

Applying the Principles of Risk Stratification to Effectively Manage Commercial Support

Luanne Thorndyke, M.D.

Jeanne G. Cole, M.S.

Catherine Thomas-King, C.M.P.

Barbara Barnes, M.D.

Objectives

- Define the concept of risk stratification
- Apply principles of risk stratification to CME
- In a series of case studies, identify elements of CME activities that confer risk for noncompliance with the Standards For Commercial Support
- Discuss targeted interventions to manage high risk activities

What is Risk Stratification?

- Risk stratification: a statistical process to determine detectable characteristics associated with an increased chance of experiencing unwanted outcomes.^[1]
- By identifying factors before the occurrence of an event, it is possible to develop targeted interventions to mitigate their impact.

- ^[1] Miller CC, Reardon MJ, Safi HJ. Risk stratification: A practical guide for clinicians. Cambridge University Press, Cambridge, UK. 2001.

Risk Factors for Heart Disease

- Hypertension
- Diabetes
- Cigarette smoking
- Dyslipidemia
- Family history
- Other
 - Obesity, sedentary lifestyle, stress

Risk Stratification Process Application to CME

- Allow providers to identify issues that place an activity *at risk*
 - for injecting bias in the educational content
 - for non-compliance with accreditation standards
 - for endangering accreditation status
- Aid providers in decision-making process about whether to certify a “risky” program
- Allow providers to determine appropriate strategies to assure that compliance is achieved

CACME Risk Stratification Tool Development Process



Risk Stratification - a mechanism to provide oversight of CACME activities

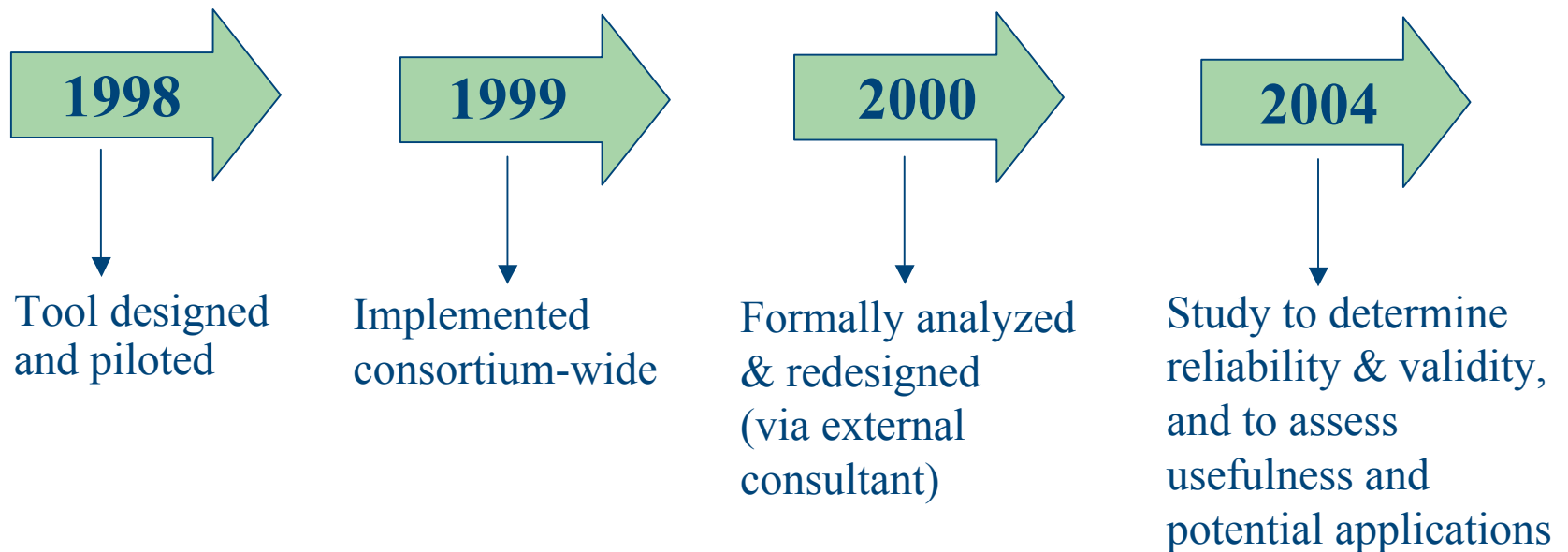
CACME developed a tool to prospectively and objectively identify activities at high risk for violation of the SCS



Quick CACME Facts:

- 2000-Accredited w/commendation
- Certified over 650 activities annually
- Dissolved in 2005

CACME Risk Stratification Tool Development Process



Purpose of Risk Stratification

- Prospectively and objectively predict relative risk for non-compliance with SCS
- Provide rationale for allocation of resources to those activities at highest risk for non-compliance
 - Lower risk activities may have certain responsibilities delegated
 - Higher risk activities require greater direct involvement of CE office in planning, monitoring and evaluation

Risk Factors: General Principles

- Primary control vs. delegation of functions
- Nature and degree of commercial support
- Involvement of for-profit organizations
- Nature and degree of conflict of interest of parties involved
- Previous experience with partners
- Objective

Risk Stratification Criteria

- Partner Information
 - Direct vs. joint sponsorship
 - ↑ risk w/ joint sponsorship
 - Content partner (vs. logistics partner)
 - ↑ risk w/ joint sponsor as a for-profit organization (MECC)
 - Logistics
 - ↑ risk w/ greater delegation of responsibilities
 - Relationship and past experience w/partner
 - ↑ risk w/ shared control (vs. CE office control)

Risk Stratification Criteria

- Type of design: repeated vs. single
 - Higher risk activities generally have the potential to reach larger audiences and usually have significant degree of commercial support involved
 - Same live curriculum repeated multiple times
 - Internet or teleconference activities
 - Primary intent involves experimental or off-label uses of medications, devices, or techniques

Risk Stratification Criteria

- Level of involvement of accredited sponsor
 - Greater risk with less direct control
 - Risk increases with degree of delegation of function
 - Some/all of logistical functions delegated by CE office
 - Some/all logistical functions delegated by joint sponsor
 - Delegation to an entity engaged by commercial supporter

Risk Stratification Criteria

- Responsibility for funds management (receipt of commercial funds, processing of tuition revenue, payment of expenses, etc.)
 - Risk increases with degree of delegation of funds management and nature of partner
 - Delegation to a not-for-profit entity (e.g., college department)
 - Delegation to a for-profit entity external to CME office (highest risk)

Risk Stratification Criteria

- Commercial Support Aspects
 - Amount of commercial support and/or exhibit support
 - % of total revenues
 - Number of commercial supporters
 - Single commercial supporter (highest risk)
 - Multiple commercial supporters
 - Previous experience with commercial supporter(s)
 - Level of involvement of commercial supporter(s)
 - Site selection, marketing, topic/speaker recommendation(s)

Risk Stratification Criteria

- Nature and degree of conflict of interest
 - Relationship between Course Director, planning committee and commercial supporter(s)
 - Research funding, speaker's bureau, stocks
 - Previous experience with course director
 - Requires Conflict of Interest management plan

Risk Stratification Process

- Every activity assessed in the planning phase
- CACME Risk Stratification Tool utilized
 - Weighted score assigned for each criteria
 - Each criterion assessed and scored
 - Overall risk score determined from sum of various criteria
 - Risk score determines risk category
- Risk Category: low, moderate, high, very high risk
- Management plan based on risk category

Risk Stratification Process

- Utilizing the risk score and category:
 - CE office determines whether to certify
 - CE office develops a plan for ensuring compliance
 - Designs/implements methods for monitoring and evaluation
 - Allocates greater resources to higher risk activities, less resources to lower risk activities
- Higher level review of all high and very high risk activities
- Prospective and retrospective review

What IF...HIGH RISK?

Sample plans for higher risk programs

- Multi-level Conflict-of-Interest Management Plan
- Discussion and involvement of Dean for CME, liaison committee/advisory board
- Complete involvement of CE office
 - Refusal to delegate functions
- Direct approval of logistics planning
- Independent academic review
- Mandatory monitoring
- Multiple methods of evaluation
- Refuse certification

Case Study: Update in Physical Medicine and Rehabilitation

- **Description**

This one-day activity will be jointly sponsored with a small, non-profit state-based physician society of physiatrists. The accredited provider's faculty will be involved in directing, planning, and implementing the course, which in the past has attracted approximately 75 participants. Topics will focus on new developments in the field that can be implemented into practice. The meeting site: a hotel close to provider.

- **Budget**

90% of budget from registration fees and society funds; two to three exhibitors.

- **Meals and Social Events**

Continental breakfast, refreshment breaks, and lunch will be provided.

- **Administration**

All conference logistics and funds management will be provided by the joint sponsor. There has been a good relationship between the organizations for many years, with prior CME activities being in good compliance.

- **Relationship with Industry**

The course director disclosure reveals no significant relationships.

Risk Criteria

- Partner information
- Commercial support aspects
- Responsibility for funds management
- Level of involvement of accredited sponsor
- Type of design: single vs. repeated
- Nature and degree of conflict of interest

Case Study

- What are the risks in this activity?
- How would you categorize the activity?
 - Low, Moderate, High, Very high risk
- Would you certify this activity?
- How would you manage the risk to ensure compliance?

Case Study: Update in Physical Medicine and Rehabilitation

- Risk Factors
 - Joint sponsorship (not-for-profit society)
 - 2-3 exhibitors (10% of revenue)
 - Delegation of all functions to joint sponsor (good history)
 - No COI issues
- Risk Category: Low
- Management Plan: Oversight

Case Study: Broncho-Endoscopy

- **Description**

This 2-day directly sponsored course will be held on the campus of the accredited sponsor, offering 8 hours of hands-on rigid and flexible endoscopic experience with live tissue and mannequins. All faculty will be from the accredited provider's institution.

- **Budget**

Registration fees will amount to 25% of the budget. The remaining 75% of revenue will come from small, unrestricted educational grants from endoscopy equipment companies. Some of the equipment that will be used in the skills sessions of the course will be loaned by one of the commercial supporters.

- **Meals and Social Events**

Continental breakfasts, breaks, and lunches will be provided.

- **Administration**

The accredited provider will do all meeting logistics, planning, funds management.

- **Relationship with Industry**

The course director has received research grants from 2 of the commercial supporters. Commercial supporters will have no role in marketing or other aspects of the course.

Risk Criteria

- Partner information
- Commercial support aspects
- Responsibility for funds management
- Level of involvement of accredited sponsor
- Type of design: single vs. repeated
- Nature and degree of conflict of interest

Case Study: Broncho-Endoscopy

- What are the risks in this activity?
- How would you categorize the risk?
 - Low, Moderate, High, Very high risk
- Would you certify this activity?
- How would you manage the risk to ensure compliance?

Case Study: Broncho-Endoscopy

- What are the risks in this activity?
 - 75% of revenue from commercial support (multiple supporters)
 - Equipment used is loaned from a commercial supporter
 - Course Director has some COI issues
- Risk Category: Moderate
- Management Plan:
 - Resolve COI issues
 - Several vendors contacted to provide equipment
 - Mandatory on-site monitoring of activity

Case Study: New Devices Seminar

- **Description:**

This 2-day formal course, which will be jointly sponsored with a for-profit medical education company, is intended for interventionalists who want to learn about the newest devices for vascular diagnosis. When the accredited provider worked with the joint sponsor several years ago, it was difficult to obtain required budgetary information and letters of agreement. The program will be held at a hotel in Orlando, Florida and features faculty from across the country. Each day of the course will include lectures as well as practical workshops that provide hands-on experience with different types of equipment. All discussions will focus on approved uses of the devices. The course director is a former faculty member at the accredited provider's institution.

New Devices Seminar

- **Budget:**

The course will be entirely supported by revenue from a large exhibit hall. There will be no tuition.

- **Meals and Social Events:**

Continental breakfast, refreshments at the breaks, and lunch will be provided. The first evening of the course will feature a buffet dinner and entertainment in the exhibit hall.

- **Administration:**

The joint sponsor will be responsible for logistical aspects of the course, management of funds, and processing registrations. It plans to contract some on-site meeting management services to a company in Orlando.

- **Relationship with Industry:**

The course director is the owner and major stockholder a company that is one of the “platinum” exhibitors (contributing 25% of the total exhibit income).

Risk Criteria

- Partner information
- Commercial support aspects
- Responsibility for funds management
- Level of involvement of accredited sponsor
- Type of design: single vs. repeated
- Nature and degree of conflict of interest

Case Study: New Devices Seminar

- What are the risks in this activity?
- How would you categorize the risk?
 - Low, Moderate, High, Very high risk
- Would you certify this activity?
- How would you manage the risk to ensure compliance?

New Devices Seminar

- Risk factors:
 - Jointly sponsored activity w/ MECC
 - Problematic past experience w/ MECC
 - 100% revenue from exhibit hall
 - Delegation of functions to joint sponsor and others
 - Major COI w/Course Director
- Category: Very High Risk
- Elements of risk modification plan:
 - Resolve course director COI
 - High level review (CACME Board of Directors)
 - Intense involvement & monitoring from CE office
 - Prospective and retrospective review

Case Study: Use of Anti-Epileptic Drugs for Migraine

Description

This jointly sponsored one-hour meeting will focus on the use of anticonvulsant (antiepileptic) therapy in the treatment of migraine headache. The session will primarily focus on new indications for these drugs that have not as yet been approved by the FDA. The course director is a full-time professor of neurology at the sponsoring institution and an internationally known expert on the topic. Three speakers will present lectures at a breakfast symposium held during an international headache association conference in Houston (the activity is not an official part of the association meeting). Attendees will be neurologists who subspecialize in headache diagnosis, management and treatment. The joint sponsor is a non-accredited, for-profit education company. The course will be held in 3 weeks. The curriculum has been planned and all speakers selected. The commercial supporter and joint sponsor have worked together on a number of projects. The idea for the proposed course grew out of one of these collaborations. The CME office has never worked with either entity.

Case Study: Use of Anti-Epileptic Drugs for Migraine

- **Budget**

There will be no tuition. The activity will be 100% supported by a \$225,000 educational grant from a single pharmaceutical company. The CME office has worked with this company in the past and discovered that its representatives paid for upgrades to speakers' hotel rooms and for a faculty dinner that was not included in the course budget. There will be no exhibits associated with this activity.

- **Meals and Social Events**

A full breakfast will be served. There will be no associated social events.

- **Administration**

The joint sponsor will handle all logistics. The accredited provider will manage all funds and maintain the budget.

- **Relationship with Industry**

The course director has disclosed relationships with the commercial supporter in the area of grants, consulting, and speakers bureaus. Disclosure has not as yet been obtained from other speakers, but it is known that they were recommended by the commercial supporter from its speakers bureau. Representatives of the commercial supporter will assist in the marketing of the program and will attend.

Risk Criteria

- Partner information
- Commercial support aspects
- Responsibility for funds management
- Level of involvement of accredited sponsor
- Type of design: single vs. repeated
- Nature and degree of conflict of interest

Case Study: Use of Anti-Epileptic Drugs for Migraine

- What are the risks in this activity?
- How would you categorize the risk?
 - Low, Moderate, High, Very high risk
- Would you certify this activity?
- How would you manage the risk to ensure compliance?

Case Study: Use of Anti-Epileptic Drugs for Migraine

- Risks
 - Jointly sponsored w/ MECC (problematic history)
 - 100% revenue from single commercial supporter
 - Delegation of logistics (not funds management)
 - Content: new/investigational therapeutic drug
 - COI issues w/Course Director, speakers (?)
- Risk Category: Very high risk
- Management Plan:
 - Do not certify

Case Study: Skeletal Complications of Malignancy

- **Description**

This course will be jointly sponsored with the National Cancer Institute and a non-profit professional organization. The accredited provider has not previously worked with these entities. The conference, which is targeted to academic oncologists and cancer researchers, will feature three days of lectures and scientific abstracts. The keynote speaker will be an eminent, well published, and well recognized leader in the field. The course director is a faculty member at the accredited institution. The curriculum will be developed by the course director and several of the proposed faculty. Experimental and off-label uses will be the subject of at least 2/3 of the presentations. The conference will be held on the NIH campus.

Case Study: Skeletal Complications of Malignancy

- **Budget**

Income sources include registration fees, which will account for approximately 25% of the budget. A number of pharma companies will provide educational grants to support the remaining 75% of the budget.

- **Meals and Social Events**

Meals will include breakfast, morning and afternoon breaks, and lunch. There will be an evening social event at the National Air and Space Museum featuring dinner.

- **Administration**

Conference administration, including funds management, will be provided by staff from the non-profit organization. The accredited provider has never worked with this group.

- **Relationship with Industry**

The course director has received major research support from several of the proposed commercial supporters. Industry representatives will not participate in any logistical or educational aspects of the program.

Risk Criteria

- Partner information
- Commercial support aspects
- Responsibility for funds management
- Level of involvement of accredited sponsor
- Type of design: single vs. repeated
- Nature and degree of conflict of interest

Skeletal Complications of Malignancy

- What are the risks in this activity?
- How would you categorize the risk?
 - Low, Moderate, High, Very high risk
- Would you certify this activity?
- How would you manage the risk to ensure compliance?

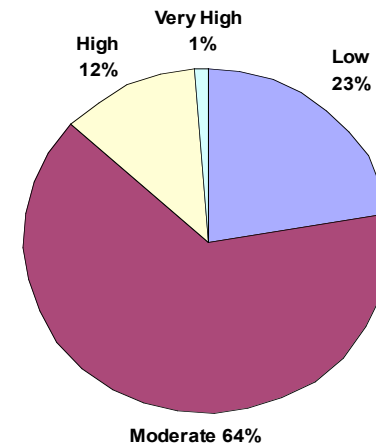
Skeletal Complications of Malignancy

- Risks:
 - Jointly sponsored (NCI and a non-profit entity)
 - Delegation of all conference administration functions
 - No experience with joint partners
 - 75% revenue from commercial supporters
 - COI issues w/ Course Director, and others (?)
- Risk Category: High
- Risk Management Plan:
 - Resolve COI issues
 - Increase involvement of CE office during implementation
 - Monitoring

Impact of Risk Stratification Process in Practice

- Ensures prospective and retrospective oversight and management
- High risk activities are not inherently “bad” or “off limits”
- Allows appropriate distribution and balancing of finite resources within CE office
- Allows profiling of the overall CE program

CACME Overall Risk Category (FY04)



Summary Points

- Risk Stratification delineates elements that place activities at risk for non-compliance with SCS
- Prospective assessment of risk can aid in appropriate management of activities
- Profiling of CE program allows allocation of CE office resources to ensure compliance with standards and regulations

Acknowledgements

- Dr. Timothy Brigham
- Ms. Tracy Allgier-Baker
- Dr. Dennis Lott
- Dr. Geno Merli
- Ms. Anne Oved
- Dr. Robert Smedley
- Ms. Becky Zukowski