CME Content Review: More than a Rubber Stamp?

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CME providers have come to recognize the potential for inherent conflict of interest (COI) to exist throughout the content development process. Accredited providers now go beyond faculty disclosures and regularly implement methods to identify and resolve COIs that ensure their activities are independent of commercial influence. The Accreditation Council for Continuing Medical Education (ACCME) cites peer review and using the best available evidence as effective mechanisms by which to resolve COI.[1] In fact, many accredited providers already have a peer review process in place; however, the process can vary considerably among providers.

Most would agree that for peer review to resolve COI and ensure scientific integrity it must be independent and credible, but should it be standardized? We believe that in order to make peer review meaningful and relevant, it needs to be based on agreed upon and established standards and definitions. Stakeholders in CME need to consider what those criteria should be and set them now—before they are set for us. The purpose of this article is to begin that discussion.

Peer Review Analogies

In a general sense, CME peer review is the evaluation of scientific content against specific criteria by a credible party with expertise in the subject matter. Absent a prescribed definition and preexisting model from which to work, we providers look for analogies, both outside and inside our industry, from which to learn. While there is no consistent definition of peer review across industries, the concept and process are not dissimilar to those of editorial review and research and development (R&D) review, nor are some of the challenges.

Most of us in CME are at least somewhat familiar with journal-based editorial peer review. Editorial peer review was not created to detect fraud, and reviewers are not charged with that responsibility even today.[2] In the early 1900s, medical journal editors would seek the advice of a colleague to decide if an article was good enough or interesting enough to print. After World War II, peer review emerged as both the norm and a credential when federal funding of research became more available, and it was determined that scientific evaluation of articles should be done by scholars rather than government agents. After an assessment of the literature on the subject of editorial peer review, Dale E. Hammerschmidt, MD,[3] ultimately concludes, "Peer review is a way of getting advice from workers in the field that can help an editor make a good decision about the acceptance or rejection of a manuscript." Another systematic review of the literature on the effects of editorial peer review concluded, "Editorial peer review, although widely used, is largely untested and its effects are uncertain."[4] Some identified challenges include the limited amount of time that reviewers have to spend on uncompensated activities, bias toward prestigious institutions, and a lack of reviewer training and quality control.

In his paper *The Expanding Role of Peer Review Processes in the United States*,[5] David Guston raises the questions of what constitutes scientific merit, who the competent persons are and how are they selected, what COIs need to be resolved in which ways, and how the process of review itself is related to actual outcomes. He concludes that increased scholarly attention is required to quantify and qualify how the federal government utilizes peer review, the political and policy issues to be resolved by peer review, and the relationship between processes of peer review and its supposed outcomes.

The issues presented in both analogies are already becoming problematic within the CME community. Clearly defining peer review and stakeholders' expectations of the process at this juncture will help to ensure an effective process and preempt challenges such as those now faced by editorial and R&D review.

Peer Review Defined

As the CME enterprise begins to define and apply standards to the peer review process, Dr Arthur Caplan, Chair of the Department of Medical Ethics at the University of Pennsylvania, and a world-renown bioethicist, puts forward three core elements for consideration: competency, independence and transparency.

Defining Competency in Peer Review

Who should be deemed proficient enough to act as a peer reviewer? What level of expertise will be required? How will competence be assessed? All are questions central to this discussion.

Peer is defined as someone of equal stature; in the case of CME peer review, this suggests someone with relevant demonstrated experience and state-of-the-art knowledge of the subject matter under review.[6] Caplan counsels that when determining what will define competency in CME peer review, it will be important to delineate standards (eg, qualifications, levels of experience and knowledge) for reviewers. Questions he presents for consideration include: Will you have a minimal experience requirement? Will they have to take a test? Do you want to certify the reviewer? Setting a standard for competence in peer review is an important first step in defining this process.

Consideration needs to be given to how to ensure that reviewers understand how to evaluate content within the context of the current regulatory guidelines and the meaning of relevant terms. For example, if the purpose of an evaluation is to assess content for potential commercial bias, scientific validity, fair balance and off-label discussion,[7] it would be prudent to train

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reviewers regarding the exact meanings of each of these requisites, so feedback is based on standard definitions.

Defining Independence in Peer Review

In CME, independence is defined as being free of the control of a commercial interest.[8] This pertains to all areas of content development, including identification of CME needs, determination of educational objectives, selection and presentation of content, selection of all persons and organizations that will be in a position to control the content, selection of educational methods, and evaluation of the activity.

Therefore, in order to act independently, a peer reviewer can not be in a position to personally profit from the content, the outcome of the review, or the success of the activity. Dr Ellen Cosgrove, Senior Associate Dean of Education of the University of New Mexico, adds that in addition to COIs with funders of the activity, a peer reviewer should have no direct connection to the activity faculty. "COI in this setting goes beyond pharma connections and includes competing interests in the clinical realm."

Based on criteria that Caplan has put forth, activity chairs/program directors, employees of the accredited provider or educational partner, members of the accredited provider's Advisory Board, and those who hold other roles within the provider organization, would not meet the level of independence required to conduct peer review. According to Caplan, "An independent evaluator of content—someone outside of the accredited provider organization, who is removed from the content development phase of the activity—would go a long way toward eliminating ethical challenges in a CME peer review process."

Defining Transparency in Peer Review

Transparency—having a process that is open, well documented and accountable—will be an important aspect of a peer review CME process. According to Caplan, "Being transparent is part of what will satisfy regulator's concerns about the independence of CME."

Providers should have policies and standard operating procedures for peer review that include the purpose of their process, how and when the process will be used, reviewer qualifications, and mechanisms to validate reviewer independence. To enhance transparency, policies and systems should be described in grant requests, documented in activity files, and shared with others in the CME community. To that end, some CME providers have already posted their conflict resolution policy and process, of which peer review is typically a part, on their websites.

Beyond Ethical Concerns:
Defining Effectiveness and Evaluation of Peer Review

An effective peer review process will include:

- Established review criteria and qualifications for credible reviewers
- Adequate time and funding for review
- A method or tool for collecting/structuring reviewer feedback
- A structured process for providing that feedback to faculty, and implementing requested changes to content based on that discussion
- Documentation regarding all steps in the peer review process
- Feedback from activity participants on the content (eg, completeness, absence of bias)
- Metrics for internal monitoring of feedback to identify challenges and trends
- Utilization of information gathered to continually improve the quality of the process and, ultimately, of the content being delivered.

Will Peer Review of CME Content Make a Difference?

When asked to speculate, Cosgrove reasoned, "Peer review may enhance the quality [of CME] if it is more than a *rubber stamp*. I think peer review is a potentially important step in increasing the credibility in the same way that articles in genuinely *peer-reviewed* journals have more cachet than those in throw-away journals."

Creating a credible process is key, and defining the core criteria is an important first step.

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