

COVID-19 Vaccine Task Force and Conflicts of Interest

Groupe de travail sur les vaccins contre la COVID-19 et conflits d'intérêts



JOEL LEXCHIN, MSc, MD

Professor Emeritus

School of Health Policy and Management, York University

Associate Professor

Department of Family and Community Medicine

University of Toronto

Toronto, ON

Abstract

Early in the COVID-19 pandemic, the federal government established a COVID-19 Vaccine Task Force to provide it with recommendations on a wide variety of issues related to vaccines. This article explores how the conflicts of interest of the Task Force members are declared and managed and what the implications are for the advice that they offer to the government. The Canadian government needs to go beyond just managing conflicts and work toward eliminating them on the Task Force.

Résumé

Au début de la pandémie de la COVID-19, le gouvernement fédéral a créé le groupe de travail sur les vaccins contre la COVID-19, qui avait comme tâche de formuler des recommandations sur une grande variété de questions liées aux vaccins. L'article explore comment les conflits d'intérêts des membres du groupe de travail sont déclarés et gérés et quelles en sont les répercussions sur les conseils qu'ils donnent au gouvernement. Le gouvernement du Canada doit aller au-delà de la simple gestion des conflits et s'efforcer de les éliminer au sein du groupe de travail.

Introduction

In June 2020 – relatively early during the COVID-19 pandemic – the federal government created

the COVID-19 Vaccine Task Force with a one-year mandate to provide it with advice around a range of vaccine-related issues. These included prioritizing vaccine projects seeking support for activities in Canada, attracting promising non-Canadian vaccine candidates to Canada or partnering with developers of non-Canadian vaccine candidates and facilitating solutions to manufacture the most promising COVID-19 vaccines in Canada (National Research Council for Canada 2020a). In setting up the Task Force, the government made a conscious decision to include people who may have current or past ties with companies engaged in vaccine research and/or manufacturing (National Research Council for Canada 2020a).

This article explores whether conflicts of interest (COIs) of Task Force members are fully disclosed, how they are managed, what the possible implications are for the advice that the Task Force has offered and, finally, how the issue of COIs could be dealt with in a more coherent way.

Discussion

The government seemed comfortable with its decision to include people with COIs on the Task Force because according to its webpage, it had “a robust process in place to manage potential conflicts of interests. The process related to this advice is in line with similar task forces around the world” (National Research Council for Canada 2020a). As part of that process, members of the Task Force were “required to sign a Conflict of Interest and Confidentiality Agreement and to disclose activities and interests that could place them in a COI situation with respect to the work of the Task Force” (National Research Council for Canada 2020b). COI items fell into nine categories including direct and indirect scientific interests, financial interests, employment and interests of family members and other personal involvement. In addition, at each meeting, the Task Force members were required to declare their interests. From the government website, it is not clear who is responsible for deciding if the COI should preclude someone from taking part in the discussions and voting, but it appears to be someone in Industry, Science and Economic Development Canada. More importantly, the criteria used for what is a relevant COI are not disclosed.

The voluntary nature of the Task Force means that the federal ethics commissioner does not have the authority to oversee the COIs of members and explains why the COIs of the Task Force members are not listed on the public registry maintained by the commissioner (WWWHive 2020).

Up until May 31, 2021, the Task Force held 11 meetings between June 22, 2020, and March 9, 2021 (not counting follow-up discussions), and considered proposals and/or research from 17 companies (National Research Council for Canada 2021). Table 1 gives the dates of the meetings and the proposals that were discussed. The website that provided this information does not give any details about the nature of the discussions or about the recommendations to the government.

There have been a total of 13 members, two of whom have resigned for separate reasons. Gary Kobinger, who worked with the Winnipeg team that developed a successful

Ebola vaccine, left because of a lack of transparency in making public the COIs of the Task Force members (Dougherty 2020). The reason why Shelly Deeks, who works for Public Health Ontario, left the Task Force was not made public (National Research Council for Canada 2021).

TABLE 1. Dates of Task Force meetings and proposals considered

Dates of meetings	Proposal(s) considered
June 22, 2020 (Follow-up discussions on July 3, 2020, and July 16, 2020)	Biodextris, Providence Therapeutics, Glycovax Pharma, Symvivo, IMV Inc.
June 22, 2020 (Follow-up discussions on July 3, 2020, July 16, 2020, and March 9, 2021)	Entos
June 22, 2020 (Follow-up discussion on June 29, 2020)	Precision Nanosystems
June 22, 2020 (Follow-up discussions on June 25, 2020, and October 22, 2020)	Medicago
June 25, 2020	AstraZeneca, Pfizer
June 26, 2020	Variation Biotechnologies Inc.
June 26, 2020 (Follow-up discussion on July 16, 2020)	Treadwell Therapeutics
June 29, 2020	AstraZeneca, Pfizer
July 3, 2020	Moderna, Inc.
July 23, 2020	Novavax
July 28, 2020	Johnson & Johnson/Janssen
August 6, 2020	Pfizer
September 3, 2020	Sanofi/GSK
December 10, 2020	Novavax
March 9, 2021 (Follow-up discussion on March 12, 2021)	VIDO

Of the Task Force members, only one has not declared a COI at any of the meetings. For the remaining 12 members, the number of COI declarations has ranged from one per person to 12 for one individual (median = 1, interquartile range = 1, 3). Table 2 (available online at www.longwoods.com/content/26732) provides all the details about the COIs that the members disclosed at the meetings. No search was conducted for other sources of COI statements.

Conflicts held by chairs and co-chairs are generally considered to be the most relevant because these are typically the people with the most power on a committee or task force. For this reason, the report from the United States (US) Institute of Medicine (now the National Academy of Medicine) recommended that chairs and co-chairs of clinical guideline committees should be completely free of any COI (IOM 2011). The co-chair of the Task Force, Joanne Langley, is the person with the 12 COI declarations (National Research Council for Canada 2021). Langley has, among other activities, worked with Variation Biotechnologies Inc. (a global biopharmaceutical company) on vaccines, collaborated on research projects outside of clinical trials with scientists from Sanofi – a French healthcare company – served as a consultant to Sanofi on influenza vaccines in 2018 and holds the CIHR-GSK Chair in pediatric

vaccinology at Dalhousie University in Halifax, NS. Yet neither these nor the rest of her 12 COIs were deemed to have direct, material linkages and, therefore, not considered conflicts and recusal was not deemed necessary. Langley has also been a scientific colleague of Medicago's (a Canadian biotechnology company) medical officer for several decades and is planning to work with this person in the Canadian Immunization Research Network on the clinical development program of a vaccine developed by the National Research Council to prevent invasive disease due to *Haemophilus influenzae* type A. This also was not felt to be a conflict, but "in an abundance of caution, [she] recused herself from deliberations and recommendations" (National Research Council for Canada 2021).

In a September 2020 interview with Global News, Langley was asked whether there should be more transparency in COI declarations. Her reply was that the government ministers receiving advice could see what was disclosed "... and whether or not the ministers decide to make that public, really, it's not for me to say ... I would have to review all the kinds of information that everyone has given to say, is it fair to make that public when people are doing this? It's volunteer service" (WWWHive 2020).

The other co-chair, Marc Lievonon, was the president of the Canadian branch of Sanofi Pasteur – a vaccine manufacturer – for 17 years until 2016, still holds \$500 (all amounts are in Canadian dollars unless otherwise indicated) worth of shares in the company (National Research Council for Canada 2021) and was previously a director of the Canadian biotech company Oncolytics Biotech and the Canadian pharmaceutical companies Acerus Pharmaceuticals and Quest PharmaTech, chair of Rx&D (the former name of the lobbying group representing the multinational pharmaceutical companies based in Canada) and chair of BIOTECCanada, the association representing Canada's biotechnology companies. He is currently a director of the Canadian biotechnology company OncoQuest Pharmaceuticals Inc. and Biome Grow Inc., a cannabis company (Mark Lievonon 2021). When the Task Force discussed the vaccine that was under development by Sanofi and GSK (a pharmaceutical manufacturing giant), Lievonon's COI was not deemed relevant and recusal was not considered necessary, although he, similar to Langley, recused himself "in an abundance of caution" (National Research Council for Canada 2021).

Besides recognizing when a COI has been disclosed, it is also important to recognize when a COI exists but has not been disclosed. Michel de Wilde is listed on his LinkedIn webpage as being a senior vice-president for Sanofi Pasteur from 1999 to 2013 and a senior advisor to the company's chief executive officer from 2013 to 2016. He is also a current advisory board member for CureVac, a European bioresearch firm in talks with the European Union to supply the vaccine it is developing (Michel de Wilde 2021; WWWHive 2020). de Wilde did not attend the meeting where the vaccine from Sanofi and GSK was discussed, and this may be why his COI with Sanofi is not disclosed on the Task Force's webpage (National Research Council for Canada 2021). The Task Force has not discussed any product or research by CureVac and this may account for the absence of any mention of de Wilde's COI with this company. However, he is a board member of Variation Biotechnologies Inc., and this was labelled a COI; as such

he did not participate in the discussion about or recommendation regarding this company (National Research Council for Canada 2021).

Table 3 summarizes seven different types of conflicts, although sometimes the declarations are vague, making it difficult to characterize the nature of the COI. For example, Langley declared on eight different occasions that her university was involved in research with a company, but it was not clear if she personally was participating in the research projects. In total, out of 30 declarations of COIs, 21 were not considered relevant, 4 were not considered relevant but the members still recused themselves and the remaining 5 were considered relevant.

TABLE 3. Summary of different types of conflicts

	Type of conflict						
	Previous or current employment with company	Collaborated on research with company	University collaborating with company	Company board member	Commercial relationship with company	Directly or indirectly owns shares in company	Previous relationship with company employee
Number declared	3	11	8	1	4	1	2

The process of declaring and managing the COIs of Task Force members is flawed. First, the information in the conflict of interest and confidentiality agreements is not made public; the only information disclosed is what is declared at the individual meetings. This practice of minimal disclosure of information about a COI is typical of declarations of people serving on Health Canada advisory committees and panels. In that case, members give yes or no answers to questions about COIs in eight categories but no monetary sums are mentioned and no companies are named (Lexchin 2019).

The situation with de Wilde illustrates another important flaw in the process of declaring a COI; if a member is absent from a meeting or if a particular company is never discussed, then the COI is never revealed. The practice of treating a COI as a discrete event fails to take into consideration that a COI is not based on isolated relationships with a single company but is a process that reflects an understanding of the nature of interactions between individuals and industry and how those interactions can affect decision making in general. Second, the process for deciding what is and is not a relevant COI is not articulated and, as such, decisions can seem arbitrary and possibly biased. Finally, when it comes to dealing with COIs, the government does not seem to have gone beyond the concept that declaring a COI is all that is required for ensuring that the Task Force recommendations are free from bias. There are no minutes released from the Task Force meetings so the public cannot see the tenor of the discussions and what views individual members took; the final recommendations coming out of the various meetings are also kept secret. As such, it is not possible to see what influence, if any, the COIs may have had on the final decisions made by the Task Force.

There are better models for managing COIs. The Canadian Agency for Drugs and Technology in Health (CADTH) requires expert committee and panel members to declare direct and indirect financial and intellectual interests. A summary of the member's expertise, experience, affiliations and COI declarations is posted and publicly available on the CADTH website. The declaration form asks members for the name of the party that they have a conflict with and for the monetary value of the benefit in dollar ranges (e.g., \$0–5,000, \$5,001–10,000) (CADTH n.d.). Company names are disclosed on the website but not the monetary value of the benefits. In the US, experts may not participate on Food and Drug Administration (FDA) advisory committees if their financial COI is in excess of US\$50,000, although the FDA can grant waivers under specific conditions. COI declarations and waivers are publicly available on the FDA website and a COI is reported in dollar ranges (e.g., US\$0–5,000, US\$5,001–10,000) (U.S. Department of Health and Human Services FDA 2014).

Transparent declaration of a COI is only a first step. The *Physician Payments Sunshine Act* (S.301 – *Physician Payments Sunshine Act* of 2009) in the US requires drug and medical device companies to declare any payments to physicians of \$10 or more (Centers for Medicare & Medicaid Services 2013). Since its implementation in 2013, there has not been any subsequent discernable changes in the behaviour of either companies or physicians nor has there been any substantial change in policies regarding the relationship between doctors and industry (Lexchin and Fugh-Berman 2021). Jerome Kassirer, the former editor of the *New England Journal of Medicine*, critiqued the fixation on “the wrong problem,” that is, the lack of transparency and “expressed concern that the need to eliminate commercial conflicts, especially from oversight bodies that assess the integrity of medical data, was being excluded as a public policy option” (Wilson 2014: e11).

Transparency alone will not mitigate the effects of COIs on advice that experts give (Cain et al. 2005). The situation in Australia shows that it is possible to go beyond just the declaration of COIs. In April 2020, the Australian government funded its National COVID-19 Clinical Evidence Taskforce (n.d.) to provide rapid, evidence-based and continually updated advice on Australia's health response to the COVID-19 pandemic (National COVID-19 Clinical Evidence Taskforce 2022). It ran its proposed COI standards by an independent panel (of which I was and still am a member) and based partly on our input developed a COI policy that required both the committee chair and more than 50% of the Taskforce to be free of any conflicts. All Taskforce members have to declare COIs over the previous five years and any individuals who have significant conflicts, such as receiving grants from entities that have commercial interests of AUS\$5,000 or more per annum in the topic under discussion, have to cease their involvement with the Task Force. The COI policy and the names of the four people on the independent panel are publicly available (National COVID-19 Clinical Evidence Taskforce n.d.). Since then, the panel has been consulted regularly about individuals' decision-making roles, whether they should be allowed to participate on the Taskforce and whether the requirements of the policy are being met.

The federal government is currently spending \$170 million to upgrade and build a new

facility in Montreal, QC, that will produce a vaccine made by the American biotechnology company Novavax, starting probably in early 2022 (Ling and Walsh 2020). It has recently announced the investment of \$415 million into an influenza vaccine manufacturing plant owned by Sanofi (Walsh 2021) and \$190 million into the expansion of a Mississauga medical facility that will eventually be able to make 640 million doses yearly of an mRNA COVID-19 vaccine when the expansion is completed in 2024 (Ballingall 2021). The size of the investments and their implications for Canada's ability to respond to the ongoing COVID-19 pandemic and future pandemics that are sure to come is evidence that the federal government needs to be assured that it is getting the best unbiased advice on how to spend taxpayers' money to help ensure public health.

Conclusion

COVID-19 has caused over 25,000 deaths in Canada, derailed our healthcare system and caused enormous psychological and economic damage. One of the keys to controlling the pandemic and stabilizing our mental, physical and economic health is vaccines. This commentary shows that some of the current Task Force members have substantial COIs. In the absence of more transparency about the nature of those COIs and about the content of the Task Force's discussions and recommendations, there is no guarantee about the quality of the advice that the Task Force is delivering. Finally, instead of just managing the COIs, the government should be working toward minimizing them on its Task Force.

Correspondence may be directed to: Joel Lexchin, School of Health Policy and Management, York University, 4700 Keele St., Toronto, ON M3J 1P3. Joel can be reached by e-mail at jlexchin@yorku.ca.

Conflicts of Interest

From 2017 to 2020, Joel Lexchin received payments for being on a panel at the American Diabetes Association, for talks at the Toronto Reference Library, for writing a brief in an action for the side-effects of a drug for Michael F. Smith, lawyer, and a second brief on the role of promotion in generating prescriptions for Goodmans LLP. Lexchin also received payments from the Canadian Institutes of Health Research (CIHR) for presenting at a workshop on conflict of interest in clinical practice guidelines. He is currently a member of research groups that are receiving money from the CIHR and the Australian National Health and Medical Research Council. He is a member of the Foundation Board of Health Action International and the Board of Canadian Doctors for Medicare. He receives royalties from the University of Toronto Press and James Lorimer & Co. Ltd., for books he has written.

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