



# Recognizing Trustworthy Guidelines: The New IOM Standards

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**CLINICAL PRACTICE  
GUIDELINES  
WE CAN TRUST**

INSTITUTE OF MEDICINE  
OF THE NATIONAL ACADEMIES

# In this session...

- IOM Process
- Review of Standards
- Response to the New Standards

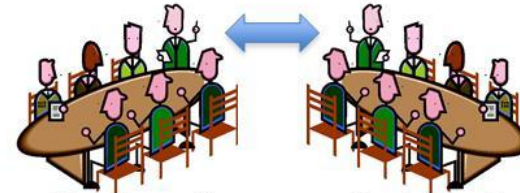
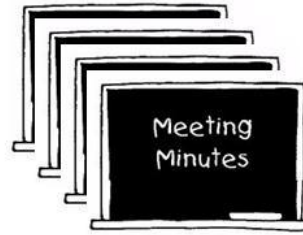
# What is the Institute of Medicine?

- Health component of the US National Academy of Sciences
- Independent, non-profit, non-governmental organization
- Aims to answer health- and healthcare-related questions posed by government and the private sector
- Provides unbiased advice to health care decision makers and the public
- Generally perceived as authoritative

# Clinical Practice Guideline Development

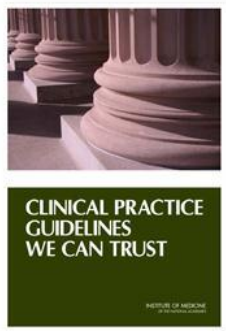


Develop evidence-based, methodological standards for SRs and CPGs

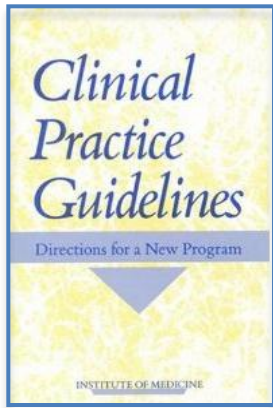


Trustworthy Guidelines

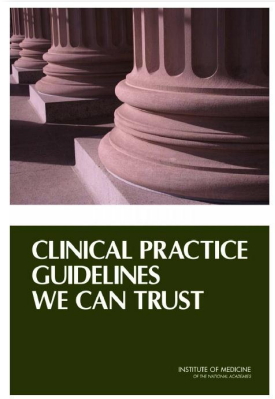
Systematic Reviews



# A New Definition for CPGs



- Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances (IOM 1990)



- 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 (IOM 2011)

# To be trustworthy, guidelines should...

- Be based on a systematic review of the existing evidence;
- Be developed by a knowledgeable, multidisciplinary panel of experts and representatives from key affected groups;
- Consider important patient subgroups and patient preferences as appropriate;
- Be based on an explicit and transparent process that minimizes distortions, biases, and conflicts of interest;
- Provide a clear explanation of the logical relationships between alternative care options and health outcomes, and provide ratings of both the quality of evidence and the strength of recommendations; and
- Be reconsidered and revised as appropriate when important new evidence warrants modifications of recommendations.

# Establishing Transparency

- ✓ 1.1 The processes by which a clinical practice guideline (CPG) is developed and funded should be detailed explicitly and publicly accessible.





# Conflict of Interest (COI)

- 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 (IOM 2009).
- A divergence between an individual's private interests and his or her professional obligations such that an independent observer might reasonably question whether the individual's professional actions or decisions are motivated by personal gain, such as financial, academic advancement, clinical revenue streams, or community standing.
- Intellectual COI: academic activities that create the potential for an attachment to a specific point of view that could unduly affect an individual's judgment about a specific recommendation (Guyatt 2010).



# Experts with Conflicts

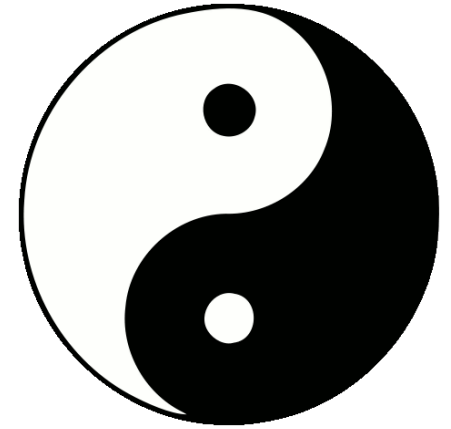
- “...the most knowledgeable individuals regarding the subject matter addressed by a CPG are frequently conflicted. These “experts” often possess unique insight into guideline relevant content domains.”
- “...they may be aware of relevant information about study design and conduct that is not easily identified.”

# Strategies for Managing COI

- Simple disclosure
- Exclude from leadership roles
- Participation in certain restricted recommendations
- Formal or informal consultation
- Fully exclude conflicted members from panel participation

# Management of Conflict of Interest

- 2.1 Prior to selection, **declare** all interests and activities potentially resulting in COI  
Current and planned, commercial, non-commercial, intellectual, and institutional activities pertinent to the potential scope of the CPG.
- 2.2 **Disclose** COIs within guideline development group:  
Explain how COI could influence the CPG development process.
- 2.3 **Divest** financial investments of panel members and their families and not participate in marketing activities or advisory boards of entities whose interests could be affected by CPG recommendations.
- 2.4 Members with COIs should be a **minority** of the GDG.  
The chair or co-chairs should not have COI.  
Funders should have no role in CPG development.

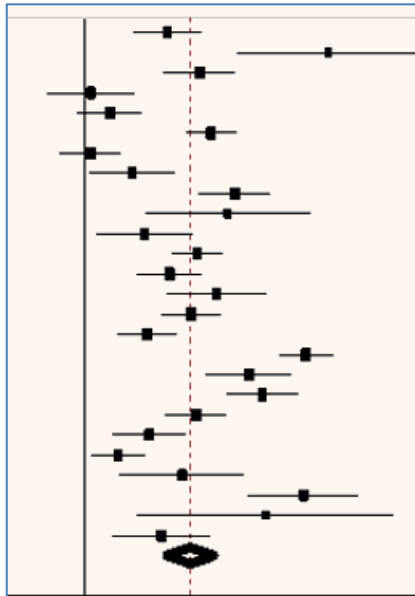


## Composition of Guideline Development Group (GDG)

- 3.1 The GDG should be **multidisciplinary and balanced**, including methodological experts, clinicians, and populations expected to be affected
- 3.2 Include (at least at the time of clinical question formulation and draft CPG review) a current or former **patient and a patient advocate or patient/consumer organization representative**
- 3.3 Adopt strategies to increase effective participation of patient and consumer representatives

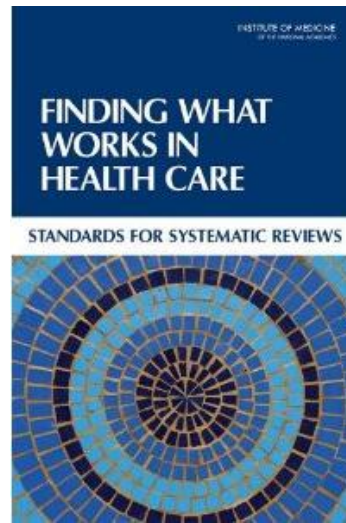
# Unintended Consequences of COI Disclosure

- Disclosure can lead to offering biased advice
  - Strategic exaggeration
    - Tendency to provide more biased advice to counteract anticipated discounting
  - Moral licensing
    - The often unconscious feeling that biased advice is justifiable because the advisee has been warned.



## Intersection of Clinical Practice Guideline and Systematic Review

1. Use systematic reviews that meet standards set by the IOM Committee on Standards for Systematic Reviews
2. The GDG and systematic review team should interact.



# Standards for Systematic Reviews

- RIGOROUS recommendations for:
  - Initiating a systematic review
  - Finding and assessing individual studies
  - Synthesizing body of evidence
  - Reporting

# Trustworthy Guidelines

- Must a "trustworthy guideline" be informed by high quality evidence?
  - How do IOM standards deal with poor/absent evidence?



# Establishing Evidence Foundations and Rating Strength of Recommendations

## 5.1 For each recommendation provide:

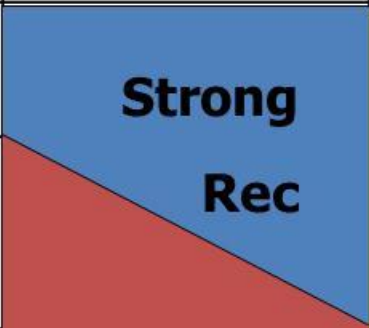
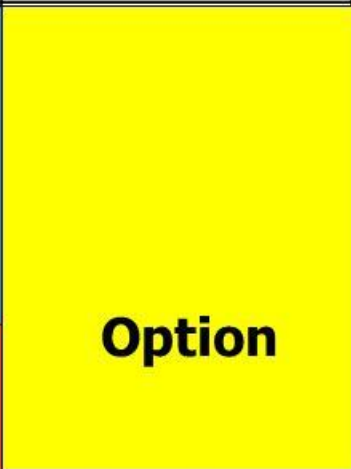
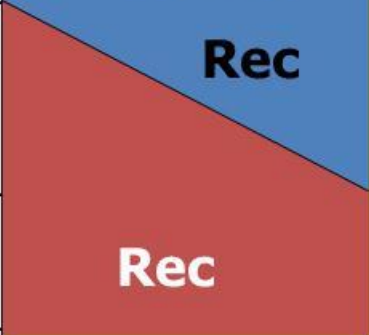




- A summary of relevant available **evidence**, description of the **quality, quantity, and consistency** of the aggregate available evidence.
- A clear description of **potential benefits and harms**.
- An explanation of the part played by **values, opinion, theory, and clinical experience** in deriving the recommendation.
- A description of any **differences of opinion** regarding the recommendation.
- A rating of the **level of confidence** in the evidence
- A rating of the **strength of the recommendation**

# Determinants of Evidence Quality

GRADE Collaboration

- RCTs start high
- Observational studies start low
- 5 factors that can lower quality
  - Limitations of design or execution
  - inconsistency
  - indirectness
  - publication bias
  - Imprecision
- 3 factors can increase quality
  - large magnitude of effect
  - all plausible confounding may be working to reduce the demonstrated effect or increase the effect if no effect was observed
  - dose-response gradient

# Grading Recommendation Strength

Evidence Quality	Preponderance of Benefit or Harm	Balance of Benefit and Harm
A. Well designed RCTs or diagnostic studies on relevant population		
B. RCTs or diagnostic studies with minor limitations;overwhelmingly consistent evidence from observational studies		
C. Observational studies (case-control and cohort design)		
D. Expert opinion, case reports, reasoning from first principles		
X. Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit or harm		



# Articulation of Recommendations

- 6.1 Articulate recommendations in a **standardized form**, detailing precisely what the recommended action is, and under what circumstances it should be performed.
- 6.2 Strong recommendations should be worded so that compliance can be evaluated.

# Authors Should Be Explicit About

- **WHEN** {under what circumstances} **Denominator**
- **WHO** {in the Intended Audience}
- **Ought to** {with what level of obligation} **Numerator**
- **DO WHAT**
- {To **WHOM**} {which members of the target population}
- **HOW**
- **WHY**



## External Review

- 7.1 External reviewers should **comprise a full spectrum** of relevant stakeholders, including scientific and clinical experts, organizations, agencies, patients, and representatives of the public.
- 7.2 The authorship of external reviews should be kept **confidential** unless that protection has been waived.
- 7.3 The GDG should consider all external reviewer comments and keep a written **record of the rationale for modifying or not modifying** a CPG in response to reviewers' comments.
- 7.4 A draft of the CPG prior to the final draft should be made available to the general **public** for comment.



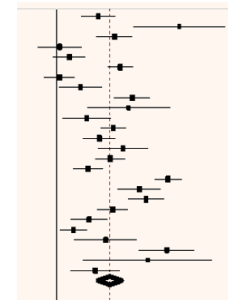
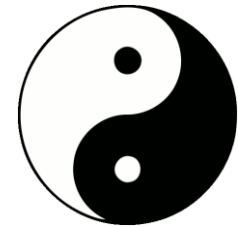
# Updating

- 8.1 The CPG publication date, date of systematic evidence review, and proposed date for future review should be **documented** in the CPG.
- 8.2 **Literature should be monitored** to identify the emergence of new, potentially relevant evidence and to evaluate the continued validity of the CPG.
- 8.3 CPGs should be updated when **new evidence** suggests the need.

# Can We Use the New IOM Standards To Improve Guideline Quality?



- Require transparency
- Reduce conflict of interest
- Assure multidisciplinary and balanced developer team composition
- Promote thorough and unbiased review of existing knowledge
- Encourage clear and transparent articulation of recommendations
- Encourage clear and transparent articulation of recommendations
- Accommodate broad-based reviewer input
- Encourage awareness and incorporation of new knowledge





# Recommendations

- To be trustworthy, a clinical practice guideline should **comply with proposed standards 1-8**. Optimally, CPG developers should adhere to these proposed standards and CPG users should adopt CPGs compliant with these proposed standards.

...sympathetic to the time and other resource requirements the standards imply

Is it worthwhile to produce a CPG  
which is based on poor quality  
evidence and expert opinion but  
developed with a rigorous  
methodology?

# Worthwhile?

- Every day, clinicians treat patients with problems whose solution lacks a strong evidence base
- Seek help with decision-making
- Input from experts is valued
- Guidelines provide a convenient resource that defines current best practice.

# American College of Cardiology / American Heart Association

Tricoci P et al. JAMA 2009;301(8):831-841

- Only 314 recommendations of 2711 (11%) are classified as level of evidence A (multiple RCTs or meta-analyses), whereas 1246 (48%) are level of evidence C (consensus, case studies, standards of care)
- Despite their high degree of precision, clinical trials are limited in scope, with evidence from RCTs often insufficient to inform general clinical practice.

# American Academy of Pediatrics Member Survey

- Annual dues = \$600
- 25% stated practice guidelines, information, and resources are the **#1 reason for** membership

# Professional Societies

- Google search “Clinical Practice Guidelines We Can Trust”
  - → 62,500 results
  - National and international
- Many organizations are updating guideline development processes (ACC/AHA, AAP, ACCP, WHO...)
- Council of Medical Specialty Societies

# New American Cancer Society Process for Creating Trustworthy Cancer Screening Guidelines

## JAMA (12/14/2011)

Standards for Clinical Practice Guidelines: Institute of Medicine (IOM) Recommendations and American Cancer Society (ACS) Process

<b>Standards</b>	<b>IOM Recommendations</b>	<b>New ACS Process for Cancer Screening Guideline Development</b>
Transparency	The process and funding of guideline development should be completely specified	The article defines the new ACS process, and all ongoing and planned work in cancer screening guideline production and revision will be posted on the ACS website
Conflicts of interest	Conflicts of interest include commercial, institutional, professional, and intellectual conflicts, all of which must be openly declared. Members should divest conflicting financial relationships.	ACS guideline developers will publicly declare financial and institutional conflicts, and all will be expert generalists to avoid the appearance of professional conflicts.
Group composition	The guideline group should include multidisciplinary methodological experts, clinicians, and patient advocates.	Guidelines will be developed by a 12-person panel of multidisciplinary experts in clinical screening, including a patient advocate
Systematic review of evidence	The guidelines should be based on systematic literature review that meets the standards set by the IOM.	ACS will commission high-quality and independent systematic evidence reviews to serve as the basis for all guidelines.
Grading strength of recommendations	For each recommendation, the test should explain the evidence and the reasoning, explain the balance of benefits and harms, and indicate the level of confidence in the recommendation.	ACS will be explicit about harms, as well as benefits, and will develop a grading scheme to rate confidence in recommendations that will be consistent with methods used by other organizations.
Articulation of recommendations	Recommendations should be clearly stated and actionable.	ACS guidelines will be written for audiences of primary care clinicians, the general public, and policy makers.
External review	The draft guidelines should be posted for public comment, and the final guidelines should be revised as appropriate before peer review.	Before publication, all draft guidelines will be vetted by relevant experts, organizations and societies, and any differences will be explicitly discussed in the published guideline.
Updating	Guidelines should be updated when new evidence should result in modifying the recommendations.	ACS guidelines will be briefly updated as needed, and at a minimum at least annually online with relevant new studies, and rewritten every 5 years.

# The Secretary of HHS should establish:

- a **public-private mechanism** to **examine**, at the request of developer organizations, the procedures they use to produce their clinical practice guidelines
- and to **certify** whether these organizations' CPG development processes comply with standards for trustworthy CPGs.



# NICE (UK) Certifies Organizations

- Organization applies for certification
- NICE reviews applicant's **procedures** and **guideline products** from applicant using AGREE
- Internal and external reviewers
- Draft decision posted on web with public consultation
- Organizations meeting accreditation requirements and agreeing to maintain the approved processes during a 3-year accreditation period **receive a mark** to be placed on future CPGs
- Accreditor may review organizational procedures at any point and accreditation can be withdrawn

# AHRQ should...

- Require the **National Guideline Clearinghouse to provide a clear indication** of the extent to which clinical practice guidelines submitted to it adhere to standards for trustworthiness.
  - The committee heard testimony that the NGC “...does not set sufficiently high standards to assure users that poor-quality guidelines are not admitted”
- NGC should **eliminate CPGs for which trustworthiness cannot be determined** and **identify the trustworthiness of those retained**.
- Guidelines that have **not included a thorough SR** of the relevant scientific evidence base **should be excluded** from the NGC.
  - Findings of no scientific evidence resulting from an SR should not preclude listing of the CPG in the NGC

# National Guideline Clearinghouse should...

- **Prominently identify guidelines originating from CPG developers certified** by the designated mechanism as trustworthy
- CPGs from an organization that requested and **failed review** should also be identified in a special category, with standards met and shortcomings specified.
- **NGC needs to be funded** at a sufficient level for it to improve the quality, timeliness, and trustworthiness of its CPGs and other products.