

Manual of Operations NASPGHAN Societal Manuscripts

I. Introduction

Pediatric gastroenterology is a constantly evolving, dynamic field. As evidence emerges that substantially impacts patient care, the NASPGHAN Executive Council will authorize the development of new or revised Practice Guidelines or Position Statements. A wealth of evolving clinical knowledge in pediatric gastroenterology, hepatology, pancreatology, and nutrition demands that NASPGHAN regularly consider subject matter that may be appropriate for the creation of manuscripts bearing the NASPGHAN name.

All published societal manuscripts officially developed by or endorsed by NASPGHAN must conform to rigorous standards and a well-defined review and approval process. Publication will occur solely in the *Journal of Pediatric Gastroenterology and Nutrition (JPGN)* or, with prior approval of NASPGHAN Council, an alternate peer-reviewed journal. Industry or institutional funds/grants shall not be utilized to fund societal manuscripts preparation, which include Practice Guidelines and Position Statements.

This Manual of Operations defines how NASPGHAN-endorsed societal manuscripts shall be proposed, budgeted, approved, developed, reviewed and revised.

II. Types of Societal Manuscripts

There are two types of societal manuscripts: **PRACTICE GUIDELINES** (previously *Clinical Practice Guidelines*) and **POSITION STATEMENTS** (previously *Position Papers*). These NASPGHAN manuscript types match the types of societal manuscripts by ESPGHAN. If appropriate, collaboration is encouraged to generate a joint NASPGHAN/ESPGHAN societal manuscript. Proposals submitted for society-endorsed papers other than Practice Guidelines or Position Statements will not be considered.

- 1) *Practice Guideline*: This type of NASPGHAN societal manuscript is a **scientific-based decision-making tool** that was originally defined in 2011 by the Institute of Medicine (now called National Academy of Medicine) to address specific clinical research questions and that abides by most rules of evidence-based medicine for guideline development (www.ncbi.nlm.nih.gov/books/NBK209538/). Guidelines should be developed using current and best practices in guideline development. In 2024, will most often involve the use of “Grading of Recommendations Assessment, Development and Evaluation” (GRADE) methodology (<https://www.gradeworkinggroup.org/>). If appropriate, PICO (Population-Intervention-Comparator-Outcome) questions should also be utilized (<https://training.cochrane.org/handbook/current/chapter-03>). Generally speaking, best practices for NASPGHAN Practice Guideline development include a thorough systematic literature review, synthesis of the evidence, data analysis, formalized consensus development, recommendations and algorithms to facilitate implementation and internal and external critique. In 2024, they will typically involve reporting of the guidelines following a formal framework, such as the Appraisal for Guidelines Research Evaluation

(AGREE) II checklist, to ensure a structured and rigorous development methodology (www.agreetrust.org/wp-content/uploads/2017/12/AGREE-II-Users-Manual-and-23-item-Instrument-2009-Update-2017.pdf). The use of specific frameworks such as AGREE II also provides the potential for NASPGHAN and others to conduct internal assessments that ensure that guidelines are methodologically sound and to evaluate guidelines from other groups for potential adaptation to their own context.

Position Statement: Position Statements are meant to be documents based on existing literature, data, and experience by recognized experts in the field that will likely have sustained relevance over five years. While there are no strict criteria regarding which topic should lead to a Practice Guideline vs. Position Statement, Practice Guidelines are typically meant for clinical practice questions related to the management of patients and answer foreground questions. Foreground questions address a certain condition's diagnosis and/or treatment and are described in the PICO (Population, Intervention, Comparison, Outcome) format. For example, in patients with functional constipation (population), should polyethylene glycol (intervention) be used compared to lactulose (control) for the resolution of symptoms (outcomes)? In contrast, background questions provide general information about a topic, e.g., what is the epidemiology of functional constipation in children or, what is the definition of functional constipation. For a given topic, there may be a combination of background and foreground questions. If most of the questions are background questions, we suggest doing a Position Statement and vice versa. Appropriate methodology should be used to address any of the foreground questions, irrespective of whether they are in a Position Statements or Practice Guidelines. A clear methodology for impartially determining expert consensus across the writing group will all be utilized to inform its writing. In particular, a clear process (i.e. Delphi and/or modified Delphi technique) for establishing expert consensus on statements and recommendations (<https://www.rand.org/topics/delphi-method.html>; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2550437/>) with interactive electronic voting on recommendations, will be encouraged. It also is recognized that experts in the field who comprise the writing group will often have preconceived stances on the topic at hand and may have academic and/or intellectual conflicts of interest (defined by the IOM as defined as a) authorship on a study reviewed by an expert writing group, b) authorship of a prior editorial related to a recommendation, or c) authorship of a prior related Position Statement or practice guideline (www.ncbi.nlm.nih.gov/books/NBK209538/)), and this should be explicitly disclosed. All Position Statements should also follow the AGREE II framework for development.

2)

- A. A Position Statement may also represent a report from a NASPGHAN committee, regarding a specific issue of importance to the field of pediatric gastroenterology, hepatology and nutrition that is not directly related to clinical care (e.g. research agenda, workforce survey; model of care e.g. Aerodigestive Center components or Pediatric Endoscopy services).
- B. In addition, a Position Statement may also be a policy statement, representing an organizational principle to guide and define the child health care system and/or improve the health of children and may contain recommendations based on interpretation of fact, values and opinions.

Please note: If a Position Statement or Practice Guideline is not accepted by NASPGHAN Council and/or the Clinical Care and Quality (CCQ) Committee for completion, some suitable manuscripts could be considered as a Review Articles for *JPGN*. Rejection of a proposal for a Position Statement to NASPGHAN Council may be based on, but not limited to reviews of lack of clinical impact, lack of significant quality evidence, concerns for a topic that is too heavily based on expert opinion, etc.

III. Development I Process

- 1) **Topic Identification** - Topics for NASPGHAN societal manuscripts should be pertinent and of high relevance for clinical practice, policy, advocacy or research and should aim to arrive at conclusions with strong evidence-based support that are helpful for practice. Repetition of previously published information will not justify publication of a societal manuscript, unless there is an urgent need to update the prior recommendations with new data. The proposal submission portal is available on the NASPGHAN website (<https://naspghan.org/professional-resources/clinical-guidelines/>). All societal manuscripts must clearly identify the NASPGHAN committee/committee chair who is sponsoring the proposal. The individual or Special Interest Group (SIG) with a proposal for a NASPGHAN or joint NASPGHAN/ESPGHAN societal manuscript on a particular topic must contact the appropriate NASPGHAN committee chair (e.g. IBD, motility, hepatology) to ensure that the chair is prepared to sponsor it on behalf of the committee. Sponsorship by a committee of a societal manuscript involves at minimum the sponsoring committee chair participating in discussions around authorship, recommendations and responses to independent and council reviews, and may involve mediating sensitive issues related to any and all phases of manuscript development.

In some cases, a NASPGHAN leader or member may identify a relevant topic for a Position Statement, which does not clearly fit into the domain of a specific committee. In such situations, the suggestion for a Position Statement should be discussed with the Clinical Care and Quality Committee Chair, who may then discuss with other members of NASPGHAN leadership (JPGN Editor, NASPGHAN Council).

- 2) **Financial Conflict of Interest:** The Writing Group Chair shall have no financial or other relationship with an affected company to disclose, where an affected company is defined as a commercial entity with a reasonable likelihood of experiencing a direct or indirect regulatory or fiscal impact as the result of a NASPGHAN-sponsored guideline or recommendation.
 - a. A majority (>50%) of the writing group members shall have no financial or other relationships with an affected company to disclose. The first and last authors on the manuscript should also have no conflicts.
 - b. Conflict of interest disclosures of all members of the writing group including the chair must be submitted at time of proposal submission to the CCQ committee and members of CCQ should recuse themselves from any decisions about development of societal papers if they have financial conflicts. (<https://naspghan.org/professional-resources/clinical-guidelines/>)
 - c. See NASPGHAN COI Policy: (www.naspghan.org/files/documents/pdfs/policies/Final%20COI.pdf)
 - d. If one is unsure what constitutes a significant industry tie, the member's disclosures should be reviewed by the NASPGHAN Ethics Committee.

3) Concept Proposal –

IMPORTANT: All proposals for societal manuscripts need formal review and approval by the CCQ Committee AND NASPGHAN Council before work on the manuscript begins. The Writing Group Chair needs to submit their proposal through the online submission portal to the NASPGHAN National Office. The National Office will then forward the proposal to the Chair of the CCQ Committee for review.

The submission of previously drafted manuscripts will be rejected for review as a societal paper.

The societal manuscript proposal must include the following information:

- **Manuscript Type** - Indication of type of societal manuscript (Practice Guideline or Position Statement) which will determine the submission form used.
- **Proposed Writing Group Members** - Information should include name, affiliated institution, one line on area of expertise and expected contribution of each writing group member to the societal manuscript. Relevant promotion of equity, diversity and inclusion should be provided.
 - Writing groups should consist of a **Writing Group Chair (either first or last author) and a set of members suitable for the proposed manuscript and recognized experts in the field to be submitted to the CCQ Committee and NASPGHAN Council for approval. Justification should be documented for 11-13 authors for Practice Guidelines and 8-9 authors for Position Statements.** Members of the Writing Group may include representation from subspecialties other than pediatric gastroenterology, hepatology, nutrition, and transplantation. Individuals with expertise in general pediatrics, pediatric surgery, nursing, psychology, epidemiology, etc., and/or other disciplines from whom their clinical and/or research perspective are paramount to the topic are encouraged whenever possible and reasonable. Per AGREE II framework, inclusion of patient representatives are particularly encouraged for Practice Guidelines. No fellows shall be included as part of the Writing Group. When a joint manuscript is being proposed (i.e. ESPGHAN), members of the Writing Group should be equitably representative of both organizations. The Writing Group members should be acknowledged experts in the clinical area to be addressed and should be inclusive and diverse in terms of geographic and gender, and if feasible, racial and ethnic, representation, as well as nationally or internationally representative, with specific attention to inclusion of an author from Canada and/or Mexico. There shall be no more than 1 author per institution. Exceptions to the above must be presented and justified at time of initial CCQ proposal for approval.

- **Once the proposal is accepted by NASPGHAN Executive Council, the author list CAN NOT BE CHANGED except by written request with subsequent approval by CCQ Committee and NASPGHAN Executive Council.**
- Members of the proposed Writing Group should be able to justify ICJME authorship guidelines based on the following 4 criteria:
 - Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
 - Drafting the work or revising it critically for important intellectual content; AND
 - Final approval of the version to be published; AND
 - Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.
- **Outline and Rationale for the Topic** - The initial proposal should include a brief (less than 1-2 pages) rationale for the proposed societal manuscript including, but not limited to, common disorders for which the standard of care is poorly defined; problems of widespread clinical/social consequences; availability of new diagnostic and/or new treatment modalities; controversial, complex, and/or challenging diagnostic, treatment or policy issue. Include a brief outline of the proposed societal manuscript. Practice Guidelines should include including formulation of clinical questions (e.g. Patient / Intervention / Comparison / Outcome - PICO format).
- **Methodology** – Each proposal should include an outline of the methodology to be used, which may include search strategy, summary of evidence, quality appraisal, development of recommendations and determination of the strength of the recommendations.
- **Budget** – NASPGHAN societal manuscripts, including clinical practice guidelines and position papers, should ideally require minimal funding. Writing groups are expected to use virtual meetings (e.g., Zoom) instead of in-person meetings, as funding for travel or face-to-face meetings will no longer be supported.
 - Each year, NASPGHAN will issue a **Request for Applications (RFA)** for new societal manuscripts. The number of accepted proposals will depend on the annual budget allocation. Applications should include a justified budget request, if needed, with priority given to cost-effective approaches, such as digital tools. Clinical practice guidelines must include at least one coauthor who is a **GRADE-trained methodologist**.
 - All budgets must be justified in advance, reviewed by NASPGHAN Council, and approved by the NASPGHAN Executive. **Proposed writing groups should not begin work until their budget has been reviewed and approved.** NASPGHAN will serve as the primary funding source for approved budgets, with limited exceptions for support from **not-for-profit, non-institutional organizations** (e.g., Cyclic Vomiting Syndrome Association, Crohn's & Colitis Foundation). However, all potential funding sources will undergo rigorous conflict-of-interest review, considering financial, academic, and intellectual influences. **Single institutions** (e.g., individual hospitals, universities, or health systems) and their foundations, even if not-for-profit, are not eligible funding sources.

- For approved budgets, all expenditures must be submitted with receipts to the NASPGHAN National Office for approval and payment.

IV. Review and Approval Process

- 1) The CCQ Chair identifies a minimum of 2 reviewers to assess the proposal with reviews typically completed within 4-6 weeks. They will evaluate the proposal based on the criteria outlined in Section II, based on what type of societal manuscript is submitted. The identity of the reviewers will be kept confidential.
- 2) Reviews will be forwarded back to the CCQ Chair and a composite review will be provided with a) recommendations for revision, b) rejection, or c) proceed for Council review and approval. The authors can either revise their proposal in accordance with the CCQ reviews or decide not to proceed. Communication between the lead author(s) and the CCQ Committee Chair (or designee) are permissible. Please note, the CCQ Committee may reject an initial proposal if it does not meet recommended criteria and if rejected, the proposal will not be sent to Council. There is an appeal process (see below, section VII).
- 3) Once the CCQ Committee has reviewed the proposal and any indicated revisions are completed, the CCQ Chair submits the recommendations and composite review to the NASPGHAN National Office. The National Office will disseminate to the NASPGHAN Council for its consideration and final decision. The Council review can occur by email, conference call, or at the NASPGHAN in-person leadership meetings. The Council's decision (approved, denied or requested changes in the proposal) will be communicated to the corresponding author by the NASPGHAN National Office. It is strongly recommended that the lead author(s) do not finalize/commit to the final writing group until they receive final approval from the NASPGHAN President in the form of a letter on official NASPGHAN letterhead.
- 4) Practice Guidelines have wider impact and are more costly to our society. Therefore, in addition to initial review by the CCQ, these proposals will undergo a second review by the NASPGHAN President and two Executive Council members (Council sub-committee) prior to full Executive Council review and approval. In addition to scientific merit, the budget and long-term impact of the proposal will be assessed by the Executive Council.
- 5) The NASPGHAN Executive Council shall review the Council sub-committee's recommendation and vote for final approval of the project. Review of the budget, secondary review (if needed) and approval of the proposal is the responsibility of the NASPGHAN Executive Council. The NASPGHAN President will notify the authors of the final approval in the form of a letter on official NASPGHAN letterhead.
- 6) **Once a proposal has been accepted by the NASPGHAN Executive Council, no changes shall be made without written approval from the NASPGHAN Executive Council.**

V. Instructions to Authors

- Council's decision on proposal will be sent to the corresponding author(s) by the NASPGHAN National Office, signed by the JPGN Section Editor for Societal Papers (SESP) and NASPGHAN President. The letter will include the following information/instructions to the authors:
 - The suggested page length of a Position Statement is 4000 words, not including references, with approximately 50-75 references. Position

Statements will be encouraged to also involve electronic appendices, which can be published online at the time of publication and allow further space for elaboration of methodology (e.g., Delphi processes, electronic iterative voting outcomes and statements and/or recommendations that did not achieve consensus).

- The suggested page length of a Practice Guideline is 4000-5000 words, not including references with 50-150 references. Practice Guidelines will be encouraged to prepare and submit electronic appendices, which can be published online at the time of publication and allow further space for elaboration of methodology (e.g., systematic search strategy, GRADE processes, evidence tables, PICO questions).
 - Due to space constraints in *JPGN*, the authors must notify the President, the SESP and the Editor-in-Chief if they anticipate the societal manuscript will exceed these limits.
- All societal manuscripts endorsed by NASPGHAN should include the Society name in the title. (i.e. NASPGHAN Practice Guideline..., The NASPGHAN xx Committee Position Statement on...)
- Timetable for Completion of NASPGHAN Societal Manuscripts: NASPGHAN societal manuscripts should be submitted for review within 12 months of NASPGHAN Executive Council approval. If the timetable for writing and submission will be extended past the 12 months, the Writing Group will need to submit an update and summary of the current state of the manuscript along with the planned date of manuscript submission to be reviewed by Executive Council for approval. The NASPGHAN National Office will periodically (3 months) request a status update from Writing Group Chair. The NASPGHAN National Office will assist the CCQ Chair and the SESP in these tasks by keeping track of proposals and completed manuscripts. Please note that any changes in scope, authors, etc. from initial approval at any time during the manuscript development must be submitted in writing and approved by CCQ and Executive Council.

VI. Peer review of NASPGHAN Societal Manuscripts

- 1) NASPGHAN societal manuscripts are to be uploaded on the *JPGN* Editorial Manager platform when completed (<https://www.editorialmanager.com/jpgn/default.aspx>). The NASPGHAN National Office should be notified when the upload has been completed. Peer review of these societal manuscripts will be overseen by the SESP who (in consultation with the NASPGHAN President) oversees the peer review process by appointing peer reviewers, communicates with the societal manuscript authors, and decides when the revised completed societal manuscript is ready to be forwarded to NASPGHAN Executive Council for final review.
- 2) The SESP appoints a minimum of 2-3 reviewers for the manuscript. The reviewers will be known content experts in the field and not necessarily Council members. If the SESP is in any way involved with the manuscript development (i.e. the chair of the committee where the guideline was proposed, co-author), an alternate SESP will be named at the discretion of the

President and JPGN Editor-in-Chief. At all times, the names of peer reviewers are kept confidential.

- 3) The JPGN Editorial Manager platform tracks the time the societal manuscript was provided to the reviewers, following similar processes and practices as all *JPGN* original manuscript submissions. The ideal time for manuscript review will be two weeks, although in selected instances, a longer time may be allowed at the discretion of the SESP.
- 4) Each societal manuscript typically undergoes two rounds of revisions, and once suggestions of the peer reviewers have been adequately addressed, the final version is reviewed via the Editorial Manager platform by the NASPGHAN Executive Council and the *JPGN* Editor-in-Chief.
 - a. In accordance with AGREE II, in addition to the peer review process above, all NASPGHAN society manuscripts will be posted on the NASPGHAN website, and forwarded to Society members for comment prior to publication.
 - b. For joint societal manuscripts, NASPGHAN Executive Council and ESPGHAN Executive Council will be invited to review after the initial round of revisions by the chosen peer reviewers and will be involved in all subsequent rounds of revision as well as reviewing the final version.
- 5) Prior to publication of joint Guidelines, the manuscript will be posted on NASPGHAN and ESPGHAN websites for comments from membership of both societies.
- 6) The *JPGN* Editor-in-Chief will make final editorial changes to the revised manuscript prior anticipated impending publication
- 7) Publication in *JPGN* will take place without further peer review and the document will be acknowledged as having undergone peer validation and be the expressed position of NASPGHAN.

VII. Appeal process

- At times, the NASPGHAN leadership or CCQ committee may reject a societal manuscript proposal on the basis of lack of importance, priority ranking for resource utilization, lack of evidence, or lack of scientific merit.
- If the proposer of the topic (either within NASPGHAN or within ESPGHAN if a joint guideline) wishes to appeal the decision, they may request an “appeal review”. In this case, the President will identify two reviewers from the NASPGHAN Executive Council. If the Council reviewers have a differing opinion from earlier recommendations, then a final consensus decision should be made by conference call between CCQ and Council.

VIII. NASPGHAN Endorsement of Guidelines Prepared by Other Societies

Periodically, NASPGHAN is contacted by other societies asking for endorsement of a manuscript under development. The decision to endorse another society’s manuscript

should be made by the NASPGHAN Executive Council, with consultation from the Chair(s) of relevant NASPGHAN committee(s) and CCQ Chair.

In general, NASPGHAN should only endorse other societal manuscripts if contacted during the early course of development of the manuscript and not after the manuscript's completion.

Criteria and procedure for endorsement of another society's manuscript:

- The document needs to be developed by a reputable society with a long track record of professional education. Examples include but are not limited to the American College of Gastroenterology, Crohn's and Colitis Foundation, American Association for the Study of Liver Diseases, and American Gastroenterological Association.
- At least one NASPGHAN member must participate in development and be an author of the document.
- The NASPGHAN President or designee must review the Practice Guideline or Position Statement policy of the other society, to make sure it is similarly rigorous to the NASPGHAN process.
- The final document should be reviewed by 2 NASPGHAN members (a member of Executive Council, and a member of the relevant committee). The President or their designee will identify the reviewers.
- The reviewers will recommend that NASPGHAN endorse the document or decline to endorse.
- If both reviewers agree with endorsement, the NASPGHAN Executive Council must vote to provide final endorsement.
- The NASPGHAN President or designee (including NASPGHAN Executive Director) will contact the entity/person seeking endorsement, stating why NASPGHAN endorsed or declined to endorse the document.

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Prior versions of this document (Melanie Greifer – October 2020, Revised by Athos Bousvaros 9/5/2021)