

Conflicts of Interest in Medicine

– Understanding the Concepts to Preserve the Integrity of Professional Judgement and Promoting Public Trust in the Profession

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Introduction

Conflicts of interest (COIs) are a core concept in professionalism. It is common practice for doctors to have to declare their COIs before a scientific or academic oral presentation and when submitting an article for publication. COIs occur in all professions including law, accountancy, engineering and architecture. They are ubiquitous in clinical practice, medical research and medical education.

Definition

A COI is a set of circumstances which create a risk that professional judgement or actions regarding a primary interest will be unduly influenced by a secondary interest.¹

COIs are widespread in Medicine as doctors have a primary duty of care and many secondary interests depending on their roles as healers, educators, researchers and clinic managers. A statement that someone has a COI does not imply that the person has been unethical or corrupt.

The ethical basis

There is a professional obligation for doctors to responsibly manage COIs as individual practitioners and as a profession. The ethical basis of this obligation in Medicine lies in the principle of primacy of patient welfare. Traditional medical professionalism dictates that the fundamental obligation of doctors as healers is to serve the best interests of patients above that of the healthcare professionals' self-interest or those of third parties. In a therapeutic relationship, doctors' primary interests are the patients' best interests. All other interests are secondary.

The doctor-patient relationship is a relationship of trust where patients place their health and medical well-being in the hands of doctors. The doctor-patient relationship is described as a relationship of imbalance of power, knowledge, expertise and experience. There is a need to recognise vulnerability and avoid exploitation. Appropriate ethical principles are necessary to govern the relationship. Putting patients' interests uppermost is necessary to build trust and confidence in the clinician and healthcare system.

Financial COIs in clinical practice

According to the Singapore Medical Council Ethical Code and Ethical Guidelines:

4.6.2 Financial conflicts in clinical practice

A doctor shall refrain from:

- a. Improperly obtaining money from patients

- b. Improperly prescribing drugs or appliances in which he has a financial interest

- c. Fee sharing or obtaining commissions from referral of patients

A financial COI occurs when doctors directly profit financially when more services are recommended, laboratory tests ordered, surgeries performed or prescriptions written. Fees for services create significant COIs with the risk for increase of services and offering services of little value for the particular patient. Where there are no clear guidelines on fees, excess fee charging is another risk. When doctors are in managed care organisations that work on capitation payment, incentives may result in withholding of beneficial services, and underservicing.

Clinician self-referrals may occur when doctors own imaging or laboratory testing in their offices or possess ownership of a free standing facility to which they refer patients for services.

Kickbacks or fee splitting refer to payments to clinicians and others for referral of patients. The risk here is unwarranted referrals or referrals to persons not most competent for the patients' problems. Hospitals, laboratories and imaging centres may offer contracts to give discounts on the fees when physicians refer patients for use of their services and facilities.

Again the mere presence of financial COIs should not be misconstrued that all doctors treating private patients provide clinical judgements of dubious integrity or exploit their patients financially.

COIs in industry relationships

Pharmaceutical, biotechnology and medical device business enterprises are genuine stakeholders in the healthcare system. They are responsible for bringing new advances for patient and public health.

Gifts to doctors (like pens, books, instruments and hampers during festive seasons) and free drug samples forming relationships beyond the professional realm, create obligations and expectations of reciprocation. Financial support for medical conferences with meals and hospitality create COIs with regard to prescribing bias. COIs arise when doctors who serve as paid scientific and marketing consultants to industry, sit on expert committees developing clinical practice guidelines.

Ghostwritten articles refer to manuscripts prepared by

writers from medical publishing companies, but authorship was subsequently attributed to academically affiliated investigators who often have industry financial support. Lending names for ghostwriters to publish articles under is unethical.

COIs and medical research

The primary interest when doctors take on the role of researchers is the integrity of research and science. Financial support for medical research from industries can result in COIs when there is pressure to delay, under-report, misreport, or not publish negative results or adverse effects of drugs.

Research with healthy humans and patients are an important part of developing new medication and techniques in combating diseases. Treating doctors may be called upon to advise, refer and recruit for research. Finders' fees are payments made to doctors for recruiting patients for clinical trials. This is analogous to kickbacks for referring patients to other doctors for therapy.

Investigators and medical institutions doing research may have intricate financial interests in biotechnology start-ups and sponsoring drug companies.

Advancement in academic careers depends on success in research, patents and publications. COIs emerge when there is pressure to announce a breakthrough or complete projects early and the integrity of science may be sidelined. Research fraud, manipulation and misrepresentation of results in scientific publications can be driven by COIs, as academic careers and future research funding are at risk.

Doctors with dual obligations in medical research

Clinician-scientists, by the nature of their job descriptions, switch from being healers when they are clinicians, to being scientists when conducting research. In the clinicians' role, their primary interest is the welfare of the patients. But as scientists in the laboratory, their primary interest lies in the integrity of science. As scientists involved in clinical research involving patients, they have dual obligations to patients' welfare and scientific integrity.

COIs appear when clinician-scientists recruit patients they are treating to participate in research where they are the clinical investigators. Patients may find it difficult to refuse and be under therapeutic deception. Therapeutic deception is a common misconception among research participants, stemming from the lack of understanding, that research would result in direct therapeutic benefits for them.

COIs in medical education

When doctors take on the role of educators, the primary interest is the educational mission and educational interest of the students. However, when education takes place in patient care areas (hospital patients or outpatient services), doctors assume a dual obligation balancing patients' welfare

and the interest of students or trainee doctors.

Doctors need to achieve clinical competence before they are qualified and licenced. This includes skills in intimate examinations and invasive diagnostic and therapeutic procedures. Promoting medical students and trainee doctors' learning could conflict with patients' best interests. Medical educators and senior clinicians in supervisory roles have to make critical assessments for when it is safe and appropriate to delegate clinical responsibilities to students and trainee doctors.

COIs and doctors as examiners

Doctors often find themselves in the role of examiners. Doctors conducting a pre-employment examination, issuing a certificate for fitness for work, doing a foreign domestic worker's medical examination, certification of mental capacity, fitness to drive or fly, assume the role of examiners.

In these situations, doctors may find themselves in a contractual relationship with third parties like insurers or employers. In other situations, there is a statutory component involving the law and public interests. There is often a position of dual obligations to the examinees and the third parties. Doctors have to balance the interest of both parties. The primary interest or overriding obligation here is in ensuring that objectivity, accuracy and integrity of professional judgements are preserved.

COIs and doctors sitting in judgement of colleagues

The primary interest of doctors sitting in judgement of colleagues is to uphold the rules of natural justice and the rule of law. They are expected to serve without favour or fear in the deliberations. When doctors have interests in either party or have formed an opinion before the appointment as judges, COIs have to be recognised.

When there are COIs, judgement would be compromised by undue influence of secondary interests. Even if the ruling appears fair, the process could have been biased. The law requires a high standard of avoidance of COIs. The perception of COIs would undermine the public trust and confidence in the justice system and may necessitate a recusal.

Why are COIs enigmatic and problematic?

COIs are problematic because they risk the patients' best interests being sidelined by secondary interests, the integrity of medical judgement being violated and clinical outcomes being compromised. When patients are harmed, the trust in the medical profession becomes undermined. When an error occurs, it is difficult to determine whether it is a result of biased judgement from COIs, lapses in judgement from human factors or incompetence.

Trust is fragile and needs to be continuously nurtured. Even a perception that physicians put other interests above

patients' best interests can undermine trust and confidence in physicians and the entire medical profession. Trust is an essential ingredient in achieving the goals of Medicine.

Understanding COIs

Only a small number of doctors are corrupt or intentionally motivated to exploit patients financially. The majority of COIs are not issues of corruption or intentioned immorality. Many doctors work hard to uphold professional ethics and do not place the objectivity of their clinical judgement for sale.

However, most doctors believe that they can be trusted to navigate financial COIs. However self-regulation or self-policing does not work most of the time, as there is a natural tendency of "optimism of self." Humans are able to easily rationalise their actions when questioned and regularly engage in self-deception.²

Research shows that when humans stand to gain by reaching a particular conclusion, they tend to unconsciously and unintentionally seek and weigh evidence in a biased fashion that favours that conclusion. This bias seeking and weighing of evidence occurs at the subconscious level. Biased individuals will sincerely claim objectivity. Human bias, on the other hand, is observable by others.

Principles of managing COIs

The aim of actions and policies of managing COIs is to preserve the integrity of the primary interests, professional judgement and public trust. The determination that the secondary interest is wielding undue influence should be made by independent, reasonable and responsible observers, and not by the doctors involved in the situation. Legal standards of natural justice should set the rules that determine when doctors sitting in judgement in medical disputes and disciplinary hearings should recuse themselves.

Disclosure is not the key in deciding the acceptability of a COI. The main function of disclosure is promoting transparency in conflict deemed permissible. In other words, when in doubt, disclose. Problems rarely flow from disclosure of a COI, but often from discovery of non-disclosure which would lead to an assumption, until proven otherwise, of biased practice, corruption and incompetence.

Individual patients are not in the best position to determine whether COIs played a negative role in the medical decision making process. The profession working with patient advocacy groups play an important role in setting the policy regarding COIs in clinical practice. COIs must be visible to all concerned, especially to patients, their families and third party payers.

All medical research needs to be administered through institutional review boards (IRBs). Research ethics boards need to determine, among other things, whether COIs are affecting the proper conduct of clinical trials and the health care of patients included in the trials, eg, review of

contracts between sponsor and researcher. Mandatory report of financial interests to designated office in medical research is good policy.

Some COIs may so deeply affect trust as to be unacceptable and ought to be prohibited. Examples include fee splitting or kickbacks (referral fees), ghostwriting, and researchers receiving excessive finders' fees.

A system of reporting and punishing abuses of COIs should be managed by all stakeholders.

Table 1: Management of COIs

1. Reaffirmation of the fiduciary relationship
2. Define boundaries and prohibitions
3. Voluntary discharge of interests
4. Disclosure
5. System of review and authorisation as in IRBs
6. Declaration of gifts from drug companies and other third parties
7. Declaration of COIs required by editorial boards of journals
8. Education and awareness about COIs
9. Recuse and avoidance

Conclusion

Ethical breaches occur in COIs when in a primary (ethical) obligation, one is motivated to or participates in a secondary (personal) activity which impairs judgement or prejudices the primary obligation.

The perception of COIs itself is damaging, though potential or actual harm is minor, as it erodes trust.

Understanding the concepts in COIs serves to preserve the integrity of professional judgement and promote the public trust in the profession. **SMA**

References

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A/Prof Chin is President of the 53rd SMA Council. Like most doctors, he too has bills to pay and mouths to feed, and wrestles daily with materialistic desires that are beyond his humble salary. He, however, believes that a peaceful sleep at night is even more essential.



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