AMA Guidelines for Doctors on Managing Conflicts of Interest in Medicine 2018

1. Introduction

1.1 A key feature of the medical profession is the primacy of patient care. The medical profession adheres to the ethic that:

> *The health of my patient will be my first consideration.*[1]

1.2 Patients and the wider community trust doctors (medical practitioners) to uphold this primary duty to patient care. Public trust and confidence in the medical profession is essential for ensuring people access medical care. If people do not trust doctors, they will seek care elsewhere, or not seek care at all, either of which may prove detrimental to the health and well-being of individuals as well as the wider public health.

1.3 Conflicts of interest in medicine have the potential to undermine public trust and confidence in the profession if not managed appropriately.

1.4 A doctor's interests should be able to withstand public and professional scrutiny and conform to professional and community standards and expectations.

1.5 These guidelines serve to assist doctors to appropriately identify and manage actual and potential conflicts of interest in the practice of medicine.

1.6 Doctors should also be aware of relevant legislation and regulations that address conflicts of interest in medicine.

2. What is an 'interest'?

2.1 An 'interest' is a commitment, goal or value arising out of a social relationship or practice.[2]

2.2 An 'interest' may be professional or personal in nature. For example, in addition to the clinical practice of medicine and direct patient care, doctors serve in a variety of professional roles and pursue various other professional interests, such as participating in research, teaching, undertaking administrative or managerial positions and acting as consultants for private enterprises. Doctors also have personal roles including familial roles (as a spouse, parent or child) and personal interests such as participating in religious or political activities.

2.3 Whether professional or personal, an 'interest' may be pecuniary or non-pecuniary in nature. A pecuniary interest is one that has a financial or other material component to it. Examples include the following**:**

- a doctor may be paid to provide professional services to the health care industry as an employee, consultant, director, speaker, advisory board member or in another similar capacity;
- a doctor may be paid to provide professional services outside the health care industry as an employee, consultant, director, speaker, advisory board member or in another similar capacity;
- a doctor may refer patients to a health care facility that employs, or is owned by, the doctor or someone with whom they have a close personal relationship.

2.4 A non-pecuniary interest does not have a financial or material component to it but may arise from a professional interest or personal relationship. For example, a doctor may have an interest in:

- being a member of a professional association;
- promoting certain political activities;
- promoting certain religious beliefs;

- advancing their career or professional reputation;
- pursuing personal relationships;
- fulfilling family responsibilities.

2.5 Usually, a doctor's personal and professional interests co-exist harmoniously and do not affect patient care. It is important, however, for doctors to identify whether a particular interest could lead to an actual or perceived conflict of interest. It is important for doctors to identify situations where the possibility could be raised that their personal and professional interests could lead to decision-making or behaviour which is at odds with their primary responsibility to the patient.

3. What is a conflict of interest?

3.1 A conflict of interest occurs when a particular relationship or practice gives rise to two or more contradictory interests;[2] that is, when the various interests that guide their decisions or behaviours can potentially generate conflicting outcomes.

3.2 The specific case of a conflict of interest in medicine that is of particular concern is that which arises when a doctor has professional or personal interests, whether pecuniary or non-pecuniary, or relationships that may lead them to make professional judgments that are in conflict with their primary responsibility to their patient.[3]

3.3 Some conflicts of interest are unavoidable and there is nothing inherently wrong with having a conflict. What is necessary is to recognise when the potential for a conflict arises and to follow a rigorous and systematic process to respond to it.

3.4 The proper management of actual and potential conflicts of interest is crucial to maintaining trust and confidence in the individual doctor and the wider medical profession.

4. Managing potential and actual conflicts of interest

4.1 'Managing' conflicts of interest in medicine involves several steps including:

- identifying the various interests that may affect patient care;
- determining whether two or more of the interests are in conflict with each other and, in particular, whether there is a risk that patient care will be compromised;
- if a conflict of interest is present, taking whatever steps are necessary to respond to it, usually by separating decisions involving the contending interests;
- continuing to emphasise the priority of patient care and the interests of individual patients.

4.2 When managing actual or perceived conflicts of interest, doctors must ensure that the quality of patient care is not compromised and, in particular, the values of respect, objectivity, honesty, integrity, accountability and transparency are protected.

5. Identifying and disclosing interests

5.1 Doctors should routinely reflect on their personal and professional interests as the potential for conflicts to develop varies according to circumstances and context. Further, doctors may relinquish some interests and take on new ones from time to time and throughout the course of their careers.

5.2 If the potential for a conflict arises it is desirable for a doctor, wherever possible, to seek advice from colleagues or others such as an ethics or departmental committee to assist them in identifying:

- interests that are relevant to a particular circumstance or context;
- whether the interests identified actually do constitute a conflict;
- third parties that may be affected by an actual or perceived conflict of interest;
- if a conflict exists what, if anything, should be done to manage it;
- how the discussion about the actual or potential conflict of interest should be recorded for future reference.

5.3 A doctor should disclose relevant interests to patients whose care could be affected as a result of the interests as well as third parties that may be directly affected should an actual or perceived conflict of interest arise.[2] Examples of such third parties include (but are not limited to):

- an academic institution with which a doctor is formally affiliated;
- a doctor's employer;
- an ethics committee considering a doctor's research proposal;
- publication editors reviewing a doctor's research article;
- clinical guideline developers;
- research funders reviewing a doctor's research grant proposal.

5.4 When a directly affected party has been identified, the doctor should disclose the interest formally and in a timely manner. Where relevant, the doctor should comply with the policies and guidelines of affected organisations. In some cases, third parties may request disclosure of past as well as current interests.

6. Determining whether an actual or perceived conflict of interest exists

6.1 Doctors will often face uncertainty as to whether they have an actual or perceived conflict of interest and, if so, what actions, if any, need to be taken in response. A doctor should recognise that they are ultimately not in a position to make this determination and should either seek the advice of, or delegate the decision to, an independent party.

6.2 If it is decided that an actual conflict of interest exists, action should be taken to manage the separation of the conflicting duties to the satisfaction of the affected parties and ensure the duty to patient care remains paramount.[2]

7. Resolving an actual or perceived conflict of interest

7.1 In some cases, it may be enough to acknowledge that a conflict exists while in other cases, active steps are needed to resolve the problem. Examples include (but are not limited to):[2]

- withdrawing from a particular decision;
- withdrawing from or curtailing involvement in a particular activity;
- divesting of financial interests;
- delegating functions or roles to another individual or group.

7.2 The action(s) should be undertaken in a timely manner and communicated to the affected party.

8. Disclosing relevant interests to patients

8.1 In addition to disclosing relevant interests to directly affected third parties, a doctor should disclose to patients (or their substitute decision-makers) any interests that could affect, or be perceived to affect, the doctor's professional judgment and ability to exercise objectivity in relation to patient care.

8.2 Such disclosure is an essential part of consent discussions and is important for informed patient decision-making. Examples of when a doctor should disclose a relevant interest to a patient includes when:

- recommending or prescribing a treatment or product in which the doctor (or a close personal relationship) has a pecuniary interest;
- recommending or referring a patient to a health care facility in which the doctor (or a close personal relationship) has a pecuniary interest.

8.3 The doctor should disclose their relevant interests to a patient in a sensitive and timely manner. The patient may even wish to seek a second opinion.

8.4 Mere disclosure of interests usually does not suffice as effective management of an actual or potential conflict. A doctor should respond to patients' concerns over what they determine to be

actual or perceived conflicts of interest. Where an actual conflict exists, active steps with respect to decisions or actions will often be required to manage it.

9. Avoiding or reducing the potential for conflicts of interests

9.1 Doctors should be cautious about taking on new interests that could lead to actual or perceived conflicts in their day-to-day medical practice. For example, the doctor should: [3]

- not ask for, accept or offer any inducement, gift or hospitality from third parties that may affect, or be perceived to affect, patient care. Third parties may include (but are not limited to) companies and organisations directly involved in the health care industry, companies and organisations outside the health care industry, employers, colleagues or other health care professionals;
- not ask for, accept or offer any inducement, gift or hospitality from patients, their family members or carers that may affect, or be perceived to affect, patient care. It may be appropriate to accept a gift of nominal value from a patient so long as it does not affect, or is not perceived to affect, patient care. In some circumstances, rejecting such a gift may insult or embarrass the patient which may actually harm the therapeutic relationship;
- avoid financial involvement with patients (such as investment schemes);
- not encourage patients, their family members or carers to make donations to others or give, lend or bequeath money or gifts that may benefit the doctor directly or indirectly;
- maintain appropriate professional boundaries with patients and their close family members;
- ensure the health and well-being of the patient takes precedence when involved in research or teaching.

10. Medical education and continuing professional development

10.1 Medical curricula should include formal training on identifying and managing actual and potential conflicts of interest in medicine.

10.2 Continuing professional development should include ongoing education and training on identifying and managing actual and potential conflicts of interest in medicine.

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[1] World Medical Association. *Declaration of Geneva.* Adopted by the 2nd General Assembly of the World Medical Association, Geneva, Switzerland, September 1948 and amended by the 22nd World Medical Assembly, Sydney, Australia, August 1968 and the 35th World Medical Assembly, Venice, Italy, October 1983 and the 46th WMA General Assembly, Stockholm, Sweden, September 1994 and editorially revised at the 170th Council Session, Divonne-les-Bains, France, May 2005 and the 173rd Council Session, Divonne-les-Bains, France, May 2006 and amended by the 68th WMA General Assembly, Chicago, United States, October 2017.

[2] Royal Australasian College of Physicians. *Guidelines for ethical relationships between physicians and industry*, 3rd edition, 2006.

[3] Medical Board of Australia. *Good Medical Practice: A Code of Conduct for Doctors in Australia*. March 2014.