Si fa presto a dire linee guida ….

Stimando che le Linee Guida:

1. Migliorino la qualità delle cure ed gli esiti di salute
2. Contribuiscano a rendere più efficiente e tempestivo il trasferimento delle evidenze scientifiche in pratica clinica
3. Crescita culturale della comunità medico-scientifica

Noi professionisti ci chiediamo:

1. Quale la metodologia ?
2. Chi deciderà le discipline coinvolte ?
3. Quali priorità di argomenti ?
4. Quali gli interlocutori coinvolti ?

Dr. Primiano Iannone *Direttore del Centro di Eccellenza Clinica, Qualità e Sicurezza delle Cure; Istituto Superiore di Sanità*

sum.school
simeu
accademia
dei direttori
BOLOGNA 18-19 SETTEMBRE 2017
OMAGGIO A FRANCESCO STEA

Si fa presto a dire linee guida…

Primiano Iannone
Direttore
Centro Nazionale per l'Eccellenza Clinica, la Qualità e la Sicurezza delle Cure

Art. 5. Legge 24/2017

(Buone pratiche clinico-assistenziali e raccomandazioni previste dalle linee guida)

1. Gli esercenti le professioni sanitarie, nell'esecuzione delle prestazioni sanitarie con finalità preventive, diagnostiche, terapeutiche, palliative, riabilitative e di medicina legale, ***si attengono,*** salve le specificità del caso concreto, alle raccomandazioni previste dalle linee guida pubblicate ai sensi del comma 3 ed elaborate da enti e istituzioni pubblici e privati nonché dalle società scientifiche e dalle associazioni tecnico- scientifiche delle professioni sanitarie iscritte in apposito elenco istituito e regolamentato con decreto del Ministro della salute……

3. Le linee guida e gli aggiornamenti delle stesse elaborati dai soggetti di cui al comma 1 sono integrati nel Sistema nazionale per le linee guida (SNLG), ……L'Istituto superiore di sanità pubblica nel proprio sito *internet* le linee guida e gli aggiornamenti delle stesse indicati dal SNLG, previa verifica della conformità della metodologia adottata a *standard* definiti e resi pubblici dallo stesso Istituto, nonché della rilevanza delle evidenze scientifiche dichiarate a supporto delle raccomandazioni. In mancanza delle suddette raccomandazioni, gli esercenti le professioni sanitarie si attengono alle **buone pratiche clinico assistenziali**.

Institute of Medicine, 2011

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

JAMA®

Allan D. Sniderman; Curt D. Furberg

JAMA. 2009;301(4):429-431 (doi:10.1001/jama.2009.15)

http://jama.ama-assn.org/cgi/content/full/301/4/429

GUIDELINES ARE A CONSTRUCTIVE RESPONSE TO THE reality that the practicing physician requires assistance to assimilate and apply the exponentially expanding, often contradictory, body of medical knowledge. Guidelines are widely perceived as evidence based, not authority based, and therefore as unbiased and valid. Because they are sponsored by organizations, staffed by experts, and conducted according to apparently formal processes, the products of the exercise—the guidelines—are generally assumed to have the same level of certainty and security as conclusions generated by the conventional scientific method. For many clinicians, guidelines have become the final arbiters of care.

Situazione
Stato dell’ arte nella produzione di LG

Consensus based guidelines

consensus

Quality of evidence

(Strength of)

recommendation

The Rational Clinical Examination

Evidence-Based Medicine

A New Approach to Teaching the Practice of Medicine

Evidence-Based Medicine Working Group

«all medical action of diagnosis, prognosis and therapy should rely on solid quantitative evidence based on the best of clinical epidemiological research»

Graded recommendations

Low quality of early guidelines

	1988–91 (n=48)	1992–93 (n=81)	1994–95 (n=125)	1996–98 (n=177)	p for trend
Full description of professionals	6 (12%)	9 (11%)	11 (9%)	27 (15%)	0·99
Search undertaken	1 (2%)	4 (5%)	14 (11%)	32 (18%)	<0·001
Grading of recommendation	3 (6%)	5 (6%)	21 (17%)	48 (27%)	<0·001

Table 2: **Number of guidelines that met the three quality criteria according to year of publication**

2012

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.

Cause principali

Metodi opachi
Cattiva gestione del conflitto di interessi
Scarsa rappresentatività dei panel di esperti

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]

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

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)

- **87%** of guideline authors have some form of interaction with pharmaceutical industry

- **59%** of authors had relationships with companies whose drugs were considered in the guideline they authored

Choudry et Al
JAMA 2002; 287: 612-617

A survey of guideline developers found that only 29% always involve consumers and 39% involve consumers only if necessary

Evidence-informed health policy 2 - survey of organizations that support the use of research evidence.

Lavis JN, Implement Sci. 2008; 3:54

NICE National Institute for Health and Care Excellence

NICE guideline

Multimorbidity: clinical assessment and management

NICE guideline
Published: 21 September 2016
nice.org.uk/guidance/ng56

BMJ

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

ANALYSIS

Better management of patients with multimorbidity

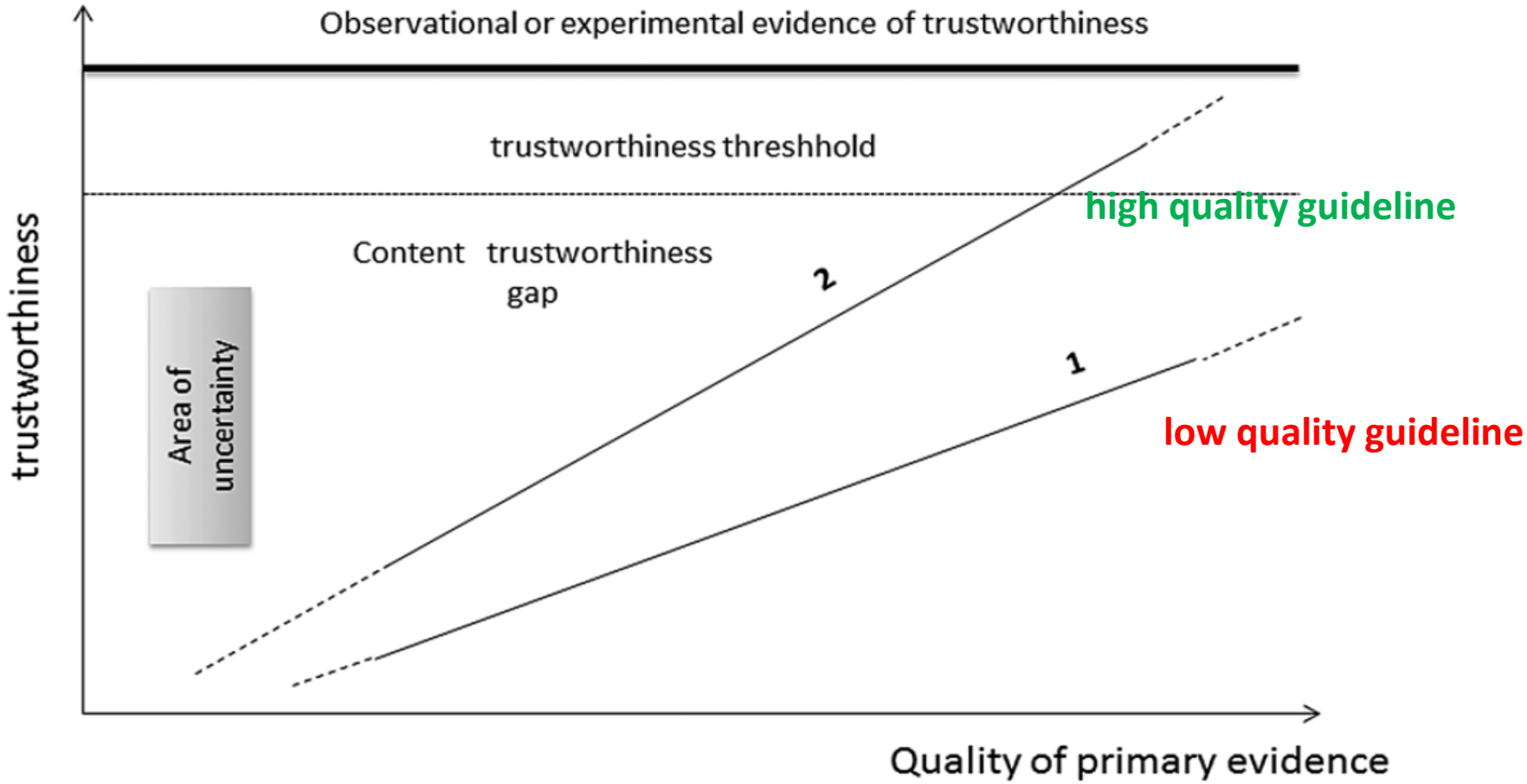
Martin Roland and **Charlotte Paddison** call for greater emphasis on continuity of care and clinical judgment to improve the experience of patients with multiple conditions

ISTITUTO SUPERIORE DI SANITÀ

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]

Credibilità delle LG: cosa significa ?



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.

What is evidence?

A collection of facts that ground one's belief that something is true, (Institute of Medicine)

The elusive nature of «evidence»

Prinicipio di causalità, INUS (Mackie)

le LG richiedono **capacità tecniche** (saper raccogliere le prove), **giudizi di valore** (sulla loro qualità) e **abilità sociali** (nella gestione dei **processi deliberativi** fra i membri dei panel di esperti) [*Burgers, Diabetes Care 2002*]

Avoidable waste in the production and reporting of research evidence

Lancet 2009; 374: 86–89

Iain Chalmers, Paul Glasziou

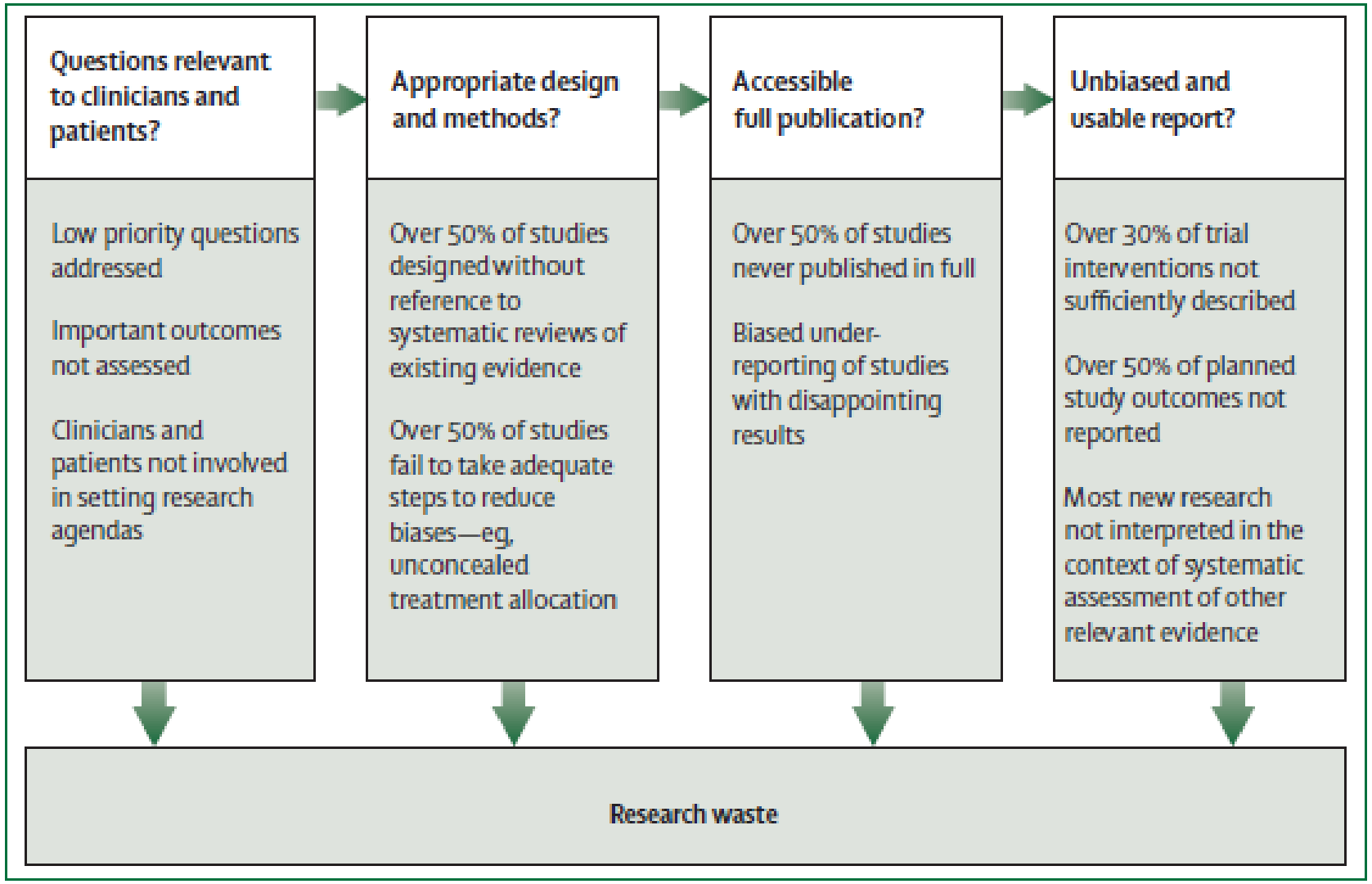
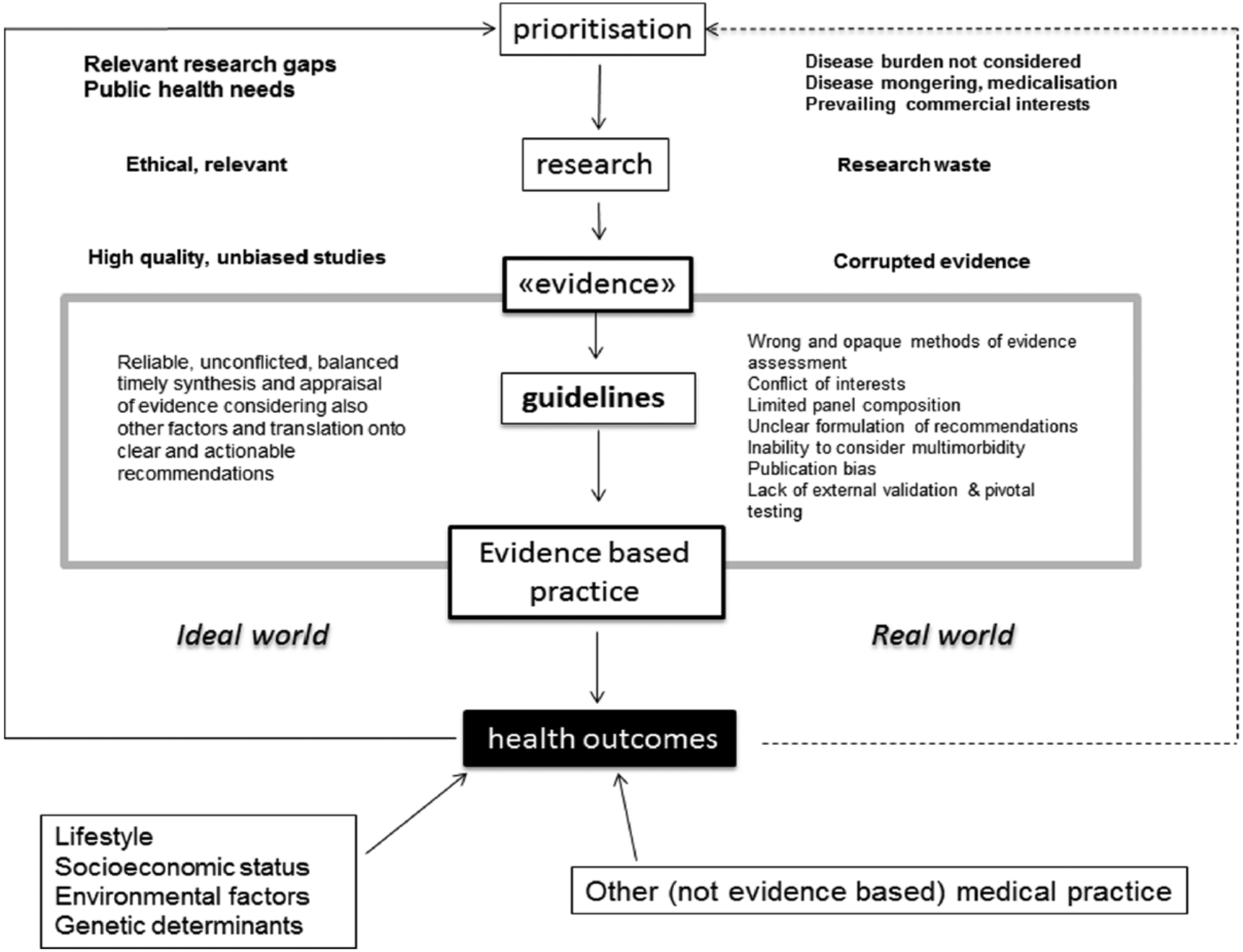


Figure: Stages of waste in the production and reporting of research evidence relevant to clinicians and patients


prioritisation
Relevant research gaps
Public health needs
Disease burden not considered
Disease mongering, medicalisation
Prevailing commercial interests
research
Ethical, relevant
Research waste
High quality, unbiased studies
«evidence»
Corrupted evidence
Reliable, unconflicted, balanced timely synthesis and appraisal of evidence considering also other factors and translation onto clear and actionable recommendations
guidelines
Wrong and opaque methods of evidence assessment
Conflict of interests
Limited panel composition
Unclear formulation of recommendations
Inability to consider multimorbidity
Publication bias
Lack of external validation & pivotal testing
Evidence based practice
Ideal world
Real world
health outcomes
Lifestyle
Socioeconomic status
Environmental factors
Genetic determinants
Other (not evidence based) medical practice

Corruption of the Evidence as Threat and Opportunity for Evidence-Based Medicine

Victor M. Montori, MD, MSc
and Gordon H. Guyatt, MD, MSc

Vol. 8 , No. 1, Spring 2007 145

thebmj

BMJ 2015;351:h5542 doi: 10.1136/bmj.h5542 (Published 23 October 2015)

ANALYSIS

Why the drug development pipeline is not delivering better medicines

Despite the large number of new medicines entering the market every year, few offer important clinical advantages for patients. **Huseyin Naci**, **Alexander Carter**, and **Elias Mossialos** explain the reasons for this innovation deficit and offer some solutions

Huseyin Naci *assistant professor of health policy*[1], Alexander W Carter *policy fellow*[2], Elias Mossialos *professor of health policy*[1]

BMJ

BMJ 2011;343:d4817 doi: 10.1136/bmj.d4817

EDITOR'S CHOICE

What is health?

Fiona Godlee *editor, BMJ*

Why should we be interested in defining health? Because if health is the goal of healthcare and research, we need to know what it looks like and how to measure it. As these articles explain, the currently accepted definition, formulated by WHO in 1948, is no longer helpful and is even counterproductive. Its emphasis on "complete physical, mental and social wellbeing" was radical in its day for stepping away from defining health as the absence of disease. But it is absolute and therefore unachievable for most people in the world. As Richard Smith, one of the authors of this week's article, pointed out in a *BMJ*

The WHO definition is also unworkable for other reasons, the authors say. In the face of an ageing global population with an increasing burden of chronic disease, it "minimises the role of the human capacity to cope autonomously with life's ever changing physical, emotional, and social challenges and to

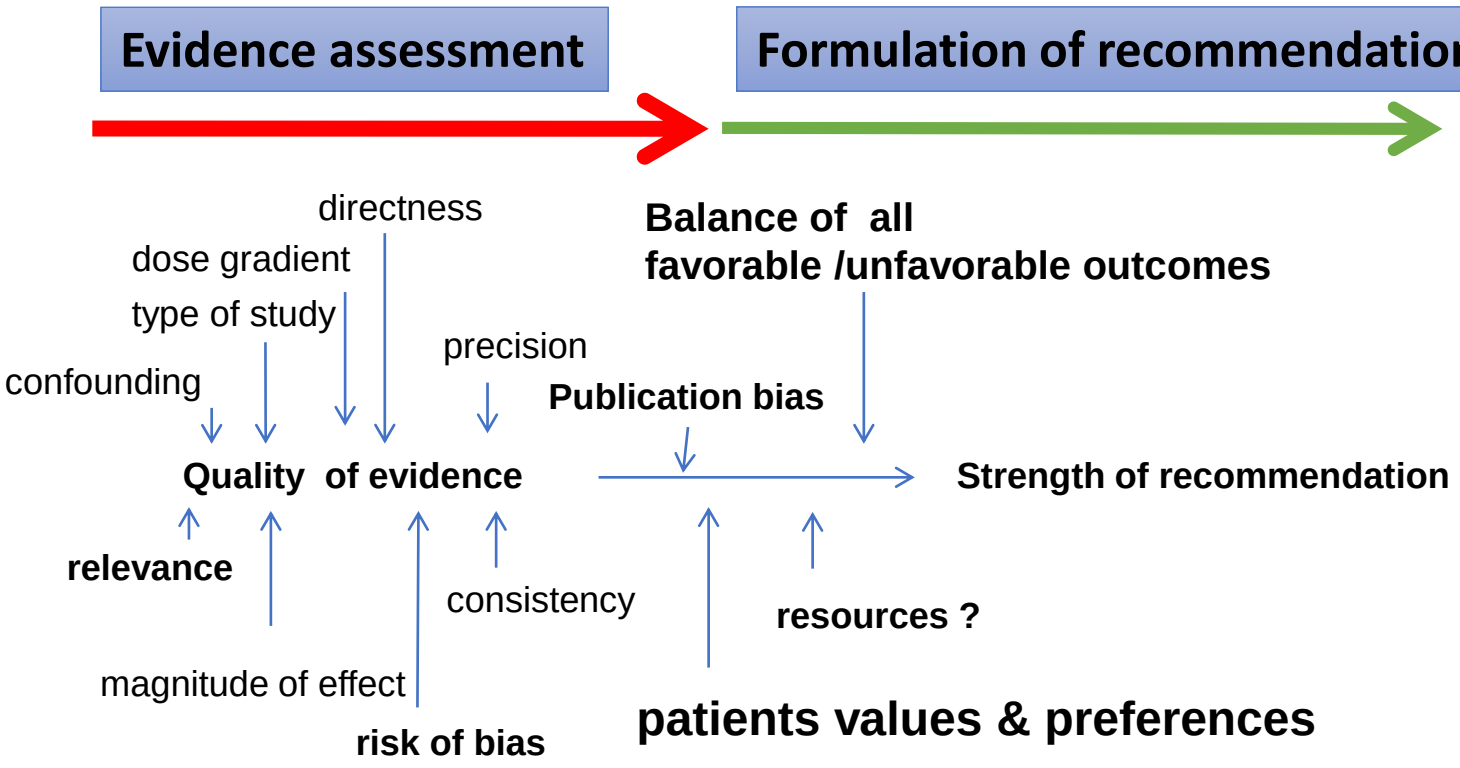
Esistono metodi infallibili per produrre LG ?

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

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

Going from evidence to recommendations is a long and risky journey

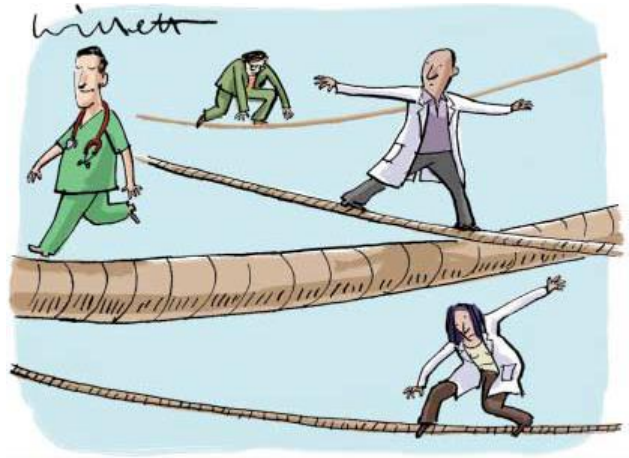


Grading quality of evidence and strength of recommendations

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



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.

GRADE terminology

Strength of recommendation:

the extent to which one can be confident that adherence to the recommendation will do more good than harm.

Determinants of strength of recommendation

Factor	Comment
Balance between desirable and undesirable effects	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. The narrower the gradient, the higher the likelihood that a weak recommendation is warranted
Quality of evidence	The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted
Values and preferences	The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted
Costs (resource allocation)	The higher the costs of an intervention—that is, the greater the resources consumed—the lower the likelihood that a strong recommendation is warranted

Synthesis of GRADE approach

G. Guyatt et al. / Journal of Clinical Epidemiology 64 (2011) 383–394

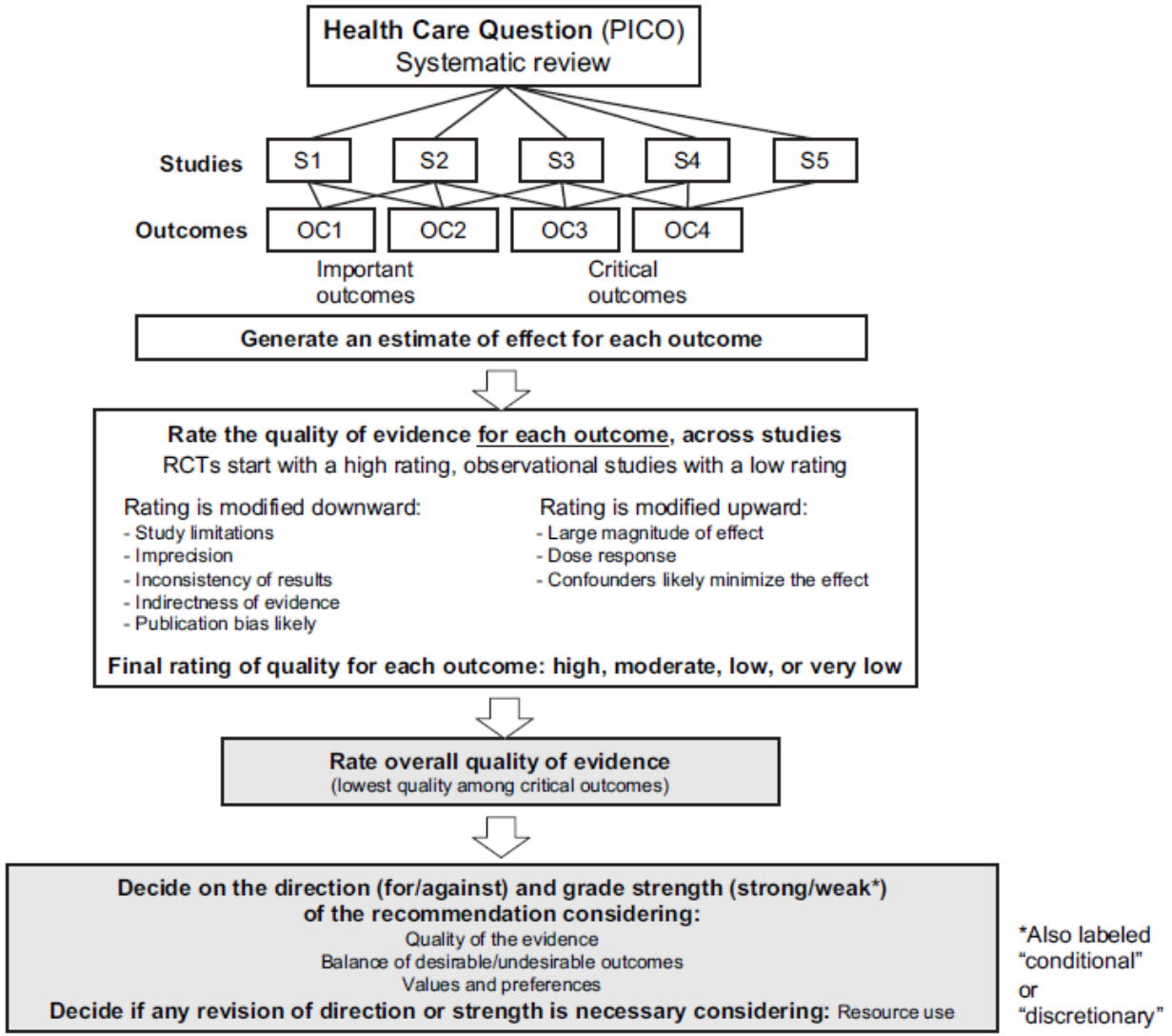


Fig. 1. Schematic view of GRADE's process for developing recommendations. *Abbreviation*: RCT, randomized controlled trials.

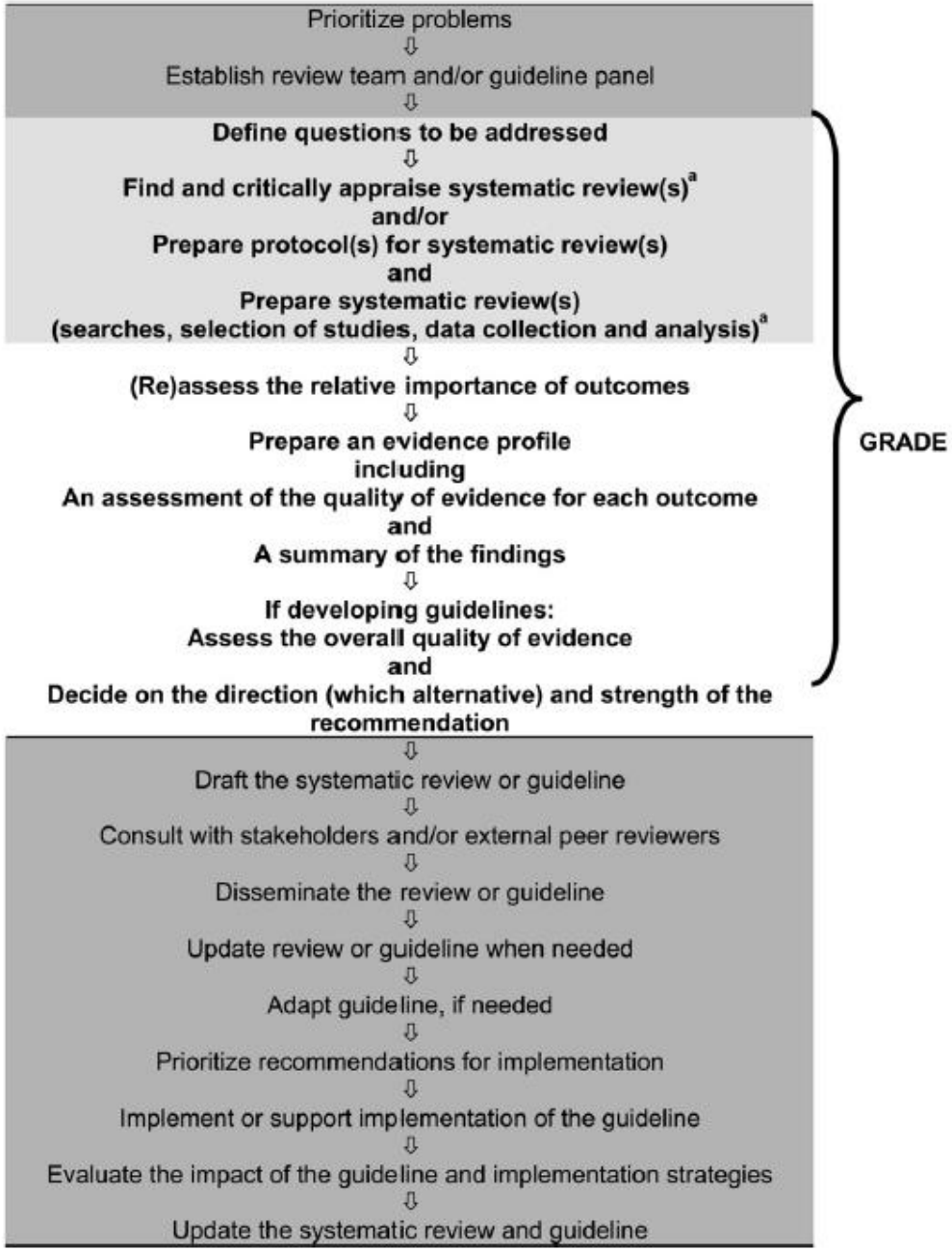
BMJ 2004;328:1490–4

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

Basta il GRADE per fare una buona LG ?


Prioritize problems
⇩
Establish review team and/or guideline panel
⇩
Define questions to be addressed
⇩
Find and critically appraise systematic review(s)[a]
and/or
Prepare protocol(s) for systematic review(s)
and
Prepare systematic review(s)
(searches, selection of studies, data collection and analysis)[a]
⇩
(Re)assess the relative importance of outcomes
⇩
Prepare an evidence profile
including
An assessment of the quality of evidence for each outcome
and
A summary of the findings
⇩
If developing guidelines:
Assess the overall quality of evidence
and
Decide on the direction (which alternative) and strength of the recommendation
GRADE
⇩
Draft the systematic review or guideline
⇩
Consult with stakeholders and/or external peer reviewers
⇩
Disseminate the review or guideline
⇩
Update review or guideline when needed
⇩
Adapt guideline, if needed
⇩
Prioritize recommendations for implementation
⇩
Implement or support implementation of the guideline
⇩
Evaluate the impact of the guideline and implementation strategies
⇩
Update the systematic review and guideline

Situazione italiana

EvidenceLive

NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

ABSTRACT SUBMISSION

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

Affiliations

(1) GIMBE Foundation, Bologna, Italy
(2) National Institute of Health - Istituto Superiore di Sanità, Rome, Italy
(3) University of Messina, Messina, Italy

Authors

Antonino	Cartabellotta	(1) Presenting
Antonio Simone	Laganà	(3)
Primiano	Iannone	(2)
Walter	Ricciardi	(2)

Risultati 3: campione di linee guida valutate

75 LG prodotte nel 2015-2016

Società Scientifica	N° LG	%
C	33	44%
Multisocietarie	22	29%
H	9	12%
K	2	3%
A,B,D,E,F,G,I,J,L	9	12%

GIMBE
EVIDENCE FOR HEALTH

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

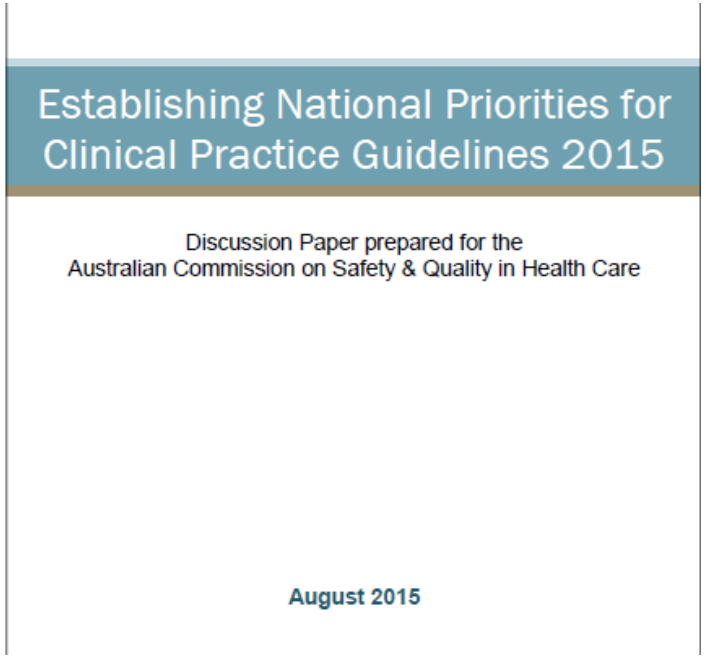
LG censite dal National Guideline Clearinghouse a Agosto 2017

- NICE: 262
- LG Italiane: 2

SNLG

Alcuni punti fermi

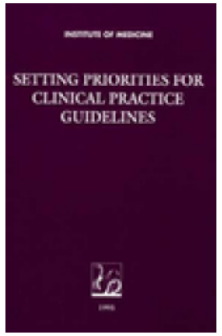
1.Stabilire le priorità del SNLG



Establishing National Priorities for Clinical Practice Guidelines 2015

Discussion Paper prepared for the
Australian Commission on Safety & Quality in Health Care

August 2015



Setting Priorities for Clinical Practice Guidelines

Marilyn J. Field, Editor; Committee on Methods for Setting Priorities for Guidelines Development, Institute of Medicine

ISBN: 0-309-58797-2, 176 pages, 6 x 9, (1995)

ELSEVIER

Journal of Clinical Epidemiology 67 (2014) 1335–1342

Journal of Clinical Epidemiology

ORIGINAL ARTICLES

Priority-based initiative for updating existing evidence-based clinical practice guidelines: the results of two iterations

Chika Agbassi[a,c,d], Hans Messersmith[a,c,d], Sheila McNair[a,c,d], Melissa Brouwers[a,b,c,d,*]

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[b]Department of Clinical Epidemiology & Biostatistics, McMaster University, 1280 Main Street West Hamilton, Ontario L8S4L8, Canada
[c]Escarpment Cancer Research Institute (ECRI), Juravinski Hospital Research Centre, 711 Concession Street, G Wing, Hamilton, Ontario, L8V 1C3, Canada
[d]Program in Evidence-based Care, Cancer Care Ontario McMaster University, Juravinski Site, 60 (G) Wing, 711 Concession Street Hamilton, Ontario, Canada, L8V 1C3

Accepted 1 June 2014; Published online 10 September 2014

Health Research Policy and Systems

BioMed Central

Review

Open Access

Improving the use of research evidence in guideline development: 2. Priority setting

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* Corresponding author

Published: 29 November 2006

Health Research Policy and Systems 2006, 4:14 doi:10.1186/1478-4505-4-14

Received: 07 April 2006
Accepted: 29 November 2006

This article is available from: http://www.health-policy-systems.com/content/4/1/14

Criteri di prioritizzazione delle tematiche di salute che dovrebbero essere oggetto di LG

- Entità dell'impatto globale delle patologie (*disease burden*) sulla popolazione italiana e sul Servizio Sanitario nazionale misurato attraverso criteri oggettivi (prevalenza, mortalità, DALY e costi)
- Variabilità delle pratiche professionali in Italia non giustificate dalle evidenze disponibili
- Diseguaglianze di processi ed esiti assistenziali
- Disponibilità di evidenze di alta qualità
- Costi elevati per il SSN di pratiche sanitarie ad alto impatto organizzativo o tecnologico
- Rischio clinico elevato
- Istanze sociali e bisogni percepiti dalla popolazione.

2.Standard di riferimento metodologici

APPRAISAL OF GUIDELINES FOR RESEARCH & EVALUATION

APPRAISAL OF GUIDELINES RESEARCH & EVALUATION

GRADE

G-I-N Public Toolkit: Patient and Public Involvement in Guidelines.

CLINICAL PRACTICE GUIDELINES WE CAN TRUST

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

NICE National Institute for Health and Care Excellence

3.Gestire efficacemente i conflitti di interesse

Table 2| Reported financial conflicts of interest (COI) among panel members by category of guideline sponsor

	All guidelines				Guidelines with declared COI			
Characteristic of guideline	No of guidelines	No of panel members	No (%) panel members with COI	P value	No of guidelines	No of panel members	No (%) panel members with COI	P value*
Diabetes	7	189	106 (56)	0.06	5	150	105 (70)	0.52
Hyperlipidaemia	7	99	44 (44)		4	61	40 (66)	
Government	6	92	15 (16)	<0.001	2	24	11 (46)	0.01
Other*	8	196	135 (69)		7	187	134 (72)	
US specialty†	4	53	31 (58)	<0.001	3	44	30 (68)	0.04
Canadian specialty	2	116	96 (83)		2	116	96 (83)	

*All non-government sponsored guidelines included in this category.

†Includes organisations designated as "medical specialty" or "professional associations" on National Guidelines Clearinghouse website.

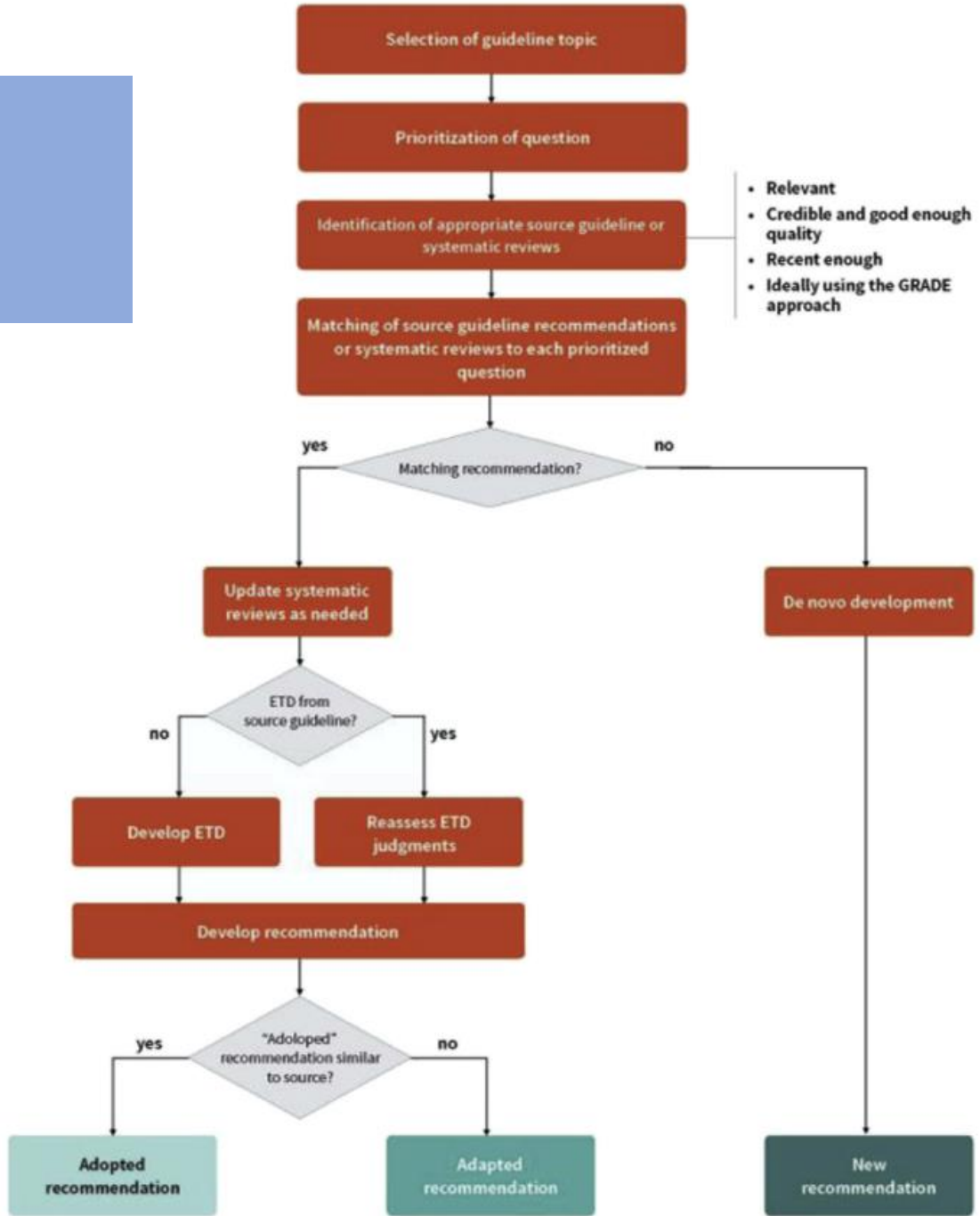
Conflicts of interest (COI) is still a pervasive flaw of many guidelines

Lenzer et Al, BMJ 2013: 347; f5535

4.Considerare i tempi (e costi) di produzione di una LG

18-24 months (average time of a full GL de-novo production)

Adattamento vs sviluppo ex novo di LG



5.Destinatari e finalità delle LG

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

RESEARCH METHODS AND REPORTING

GRADE Evidence to Decision (EtD) frameworks: a systematic and transparent approach to making well informed healthcare choices. 2: Clinical practice guidelines

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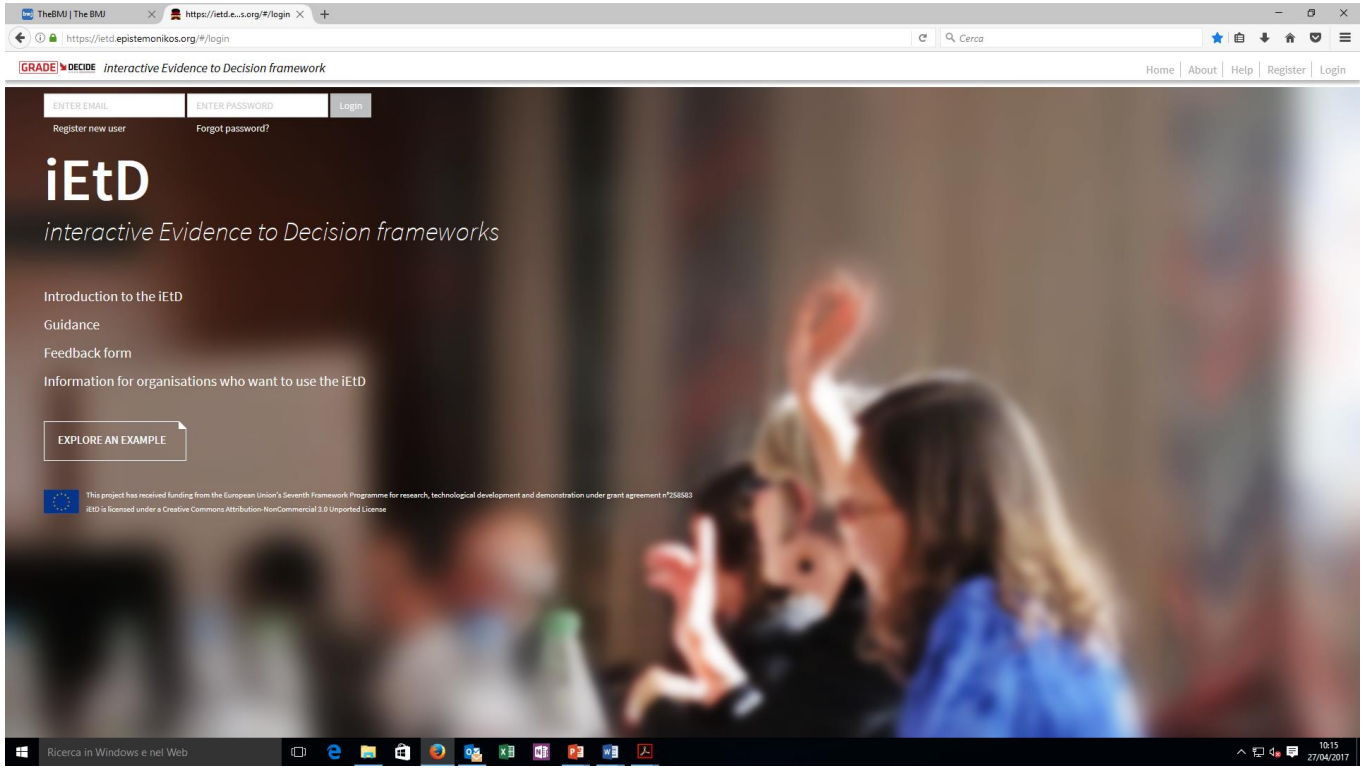
Table 1 | Criteria for EtD frameworks for five different types of decisions

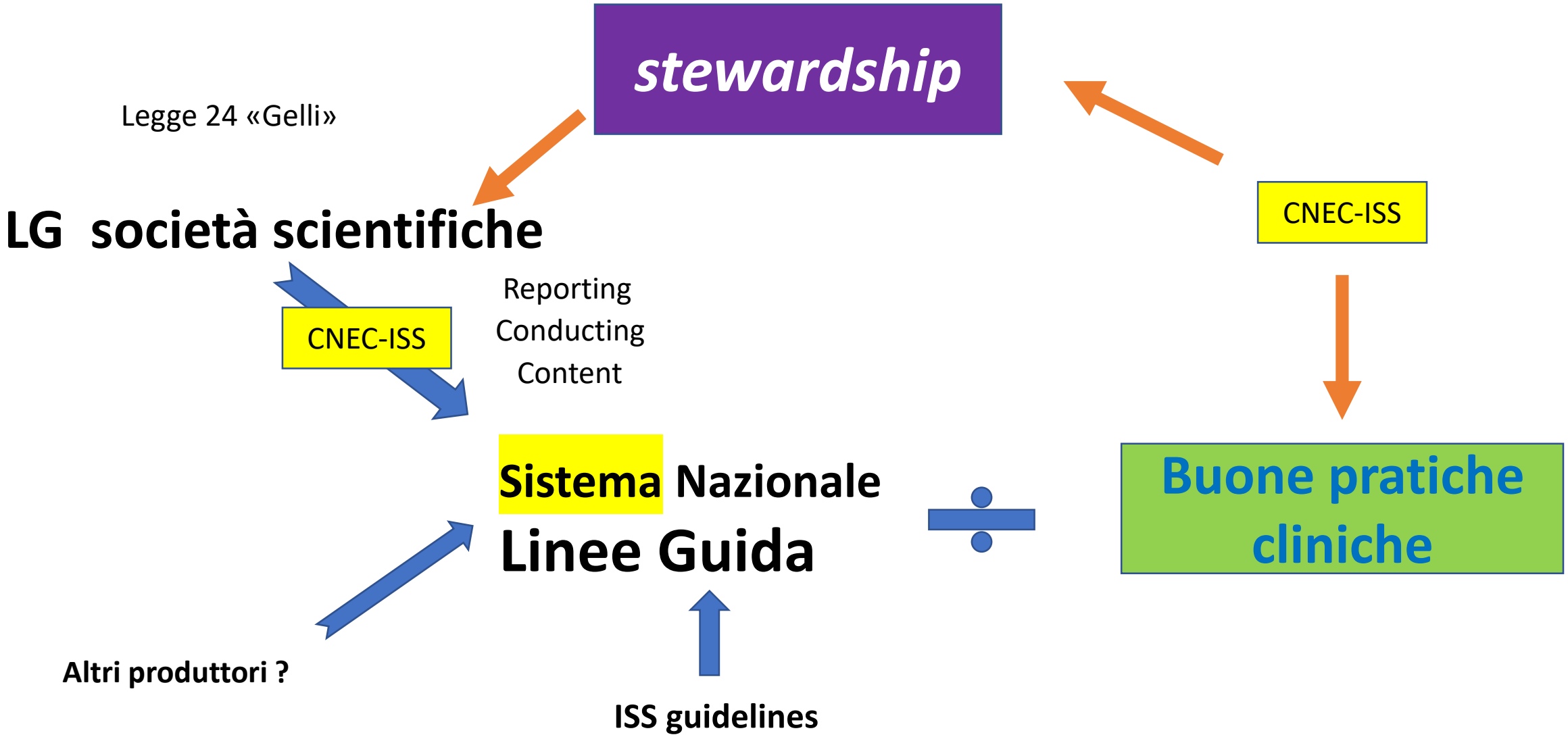
	Clinical recommendations–individual perspective	Clinical recommendations–population perspective	Coverage decisions	Health system and public health recommendations/decisions	Diagnostic, screening, and other tests*
Priority of the problem	Is the problem a priority?				
Test accuracy	Not applicable				How 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.



Health policy & public health guidelines

Coverage decisions


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

ISS guidelines

GRADE method
Developer, expert panel, evidence review panel
Accurato scoping
Definizione ruolo stakeholders rigoroso e distinto
Openness but firmness
Effective conflict of interests management
Multiprofessionality
Audit e PDTA «incorporati»

6.Buone pratiche cliniche

La Legge n.24/2017 afferma che quando le linee guida (in SNLG) non sono disponibili, gli operatori sanitari dovrebbero fare riferimento a **"buone pratiche cliniche"**.

È ragionevole che tali buone pratiche cliniche debbano essere selezionate anche dall'ISS e raccolte nel sito web dell'SNLG.

È probabile che, almeno all'inizio, la maggior parte delle indicazioni per gli operatori sanitari derivino da esse.

In questo ambito potranno ricadere : ***bad*** e ***low values practices*** (*Choosing Wisely*, per esempio), ***do not do list*** del NICE, **LG di alta qualità metodologica non (ancora) adattate e/o tradotte in lingua italiana**, nonché ***position statements*** di organismi di salute pubblica internazionali, società scientifiche e raccomandazioni di Agenzie Internazionali.

Come per le LG pubblicate nell'SNLG, la non ridondanza e la coerenza interna saranno qualità essenziali di questo elenco.

Decalogo nuovo SNLG

- **Definizione delle priorità**.
- **Stewardship**
- **Trasparenza**
- **Linee guida patient oriented**
- **Offerta di indicatori e schemi di percorsi clinici**
- **Nuovi standard metodologici di riferimento per gli sviluppatori.**
- **Produzione diretta di alcune LG da parte dell'ISS**
- **Buone pratiche clinico assistenziali**
- **Istruzioni per l'uso.**
- **Aggionamento costante**

Opportunità

- **Sistema nazionale** di linee guida di riferimento credibili, autorevoli, rilevanti per la pratica socio-clinico-assistenziale a livello individuale, di popolazione, sanità pubblica, health policy, decisioni di coverage
- Miglioramento della qualità delle cure e, possibilmente, degli esiti assistenziali ***(high value care)***
- maggiore diffusione della cultura EBM fra i professionisti della sanità e nel Paese
- Crescita culturale e del tasso di rilevanza (=eticità) della ricerca biomedica
- Miglioramento della ***comunicazione efficace e professionale dell'incertezza*** con i pazienti
- Riduzione contenziosi medico legali
- Contrasto alla deriva «difensivistica» della medicina

Criticità

- Qualità e quantità LG prodotte da società scientifiche italiane potenzialmente inseribili in SNLG rispetto al corpus di conoscenze/LG evidence based internazionali di alta/altissima qualità a disposizione

- Aspettative eccessive da parte dei medici e altri professionisti della sanità, policymakers, cittadini, pazienti (avvocati, giudici …)

- predominanza del valore regolatorio/cogente della LG rispetto al suo uso critico e consapevole
- aumento paradosso della pratica della medicina difensiva

Quale ruolo per le LG?

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

Richard Horton, Editor of *The Lancet*

ADDRESSING UNCERTAINTY IS PROFESSIONAL

'One of the key attributes of professionalism . . . should be the ability to identify and address uncertainty in medicine. Every day professionals confront and cope with uncertainties about disease pathogenesis, about diagnosis, and about treatment. Yet the intrinsic uncertainties in all these spheres of medical activity are seldom acknowledged explicitly and some professionals remain uncomfortable about admissions of uncertainty – in their dealings with patients especially.

From: Medical Research Council response to Royal College of Physicians consultation on medical professionalism. 2005

VIEWPOINT

The Connection Between Evidence-Based Medicine and Shared Decision Making

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