2° GIORNATA REGIONALE SULLE BUONE PRATICHE PER LA SICUREZZA DELLE CURE

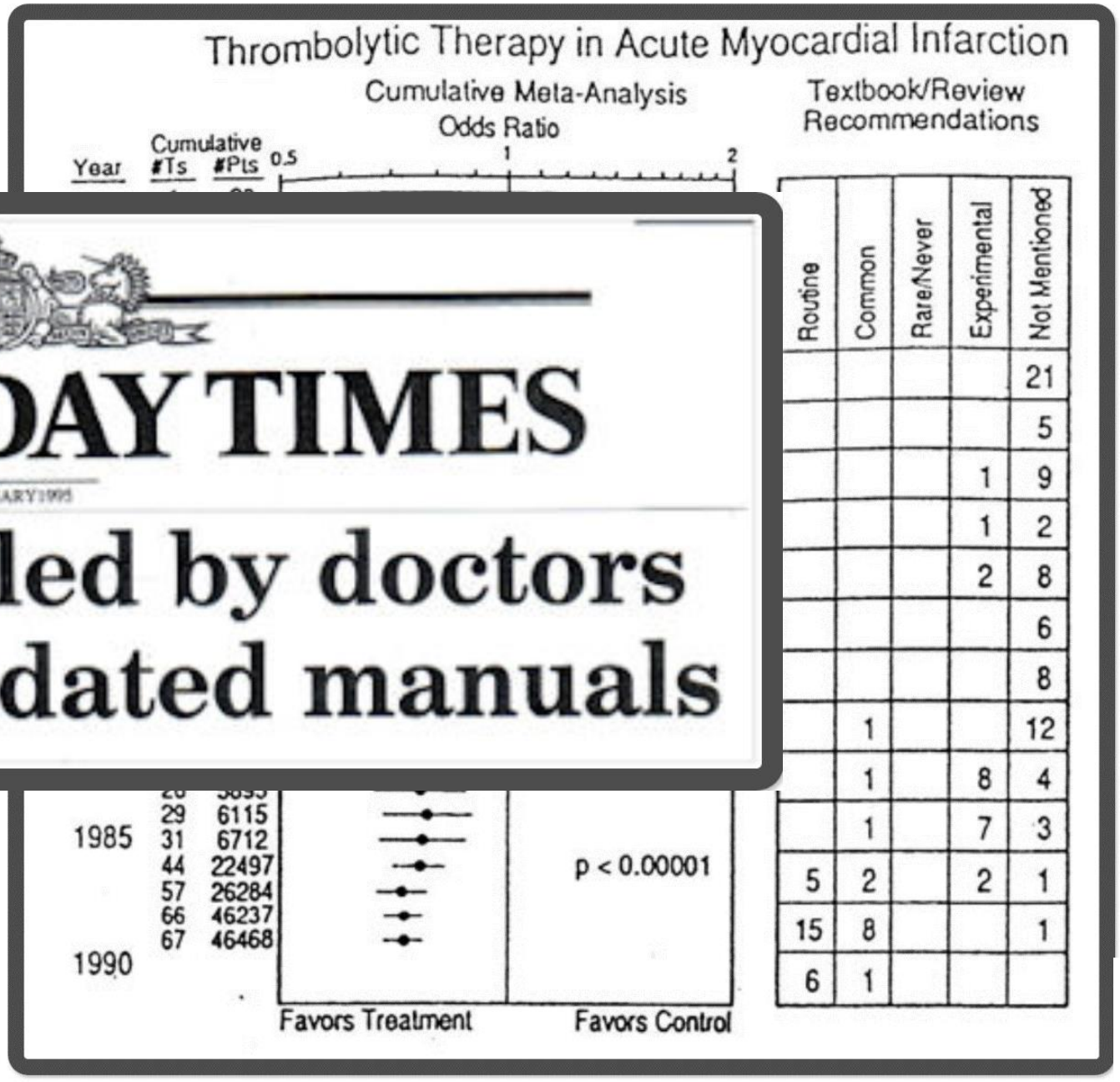
Bologna

30 OTTOBRE 2018

Il Nuovo Sistema Nazionale Linee Guida

Primiano Iannone

Centro Nazionale Eccellenza
Clinica Qualità e Sicurezza delle Cure



THE SUNDAY TIMES

5 FEBRUARY 1995

Hundreds killed by doctors relying on outdated manuals

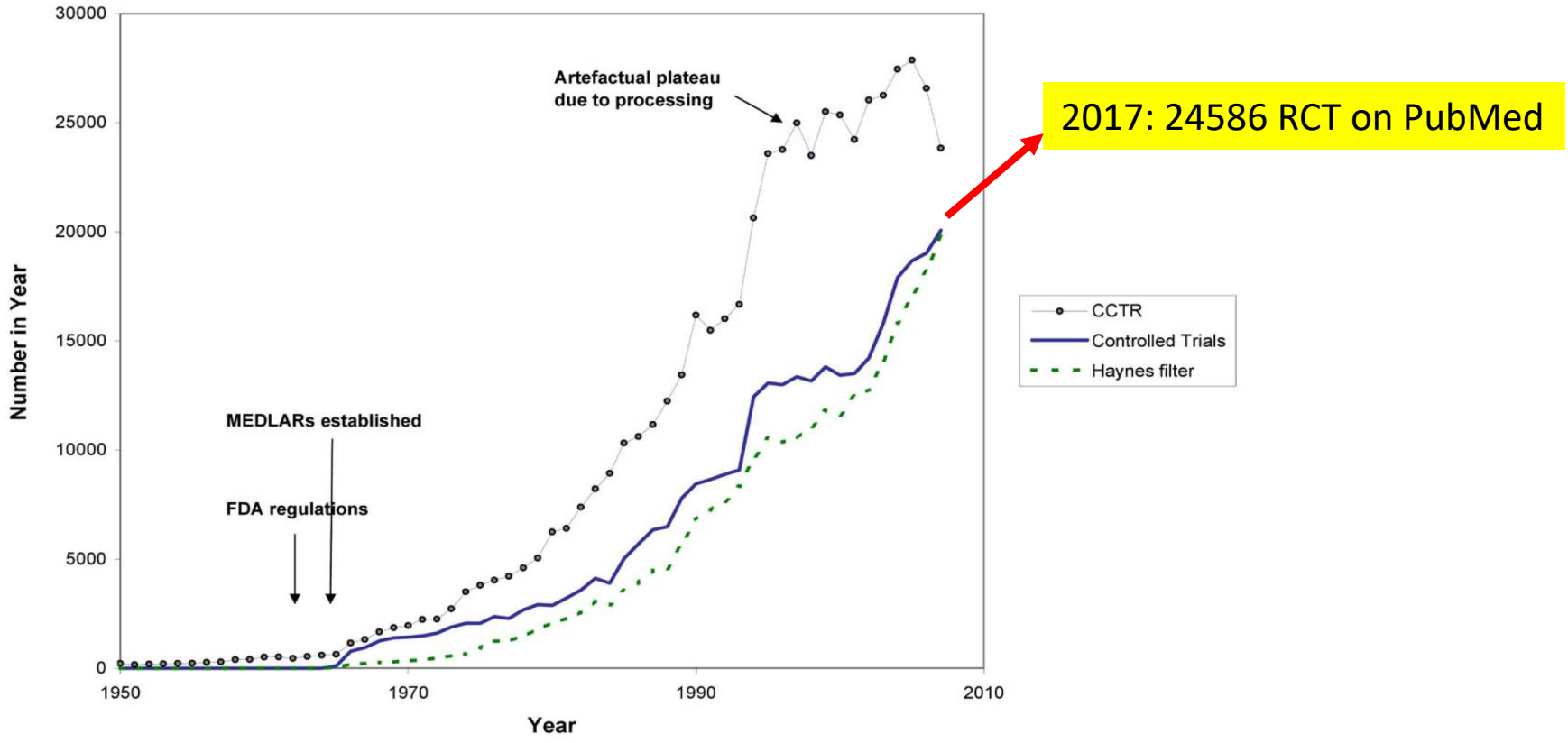


Figure 2. The number of published trials, 1950 to 2007. CCTR is the Cochrane Controlled Trials Registry; Haynes filter uses the "narrow" version of the Therapy filter in PubMed:ClinicalQueries; see Text S1.
doi:10.1371/journal.pmed.1000326.g002

Citation: Bastian H, Glasziou P, Chalmers I (2010) Seventy-Five Trials and Eleven Systematic Reviews a Day: How Will We Ever Keep Up? PLoS Med 7(9): e1000326. doi:10.1371/journal.pmed.1000326

Published September 21, 2010

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PLoS MEDICINE

Policy Forum

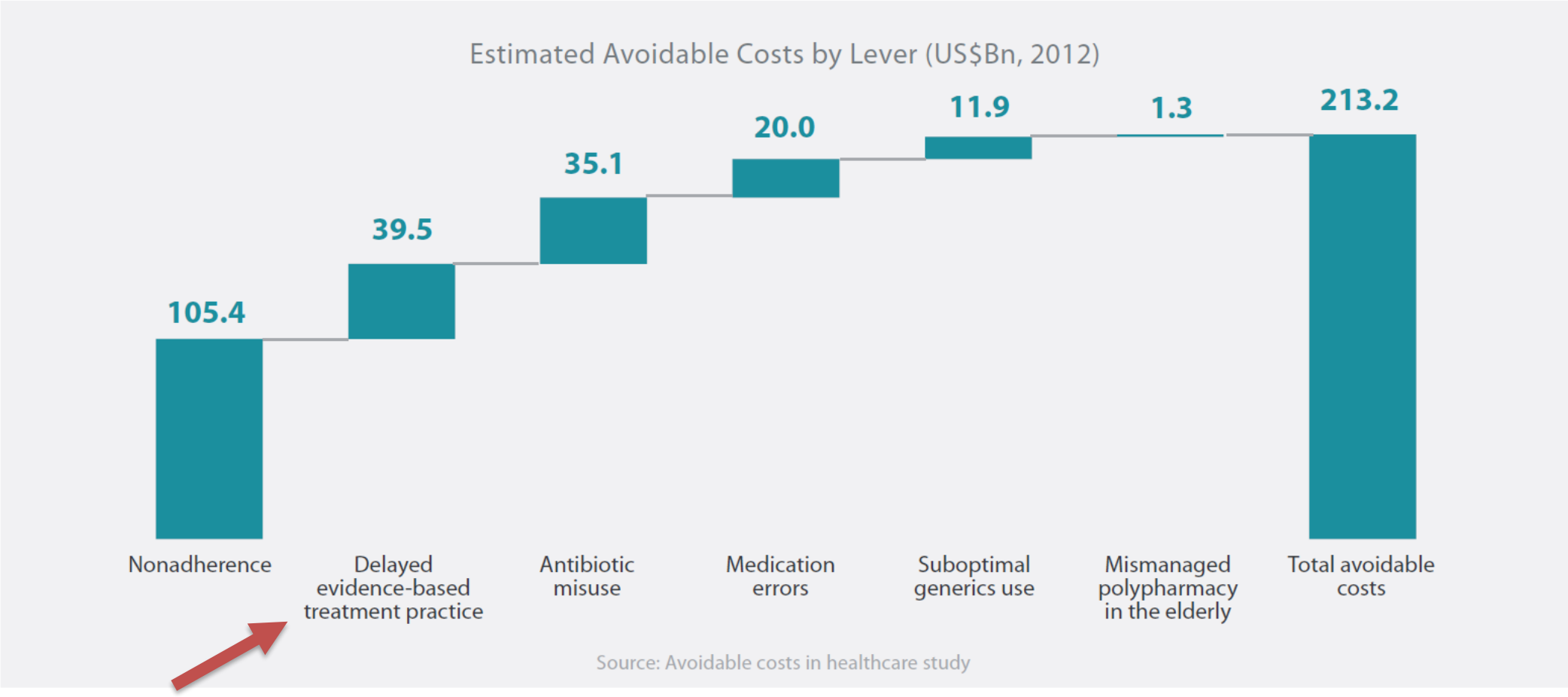
Seventy-Five Trials and Eleven Systematic Reviews a Day: How Will We Ever Keep Up?

Hilda Bastian[1]*, Paul Glasziou[2], Iain Chalmers[3]

1 German Institute for Quality and Efficiency in Health Care (IQWiG), Cologne, Germany, **2** Centre for Research in Evidence-Based Practice, Faculty of Health Sciences, Bond University, Gold Coast, Australia, **3** James Lind Library, James Lind Initiative, Oxford, United Kingdom

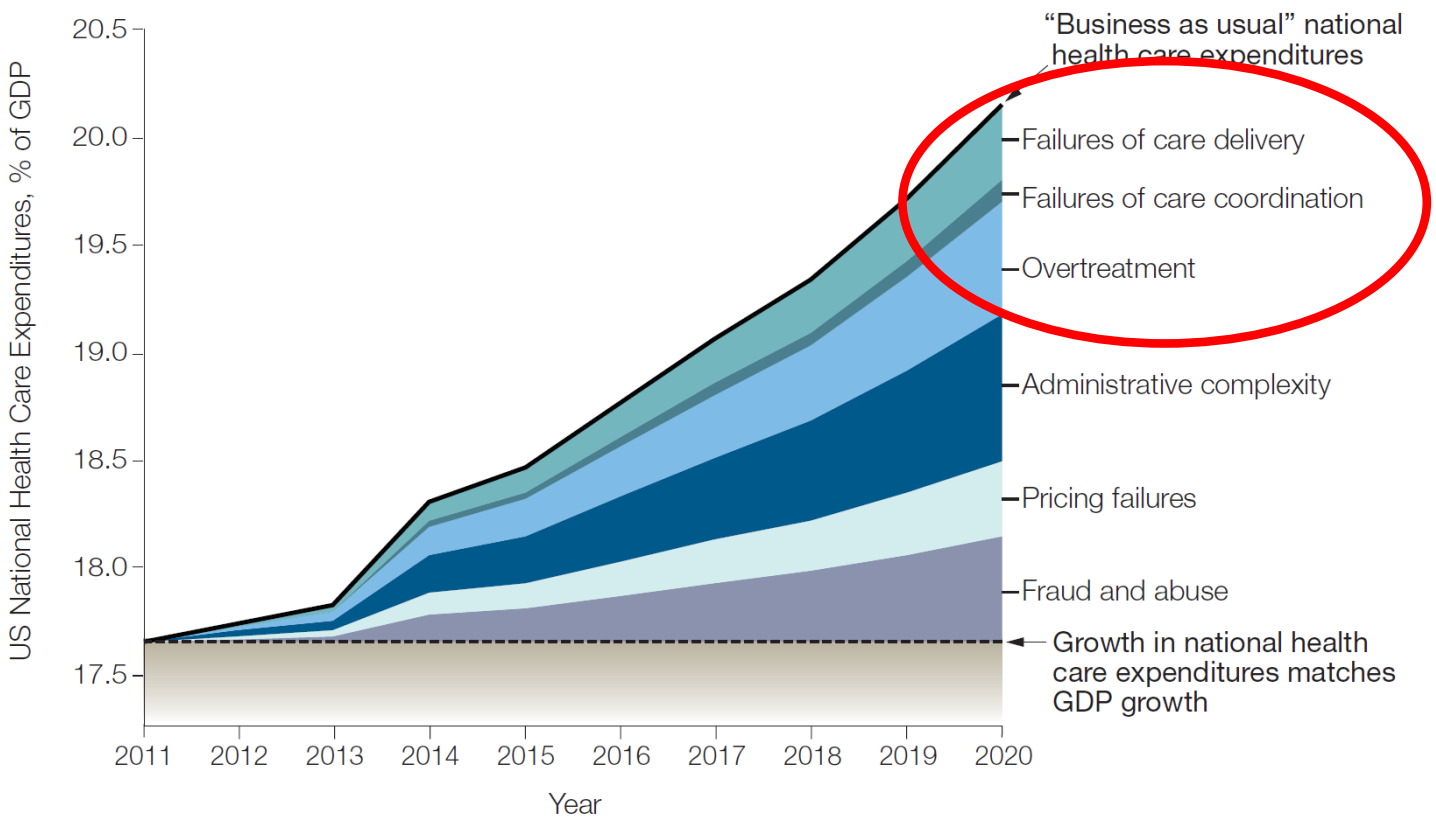
discoveries to reach clinical practice. It takes an estimated average of 17 years for only 14% of new scientific discoveries to enter day-to-day clinical practice.[4] McGlynn et al[5]

Balas EA, Boren SA. *Yearbook of Medical Informatics: Managing Clinical Knowledge for Health Care Improvement*. Stuttgart, Germany: Schattauer Verlagsgesellschaft GmbH; 2000.



Avoidable Costs in U.S. Healthcare: The $200 Billion Opportunity from Using Medicines More Responsibly. Report by the IMS Institute for Healthcare Informatics.

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

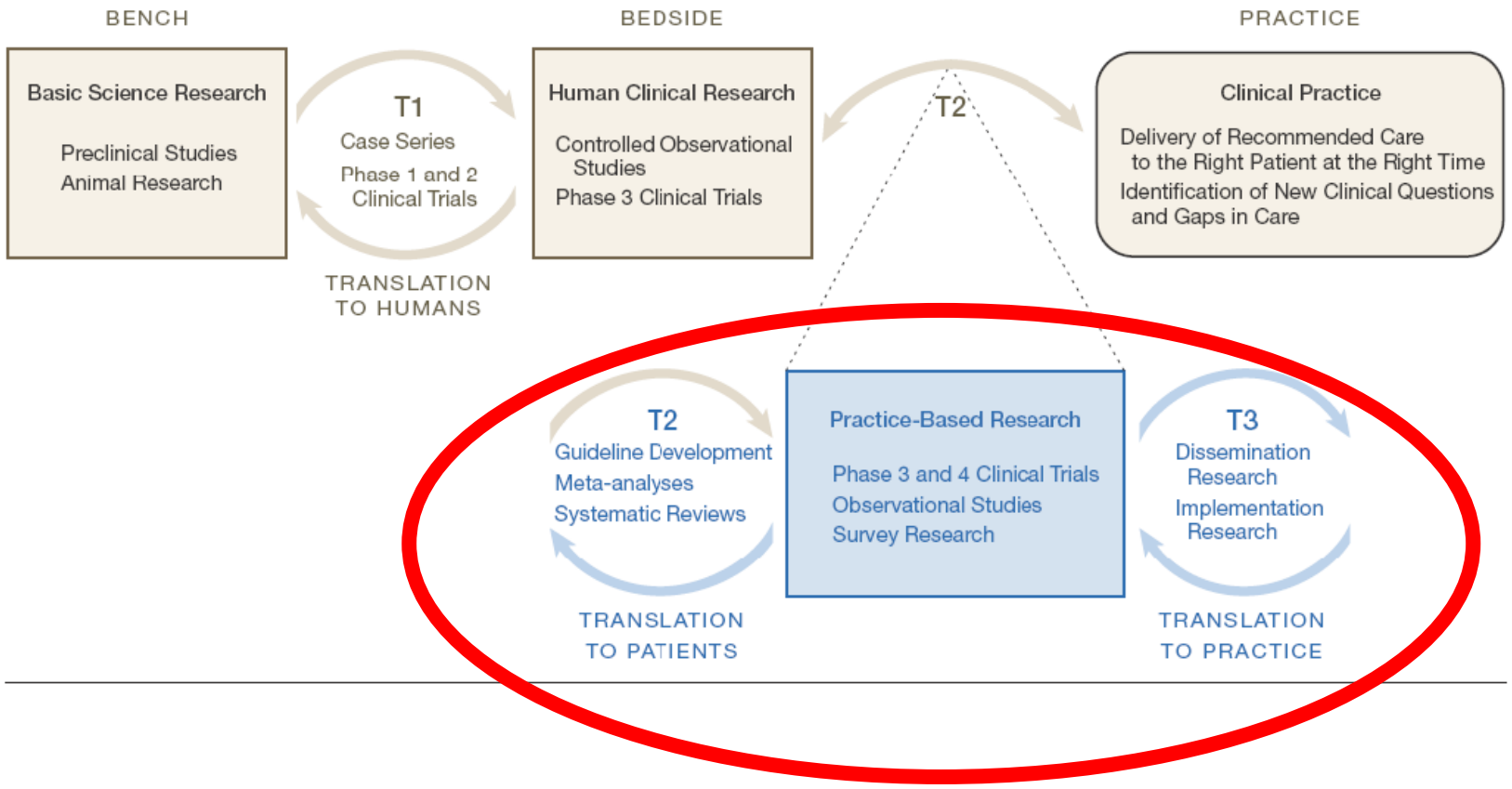


JAMA. 2012;307(14):1513-1516

SNLG guidelines

"Blue Highways" on the NIH Roadmap

Figure. "Blue Highways" on the NIH Roadmap



Westfall, J. M. et al. JAMA 2007;297:403-406.

BMJ 2015;350:h1075 doi: 10.1136/bmj.h1075 (Published 17 March 2015)

Major stroke guidelines and recommendations for alteplase at 3-4.5 hours after stroke onset

Guidelines presenting strong recommendation for ("is recommended" or highest recommendation rating)

- American Heart Association/American Stroke Association (Class I; Level of evidence B)[5]
- Canadian Stroke Network and Heart and Stroke Foundation of Canada (Evidence level A)[6]
- Chinese Stroke Therapy Expert Panel for Intravenous Recombinant Tissue Plasminogen Activator (Level 1 recommendation, Level A evidence)[7]
- European Stroke Organisation (Class I, Level A)[8]
- Haute Autorité de Santé (Professional agreement)[9]
- Japan Stroke Society (level of evidence Ia; grade of recommendation A)[10]
- National Institute for Health and Care Excellence ("is recommended")[11]
- National Stroke Foundation (Australia) (Grade A)[12]
- South African Stroke Society (Class I, Level A)[13]

Guidelines presenting weak recommendation for (lower recommendation rating)

- American College of Chest Physicians (Grade 2C)[14]
- American College of Emergency Physicians/American Academy of Neurology (Level B recommendation), currently being reconsidered by American College of Emergency Physicians[15]
- American College of Emergency Physicians (draft guideline in process) (Level B recommendation)[16]

Guidelines presenting weak recommendation against

- Canadian Association of Emergency Physicians (draft guideline in process) (Weak recommendation, moderate quality evidence)[17]

Statements that t-PA is controversial at all timeframes and should not be considered standard of care

- American Academy of Emergency Medicine[18]
- Australasian College for Emergency Medicine[19]
- Canadian Association of Emergency Physicians (currently posted policy)[20]
- New Zealand Faculty of the Australasian College for Emergency Medicine[21]

ONLINE FIRST | HEALTH CARE REFORM

Failure of Clinical Practice Guidelines to Meet Institute of Medicine Standards

Two More Decades of Little, If Any, Progress

Justin Kung, MD; Ram R. Miller, MD; Philip A. Mackowiak, MD

Table 1. Frequency of Adherence to Institute of Medicine Standards by Organization Type and Subspecialty Area

Organization Type (No. of Guidelines)	Standards Met, Median	Guidelines Meeting >50% of Standards, No. (%)
All (114)	8 (44.0)	56 (49.1)
United States (68)	8 (44.0)	34 (50.0)
Non-US (46)	9 (50.0)	22 (47.8)
US government agency (15)	9 (50.0)	10 (66.7)
Subspecialty societies (41)	8 (44.0)[a]	16 (39.0)[b]
Subspecialty area		
Infectious diseases (21)	9 (50.0)	11 (52.4)
Oncology (17)	9.5 (52.8)	9 (52.9)
OB/GYN (12)	8 (44.0)	3 (25.0)
All other (64)	8 (44.0)	36 (56.2) [c]

Abbreviation: OB/GYN, obstetrics/gynecology.
[a] $P = .34$ by Mann-Whitney test compared with all other organization types.
[b] $P = .11$ by Fisher exact test compared with all other organization types.
[c] $P = .40$ by χ^2 test across all subspecialty areas.

Perspective

Wrong guidelines: why and how often they occur

Primiano Iannone,[1] Nicola Montano,[2] Monica Minardi,[3]
James Doyle,[3] Paolo Cavagnaro,[4] Antonino Cartabellotta[5]

BMJ

Evid Based Med March 2017 | volume 22 | number 1 |

Overall, a conservative estimate is that **50%** of current evidence-based guidelines suffer from either methodological flaws, have questionable content with respect to the primary evidence to which they refer to or documented outcomes diverging from those expected. On average, guidelines sponsored by medical specialty societies were and still continue to be of lower quality compared with those endorsed by national health agencies.

Avoidable waste in the production and reporting of research evidence

Iain Chalmers, Paul Glasziou

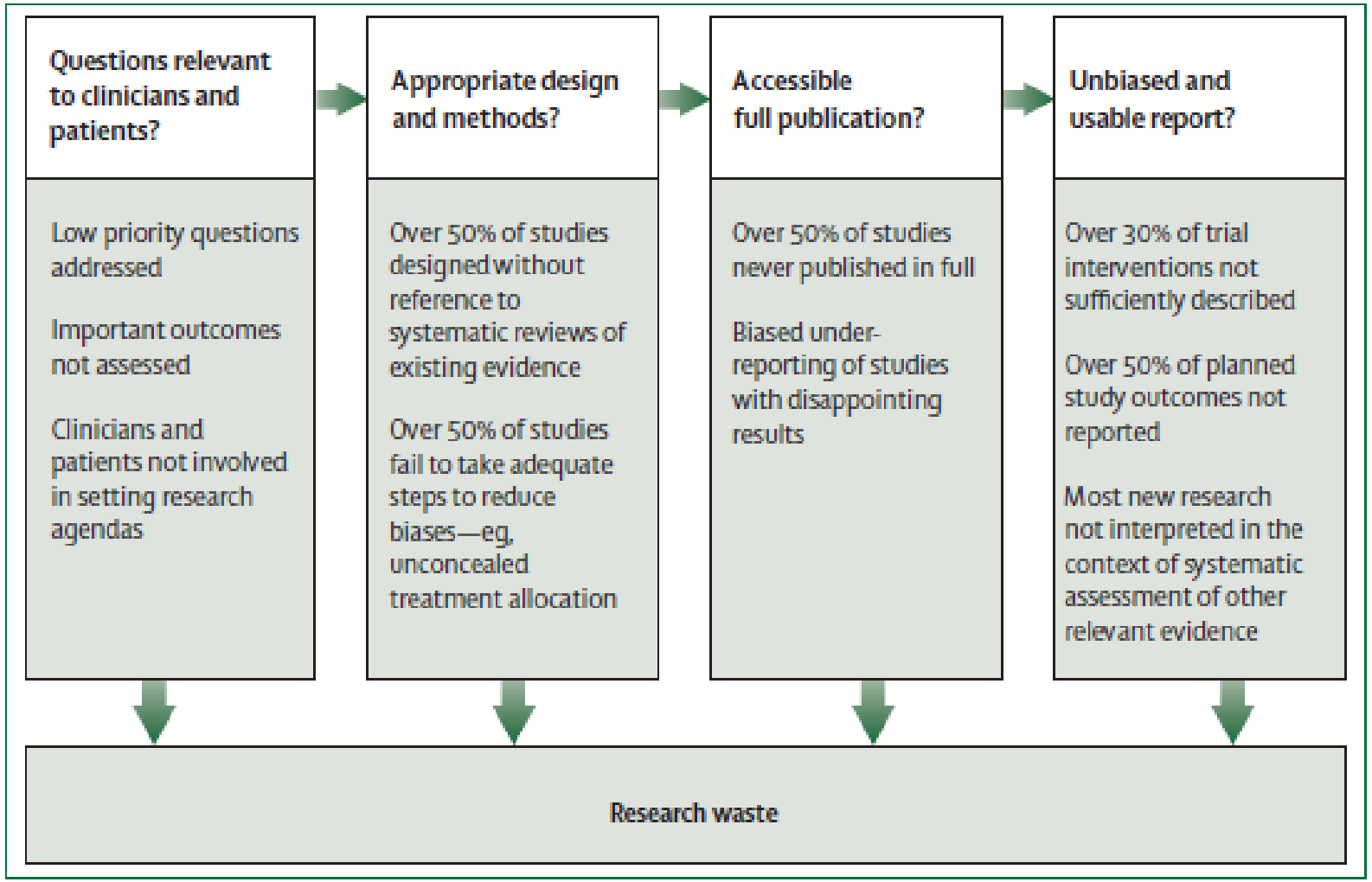


Figure: Stages of waste in the production and reporting of research evidence relevant to clinicians and patients

Lancet 2009; 374: 86–89

EvidenceLive 17
University of Oxford June 21–22 2017

Quality and trustworthiness of clinical practice guidelines developed by Italian medical specialty societies: a cross sectional study

Nino Cartabellotta, GIMBE Foundation
Antonio Simone Laganà, University of Messina
Primiano Iannone, National Institute of Health
Walter Ricciardi, National Institute of Health

Results 4: adherence to G-I-N 1 standards

Item	Yes
3. Conflicts of interest	17%
1. Composition of Guideline Development Group	63%
11. Financial support and sponsoring organization	64%
2. Decison-making process	65%
6. Evidence reviews	67%
10. Guideline expiration and updating	67%
5. Methods	71%
9. Peer review and stakeholder consultations	72%
8. Rating of evidence and recommendations	81%
7. Guideline recommendations	95%
4. Scope of a guideline	100%

GIMBE
EVIDENCE FOR HEALTH

ISTITUTO SUPERIORE DI SANITÀ

snlg.iss.it

18 aprile 2018 Editoriale

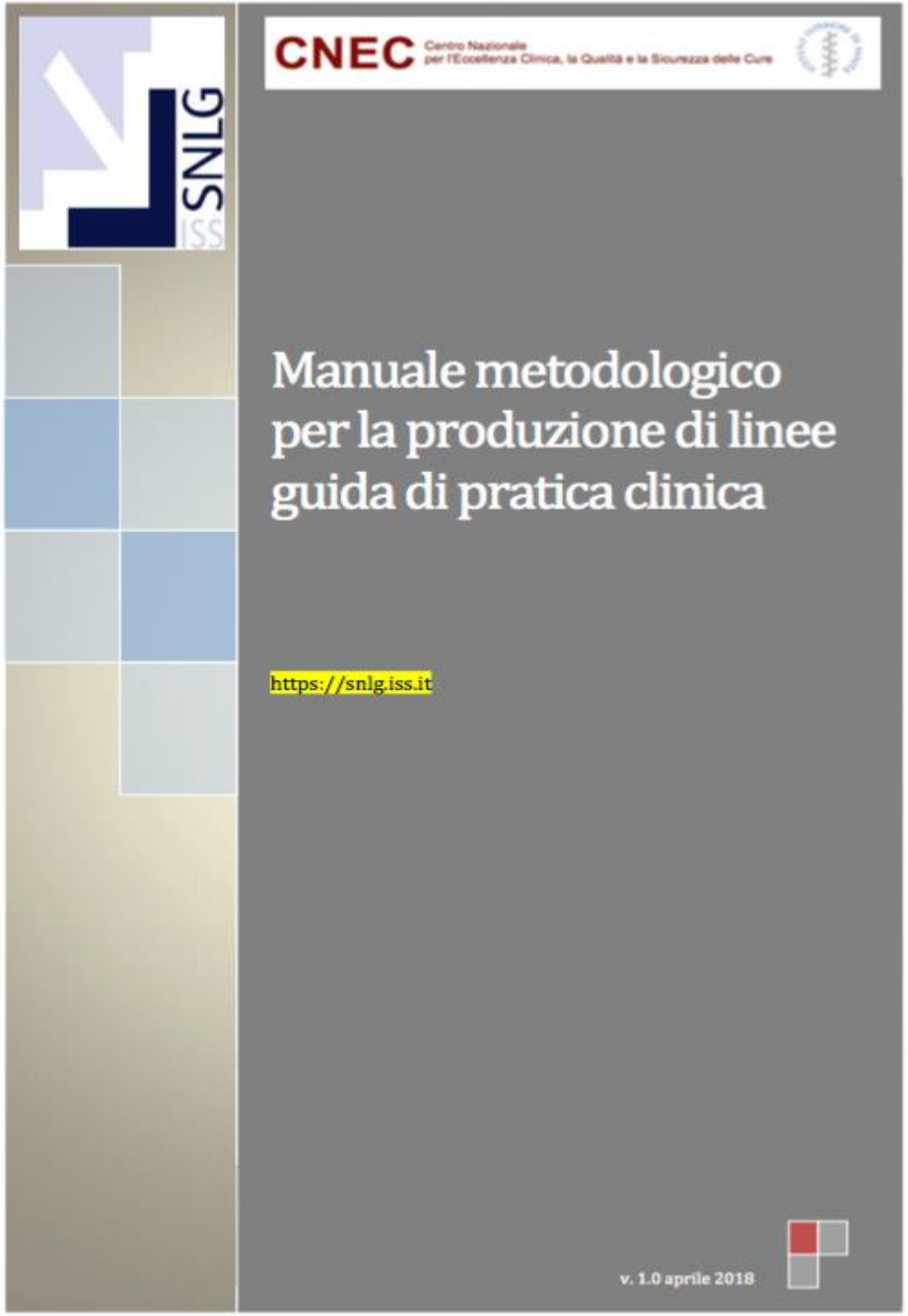
Presentazione del nuovo SNLG

Le Linee Guida (LG) di pratica clinica sono uno strumento di supporto decisionale finalizzato a consentire che, fra opzioni alternative, sia adottata quella che offre un migliore bilancio fra benefici ed effetti indesiderati, tenendo conto della esplicita e sistematica valutazione delle prove disponibili, commisurandola alle circostanze peculiari del caso concreto e condividendola-laddove possibile- con il paziente o i caregivers. Conoscere...

Continua...

Linee guida per la pratica clinica: la definizione dell'SNLG-ISS

"**strumento di supporto decisionale** finalizzato a consentire che, fra opzioni alternative, sia adottata quella che offre un **migliore bilancio fra benefici ed effetti indesiderati**, tenendo conto della **esplicita e sistematica valutazione delle prove disponibili**, commisurandola alle **circostanze peculiari del caso concreto** e condividendola-laddove possibile-con il **paziente** o i *caregivers*"



Versione 2018

Sviluppato da ISS-CNEC

Revisione esterna da parte del

GRADE working group international

ISTITUTO SUPERIORE DI SANITÀ

Quality of evidence

For a Systematic review-meta-analysis: the extent of our confidence that the estimates of the effect **are correct**.

GRADE: the extent of our confidence that the estimates of an effect **are adequate to support a particular decision or recommendation**

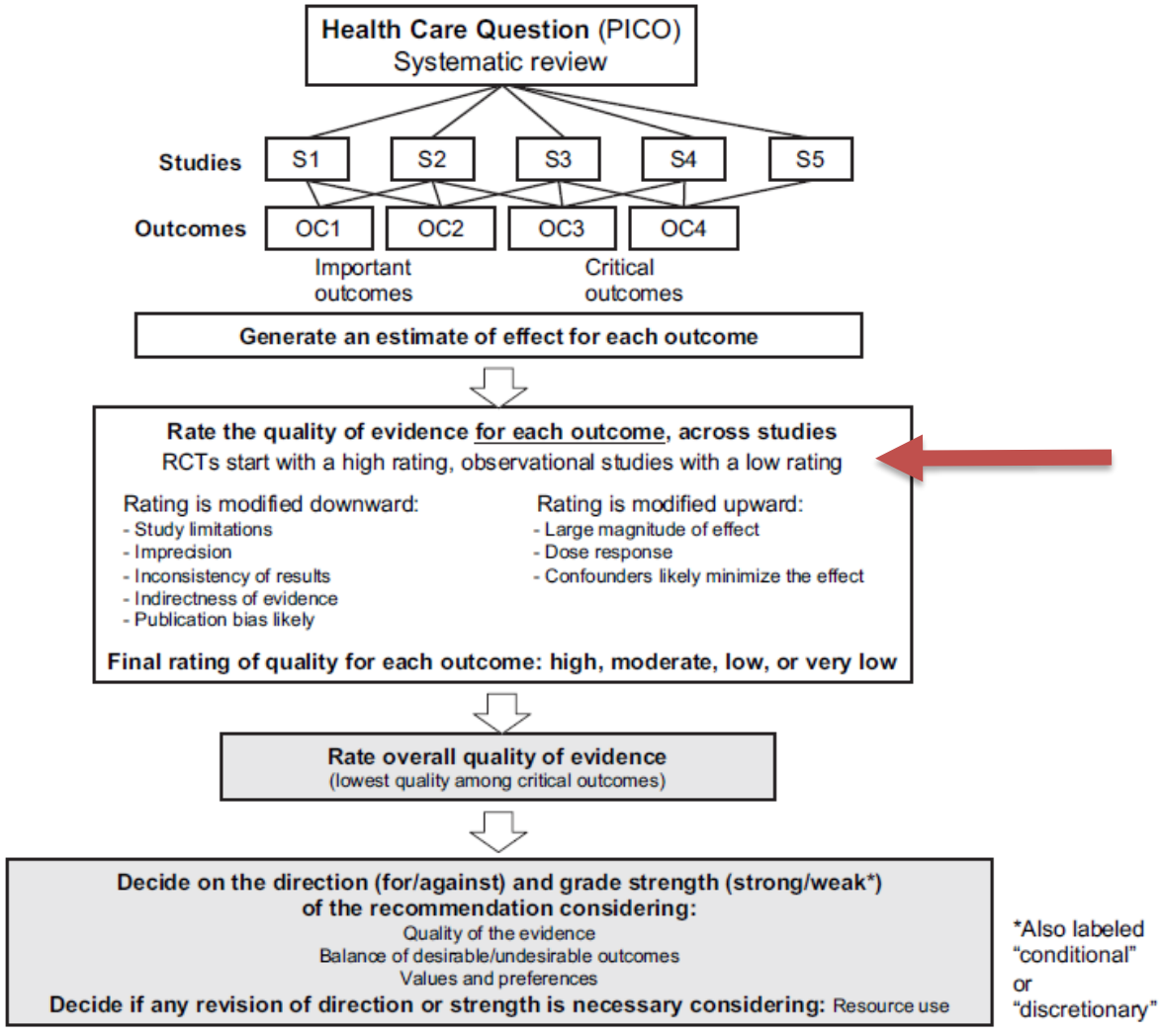


Fig. 1. Schematic view of GRADE's process for developing recommendations. *Abbreviation*: RCT, randomized controlled

Sometimes it's best just to jump in

BMJ 2006;333:701–3

Large magnitude of effect

NeuroRx®: The Journal of the American Society for Experimental NeuroTherapeutics

Observational *Versus* Experimental Studies: What's the Evidence for a Hierarchy?

John Concato

Department of Internal Medicine, Yale University School of Medicine, New Haven, Connecticut 06510, and the Clinical Epidemiology Research Center, West Haven Veterans Affairs Medical Center, West Haven, Connecticut 06516

Vol. 1, 341–347, July 2004

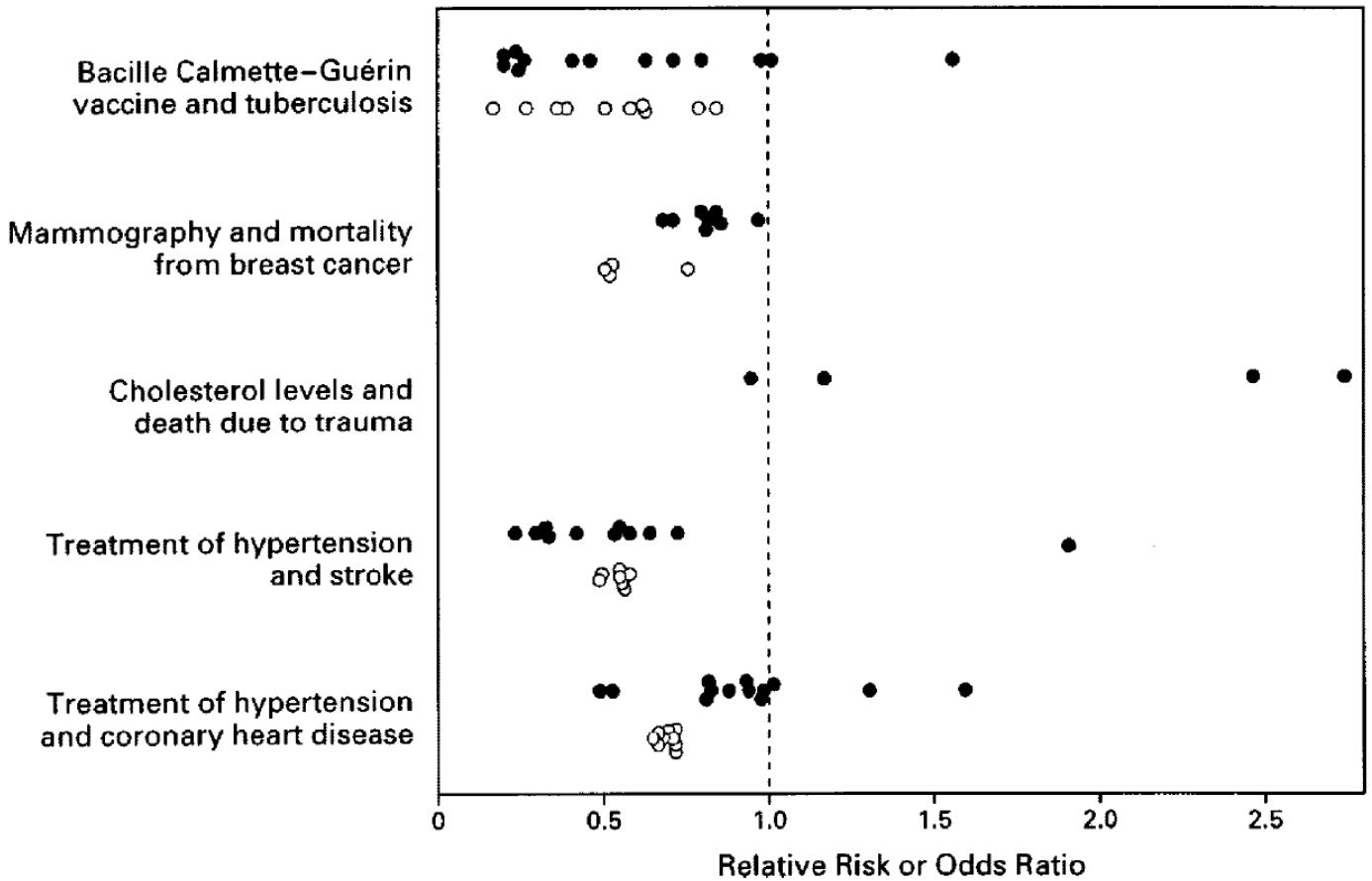


FIG. 1. Range of relative risks or odds ratios, based on the following types of research design: bacillus Calmette-Guerin vaccine and tuberculosis (13 randomized, controlled trials and 10 case-control studies), screening mammography and breast cancer mortality (eight randomized, controlled trials and four case-control studies), treatment of hyperlipidemia and traumatic death among men (four randomized, controlled trials and 14 cohort studies), treatment of hypertension and stroke among men (11 randomized, controlled trials and seven cohort studies), treatment of hypertension and coronary heart disease among men (13 randomized, controlled trials and nine cohort studies). Filled circles, randomized, controlled trials; open circles, observational studies. (Reproduced with permission.)

ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions

Jonathan AC Sterne,[1] Miguel A Hernán,[2] Barnaby C Reeves,[3] Jelena Savović,[1,4] Nancy D Berkman,[5] Meera Viswanathan,[6] David Henry,[7] Douglas G Altman,[8] Mohammed T Ansari,[9] Isabelle Boutron,[10] James R Carpenter,[11] An-Wen Chan,[12] Rachel Churchill,[13] Jonathan J Deeks,[14] Asbjørn Hróbjartsson,[15] Jamie Kirkham,[16] Peter Jüni,[17] Yoon K Loke,[18] Theresa D Pigott,[19] Craig R Ramsay,[20] Deborah Regidor,[21] Hannah R Rothstein,[22] Lakhbir Sandhu,[23] Pasqualina L Santaguida,[24] Holger J Schünemann,[25] Beverly Shea,[26] Ian Shrier,[27] Peter Tugwell,[28] Lucy Turner,[29] Jeffrey C Valentine,[30] Hugh Waddington,[31] Elizabeth Waters,[32] George A Wells,[33] Penny F Whiting,[34] Julian PT Higgins[35]

Cite this as: *BMJ* 2016;355:i4919
http://dx.doi.org/10.1136/bmj.i4919

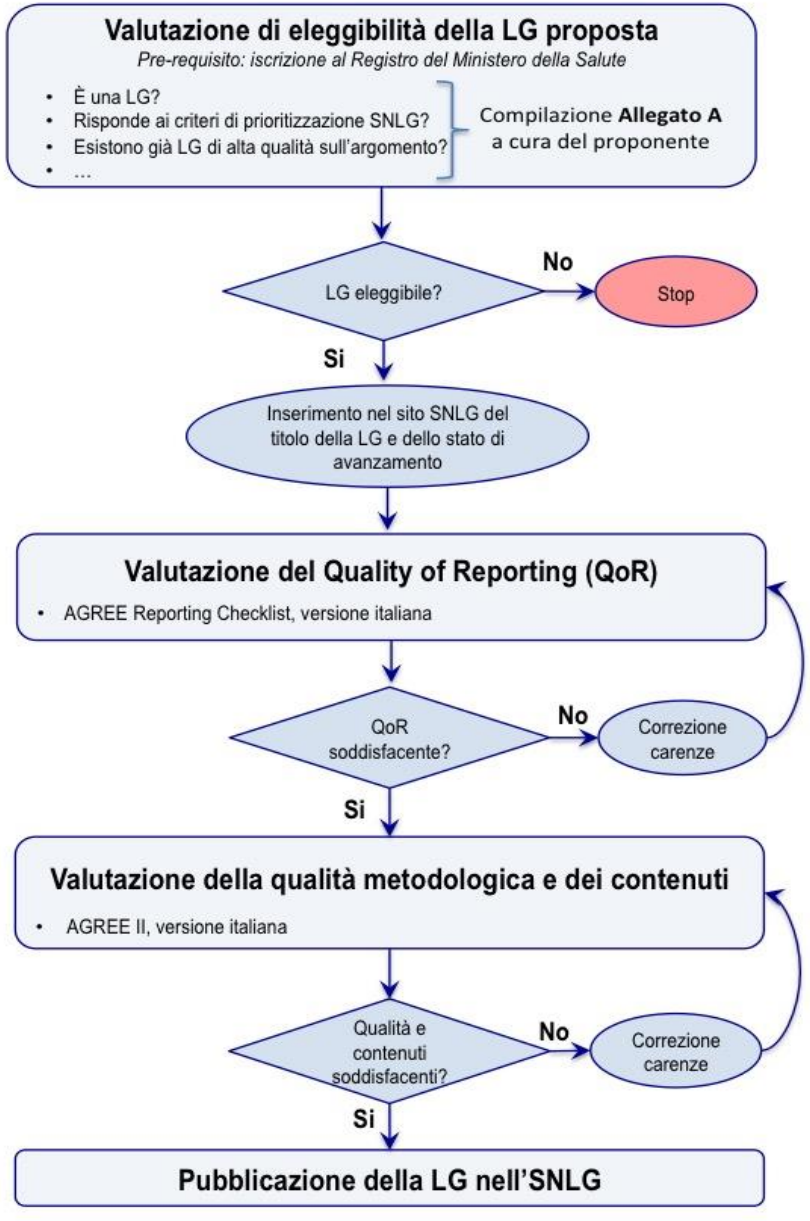
Table 1 | Bias domains included in ROBINS-I

Domain	Explanation
Pre-intervention	**Risk of bias assessment is mainly distinct from assessments of randomised trials**
Bias due to confounding	Baseline confounding occurs when one or more prognostic variables (factors that predict the outcome of interest) also predicts the intervention received at baseline ROBINS-I can also address time-varying confounding, which occurs when individuals switch between the interventions being compared and when post-baseline prognostic factors affect the intervention received after baseline
Bias in selection of participants into the study	When exclusion of some eligible participants, or the initial follow-up time of some participants, or some outcome events is related to both intervention and outcome, there will be an association between interventions and outcome even if the effects of the interventions are identical This form of selection bias is distinct from confounding—A specific example is bias due to the inclusion of prevalent users, rather than new users, of an intervention
At intervention	**Risk of bias assessment is mainly distinct from assessments of randomised trials**
Bias in classification of interventions	Bias introduced by either differential or non-differential misclassification of intervention status Non-differential misclassification is unrelated to the outcome and will usually bias the estimated effect of intervention towards the null Differential misclassification occurs when misclassification of intervention status is related to the outcome or the risk of the outcome, and is likely to lead to bias
Post-intervention	**Risk of bias assessment has substantial overlap with assessments of randomised trials**
Bias due to deviations from intended interventions	Bias that arises when there are systematic differences between experimental intervention and comparator groups in the care provided, which represent a deviation from the intended intervention(s) Assessment of bias in this domain will depend on the type of effect of interest (either the effect of assignment to intervention or the effect of starting and adhering to intervention).
Bias due to missing data	Bias that arises when later follow-up is missing for individuals initially included and followed (such as differential loss to follow-up that is affected by prognostic factors); bias due to exclusion of individuals with missing information about intervention status or other variables such as confounders
Bias in measurement of outcomes	Bias introduced by either differential or non-differential errors in measurement of outcome data. Such bias can arise when outcome assessors are aware of intervention status, if different methods are used to assess outcomes in different intervention groups, or if measurement errors are related to intervention status or effects
Bias in selection of the reported result	Selective reporting of results in a way that depends on the findings and prevents the estimate from being included in a meta-analysis (or other synthesis)

Manuale operativo richiesto dal DM 27 febbraio 2018 (GU n.66 del 20-3-2018)

- Requisiti e modalità di invio
- Procedura e strumenti di valutazione delle LG per la pubblicazione nell'SNLG
- Adempimenti per i proponenti di LG pubblicate nell'SNLG

Processo di valutazione delle LG proposte da soggetti ex art.5 L. n.24/17 per la pubblicazione nell'SNLG



Le richieste di valutazione vanno inviate online attraverso la **piattaforma SNLG**

Workflow sviluppato dal CNEC con il supporto del centro collaboratore **GIMBE**

And so, what role for clinical guidelines ?

Advocacy, standard of care, balanced synthesis of best evidence available, identifying research & healthcare gaps
….

guidelines (should) force us to scrutiny primary research literature in ways that we don't normally do

Richard Horton, Editor of *The Lancet*