

Coordinated Activities

Todd Dorman
Carlita Kearney
Anita Beyer
Rhonda Myers



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Disclosures

No Relevant Financial Relationships with Commercial Interests

Dr. Todd Dorman
Carlita Kearney
Anita Beyer
Rhonda Myers

Goals

- Define coordinated
- Application process
 - Administrative issues
- Record keeping
 - Planning notes
 - Overall objectives communication
 - Lecture objective(s) communication
 - Activity announcements or marketing material
 - Disclosure forms and public release
 - Letters of agreement/acknowledgement of support
 - Evaluations / Outcomes
 - CVs of all speakers
 - Sign-in lists
 - Final list of speakers/topics
 - Post-activity materials
- Marketing
- Services/support/monitoring
- Q&A

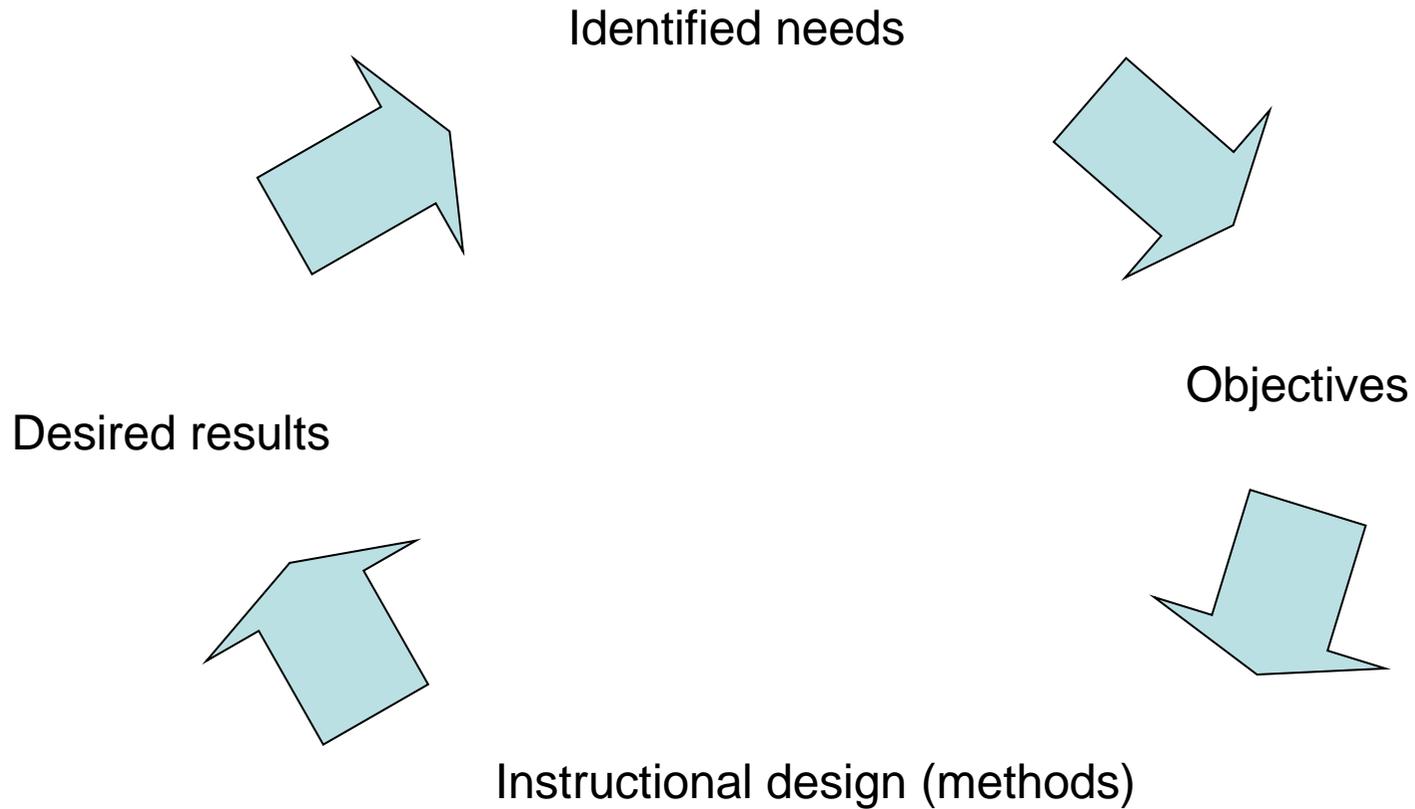
Application: Administrata

- Accreditation cycle
 - For the days of the activity
 - Application approvals required in advance and all disclosures and LOAs must be signed in advance by accredited provider
- Plan to submit 5-6 months in advance of activity
- A planning meeting with JHU OCME must occur before an application can be submitted
- Approval from the NIH is also required in advance

Application Components

- Administrative data fields
- Needs
- Objectives
- Instructional design/methods
- Results/evaluations
- Director/planner disclosures
- ***Also let us know if attendees include groups other than physicians and specifically if you desire specialty accreditation for these additional groups***

Needs Linkages



Statement of Need

- Statement of need is the overall need for the educational activity that relates to the target audience and derives from the Needs Assessment
- Educational needs provide the reason for offering CME activities. They imply a deficit in knowledge, skills, attitudes and/or behavior among prospective participants
- A minimum of 3 needs documents are required

Sample Statement of Need

- The estimated prevalence of HIV infection in inmates of correctional facilities is nearly five times than that of the general population (2.0% versus 0.4%) and AIDS-related deaths as a percentage of total deaths in state prisons is greater than that of the general population (4.6% versus 3.8%).[1,LITERATURE]

- In addition, although acquired immunodeficiency syndrome (AIDS)-related deaths in state prisons have decreased 82% from 1995 to 2004, it has not paralleled the level seen in the general population and mortality as a percentage of total deaths is greater than that in the general population (4.6% vs 3.8%). [2, LITERATURE] This rising disease burden must be addressed in spite of the complexities of modern management of HIV infection and the unique challenges within correctional systems.

- Clinicians must deal with not only the long-term consequences of the infection, but also side effect profiles of the medications, compliance issues, viral resistance, comorbidities and coinfections. While the 2008 Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents address baseline evaluations for viral burden and immunologic function, treatment goals, identification of antiretroviral treatment failure, and strategies for treating special populations (such as those with AIDS-associated nephropathy, coinfection with Hepatitis B infection, etc) [3, NATIONAL GUIDELINES],

- these guidelines— released by the Department of Health and Human Services—are geared towards infectious disease practitioners and can be somewhat overwhelming to primary care providers.
- There are additional barriers to effective management of these patients as well. For instance, emerging data documenting the severity and seriousness of the HIV-1 drug resistance problem in previously treated and untreated patient populations have emphasized the growing need for clinicians to use resistance testing so that the updated guidelines on the use antiretroviral drug combinations is most effective in preventing or treating drug resistances.[4,5, LITERATURE]

- Providers also need to examine the potential for drug-drug interactions and take proactive measures to preempt them.[3, NATIONAL GUIDELINES] Further, the rationale for using specific drug regimens in cases of HIV with HBV coinfection need to be fully applied. This is especially true with inmates, as approximately one-third of new HBV infections among inmates have been detected to co-exist with HIV infection.[6, LITERATURE] Medical care providers in correctional facilities need to apply the latest evidence, as well as overcome several unique challenges to help improve the overall outcomes of this patient group, both while they are incarcerated and after they are released into the community. [7, OUTCOMES FROM 2008 PROGRAM]

Objectives

- The provider must communicate the purpose or objectives of the activity so the learner is informed *before* participating in the activity
- Purpose or objectives of the activity express learning outcomes in terms of physician performance or patient health (i.e. in behavioral terms), and are communicated clearly and consistently to the learner

Objectives

- All activities require objectives
 - For lecture-based activities: Objectives for the year are required as part of the application **and** then a minimum of a single objective per lecture is also required
 - Both must be transmitted to learner in advance of learning
 - Documentation of that must be in the file

Communication Before Activity

- Program objectives (e.g. those listed in application) **shall** be sent to all faculty via email with OCME cc'd
- Specific lecture objective **must** be communicated to all learners in advance. Commonly this is accomplished by prominently displaying in learner environment
 - A slide could be displayed as people enter
 - An initial slide within speaker lecture
 - A print version placed with sign-in sheets/electronic system
 - A poster or sign on doors/at entry into room
 - On lecture title page of a printed syllabus
- **Documentation of these communications is required**
 - **This is a commonly missed step!**

Definition

- Goal
 - Broad statement of purpose
 - The aim of the activity
- Objective
 - Clear statement of anticipated results
 - Focus primarily on what participants will do/learn as a result of attending the activity
 - Best when measurable

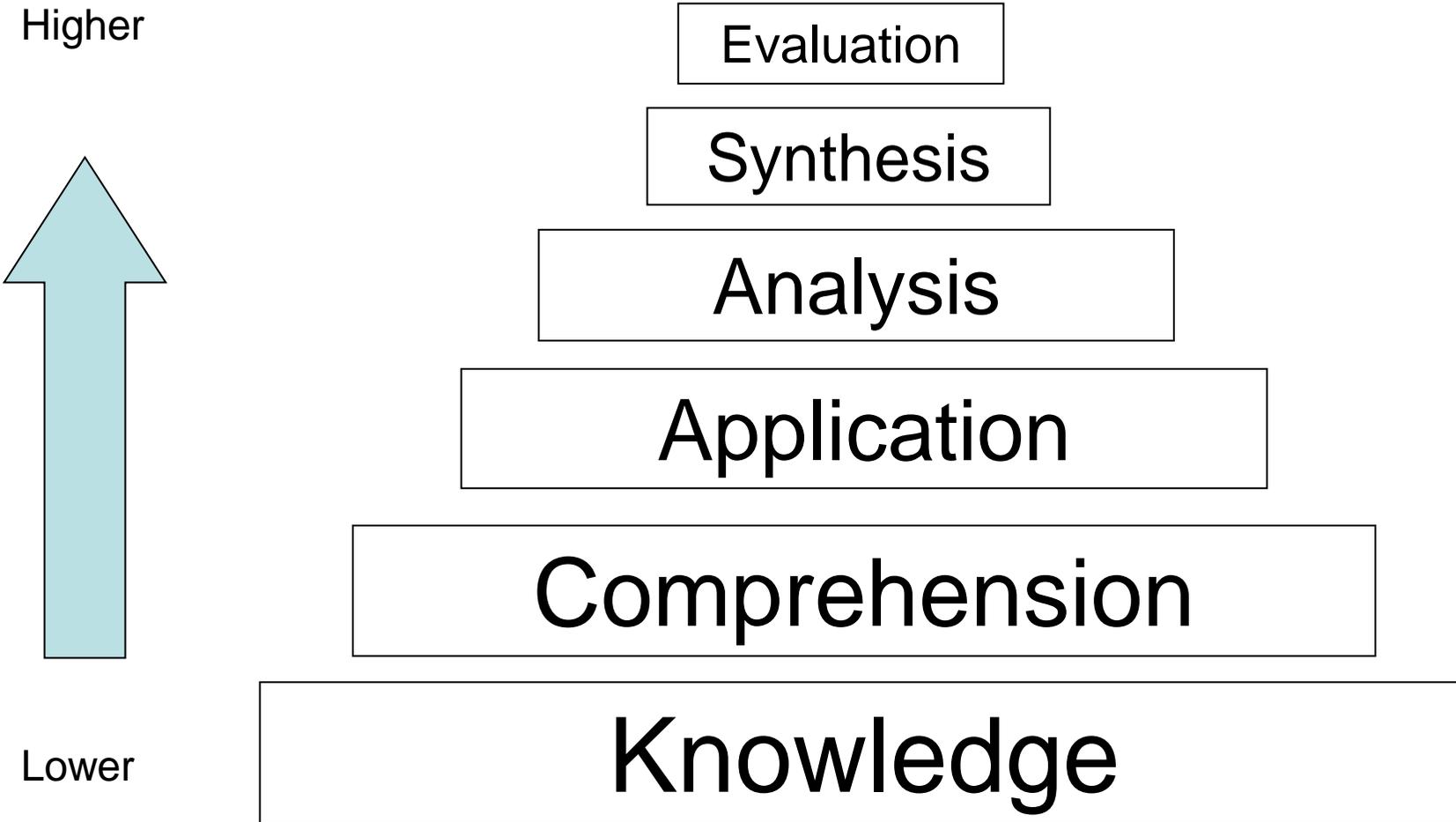
Examples

- Goal
 - Improved behavior management in patients with dementia
- Objective
 - Design treatment strategies based upon nationally published guidelines that improve behavior management in patients with dementia
 - According to NIH guidelines, select an appropriate treatment option for mood stabilization in a patient with dementia

Unacceptable Words

- Know, learn, understand, improve, increase
- Think critically, really know, expand horizons, appreciate, grow
- These words should be rarely if ever used as they are not measurable and are viewed as unacceptable words by the ACCME

Cognitive Pyramid



Instructional design/methods

- Research has repeatedly shown that learners' attention and focus are significantly improved by the instructional design and assessment process.
 - If the instruction focuses primarily on the correct identification of factual information, learners will merely direct their time and energy toward the memorization of facts and definitions
 - On the other hand, if the instruction requires learners to demonstrate a more complex understanding, learners will concentrate their effort on acquiring the relevant skills
 - This leaves the instructor with the task of implementing measures that accurately reflect the desired educational objectives & outcomes
- We encourage the use of serial education employing a variety of instructional designs

Results/evaluations

- The provider **must** evaluate the effectiveness of its CME activities in meeting identified educational needs
- Accredited CME activities are to be evaluated consistently for effectiveness in meeting identified educational needs, as measured by practice application and/or health status improvement
 - **Ideally evidence is sought for improvement in**
 - **Competency (knowledge + ability to act)**
 - **Practice**
 - **Outcomes**

Evaluations and Outcomes

- Evaluations are required and are typically conducted at the end of an activity and MUST include outcome questions
- Outcomes then MUST be assessed at an interval of time between 30 and 90 days after an activity. Although the same core outcomes questions MUST be utilized we encourage you to ask a few additional questions
- All responses from evaluations and outcomes assessments MUST be summarized
- Full evaluation and outcomes data must be stored for 6 years.

The Steps of Disclosure

- Reporting
 - The act of submitting disclosure to the activity organizers
- Managing
 - The review of these forms leading to a management decision by the accredited provider
- Transparency to learner
 - Disclosing relationships in advance of planning/learning
- Evaluation
 - Assessing the audience's and possible peer reviewer's perceptions
- Documentation of all steps

Disclosure

- The activity director(s) and planner(s) must include global disclosure as part of the applications
- Speaker disclosures must be submitted well in advance of the activity date so that management decisions can be made by our office. We prefer this to be 6-8 weeks ahead of activity.

2008-2012: New Standards

- Needs
 - Standards of care, gap analysis, barriers
- Objectives
 - Focus on application to practice, competency
- Design
 - Interactive, serial education, contracts to improvement

When Live Activity Takes Place

- Professionalism always – you represent NIH and Johns Hopkins
- Provide sign-in sheets—All participants must sign-in
- Provide handouts
 - Copies of each speaker's slides is a common approach
- Provide self-report forms for physician attendees -- their mechanism to obtain CME credit
- Collect evaluation forms and monitor the process

Record Keeping

- Planning notes
- Overall objectives & communication
- Lecture objective(s) & communication
- Activity Announcements or Marketing Material
- Disclosure report forms and evidence of provision to registrants
- Letters of agreement/Acknowledgment of Support
- Evaluations
- Outcomes
- CVs of all speakers
- Sign-in lists
- Documentation of peer review material when applicable
- Post-activity materials

Files must be saved for 6 years

Sign-In Documents

- Each participant must sign-in whether seeking credit or not
- Every activity must maintain sign-in documents for 6 years
- Sign-in will be submitted via excel spreadsheets which we will provide in templated version and made available on web
- Spreadsheet must include **all** attendees and indicate whether each is a physician or non-physician
- The sign-in excel spreadsheets should be emailed to CMETechSupport@jhmi.edu within 45 days of end of activity or to Rhonda Myers with all other activity materials, as all materials are due no later than 45 days after activity
- Certificates will be available on line

Sign-in Sheets

- Do not utilize a page with signatures scribbled on it
- Sign-in sheets have names typed on them for attendees to sign adjacently
 - A check mark is not adequate

LOAs/FINANCIAL

- When seeking commercial support, an LOA (letter of agreement) must be completed and signed by the Associate Dean for CME (JHU)
- Original will be sent to commercial supporter and a copy will be retained for the accreditation file
- Monies ***must*** come through our office
- LOA/MOUs are needed for all relationships, including involvement of a MECC or supporting company

Commercial Support from industry/
control on the content of the CME activity (SCS 1.1)

- CME providers can receive commercial support from industry. **CME providers cannot receive or request any advice or guidance, either nuanced or direct, on the content of the activity or on who should deliver that content from industry.** CME providers must ensure the content of the activity remains beyond the control of any commercial interest

Additional Items

- CVs of all speakers
- Speakers information regarding
 - FDA or non-FDA
 - Keywords
 - Core competency +

Embed into Presentation

- Collect Disclosure and objectives from speaker
- Obtain our sample slides from web
- Make a disclosure and objective slide for the speaker
- Send these to speaker and have them add to the beginning of talk
- Ask for confirmation that they are received and embedded

CME Certificate Tracking

- NIH support team or their MECC partner will submit to Hopkins OCME attendee list in excel format per provided templates
 - Materials must be submitted no later than 45 days after activity
- All attendees must be listed
- Physicians must fill out self report forms (required)
- Certificates can be printed from website

Marketing Rules

- All material must include
 - Activity Description
 - Intended audience
 - Objectives
 - Accreditation statement
 - Credit designation statement
 - Cannot say AMA credit applied for or to be announced
 - Policy on speaker and provider disclosure

OCME must review and approve all marketing material in advance of distribution and you should allow up to 5 days for this review

Accreditation Statement

This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of the Johns Hopkins University School of Medicine and the National Institutes of Health. The Johns Hopkins University School of Medicine is accredited by the Accreditation Council for Continuing Medical Education to provide medical education for physicians.

Credit Designation Statement

The Johns Hopkins University School of Medicine designates this educational activity for a maximum of *[number of credits]* AMA PRA Category 1 Credit(s)[™]. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Policy on Speaker and Provider Disclosure

It is the policy of The Johns Hopkins University School of Medicine that the speaker and provider disclose real or apparent conflicts of interest relating to the topics of this educational activity, and also disclose discussions of unlabeled/unapproved uses of drugs or devices during their presentation(s). The Johns Hopkins University School of Medicine OCME has established policies in place that will identify and resolve all conflicts of interest prior to this educational activity. Detailed disclosure will be made in the activity handout materials when appropriate.

Don't forget to disclose CRADAs

ACCME and The Johns Hopkins University School of Medicine Accreditation Policy(ies)

- The Accreditation Council for Continuing Medical Education (ACCME) policies do not permit an accredited activity to be subsequently or in parallel accredited by another organization. The Johns Hopkins University School of Medicine Office of CME has a policy that reflects this regulation.

Reminder

- NIH no longer issues certificates, Johns Hopkins does
- All materials are due to Johns Hopkins OCME no later than 45 days after last day of a “live” activity

Recent Rules

- An employee of industry, even if they are a part-time employee, may not speak at an accredited activity on the drug, device, topic or disease domain for which their company is involved
- By the end of 2010 speakers may not be involved in a Speaker's Bureau to qualify and we presently frown on their attendance

Process

- Our policies and forms must be followed completely
- Our policies and forms must remain unaltered in any fashion
- Our office must be involved in the decision for resolution of COI
- An activity is not approved until the date of approval
 - There is no such thing as retroactive approval
- All materials must be reviewed by our office
 - No changes to OCME brand or logo are permitted

Process

- Planning must involve our office AND the NIH Program officer
- Disclosure must come from the individual and be signed by them
- If we contact a NIH AD and they are unaware or unfamiliar with the activity at the level of the person in control, then we will likely need to refuse acceptance of such an activity

Process

- We are happy to receive suggestions for changes to processes or to our forms
- These suggestions should occur after the activity has concluded and should be in writing
- Most of our policies and forms are reviewed and edited on an annual basis. Suggestions may be utilized in the subsequent edit cycle.

Certification

- At the end of today you will be given an opportunity to attest to an understanding and acceptance of the material and thus will be eligible for certification
- Per the contract with the NIH, your accreditation can be revoked and you can be removed from an activity if the rules are not followed in a satisfactory manner.



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