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Conflict of interest in public health: should there be a law to prevent it?

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Abstract

"Conflict of interest", now being commonly cited, is a set of circumstances that creates a risk that professional judgement or actions regarding a primary interest will be unduly influenced by a secondary interest. Conflict of interest situations can be institutional or personal, and can stem from financial or other interests including post-employment opportunities or during public private partnerships. Conflicts of interest in the creation of public policy, especially health or nutrition related policies such as the vaccine policy, tobacco control, and research related to health, can have negative impact on the lives of millions of people. While the UN Convention Against Corruption, to which India is a signatory, identifies conflict of interest as often being a precursor to corruption, there is no serious action being taken in this direction by the Indian government, in spite of the fact there are instances of serious nature coming to light that affect our peoples lives. If conflict of interest situations are allowed to continue especially in health policy it could be detrimental to millions of people; therefore, it would be in public interest that India enacts a law to prevent conflict of interest in the making of public policies, comprehensive enough to include financial and institutional conflicts of interest.

Introduction

Most of us believe that we know what conflict of interest is, as the concept is old and has been used in an English proverb: "He who pays the piper calls the tune." Despite its long history, the term conflict of interest is a relatively new one. The first appearance of the term in ethics codes dates back to as early as the 1970s. Thereafter, the medical literature started to pay serious attention to the concept. Now the term is in common use throughout the world (1). Connected with the concept is the "Duty of Loyalty", a term used in corporate law to describe a fiduciary's "conflicts of interest" and according to which the fiduciaries must put the corporation's interests ahead of their own (2). Similarly, government officials/representatives can be considered to be in a position of trust due to their *duty of loyalty* towards the country's citizens. They are obliged to work in the interest of the public, which pays for them or has brought them to power, both ethically and legally. A round-table discussion on "Prevention and management of conflict of interest" was organised in Delhi on September 13, 2014, under the aegis of the Alliance Against Conflict of Interest (AACI) by the Breastfeeding Promotion Network of India (BPNI) /International Baby Food Action Network (IBFAN) Asia, in which several forms of conflicts of interest in public policy-making were listed. These included the inclusion of "experts" from industry in regulatory bodies; the revolving door phenomenon, which denotes the movement of policy-makers and government officials in and out of the industry that they regulate; incentives for policy-makers, regulators and monitors, including the payment of their salaries; ownership of stocks and shares of a company by its regulators; presence of private-sector experts in policy-making/recommendatory bodies, such as the National Technical Advisory Group on Immunisation (NTAGI); and institutional conflict of interest and public–private partnerships (PPPs) in general (3). Over the past few years, conflict of interest has become an important consideration in governance. Prime Minister Modi's 17-point agenda reflected the Indian government's recognition of the need to prevent conflict of interest (4). Most recently, the issue drew a great deal of attention when the Supreme Court observed that there was

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To cite: Gupta A, Holla R, Suri S. Conflict of interest in public health: should there be a law to prevent it? *Indian J Med Ethics*. 2015 Jul-Sep; 12(3): 172-7.

Published online on June 4, 2015.

a conflict of interest in Mr N. Srinivasan being the president of the Board of Control for Cricket in India (BCCI) (5).

This comment is an attempt to highlight some forms of conflict of interest in India, with a few examples of those that have a negative impact on human health. The first example is that of the clinical trials of the HPV vaccine, led by PATH and the Indian Council of Medical Research (ICMR) (6). Second, we shall take a look at how the Indian Tobacco Board (ITB) of the Government of India uses public money to subsidise the tobacco industry and promote the use of tobacco, despite having signed and fully ratified the World Health Organisation's (WHO) Framework Convention on Tobacco Control (FCTC) (Article 17). Yet another case is that of the National Health Research Policy, which fosters conflicts of interest with its objective of encouraging PPPs by engaging with the private sector. The fourth example is that of the national vaccine policy being in the hands of private bodies. Since conflicts of interest in public policy-making in these areas can have a serious impact on the citizens' fundamental rights, especially basic human rights to health, we make a case for preventing conflicts of interest in decision-making processes at the very outset, through a legal framework, since prevention is better than cure.

Definitions

Some of the definitions of conflict of interest are as follows.

Conflict of interest means that the expert or his/her partner ("partner" includes a spouse or another person with whom s/he has a similarly close personal relationship), or the administrative unit with which s/he has an employment relationship, has a financial or other interest that could unduly influence the expert's decision with respect to the subject matter being considered (7).

A conflict of interest involves a conflict between the public duty and private interests of a public official in which the public official's private-capacity interests could improperly influence the performance of his/her official duties and responsibilities (8).

Transparency International (TI) defines conflict of interest as a "situation where an individual or the entity for which they work, whether a government, business, media outlet or civil society organisation, is confronted with choosing between the duties and demands of their position and their own private interests" (9).

The free web dictionary of West's Encyclopedia of American Law, defines conflict of interest as "a term used to describe the situation in which a public official or fiduciary who, contrary to the obligation and absolute duty to act for the benefit of the public or a designated individual, exploits the relationship for personal benefit, typically pecuniary" (10).

A conflict of interest is a set of circumstances that creates a risk that professional judgement or actions regarding a primary interest will be unduly influenced by a secondary interest (11). Institutional conflicts of interest arise when an institution's own financial interests or those of its senior officials pose the risk of exerting an undue influence on decisions involving the institution's primary interests. In the case of academic institutions, such risks often involve the conduct of research within the institution and could affect the value of the institution's patents or its equity positions or options in biotechnology or pharmaceutical companies or companies dealing in medical devices. Conflicts of interest may also arise when institutions seek and receive gifts or grants from companies, for example, the gift of an endowed university chair or a grant for a professional society to develop clinical practice guidelines (11). Conflict of interest can stem from financial or other kinds of interests. A public official who serves on the board of a corporation or explicitly considers post-employment opportunities in the private sector certainly creates a situation of conflict of interest.

Conflicting policies and institutional conflict of interest

How ICMR ignored rules to benefit a vaccine maker

Several instances of conflict of interest have arisen in the past few years during the clinical trials of the HPV vaccine, jointly led by PATH, a USA-based organisation interested in the promotion of the vaccine, and the ICMR, with funding from the Bill and Melinda Gates Foundation. It is noteworthy that India's Parliamentary Standing Committee on Health and Family Welfare investigated this case. Its report (12) highlighted that during the conduct of the trials, there were conflicts of interest both in the ICMR and the inquiry committee appointed to look into the issue of conflicts of interest. The committee noted that the ICMR, the mandate of which is to formulate ethical guidelines for researchers, became a direct party in the study through its presence in the project's advisory committee. Further, the head of the department of obstetrics and gynaecology from the All India Institute of Medical Sciences (AIIMS), a premier public medical institute in the country, was appointed a member of the inquiry committee, in spite of the fact that the manufacturer of the vaccine had funded her department to carry out trials of the vaccine. In addition, the manufacturer had sponsored her visit to a conference in Seoul, a fact that was not mentioned despite the requirement of a mandatory declaration under the Foreign Contribution Regulation Act (FCRA). The committee found that the ministry had appointed a senior official of the ICMR to assist the inquiry committee. This was a clear instance of conflict of interest, as this person could not be relied upon to provide correct information, having previously been involved in discussions to help PATH carry out the project. The report held the ICMR responsible for numerous irregularities that it had reportedly committed during the study and strongly deprecated the government's casual approach in appointing a committee of inquiry without finding out whether any of its members had any conflicts of interest (12). The report also noted that the ministry had not sought written declarations on conflicts of interest from the members of the inquiry committee. It said, "No written Conflict of Interest declarations were sought from

the core members of the Inquiry Committee, as well as experts. It was understood that if there is any conflict, the highly learned members will point it out."

Conflicts of interest in tobacco control

At the level of policy-making, conflict occurs when the government has two conflicting policies, i.e. when one department may be mandated to weaken the policy of another. For example, the FCTC (13), a United Nations treaty ratified by 179 countries, clearly recognises "the need to be alert to any efforts by the tobacco industry to undermine or subvert tobacco control efforts…" in its preamble. It is clearly stated in Article 5.3, in the treaty's general obligations, that "parties, in setting and implementing their public health policies with respect to tobacco control, shall act to protect these policies from commercial and vested interests of the tobacco industry". There are detailed guidelines for the member states on conflicts of interest and the measures that can be taken to protect the relevant public health policies. The Government of India signed and fully ratified the FCTC in 2004 (Article 17) to minimise the cultivation of tobacco and promote viable alternatives to tobacco. On the other hand, the ITB, which was instituted under the Union Ministry of Commerce through a parliamentary Act, uses public money to subsidise the tobacco industry and promote the use of tobacco. In 2012–13, the ITB provided subsidies worth Rs 3.73 crore to farmers growing flue-cured Virginia tobacco (FCV) (14). According to WHO, there is an inherent contradiction between corporate social responsibility (CSR) and tobacco companies, since the industry's functions are in conflict with public health goals (15) and Article 5.3 of the FCTC explicitly requires de-normalisation and regulation of such activities (16). Section 5 of the Cigarettes and Other Tobacco Products Act 2003 (COTPA) prohibits both direct and indirect advertising of tobacco, but the Ministry of Information and Broadcasting has published rules allowing brand extension in advertising (18).

National Health Research Policy encourages conflicts of interest

The National Health Research Policy, formalised in 2011, also fosters conflicts of interest. Developed in response to the public campaign against trials, it, however, promotes "intersectoral coordination in health research, including all departments within the government, private sector and the academia, to promote innovation or innovative research and ensure effective translation to encourage/ accelerate indigenous production of diagnostics, vaccines, therapeutics, medical devices, etc.". Encouraging PPPs is mentioned as another objective of the policy in a section titled "Engage with private sector". The policy allows for the movement of policy-makers, including technical persons, to and from the private sector, which would clearly lead to a conflict of interest (19). In 2013, we obtained information under the Right to Information (RTI) Act from the Ministry of Health and Family Welfare (MOHFW) and, for that matter, several ministries of the Central government regarding the existence of any guidelines to prevent or manage conflicts of interest. We found that none of them had any mechanism to deal with conflicts of interest (20). Resolving conflicts of interest is often limited to disclosure and depends on the good intent of the conflicted individual who is expected to recuse herself/ himself. That, too, is left to individual minds.

How is the National Vaccine Policy being handled?

It is time that the National Technical Advisory Group on Immunisation (NTAGI) made a declaration of conflicts of interest, but private monies fund its secretariat, the Gates Foundation being one of them (21). The NTAGI is now being managed by the Public Health Foundation of India (PHFI), a private organisation funded by the government and several private players. Thus, a privately funded, so-called philanthropic agency has been given charge of the agenda and minutes of NTAGI meetings, This agency does not mention the reasons for dissenting votes (22). Such arrangements create serious conflicts in public policy.

What are the dangers of conflict of interest in public policy-making?

Allowing conflicts of interest to prevail literally means allowing those policies to get changed or distorted in favour of private interests or vested parties. The HPV vaccine trials show, in a very stark and dramatic manner, what can result from conflicts of interest in public policy. The vaccine has numerous adverse effects, including convulsions and death, but still no action was taken. If children are given unnecessary vaccines, it is not just a matter of an economic loss; it could also mean a serious health hazard. This is borne out by the several deaths that allegedly resulted from the injection of Pentavalent vaccines (23). As for tobacco, the health hazards (increased likelihood of lung cancer, cardiovascular diseases, etc.) are well known (24). There is a fundamental conflict between the private producer, "industry/corporation" or the organisations/ lobbying bodies/front organisations related to these and the public services/institutions. The formation of PPPs, the usual approach being taken these days, actually ends up benefitting the "vested interests" rather than the public. Corporations unashamedly continue to meddle in public policy, and profit, trade and the market give rise to conflicts of interest. For a considerable period of time, corporations had been making the point that the world could survive only if there were "PPPs" and "stakeholder dialogues". The use of this strategy allowed corporations to get closer to policy-making. As a result of this, conflicts of interest became widely prevalent. On March 4, 2011, the Supreme Court of India passed a historic order to guide policy-makers and parliamentarians on the management of conflicts of interest. The Court has directed that scientific panels of the Food Safety and Standards Authority of India (FSSAI) should not have representatives of the industry, but independent experts, in consonance with Section 13(1) of the FSSAI Act 2006 (25). Let us look at the simple example of food related policy. Recent reviews revealed how financial conflicts of interests can bias the scientific results in relation to sugar consumption and obesity (26). At the same

time the negative impact high sugar food can have on public health in terms of obesity and non- communicable diseases is also documented well (27).

Addressing conflict of interest: insights from around the world

There are global precedents in the area of legislation to prevent conflicts of interest that are associated with corruption. Canada was the first to come up with one such legislative framework. Bosnia, Turkey, Macedonia, Montenegro, Serbia, Croatia and some states of the USA have also passed such legislation (28). Today, there is growing awareness of conflicts of interest, both at the national and international levels, and several national laws have incorporated changes to make conflicts of interest in public policy a punishable offence. For instance, Article 323 of the Italian Criminal Code (29) specifically refers to "the public official or the one responsible for a public function who, as part of these functions or service, by violating the legal rules or regulations, or by failing to refrain when faced with a personal interest or with that of a close relative, or in other cases provided, intentionally procures for himself or for others an undue patrimony or unjustly causes damages to others…." Similarly, Article 432-12 of the Criminal Code of France (30) incriminates the offence of "influence peddling", calling it "breaches to the duty of honesty", along with other actions, such as active and passive corruption, taking an unlawful interest (including by a former civil servant), favouritism, misappropriation of public funds, and improper demands or exemptions in relation to taxes (31). An amendment to the new Criminal Code of Romania goes further, and aims to make remunerated and unremunerated public officials who allow conflicts of interest in policy-making criminally liable. The amendment in this law brings within its ambit all levels of the executive branch of the government, as well as autonomous bodies, public sector institutions, private partners executing jobs delegated to them by the government, and others whose actions can have a negative impact on people, such as doctors, chartered accountants, lawyers and pharmacists. The law also holds that passive acceptance of conflict of interest is criminal: it can signify being an accomplice, instigation or complicity. When the decision concerned was taken by a collective body, then all the members who knew of the existence of the conflict of interest, and did not act against it, are liable for punishment, even if they did not materially benefit from the decision (32, 33)

The way forward

Conflict of interest is generally believed to be a situation rather than an action, and thus many do not consider it an offence. The crucial difference between individual cases of corruption and corruption associated with the existence of conflicts of interest in policy-making processes is that the latter has an impact on the lives of all citizens in the country, especially when it is a policy related to meeting the basic needs of food, healthcare, water, shelter and livelihood. The most dangerous thing about such corruption is that it is very commonly disguised as public service and contribution to nation-building. The general trend has been to de-link conflicts of interest from corruption. However, conflicts of interest—both those, which are illegal and those which are present as a part of official policy—are obvious forms of corruption and in themselves contribute to the process of corruption. The UN Convention Against Corruption (34) clearly recognises that conflicts of interest can lead to corruption and urges nations to "endeavour to adopt, maintain and strengthen systems that promote transparency and prevent conflicts of interest". The 69th report on India's Prevention of Corruption Amendment Bill 2013 recommends that conflict of interest be included under bribery (15A) (35).

Rajeev Dhavan, a senior lawyer of the Supreme Court, and a constitutional expert, recently argued in favour of a law to prevent conflicts of interest. According to him, it should include political interests, it was of the utmost importance and in fact, he questioned the retainership by corporate houses of politician–advocates, who, in turn, may become influential parliamentarians or even ministers. He went to the extent of describing this as nothing short of disguised bribery (36). Even more relevant is the recent controversy around warnings on tobacco products raised by the members of the Parliamentary Standing Committee on Health.

If there were a law to prevent conflicts of interest, Srinivasan would not have been the BCCI president.

The examples we have given relating to public health are perhaps the tip of the iceberg, if one considers the size and diversity of the country and the nature of the issues that have to be dealt with. Conflicts of interest have a negative impact on the health of the people and we strongly argue that something be done to prevent them. They can be stopped only through some kind of preventive step, such as a law. Soft policy frameworks, such as self-regulation and "guidelines", including the FCTC guidelines, have not yielded the desirable results. The actions taken earlier by the Supreme Court in the case of the FSSAI and more recently, in that of the BCCI have certainly given parliamentarians some food for thought. Therefore, we strongly recommend a robust legal framework to prevent and manage conflicts of interest.

We believe that the answer lies in a mechanism of disclosure and recusal from a specific decision. Throughout the world, legislation and directives on conflicts of interest cover these two aspects. The Private Member Bill 2011, "Prevention and Management of Conflict of Interest", which was introduced in the Rajya Sabha had these elements (37). This has been introduced again in 2015. Clause 7 of that Bill placed restrictions on gifts and benefits. Politicians or government officials who have a duty of loyalty should not accept gifts, payments or any other benefits from, or even to enter into a discussion with, corporates with regard to which they are taking decisions. Such situations must be checked at the very outset as further damage may be controlled if we nip the evil in the bud. What we need is a "Prevention of Conflict of Interest Act" along the lines of the Bill of 2011. In the case of the HPV

vaccine trials, the Parliamentary Standing Committee found incriminating evidence of conflict of interest. Even though the trial resulted in the unwarranted deaths of girls, no action has been taken yet, which seems to have set a precedent that those guilty of such actions should go scot-free. The situation is unlikely to change unless preventive action is taken.

However, care should be taken to make sure that the law does not limit itself to disclosure, while allowing conflict of interest in decision-making processes, as is the case in several countries. The law should be comprehensive and cover all aspects of conflict of interest. It should cover financial as well as institutional conflicts of interest, especially in decision-making processes. Political and private interests should also come under the purview of the law, when they are linked.

This can be the beginning of a new era in the history of governance in India, with special reference here to the health and nutrition sectors. The amended Criminal Code of Romania has shown the world how one can go about preventing conflicts of interest in the making of public policy. India should take the step of enacting such a law, which should also allow *suo moto* cognizance of situations of conflict of interest. If governance moves the PPP way safeguards should be kept and this is the answer. It is only through such strict measures and their stringent enforcement that public probity can be ensured and the lives and well-being of the people protected. Public-spirited lawyers should get together to present a comprehensive Bill to the government which could take further action towards initiating a discussion in Parliament and enacting adequate laws.

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Home-based management of severely acute malnutrition: feasibility of ethically designed, community-based randomised clinical trials

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Abstract

The Indian Council of Medical Research had, on May 31, 2011, called for research proposals on severely acute malnourished (SAM) children to generate evidence for the development of practical and scalable regimens to medically rehabilitate children suffering from SAM, without serious complications, at the home/community level and/or peripheral inpatient facilities. The primary outcomes of the proposed research study are recovery from SAM in the short term, as well as sustenance of recovery (for at least six months after the initiation of treatment). The secondary outcomes are the acceptability, feasibility and safety of the regimes being tested. It was suggested that the studies be designed as individual or cluster randomised or quasi randomised controlled trials (RCTs). This paper analyses the methodological, operational, and most importantly, ethical challenges and implications of conducting community-based RCTs involving SAM children. The paper dwells in detail on why and how the RCT design is inappropriate and unsuitable for studying the effectiveness of home-based management of SAM children in the community.

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To cite: Patil RR. Home-based management of severely acute malnutrition: feasibility of ethically designed, community-based randomised clinical trials. *Indian J Med Ethics*. 2015 Jul-Sep: 12(3): 177-81.

Published online on May 12, 2015.

Introduction

Throughout the developing world, malnutrition is a major public health problem, accounting for nearly 50% of the deaths of the 10–11 million children under 5 years of age (1). In India, about 6.4% of children below the age of 60 months are suffering from severe acute malnutrition (SAM) (weight-for-height less than –3SD), according to the National Family Health Survey-III conducted in 2005–2006 (2). In the developing world, the risk of mortality among SAM children is directly proportional to the severity of the condition (3, 4). Over the years, the case fatality rate for malnutrition in health facilities has been 20–30% in the case of marasmus and up to 50–60% in that of kwashiorkor (5,6).

The Indian Council of Medical Research (ICMR) had called for research proposals on SAM children to generate evidence for the development of practical and scalable regimens to medically rehabilitate children suffering from SAM, without serious complications, at the home/community level and/or peripheral inpatient facilities. The primary outcomes of the proposed research study were to include recovery from SAM in the short term, as well as sustenance of recovery (for at least six months after the initiation of treatment). The secondary outcomes were to include the acceptability, feasibility and safety of the regimes being tested. The studies could be designed as individual or cluster randomised or quasi randomised controlled trials (RCTs). Letters of intent were solicited by the ICMR in the following areas.

1. An operationally feasible approach to identify children in