



# **Handbook on Clinical Practice Guideline Development**

## PURPOSE

The IDSA Standards and Practice Guidelines Committee (SPGC) have overseen the creation of this Handbook to assist IDSA-sponsored guideline expert panels in navigating through the often complex task of creating clinical practice guidelines. The bulk of this document consists of tools to assist guideline developers in interpreting and applying the methodology.

IDSA understands the challenges in applying a uniform methodology to guidelines that represent diverse diseases, conditions and interventions. In all cases, expert panel members should familiarize themselves thoroughly with this handbook, as these methods and standards provide the framework for guideline creation.

This handbook is to be considered a living document and will be updated as needed at the discretion of the IDSA SPGC.

## CLINICAL PRACTICE GUIDELINES

### *Definition of Clinical Practice Guidelines*

Clinical practice guidelines are defined as “Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options [1].” Guidelines are written to improve the quality of care, to improve the appropriateness of care, to improve cost-effectiveness, and to serve as educational tools.

The goal is not to create standards of care; however, other organizations may choose to adopt these guidelines or components thereof for such purposes. Practice guidelines, however, are never a substitute for clinical judgment. Clinical discretion is of the utmost importance in the application of a guideline to individual patients, because no guideline can ever be specific enough to be applied in all situations [2].

### *Clinical Practice Guidelines and Quality*

Practice Guidelines are widely used to help promote efficient and effective healthcare by improving process and patient care outcomes. Guideline quality is paramount to their credibility and implementation by the intended users. To help ensure that its guidelines are of sound quality, the IDSA looks to the [Appraisal of Guidelines Research and Evaluation Collaboration](#) (AGREE) self-assessment tool (AGREE Instrument), which provides a framework for assessing the methodological rigor and transparency of clinical practice guidelines [3].

The AGREE II instrument employs 6 domains of quality [3]:

1. Scope and purpose – refers to overall aim of the guideline, specific clinical questions and target population;
2. Stakeholder involvement – refers to the extent to which the guideline represents the views of its intended users;
3. Rigor of development – refers to the process used to gather and synthesize the evidence; methods used to formulate the recommendations and to update them;
4. Clarity and presentation – refers to language and the format of the guideline;
5. Applicability – refers to organizations, behavioral and cost implications of applying the guideline;

6. Editorial independence – independence of the recommendations and acknowledgement of possible conflict of interest

## **GUIDELINE DEVELOPMENT PROCESS**

The process as outlined in the following pages will provide guidance to the guideline expert panel and help to minimize potential biases, increase confidence by end-users resulting in increased uptake.

### ***Topic Proposal***

The clinical practice guidelines development program falls under the auspices of the SPGC. While the SPGC is charged with the review and approval of guideline topics and guideline drafts, actual guideline development is performed by topic-specific expert panels.

The SPGC will consider guideline topic proposals from any IDSA member. Proposed guideline topics will be chosen based upon the impact that they will have on the prevention, diagnosis and/or treatment of infectious diseases.

IDSA members who submit topic proposals are required to submit a 3-4 page narrative proposal that is organized around a series of the following questions:

1. What is the proposed title of the guideline?
2. What is the target patient population, target provider audience and the issue in question?
3. Is the burden/importance of the condition/intervention large enough to warrant the development of a document (prevalence/incidence should be included)?
4. Is there uncertainty/controversy about the relative effectiveness of the available clinical strategies for the condition(s) for which the document is proposed?
5. Is there a perceived or documented variation in practice management of a given condition/use of health care intervention?
6. Is there sufficient scientific evidence of good quality to allow development of document (i.e., randomized controlled trials (RCT))? If there is limited, high-quality information such that more definitive, evidence-based recommendations will not be possible, please outline how an IDSA document will still be of significant utility to IDSA members even given this limitation.
7. Are there existing documents (e.g., guidelines on the proposed topic?). *It is critical that the SPGC be aware of existing guidelines on the same topic to avoid duplication of efforts. Other groups' guidelines, if judged to be methodologically sound by the SPGC, can be submitted for endorsement consideration.*
8. If an IDSA document were to be developed as a result of your proposal, assuming appropriate dissemination, do you believe that it would make a significant impact on clinical decision-making/clinical outcomes and/or reduce practice variation?

### ***Topic Review and Approval***

After a topic proposal has been submitted to the IDSA office, it will be considered for approval by the SPGC, which meets at regular intervals. The Committee must come to consensus on the following:

- Whether or not to develop the guideline
- If the proposed topic benefits the IDSA membership at large
- If the document can be completed in a timely manner

- If there is a need for this information in a patient care setting

### ***Proposed Timeline/General Process Overview***

The process of developing a clinical practice guideline is detailed and timelines may vary depending on the scope of the topic. Awaiting new developments or data will prolong the process and should be avoided. The recommended time from the first expert panel meeting/conference call to submission of the guideline to the SPGC for approval is approximately 18 months.

In collaboration with IDSA staff, target completion dates for guideline development milestones will be assigned. The following are the steps that need to be carried out:

#### **Panel Chair/Member Clearance**

1. SPGC identifies potential panel chair (if update, may be former chair if he/she passes conflict screen).
2. Disclosure of interests form is completed and submitted for review by SPGC chair, SPGC liaison to the panel and Board liaison.
3. If approved, panel chair proposes panel members (and if applicable, collaborating organizations) to the Chair of the SPGC for approval/additions
4. Disclosure of interests form is completed and submitted for review by SPGC chair, SPGC liaison to the panel and Board liaison.

#### **Development Process**

5. Initial panel teleconference held to:
  - a. define clinical questions
  - b. decide specific roles/writing assignments of each member (i.e., specific subtopic or question to be considered)
  - c. Discuss process/milestones
6. Literature search is carried out by medical librarians. Yield provided to the panel.
7. Panel members review abstracts and select those that likely meet inclusion criteria
8. Panel members review full-text articles and make final inclusion/exclusion decisions
9. Panel members draft guideline sections as assigned
10. Panel meets (via conference call) and discusses recommendations
11. Panel reviews and approves first complete draft of guideline
12. Guideline subjected to 3-step rigorous review and approval process
13. Guideline submitted to *CID* for Publication
14. IDSA staff coordinates development of clinical tools including pocketcards and mobile device versions

### ***Expert Panel Composition and Disclosure of Conflicts of Interest***

The Expert Panel is charged with guiding the review of the evidence and subsequently, developing the guideline recommendations and drafting the manuscript.

The SPGC will identify a Chair(s) of the Expert Panel. The SPGC Chair will also identify an SPGC member to serve as the liaison-advisor to the Expert Panel. The liaison-advisor will

provide guidance to the Panel on the development, formatting and approval process of the guideline as well as monitor the progress for purposes of keeping the entire Committee informed.

The Expert Panel Chair will develop a list of potential panel members with expertise in the guideline topic. The panel chair may also suggest expertise from organizations that may have valuable input on the guideline.

The average expert panel will consist of 10 - 14 members who will meet regularly via conference call and during the annual IDSA conference. To the extent possible, ethnic, geographic, and gender diversity should be a consideration when identifying potential expert panel members. In addition, the Panel should include:

- Clinicians with expertise in the topic area in question (*It is recommended that at least one physician in private practice be included among the panels membership*)
- Inclusion of a pediatrician whenever the management of children may be considered (including the listing of antimicrobial dosing for children) (*The PIDS liaison to the SPGC is available to help identify this individual.*)
- Additional experts (**as considered necessary by the SPGC and expert panel**) may include those in the following disciplines:
  - Pediatrics
  - Epidemiology
  - Pharmacology
  - Microbiology
  - Nursing
  - Primary care
  - Subspecialty which has a unique interest in the specific field (e.g., urology for UTI) (see below regarding involvement of stakeholder organizations)
  - Hospitalists
  - Others as appropriate

Early in the guideline development process, the SPGC encourages Panels to invite stakeholder organizations (e.g., PIDS, SHEA, ASHP, SIDP, SIS, ACEP, SAEM, AAFP, etc.) to participate during the guideline development process. This might take two forms:

1. Joint development\* (See Section 2.12.2. Stakeholder Review) - Developing a guideline jointly entails having co-chairs from each organization and having equal representation on the panel.
2. Endorsement\* (See Section 2.12.2. Stakeholder Review) - Endorsement entails either:
  - a. The review of the end-product by the organization;
  - b. The addition to the Panel of a member from the potential endorsing organization and then review of the final product by the organization.

*\*Both scenarios provide an opportunity for the endorsing organizations to provide comments and suggest revisions.*

Once identified, the SPGC Chair will review and approve the list of potential panel members. Potential panel members will then receive the following:

- E-mail invitation to participate
- Disclosure of interests form

**Participation in the guideline development process is pending review and approval of the disclosure of interests form per the policy below.**

***IDSA Disclosure of Interests Policy for Clinical Practice Guidelines (Current as of April, 2012)***

**Background and Rationale**

As the leading organization for physicians, scientists, and other health care professionals dedicated to promoting excellence in infectious diseases research, education, patient care, prevention and public health, the Infectious Diseases Society of America (IDSA) has a special responsibility to support the efforts of its members to provide quality patient care. One of the primary ways in which IDSA fulfills this responsibility is through the development of clinical practice guidelines. Public confidence in IDSA guidelines and the process by which they are developed is dependent on the involvement of experts who make determinations based on the best available evidence.

In October, 2011, the IDSA adopted the [Council on Medical Specialty Societies \(CMSS\) Code of Interactions with Companies](#) principles for interactions with companies as they relate to clinical practice guideline development (Table 1).

The following describes the process and specific criteria used for disclosure for IDSA guideline development panels\* and the management of potential conflicts of interest. Process and procedures for others relevant to the guideline development process (Standards and Practice Guidelines Committee (SPGC) members, Board of Directors, reviewers) are also outlined (Figure 1).

**Introduction**

All guideline panel chairs and members should act in the best interest of IDSA, its membership, and the public. Decisions that lead to guideline recommendations should not be influenced by personal financial interests or by other extraneous considerations. Each guideline panel member has a high duty

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\* IDSA participates in or endorses guidelines developed by other organizations with established processes for disclosure. The administrative management of the guideline, including disclosure and management of conflicts of interest shall be the responsibility of the collaborating organization. IDSA does not participate in guidelines developed with funding from commercial entities.

and obligation to disclose any potential conflict of interest and to abstain from any decision where a potential conflict of interest exists. A potential conflict of interest exists if a guideline panel member has a financial or other interest that might bias his or her decisions or actions concerning matters before the Panel. In the interest of full disclosure, any relationship with a pharmaceutical, biotechnology, medical device, or health-related company or venture that may result in financial benefit to the member should be disclosed to IDSA.

### **Reporting Timeframe**

All disclosures should be for activities and financial relationships/investments that are current or planned and for the preceding two years. Current or prior relationships will not exclude candidates however participation is contingent on the candidates termination of such relationship(s) prior to their final assignment<sup>†</sup>.

### **Criteria for Panel Chair(s)**

The prospective chair will complete the IDSA Disclosure of Interests form. He/she will be free from financial or other interests that might bias his or her decisions or actions concerning matters before the Panel (see *Exceptions* below). Relationships that are both prohibited and acceptable are listed in Tables 2 & 3 respectively.

A prospective chair should disclose, if known, whether an affected commercial entity has provided financial support to the division, or department within which the individual conducts clinical research and care. The existence of such support does not necessarily disqualify the individual from service as a chair, but will be taken into consideration.

Because IDSA guidelines are subject to periodic revision or updating, panel chairs must complete and sign the IDSA Panel Chair Agreement acknowledging their commitment not to become involved in prohibited financial interests for an additional period of one year after publication of the guideline if they expect to remain in the chair position. If current financial interests preclude continuing as chair, these individuals may be considered for service as members

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<sup>†</sup> In some cases, IDSA may agree to allow for current commitments (e.g., speaking engagements) to be honored.

of the panel for the update (with full disclosure of their current financial or beneficial interests).

### ***Exceptions***

Generally, chairs will not be appointed that have financial interests in or relationships with affected companies or products. To the extent that the above restrictions are perceived as inhibiting development of a guideline, in rare circumstances, an exception may be made. A panel chair may receive research funding from an affected company that is usual and customary for the efforts needed to conduct the study, if doing so would ultimately help the panel develop a better quality guideline. In this instance, the panel chair will be unable to vote on guideline recommendations that are specifically related to the product about which his/her research is being conducted. In addition, a co-chair that has no financial or other beneficial interests must also be selected.

### **Criteria for Panel Members**

In April 2009, the Institute of Medicine (IOM) released its Report on Conflict of Interest in Medical Research, Education, and Practice. Among its recommendations, were that Groups that develop clinical practice guidelines “should generally exclude as panel members individuals with conflicts of interest.” It further recommends that “In the exceptional situation in which avoidance of panel members with conflicts of interest is impossible because of the critical need for their expertise, then groups should limit members with conflicting interests to a distinct minority of the panel.” The IDSA supports this goal, and through this expanded policy, is taking steps over time to put in place development panels with a minority of members with potential or perceived conflicts of interest. IDSA believes that individuals with expertise in a particular clinical topic are critical to developing the highest-quality and most informed practice guidelines.

All prospective panel members will complete the IDSA Disclosure of Interests form. For the duration of the development of the guideline, at least 15% of those selected as members of a guideline panel will be free of any conflicts of



interest and at least 15% will have no financial or other relationships related to the subject matter under consideration. For the remaining panel members such relationships do not preclude panel membership. However, it may be determined that an individual is not eligible to serve as part of the panel because of the nature and extent/intensity of his or her relationship with an affected company.

Relationships that are both prohibited and acceptable are listed in Tables 2 & 3 respectively.

All considerations will be balanced against the necessity of securing qualified individuals for participation in guideline development. In situations where the number of qualified experts is limited, panel members may inevitably have financial interests. IDSA will address this situation through disclosure of panel members' financial interests with publication of the guideline. In addition, the SPGC will require that panel members with a product-specific financial interest recuse themselves from specific discussions or votes. Panel chair(s) and the SPGC liaison to the Panel, will be responsible for determining the need for recusal. If there is a dispute regarding the necessity of recusal, the Chair of the SPGC, the Board liaison to the SPGC and if necessary, the COI Task Force of the Board will determine subsequent resolution. In most cases, concerns raised by panel members' financial interests may not mandate recusal depending on the breadth or specificity of the issues under consideration; that is, a financial interest may be of less concern where the matter under review is more general and less product-specific in nature.

#### ***Other Criteria for Panel Chair and Members***

Occasionally, a panel chair may have a relevant financial interest or relationship that is not covered by IDSA's formal disclosure process (e.g., an intellectual, as opposed to financial conflict). In these situations, the panel chair should disclose this interest to the Chair of the SPGC and/or the appropriate IDSA staff member prior to discussion of the guideline.

Participation in the activities of the guideline panel is prohibited until individual disclosures are reviewed and approved by the Chair of the SPGC,

SPGC liaison to the Panel, the Board liaison to the SPGC and if necessary, the COI Task Force of the Board. Assessment of disclosed relationships for possible COI will be based on the relative weight of the financial relationship (i.e., monetary amount) and the relevance of the relationship (i.e., the degree to which an association might reasonably be interpreted by an independent observer as related to the topic or recommendation of consideration).

### ***Criteria for Spouse/Dependents***

Information regarding the interests of a candidate's spouse and dependents is gathered as part of the disclosure process. Candidates should report, to the best of their ability, any known interests of his/her immediate family that may be related to the guideline topic under consideration. The extent of the family members' relationship will be considered as part of the evaluation of the candidate.

### ***Criteria for others involved in the guideline development process***

#### ***Standards and Practice Guidelines Committee***

Members of the SPGC serve in a liaison capacity to guideline development panels. In rare cases, these liaisons may serve as full members of the development panels. Liaisons who serve in this capacity are required to meet all criteria set forth above. Members of the SPGC are also charged with the review and approval of all IDSA guidelines. As with all IDSA Committees, SPGC members are required to disclose any relationship with a pharmaceutical, biotechnology, medical device, or health related company or venture that may result in financial benefit to the member. In addition, SPGC members are similarly prohibited from the activities outlined in Table 2. Participation in the activities of the SPGC is prohibited until disclosures are reviewed and approved by the Chair of the SPGC.

### **Criteria for Reviewers**

#### ***External "Peer" Reviewers***

The Editor of *Clinical Infectious Diseases* will identify at least 3 external “peer” reviewers to review and comment on the draft guideline. Additional reviewers may be identified by the SPGC Chair.

### ***SPGC Reviewers***

The SPGC Chair appoints Committee members to serve as primary reviewers of guidelines. Generally, the Chair will select members who have no financial relationships with affected companies or products to serve as guideline reviewers.

### ***Board of Directors Reviewers***

The Board liaison to the SPGC appoints Board members to serve as primary reviewers of guidelines. Generally, the Board liaison will select Board members who have no financial relationships with affected companies or products to serve as guideline reviewers.

### **Recusal**

To underscore the independence and integrity of the guideline adoption process, guidelines will be approved only by SPGC and Board members who do not have financial relationships with affected companies or products. Therefore, disclosure of any financial relationship with an affected company or product should be cause for recusal.

Rarely, relationships may be disclosed that, though not financial in nature, could undermine public confidence in the guideline process. If there is a question as to whether a particular relationship warrants recusal, a determination will be made by the SPGC Chair or Board Chair, respectively, with the assistance of IDSA staff. Any Committee or Board member who discloses a financial interest in a company or product affected by a guideline should recuse him or herself from the decision on approval of a guideline. The SPGC or Board member may take part in initial discussion of the guideline manuscript, recognizing that there may be additional discussion by remaining members after recusal and before the vote.

### **Publication of Disclosure Information**

When IDSA publishes a guideline in one of its journals, all disclosures of panel members will be published concurrently. The following language will accompany the list of disclosures within the “Acknowledgements” section:

***Potential Conflict of Interest:*** The following list is a reflection of what has been reported to the IDSA. In order to provide thorough transparency, the IDSA requires **full** disclosure of all relationships, regardless of relevancy to the guideline topic. Evaluation of such relationships as potential conflicts of interest is determined by a review process which includes assessment by the SPGC Chair, the BOD liaison to the SPGC, the liaison to the Panel and if necessary, the COI Task Force of the Board. This assessment of disclosed relationships for possible COI will be based on the relative weight of the financial relationship (i.e., monetary amount) and the relevance of the relationship (i.e., the degree to which an association might reasonably be interpreted by an independent observer as related to the topic or recommendation of consideration). The reader of these guidelines should be mindful of this when the list of disclosures is reviewed.

### **General Exceptions**

IDSA’s goal is to assemble a diverse and well-qualified group of experts to develop, approve, and adopt guideline recommendations. If required to achieve this goal, the above procedures may be modified by the COI Task Force of the Board on a case-by-case basis to the extent necessary.

<b>Table 1. Principles for Interactions with Companies on Clinical Practice Guidelines (Abstracted from the CMSS Code)</b>
<b>7.1.</b> Societies will base Clinical Practice Guidelines on scientific evidence.
<b>7.2.</b> Societies will follow a transparent Guideline development process that is not subject to Company influence. For Guidelines and Guideline Updates published after adoption of the Code, Societies will publish a description of their Guideline development process, including their process for identifying and managing conflicts of interest, in Society Journals or on Society websites.
<b>7.3</b> Societies will not permit direct Company support of the development of Clinical Practice Guidelines or Guideline Updates.
<b>7.4</b> Societies will not permit direct Company support for the initial printing, publication, and distribution of Clinical Practice Guidelines or Guideline Updates. After initial development, printing, publication and distribution is complete, it is permissible for Societies to accept Company support for the Society's further distribution of the Guideline or Guideline Update, translation of the Guideline or Guideline Update, or repurposing of the Guideline content.
<b>7.5.</b> Societies will require all Guideline development panel members to disclose relevant relationships prior to panel deliberations, and to update their disclosure throughout the Guideline development process.
<b>7.6.</b> Societies will develop procedures for determining whether financial or other relationships between Guideline development panel members and Companies constitute conflicts of interest relevant to the subject matter of the guideline, as well as management strategies that minimize the risk of actual and perceived bias if panel members do have conflicts.
<b>7.7.</b> Societies will require that a majority of Guideline development panel members are free of conflicts of interest relevant to the subject matter of the Guideline.
<b>7.8.</b> Societies will require the panel chair (or at least one chair if there are co-chairs) to be free of conflicts of interest relevant to the subject matter of the Guideline, and to remain free of such conflicts of interest for at least one year after Guideline publication.
<b>7.9.</b> Societies will require that Guideline recommendations be subject to multiple levels of review, including rigorous peer-review by a range of experts. Societies will not select as reviewers individuals employed by or engaged to represent a Company.
<b>7.10.</b> Societies' Guideline recommendations will be reviewed and approved before submission for publication by at least one Society body beyond the Guideline development panel, such as a committee or the Board of Directors.
<b>7.11.</b> Guideline manuscripts will be subject to independent editorial review by a journal or other publication where they are first published.
<b>7.12.</b> Societies will publish Guideline development panel members' disclosure information in connection with each Guideline and may choose to identify abstentions from voting.
<b>7.13.</b> Societies will require all Guideline contributors, including expert advisors or reviewers who are not officially part of a Guideline development panel, to disclose financial or other substantive relationships that may constitute conflicts of interest.
<b>7.14.</b> Societies will recommend that Guideline development panel members decline offers from affected Companies to speak about the Guideline on behalf of the Company for a reasonable period after publication.
<b>7.15.</b> Societies will not permit Guideline development panel members or staff to discuss a Guideline's development with Company employees or representatives, will not accept unpublished data from Companies, and will not permit Companies to review Guidelines in draft form.

**TABLE 2. Relationships Prohibited**

1.	Royalties, licensing fees, patents from any product or device related to the topic under consideration. This includes patents, the rights for which, have been turned over to an institution but from which the individual benefits.
2.	Serving as an officer, board of directors member or employee of any device, insurance, pharmaceutical or diagnostic product or commercial entity with a product or device related to the topic under consideration.
3.	Representation of any commercial healthcare-related entity (with a product or device related to the topic under consideration) before FDA advisory committees or in any other interactions such an entity may have with FDA.
4.	Any honoraria, gifts or other <sup>‡</sup> payments directly received from any relevant commercial healthcare-related entity <sup>§</sup> . This includes, participation in speakers bureaus labeled as promotional and/or when any associated presentation is: <ul style="list-style-type: none"> <li>a. content-restricted in any way, including, but not limited to the requirement to use only company-provided material; <ul style="list-style-type: none"> <li>i. paid for by any mechanism other than an unrestricted educational grant to a CME-approved (or other educational) entity; and/or</li> <li>ii. product-specific.</li> </ul> </li> </ul>
5.	Any activity not sponsored by the research arm of the company will <b>NOT</b> be allowed. For example, an advisory board sponsored by the marketing division, even if concentrating on “future research directions”, will <b>NOT</b> be allowed. In addition, consulting on post-research regulatory issues will <b>NOT</b> be allowed.
6.	Stock or equity in any commercial healthcare-related entities (excludes diversified funds).

**Table 3. Relationships Allowed**

1.	Advisory/consultancies when research-related will be considered as a research activity, even if the company with which you have the relationship, has products related to the guideline. Thus, work with a pharmaceutical or device company involving study design or service on a Data Safety Monitoring Board <b>WILL</b> be allowed. <i>Exception, Panel Chair</i>
2.	Serving as an investigator on a research study <sup>**</sup> .
3.	Presentations at national or international meetings provided that: <ul style="list-style-type: none"> <li>a. Presentations are non-promotional and there should be no involvement of industry in presentation content. There should be complete intellectual independence with regard to presentation content.</li> <li>b. There is NO direct payment by industry to an individual for his/her participation (any industry support of speaker expenses must be through a third-party organization (e.g, IDSA, ICAAC, ATS, etc), institution, CME or other educational provider.</li> </ul> <i>Exception, Panel Chair</i>

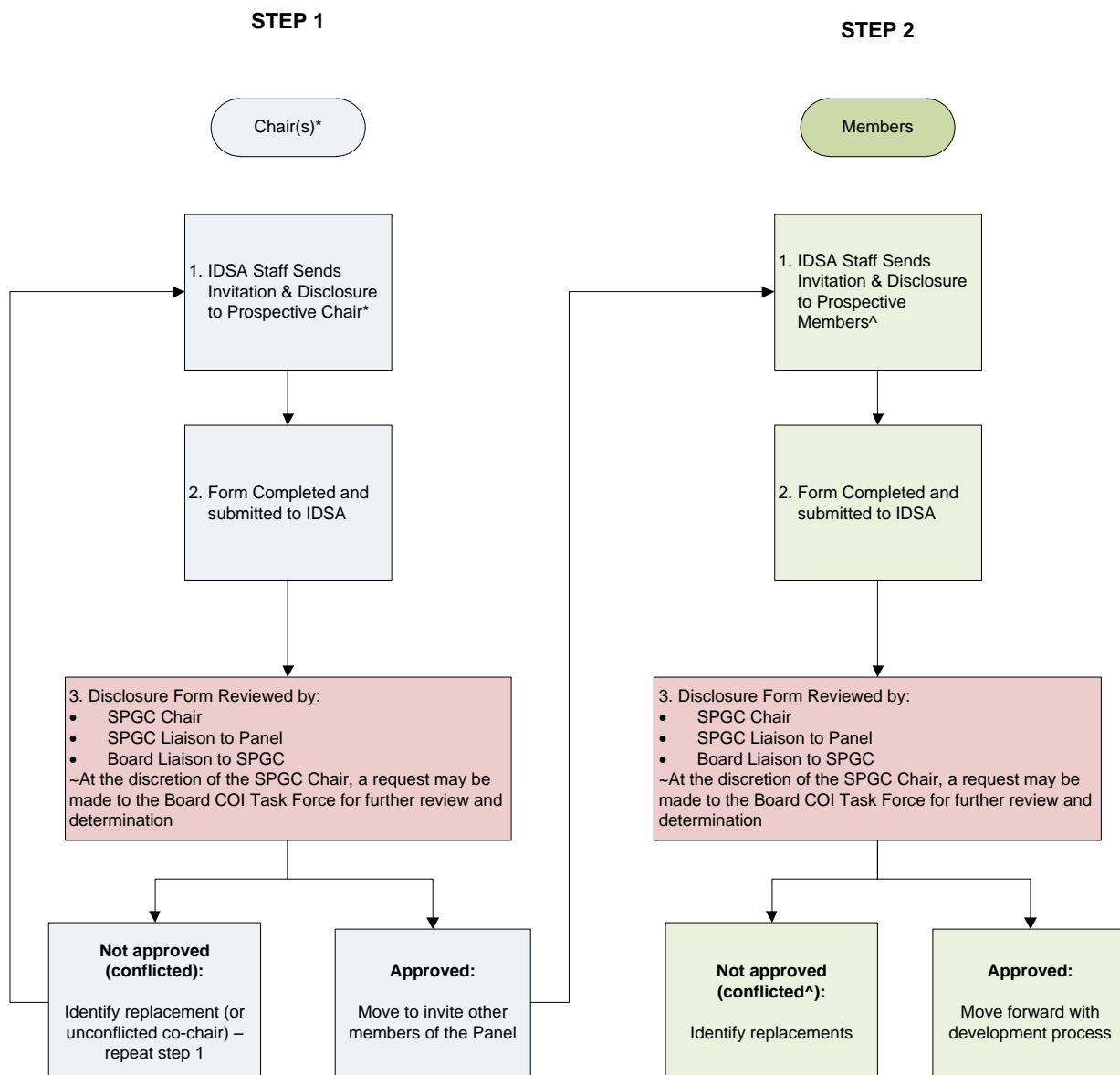
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<sup>‡</sup> Includes funds for travel/hotel

<sup>§</sup> Relevant to U.S. and International

<sup>\*\*</sup> If you are a panel chair and conduct research, IDSA may require a co-chair with no relationships/research.

**Figure 1. Disclosure Process for Clinical Practice Guideline Panels (before-during development)**



**Key:**

\* Chairs should be without conflict. If not possible, an unconflicted co-chair will be appointed. Chair contract/agreement also submitted at this time for IDSA file.

^IDSA strives for 15% of panel members to be without any conflicts; 15% should be without any relevant conflicts

See *Handbook on Guideline Development* for other Policies on Disclosure of interests.

### ***Finalize Purpose and Scope***

During the first Panel meeting/conference call, the following (much of which will have been identified and outlined in the aforementioned “topic proposal application”) will be discussed and agreed upon before moving forward:

1. *Definition of the Overall Purpose of Guideline:*

The purpose for writing the guideline should be clearly identified and written. It should be clear to the target provider audience why it is an important topic, why it has been chosen for review at this time and what impact the guideline is expected to have on the practice of medicine. Clarification of controversy, proper uses of newer technologic or diagnostic tools, and appropriate use of pharmaceuticals are examples of appropriate reasons for guideline development.

2. *Identification of Relevant Practice Setting(s):*

Specify clearly who the target provider audience is at the beginning of the guideline (e.g., hospitals; primary care or specialty care office-based practices).

3. *Specification of the Population(s) of Interest:*

The targeted patient population should be clearly specified. Consider age, sex, clinical condition or other factors that might affect the recommendations and then define these limitations. Consideration should be given to (1) the inclusion of special populations, such as demographics, pediatric patients, pregnant women, minorities or immuno-compromised individuals, and (2) how-or whether- the guideline recommendations are altered by these circumstances. It may be best to propose that a separate guideline be developed to encompass these groups if the recommendations are significantly different for specific populations.

IDSA guidelines are intended to apply to the North American population due to the variation in availability of drugs and differences in practice abroad.

4. *Specification of the Diagnostic and Therapeutic Options:*

Specify clearly the principal diagnostic or therapeutic options that are available and how they will be explored in the guideline. The reasons why these options were chosen and why other options were not considered should also be specified. This helps ensure that the document is succinct and focused.

5. *Identification of Relevant Primary and Secondary Outcome(s):*

Specify clearly the relevant primary and secondary outcomes (e.g., disease-free survival, overall survival, treatment toxicity, cost-effectiveness, quality of life).

6. *Specification of the Clinical Questions to be Addressed:*

Clinical questions flow from the broad guideline topic proposed and help focus the evidence review. In the context of making recommendations it is helpful to conceptualize all clinical questions as either:

- **FACTS** (e.g. prognosis, frequency of symptoms, etiology, pathophysiology etc.) – they provide important background information, but do not lead to recommendations per se and are not graded



### Examples:

- How do children differ from adults in disease manifestation?
- What is the rate of spontaneous resolution in ABRs?
- What are some suppurative and life-threatening complications of sinusitis?

OR

- **ACTION** (e.g. diagnosis, treatment, other management) – they do lead to recommendations and are graded.

### Examples:

- Is there a role for sinus aspiration and quantitative cultures?
- How long should antimicrobials be continued?
- Which antibiotics are preferred?

These latter questions about **ACTION** lead to recommendations.

Q: How long should antimicrobials be continued?

A: For 2 weeks.

Recommendation: We recommend that antimicrobials be continued for 2 weeks [strong recommendation, moderate quality evidence].

There is a well accepted way of framing the questions about action (addressing alternative management strategies for which GRADE is relevant) popularly known as PICO. PICO mandates carefully specifying the patient population (P), the intervention of interest (I – either diagnostic or therapeutic), the alternative intervention or comparator (C), and the outcomes (O) of interest (See Figure 2)<sup>††</sup>.

### Examples:

A question “What about decongestants?” could be broken into several precise questions:

Q1: Should **oral** decongestants versus no oral decongestants be used in **adults** with acute bacterial rhinosinusitis?

Q2: Should **oral** decongestants versus no oral decongestants be used in **children** with acute bacterial rhinosinusitis?

Q3: Should **intranasal** decongestants versus no intranasal decongestants be used in adults with acute bacterial rhinosinusitis?

Q4: Should **intranasal** decongestants versus **oral** decongestants be used in adults with acute bacterial rhinosinusitis?

Q1 and Q2 in the above example could be asked: “Should oral decongestants versus no oral decongestants be used in **patients** with acute bacterial rhinosinusitis?”, if the panel believes that these medications act similarly enough in adults and children to warrant one recommendation for all patients irrespective of age.

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<sup>††</sup> Centre for Evidence-Based Medicine, Institute of Health Sciences Old Road Campus, Headington, Oxford, OX3 7LF, United Kingdom. [http://www.cebm.net/focus\\_quest.asp](http://www.cebm.net/focus_quest.asp)

When asking these questions it is helpful to think of all outcomes of interest that would be important to patients, both desirable (e.g. less symptoms, better quality of life) and undesirable (e.g. adverse effects, burden, cost, antimicrobial resistance).

**Example:**

Q: Should amoxicillin with clavulanate be given for 2 weeks rather than for 1 week in adults with acute bacterial rhinosinusitis?

P: adults with acute bacterial rhinosinusitis

I: amoxicillin with clavulanate for 2 weeks

C: amoxicillin with clavulanate for 1 week

O: resolution of symptoms (e.g. facial pain, nasal congestion), development of complications, antibiotic resistance, cost etc.

Please note that all outcomes but antibiotic resistance are directly important to patients (patient perspective), however antimicrobial resistance may also be important but from a different perspective – that of the society as a whole. It helps to make the choice of perspective in the guidelines clear.

A guideline development panel should take the following steps when developing clinical questions:

1. Develop clinical questions into those that are either “facts” or “action”
2. Specifying all alternative management options for a given clinical situation
3. Formulating questions about action in PICO format (specifying all outcomes of interest for each question).
  - a. This may generate a long list of questions that the panel will likely have to discuss and prioritize to make it manageable.

	1	2	3	4
	Patient or Problem	Intervention (a cause, prognostic factor, treatment, etc)	Comparison Intervention (if necessary)	Outcomes
Tips for Building	Starting with your patient, ask "How would I describe a group of patients similar to mine?" Balance precision with brevity.	Ask "Which main intervention am I considering?"  Be specific	Ask "What is the main alternative to compare with the intervention?"  Again, be specific	Ask "What can I hope to accomplish?", or "What could this exposure really affect?"  Again, be specific
Example	"In patients with heart failure from dilated cardiomyopathy who are in sinus rhythm..."	"...would adding anticoagulation with warfarin to standard heart failure therapy..."	"...when compared with standard therapy alone..."	"...lead to lower mortality or morbidity from thromboembolism. Is this enough to be worth the increased risk of bleeding?"

Figure 2

### ***Comprehensive Literature Search Process***

### Researching the Evidence

Once the scope and clinical questions of the guideline have been determined, a comprehensive search of the literature search takes place. A key component to the development of clinical practice guideline methodology is the creation of recommendations based on the entirety of the evidence currently available. The Institute of Medicine describes literature searching as the key step in developing valid guidelines. Panels will work with a designated medical librarian to conduct searches of the literature and identify relevant evidence via systematic searches of appropriate databases (e.g., PubMed).

### Unpublished Data

Guideline writers are frequently familiar with data from abstracts and late breaking clinical trials that may impact the guideline's content. Generally, results from unpublished data are not acceptable. However, in special circumstances, unpublished data can be permitted if it is **no older than 2 years** and is clearly stated as such in the guideline text. Only trials presented at a major national or international scientific meeting should be considered, and **should not be used to support any recommendation**. When trial data are discussed, the text should clearly state that the data are preliminary.

### *Standard Guideline Format*

IDSA guideline manuscripts should conform to a standardized format (See Section 3.0. IDSA Standard Guideline Format).

### *Synthesis and Interpretation of the Evidence*

#### Narrative Synthesis of Evidence

Summaries of evidence should generally be in tabular form and not in the text of the guideline. Text should be reserved for qualifying or clarifying the recommendations. Clinical trial data and other evidence should be displayed in an evidence table. When multiple trials have yielded similar, non-controversial results, a single sentence with appropriate references may suffice. Long, descriptive paragraphs of the methodology and findings of individual trials are discouraged.

### Recommendations

Guideline development, unlike other methodologies, goes beyond the compilation and analysis of data to include recommendations that guide clinical practice. Guideline writers are challenged with considering a vast array of evidence and creating clinically applicable and clear recommendations from it.

As the evidence is considered, conclusions and recommendations naturally evolve. Whenever this occurs, the recommendation should be condensed into a sentence or two and separated from the text. The recommendations are the core guideline content, while the text enhances the recommendations by providing further descriptive information, such as exceptions to the recommendations and clinical options.

Guidelines are intended to be applied by health care providers at point of care. Therefore, recommendations should be practical, supported by evidence (e.g., provide references when possible), feasible and clinically flexible, thus facilitating the translation and implementation of recommendations.

### Interpretation and Classification of the Evidence

Only in rare instances is there an abundance of evidence available that leads directly to an indisputable recommendation. Expert interpretation serves as a funnel through which evidence on multiple questions and clinical situations is combined, condensed, and formulated into recommendations [4]. Despite all the evidence that may be available for writing recommendations, expert interpretation will always be necessary.

Unfortunately, most evidence falls into the "gray zone" of uncertainty. The evidence from different trials may come to divergent conclusions. The evidence may only apply to specific sub-populations, the evidence may be from methodologically weak studies, or the evidence may simply be insufficient to make a decision. In these instances, it is appropriate to rely on expert opinion so long as it is clearly indicated and attributed. The basis on which expert opinion was formed should also be specified.

The following are qualities of recommendations that may be considered when writing the guideline:

- Separate recommendations should be written that apply to specific clinical objectives
- Recommendations should be written so that they are practical at point of care
- Unambiguous language and clearly defined terms should be used when writing recommendations
- Information that contains areas of uncertainty or controversy should be documented within the recommendation
- Write recommendations that incorporate data on patient preferences, when applicable
- Specify sub-population variability and exceptions in the recommendations. List the exceptions whenever possible
- Include flexibility in applying the recommendations, where applicable
- **Recommendations must be consistent with previous IDSA guidelines/statements, unless new evidence exists to justify a change. Both the new evidence and the change should be described in detail**

### *Assigning Strength of Recommendations and Quality of Evidence*

IDSA Clinical practice guidelines *initiated* in October 2008 or later will use the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) method to assign to strength of recommendation and quality of evidence to each recommendation (See Figure 3[5]). Online training modules/tutorials and other information on the GRADE system can be found on the [IDSA website](#).

### Quality of Evidence

The quality of evidence reflects the extent to which the confidence in estimates of the effects is adequate to support a particular recommendation. Hence, judgments about the quality of evidence are always made relative to the specific context in which this evidence is used. GRADE offers four levels of the quality of evidence: high, moderate, low, and very low. In the GRADE system basic study design remains an important determinant of the quality of evidence: randomised trials begin as high quality evidence and observational studies as low quality evidence. However, additional limitations or merits may decrease or increase the quality of evidence. Quality of the available evidence may be downgraded as a result of the risk of bias

(limitations in study design or implementation), imprecision of estimates (wide confidence intervals), variability in results (inconsistency), indirectness of evidence, or publication bias. Quality of evidence may also be upgraded because of a very large magnitude of effect, a dose-response gradient, and if all plausible biases would reduce an apparent treatment effect.

### Strength of Recommendation

The strength of recommendation reflects the extent to which one can be confident that the desirable consequences of an intervention outweigh the undesirable ones. The GRADE system offers two categories of the strength of recommendations: (1) strong, and (2) weak (conditional). It is more likely to make weak recommendations when the available evidence is of lower quality, when the balance between desirable and undesirable consequences of the intervention is not clear, and when the values and preferences of those for whom the recommendations are made are either not known or are known to vary widely.

**Strong:** For a guideline panel to offer a strong recommendation, it has to be quite certain about the various factors that influence the strength of a recommendation and have the relevant information at hand that supports a clear balance toward either the benefits (to recommend an action) or the downsides (to recommend against an action) that influence a recommendation. If guideline developers are confident that the desirable effects of adherence to a recommendation outweigh the undesirable effects, they will make a strong recommendation within the context of a described intervention.

The implications of a strong recommendation are:

- for patients – most people in your situation would want the recommended course of action and only a small proportion would not; request discussion if the intervention is not offered
- for clinicians – most patients should receive the recommended course of action
- for policy makers – the recommendation can be adopted as a policy in most situations.

**Weak (conditional):** In situations when a guideline panel is uncertain whether the balance between desirable and undesirable effects of an intervention is clear or when the relevant information is not available, a guideline panel should be more cautious and, in most instances, opt to make a weak recommendation. If guideline developers believe that benefits and downsides are finely balanced, or appreciable uncertainty exists about the magnitude of benefits and/or downsides, they offer a weak recommendation.

The implications of a weak recommendation are:

- for patients – most people in your situation would want the recommended course of action, but many would not
- for clinicians – you should recognize that different choices will be appropriate for different patients and that you must help each patient to arrive at a management decision consistent with her or his values and preferences
- for policy makers – policy making will require substantial debate and involvement of many stakeholders.

**Expert Opinion:** Expert opinion is **NOT** a category of evidence as it is the most biased type of “evidence.” Expert opinion represents an interpretation of evidence, including evidence ranging

from observations in an expert's own practice (uncontrolled observations) to the interpretation of RCTs and meta-analyses known to the expert in the context of other experiences and knowledge. That said, in certain circumstances, observational studies, case reports or other such type information as well as the collective experience/observations of the group may be used in some circumstances. An example of collective experience/observations would be that 5 out of 10 of the panel members have seen **x** condition and this **x** is what has been done.

The Panel should do the following when there's limited or no evidence and they feel compelled to make a recommendation:

- come to agreement on what type(s) of information should be used (small observational studies etc., and/or collective experience/observations of panel members)
- Deliberations about the types of evidence used, votes taken etc., must be documented both in the notes from the meetings and within the guideline itself.

Obviously, the quality of the evidence in these instances will be "very low," but the strength could be "Strong."

The key is to be transparent about what's being done and to document what's being/been done.

#### Formulating Recommendations

GRADE suggests that guidelines developers present recommendations in the active voice and consistently use specific wording associated with strong and weak recommendations.

GRADE suggests the following wording:

- for strong recommendations – "we recommend..." or "clinicians should..."
- for weak recommendations – "we suggest..." or "clinicians might..."

Recommendations should always specify the population, and unless it is obvious, the comparator. A recommendation may be worded as follows (example):

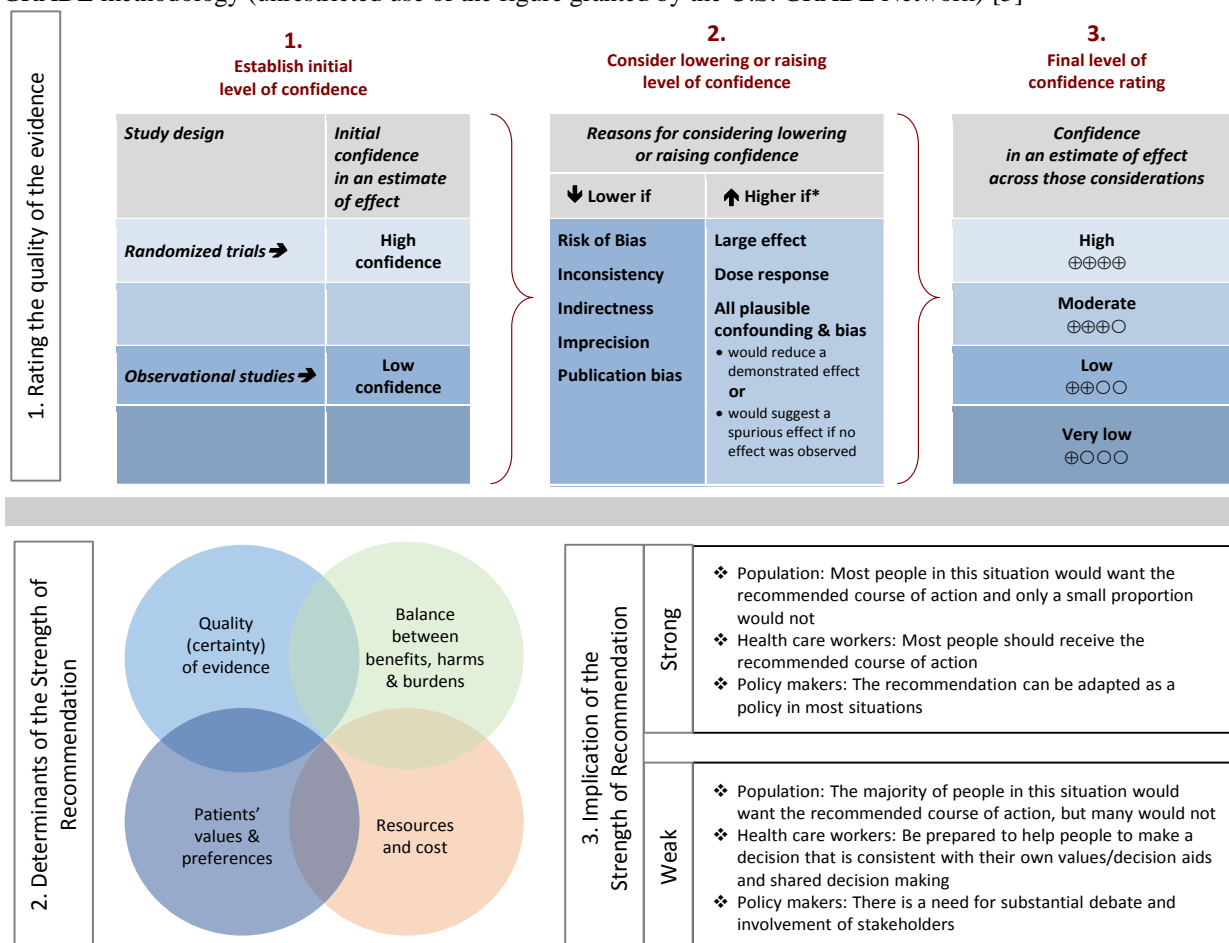
#### ***Strong recommendation:***

"For patients with chronic rhinosinusitis with nasal polyps who have nasal blockage or an impaired sense of smell, we recommend a short course of oral glucocorticosteroids (strong recommendation, moderate quality evidence). *Remark:* A typical adult regimen may be an equivalent of prednisone 20 mg twice daily for five days, followed by 10 mg twice daily for five days and then 10 mg daily for five days."

#### ***Weak (conditional) recommendation:***

"For patients with chronic rhinosinusitis with nasal polyps, who receive oral or intranasal glucocorticosteroids, we suggest leukotriene receptor antagonists (weak recommendation, moderate quality evidence). *Values and preferences:* This recommendation places a relatively high value on a small reduction in symptoms with leukotriene receptor antagonists and a relatively low value on increased resource expenditure. *Remark:* Evidence is available for montelukast only."

Figure 3. Approach and implications to rating the quality of evidence and strength of recommendations using the GRADE methodology (unrestricted use of the figure granted by the U.S. GRADE Network) [5]



### Additional criteria for applying or using the GRADE approach

One of the aims of the GRADE Working Group is to reduce unnecessary confusion arising from multiple systems for grading evidence and recommendations. To avoid adding to this confusion by having multiple variations of the GRADE system we suggest that the criteria below should be met when saying that the GRADE approach was used. Also, while users may believe there are good reasons for modifying the GRADE system, we discourage the use of “modified” GRADE approaches that differ substantially from the approach described by the GRADE Working Group.

However, we encourage and welcome constructive criticism of the GRADE approach, suggestions for improvements, and involvement in the GRADE Working Group. As most scientific approaches to advancing healthcare, the GRADE approach will continue to evolve in response to new research and to meet the needs of authors of systematic reviews, guideline developers and other users.

#### ***Suggested criteria for stating that the GRADE system was used:***

- ☐ 1. The quality of evidence (confidence in the estimated effects) should be defined consistently with the definitions (for guidelines or for systematic reviews) used by the GRADE Working Group.
- ☐ 2. Explicit consideration should be given to each of the GRADE criteria for assessing the quality of evidence (risk of bias/study limitations, directness of evidence, consistency and precision of results, risk of publication bias, magnitude of the effect, dose-response gradient, and influence of residual plausible confounding) although different terminology may be used.
- ☐ 3. The quality of evidence (confidence in the estimated effects) should be assessed for each important outcome and expressed using four categories (e.g. high, moderate, low, very low) or, if justified, three categories (e.g. high, moderate, and low [low and very low reduced to one category]) based on consideration of the above factors (#2) with suggested interpretation of each category that is consistent with the interpretation used by the GRADE Working Group.
- ☐ 4. Evidence summaries (evidence tables or detailed narrative summaries of evidence transparently describing judgements about the factors in #2) should be used as the basis for judgements about the quality of evidence and the strength of recommendations. Ideally, full evidence profiles suggested by the GRADE Working Group should be used and these should be based on systematic reviews. At a minimum, the evidence that was assessed and the methods that were used to identify and appraise that evidence should be clearly described. In particular, reasons for upgrading and downgrading the quality of evidence should be described transparently.
- ☐ 5. Explicit consideration should be given to each of the GRADE criteria for assessing the strength of a recommendation (the balance of desirable and undesirable consequences, quality of evidence, values and preferences, and resource use) and a general approach should be reported (e.g. if and how costs were considered, whose values and preferences were assumed, etc.).
- ☐ 6. The strength of recommendations for or against a management option should be expressed using two categories (weak and strong) and the definitions/interpretation for each category should be consistent with those used by the GRADE Working Group. Different terminology to express weak and strong recommendations may be used (e.g. alternative wording for weak recommendations is: conditional), although the interpretation and implications should be preserved.



☐ 7. Ideally, decisions about the strength of the recommendations should be transparently reported.

### ***Identifying Limitations in Literature Searches and Areas for Ongoing and Future Research***

Guidelines should comment on studies in progress that may help answer the clinical question more definitively and suggest areas for further study. The process of guideline development serves as a natural channel by which to identify research gaps which, if appropriately addressed, can advance future clinical care and treatment. Clinical practice guidelines identify important clinical questions and identify the quality of evidence supporting those recommendations. Thus, guidelines should include comments on studies in progress that may help answer clinical questions more definitively and suggest areas for further study.

### ***Review and Approval Process***

#### **External “Peer” Review**

External review is an integral step in the development of practice guidelines. The process of external review provides critical feedback into the comprehensiveness, validity and usability of the work performed.

Following approval of the draft guideline by the expert panel, the near-final draft of the guidelines are sent to **no fewer than 3** external peer reviewers nominated by the Expert Panel Chair. External reviewers should include:

- National (and when appropriate, international) experts on the guideline topic
- Representatives from the clinical practice setting
- Pediatrician, when warranted

**Note:** At least two of the proposed outside reviewers should be IDSA members.

Final selection of external reviewers will be done by the SPCG Chair and may include reviewers who are independent of the list provided by the Expert Panel Chair.

Once the external reviewers have been identified and approved by the SPGC Chair, the IDSA Staff will send an e-mail invitation to review along with a disclosure of interest form. The form must be completed and submitted to the IDSA for review and approval by the SPGC Chair. Once approved, the draft guideline and comment form will be forwarded onto the reviewer(s).

External reviewers are asked to provide their review within a 4 week timeframe. Additional time may be granted if needed. Reviewer comments will be sent back to the IDSA staff, compiled and distributed to the Panel Chair for response.

#### **Stakeholder Review**

When a stakeholder organization is involved in the development of an IDSA guideline at the onset or is identified later in the process as a potential endorser, IDSA staff will solicit their input and endorsement as follows:

An e-mail request is sent that includes an endorsement form and the draft guideline. The organization that IDSA is seeking endorsement from has the opportunity to provide comments and suggested revisions within a reasonable timeframe (4-8 weeks). The organization is provided with the following options for their level of endorsement:

- X organization endorses the guideline as written

- X organization endorses the guideline and suggests the attached comments for consideration
- X organization endorses the guideline on the condition that the attached comments are incorporated
- X organization **does not** endorse the guideline

If an organization is able to complete the review within the 2-month timeframe (or within a reasonable and agreed upon timeframe), the organization will be acknowledged within the manuscript prior to publication; however, if the organization is not able to meet the deadline, the guideline will continue through the review process and the organization may be acknowledged on the IDSA Website.

Once in receipt of the external reviewers' and the stakeholder organization's comments (if applicable) the Panel Chair will review the comments and incorporate them into the draft as deemed appropriate. The Panel Chair should provide (to IDSA) the revised guideline draft along with a response to each comment made, within a reasonable timeframe (typically 2 – 4 weeks) Responses should indicate where and why reviewer recommendations were included, and why others were not (if applicable).

#### SPGC Review

The SPGC Chair will designate 1-2 primary reviewers among the members of the Committee to review the guideline typically within a 2 – 4 week timeframe. The Panels responses to the external reviewers' comments will also be provided. The full Committee has the opportunity to review and provide comments on the guideline at this time as well.

Primary reviewers should consider the following questions when reviewing the guideline:

- Are the recommendations within the stated purpose and scope of the guideline?
- Are all recommendations referenced appropriately?
- Are all recommendations graded?
- Are clinically important and feasible recommendations made?
- Are areas of uncertainty and exceptions clearly identified?
- Are evidence tables and appropriate text provided to support recommendations, where applicable?
- Are recommendations and key clinical points displayed in a table when possible?
- Are the recommendations consistent with other IDSA documents?

Comments received from the SPGC are forwarded on to the Panel Chair for incorporation into the draft as deemed appropriate. Within 2-4 weeks, the Panel Chair must provide (to IDSA) the revised guideline draft along with response to each of the comments made indicating where and why reviewer recommendations were included, and why others were not (if applicable). Staff will then send the guideline and responses to the comments back to the SPGC for approval (within ~1 week).

#### Board of Directors Review

Once approved by the SPGC, the guideline will be submitted to the Board of Directors as follows:

- The Board liaison to the SPGC will identify 1-2 primary Board reviewers to review the guideline (responses to comments from the external review and the SPGC review will

also be provided). The full Board has the opportunity to review and provide comments on the guideline at this time as well.

- The Board is typically given 3-4 weeks to review the document.

Comments received by the Board are forwarded on to the Panel Chair for incorporation into the draft as deemed appropriate. Within 2-4 weeks, the Panel Chair must provide (to IDSA) the revised guideline draft along with a response to each of the comments made indicating where and why reviewer recommendations were included, and why others were not (if applicable).

The guideline and responses to the comments are then sent back to the Board for approval (within ~1 week).

### ***Pre-Publication & Publication Process***

Once approved by the IDSA Board of Directors, the guideline will be submitted for publication in the *Clinical Infectious Disease (CID)* with the understanding that publication is ultimately the decision of the Editor. As of 2010, full text of IDSA Guidelines will appear in electronic format only, with an executive summary in print. Guidelines must continue to adhere to a strict page limit (see section below on format).

Panel members are required to observe a strict policy of confidentiality of guideline documents, draft and final, pending guideline publication and are required to keep content of panel deliberations confidential.

### ***Guideline Derivatives***

Panel Chair(s) will be asked to assist in the review of a number of potential derivative products. The Chair(s) are expected to carefully review these products to ensure that the content is consistent with the published guideline. The purpose of these products is to more widely disseminate, in a practical and user-friendly form, the recommendations contained in the guidelines.

Ideally, these companion products will be developed as the first full draft of the guideline document is assembled and circulated for review, aiming for joint approval and release. Examples of guideline derivatives include:

- Mobile Device (iPhone, iPad, Droid, etc)
- Pocketcards
- National Guideline Clearinghouse Summary
- Slide Sets
- others

### ***Process for Guidelines Developed Jointly (Co-Sponsorship) with Other Organizations***

It may be appropriate and desirable to develop guidelines in conjunction with other organizations. This means that each organization will have a co-chair, equal representation on the Panel and share costs associated with the development of the guideline. In such cases, the development process should be defined and agreed upon with a memo of understanding from the onset, including:

1. A clear understanding of the topic and purpose of the guideline
2. The composition of the development panel
3. Full disclosure of conflict of interest

4. Expense-sharing arrangements
5. The review and approval process necessary for each organization
6. Publication rights (including responsibilities for derivatives)

It is preferable to have the guideline published in *CID*. However, when it is determined that the guideline is to be published in another journal, an IDSA member serving on the development panel may be identified to write an executive summary article for submission to *CID*.

### ***HIV-Related Guidelines***

On any guideline related to HIV, suggestions will be sought from HIVMA on possible members for the development panel.

The development process is virtually identical to the process described above, with the exception that guidelines on HIV will be submitted to the HIVMA Board for review and approval at the same time as for the IDSA Board.

### ***Author Permission to Use Guideline Content***

Authors retain the right to use all or part of an article in the preparation of derivative works, provided they include full acknowledgment of the original source. So for **non-commercial purposes**, authors do not need to apply for written permission from the IDSA or CID/OUP

For **commercial purposes** (e.g., a book that will be sold) permission is required. You can acquire permission through OUP's Rights & Permissions department, but the easier method is to go thru [www.copyright.com](http://www.copyright.com).

## **GUIDELINE UPDATES, PARTIAL UPDATES AND INTERIM RECOMMENDATIONS**

### ***Guideline Update (Full)***

Maintaining guideline content that is up-to-date with the clinical evidence and best practices in the field of infectious diseases is a challenge. It requires commitment to resources to monitor the emerging literature so that decisions as to whether or not a guideline should be revised, or if it has become obsolete. On average, all guidelines will be reviewed for changes and/or updates every 12-18 months.

Situations in which an evidence-based guideline might be updated include:

- Changes in the evidence on existing benefits and harms
- Changes in the outcomes which were considered important
- Changes in available interventions
- Changes in the evidence that current practice is optimal
- Changes in the values placed on outcomes
- Changes in the resources available in healthcare

IDSA Staff will contact the former expert panel chair(s) 12-18 months post-publication of the guideline and request that the chair complete an evaluation form. It is expected that the expert panel chair will continually monitor the literature for new developments that might have an effect on the current guideline recommendations. If such new data arise in between the

publication and this 12-18 month contact period, the chair should inform IDSA so that further discussion and plans can be made for the initiation of an update. Guideline updates should focus on substantive changes to recommendations.

In addition to determining whether new evidence or developments exist in the field that potentially invalidate the current recommendations, the panel should discuss the need for new recommendations on areas within the context of the current guideline that may have been previously excluded for various reasons, or that have recently arisen.

Once the decision has been made to update a guideline, an expert panel will be convened. The expert panel may include many of the preceding panelists, but must include at least two (2) new members. As with new guideline panels, membership is reviewed and approved by the SPGC chair. All guideline panel chairs and panel members, must comply with the current IDSA disclosure of interests policy for guideline panels.

The process for conducting a full update, including the review and approval of the manuscript, are the same as for an original guideline.

### ***Criteria for the conduct of partial updates/revisions***

IDSA guidelines are currently reviewed every 12 – 18 months following publication to determine whether there is new evidence or a change in practice that would warrant a change to a guideline. In some cases, evidence on a particular topic may evolve very quickly and require a more immediate review than the 12-18 month review timeframe requires.

In some cases, when a small proportion of recommendations (<25%) in a guideline need to be updated/revised, a partial update/revision may be considered IF all of the following criteria are met:

1. The guideline in question was developed using the GRADE system
2. The guideline is less than 5 years old. A guideline that is 5 years or older should either undergo a full update, or if no longer relevant/necessary, retired.
3. New evidence\* or a change/shift in practice that effects patient care, resulting in a **substantive** change to the guideline. A substantive change would be:
  - a. a change to a current recommendation(s) and/or a key portion of the text, and/or
  - b. the addition of a new recommendation(s) that must be instituted immediately (unable to wait until the full update of the guideline)

*\*The publication of new evidence/reference(s) that further support an already published recommendation or text within the guideline does not in and of itself constitute the need for a partial update/revision. Abstracts from meetings may not serve as the basis of a change to a guideline recommendation.*

### ***Process for proposing and carrying out a partial update/revision (<5 years)***

1. If during the 12 – 18 month review and following a literature search of the evidence since the last publication, a panel chair, in consultation with the guideline panel, find that the above criteria are met, a partial update/revision may be proposed to the Standards and Practice Guidelines Committee (SPGC).

2. Once considered and approved by the SPGC, the partial update/revision will be added to the IDSA guidelines slate and an estimate for initiation will be provided by the IDSA Staff.
3. The process for partial update/revision shall follow the same process as that of full guideline development/updating per the IDSA handbook on guideline development. This includes but is not limited to panel formation, COI, review and approval processes.
4. A partial update/revision will include the following sections:
  - a. Brief Abstract
  - b. Introduction: brief rationale for carrying out partial update/revision and process used, including literature search. Care should be taken to provide proper linkage to the primary guideline.
  - c. Key Changes: If a change to a current recommendation, list the current recommendation (e.g., 2010 recommendation) followed by the new/revised recommendation(s) (e.g., 2013 recommendation), followed by the summary of the evidence in support of the recommendation(s).
  - d. Acknowledgements – Includes listing of COI disclosures
  - e. Tables: If needed
  - f. References

#### *Publication of a partial update/revision*

A partial update/revision will be submitted for publication in the IDSA journal, *Clinical Infectious Diseases (CID)*. If accepted by the Editor, the update/revision will be published Online, and possibly in print if it is concise.

#### ***Criteria for Interim Recommendations***

##### Purpose

In order to more rapidly address new and significant information related to an IDSA guideline, a new classification of recommendations is proposed.

In the event that a new and significant piece of evidence is published<sup>††</sup>, a new therapy becomes available that would replace current therapy, or there is a profound change/shift in practice that is in direct conflict with a published IDSA guideline recommendation, an INTERIM Recommendation may be considered. Such information would directly affect the morbidity/mortality of a population for which an IDSA guideline recommendation covers. The goal of an INTERIM Recommendation is that it be developed quickly (within 2 – 4 months) and that it serves as temporary guidance pending a more rigorous review of the evidence. It will address an immediate problem/issue, guidance which cannot wait for the more lengthy and rigorous process of an update (partial or full). An INTERIM Recommendation is not a permanent solution, is not relevant in every situation and will not serve as a replacement for a guideline update.

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<sup>††</sup> Does not include abstract data.

Because an INTERIM Recommendation(s) is not subjected to the same rigor that a typical IDSA guideline is, it is not GRADE-ed and **may be made regardless of the use of the GRADE system** in the previous iteration of the guideline. However, if an INTERIM Recommendation **that results in a change** is made, it will serve as a trigger to carry out<sup>§§</sup> either:

- a PARTIAL Update (if the guideline is already in the GRADE system) and only a few key changes are required. See criteria for PARTIAL Update below. **OR**
- a FULL Update, should there be several significant changes/additions due to the new literature, or if there had previously been one or more PARTIAL Update(s) carried out on the topic, making it difficult for the reader to follow or have a clear picture of the guideline so that carrying out a FULL Update will bring it all back together.

## Process

Regardless of how the information is acquired (annual guideline review, Pubmed alerts, etc), a core team (former panel chair<sup>\*\*\*</sup>, SPGC Chair, SPGC liaison to the Board) will be brought together via conference call to determine the need for an INTERIM Recommendation (i.e., is patient morbidity/mortality at stake (or thought to be at stake)).

- An INTERIM Recommendation may take one of two forms:
  - Change Required – New evidence is clear that a change should be made.
  - No Change Recommended – New evidence is unclear, or consensus among panel members cannot be attained and a watchful waiting approach to the evidence should be taken. (Note: The “trigger” noted above will not be in effect in this situation.)
- Once it is determined that an INTERIM Recommendation is needed, a panel, many of whom may have participated in the previous iteration, will be established.
- COI's will be updated/collected from all participants however having a relationship may not necessarily exclude a participant.
- The panel will review the new evidence, deliberate via conference call and electronically and develop the recommendation(s), along with a summary of the evidence for which the recommendation is based (including available references).
- Draft recommendation(s) will be circulated among panel members. Votes on all changes will be taken through a survey tool such as Survey Monkey. Consensus is defined as at least 80% agreement among panel members. This 80% must be reached in order to make a change. Dissenting views will be stated.
- Recommendation(s) will next be reviewed and approved by the IDSA SPGC and Board simultaneously.
- Once approved, the INTERIM Recommendation will be announced and disseminated to the IDSA membership as described below.

## Format

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<sup>§§</sup> Timing of update will be dependent on current workload. When triggered, an update will be initiated as soon as the slate of guidelines allows.

<sup>\*\*\*</sup> Assumes that the former chair is still willing to assist AND that he/she has a proven track record of completing tasks on time.

The recommendation(s) will take a similar format to that of original IDSA guideline recommendations. Example:

**Background:** Methodology used (Description of process used to form panel, gather information, deliberate, vote, etc.).

**Original Clinical Question:** State relevant clinical question.

**Original Recommendation:** State original recommendation.

**INTERIM Recommendation:** State revised recommendation OR that “No Change Recommended at this time.”

**Votes Taken (if applicable):**

**Summary of the Evidence:** Summarize evidence that supports the new recommendation or why the panel is unable to make a change (references).

### Informing IDSA Members/Others

These INTERIM Recommendations shall reside on the IDSA website (within the guidelines section) and every attempt shall be made to assure proper linkage between these and the original guidelines (on the IDSA website, CID, etc).

A clear indication of the purpose and process used in making the INTERIM Recommendation along with an indication of the action it triggers (i.e., full or partial update), a projected timeline for partial/full update, as well as the disclosures of those panel members that participated in the development of the recommendation(s) review shall accompany the posting of the INTERIM Recommendation.

As is usual fashion, IDSA members will be informed of INTERIM Recommendations via direct e-mail and posting on the IDSA website. CID/OUP will also post a linkage/indication of change on the CID website (*pending verification with CID/OUP*).

### FAQ

What an INTERIM Recommendation is:

- IS temporary.
- IS evidence-based ‘opinion’.
- IS a thoughtful, but concise and expedited review and deliberation of new and practice changing information by experts identified by IDSA, in order to provide more immediate guidance and pending a more rigorous, full review and update.
- IS reviewed and approved by the IDSA Standards and Practice Guidelines Committee and Board of Directors.



What an INTERIM Recommendation is not:

- NOT based on a Systematic Review of the evidence.
- NOT GRADE-ed.
- NOT a replacement for an individual clinicians' clinical judgment. It [INTERIM recommendation], along with all other information available should be carefully reviewed and considered.

## IDSA STANDARD GUIDELINE FORMAT

IDSA guideline manuscripts should follow the format listed below. Guideline sections are listed, with annotation and sample wording as needed. Guidelines are most useful when they are both complete and concise; **the guideline should not exceed 50 double-spaced pages (excluding tables and references).**

### *Title Page*

The title should take the following form:

“Treatment/Use of X in X: Clinical Practice Guidelines by the Infectious Diseases Society of America (IDSA)” (e.g., The treatment of fever and neutropenia in cancer patients: clinical practice guidelines by the Infectious Diseases Society of America (IDSA))

The short title (for the running foot) will take the form of “IDSA X Guidelines” (e.g., “IDSA Fever and Neutropenia Guidelines”)

If the document is an **update** to a previously published guideline the title should read: Clinical Practice Guidelines for the use of X in X: 2013 Update by the Infectious Diseases Society of America\*

The title must be followed by an asterisk (\*) that will lead the reader to a footnote on page one that states IDSA's disclaimer:

“It is important to realize that guidelines cannot always account for individual variation among patients. They are not intended to supplant physician judgment with respect to particular patients or special clinical situations. IDSA considers adherence to these guidelines to be voluntary, with the ultimate determination regarding their application to be made by the physician in the light of each patient's individual circumstances.”

### *Executive Summary*

The Executive Summary is the only part of the guideline published in print and will include a brief introduction followed by a listing of the recommendations within the guideline. The following paragraph should be included within the introduction, just prior to the listing of recommendations:

“Summarized below are the recommendations made in the new guidelines for X.  
A detailed description of the methods, background, and evidence summaries that

support each of the recommendations can be found online in the full text of the guidelines.”

**Note: Although the full guideline is being published online only, Panels still must maintain the page limits set for the guideline (50 manuscript pages).**

### ***Introduction***

This section outlines in **1-2 manuscript pages** the rationale for the guideline in terms of the questions addressed in the original topic proposal, i.e., burden of the condition or importance of the health care intervention, controversy or uncertainty concerning appropriate management or use, perceived or documented variation in practice and need for guidelines to facilitate decision-making in clinical practice.

**Clinical Questions:** List the clinical questions to be addressed by the guideline.

### ***Practice Guidelines***

This section is boilerplate material that defines practice guidelines and outlines attributes of good guidelines. The section concludes with legal boilerplate material that underscores the voluntary nature of adherence to the guideline and the critical role of individual physician judgment. Language follows:

“Practice guidelines are systematically developed statements to assist practitioners and patients in making decisions about appropriate health care for specific clinical circumstances [6]. Attributes of good guidelines include validity, reliability, reproducibility, clinical applicability, clinical flexibility, clarity, multidisciplinary process, review of evidence and documentation [6].

### ***Methods***

The methodology section of the guideline is mostly boilerplate and includes subsections that, among other things, describe the composition of the panel, how the literature was reviewed and the yield, what the process was that was used in the guidelines development. Although this section does add to the overall length of the guideline, it is critical in providing transparency about the process and conclusions.

**Note: Limit to 3-6 manuscript pages, and include the following subsections (sample wording is provided):**

**Panel Composition:** “A panel of experts composed of infectious disease specialists, X, X, X and X with an expertise in X disease was convened. Both academic and community practitioners were included.

**Literature Review and Analysis:** Describes the methodology of the literature review from beginning to end and includes databases searched (e.g., PubMed, Cochrane Library), search

terms used, the inclusion and exclusion criteria employed, the abstract review processes, and so on.

**Process Overview:** In evaluating the evidence regarding the management of X, the Panel followed a process developed by the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) Working Group (<http://www.gradeworkinggroup.org/>). The process included a systematic weighting of the quality of the evidence and the grading of recommendations (Table X).

**Consensus Development Based on Evidence:** Boilerplate “The entire Panel met X number of times. All members of the Panel participated in the preparation of the draft guideline, which was then disseminated for review by the entire Panel. Feedback from external reviewers was also solicited (See Section 3.12. Acknowledgements). The content of the guideline and the manuscript were reviewed and approved by the SPGC and by the IDSA Board of Directors before dissemination.”

**Guidelines and Conflict of Interest:** Boilerplate “All members of the Expert Panel complied with the IDSA Disclosure of Interests Policy for Clinical Practice Guidelines, which requires disclosure of any potential conflict of interest and to abstain from any decision where a potential conflict of interest exists. In order to provide thorough transparency, the IDSA requires **full** disclosure of all relationships, regardless of relevancy to the guideline topic. Evaluation of such relationships as potential conflicts of interest is determined by a review process which includes assessment by the SPGC Chair, the SPGC liaison to the Panel, the BOD liaison to the SPGC and if necessary, the COI Task Force of the Board. This assessment of disclosed relationships for possible COI will be based on the relative weight of the financial relationship (i.e., monetary amount) and the relevance of the relationship (i.e., the degree to which an association might reasonably be interpreted by an independent observer as related to the topic or recommendation of consideration).

**Revision Dates:** Boilerplate “At annual intervals, the SPGC will determine the need for revisions to the guideline based on an examination of current literature. If necessary, a Panel will be convened (or reconvened) to discuss potential changes.

**Summary of Outcomes Assessed:** Describes the outcomes considered in the guideline and what information has been/can be drawn from the initial outline.

## ***Recommendations***

***Clinical Question 1*** (List first clinical question here)

**Recommendation:** Succinct recommendations with references should be listed here  
**[Strength of Recommendation and Quality of Evidence]** (See Table 2 in Section 2.9. Assigning Strength of Recommendations and Quality of Evidence).

**Evidence Summary:** This section should provide a synopsis of the supporting evidence. Subsequent topically organized subsections can be used to review specific study results in

detail. Pertinent data in support of the recommendation should be presented in tabular form wherever possible.

**Note:** After reading the evidence summary, the guideline user should be able to delineate the bases for the practice recommendation.

***Clinical Question 2*** (List second clinical question here)

**Recommendation:** Succinct recommendations with references should be listed here  
**[Strength of Recommendation and Quality of Evidence]** (See Table 2 in Section 2.9. Assigning Strength of Recommendations and Quality of Evidence).

**Evidence Summary:** See above for guidance.

### ***Limitations of the Literature and Ongoing and Future Studies***

Guidelines should comment on studies in progress that may help answer the clinical question more definitively and suggest areas for further study. The process of guidelines development serves as a natural channel by which to identify research gaps which, if appropriately addressed, can advance future clinical care and treatment. Clinical practice guidelines identify important clinical questions and identify the quality of evidence supporting those recommendations. Thus, guidelines should include comments on studies in progress that may help answer clinical questions more definitively and suggest areas for further study. Principles to be considered when proposing and prioritizing research topics include clinical consequences/burden of disease, feasibility, economic consequences, broadness of applicability, and degree of uncertainty.

### ***Acknowledgments***

Boilerplate: “The expert panel expresses its gratitude for thoughtful reviews of an earlier version by...”.

Funding: The guideline was funded by the Infectious Diseases Society of America.

Potential Conflict of Interest:

When IDSA publishes a guideline in one of its journals, all disclosures of panel members will be published concurrently. The following language will accompany the list of disclosures within the “Acknowledgements” section:

“The following list is a reflection of what has been reported to the IDSA. In order to provide thorough transparency, the IDSA requires **full** disclosure of all relationships, regardless of relevancy to the guideline topic. Evaluation of such relationships as potential conflicts of interest is determined by a review process which includes assessment by the SPGC Chair, the SPGC liaison to the development panel and the BOD liaison to the SPGC and if necessary, the COI Task Force of the Board. This assessment of disclosed relationships for possible COI will be based on the relative weight of the financial relationship (i.e., monetary amount) and the relevance of the relationship (i.e., the degree to which an association might reasonably be interpreted by an independent observer as related to the topic or recommendation of

consideration). The reader of these guidelines should be mindful of this when the list of disclosures is reviewed.”

### ***Tables, Figures and other Artwork***

The total number of tables, figures and other artwork should generally not exceed **10**. The first table should outline the IDSA grading system for ranking recommendations in clinical guidelines (GRADE). Remaining tables and figures should serve as easy references for clinicians making diagnoses and treatment decisions. Any tables, figures or other artwork that are adapted from other sources must have permission to use/adapt/reprint the information from the originator before the guideline is submitted for publication. Exception is when a table, figure etc., is published in an IDSA journal (CID/JID). Tables, figures and other artwork should follow the same general format that is outlined on the *CID* website (<http://www.journals.uchicago.edu/page/cid/msprep-tables.html>; <http://www.journals.uchicago.edu/page/cid/msprep-art.html>)

### ***References***

Self-explanatory.

### **GUIDELINE RETIREMENT**

A guideline may be considered for retirement if its recommendations no longer apply or are adequately covered and more rapidly updated elsewhere, rendering any attempt by IDSA to carry out an update, repetitive and costly. As guidelines are evaluated by the SPGC for need for update, retirement will be considered. If retired, a notification will be made on the IDSA website and will include information and links to other relevant resources when appropriate.

### **RELATED GUIDELINE INFORMATION**

#### ***Guideline Policy Internal and External Usage***

IDSA Guidelines serve as an integral part of the organizations communication regarding evidence-based research used in the infectious diseases arena. Many times, IDSA members and the public request to discuss and/or use the guideline at various conferences and CME activities. As a result, IDSA has developed standard policies for use of these guidelines.

#### ***Policy at IDSA Meetings***

The Annual IDSA Conference serves as the perfect opportunity for invited IDSA guideline development panel chairs to present new or revised clinical practice guidelines to the IDSA Membership during the “*New Clinical Practice Guidelines Symposium*”.

During these presentations, specific recommendations should not be considered final nor should they be reproduced or disseminated in any form by unauthorized individuals or groups until fully vetted, approved and published by the IDSA (and its collaborators).

#### ***Policy for Outside IDSA Meetings and Industry-sponsored Symposia***

IDSA Guidelines that are in development (i.e., they have not been reviewed and approved by IDSA or its collaborators) **WILL NOT** be presented at any Meeting outside of the IDSA Annual Meeting SPGC-Sponsored Symposium without the approval of the IDSA Staff and SPGC Chair. Recommendations and specific text are not permitted for dissemination nor should they be discussed in detail at these sessions.

#### 4.1.3. Policy for Continuing Medical Education Activities

IDSA Guidelines that are in development (i.e., they have not been reviewed and approved by IDSA or its collaborators) **WILL NOT** be used by any entity to develop any continuing educational activity, tools or products.

Published IDSA Guidelines may be discussed and/or disseminated provided that:

1. IDSA Headquarters reviews and approves the CME activity content before finalized and disseminated
2. That proper acknowledgement of the IDSA is given and that the published article is referenced appropriately.

#### ***Policy for Organizations Seeking IDSA Endorsement***

The IDSA acknowledges that many organizations are producing quality guidelines that are relevant and appropriate to the mission and interests of IDSA and its membership. IDSA is committed to systematically evaluating these guidelines and disseminating them as appropriate to its membership.

#### ***Endorsement Process***

The primary criteria used to assess guidelines submitted for endorsement is the quality of the process used to develop the document. This includes an assessment of the use of evidence vs. consensus and the appropriate linkage of evidence to recommendations. The following criteria will be applied to requests for IDSA endorsement:

- A formal request has been made to IDSA
- IDSA participated (officially) in the development process and is afforded the opportunity to review (see below) and comment on the guideline before it's made final.
- Guidelines should be relevant and appropriate to the mission and interests of IDSA and its membership and not be duplicative of existing IDSA guidelines
- Proposed guidelines for endorsement should be based on a comprehensive literature review of the available evidence
- There should be an explicit statement of the purpose, methodology utilized and recommendations created
- The proposed guideline development process is free of any inappropriate support or influence from industry

**Note:** Eligibility for endorsement does not guarantee that the request for endorsement will be accepted.

### ***Review Process***

Guidelines submitted for endorsement by IDSA will be handled as follows:

- the SPGC will review and comment on the guideline based on the above criteria and make a recommendation to the Board for endorsement
- The Board will review and comment on the guideline with the goal of endorsement

Due to time constraints, the SPGC and Board review may take place simultaneously.

IDSA encourages other organizations to inform IDSA of their intent to request endorsement as early in the process of developing the guideline as possible.

INTERNAL ACTIONS FOR ENDORSING OTHER ORGANIZATIONS GUIDELINES		
LEVEL	Circumstance	Presentation/Dissemination
Endorsement	IDSA full partner in development of the document	<ul style="list-style-type: none"> <li>○ May bear IDSA logo;</li> <li>○ IDSA may publish an executive summary of the guideline in <i>CID</i>;</li> <li>○ IDSA may disseminate the document to its members with the permission of the primary organization;</li> <li>○ IDSA may request permission to publish all, a portion or a summary of the document on the IDSA website after publication of the article by the collaborating organization.</li> </ul>
	IDSA provided an official representative to the development of the document	<ul style="list-style-type: none"> <li>○ May bear IDSA logo;</li> <li>○ IDSA may disseminate the document to its members with the permission of the primary organization;</li> <li>○ IDSA may request permission to publish all, a portion of or a summary of the document on the IDSA website after publication of the article by the collaborating organization.</li> </ul>
LEVEL	Circumstance	Presentation/Dissemination
No Endorsement	IDSA full partner in development of the document	<ul style="list-style-type: none"> <li>○ IDSAs logo and/or name may not be used;</li> <li>○ IDSA will not disseminate the document to its membership;</li> <li>○ The document may not state that the IDSA endorses the document</li> </ul>
	IDSA provided an official representative to the development of the document	



## REFERENCES

1. No authors listed. Clinical Practice Guidelines We Can Trust. In: Graham R, Mancher M, Wolman DM, Greenfield S, Steinberg E, eds.: The National Academies Press, **2011**:15.
2. Kish MA. Guide to development of practice guidelines. Clin Infect Dis **2001**; 32:851-4.
3. Brouwers MC, Kho ME, Browman GP, et al. AGREE II: advancing guideline development, reporting and evaluation in health care. CMAJ **2010**; 182:E839-42.
4. ACC/AHA. Section II: Tools and Methods for Creating Guidelines - Step Five: Synthesize and Interpret the Evidence; Manual for ACC/AHA Guideline Writing Committees, 2005. Available at. Accessed.
5. U.S. GRADE Network. Approach and implications to rating the quality of evidence and strength of recommendations using the GRADE methodology, 2015. Available at: <http://www.gradeworkinggroup.org/>. Accessed: July, 2015.
6. Field MJ, Lohr KN, eds. Institute of Medicine Committee to Advise the Public Health Service on Clinical Practice Guidelines, Clinical Practice Guidelines: Directions for a New Program. Washington, DC: National Academy Press, **1990**.