

#### **COMMENTARY**

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# Is 'conflict of interest' a Misnomer? Managing interests in immunization research and evaluation

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#### **ABSTRACT**

Potential conflicts of interest in vaccine research can lead to negative consequences that undermine public trust and thereby put communities at risk. However, collaborations that may give rise to potential conflicts between interests can also greatly facilitate appropriate, scientifically robust, and timely vaccine development, implementation, and evaluation. At present, policies regarding the management of potential conflicts between interests are not ideal. To optimally manage interests in vaccine research, we recommend acknowledging all forms of interests and treating them all as relevant, developing appropriate collaborations, referring to all "conflicts of interest" simply as "interests" or "declarations," and promoting transparency through developing consistent reporting mechanisms.

#### **ARTICLE HISTORY**

Received 23 December 2020 Accepted 15 January 2021

#### **KEYWORDS**

Conflict of interest; vaccines; disclosure; collaboration; research

#### Introduction

The Canadian Association for Immunization Research, Evaluation, and Education (CAIRE) is a professional organization aimed at encouraging and enhancing vaccinology research and immunization program evaluation (www.caire.ca). CAIRE members conduct or support vaccine research and immunization program development, education, and training. CAIRE brings together interdisciplinary stakeholders in vaccine research for discussion of pertinent issues in the field. Following recent discussions of how vaccine manufacturers, government, clinicians, and academics can collaborate to foster and maintain public trust in vaccine research and immunization programs as well as how best to facilitate this, we reviewed policies and developed recommendations for managing interests in vaccine research.

Individuals working in healthcare have numerous interests stemming from personal beliefs, monetary benefits, professional pressures, and more. Commonly referred to as "conflicts of interest," the presence and implications of these interests are relevant to all areas of health, including provision of services, research, policy development, and public communications. Such interests represent a particularly important issue for preventive public health approaches, such as immunization, because they may undermine trust in programs, institutions, and recommendations, thereby putting communities at risk. Terrible consequences have arisen out of actions based on conflicting interests; a notable contemporary example is the opioid crisis.<sup>1</sup> The presence of real or perceived conflicts between interests in the context of immunization has fuelled

vaccine hesitancy.2 Ironically, the very collaborations (e.g., between researchers and industry) that give rise to potential conflicts between interests can also greatly facilitate appropriate, scientifically robust, and timely vaccine development, implementation, and evaluation.<sup>3</sup> For example, this kind of collaboration recently generated the evidence to support reduced dosing schedules for human papillomavirus (HPV) vaccination in younger age groups, based on demonstration of non-inferiority of fewer doses.4

Current terminology most often used to describe the issue that is "conflict of interest" - poses a challenge in that it prejudges the outcome of the discussion and labels partnerships as inherently negative or adversarial. Interests that differ are not necessarily in conflict. In many situations, the effective combining of diverse opinions can yield a more acceptable and successful outcome.

At present, policies regarding the management of potential conflicts between interests, from journals, organizations, or expert groups, are not ideal. They are almost always restricted to individual, voluntary self-assessment, and declaration with minimal policing to verify declarations.<sup>5</sup> Definitions of conflict of interest are often limited or absent, sometimes with the intent to be broad-ranging and inclusive, but this can also minimize or completely overlook many of the interests actually present (Panel 1). There are substantial discrepancies between disciplines and institutions as to how conflict of interest is defined and addressed.<sup>5</sup> There is also a general lack of transparency, which fosters distrust between the public and health care providers, researchers, university

administrators, public health agencies, and governments. In some instances, concern about real and perceived conflicts has led to policies that block potentially beneficial interactions between particular groups - notably public health and industry. Through consultation with a range of experts in immunization research and provision, it was apparent that there is substantial variation in policies between clinical disciplines, fields of research, and specific institutions. There also appears to be large variation in adherence to, and knowledge of, such policies. Improved clarity and consistency can improve management of these interests, and also foster improved trust and understanding of why these partnerships are important.

# **Scope of interests**

Existing declarations and policies regarding conflicts of interest are often limited to financial partnerships with industry and sometimes are further limited based on time (e.g., prior 3 years). It is critical to acknowledge and declare interests beyond this narrow scope. Important interests may also be present in partnerships with governments that have motivations to provide some services and not others; health authorities/agencies that are integrated with and potentially motivated by governments; funding agencies that set research agendas; and institutes, foundations, and non-governmental organizations that solicit donations as sources of funding. Furthermore, interactions with industry can vary substantially in nature, resulting in a broad scope of contexts within which interests can operate.

Within academia, one must manage not only motivations for positive results and research outputs that will more likely lead to professional benefits such as promotion, but also preconceptions and preexisting biases of individual investigators. Such preexisting biases and preconceptions can greatly influence interpretation of findings. For example, reports of increased risk of 2009 pandemic influenza A (H1N1) requiring medical attention among individuals who had received the 2008-09 seasonal influenza vaccine were challenging for many researchers, public health decision-makers, and academic journals to accept. Findings of increased risk of childhood narcolepsy following H1N1 vaccination were similarly difficult for many to accept, resulting in delayed publication and dissemination of findings. Initially, both of these observations were actively dismissed by many as they were counter to the existing knowledge paradigm.

In line with the publication bias experienced by unexpected findings, medical journals are not immune to issues that can accompany interests. Although medical journals require author interest declarations, they themselves may be heavily swayed by income and impact factor benefits that can be realized through prioritizing publication of industrysupported studies.<sup>8</sup> As a result, vaccine trials are more likely to be published in high-impact journals and have expanded possible impact if they are supported by industry.9

### Fostering trust among the public

It is important to acknowledge that although conflicts between interests may be more "perceived" than "real," they are nonetheless valid. Both perceived and real conflicts between interests can significantly damage public trust. Unfortunately, all relevant parties have a history of actions that may have reduced public trust, including but not limited to: industry, academia, patient advisory groups, and governments (Table 1). While some authors have not found a relationship between industry sponsorship of studies and favorability of results, 14 multiple reviews have documented that industry-sponsored studies and health economic analyses tend to be more favorable toward the sponsors' products than non-industry sponsored studies. 15 Evidence suggests that physician prescribing behavior is impacted by industry contacts, even when the interactions are subtle and even subconscious in nature.16 Given the subtle ways in which clinical care and prescribing can be affected, it is perhaps surprising that organizational interests are not declared in Canadian clinical practice guidelines.<sup>17</sup> Even individual investigators working at seemingly independent institutions are subject to competing interests driven by their own motivations for career benefit or fame which have, in some extreme but welldocumented cases, led them to produce fraudulent data for publication.<sup>18</sup> More subtle and perhaps more frequent is the support offered to resource-constrained public health decision-makers and clinicians by better-resourced industry representatives, which can result in industry becoming the main source of information or knowledge translation.<sup>19</sup>

Impacts resulting from conflicts between interests are concerning to the general public and other groups involved in research and healthcare provision, since trust is such a pivotal factor in the provision and acceptance of effective health interventions. Vaccine hesitancy is a growing issue globally. One of the key determinants of vaccine hesitancy is deep mistrust of the pharmaceutical industry and extensive links between academic vaccine scientists and industry.<sup>2</sup> Moving forward and fostering trust with the public must begin with improved transparency and helping the public to better understand why some of these interests are not only present, but can also be beneficial.

# The positive side of interests

The presence of multiple interests is a marker of collaboration between entities. As long as there is full transparency regarding the partnership, and the output is not controlled by any one

Table 1. Examples of actions which may have contributed to the eroding of public

Responsible Party	Description
Academia and academic publishers	Data fraud pertaining to effects of MMR vaccination in children by AJ Wakefield et al., 1998 published in The Lancet. <sup>10</sup>
Industry	Press release of premature, not peer-reviewed data from eight study subjects in a COVID-19 vaccine trial, with perceived corporate rather than scientific benefit. <sup>11</sup>
Patient advisory groups	Lobbying by meningitis charities in the UK for inclusion of the meningococcal B vaccine in the routine immunization schedule for older children despite a lack of evidence to support the costeffectiveness of inclusion. <sup>12</sup>
Government	Press release from NIAID describing early trial results of remdesivir as a treatment for COVID-19 prior to the publication of peer-reviewed data. <sup>13</sup>

party, cross-sectoral collaborations often result in the strongest science. 20-23 This collaborative approach is central to both innovation and pace at which new research discoveries and advances can be translated into effective products and strategies to improve health. The HPV vaccine studies are an example of broad collaboration between industry, academic researchers, healthcare providers, and the public, leading to a highly successful outcome. Prior to HPV vaccine licensure in Canada, a Canadian HPV Vaccine Research Priorities Workshop occurred in 2005, facilitated by CAIRE, <sup>20</sup> which brought together various stakeholders to determine priorities for HPV vaccine research to facilitate optimal development and implementation of HPV vaccine programs in Canada. Federal funding was dedicated to answering key research questions identified and the subsequent findings contributed to optimization of HPV vaccination programs. Broad collaboration was central to setting the research agenda and successful implementation. Importantly, this collaboration was not without controversy due to what some perceived as industry involvement in setting public health priorities for vaccine programming.<sup>21</sup>

Within the current COVID-19 pandemic, examples abound of partnerships that have allowed for rapid development of new knowledge and evaluation of candidate interventions. These include almost unprecedented partnerships between government, industry, philanthropic organizations, and research bodies to expedite research, approvals, and provision of evidence-informed care, including extraordinary advances in provision and use of personal protective equipment and hand sanitizers, as well as vaccines.<sup>22</sup> In terms of vaccine development for COVID-19 and beyond, much of the world's expertise in vaccine research lies within industry. Rapid advancement in the vaccine development space is unlikely without partnerships between researchers, government, and industry to fund the substantial costs associated with bringing a candidate vaccine through clinical trials. Thus, partnerships with industry can catalyze research and development. Rapid advancement of vaccine research also requires partnerships with public health, healthcare professionals, researchers, and the public, in order to facilitate human trials, bring new vaccines into public health programming, and optimize uptake. Such partnerships have been expanded and formalized in the pursuit of COVID-19 therapies and vaccines. These COVID-19 specific partnerships include the ACTIV public-private partnership developed by the National Institutes of Health.<sup>23</sup>

It is critical to note that the oft-touted "alternative" of simply not working with industry is very unlikely to be better for the public or the advancement of science. In the current model, whereby private funding from industry or philanthropic foundations (e.g., Coalition for Emerging Pathogen Innovation [CEPI]) is required for clinical development of new vaccines, researchers must partner with industry and other private funders to secure the funding needed to bring candidate vaccines through clinical trials and to market. This is particularly true in the case of pandemic vaccines, since there is no compelling business case for their development until a pandemic is occurring and no real market for the vaccine(s) in the inter-pandemic period. Indeed, without input from researchers, industry would be driving the research and

product development agenda, which may not align well with the needs of the public. Finding ways to collaborate through determining where the interests of each party coincide can thereby be a force for good.

#### Recommendations

In consideration of the scope of interests that may be present and the possible positive and negative impacts of such interests, several recommendations for the management of interests were formulated. The purpose of these recommendations is to move vaccine research and evaluation forward in a collaborative, public-centered manner with the best possible outcomes and in a way that is acceptable to the public to promote trust in individuals and organizations involved in the development, procurement, promotion, and administration of vaccination. We acknowledge that there will be different perspectives on how to move forward, and that further steps will be needed to bring those perspectives together in a productive way.

## Acknowledge all forms of interests and treat them all as relevant

Partnerships with industry and non-industry bodies should be declared, including, but not limited to, government, funding agencies, public health organizations, health authorities, institutions, foundations, and non-governmental organizations. In addition, individual-level interests should be disclosed. All forms of interest should be declared within all settings, including academic conferences and medical journals that only require industry-related or financial interests. Failing to disclose these interests reinforces negative perceptions, as well as the inappropriate historical focus on industry as the primary source of conflicts of interest. When disclosing partnerships, it is also important to communicate why the partnership is important to improve understanding. Such declarations should also be made by the organizations that draw on expert advice. For example, the membership of industry standing and ad hoc advisory committees related to vaccines should be made public by industry, in the same way that expert advisory committee membership should be made public by governments.

### **Develop appropriate collaborations**

All partners should collaborate in ways that are more acceptable to the public (e.g., free of explicit personal monetary benefits) and be open and transparent about such collaborations. It is important to address partnerships and interests similarly when speaking to a research audience and the general public as transparency is critical to fostering trust. Additionally, readily acknowledging interests with all audiences will spark important conversations that provide the opportunity to communicate the reasons for these interests and partnerships. For this to happen, a form of governance process is needed, such as an international statement and ability for individuals and organizations to openly commit to this approach.



## Refer to all conflicts of interest simply as "interests," "declarations," or "disclosures"

By using the terminology "conflict of interest," we are effectively putting the conclusion in the title. The negative connotations of the word "conflict" prejudge such relationships as more likely to be "bad" than "good." Alternative terminology of "competing interests" faces some of the same issues. The interests that are present in healthcare are not inherently negative, and the positive aspects must also be communicated to develop and maintain trust and understanding. It is more appropriate to refer to these varied interactions as "interests," "declarations," or "disclosures."

# Promote transparency through developing consistent reporting mechanisms

Prior publications have advocated for the introduction of a centralized repository of interest declarations, both for financial and non-financial interests.<sup>24</sup> Transparency must be central to this repository, to allow anyone to access declarations and facilitate enforcement of standards for completeness and timeliness of individual reporting.<sup>24</sup> As with ClinicalTrials.gov, enforcement may be achieved through a requirement by medical journals for authors to update their declarations in the repository prior to publication. The benefits of such an approach include providing a centralized and transparent location for all interests to be declared to the public, ensuring consistency of reporting, and reducing duplicate reporting. An automated output from the repository could be generated for each individual for use by conferences, medical journals, institutions, etc.<sup>24</sup> One such system has been developed, known as Convey [https://www.aamc. org/services/convey], however, large steps are needed to bring this system into widespread use, including the buy-in and dedication of medical journals and institutions. Additionally, Convey does not include non-financial interests, which we have identified as an area of future improvement for such a platform.

### **Conclusion**

Multi-sectoral partnerships within vaccine research are almost certainly the best approach to maximize advancement of science and rapid translation of scientific discoveries into health benefits for the public. Many of these partnerships have indeed resulted in enormous health benefits. Through consistent and transparent reporting of the broad range of interests present, stakeholders and participants in vaccine research and development can provide the best possible patient health outcomes while improving public trust in our work.

### Acknowledgments

The authors wish to acknowledge Karen Beckermann, Erica Ehm, and Carly Weeks for their participation in the CAIRE meeting.

### **Disclosures**

EM receives salary support from the Canadian HIV Trials Network and the Michael Smith Foundation for Health Research. EM has also received grant funding from Lundbeck Fonden and has been a co-investigator on grants from the Canadian Institutes of Health Research, the BC Women's Foundation, and the Public Health Agency of Canada.

JB has received consulting fees from Merck Canada Inc. and is employed by the Clinton Health Access Initiative as a Clinical Advisor.

VD has no conflicts to disclose.

JK has no conflicts to disclose.

SMeyer has no conflicts to disclose.

NC discloses a professional interest in maximizing the health benefits of vaccines for which NC has received salary from government sources in the UK and Canada either directly or indirectly (via arm's length agencies of government). NC has also won competitive research funding from CIHR, PHAC and other sources. The governments that fund the agencies for which NC has worked make decisions on whether and which vaccines will be funded for their populations. They may seek expert advice from individuals such as NC but may not follow that advice.

SH has multiple interactions on advisory committees for government (provincial and federal) and industry (ad hoc advisory boards), unrelated to this manuscript.

SMacDonald is supported by a salary award from the Canadian Child Health Clinician Scientist Program. She has received research operating grants from national and provincial government funding sources.

KS salary is paid in full by the University of British Columbia to support the activities of CAIRE and the Vaccine Evaluation Center at BC Children's Hospital Research Institute.

KT has received grants from GSK outside the submitted work.

BW receives salary support as Medical Officer for Medicago Inc. and serves as a consultant for Novartis to evaluate infectious complications in multiple sclerosis. BW is also a site investigator for vaccine trials for multiple manufacturers.

MS is supported via salary awards from the BC Children's Hospital Foundation, the Canadian Child Health Clinician Scientist Program and the Michael Smith Foundation for Health Research. MS has been an investigator on projects funded by GlaxoSmithKline, Merck, Pfizer, Sanofi-Pasteur, Seqirus, Symvivo and VBI Vaccines. All funds have been paid to his institute, and he has not received any personal payments.

### **Funding**

There was no specific funding to support this manuscript, however, CAIRE is partly funded through unrestricted grants provided by multiple vaccine manufacturers.

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# **Appendix**

# Panel 1: Example Variations Between Conflict of Interest Definitions

Source	Definition
Faculty of Medicine, University of Ottawa (http://www.med.uottawa.ca/ Organisation/ProfessionalAffairs/eng/policies_procedures_fom_industry_rela tions_policy.html – s2)	"Conflict of Interest may be actual, potential or perceived. A conflict of interest occurs when an individual has a significant financial, professional or other personal consideration with Industry that may compromise, or have the potential to compromise or the appearance of compromising, their professional judgment or integrity in clinical responsibilities, teaching, conducting or reporting research, or performing other obligations."
College of Physicians and Surgeons of British Columbia ( <i>Practice Standard: Conflict of Interest</i> . 2019.)	"A conflict of interest arises when a physician's duty to act in the patient's best interests may be affected or influenced by other competing interests. Conflicts of interest can be real, potential or perceived. Conflicts of interest may arise in a variety of circumstances including financial, non-financial, direct, and indirect transactions with patients and others. Financial gain by a physician is not necessary to establish a conflict of interest. Additionally, a physician does not need to directly profit from the relationship. A conflict of interest may arise where the benefit is, or could be, accrued by a physician's family, close friends, corporation or other businesses, and business partners."
Treasury Board Secretariat, Public Health Agency of Canada ( <i>Policy on People Management</i> . 2020.)	"A situation, whether real, apparent or potential, in which the person employed has private interests that could influence the performance of their official duties and responsibilities or in which the person employed uses their office for personal gain."
World Health Organization (https://www.who.int/about/ethics/declarations-of-interest)	"Generally speaking, a conflict of interest arises when a secondary interest interferes with the primary interest of WHO and its staff. The scope of conflict of interest goes beyond financial interest."
ICES (Conflict of Interest Policy and Declaration Form. 2020.)	"Refers to any situation where there is a potential divergence between an individual's interests and his or her obligations to ICES. A conflict of interest may be actual, perceived or potential."
Pfizer (The Blue Book: Summary of Pfizer Policies on Business Conduct. 2019.)	"A conflict of interest arises when you place your personal, social, financial or political interests before the interests of the Company."