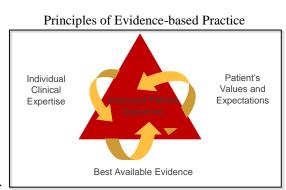
## Evidence-based Clinical Practice Guidelines: The Foundation for Clinical Practice

Linda Hatfield PhD, NNP-BC: Assistant Professor of Evidence-based Practice University of Pennsylvania School of Nursing Director of Research and Evidence-based Practice Pennsylvania Hospital



- When caring for patients healthcare providers are often faced with difficult decisions and a significant amount of uncertainty
- We rely on the best available evidence, our expertise and the patient's preferences



Sackett DL, Rosenberg MC, Gray JA, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. BMJ. 1996;312:71-72.

#### **Clinical Practice Guidelines**

- Clinical practice guidelines are statements that include recommendations intended to optimize patient care
- They are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options



Wolf, J. S., Jr., Hubbard, H., Faraday, M. M., & Forrest, J. B. (2011). Clinical practice guidelines to inform evidence-based clinical practice. World Journal of Urology, 29(3), 303-309. doi: 10.1007/s00345-011-0656-5

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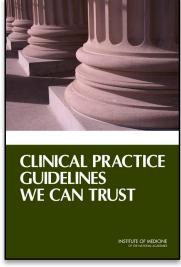
- The plethora of clinical practice guidelines make it challenging for practitioners to identify high quality guidelines
- Practitioners need a valid and reliable, scientific process to identify high quality, trustworthy clinical practice guidelines



Clinical Quality and Safety The Royal Children's Hospital. (2007). Clinical practice guidelines a guide for clinicians. Retrieved September 20, 2015, from http://www.slideshare.net/abenedicto/clinical-practice-guidelines

# What are Evidence-based Practice Clinical Practice Guidelines?

The Institute of Medicine defines clinical practice guidelines as "...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."



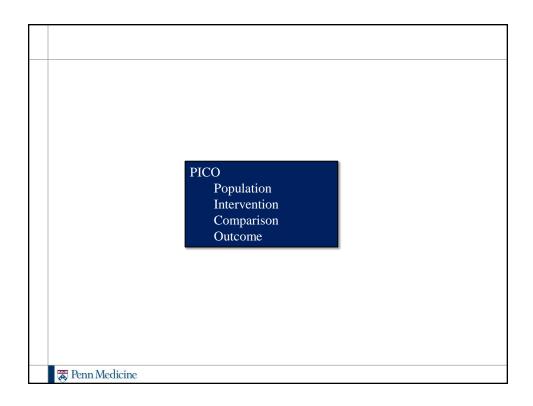
IOM (Institute of Medicine). (2011). Clinical Practice Guidelines We Can Trust. Washington DC: National Academies Press.

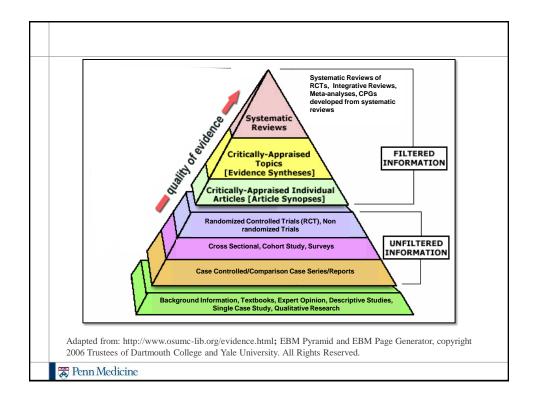
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# **Components of Evidence-based Clinical Practice Guidelines**

- Based on this definition of evidence-based clinical practice guidelines; guidelines have two parts:
  - Part I: The quality of the guideline
    - It is a transparent process of a systematically reviewing the research evidence to answer a clinical question (in PICO format)
    - The quality of the guideline is focused on the strength of the evidence
    - The level of evidence guides the clinical decisionmaking for the condition

Snesene, P. (2014). Unitical Fractice Guidenines. UptionAnt. Retrieved September 18., 2015, from <a href="http://www.nousmeib.org/evidence.html">http://www.nousmeib.org/evidence.html</a>, EBM Pyramid and EBM Page Generator, copyright 2006 Trustees of Dartmouth College and Yell University. All Rights Reserved.





# Components of Evidence-based Clinical Practice Guidelines

- Part II: A set of recommendations addressing how patients with that condition should be managed.
- The recommendations should consider the best available evidence, the clinician's expertise regarding benefits and harms of alternative care options and the patient's value judgments

Shekelle, P. (2014), Clinical Practice Guidelines. UpToDate. Retrieved September 18., 2015. from http://www.uptodate.com/contents/clinical-practice-guidelines

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#### **Evidence-based Clinical Practice Guidelines**

• Thus, a meaningful answer to the question "What are evidence based clinical practice guidelines?"

Evidence-based CPGs are a series of recommendations on clinical care, supported by the best available evidence in the clinical literature

Watters, W. C. (2008). Defining evidence-based clinical practice guidelines. AAOS Now. Retrieved September 20, 2015 from http://www.aaos.org/news/aaosnow/jul08/research2.asp

## **Typical Clinical Practice Guidelines (CPGs)**

- CPGs (aka position statements) have been used for a long time
- Early efforts to develop CPGs were intended to support highquality care and were consensus-driven
- In a consensus-driven process, a panel of experts on a certain topic are brought together, a literature review is done, and a document of recommendations is produced based on the consensus of the review panel

Watters, W. C. (2008). Defining evidence-based clinical practice guidelines. AAOS Now. Retrieved September 20, 2015 from http://www.aaos.org/news/aaosnow/jul08/research2.asp

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# Are Evidence-based CPGs Superior to Typical CPGs?

- CPG were meant to be unbiased, however, typical CPG or position statements reflecting best care were problematic
- The development process was not transparent and experts were biased toward their own treatment goals
- The same literature review could be reviewed by a different group (industry or insurance companies) to derive different conclusions consistent with their goals
- These outcomes provided support that the approach was biased and untenable
- Healthcare professionals and patients felt confused and cheated when care decisions were based on guidelines more oriented to personal or economic rather than quality goals

Watters, W. C. (2008). Defining evidence-based clinical practice guidelines. AAOS Now. Retrieved September 20, 2015 from http://www.aaos.org/news/aaosnow/jul08/research2.asp

# Evidence-based CPGs <u>ARE</u> Superior to Typical CPGs

- By applying the process of evidence-based practice in guideline development, opinion—and thus bias—is significantly reduced
- The value of the strong scientific findings elevated and evaluated in a systematic fashion to provide transparency and minimize bias in evidence-based CPGs
- Evidence-based CPGs <u>ARE</u> thus superior to non-evidencebased CPGs and are true instruments of improved patient care

Watters, W. C. (2008). Defining evidence-based clinical practice guidelines. AAOS Now. Retrieved September 20, 2015 from http://www.aaos.org/news/aaosnow/jul08/research2.asp

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# EVALUATING EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES

## **Medicare Improvements for Patients and**

## **Providers Act, 2008**

■ The U.S. Congress, through the Medicare Improvements for Patients and Providers Act of 2008, requested the IOM study the best methods used to develop clinical practice guidelines.

H. R. 6331

#### One Hundred Tenth Congress of the United States of America

AT THE SECOND SESSION

Begun and held at the City of Washington on Thursday, the third day of January, two thousand and eight

#### An Act

Be it enacted by the Senate and House of Repre the United States of America in Congress assembled, SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SRORT TITLE—This Act may be cited as the "Medicare Improvements for Patients and Providers Act of 2008".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

TITLE I—MEDICARE
Subtitle A—Beneficiary Improve

Subtitle A—Beneficiary Improvements

PART I—PARTENTION, MORAL HALMIT, AND MAKETIMO

Soc. 101. Improvements to coverage of preventive services.

Soc. 102. Elimination of discriminatory copayment rates for Medicare outpatient psychiatric services.

Soc. 103. Prohibition and limitations on certain sales and marketing activities services.

Soc. 104. Improvements to the Medigap program.

Rangel, C. (2008). H.R. 6331 - 110th Congress: Medicare Improvements for Patients and Providers Act of 2008. Retrieved September 20, 2015, from https://www.govtrack.us/congress/bills/110/hr6331

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Title III: Miscellaneous - (Sec. 301) Amends the Deficit Reduction Act of 2005 to extend through FY2009 supplemental grants under SSA title IV part D (Temporary Assistance for Needy Families) (TANF).

(Sec. 302) Amends SSA title IV part E (Federal Payments for Foster Care and Adoption Assistance) to set at 70% the federal matching rate for foster care and adoption assistance for the District of Columbia.

(Sec. 303) Amends the Public Health Service Act to extend through FY2011 special diabetes grant programs for Type I diabetes and for Indians.

(Sec. 304) Directs the Secretary to contract with the Institute of Medicine (IOM) of the National Academies to identify, and report to the Secretary and Congress on, the methodological standards for conducting systematic reviews of clinical effectiveness research on health and health care in order to ensure that reviewing organizations have objective, scientifically valid, and consistent information on methods.

Requires the Secretary to contract with the IOM, also, to study and report to the Secretary and the appropriate congressional committees on the best methods used in developing clinical practice guidelines in order to ensure that organizations developing such guidelines have objective, scientifically valid, and consistent information on approaches.

#### **CONGRESS.GOV**

The IOM developed eight standards for developing rigorous, trustworthy clinical practice guidelines

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## IOM Standards for Developing Rigorous, Trustworthy Clinical Practice Guidelines

- STANDARD 1 Establish transparency
- STANDARD 2
   Management of conflict of interest (COI)
- STANDARD 3
   Guideline development group composition
- STANDARD 4
   Clinical practice guideline—systematic review intersection
- STANDARD 5
   Establish evidence foundations for and rating strength of recommendations
- STANDARD 6
   Articulation of recommendations
- STANDARD 7 External review
- STANDARD 8 Updating

IOM (Institute of Medicine). (2011). Clinical Practice Guidelines We Can Trust. Washington DC: National Academies Press

## **Establishing Transparency**

 The processes by which a CPG is developed and funded should be detailed explicitly and publicly accessible



Retrieved from: http://one-org.s3.amazonaws.com/us/wp-content/uploads/2014/09/Corruption4-655x436-600x399 ing

 $Institute \ of \ Medicine. \ (2011). \ Clinical \ practice \ guidelines \ we \ can \ trust. \ Retrieved \ from \ Washington \ DC: \ http://www.nap.edu/download.php?record\_id=13058$ 

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#### **STANDARD 2**

## **Management of Conflict of Interest (COI)**

 Prior to selection of the Guideline Development Group (GDG), individuals being considered for membership should declare all interests and activities potentially resulting in COI with development group activity, by written disclosure to those convening the GDG

Some Highlights of Institute of Medicine Report on

Conflict of Interest in Medical Research, Education, and Practice

As Related to Practice Guidelines

Remarks by
Robert Krughoff, President
Consumers' CHECKBOOK (Center for the Study of Services

AHRQ 2009 Annual Conference

Institute of Medicine. (2011). Clinical practice guidelines we can trust. Retrieved from Washington DC: http://www.nap.edu/download.php?record\_id=13058

## **Composition of Guideline Development Group**

- The GDG should be multidisciplinary and balanced, comprising a variety of methodological experts and clinicians, and populations expected to be affected by the CPG
- Patient and public involvement should be facilitated by including a current or former patient and a patient advocate or patient consumer organization



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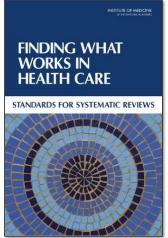
nstitute of Medicine (2011) Clinical practice guidelines we can trust. Retrieved from Washington DC: http://www.nan.edu/download.nhn?record\_id=13058

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#### **STANDARD 4**

# Clinical Practice Guideline – Systematic Review Intersection

 CPG developers should use systematic reviews that meet standards set by the Institute of Medicine's Committee on Standards for Systematic Reviews of Comparative Effectiveness Research



Retrieved from: https://iom.nationalacademies.org/Reports/2011/Finding What-Works-in-Health-Care-Standards-for-Systematic-Reviews aspx

Institute of Medicine. (2011). Clinical practice guidelines we can trust. Retrieved from Washington DC: http://www.nap.edu/download.php?record\_id=13058

# **Establishing Evidence Foundations for and Rating Strength of Recommendations**

- For each recommendation, the following should be provided:
  - An explanation of the reasoning underlying the recommendation, including:
  - A clear description of potential benefits and harms
  - A summary of relevant available evidence (and evidentiary gaps), description
    of the quality (including applicability), quantity (including completeness), and
    consistency of the aggregate available evidence
  - An explanation of the part played by values, opinion, theory, and clinical experience in deriving the recommendation
  - A rating of the level of confidence in (certainty regarding) the evidence underpinning the recommendation
  - A rating of the strength of the recommendation in light of the preceding bullets
  - A description and explanation of any differences of opinion regarding the recommendation

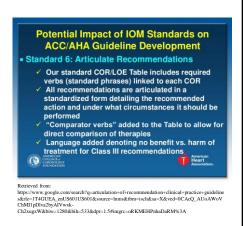
Institute of Medicine. (2011). Clinical practice guidelines we can trust. Retrieved from Washington DC: http://www.nap.edu/download.php?record\_id=13058

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#### **STANDARD 6**

#### **Articulation of Recommendations**

- Recommendations should be articulated in a standardized form detailing precisely what the recommended action is and under what circumstances it should be performed
- Strong recommendations should be worded so that compliance with the recommendation(s) can be evaluated



Institute of Medicine. (2011). Clinical practice guidelines we can trust. Retrieved from Washington DC: http://www.nap.edu/download.php?record\_id=13058

#### **External Review**

 External reviewers should comprise a full spectrum of relevant stakeholders, including scientific and clinical experts, organizations (e.g., health care, specialty societies), agencies (e.g., federal government), patients, and representatives of the public



tetrieved from: http://bestpracticenet.co.uk/sites/default/files/program-detail-images/discussion-5.png

Institute of Medicine. (2011). Clinical practice guidelines we can trust. Retrieved from Washington DC: http://www.nap.edu/download.php?record\_id=13058

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#### **STANDARD 8**

## **Updating**

- The CPG publication date, date of systematic evidence review, and proposed date for future CPG review should be documented in the CPG
- Literature should be reviewed regularly to identify new, potentially relevant evidence and to evaluate the continued validity of the CPG
- CPGs should be updated when new evidence suggests the need for modification of clinically important recommendations



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Institute of Medicine. (2011). Clinical practice guidelines we can trust. Retrieved from Washington DC: http://www.nap.edu/download.php?record\_id=13058

# Appraisal of Guidelines for Research &

## **Evaluation (AGREE)**

- The AGREE II instrument was developed through a collaboration of international researchers and policy makers
- Addresses the variability in guideline quality by assessing the transparency and methodological rigor in guideline development
- Informs what and how information ought to be reported in guidelines



Brouwers, M. C. et al. (2010). AGREE II: advancing guideline development, reporting and evaluation in health care. CMAJ: Canadian Medical Association laurnal 187(18) 1839-1842. doi: 10.1503/cmai.090449

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# Appraisal of Guidelines for Research & Evaluation (AGREE)

- The AGREE II has 23 core items and two overall assessment items
- The 23 items are organized into six domains of practice guideline quality as follows
  - Domain 1- Scope and Purpose (3 items)
  - Domain 2- Stakeholder Involvement (3 items)
  - Domain 3- Rigour of Development (8 items)
  - Domain 4- Clarity of Presentation (3 items)
  - Domain 5- Applicability (4 items)
  - Domain 6- Editorial Independence (2 items)
- Overall assessment items: (1) quality of guideline and (2) should the recommendations be used in practice

Brouwers, M. C., et al. (2010). AGREE II: advancing guideline development, reporting and evaluation in health care. CMAJ: Canadian Medical Association Journal, 182(18), E839-E842. doi: 10.1503/cmaj.090449

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# **Appraisal of Guidelines for Research & Evaluation (AGREE)**

- Each item is rated using a 7 point scale with anchors ranging from "1 = Strongly Disagree" to "7 = Strongly Agree"
- Higher rated individual items lead to higher domain scores, which indicate that the reporting quality of a given practice guideline is high

Brouwers, M. C. et al. (2010). AGREE II: advancing guideline development, reporting and evaluation in health care. CMAJ: Canadian Medical Association Journal, 182(18), E839-E842. doi: 10.1503/cmaj.090449

etrieved from: http://www.agreetrust.org/

## **DOMAIN 1: Scope and purpose**

# ITEM 1: The health question(s) covered by the guideline is (are) specifically described

#### **Description:**

 A detailed description of the health questions covered by the guideline should be provided, particularly for the key recommendations, they need not be stated as questions

#### Where to Look:

Opening paragraphs/chapters for a description of the scope and purpose of the guideline.

**How to Rate:** *Item content includes the following CRITERIA:* 

- Target population
- Intervention(s) or exposure(s)
- Comparisons (if appropriate)
- Outcome(s)
- Health care setting or context

#### Additional CONSIDERATIONS:

- Is the item well written? Are the descriptions clear and concise?
- Is the item content easy to find in the guideline?
- Is there enough information provided in the question(s) for anyone to initiate the development of a guideline on this topic or to understand the patients/populations and contexts profiled in the guideline?

Retrieved from Agree Trust: http://www.agreetrust.org/

# Individual Scoring The health question(s) covered by the guidelines is (are) specifically described. Strongly Disagree 1 2 3 4 5 6 7 Comments Retrieved from: http://www.agreetrust.org/

Four apprais Domain 1 (S	C	•	g scores fo	or	
	Item 1	Item 2	Item 3	Total	
Appraiser 1	5	6	6	17	
Appraiser 2	6	6	7	19	
Appraiser 3	2	4	3	9	
Appraiser 4	3	3	2	8	
Total	16	19	18	53	

## **Domain Scoring**

- Maximum possible score7 (strongly agree) x 3 (items) x 4 (appraisers) = 84
- Minimum possible score1 (strongly disagree) x 3 (items) x 4 (appraisers) = 12
- The scaled domain score will be:
   Obtained score Minimum possible score
   Maximum possible score Minimum possible score
- $\frac{53 12 \times 100}{84 12} \times 100 = \frac{41}{72} \times 100 = 0.5694 \times 100 = 57 \%$

Retrieved from: http://www.agreetrust.org/

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#### **AGREE II Overall Assessment**

- Each domain is scored independently
  - Useful for comparing guidelines
- Rate the overall quality of the guideline
  - 1: Lowest possible quality
  - 7: Highest possible quality
- Statement on whether the user recommends the guideline for use in practice:
  - Yes
  - Yes with modifications
  - No

Retrieved from: http://www.agreetrust.org/

#### **IOM -- AGREE II Concordance**

Institute of Medicine Standard	AGREE II Domain, item
Transparency	Domain 3, item 10
Conflict of Interest	Domain 6, items 22,23
Group composition	Domain 2, items 4, 5
Systematic review	Domain 3, items 7, 8
Evidence foundation	Domain 3, items 9, 11, 12
Articulation of recommendations	Domain 4, items 15, 16, 17, Domain 5, item 21
External Review	Domain 3, item 13
Updating	Domain 3, item 14

Adapted with permission: Umscheid, C. (August 2015). Trustworthy Guidelines TEACH Level II Workshop 3. Paper presented at the Teaching Evidence Assimilation for Collaborative Health Care, New York, New York.



## University of Pennsylvania Center for Evidence based Practice Trustworthy Guideline Appraisal Instrument

- Based on the 8 standards recommended by the IOM
- Assesses guideline methodologic reliability and development, not the level of evidence for guideline recommendations
- Distinguish between weaknesses in documentation (e.g. no documented guideline updating process) and weaknesses in the guidance itself (e.g. recommendations are outdated).
- Has been field tested at the New York Academy of Medicine Teaching Evidence Assimilation for Collaborative Healthcare program and the EBM curriculum at the Perelman School of Medicine
- Further work on validation of the instrument and comparison to other instruments is in progress

# **Exemplar: Assessment of Evidence-based Pain Guidelines**

Review

#### **Annals of Internal Medicine**

#### Opioid Prescribing: A Systematic Review and Critical Appraisal of Guidelines for Chronic Pain

Teryl K. Nuckols, MD, MSHS; Laura Anderson, MPH; Ioana Popescu, MD, MPH; Allison L. Diamant, MD, MSHS; Brian Doyle, MD; Paul Di Capua, MD; and Roger Chou, MD

Background: Deaths due to prescription opioid overdoses have increased dramatically. High-quality guidelines could help clinicians mitigate risks associated with opioid therapy.

Purpose: To evaluate the quality and content of guidelines on the use of opioids for chronic pain.

Data Sources: MEDLINE, National Guideline Clearinghouse, specialty society Web sites, and international guideline clearinghouses (searched in July 2013).

Study Selection: Guidelines published between January 2007 and July 2013 addressing the use of oploids for chronic pain in adults were selected. Guidelines on specific settings, populations, and conditions were excluded.

Data Extraction: Guidelines and associated systematic reviews were evaluated using the Appraisal of Guidelines for Research and Evaluation II (AGREE II) instrument and A Measurement Tool to Assess Systematic Reviews (AMSTAR), respectively, and recommendations for mitigating opioid-related risks were compared.

Data Synthesis: Thirteen guidelines met selection criteria. Overall

equivalents per day, have additional knowledge to prescribe methadone, recognize risks of fentanyl patches, titrate cautiously, and reduce doses by at least 25% to 50% when switching opioids. Guidelines also agree that opioid risk assessment tools, written treatment agreements, and urine drug testing can mitigate risks. Most recommendations are supported by observational data or expert corresnus.

Limitation: Exclusion of non-English-language guidelines and reliance on published information.

Conclusion: Despite limited evidence and variable development methods, recent guidelines on chronic pain agree on several opioid risk mitigation strategies, including upper dosing thresholds, cautions with certain medications; attention to drug-drug and drug-disease interactions; and use of risk assessment tools, treatment agreements, and urine drug testing. Future research should directly examine the effectiveness of opioid risk mitigation strategies.

Primary Funding Source: California Department of Industrial Relations and California Commission on Health and Safety and Workers' Compensation.

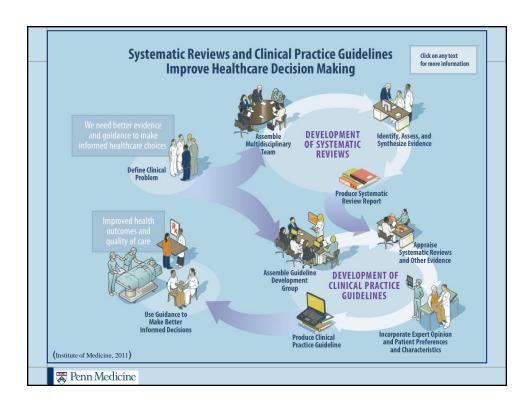
Nuckols, T. K., et al. (2014). Opioid Prescribing: A Systematic Review and Critical Appraisal of Guidelines for Chronic Pain. Annals of Internal Medicine, 160(1), 38-47.

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# Ratings Highest for American Pain Society and American Academy of Pain Medicine

Variable	Guideline Development Group (Reference)										Mean (Range), %			
	ACOEM (55)	AGS (51, 52)	APS-AAPM (13, 57, 58)	ASA (53)	ASIPP (49, 59)	NOUGG (46, 60–62)	Colorado DWC (19)	Fine et al (54)	ICSI (47)	UMHS (44)	UDOH (48, 50)	VA/DoD (45)	WLDI (56)	
AGREE II domain score, %														
Scope and purpose (the overall aim of the guideline, the specific health questions, and the target population)	78	68	89	72	85	76	53	39	86	51	49	88	69	69 (39–89)
Stakeholder involvement (the extent to which the guideline was developed by the appropriate stakeholders and represents the views of its intended users)	55	39	73	43	53	77	41	23	69	39	50	58	59	52 (23–77)
Rigor of development (the process used to gather and synthesize the evidence and the methods used to formulate and update the recommendations)	60	44	84	33	56	74	27	24	56	20	43	55	49	48 (20–84)
Clarity of presentation (the language, structure, and format of the guideline)	67	68	84	54	79	93	37	71	80	64	74	78	-*	71 (37–93)
Applicability (the likely barriers to and facilitators of implementation, strategies to improve uptake, and resource implications of applying the guideline)	55	30	41	21	40	56	13	28	41	46	42	42	31	37 (13–56)
Editorial independence (the influence of the funding body on development and disclosure of conflicts of interest)	75	63	88	2	69	56	0	23	52	37	48	8	50	44 (0–88)
Mean domain score	63	49	76	38	61	73	29	33	62	39	49	57	51	52 (28-76)
Overall outcome of guideline development			=											
Mean overall quality score  Votes to recommend use	4.75	4.00	6.20	3.00	4.67	6.00	3.00	3.40	4.50	3.60	3.60	4.75	3.50	4.23 (3.00-6.20
Yes, n (%)	2 (50)	1 (20)	5 (100)	0	1 (17)	3 (75)	0	1 (20)	2 (40)	0	0	1 (25)	_*	-
Yes, with modifications, n (%)	0	4 (80)	0	0	4 (67)	1 (25)	2 (40)	1 (20)	2 (40)	1 (20)	3 (60)	3 (75)	-21	-
No, n (%)	2 (50)	0	0	4 (100)	1 (17)	0	3 (60)	3 (60)	1 (20)	4 (80)	2 (40)	0	-*	-
Total votes. n	4	5	5	4	6	4	5	5	5	5	5	4		

Nuckols, T. K., et al. (2014). Opioid Prescribing: A Systematic Review and Critical Appraisal of Guidelines for Chronic Pain. Annals of Internal Medicine, 160(1), 38-47.



## **Implications for Clinical Practice**

- Nationally Trustworthy clinical practice guidelines are important in the development of performance measures for payfor-performance reimbursement programs
- Locally Inform and influence hospital guidelines to promote evidence based practices
  - Minimize the use of opinion-based guidelines
  - Can be used to challenge payors' decisions that are not based on high-quality evidence
- Individually Promotes good clinical practice by reviewing, rating, and synthesizing a large amount of literature and presenting an unbiased, evidence-based series of recommendations on clinical problems
  - EB CPGs serve to improve health care providers performance and patient outcomes

Watters, W. C. (2008). Defining evidence-based clinical practice guidelines. AAOS Now. Retrieved September 20, 2015 from http://www.aaos.org/news/aaosnow/jul08/research2.asp

