



Faculty Responsibilities and Obligations For CME-Certified Activities

Faculty (speakers and authors) responsibilities and obligations are described below. In addition, all faculty are strongly encouraged to complete the *National Faculty Education Initiative* (see www.acme-assn.org).

Disclosure of Faculty Relationships and Unapproved and Investigational Use of Products

- As required by the Standards and Policies of the Accreditation Council for Continuing Medical Education (ACCME), you¹ must disclose to LCMEI all relevant relationships² with or financial interests yourself and your spouse/life partner have in any commercial company³, in any amount (for the previous 12 months), that manufactures products, classes of products, or devices related to the content of your educational activity. Please complete and submit the attached *Authorship Responsibility, Disclosure, and Copyright Transfer Form*. Information regarding the disclosed financial relationships will be provided in writing to the activity participants. If you fail to provide disclosure information, you will be ineligible to participate in the development, implementation, or evaluation of this activity.
 - If it is determined that you have a conflict of interest, you must work with LCMEI to resolve that conflict before participation in the planning or implementation of the activity.
- As required by the Food and Drug Administration (FDA) and best practices in CME, you must disclose the following if they are discussed in your content (please complete the section that relates to investigational and off-label uses on the Disclosure Form mentioned above):
 - Unapproved uses of FDA-approved pharmacological, biological, and medical products and devices.
 - Investigational uses of pharmacological, biological, and medical products or devices not yet approved by the FDA.
- As required by the ACCME, when discussing biopharmaceutical products and medical devices, your educational materials must give a balanced view of therapeutic options. You must make every effort to use generic names or descriptions, both verbally and in print. Your material may include trade names (if absolutely necessary to avoid confusion for the learner), but if they are used, those of all similar products must be mentioned rather than that of only a single company. Trade names should be used only at first mention. (Please see “Use of Drug and Device Names in CME Activities” in Appendix 1 for more detail.)

Learning Objectives

- Your content should be designed to help learners achieve the identified learning objectives—the desired outcomes of the educational activity. The set of objectives should begin with the phrase, “After participating in this activity, physicians should be better able to ...” followed by your learning objectives. Please use measurable action verbs, such as “compare, select, apply, implement, educate,” etc. (Please see “Creating Learning Objectives to Reflect Desired Outcomes” in Appendix 2 to aid you in ensuring that learners will achieve the desired outcomes for your activity.)

Content and Design of CME Activities

According to the standards of the ACCME (eg, ACCME Definition of CME, Content Validation Statement, Accreditation Elements), the content of a CME activity should be objective, balanced, based on valid and sound scientific studies, and free of commercial bias. You must ensure that:

- Your content reflects all reasonable perspectives.
- Your clinical care recommendations are based on evidence that is accepted within the profession of medicine as adequate justification for their use.
 - You present data based on credible scientific studies and not on commercial relationships or biases or on anecdotal evidence or unsupported personal opinion.
 - All research supporting patient care recommendations conforms to generally accepted standards of experimental design, data collection, and analysis.
- The content and format of the activity must promote improvements in health care.
- You do not advance, either through your content or its format or delivery, the proprietary interests, products, or services of commercial organizations.
- You include references for all patient care recommendations.

In addition, ACCME, adult learning principles, and best practices in CME require that:

- Your content and its delivery should help narrow the identified gap in clinicians' competence, performance, or patient care: you help learners move from "current practice" to "best practice."
- Content must address the learning objectives and be designed to ensure attainment of the desired outcomes in terms of enhancing competence, performance, or patient outcomes.
- Content should be practical and relevant to the learners' expected scope of practice.
- Delivery of educational content should be interactive and engage participants in the learning process.
 - Content delivery should facilitate reflection on, and application to, practice.
 - Faculty should assist learners in identifying barriers to implementing what they learn, as well as strategies to overcome those barriers.
- Content and its delivery should facilitate learners' maintenance of licensure and Maintenance of Certification™, as well as help them address relevant competencies (eg, those of the Federation of State Medical Boards, Accreditation Council for Graduate Medical Education, Institute of Medicine, and their specialty boards).

Cooperation with LCMEI

- Please coordinate the planning and implementation of your portion of this activity with LCMEI staff. ACCME accreditation makes LCMEI accountable for the planning and implementation of all educational activities that it certifies for credit. Thus, LCMEI must review all content before it can be approved for inclusion in the activity.
 - If you need to use any previously published material (eg, photographs, graphics), you must receive permission from the copyright holder and provide documentation of this permission to LCMEI.
- You must not accept honoraria, payment, arrangements for travel expenses, or any other remuneration from a commercial company for your participation as a faculty member in this educational activity.
- The ACCME requires that LCMEI evaluate its CME activities. You may be asked to complete a brief evaluation of the activity, and your feedback and suggestions are welcome.

Assessment Questions

- This activity will contain a quiz to be completed by physicians seeking credit for this activity. Physicians successfully completing the activity and the quiz will be eligible to receive *AMA PRA Category 1 credit*.™ Please provide us with ____ multiple choice questions that measure attainment of your learning objectives and desired outcomes in terms of improving competence, performance, or patient outcomes based on your contributed material. Questions involving short cases and decision-making are strongly encouraged; simple knowledge recall questions are not appropriate. Please indicate the objective being measured and include the correct answer and 1 or more references for each question.

Definitions

1. An individual (and his/her spouse or partner and children) who is in a position to control the content of the educational activity. Such individuals include, but are not limited to: Editor-in-Chief, Associate Editor, CME Editor, Planning Committee Member, freelance writer, author, LCMEI employee, contributor, joint sponsor personnel, and vendor.
2. "Relevant" financial interests or relationships are defined as receipt of funds by the individual (and his/her spouse or partner and children) in any amount over the past 12 months directly from a commercial interest whose products or services are discussed in or pertain to the content of the educational activity. For purpose of LCMEI identification and resolution of conflict of interests, disclosure of "relevant" financial interests or relationships are further delineated as "past" (any interests or relationships over the past 12 months) and "current" (any interests or relationships in place and/or active at the time of the individual's involvement in the CME activity).
3. "Commercial Interests" are defined as any proprietary entity producing healthcare goods or services consumed by or used on patients, with the exemption of nonprofit or government organizations or non-healthcare-related companies. Providers of clinical service directly to patients are NOT commercial interests.

Appendix 1: Use of Drug and Device Names in CME Activities

Generic names of drugs and devices/instruments are preferred in CME to avoid the appearance of commercial bias. A goal for every CME activity is fair balance; thus, authors and speakers should avoid using brand and manufacturer names to prevent the appearance of promoting a specific product, device, or manufacturer.

Drugs

- Use generic names for all drugs whenever possible. If it is absolutely necessary to mention a drug by its trade name (ie, to enhance the education of the learner, if it's the only drug of its kind on the market, or if several products have very similar names), state the trade name of the drug in parentheses only on first mention, following the generic name. Afterward, use only the generic drug name.
- If more than one brand name is available for the chemical entity being discussed, list all of them: ie, galantamine hydrobromide (Razadyne, Razadyne ER, and Reminyl); alprostadil (Muse, Caverject, Caverject Impulse, and Edex).
- Investigational or off-label use should be identified for the learner and should be indicated on the *Authorship Responsibility, Disclosure, and Copyright Transfer* form.

Example of using trade names of drugs on first mention

- *In the study, researchers gave patients 0.3 mg injections of bevacizumab (Avastin) bimonthly for 1 year.*

Example of using generic names of drugs after the first mention

- *In the BRAVO study, patients who received monthly 0.5-mg injections of ranibizumab gained three lines of letters at the 6-month endpoint.*

Example of off-label/investigational use statements

- *In the study, researchers gave patients 0.3 mg injections of bevacizumab bimonthly for 1 year. Bevacizumab is used for the treatment of colorectal cancer but has been used off-label successfully for the treatment of neovascular AMD.*

Vaccines/Biologics

- Use generic names for all biologics whenever possible.
- However, there are biologic products with similar complex names. Use brand names for vaccines and biologics to differentiate them only on first mention. Afterward, use only the generic drug name. If it is absolutely necessary to mention a vaccine/biologic by its trade name (ie, to enhance the education of the learner if it's the only product of its kind on the market, or if several products have very similar names), state the trade name of the drug in parentheses only on first mention, following the generic name. Afterward, use only the generic drug name.
- As with other drugs, please indicate approved, investigational, or off-label status; this should also be indicated on the *Authorship Responsibility, Disclosure, and Copyright Transfer* form.

Examples of off-label/investigational use statements for biologics

- *Few biologic agents have been used off-label to treat atopic dermatitis, the two major pediatric chronic inflammatory skin diseases. They include interferon gamma (Actimmune) and intravenous immunoglobulin (IVIg).*

- *Indicated for the treatment of rheumatoid arthritis, adalimumab has been used effectively for psoriasis as an off-label indication.*
- *FDA-approved for use in diabetic foot ulcers, becaplermin has been used off-label for the treatment of ulcers from inflammatory conditions (pyoderma gangrenosum, scleroderma, and necrobiosis lipoidica diabetorum), as well as for pressure ulcers and venous leg ulcers.*

Devices

- Use generic names or descriptions for all devices, instruments, and systems of technology whenever possible. If trade names are critically important for the learner, use them only on first mention. Afterward, use the generic names, a description, or abbreviation. If abbreviations are used, they should be consistent throughout the CME activity.

Example of using trade names of devices on first mention with abbreviations for generic descriptions

- *Both methods are performed hysteroscopically and include the Essure micro-insert device (MID) and the Adiana permanent contraceptive system (PCS).*

Example of using abbreviated generic description of devices after the first mention

- *In 2008, Franchini et al. assessed laparoscopic sterilization versus MID to determine which was most cost effective.*

Example of using generic names of devices without an abbreviation after the first mention

- *In 2006, Gerard et al. assessed laparoscopic sterilization versus a permanent contraceptive system to determine which was most cost effective.*

For all Drugs, Biologics, and Devices

- Approved, investigational, or off-label use should be identified for the learner.
 - If investigational uses are described, state why. How will they impact practice? What other investigational agents are on the horizon?
- Avoid using manufacturer names.
- Mention all approved products in the class of agents being discussed or those indicated (or soon to be approved) for the same use.
 - It is not required to give equal weight to various products, but the focus on a single one should be explained.

Appendix 2: Creating Learning Objectives to Reflect Desired Outcomes

The identification of learning objectives is inherently valuable for clarifying the purpose of educational offerings. Well-constructed objectives guide selection and organization of learning experiences. This is a key consideration to promoting not only the achievement of the objectives, but also the desired outcomes against which we can evaluate achievement. The verbs used in objectives should be measurable and reflect observable behaviors expected of the learner.

The ACCME requires that education be designed to improve competence, performance, or patient outcomes; increasing knowledge is required but not sufficient for meaningful education. Thus, objectives and desired outcomes relating only to knowledge and comprehension are not appropriate.

Cognitive Outcomes

Much of CME is designed to help learners achieve cognitive outcomes. Each of the classes listed on the next page becomes progressively more complex and builds upon the previous level. In other words, not only is synthesis a more complex operation than knowledge, but the ability to synthesize depends upon the foundation of knowledge possessed by the learner.

Verbs in shaded columns are generally not appropriate in CME because the ACCME requires providers to promote improvements in learners' competence, performance, or patient outcomes (rather than simply knowledge acquisition).

Examples of poor objectives and improved ones are provided below.

| <i>Traditional knowledge-based objectives</i> | <i>Objectives that reflect desired outcomes in terms of competence or performance</i> |
|---|---|
| Explain general treatment principles of ... | Select patient-specific treatment approaches for ... |
| Describe basic screening for amblyopia. | Screen patients for amblyopia. |
| Explain how markers are used for ... | Use markers to ... |
| List the risk factors for ... | Assess patients at risk for ... |
| Discuss the use of new diagnostic tests for ... | Use XYZ test to ... |

| | | | | | |
|------------------|----------------------|--------------------|-----------------|--------------------------|-------------------|
| | | | | Critical Thinking | Evaluation |
| | | | | | Judge |
| | | | | Synthesis | Appraise |
| | | | | Design | Estimate |
| | | | Analysis | Plan | Evaluate |
| | | | Compare | Compose | Revise |
| | | Application | Distinguish | Propose | Score |
| | | Use | Differentiate | Formulate | Select |
| | Comprehension | Employ | Diagram | Arrange | Rate |
| | Express | Interpret | Analyze | Assemble | Choose |
| Knowledge | Restate | Dramatize | Categorize | Collect | Measure |
| Define | Identify | Sketch | Appraise | Construct | Compare |
| Repeat | Explain | Practice | Experiment | Create | Value |
| Name | Recognize | Illustrate | Test | Set up | Assess |
| Recall | Discuss | Operate | Contrast | Organize | |
| List | Describe | Demonstrate | Inspect | Prepare | |
| Relate | Tell | Apply | Debate | Manage | |
| Record | Locate | Schedule | Inventory | Predict | |
| Underline | Report | Show | Question | | |
| Outline | Review | Translate | Examine | | |
| Delineate | Summarize | Interpret | Criticize | | |
| Specify | | Solve | Relate | | |
| State | | | Solve | | |
| Label | | | Calculate | | |
| Match | | | Critique | | |



Content and Educational Design Review

Please evaluate your content and planned educational methods to ensure that they meet all of the criteria below. Please indicate compliance with each item and return this form with your materials to _____ for review by _____.

| | |
|--|---|
| | My content helps narrow the identified gap in, and will improve, learners' competence, performance, or patient care outcomes. |
| | My content addresses the objectives and desired outcomes for this activity. |
| | My content is accurate, fair, balanced, and objective. |
| | All my clinical recommendations are based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications. |
| | All data and recommendations are referenced to peer-reviewed sources; all scientific research supporting patient care recommendations conforms to the generally accepted standards of experimental design, data collection, and analysis. |
| | All recommendations discussed are within the definition of CME* and are not known to have risks or dangers that outweigh the benefits or to be ineffective in the treatment of patients. |
| | I have obtained permission to use all previously published material (attach documentation). |
| | All off-label or investigational uses are identified and disclosed. |
| | Generic names are used consistently. |
| | My content is practical and relevant to the learners' expected scope of practice. |
| | My content and format of delivery are interactive and engage learners in the educational process. |
| | My content and format of delivery encourage reflection on and application to practice; content includes specific suggestions for how learners should apply what they learn to their practice. |
| | My content identifies for learners the barriers they may encounter in implementing what they learn, as well as strategies to overcome those barriers. |
| | My content and its delivery facilitate learners' maintenance of licensure and Maintenance of Certification™, as well as help them address relevant competencies (eg, those of the Federation of State Medical Boards, Accreditation Council for Graduate Medical Education, Institute of Medicine, and their specialty boards). |

* CME consists of educational activities that serve to maintain, develop, or increase the knowledge, skills, professional competence, and relationships a physician uses to provide services for patients, the public, or the profession. The content of CME is the body of knowledge and skills generally recognized and accepted by the profession as within the basic medical sciences, the discipline of clinical medicine, and the provision of health care to the public.