Society of Family Planning Clinical Guidance Author Instructions

2021

Overview

The Society of Family Planning (the Society) Clinical Recommendations (formerly Clinical Guidelines) are widely read by the membership, and are frequently used as clinical references and teaching materials. In 2021, the Clinical Affairs Committee (the Committee) endorsed the creation of four new document categories to serve the different circumstances in which the Society's expert perspectives are appropriate and necessary. Collectively, we refer to these documents as Clinical Guidance. Clinical Guidance produced by the Society will capture the specific expertise and leadership of Society members within a given topic area. Ultimately, all Clinical Guidance created by the Society should reflect the Society's mission and values.

The four categories of Clinical Guidance produced by the Society will include:

- Committee Statement
 - Opinion or editorial written on behalf of the Society's Clinical Affairs Committee, with Committee review and approval
- Committee Consensus
 - Document published in lieu of a full Clinical Recommendation when responsive guidance is critical but evidence is limited or conflicting
- Clinical Recommendation
 - Full review of existing evidence with GRADE analysis, intended to provide a comprehensive overview of a topic and practical guidance for clinicians
- Interim Clinical Recommendation
 - Time-sensitive recommendation using best-available evidence and expert opinion to provide a sufficient overview of a topic and practical guidance for clinicians in emergent situations

Clinical Guidance documents are published in *Contraception*, the official journal of the Society. Interim clinical recommendations are published on the Society's website and may be submitted for publication in *Contraception*.

The content of a Clinical Guidance document is based on a thorough, methodical review of available clinical evidence, best practices, and expert opinion. The primary sources should be peer-reviewed publications of the highest quality available. However, for some topics, the available literature may be limited, and in these situations the limited nature of the evidence should be stated. Despite the continual changes in statutory and political situations (both in the United States and other countries), content should be oriented towards clinical care, not compliance with statutory or institutional restrictions or mandates.

Process

Summary of steps (described in detail below)

- Topic selected
- Authors selected
- Reviewer and liaison (where applicable) selected
- Document outline created and approved
- Document drafted
- Document reviewed, revised
- Document submitted to *Contraception* (where applicable)
- Revisions per Contraception review completed
- Document published

Topic selection

The Clinical Affairs Committee will generate topics. Topics may also be generated via input from members, feedback at clinical meetings, and suggestions from partner organizations; however, the Clinical Affairs Committee must approve all topics. Individuals can submit suggestions for topics to the Society at Clinical @SocietyFP.org.

Authorship

The Clinical Affairs Committee recommends the primary author for Clinical Guidance according to these general policies:

Committee Statement: The primary author must be a member of the Society, but does not have to be a Committee member. Up to three volunteers from the Committee will be selected to serve as co-authors. They will review, revise and ultimately endorse the statement. These co-authors will be selected with attention to achieving diversity in racial and ethnic background, geography, and clinical practice setting (eg, independent clinics, Planned Parenthood affiliates, and academically-affiliated practices). Authorship will be stated as "Written by Author 1 on behalf of the Society of Family Planning Clinical Affairs Committee in collaboration with Author 2, Author 3, etc."

Committee Consensus: The majority of authors will be Clinical Affairs Committee members. The Committee Chair will solicit up to three volunteers to author the statement on behalf of the Committee, with attention paid to achieving diversity in racial and ethnic background, geography, and clinical practice setting (eg, independent clinics, Planned Parenthood affiliates, and academically affiliated practices). In some cases, content experts who are not members of the Committee may serve as authors.

Clinical Recommendation: The primary author must be a member of the Society. Up to three coauthors are permitted and do not have to be members of the Society. The primary author will have an opportunity to identify coauthors during outline submission and approval (described below), with attention paid to achieving diversity in racial and

ethnic background, geography, and clinical practice setting (eg, independent clinics, Planned Parenthood affiliates, and academically affiliated practices).

Interim Clinical Recommendation: The primary author must be a member of the Society. Up to three coauthors are permitted and do not have to be members of the Society. The primary author will have the opportunity to identify coauthors during outline submission and approval (described below), with attention paid to achieving diversity in racial and ethnic background, geography, and clinical practice setting (eg, independent clinics, Planned Parenthood affiliates, and academically affiliated practices).

Individuals who wish to be considered for authorship of a specific Clinical Recommendation should notify the Society by writing to Clinical@SocietyFP.org.

Committee oversight and review

Committee Statement: The Clinical Affairs Committee Chair, in consultation with the Committee Board Liaison, will review and approve the proposed outline for Committee Statements before the primary author begins drafting. The Committee's coauthors will review, revise, and ultimately endorse the Statement before it is submitted for publication.

Committee Consensus: The Clinical Affairs Committee Chair, in consultation with the Committee Board Liaison, will review and approve the proposed outline for a Committee Consensus before the primary author begins drafting. Coauthors from the Clinical Affairs Committee will assist the primary author in drafting and revising. Up to three reviewers from the Clinical Affairs Committee will review and ultimately endorse the Consensus before it is submitted for publication.

Clinical Recommendation and Interim Clinical Recommendation: A Clinical Affairs Committee member will serve as the liaison for each Clinical Recommendation and represent the perspective of the Committee at all stages of the process. The liaison will generate the Clinical Recommendation outline in collaboration with the primary author. The liaison will work with the primary author to ensure that the outline reflects the priorities and expectations for the document as set forth by the Committee. The outline will be approved by the liaison before the primary author begins drafting.

The Clinical Affairs Committee Chair will solicit up to three reviewers for each Clinical Recommendation. These Committee volunteers will review and ultimately endorse the document before it is submitted for publication.

The liaison will be recognized as an author of the Clinical Recommendation when they make significant contributions to the overall document. When the liaison is involved in later stages of document development or revision, the liaison's contributions may not merit authorship but will be recognized through an acknowledgment. Reviewers will not be noted as authors but may also be recognized through an acknowledgment. The Clinical Affairs Committee Chair will resolve any questions about authorship.

Outline

The Committee liaison, in collaboration with the primary author, will develop an outline based on the standard structures described below. The outline will incorporate the perspective of the Clinical Affairs Committee.

Committee Statement: The outline should summarize the key clinical issue and opinion of the Committee. Statements should have supporting sub-points (approximately 2-4) to reinforce the overall opinion.

Committee Consensus: The outline should contain a summary of the clinical issues, and the proposed clinical questions or challenges, focusing on areas of limited or conflicting data/recommendations. Where possible, the Consensus should highlight areas of agreement with existing guidance in the field. These documents will likely have a limited number of clinical questions (approximately 2-4).

Clinical Recommendation and Interim Clinical Recommendation: The outline should contain a summary of the clinical issues, and the proposed clinical questions. For Clinical Recommendations, there should be approximately 10 (range: 8-12) clinical questions, depending on the complexity of the topic. Interim Clinical Recommendations may have fewer clinical questions. If authors do not intend to use the GRADE system (Appendix 1) to rate recommendations, they must provide a justification to the liaison for Committee approval. The authors should submit a first draft of the manuscript within three months of outline approval.

Review process and submission

A staff member from the Society will assist with application and review of the GRADE structure as appropriate for the document type. The liaison will complete a detailed review of the document in collaboration with three viewers from the Clinical Affairs Committee, providing feedback on the following:

- Adherence to pre-approved outline (shared with reviewers at time assignment)
- Clarity of writing
- Appropriateness of recommendations and adequacy of supporting citations
- · Depth and breadth of literature referenced
- Compliance with GRADE structure (Appendix 1), where applicable. A staff
 member from the Society may assist with application and review of the GRADE
 structure as appropriate for the document type.
- Adherence to appropriate style for document type (see next section)

Note: A detailed checklist for authors and reviewers is provided in Appendix 3.

After the Clinical Affairs reviewers have approved the final revisions to the manuscript, the authors will submit it to *Contraception*, using a cover letter template supplied by the Society. The cover letter will provide some of the details necessary for formatting the final manuscript so that it is clearly identified as a Society Clinical Guidance document

and will also request that a designated Society staff person be notified of decisions and actions by *Contraception*.

Authors are responsible for revisions and adhering to the timeline requested by *Contraception*. The Clinical Affairs Committee Chair, liaison, and qualified staff member will determine whether the extent of revisions warrants re-approval by the Clinical Affairs Committee.

Timeline

It is expected that the liaison, authors, and reviewers will be timely in their contributions to all documents. It is the goal of the Clinical Affairs Committee to move documents from conceptualization to submission for publication within six months. As such, Society staff will be clear about expected timelines and deliverables for each stage of document development and liaisons, authors, and reviewers are asked in return to be candid if requested timelines are not feasible.

Manuscript instructions and format

Committee Statement

A Committee Statement should clearly state the Committee's interest in the topic as it aligns with the Society's mission and vision, the scientific and/or expert opinion basis for its statement, and a summary of the clinical implications. Format will depend on the topic, but in general should follow the Editorial or Commentary styles of *Contraception*.

Committee Consensus

Patterned after *Contraception* brief research articles, a Committee Consensus should consist of approximately 1000 words, with an abstract of 100 words or less. A Consensus should generally have no more than a combined total of 2 figures and/or tables, and a maximum of 10 references.

Clinical Recommendation and Interim Clinical Recommendation

A Clinical Recommendation should generally be between 4,000-5,000 words depending on the topic. Interim Clinical Recommendations may be shorter. Appendix 1 contains a summary of the GRADE system that authors should use for rating recommendations.

Updates to existing Clinical Recommendations

The Society will request updates to existing Clinical Recommendations when it appears that an update is necessary. The Society staff, in collaboration with the Clinical Affairs Committee, will initiate the review and update process within 4 years of a document's publication.

- The Society will request revisions from the primary author. If the primary author declines, the revision may be offered to another author, to be determined by the Clinical Affairs Committee.
- The primary author may request different coauthors than the original Clinical Recommendation. If the original author group does not reflect the diversity, equity, and inclusion standards of the Society, the Society will add additional authors to ensure appropriate representation.
- The primary author will notify the Society of 1) any changes in authorship and 2) any major changes in the clinical questions. If the changes are extensive, the Clinical Affairs Committee may need to approve a revised outline.
- Authors should rate recommendations using the GRADE system (Appendix 1).
- Authors should comply with the most recent set of author instructions (not the instructions at the time that the original document was written).
- The Clinical Affairs Committee review process, and the process for submission to *Contraception*, are the same for updates and for new Recommendations.

Author compensation and expectations

Authors will work collaboratively to translate document outlines into drafts. All authors will contribute to revisions. Generally, documents will have no more than four authors; additional authors will be considered on a case-by-case basis. The primary author will have the greatest responsibility for document progress and will typically be the first author in the final publication. Liaisons will make the second-largest contributions to document progress and will generally be the last author in the final publication. Exceptions to author order will be considered on a case-by-case basis. In addition to document creation, authors and liaisons will play roles in clinical guidance dissemination and continuing education. Expected distribution of work is described below; compensation for authors reflects these duties.

Committee Statement

- Primary author: Creates the document outline based on Committee guidance, initiates drafting, authors sections of the document, finalizes the manuscript based on coauthor feedback, and manages *Contraception* submissions and revisions. Compensation: \$400
- Coauthor: Authors sections of the document, participates in review and revision to finalize drafts, and approves revisions requested by *Contraception*.
 Compensation: \$200

Committee Consensus

- Primary author: Creates the document outline, conducts the literature review, initiates drafting, authors sections of the document, completes revisions based on Committee feedback, finalizes the manuscript, and manages Contraception submission and revisions. Compensation:\$1,000
- Coauthor: Authors sections of the document, participates in review and revision to finalize drafts, responds to Committee feedback, and assists with or approves revisions requested by *Contraception*. Compensation: \$500

Clinical Recommendation and Interim Clinical Recommendation

- Primary author: Creates the document outline (in collaboration with the liaison), conducts the literature review, initiates drafting, authors sections of the document, completes revisions based on Committee feedback, finalizes the manuscript, and manages *Contraception* submission and revisions. Compensation: \$1,500
- Coauthor: Authors sections of the document, participates in review and revision to finalize drafts, responds to Committee feedback, and assists with or approves revisions requested by *Contraception*. Compensation: \$750

Clinical Recommendation Update

- Primary author: Creates the document outline (in collaboration with the liaison), conducts the updated literature review, authors sections of the document, completes revisions based on Committee feedback, finalizes the manuscript, and manages *Contraception* submission and revisions. Compensation: \$1,000
- Coauthor: Authors sections of the document, participates in review and revision to finalize drafts, responds to Committee feedback, and assists with or approves revisions requested by *Contraception*. Compensation: \$500

Authors will receive compensation when the Clinical Guidance is accepted for publication in *Contraception*. The Clinical Affairs Committee liaison will not receive an honorarium but will be listed as an author.

Appendix 1: GRADE summary table

The GRADE system is described in several publications, with a comprehensive set of articles in the Journal of Clinical Epidemiology

(J Clin Epidemiology, (2011) 64:383-394, 64:395-400, 64:401-406, 64:407-415, 64:1277-1282, 64:1283-1293, 64:1294-1302, 64:1303-1312, 64:1311-1316, (2013) 66:140-150, 66:151-157, 66:158-172. 66:173-183, 66:719-725, 66:726-735)

These tables are adapted from a summary in www.uptodate.com/home/grading-guide.

	adapted from a s	summary in <u>www.uptodate.com</u>	<u>i/nome/grading-guide</u> .
Table 1. Grading			
Grade of recommendation	Clarity of risk/benefit	Quality of supporting evidence	Implications
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.
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, methodological 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 estimate of benefit and risk and may change the estimate.	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.
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, and applies to most patients. Some of the evidence base supporting the recommendation is, however, of low quality.
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, patients, or societal values.
2B. Weak recommendation, moderate quality evidence	Benefits closely balanced with risks and burdens, some uncertainly in the estimates of benefits, risks, and burdens.	Evidence from randomized, controlled trials with important limitations (inconsistent results, methodological 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 estimate of benefit and risk and may change the estimate.	Weak recommendation, alternative approaches likely to be better for some patients under some circumstances.
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.

Table 2. Factors panels	should consider in deciding on a strong of	or weak recommendation
Issue/what should be considered	Recommended process	Examples
Quality of evidence	Strong recommendations usually require at least moderate-quality evidence for all the critical outcomes. The lower the quality of evidence, the less likely it becomes a strong recommendation.	Many high quality randomized trials have demonstrated the benefit of inhaled steroids in asthma while only case series have examined the utility of pleurodesis in pneumothorax.
Relative importance of the outcomes (benefits of therapy, harm of treatment, burdens of therapy, cost)	Authors and editors consider the relative values and preferences that patients and other stakeholders place on outcomes and the variability in values and preferences across patients. If values and preferences vary widely, a strong recommendation becomes less likely.	Preventing post-phlebitic syndrome with thrombolytic therapy in DVT in contrast to preventing death from PE. Most young, healthy people will put a high value on prolonging their lives (and thus incur suffering to do so); the elderly and infirm are likely to vary in the value they place on prolonging their lives (and may vary in the suffering they are ready to experience to do so).
Baseline risks of outcomes (benefits of therapy, harm of treatments, burdens of therapy)	The higher the baseline risk of an adverse outcome, the greater the magnitude of benefit from a treatment, and the more likely a strong recommendation. If the baseline risk is very different in two subpopulations then UpToDate may make separate recommendations for these different populations.	a. Some surgical patients are at very low risk of post-operative DVT and PE while others surgical patients have considerably higher rates of DVT and PE b. ASA and clopidogrel in acute coronary syndromes anticoagulation have a higher risk for bleeding than ASA alone c. Taking adjusted-dose warfarin is associated with a higher burden than taking aspirin; warfarin requires monitoring the intensity of anticoagulation and a relatively constant dietary vitamin K intake
Magnitude of relative risk including benefits (reduction in RR), harms (increase in RR), and burden (increase in RR)	Larger relative risk reductions with treatment make a strong recommendation for treatment more likely, while larger increases in the relative risk of harms make a strong recommendation for treatment less likely.	Clopidogrel versus aspirin leads to a smaller stroke reduction in TIA (8.7 percent RRR) than anticoagulation versus placebo in AF (68 percent RRR).
Absolute magnitude of the effect (benefits, harms, and burden)	The larger the absolute benefits with treatment, the greater the likelihood of a strong recommendation in favor of treatment. The larger the absolute increase in harms, the less likely a strong recommendation in favor of treatment.	The absolute reduction in stroke risk in atrial fibrillation patients at yearly stroke risk is 8 percent and in the lowest risk patients less than 1 percent.
Precision of the estimates of the effects (benefits of therapy, harm of treatments, burdens of therapy)	The greater the precision, the more likely a strong recommendation.	ASA versus placebo in AF has a wider confidence interval than ASA for stroke prevention in patients with TIA.
Costs	The higher the cost of treatment, the less likely a strong recommendation.	Clopidogrel has much higher cost than aspirin as prophylaxis against stroke in patients with TIA.

Appendix 2: Manuscript instructions and formatting

Authors should comply with the <u>author instructions for Contraception</u>, as well as the following requirements that are specific to Clinical Guidance document types. Number each section as shown below and use bold section headings. Contact Society staff (<u>Clinical@SocietyFP.org</u>) for sample documents.

Committee Statement

- 1. Introduction
- 2. Recommendations
- 3. Future Considerations
- 3. Authorship. This section should state: "Written by Author 1 on behalf of the Society of Family Planning Clinical Affairs Committee in collaboration with Author 2, Author 3, etc."
- 4. Conflict of Interest. All authors and Society Board members must identify any potential conflicts of interest. This section should also include the line "The Society of Family Planning receives no direct support from pharmaceutical companies or other industries for the development of clinical guidance."
- 5. References

Committee Consensus

Abstract: 100 words

- 1. Background
- 2. Clinical questions
- 3. Recommendations
- 4. Future considerations/ research
- 5. Authorship. This section should state: "This Committee Consensus was prepared by [author(s)], and was reviewed and approved by the Clinical Affairs Committee on behalf of the Board of Directors of the Society of Family Planning."
- 6. Conflict of Interest. All authors and Society Board members must identify any potential conflicts of interest. This section should also include the line "The Society of Family Planning receives no direct support from pharmaceutical companies or other industries for the development of clinical guidance."
- 7. References

Clinical Recommendation and Interim Clinical Recommendation

Abstract: Abstracts should summarize the Clinical Recommendation. Although the *Contraception* author instructions indicate that abstracts should be no more than 250 words, abstracts for Clinical Recommendations can be longer. The abstract can be structured or unstructured, but should include the following:

- Objective: Summary of clinical focus
- <u>Methods:</u> Description of literature search process
- Results/Conclusion: Status, quality and content of evidence
- Recommendations: Summary of recommendations

Key words: Following the abstract, provide 10-15 keywords or phrases (not included in the word count).

- 1. Background. Describe the primary topic that the Recommendation addresses. Summarize the literature to date. Conclude with a description of the goal(s) that the recommendation is expected to achieve.
- 2. Clinical Questions. Provide approximately 10 questions (suggested range: 8-12) that highlight important areas of discussion of the evidence. The questions should follow the outline, although they may need to be modified. Each clinical question should be numbered and italicized. Do not use sub-questions. Authors are strongly encouraged to use the GRADE system (Appendix 1).

Clinical questions should be answered using the best available medical literature, describing the strengths and weaknesses of the studies (when applicable), and without bias. Each recommendation made in response to a clinical question should be followed by the grade of the recommendation (see Table 1, first column) and have nearby primary source citations. It is not necessary to provide a GRADE for each individual citation. If the literature does not provide clear evidence, the author should indicate this.

Example: For women who receive immediate postabortion IUDs and implants, method satisfaction and continuation rates are high (GRADE 1B) [67,70–72].

3. Conclusions and Recommendations. List appropriate conclusions based on the data presented. In general, each clinical question should be linked to a recommendation (or acknowledgement that a recommendation cannot be made). Recommendations should be reiterated in the order they are discussed in the manuscript. Include a grading of the overall body of evidence on which the recommendation is based.

Example:

 Women who desire an IUD or implant should be offered placement at the time of abortion (GRADE 1A).

- Staff training in contraceptive counseling and IUD placement and simplified STI screening protocols are associated with increased access to IUDs after abortion (GRADE 1B).
- 4. Recommendations for Future Research. List areas where additional research is needed. The areas for research should relate to the content of the questions addressed in the Clinical Recommendation. Explain why addressing such gaps in the research is valuable to the topic. The author should also comment on how these studies should be designed and their practicality.

For example, how would a clinical trial address the issue?

- 5. Sources. Describe the literature search process, including how articles were obtained (e.g., PubMed, Cochrane Library, review of reference lists in published articles, etc.), the search terms, and timeframe (e.g., all articles from 2004 through 2014). Authors should state whether they performed a comprehensive systematic review; this may not be possible or desirable for some topics.
- 6. Intended Audience. Describe the intended users of the Recommendation (e.g., provider type, patients, etc.) and the setting(s) in which it is intended to be used.
- 7. Authorship. This section should state: "This Clinical Recommendation was prepared by [author(s)], and was reviewed and approved by the Clinical Affairs Committee on behalf of the Board of Directors of the Society of Family Planning."
- 8. Conflict of Interest. All authors and Society Board members must identify any potential conflicts of interest. This section should also include the line "The Society of Family Planning receives no direct support from pharmaceutical companies or other industries for the development of clinical guidance."
- 9. References. References should be original research articles published in peer-reviewed journals (no commentaries or editorials). Abstracts and presentations should generally not be used. It may be appropriate to reference high-quality systematic reviews (e.g., Cochrane Reviews), and other clinical guidelines, opinions, or recommendations (e.g., WHO or RCOG guidelines).

Appendix 3: Manuscript checklist for authors and reviewers

In accordance with our commitment to scientific rigor as well as diversity, equity, and inclusion, the Society expects all Clinical Guidance will follow these guidelines.
\square Use gender-inclusive language such as "people," "patients," or "individuals" wherever possible. The Committee must approve uses of gendered language.
In some cases, gender-inclusive language may be imprecise. In such cases, it may be beneficial to state in the introduction that the document references existing publications that use the term "women," for example, but that the recommendations should be interpreted to include all people who were female sex assigned at birth.
\square Use person-first language (eg, "people with disabilities") where applicable
\square Reference the effects of "racism" or "systemic racism" as opposed to "racial disparities" where applicable
☐ Make patient-centered recommendations
If applicable, include explicit statements against contraceptive coercion, especially when discussing LARC or permanent contraception.
\Box Include supporting citations for each recommendation, if applicable. If no supporting evidence is available, explain that the recommendation is based on expert opinion.
$\hfill\square$ Consider the potential effects of recommendations on diversity, equity, and inclusion
Discuss how recommendations may impact those who live in restrictive states or rural areas and those who are members of a population that has historically faced discrimination in medical settings (eg, people of color, LGBTQ people)
\square Capitalize "Black" when referring to race. Do not capitalize "white."
\Box Ensure that Clinical Guidance will be relevant to the widest possible audience. For example, do not specify "physicians" when "clinicians" or "providers" would be accurate.
\Box Identify drugs and products by chemical formulas or by generic name. Promotion of any product or service by trade name is prohibited.