Use Of A Risk Stratification Tool (RST) to Prospectively Assess Potential for Commercial Influence on CME

Presented at the CME Congress 2008
Vancouver BC
May 29 2008

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None of the authors have anything to disclose in relation to the content of this presentation
Objectives

- Define risk stratification
- Apply principles of risk stratification to CME
- Discuss elements of CME activities that confer risk for noncompliance with the Standards For Commercial Support
- Apply a risk stratification tool to a sample group of activities
- Discuss targeted interventions to manage high risk activities
Agenda

- Introduction 10 min
- Large Group Case Study 5 min
- Risk Stratification Tool 15 min
- Small Group Exercise 30 min
- Large Group Report Out 15 min
The Current Environment
Increasing Levels of Commercial Support

ACCME DATA
Commercial Support by Provider Type

- Medical Schools: 15%
- Publishing/Education Companies: 52%
- Specialty Societies: 22%
- Hospitals/Health Systems: 5%
- Other: 6%

Specialty societies receive 75% of the advertising/exhibit revenue.
Concerns About Commercial Support

- Can industry-sponsored CME activities be balanced and unbiased?
- Does industry support drive the overall agenda for CME?
- Do CME providers and learners have the capability to manage and identify commercial bias?
- Does industry support for CME erode public trust?
The Response

- Position papers
  - Macy Foundation Report
  - AAMC Task Force on Industry Funding of Medical Education
  - AMA Ethical Opinion Draft

- Regulatory responses
  - Senate Finance Committee
The Response

- ACCME position
  - Response to Senate Comm.
  - “Bridge to Quality”
  - Implementing New Criteria

- Academic Medical Centers
  - Policies on institutional COI
Challenges to CME Providers

- Producing quality, unbiased, scientifically rigorous education
- Complying w/ Standards and Guidelines
- Funding CME with institutional dollars
- Managing COI of 1° content developers
- Managing COI of institutions
- Appropriately using resources and people
- Managing change
Table 10: Summary of Compliance with the Essential Areas and Elements (2006)

<table>
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<tr>
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<td>97%</td>
<td>3%</td>
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<td>3.3(SCS1)</td>
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<td>88%</td>
<td>3%</td>
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<tr>
<td>3.3(SCS2)</td>
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<td>99%</td>
<td>3%</td>
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<td>1%</td>
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<td>3.3(SCS3)</td>
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<td>1%</td>
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<td>3.3(SCS4)</td>
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<td>99%</td>
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<td>2%</td>
<td>1%</td>
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<td>3.3(SCS5)</td>
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<td>3.3(SCS6)</td>
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<td>81%</td>
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<td>2%</td>
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</table>
Case Study: Broncho-Endoscopy

- Based on your experience as a CME professional, what “risk category” would you assign to this case?
  - Very high risk
  - High risk
  - Moderate risk
  - Low risk
What is Risk Stratification?

- A statistical process to determine detectable characteristics associated with an increased chance of experiencing unwanted outcomes.

- By identifying factors before the occurrence of an event, it is possible to develop targeted interventions to mitigate their impact.

Risk Stratification Allows Providers to Identify, Quantify and Modify Risk

- Identify issues that increase risk for
  - injecting bias in the educational content
  - non-compliance with accreditation standards
  - endangering accreditation status

- Aid providers in decisions about whether and/or how to certify a “risky” program

- Stimulate providers to apply strategies to assure that compliance is achieved
Risk Stratification Tool (RST) has Been Analyzed and Validated

- **1998**: Design & Pilot process
- **1999**: Implementation across four schools
- **2000**: Analysis & redesign
- **2004**: Reliability & Validity study conducted
- **2007**: Validation completed, published

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

**TOTAL**

Low risk: \( \leq 2 \)
Moderate risk: 3 to 11
High risk: 12 to 19
Very high risk: \( \geq 20 \)
Risk is Affected by Commercial Support and Degree of Delegation

- 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
The RST Predicts Risk: Prospectively and Objectively

- Provides rationale for allocating resources to activities at highest risk for non-compliance
- Higher risk activities require greater direct involvement of CE office in planning, monitoring and evaluation
- Lower risk activities may have responsibilities delegated
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
- Supports a variable CE management fee
CE Office Develops a Management Plan

- Multi-level COI Management Plan
- Involvement of Dean for CME
- CME committee or advisory board
- Degree of delegation by CE office
- Independent academic review
- Mandatory on-site monitoring
- Multiple methods of evaluation
Large Group Exercise
Broncho-Endoscopy *Revisited*

- Review the case again
- Use the Risk Stratification Tool to score and assign a risk category to the case

- Did you get the same answer?
Small Group Exercise
Applying the Risk Stratification Tool

- Break into small groups of 4-6
- Score each case individually
- Discuss each case
  - What category of risk is present?
  - Where are the major risks?
  - Would you proceed?
  - What management plan would you develop to manage the risk?
Large Group Discussion

- Was there agreement within your group with risk category assignment?
- Was the RST a useful instrument in the process?
- How did the risk category affect the management plans for each case?
- How would the RST be useful in your office?
Use the RST for Individual Activity Assessment and Program Evaluation

○ Prospective - Allows appropriate distribution & balance of CE office resources
○ Retrospective - Allows profile of overall CE program

○ Useful in training staff
○ High risk activities are not inherently “bad” or “off limits”

CACME Overall Risk Category (FY04)

- Low 23%
- Moderate 64%
- High 12%
- Very High 1%
Conclusions

- The RST delineates elements that place activities at risk for non-compliance with SCS
- Prospective assessment of risk can aid in:
  - Appropriate activity management
  - CE program overall profile
  - Allocation of CE office resources
  - Compliance with standards and regulations
Acknowledgements

- Dr. Timothy Brigham
- Dr. Dennis Lott
- Dr. Geno Merli
- Dr. Doris Rubio
- Dr. Robert Smedley
- Ms. Catherine Thomas-King
- Ms. Becky Zukowski

Funding for the project was provided by the Consortium for Academic Continuing Medical Education (CACME) and through the Alliance for CME’s Collaboration Award (2001).
References

- Accreditation Council for Continuing Medical Education (ACCME) website: http://www.accme.org/index.cfm/fa/home.home/home.cfm
Thank you!

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