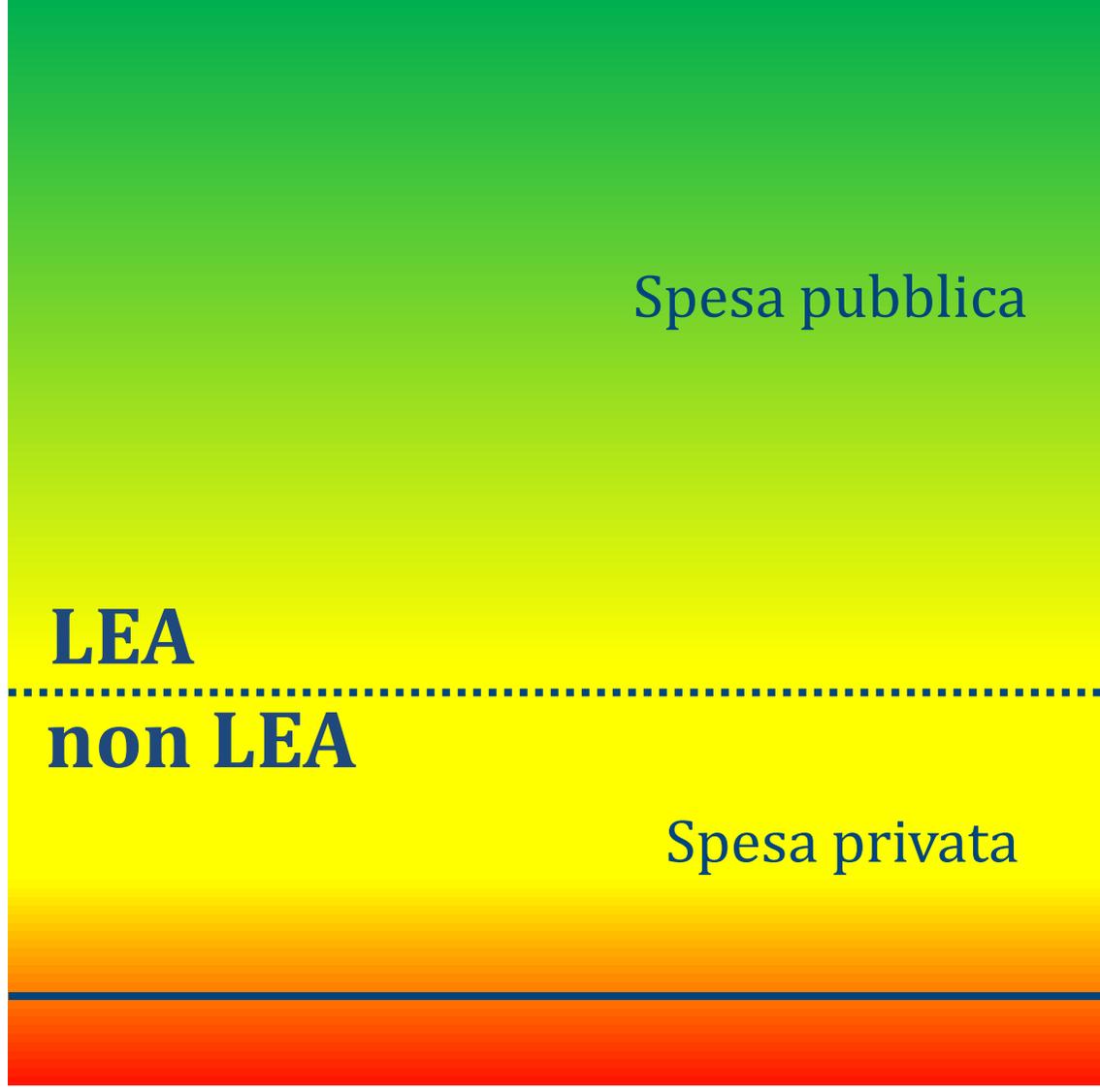
Benefici non noti (aree grigie)
Spesa privata, partecipazione,
ricerca comparativa indipendente

Value negativo

Rischi maggiori dei benefici
Liste negative

Prestazioni sanitarie

Dannose Futili Necessary Indispensabili



Elevato

Basso/incerto

Negativo

Value

Value for money della spesa sanitaria

- **No value expenditure:** non si traduce in servizi e prestazioni sanitarie a non ha alcun impatto sugli esiti di salute
- **Negative value expenditure:** servizi e prestazioni sanitarie che peggiorano gli esiti di salute e, a cascata, generano ulteriori costi
- **Low value expenditure:** servizi e prestazioni sanitarie che, rispetto al costo, determinano benefici marginali o nulli sugli esiti di salute o hanno un profilo rischio-beneficio non noto
- **High value expenditure:** servizi e prestazioni sanitarie che, rispetto al costo, determinano benefici rilevanti in termini di salute



Cosa riduce il *value for money* della spesa sanità?

- Sottrazione indebita di risorse
- Costi di acquisto superiori al valore del prodotto
- Inefficienze amministrative
- Bassa produttività
- Inadeguato coordinamento tra setting di cura
- Erogazione di interventi sanitari inefficaci, inappropriati, dal *value* basso o negativo
- Mancata erogazione di interventi sanitari efficaci, appropriati e dall'elevato *value*



*“gli sprechi sono generati da
attività che consumano risorse
senza generare value”*

Taiichi Ohno, Toyota

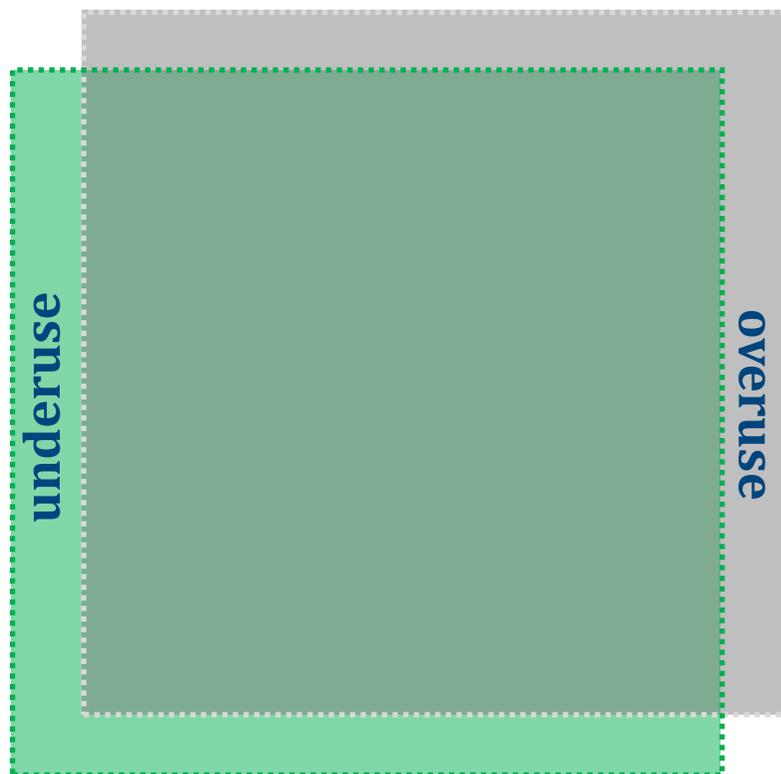


Stima sprechi e inefficienze 2017

Categoria	%	Mld €*	(± 20%)
1. Sovra-utilizzo	30	6,45	(5,16 – 7,74)
2. Frodi e abusi	22	4,73	(3,79 – 5,67)
3. Acquisti a costi eccessivi	10	2,15	(1,72 – 2,58)
4. Sotto-utilizzo	15	3,22	(2,58 – 3,87)
5. Inefficienze amministrative	11	2,36	(1,89 – 2,84)
6. Inadeguato coordinamento assistenza	12	2,58	(2,06 – 3,10)

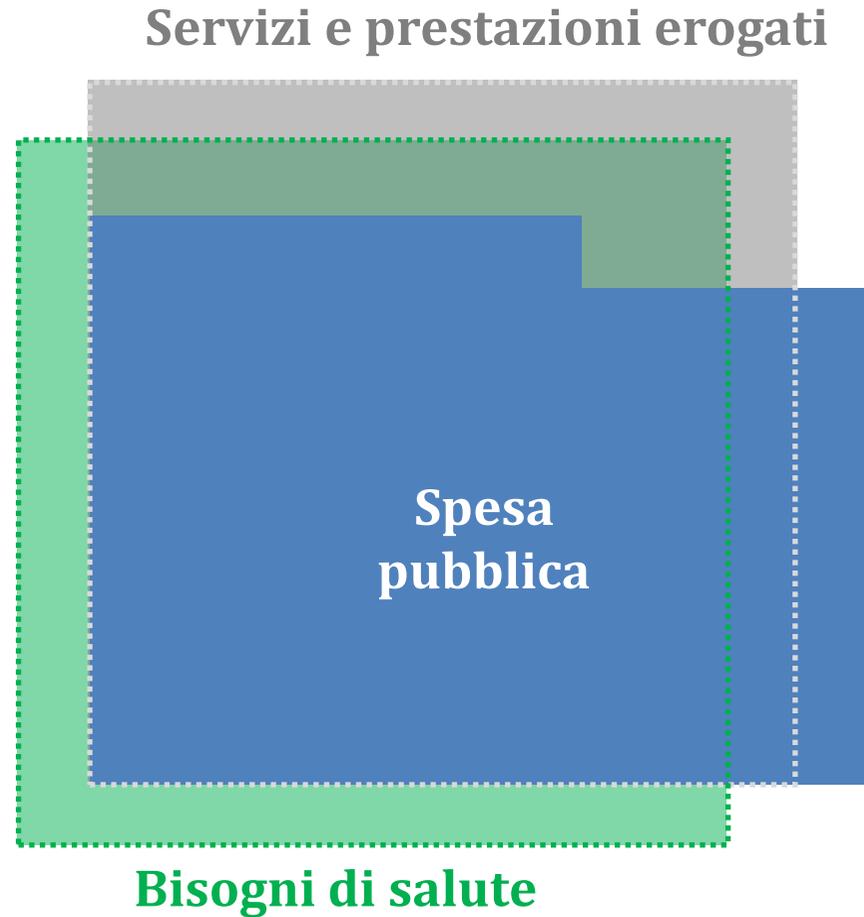
*€ 21,5 miliardi (range 17,20 – 25,79) calcolati proiettando la stima del 19% sui € 113,131 miliardi di spesa pubblica

Servizi e prestazioni erogati



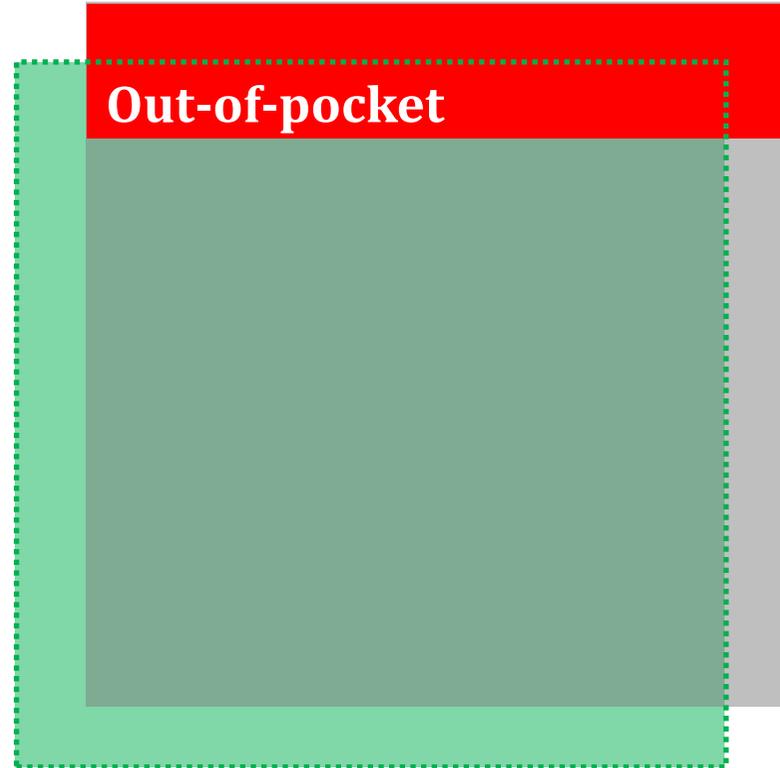
Bisogni di salute

€ 113,1 miliardi



€ 35,9 miliardi

Servizi e prestazioni erogati



Bisogni di salute

€ 5,8 miliardi



Spesa sanitaria 2017

€ 154,9 mld

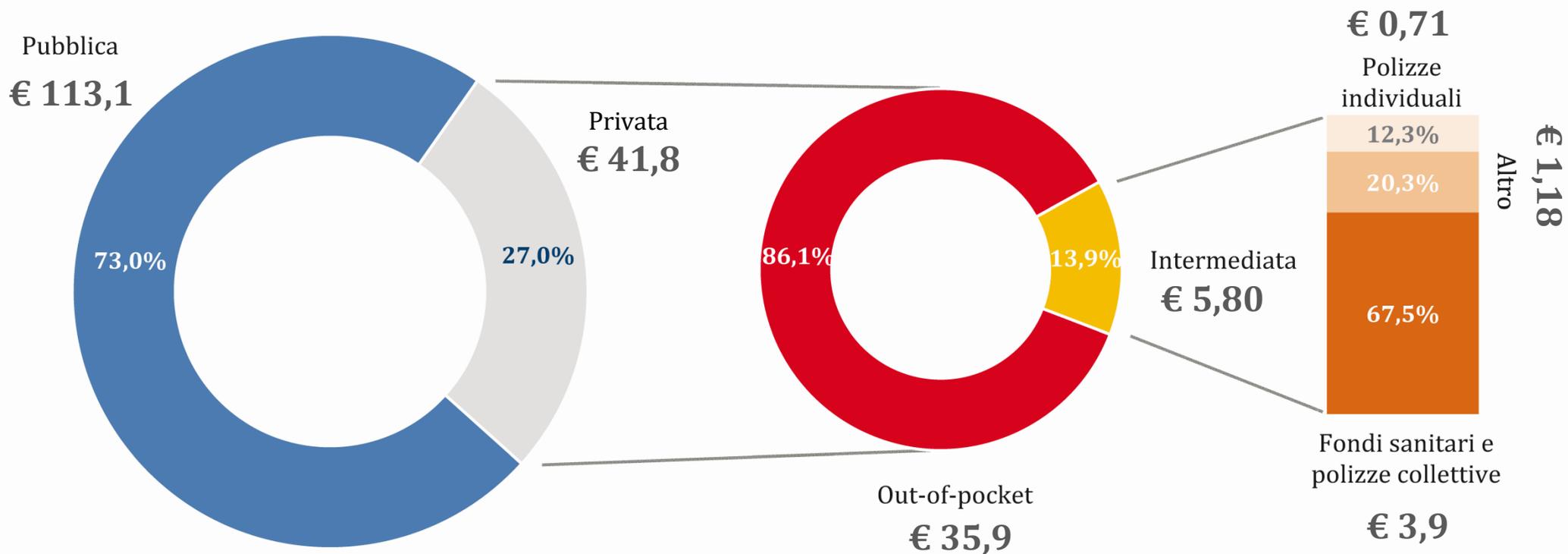


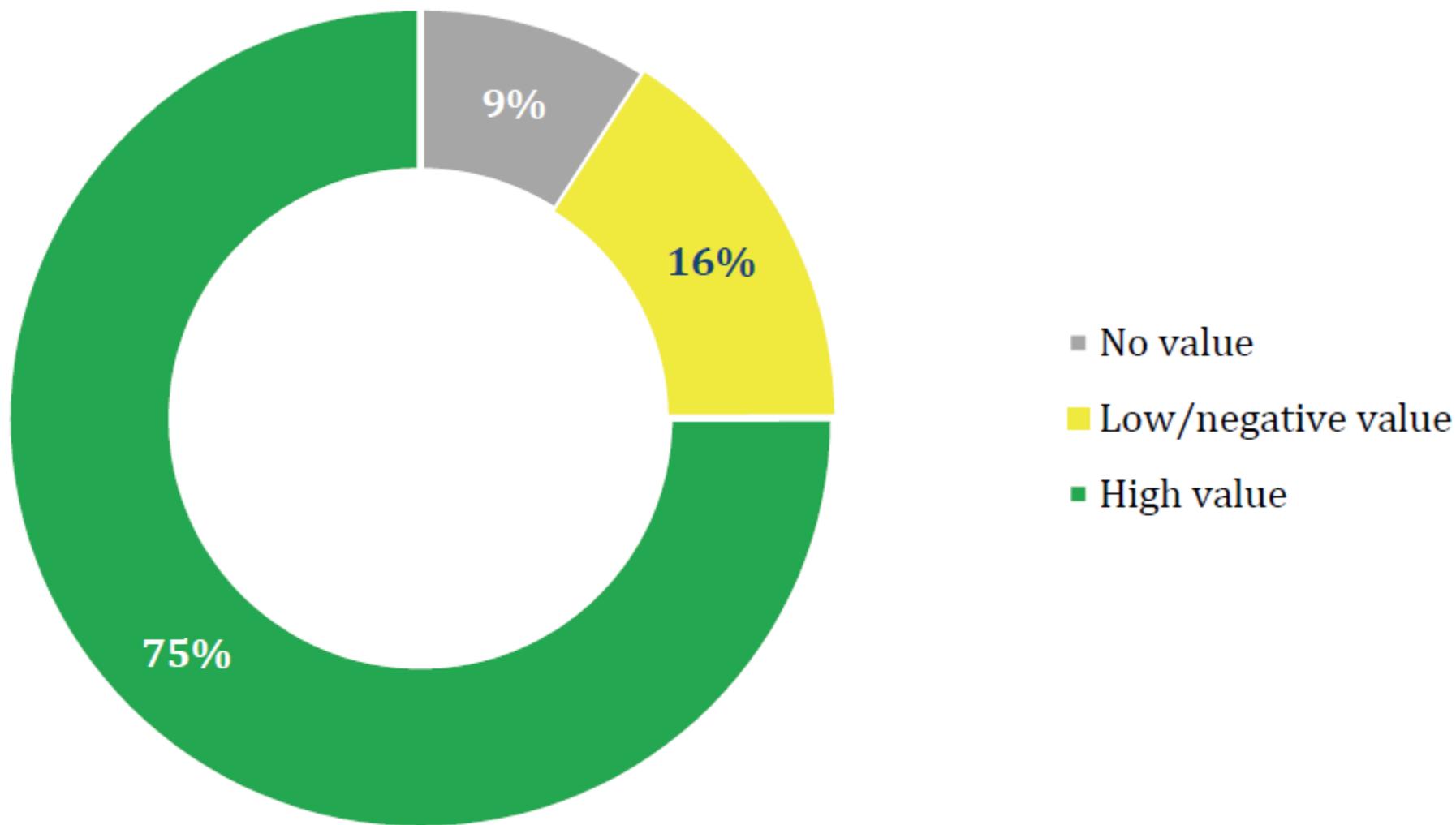
Tabella 2.14. Value for money della spesa sanitaria, valori assoluti (anno 2017)

Spesa sanitaria 2017		<i>No value</i>	<i>Low/negative value</i>	<i>High value</i>
Pubblica	€ 113.131	€ 11.822	€ 9.673	€ 91.636
Out-of-pocket	€ 35.989	€ 0	€ 14.075	€ 21.914
Intermediata	€ 5.800	€ 2.320	€ 812	€ 2.668
Totale	€ 154.920	€ 14.142	€ 24.560	€ 116.218

Tabella 2.13. Value for money della spesa sanitaria, valori percentuali (anno 2017)

Spesa sanitaria	<i>No value</i>	<i>Low/negative value</i>	<i>High value</i>
Pubblica	10%	9%	81%
Out-of-pocket	0%	39%	61%
Intermediata	40%	14%	46%

Figura 2.28. Value for money della spesa sanitaria (anno 2017)



Value for money della spesa sanitaria

Avviare riforme sanitarie e fiscali e azioni di governance a tutti i livelli per:

- ridurre al minimo *overuse* e *underuse* che determinano gravi conseguenze cliniche, sociali ed economiche
- aumentare il *value for money* di tutte le forme di spesa sanitaria al fine di pervenire ad una distribuzione ottimale delle tre componenti di spesa



€ 154,9 miliardi



€ 154,9 miliardi



ADEMPIMENTI LIVELLI ESSENZIALI DI ASSISTENZA 2010-2017



Adempimento >84,5%

Emilia Romagna (92,2%), Toscana (89,6%), Piemonte (86,9%), Veneto (86,7%), Lombardia (85,3%)

Adempimento tra 75,3% e 84,5%

Umbria (83,9%), Marche (81,9%), Liguria (80,3%), Friuli Venezia Giulia* (79%), Prov. Aut. di Trento* (77,8%), Basilicata (75,3%)

Adempimento tra 62,6% e 75,2%

Abruzzo (72,8%), Lazio (72%), Sicilia (67,9%), Molise (66,7%), Puglia (63,1%)

Adempimento <62,6%

Valle d'Aosta* (62%), Calabria (58,9%), Sardegna* (56,1%), Prov. Aut. di Bolzano* (55,4%), Campania (53,9%)

*Regioni e Province autonome non sottoposte alla verifica degli adempimenti

Adempimenti livelli essenziali di assistenza 2010-2017

Regione	Adempimento %	2010	2011	2012	2013	2014	2015	2016	2017	Totale
Emilia Romagna	92,2%	208	205	210	204	204	205	205	218	1.659
Toscana	89,6%	185	168	193	214	217	212	208	216	1.613
Piemonte	86,9%	174	170	186	201	200	205	207	221	1.564
Veneto	86,7%	178	182	193	190	189	202	209	218	1.561
Lombardia	85,3%	171	195	184	187	193	196	198	212	1.536
Umbria	83,9%	191	184	171	179	190	189	199	208	1.511
Marche	81,9%	180	164	165	191	192	190	192	201	1.475
Liguria	80,3%	137	166	176	187	194	194	196	195	1.445
Friuli Venezia Giulia*	79,0%	171	172	167	168	163	185	203	193	1.422
Prov. Aut. di Trento*	77,8%	145	153	163	186	184	185	200	185	1.401
Basilicata	75,3%	164	167	169	146	177	170	173	189	1.355
Abruzzo	72,8%	133	145	145	152	163	182	189	202	1.311
Lazio	72,0%	122	152	167	152	168	176	179	180	1.296
Sicilia	67,9%	108	147	157	165	170	153	163	160	1.223
Molise	66,7%	126	142	146	140	159	156	164	167	1.200
Puglia	63,1%	74	123	140	134	162	155	169	179	1.136
Valle d'Aosta*	62,0%	162	153	135	129	120	132	137	149	1.117
Calabria	58,9%	99	128	133	136	137	147	144	136	1.060
Sardegna*	56,1%	88	130	115	166	124	118	130	140	1.011
Prov. Aut. di Bolzano*	55,4%	120	131	126	113	113	121	153	120	997
Campania	53,9%	95	101	117	136	139	106	124	153	971
Totale punteggio ottenuto		3.031	3.278	3.358	3.476	3.558	3.579	3.742	3.842	27.864
Massimo punteggio raggiungibile		4.725	37.800							
Inadempimento %		35,9%	30,6%	28,9%	26,4%	24,7%	24,3%	20,8%	18,7%	26,3%

*Regioni e Province autonome non sottoposte alla Verifica degli adempimenti

Quartili delle percentuali di adempimento	95,2 – 84,6	84,5 – 75,3	75,2 – 62,6	62,5 – 53,9
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PREVENTING CHRONIC DISEASE

PUBLIC HEALTH RESEARCH, PRACTICE, AND POLICY

Volume 12, E216

DECEMBER 2015

SPECIAL TOPIC

A Framework for Assessing the Value of Investments in Nonclinical Prevention

George Miller, PhD; Charles Roehrig, PhD; Pamela Russo, MD, MPH

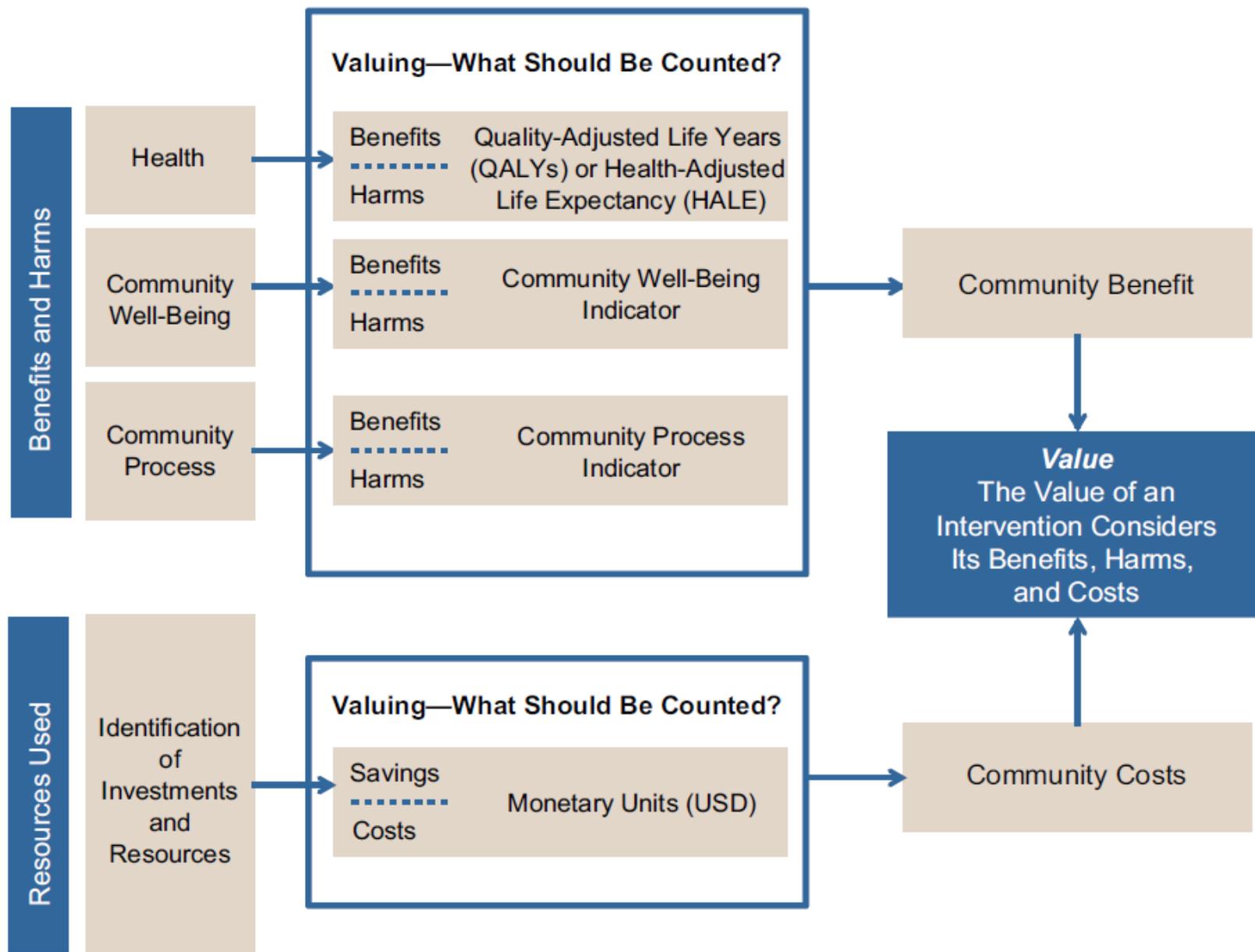
INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

AN INTEGRATED FRAMEWORK FOR ASSESSING THE VALUE OF COMMUNITY-BASED PREVENTION



TABLE 5-1 Nine Frameworks Summarized

	Includes Comprehensive Set of Valued Outcomes	Compares Benefits with Costs	Accounts for Differences Among Communities
Benefit–cost analysis	Yes, can account for all benefits	Yes	Low; can account for context
Cost-effectiveness analysis	No, health only	Yes	Low; can account for context
Congressional Budget Office scoring	No, only federal spending and revenue	Yes	Low; designed for Congressional budget process
PRECEDE–PROCEED framework	No, although it includes both health and community process	No	High; used in communities
RE-AIM framework	No, health only	No	High; used by evaluators
Health Impact Assessment framework	No, health only	No	High; used in communities
Community Preventive Services Task Force guidelines	No, health only	No	Moderate; focus on community
Lomas model	No, valued outcomes not specified	No	Moderate; focus on decision-making process
Proposed framework	Yes	Yes	High; involves communities in process

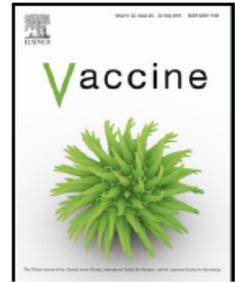




Contents lists available at [ScienceDirect](http://www.sciencedirect.com)

Vaccine

journal homepage: www.elsevier.com/locate/vaccine



Review

How and why researchers use the number needed to vaccinate to inform decision making—A systematic review



Ahmed Hashim^{a,1}, Vica Dang^a, Shelly Bolotin^{a,b}, Natasha S. Crowcroft^{a,b,c,*}

Results: We identified 27 studies, the designs including observational studies, economic analyses, systematic reviews, and commentaries. The NNV has been used in the literature to describe three main themes: potential benefits of vaccination programmes, cost-effectiveness, and economic analyses, and modelling studies to compare different vaccination strategies.

Conclusions: NNV has been used in a wide variety of ways in the literature, yet there are no defined thresholds for what is a favourable NNV. Furthermore, the generalizability of the NNV is usually limited. Further work is required to determine the most appropriate use of this measure.



Cochrane
Library

Cochrane Database of Systematic Reviews

Vaccines for preventing influenza in healthy adults (Review)

Demicheli V, Jefferson T, Ferroni E, Rivetti A, Di Pietrantonj C

Demicheli V, Jefferson T, Ferroni E, Rivetti A, Di Pietrantonj C.

Vaccines for preventing influenza in healthy adults.

Cochrane Database of Systematic Reviews 2018, Issue 2. Art. No.: CD001269.

DOI: [10.1002/14651858.CD001269.pub6](https://doi.org/10.1002/14651858.CD001269.pub6).

Number Needed to Vaccinate

Outcome	NNV
Prevenzione influenza	77
- Anziani	29
- Bambini	5
Prevenzione malattie simil-influenzali*	29
- Anziani	42
- Bambini	12

* Influenza-like Illness (ILI)



Ministero della Salute

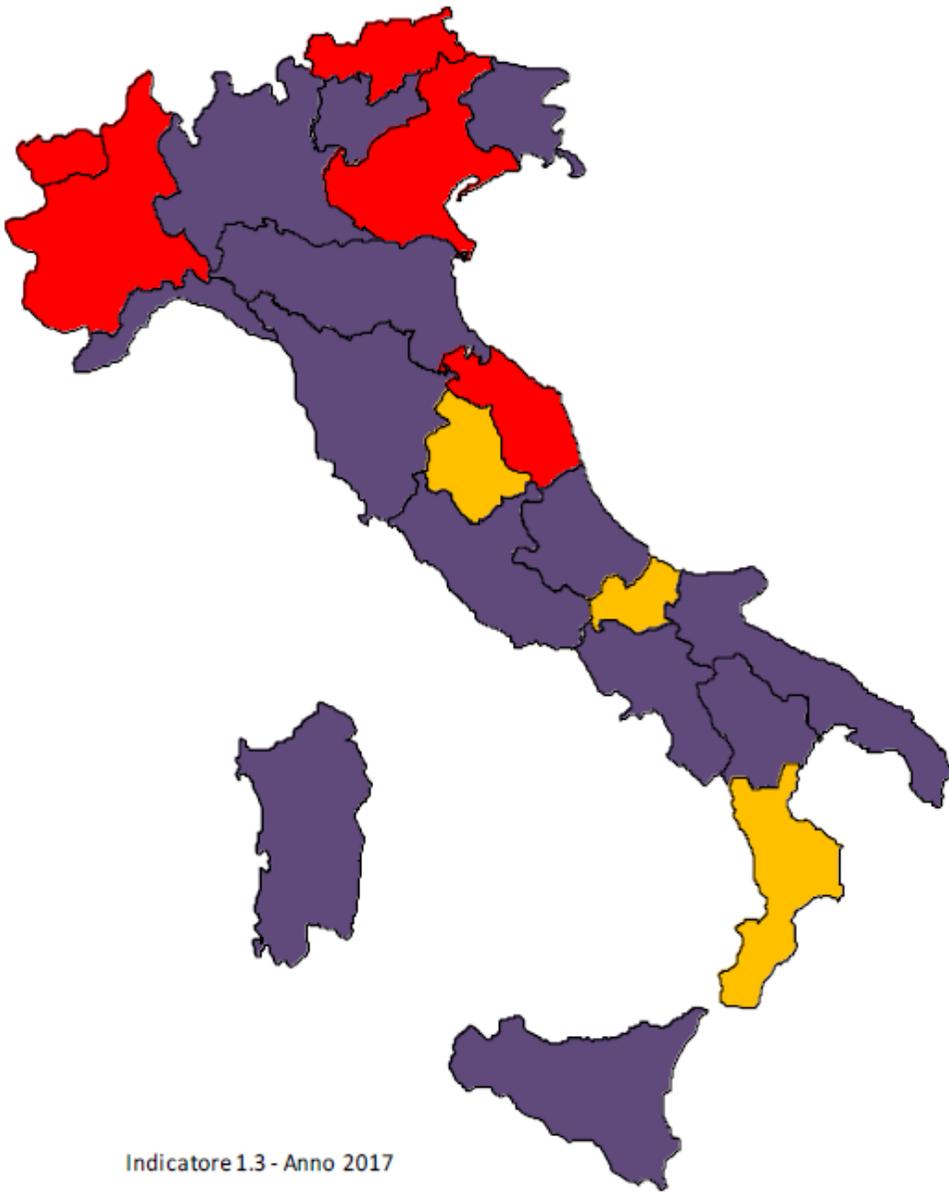
DIREZIONE GENERALE DELLA PROGRAMMAZIONE SANITARIA
UFFICIO VI

Monitoraggio dei LEA attraverso la cd. Griglia LEA

Metodologia e Risultati dell'anno 2017

Disponibile 6 aprile 2019

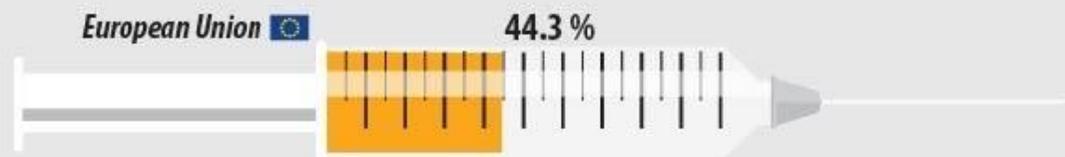
1.3. Copertura vaccinale per vaccinazione antinfluenzale nell'anziano (≥ 65 anni) (%)



Indicatore 1.3 - Anno 2017

Influenza vaccination rate

(% of persons aged 65 and over, 2017)



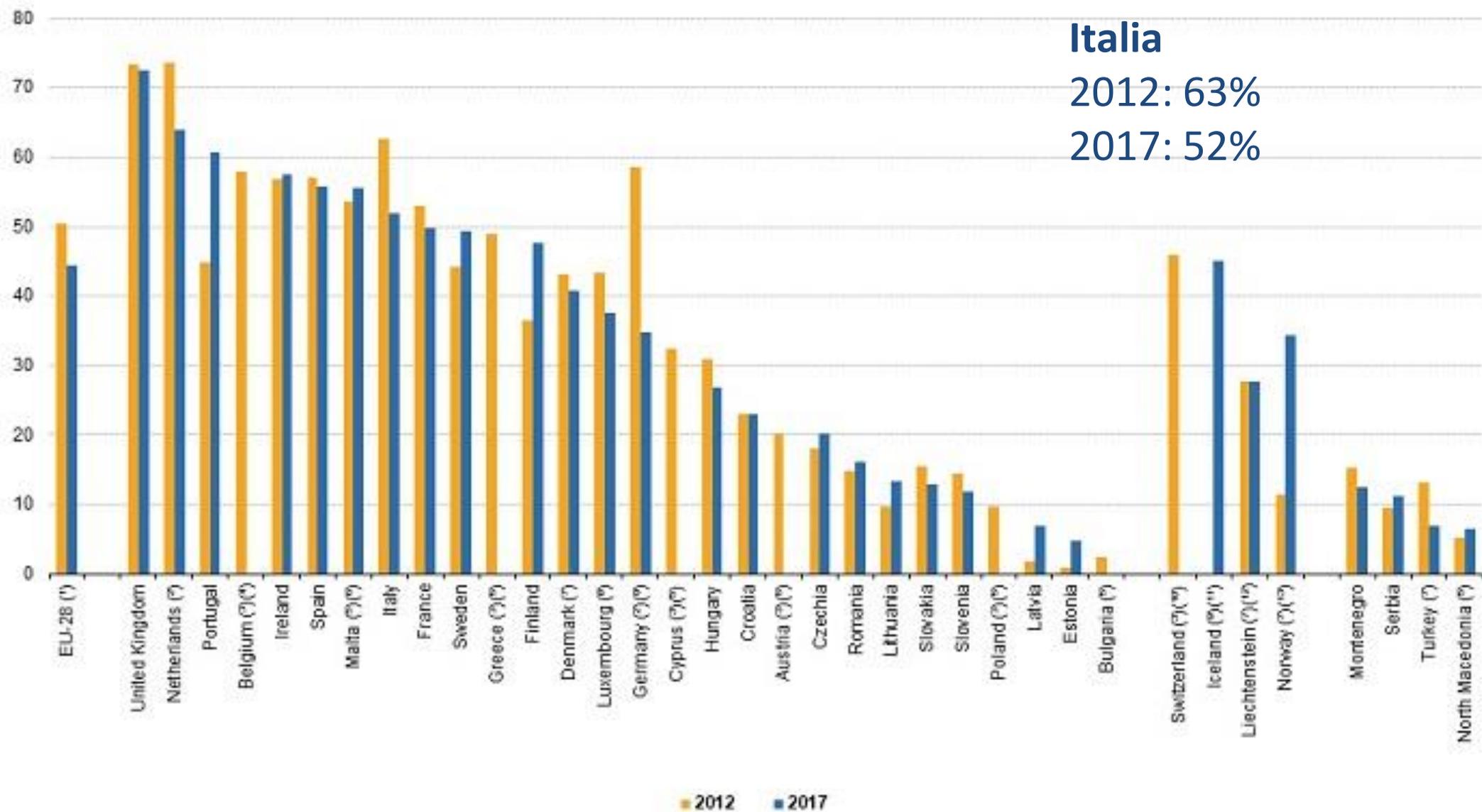
Austria, Belgium, Bulgaria, Cyprus, Greece, Poland: data for 2017 not available.

Source: Eurostat (online data code: hlth_ps_immu)

*Denmark: data for 2016.

**Germany: persons aged 60 and over.

Tasso di vaccinazione antinfluenzale, persone di età pari o superiore a 65 anni, 2012 e 2017 (%)



Report Osservatorio GIMBE 3/2019

Vaccinazioni in età pediatrica: impatto dell'obbligo sulle coperture vaccinali in Italia



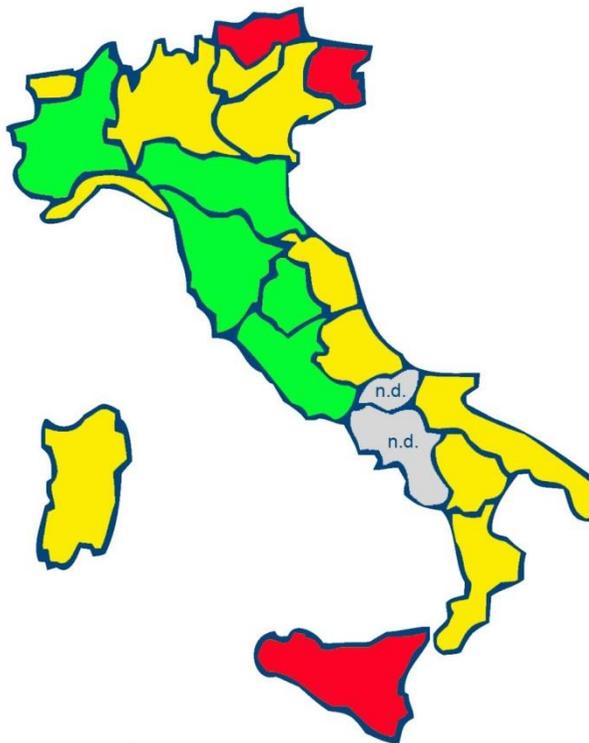
Marzo 2019

Coperture vaccinali in Italia al 30 giugno 2018 (coorte 2015)

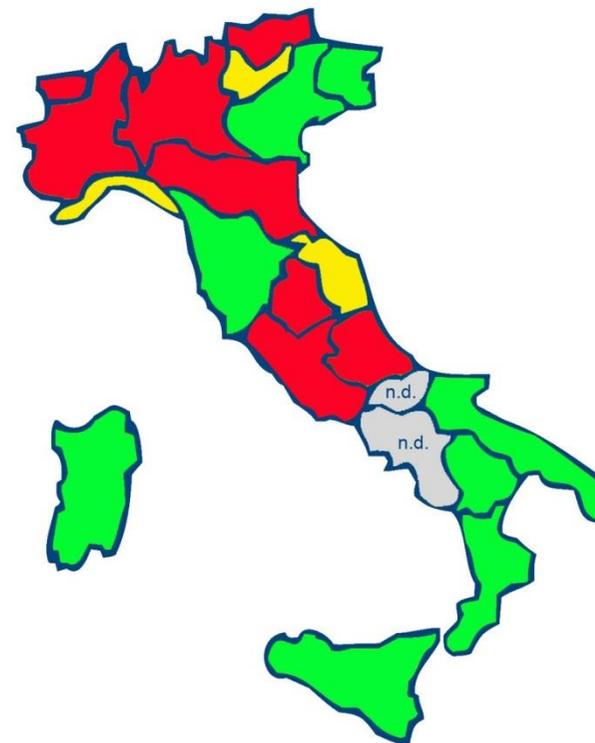
Esavalente



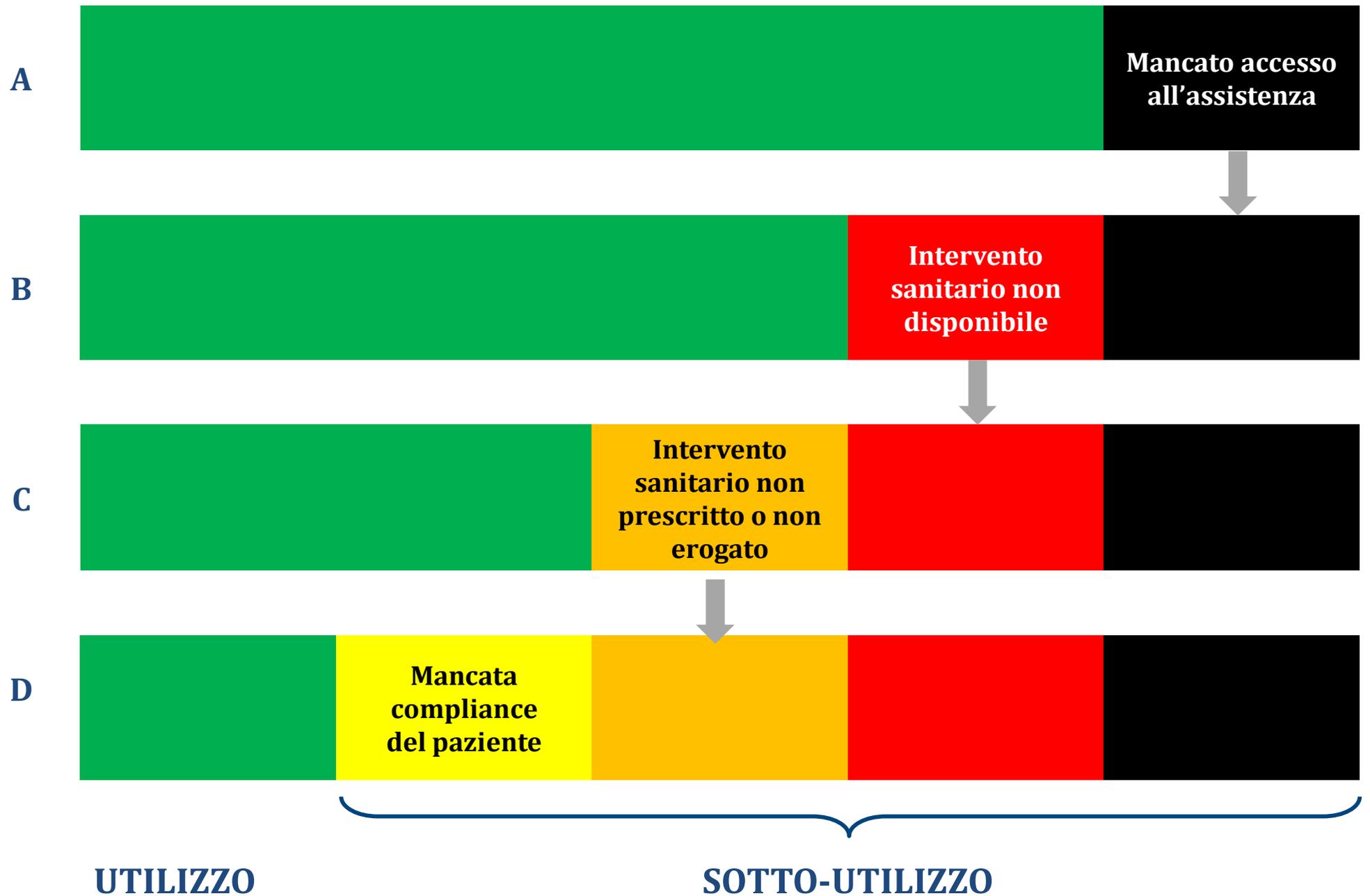
Trivalente



Varicella



	Soglie		
Esavalente e Trivalente	≥ 95%	92-94,99%	< 92%
Anti-varicella	≥ 75%	60-74,99%	< 60%



Conclusioni

VBHC modello ideale per aumentare il *value for money*, ma:

- Mancata condivisione tra stakeholders su numeratore e denominatore formula *value*
- Studi registrativi mancano di outcome a medio e lungo termine
- Pochi studi comparativi → network meta-analysis?
- «Doppia veste» AIFA inadeguata
- Scarso coinvolgimento pazienti
- Nel SSN, criteri di riparto e silos MEF ostacolano VBHC → sprechi da *overuse* di prestazioni *low value* e *underuse* da prestazioni *high value*
- Scarsa considerazione elevato *value* interventi preventivi

