

Conflitto di Interessi: la posizione della Consulta

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COI: una possibile definizione

Il conflitto di interessi è la condizione in cui un *interesse secondario* (finanziario o non finanziario) può interferire con *l'interesse primario* (principale), al cui perseguimento il decisore deve tendere, nell'ambito delle sue responsabilità.

COI: alcune riflessioni da cui partire

- E' utile tutelare l'interazione tra accademici e mondo aziendale, sia pur prevedendo l'interposizione di appropriate barriere protettive?

COI: alcune riflessioni da cui partire

- Una parte importante della ricerca scientifica, specie in ambito medico, è ormai resa possibile dai finanziamenti delle aziende del settore
- La ricerca di interesse aziendale è condotta, sempre più spesso, con la collaborazione di esperti esterni, di origine accademica
- Questa partnership può contribuire a mantenere elevato lo standard della ricerca aziendale, e ad orientarla verso i needs più rilevanti

VIEWPOINT

Confluence, Not Conflict of Interest Name Change Necessary

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The primary interest of the biomedical scientific endeavor is to benefit patients and society. Frequently, this primary interest coincides with secondary interests, most commonly financial in nature, at the interface of the investigator's relationship with a private sponsor, typically a drug or device company or, increasingly, venture capital firms. Academia and the public have become sensitive to how such a secondary interest might be unduly influential, biasing the interpretation of results, exposing patients to harm, and damaging the reputation of an institution and investigator. This concern has prompted efforts to minimize or "manage" such "conflicts of interest" resulting in a plethora of policies at both the local and national level. Although these policies are often developed in reaction to a limited number of investigators, once introduced, they apply to all. Given the broad array of stakeholders, the diversity of approaches, and the concern that such policies might restrain innovation and delay translation of basic discoveries to clinical benefit, the Institute for Translational Medicine

may be even more seductive than fortune. Thus, the outcome of a study may influence publication in a high-impact journal, invitations to speak at conferences, promotion, salary, and space. Even though an investigator may publicly eschew any direct financial reward from a sponsor, such fiscal and professional benefits may accrue to them indirectly from the institution, if they attract clinical trials with their attendant indirect costs. Estimation of how fame—which again may apply to institutions, funders, and journals—might introduce bias is a considerable challenge. However, even in the case of monetary gain, which can be readily quantitated, bias is complex.² A possible strategy is to consider a terrain-mapping approach to potential sources of bias. Much like a heat map of gene expression, a dashboard would express and give weight to elements of fame and fortune on the y-axis, charted against individuals and entities on the x-axis that are likely to gain from the endeavor. Experience would refine the approach over time. Disclosure of such information on institutional websites and its provision in consent forms to participants in trials

COI: implicazioni e problemi da affrontare

- E' giustificato considerare di valore limitato la ricerca e le opinioni dei ricercatori che collaborino con l'industria?

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- E' giustificato considerare di valore limitato la ricerca e le opinioni dei ricercatori che collaborino con l'industria?
- I ricercatori che collaborano con aziende devono essere esclusi dalla preparazione di rassegne, editoriali, linee-guida, ecc.?

The origin of the debate: Big Pharma and MD's dangerous liason

Revisiting the Commercial–Academic Interface

Jeffrey M. Drazen, M.D.

N ENGL J MED 372;19 NEJM.ORG MAY 7, 2015

ESSAY

Justifying conflicts of interest in medical journals: a very bad idea

A series of articles in the *New England Journal of Medicine* has questioned whether the conflict of interest movement has gone too far in its campaign to stop the drug industry influencing the medical profession. Here, three former senior *NEJM* editors respond with dismay

Robert Steinbrook *professor adjunct of internal medicine*¹, Jerome P Kassirer *distinguished professor*², Marcia Angell *senior lecturer on social medicine*³

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The origin of the debate: Big Pharma and MD's dangerous liason

Revisiting the Commercial–Academic Interface

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... many medical journal editors (including me) have made it harder and harder for people who have received industry payments or items of financial value to write editorials or review articles. ***The concern has been that such people have been bought by the drug companies.*** Having received industry money, the argument goes, ***even an acknowledged world expert can no longer provide untainted advice.***

But is this divide between academic researchers and industry in our best interest? I think not - and I am not alone.

The BMJ position:

A seriously flawed and inflammatory attack on conflict of interest policies and regulations appeared recently in a most unexpected location: the venerable and trusted New England Journal of Medicine (NEJM). In a series of rambling articles, one of the journal's national correspondents, Lisa Rosenbaum, supported by the editor in chief, Jeffrey Drazen, tried to rationalise financial conflicts of interest in the medical profession.

The concern is not whether physicians and researchers who receive industry money have been bought by the drug companies, as Drazen writes, or whether members of guideline panels or advisory committees to the US Food and Drug Administration with ties to industry make recommendations that are motivated by a desire for financial gain, as Rosenbaum writes.

The essential issue is that it is impossible for editors and readers to know one way or the other.

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Ma è veramente così?

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Critical issues with studies supported by Companies, and possible sources of bias:

- Design and Protocol, Study execution, Statistical Analysis of data, Interpretation of results:

all these section must be performed according to best standards in sponsored research and the referees of the journal to which the manuscript is sent for publication **must be able** to understand if everything has been done in a scientifically sound way

- Conclusion:

the referees **must be able** to understand if they are supported by data collected

A critical issue

- The scientific community should actively defend the concept that the quality of a paper must be evaluated independently of its funding, and that it is possible to make such an evaluation

I necessari interventi "protettivi"

- Va preclusa la possibilità da parte dello sponsor di promuovere modifiche del protocollo, una volta che esso sia stato definito.
- Va preclusa la possibilità di "non pubblicare" i dati, se difformi dalle attese e/o potenzialmente sfavorevoli per lo sponsor.
- Va preclusa la possibilità di non menzionare la sponsorizzazione nella reportistica dei risultati dello studio.
- Massima cautela quando sono in gioco decisioni con immediati riflessi economici

Possibili interventi protettivi

- Queste “clausole di salvaguardia” andrebbero chiaramente esplicitate in ogni contratto di collaborazione o consulenza tra un'azienda e una istituzione pubblica di ricerca o un singolo ricercatore esterno all'azienda.
- La valutazione degli articoli scientifici relativi a progetti di ricerca sponsorizzati dovrebbe essere effettuata da esperti non collegati in alcun modo all'azienda sponsor dello studio.

Riflessioni aggiuntive

- Il progresso scientifico tende ad "autopurificarsi" da errori (voluti o non voluti che siano)
- La necessaria riproducibilità del dato rappresenta, al proposito, un principio fondante, inamovibile ed irrinunciabile
- Le retraction, specie se causate da frode scientifica, macchiano irreversibilmente il curriculum e l'immagine dei ricercatori che ne sono colpiti

Are only financial COI relevant?

“Ideological” or “Career driven” COI

One appropriate example is the COI declared at the bottom of a recent editorial

- "The author is a member of the National Breastfeeding Committee and tends to be biased toward breastfeeding"

- I paletti predisposti per limitare i possibili effetti dei COI, nella collaborazione aziende-accademia, vanno rispettati in modo assoluto, ed applicati con rigore.
- **Se i COI verranno gestiti correttamente ed in modo trasparente dalla Comunità Scientifica, il criterio di riferimento potrà tornare ad essere quello generale: e cioè valutare gli esperti e i loro contributi sulla base del loro valore scientifico assoluto (e non di chi li ha finanziati).**