
Edward L. Langston, MD, AMA Board Member
NMMS Annual Meeting
May 7, 2010
Objectives

- Participant will understand the history of Clinical Practice Guideline (CPG) development
- Participant will understand how CPGs are developed
- Participant will have a greater appreciation and understanding for how CPGs can be used in clinical practice
History of Clinical Practice Guidelines (CPGs)

- What is a CPG?
- Who develops them?
- Landmarks in CPG development, use, evolution
What is a CPG?

IOM definition:

*Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.*

Institute of Medicine, 1990. *Clinical Practice Guidelines: Directions for a New Program*
Who develops CPGs?

- Medical specialty societies, including:
  - American Academy of Ophthalmology
  - American College of Cardiology/American Heart Association
  - American College of Obstetricians and Gynecologists*
  - American College of Obstetricians and Gynecologists* including CPGs for breast, cervical, and/or prostate cancer
  - American College of Radiology*
  - American Urological Association*

* including CPGs for breast, cervical, and/or prostate cancer
Who develops CPGs?

• Government agencies, including:
  • United States Preventive Services Task Force (USPSTF)*
  • Centers for Disease Control and Prevention (CDC)
  • National Heart, Lung, and Blood Institute (NHLBI)

* including CPGs for breast, cervical, and/or prostate cancer
Who develops CPGs?

- Other public or private entities, including:
  - American Cancer Society*
  - Institute for Clinical Systems Improvement*
  - National Kidney Foundation

* including CPGs for breast, cervical, and/or prostate cancer
Landmarks in CPG development, use, evolution

- 1990: IOM proposed a new program of guideline development to reduce inappropriate health care variation by assisting patient and practitioner decisions
- 1990 – 2003: Various proposals for CPG standardization
- 2000 – present: Growing interest in deriving performance measures from CPG recommendations
- 1999: National Guideline Clearinghouse launched
National Guideline Clearinghouse

- Launched in 1999 by AHRQ, AMA, and American Association of Health Plans
- Features include: Structured abstracts, summarized recommendations, side-by-side comparisons
- Searchable by date, specialty, methodology, etc.
- Content as of Jan. 2009: 2373 guidelines, from 285 organizations
- www.guideline.gov
Development of Clinical Practice Guidelines

- Key elements, process steps
- Proposals for standardization
- Specialty-specific CPG development methodologies
- Evidence and strength of recommendation ratings
Key elements, process steps in CPG development

1. Define topic
2. Identify leadership and content experts
3. Select methodology for literature search
4. Conduct evidence review
5. Develop recommendations
6. External review
Proposals for guideline standardization

• AMA, 1990: Proposal of a standardized methodology for “practice parameter” development\(^1\)

• 2001, Appraisal of Guidelines for Research & Evaluation (AGREE) Instrument: Result of a UK initiative to establish criteria for consistent evaluation of guideline quality\(^2\)

• 2003, Conference on Guideline Standardization (COGS) checklist: Essential steps in the CPG development process, from an AHRQ-funded collaboration among experts in CPG development and implementation\(^3\)

3 Shiffman RN, et. al. Annals of Internal Medicine, 2003
# Scope and Purpose

1. The overall objective(s) of the guideline is (are) specifically described.

2. The clinical question(s) covered by the guideline is (are) specifically described.

3. The patients to whom the guideline is meant to apply are specifically described.

# Stakeholder Involvement

4. The guideline development group includes individuals from all the relevant professional groups.

5. The patients’ views and preferences have been sought.

6. The target users of the guideline are clearly defined.

7. The guideline has been piloted among target users.

# Rigor of Development

8. Systematic methods were used to search for evidence.

9. The criteria for selecting the evidence are clearly described.

10. The methods used for formulating the recommendations are clearly described.

11. The health benefits, side effects and risks have been considered in formulating the recommendations.

12. There is an explicit link between the recommendations and the supporting evidence.

13. The guideline has been externally reviewed by experts prior to its publication.

14. A procedure for updating the guideline is provided.

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## Appraisal of Guidelines Research & Evaluation (AGREE) Instrument

<table>
<thead>
<tr>
<th>Clarity and Presentation</th>
<th>15. The recommendations are specific and unambiguous.</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>16. The different options for management of the condition are clearly presented.</td>
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<tr>
<td></td>
<td>17. Key recommendations are easily identifiable.</td>
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<td></td>
<td>18. The guideline is supported with tools for application.</td>
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<tr>
<td>Applicability</td>
<td>19. The potential organisational barriers in applying the recommendations have been discussed.</td>
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<td></td>
<td>20. The potential cost implications of applying the recommendations have been considered.</td>
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<tr>
<td></td>
<td>21. The guideline presents key review criteria for monitoring and/or audit purposes.</td>
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<tr>
<td>Editorial Independence</td>
<td>22. The guideline is editorially independent from the funding body.</td>
</tr>
<tr>
<td></td>
<td>23. Conflicts of interest of guideline development members have been recorded.</td>
</tr>
</tbody>
</table>

## Conference on Guideline Standardization (COGS) checklist for clinical practice guidelines

<table>
<thead>
<tr>
<th>1. Overview material</th>
<th>Provide a structured abstract that includes the guideline’s release date, status (original, revised, updated), and print and electronic sources.</th>
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<tbody>
<tr>
<td>2. Focus</td>
<td>Describe the primary disease/condition and intervention/service/technology that the guideline addresses. Indicate any alternative preventive, diagnostic or therapeutic interventions that were considered during development.</td>
</tr>
<tr>
<td>3. Goal</td>
<td>Describe the goal that following the guideline is expected to achieve, including the rationale for development of a guideline on this topic.</td>
</tr>
<tr>
<td>4. Users/setting</td>
<td>Describe the intended users of the guideline (e.g., provider types, patients) and the settings in which the guideline is intended to be used.</td>
</tr>
<tr>
<td>5. Target population</td>
<td>Describe the patient population eligible for guideline recommendations and list any exclusion criteria.</td>
</tr>
<tr>
<td>6. Developer</td>
<td>Identify the organization(s) responsible for guideline development and the names/credentials/potential conflicts of interest of individuals involved in the guideline’s development.</td>
</tr>
<tr>
<td>7. Funding source/sponsor</td>
<td>Identify the funding source/sponsor and describe its role in developing and/or reporting the guideline. Disclose potential conflict of interest.</td>
</tr>
<tr>
<td>8. Evidence collection</td>
<td>Describe the methods used to search the scientific literature, including the range of dates and databases searched, and criteria applied to filter the retrieved evidence.</td>
</tr>
<tr>
<td>9. Recommendation grading criteria</td>
<td>Describe the criteria used to rate the quality of evidence that supports the recommendations and the system for describing the strength of the recommendations. Recommendation strength communicates the importance of adherence to a recommendation and is based on both the quality of the evidence and the magnitude of anticipated benefits or harms.</td>
</tr>
</tbody>
</table>

Conference on Guideline Standardization (COGS) checklist for clinical practice guidelines

<table>
<thead>
<tr>
<th>10. Method for synthesizing evidence</th>
<th>Describe how evidence was used to create recommendations, e.g., evidence tables, meta-analysis, decision analysis.</th>
</tr>
</thead>
<tbody>
<tr>
<td>11. Prerelease review</td>
<td>How guideline developer reviewed/ tested guideline prior to release.</td>
</tr>
<tr>
<td>12. Update plan</td>
<td>Developer’s plan to update the guideline (if any) and expiration date for this version (if applicable).</td>
</tr>
<tr>
<td>13. Definitions</td>
<td>Definitions of unfamiliar terms and those that may be subject to misinterpretation.</td>
</tr>
<tr>
<td>14. Recommendations and rationale</td>
<td>Precise statement of each recommended action and circumstances under which to perform it, with linkage between recommendation and supporting evidence.</td>
</tr>
<tr>
<td>15. Potential benefits and harms</td>
<td>Anticipated benefits and potential harms associated with implementation of guideline recommendations.</td>
</tr>
<tr>
<td>16. Patient preferences</td>
<td>Role of patient preferences, when an element of personal choice or values is relevant to a recommendation.</td>
</tr>
<tr>
<td>17. Algorithm</td>
<td>Provide (when appropriate) a graphical description of the stages and decisions in clinical care described by the guideline.</td>
</tr>
<tr>
<td>18. Implementation considerations</td>
<td>Describe anticipated barriers to application of the recommendations. Provide reference to any auxiliary documents for providers or patients that are intended to facilitate implementation. Suggest review criteria for measuring changes in care when the guideline is implemented.</td>
</tr>
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</table>

Specialty-specific CPG development methodologies

- Examples:
  - American College of Cardiology Foundation/American Heart Association
  - American Academy of Otolaryngology–Head and Neck Surgery Foundation

One example of an element of CPG development methodology where much variation can be found among developers:
Evidence and strength of recommendation ratings

U. S. Preventive Services Task Force (USPSTF) Grades of Recommendation

- **Grade A** – USPSTF strongly recommends that clinicians provide [the service] to eligible patients. Good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.

- **Grade B** – USPSTF recommends that clinicians provide [the service] to eligible patients. At least fair evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.

- **Grade C** – USPSTF makes no recommendation for or against the routine provision of [the service]. At least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.

- **Grade D** – USPSTF recommends against routinely providing [the service] to asymptomatic patients. At least fair evidence that [the service] is ineffective or that harms outweigh benefits.

- **Grade I** – USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. Evidence that [the service] is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

### ACCF/AHA Classification of Recommendations and Level of Evidence

<table>
<thead>
<tr>
<th>Size of Treatment Effect</th>
<th>Class I</th>
<th>Class IIa</th>
<th>Class IIb</th>
<th>Class III</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Benefit &gt; Risk</em></td>
<td>Procedure/treatment <strong>SHOULD</strong> be performed/administered</td>
<td>Procedure/treatment <strong>REASONABLE</strong> to perform procedure/administer treatment</td>
<td>Procedure/treatment <strong>MAY BE CONSIDERED</strong></td>
<td>Procedure/treatment <strong>should NOT</strong> be performed/administered</td>
</tr>
<tr>
<td><em>Benefit &gt; Risk</em></td>
<td>Recommendation that procedure or treatment is useful/effective</td>
<td>Recommendation in favor of treatment or procedure being useful/effective</td>
<td>Recommendation’s usefulness/efficacy less well established</td>
<td>Recommendation that procedure or treatment is not useful/effective and may be harmful</td>
</tr>
<tr>
<td><em>Benefit ≥ Risk</em></td>
<td>Sufficient evidence, multiple randomized trials or meta-analyses</td>
<td>Some conflicting evidence, multiple randomized trials or meta-analyses</td>
<td>Greater conflicting evidence, multiple randomized trials or meta-analyses</td>
<td>Sufficient evidence, multiple randomized trials or meta-analyses</td>
</tr>
<tr>
<td><em>Benefit ≥ Risk</em></td>
<td>Limited evidence, single randomized trial/nonrandomized studies</td>
<td>Some conflicting evidence, single randomized trial or nonrandomized studies</td>
<td>Greater conflicting evidence, single randomized trial/nonrandomized studies</td>
<td>Limited evidence, single randomized trial or nonrandomized studies</td>
</tr>
<tr>
<td><em>Benefit ≥ Risk</em></td>
<td>Only expert opinion, case studies, or standard-of-care</td>
<td>Only diverging expert opinion, case studies, or standard-of-care</td>
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<td>Only expert opinion, case studies, or standard-of-care</td>
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(excerpt from full ACCF/AHA rating scheme; see [www.acc.org/qualityandscience/clinical/statements.htm](http://www.acc.org/qualityandscience/clinical/statements.htm))
Evidence and strength of recommendation ratings

IOM recommendations on “common language”

“… a common language that describes both the quality of the underlying evidence and the strength of recommendations is an important tool for promoting greater consistency among clinical practice guideline developers… [and] will reduce the requirements placed on end users in… navigating all the various terms, symbols, and expressions that currently exist.”

Integration of CPGs into clinical practice

- Clinical decision support
- Performance measurement
- Unintended consequences & unresolved issues
Clinical decision support systems

- Integration of CPGs & critical pathways to generate suggestions for appropriate care
- Input of patient-specific clinical variables enables patient-specific recommendations
- May facilitate and promote use of CPG recommendations in practice

For those who do not have access to these systems, here’s a more practical approach…
Performance measurement

“You cannot improve what you do not measure”
Performance measurement

Physician Consortium for Performance Improvement® (PCPI)

- Established in 2000, convened and staffed by the AMA
- PCPI: A national physician-led initiative committed to enhancing quality of care and patient safety by taking the lead in the development, testing, and maintenance of evidence-based clinical performance measures and measurement resources for physicians
- Individual, multidisciplinary work group convened for each measure topic
Performance measurement

Physician Consortium for Performance Improvement®

- Over 170 member organizations
  - Medical specialty societies
  - State medical societies
  - Medical board representatives
  - AHRQ, CMS, The Joint Commission, NCQA
- Current measures portfolio
  - 43 measurement sets
  - 270+ individual measures
- 117 NQF-endorsed® measures
- Of 179 measures in PQRI 2010, 122 were developed (or co-developed) by the PCPI (68%)
- www.physicianconsortium.org
Performance measures: A means to promote adherence to guideline recommendations

**From PCPI Prostate Cancer measure set:**

Measure: *Adjuvant Hormonal Therapy for High-Risk Patients*

- Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high risk of recurrence, receiving external beam radiotherapy to the prostate who were prescribed adjuvant hormonal therapy

... derived from CPG recommendations:
Performance measures: A means to promote adherence to guideline recommendations

**PCPI **Adjuvant Hormonal Therapy **measure**

**CPG recommendations:**

- High risk patients… considering specific treatment options should be informed of findings of recent high quality clinical trials, including that: for those considering external beam radiotherapy, use of hormonal therapy combined with conventional radiotherapy may prolong survival. (AUA\(^1\)) ("Standard" recommendation)

- Men with prostate cancer that is clinically localized stage T3a, with Gleason score of 8 to 10, or PSA level >20 ng/mL are categorized… to be at high risk of recurrence after definitive therapy… Hormonal therapy (eg, androgen ablation) plus external-beam RT is recommended. (NCCN\(^2\)) ("Category 1" recommendation)

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Integration of measures & CPG recommendations into reporting & incentive programs

- CMS Physician Quality Reporting Initiative (PQRI, “pay-for-reporting”)
- Private plan incentive programs (“pay-for-performance”)
- ABMS Member Board “maintenance of certification” (MOC) programs
National Quality Measures Clearinghouse™

- Launched by AHRQ in 2002
- Structured abstracts, links to CPG recommendations (NGC)
- >220 PCPI measures listed currently
- www.qualitymeasures.ahrq.gov
Unintended consequences & unresolved issues related to CPGs and measures

- Potential to promote inappropriate care for older patients with multiple comorbid diseases

- CPGs must explicitly indicate strength of evidence underlying recommendations; many based on expert opinion

1 Boyd CM, et al. JAMA, 2005
Unintended consequences & unresolved issues related to CPGs and measures

Strength of evidence/expert opinion – **Example:**

**Use of Prostate-Specific Antigen (PSA) for Early Detection of Prostate Cancer**

- Because there is now evidence from a randomized, controlled trial regarding a mortality decrease associated with PSA screening, AUA is recommending PSA screening… for well-informed men who wish to pursue early diagnosis.

- Proportion of clinically significant prostate cancer detected with PSA is unknown.

- The three most common prostatic diseases – prostatitis, benign prostatic hyperplasia (BPH), and prostate cancer – can all be associated with elevated serum PSA levels.

“Policy statements and recommendations are based on review of the literature and the panel members' own expert opinions or consensus.”

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Unintended consequences & unresolved issues related to CPGs and measures

Disclosure of Potential Conflicts

“If guidelines continue to exist, they need to undergo major changes… not only creating codes to “govern conflict of interest,” as disclosure and governance alone will not ensure unbiased recommendations, but also by guideline panel membership limiting (if not excluding) those with financial or other potential conflicts of interest or at least being balanced by members having no conflicts of interest.”

Unintended consequences & unresolved issues related to CPGs and measures

- Other calls for reform in CPG development\(^1\):
  - Multi-disciplinary expertise in writing groups
  - Minority opinions disclosed
  - Independent, pre-publication review
  - No industry sponsorship

\(^1\) Sniderman AD, Furberg CD. JAMA 2009
Review of objectives

- History of clinical practice guideline development
- How CPGs are developed
- Integration of CPGs into clinical practice