




# Individual and organizational financial relationships with industry: what do we know?

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# Acknowledgements

- n Research for this presentation is based on a paper prepared for the American Thoracic Society/European Respiratory Society.
- n Additional research based on a paper prepared for the World Health Organization, co-authored with Lisa Bero.
- n Workshop discussion participants at the Guideline Development Workshop, June 13-14, 2007, sponsored by American Thoracic Society/European Respiratory Society.
- n I have no financial relationships with any commercial entities.

# The Issues

- n Clinical practice guidelines ideally provide clinicians with impartial, evidence-based recommendations
- n Clinical practice guidelines should be free from outside biases and competing interests
- n Two important sources of bias:
  - u Commercial sponsorship of guideline development
  - u Conflicts of interest among guideline committee members

# Commercial Sponsorship

- n** Guideline development and maintenance is costly and labor-intensive-- who pays for this?
  - t** Professional society
  - t** Government
  - t** Third party non-profit organizations
  - t** Commercial sponsors

# Commercial Sponsorship

- n “The perception that a commercial entity, especially pharmaceutical or medical device companies, influenced the conclusions and recommendations of a practice guideline committee could undermine the credibility of both the guidelines and the group that produced it.” Cochrane Collaboration 2004

# Conflicts of Interest

- n A conflict of interest exists when an individual's secondary interests (financial) have the potential to compete with primary interests or obligations (impartial evaluation of evidence)
- n The integrity of clinical guidelines and the process that produced them may be threatened by conflicts of interest, especially when individual committee members have personal financial interests with companies developing or marketing the products under review

# Questions to address

- n What do we know about:
  - n Funding of clinical guidelines
  - n Risks associated with commercial sponsorship
  - n Disclosure of funding sources

# Questions to address

- n What do we know about:
  - n Financial ties of committee members
  - n Risks associated with members' conflicts of interest
  - n Management of conflicts of interest
  - n Enforcement of conflicts of interest policies

# Methods

- n Review of direct evidence
- n Review of related (indirect) evidence
- n Select survey of policies and procedures of professional societies and other guideline-producing groups

# Results

- n Very little direct evidence regarding practice guidelines
- n Consistent evidence from studies of research funding and conflicts of interest of investigators
- n Little evidence of 'best practices' for disclosing, evaluating, and managing conflicts of interest
- n Most professional societies and other guideline-producing groups are overtly addressing concerns about possible bias

# Funding of clinical practice guidelines

- n No systematic evidence investigating funding of clinical guidelines
- n Most commonly funded through:
  - n Medical specialties/professional societies
  - n Independent groups (Cochrane, NICE, ARHQ, WHO)
- n Role of commercial sponsors:
  - n Complete prohibition (Cochrane, ECRI, NICE)
  - n Unrestricted fund (WHO, ACCP)
  - n Multiple funders

# Risks of commercial sponsorship

- n Little systematic evidence regarding commercial sponsorship of guideline committees
- n Lurie et al (2006) – FDA advisory committees members disclose financial interests but are rarely dismissed; weak association between conflicts and voting behavior
- n Eichacker et al (2006) – Eli Lilly and sepsis campaign

# Risks of commercial sponsorship

- n Abundant evidence regarding commercial sponsorship of research:
  - u Commercially sponsored studies more likely to support the sponsors' products than non-commercially sponsored studies
    - t Across study types and medical specialties
- n Consistency of findings suggest industry involvement in research may influence published results
- n Is evidence behind evidence-based guidelines biased?
- n Is interpretation of this evidence biased?

# Disclosure of funding sources

- n Disclosure highly variable; often inadequate
- n 50-67% of practice guidelines studies did not report who was involved in the guideline development or the funding sources (Grilli 2000; Taylor 2005)
- n Adequacy of disclosures in scientific articles questioned
- n Even when financial relationships are disclosed, few studies describe the role of the sponsor in design, conduct, or reporting of results

# Financial Ties of Guideline Committee Members

- n Little evidence regarding financial ties of committee members
- n Different standards of disclosure -- Variation along many dimensions:
  - u When and how often to disclose? How much detail?
  - u Period covered by disclosure? Who covered?
- n 3 models of disclosure:
  - u Minimal: “Please disclose all related financial interests ...”
  - u Structured: “Describe consulting, employment, etc.”
  - u Checklists

# Significant Conflicts of Interest

- n Few precise specifications of disqualifying or prohibited relationships
- n 4 approaches; little consistency:
  - u No relationships a priori disqualifying (most)
  - u No ties, with exceptions (AAMC: “rebuttable presumption clause”)
  - u Disqualifying relationships: No stock ownership or income >\$10,000 or other factors (CARI; AACCP)
  - u Alternative model: no financial ties on decision-making panel (NIH Consensus Dev. Program)

# Managing conflicts of interest

- n Few explicit descriptions or management criteria
- n Disclosure most common, but adequacy challenged
  - n Papanokolaou et al (2001); Choudry et al (2002); Nature (2005)
- n Possible range of management strategies:
  - u Disclosure
  - u Management (reducing equity, eliminating income)
  - u Recusal from voting
  - u Excused from committee

# Review and Enforcement

- n Few groups have enforcement power beyond dismissal from committee if interests not disclosed
- n Review may be single or multi-step process
- n Appeal process?

# Summary and Discussion

- n Professional societies and other organizations currently depend, at least in part, on commercial sponsorship of guidelines
- n Many members of guideline committees have financial relationships with commercial entities
- n Existing models for insulating guideline committees from external biases are varied and, as yet, unstudied in a systematic way
- n Public perception is critically important – perception of risk is key

# Model of Risk Perception

- 1) Commercial Sponsorship + Financial Ties à High Risk à Management: Prohibited
- 2) Commercial Sponsorship + No Financial Ties à Moderate Risk à Management: Firewalls/General Fund
- 3) No Commercial Sponsorship + Financial Ties à Moderate Risk à Management: Balance of views/documentation of process
- 4) No Commercial Sponsorship + No Financial Ties à Low Risk à Management: None à IDEAL



# Discussion