



Applying CACME's Risk Stratification Process to Mitigate Potential Non-compliance with the Standards for Commercial Support

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The speakers disclose that they have no financial relationships relative to the content of this presentation




Objectives

- Apply a risk stratification process to case studies of CME activities
- Identify best practices and develop strategies in managing activities to reduce non-compliance with the Standards for Commercial Support




Agenda

- Introduction
- Demonstration: Case 1
- Group Exercise:
Discuss Case 2/Case 3
- Facilitated Discussion
Develop a Management Plan
- Key Points & Wrap-Up



Introduction

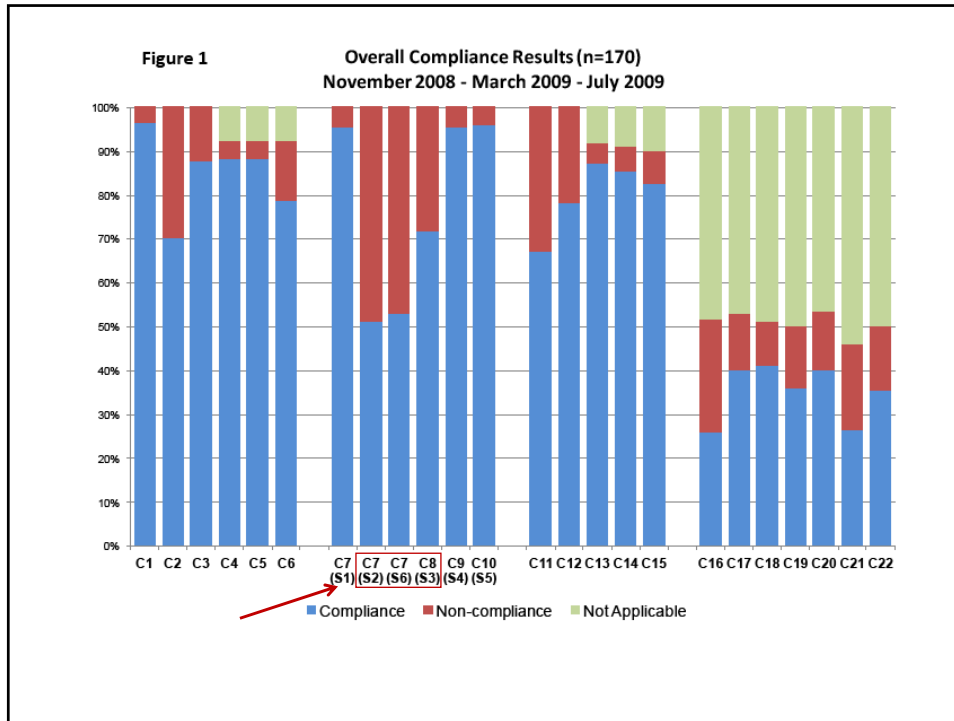
Why do we need it?
What is risk stratification?



Environment for Commercial Support

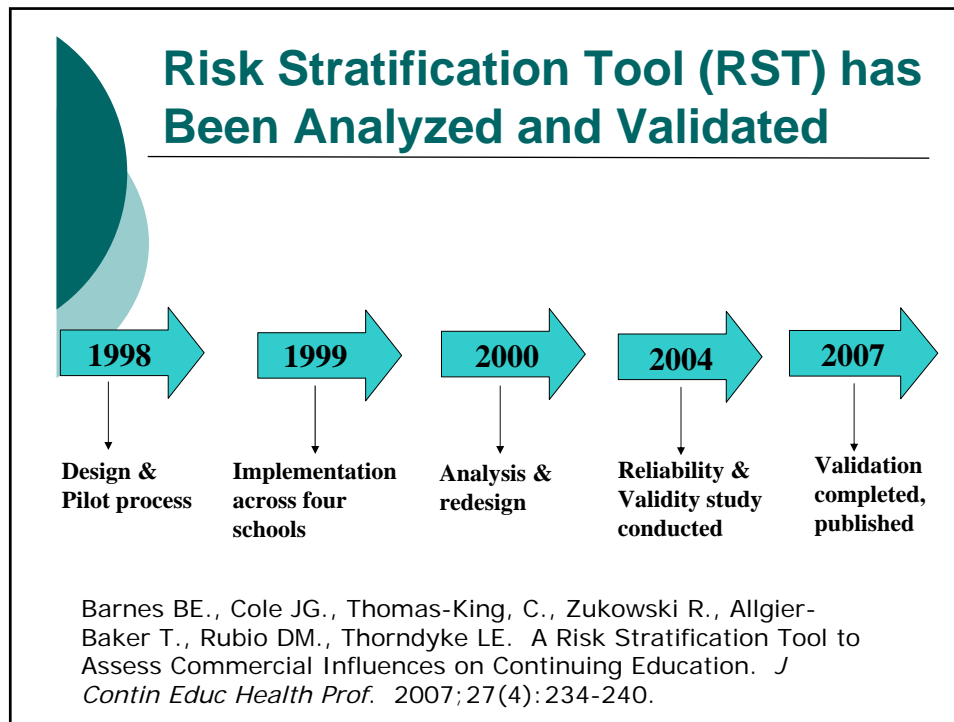
- 2008 ACCME Annual Report: Commercial Support totaled \$1,035,942,134 (primarily to MECs, Schools of Medicine, and Physician Organizations)
- Intense scrutiny and controversy over commercial support of CME
- ACCME defense: We have the SCS
 - If providers comply, the opportunity of commercial bias reduced/eliminated commercial support in CME
- Monitoring for compliance likely to increase in frequency/detail in the future

ACME Workshop January 29, 2010 (New Orleans LA)



CACME RISK STRATIFICATION
January, 2002

ISSUE	SCORE
1. Joint or co-sponsorship	
No	0
Yes	
Joint or co-sponsor is non-profit organization	1
Joint or co-sponsor is a for-profit organization	2
2. Experience with joint sponsor	
Positive experience (in compliance with Essentials and SCS and CME office's policies and procedures)	-1
Not applicable	0
No experience	1
Negative (not in compliance with Essentials, SCS, or CME office's policies and procedures)	3
3. Same live curriculum repeated on multiple occasions in a commercially supported activity (includes live internet activity or teleconference)	
No	0
Yes	3
4. Involvement by an entity outside of the CME office in logistical activities (marketing, conference management, endorsing material development, etc.)	
Handled entirely by the CME office	0
Some or all of logistical functions delegated by the CME office to one or more entities (including joint or co-sponsor)	1
Some or all of logistical functions delegated by a joint or co-sponsor to one or more entities	2
Some or all of logistical functions delegated by the CME office or joint or co-sponsor to an entity engaged by a commercial supporter	3
5. Experience with entity external to the CME office responsible for logistics	
Positive (in compliance with Essentials and SCS and CME office's policies and procedures)	-1
Not applicable	0
No experience	1
Negative experience (not in compliance with Essentials or SCS or CME office's policies and procedures)	3
6. Responsibility for funds management (receipt of commercial funds, processing of tuition revenue, payment of expenses, etc.)	
Handled entirely by the CME office	0
Some or all aspects handled by a not-for-profit entity outside of the CME office (including another department within the accredited institution)	2
Some or all aspects handled by a for-profit entity external to the CME office	3
7. Level of involvement of any of the commercial supporters or their agent(s) (risk score is additive but cannot exceed 3)	
Educational grant only	0
Site selection	1
Marketing	1
Target audience selection	1
Topic recommendation	1
Speaker recommendation	1
8. Number of commercial supporters	
None	0
2 or more	2
1, prior good experience (all commercial supporters in compliance with Essentials, SCS, and CME office's policies and procedures)	3
1, no prior experience	4
1, had prior experience (one or more commercial supporters not in compliance with Essentials, SCS, or CME office's policies and procedures)	5
9. The primary intent of the activity involves the discussion of experimental or off-label uses	
No	0
Yes	2
10. Amount of commercial support as a % of anticipated total revenue	
None	0
Up to 50% of revenue will be commercial support	1
51% - 99% of revenue will be commercial support	3
100% of revenue will be commercial support	4
11. Amount of exhibit support as a % of anticipated total revenue	
None	0
Up to 50% of revenue will be exhibit revenues	1
51% - 99% of revenue will be exhibit revenues	2
100% of revenue will be exhibit revenue	3
12. Presence of a relationship between course director and commercial supporter that might affect the scientific balance of the activity	
No	0
Yes	2
TOTAL _____	
Low risk: ≤ 2 Moderate risk: 3 to 11 High risk: 12 to 19 Very high risk: ≥ 20	





What affects Risk?


Commercial Support, Delegation, Experience

- Elements of Risk Stratification Tool
 - Primary control vs. delegation of functions
 - Involvement of for-profit organizations
 - Potential reach of activity
 - Previous experience with partners
 - Nature and degree of conflict of interest
 - Nature and degree of commercial support
- Develop a management plan to reduce risk



Risk Category Drives Decisions

- Whether to certify the activity
- Oversight plan for ensuring compliance
- Selection of methods for monitoring
- High risk activities → greater CE resources
- Lower risk activities → fewer CE resources
- High/Very high risk → higher review levels
- allocating resources to activities at highest risk for non-compliance
- Supports a variable CE management fee



Case 1: Immunization (risk score = 2 [low risk])

Description

The state Department of Health conducts an annual half-day conference to improve compliance with immunization guidelines in state health centers and physician practices. Curriculum is developed by a committee comprising DOH physicians and pediatricians from the accredited institution. The course director and faculty have no relationships with industry.

Logistics Management

Speaker and planning logistics are handled by DOH. The joint sponsors have worked on a number of previous projects, all of which are in good compliance.

Budget

The CME office processed all income. All expenses are paid by the DOH. No commercial support, no exhibits.



Case 1: Management Plan

Planning

- CME office involvement in early content development meetings
- All required forms (CME application, disclosure) submitted to CME

Implementation

- DOH submits minutes of planning calls

Delegation

- DOH is primary contact for speakers
- CME handles all income; DOH pays expenses

Review

- CME office reviews slides in advance. Referral to content expert if necessary.

Monitoring

- No monitoring needed based on past experience.

Evaluation

- Review of bias indicators on standard evaluation form



Case 2: “Love Boat” CME (risk score = 5 [moderate risk])

Description

CME office will work with No Frills Travel Agency to offer a series of CME programs on multiple topics on select cruises throughout the year. Curriculum to be developed by a medical director from the accredited institution and two faculty members. The medical director and faculty have no relationships with industry.

Logistics Management

All meeting/travel logistics and funds management will be handled by the travel agency. CME office and travel agency have no experience working together.

Budget

All expenses will be paid by participant fees.



Case 3: Satellite Symposium (risk score = 16 [high risk])

Description

- An unaccredited MECC and an Academic CME provider collaborate to successfully respond to an RFP. Content will be jointly developed to produce a 3.5 hr symposium during a national association meeting. The MECC and CME Provider have worked on RFPs before, but this is the first time they will implement a CME activity together.

Logistics

- The MECC will handle logistics, including marketing, faculty coordination, hotel and travel arrangements.

Budget

- The budget is \$500,000, 100% funded by a single commercial supporter, with no prior experience. No exhibits.
- The funder requires the CME Provider to receive the funds. The CME provider will then transfer all the funds to the MECC since they are handling logistics.
- The 3.5 hour Satellite Symposium will include dinner (\$75 pp) and will be held at the convention hotel. No registration fee.



Small Group Exercise: Dealing with the Results of Risk Assessment

- Break into groups
- Discuss the cases
 - What are the major risks?
 - What tools/techniques would you use to manage these risk



Management Plans – Areas to Consider

- Content development
- Process and timeline
- Communication
- Review of documents
- Who handles what?



Large Group Discussion

- What are the components of your management plan?
- How do the management plans differ between the two cases?




Key Points

- Decide if/how to proceed with activity
- Determine appropriate activity management plan
- Allocate CE office resources according to risk/need
 - Set appropriate fees to implement management plan



**Key Points:
Components of a Management Plan**

- Planning
 - Involvement of CME office
 - Involvement of Dean, CME committee, advisory board
- Implementation
 - Regular communications between partners
 - Sign offs at established milestones
- Delegation
 - Budget review and approval
 - Funds management
 - Logistics



**Key Points:
Components of a Management Plan**

- Review
 - By CME office
 - CME committee or advisory board
 - Independent academic review (internal or external)
- Monitoring
 - by CME, content expert, or both
 - Announced or unannounced? How often?
- Evaluation
 - Consider multiple methods of evaluation



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Barnes BE., Cole JG., Thomas-King, C., Zukowski R., Allgier-Baker T., Rubio DM., Thorndyke LE. A Risk Stratification Tool to Assess Commercial Influences on Continuing Education. *J Contin Educ Health Prof.* 2007; 27(4): 234-240



Resources

- Accreditation Council for Continuing Medical Education (ACCME) website:
<http://www.accme.org/index.cfm/fa/home.home/home.cfm>
- Association of American Medical Colleges. AAMC Task force on Industry Funding of Medical Education to the AAMC Executive Council 2008. Retrieved May 20, 2008 from
<http://www.aamc.org/research/coi/industryfunding.pdf>.
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- Miller CC, Reardon MJ, Safi HJ. Risk stratification: A practical guide for clinicians. Cambridge University Press, Cambridge, UK. 2001.



Thank you!

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