

# Conflicts of interest and an approach to managing them

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## ARTICLE INFO

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## ABSTRACT

Conflicts of interest (COI) exist in every step of life, including in medicine and science. Professionals who work in different areas of Health systems, such as physicians in care patient, in pharmaceutical and biomedical devices industries, in management positions, in teaching or in research, all must apply rigid ethical principles.

It is possible with these actions that COI were detected in several circumstances such as in the prescribing therapy, in production or employment of technology in services of Health system, in article publications, and in decision-making for those who have decided to occupy positions of responsibility in scientific and healthcare institutions, in industry or professional associations, among others. These actions must be consistent with the essential principles of Bioethics.

At present, COI disclosure has been irreversibly installed in Medicine. A detailed description of the classification of conflicts of interest and its ethical and legal implications in the practice of health sciences such as those that appear in the practice of clinical and laboratory medicine, pharmaceutical industry and also,

research and publications are included. Final considerations on the management of COI are also included.



Conflicts of interest (COI) exist in every step of life and in every corner of society, including medicine and science (1, 2). Professionals who work in different areas of Health systems, such as physicians in patient care, in pharmaceutical and biomedical devices industries, in management positions, in teaching or in research, must apply rigid principles even if their main objective is not to produce new knowledge as researchers are interested in. It is possible with these actions that COI were detected in several circumstances such as in the act of prescribing a therapy (3), in production or employment of technology in services of Health system, in article publications, and in decision-making for those who have decided to occupy positions of responsibility in scientific and healthcare institutions, in industry or professional associations (4- 6) among others. These actions must be consistent with the essential principles of Bioethics in the field of Health that are implicit in documents and fundamental principles such as those arising from the Helsinki declaration, the Belmont report and others (7-10). This is extended to modern and serious societies where justice and social ethics require absolute transparency in decision-making involving third parties (11).

When the term COI is analyzed in a search database such as Pubmed (12), it appears registered – as part of the title – between 1962 and 2018 there are 1,288 registered articles, with a sustained increase. It was noted though that it obtained more relevance in the field of medicine from the 80s. This shows that COI consideration has been irreversibly installed. In this article several aspects pertaining to conflict of

interest, in terms of its definition, classification, applications, management and other challenges are described.

## DEFINITION OF THE CONCEPT

Sometimes the term is used unclearly or used as a prejudice that leads to anticipated moral condemnation. It is necessary to have a more flexible look since the presence of a conflict of interest is a situation that appears frequently and sometimes it is not possible to avoid that other people were involved. Therefore, biased conclusions can be drawn to qualify a behavior as reprehensible when in facts it is not. So it is essential to review and adjust its meaning. According to the Thompson definition (13), COI “is a set of conditions in which professional judgment concerning a primary interest tends to be unduly influenced by a secondary interest.” It can also be defined as a situation where a judgment or action that should be determined by a primary value established for professional or ethical reasons (protection of research subjects, production of safe knowledge, adequate assistance to the patient), may be influenced or appear skewed to obtain a secondary benefit.

For example, a person in a high professional position is in a COI when the decision he/she has to take may affect his/her personal interests, of an economic or professional nature, as his/her decision could attract benefit or harm to those interests. For a better understanding of the nature of personal interests, Table 1 enumerates an ordered description of different types of factors involved besides own interests (relatives, affective and professional relations).

The term conflict of interest is a moral concept that means a challenge to the behavior of those who have an obligation or a duty that collides with a personal interest. Such interest can therefore distort a judgment in an irrational or unacceptable way, thus creating a mantle of

suspicion if justice has been damaged (11,13). In other words, it is the person's actions in the context of a particular situation that may be a cause for concern (14).

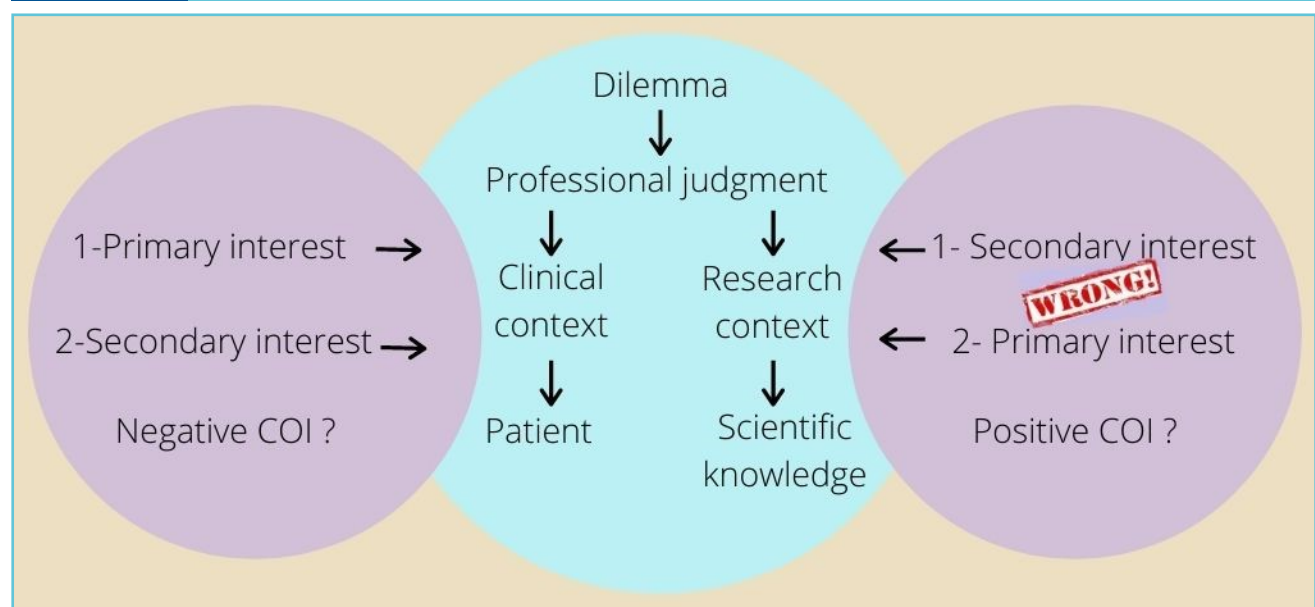
Accordingly, the ethical dilemma that the presentation of a COI entails has more to do on

how to proceed and resolve the conflict since the appearance of a COI does not imply by itself reprehensible conduct or taking a reprehensible position by the professional involved. The challenge is the management and resolution of the dilemma (Figure 1).

**Table 1** Classification of personal interests

a)	Own interests.
b)	Family interests, including close relatives or persons with whom the professional lives in a relationship of affectivity and relatives within the fourth degree of consanguinity or second degree of affinity.
c)	Interests of persons with whom the professional has a dispute pending.
d)	Interests of persons with whom they have close friendship or manifest enmity.
e)	Interests of legal persons or private entities with whom the professional has been related by an employment or professional relationship of any kind in previous years.
f)	Interests of legal persons or private entities to which professional relatives mentioned in point (b) are related by an employment or professional relationship of any kind, provided that it implies management, advisory or administration functions.

**Figure 1** Scheme for decision making to solve dilemmas



**DIFFERENTIAL CHARACTERISTICS OF THE CONCEPT**

At this point it is convenient to start by asking ourselves what we are talking about in professional terms or in a colloquial environment when we say COI since it is possible to give it a meaning that is not appropriate. A particular situation may arise when there is a dispute over “conflicting interests” between two or more persons or entities, for example in a fight between two or more manufacturers when a contract is in dispute. In this case, the genesis of the conflict may appear if the institutional evaluator who must give his opinion on proposals quality has held a position in one of the companies that aspires to obtain the contract.

There would be a real conflict of interest due to the hypothetical possibility that this evaluator could make a biased opinion that unjustifiably benefits one of the companies. Different situations can occur such as receiving important gifts as an exchange for those benefits or receiving a hidden payment, for example to favor one of the companies, thus criminal figures of bribery is produced. Another possibility of conflict for a professional who works as chief staff in an industry or in a public administration department who could have a “conflict of duties”. As an

example this could appear when an employee requests to be absent in his/her labor by a non-contemplated statutory cause, although important from personal point of view, which may be understandable within the framework of a labor relationship. That person, exercising his/her work with professionalism, must decide between the obligation to respond to their superiors who trust on his/her actions to allow, only for valid reasons, the withdrawal of a person. On the other hand, to consider that the reason for the request is not appropriate although understandable from other points of view (14).

Another condition that is in fact a conflict of interest appears when a health professional gives preferential treatment to a family member on a waiting list. A different situation that can generate conceptual confusion occurs when a physician is under the effect of an emotional involvement with a patient and does not handle the situation with sufficient professional distance, which can lead to failures associated with a loss of objectivity. These arguments have led to the existence of codes of ethics that specifically prohibit medical professionals, especially in the field of psychiatry, to engage in personal relationships with patients. Table 2 summarizes these concepts and in Table 3 detailed types of secondary interests are described.

**Table 2** Decision-making conflicts in Medicine

Type of conflict	Classification	Comments
Conflicts of interest	Due to different types of interests <ul style="list-style-type: none"> <li>• Economic</li> <li>• Non-economic</li> <li>• Related to third parties interests</li> </ul>	To protect moral integrity at decision-making challenges
Other conflicts		
Conflicting interests	-	Commercial arguments

Bribery	-	Criminal behavior. There is ethical and legal conflict
Conflict of duties	-	Social responsibility to guarantee the administration regulations compliance

**Table 3** Categories of secondary interests

Class	Comments
Direct sponsored	Payment for conferences, articles writing, patient registrations for clinical studies , for research of a product
Indirected sponsored	Gifts , travels, meals
Laboral and academic development	For prestige, academic acknowledgment or promotion
Others	Physician in charge of patients care and also as researcher, and/or as administrator of Health resources and/or as consultor for marketing strategies.

**ETHICAL AND LEGAL IMPORTANCE OF CONFLICTS OF INTEREST IN MEDICINE AND HEALTH SCIENCES**

Since 1978 when the Belmont report (10) was produced, basic fundamental principles of justice, autonomy and beneficence/non-maleficence support, among other aspects, the decision-making on patients’ own body. This position completely relegated the paternalistic model of physician-patients relationships. Nevertheless, some very unprotected and needy sectors request assistance, fully trusting on suitability and integrity of physicians without perceiving that they may be in a disadvantageous situation in which COIs could occurs. Harmful decisions can be made, biased towards defenseless people, so these COIs must be treated more rigorously than in other settings in medical fields.

In relation to COI in medical research, it is well known that there are research studies where results have been reported in a biased way as

a consequence of COI, these effects may prove harmful and may be reversed only after a considerably long time. In relation to teaching and in recommendations elaboration, deviations can occur due to COI that installs concepts that later are transferred for years to clinical practice and that persist over time. Likewise, there are doubts in society about the integrity of health professionals who lose credibility in front of public opinion. This loss of credibility is due to the mantle of doubt that is installed before the eyes of patients who may consider that gifts, invitations or other types of benefits can affect their health and finally, their lives. It is difficult to prevent all negative effects of COI as Chren et al mentioned (15) “preserving justice, the trusteeship relationship with our patients, and our own altruism are regulative ideals — that is, standards not always achievable by all of us, but useful templates ‘against which all efforts can be measured.”

From a legal point of view, the responsibility for the administration done by anybody who acts for or on behalf of another person has limits on his/her autonomy and freedom as there is a more powerful party entrusted to protect interests of a less powerful party. This could be similar to physician/patient relationship so any possibility of COI should be avoided to preserve the interests of the protected part. In order to regulate health care professionals, specific codes for various professionals have been approved. These codes for example prohibit members of a health care professional for practicing the profession if they are in a COI or in a professional misconduct (16).

Many professions have their own COI legal documents. These documents were composed quite some years ago, but for medicine it was not until about 40 years ago that legal bodies were incorporated. Many medical organizations and journals were concerned about interactions between the industry and the medical profession and have introduced requirements for authors to disclose any financial interest they have in a study (16). Moreover, different types of articles written by authors with a financial interest were rejected. For example a very complete and excellent disclosure form was approved by American Association of Clinical Chemistry (AACC) (17).

In the 1990s, many Colleges and Associations of Physicians from several countries outlined in position papers how to deal with relations between physicians and the industry, and it was acknowledged that not only real bias but also perceived bias should be avoided (18). Moreover, gifts or subsidies from industry “ought not to be accepted if acceptance might influence or appear to others to influence the objectivity of clinical judgment”. Also detailed recommendations on gifts and subsidies can be found in an opinion of the Council on Ethical and Judicial Affairs, which the American Medical Association

(AMA) incorporated into its Code of Medical Ethics (18,19). Sections on continuing education, research, clinical evaluation and surveillance studies were included, nonetheless, it was remarked that the main focus on patient care must be included. The guidelines do not forbidden research and education sponsoring by industry but only under regulated nature of manufacturers’ and physicians’ alliances. In relation to this, conference and courses organizers must have under control the content of events and no reference for endorsement of a sponsor’s product should be done. As regards to industry gifts, some associations guidelines are stricter. Furthermore, health professionals are discouraged from investing in companies where commercial success could be affected by practices of the professional. Criticism has frequently emerged and proposal for improvement have been sought (16).

In 2012, the International Federation of Clinical Chemistry (IFCC) approved a statement for all members integrating its structure at different levels that they are required to read this policy and sign the disclosure statement (20). As part of the statement definition, conditions for participant’s exclusion, examples of potential COI and disclosure statement were included. At the same time also a statement for Ethics publication was also approved. Also Council of International Medical Societies (CIOMS) in its Ethical Guidelines for clinical research in COI guideline 25 dedicated to researchers, research institutions and research ethics committee mention, as an important topic for disclosure, requirements for education and highlight recommendations on disclosure to research ethics committees and to participants (21).

The World Medical Association produced a statement on conflict of interest (22) with recommendations for research, needs in education and also items for health organization and Institution conflicts were included. Two other aspects of interest for laboratory medicine are included.



One is related to self-referrals and fee-splitting as a point to keep in consideration and expresses that “all referrals and prescriptions (whether for specific goods or services) should be based on an objective assessment of the quality of the service or of the physician to whom the patient has been referred. Referral by physicians to health care facilities (such as laboratories) where they do not engage in professional activities but in which they have a financial interest is called self-referral. This practice has the potential to significantly influence clinical decision-making and is not generally considered acceptable unless there is a need in that particular community for the facility and other ownership is not a possibility (for example, in small rural communities)”. Also mentions that “kickbacks (or fee-splitting) occur when a physician receives financial benefit for referring a patient to a specific practitioner or for a specific service for which a fee is charged. This practice is not acceptable”. Second important point considers for “patient convenience, occurs if many physician offices are located in close geographic proximity to other medical services such as laboratories. The physician should not receive any financial compensation or other consideration either for referring a patient to these services, or for being located in close geographical proximity to them” (22).

Some authors have researched the extent to which physicians interact with industry. Considering this goal there are many different types of articles published from 70s up to now referred to COI, industry and medical specialties and organizations in which frequency, relevance and implications of gifts from companies to researchers and others members in academic life, such as scientists, and found that these studies indicate that interactions are common and in various forms. Unfortunately studies have shown these interactions influence physicians and medical researchers for example on prescribing patterns (23), and the outcome of research studies

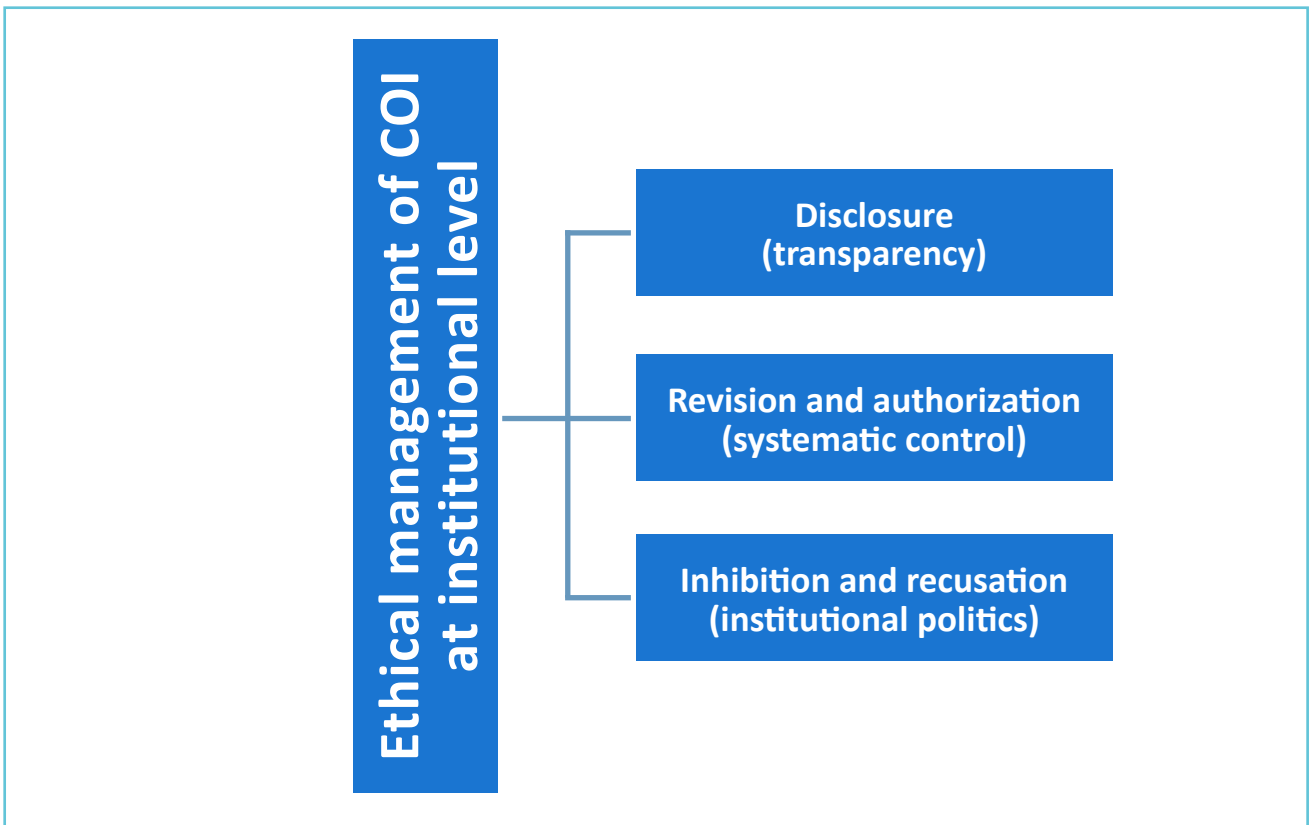
to support a product. These findings did not show something unexpected and are in parallel with the budget spent for products promotion. Even taking into account these finding, many physicians consider that they are not likely to be influenced by their interactions with industry.

In relation to publication ethics, focus on duplicate publication, inappropriate authorship, fabrication of data, plagiarism, and conflict of interest (COI) is paramount. The issue of COI is an important problem for medical journals. Relevant documents related to COI definition and disclosure include the COI Disclosure Form are those done by the International Committee of Medical Journal Editors (ICMJE) (24) and flow-charts by the Committee on Publication Ethics (COPE) dealing with the omission of essential COI notes in research publications (25), which provide advice for publishers and editors.

#### **AN APPROACH TO MANAGEMENT OF CONFLICTS OF INTEREST**

As was mentioned earlier there are conflicts of interest in every aspect of human activity, including medicine and science. The moral problem arising when the influence of a secondary interest that can threaten the ethics of a professional decision is accepted as natural. A conflict of interest could be an inducement or temptation that must be distinguished from its acceptance. However, there are situations that are consciously ignored. Awareness, acknowledgement of COI and evaluation of the influence of secondary interests are important in these situations. As such, focus must be directed to recognize and manage COI appropriately. The ethical management of COIs by institutions must be carried out through explicit regulations with corporative supervision through their governing bodies or by special committees. The types of conflict and the potential for real or perceived damage can be approached by different

Figure 2 Strategy for an approach to management of conflicts of interest



strategies and they are: disclosure, hierarchical steps of review and authorization, and prohibition (Figure 2) (16).

### **Disclosure**

The main action to solve a conflict of interest is its disclosure. Transparency by public declaration is considered as the golden rule. It is morally very healthy to highlight the secondary interests that could affect the rigor of professional judgment because it implies to show potential bias intentionally desired to be prevented by offering their exposure openly. To judge whether one is in a conflict of interest, it can be revealing to ask a recommended question in relation to how comfortable patients and others people are about his/her interest in the matter under discussion and in function of answers.

### **Review and authorization**

By means of laws and regulations, formal review systems were introduced to control conflict of interest additional to disclosure as is the case of medical research. Research ethics boards have a duty to determine, among other items, whether conflicts of interests are affecting clinical trials and the health care of patients participating in trials. Members of review boards should themselves not be in a conflict of interest. Universities have systems of authorization and reception of financial interests from researchers to the university administration and that could verify if the required conditions are achieved (16).

### **Prohibition**

But disclosure and review and authorization are not always enough and adequate. Some con-



flicts of interest may so deeply affect trust that they have to be forbidden (16). The policies of some entities disapprove of researchers being remunerated over and above reasonable compensation for extra work and in a condition of decrease of other income (16). The remuneration for merely including research subjects in a clinical trial, should not be accepted. In that case, the temptation to include subjects without proper informed consent and without respecting selection criteria is huge. The policy further discourages physicians from accepting a fee from industry in exchange for meetings with representatives or for attending promotional activities. The organizers of educational program events are also requested not to be in a potential COI by virtue of any relationship with companies that fund such events. Additionally, to ensure quality of clinical practice guidelines, organizations need to formulate policies related to COI (26).

In conclusion, it is important to arise awareness for COI acknowledgment to evaluate the influence of secondary interests. In this article we include a detailed description of conflicts of interest classification and its ethical and legal implications in the practice of health sciences such as those that appear in the practice of clinical and laboratory medicine, pharmaceutical industry and also, research and publications. Final considerations on the management of COI are also included.

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