

Clinical Practice Guidelines and Quality Indicators

2004 Evidence-Based Decision-Making for Health
Policy Leaders Workshop

Session 7

December 7, 2004



Paul G. Shekelle, MD, PhD
West LA VAMC
RAND
Los Angeles, CA



Clinical Practice Guidelines Defined

- Clinical practice guidelines:
 - “...systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.”

(IOM, 1992)

Uses of Clinical Practice Guidelines

- Assist clinical decision-making
- Improve quality of care
- Educate patients
- Reduce costs
- Inform coverage and reimbursement decisions
- Guide resource allocation
- Reduce legal liability risks

Scientific Underpinnings of Clinical Practice Guidelines

- Guidelines specify processes, to be valid these processes should be related to improved outcomes.
- Guidelines are more likely to be valid if the processes are supported by evidence that the processes recommended will result (if followed) in improved health outcomes in the population of interest.

The Role of Evidence

- What is needed to improve the validity of guidelines is to assemble the evidence with as little bias as possible.
- Two common ways bias creeps into evidence.
 - By selective collection of available evidence (scientific studies).
 - Within individual scientific studies as a result of the design or conduct of the study.

The Role of Evidence (cont.)

- What is known about collecting evidence:
 - MEDLINE, EMBASE, and other computerized searches
 - Citation searches
 - Hand searches
 - Language restrictions
 - Unpublished material
 - Review by content experts

Synthesis of Evidence

- Meta-analysis
- Decision analysis
- Cost effectiveness analysis

The Role of Expert Panels

- Available evidence at best covers only about 20% of procedures/conditions.
- Available evidence may be from populations which differ from the target population of interest, or in health care delivery systems which differ from that of interest.
- “Expert panels” are commonly used to deal with both problems.

From Evidence to Recommendations

1. Guideline statements should be clear and as specific as the evidence will support.
2. Guideline statements should be linked to the evidence supporting them.
3. Guideline statements should be designated by the “strength of recommendation,” which is a combination of the strength of the evidence and the magnitude of the benefit and takes into account the economic implications and knowledge of the health care system.

What Elements are Important for a Guideline?

Empirical evidence supports the following:

- Based on a systematic review of the evidence
- Uses multidisciplinary expert group to interpret the evidence
- Produces clinically explicit recommendations
- Developed within the past 3 years

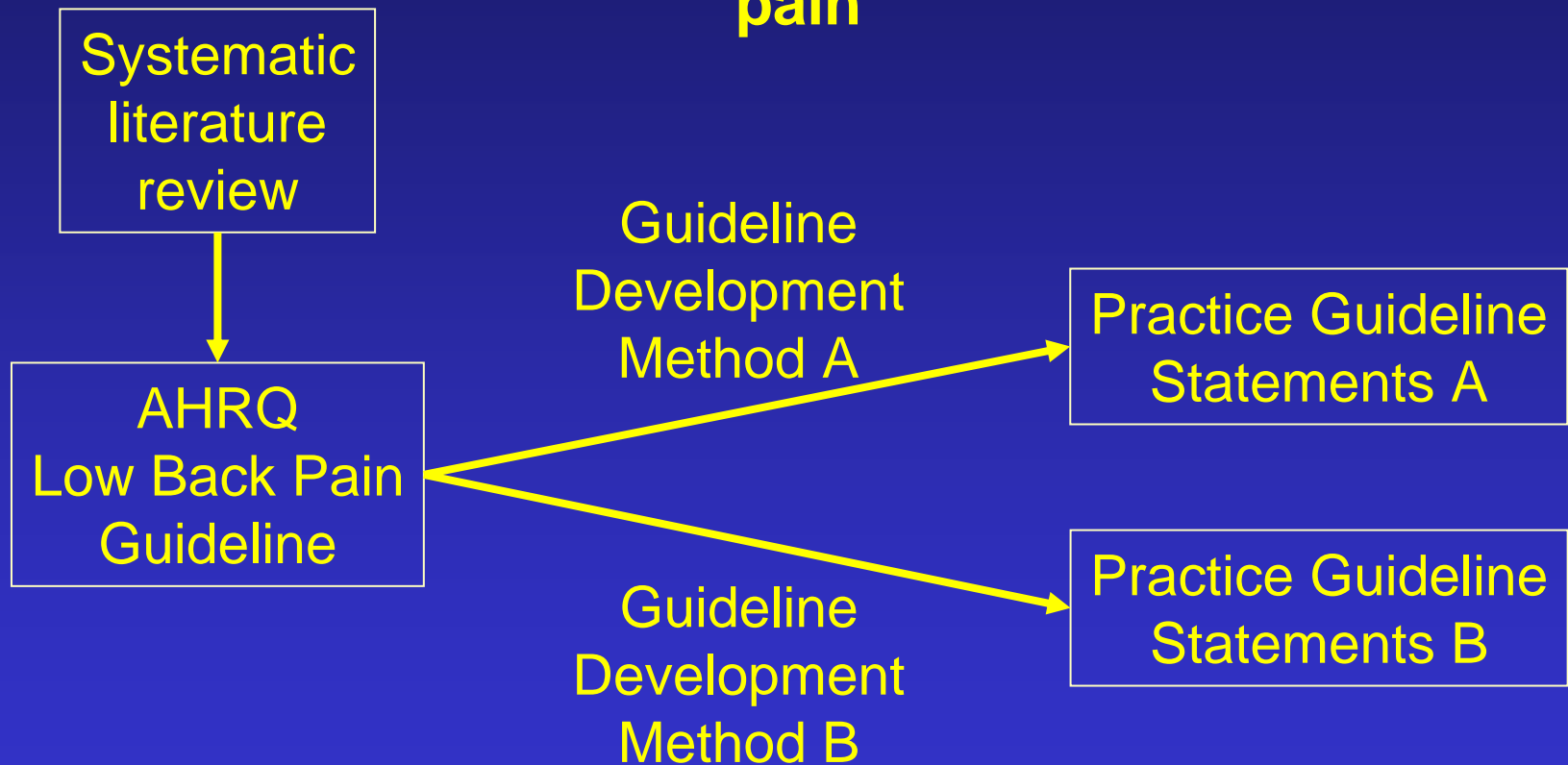
Single versus Mixed Expert Opinion

- Numerous observational analyses by independent groups have shown that recommendations developed by mixed groups of experts are systematically different than recommendations developed by single specialty groups
- We experimentally assessed this in England as part of a Delphi and confirmed this finding
- No direct evidence to say “who is right,” but some evidence and theory suggest mixed panels reach more valid decisions

Campbell. Medical Care 1999;37(9):964-968. Leape. Quality Assurance in Health Care 1992;4(2):151-159. Kahan. Medical Care 1994;32(4):357-365. Coulter. Health Services Research 1995;30(4):577-591. Kahan. Medical Care 1996;34(6):512-523. Fraser Int'l J for Quality in Health Care 1994;6(3):251-255.

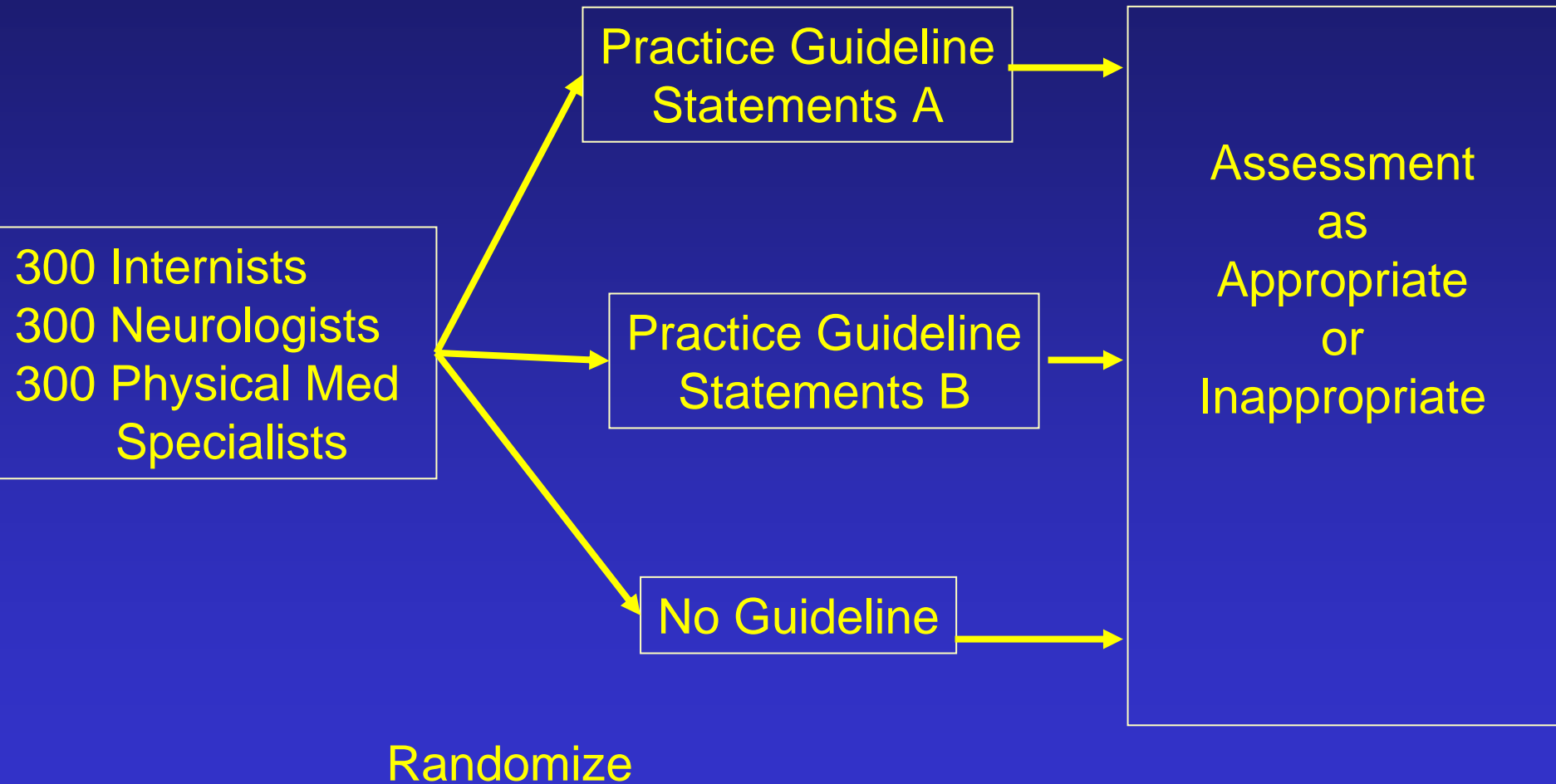
Are Non-specific Practice Guidelines Harmful?

Use of electrodiagnostic studies in patients with back pain



Shekelle. Health Services Research 2000;34(7):1429-1448.

Assessment of Guidelines



Results

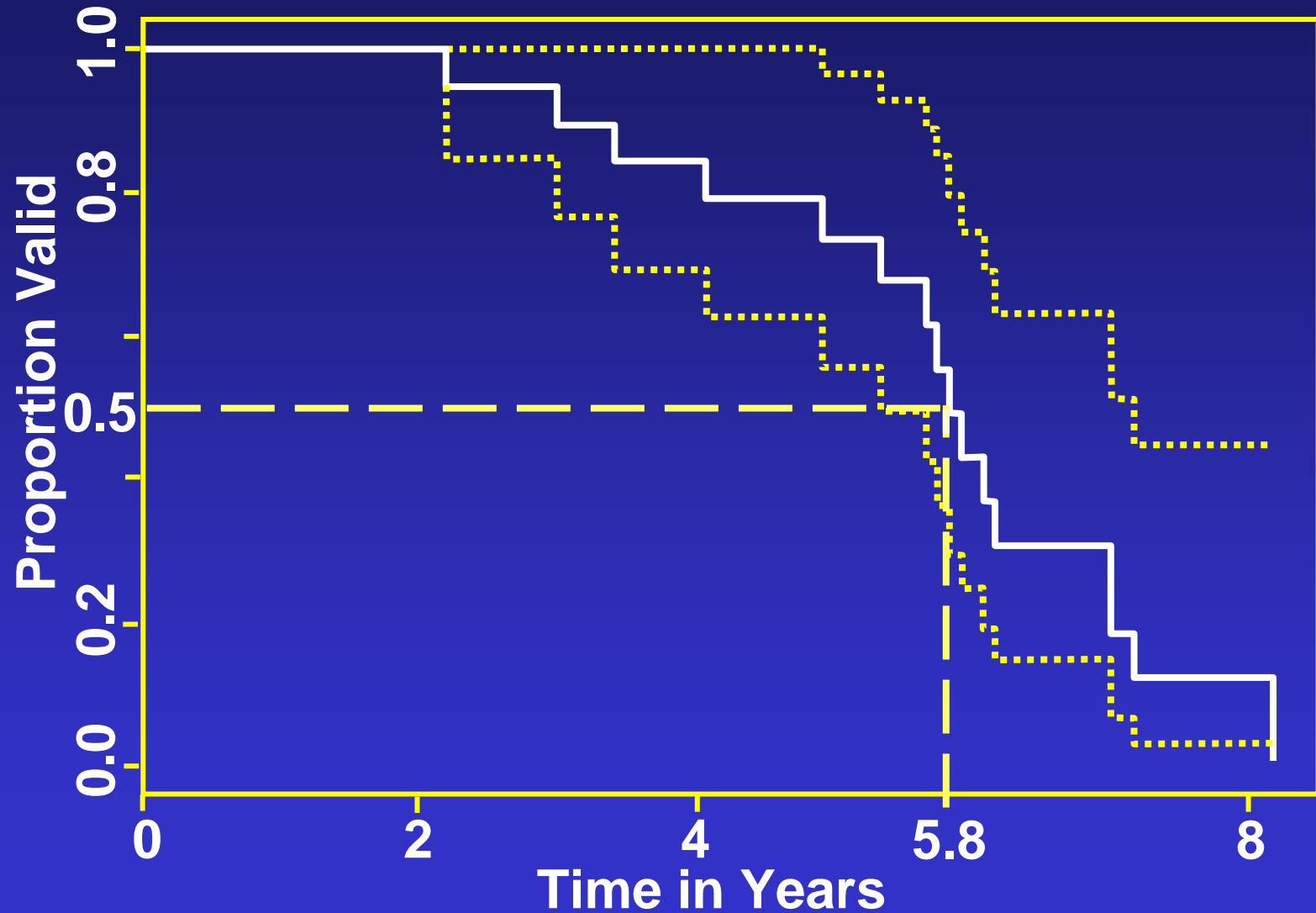
	Mean proportion of electrodiagnostic tests ordered			
Clinical Vignettes	No Guideline	Guideline A	Guideline B	
5 appropriate vignettes	77%	71%	79%	P=.002
5 inappropriate vignettes	32%	32%	27%	P=.08
Optimal test ordering	71%	68%	75%	P=.0002

How Quickly Do Guidelines Become Outdated?

- AHRQ developed 17 guidelines between 1990-1996
- In 2000, we assessed these for current validity using a mixture of focused literature reviews and expert judgment
- We determined:
 - 40% of guidelines needed a major update
 - 35% of guidelines needed a minor update

Shekelle. JAMA 2001;286:1461-1467.

How Quickly do Guidelines become Outdated?



Expert Opinion about How to Evaluate Guidelines

- Empirical data only take us so far
- Several groups have developed guideline appraisal instruments
 - Shaneyfelt
 - Cluzeau (AGREE)
<http://www.agreecollaboration.org>
 - COGS
 - JAMA

Most Practice Guidelines Do not Meet Criteria Considered Important for Development

- Compared 279 guidelines from 69 developer agencies to rigorously defined standards from 1985 - 6/97
- 51% of guidelines followed methodology for development and format
 - 34% followed standards for identification and summary of evidence (more than 25% did not cite references)
 - 46% followed standards for formulation of recommendations
- Quality of guideline development was improving over time

Shaneyfelt et al. JAMA 1999;281(20):1900-5

What happens now that AHRQ is no longer producing guidelines?

- AHRQ developed 19 guidelines between 1990-1996
 - 1 guideline was withdrawn (HIV)
 - 1 guideline was an update
- In 2000 we evaluated the remaining 17
- We identified 52 guidelines in the same topic areas published since release of the AHRQ guidelines
 - 5 guidelines specifically identified themselves as “updates”
- We assessed these guidelines using our modification of the instrument developed by Shaneyfelt (30 items)

Hasenfeld R and Shekelle P. Is the methodological quality of guidelines declining in the US? Comparison of the quality of US Agency for Health Care Policy and Research (AHCPR) guidelines with those published subsequently. Qual Saf Health Care. 2003 Dec;12(6):428-34.

Guidelines Developed Since AHRQ Guidelines

Score of 80% or
Greater on Criteria

AHRQ guidelines	24/ 30
“Update” guidelines	14/ 30
Other guidelines	11/ 30

Proportion of guidelines documenting a systematic review of the literature and use of a multidisciplinary expert panel

AHRQ guidelines	100%
“Update” guidelines	20%
Other guidelines	13%

Practice Guidelines Do They Work?

- Positive effects of practice guidelines are inextricably linked to the method of implementation.

Practice Guidelines

Methods of Implementation

- Printed materials → generally ineffective
- CME → ineffective
- Audit and feedback → moderately effective for simple guidelines (prescribing, test ordering)

Practice Guidelines

Methods of Implementation (cont.)

- Local opinion leaders → moderately effective
- Intensive conferencing → moderately effective
- Computerized tools → good for preventive test ordering, prescribing

Practice Guidelines

Methods of Implementation (cont.)

- Outreach (“detailing”) → good for prescribing behavior
- Multifaceted approaches → generally felt to be more effective, but we don’t know which ones to mix

Where can I find Practice Guidelines?

- The National Guideline Clearinghouse is sponsored by the Agency for Healthcare Research and Quality.
- Guidelines listed are contained in the Clearinghouse meet certain minimum criteria.
- www.guidelines.gov



NGC - National Guideline Clearinghouse - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address <http://www.guidelines.gov/>

Links Online Computing Helpdesk RAND External Home Page RAND Intranet Home Page

Google Search Web 49 blocked AutoFill Options

What's New Contact Us About Site Map Help


Search

Search

Browse

Compare

Resources



Search

20 Results Search

[Search Help](#)
[Detailed Search](#)

Resources

- » [Annotated Bibliographies](#)
- » [Bioterrorism](#)
- » [Discussion List](#)
- » [EPC Reports](#)
- » [FAQ](#)
- » [Glossary](#)
- » [Guideline Archive](#)
- » [Guideline Index](#)
- » [Guideline Resources](#)
- » [New Features](#)
- » [NLM Links](#)
- » [Patient Resources](#)
- » [PDA/Palm](#)
- » [SARS](#)
- » [Search Form](#)
- » [Web Developer Tools](#)

Browse

- » [Disease / Condition](#)
- » [Treatment / Intervention](#)
- » [Organization](#)

Welcome!

You are connected to the National Guideline Clearinghouse™ (NGC), a public resource for evidence-based clinical practice guidelines. NGC is an initiative of the [Agency for Healthcare Research and Quality \(AHRQ\)](#), U.S. Department of Health and Human Services. NGC was originally created by AHRQ in partnership with the [American Medical Association](#) and the [American Association of Health Plans](#) (now America's Health Insurance Plans [AHIP]). Click on [About NGC](#) to learn more about us.

Start your search by typing keywords into the search box on this page, or use the [NGC Browse](#) or [Detailed Search](#) features.

NGC News

[New/updated ASGE, CTFPHC, ICSI, Pediatric Bariatric Group, SAMSHA guidelines. Go to "What's New This Week."](#)

[The Institute for Clinical Systems Improvement \(ICSI\) has recently released a new guideline on prevention and management of obesity.](#)

[A new field has been added to NGC's Complete Summary! The Implementation Tools field identifies specific tools that are provided by the guideline developer to facilitate implementation of their guideline.](#)

Visit NGC's sister sites:

- [QualityTools \(QT\)](#)
- [National Quality Measures Clearinghouse \(NOMC\)](#)

[Subscribe to the NGC Weekly E-mail Update Service.](#)

http://www.icsi.org/knowledge/browse_category.asp?catID=29

Internet

Start C T O P I E 1 s 0 E 1 0 0 0 S N 11:59 AM

NGC - Search Results - Microsoft Internet Explorer



File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Media Print Copy Paste

Address <http://www.guidelines.gov/search/searchresults.aspx?Type=3&txtSearch=urinary+tract+infection&num=20> Go


Links Online Computing Helpdesk RAND External Home Page RAND Intranet Home Page

Google Search Web 49 blocked AutoFill Options

[What's New](#) | [Contact Us](#) | [About](#) | [Site Map](#) | [Help](#)

- ▶ Search
- ▶ Browse
- ▶ Compare
- ▶ Resources



Search

20 Results
Search

[Search Help](#)
[Detailed Search](#)

Browse

- ▶ [Disease / Condition](#)
- ▶ [Treatment / Intervention](#)
- ▶ [Organization](#)

Compare

- ▶ [View My Collection](#)
- ▶ [Guideline Syntheses](#)

NGC Search Results

Your search criteria:

Keyword: *urinary tract infection*

Your search found 179 related guidelines, which are listed below.

To view a guideline summary, click on a title. The default view is the Brief Summary, from which you can also view the Complete Summary, XML View, Full Text, Palm Download, MS Word, Adobe PDF, or Guideline Synthesis by choosing the appropriate option in the Summary Box on the side menu.

To prepare a Guideline Comparison, add any of the guidelines listed to "My Collection" by selecting that guideline (check the box) and clicking the "Add to My Collection" button. For additional help, see [Guideline Comparison Help](#).

Remember - Check the box next to a guideline to add it to "My Collection". Then click on the "Add to My Collection" button located on the page.

Search Results:

The following guidelines were retrieved because they are linked to [concepts related to your query](#) or because they [contain the words in your query](#). Search results are listed in order of [relevance](#), unless otherwise specified in a Detailed Search.

Display results 1 to 20 of 179

Title
<input type="checkbox"/> Urinary tract infection - University of Michigan Health System - Academic Institution - 1000

Done

Start | Internet | 12:00 PM

Uncomplicated urinary tract infection in women. - Microsoft Internet Explorer


File Edit View Favorites Tools Help


Back Forward Stop Home Search Favorites Media Print Copy Paste

Address http://www.guidelines.gov/summary/summary.aspx?doc_id=5570&nbr=3767&string=urinary+AND+tract+AND+infection Go

Links Online Computing Helpdesk RAND External Home Page RAND Intranet Home Page

Google Search Web 49 blocked AutoFill Options

 **National Guideline Clearinghouse**
www.guideline.gov



hide menu What's New Contact Us About Site Map Help

Search

20 Results Search

[Search Help](#)
[Detailed Search](#)

Brief Summary

GUIDELINE TITLE
Uncomplicated **urinary tract infection** in women.

BIBLIOGRAPHIC SOURCE(S)
Institute for Clinical Systems Improvement (ICSI). Uncomplicated **urinary tract infection** in women. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2004 Jul. 21 p. [38 references]

BRIEF SUMMARY CONTENT

[RECOMMENDATIONS](#)
[EVIDENCE SUPPORTING THE RECOMMENDATIONS](#)
[IDENTIFYING INFORMATION AND AVAILABILITY](#)

[Go to the Complete Summary](#)

RECOMMENDATIONS

MAJOR RECOMMENDATIONS
The recommendations for uncomplicated **urinary tract infection** in women are presented in the form of an algorithm with 13 components, accompanied by detailed annotations. An algorithm is provided for [Uncomplicated Urinary Tract Infection in Women](#); clinical highlights and selected annotations (numbered to correspond with the algorithms) follow.

Class of evidence (A-D, M, R, X) ratings are defined at the end of the "Major Recommendations" field.

Clinical Highlights for Individual Clinicians

Summary

Brief Summary
[Complete Summary](#)
[XML View](#)
[Full Text](#)
[Palm Download](#)
[MS Word](#)
[Adobe PDF](#)

Browse

- » [Disease / Condition](#)
- » [Treatment / Intervention](#)
- » [Organization](#)

Compare

- » [View My Collection](#)
- » [Guideline Syntheses](#)
- » [Add to My Collection](#)

Other Sources of Guidelines

- Specialty Societies
 - AHA/ACC
 - AAFP
 - ACP
 - AAN
 - Many others
- UK National Institute for Clinical Excellence
 - www.nice.org.uk
- Scottish Intercollegiate Guideline Network
 - www.sign.ac.uk
- Internet

Practice Guidelines vs. Quality Indicators

- Practice guidelines and quality (performance) indicators are related but distinct.
- Practice guidelines usually define optimal care and are intended to be used by clinicians to guide individual patient care. They allow for clinical flexibility.
- Quality indicators usually define a floor of care and are intended to be used for accountability. They are much more inflexible than practice guidelines.

Practice Guidelines vs. Quality Indicators: Specific Characteristics

Characteristics	Clinical Practice Guidelines	Quality Indicators
Level of evidence	Moderate levels of evidence plus expert opinion	High levels of evidence: 'A' level of evidence from clinical trials plus observational or field studies
Standardization, specification of measures	Unnecessary, not mandatory	Essential, mandatory

From S. Greenfield

Practice Guidelines vs. Quality Indicators: Specific Characteristics (cont'd)

Characteristics	Clinical Practice Guidelines	Quality Indicators
Case-mix	Not needed	Must be taken into account in either measures design or post-hoc adjustment
Measurement considerations (scoring, mutability, ceiling/floor effects, majority of variance must be explained by target of evaluation)	Not needed	Essential

From S. Greenfield

Practice Guideline and Quality Indicators - Example

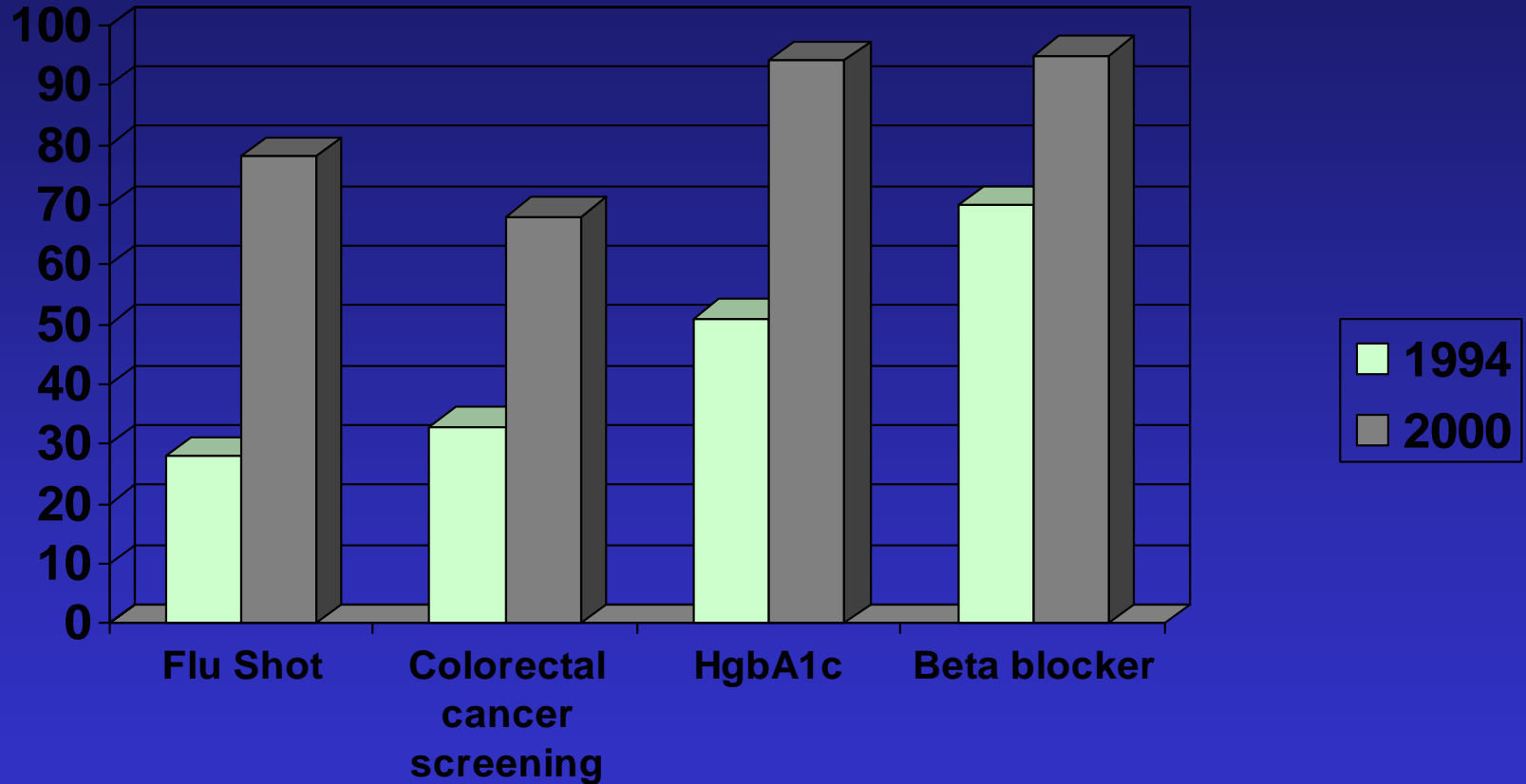
- Practice guideline
 - Patients with diabetes and hypertension should have their blood pressure titrated to 130/85.
- Quality indicator
 - Proportion of patients with diabetes whose blood pressure is less than 140/90.

An Example of Quality Indicator Use The VA Health Care System

Changes implemented by VA in mid-1990s:

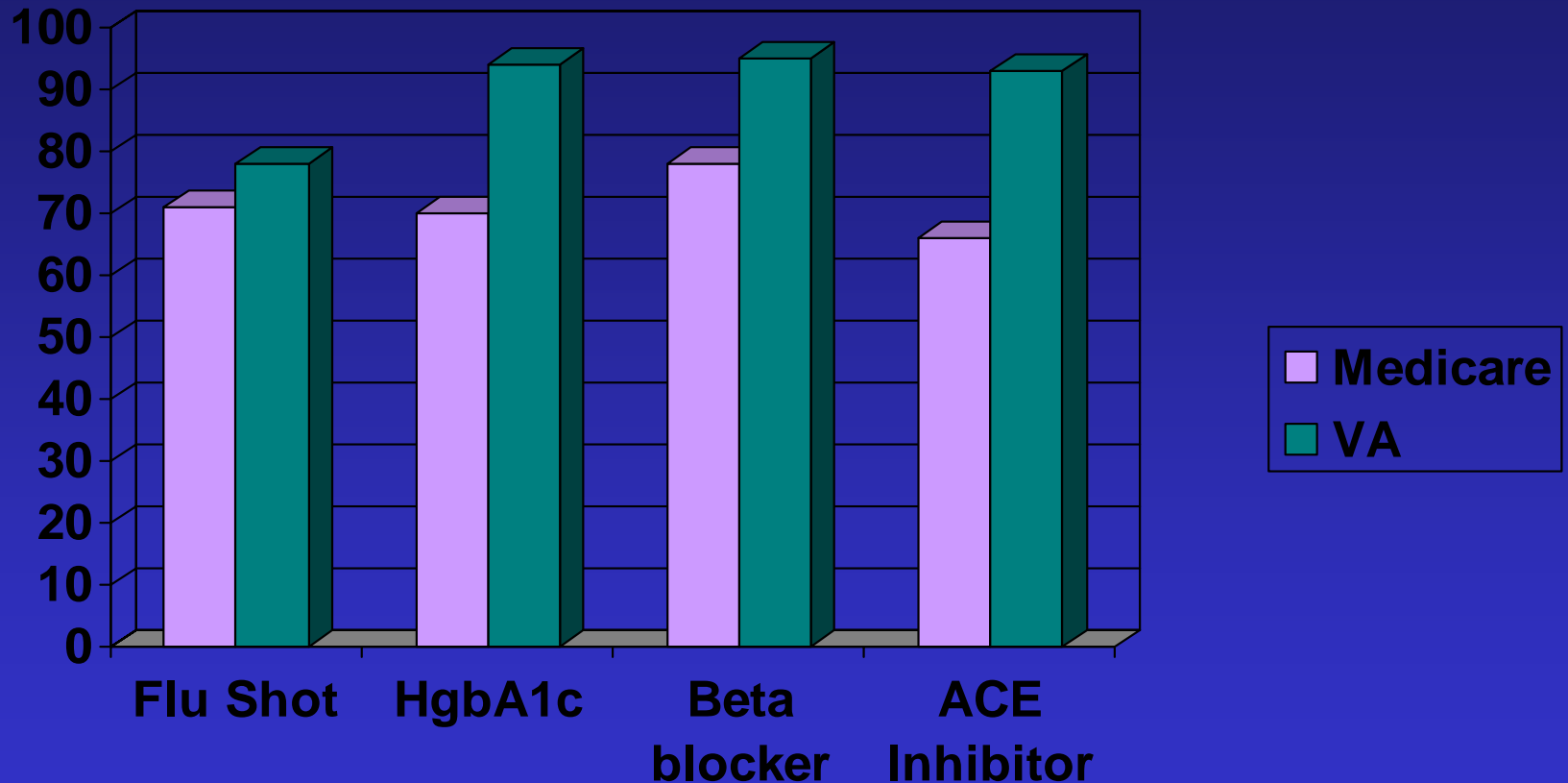
- Investment in information technology
- Development of quality indicators
- Independent measurement & reporting of indicator performance
- Incentives

Quality of VA Care 1994-2000



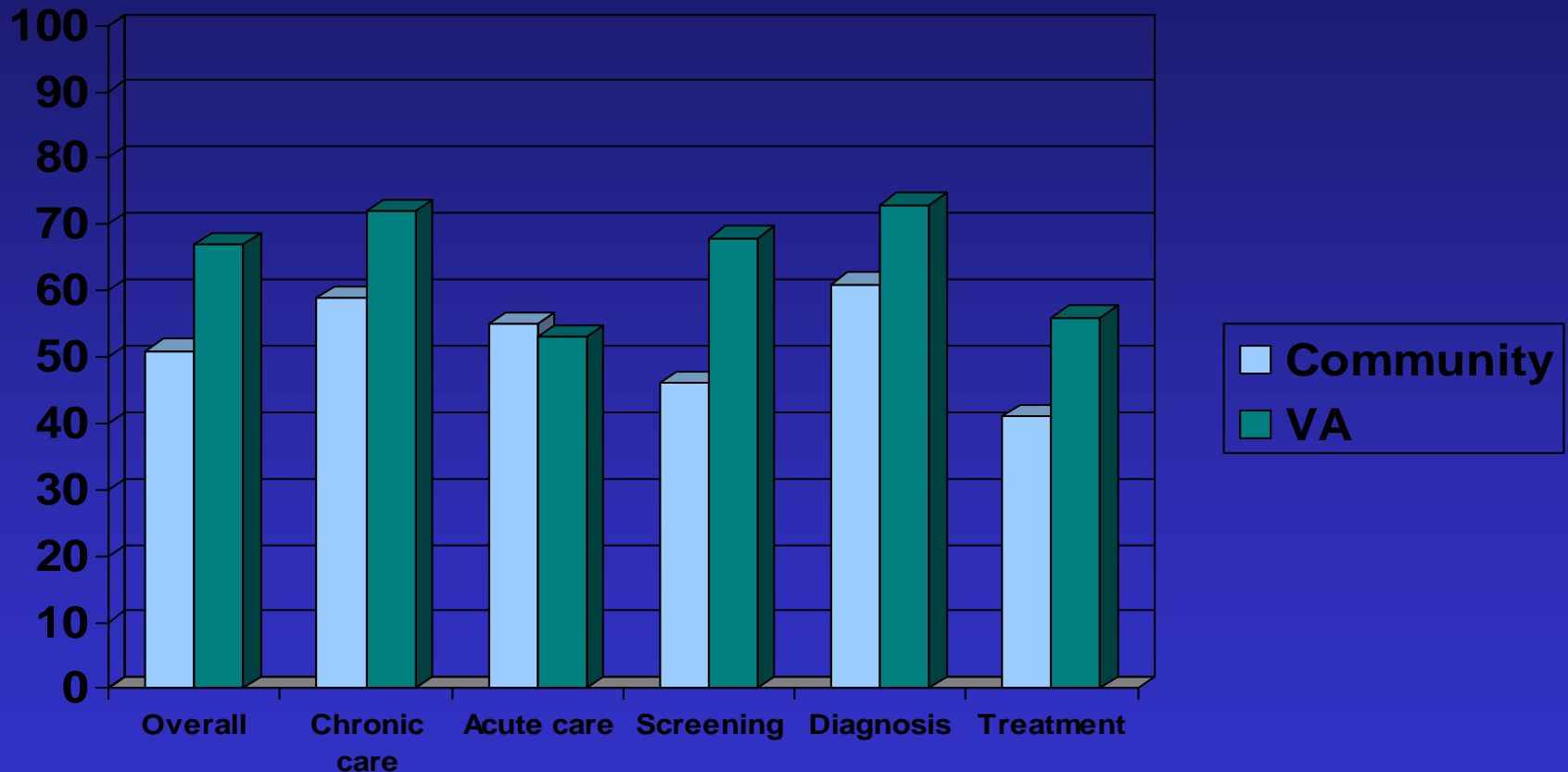
Jha AK, Perlin JB, Kizer KW, Dudley RA. Effect of the transformation of the Veterans Affairs Health Care System on the quality of care. *N Engl J Med*. 2003 May 29;348(22):2218-27.

Quality of VA Care Compared to Medicare



Jha AK, Perlin JB, Kizer KW, Dudley RA. Effect of the transformation of the Veterans Affairs Health Care System on the quality of care. *N Engl J Med.* 2003 May 29;348(22):2218-27.

VA Performance Compared to Community Performance



Asch SM, et al. Comparison of Quality of Care for Patients in the Veterans' Health Administration and Patients in a National Sample, *Ann Int Med* (*in press*)

Paying for Performance Using Quality Indicators: A Major Experiment in the UK

- Quality payments, 90% of which are new, will make up around 20% of the family practice budget
- Increase in gross earnings of £42,000 (\$77,000) per physician

New General Practitioner contract: Quality and Outcomes Framework

**Increased income is derived from a complex set
of quality incentives**

- Chronic disease management
(Ten conditions)**
- Practice organisation
(Five areas)**
- Patient experience**

Seventy six clinical indicators covering:

- **Coronary heart disease and heart failure (15)**
- **Stroke and transient ischaemic attack (10)**
- **Hypertension (5)**
- **Diabetes (18)**
- **Asthma (7)**
- **Epilepsy (4)**
- **Mental health (5)**
- **Chronic obstructive pulmonary disease (8)**
- **Cancer (2)**
- **Hypothyroidism (2)**

Exception Reporting for Clinical Indicators

- Patient refused/not attended despite three reminders
- Not appropriate e.g. supervening clinical condition, extreme frailty, adverse reaction to medication, contraindication etc
- Newly diagnosed or recently registered
- Already on maximum tolerated doses of medication
- Investigative service is unavailable

What might the Effects be of Paying for Performance using Quality Indicators?

- Improved health outcomes
- More medicalization, less holistic approach
- Fragmentation
- Worse care for un-incentivized conditions
- Increased computerization / administrative costs
- Gaming or misrepresentation
- Change in professional motivation

Summary

- Practice guidelines are an important part of practice
- Well constructed guidelines have predictive validity
- In order to achieve their intended effect, guidelines must be linked with effective methods of implementation

Summary

- There is good evidence that quality indicators can be a very useful tool to help improve quality.
- Quality indicators may cause some unwanted effects.
- Therefore the use of quality indicators needs to be combined with evaluations of the health benefits and unwanted effects, so that appropriate policies can be implemented to maximize the overall effect.

Shaneyfelt Criteria

1. Purpose of the guideline is specified
2. Rationale and importance of the guideline are explained
3. The participants in the guideline development process and their areas of expertise are specified
 - 3a. Are the participants multidisciplinary? (our adaptation)
4. Targeted health problem or technology is clearly defined
5. Targeted patient population is specified

Shaneyfelt et al. JAMA 1999;281(20):1900-5

Shaneyfelt Criteria

6. The principal preventive, diagnostic, or therapeutic options available to clinicians and patients are specified
7. The method by which the guideline underwent external review is specified
8. An expiration date or date of scheduled review is specified
9. Method for grading or classifying the scientific evidence is specified
- 10a. Benefits of specific health practices are specified
- 10b. Harms of specific health practices are specified

Shaneyfelt Criteria

- 11a. Benefits are quantified
- 11b. Harms are quantified
- 12. Recommendations are graded according to the strength of evidence
- 12a. Is there a definition for the strength of evidence they use?
- 13. The effect on health care costs from specific health practices is specified
- 14. Costs are quantified
- 15. The role of patient preferences is discussed

Shaneyfelt Criteria

16. The health outcomes are specified
17. Flexibility in the recommendations is specified
18. The evidence used is identified by citation and referenced
19. Formal methods of combining evidence or expert opinion are used and described
20. Recommendations are specific and apply to the stated goals of the guideline
21. The role of value judgments used by the guideline developers in making recommendations is discussed

Shaneyfelt Criteria

- 22. Intended audience or users of the guideline are specified
- 23. Method of identifying evidence is specified
- 23a. Was there a systematic review of the evidence?
(our adaptation)
- 24. Time period from which evidence is reviewed is specified
- 25. Method of data extraction is specified

AGREE Criteria

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.
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.

AGREE Criteria

7. The guideline has been piloted among target users.
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.

AGREE Criteria

13. The guideline has been externally reviewed by experts prior to its publication.
14. A procedure for updating the guideline is provided.
15. The recommendations are specific and unambiguous.
16. The different options for management of the condition are clearly presented.
17. Key recommendations are easily identifiable.
18. The guideline is supported with tools for application.

AGREE Criteria

19. The potential organizational barriers in applying the recommendations have been discussed.
20. The potential cost implications of applying the recommendations have been considered.
21. The guideline presents key review criteria for monitoring and/or audit purposes.
22. The guideline is editorially independent from the funding body.
23. Conflicts of Interest of guideline development members have been recorded.

Conference on Guideline Standardization (“COGS”)

- Brought together guideline developers, disseminators, “implementors” (N=23)
- Reviewed literature on quality and appraisal of guidelines
- Assembled 58 candidate guideline components
- A process of review and group judgment left 35 items to use in assessment

Shiffman R, Shekelle P, Overhage M, et al. Standardized Reporting of Clinical Practice Guidelines: A Proposal from the Conference on Guideline Standardization. *Ann Intern Med.* 2003; 139:493-498

COGS Components

- Description of evidence collection
- Criteria for selection of evidence to review
- Eligibility
- Recommendation
- Reason
- Evidence quality
- Evidence time period
- Evidence quality rating scheme
- Description of evidence combination
- Strength of recommendation rating scheme

COGS Components

- Methods used to reach judgment
- Update plan
- Linkage between recommendations and evidence
- Recommendation strength
- Technical report
- Main focus
- Quantification of harm and benefit
- Funding
- Conflict of interest
- Specification of harm and benefit
- Member expertise

COGS Components

- Role of sponsor
- Peer review
- Reference
- Definitions
- Outcomes
- Developer name
- Status
- Objectives
- Number of source documents
- Role of patient preference
- Committee member
- Release date
- Alternative strategies
- Care setting

Critical Appraisal of Guidelines

Are the results valid?

- Were all important options and outcomes clearly specified?
- Was an explicit and sensible process used to identify, select, and combine evidence?
 - How were articles selected/information obtained for each decision node?
 - How was expert opinion used to fill gaps in the evidence?
 - Sensitivity analyses

Hayward. JAMA 1995;274(7):570-4.

Critical Appraisal of Guidelines

Are the results valid?

Was an explicit and sensible process used to consider the relative value of different outcomes?

- What was the make-up of the panel and who, specifically was on it?
 - Intellectual, territorial and financial biases
- Implicit values

Critical Appraisal of Guidelines

Are the results valid?

- Is the guideline likely to account for recent developments?
 - Date of the most recent evidence
 - Date of the recommendations
 - Mention of important studies in progress
- Has the guideline been subjected to peer-review and testing?

Critical Appraisal of Guidelines

What are the recommendations?

- Are practical, clinically important recommendations made?
- How strong are the recommendations?
 - Quality, consistency of the underlying evidence
 - Potential magnitude of the benefits versus costs, discomfort, impracticalities

Critical Appraisal of Guidelines

What are the recommendations?

- What is the impact of uncertainty associated with the evidence and values used in the guidelines?
 - How strong is the evidence linking interventions and outcomes?
 - Sensitivity analysis and the risk of breast cancer with HRT

Critical Appraisal of Guidelines

Will the recommendations help you in caring for your patients?

- Is the primary objective of the guideline consistent with your objective?
 - Improve quality, decrease cost
 - Improve quality, maintain or increase cost
 - Maintain quality, decrease cost
- Are the recommendations applicable to your patients?
 - General and high-risk populations
 - Treatment of bacterial diarrhea