Seminario

GIORNATA REGIONALE DELLA SICUREZZA E QUALITÀ DELLE CURE 2019

RETE CURE SICURE FVG

REGIONE AUTONOMA FRIULI VENEZIA GIULIA

azienda sanitaria universitaria integrata di udine

REGIONE AUTONOMA FRIULI VENEZIA GIULIA

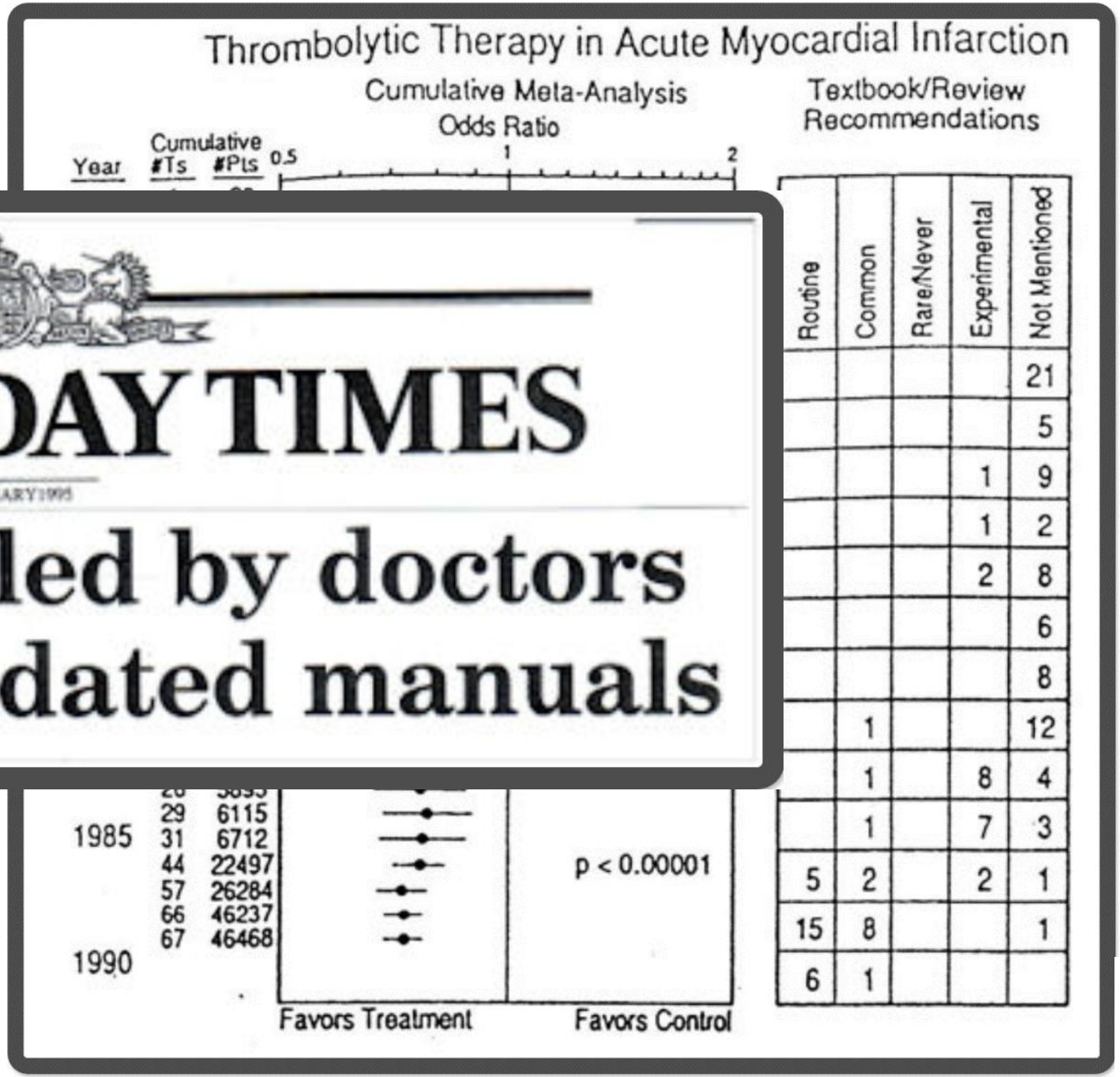
Le linee guida e le raccomandazioni

P. Iannone

10.12.2019

Centro Nazionale Eccellenza
Clinica Qualità e Sicurezza delle Cure

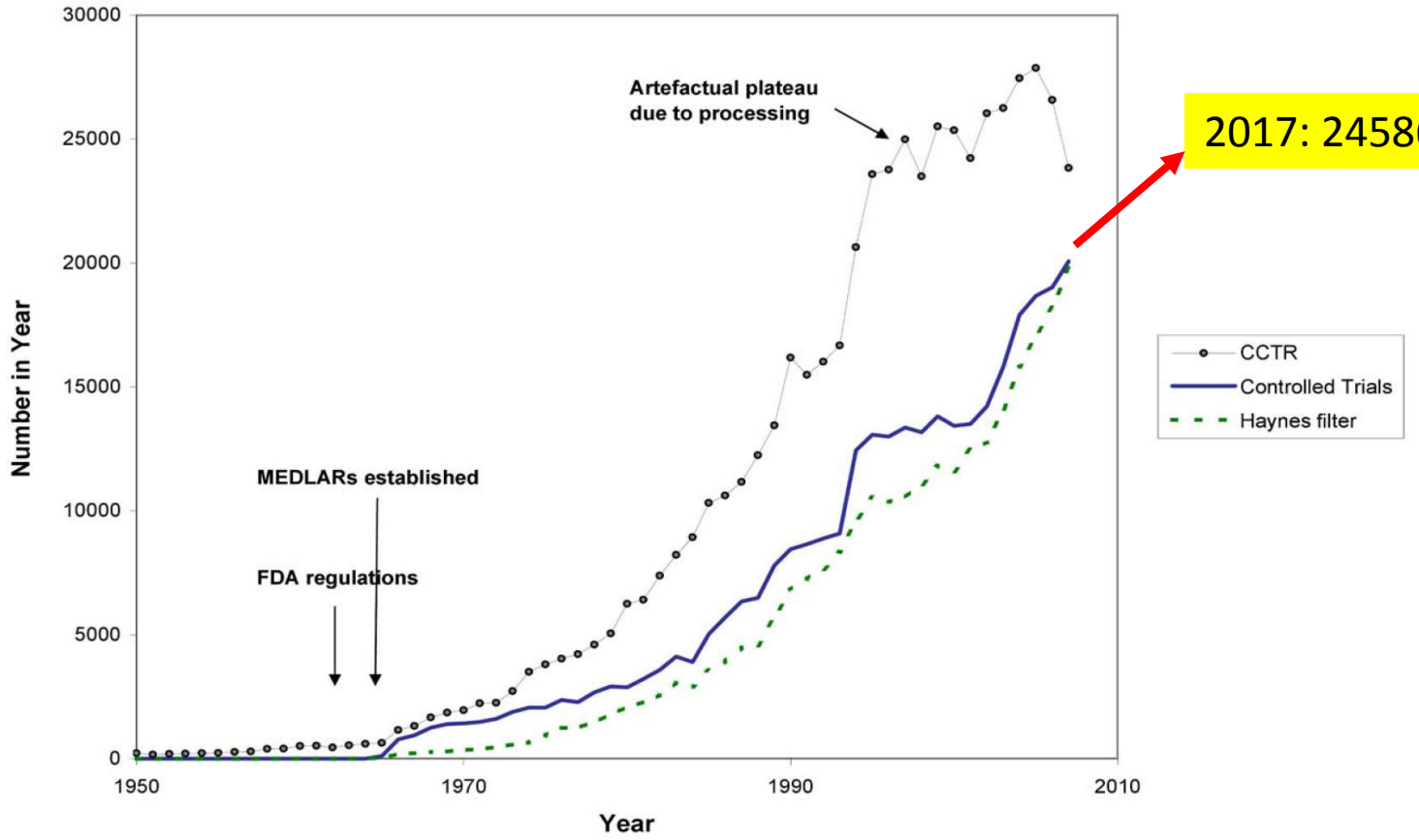
ISTITUTO SUPERIORE DI SANITÀ



THE SUNDAY TIMES

5 FEBRUARY 1995

Hundreds killed by doctors relying on outdated manuals



2017: 24586 RCT on PubMed

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

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

1. Clinical questions and information needs

Jeremy C Wyatt DM FRCP

J R Soc Med 2000;93:168–171

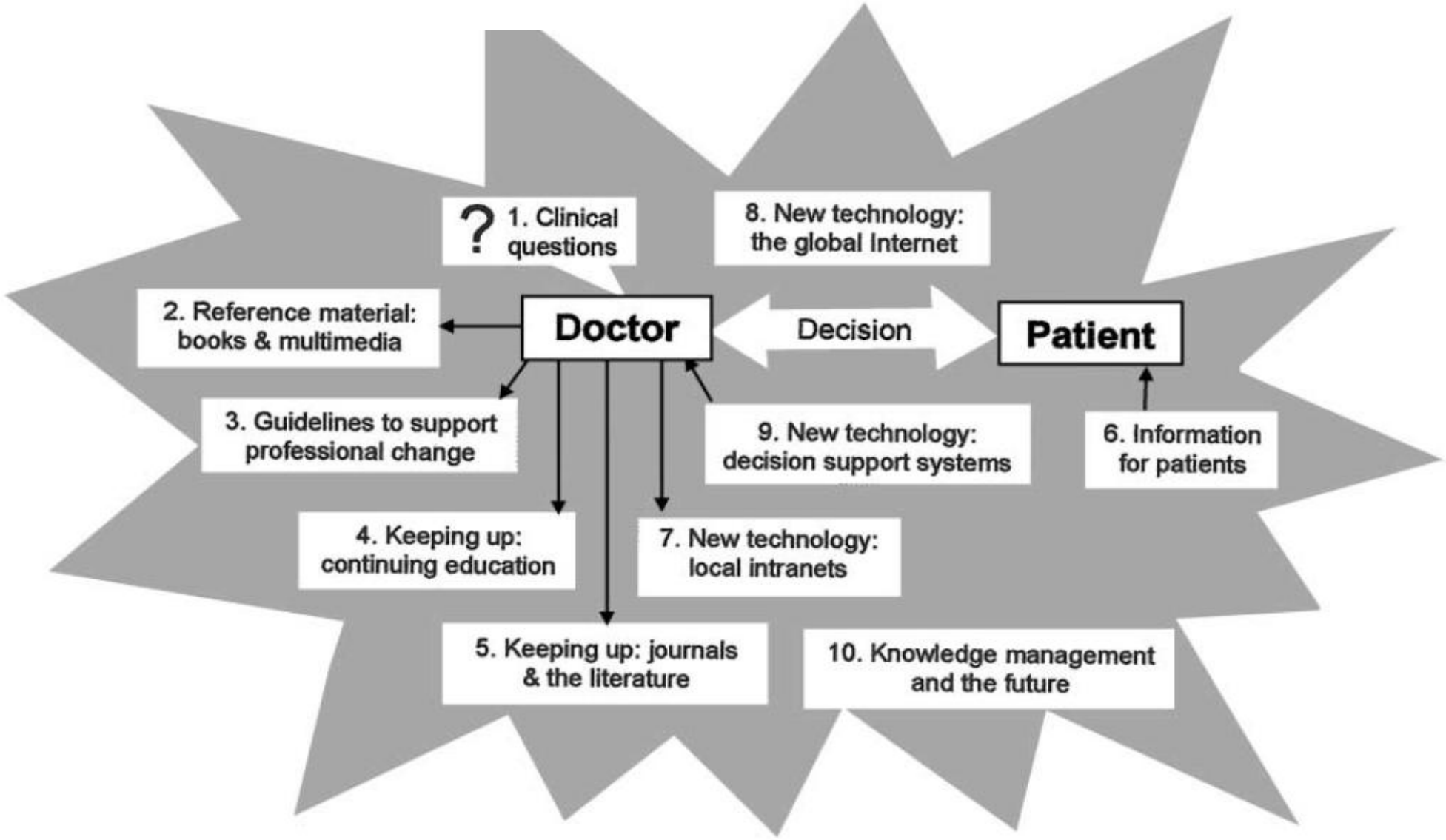
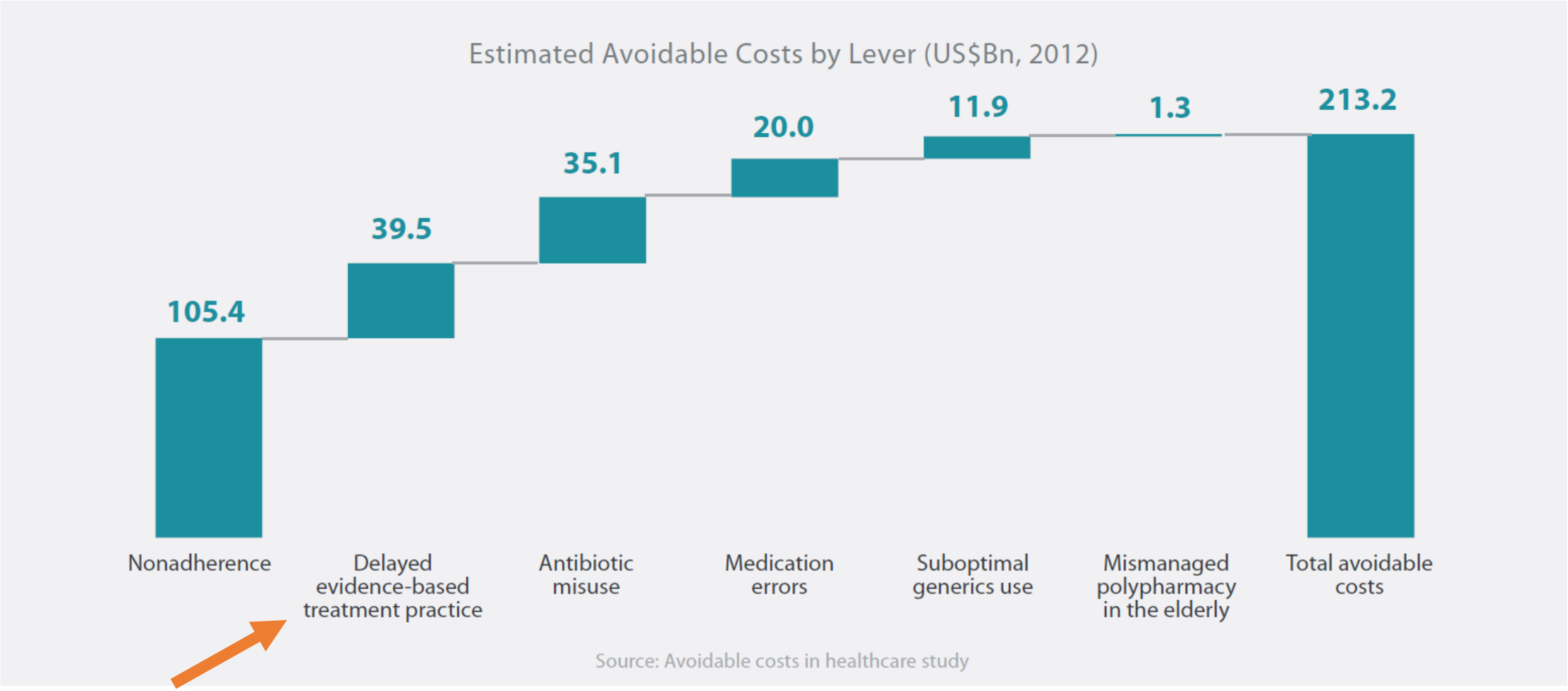


Figure 1 **Structure of Knowledge for the Clinician**



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

JAMA®

The Rational Clinical Examination

Evidence-Based Medicine

A New Approach to Teaching the Practice of Medicine

Evidence-Based Medicine Working Group

JAMA, November 4, 1992—Vol 268, No. 17

tion is as follows: **Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.**

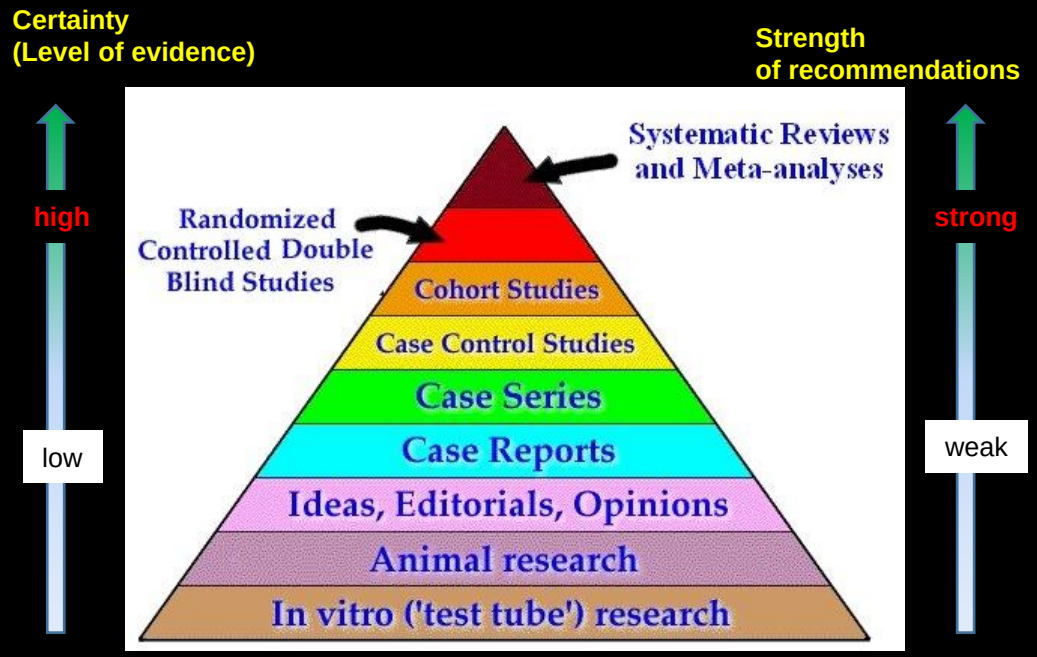
To be *trustworthy*, guidelines should

scelta

Guidelines, not tramlines

Institute of Medicine, 2011


Consensus based
consensus
Quality of evidence
(Strength of)
recommendation



Graded recommendations

BMJ 2003;327:1459–61

Parachutes reduce the risk of injury after gravitational challenge, but their effectiveness has not been proved with randomised controlled trials

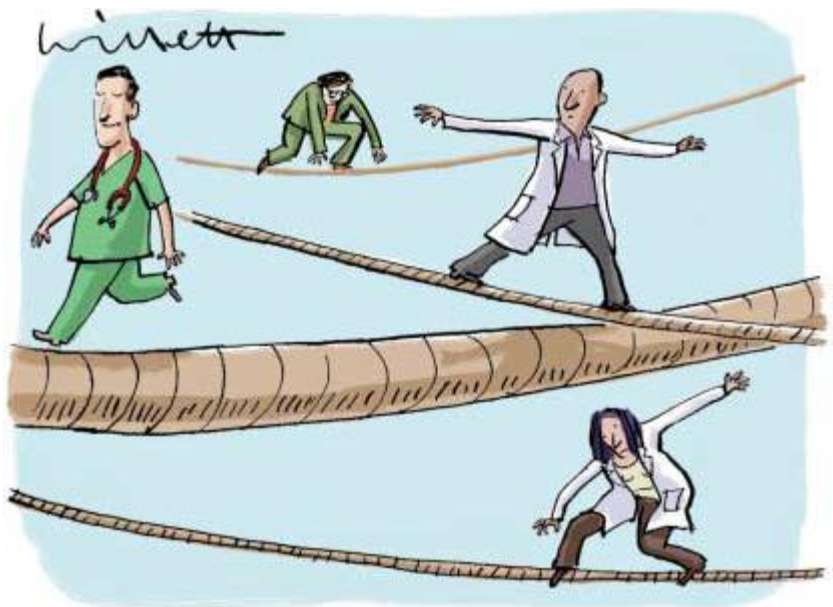
Sometimes trials are unethical or impossible yet some treatments are quite effective

Grading quality of evidence and strength of recommendations

Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) Working Group

Clinical guidelines are only as good as the evidence and judgments they are based on. The GRADE approach aims to make it easier for users to assess the judgments behind recommendations

BMJ 2004;328:1490–4



Qualità delle prove

Fino a che punto possiamo credere che le stime di effetto di un intervento siano vere?

Forza delle raccomandazioni

Quanto siamo certi che l'aderenza ad una determinata raccomandazione porti ad un beneficio superiore ai possibili danni

2008;336;924-926 *BMJ*
2008;336;995-998 *BMJ*
2008;336;1049-1051 *BMJ*

RATING QUALITY OF EVIDENCE AND STRENGTH OF RECOMMENDATIONS

GRADE: an emerging consensus on rating quality of evidence and strength of recommendations

Guidelines are inconsistent in how they rate the quality of evidence and the strength of recommendations. This article explores the advantages of the GRADE system, which is increasingly being adopted by organisations worldwide

Guideline developers around the world are inconsistent in how they rate quality of evidence and grade strength of recommendations. As a result, guideline users face challenges in understanding the messages that grading systems try to communicate. Since 2006 the *BMJ* has requested in its "Instructions to Authors" on bmj.com that authors should preferably use the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system for grading evidence when submitting a clinical guidelines article.

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Gunn E Vist researcher, Norwegian Knowledge Centre for

advantages and disadvantages but also by their confidence in these estimates. The cartoon depicting the weather forecaster's uncertainty captures the difference between an assessment of the likelihood of an outcome and the confidence in that assessment (figure). The usefulness of an estimate of the magnitude of intervention effects depends on our confidence in that estimate.

Expert clinicians and organisations offering recommendations to the clinical community have often erred as a result of not taking sufficient account of the quality

www.gradeworkinggroup.org

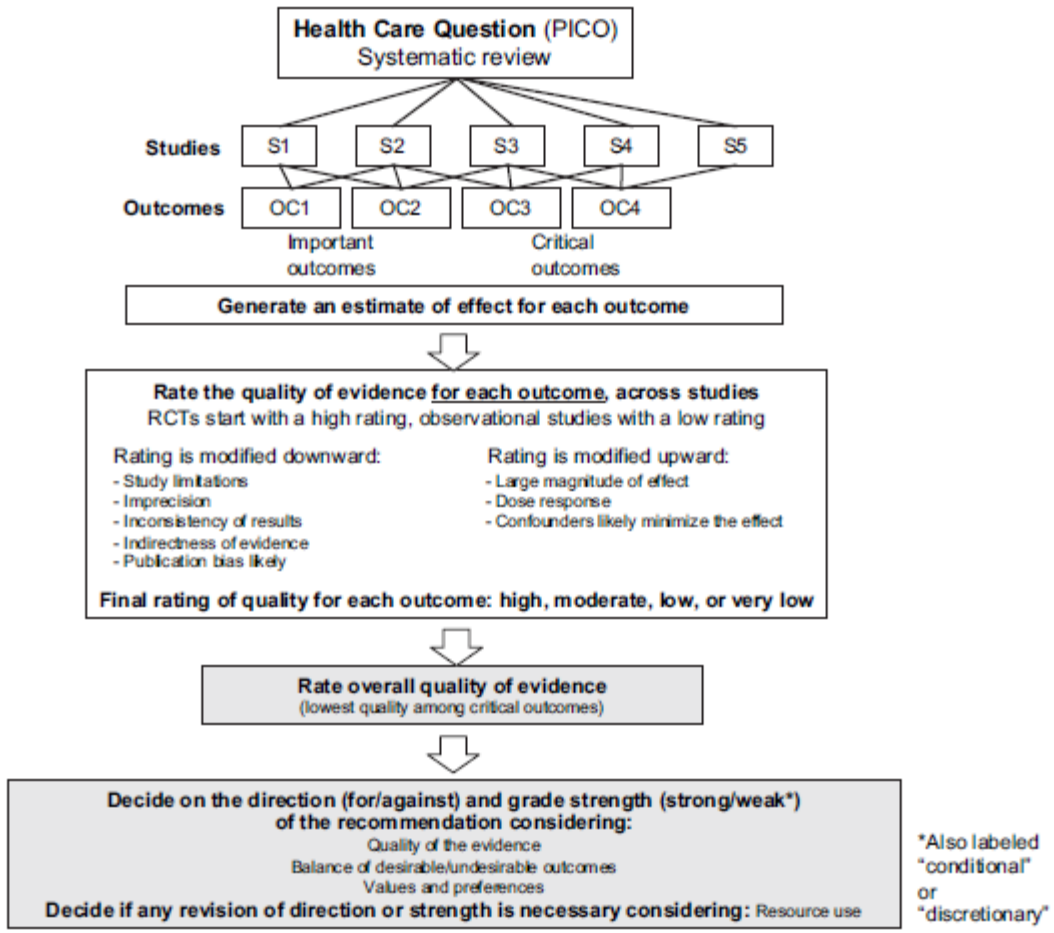


Fig. 1. Schematic view of GRADE's process for developing recommendations. *Abbreviation*: RCT, randomized controlled trials.

VALUTAZIONE EtD

1. Priorità del problema
2. Effetti desiderati
3. Effetti indesiderati
4. Certezza delle prove
5. Valori
6. Bilancio dell'effetto
7. Risorse richieste
8. Certezza delle risorse
9. Costo-efficacia
10. Equità
11. Accettabilità
12. Fattibilità

Box 4. Criteri considerati nel GRADE EtD framework

Problema: Il problema è una priorità? (già valutato nella fase iniziale di sviluppo della LG, quindi si può omettere dalla descrizione del framework EtD)

Benefici attesi: Quanto sono importanti i benefici attesi?

Effetti indesiderati: Quanto sono importanti gli effetti indesiderati?

Qualità globale delle prove: Fino a che punto si può confidare nel fatto che la stima di beneficio/danno possa essere usata a favore/contro il raccomandare l'uso dell'intervento proposto?

Valori: Vi è incertezza o variabilità rispetto al valore che le persone attribuiscono agli outcome principali?

Bilancio tra benefici e danni attribuibili all'intervento: Il bilancio tra benefici ed effetti indesiderati favorisce l'intervento proposto o il confronto?

Risorse richieste:

- Quali sono i costi richiesti?
- Qual è il livello di evidenza relativo ai costi richiesti?
- L'analisi di costo-efficacia o di costo-utilità favorisce l'intervento proposto o il confronto?

Equità: Quale potrebbe essere l'impatto sull'equità?

Accettabilità: L'intervento proposto è accettabile da parte degli stakeholder?

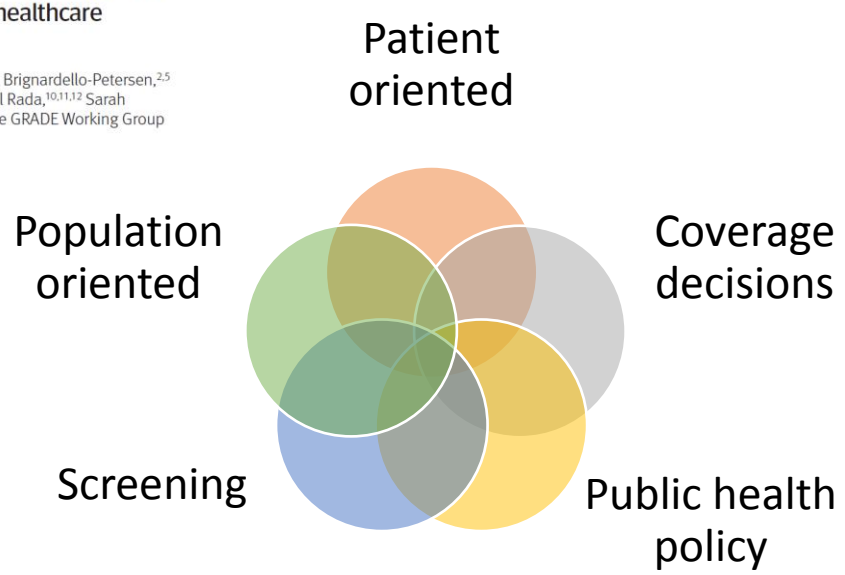
Fattibilità: L'intervento proposto può essere implementato?

LG differenziate per scopi

GRADE Evidence to Decision (EtD) frameworks: a systematic and transparent approach to making well informed healthcare choices. 1: Introduction

Pablo Alonso-Coello,[1,2] Holger J Schünemann,[2,3] Jenny Moberg,[4] Romina Brignardello-Petersen,[2,5] Elie A Akl,[2,6] Marina Davoli,[7] Shaun Treweek,[8] Reem A Mustafa,[2,9] Gabriel Rada,[10,11,12] Sarah Rosenbaum,[4] Angela Morelli,[4] Gordon H Guyatt,[2,3] Andrew D Oxman[4] the GRADE Working Group

Cite this as: *BMJ* 2016;353:i2016
http://dx.doi.org/10.1136/bmj.i2016



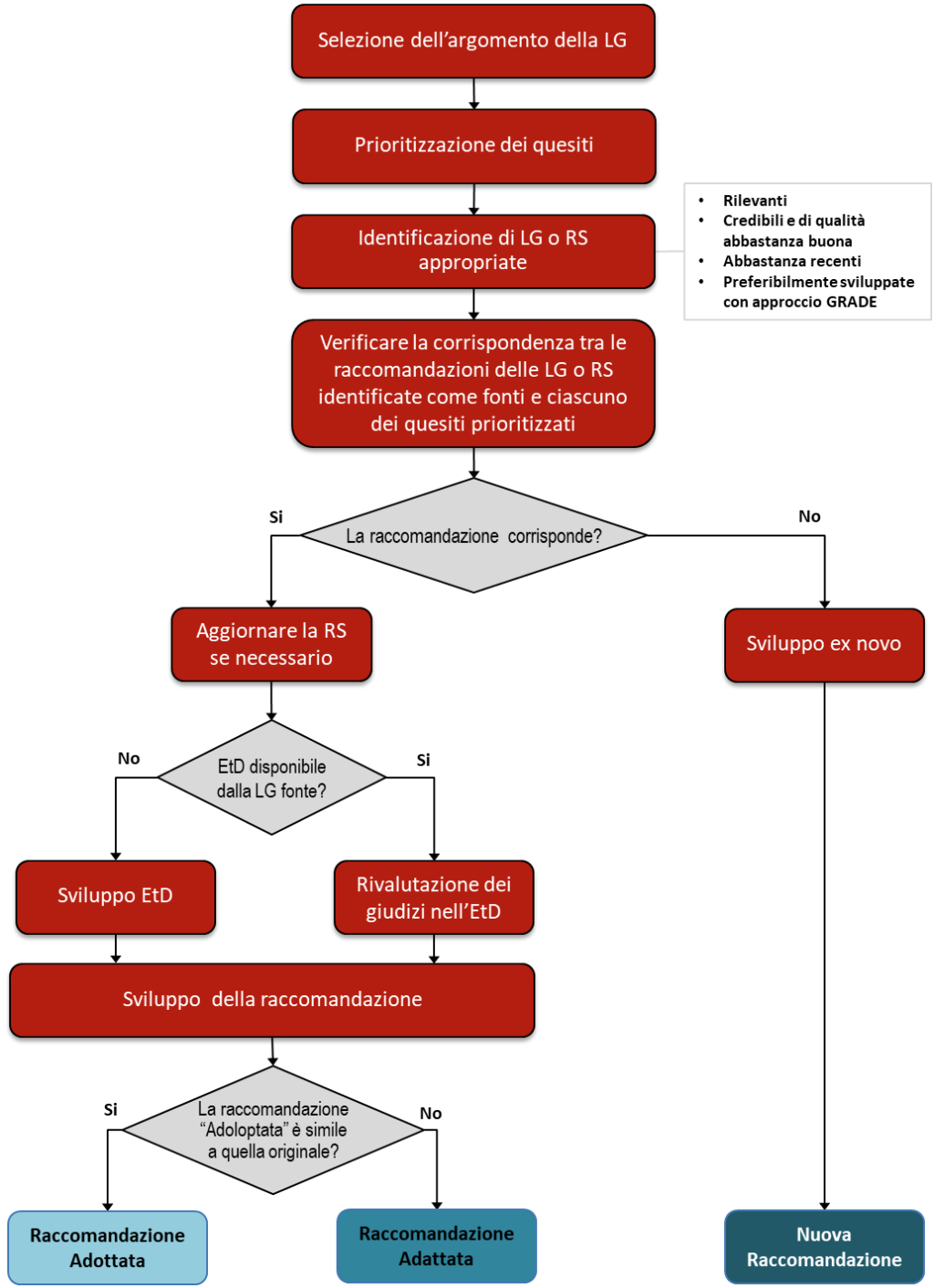
GRADE

Per adattamento LG

Il metodo GRADE-ADOLOPMENT

Tradotto da: Schünemann et al. *Journal of Clinical Epidemiology* 2017 81, 101-110DOI (10.1016/j.jclinepi.2016.09.009)

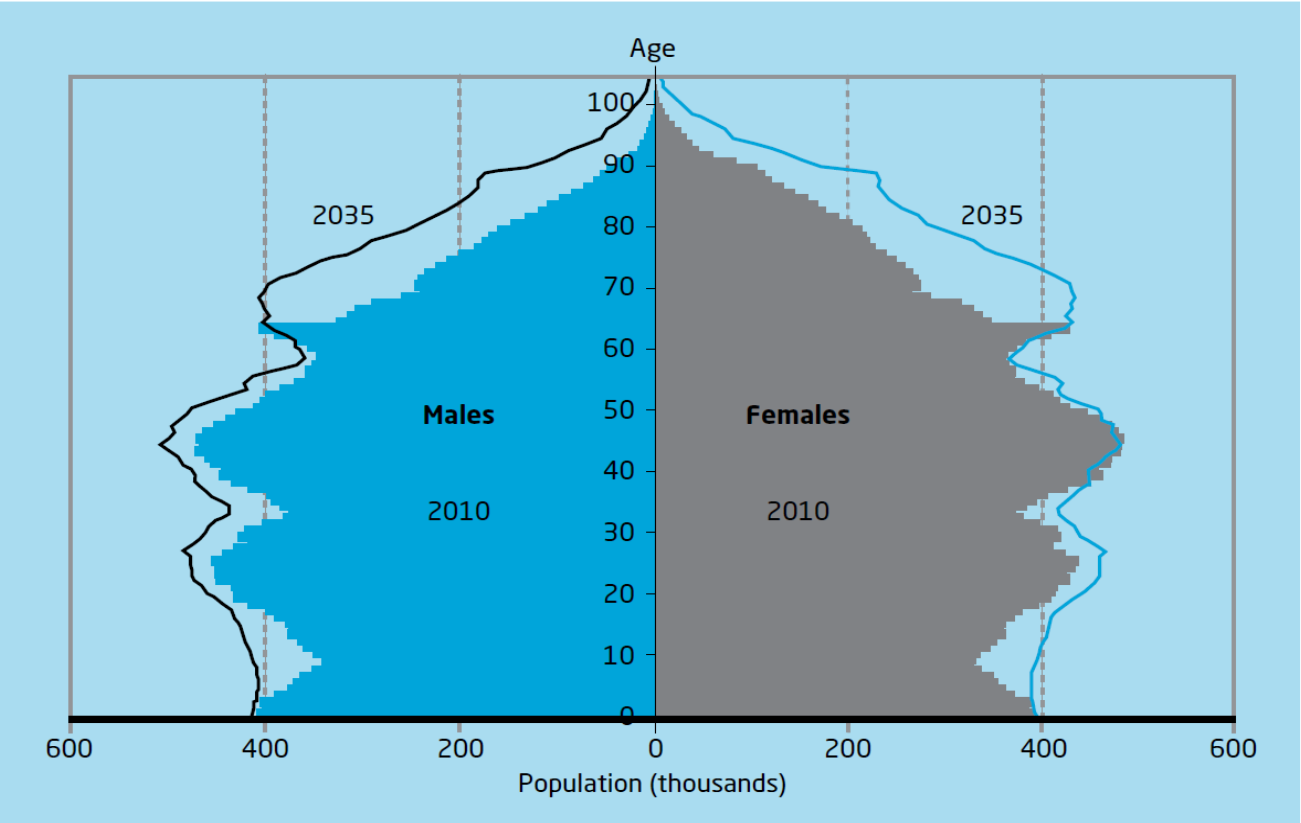
Essenziale per la prospettiva nazionale SSN



producing a guideline is a
very complex process involving technical skills (searching for primary evidence efficiently), value judgements (rating that evidence) and social aspects (managing discussion
and achieving consensus within the guideline
panel group)

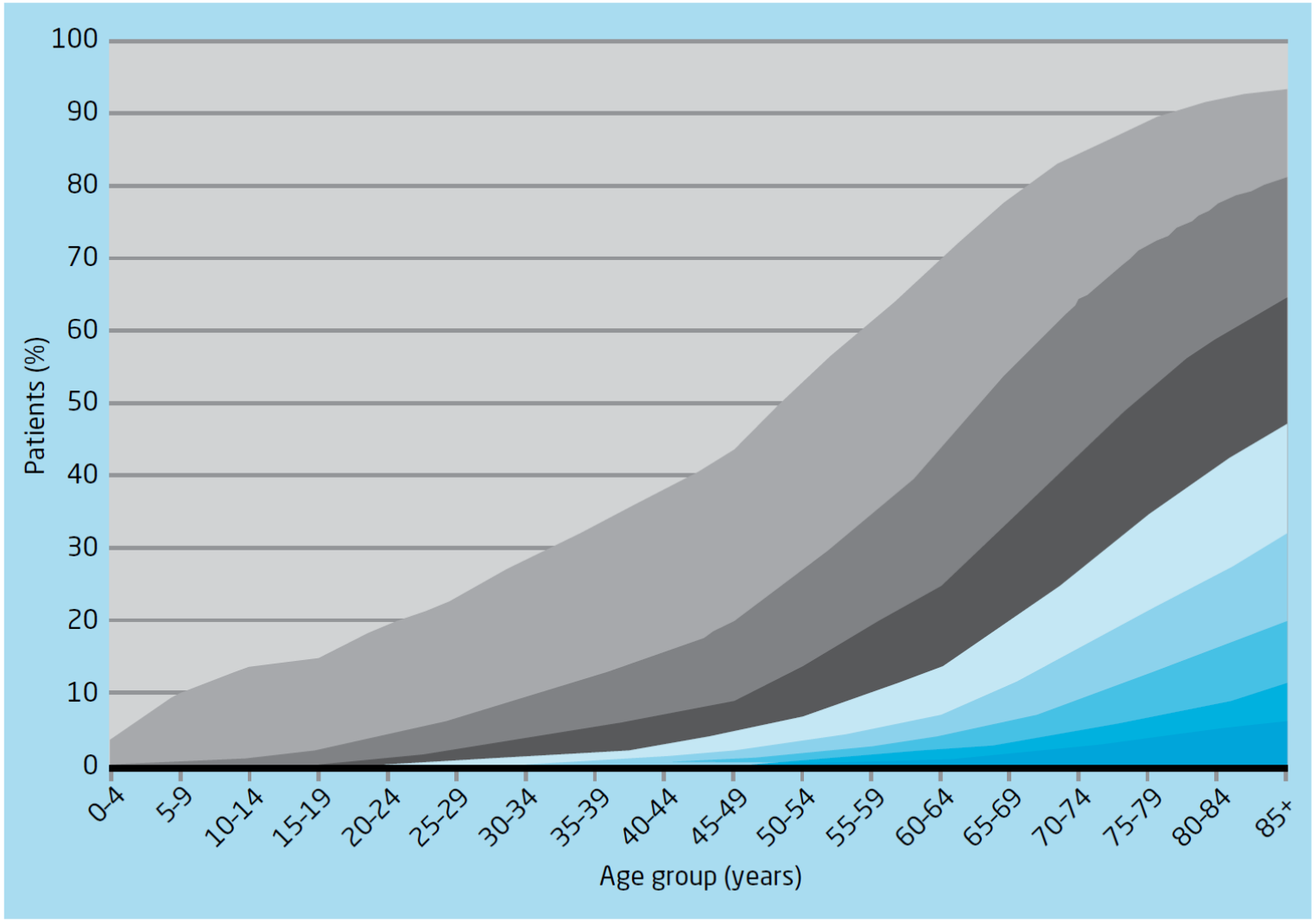
Burgers JS, Bailey JV, Klazinga NS, et al. Inside guidelines: comparative analysis of recommendations and evidence in diabetes guidelines from 13 countries. Diabetes Care 2002;25:1933–9.

Figure 6 Estimated and projected age structure, UK population, mid-2010 and mid-2035



The King's Fund

Figure 5 Number of chronic disorders by age group



Note: This figure shows how common it is to have significant long-term conditions in relation to age. Few people (fewer than 30 per cent) do not have at least one condition by the age of 60, and many people will have two or three.

Il ruolo e l'attività del Centro Nazionale Eccellenza Clinica, Qualità e Sicurezza delle Cure in relazione al Sistema Nazionale Linee Guida

Milano 26 giugno 2019

Primiano Iannone

Centro Nazionale Eccellenza Clinica Qualità e Sicurezza delle Cure

multimorbidità

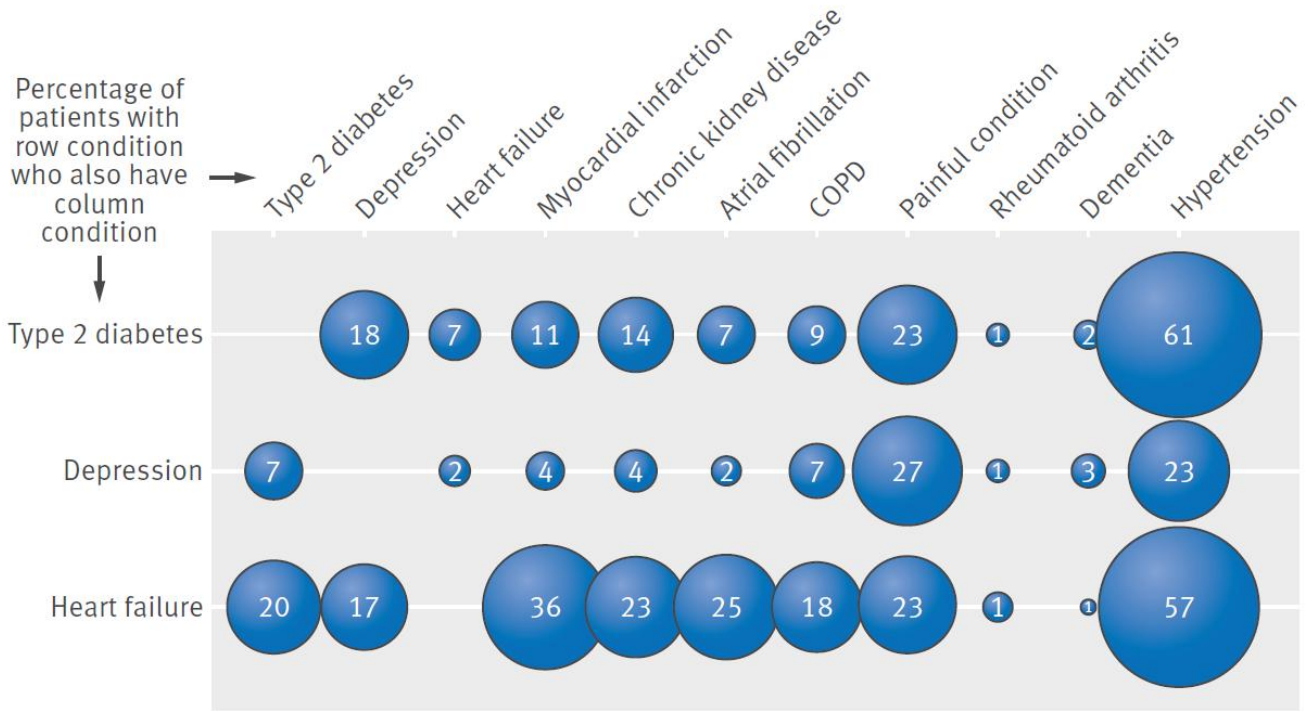


Fig 1 | Proportion of people with three index conditions who have each of other conditions. Morbidity data were not available for osteoarthritis or neuropathic pain; "painful condition" data shown are defined by receipt of four or more prescriptions for non-over the counter analgesics in previous 12 months

BMJ 2015;350:h949

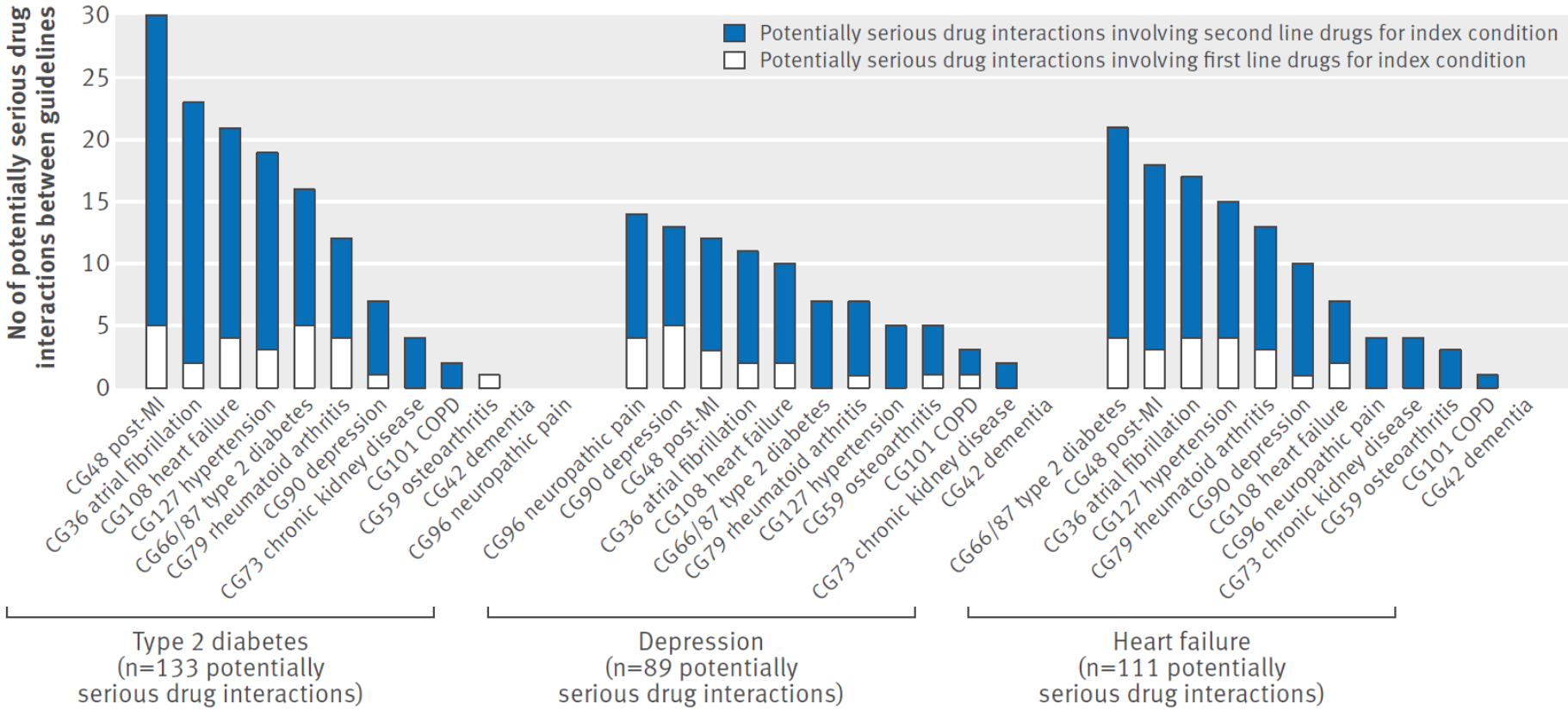


Fig 2 | Potentially serious drug-drug interactions between drugs recommended by clinical guidelines for three index conditions and drugs recommended by each of other 11 other guidelines

Allineamento ISS allo standard di riferimento internazionale per LG WHO, NICE, SIGN…

Offrire LG di alta qualità metodologica rilevanti e valide per le finalità dell' SSN

SNLG
dell'Istituto Superiore di Sanità

> Archivio per categoria "LG internazionali"

Archivi categoria: *LG internazionali*

LG internazionali

In questa sezione sono riportate le **LG internazionali** selezionate e indicate dal CNEC come punto di riferimento per i produttori di LG SNLG per l'adattamento delle stesse al contesto nazionale. Tali LG sono selezionate dal CNEC attraverso un processo di ricognizione della letteratura biomedica e la sorveglianza attiva dei documenti pubblicati dagli enti, dalle società scientifiche e dalle agenzie internazionali che producono LG.

I criteri adottati per la selezione delle LG sono i seguenti:

- corretta gestione del conflitto di interessi
- buona/elevata qualità metodologica
- composizione multidisciplinare/multiprofessionale del panel di esperti della LG
- revisione della LG condotta da referee esterni indipendenti.

Disclaimer. Le LG internazionali non sono assimilabili alle LG SNLG ai fini della L. 24/2017 in quanto non elaborate dai soggetti ex art 5 comma 1. Inoltre, pur provenendo da fonti di alto valore scientifico, tali LG possono, tuttavia, contenere raccomandazioni e consigli clinici non direttamente applicabili al contesto sanitario italiano e/o non compatibili con le disposizioni di legge, i regolamenti degli ordini professionali o i provvedimenti delle agenzie regolatorie italiane. Pertanto, i lettori sono invitati a considerare attentamente questa eventualità nel processo di adattamento delle raccomandazioni al contesto nazionale.

International Guidelines Evaluation Screening Tool (IGEST) Content Validity Questionnaire

CNEC Centro Nazionale per l'Eccellenza Clinica, la Qualità e la Sicurezza delle Cure

Content Validity Questionnaire

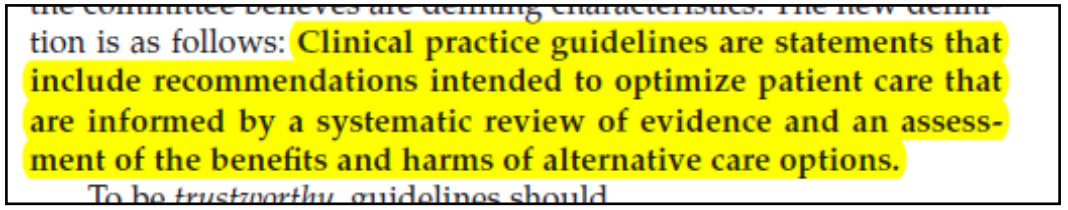
Excellence, Quality and Safety

al Practice Guidelines in the SNLG-ISS

ary 2019

ertain whether to include international Clinical
s database held by the SNLG-ISS. The 13 criteria,
eening of CPGs. In addition, it is recommended
opting the tools suggested in the specific sections

Clinical practice guideline


tion is as follows: Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.

To be *trustworthy*, guidelines should

Clinical pathway

Schedules of medical and nursing procedures, including diagnostic tests, medications, and consultations designed to effect an efficient, coordinated program of treatment. (From Mosby's Medical, Nursing and Allied Health Dictionary, 4th ed)

Year introduced: 1996

Lawal et al. BMC Medicine (2016) 14:35
DOI 10.1186/s12916-016-0580-z

BMC Medicine

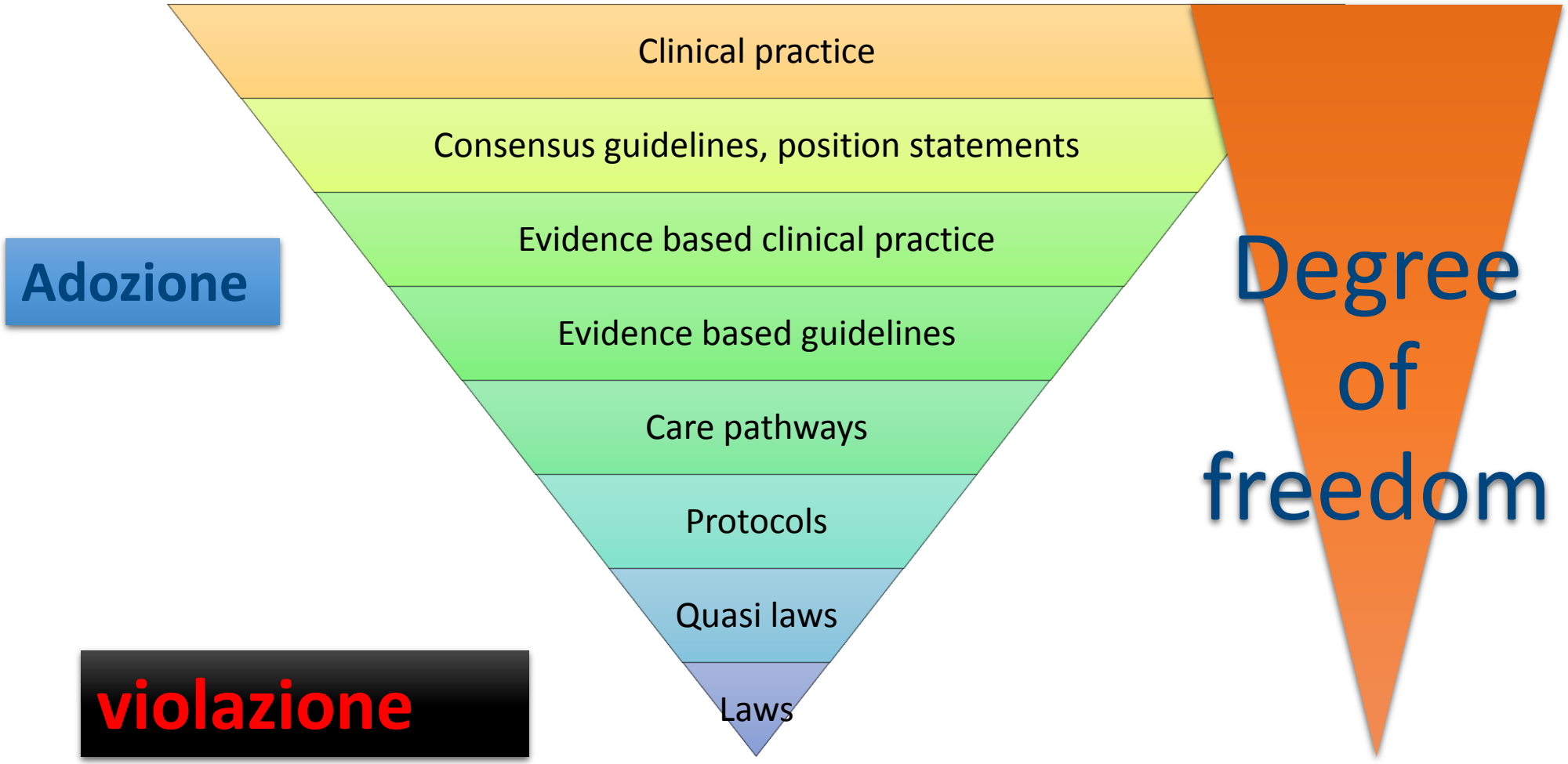
CORRESPONDENCE Open Access

What is a clinical pathway? Refinement of an operational definition to identify clinical pathway studies for a Cochrane systematic review

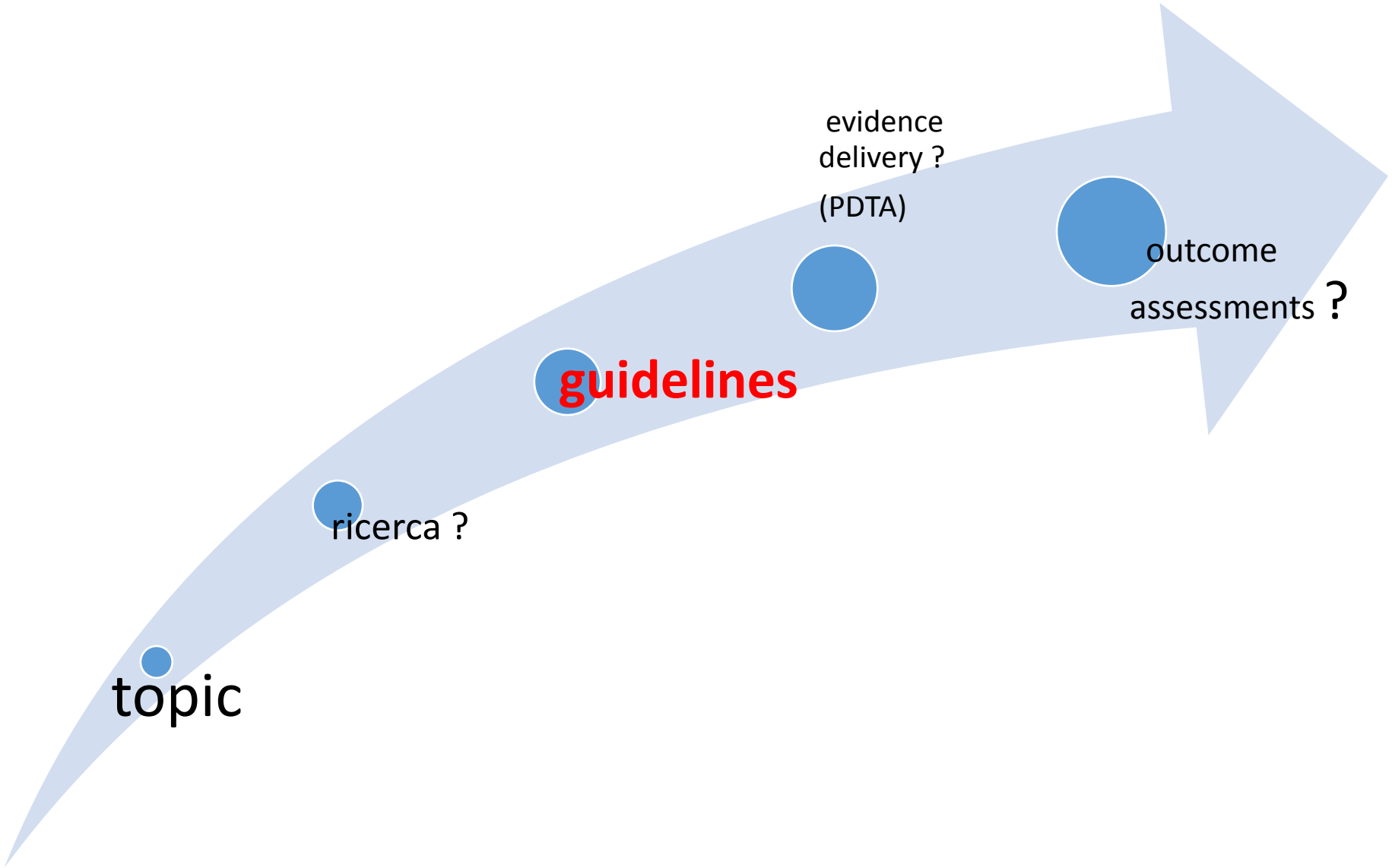
Adegboyega K. Lawal[1*], Thomas Rotter[1], Leigh Kinsman[2], Andreas Machotta[3], Ulrich Ronellenfitsch[4], Shannon D. Scott[5], Donna Goodridge[6], Christopher Plishka[1] and Gary Groot[6]

- Pianificazione strutturata e multidisciplinare di un percorso clinico (-assistenziale)
- **Finalizzato a trasferire linee guida o evidenze** in organizzazioni sanitarie locali (specifiche)
- Dettaglia i passaggi in un piano, algoritmo, percorso, protocollo o altro inventario di azioni da compiere in un arco di tempo o sulla base di specifici criteri di progressione
- Inteso a standardizzare l'assistenza per una popolazione specifica

LG come *safe harbour* ?



80 % circa raccomandazioni deboli: quale valore medicolegale ?


evidence
delivery ?
(PDTA)
outcome
assessments ?
guidelines
ricerca ?
topic

Do we need more research or more translation of research findings ?

RESEARCH METHODS & REPORTING

How to estimate the health benefits of additional research and changing clinical practice

Karl Claxton,[1,2] Susan Griffin,[1] Hendrik Koffijberg,[3,4] Claire McKenna[1]

[1]Centre for Health Economics, University of York, York YO10 5DD, UK
[2]Department of Economics and Related Studies, University of York, York, UK
[3]Julius Centre for Health Sciences and Primary Care, University Medical Centre Utrecht, The Netherlands
[4]Department of Health Technology & Services Research, University of Twente, Enschede, The Netherlands
Correspondence to: S Griffin
susan.griffin@york.ac.uk

Additional material is published online only. To view please visit the journal online (http://dx.doi.org/10.1136/bmj.h5987)
Cite this as: *BMJ* 2015;351:h5987
doi: 10.1136/bmj.h5987
Accepted: 13 October 2015

A simple extension of standard meta-analysis can provide quantitative estimates of the potential health benefits of further research and of implementing the findings of existing research, which can help inform research prioritisation and efforts to change clinical practice

Decisions about undertaking further research and at what point evidence should be implemented are important questions for research prioritisation and health policy. The results of standard meta-analysis can be extended to provide a quantitative assessment of the potential health benefits of gathering additional evidence and of implementing the findings in a way that consideration of statistical significance cannot.[1]

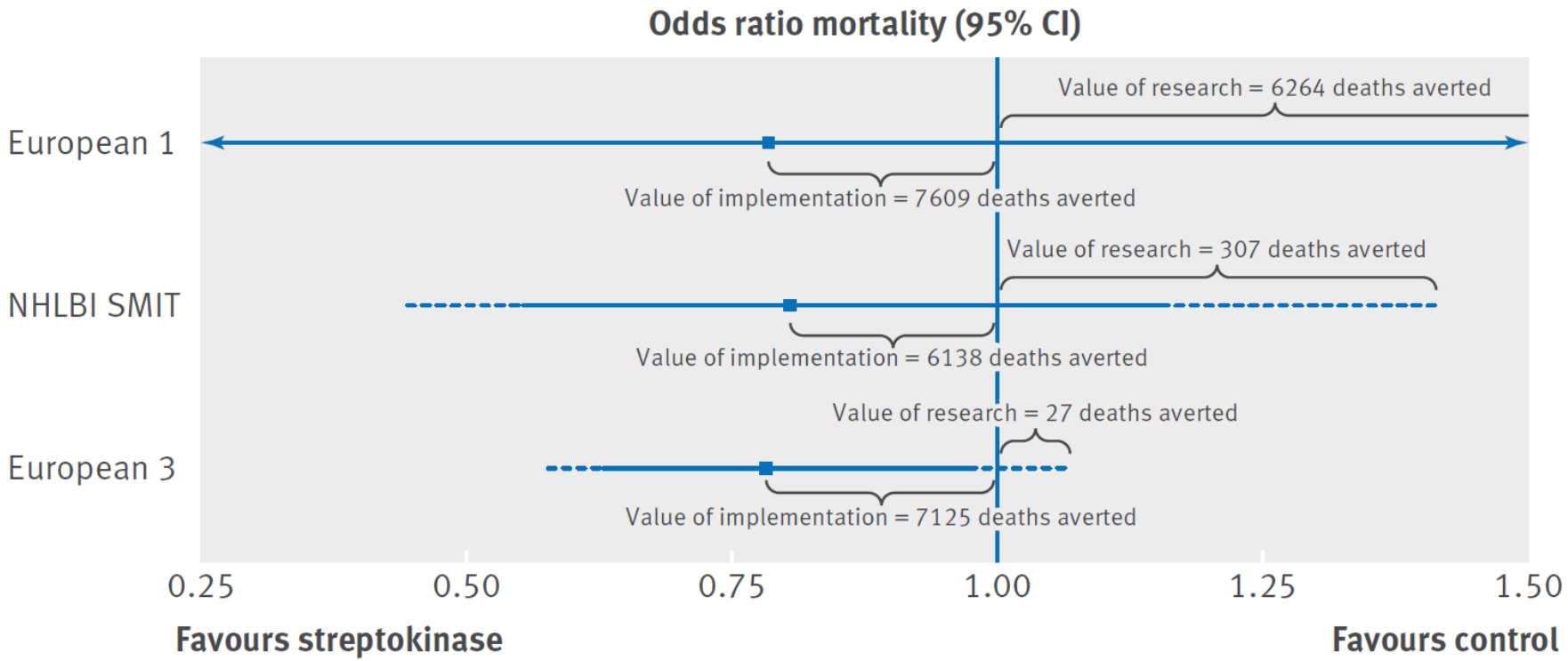


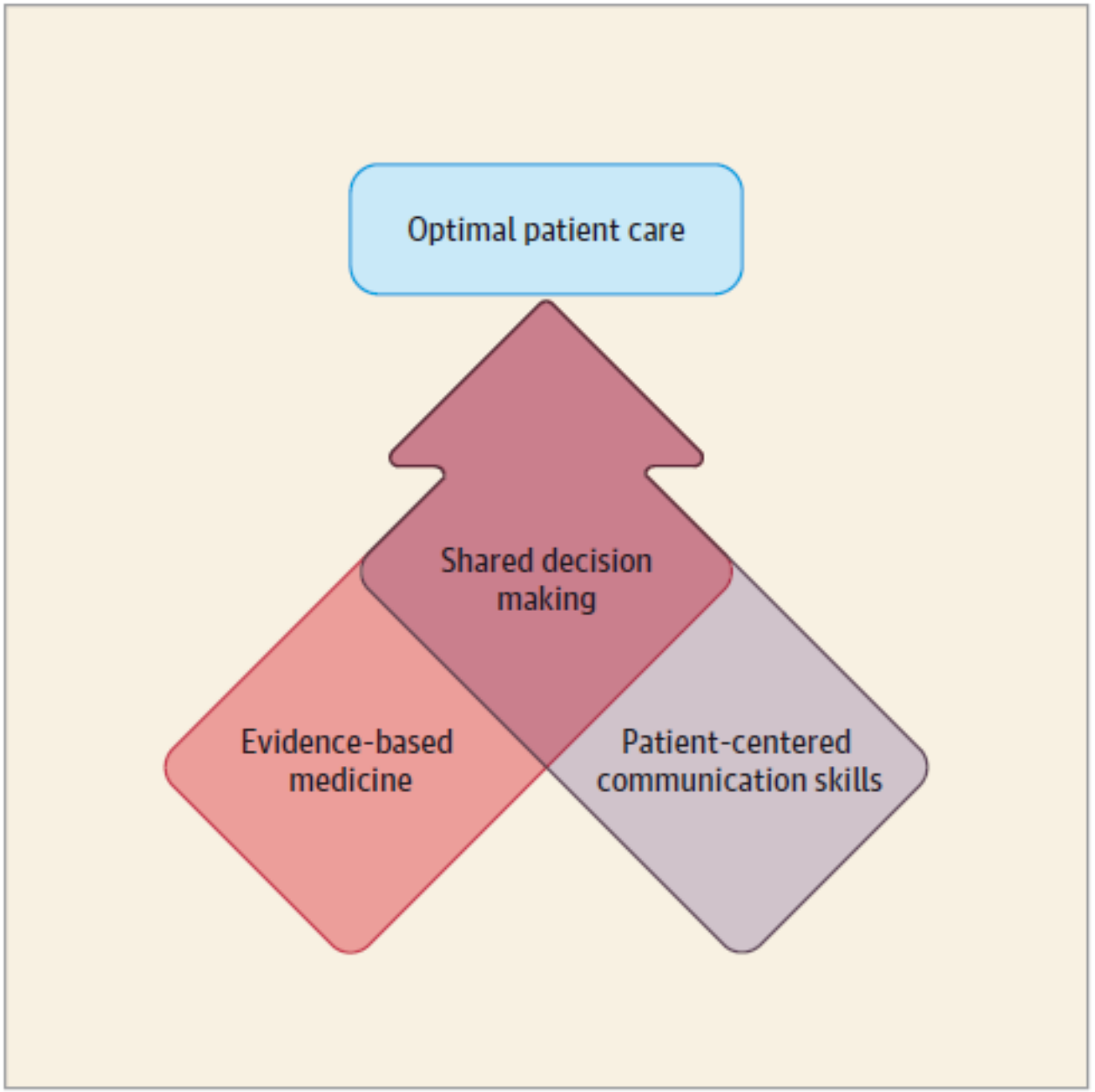
Fig 4 | Expected benefits of implementation (of streptokinase use following acute myocardial infarction) and potential benefits of further research, according to selected trials in example meta-analysis shown in figure 3. Solid line=95% credible interval; dashed line=90% credible interval

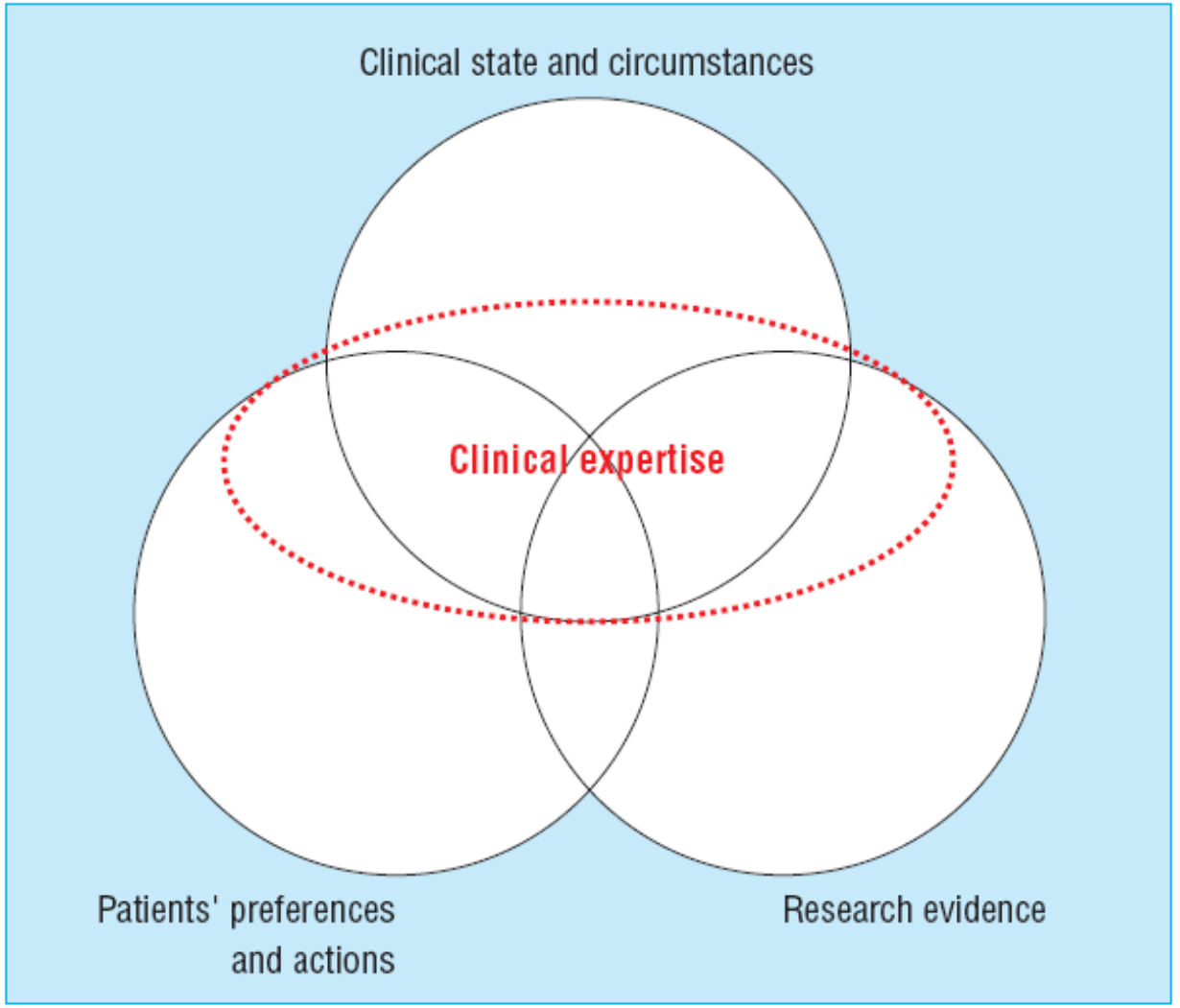
VIEWPOINT

The Connection Between Evidence-Based Medicine and Shared Decision Making

JAMA October 1, 2014 Volume 312, Number 13 1295

Figure. The Interdependence of Evidence-Based Medicine and Shared Decision Making and the Need for Both as Part of Optimal Care





An updated model for evidence based clinical decisions[1]

Haynes RB et al. BMJ 2002;324:1350

HealthAffairs

At the Intersection of Health, Health Care and Policy

Cite this article as:
John M. Eisenberg
Globalize The Evidence, Localize The Decision: Evidence-Based Medicine
And International Diversity
Health Affairs, 21, no.3 (2002):166-168

doi: 10.1377/hlthaff.21.3.166

Globalize The Evidence, Localize The Decision: Evidence-Based Medicine And International Diversity

The use of evidence is most successful when local differences are factored into the decision-making process, whether at the clinical, system, or policy level.

by John M. Eisenberg

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*