

Symposium organisé par la PMU « Les enjeux d'un conflit d'intérêt en recherche clinique » Jeudi 5 février 2015 PMU, CHUV

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Quelle est l'importance d'une déclaration de conflit d'intérêts ?

Contenu

- Quelle est l'importance d'une déclaration de conflits d'intérêts
 - Qu'est-ce qu'un conflit d'intérêts ?
 - En quoi cela pose-t'il un problème éthique ?
 - Pourquoi déclarer un conflit d'intérêts ?
- II. Comment apprécier un conflit d'intérêts
- III. Approches complémentaires à la déclaration de conflit d'intérêts

Un souci pour les éditeurs...

Angell M. Is academic medicine for sale?. N Engl J Med 2000; 1516-1518

The New England Journal of Medicine

Editorials

IS ACADEMIC MEDICINE FOR SALE?

TN 1984 the *Journal* became the first of the major I medical journals to require authors of original research articles to disclose any financial ties with companies that make products discussed in papers submitted to us.1 We were aware that such ties were becoming fairly common, and we thought it reasonable to disclose them to readers. Although we came to this issue early, no one could have foreseen at the time just how ubiquitous and manifold such financial associations would become. The article by Keller et al.2 in this issue of the Journal provides a striking example. The authors' ties with companies that make antidepressant drugs were so extensive that it would have used too much space to disclose them fully in the Journal. We decided merely to summarize them and to provide the details on our Web site.

Finding an editorialist to write about the article presented another problem. Our conflict-of-interest policy for editorialists, established in 1990,³ is stricter than that for authors of original research papers. Since editorialists do not provide data, but instead selectively review the literature and offer their judgments, we require that they have no important financial ties to companies that make products related to the issues they discuss. We do not believe disclosure is enough to deal with the problem of possible bias.

The ties between clinical researchers and industry include not only grant support, but also a host of other financial arrangements. Researchers serve as consultants to companies whose products they are studying, join advisory boards and speakers' bureaus, enter into patent and royalty arrangements, agree to be the listed authors of articles ghostwritten by interested companies, promote drugs and devices at company-sponsored symposiums, and allow themselves to be plied with expensive gifts and trips to luxurious settings. Many also have equity interest in the companies.

Although most medical schools have guidelines to regulate financial ties between their faculty members and industry, the rules are generally quite relaxed and are likely to become even more so. For some years, Harvard Medical School prided itself on having unusually strict guidelines. For example, Harvard has prohibited researchers from having more than \$20,000 worth of stock in companies whose products they are studying.6 But now the medical school is in the process of softening its guidelines. Those reviewing the Harvard policy claim that the guidelines need to be modified to prevent the loss of star faculty members to other schools. The executive dean for academic programs was reported to say, "I'm not sure what will come of the proposal. But the impetus is to make sure our faculty has reasonable opportunities."7

Academic medical institutions are themselves growing increasingly beholden to industry. How can they justify rigorous conflict-of-interest policies for individual researchers when their own ties are so extensive? Some academic institutions have entered into partner-



Qu'est-ce qu'un conflit d'intérêts?

Définition:

A conflict of interest is a set of circumstances or conditions that creates a risk that professional judgement or actions regarding a primary intersest will be unduly influenced by a secondary interest

Lo and Field, 2009; Emanuel and Thompson, 2008

•Intérêt-s primaire-s → profession/rôle professionnel (buts, obligations, droits)

ex. bien-être du patient, intégrité de la recherche, etc.

- •Intérêt-s secondaire-s → intérêts financiers, liés à la carrière, reconnaissance de ses mérites, bénéfices à son entourage, etc.
- Des conflits ubiquitaires, parfois inévitables, souvent acceptables...

En quoi cela pose-t'il un problème éthique?

- Circonstances/situations qui augmentent le risque de biais
 - conflit potentiel = risque réel de biais
- Risque de biais
 érosion de la confiance du public préjudices (santé, environnement, etc.)
- Biais en recherche: du déroulement de la recherche, à ses résultats, à leur communication aux pairs
- Plus la frontière entre intérêt-s primaire-s et secondaire-s devient ténue, plus le risque de biais augmente
- Conflit d'intérêts ≠ comportement incorrect : tendance à minimiser/ne pas déclarer ses conflits d'intérêts

Pourquoi déclarer un conflit d'intérêts?

Déclarer les conflits d'intérêts afin de :

- Maintenir l'intégrité de la recherche/la confiance du public
- Assurer la transparence du système (cohabitation entre intérêt-s primaires et secondaires)

Destinataires de la déclaration :

- •Toute personne pouvant être affectée par les résultats de la recherche aura accès aux informations utiles pour juger de son intégrité
- •Reviewers : demande de fonds, protocole de recherche, publications
- Comités institutionnels pour l'évaluation de conflits d'intérêts,
 CER, éditeurs, lecteurs participants aux essais cliniques ?

Déclarations : quelques évidences

Sah S, Loewenstein G. Psychological Science 2014; 25(2): 575-584

ODS
ASSOCIATION FOR
PSYCHOLOGICAL SCIENCE

Research Article

Nothing to Declare: Mandatory and Voluntary Disclosure Leads Advisors to Avoid Conflicts of Interest

Psychological Science 2014, Vol. 25(2) 575–584 © The Author(s) 2013 Reprints and permissions: sagepub.com/journalsPermissions.nav DOI: 10.1177/0956797613511824 pss.sagepub.com

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with real monetary stakes. These results show that, although disclosure has generally been found to be ineffective for dealing with unavoidable conflicts of interest, it can be beneficial when providers have the ability to avoid conflicts. Mandatory and voluntary disclosure can deter advisors from accepting conflicts of interest so that they have nothing to disclose except the *absence* of conflicts. We propose that people are averse to being viewed as biased, and that

Abstract

Professionals face conflicts of interest when they have a personal interest in giving biased advice. Mandatory disclosure—informing consumers of the conflict—is a widely adopted strategy in numerous professions, such as medicine, finance, and accounting. Prior research has shown, however, that such disclosures have little impact on consumer behavior, and can backfire by leading advisors to give even more biased advice. We present results from three experiments with real monetary stakes. These results show that, although disclosure has generally been found to be ineffective for dealing with unavoidable conflicts of interest, it can be beneficial when providers have the ability to avoid conflicts. Mandatory and voluntary disclosure can deter advisors from accepting conflicts of interest so that they have nothing to disclose except the *absence* of conflicts. We propose that people are averse to being viewed as biased, and that policies designed to activate reputational and ethical concerns will motivate advisors to avoid conflicts of interest.

Déclarations : quelques évidences

Jagsi R et al. *Cancer* 2009; 2783-2971
Frequency, Nature, Effects, and
Correlates of Conflicts of Interest in
Published Clinical Cancer Research

Table 1. Funding Sources and Conflicts of Interest in Original Cancer Research Publications Appearing in Selected Journals in 2006

	No. of Oncology Studies	% With Conflict of Interest	% Declaring Industry Funding	% Declaring Government Funding	% Declaring Private Philanthropic Funding
Overall	1534	29	17.	50	29
Cancer	602	16	11	38	27
Clin Cancer Res	144	40	25	52	40
JAMA	27	44	19	78	22
JCO	565	39	23	50	30
JNCI	123	20	6	89	33
The Lancet	8	38	25	63	38
The Lancet Oncology	34	35	18	41	38
NEJM	31	61	39	77	10

research effort from industry merit further attention, and journals should embrace both rigorous standards of disclosure and heightened scrutiny when conflicts exist. Cancer 2009;115:2783-91. © 2009 American Cancer Society.

KEY WORDS: conflict of interest, neoplasms, research, publications.

Que déclarer ? : exemples



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Declaration of interests form for authors submitting editorials and education articles to The BMJ

I declare that I have read and understood BMJ policy on declarations of interest. [Please add "X" next to either item 1 or 2:]

1. I have the following relevant interests to declare, according to the policy, for the preceding 36 months and the next 12 months from today [please complete the table, including interests that may influence or appear to influence your writing of this article]:

Type of relationship	What is the name of the organisation?	What is the organisation's role?	relate to article topic?	Is there a contractual agreement to disseminate product information?	Payments to you? Yes/No	Payments to your institution? Yes/No
Board membership (when describing the funding body's role, please mention the type of board e.g. advisory board.)						
Example: Advisory board	AA company	Produces pharmaceuticals for XYZ disease	Article will mention commonly used drugs produced by this company and by others	N	Y	Y
Consultancy (when describing the funding body's role, please describe the nature of the consultancy.)						
Employment				Y/N	Y/N	Y/N
1 2				Y/N Y/N	//////////////////////////////////////	//////////////////////////////////////
Expert testimony				Not applicable	Y/N	Y/N

Apprécier un conflit d'intérêts : points de repère

Emanuel E, Thompson DF. The concept of conflict of interest. In: *The Oxford textbook of clinical research ethics* 2008; 758-766

Table 69.1 Likelihood and Seriousness in Evaluating Conflicts of Interest

Standard	Considerations	Examples			
Likelihood	Value of the secondary interest	 The size of the investment relative to the overall income of a researcher or an institution 			
		 The structure of the incentives 			
		 The importance to the research 			
	Scope of conflict	 Is the arrangement a one-time interaction or a continuing relationship? A single payment for research support is not as risky as an ongoing investment in the company. 			
	Extent of discretion	 How much room there is for influence of secondary factors? The greater the number and importance of researchers' judgments the higher the likelihood of conflict. 			
Seriousness	Value of the primary interest	 The more central the research, the more risk if there is a conflict. 			
		 To what degree does a conflict affect the trust in other researchers? 			
	Scope of consequences	 What types of harms might result for research participants, the integrity of the study, or approval of a product? 			
		 What are the effects on the profession as a whole, or on research funding in general? 			
		 Will an institution's arrangements encourage others to do the same and further erode professional standards? 			
	Extent of accountability	 Are the potentially harmful outcomes discoverable by others and reversible? 			
		 Is there review by independent researchers or an outside body? 			

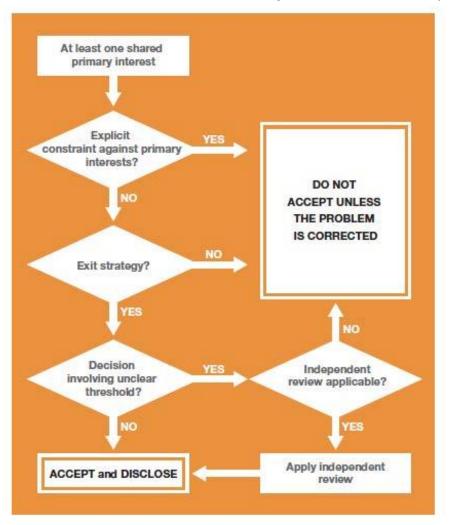
Apprécier un conflit d'intérêt : points de repère

Conflit d'intérêts ± important selon :

- 1.Probabilité que le jugement soit biaisé par l'intérêt secondaire
 - ✓ Valeur de l'intérêt secondaire ?
 - ✓ Étendue du conflit ?
 - ✓ Poids accordé au jugement professionnel ?
- 2.Gravité du préjudice (dommage, tort) qui pourrait découler du biais
 - √ Valeur de l'intérêt primaire ?
 - √ Étendue des conséquences du conflit ?
 - ✓ Marge d'accountability?

Identifier et gérer un conflit d'intérêts : une question de méthode

Hurst S, Mauron A. A question of method. The ethics of managing conflicts of interest. *EMBO reports* 2008; 9(2): 119-122



- I. Au moins un intérêt primaire partagé
- II. Réglementation applicable pour protéger l'intérêt primaire
- III. Exit strategy si les intérêts des partenaires divergent trop
- IV. Cas particulier : frontière trop ténue entre intérêts primaires et secondaires
 - Revue indépendante

Approches complémentaires à la déclaration

- Limites de la déclaration de conflit d'intérêts :
 - ✓ compréhension (ex. participants aux essais cliniques)
 - ✓ illusion de caution éthique
 - conflit d'intérêts concernant des institutions
- Approches complémentaires :
 - Management des conflits d'intérêts
 - Interdiction

Exemple d'interdiction de conflit d'intérêts

Chew M et al. *BMJ* 2014; 349:g7197

BMJ 2014;349:g7197 doi: 10.1136/bmj.g7197 (Published 28 November 2014)

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EDITORIALS

Medical journals and industry ties

Zero tolerance on education articles with financial links to industry

Mabel Chew practice editor, Catherine Brizzell head of education, Kamran Abbasi international editor, Fiona Godlee editor in chief

The BMJ, London WC1H 9JR, UK

The BMJ was one of the first medical journals to seek declarations of competing interests from authors. Our focus is on financial competing interests as we believe these to be the most identifiable. We do, however, understand that competing interests come in many forms and we also routinely ask authors to declare relevant non-financial competing interests. The governing principle has been that transparency is a panacea.¹

Financial competing interests are endemic to the culture of medicine and are rarely driven by malign motives or actions. The mechanisms of influence are diverse. An author of a review article might be an advisory board member for companies selling drugs for that condition, a commentator might have received honorariums from industry for lectures on the topic, or an editorialist on a disease might be a patent holder for one of its

Conclusions

- Conflit d'intérêts potentiel = risque réel de biais
- Déclarer un conflit d'intérêts pour garantir l'intégrité de la recherche, la confiance du public, la transparence du système
- Points de repère et méthodes pour identifier, évaluer et gérer les conflits d'intérêts
- Déclaration de conflit d'intérêts, nécessaire mais pas suffisante → approches complémentaires (management, interdiction)