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Manual of operations. NASPGHAN Guidelines

I. Aim of this manual

The purpose of this manual is to clarify the process of guideline development and review, and attempt to clarify the general guidelines document developed by Steven Schwarz [chair of the Clinical Care and Quality Committee (CCQ)] and passed by NASPGHAN council in 2008. The initial document provided a framework for review, but left many of the details to the president, president elect, and chair of the CCQ. This manual has been developed by those three individuals in 2010, and can be revised in the future by those three individuals. The NASPGHAN council should be made aware of substantive changes to the manual.

II. Overview

There are three main components to the guideline process:

A. Review of proposals for clinical practice guidelines, clinical reports, technical reports, and position statements is the primary responsibility of the Clinical Care and Quality committee. Review of the budget, secondary review (if needed), and approval of the guideline is the responsibility of NASPGHAN council.

B. Peer review of completed guideline manuscripts is the responsibility of the NASPGHAN president or a person designated by the president (e.g. president-elect, chair of CCQ). The president or designee acts as "editor", appoints reviewers, communicates with the guideline authors, oversees the peer review process, and decides when the completed manuscript is ready to be forwarded to NASPGHAN council for approval. At the time the revised and near-final manuscript is forwarded to council, the NASPGHAN president then notifies the JPGN editor of the pending guideline submission.

C. Tracking of published guidelines will be done by the Clinical Care and Quality committee. This committee will perform an annual review and evaluation of the published NASPGHAN guidelines and clinical reports, beginning three years after publication. The committee will suggest whether they should be allowed to stand as is, be revised, or retired.

The NASPGHAN administrative staff will assist the CCQ chair and NASPGHAN president in these tasks by keeping track of guideline proposals, completed guideline manuscripts, and published guidelines. The staff will also track which reviewers have received the proposal or guideline, and whether or not they have completed their reviews.

The identities of the peer reviewers should be kept confidential..

III. Outline for submission of NASPGHAN guideline proposals.

A. For purposes of simplicity, from here on out in this document, the term "NASPGHAN guideline" refers to Clinical Practice Guidelines (CPGs), clinical reports, technical reports, and position statements.

B. Review of proposals for NASPGHAN guidelines and clinical reports

B.1. New guideline ideas are usually proposed by an individual or committee. The idea should first be discussed with the NASPGHAN president by the individual or committee chair.

B.2. If the president agrees that the topic warrants further investigation, the proposed guideline author then prepares a 1-2 page proposal, and proposes a budget. The proposal should include a rationale for the guideline, a proposed writing committee, and a brief outline of the proposed manuscript. The proposal can be submitted to Margaret Stallings of Kate Ho (see B.3).

For most clinical reports, technical reports and position statements, a limited budget (suggested amount under $1,500, limited to conference calls and minor administrative assistance) should suffice. For formal Clinical Practice Guidelines, a higher budget may be necessary (suggested amount $10,000, including travel and one face to face meeting), but this budget will be closely scrutinized by council. Proposals for all reports, guidelines, statements, should be submitted to the Clinical Care and Quality Committee by March 1, June1, September 1, and December 1 of each year. The chair of CCQ Committee will arrange for reviewers, with reviews hopefully completed within 4-6 weeks of each cycle (e.g. April 1-April 15 for proposals submitted on or before March 1).

Final approval to proceed will be given by the council can either occur by email, conference call, or at the NAPSGHAN leadership meetings at DDW (May for the proposals submitted by March 1) and at NASPGHAN (October for the proposals submitted by September 1). Once final approval is given, a member of the executive council (usually the president or president elect) will notify the head of the guideline writing committee and the head of the relevant NASPGHAN committee that the proposal has been approved.

B.3. The proposal is submitted to Margaret Stallings or her designee at NASPGHAN Central. Currently (May 2011), the NASPGHAN administrator in charge of guidelines is Kate Ho. The administrator will then forward the proposal to the NASPGHAN president and the chair of the Clinical Care and Quality Committee and the president of NAPSGHAN. The NASPGHAN administrator (currently Kate Ho) will track when the proposal is received, when it has been approved by CCQ, and when it has been approved by council.

B.4 The chair of the CCQ identifies at least 2 reviewers to assess the proposal. Reviewers may be CCQ members, NASPGHAN council members, or other experts in the field. Reviewers should evaluate the importance of the topic, the need for guidance to members on the issue, and the scientific merits of the proposal. The identity of the reviewers should be kept confidential. Reviews should be forwarded back to the CCQ chair, and feedback is given back to the person or committee proposing the guideline. The authors can then either revise their proposal in accordance with their reviews, or

decide not to proceed. Prior to submission to Council, the CCQ chair and guideline authors should decide whether the proposed idea should be a CPG, clinical report, technical report, or position statement.

B.5. The CCQ chair then approves the final submitted outline, and forwards the proposal to council. If the CCQ chair recommends that work proceed on the guideline, and the budget is under $1,500, the NASPGHAN council may recommend expedited approval of the proposal (such expedited approval can be given for up to 5 proposals in any calendar year).

B.6. Full clinical practice guidelines (CPGs) have wider impact, greater legal ramifications, and are more costly to the society. Therefore, in addition to initial review by CCQ, these proposals will undergo a second in depth review by the NASPGHAN president and two council members. In addition to scientific merit, the budget and long term impact of the proposal will be assessed by council. In depth discussions may potentially occur at the NAPSGHAN leadership meetings in January, May, September, and October. Final approval of a CPG proposal to the authors will be given by NASPGHAN president after a vote by council (either in person, or by email).

B.7. Review of potential conflicts of interest for the members of the committee. The NASPGHAN conflict of interest policy requires that the chair of a guideline committee does not have any financial ties to industry for at least one year prior to the writing of a guideline, and that the majority of guideline authors not have significant industry ties. Prior to approval of a guideline proposal, all authors must fill out a conflict of interest form. The forms for the proposed guideline panel will be reviewed by the NASPGHAN Conflict of Interest Committee (which includes the Chair of Clinical Care and Quality, the Chair of Ethics, and the Chair of Professional Development). This group will determine if the committee chair, or the committee as a whole, has a conflict of interest. If this group determines a significant conflict exists, the membership of the committee may need to be changed. Additional information on conflict of interest is available in section VIII below, as well as on the Conflict of Interest Policy on the Website.

B.8. Appeal process. At times, the NASPGHAN leadership or CCQ committee may decide to reject a guideline proposal on the basis of lack of importance, 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, either the president (or president elect, if the president is the person who rejected the proposal) will identify two reviewers from the NAPSGHAN council. If the council reviewers have a differing opinion from the recommendation of the Clinical Care and Quality Committee, then a final consensus decision should be made by conference call.

B.9. Suggested page length. The suggested page length of a clinical report should be 15-20 double spaced typewritten pages (5-10 journal pages), with approximately 50-75 references. The suggested page length of a Clinical Practice Guideline is 20-30 double spaced typewritten pages (10-15 journal pages), with 50-150 references. Due to space constraints in the JPGN, it is suggested that authors notify the president and editor if they anticipate the document will exceed these page limits.

IV. Peer review of completed NASPGHAN CPG and NASPGHAN Report manuscripts.

A. The completed manuscript is forwarded to the chair of the CCQ, who then documents the receipt of the completed draft, and forwards it to NASPGHAN central and to the NASPGHAN president.

B. The NASPGHAN president then either themselves serves as manuscript editor, or appoints a designee to serve as editor. The designee may be either the president-elect, chair of the CCQ, or a council member. Anyone even peripherally involved with the manuscript development (i.e. the chair of the committee where the guideline was proposed) should not serve as editor. The editor should not have a personal or financial conflict of interest with recommendations in the manuscript.

C.. The editor then appoints 2-3 reviewers for the manuscript (CPG, Clinical Report, or Technical Report). The reviewers may be CCQ members, council members, or other experts in the field. NASPGHAN Central tracks the time the manuscript was provided to the reviewers, and when reviews are returned. Ideal time for manuscript review should be two weeks. For full CPG's, in addition to the peer review process above, the document is posted on the NASPGHAN website, and forwarded to members for commentary.

D. The reviews and comments are then forwarded back to the authors anonymously. The authors revise the manuscript, and then submit it back to the editor. The editor may then feel the comments have been addressed, or forward it back to the reviewers for re-review. Once the reviewer's suggestions have been adequately addressed, the editor presents the final manuscript to the NASPGHAN president and council, who give it final approval (either electronically, by phone, or in a meeting).

E. Brief society position statements should be reviewed by three individuals: the president, president-elect, and one member of council to be chosen by the president. If all three do not recommend revisions, the statement may be approved by executive council in an expedited manner and submitted to the JPGN.

F. Clinical practice guidelines, clinical reports, technical reports, and position statements can then be submitted directly to the JPGN by the author and president of NASPGHAN. No additional peer review is performed outside of the society.

V. Tracking of published guidelines

The Clinical Care and Quality Committee will perform an annual review of all published guidelines and reports which have been in circulation for more than three years. The committee will suggest to NASPGHAN Council whether the guideline should remain in circulation, be revised, or be retired. The chair of CCQ will send an annual report to Council on the status of all guidelines, including their suggested recommendations. Guidelines that are deemed out of date and "retired" by the CCQ will be removed from the NASPGHAN website.

VI. NASPGHAN endorsement of guidelines prepared by other societies.

Periodically, the NASPGHAN president or executive director is contacted by other societies asking endorsement of a guideline under development. The decision as to

whether or not to endorse another society's guideline should be made by the Executive Council, the Chair of the relevant subspecialty committee (eg. IBD, motility, nutrition, Hepatology), and the chair of the Clinical Care and Quality committee. In general, NAPSGHAN should only endorse guidelines if contacted prior to the time the final manuscript is written. The correspondence between the other society and NASPGHAN should be saved by the Executive Director or her designee, and the date of correspondence logged in the guideline tracking sheet.

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

1. The document needs to be developed by a reputable society with a long track record of professional education. Examples include the American College of Gastroenterology, Crohn's and Colitis Foundation of America, Infectious Disease Society of America and American Association for the Study of Liver Diseases. (eg AASLD, CCFA, AGA, etc).
2. At least one NASPGHAN member needs to have been a coauthor on the document.
3. The NASPGHAN president or a designee (eg. Chair of Clinical Care and Quality Committee) needs to review the guideline policy of the other society, to make sure it is similarly rigorous to ours.
4. The final document should be reviewed by 2 NASPGHAN members (a member of council, and a member of the relevant committee). The president or presidential designee (ie president elect or chair of CCQ) can identify the reviewers.
5. The reviewers will simply give "thumbs up or thumbs down" to the NASPGHAN endorsement.
6. If both reviewers agree with endorsing, NASPGHAN executive council can then vote and endorse it. . If the reviewers decide not to endorse the document, the NASPGHAN president or designee should contact the appropriate medical contact in the other society, stating why NASPGHAN declined to endorse the document. The executive director of NASPGHAN can formally notify the other society of the executive council's decision.

VII. Joint NAPSGHAN and ESPGHAN guidelines

Background: In the past, NASPGHAN and ESPGHAN have published guidelines on similar topics with different recommendations. These separate guidelines were published one after the other and often created confusion for the members. Thus, in certain cases, combined NASPGHAN and ESPGHAN guidelines may be desirable. However, such guideline proposals and documents are subject to review by both societies. Joint guidelines should be undertaken only with firm support from the leadership of both organizations.

A. Mechanism for joint guideline creation.

1. Typically, within ESPGHAN or NASPGHAN, a guideline proposal comes from a committee chair or individual. If a proposer feels that a topic warrants a joint guideline, he should contact the president of his/her society (eg. for a constipation guideline suggested by ESPGHAN, the chair of the ESPGHAN motility committee should contact the president of ESPGHAN).
2. The president should then speak to their counterpart in the other organization (eg. the ESPGHAN president contact ths NASPGHAN president).
3. Assuming both presidents agree that a joint guideline should be considered, the presidents assign the preparation of an outline to the chairs of the respective committees (e.g. for a constipation guideline, the idea would be referred to the chair of the motility committee).
4. The committee chairs from each organization then either prepare the proposal themselves, designate a member of the society to prepare the proposal. Proposals should be developed jointly, and submitted for peer review to both societies. Budget and committee membership should be included at the time of the submission.
5. Membership of the writing committee. It is suggested that three members from each society (suggested total 6 members) be involved in the writing of a joint guidelines. Guideline members will be proposed by the chairs of the appropriate NASPGHAN/ESPGHAN committee. Members of the guideline panel will be selected on the basis of a) their proven scientific interest b) knowledge of the topic. c) Diversity issues (gender, discipline geographic, localization) and d) Ability to work in a group. While 6 is a suggested number, the total number required can be decided by the group, bearing in mind cost and organizational issues.
5. Given the cost and labor intensive process involved in creating joint NASPGHAN/ESPGHAN guidelines, these will be carefully tracked by leadership of both societies. At this time, it is suggested that no more than one joint guideline every two years be proposed.

B. Review of joint NAPSGHAN/ESPGHAN proposals within NASPGHAN.

All joint guideline proposals should be submitted to the chair of the Clinical Care and Quality committee, the NASPGHAN president, and the NASPGHAN administrative staff as outlined in section III of this document. The CCQ will review the document for scientific merit, and then forward to council for approval of the proposed budget. A suggested budget for such a joint guideline in 2011 is approximately $10,000 per society

($20,000 total). If the councils of both societies deem a project has exceptional need an/or merit, additional moneys may be budgeted.

C. Manuscript preparation and peer review.
Once approved, the joint committee will review the literature and prepare the manuscript in accordance with best evidence. The recent publication of the Institute of Medicine is a useful reference in guideline preparation. While a face to face meeting may be necessary, it is suggested such meetings be limited to one face to face meeting per guideline. Between the meetings, collaboration should take place electronically, by conference call, e-mail, and or web. Under exceptional circumstances with approval of both societies, two face to face meetings (one to be held in the US and the other in Europe) may take place. Ideally, the manuscript draft should be completed within 1 year after the guideline proposal is approved.

D. Peer review of completed manuscript.
Once the manuscript has been completed by the working group, it will be reviewed in accordance with the policy of each society. For NASPGHAN, the review process is outlined above in section IV of this document.

E. Publication
Publication of the joint guideline should occur in the Journal of Pediatric Gastroenterology and Nutrition. Once the guideline is finalized, the president of the society that initially proposed the document can submit the manuscript to the editor of the journal of their respective society (i.e. if the initial idea came from NASPGHAN, the NASPGHAN president can submit to the NASPGHAN editor of JPGN).

VIII. Conflict of interest management

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Industry grants will not be utilized to fund guideline preparation. The NASPGHAN conflict of interest regulations apply to joint guideline preparation. All industry support and ties should be disclosed at the time of the proposal. While guideline panel members may receive research support from industry, the chair of the guideline committee should not have significant industry ties. If one is unsure what constitutes a significant industry tie, the member's disclosures should be reviewed by the NASPGHAN ethics committee.

As per established NASPGHAN policy, potential conflicts of interest for any co-author of a NASPGHAN or joint NASPGHAN/ESPGHAN sponsored report, position statement or clinical practice guideline will be disclosed and assessed as follows:

> *The committees designated to author these documents are charged to review and recommend therapeutic and/or procedural protocols, as well as to present official NASPGHAN or joint NASPGHAN/ESPGHAN positions in areas that may impact standard-of-care and/or influence healthcare policy. These committees shall be constituted such that:*

- *The Committee Chair shall have no financial relationships with an affected company to disclose, where an affected company is defined as a commercial entity with a reasonable likelihood of experiencing a direct regulatory or fiscal impact as the result of a NASPGHAN-sponsored guideline or recommendation.*

- *A majority of committee members (to include the Chair) shall have no financial relationships with an affected company to disclose.*

- *All decisions rendered by the committee that impact clinical management recommendations shall be approved only upon receipt of a supermajority vote (≥67%) of committee members.*

All potential or standing committee members will complete a financial disclosure grid, as indicated below:

Criteria	Disclosure	Category		
		I	II	III
1	A research grant from an affected company supports my salary, or I receive *per capita* payments for clinical trials research.			
2	A research or educational grant from an affected company supports my professional activities, with no direct payments or salary support to me.			
3	I provide consulting services for, or participate in CME activities sponsored by and affected company, that generate personal income as direct payments to me, in the form of either salary or honoraria.			
4	I receive personal royalties from an affected company.			
5	I or a member of my immediate family has an equity interest in an affected company.			

Committee members disclosing financial relationships in Category III under Criteria 1, 3 and 4, as well as disclosures under Criteria 5 may represent disqualifying conflicts of interest. Pending review either the NASPGHAN Ethics Committee or by a constituted Conflict of Interest Subcommittee (to be appointed by the NASPGHAN Executive Council), such relationships may prohibit these individuals from proposed or continued participation in the preparation of Clinical Practice Guidelines, Position Statement, Clinical and Technical Reports. Disclosure of individual-industry associations is not a static process, and must be

reported on an ongoing basis before and during the development and generation of all guidelines and reports.