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# A Risk Stratification Tool to Assess the Need for Peer Review of CME Content

ACME 36<sup>th</sup> Annual Conference  
Friday, January 28, 2011  
1:30-2:30 p.m.  
F40-Breakout

American College of Cardiology  
CME Peer Review, LCC





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# Objectives

*At the conclusion of this session, participants should be able to:*

- 1. Assess an organization's risk stratification process for employment of peer review.**
- 2. Identify potential "red flags" in the selection of planners, topics, faculty, and commercial support.**
- 3. Utilize a risk stratification tool to determine whether or not a peer review is needed.**





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# Disclosures

## **PRINCIPAL PRESENTER:**

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**DISCLOSURE:** Does not have an interest in selling a technology, program, product, and/or service to CME professionals.

## **CO-PRESENTER:**

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**DISCLOSURE:** Does have an interest in selling a service to CME professionals.



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# Agenda

- Introduction
- Continual Changes in the Industry
- Review of Literature
- Specific rationale for the Need for Risk Assessment Tools
- Review of Form
- Group Exercise





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# Question 1



- How many of you have a formal process for risk stratification?
  - Internal
  - External





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## Question 2



- How many of you use an independent peer review process?





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# Developing a Risk Stratification Tool: An Introduction-ACC's Viewpoint

- ACC needed to develop a formal process
- What steps did ACC take to develop a risk stratification tool





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# Continual Changes in the CME Industry







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# Continual Changes

- FDA's Guidance for Industry
- PhRMA Code
- ACCME
- AMA PRA Credit System
- CEJA Reports
- Office of the Inspector General
- Kohl Senate Hearings on CME
- Institute of Medicine Reports
- Council of Medical Specialty Societies
- Other Media



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# Literature Review

## Evaluating Conflicts of Interest in Research Presented in CME Venues

Journal of Continuing Education in the Health Professions

Volume 28, Issue 4, Date: Autumn (Fall) 2008, Pages: 220-227

Nancy L. Davis, James M. Galliher, Mindy S. Spano, Deborah S.

Main, Michael Brannigan, Wilson D. Pace

<http://onlinelibrary.wiley.com/doi/10.1002/chp.188/pdf>

This pilot study investigated the presence of perceived bias in oral and print content of research findings presented in certified CME activities.

- Knowledge of the presenter's Col may increase learners' awareness of a single product in the presentation.
- Knowledge of the Col appeared to have little effect on evaluators' assessment of the presenters' strong opinion regarding the nature of care.
- There was no consensus from evaluators whether knowledge of Col affected perception of strength of evidence in presentations.
- CME providers must be diligent about investigating potential conflicts of interest in the reporting of original research. Researchers are often not aware of the need to disclose conflicts of interest during presentation of findings.
- More study is required to guide resolution of conflicts of interest in research and CME.





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# Literature Review

## A Risk Stratification Tool to Assess Commercial Influences on Continuing Medical Education

Journal of Continuing Education in the Health Professions

Volume 27, Issue 4, Date: Autumn (Fall) 2007, Pages: 234-240

Barbara E. Barnes, Jeanne G. Cole, Catherine Thomas King, Rebecca Zukowski, Tracy Allgier-Baker, Doris McGartland Ruio, Luanne E. Thorndyke

<http://onlinelibrary.wiley.com/doi/10.1002/chp.143/pdf>

Measurement tool developed by CACME available to CME providers for their use to:

- help identify activities that must be closely monitored for potential industry influence
- become aware of factors that place programming at risk for noncompliance with accreditation standards
- appropriately allocate resources by the CME office.



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# Literature Review

## Commercial Influence and Learner-Perceived Bias in Continuing Medical Education

Academic Medicine

Volume 85, Issue 1 2010 January, Pages: 74–79

Michael A. Steinman, MD, Christy K. Boscardin, PhD, Leslie Aguayo, CCMEP, Robert B. Baron, MD, MS

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2801075/pdf/nihms127880.pdf>

- Example of a provider that used a modified version to assess bias in their activities
- Heightened concerns about industry influence on continuing medical education (CME) have prompted tighter controls on the management of commercial funding and conflict of interest.
- Potential for industry influence can be difficult to assess at a stage in the planning process when mitigation strategies can assure balance and content validity.



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# Rationale for Implementing a Risk Assessment Tool





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## Question 3



- Is a standardized process needed?





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# Why a Standardized Process?

- Important to assess potential commercial bias prior to implementing an activity.
- Historically, many of these screening processes have been based on the personal and collective experience of CME professionals.
- Important to standardize process and document it for both ACCME and commercial supporters.
- Objective method for determining whether internal peer review is sufficient vs. external review for higher-risk activities.



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# ACC's viewpoint

- An objective way to implement
- Process driven
- Puts the burden off the CME Director
- Formal process to mitigate risk







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# Before Beginning Development of a Tool





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# Before you Begin

1. Identify stakeholders in your organization
2. Establish goals for the process
3. Review internal policies
4. Review ACCME criteria
5. Determine areas of risk
6. Define terms





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## Before you Begin

7. Consider how you will stratify the risk
8. Who will be responsible for completing the form?
9. What will be done with the information?
10. What level of risk are you willing to accept?
11. What actions will be taken?





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# After Developing the Form

## Pilot with your team

- Ease of use
- Consistent responses among users
- Test the risk thresholds established and subsequent actions
- Compare results with participant evaluation data





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# ACC Pilot

A set number of Program Managers (PMs) completed the Risk Assessment Tool with their CME/CNE activities

All completed online post-survey

Rate level of agreement with the following statements (with 1 being strongly disagree and 5 being strongly agree)

1. I was comfortable in completing the Risk Assessment Tool
2. The instructions provided for section 1 & 2 were easy to understand and follow
3. The investment in time was worth the added confidence I felt after completing the tool
4. It took me no more than 30 minutes to complete the tool
5. I would consider utilizing this tool for future activities in determining peer review





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# ACC Risk Assessment Tool





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# Potential Areas of Risk

- Third Parties
- Course Director, Editor
- Faculty, Planners
- Content





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# Overall Activity

- Consider:
  - If first time activity or previous feedback
  - Number of commercial supporters

| Item   | Reference          | Low | Moderate | High |
|--|--------------------|-----|----------|------|
| First-time this activity has been planned by ACCF  | ACCME Criteria 2-6 |     |          |      |
| Activity has a single commercial supporter   | SCS 3.3            |     |          |      |
| Activity received in-kind support from a single medical equipment/device companies   | SCS 3.3            |     |          |      |
| Previous participant feedback for this activity indicated commercial bias greater than or equal to the internal benchmark of 3% of participants completing post-activity evaluation form | SCS 3.3            |     |          |      |







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# Third Parties

- Joint sponsors, Co-providers, Event planners?
- If so, consider their history with the provider

| Third Parties   |                    | Low | Medium | High |
|---|--------------------|-----|--------|------|
| Activity is joint, co-provided or co-sponsored                            | ACCME Criteria 2-6 |     |        |      |
| First-time joint, co-provided or co-sponsor                               | ACCME Criteria 2-6 |     |        |      |
| Joint, co-provided or co-sponsor has history of poor compliance*with ACCF | ACCME Criteria 2-6 |     |        |      |
| First-time third party event planner for ACCF event                       | ACCME Criteria 2-6 |     |        |      |
| Third party event planner has history of poor compliance*with ACCF        | ACCME Criteria 2-6 |     |        |      |



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# Course Director, Editor

- Consider:
  - If first time activity
  - Previous activity feedback
  - Disclosures
  - Course Director's history with provider





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| Course Director/Editor  |                    | Low | Medium | High |
|---|--------------------|-----|--------|------|
| First-time Course Director for ACCF live activity or Editor for enduring activity   | ACCME Criteria 2-6 |     |        |      |
| Activity Course Director has relevant * financial relationships with the supporter(s) of the activity or other commercial interests   | SCS 3.3            |     |        |      |
| Activity Course Director has board member, royalty, speakers' bureau, and/or consultant relationship with the supporter(s) of the activity or other relevant commercial interests [Include 2 points for each relationship]    | SCS 3.3            |     |        |      |
| Activity Course Director is an employee or owner of the supporter(s) of the activity or other relevant commercial interest  | SCS 1.1            |     |        |      |
| Activity Course Director is a principal investigator for a study of a product discussed in the activity content   | SCS 1.1            |     |        |      |
| Activity course director delegates major responsibilities* to his/her support personnel   | ACCME Criteria 2-6 |     |        |      |
| Activity Course Director has history of poor compliance* with ACCF  | ACCME Criteria 2-6 |     |        |      |
| Previous activity planned by this course director received participant feedback that indicated commercial bias greater than or equal to the internal benchmark of 3% of participants completing post-activity evaluation form | ACCME Criteria 2-6 |     |        |      |



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# Faculty, Planners

- Consider
  - The percent of speakers/faculty/planners have relevant financial relationships
  - Whether COIs have been resolved and documented

| Faculty, Planners  |           | Low | Medium | High |
|--|-----------|-----|--------|------|
| 25% or more of speakers/faculty have relevant financial relationships* with the supporter(s) of the activity or other commercial interests                               | SCS 3.3   |     |        |      |
| One or more planners have relevant financial relationships* with the supporter(s) of the activity or other commercial interests [Include 2 points for each relationship] | SCS 3.3   |     |        |      |
| Evidence of COI resolution* has not been completed   | SCS 3.3   |     |        |      |
| <b>If CNE</b> , nurse planner, content expert, and nurse target audience representatives are not involved in the planning process  | ANCC FAQs |     |        |      |



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# Content

- Consider
  - Whether information presented is evidence based
  - The level of evidence
  - Whether off-label use or investigational products are discussed





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# Group Activity





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# Q & A

