

# **Guidelines, recommendations, etc. Based on eminence or evidence?**

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# **In guidelines we cannot trust.**



**Do you agree?**

# A number of terms exist

- Guidelines
- Recommendations
- Regulations
- Directives
- Standards
- Position papers
- Opinions
- Etc.

**There is a distinction between these terms; often they are used interchangeably**

**Some of them have the power of law in some, albeit not all, countries**

**Eminence**

**versus**

**Evidence**

# What is 'eminence based medicine'?

**Making the same mistakes with increasing confidence over an impressive number of years....**



# What is 'eminence based medicine'?

- Relying on the opinion of a medical specialist or other prominent health official when it comes to health matters, rather than relying on a careful assessment of relevant research evidence.

# **'Who am I to judge?'**

**Pope Francis, 2013**

Who am I to question an 'expert'  
(especially a physician, a specialist or a  
prominent medical researcher who knows  
so much more than me)?

# What is 'evidence based medicine'?

**Evidence based medicine: what it is and what it isn't**

*It's about integrating individual clinical expertise and the best external evidence*

**The use of current best evidence  
in making decisions about the  
care of individual patients.**



# Current situation

- **Poor quality**

- Too often clinical practice guidelines, or similar documents, are of poor quality or are eminence-based

- **Consequences**

- Health care decisions might be based on biased or erroneous information

# Standards for the development of evidence-based guidelines



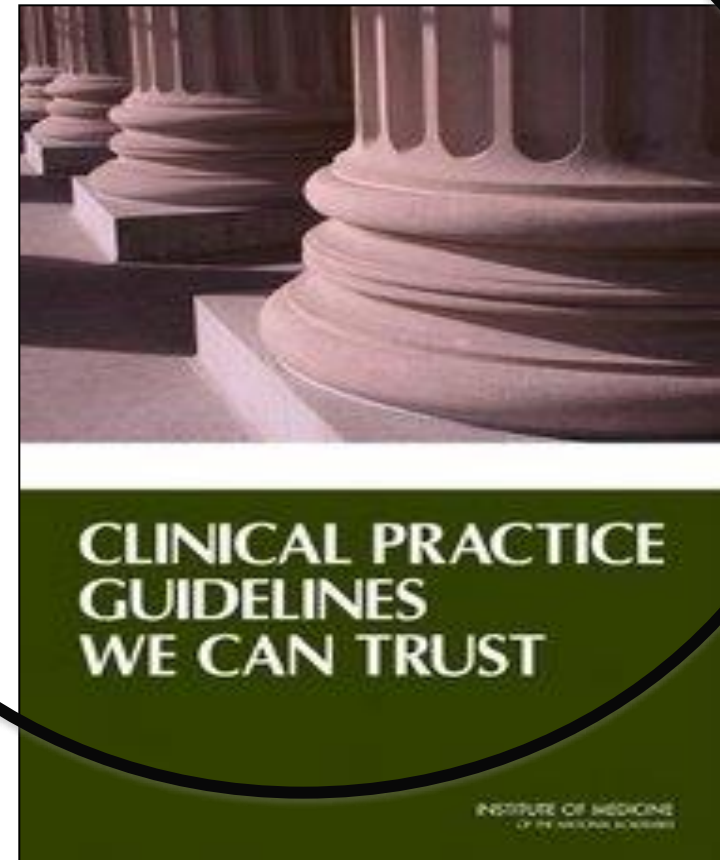
Institute of Medicine 2011

**NICE** National Institute for Health and Care Excellence

Find guidance ▾ NICE Pathways Quality standards Into practice

Process and methods guides Published 30 November 2012

## The guidelines manual



# Clinical practice guidelines

Institute of Medicine 2011

## Standard

- 1. Establishing transparency**
  - 2. Management of conflict of interest**
  - 3. Guidelines development group composition**
  - 4. Clinical practice guideline-systematic review intersection**
  - 5. Establishing evidence foundations for and rating strength of recommendations**
  - 6. Articulation of recommendations**
  - 7. External review**
  - 8. Updating**
-

# 1. Establishing transparency



**The processes by which a clinical practice guideline is developed and funded should be described transparently.**

## 2. Management of conflict of interest



**There's no such thing as a free lunch**

Milton Friedman, an American economist

# What is a conflict of interest?

- A set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.

**71% of chairs of clinical policy committees and 90.5% of co-chairs had financial conflicts**

Kung et al. Arch Intern Med. 2012 Nov 26;172(21):1628-33.

## 2. Management of conflict of interest

- Potential guideline development group members should declare conflicts.
- None, or at most a small minority, should have conflicts, including services from which a clinician derives a substantial proportion of income.
- The chair and co-chair should not have conflicts.
- Eliminate financial ties that create conflicts.

# 3. Guideline development group composition

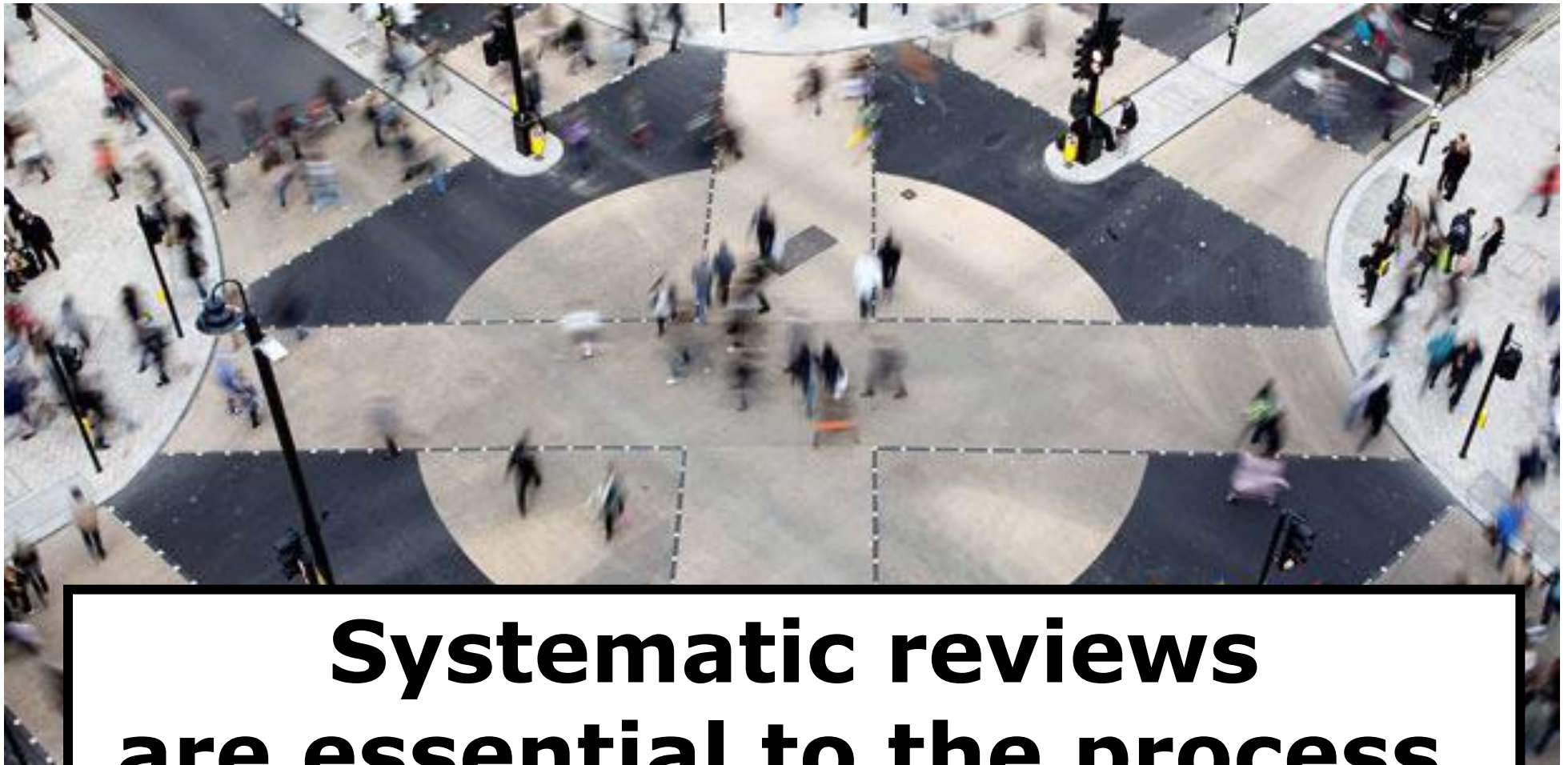


**As representative  
as possible**

- The group should be composed of methods experts, clinicians, representatives of stakeholders, and affected populations.



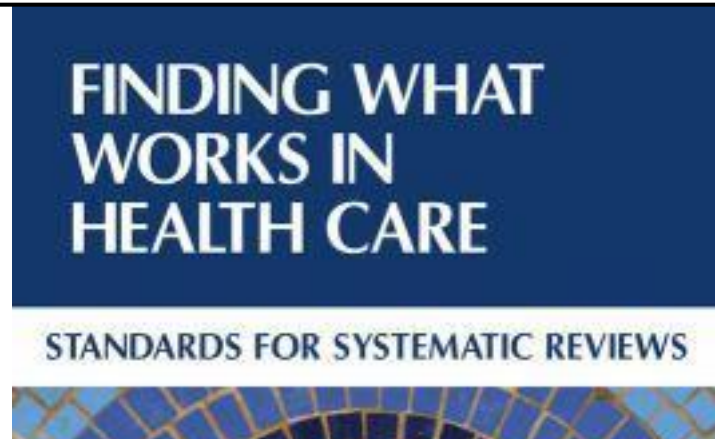
# 4. Clinical practice guideline-systematic review intersection



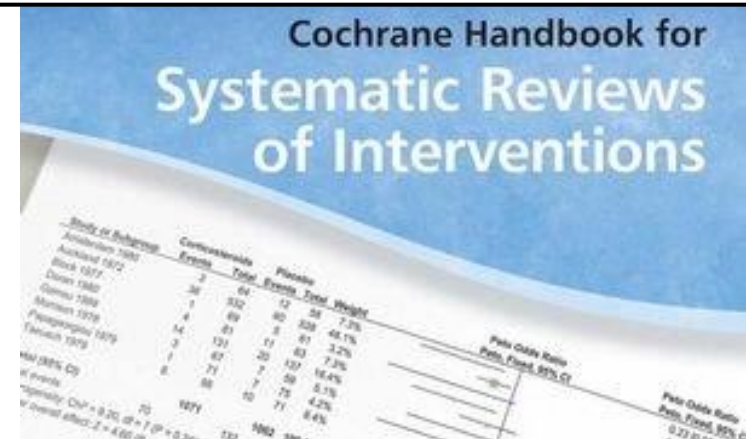
**Systematic reviews  
are essential to the process.**

# Standards for systematic reviews

Institute of Medicine



Cochrane Collaboration



**Time-consuming and costly**

**Estimates vary from 216 to 2,518 h**

**(with a mean of 1,139 h)**

**and an average of approximately \$104,750**

(Petticrew & Roberts, 2006).

# **5. Establishing evidence foundations for and rating strength of recommendations**

- Explain the reasoning behind each recommendation, summarize evidence for benefits and harms, characterize the quality and quantity of relevant evidence and the role of subjective judgments.
- Rate the level of evidence and the strength of the recommendation.
- Describe differences of opinion about recommendations.

# The GRADE system

to grade the strength of evidence and grades of recommendations

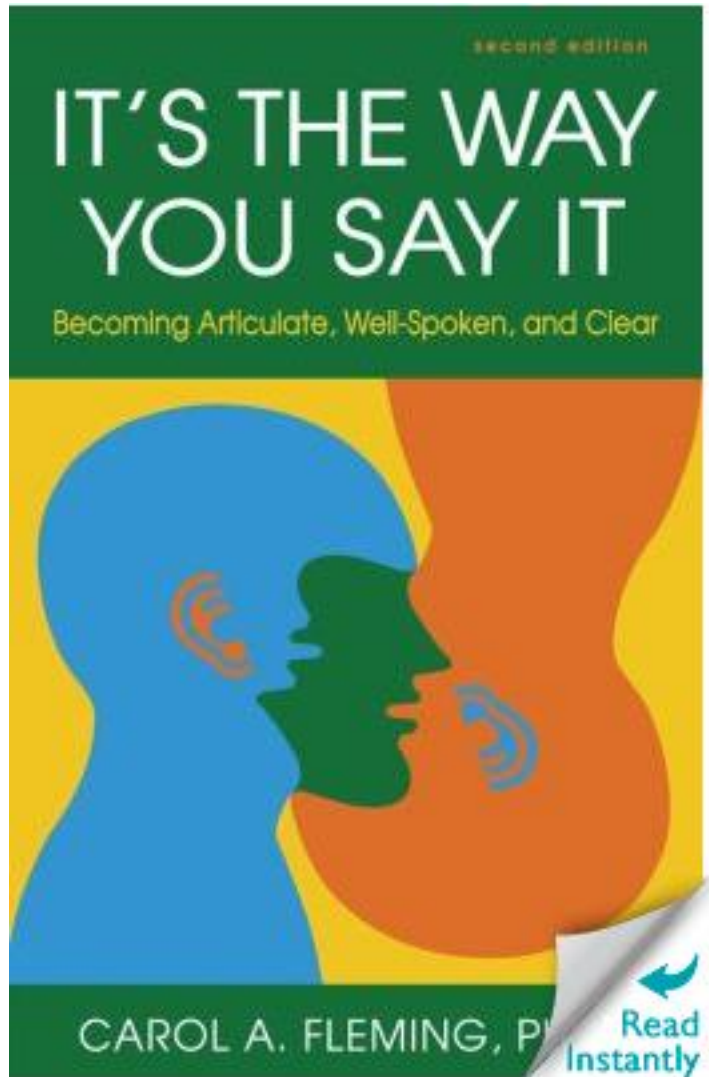
## Quality of evidence

<b>High quality</b>	Further research is unlikely to change our confidence in the estimate of effect.
<b>Moderate quality</b>	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
<b>Low quality</b>	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
<b>Very low quality</b>	Any estimate of effect is very uncertain.

## Grade of recommendation

<b>Strong</b>	When the desirable effects of an intervention clearly outweigh the undesirable effects, or clearly do not.
<b>Weak</b>	When the trade-offs are less certain.

# 6. Articulation of recommendations



- Describe the action recommended by the guideline and when it should be used;
- wording should facilitate measurement of adherence.



# 7. External review

**External reviewers....**



**..... should comprise a full spectrum of relevant stakeholders, including scientific and clinical experts, organizations, agencies, patients, and representatives of the public....**

# 8. Updating



- Document the dates of the guideline, systematic review, and planned update;
- Monitor the literature and update the guideline when new evidence suggests the need for change.

# Discussion on the guidelines development

BMJ

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

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**FEATURE**

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EVIDENCE BASED MEDICINE

## Why we can't trust clinical guidelines

Despite repeated calls to prohibit or limit conflicts of interests among authors and sponsors of clinical guidelines, the problem persists. **Jeanne Lenzer** investigates

*Jeanne Lenzer* medical investigative journalist

New York, USA



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Journal of Pediatric Gastroenterology & Nutrition:

[POST ACCEPTANCE, 2 January 2014](#)

doi: 10.1097/MPG.0000000000000284

Societal Paper: PDF Only

## Public Private Collaboration in Clinical Research During Pregnancy, Lactation and Childhood. A Joint Position Statement of the Early Nutrition Academy (ENA) and the European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN)

Koletzko, Berthold; Benninga, Marc A.; Godfrey, Keith M.; Hornnes, Peter J.; Kolacek, Sanja; Koletzko, Sibylle; Lentze, Michael J.; Mader, Silke; McAuliffe, Fionnuala M.; Oepkes, Dick; Oddy, Wendy H.; Phillips, Alan; Rzehak, Peter; Socha, Piotr; Szajewska, Hania; Symonds, Michael E.; Taminiau, Jan; Thapar, Nikhil; Troncone, Riccardo; Vandenplas, Yvan; Veereman, Gigi

PAP

# How good are guidelines if most published research is false?

Essay

## Why Most Published Research Findings Are False

John P. A. Ioannidis

# When the research findings are less likely to be true

- The smaller the studies
- The smaller the effect sizes
- The greater the number and the lesser the selection of tested relationships
- The greater the flexibility in designs, definitions, outcomes, and analytical modes
- The greater the financial and other interests
- The hotter a scientific field (with more scientific teams involved)

# The potential benefits of practice guidelines are only as good as the quality of the guidelines themselves.

CMAJ

ANALYSIS

## AGREE II: advancing guideline development, reporting and evaluation in health care

Melissa C. Brouwers PhD, Michelle E. Kho BHSc(PT) MSc, George P. Browman MD MSc, Jako S. Burgers MD PhD, Francoise Cluzeau PhD, Gene Feder MD, Béatrice Fervers MD PhD, Ian D. Graham PhD, Jeremy Grimshaw MBChB PhD, Steven E. Hanna PhD, Peter Littlejohns MD, Julie Makarski BSc, Louise Zitzelsberger PhD, for the AGREE Next Steps Consortium

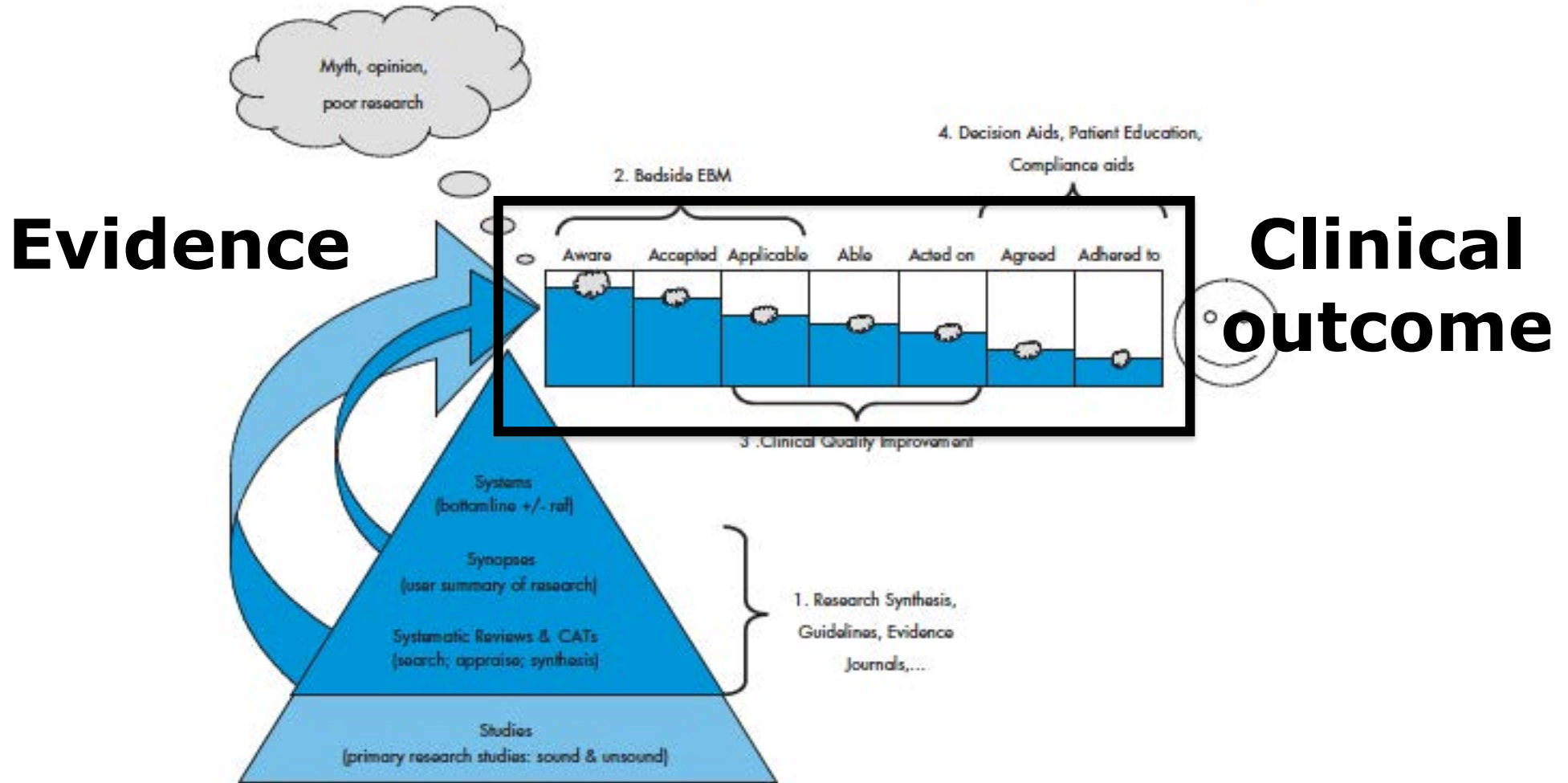
Original AGREE Item
<b>Domain 1: Scope and purpose</b>
The overall objective(s) of the guideline is (are) specifically described.
The clinical question(s) covered by the guideline is (are) specifically described.
The patients to whom the guideline is meant to apply are specifically described.
<b>Domain 2: Stakeholder involvement</b>
The guideline development group includes individuals from all the relevant professional groups.
The patients' views and preferences have been sought.
The target users of the guideline are clearly defined.
The guideline has been piloted among end users.
<b>Domain 3: Rigour of development</b>
Systematic methods were used to search for evidence.
The criteria for selecting the evidence are clearly described.
The methods for formulating the recommendations are clearly described.
The health benefits, side effects and risks have been considered in formulating the recommendations.
There is an explicit link between the recommendations and the supporting evidence.
The guideline has been externally reviewed by experts prior to its publication.
A procedure for updating the guideline is provided.
<b>Domain 4: Clarity of presentation</b>
The recommendations are specific and unambiguous.
The different options for management of the condition are clearly presented.
Key recommendations are easily identifiable.

**AGREE II is the international tool to assess the quality and reporting of practice guidelines.**

AGREE Collaboration (Appraisal of Guidelines, Research and Evaluation)

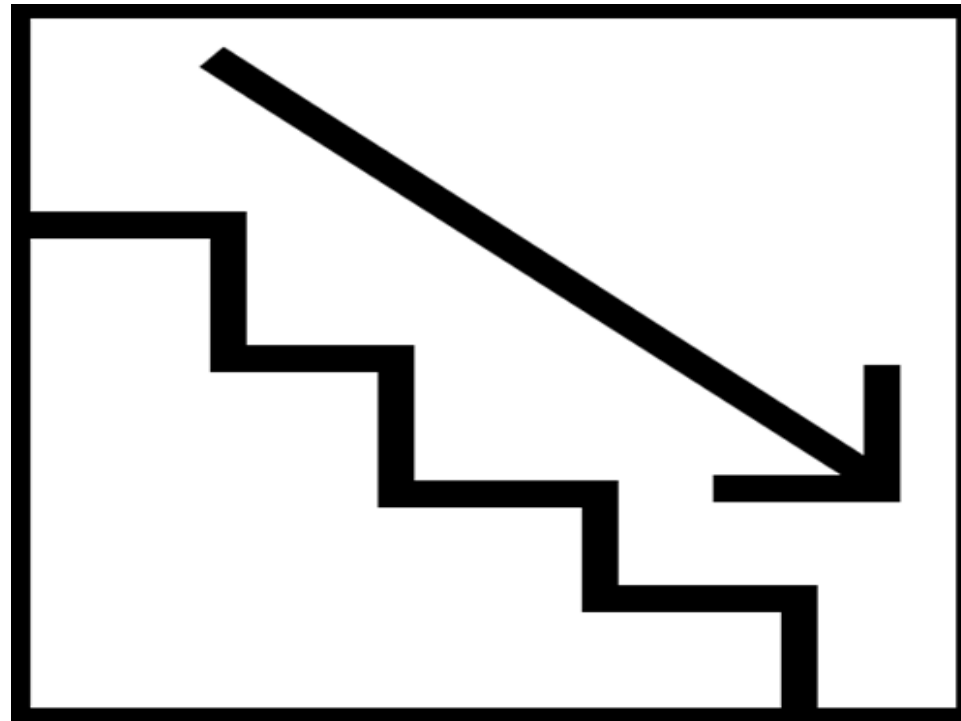
# The paths from research to improved health outcomes

5



# The paths from research to improved health outcomes

**Evidence**



**Clinical outcome**

<b>Aware</b>	<b>Accepted</b>	<b>Applicable</b>	<b>Able</b>	<b>Acted on</b>	<b>Agreed</b>	<b>Adhered to</b>
<b>Physician</b>					<b>Patient</b>	

# Take home messages

- **Variations in quality**

- Clinical practice guidelines vary significantly in quality, therefore in the trustworthiness of the yielded recommendations.

- **Evidence versus eminence**

- It is important that one can distinguish evidence-based clinical practice guidelines from guidelines that are not.

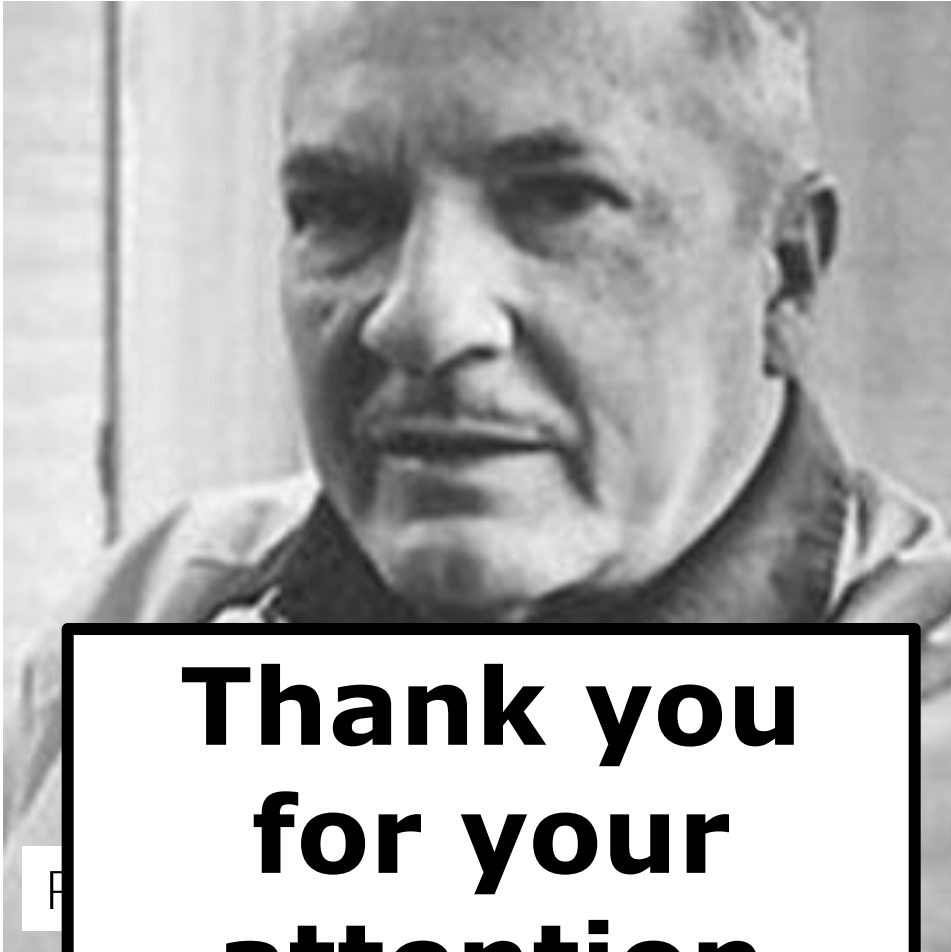
- **Standards available**

- Standards for the development of evidence-based guidelines have been developed.
- If adhered to, trustworthy guidelines should follow.

**Do you remain sceptical?**



# A final comment....



**Thank you  
for your  
attention**

**Always listen to  
experts.**

**They'll tell you what  
can't be done and  
why.**

**Then do it.**