Guidelines We Can Trust

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August 9, 2019

Clinical Practice Guidelines - Background

- Clinicians are often faced with difficult decisions and considerable uncertainty
- Rely on
  - Knowledge
  - Skills
  - Experience
  - Patient preferences

Clinical Practice Guidelines - Background

- Guidelines are “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

Who makes guidelines?

Who makes guidelines?

- Government-sponsored or organized
  - USPSTF
  - CDC
- Physician specialty societies
  - American College of Cardiology
  - American Thoracic Society
  - American College of Physicians
- Disease specific organizations
  - American Diabetes Association
  - American Heart Association
  - American Cancer Society

Common guideline flaws

- Conflict of interest
- Too many recommendations and poorly articulated recommendations
- Based entirely on expert opinion and/or low level evidence
- Not useful for generalists and real world patients
- Don’t appropriately weigh harms and benefits

Common guideline flaws

- Conflict of interest

Common guideline flaws

- Conflict of interest
  - 56% of authors of 17 most recent ACC/AHA guidelines report COI
    - Arch Intern Med 2011 171(6)
  - Cholesterol guideline
  - 2016 “Focused update” on new pharmacologic therapy for heart failure
  - 72% COI in Hepatitis C guideline
  - American Psychiatric Association 2010 Depression guideline

Common guideline flaws

- Too many recommendations and poorly articulated recommendations

Common guideline flaws

- Based entirely on expert opinion
  - "A group of experts expressing their views is not evidence." (Am Fam Phys 2012)
  - "Strong recommendation based on low level evidence" (ACC/AHA)

Common guideline flaws

- Not useful for generalists and real world patients

Common guideline flaws

- Don’t appropriately weigh harms and benefits

Institute of Medicine – 8 Standards

- Transparency
- Management of conflict of interest
- Group composition
- Guideline intersection with systematic review
- Establish evidence foundation for and rating strength of recommendations
- Articulation of recommendations
- External review
- Updating

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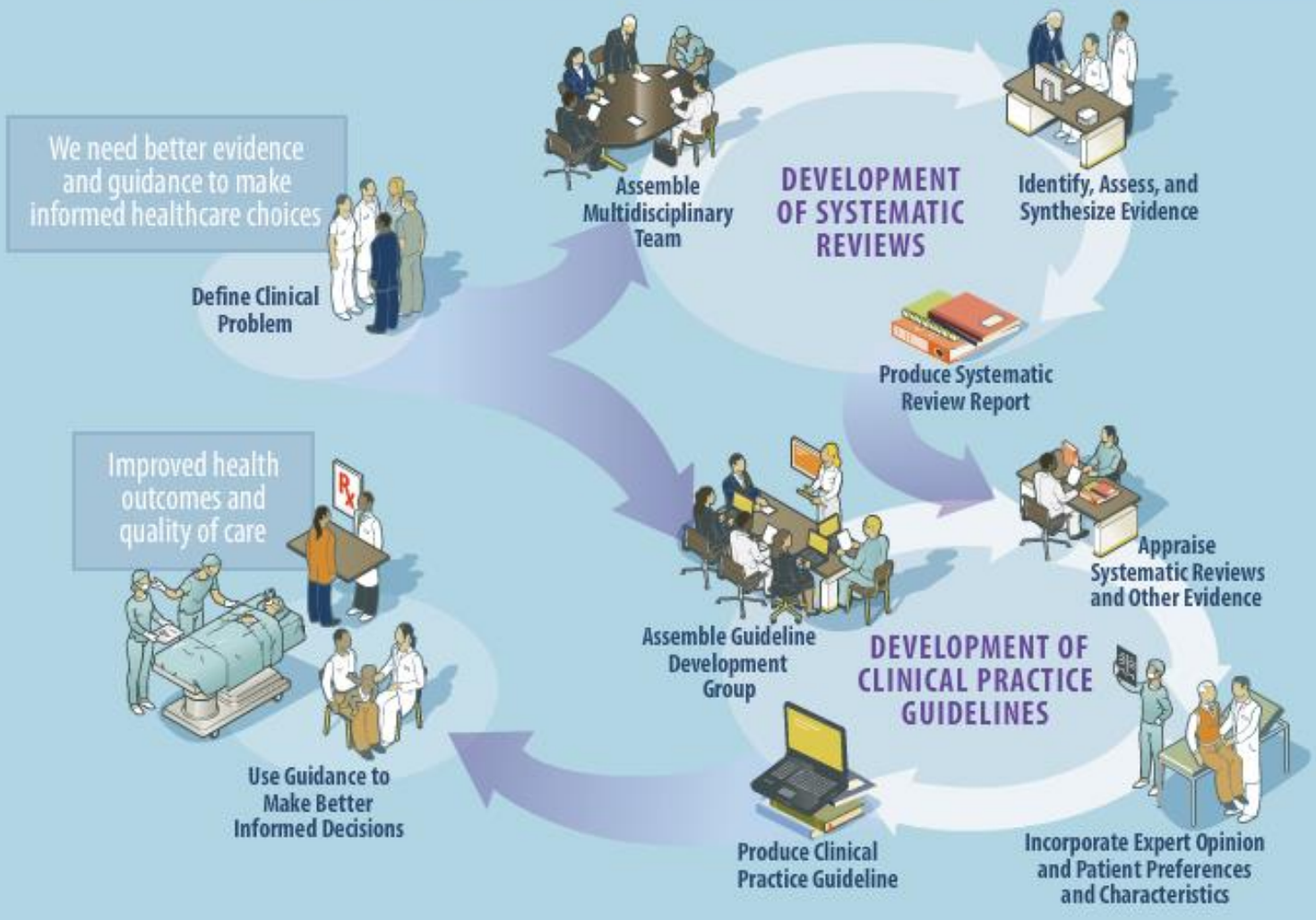
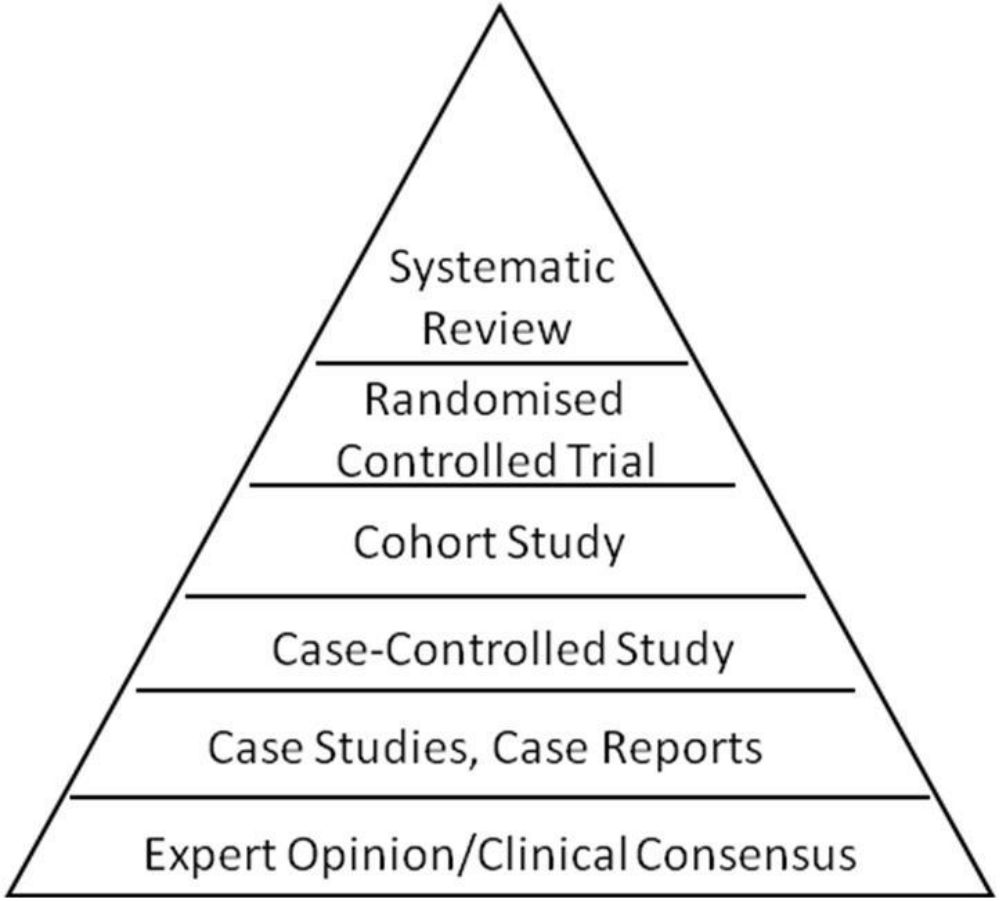
Guidelines are not doing well to meet these standards – Arch Intern Med 2012 172 (21)

Systematic Reviews and Clinical Practice Guidelines Improve Healthcare Decision Making

Click on any text for more information



Evidence Pyramid



“evidence does not make decisions.”

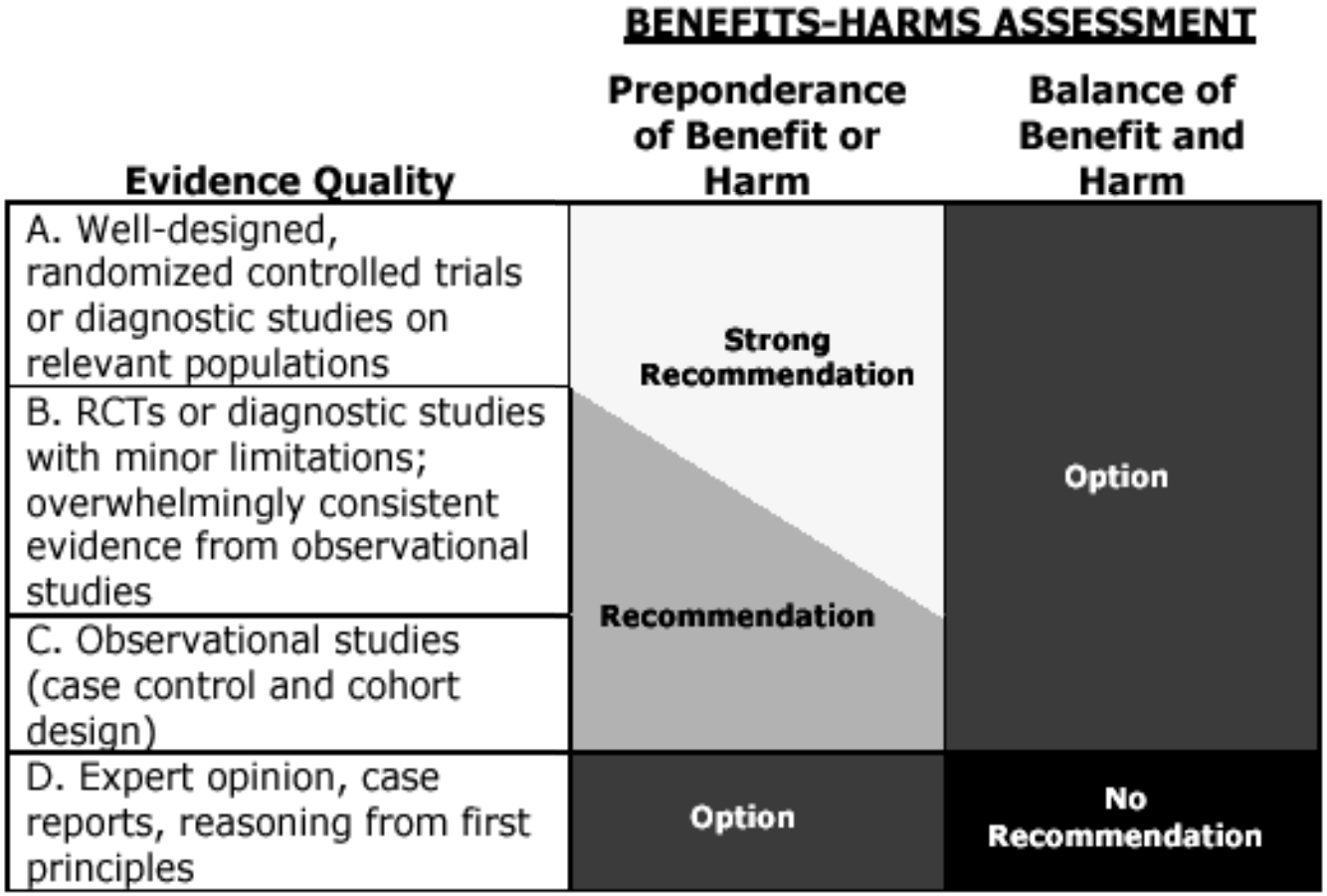
Haynes RB, Devereaux PJ, Guyatt GH. Clinical expertise in the era of evidence-based medicine and patient choice. *ACP J Club* 2002;136(2):A11-A13.

Guidelines We Can Trust

- Quality driven approach
- “Key action statements”
  - **When** (under what specific conditions)
  - **Who** (specifically)
  - **Must/should/may** (level of obligation)
  - Do **what** (precisely what actions)
  - To **whom**

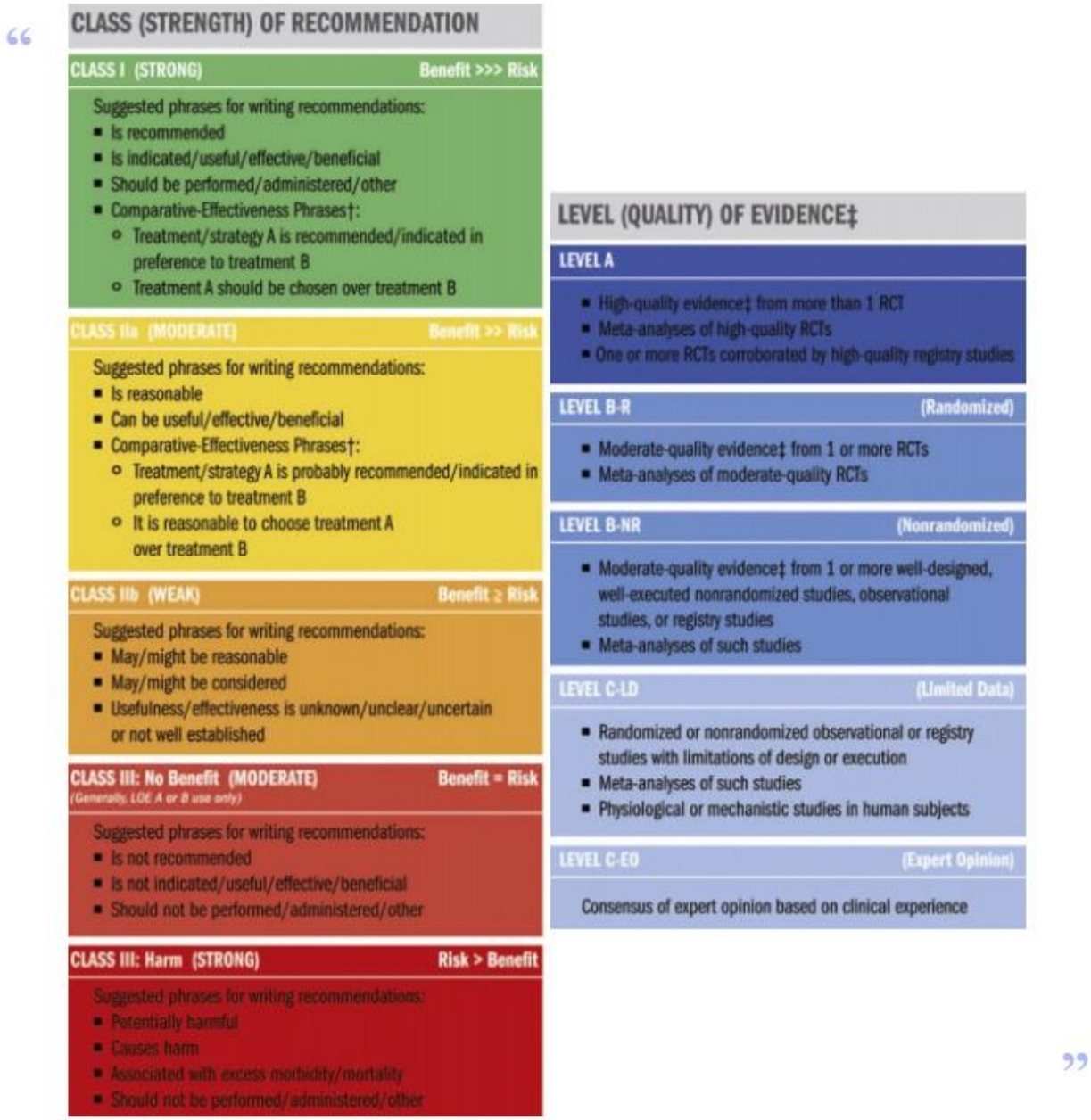
Classifying Recommendations for Practice Guidelines

AAP Steering Committee on Quality Improvement and Management



Pediatrics 2004; 114:874-877

2016 Classification of Recommendations and Level of Evidence



CLASS (STRENGTH) OF RECOMMENDATION

CLASS I (STRONG) — Benefit >>> Risk

Suggested phrases for writing recommendations:
- Is recommended
- Is indicated/useful/effective/beneficial
- Should be performed/administered/other
- Comparative-Effectiveness Phrases†:
  - Treatment/strategy A is recommended/indicated in preference to treatment B
  - Treatment A should be chosen over treatment B

CLASS IIa (MODERATE) — Benefit >> Risk

Suggested phrases for writing recommendations:
- Is reasonable
- Can be useful/effective/beneficial
- Comparative-Effectiveness Phrases†:
  - Treatment/strategy A is probably recommended/indicated in preference to treatment B
  - It is reasonable to choose treatment A over treatment B

CLASS IIb (WEAK) — Benefit ≥ Risk

Suggested phrases for writing recommendations:
- May/might be reasonable
- May/might be considered
- Usefulness/effectiveness is unknown/unclear/uncertain or not well established

CLASS III: No Benefit (MODERATE) — Benefit = Risk
(Generally, LOE A or B use only)

Suggested phrases for writing recommendations:
- Is not recommended
- Is not indicated/useful/effective/beneficial
- Should not be performed/administered/other

CLASS III: Harm (STRONG) — Risk > Benefit

Suggested phrases for writing recommendations:
- Potentially harmful
- Causes harm
- Associated with excess morbidity/mortality
- Should not be performed/administered/other

LEVEL (QUALITY) OF EVIDENCE‡

LEVEL A
- High-quality evidence‡ from more than 1 RCT
- Meta-analyses of high-quality RCTs
- One or more RCTs corroborated by high-quality registry studies

LEVEL B-R (Randomized)
- Moderate-quality evidence‡ from 1 or more RCTs
- Meta-analyses of moderate-quality RCTs

LEVEL B-NR (Nonrandomized)
- Moderate-quality evidence‡ from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies
- Meta-analyses of such studies

LEVEL C-LD (Limited Data)
- Randomized or nonrandomized observational or registry studies with limitations of design or execution
- Meta-analyses of such studies
- Physiological or mechanistic studies in human subjects

LEVEL C-EO (Expert Opinion)

Consensus of expert opinion based on clinical experience

Opportunities for quality improvement

1. Promoting appropriate care
2. Reducing inappropriate or harmful care
3. Reducing variations in delivery of care
4. Improving access to care
5. Improving knowledge base across disciplines
6. Educating and empowering clinicians and patients
7. Facilitating coordination and continuity of care
8. Facilitating ethical care

Suggested action terms

- Test
- Prescribe
- Perform
- Educate/counsel
- Dispose
- Monitor
- Refer/consult
- Prepare
- Document
- Advocate
- Diagnose/conclude

You try!

AAO-HNS Clinical practice guidelines

1. Define clinical problem
    1. Relevant to primary care. Commonly seen problems. Written for "first contact" care.
2. Systematic reviews
3. Development of guideline
    1. Search for "best available" evidence
    2. Incorporate expert opinion and patient preferences
        1. Panel includes patient advocates
    3. Multidisciplinary team
        1. Including primary care guideline/evidence experts

Rosenfeld RM, Shiffman RN. Clinical practice guidelines: a manual for developing evidence-based guidelines to facilitate performance measurement and quality improvement. Otolaryngol Head Neck Surg 2006;135(Suppl):S1-S28.

What should we do about the guideline madness?

- Read and implement guidelines with skepticism
- Find trusted organizations following the IOM standards and (critically) read their guidelines
- Apply the most conservative, least interventional guidelines first
- You are stuck knowing the guidelines “everybody is talking about.”
- Be a leader
- Hope