# Conflicts of interest in medicine: understanding the concepts to preserve the integrity of professional judgement and promote trust in the profession

### **Opening Vignette**

Doctor A, an upper gastroenterology surgeon, received a letter from the defendant lawyer for a request to be a medical expert witness for a disciplinary tribunal case. Doctor A has the experience and expertise to be an expert witness in this case. The defendant doctor, Doctor B, was his school rugby teammate more than 20 years ago. They were in the same medical school but of different class and were surgical trainees at XGH hospital about 10 years ago. They were both active members of the College of Surgeons at different times. Doctor B now works in a private hospital. Doctor A is the Head of Surgery at TSR hospital, a restructured hospital. Doctor A wonders whether he should exclude himself as an expert witness on the grounds of conflict of interest. Since the medical tribunal is part of the medical council and under the purview of the ministry, which is indirectly his employer, he should not be defending a doctor from a private hospital. He is also concerned that he may have to write a favourable report for Doctor B, as they were schoolmates and are now collegiate members of the College of Surgeons.

### INTRODUCTION

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

### **DEFINITION**

A COI is a set of circumstances that create a risk that a professional judgement or actions regarding a primary interest will be unduly influenced by a secondary interest. [1] COI is widespread in medicine, as doctors have a primary duty of care and many secondary interests depending on their roles as healers, educators, researchers or clinic and hospital 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 in responsibly managing COI as an individual practitioner and as a profession. The ethical basis of this obligation in medicine lies in the principle of the primacy of patient welfare. Traditional medical professionalism enunciates that the fundamental obligation of the doctor as a healer is to serve the best interest of the patient above the healthcare professional's self-interest or that of any other third party. In a therapeutic relationship, the primary interest of the doctor is the patient's best interest. All other interests are secondary interests.

The doctor—patient relationship is a relationship of trust where the patient places his health and medical wellbeing in the hands of the doctor. The doctor—patient relationship is described as a relationship of imbalance of power, knowledge, expertise and experience. There is a need to recognise the vulnerability of the ill patient and deliberately avoid exploitation. Appropriate ethical principles are necessary to govern this relationship. Putting the patient's interest uppermost is necessary to build trust and confidence in the clinician and healthcare system.

There are several professional roles of doctors where COI, if not properly managed, would compromise their professional judgement and duties. Appropriately managing COI is essential to maintain patient and public trust in both the healthcare professional and the profession.

### FINANCIAL COI IN CLINICAL PRACTICE

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

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

Kickbacks or fee splitting refers to payments to clinicians and others for referral of patients. The risk here is unwarranted referrals or referrals to persons not appropriately competent for the patient's problem. Hospital, laboratories and imaging centres may offer a contract to give a discount on the fees, when a physician refers patients to use their services and facilities. This creates a secondary financial interest, which risks sidelining the primary interest of the patient's needs and welfare.

Again, the mere presence of a financial COI should not be misconstrued to mean that all doctors treating private patients provide a clinical judgement of dubious integrity or exploit their patients financially.

### H3. Financial conflicts of interest

Patients trust that their doctors will act in their best interests when they give advice or offer treatment to them. When you have financial interests that compete with your professional duty towards patients, conflicts of interest arise. You must always resolve these conflicts in the best interest of patients.

— Singapore Medical Council Ethical Code and Ethical Guidelines (2016 Ed)<sup>[2]</sup>

### COI IN RELATIONSHIP WITH INDUSTRY

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

Gifts (from pens to books, instruments and hampers during festive seasons) and free drug samples given to doctors create relationships beyond the professional realm, which may generate obligations and expectations of reciprocation. Financial support for medical conferences that are laced with meals and hospitality creates COI in regard to prescribing bias. COI arises when doctors who serve as paid scientific and marketing consultants to industry sit on expert committees developing clinical practice guidelines.

Ghost writer articles refer to manuscripts prepared by writers from medical publishing companies, but the authorship was subsequently attributed to academically affiliated investigators, who often have financial support from industry. Lending names to ghost writers to publish articles is unethical.

### 11. Relationships with the medical industry

There can be mutually beneficial relationships between medical companies and doctors that improve patient care. However, given the potential for conflicts of interest to arise, these relationships must be handled with care.

— Singapore Medical Council Ethical Code and Ethical Guidelines (2016 Ed)<sup>[2]</sup>

#### COI AND MEDICAL RESEARCH

The primary interest when the doctor takes on the role of a researcher is the integrity of research and science. Financial support for medical research from industry (whose primary interest is economic spinoffs from research) can result in COI when there is pressure to delay, underreport, misreport or not publish negative results or adverse effects of drugs.<sup>[3]</sup>

Research with healthy humans and patients is an important part of developing new medication devices and procedures in combating diseases. Treating doctors may be called upon to advice, refer and recruit patients to participate in research. Finder's fees are payments made to doctors for recruiting patients for clinical trials. This is analogous to kickbacks for referring patients to another doctor for therapy.

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

Advancement in academic careers depends on success in research, patents and publications. COI emerges 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 COI as academic career and future research funding are at risk.

## DOCTORS WITH DUAL OBLIGATIONS IN MEDICAL RESEARCH

Clinician-scientists, by the nature of the job description, switch roles from being healers when they are clinicians to scientist when conducting research. In the clinician role, the primary interest is the welfare of the patient. As scientists in the laboratory or a clinical trial, their primary interest lies in the integrity of science. As scientists involved in clinical research involving patients, there are dual obligations to the welfare of patient and scientific integrity.

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

### **COI IN MEDICAL EDUCATION**

When a doctor takes on the role of an educator, 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 service), the doctor assumes a dual obligation in balancing the patient's welfare and the interest of the student or trainee doctor.

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 the medical students' and trainee doctors' learning could conflict with the patients' best interest.

Medical educators and senior clinicians in supervisory roles must make critical assessment regarding when it would be safe and appropriate to delegate clinical responsibilities to students and trainee doctors. Medical schools and residency programmes must have appropriate policies, protocols, practices and audits to ensure that the patient's welfare and interests are not sidelined in medical education and clinical training.<sup>[4]</sup>

### COI AND THE DOCTOR AS AN EXAMINER

Doctors often find themselves in the role of a medical examiner. A doctor who conducts a pre-employment or foreign domestic worker medical examination, or issues a certificate for fitness for work, mental capacity or fitness to drive or fly assumes the role of a medical examiner. In these situations, the doctor may find himself/herself in a contractual relationship with third parties like the insurer or employer. In other situations, there is a statutory component involving the law and public interest. There is often a position of dual obligation to the examinee and the third party. The doctor must balance the interest of both parties. The primary interest or overriding obligation here is in ensuring that objectivity, accuracy and integrity of the professional judgement in carrying out and reporting the examination is preserved.

### COI AND THE DOCTOR AS A MEDICAL EXPERT

Doctors are called upon to serve as medical experts in the court of law (for civil, criminal and coroners), medical disciplinary tribunals of professional misconduct or complaint committees and peer reviews of hospitals and professional bodies. The evidence in a medical expert report and the testimony offered by a medical expert witness are often critical components in arriving at an equitable, timely and fair decision in any medical dispute.

Expert witnesses provide independent assistance to the court or tribunal through objective and unbiased opinion supported by good reasons and evidence and founded on facts relating to matters within their expertise. The expert's duty to the court or tribunal and justice overrides any obligation to the person who is instructing or paying the expert.

Before agreeing to be medical experts, doctors must exercise due diligence to establish that there are no COIs, by reviewing their relationship with the parties involved and ensuring that they have not formed a judgement before having the full facts of the case.

## COI AND THE DOCTOR SITTING IN JUDGEMENT OF COLLEAGUES

Doctors may be called upon to sit in judgement of their colleagues' performance, by serving on a complaints committee, a hospital inquiry or a disciplinary tribunal. The primary interest of a doctor sitting in judgement is to uphold the rules of natural

justice and the rule of law. He/she is expected to be objective and serve without favour or fear in the deliberations.

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

When the doctor has an interest in or a special relationship with either parties, or has formed an opinion before the appointment as a judge, COI must be recognised and best declared.

### WHY IS COI ENIGMATIC?

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

At the same time, when physicians serve in the non-therapeutic roles described in this article, the perception of COI may erode trust in the integrity of the process and outcomes.

Trust is fragile and needs to be continuously nurtured. Even a perception that a physician puts other interest(s) above the patients' best interests can undermine trust and confidence in the physician and the entire medical profession. The perception of a COI itself is damaging, as it erodes trust in the system and profession. Trust is an essential ingredient in achieving the goals of medicine.

### UNDERSTANDING THE PSYCHOLOGY OF COI

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.

Most doctors believe that they can be trusted to navigate financial COI. However, self-regulation or self-policing does not work most of the time, as there is a natural tendency of 'optimism of self'. Humans can easily rationalise their actions when questioned and regularly engage in self-deception.<sup>[5]</sup>

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 biased seeking and weighing of evidence occurs at the subconscious level. Biased

### Box 1. Management of conflict of interest (COI).

- 1. Reaffirmation of the fiduciary relationship
- 2. Define boundaries and prohibition
- 3. Voluntary discharge of interests
- 4. Disclosure
- 5. System of review and authorisation as in institutional review boards
- 6. Declaration of gifts from drug companies and other third parties
- 7. Editorial boards of journals require declaration of COI
- 8. Education and awareness on COI
- 9. Recuse and avoidance

individuals will sincerely claim objectivity. Human bias, on the other hand, is best observed by others.

### PRINCIPLES IN MANAGEMENT OF COI

The aim of actions and policies in managing COI [Box 1] is to preserve the integrity of the primary interest, professional judgement and public trust. The determination of whether a secondary interest is wielding undue influence should be made by independent, reasonable and responsible observers and not the doctors involved in the situation. Legal standards of natural justice should set the rules that determine when a doctor sitting in judgement in medical disputes and disciplinary hearings should recuse himself/herself.

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 conflict, but often, discovery of non-disclosure 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 a COI has played a negative role in the medical decision-making process. The medical profession, working with patient advocacy groups, plays an important role in setting the policy regarding COI in clinical practice. COI must be visible to all concerned, especially patients, their families and third-party payers.

All medical research needs to be administered through institutional review boards. Research ethics board must determine, among other things, whether COI is affecting the proper conduct of clinical trials and the welfare and medical care of patients included in the trials (e.g. review of contracts between sponsor and researcher). Mandatory reporting of financial interests to a designated office in medical research is a good policy.

Some COIs may affect trust so deeply that they are deemed unacceptable and ought to be prohibited. Examples include fee splitting or kickbacks (referral fees), ghost writing and researchers receiving excessive finder's fee. Systems of reporting and punishing abuses of COI should be managed by all stakeholders.

### **KEY LEARNING POINTS**

- A COI is a set of circumstances that create a risk that a
  professional judgement or action regarding a primary
  interest will be unduly influenced by a secondary interest.
- 2. Ethical breaches occur when one who has a primary (ethical) obligation participates or is motivated to participate in a secondary (personal) activity that impairs judgement or prejudices the primary obligation.
- 3. The fundamental obligation of the doctor as a healer is to serve the best interest of the patient above his/her self-interest or that of any other third party.
- A financial COI occurs when doctors directly profit financially when there are more services recommended, laboratory tests ordered, surgeries performed or prescriptions written.
- Research fraud, manipulation and misrepresentation of results in scientific publications can be driven by COI, as academic career and future research funding are at risk when publications are rejected.
- 6. The perception of COI itself is damaging, even though the potential or actual harm is minor, as it erodes trust.
- Understanding the concepts in COI and appropriately managing COI serve to preserve the integrity of professional judgement and promote public trust in the profession.

### **Closing Vignette**

Doctor A should declare and share the facts of his relationships with Doctor B with his instructing lawyer. A third party is often in a better position to objectively assess whether there is a COI. The instructing lawyer could decide whether to engage Doctor A as an expert witness based on the facts. Doctor A could also include the facts of his relationship with Doctor B as an addendum to his Expert Report, so that the disciplinary board members and opposing lawyers are informed and can decide whether to accept him as an objective expert witness. Medical expert witnesses must have the relevant expertise and must be objective and independent in articulating their opinion. When in the process of preparing and writing a medical expert witness report, doctors must be aware that their primary duty is to assist the courts or tribunals, not the instructing party, in finding the truth.

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### **Conflicts of interest**

There are no conflicts of interest.

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### **SMC CATEGORY 3B CME PROGRAMME**

Online quiz: https://www.sma.org.sg/cme-programme

Deadline for submission: 6 pm, 17 March 2023

Question	True	False
1. A statement that someone has a conflict of interest implies that the person:		
(a) Has other secondary interests.		
(b) Is corrupt.		
(c) Is unethical.		
(d) Is absolved of any conflicts of interest in decision-making.		
2. In a therapeutic relationship, the physician's primary interest is:		
(a) Medical education to train future professionals.		
(b) Clinical research to cure disease.		
(c) Manage healthcare resources efficiently to benefit as many people as possible.		
(d) The patient's best interest and welfare.		
3. The following is a financial conflict of interest:		
(a) Being paid for clinical services that are directly rendered to the patient.		
(b) Splitting fees with clinicians to whom you refer a patient to be co-managed.		
(c) Having discounts from laboratory services for investigations ordered.		
(d) Limiting necessary medical services using the capitation model of funding.		
4. Conflicts of interest are problematic because:		
(a) A patient's best interests are sidelined by a secondary interest.		
(b) The integrity of medical judgement is violated.		
(c) Clinical outcomes can be compromised.		
(d) Trust in the medical profession can be undermined.		
5. Conflicts of interest can be managed by:		
(a) Defining boundaries and prohibition.		
(b) Disclosure of conflicts and gifts to create transparency.		
(c) Independent review (e.g. Institutional Review Boards).		
(d) Self-regulation.		