

CME BRIEFING

NEWS, OPINIONS, AND PERSPECTIVES IN CONTINUING MEDICAL EDUCATION ~ SPRING 2002

A Service of Professional Postgraduate Services®, a division of Physicians World/Thomson Healthcare

AAFP, EB, CME: What Does It All Mean?

Responding to concerns from the Federation of State Medical Boards, which governs the licensing boards in each state, the American Academy of Family Physicians (AAFP) has implemented the *option* of evidence-based (EB) CME for Prescribed credit. January 2002 marked the end of the phase-in period and the official start of the EB CME initiative at AAFP. *CME Briefing* recently spoke with Nancy Davis, PhD, Director, Division of CME, to learn more about this endeavor.

It Started With Complementary/ Alternative Medicine Topics

"The number of complementary/alternative medicine topics being

approved for CME credit was the main issue," noted Davis. In total, 37 states now require CME credit for licensure of physicians, but the Federation of State Medical Boards was not sure that obtaining CME credit in complementary/alternative medicine was enough to assure the competence of physicians. On one hand, with more patients coming to physicians with questions related to this area of medicine, physicians need to be informed. On the flip side, it was apparent that too many programs in CME were addressing these topics, which are not always based on sound, scientific studies and principles. A change was needed.

Coupled with this, AAFP was

noting from CME evaluations that program participants were not sure of the basis for some CME presentations. Whether faculty members, in developing their presentations, were reviewing the literature *as comprehensively* as an evidence-based approach was not certain.

"Our Commission on CME, which ultimately reviews and approves CME activities for AAFP credit, also was concerned," said Davis. Facing a dilemma between not providing enough information on complementary/alternative medicine and providing too much, the commission decided to consider these topics for Prescribed credit only if they were evidence-based. Under the new system, if these topics are not evidence-based but are not dangerous to patients, they are eligible for elective credits.

Continued on page 6

IN THIS ISSUE

*Read about a unique
collaboration between
an academic CME
department and the
pharmaceutical industry.*



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Breaking Down the Historic Wall: A Look Inside the Duke Industry Advisory Board

CME Briefing recently spoke with Kathleen G. Hundley, MEd, about her pioneering role in spearheading an innovative collaboration between the pharmaceutical industry and an academic CME department. Hundley is Director of CME and Business Development at the Duke Office of CME (DOCME) in Durham, North Carolina. Here is an inside view of the Duke Industry Advisory Board (DIAB), an educational partnership unlike any in the world of CME.

Inviting industry to collaborate with an academic CME office is a bold move. How did the idea of creating an industry advisory group come about?

When I came to Duke following 21 years managing an office of continuing health care education, primarily in nursing and pharmacy, at Burroughs Wellcome Co., my experience had already led me to rethink my views of the provider-grantor rela-

Continued on page 4

CME BRIEFING

CME BRIEFING is published by Professional Postgraduate Services® (PPS), a division of Physicians World/Thomson Healthcare. The mission of this newsletter is to disseminate news and information about CME and to foster dialogue among the concerned parties, including the medical profession, government, industry, and CME sponsors.

PPS is dedicated to health-related education for physicians, para-professionals, and patients.

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We are proud of our 30-year history of medical publishing, and feel a responsibility to enhance medical education by improving communication among interested parties. Our proactive relationship with the government, the medical profession, industry, and CME sponsors will benefit from the input of our readers. Please send comments or questions about this newsletter to the CME BRIEFING Editor.

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Speaker Honoraria (from Spring 1998 issue)
Liability and CME (from Spring 1999 issue)
Distance Learning and CME (from Winter 2000 issue)

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Revising the ACCME Standards for Commercial Support: Where Are We?

Norman B. Kahn, Jr, MD, Vice President, Science and Education, American Academy of Family Physicians, briefed attendees on progress made in revising the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support.

Kahn chairs an ACCME Task Force for this review process. Speaking on behalf of the task force, he explained ACCME's rationale for revisiting the 10-year-old Standards, which have governed the conduct of CME activities for the past decade. The revision process is part of a four-phase modernization of all ACCME positions, including those governing CME program content and eligibility, Internet activities, and foundation bylaws. The process was started in November 2000, in keeping with the ACCME's dedication to continuous quality improvement across all its standards and programs.

According to Kahn, providers, physicians, and industry supporters all agree that the world of CME has changed dramatically since the ACCME Standards for Commercial Support were formalized from the earlier guidelines in use from 1984 to 1991. While in many respects the Standards have withstood the test of time, they do need to be re-examined in light of today's academic challenges, actual practices, current FDA thinking, and the heightened concerns of the public and medical professionals as to what constitutes sound medical education. Specifics on this are noted in the Table.

As a first step in this process, in early 2001, the ACCME issued a call for ideas and input from all interested parties in industry, government, and US citizenry.

Far-Ranging Opinions, Positive Response

Kahn said his Task Force received hundreds of emails in response to the call for comments, as well as face-to-face testimony from representative groups of the potential respondent universe. While the input on what revised Standards should include was far-reaching and often at opposite ends of the spectrum, there was genuine interest in changing some ACCME "shoulds" to "musts." Others felt that it was time to clarify the nuances of key terms like "commercial *interests*" versus "commercial *support*" and "off-label," as well as firming up the rules for producing live and print programs that may be repackaged for the Internet.

After analyzing all input from 2001, the Task Force distilled the comments into major categories or themes that will need to be carefully examined when revising the content and wording of the Standards. These themes, and the issues surrounding them, are:

Separating product promotion from medical education: Virtually all respondents agreed that it is critical that the new ACCME Standards better define and distinguish the nature and conduct of these two types of communication where the lines can get easily blurred, to the detriment of both industry and providers.

Clearer disclosure of relationships and the concept of "agency": It was strongly felt by many that fuller disclosure is key to ensuring objectivity in program planning on the part of both speakers and members of Planning Committees. Many observers stressed that faculty and Planning

Committee members working with commercial groups in developing CME activities should be perceived as agents of the accredited provider, and therefore should clearly disclose any proprietary relationships, in order to avoid misperceptions of bias and control.

Management of funds: Considerable interest was expressed in requiring

Table. What Constitutes Sound Medical Education?

- Where is the dividing line between "product promotion" and "physician education"?
- How can providers ensure adherence to proper procedures—throughout a program's life cycle—when producing core components of medical education?
- How should the relationships between industry and CME providers be defined and reported?

better enforcement of Standards governing disbursement of funds, such that only accredited providers handle grant money from industry when issuing faculty honoraria, in particular, even if other program payments are delegated to a third party.

Gifts to physicians: Payments and inducements made to physicians in connection with participation in CME activities and/or social events is an area of heightened concern in the wake of recently published articles in medical and lay press about certain abuses. Clarification of this area—a topic of intense interest for other governing bodies as well, including the American Medical Association (AMA) and Pharmaceutical Research and Manufacturers of America (PhRMA)—is seen as top priority, with many feeling the best

Continued on page 7

Breaking Down the Historic Wall: A Look Inside the Duke Industry Advisory Board

Continued from page 1

tionship. In my mind, developing CME activities behind the “historic wall of separation” and then soliciting grant money seemed limiting—after all, industry has a great deal more to offer than just money. When I first mentioned the idea of forming a collaborative group—a panel of people from pharmaceutical companies, the medical community, and academic CME—I was told it might not work, because competitors would refuse to sit at the same table due to conflicts of interest and other legal concerns. I persisted, however, and eventually got a green light to try.

What is the primary goal you have set for the DIAB?

We have several goals [see All About DIAB], but the primary one is to enhance the role of CME in the medical and pharmaceutical communities—to create new and innovative ideas regarding CME, proving that industry and CME can work well together within the boundaries of the Accreditation Council for Continuing Medical Education (ACCME) Essential Areas and Elements and the FDA guidance letter. Specific ways we see industry contributing to CME include sharing ideas and information in addition to funding—providing disease state data and research findings, access to nationwide therapeutic experts, and their internal medical/clinical knowledge.

Can you tell us a bit about the working structure of DIAB? How many members are there and who is represented?

We wanted to have a good mix of people, not just pharmaceutical industry and CME officials. From industry, we have nine member companies represented by middle-level

CME or product managers. We also have the Duke Director of Pharmacy; the Duke Associate Dean of CME; the Duke Director, CME/Business Development; the Duke Office of Science and Technology; several Duke medical staff physicians; a branch chief from the FDA’s Division of Drug Marketing, Advertising, and Communications, Center for Drug Evaluation and Research (DDMAC CDER); and a representative in patient issues. In total, about 13 to 16 people have attended each quarterly meeting.

How did you determine who should sit on the Board?

We originally invited representatives from six companies I had worked with most closely at Duke. At our first meeting, four of these six attended. We asked them a lot of questions about the Board’s purpose and structure: Are we on track? Are two meetings a year sufficient? Is the Board well represented?

We were surprised to hear members say we needed more frequent

meetings and more industry representation, as well as the inclusion of people outside Duke and commercial industry—which led us to add FDA, patient, and pharmacy interests to the group. We wanted to invite a member of the health insurance industry too, but decided to wait until the Board is more fully developed.

What kinds of issues do you talk about at your quarterly meetings? What’s on your agenda for this year?

Our earlier meetings dealt with technical changes in the ACCME Essential Areas and Elements, American Medical Association concerns such as the new Physician’s Recognition Award (PRA) requirements, and other CME issues. We also explored the impact of the media attention on industry involvement with CME—and agreed that while some behavior has been inappropriate, there has been much proper involvement as well. As a Board, we

All About DIAB

Mission

To develop a collaborative relationship between academia and industry that enhances the value of CME in the community

Goals

- Foster positive working relationships between academic CME and industry
- Provide a forum for discussion of new and innovative ideas regarding CME
- Enable industry to contribute more to CME than funding alone
- Demonstrate that industry-CME partnership can flourish within the spirit and jurisdiction of the ACCME Essentials

Roles

- Represent their companies as part of industry support of CME
- Be a colleague in CME to all members of the board
- Be a consultant to the DOCME on issues regarding industry and CME
- Consult with each other, appropriately, on CME issues

Responsibilities

- Attend, participate in, and prepare for meetings
- Respect the confidentiality of competing interests
- Support the concept of collaboration between CME and industry in adherence to CME guidelines
- Share DIAB activities and progress with their internal executives
- Support DOCME as a premier accredited CME provider

talked about clearing up misinformation in this area.

But since the Board was meant to be more than a think tank, we recently talked about creating a Board product, an actual educational activity. To me, this seemed extremely exciting, the chance to design and deliver a long-term, multifaceted educational initiative, unique in that it would be generated and produced by an industry-academic partnership.

Have you decided on a topic for this initiative?

We initially considered creating traditional CME activities in areas of major international therapeutic concern, such as women's health or diabetes. But we have information pointing to the fact that among three critical groups in CME—physicians, industry, and communications companies—there is a lack of understanding of CME itself: what it is, its limitations, and its benefits. We realized that a course about CME that fits the varying needs of the target audiences we want to educate, is exactly what we need. In fact, we all agree this is the perfect type of educational activity for a Board like ours to build. At our last meeting, we began to flesh out some ideas. Given all the issues before us, we acknowledged such a curriculum might take a full year to develop.

In looking back since the DIAB was formed, what do you see as your greatest challenges?

We've faced a number of challenges, starting with the fact that we are blazing new trails and the purpose of our very existence, which has no precedent or guide, is to survive, grow, get more cohesive and focused, and become a recognized avenue of collaboration between academic CME and industry. Other challenges include maintaining the enthusiasm of members and member companies, creating activities for multiple audiences in areas appropriate to CME, and serving as a model of how CME can incorporate industry viewpoints in program planning.

And obstacles?

The biggest one seems to be a lack of industry appreciation for CME and the value it can bring to each company. We need to educate industry about the value of CME beyond instant gratification or dollar return, because it shows the medical community that the pharmaceutical industry is committed to more than selling products.

Why is this collaboration important for DOCME and Duke?

The DIAB presents our CME office as an innovator—not afraid to do things differently, willing to risk within reason—a leader in a heretofore suspect area: associating with industry. For Duke University, we are now part of a more extended community, indeed the larger world of CME. We have the opportunity to break through the historic wall of perceived opposing interests to produce a better educational product and ultimately enhance the value of CME. ~

Follow the Leaders in 2002

Those who are leaders in CME—and those who hope to be—have a unique opportunity awaiting them. An intensive, interactive, primarily case-based conference titled **CME Leadership in the 21st Century: A Case-Based Conference for Current and Future Leaders in Continuing Medical Education** will be held September 21-24, 2002, at Duke University in Durham, North Carolina. The conference is cosponsored by the Duke University Office of Continuing Medical Education and Professional Postgraduate Services®, a division of Physicians World/Thomson Healthcare, in Secaucus, New Jersey.

The conference has a three-pronged approach to building leadership skills.

1. The 5-day session will assign participants to one of five working groups based on background. Each group will work through a major case project during the conference and present results on the final day.
2. Workshops that pinpoint leadership challenges will be held in the areas of:
 - Strategic Planning
 - Building Leadership Skills
 - Linking CME to Health Care Quality and Outcomes
 - Maintaining Professionalism in CME

3. Faculty members for the conference—recognized leaders in the field—will serve as “personal conference mentors” to participants, helping them assess leadership

“This is an ideal venue to build or enhance your core competencies as a leader in CME.”

Joseph S. Green, PhD
Co-chair
Associate Dean of CME
Duke Office of CME

strengths and weaknesses and guiding them through a customized leadership plan for the future.

The level of interaction is a key element of this conference; therefore, registration will be limited. Take advantage of this session to enhance your leadership role. Register today.

For more information or to register, contact Duke University, Office of Continuing Medical Education, at 800-222-9984 or 919-681-7462 (fax).

This conference is approved for AMA Physician's Recognition Award credit.

AAFP, EB, CME: What Does It All Mean?

Continued from page 1

What Is Evidence-Based Medicine?

As explained by Davis, physicians indeed use evidence every day in the practice of medicine. That evidence includes opinion, judgment, experience, input from colleagues and consultants, or professional readings from the literature. Valued and valuable, but not always scientifically based.

Evidence-based medicine is more formalized. It is a systematic review of the available, current best evidence in a particular area of medicine and a critical appraisal of the quality of that

evidence by reviewers. Essentially, it's been sifted, sorted, and commented on. The concept originated at McMaster University, Ontario, Canada. Medical schools have been teaching evidence-based medicine techniques and implementing them in their clinical training for several years. "Presented with all of the current best evidence," said Davis, "the physician can make a more informed decision on how to practice."

EB CME Prescribed Credit:

How It Works

There is a specific process that is undertaken by faculty members in order for a topic to be approved as evidence-based, and the AAFP provides detailed instructions for this

on their website (see *Check It Out*). EB CME hours are still optional; the AAFP will continue to approve Prescribed credit for customary and generally accepted medical practice (defined as diagnostic and therapeutic interventions that are accepted by the practicing medical community for given indications in individual patients, families, and communities). Additionally, AAFP expects that longer activities might have both customary and generally accepted hours and EB CME hours associated with it. For example, in a 6-hour program, only 2 or 3 hours may qualify for EB CME.

"As with all CME planning, EB CME starts with a needs assessment conducted by the provider, followed by objectives based on those needs," noted Davis. The next step is where traditional CME and EB CME split (Figure). With EB CME, faculty members review one of the 11 AAFP-approved evidence-based sources and develop practice recommendations based on this critically reviewed literature. Davis explained, "These are key take-home messages that physicians can implement to improve patient care." Moreover, because they are derived from an evidence-based source, they represent all of the available evidence.

The strength or the weight of that evidence simply implies the type of analysis that was performed—randomized controlled trial, cohort study, meta-analysis, etc. Inherent in these terms are indications of what one might expect from the results. For example, a physician learner may view results derived from a large-scale randomized, placebo-controlled trial differently from those derived from a meta-analysis, which is an overview of studies that pools results. At this time, citing of the strength of that evidence to the learner is optional.

AAFP: Lone Star or Leader of the Pack?

All indications point to the fact that the AAFP may be a lone star now, but ultimately they will be the leader in a pack that will follow suit over time. Partners in the AAFP process

**Figure. Traditional CME vs EB CME:
A New Pathway for Content Validity**

Traditional CME	EB CME
<i>Needs assessment (CME Provider)</i>	<i>Needs assessment (CME Provider)</i>
<i>Learning objectives (CME Provider and Faculty)</i>	<i>Learning objectives (CME Provider and Faculty)</i>
To AAFP for consideration of Prescribed credit by AAFP's Commission on CME (CME Provider)	Practice recommendations (maximum 3 per credit hour) and the source of the evidence for these recommendations (any of the 11 AAFP-approved Web-based sources on evidence-based medicine) to CME Provider and AAFP (Faculty)
	Review of evidence-based medicine website URL and practice recommendations for consideration of EB CME Prescribed credit (AAFP's Commission on CME)
<i>Content development to satisfy learning objectives (Faculty)</i>	<i>Content development to satisfy learning objectives (Faculty)</i>
<i>Objectives disclosed to learners (CME Provider)</i>	<i>Objectives disclosed to learners (CME Provider)</i>
	Practice recommendations disclosed to learners (CME Provider)
	Level of evidence (eg, "randomized, controlled trial" or "meta-analysis") disclosed to learners.
	OPTIONAL BUT ENCOURAGED

Check It Out!

Here's what you will find at AAFP's website on EB CME: (www.aafp.org/cme/accreditation)

- What's different and what's still the same under the new initiative
- Definitions and criteria
- Listing of the 11 AAFP-approved evidence-based data sources
- Faculty document form for submission to AAFP
- Guidelines for faculty: a sample of how it works
- Credit statements

for EB CME include the American Medical Association, the American Osteopathic Association, and the Accreditation Council for Continuing Medical Education (ACCME). Also, an ACCME Task Force recently put out a call for comment and input on a process to validate the clinical content of accredited CME in the United States.

"We are all headed in the same direction," noted Davis, "although it will take time for CME providers—and some physician learners—to become familiar with the evidence-based literature." But as Davis explained, with evidence-based medicine now part of the curriculum of most medical schools and residency programs, new physicians will expect it as they continue their education through CME.

Testing the EB CME Waters

The main criticism the AAFP has heard during the pilot phase of the EB CME initiative is that it's too much work, especially on the part of the CME faculty. How does Davis respond to this? "What I try to tell providers is that it won't be more work, but different work. We assume faculty conducts some type of literature search in preparation for a CME program, so that if they now conduct their search through an evidence-based source, it shouldn't be additional work." At the same time, if a CME presentation has not had the benefit of a recent review

against the literature, the AAFP recommends a new literature review—through an evidence-based source—to be sure the message is consistent with the literature. "Based on their clinical experience, faculty members may have a different opinion from the literature," noted Davis, "but the learner has a right to know opinion from evidence in order to make an informed decision."

Davis acknowledges that literature can take up to 6 months to be included in an evidence-based source. Faculty members need to consider these evidence-based sources as a foundation, and then incorporate new literature and clinical experience to form the "big picture." Additionally, scientific evidence is not yet available for all areas of medicine. "By encouraging EB CME," said Davis, "we can identify those gaps in the literature and stimulate new research in those areas." That is certainly a welcomed by-product in the AAFP's pursuit.

Undoubtedly, there are challenges ahead for CME providers. The AAFP promises a 30-day turnaround (often shorter) on their review process for EB CME submissions. Coming from a CME provider background, Davis knows the hurdle this can present: review of evidence-based sources (and formulating practice recommendations) requires a commitment from faculty for preparation of their materials even more in advance than do traditional CME programs. But the ultimate goal outweighs the hurdles: "We hope that encouraging the use of evidence-based sources, as well as new evidence and clinical experience, will enlarge the CME picture and assure that lecture content will present all of the best evidence to physician learners."

So, here are a few "Practice Recommendations" from *CME Briefing*:

- Visit www.aafp.org/cme/accreditation.
- Become familiar with EB CME principles and processes.
- Think about your CME activities (or portions of) that may be considered for EB CME by the AAFP and start talking about it with CME faculty. ~

Revising the ACCME Standards for Commercial Support: Where Are We?

Continued from page 3

approach is to align the Standards with those of the AMA.

Exhibits and advertising: Special attention needs to be paid to the timing and logistics of promotional activities that might occur near CME events. Many feel stronger direction from ACCME is needed to ensure that promotional activities do not disrupt the CME learning experience in any way.

The Timeline

Faced with the challenges of incorporating all these suggestions into newly revised ACCME Standards and then obtaining consensus of the final language, the Task Force has set an ambitious timetable for completing this much-needed revision of the Standards.

Plans call for a new draft document to be ready for release and comment by spring 2002. Following full discussion at the ACCME's spring meeting, final comments will be addressed and accepted, so that the group can present their final revised Standards for Commercial Support at the summer meeting of the ACCME in mid 2002. This new document, to be followed by all accredited providers, should then be valid for another 8 to 10 years.

Concluding his report, Kahn expressed satisfaction with the work of the Task Force to date, as well as the overall mission and goal of this task. For Kahn, the importance of having a clear, modern set of governing Standards that clear up the blurring of lines and the verbal "grays" will go a long way to guarding all players—industry, providers, physicians—from the aura of misdirected influence and bias in the development of CME activities.

Watch for continued reports and analysis as the new Standards become finalized. ~

FOR YOUR CALENDAR— *Upcoming CME Meetings for CME Professionals*

Global Alliance for Medical Education (GAME) 7th Annual Meeting *“How Physicians Learn Around the World”*

June 23-25, 2002

Montreal, Quebec, Canada

For more information, contact:

Celene Chasen

Membership Chairman, Baylor College of Medicine

Phone: 713-798-4024

Fax: 713-798-6600

e-mail: cchasen@bcm.tmc.edu

website: www.GAME-cme.org

Accreditation Council for Continuing Medical Education

ACCME Workshops for 2002

“Understanding ACCME Accreditation”

July 28-29, 2002

December 13-14, 2002

Chicago, IL

For more information, contact:

ACCME

Phone: 312-464-2500

Fax: 312-464-2589

Visit: www.accme.org, Workshops section

13th Annual Conference of the National Task Force on CME Provider/Industry Collaboration

*“Changing CME From Silos to Synergies:
A Collaborative Vision and Mission”*

September 10-12, 2002

Baltimore, MD

For more information, contact:

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