SMFM Clinical Practice Guidelines Development Process

The Society for Maternal-Fetal Medicine (SMFM) publishes clinical practice guidelines in two types of documents: SMFM Clinical Guidelines, which address topics of particular interest to maternal-fetal medicine (MFM) subspecialists, and the SMFM Consult Series, which consist of more focused clinical questions on obstetric topics that may be useful to all obstetric care providers. The SMFM guideline development process includes a rigorous review and grading of the evidence in the relevant scientific literature, input of a committee of expert members, and a multilayered peer review approval process. To facilitate transparency in SMFM's guideline development process, a brief overview of the key stages in development is provided below.

Topic and Author Selection

The SMFM Publications Committee may develop clinical guidance on a given topic for many reasons, such as a change in evidence or practice patterns, to address a new or evolving issue, and or to update existing guidance if the supporting evidence changes. The overarching goal of these documents is to provide guidance for SMFM members and to optimize clinical care for patients. Once the Publications Committee has decided to develop clinical guidance on a given topic, they create an outline and select an author to draft a manuscript.

Manuscript and Recommendation Development

SMFM employs the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system during the development of clinical guidance. GRADE is a recognized and standardized process used to rate the quality of supporting evidence and determine the strength

of recommendations. This process informs three key stages in SMFM's guidance development process: the formulation of clinical questions, review of the evidence, and grading of recommendations (1).

First, the SMFM Publications Committee develops an outline for clinical guidance on a new topic that includes key clinical questions based on PICO (**p**atient/population, **i**ntervention, **c**omparison, **o**utcome) parameters. Framing the questions that will be answered in the guideline with these four elements defines the scope of the guideline and allows for focused, actionable recommendations to be made for the most critical outcomes.

Next, a literature search is performed using the PICO parameters as key words. In drafting the manuscript, authors are encouraged to incorporate systematic reviews, randomized clinical trials, and prospective studies as evidence to support the recommendations for each clinical question. The quality of this evidence is assessed by the author for each outcome according to criteria such as study design, risk of bias, and effect size during manuscript development and by the SMFM Publications Committee during manuscript review. A summary of evidence table is created to display the quality of evidence supporting the recommendation for each clinical question and provide transparency in the recommendation making process (2).

After the author has drafted the manuscript, the Publications Committee creates and grades the recommendations for each clinical question. SMFM uses the GRADE letter-and-number classification system for recommendations, with the letter grade specifying the quality of the available evidence (high = A, moderate = B, or low = C), and the number grade demonstrating the strength of the recommendation (strong = 1 or weak = 2). The quality of supporting evidence, risks and benefits of alternative management strategies, and patient preferences and resource availability for a given outcome are considered when assigning a recommendation grade (2, 3).

Manuscript and Recommendation Review

After an author submits a manuscript (either a Clinical Guideline, Consult, or Statement), Primary Reviewer(s) are identified by the SMFM Publications Committee Chair and Vice Chair to comprehensively review the evidence and overall content, and to draft recommendations. The SMFM Publications Committee then reviews the document to finalize the recommendations, evidence tables, and references. Next, the SMFM Document Review Committee reviews the document for clinical accuracy, as well as for conflict or consistency with existing SMFM guidance, and practice and policy implications. Finally, the SMFM Executive Committee extensively reviews the document for global considerations. Each stage of review is a collaborative process between the Publications Committee, author(s), and Primary Reviewer(s). A manuscript may go through several rounds of review at each stage to ensure recommendations accurately reflect the best available evidence.

If the document has implications for members outside SMFM, additional review may be sought from partner organizations. The manuscript will then proceed through that organization's formal review process.

Manuscript Submission and Publication

After a manuscript has received approval from all stages of review, it is submitted to the American Journal of Obstetrics and Gynecology (AJOG). All SMFM clinical guidance is published by AJOG in print and online.

Reaffirmation, Revision, and Withdrawal of SMFM Clinical Guidance

SMFM clinical guidance (clinical guidelines, consults, and statements) is reviewed every 18-24 months. Members of the Publications Committee review recently published literature to evaluate whether the evidence continues to support the recommendations and whether guidance on a given topic is still necessary for the SMFM community. Based on these criteria, the Publications Committee decides if the guidance should be reaffirmed, revised, or withdrawn.

Management of Conflicts of Interest

The disclosure and management of potential conflicts of interest occur at each stage of the guidance development process. Authors, reviewers, and committee members are required to disclose potential conflicts of interest at least each year or whenever such conflicts change. Management of conflicts of interest will follow SMFM's Conflict of Interest policy.

Figure 1. Development of SMFM Clinical Guidelines, Consult Series, and Statements

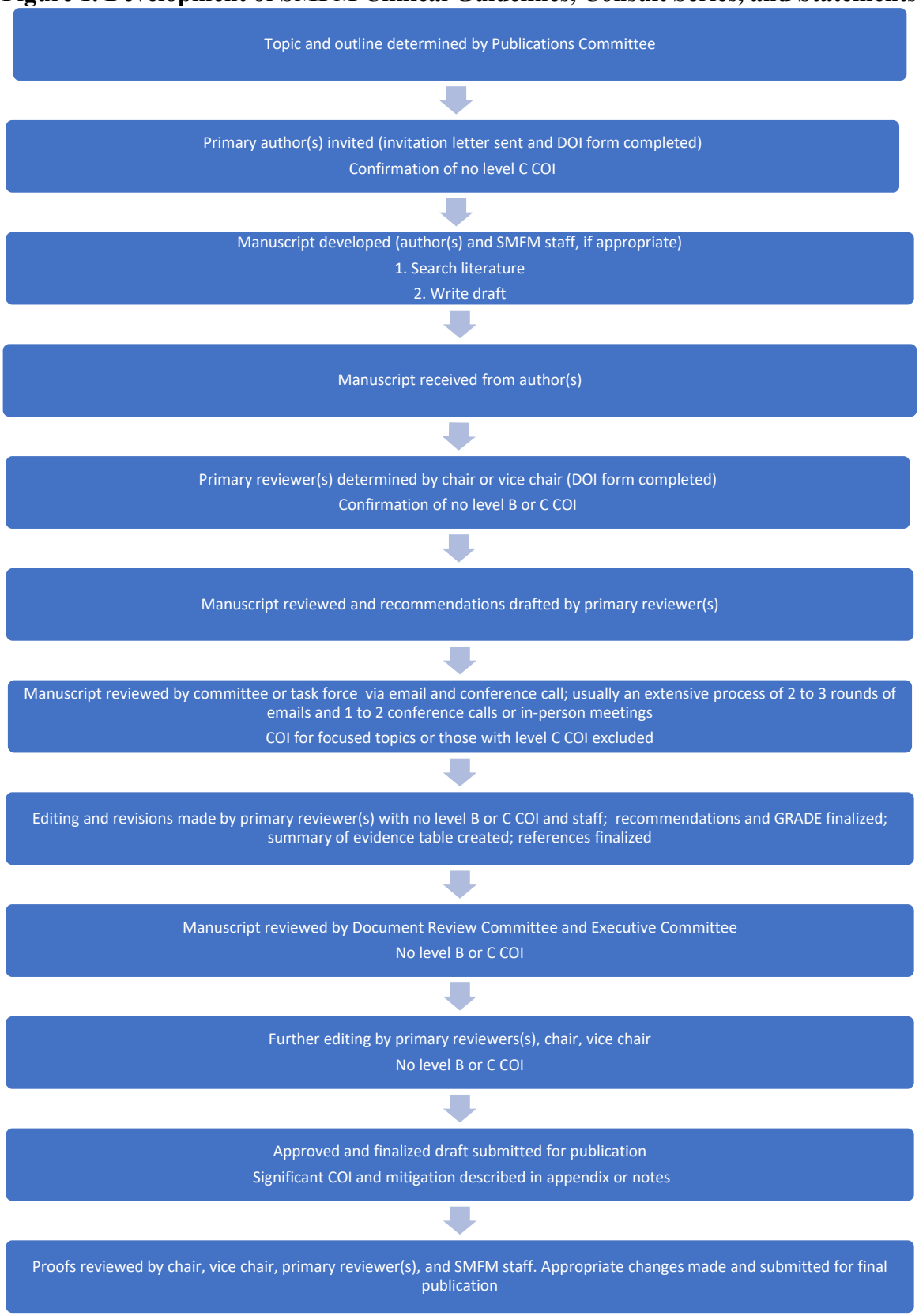

Table 1. Society for Maternal-Fetal Medicine Grading System: Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Recommendations

Grade of Recommendation	Clarity of risk/benefit	Quality of supporting evidence	Implications	Suggested language
1A. Strong recommendation, high-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa.	Consistent evidence from well-performed randomized, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk.	Strong recommendations, can apply to most patients in most circumstances without reservation. Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.	• We strongly recommend…. • We recommend that … should be performed/ administered…. • We recommend that …. is indicated/ beneficial/ effective…..
1B. Strong recommendation, moderate-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa.	Evidence from randomized, controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on our confidence in the	Strong recommendation and applies to most patients. Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.	• We recommend…. • We recommend that … should be performed/ administered…. • We recommend that …. is (usually) indicated/ beneficial/ effective…..

		estimate of benefit and risk and may change the estimate.		
1C. Strong recommendation, low-quality evidence	Benefits appear to outweigh risk and burdens, or vice versa.	Evidence from observational studies, unsystematic clinical experience, or from randomized, controlled trials with serious flaws. Any estimate of effect is uncertain.	Strong recommendation that applies to most patients. Some of the evidence base supporting the recommendation is, however, of low quality.	• We recommend…. • We recommend that … should be performed/ administered…. • We recommend that …. Is (may be) indicated/ beneficial/ effective…..
2A. Weak recommendation, high-quality evidence	Benefits closely balanced with risks and burdens.	Consistent evidence from well-performed randomized, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk.	Weak recommendation; best action may differ depending on circumstances or patients or societal values.	• We suggest… • We suggest that …. may/might be reasonable...
2B. Weak recommendation, moderate-quality evidence	Benefits closely balanced with risks and burdens, some uncertainty in the estimates of benefits, risks and burdens.	Evidence from randomized, controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong	Weak recommendation; alternative approaches likely to be better for some patients under some circumstances.	• We suggest… • We suggest that …. may/might be reasonable...

		evidence of some other research design. Further research (if performed) is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate.		
2C. Weak recommendation, low-quality evidence	Uncertainty in the estimates of benefits, risks, and burdens; benefits may be closely balanced with risks and burdens.	Evidence from observational studies, unsystematic clinical experience, or from randomized, controlled trials with serious flaws. Any estimate of effect is uncertain.	Very weak recommendation; other alternatives may be equally reasonable.	• We suggest… is an option • We suggest that …. may/might be reasonable...
Best practice	A recommendation that is sufficiently obvious that the desirable effects outweigh undesirable effects, despite the absence of direct evidence, such that the grading of evidence is unnecessary			• We recommend…. • We recommend that … should be performed/ administered…. • We recommend that …. is (usually) indicated/ beneficial/ effective…..

References

1. Chauhan SP, Blackwell SC. SMFM adopts GRADE (Grading of Recommendations Assessment, Development, and Evaluation) for clinical guidelines. Am J Obstet Gynecol 2013 Sep;209(3):163-5.

2. Guyatt G, Oxman AD, Akl EA, Kunz R, Vist G, Brozek J, et al. GRADE guidelines: 1. Introduction-GRADE evidence profiles and summary of findings tables. J Clin Epidemiol 2011 Apr;64(4):383-94.

3. Guyatt GH, Oxman AD, Kunz R, Falck-Ytter Y, Vist GE, Liberati A, et al. Going from evidence to recommendations. Bmj 2008 May 10;336(7652):1049-51.