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Avoiding Bias and Ensuring Content Validity in Accredited Continuing Education: What Do the Latest ACCME Standards Mean for Medical Writers?

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ABSTRACT

Some continuing medical education (CME) activities are developed using financial support from entities such as pharmaceutical companies that may have a commercial interest in the therapeutic area being discussed. Accordingly, standards intended to shield CME from industry bias have been in place for decades. The latest iteration of these standards from the Accreditation Council for Continuing Medical Education (ACCME) has a special significance to medical writers due to their emphasis on clinical content validity. Once a separate entity, the content validity requirement is now incorporated into the ACCME standards. In fact, it is positioned as the number 1 standard, emphasizing its importance. It should be relatively straightforward for writers to support the goals of the guidance—that is, to provide relevant and scientifically accurate content that is free from industry manipulation or influence. However, the standards as published are not prescriptive in how to achieve these goals, leaving writers to ponder exactly what it means to be "fair and balanced." This article provides background on the ACCME standards with a special emphasis on their relevance to CME writers, describes helpful downloadable resources for writers, discusses some scenarios that medical writers may encounter, and provides practical advice in interpreting and applying the current standards when developing content for CME activities.

Medical writers are instrumental in the development of continuing medical education (CME) content. The key opinion leaders and expert faculty members may get premier placement on the marquee, but it is often the medical writer (staff or freelancer) generating the manuscript text, PowerPoint slides, clinical multiple-choice questions, interactive patient cases, animation storyboards, video and podcast scripts, and other scientific content that helps drive improvements in clinician knowledge, competence, and performance.

These CME writing assignments are often rigid and flexible at the same time. Medical writers may be asked to stay within the guardrails of preexisting learning objectives and content outlines, and their work is typically subject to multiple reviews by faculty experts, peer reviewers, and CME providers. Even so, writers often find themselves in the position of making high-level decisions regarding content direction, often entirely on their own, or with a minimum of guidance.

The nature of CME content decisions that medical writers tackle independently can vary widely. One day, it's selecting citable peer-reviewed sources for a PDF monograph on best practices in diabetes management. The next day, it's describing the complexities of therapeutic selection in a PowerPoint deck on relapsed/refractory multiple myeloma—a disease state in which (at last count) there were 30 reasonable multidrug regimens to choose from, depending on the number and type of previous treatments given.[1]

This task of content decision making becomes even more challenging when writers consider the potential for bias in the materials they are developing. Many CME-related writing assignments are to provide content for activities that are supported—that is to say, developed using a financial grant from a company or companies that likely have a commercial interest in the therapeutic area. Thus, direct industry support for an activity is a potential source of bias (although not the only source, eg, faculty may have their own conflicts of interest that need to be resolved).

Although data from the Accreditation Council for Continuing Medical Education (ACCME) indicate that the vast majority of accredited educational activities (upwards of 90%) receive no commercial support at all, the total sum of grant funding is nevertheless large. Accredited providers have reported more than $700 million per year in commercial support since 2016 with a grand total of nearly $723 million in 2020, the most recent year for which this statistic is available.[2]

With those kinds of numbers in mind, medical writers have a considerable responsibility to help ensure that supported CME content is scientifically sound and devoid of industry manipulation or influence. Toward that end, standards have been promulgated by the ACCME, the nonprofit

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that accredits organizations that offer CME and recognizes state medical societies as accreditors of local CME programs.

NAVIGATING COMMERCIAL INTERESTS

The first set of ACCME standards intended to guide the CME-industry relationship was released in 1992, and in 2004, more stringent standards were put in place to ensure the independence of CME activities, particularly with regard to conflict of interest. The latest iteration, "Standards for Integrity and Independence in Accredited Continuing Education,"[3] was released in December 2020 and has been adopted by 7 additional accrediting bodies across multiple health professions. As of January 1, 2022, all providers in the ACCME system are expected to comply with the new standards.

Medical writers should take note of how content validity is central to the new ACCME standards (Table 1). In a Viewpoint published in *JAMA*, ACCME President Graham McMahon, MD, MMSc, explained that content validity requirements had been part of ACCME policy for many years, but separately from the standards. Now, McMahon said, content validity is included as the very first standard, which was intentionally done to emphasize its significance: "With the proliferation of medical misinformation and disinformation, as well as questions about the validity of science, issues related to content validity are more important than ever."[4]

In a nutshell, the expectations for content validity are as follows:

- Recommendations for patient care have to be based on current scientific evidence and clinical reasoning while providing a fair and balanced view of options for diagnosis and treatment.
- Any scientific research used to support or justify a patient care recommendation has to conform to generally accepted standards for study design, data collection methods, analysis, and interpretation.
- Although discussion and debate are appropriate, the education can't advocate or promote practices that are not firmly based on current scientific evidence and clinical reasoning.
- On a related note, the education cannot advocate for unscientific approaches or medical practices that are known to be ineffective, or have risks that outweigh the benefits.

APPLYING THE ACCME STANDARDS

Those requirements may sound straightforward on paper, but they are sometimes challenging to apply in actual day-to-day medical writing practice. The ACCME does offer some helpful general advice on best practices (Table 2) along with a helpful peer review checklist available for download. For example, multiple perspectives can be

Table 1. New ACCME Standards for Integrity and Independence in Accredited Continuing Education

Standard	Applicability	Accredited Provider Responsibility
1. Ensure Content is Valid	All accredited CE	Ensure that education is fair and balanced, and that any clinical content presented supports safe, effective patient care
2. Prevent Commercial Bias and Marketing in Accredited CE	All accredited CE	Protect learners from commercial bias and marketing in accredited CE
3. Identify, Mitigate, and Disclose Relevant Financial Relationships	All accredited CE	Identify relevant financial relationships between individuals in control of educational content and ineligible companiesa and managing these to ensure they do not introduce commercial bias
4. Manage Commercial Support Appropriately	Accredited CE that receives financial or in-kind support from ineligible companies	Ensure that the education remains independent of the ineligible company and that the support does not result in commercial bias or commercial influence
5. Manage Ancillary Activities Offered in Conjunction With Accredited CE	When there is marketing by ineligible companies or nonaccredited education associated with the accredited CE	Ensure that education is separate from marketing by ineligible companiesb and from nonaccredited education offered in conjunction with accredited continuing education

CE, continuing education.

[a]*An ineligible company is a company ineligible to be accredited in the ACCME system; their primary business is producing, marketing, selling, re-selling, or distributing health care products used by or on patients.*

[b]*Includes advertising, sales, exhibits, and promotion.*

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Table 2. New ACCME Standards for Integrity and Independence in Accredited Continuing Education

Focus Area	Recommendation
Level of Evidence	Clearly describe the level of evidence on which the presentation is based and provide enough information about data (study dates, design, etc.) to enable learners to assess research validity
Sources	Ensure that, if there is a range of evidence, that the credible sources cited present a balanced view of the evidence
Recommendations	If clinical recommendations will be made, include balanced information on all available therapeutic options
Risks and Adverse Effects	Address any potential risks or adverse effects that could be caused with any clinical recommendations
Evidence Base	If the evidence base is low (or absent) for a topic or treatment, consider alternate strategies, eg, a debate or dialogue between multiple faculty representing a range of opinions and perspectives

Adapted from the Toolkit for the Standards for Integrity and Independence in Accredited Continuing Education. Copyright 2020 by the ACCME.

provided to address a clinical question in which there is considerable debate (eg, "should routine colorectal cancer screening begin at age 45?").[5]

However, many questions remain that are not necessarily covered in detail in formal guidance. For example,

- If one treatment is discussed in detail, does that mean others need equal coverage in order to be fair and balanced?
- What if there is only 1 relevant treatment for a specific disease state covered in the education?
- Is it strictly forbidden to use brand names for drugs? And if so, what do I do when the use of generic descriptors is overly complicated or confusing?
- Can I cite a company press release? And if not, how do I properly cite research that apparently hasn't been published or presented yet?

I consulted several medical writers and others with CME experience (see **Acknowledgement**) to review possible solutions to these and other issues. A summary is below. First, however, it's important to emphasize that it is generally *not* all on the medical writer's shoulders to parse out difficult situations regarding fair balance, potential conflicts of interest, or other issues. On the contrary, it is *the accredited provider of the educational activity* that is ultimately responsible for ensuring that the overall activity is in alignment with the ACCME standards. The staff of the accredited provider should be skilled and experienced in applying the ACCME standards and can be an excellent resource for anyone who is involved in CME content creation or execution. Accordingly, writers are strongly encouraged to reach out to the accredited provider for the activity when they are unsure how to proceed. Ideally, this would occur early on rather than later in the content development process, especially so that carefully crafted content isn't unexpectedly sidelined by content revision needs at the last minute.

Although the following tips should not be taken as gospel or unassailable expert advice, they may offer a path forward that may be acceptable for your dilemmas regarding content validity:

Provide fair balance—but not necessarily equal time. Although it's important to avoid focusing on a specific treatment and to discuss efficacy as well as safety data, there is no need to discuss each treatment option with exactly the same emphasis. Let the strength of evidence and US Food and Drug Administration (FDA)-approved indications guide the weight of discussion. For example, 2 treatments for a specific dermatologic condition may appear to have similar rates of response and tolerability, although upon closer inspection, the evidence for treatment A is from a randomized, placebo-controlled phase 3 trial, whereas treatment B is supported by a single-arm phase 2 trial. Furthermore, treatment A may have a specific FDA indication for the dermatologic condition, whereas treatment B is used off-label to treat the condition (off-label use is common and sometimes necessary, but the education should be upfront about that, and ideally refer to the evidence supporting the unapproved usage).[6] High-quality review articles and clinical practice guidelines may offer clues in terms of cataloging the evidence to date, although caution is advised in relying on stale information, particularly in fast-moving areas like immuno-oncology in which new data are always a meeting away (or less).

In some cases, a therapeutic area may be so underserved that there is only 1 relevant emerging or novel treatment option (eg, in a rare disease in which the previous standard of care was supportive care). In that case, providing fair balance may be a discussion of emerging therapeutic options in earlier stages of clinical investigation. Failing that, balance can be provided by ensuring adequate discussion of the potential risks of therapy alongside the potential benefits (as is good practice for CME writing in any case).

Cite credible and acceptable sources. Experienced CME writers generally recognize a hierarchy of evidence and sources, although caveats apply at each level:

- Peer-reviewed and PubMed-indexed medical journal articles are usually considered highly citable, but some judgment is required on the part of the writer, as not all peer-reviewed research is of high quality, and not all journals are as impactful as others (did that promising-looking study end up in the *New England Journal of Medicine* or in a little-known journal?).
- Clinical practice guidelines also rank high, particularly if provided by well-known medical societies or organizations (such as the American Heart Association), although not all guidelines are rigorously developed. Look for methodologies such as the GRADE (Grading of Recommendations, Assessment, Development, and Evaluations) system, which can be used to evaluate evidence quality and quantify the strength of health care recommendations.[7]
- Medical meeting presentations are generally considered fair game. However, the information in a meeting abstract may not be peer reviewed. In addition, the conclusions of the research may change substantially from the submission of a meeting abstract to the actual meeting presentation, and sometimes, to the subsequent publication of those results in a peer-reviewed journal.
- Many agree that company press releases are not appropriate to cite, although as a result, it can be tricky to develop a state-of-the-art CME presentation when a potentially practice-changing clinical trial result is available only in the form of a press release. Although there are no easy solutions, one approach may be to reference publicly available details of the clinical trial design (eg, from the ClinicalTrials.gov database) and state in the activity that published/presented results are awaited.

Avoid corporate logos and (usually) brand names. When it comes to avoiding industry influence in CME activities, it's a no-brainer to omit corporate logos, and it's considered best practice to eschew brand names—although this is not always straightforward or without challenges. Medical devices, biosimilars, and proprietary formulations of common drugs are just 3 of the categories of products that are sometimes difficult to discuss without dropping brand names. The COVID-19 vaccines present a new wrinkle, as they are widely referred to by the manufacturer's name, so many learners won't immediately know whether the Pfizer mRNA vaccine is BNT162b2, mRNA-1273, or Ad26.COV2.S (it's BNT162b2). Finally, some audiences may know a specific drug only by its brand name, making education based on generic names an uphill battle. If the brand name can't be avoided, make sure to apply the standard equally, for example, don't use a brand name for one drug and a generic name for the others.

Don't forget about the other standards. Content validity is just 1 puzzle piece (although an important one) in the new ACCME Standards for Integrity and Independence in Accredited Continuing Education. There are important intersections between this guidance and the medical writer's work. Writers should make sure that disclosure information, including their own, is provided in the activity they are developing (Standard 3: Identify, Mitigate, and Disclose Relevant Financial Relationships), and may need to solicit that information if it's not already available. Another example: a faculty member tries to add a PowerPoint slide that their local drug rep said would be "just perfect" for the accredited activity; the writer should decline and remind faculty that decisions regarding the education must be made without influence or involvement from pharmaceutical company employees (Standard 2: Prevent Commercial Bias and Marketing in Accredited CE).

CONCLUSION

Medical writers are often on the front lines of developing accredited continuing education. Accordingly, writers must help ensure that the fundamental principles of integrity and independence govern the development of specific educational activities. Toward that end, writers should have a thorough working knowledge of the latest ACCME Standards for Integrity and Independence in Accredited Continuing Education. Reviewing available ACCME resources (including the aforementioned guidance and checklist for clinical content validity) will help writers apply the standards to their current projects and navigate some of the nuances described in this article. With that background, medical writers will be better prepared to develop clinical CME content that is fair and balanced, unbiased, and supportive of safe and effective patient care.

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RESOURCES

- ACCME Standards for Integrity and Independence in Accredited Continuing Education (PDF)
- Toolkit for the Standards for Integrity and Independence (in particular, pages 7-8, "Guidance for Planners, Authors, and Faculty: Ensuring that Clinical Content is Valid")