Progetto
Team Multidisciplinare Uro-Oncologico
Una Sfida Comune

Consensus Conference TMD (Team Multidisciplinare Uro-Oncologico)

MILANO 12.13 DICEMBRE 2017
Hilton Milan via L.Galvani 12

Linee Guida: Ruolo dell'Istituto Superiore di Sanità

Primiano Iannone

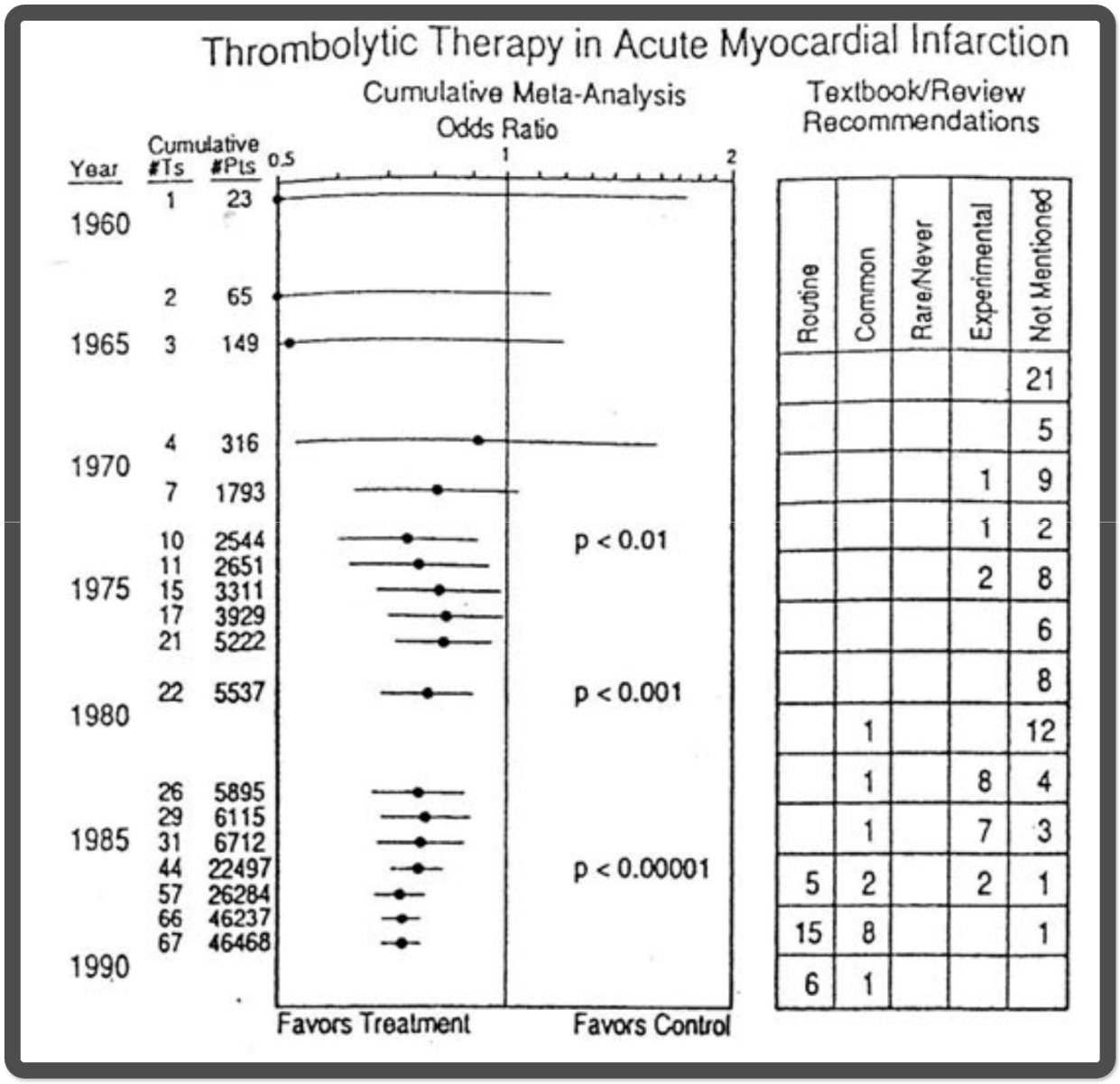
Centro Nazionale Eccellenza
Clinica Qualità e Sicurezza delle Cure

THE SUNDAY TIMES

5 FEBRUARY 1995

Hundreds killed by doctors relying on outdated manuals

JAMA. 1992 Jul 8;268(2):240-8.
A comparison of results of meta-analyses of randomized control trials and recommendations of clinical experts. Treatments for myocardial infarction.
Antman EM[1], Lau J, Kupelnick B, Mosteller F, Chalmers TC.



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 mbH; 2000.

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

Piramide delle evidenze

Cos'è una Linea Guida

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

IOM 2011

Low quality of contemporary guidelines

ORIGINAL INVESTIGATION

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.

2013

BMJ

BMJ 2013;346:f3830 doi: 10.1136/bmj.f3830 (Published 14 June 2013)

FEATURE

EVIDENCE BASED MEDICINE

Why we can't trust clinical guidelines

Jeanne Lenzer *medical investigative journalist*

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 (Agreement)[9]
- Japan Stroke Society (Level of evidence A, Grade of recommendation A)[10]
- National Institute for Health and Care Excellence ("is recommended")[11]
- National Stroke Foundation (Australia) (Level 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]

Avoidable waste in the production and reporting of research evidence

Iain Chalmers, Paul Glasziou

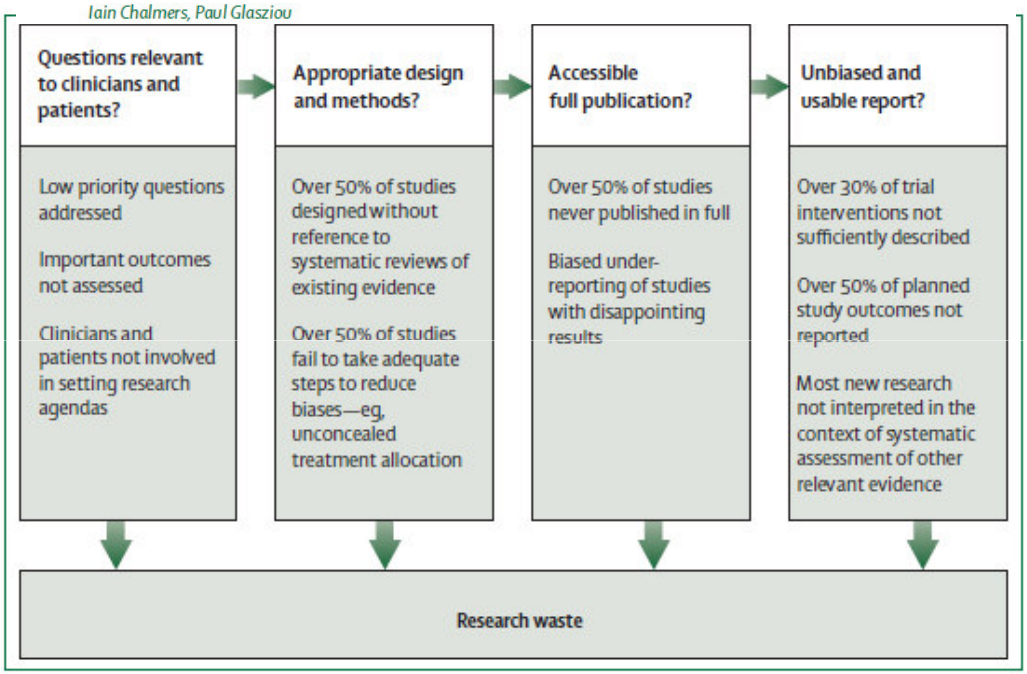


Figure: Stages of waste in the production and reporting of research evidence relevant to clinicians and patients

Lancet 2009; 374: 86–89

the temporal gap between current "best" evidence and guidelines lowers their overall reliability

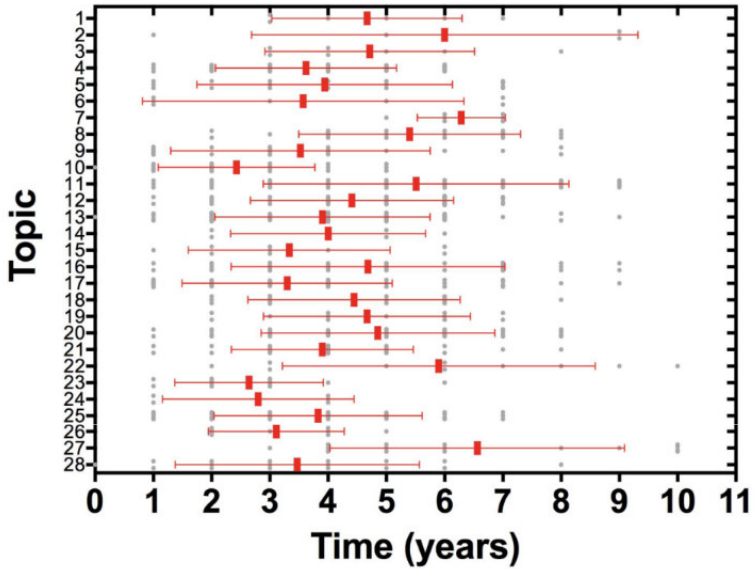


Figure 1. Time from primary study publication to incorporation in systematic review. Analysis of 792 study reports incorporated into 73 systematic reviews across 28 high priority topics in the field of neurotrauma. Study reports were included in the analysis if they were incorporated into a systematic review relevant to one of the high priority topics and published in the period 2001–2009. Systematic reviews were included in the analysis if they were relevant to one of the high priority topics and published in the period 2001–2012. Bars represent medians and interquartile range.

doi:10.1371/journal.pmed.1001603.g001

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

BMJ

BMJ 2013;346:f2510 doi: 10.1136/bmj.f2510 (Published 2 May 2013)

ANALYSIS

Better management of patients with multimorbidity

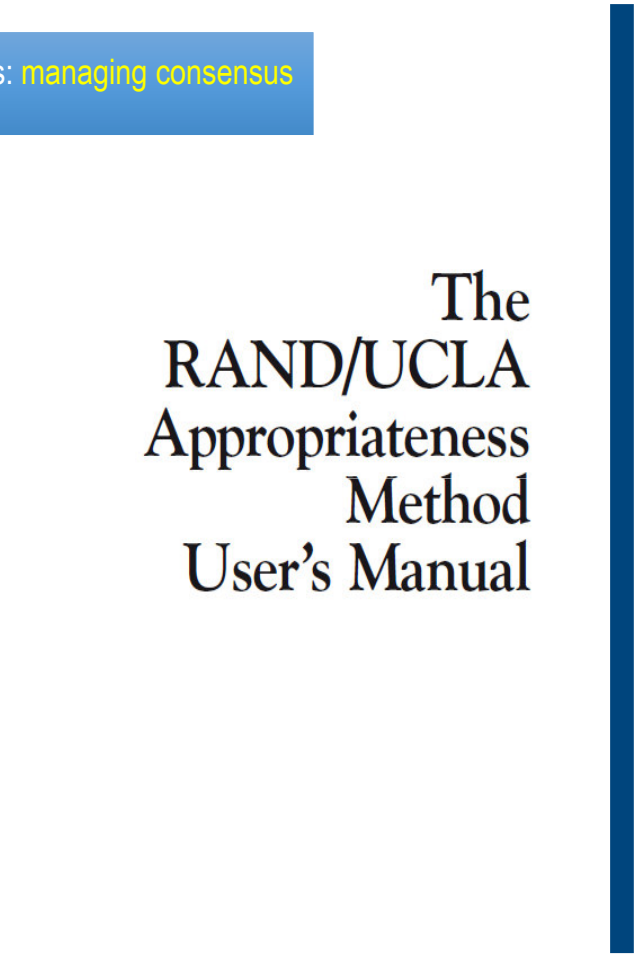
Martin Roland and **Charlotte Paddison** call for greater emphasis on continuity of care and clinical judgment to improve the experience of patients with multiple conditions

Role of guidelines

It has been argued that evidence based guidelines (mostly developed for people with single diseases) are inappropriate for people with multiple conditions, resulting in overtreatment and overcomplex regimes of assessment and surveillance.[4 5] This is a particular problem for patients who are elderly, less well educated, or from less affluent communities.[6 7]

Defects of guideline making process: managing consensus

Consensus and discussion about controversial issues within the panel group needs a careful methodology too… (and full disclosure of the minority views)



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1200 South Hayes Street, Arlington, VA 22202-5050
RAND URL: http://www.rand.org

KEY OPINION LEADERS
Independent experts or drug representatives in disguise?

Ray Moynihan examines the role of the influential experts paid by industry to help "educate" the profession and the public

Key opinion leaders—what fees can they command?

Single lecture or scientific speech $3000
(source: Marketwire)

Hourly rate for influential physicians offering advice—up to $400
(source: Cutting Edge Information)

Work for drug companies on clinical trials—More than £200 an hour
(source: BMA)

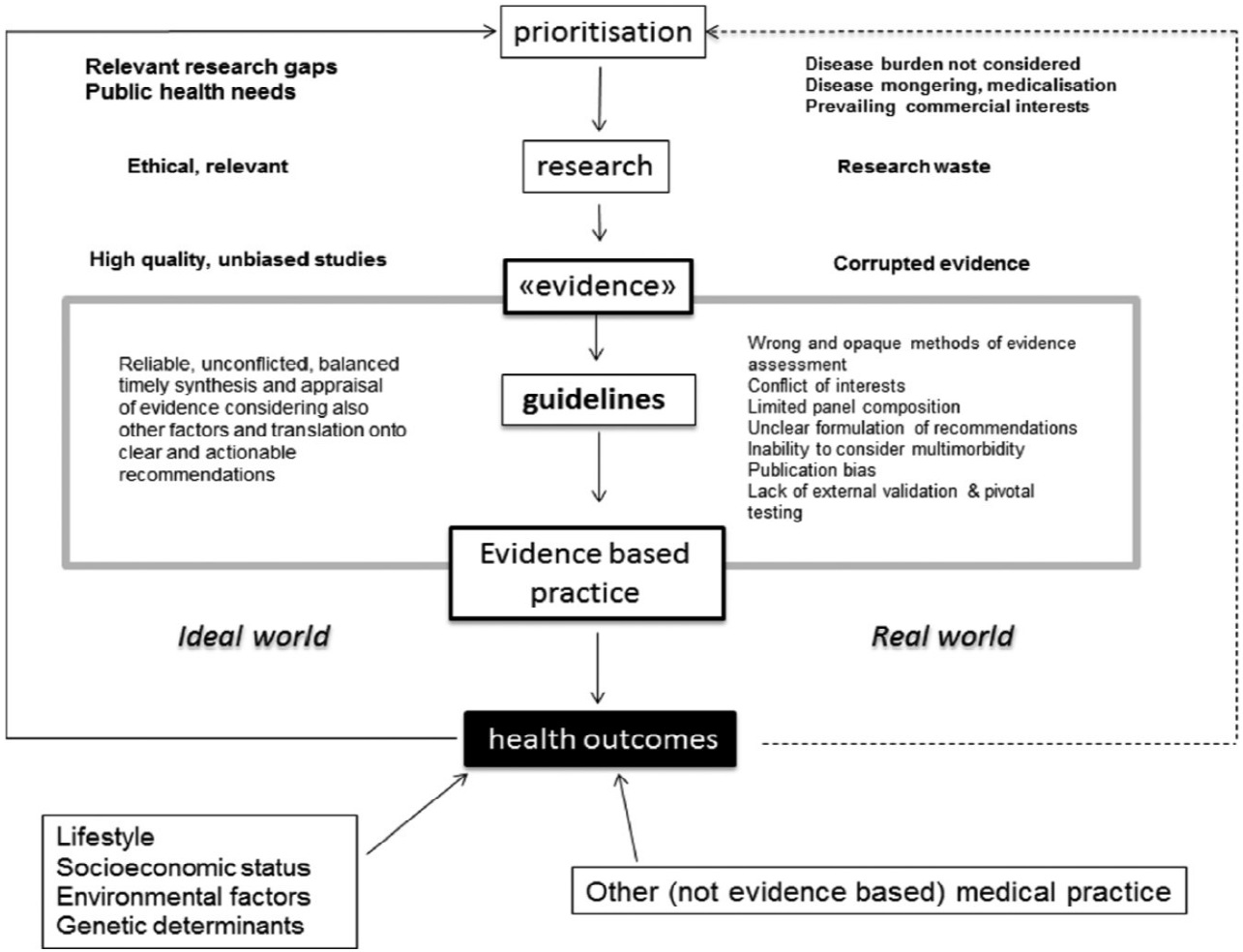
BMJ | 21 JUNE 2008 | VOLUME 336

Many key opinion leaders participate of guideline panel groups (or chair them)

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]

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



Methods, content, outcomes

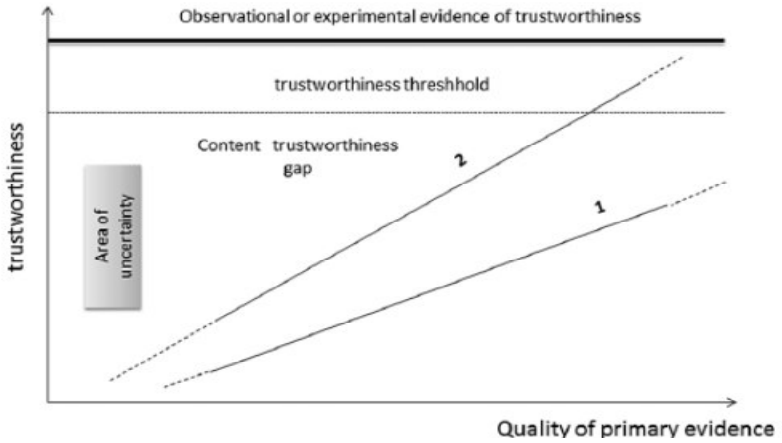


Figure 1 1: Low-quality guidelines; 2: high-quality guidelines. The tradeoff between quality of guideline methods, evidence available and trustworthiness. Decision threshold of trustworthiness has to be decided on a case-by-case basis. When little or no evidence is available (area of uncertainty) and recommendations follow from a consensus process, trustworthiness can be achieved only by assessing outcomes prospectively.

Synthesis of GRADE approach

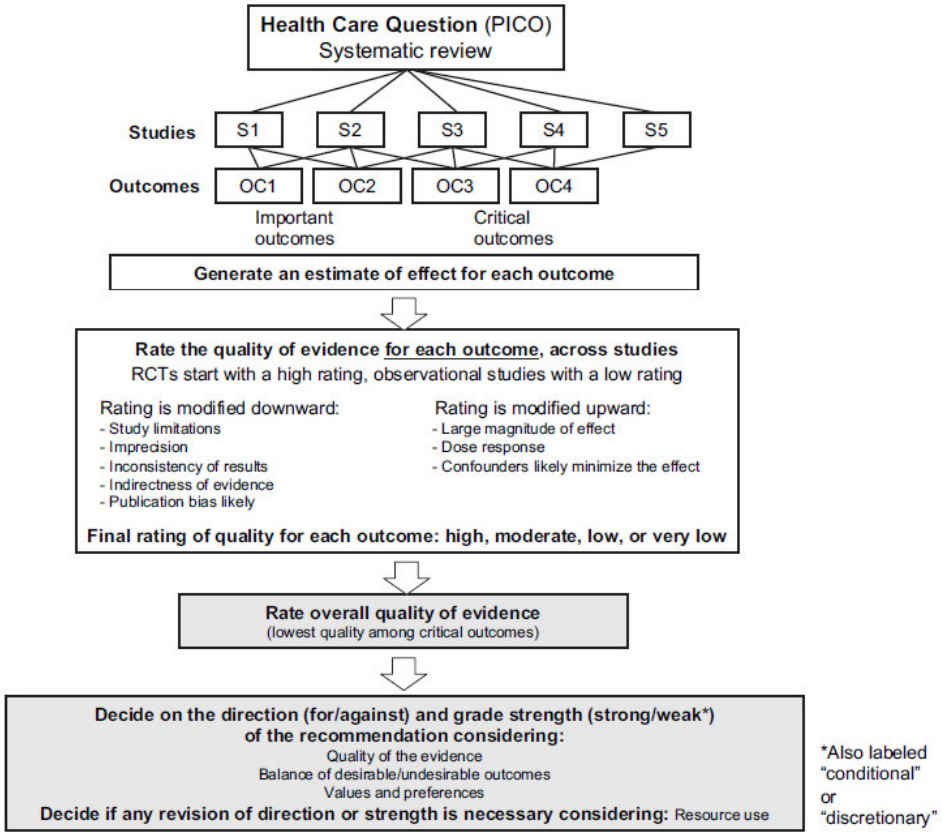


Fig. 1. Schematic view of GRADE's process for developing recommendations. *Abbreviation*: RCT, randomized controlled trials.

Table 1 | Criteria for EtD frameworks for five different types of decisions

	Clinical recommendations–individual perspective	Clinical recommendations–population perspective	Coverage decisions	Health system and public health recommendations/decisions	Diagnostic, screening, and other tests*
Priority of the problem	Is the problem a priority?				
Test accuracy	Not applicable				How accurate is the test?
Benefits and harms	How substantial are the desirable anticipated effects?				
	How substantial are the undesirable anticipated effects?				
Certainty of the evidence	What is the overall certainty of the evidence of effects?				What is the certainty of the evidence of: - Test accuracy? - Any critical or important direct benefits, adverse effects, or burden of the test? - Effects of the management that is guided by the test results? - Link between test results and management decisions? - Effects of the test?
Outcome importance	Is there important uncertainty about or variability in how much people value the main outcomes?				Is there important uncertainty about or variability in how much people value the main outcomes, including adverse effects and burden of the test and downstream outcomes of clinical management that is guided by the test results?
Balance	Does the balance between desirable and undesirable effects favour the intervention or the comparison?				Does the balance between desirable and undesirable effects favour the test or the comparison?
Resource use	—	How large are the resource requirements (costs)?			
	—	What is the certainty of the evidence of resource requirements (costs)?			
	Does the cost effectiveness of the intervention (the out-of-pocket cost relative to the net benefits) favour the intervention or the comparison?	Does the cost effectiveness of the intervention favour the intervention or the comparison?		Does the cost effectiveness of the option favour the option or the comparison?	Does the cost effectiveness of the test favour the test or the comparison?
Equity	—	What would be the impact on health equity?			
Acceptability	Is the intervention acceptable to patients, their care givers, and healthcare providers?	Is the intervention acceptable to key stakeholders?		Is the option acceptable to key stakeholders?	Is the test acceptable to key stakeholders?
Feasibility	Is the intervention feasible for patients, their care givers, and healthcare providers?	Is the intervention feasible to implement?		Is the option feasible to implement?	Is the test feasible to implement?

*Tests cover clinical and public health recommendations at individual and population perspectives.

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.

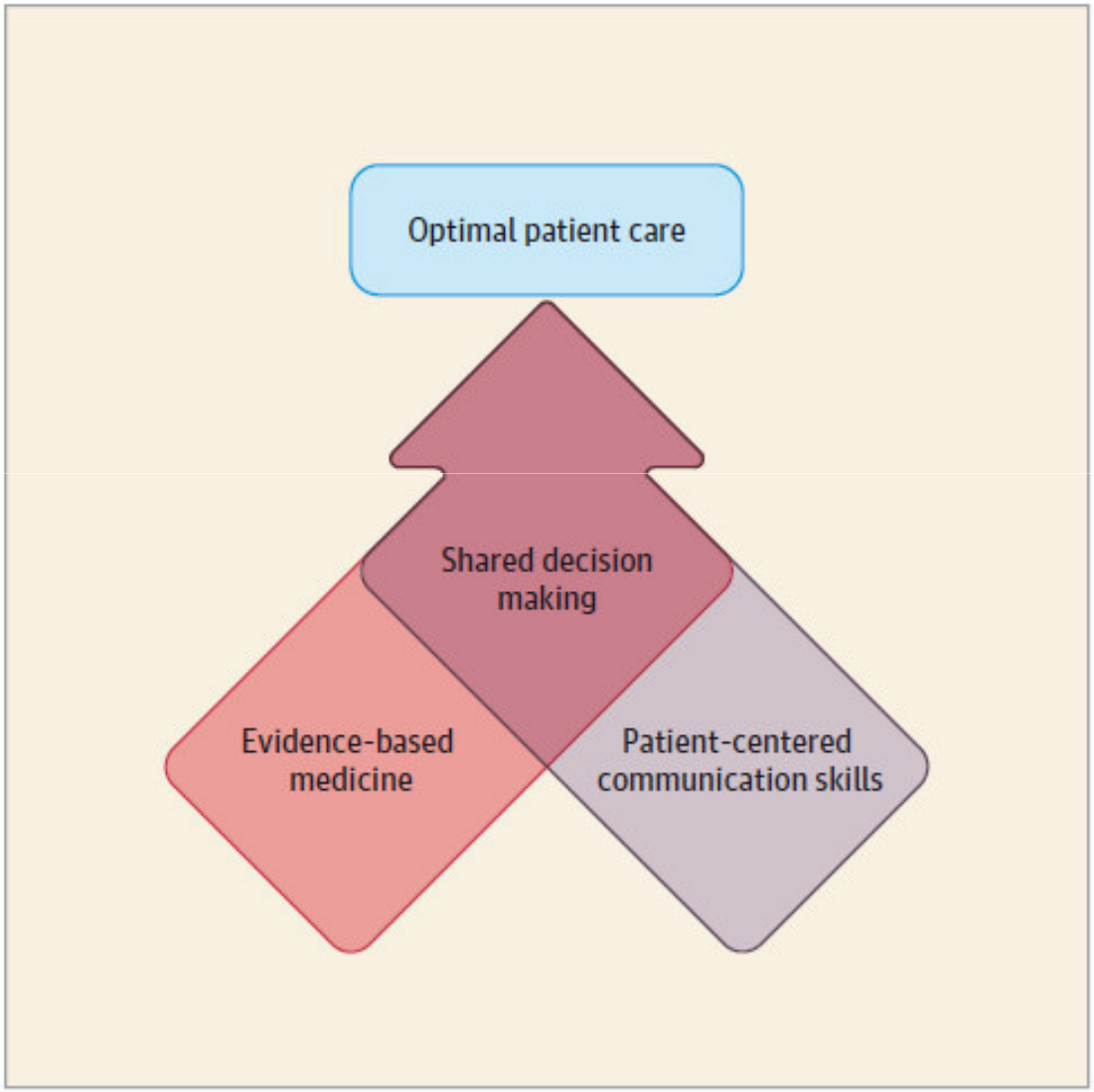
by John M. Eisenberg

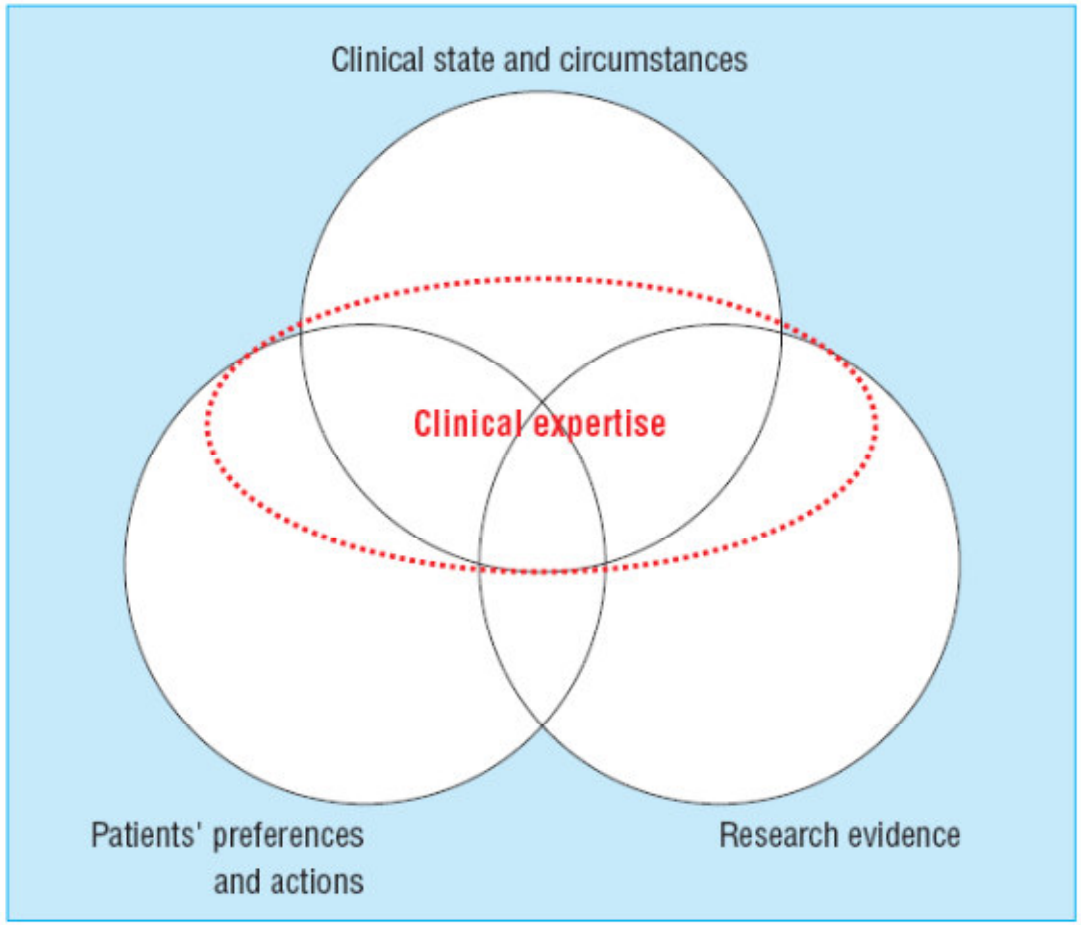
VIEWPOINT

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

The NEW ENGLAND JOURNAL of MEDICINE

SOUNDING BOARD

Precision Medicine — Personalized, Problematic, and Promising

J. Larry Jameson, M.D., Ph.D., and Dan L. Longo, M.D.

N ENGL J MED 372;23 NEJM.ORG JUNE 4, 2015

Situazione italiana

Risultati 4: aderenza standard G-I-N 1

Item	Sì
3. Conflitti di interesse	17%
1. Composizione del gruppo di sviluppo della linea guida	63%
11. Finanziamenti e sponsor	64%
2. Processo decisionale	65%
6. Revisione delle evidenze	67%
10. Validità e aggiornamento della linee guida	67%
5. Metodi	71%
9. Peer review e consultazione degli stakeholders	72%
8. Rating delle evidenze e delle raccomandazioni	81%
7. Raccomandazioni della linea guida	95%
4. Ambito della linea guida	100%

GIMBE
EVIDENCE FOR HEALTH

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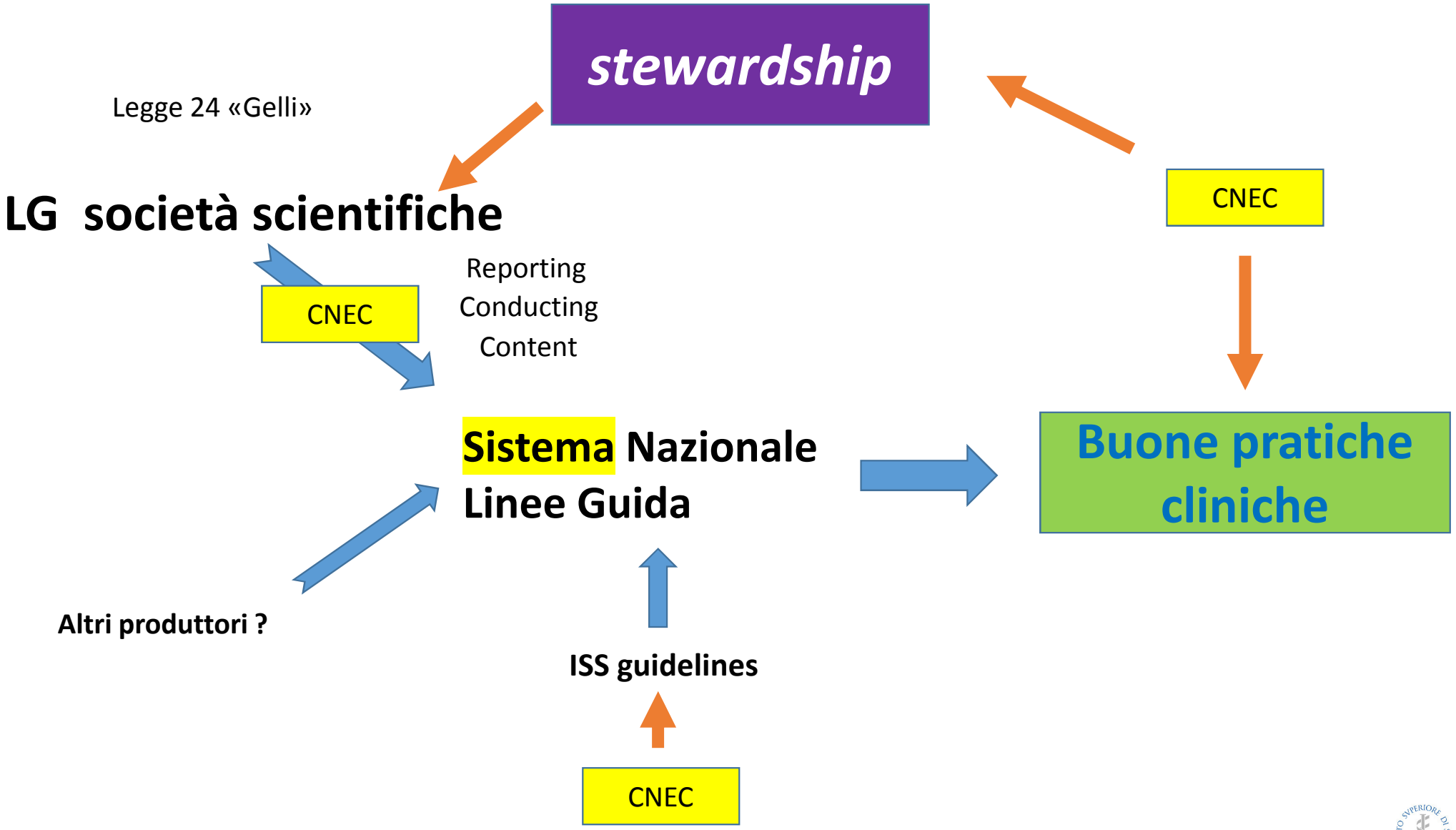

stewardship
Legge 24 «Gelli»
LG società scientifiche
CNEC
CNEC
Reporting
Conducting
Content
Sistema Nazionale
Linee Guida
Buone pratiche cliniche
Altri produttori ?
ISS guidelines
CNEC

Archivi categoria: *Linee guida*

Protetto: Pubblicazione nell'SNLG delle LG proposte da soggetti ex art.5 Legge 8 mar[illegible]017 n.24

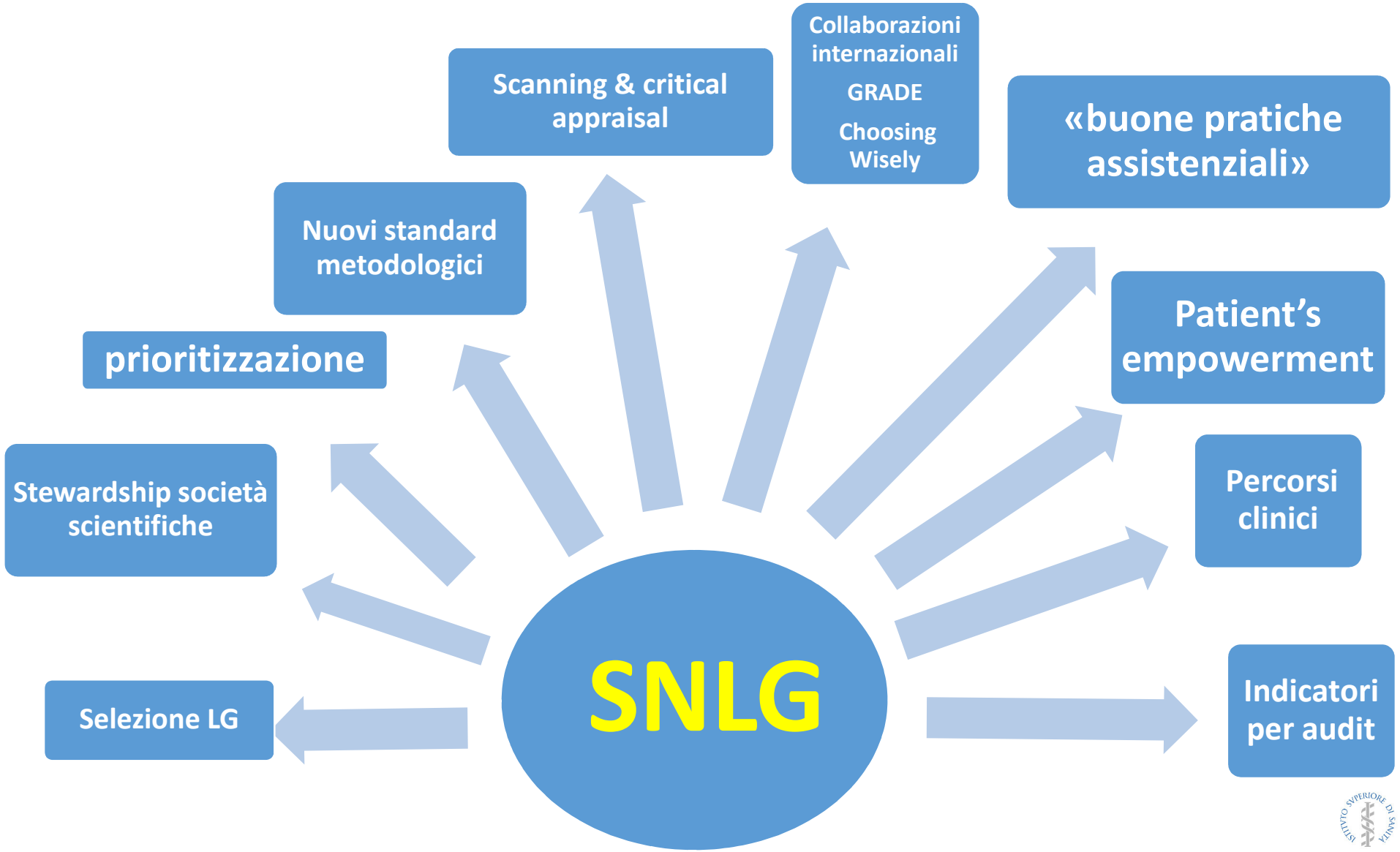
N.B.: le modalità di pubblicazione sono suscettibili di modifiche sulla base dei decreti [illegible]vi di p[illegible]ssi[illegible] div[illegible]zione della L. 24/2017.
Eventuali commenti e proposte di modifica possono essere inviati all'indirizzo e-m[illegible]l: cnec[illegible]lg@iss.

new

In questa sezione sono riportate le modalità di invio e la procedura di [illegible]cazion[illegible]elle L[illegible]e Guid[illegible](LG) per la pubblicazione nell'SNLG.

Gli enti e le istituzioni pubbliche e private, le società scientifiche e le asso[illegible]zioni tec[illegible]co-scientifiche delle professioni sanitarie iscritte in apposito elenco istituito e regolamentato con DM 2 agosto 2017 (GU n.18[illegible]el 10-8-2017) propongono al CNEC la LG da pubblicare nell'SNLG.

Il CNEC verifica in primo luogo l'eleggibilità della LG in base a pre-requisiti di priorità e non ridondanza e, successivamente, valuta la LG con criteri


Collaborazioni internazionali
GRADE
Choosing Wisely
Scanning & critical appraisal
«buone pratiche assistenziali»
Nuovi standard metodologici
Patient's empowerment
prioritizzazione
Percorsi clinici
Stewardship società scientifiche
SNLG
Indicatori per audit
Selezione LG

And so, what is SNLG for?

More trustworthy, relevant, timely, evidence based, unconflicted, balanced national tools to inform wise clinical & health policy decisions and manage uncertainty