

Content Integrity, Conflict of Interest, and Commercial Support

Defining and Operationalizing the Terms

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One of the hallmarks of quality continuing education developed using accreditation criteria is content integrity. Components of content integrity include identifying, resolving, and disclosing conflict of interest; ensuring content is based on the best available evidence; managing commercial support (if applicable); and presenting the educational activity free of promotion or bias. This article explores content integrity, conflict of interest, and commercial support. Understanding and being able to operationalize these concepts will enable providers to offer high-quality educational activities that promote the professional development of nurses and/or improve the quality of patient care.

cational activity from an organization that is defined as a commercial interest (see www.nursecredentialing.org).

INTRODUCTION

Providers of continuing nursing education have a responsibility to develop and implement educational activities that help participants learn and grow. The process can seem daunting if providers are unsure how to address those factors that help to ensure content integrity. This article allays those concerns by describing the steps to take and giving specific examples to help activity planners make appropriate decisions.

UNDERSTANDING THE CONCEPTS

Using accreditation criteria to plan high-quality educational activities designed to promote the professional development of registered nurses and positive outcomes for patients requires that educational activity providers ensure content integrity throughout the planning and implementation processes. The principle behind addressing the issues of commercial support and conflict of interest is *content integrity*. There are four key components of content integrity.

Managing conflict of interest: Ensuring that individuals who are planners, presenters, content reviewers, authors, or others in the position to control the content of an educational activity do not have a role with a commercial interest organization (see Table 1). Having the ability to control or influence content could slant the focus of the learning experience in favor of a particular product or service. Conflict of interest relates to people, not to companies or organizations.

Ensuring that educational activities are free of commercial control: Maintaining separation of any commercial funding for an activity, so that the organization providing funding cannot dictate speakers, content, or any other component of educational design. “Commercial Support” for a learning activity includes money or in-kind contributions provided by a commercial interest organization. A commercial interest organization, as defined by the American Nurses Credentialing Center, is any organization that produces, markets, sells, or distributes healthcare goods or services consumed by or used on patients; that is owned or operated,

KEY POINTS:

1. Content integrity is the responsibility of an accredited continuing education provider (“Provider”) to ensure that educational activities are developed independent of the influence of commercial interest organizations, educational content is evidence based, and educational activity is presented free from promotion or bias.
2. Conflict of interest occurs when a person who has the ability to control the content of an educational activity has a nonemployee financial relationship with a commercial interest organization, the products or services of which are relevant to the educational activity. Employees of commercial interest organizations may not participate in planning or presenting educational activities if the content of the activity is related to the products or services of the commercial interest.
3. Commercial support involves receipt of money or in-kind contributions (nonmonetary support) for an edu-

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The authors have disclosed that they have no significant relationship with, or financial interest in, any commercial companies pertaining to this article.

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TABLE 1 Definitions Related to Educational Activities

Term	Definition
Commercial interest	Any entity either producing, marketing, reselling, or distributing healthcare goods or services consumed by or used on patients or an entity that is owned or controlled by an entity that produces, markets, resells, or distributes healthcare goods or services consumed by or used on patients
Commercial support	Money or in-kind services given by a commercial interest to the provider of a learning activity to pay for all or part of the cost of the activity
Conflict of interest	An affiliation or relationship of a financial nature with a commercial interest organization that might bias a person's ability to objectively participate in the planning, implementation, or review of a learning activity
Bias	Tendency or inclination to cause partiality, favoritism, or influence

Adapted from American Nurses Credentialing Center (2013).

in whole or part, by an organization that produces, markets, sells, or distributes healthcare goods or services consumed by or used on patients; or that advocates for the use of products or services of commercial interest organizations (American Nurses Credentialing Center, 2014). A continuing education provider can accept commercial support but can never allow a commercial entity to control the content of an educational activity. In contrast to conflict of interest, commercial control relates to companies, not to individuals.

Ensuring that the educational activity is presented without promotion or bias: Separate from the concepts of conflict of interest or commercial support, there may be cases in which an individual involved with an educational activity has a particular perspective that could result in promotion or bias. Examples might include the author of a book who uses the educational activity as a means to promote her book or an individual who owns a consulting company and wants to use the educational activity to attract new clients. This type of promotion is distracting to learners and detracts from the integrity of the educational activity.

Ensuring that the content in the educational activity is based on best-available evidence: Content must be vetted by the educational activity provider to ensure that it is accurate and up-to-date. There is no “magic” time frame for use of books, articles, or other written materials. Rather, the decision rests on the timeliness and relevance of the resource related to the content to be presented. In a rapidly changing field, references published a year ago might be outdated, whereas some seminal works are valid for lengthy periods of time because they remain relevant to today's practice environment.

MANAGING CONFLICT OF INTEREST

There are three key steps in managing conflict of interest: (a) *identifying* relevant relationships with commercial interest organizations for all individuals in a position to

control content of the educational activity; (b) *resolving* any relevant relationships that exist; and (c) *disclosing* relevant relationships to learners. Within the American Nurses Credentialing Center accreditation system, for example, it is the responsibility of the nurse planner to ensure that all conflicts of interest have been identified, resolved, and disclosed. Managing conflict of interest is critical to ensuring independence of the activity from external control. In considering possible conflict of interest situations, it is important to keep these key points in mind: (a) all individuals in a position to control content of an educational activity are required to disclose relevant financial relationships with commercial interest organizations; (b) relationships with commercial interest organizations also include those of the spouse or partner of the individual involved with the educational activity; (c) relationships are considered relevant if they are current or have existed within the past 12 months; and (d) employees of commercial interest organizations are always prohibited from involvement with an educational activity if the products or services of the commercial interest are relevant to the content of the activity.

There are several methods an educational activity provider may use to identify whether a conflict of interest exists. One of the most common methods is to require all individuals in a position to control content of the educational activity to document relevant relationships with commercial interest organizations on a hard copy form or via a Web-based documentation system. Relevant relationships may include roles such as serving on a speakers' bureau, receiving royalties from a product produced or sold by the organization, owning stock, or serving as a consultant. Additional ways of collecting data might include reviewing the person's resume or curriculum vitae and conducting a Web search under the person's name. Educational activity providers and potential speakers should be mindful of terms like “conflict of interest” and “relevant relationships” when operating under accreditation criteria for nursing, medicine, or pharmacy.

The term “relevant” relates to the congruence between the products of the commercial interest and the topic of the educational activity. For example, a person who serves on the speakers’ bureau for a pharmaceutical company that makes drugs for patients with diabetes would have a conflict of interest if the topic of the event was related to managing care of the patient with Type 2 diabetes. That same person would not have a conflict of interest if the topic of the event was developing preceptor skills. Relevance is also time based—if the relationship is current or has existed for any of the past 12 months, it is considered to be relevant. Relationships that ended more than 12 months before the learning activity are no longer considered relevant from a conflict of interest perspective.

If there is no financial relationship with a commercial interest that is relevant to the activity, the person can continue to be involved with the activity. If such a relationship does exist, the educational activity provider must take additional steps to resolve the conflict. There are several possible options. These include, but are not limited to, the following:

1. Removing the individual with the identified conflict from participating in the educational activity.
2. Revising the role of the individual so the relationship is no longer relevant (e.g., having that person participate in planning an activity on a different topic).
3. Not awarding contact hours for the portion of the educational activity in which this person is engaged, or not awarding contact hours for the entire activity.
4. Evaluating the content of the proposed activity for bias prior to the activity (this work can be completed by another member of a planning committee or by a content reviewer who has not participated in earlier phases of the planning process), along with monitoring the educational activity to assure that no commercial bias is inserted.
5. Evaluating the content of the proposed activity as noted above, along with reviewing learner feedback to determine if activity participants perceived bias in the activity.

In summary, the key points and questions one should ask when addressing conflict of interest include the following:

- Does any individual in control of content of an educational activity have a relationship with a commercial interest organization?
- If so, is the relationship relevant to the educational activity being planned?
- If so, how is the issue going to be resolved so the activity can be presented without undue influence or bias?

MANAGING COMMERCIAL SUPPORT

Commercial support might be obtained to help cover the costs of providing an educational activity. This support

might include funds given to the educational activity provider or might be in-kind services offered by the commercial interest, such as marketing or printing of brochures. It is important to note that commercial support only relates to money or in-kind services provided by a commercial interest (see Table 1). Contributions that come from entities that are not commercial interests are not considered commercial support.

For the purpose of continuing education within the accreditation system, a commercial interest organization is an organization that produces, markets, sells, or distributes healthcare goods or services consumed by or used on patients; that is owned or operated, in whole or part, by an organization that produces, markets, sells, or distributes healthcare goods or services consumed by or used on patients; or that advocates for the use of products or services of commercial interest organizations (American Nurses Credentialing Center, 2014). This can be confusing, because in lay terms, a “commercial company” is typically considered to be any business, particularly a for-profit business. For example, a printing company may be considered to be a commercial business in the community in which it operates, but a printing company does not make a health-care good or service consumed by or used on patients, so it would not meet the accreditation system’s definition of a commercial interest. A clear understanding of the definition of commercial interest is critical to appropriate management of commercial support for an educational activity.

A commercial interest organization wishing to provide support for an activity must sign an agreement specifying what type of support will be provided and verifying that the organization and its agents will not attempt to control any part of the educational activity. These agreements are often negotiated between a sales representative of the commercial interest organization and the educational activity provider, though they may be signed by anyone authorized by either party to enter into these types of agreements. Educators and nursing professional development specialists are often called upon to do so. The document itself can come from the commercial interest organization or can be from the educational activity provider. The source of the document does not matter, as long as the agreement clearly stipulates the separation of educational content from commercial control. Any time money changes hands, the agreement should include the amount of money involved and the plan for its use. The provider of the activity is accountable for appropriate use of funds and may be asked to provide evidence to the commercial interest organization documenting how funds were used. The agreement may specify that unused funds be returned to the commercial interest organization.

MANAGING BIAS

Bias is defined as “the tendency or inclination to cause partiality, favoritism, or influence” (American Nurses Credentialing

TABLE 2 Examples Related to Decision-Making for Conflict of Interest, Commercial Support, and Bias

Scenario	Identify	Evaluate	Resolve
A class is being planned on the concept of meaningful use of electronic medical records. A company that produces HIPAA-compliant software for smart devices provides \$1,000 to support the cost of the educational activity.	Is there commercial support? No—a software company does not fit the definition of a commercial interest organization	No action required	No action required
A durable medical equipment company offers to lend you wheelchairs, walkers, and other assistive devices for a workshop of safe handling and transfer skills.	Is there commercial support? Yes—this is an “in-kind” contribution from a commercial interest organization	Can you accept this offer? Yes	Ensure content integrity: 1. No advertising for the company 2. No company logos 3. Acknowledgment of commercial support to learners 4. Evaluate content for focus on topic, not on the company’s product
A one-woman business makes herbal products purchased by the public via her website. The woman wishes to donate \$100 to your educational activity.	Is there commercial support? Yes—even though this is a small business, the products are sold to patients	Can you accept this offer? Yes	Ensure content integrity: 1. The person cannot control how the money is being used 2. The provider maintains responsibility for all decisions related to the educational design of the activity 3. No advertising for the company 4. Acknowledgment of commercial support to learners 5. Evaluate content for focus on topic, not on the company’s product
Your organization has received a grant from the National Institutes of Health. Part of the grant purpose is to provide education to healthcare professionals about emerging issues in cancer care.	Is this commercial support? No—federal government agencies are not considered commercial interests	Can you use this funding to plan and present a continuing nursing education activity? Yes	No action required, though sharing with learners that NIH grant funding has supported the activity may be considered.
Mark White is invited to be on the planning committee for an educational activity on congestive heart failure. He declines to provide information about whether his wife has a financial relationship with a commercial interest.	Is there a problem here? Yes—Conflict of interest (COI) information must be obtained relevant to the person involved with the activity and his/her spouse or partner	Can Mark continue to serve on the planning committee? No	Mark must be advised that he cannot serve in any capacity that influences content for the activity unless he provides the required information for his wife.
Ruth Markham is invited to be a speaker at your symposium on heart disease. She shares that she provides consulting services to the American Heart Association (AHA).	Does Ruth have a COI? No—AHA is not a commercial interest organization	No action required	No action required; this relationship does not need to be disclosed to learners.

Continued

TABLE 2 Examples Related to Decision-Making for Conflict of Interest, Commercial Support, and Bias, Continued

Scenario	Identify	Evaluate	Resolve
Samantha Green is invited to be a speaker for your session on dealing with incivility in nursing practice. She shares that she has done research for High Reach Prosthetic Device Company, but that relationship ended 2 years ago.	Does Samantha have a COI? No—the relationship ended 2 years ago	Two factors need to be considered: 1. The relationship with a commercial interest entity is not current (within the past 12 months). 2. The relationship with a commercial interest organization has no relationship to the topic to be presented.	Samantha can be a speaker. No disclosure to learners is required.
Roberto Alonzo is speaking for your conference on medications used for transplant patients. He advises you that he currently serves on the speakers' bureau for a pharmaceutical company that makes drugs used for patients who receive transplants. He is a nationally known authority on care of transplant patients.	Does Roberto have a COI? Yes—(1) he is on the speakers' bureau for a commercial entity that makes a product used on patients and (2) the relationship is relevant to the topic being presented	Can Roberto be a speaker for your conference? Yes	Ensure content integrity: 1. Review guidelines with speaker when he is accepted 2. Review content to ensure fair and balanced presentation 3. Monitor session to ensure integrity 4. Ask learners to evaluate whether they perceived bias in the presentation
As part of your 3-day conference, you are inviting vendors to display products or services they offer. Some of these vendors are commercial interest organizations, some are jewelry and personal product vendors. You are looking for diverse displays to capture the interest of the participants in your conference as well as to raise money to offset the cost of the conference.	Do any of these vendors need to sign commercial support agreements? Vendors may or may not be commercial interest organizations. When they are simply "renting space" to display their products or services, they are not providing commercial support for an activity.	There is no commercial support from any of the vendors.	No commercial support agreements need to be signed; no disclosures need to be made to learners. It is acceptable to include a "thank you" to vendors in marketing materials or other noneducational information provided to learners.
Margaret Symanski is the author of several books and articles on evidence-based practice and is a national authority on the topic. You invite her to speak at your conference. She agrees, only if she can have a table to do a book signing.	Is this ok? Is there a conflict of interest? No—Margaret has no relationship with a commercial interest organization Is there commercial support? No—the publisher is not a commercial entity	Margaret has expertise relevant to the theme of your conference and can be a speaker. There is a potential for bias in that she may choose to present only her own work.	Ensure content integrity: 1. Talk with Margaret about presenting objective evidence. 2. Review content to ensure a balanced presentation. 3. Set up the book-signing table away from the educational venue. 4. Do not promote the book signing during the session.

Center, 2013, p. 22). It is important to realize that bias can occur in the absence of commercial support or conflict of interest, so bias must be addressed as a separate component of ensuring content integrity. Bias can be an issue, for example, if a person develops an activity that is based only on

his/her own publication, rather than on current best available evidence in the field. An author of a book on alternative therapies might choose to present only the particular therapies described in his book rather than providing a more global view of all types of these treatment options. Both planners

and presenters must be alert to the potential for bias that could negatively impact the learning experience. Possible strategies for addressing bias could include having open and frank conversations with speakers at the time of the invitation to present, obtaining written validation from the speaker that content will be presented objectively, and reviewing a speaker's slides ahead of time to ensure that content is fair and balanced.

DISCLOSURES TO THE LEARNER

In the interest of preserving content integrity and promoting transparency to learners, the provider of a continuing education activity is required to disclose to learners information about both conflict of interest and receipt of commercial support. These acknowledgments must precede the beginning of educational content. Regarding conflict of interest, the activity provider may state that there is no conflict of interest for any planner or presenter involved with the educational activity, if that is the case. It is not necessary to list every planning committee member and every speaker individually. If there is a conflict of interest, the provider of the activity must disclose the name of the person, the type of relationship, and the name of the commercial interest. For example, an appropriate disclosure would be "There is no conflict of interest for any planner or presenter involved with this activity except for Susan Smith, who is on the speakers' bureau for XYZ Pharmaceutical Company." It is not necessary to address how that conflict was resolved.

In disclosing receipt of commercial support, the provider may state, "We appreciate the support of ABC Wound Care Product Company for this event." The type of support

(money, food, materials) does not need to be disclosed. The provider could also just list the names of commercial support providers. Of note, logos of the commercial entities may not be used in the disclosure or anywhere else on materials received by the learner.

EXAMPLES

Table 2 includes a number of examples related to content integrity, conflict of interest, and commercial support. For each example, a scenario is provided, followed by the decision making steps: identifying the issue, evaluating the situation, and resolving the dilemma, if one exists. These examples may be helpful to nursing professional development specialists as they plan, organize, and implement educational activities.

SUMMARY

Managing conflict of interest and commercial support is key to maintaining the content integrity of educational activities. Learners deserve to participate in activities that enhance their professional development and the patient care they provide, knowing that the content is free from bias and control. The activity provider is accountable for assuring that content integrity standards are maintained.

References

- American Nurses Credentialing Center. (2013). *Primary accreditation application manual for providers and approvers* (Version 3.0). Silver Spring, MD: Author.
- American Nurses Credentialing Center. (2014). *ANCC content integrity standards for industry support in continuing nursing educational activities*. Retrieved from <http://www.nursecredentialing.org/Accreditation/ResourcesServices/Accreditation-CEContentIntegrity>