# CMSS Principles for the Development of Specialty Society Clinical Guidelines

## 1 INTRODUCTION

The Council of Medical Specialty Societies (CMSS) recognizes that medical specialty societies (Societies) have a responsibility to lead the profession, often serve as independent sources of evidence-based clinical practice guidelines, and can help to reconcile conflicting, high-quality guidelines. CMSS offers these principles as a resource for the development of clinical practice guidelines based on systematic reviews of the evidence.

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 robust body of evidence;
2. Guideline panels should be multidisciplinary and include individuals whose knowledge, skills, or experience will contribute to the content from a variety of stakeholder perspectives;
3. Guideline development should incorporate transparent processes, including disclosure of interests and management of conflicts of interest; and
4. Guideline development should include broadly defined stakeholder involvement (including patients, patient representatives, family members, and/or caregivers, when possible and if applicable).

The charge to developers of clinical practice 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 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.

This document should serve as a roadmap or set of aspirations for guideline development; we acknowledge that it may be impossible to achieve every recommendation due to resource availability, including staff time and volunteer time. It should be noted that these principles are only for systematic review and guideline development, not for derivative works, such as clinician summaries, patient summaries, or abbreviated versions of guidelines or systematic reviews.

The 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. If Societies desire to keep their guidelines up to date, adequate resource considerations should be made to keep guidance relevant to current practice.

**Using These Principles**

These Principles were developed by CMSS as a resource for its members and others who develop systematic reviews and evidence-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 evidence-based document development. Societies will interpret and implement these Principles in the context of their organizational structure, policies and procedures, available resources, and member needs.

These Principles will be reviewed and updated (or sunsetted) at a maximum of five years following publication. A review may take place earlier if warranted due to changes in the guideline development field.

# 2 DEFINITIONS

2.1 **Clinical Practice Guidelines (CPG),** as used in this document (also referred to in this document as "guidelines"), are statements that include recommendations intended to optimize patient care. Systematic reviews should be utilized to develop reliable and valid guidelines and guideline updates.

2.2 **Guideline Development Group (GDG)** consists of a panel of members with differing expertise responsible for utilizing systematic reviews to generate clinical practice guidelines in an objective and unbiased manner.

2.3 **Writing Panel** consists of either the entire guideline development group or a smaller subset of the guideline development group charged with producing the CPG manuscript and all supporting documents.

2.4 **Systematic Review** is a scientific investigation that focuses on a specific question; it uses explicit, planned, and transparent scientific methods to identify, select, assess, and summarize the findings of a body of literature. It may or may not include a quantitative synthesis (meta-analysis) of the results from separate studies. Recommendations are not included in these documents.

2.5 **Guideline Recommendation(s)** are statements developed by the GDG to guide patient care based on the systematic review and an assessment of benefits and harms. These statements are supported by a rating of both the quality of the evidence and the strength of the recommendation.

2.6 **Methodologists** are GDG advisors with expertise and/or training in evidence-based medicine and guidelines development methodology. These individuals may also contribute to the writing of the guideline manuscript.

2.7 **Stakeholders** are individuals or groups including scientific or clinical experts, organizations (e.g., health care, specialty societies), agencies (e.g., federal government), patients, and representatives of the public who have relevant interests and may be affected by the CPG.

2.8 **Consumer or Patient Representatives** are persons who represent the patient experience, values, and preferences during the guideline development process.

2.9 **Industry** is defined as for-profit companies, businesses, pharmaceutical companies, or device manufacturers.

# 3 TRUSTWORTHY GUIDELINE PRINCIPLES

3. Disclosure of Interests

It is critical for societies to demonstrate their intent to develop guidelines with minimal bias. Physicians, patients, consumers, and the public need to be confident that Societies' guidelines are not biased toward the interests of their members but rather, reflect the current state of the evidence and the strength of that body of evidence. Societies' guideline policies and procedures should include a process for disclosures of interest (DOI) and for review and identification of conflicts of interest (COI). Societies will require that the majority of members of the GDG are free of conflicts of interest (CMSS Code 7.7). Processes should be in place to manage COIs and may involve exclusion of panel members, restrictions on voting, or other mitigation strategies. Management of COIs should be consistent and transparent with relevant conflicts made available in the guideline document or on the Society website.

GDG members should provide current and previous DOIs for a defined period of time--spanning one year prior to initiation of the project through publication. Societies should review all DOIs and then determine a mitigation strategy for all identified COIs. Following appointment to the GDG, an additional DOI review should be performed before the start of each meeting (in person or virtually). Additionally, GDG members should decline offers from industry to speak about content related to the guideline as outlined in the CMSS Code. Societies may consider using more stringent criteria for disclosures than outlined above regarding longer time frames for disclosures and restrictions on industry-sponsored talks.

3.1 Societies developing guidelines should define and document their interpretation of DOI and management of COIs. The focus of the disclosures is principally on the monetary relationships with Companies at the individual and Society levels. In addition to direct financial conflicts, Societies should have processes for the disclosure and management of intellectual conflicts (e.g., academic advancement, clinical revenue streams, community standing, and scientific interest).

DOI policies should include (CMSS Code 7.6):

> 3.1.1 Criteria for determining relevance when a disclosure (both financial and intellectual) is material or pertinent to the topic of the writing panel or GDG.
>
> 3.1.2 Options for the management of significantly relevant financial and intellectual COIs may include removal of a panel member or restrictions on participation such as not voting, abstaining from participating in discussions, or not participating in evidence-based reviews.

3.2 Societies should create processes for collecting DOIs and managing COIs, for members of GDGs. These processes should be reviewed annually, and Societies should make a summary of them available via publication or upon request. Processes should include:

> 3.2.1 Societies will require that members of GDG and staff involved in the guideline process disclose interests of themselves and household members. Societies are encouraged to use a time frame for disclosures that includes one year prior to initiation of the project until publication. Disclosures should be updated before the start of each meeting (in person or virtually) of the GDG (CMSS Code 7.5)

3.2.2 Societies will require that at least a majority, including the chair, of the GDG are free of COIs pertinent to the subject matter during and ideally for one year prior to their work on guidelines or their revisions. If the Society is unable to use a chair that is conflict free, the GDG should appoint a co-chair who is free of conflicts. The GDG chair should remain conflict free for at least one year after guideline publication (CMSS Code 7.8).

3.2.3 Societies should pursue fair and consistent interpretation and application of the DOI policy across guideline projects and with partner/collaborator organizations.

3.2.4 Societies should have a process to ensure that the individuals participating in the guideline process understand and adhere to the DOI policy.

3.3 Transparency

3.3.1 Societies will ensure that any relevant disclosures are publicly available, along with a summary of the COI management strategies. Societies may note in their published guidelines who they identified as conflicted vs. non-conflicted.

# 4 COMPOSITION OF GUIDELINE DEVELOPMENT GROUP

GDGs should be multi-specialty, multidisciplinary, and include individuals with the relevant expertise to develop a high-quality guideline. To accomplish this, a Society can establish a core group of members with sufficient expertise in guideline development to assure future guideline groups' access to experts within their Society. However, training in guideline development and evidence-based methodology should be encouraged for all GDG members. It is acceptable that one individual may serve more than one role (e.g., methodologist AND statistical analyst).

To the extent possible, Societies should include patients, family members, caregivers, and/or consumers on the GDG. Representatives from patient advocacy groups may be a part of the GDG to provide insight into patient preferences and values. However, as advocacy groups may have different funding sources than Societies, investigations into the group's composition and funding is encouraged prior to appointment of the representative. External review of the guideline by patient advocacy groups may be an alternative if conflicts preclude their inclusion on the guideline panel.

4.1 All personnel directly and substantively involved in the development process should be subject to the same DOI policies and management procedures as the rest of the GDG.

4.2 Key Stakeholder Input

4.2.1 Societies should incorporate stakeholders in both the development and review of their guidelines. Stakeholders may include external medical societies, patient or consumer groups, or other health organizations. To the extent possible, the development panel should be multidisciplinary with members who can represent or communicate values of key stakeholders.

4.2.2 Participants' names, academic and professional credentials, organizational affiliations, and their role on the document should be publicly available in a manner determined by the Society (printed publication, online supplement, appendix).

4.3 Methodologists or Evidence-based Medicine Expert

4.3.1 Societies should incorporate a methodologist with expertise and/or training in evidence-based medicine and guideline development methodology. Methodologists may serve in multiple roles and assist with writing, statistical calculations, literature searches, and other specialized tasks in the development process.

4.4 Information Specialist

4.4.1 The GDG should include input from an information specialist with knowledge and experience in literature searching (e.g. librarian). The information specialist may be a member of the GDG or act as consultant to the group.

4.4.2 The information specialist should be experienced in systematic search strategies and health information resources. Societies may consider recruiting information specialists with experience in guideline development/methodology or include them in the training provided to the GDG.

4.5 Statistical Analyst

4.5.1 The GDG should include at least one participant who is skilled in the appropriate interpretation and application of statistical analyses. This participant may serve multiple roles in the GDG.

4.6 Patient/Consumer Representative

4.6.1 Patients or consumer involvement should be included in guideline development, review, or formulation of clinical questions.

4.6.2 Patient preferences and patient-oriented outcomes should be addressed in the guideline recommendations as appropriate. The role of patient preferences in the development of guidelines should be defined in the Societies' development methodology.

# 5 GUIDELINE DEVELOPMENT PROCESS DOCUMENTATION

The entire development process should be documented and available in the guideline itself or upon request to ensure transparency and reproducibility. The search strategy, the methodology used to assess the quality of included studies, the process used to develop recommendations, and the summary of the evidence assessment (such as evidence tables) are examples of guideline development processes to be documented. Societies may refer users to related resources that are outside the scope of the guideline. Societies should also acknowledge gaps in the evidence base to identify areas in need of further research.

Documentation of the search strategy is a key component for transparency and reproducibility. It will also facilitate publication of guidelines in peer-reviewed journals and in the National Guideline Clearinghouse. Societies are encouraged to use independent, well-done systematic reviews to produce transparent and evidence-based documents. If Societies perform their own searches, every effort should be made to ensure a consistent, reproducible, and comprehensive search strategy. All search strategies should be saved and should include search terms, databases searched, time period searched, and

predetermined inclusion and exclusion criteria. When possible, electronic copies of retrieved literature should be archived per the Societies' archiving policy. Societies should either publish their search strategies as companion documents to the systematic review and/or guideline, or make them available upon request. A list of included and excluded studies should be maintained with reasons given for study exclusion and should be saved in an electronic database. A summary of this information may be included in the guideline (e.g. PRISMA diagram). In addition to the search strategy, the following items should be included in the guideline:

5.1 The intent of the guideline should be clearly stated.

5.2 The rationale for the guideline should 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. Use of the PICO (Population, Intervention, Comparison, Outcome) format is recommended.

5.3.5 Clear descriptions of what the guideline covers related to diagnosis, prognosis, screening, and treatment(s) for diseases/conditions, and what is excluded.

# 6 EVIDENCE AND RECOMMENDATIONS

Developers should consider the impact of practice recommendations that are based on low-level evidence. There are occasions when expert opinion is the only available evidence on a topic with a high need for a recommendation. 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 or when the benefits greatly outweigh the risks. When this occurs, Societies should annotate or flag the recommendation and provide an explanation in the supporting text.

6.1 Evidence assessment should document:

6.1.1 The search strategy, including the time period for searched literature, databases searched, inclusion and exclusion criteria, and search terms. Societies should be able to make these publicly available through inclusion in the publication itself or as an addendum, referral to an electronic media source, or provision upon requested.

6.1.2 The classification system or methodology used to assess (grade) the quality of the evidence.

6.1.3 The process used for reconciling differences in agreement on the strength of evidence and strength of the recommendations.

6.1.4 The method of data extraction, if not already included in an independent systematic review or evidence report.

6.2 Recommendations should classify the quality or level of evidence as well as the strength of the recommendation itself; these strengths should not be a restatement of the evidence, but should be determined by consideration of the spectrum of evidence and the assessment of benefits and harms. As outlined above, the recommendation strength should be consistent with the quality of the evidence. When strong recommendations are made on low quality of evidence, Societies should be transparent and provide an explanation in the supporting text.

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

6.2.2 Whenever possible and appropriate, cost-effectiveness and comparative effectiveness information from unbiased sources should be incorporated into guidelines.

6.2.3 Each citation identified as affecting the evidence review should be evaluated for its quality and its limitations and described.

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

6.4 Recommendations based on only expert opinion, consensus, or low-quality evidence should be documented.

6.5 When a specific process for finalizing the group recommendations is employed (such as a recommendation rating process or recorded voting), it should be made available upon request.

6.6 All recommendations should be linked to an evidence profile or assessment that transparently documents reasoning behind each recommendation. Evidence tables or summaries should be provided outlining the quality assessment of the evidence, and should be available upon request. Societies are encouraged to include these documents in the guideline appendices.

6.7 Recommendation statements should be actionable and formatted consistently. To facilitate implementation of guidelines, Societies should consider limiting the number of recommendations and length of the document, as appropriate.

6.8 Recommendations should consider related guidelines from other development groups to reduce duplicating or overlapping recommendations that may confuse users.

6.8.1 When feasible, Societies should include relevant stakeholders from other organizations in the guideline development process.

6.8.2 Harmonization with related recommendations from similar guidelines is encouraged.

6.8.3 When significant differences between existing guidelines cannot be harmonized, an explanation should be provided.

# 7 GUIDELINE REVIEW

The guideline should undergo review within the Society and should undergo external review. The Society should seek feedback on draft guidelines from independent reviewers, which may include subject matter experts, health-care practitioners, biostatisticians, and patient representatives (CMSS Code 7.9). 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.

The Society should encourage a minimum of 30 days for review and comment on the guideline document by external reviewers. Each Society should develop consistent processes for internal and external review of the draft guideline.

7.1 Key processes for internal review should include:

7.1.1 Review and approval before submission for publication by at least one internal body beyond the Guideline development panel, such as an internal committee, section, council and/or the Board of Directors (CMSS Code 7.9).

7.1.2 Final acknowledgement of or approval by the Society after all internal, external, and peer reviews, as determined by the Society.

7.2 External and peer review should:

7.2.1 Include relevant stakeholders composed of content and technical experts, patients or consumers, practicing clinicians, and members from affected groups.

7.2.2 Include independent editorial review by the journal or other source where guideline is first published (CMSS Code 7.11).

# 8 TIMELINES

Within guideline text, clearly state when a guideline is expected to be considered for review and update. In lieu of periodic review, indicate that the guideline will be considered valid up to five years. If the guideline review is deemed out of date, adequate resources should be allocated to update the guideline or the guideline should be deemed expired.

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

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

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

8.2.2 A process should be in place for identifying and managing guidelines that are no longer current. Societies should publicize, in a manner of their choosing, the status of the guideline to inform users if the guideline is new, under review, revised, or expired.

# 9 DISTRIBUTION AND IMPLEMENTATION

9.1 Society guidelines should be freely accessible on an organizational website.

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

9.3 Societies should consider guideline derivatives for licensed health-care professionals, patients, caregivers, and other lay audiences to facilitate provider-patient interactions and to incorporate recommendations at the point of care. Societies are encouraged to publicize all products related to a guideline to all relevant audiences.

9.4 Guideline developers are encouraged to explore additional implementation opportunities based on the guideline recommendations.

9.5 Societies developing guidelines jointly should have a process outlining the principles of collaboration using a memorandum of understanding (MOU) or other type of legal document. This document can be used to determine the following:

> 9.5.1 Copyright ownership and licensing should be documented. Societies may wish to consider that one Society or journal/publisher owns the copyright and provides a license to the other Society(ies) or journal(s). This would avoid legal burdens of joint copyright ownership.
>
> 9.5.2 The agreement should outline the terms for the creation of derivative works.
>
> 9.5.3 The agreement should include stipulations that no Society should be able to unilaterally modify the guideline without written agreement from the other Society(ies).

# 10 FINANCE AND FUNDING

For financing the development or updating of clinical practice guidelines, Societies should adhere to the principles outlined in the CMSS Code.

10.1 Societies will not permit direct external company support of the development of clinical practice guidelines or guideline updates, including travel reimbursement from industry or pharmaceutical companies. Societies will not accept corporate sponsorship, educational grants, 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 (CMSS Code 7.3).

10.2 Societies will not permit direct company support for the first printing, publication, and distribution of 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 guidelines or guideline update, translation of the guideline or guideline update, or re-purposing of the guideline content (CMSS Code 7.4).

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

10.4 Regardless of source, all funding should be transparent and documented in the guideline text.

10.5 Honoraria, travel reimbursement, and compensation for developers should occur transparently.

10.6 Societies are encouraged to ensure intellectual property ownership of their guidelines by obtaining written copyright agreements for all contributions made by members of the panel. If a guideline is published in a journal, Societies should work with the publisher to obtain licenses to the copyrights. Full copyright ownership of a guideline permits the creation of derivative works based on it.

# 11 REFERENCES


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