

Navigating the Slippery Slope of Commercial Support: Applying the Principles of Risk Stratification

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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 Stratification Process Application to CME

- Allow providers to identify issues that place an activity at risk for non-compliance with accreditation standards
- 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

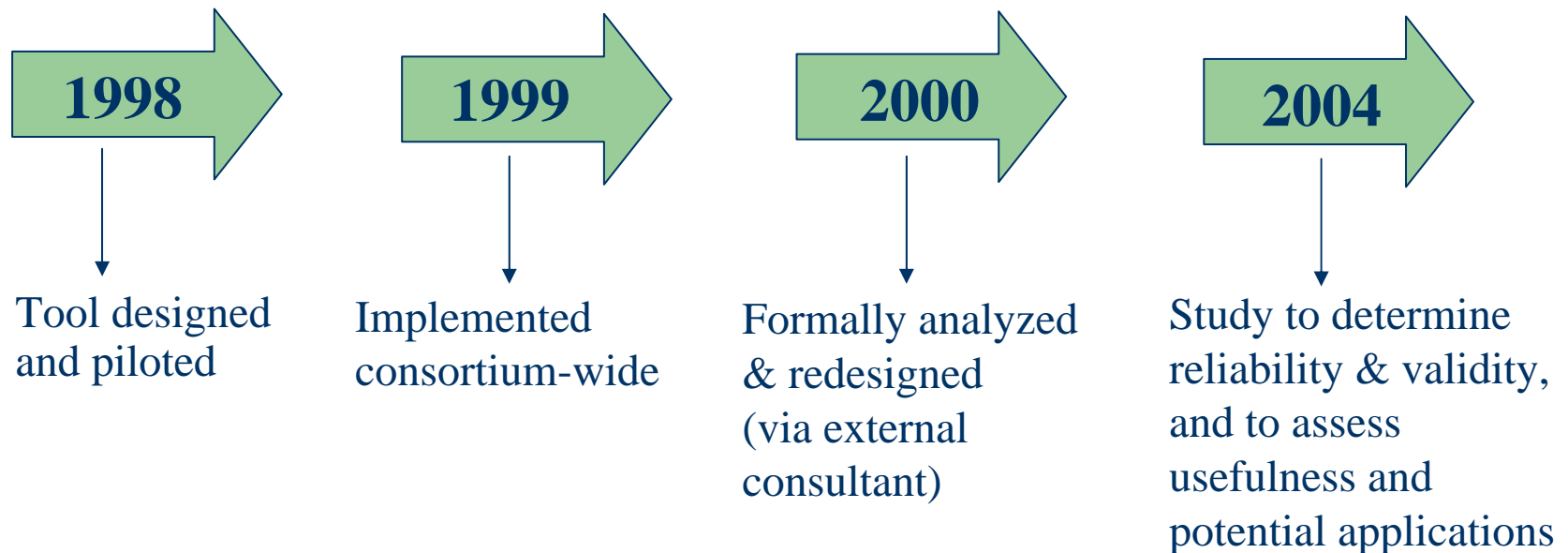
CACME developed a tool to prospectively and objectively identify activities at high risk for violation of the SCS



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
- Appropriate resource allocation/management
 - Lower risk activities may have certain responsibilities delegated
 - Higher risk activities require greater direct involvement of CE office in planning, monitoring and evaluation

CACME Risk Stratification

- Utilizing the risk score and category
 - CE office develops a plan for ensuring compliance
 - Designs and implements methods for monitoring and evaluation
 - Allocates greater resources to higher risk programs, less resources to lower risk activities
 - CACME Board review and approval
- Provides rationale for allocation of resources to those activities at highest risk for non-compliance

Risk Stratification Criteria

- Partner Information
 - Content and/or logistics
 - Relationship, nature of partner, past experience
- Type of design: repeated vs. single
 - Same live curriculum repeated multiple times in a commercially supported activity
- Level of involvement of accredited sponsor
- Responsibility for funds management

Risk Stratification Criteria (cont'd)

- Commercial Support Aspects
 - Number of commercial supporters
 - Amount of commercial support
 - Amount of exhibit support
- } % of income
- Off-label or experimental therapies
 - Relationship between Course Director and commercial supporter

Use of Risk Stratification Tool

- Every activity* assessed in the planning phase
- Weighted score assigned for each criteria
- Each criteria assessed and scored
- Overall risk score determined from sum of various criteria
- Risk score determines risk category
 - Low, moderate, high, very-high risk
- CACME reviewed all high, very high risk activities
 - Retrospective and prospective review

**non RSC activities*

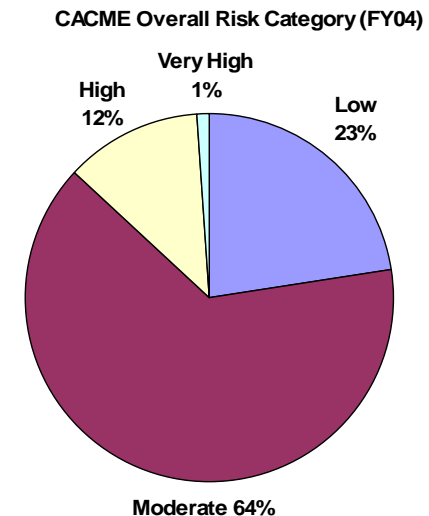
What IF...HIGH RISK?

Sample plans for higher risk programs

- Discussion and involvement of dean for CME, liaison committee/advisory board
- Complete involvement of CE office
- Direct approval of logistics planning
- Independent academic review
- Mandatory monitoring
- Multiple methods of evaluation

Impact of Risk Tool in Practice

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



Summary Points

- CACME Risk Stratification Tool
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

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