

Emerging Issues in Neurology
Policy and Procedure Manual
American Academy of Neurology
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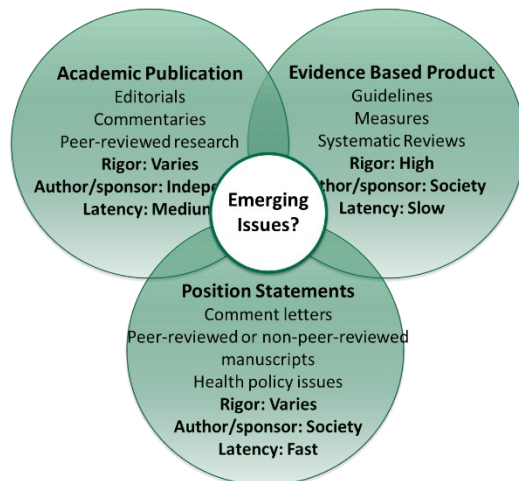
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Introduction

The American Academy of Neurology (AAN) is the leading national neurology society, representing more than 38,000 neurologists and clinical neuroscience professionals and is dedicated to promoting the highest quality patient-centered neurologic care and enhance member career satisfaction. In support of its members and its mission, the AAN produces several publications to inform neurologists, patients, and the general public. There are academic publications, evidence-based products, and position statements. Each has its advantages and disadvantages, including rigor of the evidence review, latency of development, and sponsorship.



Responding to a gap in guidance for members related to emerging issues that affect our specialty, in 2021 the AAN published "COVID-19 and Vaccination in the Setting of Neurologic Disease: An Emerging Issue in Neurology" in Neurology® providing background and guidance on SARS2 COVID19 vaccination for neurology providers. This document was widely accessed, and its reception supported the impression that there is a broader gap in providing guidance for emerging issues in our specialty. The Quality Committee proposes there are likely to be other urgent topics in neurology practice for which AAN guidance is desired. To fill the gap, the Quality Committee proposed development of a new Emerging Issues product to address new or emerging concerns in the healthcare market or in

clinical practice. They would provide a perspective that, if not provided, patient care would be impacted. The Quality Committee anticipates that issues will typically be too novel to have a substantial evidence base wherein a rigorously developed guideline would provide conclusions from data and make practice recommendations. Emerging Issues manuscripts will be "transitional" or interim in nature, providing interim information and application to practice in the interval prior to maturing evidence and the potential creation of an evidence-based guideline product.

Systematic Reviews and Practice Guidelines	Include a systematic literature search, assessment of the strength of the evidence, rating articles, and conclusions based on the review. Practice guidelines include recommendation statements based on SR the conclusions.
Evidence in Focus	A review of the relevant evidence for new or emerging therapies with discussion on clinical context. Does not include conclusions or recommendations.
Emerging Issues	An Emerging Issues document is focused and designed to lead to improvements in clinical care. These documents address new or emerging concerns in the healthcare market or in clinical practice and provide a perspective that, if not provided, patient care would be impacted.
Position Statement	A position statement is a description of the AAN position on a certain issue. Position statements may be short declarations on positions (e.g., comment letters), in-depth descriptions/analyses of complex issues (with reference sections), or documents that fall in between these two categories.

Identification and Selection of Emerging Issues Topics

Topic Principles

It is likely no topic will meet all the following principles, rather this is guidance for identifying, selecting, and developing such documents. There may be instances where the surfacing of an issue and the availability of meaningful data or consensus requires that the AAN suspend efforts until the data needed are available.

Topics should align with some of the following criteria:

- Immediate clinical importance to practicing neurologists
- Potential to significantly impact neurologists' ability to provide high quality care to patients with neurologic disease, including issues that may lead to disparities in patient outcomes
- Recent or rapidly evolving circumstances creating a knowledge gap among neurologists and the gap in knowledge may lead to poor patient outcomes or disparities in care
- Meaningful public health impact
- Relevant to a large audience of members or potential population. However, the topic may be relevant to a smaller population, but the scope and public awareness is broad, meaning the topic is highly visible and likely to generate questions directed toward members from patients or the general public
- Not otherwise better served by an alternative AAN evidence-based product or publication or otherwise resolved through another guidance mechanism (e.g., AAN Guideline or Evidence in Focus)
- Not otherwise better served by a more standard academic publication
- The AAN provides an important, distinct, or neurology specific perspective that would not reiterate other perspectives
- An existing product requires an update due to changes in circumstances

Topic Examples

- Covid-19 infection and vaccination
- Epidemic tic-like functional movement disorders
- Approval of aducanumab
- Evidence of harm from butterbur following migraine guideline
- Recall of CPAP device

Nomination Sources

Emerging Issue topic ideas may be submitted by any AAN member or by the following groups using the online nomination form. Nominations may be made on behalf of a group

- Quality Committee, Subcommittees and workgroups
 - Quarterly pulse-check among Quality Committee members on emerging concerns the AAN might address.
- Board of Directors, AAN Officers, or other AAN Committees, Subcommittees, Work Groups, Task Forces, or Sections
- AAN members
- External stakeholders (government, other specialty societies, patient groups)

Nomination Review and Topic Selection

The Quality Committee evaluates and votes on nominated topics. Voting is conducted electronically with a simple majority vote to approve required by the Quality Committee to proceed. If requested by

2 or more Quality Committee members, there is an opportunity to call an interim Quality Committee meeting to discuss, which given the presumed urgency of topics and the product development outline summarized below, should be scheduled within 2 weeks, when possible. If a quorum of Quality Committee members cannot be assembled within that timeframe, the available group can discuss with a subsequent electronic summary and vote by the committee. Once approved, project initiation and development begin, and the AAN Communications staff are notified so member communications can be coordinated across all channels.

Forming the Emerging Issues Panel

The Quality Committee leadership assigns a committee member to serve as the project facilitator; this person may or may not be the lead author. The facilitator, the Quality Committee leadership, and AAN staff assemble a panel of 5-7 members, which may include members of other AAN committees, subcommittees, or work groups, the nominator of the topic, and other recommendations from the nominator. Ultimately the decision on panel membership is determined by the Quality Committee. The volume and pace of work for these rapid-turnaround projects will need to be clearly and transparently communicated to panel members so that the timelines can be met and commitment to complete in the given timelines is confirmed.

Relationship Disclosure and Management

The AAN is committed to producing independent, critical, and trustworthy Emerging Issues manuscripts. Therefore, disclosure and management of author relationships and potential conflicts of interest are conducted in compliance with the *AAN Relationships & Conflicts of Interest Policy* and the *Principles Governing Academy Relationships with External Sources of Support*. The following procedures implement the relevant policies and outline the process followed for development of Emerging Issues manuscripts:

Disclosing Relationships and Determining Relevance

Prospective authors must disclose all financial and certain nonfinancial relationships with commercial interests (any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients, or is otherwise involved in and seeking to profit from activities related to the provision of health care, e.g., pharmaceutical, medical device, and scientific product companies, manufacturers of health-related wearable products, group purchasing organizations, pharmacy benefit managers, contract research organizations, electronic health record companies, health care technology companies, and insurers), as well as relevant relationships with other entities (including payers, government entities, and not-for-profit organizations) and intellectual biases by completing the [AAN's Relationship Disclosure Form](https://www.aan.com/disclosures/portal) (at <https://www.aan.com/disclosures/portal>) before commencing work on or reviewing Emerging Issues manuscripts. The form describes the categories or types of relationships to be reported. Members of the Quality Committee and the Board of Directors who review Emerging Issues are required to make the same disclosures. The term "relationship disclosure" is preferred to conflict of interest disclosure, as not all relationships necessarily imply conflict or bias.

All relationships with commercial interests must be disclosed regardless of the perceived relevance to the topic. However, to assist the reviewers, prospective authors are asked to highlight relationships that they deem to be "relevant" to the topic (see the following description of relevance). Regarding relationships with non-commercial entities or intellectual biases, only those relationships or potential biases that are relevant to the topic must be disclosed. Intellectual biases may include "academic activities that create the potential for an attachment to a specific point of view that could unduly affect an individual's judgment about a specific recommendation" (Guyatt et al., 2010, *page 739*), examples of which are receipt of a grant or participation in research or article(s) directly related to the topic.

Quality Committee leadership and AAN staff will review each Disclosure Form for any relevant relationships that may constitute a conflict of interest before the prospective author is officially invited to begin work on the project. Relevant relationships may include any of the following:

- A relationship or interest that relates to the same or similar topic, intellectual property or asset, or issue addressed in the manuscript
- A relationship of the person or an immediate family member having a reasonable possibility of financial, professional, or other personal gain or loss as a result of the manuscript
- A relationship with an “affected” company within industry, meaning there is a reasonable likelihood of direct regulatory or commercial impact (positive or negative) on the company as a result of care delivered in accordance with the manuscript.

Quality Committee leadership and AAN staff will consider the relevance of the relationship and the degree of influence when determining whether a conflict of interest exists. Depending on the severity of the conflict, mitigation or management steps may include not inviting the prospective author to participate or restricting the author’s involvement in the development process.

The relevance and severity of an intellectual bias can be difficult to objectively identify and measure. Quality Committee leadership will mitigate intellectual bias as much as possible.

Identifying Relationships Considered Conflicting That Preclude Prospective Author Involvement

Although some relationships may be appropriately managed with the mitigation techniques described in this section, others constitute conflicts of interest incapable of being managed and inconsistent with the AAN’s goal of producing an independent manuscript. Relationships that render an individual ineligible to author an Emerging Issues manuscript include any of the following:

- Serving on a speakers bureau on behalf of an affected company in industry (this is a compensated role as a presenter for which any of the following circumstances are met: the company has a contractual right to dictate or control the content, the company created the slides/presentation for the speaker, or the presenter is expected to act as the company’s agent or spokesperson for the primary purpose of disseminating company or product information)
- Being employed, or having been employed during the year before authorship appointment, by a company in industry
- Holding significant ownership interest (shares greater than \$50,000 in value or an equity interest in a privately held company greater than five percent) in an affected company

In addition, Quality Committee leadership may choose not to appoint an individual as the lead author if the individual has any of the following relationships to the issues or products being assessed: having any stock or stock ownership, being compensated for expert testimony, being a pioneer or having any substantial direct or indirect compensation or other relationship that the Quality Committee leadership deems as creating a conflict.

Understanding Author Responsibilities

Authors must update their [Relationship Disclosure Form](https://www.aan.com/disclosures/portal) (at <https://www.aan.com/disclosures/portal>) at least annually but also promptly at any time a relationship changes.

Roles and Responsibilities

- **Quality Committee Facilitator:** This Quality Committee member is assigned to guide the project, advise on process matters, and ensure the project is advancing. This person may or may not be the lead author.

- *Lead Author:* This person works with the facilitator to set the timeline, assign tasks to panel members, and coordinates activities such as literature reviews, drafting the manuscript, and journal approval and publication processes.
- *Panel Member:* Each panel member is an active participant in the project who reviews articles and writes portions of the manuscript.
- *AAN Staff:* Staff provide administrative support, advice, facilitate meetings and group communications, provide manuscript management, coordinate resource allocation (e.g., medical librarian), and coordinate any necessary internal review and approval processes.

Developing the Emerging Issues Manuscript

Authorship assignments

All participating panel members, including the facilitator, are listed as authors. The lead author and facilitator determine the order of authorship and arbitrate any questions regarding who qualifies for authorship. There are strict guidelines regarding who should and should not be considered an author. At the time of journal submission, all development panel members will be required to complete a form affirming their contribution to the project as involving either study design/conceptualization, data/statistical analyses, or writing/revising of the manuscript.

Setting the scope of the document

An Emerging Issues document should be focused, manageable, and designed to lead to improvements in clinical care. Recommendations for article structure is provided in Figure 1. The target length for these reviews is 2000-3000 words (the shorter the better).

With input from the Quality Committee, the facilitator, lead author, and panel members will determine the scope and content of the Emerging Issues manuscript. In general, there are several categories or headings that will be included:

Figure 1: Recommended article structure

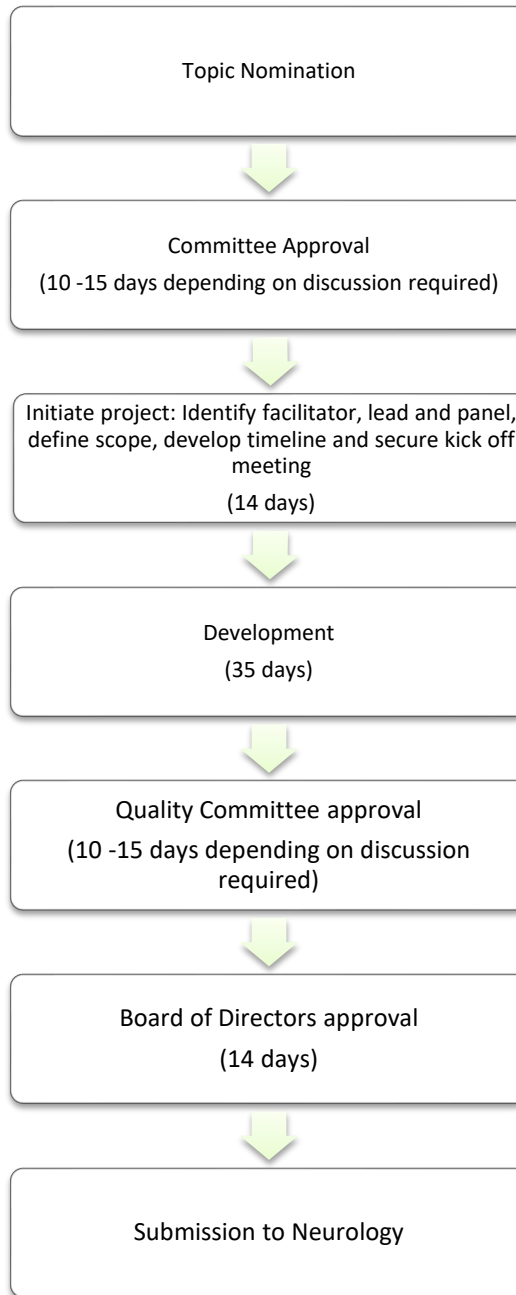
Title: Emerging Issues in Neurology: Title
Background
Rationale (<i>i.e., Why is this emerging issue important and urgent, which criteria met, etc.</i>)
Problem Statement (<i>What problem or question will this manuscript address</i>)
Specific Scope (<i>e.g., “in this manuscript we will be discussing our best understanding of how neurologists and staff can use PPE to reduce the risk of Covid-19 transmission. We will not be discussing treatment, exposure protocols,” etc.</i>)
What We Know (<i>based on the best available information</i>)
What We Don’t Know (<i>highlight the key knowledge gaps</i>)
Discussion (include the following content, if relevant)
Potential controversies
Application to practice
What’s Next
Forthcoming Developments (<i>i.e., external timelines, ongoing AAN responses, etc.</i>)

Emerging Issues manuscripts will not include systematic reviews of evidence. While manuscripts may include application to practice, the body of the manuscript should include an explicit statement that it is not an evidence-based guideline. Part of the role of the facilitator will be to help the lead author avoid language that could be misconstrued as an evidence-based recommendation.

Setting the timeline

The lead author will work with the facilitator to set a reasonable timeline. Ideally, the manuscript would be completed in no more than three months, from approval to submission to Neurology® if applicable. See figure 2 for a proposed timeline. As these issues are of immediate importance to members, the goal is to ensure rapid dissemination to members.

Figure 2: Proposed Timeline (target 3 months from nomination to submission)



Literature searches

Due to copyright laws, the AAN manages distribution of literature to panels through a clearance center. If needed, a medical librarian contracted by the AAN will develop and perform a comprehensive literature search based on the search terms and databases identified by the panel. AAN staff will facilitate these interactions with the medical librarian and the clearance center, providing any required literature to the panel.

Rigor of the document

Emerging Issues manuscripts are not formal evidence-based products. The urgency of the issue and the absence of existing evidence to inform readers preclude long development timelines or systematic literature or evidence analysis. From a rigor perspective, Emerging Issues manuscripts are similar to a position statement, albeit with a specific development structure (as defined in this document) to facilitate a shared understanding with stakeholders (including the AANI Board of Directors and editorial leadership at *Neurology*[®]). This shared understanding will be an essential feature of ensuring smooth and timely development, approval, submission, and review processes.

Decision making processes

Emerging Issues manuscript content will be approved by consensus of the writing group, led by the lead author. Approval of manuscripts submitted to the Quality Committee and the AANI Board of Directors will follow the applicable quorum and voting requirements.

Clear disclaimer of document limitations

All Emerging Issues documents will contain a disclaimer acknowledging the limitations of the document including, but not limited to the availability of evidence, likelihood of forthcoming evidence, and the intent of the document as an educational service.

AAN approval process

When the manuscript is final, the Quality Committee will be asked to approve the document. The committee may have additional revision requests, and if these are substantive it may require re-review by the committee, at the discretion of Quality Committee leadership. Once the Quality Committee has approved the manuscript, it will be submitted to the AAN Institute Board of Directors for approval. Requests for additional changes during the Board review process are reviewed by the Quality Committee leadership. Substantive revisions may require reapproval by the committee and the BOD, at the discretion of Quality Committee leadership and the Executive Committee (as applicable), but at a minimum the revised document will be submitted to the committee and BOD for informational purposes.

Publication in *Neurology*[®]

The *Neurology*[®] journal solicits reviewers from its network to review and comment on the manuscript. Providing potential recommended reviewers may help expedited review. Comments are sent directly to the lead author. The lead author drafts a revision letter presenting all comments from *Neurology*[®] peer reviewers. Lead authors are encouraged to consider all revisions suggested by the journal peer reviewers. The lead author then submits the revised draft to the journal with the completed revision letter denoting the panel's responses to all of the journal reviewers' comments. The revised draft must show all changes made to the manuscript, using an electronic editing tool (e.g., changes tracker, strikethrough font, or highlighted font).

Dissemination

While publication in a peer reviewed journal is ideal, the intent is to provide rapid guidance for members. Dissemination may include the following:

- Published in *Neurology*[®] journal, if accepted by *Neurology*[®]
- Posted on the AAN website
- Announced by email to all AAN members or a subset of members
- Announced in *AANnews*[®] and *AANe-news*[®]

AAN communications staff may launch a media publicity campaign, including tactics such as issuing a press release. Facilitator and lead author will collaborate with AAN communications staff on messaging related to the manuscript.

On-going review for currency

By their nature, Emerging Issues manuscripts may be less durable than other quality products. Development of evidence bases to inform more rigorous documents, or evolution of underlying circumstances, may result in manuscripts that may quickly become dated. Documents will be reviewed for currency on an annual basis or upon creation of a more definitive document, whichever is sooner. Document reviews will be completed by two members of the Quality Committee, who will make a recommendation to the Quality Committee. Documents will be sunset with a majority vote from the Quality Committee.