



Tomorrow's Doctors, Tomorrow's Cures

Enhancing the Ethical Climate in Academic Medicine: *Conflicts of Interest and the Role of a Faculty Practice Plan*

Learn

Serve

Lead

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Group on Faculty Practice Annual Symposium

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Association of
American Medical Colleges

Academic Medicine and COI:





*Susan and
Conflicts of
Interest*

Kassandra

National Context for COI: JAMA, 4/16/08

- “The profession of medicine, in every aspect – **clinical, education, and research** – has been inundated with profound influence from the pharmaceutical and medical device industries.”
- “This has occurred because physicians have allowed it to happen, and it is time to stop.”
- “*Primum non nocere* . . . also holds true for all involved in medical research, biomedical publication, and medical education.”

More Context

- MedPAC (3/08) voting that public reporting of physician-industry financial relationships should be mandatory, citing “negative acculturation” of students and trainees
- Macy Foundation Report on CME
- Consideration of AMA CEJA Report at AMA Annual Meeting, June 16
- Consideration of Physician Payment Sunshine Act in Congress; AAMC endorsement of it
- Congressional concern about prescribing expensive, brand-name drugs and not generics, selection of devices
- Grassley’s latest letters -- to Zerhouni and to Presidents of Harvard, Mass General, Stanford, U.T.; more to come
- Deconstruction of various practice guidelines

Still More Context

- House and Senate appropriations bills directed NIH to implement new policies and regs to address COIs in research among extramural faculty
- Zerhouni testified before Congress this summer that some form of external accreditation or certification process is necessary for extramural COI programs (self-certification is no longer enough)
- ANPRM is on its way

Local Context

- AMC faculty are more accustomed now more than ever to outside earnings
- “Relevance” factor
- Importance of freedom to earn outside income in recruiting and retaining faculty
- Economy is in the tank
- Institutions are now talking about capping outside earnings at some level tied to clinical earnings/day; capping royalty payments

Change

- Wave of new policies on industry funding of medical education
- CME focus
 - 113,000 ACCME-accredited courses, activities, etc. in 07; 30% produced by medical schools
 - Medical schools' share of total CME income: \$428M, of which 63% (\$269M) derives from industry support
 - Memorial Sloan-Kettering, Stanford
- Focus on COI in clinical care

What's at Stake?

- Responsibility to Patients
- Institutional Integrity
- Personal Integrity
- Independence of Institutional and Individual Decision-Making
- Public Trust
- Ability/Capacity of Academic Medicine to Self-Regulate

AAMC and Enhancing the Ethical Climate

- AAMC Reports on Individual and Institutional COI (2001-02)
- Survey on Individual COI policies in AMCs (9/04)
- AAMC Symposium on the Emerging Science of Influence and Reciprocity (6/07)
- Survey on Institutional COI in AMCs (*JAMA*, 2/08)
- AAMC-AAU Advisory Committee on Conflicts of Interest in Clinical Research (2/08)
- AAMC Task Force on Industry Funding of Medical Education (6/08)

AAMC Current Activity: Symposium on the Emerging Science of Influence and Reciprocity, June 07

- Even small favors can influence choice and brain response in measurable ways
- Self interest can bias in unconscious ways
 - Seeking information selectively
 - Processing information in a biased way
 - Being unaware of effects of self interest
- People act unethically beyond their own awareness; “commonality of unintentional corruption”
- Gifts create reciprocal relationships

Report of the AAMC-AAU Advisory Comm. on COI in Human Subjects Research

- Published February 2008
- Three messages
 - Reaffirmation of 2001-2002 recommendations, with refinements
 - Necessity for more consistent policies and practices across academic institutions
 - Time is of the essence in fully implementing effective and comprehensive COI programs
- Three chapters
 - Individual COI, Institutional COI, and Implementation

Chapter 1: Individual COI Policies

- The Advisory Committee recognizes that many scientists who are engaged in HSR and have significant financial interests also have active clinical practices in which their financial interests may be problematic and warrant institutional oversight.
- *“Recommendation: Institutions should adopt policies and establish standards that minimize bias in the practice of medicine due to real or perceived conflicts of interest of their medical faculty.”*

Chapter 2: Institutional COI Policies

- All AAMC and AAU institutions should:
 - Develop ICOI policy covering FIs of institution and of institutional officials in HSR, including department chairs and division chiefs
 - Implement an ICOI reporting, evaluation, and management process and a credible review mechanism
 - *Complete policy development and implementation within 2 years of this Report*

Chapter 3: Implementation of COI Policies

- Practical advice: Detailed discussion of processes necessary for full implementation of comprehensive COI programs
- Analysis template: How to approach COI cases; the right questions to ask
- Management of COI: Toolkit approach

Public Perception Persists



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Task Force Background

- Research demonstrating that gifts and favors tend to influence the recipient in favor of the donor (Dana)
- Research showing that prescribing patterns are influenced by the receipt of drug samples (Chren)
- Research indicating that people are unlikely to think they're susceptible to being influenced but suspect their colleagues are (Dana)
- Meta analysis of clinical trials results showing that industry funding is associated with pro-industry results (Wazanza)
- Neurobiological (fMRI) evidence suggesting that gifts and sponsorships create reciprocal relationships, operating at the unconscious level (Montague)



Task Force Coverage

- Professionalism: Individual and institutional
- Gifts
- Pharmaceutical samples
- Site access by pharmaceutical reps
- Site access by device reps
- Continuing medical education
- Participation in industry-sponsored programs
- Industry-sponsored scholarships and other educational funds for trainees
- Food
- Professional travel
- Ghostwriting
- Purchasing

Recommendations

- AMCs should adopt policies recommended in TF Report to promote a learning environment that supports professionalism.
- To the extent that certain interactions with industry are prohibited within AMCs, they should also be prohibited off-site.
- AMCs should expect off-site training facilities to adhere to the standards of the AMC regarding interactions with industry.

Conflicts in Clinical Practice

- Types of interests that may be implicated
 - Equity holdings in vendor companies
 - Consulting, honoraria, or other payments from vendors
 - Royalties from inventions licensed to vendors
 - Service on SABs
 - Gifts
 - “Interests” deriving from clinical trial sponsorships
- Areas in which these interests are implicated, beyond “vendor policy” boundaries
 - Professionalism, hidden curriculum
 - Integrity and independence of decision making
 - Patients’ trust of providers and institutions

Expectations and Responses

- The Mayo Clinic experience: focus group research noted
 - Patients want information about institution's relationships with industry
 - They expect that the institution will manage them
- Mayo's response:
 - General disclosure in all patient materials
 - Specific disclosure by conflicted MD to pt
 - Documentation in MR?
 - Corroboration of Rx by colleague in MR?
 - Financial limits on outside earnings? Tiered?
 - Transfer of pt care to another colleague
 - Oversight committee?
 - Elimination of financial relationship?

Mayo Patient Information

“Mayo Clinic and its staff often collaborate with industry to improve patient care through research agreements, invention licenses, consulting activities, etc.

“Mayo Clinic’s Conflict of Interest Review Board oversees all such activities.

“Mayo Clinic and its staff members do not receive any royalties for inventions or technology developed at Mayo and subsequently prescribed for Mayo Clinic patients.

“If you have questions about Mayo’s relationships with industry, please ask your physician or contact the Office of Conflict of Interest Review at....”

Problem Areas

- Oversight of practice patterns (prescribing/implanting/etc.) and limited therapeutic options
- Reconciliation of publicly reported categories with what's reported internally and how it's reported
 - Payments or other transfers of value of any kind
 - to a physician or a physician medical practice
 - or to an entity at the request of or designated on behalf of that physician or physician practice
 - Consulting payments, gifts, entertainment, food, travel, education, research
- Explaining the differences to the public and to patients

Next Steps for the AAMC

- Grassley bill: Continuing to work with staffers on clarifications, ambiguities, misunderstandings
- MedPAC: Ditto
- Working with AAMC members
 - 2 year “deadline” on institutional COI in research policies
 - 1 year “deadline” on policies on industry funding of medical education
 - Needs assessment
 - CME focus
 - New task force/advisory committee on COI in clinical practice?
 - Development of more principled means of interaction with industry?

*This is
Chicken
Little*



*This is
Sisyphus*



*This is
A Dead
Duck*

