



Council of Medical Specialty Societies

Principles for the Development of Specialty Society Clinical Guidelines

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CMSS Principles for the Development of Specialty Society Clinical Guidelines

1. INTRODUCTION

- 1.1. Recognizing that medical specialty societies (Societies), having a responsibility for leading the profession, often serve as an independent source of evidence based clinical practice guidelines, and can help to reconcile conflicting, high-quality guidelines, the Council of Medical Specialty Societies offers these principles as a resource for development of systematic review-based guidelines.

Core to these development principles are the following concepts:

1. Guideline recommendations should be informed by a review of available evidence and, where possible, should be based on an extensive, reproducible, and strong body of evidence;
 2. Guideline panels should include knowledgeable, multispecialty/disciplinary development individuals;
 3. Guideline development should incorporate transparent conflict of interest management; and
 4. Guideline development should include broadly defined (including patient, when possible and if applicable) stakeholder involvement.
- 1.2. The charge to developers of clinical guidelines is generally much more complex than is often realized. There is an inverse relationship between the specificity of clinical questions and the availability of high-quality evidence. Commonly, there are many more clinical and appropriate use questions than there is clear evidence to answer them. Hence, the transparent interaction among knowledgeable stakeholders in evaluating evidence and developing guidelines is the basis for trustworthy guidelines.

Annotation: This document should serve as a broad roadmap or set of aspirations for guideline production; we acknowledge that it may be impossible to achieve every recommendation. Societies may meet member needs and further their missions through the use of other types of clinical guidance or applications thereof, such as quality measure development.



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- 1.3. The recent CMSS Code for Interactions with Companies (CMSS Code) addressed some guideline principles: none of the principles here should be interpreted as superseding the CMSS Code. These additional principles have been developed without resource consideration. Specialty Societies generally do not have that luxury, but they can and should transparently document the manner in which their guidelines are developed. Reference to which of these principles were addressed and which were impractical to apply may be helpful in this regard.

2. DEFINITIONS

- 2.1. ClinicalPracticeGuidelines, as used in this document (also referred to in this document as “guidelines”), are statements that include recommendations intended to optimize patient care. They are created after a systematic review of evidence and an assessment of the benefits and harms of alternative care options. From Clinical Practice Guidelines We Can Trust <http://www.nap.edu/catalog/13058.html>. This definition may or may not apply to other Society deliverables, including appropriate use criteria, technology assessments, scientific statements, and Society position statements. Societies are encouraged to document these differences transparently.
- 2.2. GuidelinesDocuments are the collection of publicly available documents that define the guidelines, their development methodology, their supporting evidence and other relevant documentation.
- 2.3. GuidelineDevelopmentGroup consists of a panel of members with differing expertise responsible for utilizing systematic reviews to generate clinical practice guideline statements in an objective and unbiased manner.
- 2.4. WritingPanel consists of either the entire guideline development group or a smaller subset of the guideline development group charged with producing the guideline manuscript and all supporting documents.
- 2.5. SystematicReview is a scientific investigation that focuses on a specific question; it uses explicit, planned scientific methods to identify, select, assess, and summarize the findings of similar but separate studies; it may or may not include a quantitative synthesis (meta-analysis) of the results from separate studies.
- 2.6. Methodologists are writing panel advisors with expertise and/or training in evidence-based medicine and guidelines development methodology.

TRUSTWORTHY GUIDELINE PRINCIPLES

3. CONFLICT OF INTEREST Principles for Guideline Development Group

3.1. Organization Commitment/Responsibility

Annotation: Societies have a strong interest in demonstrating the independence and trustworthiness of their guidelines. Patients and the public need to be confident that Societies' guidelines are not biased towards the interests of their members. Societies' guidelines policies and procedures should result in balanced development groups that focus on impactful patient interventions with appropriate expert input.

- 3.2. Societies developing guidelines must define and document their interpretation of Conflict of Interest (COI). At a minimum, Societies should follow the principles set out in the CMSS Code. These focus principally on financial relationships with Companies at the individual and Society levels. In addition, Societies should be cognizant of the existence of indirect and non-financial interests (e.g., research bias, institutional mission, practice bias) and their potential impact on the process.

Definitions should include:

- 3.2.1. Criteria for determining relevance if and when a relationship is material or pertinent to the topic of the writing panel or Guideline Development Group.
- 3.2.2. Criteria may include determining the level if and when a relationship is modest or significant.
- 3.2.3. A process, including options, for the resolution of all significantly relevant financial and non-financial COI, such as not voting or participating in evidence based reviews.
- 3.2.4. Societies will require that at least a majority, including the chair, of the Guideline Development Group and/or Writing Panel members are free of relevant conflicts of interest pertinent to the subject matter during and for one year after their work on guidelines or their revisions.



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Annotation: Processes should be in place to achieve balance, not only when the group or panel is commissioned but also reviewed periodically during the writing process. Processes should include the ability to add non-conflicted members or remove conflicted members to achieve balance. Transparency is critical if changes to the writing panel occur because of a relationship with a Company. Processes can involve management of COI per the Society's policies and need not exclude participation on a panel or other development group. .

Panel members should decline offers from industry to speak about guidelines related to their products as outlined in the CMSS Code. Similarly, panel members should not discuss a guideline under development with industry employees or representatives (CMSS Code).

A process should be in place to document disclosure of relationships, and management of conflicts of interest. The guideline document or material publicly available online should have a clear description of the management that was employed. Annotation: Disclosure should occur in writing, prior to the selection of the Guideline Development Group, and updated at every meeting as necessary.

3.2.5. Societies will create processes for collecting, managing, and disclosing COI information for Guideline Development Groups and/or Writing Panel members as well as any person with direct influence as defined by the Society, over the review or approval of guideline content. This includes any external consultants, methodologists and boards.

Annotation: Systems should be established to help ensure compliance with these processes.

3.2.6. Societies should pursue fair and consistent interpretation and application of the policy across guideline type and with partner/collaborator organizations.

Annotation: Routine review of COI management outcomes is suggested in order to ensure appropriate decisions. The review may result in policy or process changes.

3.2.7. Societies should have a process in place to make sure that the members of a guideline development group understand the COI policy and importance of disclosing all relevant relationships and interests.

3.3. Transparency

- 3.3.1. Societies will ensure that any relevant relationships are publicly disclosed, along with relevant COI management strategies. This includes relationships that the Society determines a reasonable user of a guideline would like to know.

Annotation: All Societies developing guidelines should have a published COI disclosure policy to include relevant COI and management policies.

- 3.3.2. All relationships relevant to the topic must be disclosed and reaffirmed periodically during the development process per Society policy on COI (see 3.1).

Annotation: This information should be readily available to the public for inspection and review and can be accessible via the internet, print or both. Disclosures should be actively updated during the development process and available publically upon guideline release. This can include referring the reader to the electronic or print media containing the policies.

- 3.3.3. Societies should require disclosure and release of all relationships that are considered to give rise to potential conflicts of interest.

Annotation: See CMSS Code section 2.1. Societies may also disclose related COI procedures. This material can be disclosed on the Society's web site.

- 3.3.4. COI disclosure should conform to Societies policies with the understanding that relevant relationships will be managed as potential COI and publically available.

4. DEVELOPER QUALIFICATIONS: Ancillary Members

Annotation: Guideline Development Groups should be, as appropriate, multispecialty, multidisciplinary and include individuals with the proper expertise to develop a high-quality guideline.

- 4.1. All personnel directly and substantively involved in the development process should be subject to the same COI disclosure policies and management procedures as the rest of the Guideline Development Group.

4.2. Systematic Review Authors:

- 4.2.1. Systematic review authors under the direction of the Society should be subject to the same COI policies and procedures as the guideline development group.

4.2.2. Independent systematic reviewer developers contracted by the Society should have published COI policies and procedures that are consistent with or acceptable to the Society.

4.3. Multispecialty/disciplinary panel composition:

4.3.1. Specialty Societies should incorporate relevant stakeholders in both the development and review of their guidelines. The development panel should be multidisciplinary and balanced, comprising a variety of methodologic experts and clinicians.

4.3.2. Participants and their area of expertise should be published.

4.4. Methodologists or evidence-based medicine expert:

4.4.1. Societies should incorporate a methodologist with expertise and/or training in evidence-based medicine and guidelines development methodology into guideline development.

4.5. Librarian:

4.5.1. The systematic research group should have a librarian or a person with similar knowledge and experience as determined by the Society involved in the guideline process.

4.5.2. The librarian should be experienced in guideline methodology, systematic search strategies, and database content.

Annotation: All search strategies should be saved, and when possible electronic copies of retrieved literature should be archived. Every effort should be made to ensure a consistent, reproducible and comprehensive search strategy.

4.6. Statistician:

4.6.1. If statistical analyses are warranted and performed, they should be done by qualified personnel as determined by the Society, and the appropriate application of statistics should be utilized.

4.7. Patients:

4.7.1. Patients or patient advocate groups' involvement may be considered in guideline development, review, or formulation of clinical questions. Any patient or patient advocacy group must comply with the COI disclosure requirements set forth elsewhere in this document.

4.7.2. Patient preferences and feedback should be addressed in the guideline as appropriate. The role of patient preferences in the development of guidelines should be defined in the methodology.

4.8. Panel Training:

4.8.1. When necessary and depending on their prior knowledge, Societies should incorporate methodology training into guideline development panels.

Annotation: Ideally, Societies can establish a core group of members with sufficient expertise in guideline development to assure future guideline groups' access to experts within their Society. When possible, training should be a requisite for membership on the guideline development group.

5. GUIDELINE DEVELOPMENT PROCESS

5.1. The intent of the guideline must be clearly stated.

5.2. The rationale for the guideline must be elucidated.

5.3. The scope of the guideline should be described and include:

5.3.1. A clear description of the intended guideline audience and the setting(s) in which the guideline is to be used.

5.3.2. A concise statement of guideline objective(s)

5.3.3. A clear description of the patient population(s) covered by the guideline (e.g., age groups, gender, clinical conditions, co-morbidities, exclusions).

5.3.4. A clear and concise statement of guideline questions to be answered. When possible, use of the PICO format is recommended.

Annotation: PICO refers to the framing of the clinical question in terms of the Population, Intervention, Comparison, and Outcome. Limit recommendations to key questions that are relevant to the goals and objectives of the guideline.

- 5.4. Provide clear descriptions of what the guideline covers related to diagnosis, prognosis and treatment(s) for diseases/conditions, and what is excluded.

Annotation: It is preferable to acknowledge and, when possible, refer to other evidence-based resources for related information for areas that are outside the guideline scope and acknowledge clinical overlap as well as gaps.

- 5.5. The methods should:

- 5.5.1. Include addenda for search strategies, and literature selection rules for each question answered. These can be referenced to electronic media and do not necessarily need to be part of the printed manuscript.

- 5.5.2. Disclose the system used to grade the evidence.

- 5.5.3. Document the process for reconciling low quality evidence.

- 5.5.4. Include time period of the searched literature, including secondary searches and updates.

- 5.5.5. Specify the method of data extraction.

- 5.6. In systematic review-based guidelines, systematic evidence reviews should be utilized to develop reliable and valid guidelines.

Annotation: Best use of systematic review resources has not been established.

- 5.6.1. Evidence reviews should include documentation on handling systematic gaps in the literature. Gaps in the literature occur when there is insufficient or non-existent evidence but a strong clinical need for a recommendation.

- 5.6.2. Evidence reviews should evaluate potential benefits and harms of an intervention, when feasible.

5.6.3. Whenever possible and appropriate, cost effectiveness and comparative effectiveness information should be incorporated into guidelines.

5.6.4. Each citation identified as affecting the evidence review must be evaluated for its quality and its limitations.

5.7. Evidence tables must be provided with information summarizing the relevant articles and standardized quality ratings, and should be available electronically.

5.8. A process for reconciling differences in agreement on the strength of evidence grades should be established.

6. RECOMMENDATIONS

6.1. Recommendations should classify the strength of evidence as well as the strength of the recommendation itself; these strengths should be determined by consideration of the spectrum of evidence and the assessment of benefits and harms, not just be a restatement of the evidence.

Annotation: It should be a rare instance where the recommendation strength exceeds the evidence strength. When this occurs, detailed supporting documentation should accompany the recommendation. It is recognized that there are times when the need for recommendations exceeds the available evidence.

6.2. Recommendations should be based on unbiased systematic review of the highest quality peer-reviewed evidence available.

6.3. Recommendations should be linked with evidence tables and with specific citations when relevant.

6.4. Recommendations supported by expert opinion, consensus, or the lack of quality evidence must be clearly stated as such.

Annotations: Developers should consider the impact of recommendations that are based on low-level evidence. There are occasions when expert opinion is the only available information on a topic with a high need for a recommendation, low risk and clear potential benefit. There

should rarely be "strong recommendations" based on low-level evidence; this might happen when high-level studies would be impossible or unethical to perform.

- 6.5. Results of development panel votes on recommendations, including abstentions, should be summarized and publically available.

Annotation: This is a transparency issue. Readers may infer that strong recommendations are the result of nearly unanimous votes, while less strong recommendations may be associated with majority votes. Documenting variations from such presumed voting patterns is acceptable if the voting system is clearly documented.

- 6.6. All recommendations should be linked to an evidence profile that transparently document reasoning behind the recommendation.

Annotations: Knowing what actions are harmful or unsubstantiated useful to clinicians, policy makers, and patients. Suggested elements (From AAO-HNS Guideline Development Manual: <http://www.entnet.org/Practice/upload/Rosenfeld-and-Shiffman-2009-6.pdf>, Table 13) could include:

- Aggregate Evidence Quality
- Benefits/harms/risks/costs: As appropriate for each key action
- Benefit-harms assessment: Is there a preponderance of benefit over harm or harm over benefit, or are they balanced?
- Value judgments: Considerations the committee members included when deciding to make this recommendation.
- Role of patient preferences: When there is a discrepancy between patient preferences and published evidence, a weighting system should be employed to resolve this discrepancy.
- Exclusions: Does this recommendation exclude any patient groups not already excluded by the scope.
- Intentional vagueness: Answered as "none" or specified why some type of AVUL (ambiguous, vague, and under specified language) which was used in the action statement.
- Strength of Recommendation: Determined by consideration of level of evidence and benefits-harms assessment.
- When supported by the literature, negative recommendations should be part of the guideline.

- 6.7. Recommendation statement formats should be consistent and actionable:

Annotations:

- Recommendations should be explicit about WHO ought to Do WHAT, WHEN (under what circumstances), To WHOM, HOW, and WHY
- Should be actionable and not a statement of fact
- Recommendations should avoid AVUL (ambiguous, vague, and under specified language) whenever possible - sometimes there are reasons for being intentionally vague, such as the case with insufficient evidence or inability to reach consensus.
- When recommendations are ambiguous or vague, transparency may include disclosing results of voting and/or contrary opinions.
- Recommendations should not be in a passive voice, use an active verb wherever possible (i.e. the clinician should prescribe amoxicillin rather than amoxicillin should be prescribed).
- Unless options are clearly specified, recommendations should avoid use of the term "consider."
- Every recommendation should be described clearly, so that reasonable practitioners would agree when the recommendation should be applied.
- Recommendations should be clearly identified - either summarized in a box, typed in bold, underlined, presented in an algorithm, etc.
- There should be a limited number of recommendations based on the scope of the guideline.

6.8. Appropriate, related guidelines as determined by the guideline development group should be acknowledged:

6.8.1. Recommendations should consider related guidelines from other high-quality development groups.

6.8.2. Harmonization with related guidelines is strongly encouraged and efforts should be made to include relevant specialty societies in new guideline development.

6.8.3. When significant differences with existing guidelines cannot be harmonized, there should be a rationale and explanation citing all relevant literature.

6.9. Identify all contributing guideline organizations, work group-panel, writers, consultants, and staff as per publishing journal requirements.

7. GUIDELINE EFFECTIVENESS

- 7.1. Where possible, guidelines should contain measurable objectives, which can be assessed by users of the guideline.
- 7.2. Societies should consider processes for reviewing the effectiveness of their guidelines.
- 7.3. Whenever possible, the guidelines should contain or give rise to an implementation tool kit that can assist users in measuring guideline-related outcomes.

8. GUIDELINE REVIEW

8.1. Internal Review may include:

- 8.1.1. Vetting draft recommendations should occur through relevant internal committees, sections, and councils as defined by the Society.

Annotation: Incorporating appropriate comments from these internal groups is recommended, when supported by the evidence.

- 8.1.2. As stated in the CMSS Code, 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 individuals employed by or engaged to represent a Company as reviewers. (CMSS Code 7.9)

Annotation: As part of their published guideline development processes, Societies will seek critical feedback on draft guidelines from independent reviewers. These may include subject matter experts, healthcare practitioners, biostatisticians, and patient representatives. (CMSS Code 7.9)

- 8.1.3. The Society's guideline recommendations will be reviewed and approved before submission for publication by at least one internal body beyond the Guideline development panel, such as a committee or the Board of Directors.(CMSS Code 7.9)

- 8.1.4. A final acknowledgement of or approval by the Society after all internal, external and peer reviews.

8.2. External and Peer Review should include:

8.2.1. External reviews should incorporate relevant stakeholders comprising a variety of experts and clinicians.

8.2.2. Guideline manuscripts should be subject to independent editorial review by the journal or other source where they are first published (CMSS Code 7.11)

8.2.3. Comments from other stakeholders and feedback from affected groups for provide general appropriateness should be obtained.

Annotation: Disposition of the comments and suggestions should be documented in responses forwarded to the external reviewers. When possible and if applicable, patients and patient advocacy groups should be invited to comment on proposed guidelines.

Annotation: If a Society decides to seek broad external or public comment, the fact that Company representatives might access the review draft and comment should not conflict with CMSS Code 7.9 or 7.15 as long as a reasonable procedure is in place to assure that Company comments are incidental and minimize the potential for abuse.

9. TIMELINES

Annotation: These Principles will be reviewed at least every 5 years per CMSS policy and updated as warranted.

9.1. An expiration date or date of anticipated review or revision should be disclosed within the published guideline.

Annotation: Within guideline text, clearly state when a guideline is expected to be considered for review and update. In lieu of periodic review, indicate the guideline will be considered maximally valid for five years.

9.2. Specialty Societies should implement a process for maintaining the currency of guidelines.

9.2.1. Following publication, guidelines should be assessed regularly for relevant additions to the literature.

9.2.2. A process should be in place to determine if a guideline requires a partial or full update.

9.2.3. A process should be in place for identifying and managing guidelines that are no longer current.

10. DISTRIBUTION AND IMPLEMENTATION

10.1. Society guidelines should be publically available on an organizational website.

10.2. If appropriate, guidelines should be submitted to the National Guidelines Clearinghouse and Guidelines International Network for guideline dissemination.

10.3. Societies should consider guidelines derivatives for physicians, patients, caregivers and other lay audiences to facilitate provider-patient interactions and to incorporate recommendations at the point of care. Publicize all products related to a guideline to relevant audiences.

Annotation: The quality or trustworthiness of a guideline is not necessarily related to the success of its implementation or presence/absence of derivative products.

11. FINANCE AND FUNDING

11.1. Societies will not permit direct external company support of the development of Clinical Practice Guidelines or Guideline Updates (CMSS Code 7.3).

Annotation: Societies will not accept Corporate Sponsorship, Educational Grants, Charitable Contributions, Research Grants, or any other direct industry support of Guideline development activities. Company support of the overall mission based activities of a Society is not considered direct support of Guideline development. Societies will not permit direct company support for the first printing, publication, and distribution of Clinical Practice Guidelines or Guideline Updates. After initial development, printing, publication and distribution are 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 re-purposing of the Guideline content. (CMSS Code 7.4) Sponsorship should be consistent with the rest of these guidelines.

11.1.1. In developing a guideline, a Society should anticipate resources needed for dissemination and updates over the lifetime of the guideline.

11.1.2. Regardless of source, all funding must be transparent and documented.

11.2. Honoraria, travel reimbursement and compensation for developers, should occur transparently, at customary rates for the effort and activities involved.

11.3. Societies developing trustworthy guidelines will likely have several distribution, publication and revenue models, including free or minimal cost availability. It is unlikely that end user prices correlate with the quality or trustworthiness of a given guideline.

11.4. Travel reimbursement from Companies is not permitted.

11.5.

Societies preferably should insure intellectual property ownership of their guidelines by obtaining written copyright assignments for all contributions. Full copyright ownership of a guideline permits the creation of derivative works based on it. If a guideline is developed by more than one society, it is simpler for one society to own the copyright and to license to the other society, thus avoiding the legal burdens of joint copyright ownership. The license could include terms that give the licensee society the ability to create derivative works. Neither society should be able to unilaterally modify the guideline without written agreement from the other society.

11.6. Development of derivative products is an important distribution challenge for guideline developers both from funding and compensation perspectives. It is suggested that:

11.6.1. Individual guideline panelists involved in derivative products are never compensated beyond their time at standard rates.

11.6.2. Derivative product development should be independent of guideline development.



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Using these Principles

These Principles were developed by CMSS as a resource for its members and others who develop systematic review-based clinical practice guidelines. Following these Principles is voluntary and is not a condition of continued membership in CMSS. Societies that choose to follow these Principles do so in the spirit of supporting awareness of sound practices in guideline development. Societies will interpret and implement these Principles in the context of their organizational structure, their policies and procedures, their resources, and their member needs.

Any comments received by CMSS relating to a Society's adherence to these Principles will be referred to the Society.

Questions about these Principles may be addressed to CMSS. CMSS will not interpret these Principles on an individual basis. However, CMSS may periodically gather its members' views and update the Annotations, or publish answers to "frequently asked questions."

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