

The role of institutional policy

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What is institutional policy?

- Policies are the written or unwritten guidelines that governments, organizations and institutions, communities, or individuals use when responding to issues and situations
- Policy is more than a set of rules, it also includes knowing how to apply the rules and having the motivation and strength to behave in a certain manner

Why to change policies?

- Policies are the basis for decisions
- Attempting to change policies can start a conversation about the issues in question
- Changing policy is easier in the long run than fighting the same battles over and over again
- Changed policies can change people's minds and attitudes
- Policy change is one path to permanent social change

Policy analysis

- What is the current practice (what policies/regulations are in place)?
- What are the policy gaps and areas in need of improvement?
- How do those impact the practice?
- What are the necessary changes?
- How to implement the policy?

Policy analysis

J.P.Lester & J.Stewart , 2000

- (1) Agenda setting
- (2) Policy formulation
- (3) Policy implementation
- (4) Policy evaluation
- (5) Policy change and termination

Change agents

Who should/will initiate and implement policy changes?



Stakeholders

Stakeholder group	Definition
Primary Stakeholders	<ul style="list-style-type: none"> • Those who are ultimately affected, ie who expect to benefit from or be adversely affected by the intervention • Those with high power and interest
Secondary Stakeholders	<ul style="list-style-type: none"> • Those with intermediary role. • Those with high interest but low power , or high power but low interest



Students are a force!!!

Case study

- In 2002, the Association of American Medical Colleges released policy recommendations regarding institutional conflicts of interest
- Four years later, these policy recommendations had only been implemented by 38% of US medical colleges

AMSA PharmFree Scorecard

- *Scorecard* is ranking of US medical schools' policies on pharmaceutical company access and influence
- It is based on evaluation of COI policies and curricula



AMSA Scorecard 2014

Methodology

- In-depth assessments of individual policies that govern industry interaction between students, faculty, and the pharmaceutical and medical device industries
- Uses letter grades to assess schools' performance in fourteen potential areas of conflict of interest
A \geq 85%, B = 70%–84%, C = 60%–69%, D = 40%–59%, F < 40%. Non-reporting institutions received a grade of F.

Methodology

- Policies are rated on each of the domains, using the following general format
 - 3 = Model policy
 - 2 = Good progress toward model policy
 - 1 = Policy is absent or unlikely to have a substantial effect on behavior
- Uses letter grades to assess schools' performance in fourteen potential areas of conflict of interest
 - A \geq 85%, B = 70%–84%, C = 60%–69%, D = 40%–59%, F < 40%. Non-reporting institutions received a grade of F.

Policy domains (2014)

1. Gifts from industry
2. Meals from industry
3. Industry-sponsored promotional speaking relationships
4. Industry support of CME
5. Attendance of industry-sponsored promotional events
6. Industry-funded scholarships and awards
7. Ghostwriting and honorary authorship
8. Consulting and advising relationships
9. Access of pharmaceutical sales representatives
10. Access of medical device representatives
11. COI disclosure
12. Existence of an adequate COI medical school curriculum
13. Extension of COI policies to adjunct/courtesy faculty and affiliated hospitals/clinics
14. Enforcement and sanctions of policies
15. (Pharmaceutical Samples)
16. (Purchasing & Formularies)

Compare Institutions

Select the institutions below and click "Go" to compare.

	Grade	Gifts	Meals	Speaking relationships	CME	Promotional events	Scholarships and awards	Ghostwriting	Consulting	Sales reps	Device reps	Disclosure	COI curriculum	COI policy extension	Enforcement
<input type="checkbox"/> California, San Francisco, School of Medicine San Francisco, CA	A	●	◐	●	○	◐	◐	●	◐	●	●	●	◐	●	●
<input type="checkbox"/> University of Central Florida College of Medicine Orlando, FL	A	●	◐	●	○	◐	◐	●	◐	◐	●	●	●	●	●
<input type="checkbox"/> University of Florida College of Medicine Gainesville, FL	A	●	●	●	○	◐	◐	●	◐	◐	●	●	●	◐	●
<input type="checkbox"/> University of Michigan Medical School Ann Arbor, MI	A	◐	●	●	●	◐	○	●	●	◐	●	●	◐	◐	●
<input type="checkbox"/> Vanderbilt University School of Medicine Nashville, TN	A	●	◐	●	◐	◐	◐	●	◐	◐	◐	●	●	●	●
<input type="checkbox"/> Albert Einstein College of Medicine-Yeshiva University New York, NY	B	●	◐	●	◐	◐	○	●	◐	◐	●	●	◐	●	●
<input type="checkbox"/> Boston University School of Medicine Boston, MA	B	●	●	●	◐	◐	◐	●	◐	◐	◐	●	◐	◐	●
<input type="checkbox"/> East Tennessee State University James H. Quillen College of Medicine Johnson City, TN	B	●	◐	●	◐	●	◐	●	◐	◐	●	◐	◐	◐	●

Gifts

Background: Numerous published studies demonstrate that small and large gifts play a role in influencing prescribing decisions, which directly affect patients. Medical personnel consistently underestimate the extent to which they personally are influenced.

3 = All gifts funded by industry are prohibited, regardless of nature or value.

2 = Gifts allowed but only if value \leq \$10 or if the gifts are limited to educational items for physicians such as textbooks.

1 = Gifts allowed of value above \$10 or no restriction specified.

Meals

Background: Like gifts, studies have shown that free meals can influence prescribing decisions.

3 = No industry-funded meals of any nature or value allowed.

2 = Meals allowed but only if:

(a) the value of the meal is \leq \$10,

(b) or when provided at industry-funded accredited CME events,

(c) or when provided on-site as part of an indirect grant from industry

1 = Meals allowed of value above \$10 or no restrictions specified

Disclosure

Background: Disclosure is an important component of COI policies. Faculty should be transparent about any financial relationships that could potentially influence their clinical and educational duties.

3=Policy requires both of the following types of disclosure:

- (a) Internal disclosure to the institution, and
- (b) Disclosure to trainees/audiences

2=Policy requires at least one of the following:

- (a) Internal disclosure to the institution,
- (b) Disclosure to trainees/audiences

1=No form of disclosure required, or no policy

COI Curriculum

Background: A formal curriculum on COI aims to teach medical students how to prevent marketing activities from inappropriately influencing their treatment decisions.

3=COI curriculum/education is required for medical students. It must reflect and cover most of the curricular content and objectives in the AMSA standards

2=COI curriculum/education is required for medical students but it is more limited.

1=No COI curriculum/education for medical students is required or there is no policy in place.

Scholarships and awards

Background: Industry frequently provides funding to support students attendance at medical conferences.

3=Industry support for residents and medical students to attend conferences or trainings is prohibited

2=Industry support to attend conferences or trainings is allowed, but there are one or more safeguards in place to ensure the funds are not used by the company to establish a marketing relationship with the trainee. An example of such a measure may include selection of recipients through a competitive process managed by the dean or university administration.

1=Industry support is allowed without stipulations or there is no policy.

Ghostwriting and honorary authorship (2014)

Background: Physicians rely on the information they read in journal articles to make prescribing decisions, and they should be able to trust that any recommendations made reflect the research and opinions of the authors and not the hidden influence of writers hired by industry.

3=Industry-funded ghostwriting and honorary authorship are strictly prohibited.

2=The practice is discouraged, but not prohibited.

1=No policy.

Access of sales reps

3=Pharmaceutical sales representatives are not allowed access to any faculty or trainees in academic medical centers or affiliated clinical entities. However, faculty may invite other industry scientists who are not acting as sales representatives for specific discussions that do not involve marketing a specific product.

2=Pharmaceutical representatives are allowed to meet with faculty and the following two criteria must be met:

- (a) meetings must take place only in non-patient care areas and
- (b) meetings must take place by appointment only.

1=No policy, or a policy that does not substantially limit access.

Enforcement and sanctions (2014)

- A perfect score requires general oversight to ensure compliance with policies and sanctions for noncompliance



AMSA PharmFree Scorecard

- Official policies do not always correspond to day-to-day reality
- Policy Communication & Compliance Feedback
 - Are the policies being followed?
 - What changes have happened or have not happened since the policies went into effect?
 - To what extent do people in the university community know about these rules?

AMSA PharmFree Scorecard

- In 2007 the AMSA found that only 21 of 150 medical schools had adequate policies
- Harvard Medical School has launched a review of its ethics policies, under pressure from students there who thought that pharmaceutical industry's influence has become too pervasive
- The F that Harvard received on AMSA's was because they had what they call long-standing institution policies that were not written down anywhere



A Harvard medical student protests the school's flunking grade



A Harvard medical student signs a "pharm-free pledge" promising not to accept gifts or entertainment from drug and medical device companies

Discussion

Is it enough to require faculty members to reveal their financial dealings with drug and device makers, not avoid them altogether?

"It's not that you want your wife, when she's being unfaithful to you, to disclose that to you. You want her to stop being unfaithful to you. That's the root of the issue."

Dr. Adam Urato

Discussion

"There's a study that shows that when people disclose, they often feel that they've kind of washed their hands of that, and then can go about and provide perhaps even more biased or influenced information at that point"

Dr. Adam Urato

Results

- In 2007 the AMSA found that only 21 of 150 medical schools had adequate policies (
- In 2014 of the 161 US medical schools, 25 received “A”s (15%), 83 “B”s (52%), 26 “C”s (16%), and 26 Incompletes (16%)

Question

If your University is evaluated according to these criteria what will be the grade?