American Urological Association

Advancing Urology™

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Standard Operating Procedures: Developing AUA White Papers

INTRODUCTION

The American Urological Association (AUA) is the premier professional association for the advancement of urologic patient care. Quality improvement and patient safety initiatives are important parts of the AUA's mission to promote the highest standards of urological clinical care through education and research. To this end, the AUA develops a variety of publications for its members, such as clinical practice guidelines, best practice statements, policy statements and white papers coordinated by the Science and Quality Division. The Quality Department within the Science and Quality Division develops white papers on patient safety and other critical issues. Additionally, the Quality Department serves as a clearinghouse for white papers developed by other AUA departments, but all reviews, updates and revisions are completed by the department who originally completed the white paper. The management of clinical practice guidelines and technology assessments fall under the purview of the Guidelines Department. Each publication has been clearly defined by the AUA; for more information on standardized definitions, please see *Standard Definitions for Clinical and Technology-Related Recommendations/Statements* (2008) or a summary table in Appendix A. This overview of white papers is intended to describe the AUA's process of developing white papers.

DEFINITION

A white paper is a comprehensive qualitative assessment of a topic or topics that are approved by the Science & Quality Council and the AUA Board of Directors for development by a panel of experts that include urologists and may include other specialists. It states the AUA's position or philosophy on a topic, often focusing on issues of patient safety or other issues of importance to urology. It can also be a brief explanation of an available technology in the field of urology. A white paper may present a policy statement on the topic. The process, use of evidence and expert opinion, and scope and length of a white paper are the focus of this document. For a list of stages in the process and approximate time required for each, see Appendix B.

Process. The AUA's process of developing white papers begins with identification of the key issue(s) by the Quality Improvement and Patient Safety (QIPS) Committee or other sources, such as the Agency for Healthcare Research and Quality, the Food and Drug Administration and the National Urology Research Agenda. The QIPS Committee has created a white paper topic scoring tool which will be used during the topic evaluation process to rate suggestions on: quality/patient safety relevance, clinical importance, availability of evidence, practice variability, existence of similar documents, and identification of project leader. For more details on the tool, see Appendix C. Additionally, when a topic is being considered, QIPS will also ascertain the opportunity for collaboration with other subspecialties. Recognizing the expertise of ancillary professionals as well as the collaborative nature of healthcare delivery, the AUA is committed to multi-disciplinary panels, if appropriate based on the topic, and partners with other subspecialties

to populate the panel and develop the white paper. When appropriate, a memorandum of understanding (MOU) between societies is drafted to ensure clear roles and responsibilities as well as requirements for approval by all parties; however, there are times when another organization is lending intellectual expertise in the form of representatives on the workgroup only to the AUA white paper, and therefore a MOU is not required.

The QIPS Committee submits the topic to the Science and Quality Council for approval and then on to the AUA Board of Directors for review and final approval.

To initiate the project, the panel chair is selected by the QIPS chair with input from other experts, as necessary. The panel chair and QIPS chair then select additional members of the panel with expertise in the topic area under consideration; in all, the panel should not exceed 10 members, which allows for adequate expertise and diversity of opinions without becoming cumbersome for scheduling and discussion purposes. All panel members are required to adhere to S&Q's guideline principles on conflicts of interest (COI) and disclose any potential COIs through the AUA's electronic submission process and sign non-disclosure agreements. These relationships are reviewed by staff to determine eligibility for panel inclusion.

The white paper panel accomplishes most of its work through conference calls and webinars, as needed. If necessary, an in-person meeting can be held if there are issues to be discussed.

The panel chair will determine if consultants should be included in the development process. Consultants may include: a methodologist to review the literature and complete data extractions from relevant materials; a medical librarian to conduct literature searches to identify appropriate articles; a data extractor to obtain literature requested by the panel chair and/or methodologist; a medical writer, who may assist the panel chair in consolidating and refining the white paper as

well as drafting an abbreviated version to be submitted for publication; and others as determined by the panel chair.

After careful review of the evidence, which either they or the methodologists have analyzed, the panel develops a summary of findings with conclusions and drafts the white paper. Through email and conference calls, the panel revises and finalizes its document. Often panel members compose individual sections which are then unified by the panel chair and/or medical writer to make a cohesive document. Once the white paper is finalized, it is reviewed by the QIPS Committee and the Science & Quality Council, and peer reviewed by external reviewers. If the white paper will be submitted to *Urology Practice*, it is appropriate to include peer reviewers recommended by the publication. The panel revises the document to incorporate feedback, as appropriate, and it is then sent to QIPS, the Science and Quality Council, and the BOD for final approval. If any collaborating organizations must seek approval, it should be done during this timeframe as well.

Literature-Based Evidence. A white paper includes background information on the topic and discussion of the key findings in the literature. Under direction from the panel chair, a medical librarian conducts searches of online databases, such as PubMed and EMBASE, to identify relevant literature on the topic. To ensure no key articles are overlooked, the panel chair, along with the panel, provides guidance on relevant literature and the literature search timeframe that should be included in the white paper. Panel members or a methodology consultant conducts a qualitative analysis of the available evidence, and the panel ultimately bases its white paper on this analysis. References are cited in the document, and evidence tables may be included as well.

Expert Opinion. The panel's expert opinion is critical to a white paper. Often the scarcity of the literature does not allow for a more rigorous evidence-based document. Therefore, the panel must review the qualitative analysis and employ expert opinion to provide guidance on the selected topic. AUA panel members represent the leading experts in the field; therefore, their years of clinical and research experience are invaluable in assessing the literature and drawing conclusions that will be beneficial to the field of urology. In addition, the appropriate committees and councils review the white paper and provide valuable feedback; ultimately the AUA Board approves the final document.

Scope and Length. AUA white papers are limited to a narrow topic of immediate interest to AUA membership and should be focused on the needs of the audience. The development of a white paper is often initiated in an effort to be responsive to emerging issues of critical importance to the membership or to address issues of patient safety. For example, the AUA has developed the following:

- *Non-Neurogenic Chronic Retention: Consensus Definition, Management Strategies, and Future Opportunities* (2016)
- *The Prevention and Treatment of the More Common Complications Related to Prostate Needle Biopsy Update* (2016)
- *Implementation of Shared Decision Making into Urological Practice* (2015)
- *The Beers Criteria for Potentially Inappropriate Medication Use in Older Adults* (2015)
- *Catheter-Associated Urinary Tract Infections: Definitions and Significance in the Urologic Patient* (2014)

While other more rigorous projects take a considerably longer period of time to develop (2+ years), white papers, which are approximately 10-20 pages in length and not intended to be comprehensive, can be completed within 12 - 18 months, thus providing the membership with an assessment of the literature and AUA expertise on a particular topic in a quick timeframe. This is very important when an emerging issue needs to be quickly addressed.

The scope of the topic is defined by the panel. The panel may also note the research issues to be addressed, index patient(s), literature search terms, and timeframe of publications to be included so that project consultants can begin their work.

Publication. The panel will submit the document to an AUA publication, such as *Urology Practice* or, where appropriate, *Journal of Urology*. The chair, with the assistance of Quality staff and the medical writer if needed, develops a summary version (4,000 words or less) for this purpose (see Appendix D for *Urology Practice* submission steps).

Dissemination. The white paper is published on the AUA's website, and members are informed through various AUA publications, such as *Policy & Advocacy Brief, AUA News,* or other AUA publications. Additionally, a marketing plan to publicize and distribute the white paper is jointly developed by both the Marketing and Communications and Quality staff and may include plenary presentations or educational courses at the AUA Annual Meeting. QIPS Committee, Science & Quality Council and white paper panel members are encouraged to widely disseminate the document. If the white paper is developed through a partnership with another subspecialty organization, the subspecialty disseminates the white paper to its members. Also,

the AUA provides the white paper to the American Board of Urology (ABU) to inform its standards of certification and ensure that its programs are based on the most current evidence-based information.

Updates. The AUA is committed to ensuring the accuracy and currency of its publications. Therefore, white papers are assessed by the Quality Department every three years to determine if relevant evidence has been published since the publication of the white paper that would require revisions to the panel's findings. If a topic is of high priority, the AUA may decide to update it earlier than 3 years in order to ensure the incorporation of key articles. To assure currency, Quality staff will evaluate the publication date of a white paper and note when an update review is needed. They will then alert the QIPS Committee that an assessment and potential revisions are due.

Similar to the AUA's Update Literature Review process for its clinical practice guidelines, the update process for white papers ideally entails a three-member panel comprised of the panel chair, another panel member and a new member not previously involved in the original panel but considered an expert in the subject.

The update is conducted in four stages:

- Stage 1: Identify the panel
- Stage 2: Define the scope of the document
- Stage 3: Conduct the literature review
- Stage 4: Develop the recommendation to revise or delay

To conduct the review, the medical librarian performs a search of literature published since the cutoff date in the existing white paper. The panel or methodologist will conduct a qualitative analysis so that a decision can be made about the accuracy of the white paper. The panel then determines whether a limited update is required or if a full revision of the white paper is warranted.

If the update panel decides that a revision or update is warranted, the QIPS chair is notified. If the decision is to revise the white paper, the QIPS chair and AUA staff determine a feasible timeline. If the panel recommends adding a limited update to the white paper, the literature search and appraisal will be used by the panel to develop the new language for the white paper. The panel may also decide against these options and determine that an update should be conducted again the following year, and the AUA website will be updated reflect that the white paper has been verified as accurate.

CONCLUSION

Since white papers offer the advantage of relatively quick turnaround, they can address important topics in a timely manner. However, the disadvantage is a less rigorous evidence review process often due to lack of available evidence. White papers provide the AUA with one more evidence-based resource to educate its members, research critical issues facing urologists and confront challenges facing the field of urology.

Appendix A
Definition Summary for AUA Clinical and Technology Related Recommendations/Statements*

*Adapted from the AUA Definitions Document

	Guideline Related Products (Guidelines Dept.)			Other Departments		
	Guidelines	**Best Practice Statements (BPS)**	**Technology Assessment (TA)**	**Policy Statement**	**Consensus Statement**	**White Paper**
Definitions	Evidence-based guidance with an explicit clinical scope and purpose	Evidence-based guidance that reflects the principles of the urology profession	Guideline process directed at an intervention	A straightforward declaration on a particular topic(s)	The collective opinion of an expert panel	A topic review focusing on issues of patient safety or other issues of importance to urology
Source of Evidence	Randomized controlled trials (RCTs) utilized when available; non-RCT data are used if considered robust; strongest document	Literature is reviewed; no data analysis performed	Systematic review of the literature	A cursory review of the literature	Opinions	Literature review
Expert Opinion	Panel members review the literature and determine data to be extracted	Panel members contribute knowledge and experience to conclusions	Panel members review the literature and determine data to be extracted	Developed by experts	Opinion of an expert panel	Opinion of an expert panel
Process	Systematic/scientific review, data extraction, meta-analysis	Extractions and meta-analysis are not performed; Consensus is based on literature review	Appropriate qualitative and quantitative methods of synthesizing data from multiple studies are utilized	Dictated by government agencies or endorsement of policies from other sources (e.g. AMA)	Consensus, either formal or informal	Review of the available literature by an expert panel
Length	Approximately 50-100 pages	Up to 50 pages	Similar to a guideline or BPS in length	1-2 pages	5-10 pages	10-20 pages
Average Time	24-30 months	N/A	24-30 months	1-3 months	6 months	9-12 months

Appendix B

Process of Developing an AUA White Paper

(Average Timeframe: 12-18 months)

Stage	*Timeframe*
Stage 1: Formulate topic	1 month
Stage 2: Identify panel members	1 month
Stage 3: Define scope of the topic	1 month
Stage 4: Review literature	1-2 months
Stage 5: Develop qualitative analysis	2 months
Stage 6: Review analysis and form conclusions	1 month
Stage 7: Draft white paper	2 months
Stage 8: Peer review by appropriate committees, councils, UP editors	2-3 months
Stage 9: Obtain AUA Board approval	1 month
Stage 10: Disseminate white paper	ongoing
Stage 11: Update Literature Review	every three years following publication

APPENDIX C

WHITE PAPER SCORING TOOL

Criteria	SCORE:	1	2	3	4	5
I.	**Quality/Patient Safety Issue**	not relevant to quality or patient safety	minimal relevance	moderately relevant to quality/patient safety	somewhat relevant to quality/patient safety	a high quality/patient safety issue
II.	**Clinical Importance**	no importance to urology	minimal	moderate	somewhat important/emerging as an issue	high importance to urology
III.	**Availability of Evidence**	level of evidence not known	minimal evidence available	moderate literature	fairly high level and quality of literature	high literature
IV.	**Practice Variability**	no variability	minimal variability	moderate variability in practice	some variability across regions	high practice variability nationally
V.	**Similar Publication Exists**	multiple strongly related publications recently	strongly related publication recently	moderately related publication recently/strongly related publication in distant past	unknown if prior work	no prior work
VI.	**Available Leader**	no volunteer leader available	unlikely to identify a leader	possible leader available	probable leader	key leaders have volunteered

Appendix D

White Paper Publication Track