

Standard Operating Procedures (SOP) for Preparing AACC Academy Guidance Documents

This SOP outlines the process of developing clinical guidance documents under the AACC Academy.

DEFINITION:

Clinical guidance document: an expert-opinion paper based on the preponderance of available evidence that provides guidance on clinical laboratory practices in a targeted, defined area of clinical or laboratory medicine

PURPOSE:

The purpose of **AACC Academy guidance documents** is to inform the laboratory medicine community of current best practices to improve healthcare and patient outcomes. This might include identifying data gaps as well as highlighting available evidence. Guidance documents allow recognized experts and authorities to summarize the existing data and then offer their perspective on the current best course of action without formal evidence-based research.

PROCEDURES:

1. Selection of topics for guidance documents

Oversight of guidance documents is under the direction of the AACC Academy Council. On an annual basis, the Council will review potential topics and prospective authors for guidance document preparation. If a topic is deemed significant enough to warrant a guidance document, the Council will identify a prospective author and invite them to chair the guidance document and submit a proposal. Any member of the Academy may also submit recommendations or proposals for topics to the Council. Proposals should contain the following components:

- Title
- Author list, contact information, short bio
- History, motivation and significance of topic
- List of questions to be answered

All proposals will be evaluated by the Council, or designee, based on the following criteria:

- 1) relevance and importance of the proposed topic as a guidance document;
- 2) track record of the proposed author (knowledge about the subject and prior record, if any, in writing this style of paper).

The review process may include constructive comments for improving the proposal and a recommendation to invite, resubmit or reject. Based on the review results, a decision is made by the Council and communicated back to the proposers/authors.

2. Writing Group selection

Guidance Document chairs may select their writing group with approval of the Academy Council. Writing groups should consist of 4-6 authors, including a clinician, from multiple institutions. Authors are not required to be Academy fellows, though it is preferred.

3. Review process for guidance documents

In the case of a positive decision on the proposal, the guidance document will be invited. Positive review of the proposed guidance document and invitation for submitting the full manuscript should not be interpreted as acceptance of the full guidance document manuscript. Each completed guidance document will undergo a separate peer review process handled by the Council, or designee. A period for public review and comment will occur for all guidance documents. The comments received during the public comment period must be addressed before the document is approved by the Academy Council. The acceptance/rejection decision will be made based on criteria defined by the Council.

4. Instructions for Authors

Guidance documents should include a statement that it is expert opinion. Conflicts of interest should be included in all guidance documents. The recommendation for the length and preparation of the document is as follows: Up to 20 double-spaced pages, Calibri font, 11 point font size, excluding figures, tables and references; the total number of tables and figures up to 7, and the total number of references up to 50.

5. Suggested timeline for preparation of guidance documents

Begins after topics and document chairs have been identified

- I. Guidance document chair proposes their committee (4 to 5 other members; inclusion of a clinician may be beneficial to the process). Proposed committee is reviewed by the AACC Academy Council - 2 weeks.
- II. Committee members are invited to join the project - 1 month (for invitations and responses).
- III. Committee formulates questions and submits questions for review by the AACC Academy Council - 1 month.
- IV. AACC Academy Council reviews the proposed questions - 2 weeks.
- V. The committee formulates answers to the questions and creates a "guidance document draft" - 4-6 months
- VI. Guidance document draft is reviewed by the AACC Academy Council - 2 weeks.
- VII. Committee responds to the comments from the Council. - 2 weeks.
- VIII. Document is publicly posted for comments - 1 month.
- IX. Committee responds to comments - 2 weeks.
- X. Document is sent to AACC BOD for approval – 2 weeks
- XI. Final draft of guidance document is "published."

6. Online submission

The guidance document submission will be conducted electronically. At least two reviewers will be chosen to reach a consistent decision. The AACC general policy about conflict of interest in selecting reviewers will be followed.

6. Distribution

Guidance documents will be made available for distribution on the AACC Academy web site and will be promoted through regular channels. Some guidance documents may be submitted for publication in a peer-reviewed journal (preferably an AACC journal).