

Challenges of Conflicts of Interest in the Caribbean: An Ethical Concern

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ABSTRACT

A conflict of interest occurs when a person, institution, organization, or government allows a secondary interest to interfere with a primary interest. The issue does not necessarily refer to character or integrity, as even the most highly placed persons may have several competing interests. However, governments should adhere to prescribed policies for procurement and awarding of contracts. Public health personnel and organizations should not align themselves with corporate entities and industries whose products are high in sugar, salt, and fat, all of which contribute to chronic and non-communicable diseases.

Health care personnel whose primary obligation concerns the best interests of their patients may be conflicted when they accept gifts from pharmaceutical companies seeking to have doctors prescribe their particular products. Specialists who receive honoraria from drug companies to address medical meetings are likewise conflicted when the disease condition about which they speak is amenable to a product produced by the particular company. Clinical researchers who enrolled their patients in research are also conflicted regarding the best interests of their patients and the possible outcome of the research that could bring fame, fortune, or promotion. Doctors who give expert testimonies in court hearings may also be conflicted.

Institutions, organizations, and members of governments may also be conflicted as local companies, international corporations and other private sector entities seek to influence them on specific matters. Where possible, conflicts of interest should be avoided, and when not possible, they should be managed as described in this article.

BACKGROUND:

The term ‘conflict of interest’ is often used in civil society and political arenas in many countries. In a biomedical setting, a conflict of interest occurs when a clinician, researcher, public health official, research ethics committee/IRB member, university official, medical author, medical reviewer, journal editor, or a public health institution/organization, civil society organization, or government interacting with the private sector, allows a **secondary interest** (e.g. financial gain, career advancement, outside employment, publication opportunity, personal considerations, personal relationships, personal investments, or gifts) to interfere with a **primary interest** (e.g. patient welfare, research validity, the publication of research, or an obligation to act in the best interest of another person, group of persons, or an entity) [1].

The term does not speak to the ‘character’ or integrity of the person concerned, as anyone, even those most highly placed or with an impeccable character, may find themselves in a conflict of competing interests. According to the World Health Organization (WHO) in its Declaration of Interests: A **conflict of interest** occurs when “the expert or his or her partner (a spouse or a person with a close personal relationship), or the administrative unit with which the expert has an employment relationship – has a financial or other interest that could unduly influence the expert’s opinion with respect to the subject matter under consideration.” [2]

An ‘**apparent conflict of interest**’ exists when the existence of another interest could result in the person’s objectivity being questioned by others [2]. This questioning is a real if not foreseeable possibility, especially in situations where transparency and impartiality are desirable. Consequently, situations of possible conflicts in the public arena would best be avoided. This article outlines some examples of conflicts of interest and recommends procedures for their effective management.

EXAMPLES OF INTERESTS

Interests may be ‘tangible’ and ‘intangible.’ A tangible interest is quantifiable or measurable (e.g. financial), while intangible interests are not easily measured, such as scholarly, academic, professional or social concerns (e.g. an interest in one’s reputation). Conflicting financial interests include: conflicting salary, fees (e.g. speakers’ fees), or other forms of income (e.g. corporate advisory committee memberships, providing expert testimony in legal cases), invention rights (intellectual property rights) and royalties, and investment interests [2].

We may also have conflicting duties or other interests, such as: employment interests (e.g. professional position, title), working on a project that can directly benefit a friend or relative, a professional relationship with any entity involved in tobacco production, distribution, or sale, interests that compromise the well-being of participants in clinical research, favouritism (e.g. involving someone who paid you a salary, a fee, honorarium, or similar, or involving an individual with whom you have a close personal or professional relationship), or gifts offered as inducements (e.g. gratuity, favour, discount, entertainment, hospitality, loans, travel costs, or other items having monetary value) [1].

Added to these are the various non-financial sources of bias, such as political bias (political beliefs or opinions influencing decisions), ideological bias (decisions influenced by ideological considerations), professional bias (e.g. professional jealousy), and religious bias (religious beliefs, concerns, or considerations possibly influencing decisions).

THE ANATOMY OF A CONFLICT OF INTEREST

The process that may result in a conflict of interest involves three stages:

Stage 1 – The Antecedent Acts: These are factors that condition a person’s mind towards ‘partiality’, thereby compromising the person and their duty to foster the public’s interest over their own private or personal interest [1]. Example: government employees accepting gifts, paid dinners, and similar.

Stage 2 – The State of Mind: This represents the affected sentiments, dispositions, proclivities, or affinities that are conditioned by the antecedent acts. So, a politician who accepts a substantial campaign contribution from an individual may be more inclined to favour that individual’s special business needs in legislative decisions, or in the awarding of contracts, etc., than if no contribution were given [1].

Stage 3 – The ‘Outcome’ behaviour or Behaviour of Partiality: Those actions taken by the conflicted individual (decisional behaviour) arising from the state of mind affected by the antecedent acts [1]. The outcome behaviour could result in self-aggrandizement, or in rewarding friends or associates at the expense of the general public and their best interests.

EXAMPLES OF CONFLICTS OF INTEREST

Conflicts of interest invariably raise ethical concerns of potential bias, perceived deception, and loss of trust. Some countries have policies and legislation that govern contracts and procurement, and these customarily underscore the principles of accountability and transparency [3]. In public procurement, there are direct as well as indirect ways that personal relationships can create problems, and these customarily involve close and extended family members, suppliers, bidders, consultants, contractors, friends, and employees.

Conflicts of interest are also deeply embedded in many areas of public health. For example, commercial entities whose products are high in fat, salt, and sugar may contribute to obesity and

non-communicable diseases, therefore, persons who work in the public health arena and are thus entrusted with safeguarding the public's best interests should not be perceived to be accepting gifts, lunches, or 'drinks' from persons or companies whose primary interests do not lie in the same public domain [4].

Ministries of Health and other public health organizations should also adopt a similar approach. In the past, corporate funding and partnerships have been associated with biased outcomes in scientific studies and the adoption of less effective measures in public health partnerships for NCD prevention [4]. So while ministries and public health organizations may wish to partner with members of the private sector to ameliorate specific problems, the choice of the private sector partner should be made carefully against the background of public perception, as the aims of the two entities may be different. The primary aim of the private sector company may be financial gain, while that for the public health organization is to prevent and mitigate disease states in the general population.

In the health care sector, medical practitioners treat patients with chronic diseases, and numerous medications exist on the market for these diseases. Pharmaceutical representatives frequently visit private doctors' offices with the aim of influencing increased prescriptions for their pharmaceutical products. Some doctors may receive small mementos as reminders, while others may receive substantial gifts including airfares to attend overseas conferences.

Specialists may receive honoraria to speak at medical meetings or conferences about a specific chronic disease which may be amenable to the medical product that the particular company manufactures. These specialists, whose primary duty is to promote and prescribe the best medication for patients, may be conflicted since the drug company will expect them to promote and prescribe their marketed products.

A conflict of interest may also exist for the clinical researcher, a medical doctor who does research. In medicine and health care, the medical doctor has a primary duty to always seek to benefit the individual patient under their care [6-11]. In research, the aim is to acquire new knowledge to benefit the wider society [12]. The focus is not the individual patient who may be enrolled in the research. A positive outcome to the research may bring fame, fortune, and promotion to the individual researcher [13]. The researcher is therefore conflicted in regards to the interests of the enrolled participants and their specific interest in the outcome of the research [14]. Consequently, researchers may be tempted to understate or not disclose all the possible risks of the research when seeking to enrol their patients, as they seek to achieve the required number of research participants.

In seeking to protect their reputation and trust in the validity of published research, most medical journals now require researchers to make a declaration of any conflicts of interest before their manuscripts are accepted for publication [5]. This is important, since professional judgement concerning a primary interest – the integrity of research, may be adversely influenced by a secondary interest – financial gain, particularly where the researcher may have a financial relationship with a pharmaceutical company.

Thus, a company might finance a researcher with the understanding that he or she will publish only the data that is favourable to the company's financial interest [5]. If this happens, the published study might constitute only a fraction of the work that was undertaken. Readers, even experts in that field, might not be able to properly assess the primary data on which the conclusions of the study were based, yet in research, it is crucial that persons be able to assess the trustworthiness of their source [15]. Consequently, such disclosure is necessary to alert regarding possible bias in the study design and conclusions.

Doctors and other scientists, based on their perceived expertise, may also be called to provide expert testimony in a court proceeding [5]. Their opinions are likely to be accepted as authoritative, as the judge and members of the jury are unlikely to have the requisite knowledge to critically assess what the doctor said. If the doctor is testifying about an injury to their patient, the doctor could be further conflicted. The court should therefore be informed of any relationships, financial or otherwise, that may compromise the judgement and pronouncements of the doctor or scientist, and expert witnesses should be cross-examined with regard to possible conflicts of interest. This can help the jury assess the witness's reliability as an expert on the issues under discussion [5].

‘ETHICS’ VERSUS ‘LAW’

The USA has federal conflict of interest laws that are designed to protect the government process from ‘actual or apparent conflicts of interest’ (e.g. the 1972 *Federal Advisory Committee Act* [FACA]) (1). However, Caribbean countries do not have such legislation and so must depend on a respect for ‘ethics’ and ethical considerations. Unfortunately, however, a disregard for ‘ethics’ carries no legislative penalty.

We should also note that ‘law’ is minimalistic in its approach, specifying what we ought **not** to do – at the risk of some penalty, but law doesn’t tell us what we ought to do. The latter falls to the domain of ‘ethics.’ ‘Ethics’ functions within the parameter or perimeter that is set by the law, and has 2 aims: 1) It tells what ‘ought’ to be done, and 2) It provides strong reasons for doing so (ethical justification or rationale). Both of these stipulations are crucial for every society, and persons or groups that break society’s ethics ‘dictates’ are customarily publicly shamed in the media or elsewhere, and may be socially ostracized in the process. However, the penalty may not be as devastating as those imposed by law.

MANAGING CONFLICTS OF INTEREST

It is difficult, if not impossible, to determine to what extent a person's secondary interest (personal, financial, etc.) is likely to interfere with or influence the judgement that they are required to make regarding the primary interest under consideration. This matter assumes even greater importance when the public's interest is one of, if not the main issue of concern [16].

Regardless of its source, the bias that is associated with conflict of interest situations may permanently damage both the public's trust, as well as a person's reputation. Hence, whenever possible, conflicts of interest situations should be avoided.

The 'reasonable person' standard:

A person should re-consider their level of involvement in a project, if a *'reasonable person'* who knew the circumstances, could: a) legitimately question the degree of fairness in the issue, or b) imply bias or favouritism. Despite the foregoing, in the smaller islands of the Caribbean or within small communities, conflicts of interests are very likely to occur.

If conflicts of interest cannot be avoided, then effective steps should be undertaken to 'manage' the conflicts. Three essential steps are required. There must be:

- A **public disclosure** of the conflict of interest
- A **limitation** of the conflicted person's involvement in the particular decision or work; or
- An **exclusion** of the conflicted person from the work altogether!

In such disclosure, both the nature of the conflict as well as its magnitude are very important considerations [5]. Nevertheless, we should note that simple disclosure does not eliminate bias. Complicating this approach is the perception of *'possible bias'* by the person in the eyes of the public. One can never 'prove' the absence of bias in the decision-making process, and so the

option of ‘simple disclosure’ of a conflict of interest may not be fully satisfactory in matters that are related to the public’s interest. Therefore, limiting the person’s involvement in decisions in which they have an interest, or totally excluding them from particular positions where their decision-making may be questioned, are options that should be taken, depending on the particulars of each case.

In addition to conflicts of interest occurring at the ‘micro’ or individual level, conflicts may also occur at the ‘meso’ level (the level of institutions or organizations) and at the ‘macro’ level (national or governmental level). For example, at the organizational level, the UK Royal College of Paediatrics and Child Health was recently strongly criticized when it voted in October 2016 to continue accepting funding from manufacturers of breast milk substitutes [17]. At the national level, transnational corporations often interfere in the policy-formulation process of governments, and seek to avoid any existing regulations that would inhibit market concentration and wealth accumulation [18]. The potential for major private sector donors or partners to distort the priorities of governments and international agencies has been a major concern [19].

Due to conflicts of interest arising at that level, in 2015 the WHO developed principles and policies of engagement with non-State actors that distinguished between actors in the public and in the commercial interest, and the avoidance, prevention, and management of conflicts of interest [18]. Private commercial actors can benefit greatly when they are able to influence the formulation of WHO policies. Likewise, transnational corporations lobby countries in order to gain influence in matters related to their own financial interests. Unfortunately, political power is sensitive to and highly influenced by economic considerations and pressures.

Yet global health partnerships have contributed to both the manner in which global health is governed as well as to improved global health outcomes [20]. However, the need to accelerate

the development, production, and distribution of beneficial products to meet the health needs of the poor and vulnerable must be balanced and supported by good governance and the avoidance or adequate management of conflicts of interest. Strong strategic planning, transparency and accountability, well defined roles and responsibilities of partners in the process, policies and funding allocations that are based solely on the strategic priorities, identification of cost-effective remedies for anticipated problems, and adequate attention to promoting equitable access are all crucial to the process [20].

CONFLICT OF INTEREST POLICIES

In light of all the foregoing, written policies should exist to manage conflicts of interest, and be implemented to reduce or eliminate perceived bias [21]. Such policies should include a definition of terms, a policy statement of the institution or organization, examples of relevant interests, and the step-wise process for managing conflicts of interests as outlined above.

Where institutions or organizations wish to engage or enter into partnerships with commercial entities, there must be *a priori* deep deliberation regarding whether: 1) The partnership is desirable or necessary (risk/benefit assessment); 2) It allows independence, and the maintenance of integrity and credibility; 3) It may positively advance public health, beneficial public agendas, or the common good; 4) Ethical assessment and due diligence will be done before engaging the commercial entity; 5) On-going reviews of the engagement or partnership will be done to assess the degree to which it is meeting the initial objectives; and 6) Whether criteria for disengagement will be developed. In order to proceed, the answers to all the above-mentioned questions and related concerns should be positive [21].

These policies should also be made public to foster public trust. Individuals or organizations that promote transparency will be better able to recognize when conflicts of interest might or will occur. Objectivity is fundamental for identifying situations of conflicts of interest. At the institutional, organizational and national levels, the analysis should not only include, for instance, the contents of any products manufactured by the commercial interests, but also their policies and practices, mission, goals, aims, principles, and vision [18]. The specific interests of a company can reveal possible sources of conflicts of interest for entities that may wish to engage with them. Public-private partnerships with large corporations offer potential benefits to the health sector, but adequate and appropriate safeguards should exist [19].

CONCLUSION

Written policies and procedures that can help identify and eliminate conflicts of interests should exist within all centres, institutions and organizations. Within any conflict of interest management plan, there should be a public disclosure of the conflict and a modification of the plan of work, as necessary. There should also be a monitoring of the work by independent persons to ensure that the conflicted person eliminates their conflicting interest. If not, then the person should be removed and replaced by someone who is not conflicted in the matter.

Institutions and organizations should follow the procedures outlined in this article to manage conflicts of interest. The criteria outlined for possible engaging in partnerships should also be followed.

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