

# Developing Trustworthy Clinical Practice Guidelines: International Standards and Current Challenges

**Amir Qaseem, MD, PhD, MHA, FACP**  
**Vice President, American College of Physicians**  
**Adjunct Faculty, Thomas Jefferson University**

October 27, 2017

# Disclosure of Interests

- Financial: None
- Non-financial (intellectual):
  - World Health Organization (WHO)
  - Guidelines International Network (G-I-N)
  - Centers for Disease Control and Prevention (CDC)
  - National Quality Forum (NQF)
  - American Medical Association PCPIF
  - GRADE Working Group
  - AHRQ
  - VA

# American College of Physicians

- Largest medical specialty organization in the United States
- 152,000 members
  - Internists and internal medicine subspecialists
  - Residents and Fellows training in IM or its subspecialties
  - Medical students
- Headquarters in Philadelphia
- Advocacy wing in Washington, DC

# Fun Facts

- When was the first RCT published?
  - 1948 Streptomycin for Tuberculosis
- # of RCTs results on Medline per day?
  - 75-100
- First “sort” of clinical guideline?
  - AAP-Red Book of ID (1938)
- Clinical Epidemiology as a discipline?
  - 1968 – Yale
- Evidence-based Medicine?
  - 1990

# Fun Facts

- First organization in the US to develop a clinical guideline based on a systematic literature review



- ACP entered the arena in 1976

# What is a Clinical Guideline?

- “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”.

*Institute of Medicine, 2011*

**Clinical Guideline ≠ Best Practice Advice**  
**Clinical Guideline ≠ Expert Based Opinion**  
**Clinical Guideline ≠ Standard of Care**

# The Need for a Good Guideline

- Medical literature is expanding at an extremely fast rate
- RCTs in MEDLINE: 5,000 per yr from 1978-1985 to 25,000 per year in 1994-2001
- 15 million citations on MEDLINE and 10,000-20,000 added per week



# The Need for a Good Guideline

- G-I-N Library: 3,636 guidelines from 46 countries
- National Guidelines Clearinghouse: 2,426 guidelines from 96 organizations

# Shortcomings of Guidelines

- Major variation in quality (variable quality of individual scientific studies)
- Limitations of systematic literature review
- Lack of transparency (guideline development methods)
- Poor methods or poorly documented methods

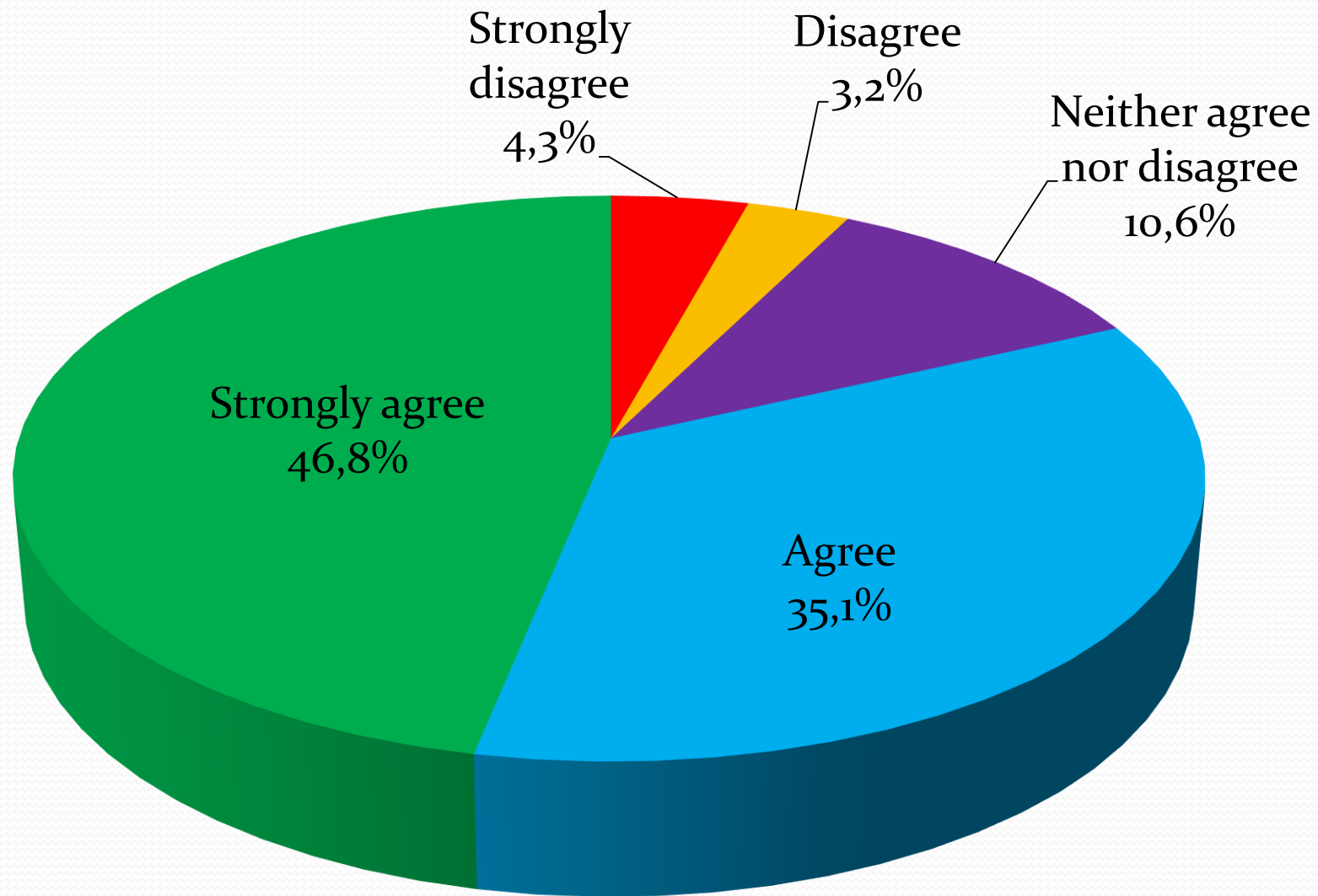
# Shortcomings of Guidelines

- COI (not reported or have deficiencies in disclosure as well as management)
- Failure to convene a multidisciplinary panel
- No standardized reporting system
- Lack of a grading system

# The Need for International Standards for Clinical Guidelines

- General agreement regarding the basic elements that are essential to develop a good guideline
- There were no uniformly endorsed international standards for clinical practice guidelines development

# But is there a Need for Standards?



# Annals of Internal Medicine

2012 (April); 156: 525-531

Annals of Internal Medicine

CLINICAL GUIDELINE

## Guidelines International Network: Toward International Standards for Clinical Practice Guidelines

Amir Qaseem, MD, PhD, MHA; Frode Forland, MD, DPH; Fergus Macbeth, MD; Günter Ollenschläger, MD, PharmD, PhD; Sue Phillips, PhD; and Philip van der Wees, PhD, PT, for the Board of Trustees of the Guidelines International Network\*

Guideline development processes vary substantially, and many guidelines do not meet basic quality criteria. Standards for guideline development can help organizations ensure that recommendations are evidence-based and can help users identify high-quality guidelines. Such organizations as the U.S. Institute of Medicine and the United Kingdom's National Institute for Health and Clinical Excellence have developed recommendations to define trustworthy guidelines within their locales. Many groups charged with guideline development find the lengthy list of standards developed by such organizations to be aspirational but infeasible to follow in entirety.

Founded in 2002, the Guidelines International Network (G-I-N) is a network of guideline developers that includes 93 organizations and 89 individual members representing 46 countries. The G-I-N board of trustees recognized the importance of guideline development processes that are both rigorous and feasible even for modestly funded groups to implement and initiated an effort toward consensus about minimum standards for high-quality guidelines. In

contrast to other existing standards for guideline development at national or local levels, the key components proposed by G-I-N will represent the consensus of an international, multidisciplinary group of active guideline developers.

This article presents G-I-N's proposed set of key components for guideline development. These key components address panel composition, decision-making process, conflicts of interest, guideline objective, development methods, evidence review, basis of recommendations, ratings of evidence and recommendations, guideline review, updating processes, and funding. It is hoped that this article promotes discussion and eventual agreement on a set of international standards for guideline development.

*Ann Intern Med.* 2012;156:525-531.

[www.annals.org](http://www.annals.org)

For author affiliations, see end of text.

\* For a list of members of the board of trustees of the Guidelines International Network, see the Appendix (available at [www.annals.org](http://www.annals.org)).



# Guidelines International Network

## Guideline Development Standards

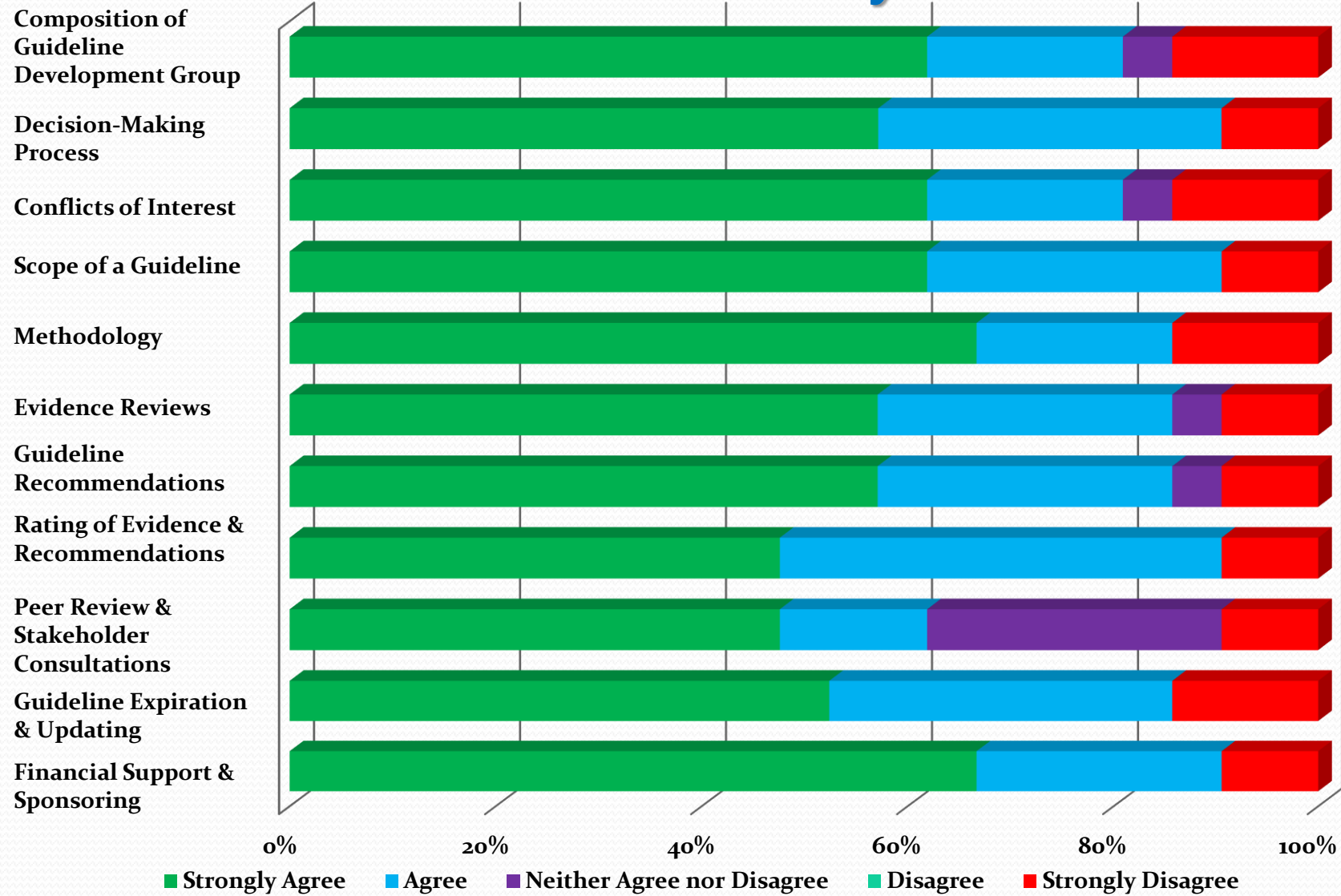
*Table. Key Components of High-Quality and Trustworthy Guidelines*

Component	Description
Composition of guideline development group	A guideline development panel should include diverse and relevant stakeholders, such as health professionals, methodologists, experts on a topic, and patients.
Decision-making process	A guideline should describe the process used to reach consensus among the panel members and, if applicable, approval by the sponsoring organization. This process should be established before the start of guideline development.
Conflicts of interest	A guideline should include disclosure of the financial and nonfinancial conflicts of interest for members of the guideline development group. The guideline should also describe how any identified conflicts were recorded and resolved.
Scope of a guideline	A guideline should specify its objective(s) and scope.
Methods	A guideline should clearly describe the methods used for the guideline development in detail.
Evidence reviews	Guideline developers should use systematic evidence review methods to identify and evaluate evidence related to the guideline topic.
Guideline recommendations	A guideline recommendation should be clearly stated and based on scientific evidence of benefits; harms; and, if possible, costs.
Rating of evidence and recommendations	A guideline should use a rating system to communicate the quality and reliability of both the evidence and the strength of its recommendations.
Peer review and stakeholder consultations	Review by external stakeholders should be conducted before guideline publication.
Guideline expiration and updating	A guideline should include an expiration date and/or describe the process that the guideline groups will use to update recommendations.
Financial support and sponsoring organization	A guideline should disclose financial support for the development of both the evidence review as well as the guideline recommendations.

# What do clinicians say about these standards?



# Annals Survey



# What about the Institute of Medicine (National Academy of Medicine) standards?

G-I-N	IOM
Composition of Guideline Development Group	Yes
Decision-making Process	Not Explicit
Conflicts of Interest	Yes
Scope of a Guideline	Not Explicit
Methodology	Yes
Evidence Reviews	Yes
Guideline Recommendations	Yes
Rating of Evidence and Recommendations	Yes
Peer Review and Stakeholder Consultations	Yes
Guideline Expiration and Updating	Partly Yes
Financial Support and Sponsoring Organization	Not Explicit

# Challenges

***“A guideline development panel should include diverse and relevant stakeholders, such as health professionals, methodologists, experts on a topic, and patients.”***

- Size of guideline committee is important (10-15)
- How to best incorporate patients values and preferences
- NAM contradiction: exclusion (COI) but encourages inclusion & also public comment

***“Guideline developers should use systematic evidence review methods to identify and evaluate evidence related to the guideline topic.”***

- 84 standards for systematic review laid out by NAM can be ideals but may need some flexibility.
- Cost
- Time

***“A guideline should include disclosure of the financial and nonfinancial conflicts of interest for members of the guideline development group. The guideline should also describe how any identified conflicts were recorded and resolved.”***

- No standardized declaration of interest
- Define “interest?”
- Processes for conflict management

***“A guideline should include an expiration date and/or describe the process that the guideline groups will use to update recommendations.”***

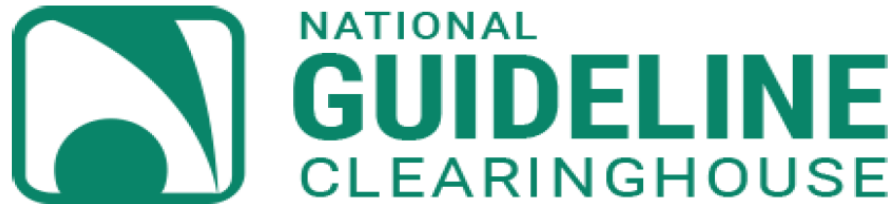
- How do we define living document?
- Literature should be monitored regularly. When does systematic review kick in?
- How to define “regularly?”
- Update when there is a change or re-affirm?
- How to do it?
- Resources



***“Review by external stakeholders should be conducted before guideline publication.”***

- Bias
- Political influence on the content
- Resources

# Quality Ratings? Accreditation?



## **NEATS Assessment NGC-11196**

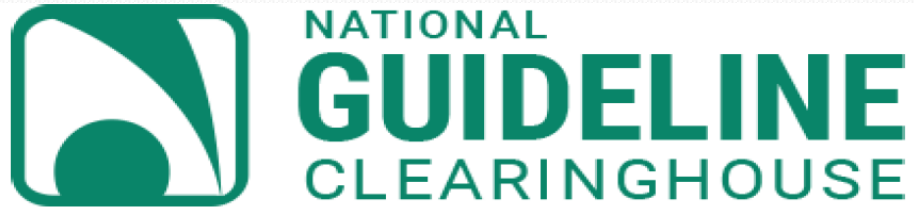
### Guideline Title

**Noninvasive treatments for acute, subacute, and chronic low back pain: a clinical practice guideline from the American College of Physicians.**

National Guideline Clearinghouse (NGC) has assessed this guideline's adherence to standards of trustworthiness, derived from the Institute of Medicine's report [\*Clinical Practice Guidelines We Can Trust\*](#).

■■■■■=Poor ■■■■=Fair ■■■=Good ■■■=Very Good ■■■=Excellent

# Quality Ratings? Accreditation?



## **NEATS Assessment NGC-11186**

---

### Guideline Title

**Pharmacologic treatment of hypertension in adults aged 60 years or older to higher versus lower blood pressure targets: a clinical practice guideline from the American College of Physicians and the American Academy of Family Physicians.**

National Guideline Clearinghouse (NGC) has assessed this guideline's adherence to standards of trustworthiness, derived from the Institute of Medicine's report [\*Clinical Practice Guidelines We Can Trust\*](#).

||||| =Poor    ||||| =Fair    ||||| =Good    ||||| =Very Good    ||||| =Excellent

# Clinical Guidelines

- Translate best available evidence into recommendations
- Clinical guidelines are guides only
- Do not apply to all patients or all clinical situations
- Population vs Individual patient
- Not intended to override clinicians judgement

# Clinicians Are...

- Making decisions everyday on clinical scenarios or conditions that lack high quality evidence or sometimes any evidence



“Next, an example of the very same procedure when done correctly.”

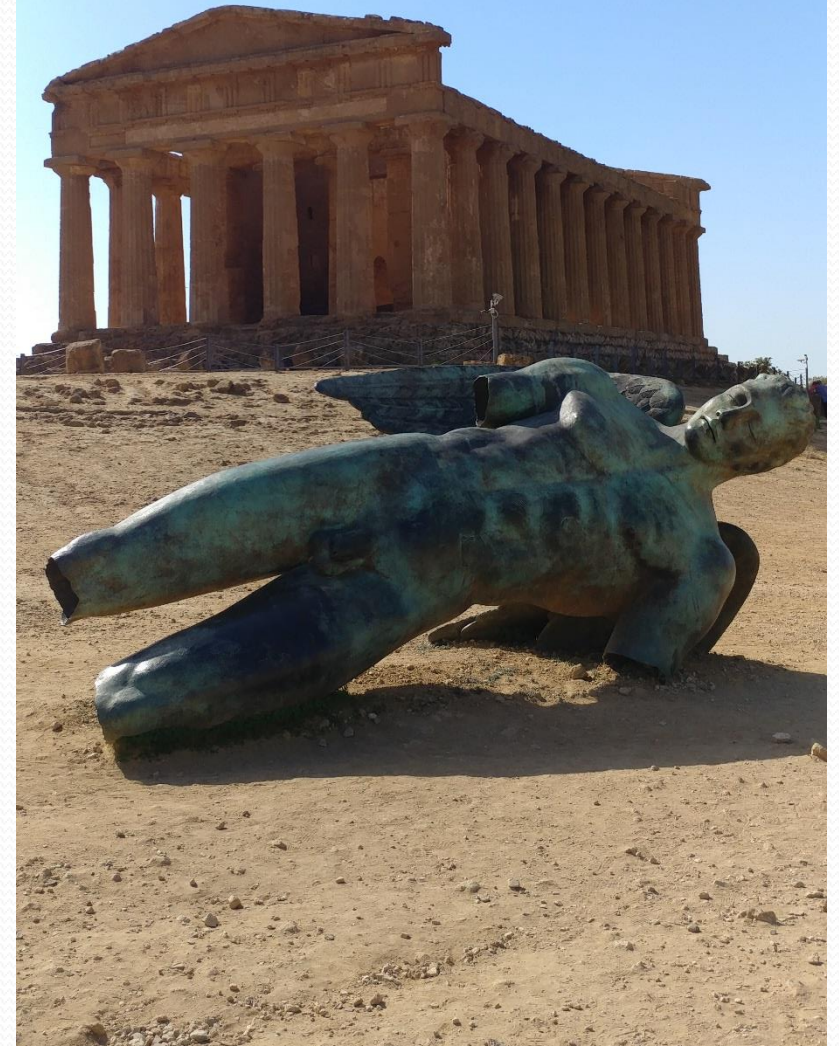
© The New Yorker Collection 2015 from cartoonbank.com. All Rights Reserved.

**Something to ponder.....**





















# Questions/ Comments