

## NASPGHAN POLICY ON CLINICAL PRACTICE GUIDELINES AND RELATED STATEMENTS

**Overview.** Pediatric gastroenterology is a constantly evolving, dynamic field. As clinical and basic scientific evidence emerges that substantially impacts practice, the NASPGHAN Executive Council may authorize the development of new or revised clinical practice guidelines or related official, authoritative statements. All published guidelines and statements officially developed by or endorsed by NASPGHAN will conform to rigorous standards and a well-defined review and approval process. Publication will occur in the *Journal of Pediatric Gastroenterology and Nutrition* or, with prior approval, an alternate peer-reviewed journal.

This policy defines how NASPGHAN-endorsed guidelines or other official statements shall be proposed, budgeted, approved, developed, reviewed and revised. Official definitions of NASPGHAN clinical practice guidelines and related authoritative statements are provided below. A manual of operations (MOO) developed by NASPGHAN leadership in 2011 further outlines the precise mechanisms by which:

1. A guideline proposal is submitted to NASPGHAN, reviewed by the Clinical Care and Quality Committee, and approved by Council.
2. How guidelines undergo peer review once the manuscript is completed.
3. How published guidelines are reviewed periodically by the clinical care and quality committee.
4. NASPGHAN endorsement of guidelines prepared by other societies
5. The development of joint NASPGHAN/ESPGHAN guidelines.

**Development of new guidelines and related official statements.** A wealth of evolving clinical knowledge in pediatric gastroenterology, hepatology and nutrition demands that NASPGHAN regularly consider subject matter that may be appropriate for the creation of clinical practice guidelines or other official statements.

A proposal for a NASPGHAN-endorsed statement must be first submitted to the NASPGHAN president and the Clinical Care and Quality Committee for review. The initial proposal should include a brief rationale for the planned document. In determining the feasibility and desirability of a new guideline or official statement, favorable criteria may include, but not be limited to:

- *common disorders for which the standard of care is poorly defined;*
- *common problems with widespread clinical/social consequences;*
- *the availability of new diagnostic and/or new treatment modalities;*
- *controversial, complex, and/or challenging diagnostic, treatment or policy issues.*

The outline may include a proposed budget and suggested members of a writing committee. The Clinical Care and Quality Committee reviews the proposal for scientific merit and importance to the membership. Once the proposal is approved by the Clinical Care and Quality Committee, the proposer (with guidance from the NASPGHAN council) will finalize the writing committee membership. The composition of the writing committee membership must be in accordance with

NASPGHAN conflict of interest criteria, as outlined both in the conflict of interest policy and in the Manual of Operations. The final proposal will be reviewed by NASPGHAN council (either at one of the NASPGHAN meetings that occur four times a year, or during a conference call). If approval is given for the project to proceed, a member of the NASPGHAN executive council (generally the president or president-elect) will communicate approval to the leader of the guideline writing group. If Council approves, the development process shown in the flow diagram at end of this policy ensues.

**Revision of guidelines and other official NASPGHAN statements.** Clinical practice guidelines and official NASPGHAN statements must be reviewed and updated on a regular basis to ensure accuracy and timeliness of information. Accordingly, each official NASPGHAN document listed at [www.naspgghan.org](http://www.naspgghan.org) and published in the *Journal of Pediatric Gastroenterology and Nutrition* will be formally reviewed three years following publication, with the goal of submitting a revised document or retiring the guideline 5-6 years after publication.

It is the duty of the Clinical Care and Quality Committee to formally review existing guidelines and other official statements three years after publication. The details of this review process are outlined in the manual of operations. Any document deemed to be out of date or no longer relevant to the field may be retired upon recommendation of the Clinical Care and Quality Committee and approval of Executive Council. Alternately, a document revision may be recommended.

**Writing committee size and membership:** Committee members are appointed by the NASPGHAN president and Executive Council with input from relevant NASPGHAN committees and the person(s) proposing document development. The composition of the writing committee membership must be in accordance with NASPGHAN conflict of interest criteria, as outlined both in the conflict of interest policy and in the Manual of Operations. Writing committees should be kept relatively small, in order to assure that the task of writing and reviewing is completed expeditiously. Committees may work by electronic mail, conference calls, videoconferencing and face-to-face meetings. In general, it is anticipated that no more than two face-to-face meetings will be required. For a proposed new or revised guideline or document, writing committees will typically include 6-10 members, as follows:

- *3-4 members from NASPGHAN and 3-4 members from ESPGHAN (for joint guidelines);*
- *6-8 members (for NASPGHAN only guidelines);*
- *At least 1 member with expertise in statistics, epidemiology and evidence-based analysis. An epidemiologist is not required, as long as at least one member of the writing committee is an expert in evidence-based medicine*
- *Consideration of involvement of one representative of the American Academy or Pediatrics.*

The following will be considered in selection of committee members:

- Expertise and publication record in the field
- Clinical experience
- Conflicts of interest and how they are mitigated or resolved
- Willingness to commit to the document development process and timelines
- Academic rank, work setting
- Diversity (gender, race, ethnicity, geographic origin)
- For revision committees, at least 3 members will “carry-over” from the initial authors.

## Definitions of official NASPGHAN documents.

1. A **Clinical Practice Guideline** is an evidence-based decision-making tool for managing a common or important condition. Clinical Practice Guidelines may be proposed by a NASPGHAN committee, subject to the conditions outlined herein. Alternately, guidelines may be solicited by the Executive Council. NASPGHAN Clinical Practice Guidelines are developed using a methodology that meets the criteria of the Agency for Healthcare Research and Quality for posting on [www.guideline.gov](http://www.guideline.gov) in the National Guideline Clearinghouse. Guideline development includes a thorough systematic literature review, synthesis of the evidence, data analysis, formalized consensus development, recommendations and algorithms for clinical management, and internal and external critique (*J Pediatr Gastroenterol Nutr* 2002;35:242-3). The final draft requires commentary by the entire NASPGHAN membership prior to official approval for publication. Once authorized for publication in the *Journal of Pediatric Gastroenterology and Nutrition* by the Executive Council, the Clinical Practice Guideline is submitted to the Journal by the President of NASPGHAN and is not subject to further peer or editorial review.
2. A **Clinical Report** is a guidance document for the clinician providing care. A Clinical Report presents an extensive review of state-of-the-art of care for an important clinical topic. Because a Clinical Report is not prepared with the rigorous methodology applied to development of a Clinical Practice Guideline, there are no or few formal recommendations in a Clinical Report, although generally accepted best practices can be described. A Clinical Report may be proposed by a NASPGHAN committee. Otherwise, the report is solicited by, reviewed by and subject to approval by the Executive Council. The final document requires review and critique by either a committee other than the authoring committee or by three members of the Executive Council, then final approval by the Executive Council. Once authorized for publication in the *Journal of Pediatric Gastroenterology and Nutrition* by the Executive Council, the Clinical Report is submitted to the Journal by the President of NASPGHAN.
3. A **Technical Report** is a scientific evidence-based report. A Technical Report describes the scientific evidence on a specific topic. It does not include recommendations for clinical practice. A Technical Report may be proposed by a NASPGHAN committee. Otherwise, the report is solicited by, reviewed by and subject to approval by the NASPGHAN Executive Council. The final document requires review and critique by either a committee other than the authoring committee or by three members of the Executive Council, then final approval by the Executive Council. Once authorized for publication in the *Journal of Pediatric Gastroenterology and Nutrition* by the Executive Council, the Technical Report is submitted to the Journal by the President of NASPGHAN.
4. A **Committee Report or Task Force Report** is a report from a NASPGHAN Committee or Task Force regarding an issue of importance to the field of pediatric gastroenterology that is not related to clinical care (e.g. a research agenda or workforce survey). These documents may be proposed by a NASPGHAN committee. Alternately, the report is solicited by, reviewed by and subject to approval by the Executive Council. Once authorized for publication in the *Journal of Pediatric Gastroenterology and Nutrition* by the Executive Council, the Report is submitted to the Journal by the President of NASPGHAN and is not subject to peer or editorial review.

5. A **Policy Statement** is an organizational principle to guide and define the child health care system and/or improve the health of children. Policy statements contain recommendations based on interpretation of fact, values and opinions. Some may require background from a technical report that contains a literature review and data analyses. Policy Statements may be proposed by a NASPGHAN committee or solicited by the Executive Council. All policy statements are reviewed and approved by the Executive Council before being published. Once authorized for publication in the *Journal of Pediatric Gastroenterology and Nutrition* by the Executive Council, the Policy Statement is submitted to the Journal by the President of NASPGHAN and is not subject to peer or editorial review.

**Timeline for Authorship and Review.** The flow chart below presents a idealized timeline for proposal, initial approval, initiation, preparation, review and final approval of official NASPGHAN documents. Although the “lifespan” of a published guideline or other such statement should not exceed 5 years, the actual time period required to complete the cycle from document inception to publication to revision may approximate 6-7 years.

Additional information regarding this process is available in the NASPGHAN Manual of Operations. All guideline preparation should be prepared with strict adherence to the NASPGHAN conflict of interest policy.

# FLOW DIAGRAM FOR CLINICAL PRACTICE GUIDELINES AND RELATED STATEMENTS

