



Methodology for Research in Medical Professionalism

Susan Chimonas, PhD
Research Scholar
IMAP/CMAP
Columbia University

How has IMAP researched Conflict of Interest (COI)

- Focus Groups
- Surveys
- Policy Analysis
- Fieldwork
- Content Analysis

Focus Groups

- What are focus groups?
 - Small group discussions on a specific topic.
 - 5-10 participants guided by a trained moderator.
- Why use focus groups?
 - Gather information from many people at one time.
 - Learn not just what people do or think, but also why or how: explore the logic underlying their beliefs or behaviors

Focus Groups

- Advantages
 - Cost effective
 - Allows participants to use their own words and concepts - not limited to language set by researchers
 - Participants can share ideas, elaborate on what other participants are saying
- Disadvantages
 - Minority opinions marginalized - possibility of “groupthink.”
 - Hard to generalize results

Physicians and Drug Representatives: Exploring the Dynamics of the Relationship

Susan Chimonas¹, Troyen A. Brennan², and David J. Rothman¹

¹Center on Medicine as a Profession, Columbia University, 630 West 168th Street, P&S Box 11, New York, NY 10032, USA; ²Aetna, Inc., Hartford, CT, USA.

BACKGROUND: Interactions between physicians and drug representatives are common, even though research shows that physicians understand the conflict of interest between marketing and patient care. Little is known about how physicians resolve this contradiction.

OBJECTIVE: To determine physicians' techniques for managing cognitive inconsistencies within their relationships with drug representatives.

DESIGN, SETTING, AND PARTICIPANTS: Six focus groups were conducted with 32 academic and community physicians in San Diego, Atlanta, and Chicago.

MEASUREMENTS: Qualitative analysis of focus group transcripts to determine physicians' attitudes towards conflict of interest and detailing, their beliefs about the quality of information conveyed and the impact on prescribing, and their resolution of the conflict between detailers' desire to sell product and patient care.

RESULTS: Physicians understood the concept of conflict of interest and applied it to relationships with detailers. However, they maintained favorable views of physician-detailer exchanges. Holding these mutually contradictory attitudes, physicians were in a position of

INTRODUCTION

One of the most pressing problems in American health care is conflict of interest. Medicine is now a \$2-trillion industry, and conflicts frequently arise when physicians' "interests or commitments compromise their independent judgment or their loyalty to patients."¹ Financial-incentive structures in managed care create potential conflicts between physicians' desire to maximize their income and the patients' best interests.² Researchers funded by industry face "an implicit demand for a positive finding to obtain further financial support."³

Among the most prevalent conflicts of interest are those arising from physicians' interactions with drug company sales representatives, or "detailers." Pharmaceutical companies employ about 90,000 detailers and spend over \$7 billion annually to market their products to physicians, averaging \$15,000 per year per physician.⁴ Prescribing decisions can become conflicted by free gifts, meals, travel, and other benefits. Because physician-detailer interactions bias medical decision-making, undermine public trust, and increase healthcare costs,⁵⁻¹⁰ the medical profession is now under unprecedented pressure to "recognize, disclose to the general public, and deal with conflicts of interest."¹¹

We sought to investigate the extent to which individual



Journal of General Internal Medicine, 2007

6 focus groups, with 32 physicians, to explore:

- Physicians' awareness and perceptions of COI
 - How do you define COI? What are some examples?
- Physicians' opinions on situations where COI might arise
 - Do you interact with drug company salespeople? Is this a COI? Why or why not?
- How to manage COI
 - Should you disclose COI to patients? Should interactions with industry salespeople be prohibited?



Journal of General Internal Medicine, 2007

Findings:

- Physicians understood the concept of conflict of interest and could apply it to hypothetical situations, such as interactions with industry salespeople.
- However, this knowledge did NOT prevent them from meeting with industry salespeople – they enjoyed the meetings and defended them as educational and good for patients

Journal of General Internal Medicine, 2007

Implications:

- Physicians had contradictory attitudes about physician-industry relationships – they understood the problem in theory, but did not apply it to their own interactions with industry.
- With this contradictory logic, physicians cannot be relied upon to regulate their own industry relationships.
- **Voluntary codes of conduct are insufficient.**
- **Prohibition may be necessary**

Surveys

- What is a survey?
 - Questionnaire or other instrument to collect quantitative or categorical information about a group or population
 - Different methods of collection: in-person, mail, online, telephone, etc.
- Why use a survey?
 - Study a sample to make inferences about the whole

Surveys

- Advantages
 - Simple and cost-effective (low cost per person)
 - Can be administered remotely
 - Efficient for gathering information from a large number of individuals
- Disadvantages
 - Response bias
 - Question design can limit accuracy of responses
 - Low response rates can limit data reliability

Managing Conflicts of Interest in Clinical Care: A National Survey of Policies at U.S. Medical Schools

Susan Chimonas, PhD, Lisa Patterson, MSc, Victoria H. Raveis, PhD, and David J. Rothman, PhD

Abstract

Purpose

Policy recommendations specify how academic medical centers should manage clinical conflicts of interest (CCOIs), including gifts and payments to physicians from pharmaceutical companies. However, no reliable data exist on the extent to which schools have policies to manage CCOIs. The authors sought to determine the extent and strength of medical schools' CCOI policies.

Method

A survey asked compliance officers at 125 MD-granting medical schools in the United States to indicate whether their institutions had policies covering 11

areas of CCOI and to provide copies of relevant policies. Policies were scored as 0 (no policy), 1 (permissive), 2 (moderate), or 3 (stringent), based on published recommendations. Each school's scores were averaged to create a measure of overall policy strength. The authors also collected information on schools' public/private status, hospital ownership/affiliation, and NIH funding to determine whether these characteristics were associated with differences in policy strength.

Results

A representative sample of 77 of 125 (62%) medical schools responded between October 2007 and December

2008. Absence of policy was the most frequent finding in 7 of 11 CCOI areas. The mean score for overall policy strength was 1.2. Greater NIH funding was associated with stronger policies in 9 areas.

Conclusions

This analysis provides a comprehensive overview of medical schools' CCOI policies. Wider adoption of CCOI policies is crucial to eliminate undue industry influence in clinical care and to preserve public trust in the medical profession. The authors close with a consideration of why so few medical schools have implemented strong policies.

Academic Medicine, 2011

- Questionnaires were sent to compliance officers at all 125 U.S. academic medical centers (AMCs)
- The survey asked whether the AMC had policies for different areas of COI – if the answer was “yes,” the survey asked the compliance officers to send IMAP the policies.
- Many “follow up” reminders to ensure good response rate

**DOES YOUR INSTITUTION HAVE FORMAL POLICIES
THAT COVERS THE FOLLOWING AREAS?
(PLEASE CHECK ONE FOR EACH CATEGORY.)**

PLEASE ATTACH ALL RELEVANT POLICIES.

Category	Yes	No	In progress/ under consideration
1: Gifts to healthcare providers from drug/device vendors			
2: Meals paid for by companies			
3: Drug or device representative access			
4: Drug samples to physicians			
5: Conflict of interest among P&T committee members			
6: Industry funding of continuing medical education			
7: Faculty consulting or speaking honoraria from industry			
8: Industry gifts for scholarships, fellowships and travel funds			

Academic Medicine, 2011

- Response rate 62% (77/125) - representative sample
- “No policy” was the most common result
 - Even the best regulated areas— gifts and consulting— had “no policy” rates of 25% and 23%,.
 - Ghostwriting was the most neglected policy area: 70% of AMCAs in our sample had no policy for this practice
- “In progress” responses were also common (17% to 29%) – this indicates changes to come.

Policy Analysis

- What is policy analysis?
 - Close, systematic reading of policy texts
 - Use a codebook to ensure consistent analysis
 - Use multiple coders – compare their codes to test reliability of codebook
- Why conduct policy analysis?
 - To understand, compare, or contrast policies
 - To make recommendations for better policies: identify gaps, inconsistencies, or other flaws

Policy analysis

- Advantages
 - Gives a detailed understanding of policies
 - Allows policies and organizations to be compared based on policy qualities
- Disadvantages
 - Time consuming
 - Hard to create a codebook with high inter-coder reliability
 - Necessary to update codebook over time, as policies change

Academic Medicine, 2011

- IMAP designed a coding system to gauge the strength of schools' COI policies:
 - 0 = no policy
 - 1 = permissive
 - 2 = moderate
 - 3 = stringent
- All policies independently coded by two researchers— high inter-coder reliability

Supplemental Digital Table 1

Codebook for Assessing the Strength of Medical Schools' Clinical Conflict of Interest Policies*

Response	Code	Example
Gifts		
Stringent – No gifts or payments permitted, regardless of dollar amount (best practice)	3	
Modest restrictions – Imposes some limits on gifts	2	Value of gifts accepted may not exceed a specific dollar amount per year; educational gifts are permitted
Permissive/weak – No restrictions on gifts; disclosure of gifts may be suggested or required	1	All gifts are permitted; cumulative value of gifts during a specified time period may be reported
No policy	0	
Meals		
Stringent – No meals permitted on campus; industry grants for food are funneled to a central repository (best practice)	3	
Modest restrictions – Puts some limits on meals	2	Acceptance of certain foods permitted; food may be directly accepted by staff for CME and educational events
Permissive – No restrictions on meals	1	Staff may accept any food provided by industry
No policy	0	
Vendor access		
Stringent – Vendors require registration, appointments, and badges; they are not permitted in public/patient-care areas; they must undergo training/orientation (best practice)	3	
Modest restrictions – Puts some limits on vendor access	2	Vendors are permitted with some conditions: may only require appointments OR badges OR registration
Permissive – No restrictions on vendor access; interaction left to the discretion of physicians or departments	1	Vendors are permitted without conditions; may require staff escort
No policy	0	
Samples		

Academic Medicine, 2011

Findings:

- The majority of AMCs who submitted policies through our survey did NOT have policies of adequate strength.
- AMCs must do more work to ensure their policies meet recommended standards

Fieldwork

- What is fieldwork?
 - Research conducted at locations of interest
 - Can involve interviews and/or observation (e.g. watching behavior and interactions)
- Why conduct fieldwork?
 - Provides in-depth data about the location that would not be accessible through other methods
 - Shows what people do and say in the environment

Fieldwork

- Advantages
 - In-depth data
 - Comprehensive data: easier to get many different perspectives in a single visit
- Disadvantages
 - More expensive than surveys or focus groups
 - Must gain physical access the location, which can be difficult

“Promoting Policy Change at AMCs,” 2011-present

- IMAP is now conducting fieldwork at 15-20 AMCs to learn about COI policy change
- At each AMC, 15-30 interviews with faculty, deans, compliance officers, and others:
 - How were policies developed?
 - What is working well? What needs improvement?
 - What are the barriers to progress?
 - What might help overcome the barriers?
- All interviews will be analyzed (content analysis)

Content Analysis

- What is content analysis?
 - A technique for developing a **quantitative** description of **qualitative** content.
 - The researcher codes texts for significant words, phrases, concepts and themes, which are then quantified and analyzed.
- Why use content analysis?
 - To systematically extract data from textual information (e.g., transcripts from interviews).

Content Analysis

- Advantages
 - Allows for quantitative analysis of qualitative data
 - Distills large amounts of information into more manageable themes and trends
- Disadvantages
 - Time consuming
 - Can be difficult to account for context
 - Can be difficult to develop an effective coding schema

Many methods for COI research

- IMAP used focus groups to explore physicians' thinking about COI
- IMAP used surveys and policy analysis to assess COI policies at AMCs in the U.S.
- IMAP is using fieldwork and content analysis to understand the process of COI policy change at AMCs

Many methods for COI research

- In sum, different methods can be used to study COI
- All have strengths and weaknesses
- The choice of technique will depend on the research question:
 - What do you want to learn?
 - Which method(s) would be best for this purpose?



Thank You!