

For Your Information

The AUA Guidelines Department

Overview: Standard Operating Procedures

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**American
Urological
Association**

Education and Research, Inc.

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American Urological Association Guideline Development Process

The American Urological Association (AUA) is the premier professional association for the advancement of urologic patient care. The development of practice guidelines is a critical component of the organization's mission to promote the highest standards of urological clinical care through education, research and in the formulation of health care policy. The American Urological Association Education and Research, Inc. (AUAER) is the arm of the AUA which is responsible for guideline development. For the purposes of this document, the term "AUAER" will be referred to as "AUA."

This overview is intended to describe AUA's rigorous guideline development process and to be a helpful resource for other guideline developers. In addition to this overview, two related internal resources are available: *A Handbook for Guidelines Panel Members* and *a Guidelines Department Staff Training Manual*. For additional guideline information, please visit the AUA Web site at www.AUAnet.org.

The Guidelines Department is one of five departments within the AUA Health Policy Division and provides staff support for the Practice Guidelines Committee (PGC), the body that provides physician oversight of the guidelines program. All guidelines are developed using an efficient nine-stage process through a partnership between Guidelines Department staff and guideline panel members.

Nine Stages of Guideline Development

1. *Nominate Topic*
2. *Identify Panel*
3. *Define Research Questions and Review Schedule*
4. *Review Literature*
5. *Extract, Synthesize, and Analyze Data*
6. *Review Evidence Report and Develop Guideline Statements*
7. *Write Guideline*
8. *Undergo Peer Review*
9. *Obtain Approval and Publish*

The guideline statements are based on a scientific, transparent, and methodologically rigorous systematic review of published literature. The AUA system of explicitly linking guideline statements to strength of evidence ensures that the guideline is driven by a systematic assessment of relative benefits and risks to the patient.

Stage 1: Nominate Topic

Nomination of the topic is the first step in the guideline development process. There are two sources for this nomination.

- 1) Online topic nomination: AUA members are encouraged to submit topic suggestions through an online form on the AUA Web site. The member is asked to provide information on disease burden, treatment interventions, clinical outcomes and complications.
- 2) Update literature review (ULR): This process uses systematic review and analysis to ensure that existing guidelines are current and remain accurate. If it is decided that a guideline is in need of revision, it becomes a candidate for undergoing the full guideline development process de novo.
- 3) Additional avenues for topic nomination: AUA also pursues a variety of other sources for topic nomination, such as topics of interest to the Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Centers (EPC) program, the National Quality Forum, the AUA Core Curriculum, the American Board of Urology (ABU) and the Institute of Medicine.

The AUA guidelines are not funded by industry in any way; the association underwrites all costs related to guideline development. If appropriate, the AUA may partner with other organizations to develop guidelines. This partnership can provide additional funding for guideline development and offer a potential vehicle for increased dissemination of the guideline.

Potential guideline topics are reviewed and prioritized by the PGC prior to being approved by the AUA Board of Directors (BOD). Once a topic is chosen, the PGC chair nominates a panel chair based on leadership, expertise, research experience and understanding of evidence-based medicine, as well as selects a PGC representative. The panel chair selects a vice chair to assist him/her in directing the activities of the panel. The director of guidelines assigns staff and consultants (panel manager, medical librarian methodologist) to the project.

The panel chair, vice chair, PGC representative and the panel manager are responsible for keeping the project within its initial scope, adhering to the project stages and timeline, and developing the guideline in accordance with the system of aligning strength of evidence to guideline statements. The panel manager keeps the project on time and within budget. S/he oversees and coordinates almost every aspect of the project. A medical librarian conducts thorough literature searches and works closely with a methodologist to ensure that all relevant literature is systematically identified during the development of the guideline. The methodologist conducts the systematic review and analysis of the data, prepares a comprehensive evidence report, works with the panel to interpret the evidence and formulates guideline statements.

Stage 2: Identify Panel

The panel chair identifies seven panel members based on expertise, ability to work as part of a team and willingness to participate bringing the total number of panel members to ten. Other factors that influence panel composition include geographic diversity, representation of other clinical specialties such as nursing or pharmacy, and at times, inclusion of patient advocates. A variety of academic institutions are represented on the panel, however, only two panel members from a single institution are considered.

All panel members are volunteers, and as such, their recompense is to advance the field of urology. The AUA recognizes that full participation on a guideline panel is an educational effort; therefore, panel members are awarded up to 15 Continuing Medical Education (CME) credits at the completion of the guideline.

In addition to training by AUA staff, panel members are provided with *A Handbook for Guidelines Panel Members*. All panel members must sign a non-disclosure agreement barring them from discussion of the guideline statements or any other content prior to publication on the AUA Web site. Additionally, AUA guideline panels conform to stringent COI policies based on the *Council of Medical Specialty Society's (CMSS) Code for Interactions with Companies* (www.CMSS.org) to minimize bias or the appearance of bias. For example, panel chairs cannot have any COI that pertains to the guideline topic. Panel nominees record their COI statements on the AUA interactive Web site, providing specific details of their relationships. These details are vetted by representatives from the PGC and by the AUA Judicial and Ethics (J&E) committee. A majority of panel members may not have relationships relevant to the guideline.

Before the start of each face-to-face panel meeting or full panel web conference, the individual COIs of panel members are reviewed, and members are asked to comment and provide details of their relationships to the rest of the panel. Panel members are to recuse themselves from any discussion where there might be a conflict. Discussion is monitored to ensure that individuals do not comment when there is a conflict.

To launch the project and begin collaboration with the panel chair and vice chair, the panel manager briefs them on their roles and the responsibilities of staff and consultants, as well as on the project budget and production schedule. This briefing aims to clearly explain the guideline process, methodology and various strengths of evidence. It is important for the panel chair and vice chair to fully understand and embrace these processes in order to effectively lead the panel.

Stage 3: Define Research Questions and Review Schedule

At the beginning of guideline development, two key documents are produced to determine its scope: the topic refinement document (TRD) and the methodology protocol.

- 1) **Topic Refinement Document:** This document determines the general scope of the guideline by stating the core questions that the systematic review will address. The TRD defines participants, interventions, comparisons and outcomes (PICO), as well as the date range for a literature search.
- 2) **Methodology Protocol:** This is the tool on which the systematic review is based. It features a systematic expansion of the core questions from the TRD into detailed research questions. It guides the literature search, selection of studies for the evidence-base, development of a data extraction template and the creation of the evidence report.

The first face-to-face panel meeting occurs during this stage, allowing staff to conduct an orientation of the guideline development process. Next, the panel revises the TRD as necessary. In addition, the methodologist engages the panel in extensive discussion to clarify the research questions and identify critical issues so s/he can develop the methodology protocol.

Stage 4: Review Literature

The literature review stage consists of two components: a literature search and literature appraisal.

- 1) **Literature search:** The medical librarian translates clinical research questions from the methodology protocol into search strategies consistent with the requirements of the National Library of Medicine's MEDLINE database. Certain search parameters include English-language-only articles, as well as e-publications and articles pertinent to domestic clinical practice; and the exclusion of abstracts for which there is no article, grey literature or articles that have not yet been published.
- 2) **Literature Appraisal:** The methodologist systematically applies the explicit inclusion and exclusion criteria listed in the methodology protocol to select articles for the evidence base as well as for background information. S/He narrows the list through a title and abstract review and then examines the full text of the remaining articles.

Detailed records of the comprehensive literature search and appraisal are maintained to keep the literature review process transparent and reproducible.

Stage 5: Extract, Synthesize and Analyze Data

The methodology protocol is used to develop a data extraction template for each research question. Key data are then captured from the articles. The data include relevant patient characteristics, treatment alternatives, outcomes of interest, complications and adverse events. To ensure accuracy, the data are quality checked and there is ongoing consultation with the panel chairs.

Next, the methodologist evaluates the study design used in each article and assigns a quality rating using an assessment tool. The methodologist then analyzes and qualitatively describes the data using charts, graphs, tables and figures. If the studies are sufficiently homogenous, s/he may perform a quantitative meta-analysis across studies. At this point, the medical librarian conducts a second and final literature search ensuring that the latest evidence is considered when the panel formulates its guideline statements. This is followed by the assessment of the strength of the entire body of literature for each question (see box).

After the analytical work is completed, the methodologist assembles all the materials in an evidence report that the panel references in developing evidence based guideline statements.

Strength of Evidence

Grade A - high quality evidence: well-conducted randomized clinical trials ([RCTs](#)); exceptionally strong observational studies

Grade B - moderate quality evidence: [RCTs](#) with some weaknesses; generally strong observational studies

Grade C - low quality evidence: observational studies that provide conflicting information or design problems (such as very small sample size)

Stage 6: Review Evidence Report and Develop Guideline Statements

After several conference calls that give panel members ample opportunity for clinical input, a second face-to-face panel meeting is convened to review and discuss the evidence report, and to develop guideline statements. A modified Delphi technique is used to document panel consensus or disagreement.

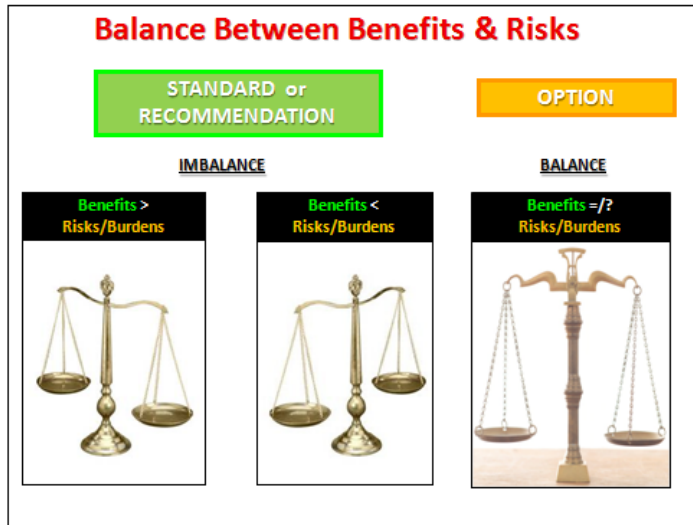
As panel members develop guideline statements, they categorize them according to three statement types: Standard, Recommendation and Option.

Standard: If the benefits of taking a decisive action outweigh the risks/burdens OR the risks/burdens outweigh the benefits based on Grade A or B evidence, the statement is categorized as a Standard. The panel is making a directive statement to take or to *not* take a specific action.

Recommendation: If the benefits outweigh the risks/burdens OR the risks/burdens outweigh the benefits based on Grade C evidence, the statement is categorized as a Recommendation. The panel is making a directive statement to take or to *not* take a specific action.

Option: If the benefits and the risks/burdens are either evenly balanced or unclear based on Grade A, B or C evidence, the statement is categorized as an Option. In this case, the decision to take or to *not* take a specific action is up to the practitioner and patient.

The development of guideline statements is thus driven by a balance of benefits and risks/burdens, as represented in the figure below.



The strength of the body of evidence for each research question is then linked to the type of guideline statement, as illustrated below.

Strength of Evidence and Guideline Statement Types in AUA Guidelines

Guideline Statement Type	Evidence Grade		
	A	B	C
STANDARD	✓	✓	
RECOMMENDATION			✓
OPTION	✓	✓	✓

The panel also has the opportunity to link guideline statements to two other definitions—Expert Opinion or Clinical Principle.

- 1) Expert Opinion: A statement achieved by panel consensus that is based on members' clinical training, experience, knowledge and judgment and for which there is no published evidence.
- 2) Clinical Principle: A statement about a component of clinical care that is very widely agreed upon by urologists or other clinicians and for which there may or may not be evidence in the medical literature.

Stage 7: Write Guideline

Working from the guideline statements, panel members draft sections of the guideline. A medical editor assists the panel. As the final drafting of statements nears its end, the panel follows a modified Delphi technique to document input and achieve consensus.

The guideline format is concise and reader-friendly. Guideline statements are prominent in that a summary of the methodology and all guideline statements appear at the beginning of the document. For reference, please see *AUA Guideline: Diagnosis and Treatment of Interstitial Cystitis/Bladder Pain Syndrome* at [http://www.auanet.org/content/guidelines-and-quality-care/clinical-guidelines.cfm?sub=ic-
bps](http://www.auanet.org/content/guidelines-and-quality-care/clinical-guidelines.cfm?sub=ic-bps).

Once the panel approves the draft guideline, it is reviewed by the Guideline Validation Committee for external review. This three-person committee is comprised of 1) the PGC vice-chair, 2) a second PGC member with extensive methodological expertise, and 3) a content expert that has specialized knowledge on the guideline topic. This panel reviews each guideline from an overview perspective, ensuring clarity, focus on the clinical questions, and consistency with AUA guideline methodology and the overall association mission.

Stage 8: Undergo Peer Review

It is the goal of the guideline panels to identify and confirm at least 30 peer reviewers (in addition to the PGC and BOD members) for each guideline. The intent is to include reviewers from specialties other than urology such as radiologists, nurses, oncologists, pediatricians, family physicians, physical and behavioral therapists and patient representatives. COI disclosures are sought from all peer reviewers. During the peer review period, AUA legal counsel reviews the document to update the legal disclaimer, if needed, and raise any issues of concern. Once reviews are returned, the guideline panel assesses the peer review comments, revises the document accordingly, and votes on approval.

Stage 9: Obtain Approval and Publish

The panel-approved document is then sent to the PGC for approval prior to BOD final review. The guideline is copyrighted and published on the AUA Web site (www.auanet.org).

Update Literature Reviews (ULRs)

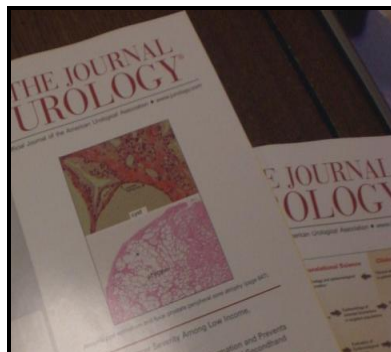
Every 12 to 18 months, a three-person expert panel assesses the currency of each existing guideline through an update literature review (ULR). Based on a literature review and qualitative assessment, the panel determines whether a revision of the guideline is warranted.

Sunsetting of Guidelines

If after eight years the ULR process does not result in the recommendation of a full revision, a guideline is sunsetted. A full panel is convened, and the guideline is revised.

Dissemination of Guidelines

The Journal of Urology® Article: In addition to the publication of the full guideline on the AUA Web site, an executive summary (4,000 words maximum) is developed and submitted to *The Journal of Urology*®.

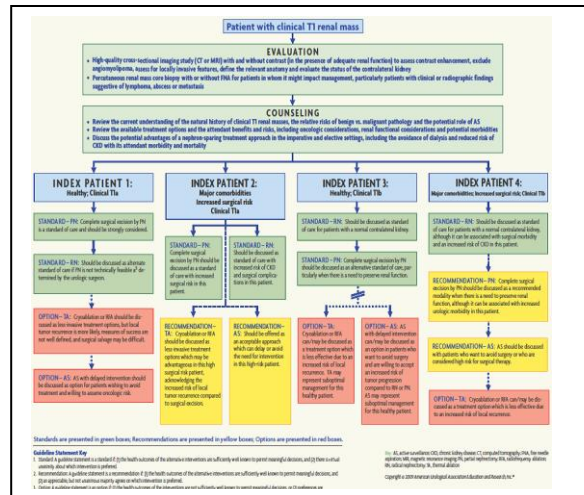
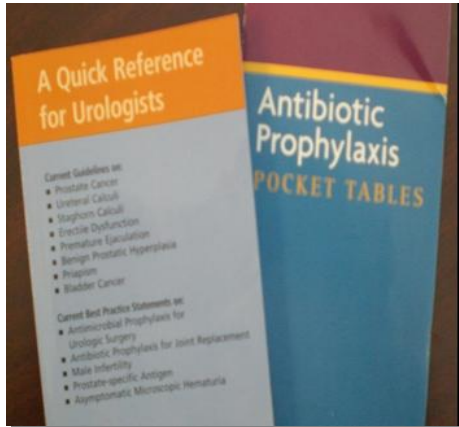


Guidelines are also submitted in full text to the Agency for Healthcare Research and Quality's National Guidelines Clearinghouse (AHRQ-NGC), as well as to the Guidelines International Network (GIN) to be posted on their respective Web sites.

Each new guideline is presented at an AUA Annual Meeting Plenary Session by the panel chairs, and many are featured in educational courses offered through the Office of Education, ensuring a wide domestic and international urologic audience.

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Other means of dissemination include webinars, tri-fold pocket tables, wall charts and Guidelines-at-a-Glance, a pocket guide that contains essential, summarized information from a number of AUA guidelines. In addition to products developed by the Guidelines Department, the development of a patient guide may be supported through the AUA Foundation.



To further facilitate wide dissemination of the guideline to urologists and other clinicians alike, endorsement from other relevant specialty societies may be pursued.

The guidelines may also be used to specify quality performance measures. In addition, they may be used in the development of criteria for Maintenance of Certification (MOC) and for the AUA Update and Patient Management Series, other educational courses and in the Urology Core Curriculum and Self Assessment Study Program (SASP).

DISCLAIMER: AUAER guidelines provide guidance only, and do not establish a fixed set of rules or define the legal standard of care. As medical knowledge expands and technology advances, the guidelines will change. Today these evidence-based guideline statements represent not absolute mandates but provisional proposals for treatment under the specific conditions described in each document. For all these reasons, the guidelines do not preempt physician judgment in individual cases. Also, treating physicians must take into account variations in resources and in patient tolerances, needs and preferences. Conformance with AUAER guidelines cannot guarantee a successful outcome.