

A Review of Canadian Medical School Conflict of Interest Policies

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Background: Growing evidence of behavioral bias has caused a surge of interest in the area of Conflict of Interest (COI) within the medical community. The present study sought to evaluate the landscape of Faculty of Medicine COI policies among Canadian medical schools using an evaluation system adapted from the AMSA PharmFree Scorecard. **Methods:** The authors contacted leaders at the CPD/CME offices of all 17 Canadian medical schools in 2011 to determine how many had formal policies guiding interaction with the pharmaceutical industry. Existing policies were evaluated based on 16 criteria developed by a steering committee. A Policy Score was calculated and a letter grade assigned for each of the existing policies. **Results:** At the time of review, roughly 35% of the Canadian medical schools had faculty-wide COI policy/guidelines, half of which had been implemented. Other policies are currently in development. Policy Scores ranged from 25.00% to 70.83% with a Mean Policy Score of 52.08%. Policies that were implemented all scored higher than those that were not implemented. Additionally, several strengths and weaknesses among policies were identified. **Conclusions:** Canadian schools have recognized that COI and bias have become a serious issue and are taking steps toward its management. The authors propose that the CMFS employ a system similar to the AMSA Scorecard to evaluate progress in a longitudinal study.

Keywords: Conflict of Interest; Policy Evaluation; Continuing Medical Education; Continuing Professional Development; Quality Control

Introduction

Conflict of Interest (COIs) are becoming increasingly relevant to the medical field. A COI may be defined as “a set of conditions in which professional judgment concerning a primary interest (such as a patient’s welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain)” (Thompson, 1999). Interactions with the pharmaceutical industry begin early during medical education, shaping behaviour that continues well into practice (Wazana, 2000; Institute of Medicine, 2009). Residents exposed to pharmaceutical representatives during training are more likely to be skewed towards industry values (Zipkin & Steinman, 2005) and are more likely to recall misinformation about the company’s and its competitors’ products (Wazana, 2000). However, these biases may be attenuated by the introduction of more stringent policies. A Canadian study demonstrated that residents trained under policies that restricted interaction with pharmaceutical representatives were more skeptical about information provided by pharmaceutical representatives compared to residents trained under non-restrictive policies (McCormick et al., 2001).

Although the majority of practicing physicians dismiss the notion that interaction with the industry introduces bias, their behaviour is influenced in a number of ways. Notably, physicians and their organizations are more likely to prescribe a company’s products for up to two years following a direct in-

teraction (Wazana, 2000). COI among authors of popular North American and European clinical practice guidelines are prevalent (Choudry et al., 2002; Neuman et al., 2011), and many guidelines recommend products sold by the companies with which authors have ties (Choudry et al., 2002). Gifts may also alter physicians’ abilities to weigh information (Dana & Loewenstein, 2003). Although drug samples are considered by many to be the most appropriate incentive from industry (Morgan et al., 2006), it has been demonstrated that a correlation exists between access to drug samples and prescription rates of that product (Adair & Holmgren, 2005).

Conflict of interest extends beyond clinical practice. Nearly one quarter of medical research performed at academic institutions is at least partially funded by the pharmaceutical industry (Bekelman et al., 2003). Industry funding influences study design, execution, reporting, access to data, and publication of results (Lexchin et al., 2008). Industry-sponsored research design tends to be less objective (Rochon et al., 2011) and is more likely to yield results favouring the sponsor (Bekelman et al., 2003; Lexchin et al., 2003). Among Canadian academic medical centers, definitions of what constitutes a COI in research is variable with many potential conflicts often being excluded (Lexchin et al., 2008).

It has been estimated that industry spent \$57.7 billion American dollars on promotion in 2004. This figure represents nearly 25% of industry sales and double the amount spent on research and development. Perhaps more alarming is that 80% of promotional spending was spent marketing to physicians (Gan-

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gon & Lexchin, 2008). Of large concern is that COIs are often self-reported. A recent study found that physicians disclose only 20.7% of directly related payments from industry and 50.0% of indirectly related payments (Okike et al., 2009).

In an attempt to persuade academic medical centers to manage COI, a number of American groups have published recommendations for more stringent regulation of physician-industry relationships (Brennan et al., 2006; AAMC, 2008; AMSA, 2012). In 2008, the American Association of Medical Colleges (AAMC) Task Force released an assessment of COI policies from academic medical centers across America and made recommendations for improvements (AAMC, 2008). Using similar criteria, the American Medical Student Association (AMSA) continues to monitor and grade COI policies of academic medical centers in the United States using their PharmFree Scorecard. Criteria from six COI domains (Gifts and Individual Financial Relationships with Industry; Pharmaceutical Samples; Purchasing and Formularies; Industry Sales Representatives; Education; and Enforcement) are given scores ranging from 1 (weak or no policy) to 3 (strong policy). The cumulative score of these domains, excluding Enforcement, is used to determine a percentage score out of a maximum 15 points. The 2011-2012 report concluded that 67% of American medical schools have policies scoring A (score of 85% or higher) or B (score of 70% or higher). This is a significant improvement from 19%, 30% and 51% of schools in 2008, 2009, and 2010, respectively (AMSA, 2012). It is conceivable that implementation of the AMSA scorecard has raised awareness about the issue of COI and contributed to improvements in medical school COI policies. However, Chimonas et al. evaluated American medical school COI policies using their own method and found that half of those surveyed had poor or non-existent COI policies (Chimonas et al., 2011).

In Canada, physicians are encouraged to follow Canadian Medical Association (CMA)'s "Guidelines for Physicians in Interactions with Industry" (CMA, 2007). These guidelines apply to all physicians, residents, and medical organizations in Canada, including the College of Family Physicians of Canada (CFPC) and the Royal College of Physicians and Surgeons of Canada (RCPSC). Although the Association of Faculties of Medicine of Canada (AFMC) has not issued its own policy guiding interactions between industry and Canadian medical schools, it endorsed the AAMC report on "Industry Funding of Medical Education" (AAMC, 2008).

To address the issue of COI in Canadian medical education, the AFMC created the Standing Committee on Continuing Professional Development (SCCPD). This committee brought leaders from the 17 Canadian medical schools' Continuing Professional Development (CPD)/Continuing Medical Education (CME) offices together at a national meeting to discuss relations between industry and CPD/CME. The SCCPD Working Group on Industry Relations issued a position paper urging Canadian medical schools to develop individual COI policies, and provided consensus statements to help guide the creation of such policies (SCCPD, 2010). The Canadian Federation of Medical Students (CFMS) has also called upon Canadian medical schools to develop policies in collaboration with their medical student societies and educate medical students about appropriate industry relationships. Their report briefly addresses COI policies and guidelines from a number of organizations, including the CMA and the Faculties of Medicine at the University of Toronto and the University of Ottawa (CFMS,

2011).

As a result of these initiatives, increasing attention has been paid to COI documents among Canadian universities. In 2008, Williams-Jones and MacDonald evaluated COI policies from thirteen of Canada's largest and most prominent universities for readability and content. The authors found that most schools' policies had low readability, using complex legal language to focus on prohibitions and mitigate institutional liability, rather than providing readers with clear definitions of COI, examples of what constitutes COI, and procedures for addressing COI (Williams-Jones & MacDonald, 2008). More recently in 2012, Mathieu et al. applied a modified version of the AMSA PharmFree Scorecard to COI policies from Canadian universities with medical schools. The authors found that Canadian universities studied scored very poorly, with all but one receiving overall grades of D or F. However, it is important to note that this study evaluated university-wide COI policies from universities with medical schools rather than investigating policies specific to the Faculties of Medicine. Many of the weaknesses in policies could be attributed to evaluation of general university-wide COI policies using AMSA's grading scheme, which was developed specifically for medical school COI policies (Mathieu et al., 2012).

To the best of our knowledge, no comprehensive assessment of Faculty of Medicine COI policies from all 17 Canadian medical schools has been performed. The present study sought to raise awareness about this issue by evaluating the landscape of medical school COI policies in Canada using a scoring system similar to the AMSA PharmFree Scorecard.

Methods

The associate and vice deans of CPD/CME offices of all 17 Canadian medical schools were contacted in August 2011 to determine which schools had developed formal COI policies and whether these policies had been implemented. CPD/CME leaders were contacted because they are currently taking the lead on these issues as the majority of policies are vetted through these offices.

Existing policies, which were all available within the public domain, were obtained from each Faculty of Medicine's website for evaluation. University-wide policies were excluded from analysis because they were not developed specifically for the physician community. Once policies were obtained, a steering committee was formed to discuss policy evaluation. This committee consisted of the Associate Dean of CPD, the Vice Dean of Hospital and Interfaculty Relations, educators from various disciplines within the Schulich School of Medicine, a resident representative, and a medical student representative. The committee created criteria and a scoring system for policy evaluation based on relevant COI criteria commonly found in the literature. The criteria selected for evaluation included all areas of the AMSA PharmFree Scorecard as well as additional areas deemed important by the committee (Chimonas et al., 2011; AMSA, 2012; Mathieu et al., 2012).

Policies were reviewed and graded by a single scorer and calculations were verified independently by a second reviewer. The scorer was not blinded to the identities of medical schools. Each policy was evaluated based on the strength of each criterion using a four-point scale reported by Mathieu et al. (2012), which was adapted from the AMSA PharmFree Scorecard (AMSA, 2012). The scoring scale was follows: 0 points for a

policy element that was absent; 1 point for a policy element that was only partially addressed or for which the reader was directed to another institutional policy; 2 points for a policy element that was addressed, but the policy was incomplete or weak; and 3 points for a policy element that was considered complete and strong.

A raw score was determined for each COI policy by calculating the sum of scores for each criterion within that policy. This was then used to express each school's Policy Score as a percentage of the highest possible score, or 48 points. Each school's policy was assigned a letter grade based on its policy score percentage according to the cutoffs used for AMSA's PharmFree Scorecard (AMSA, 2012): A for a policy with a score of 85% or higher; B for a policy with a score of 70% or higher; C for a policy with a score of 60% or higher; D for a policy with a score of 40% or higher; and F for a policy with a score below 40%. Additionally, an Average Criterion Strength was determined for each criterion by calculating the mean score for that criterion from all six policies.

Results

The presence of COI policies among Canadian medical schools can be seen in **Figure 1**. In August 2011, six of the 17 Canadian medical schools (35.2%) had completed their faculty-wide policies on physician interaction with industry, while the remaining 11 schools had not (64.7%). Among schools with existing policies, three had been implemented at the time of review (17.6%). The other three existing policies had not been implemented (17.6%), but will be in the near future.

Results from the evaluation of the six existing policies are shown in **Figure 2**. For reporting purposes, medical schools were assigned an identifier based on the implementation status of their policy. Medical Schools A through C had policies that

were implemented, while Medical Schools D through F had not yet implemented theirs.

Policy Scores ranged from 25.00% (Medical School F) to 70.83% (Medical Schools B and C), corresponding to letter grades of F and B, respectively. When taken together, the average Policy Score for all six schools was 52.08%, which corresponds to a letter grade of D. However, when implemented and non-implemented policies were considered separately, there appeared to be some differences. The average Policy Score among implemented policies was 69.44% (corresponding to a letter grade of C), while the average Policy Score among non-implemented policies was 34.72% (corresponding to a letter grade of F).

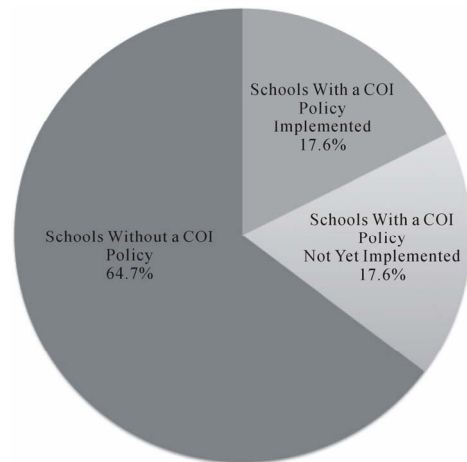


Figure 1. Status of COI policies among all 17 Canadian medical schools.

Criteria	Medical School						Mean Criterion Strength
	A*	B*	C*	D	E	F	
Gifts and Meals	3	3	3	2	2	2	2.50
Drug and Device Samples	1	2	2	2	2	1	1.67
Guidelines for Compensation (Including Amount)	3	3	0	0	0	0	1.00
Travel Expenses	1	1	2	1	1	1	1.17
Support for Educational Programs	3	3	2	2	2	2	2.33
Support for Scholarships & Educational Funds	2	2	2	2	1	1	1.67
Support for Research	3	3	3	3	2	0	2.33
Participation in Industry Sponsored Programs	0	0	3	1	2	1	1.17
Industry Access to Faculty, Trainees, and Students	3	3	3	1	2	1	2.17
Guidelines for OFF-Campus Events	2	2	1	0	0	0	0.83
Ghostwriting	0	1	3	1	0	1	1.00
Purchasing	1	1	2	0	0	2	1.00
Consulting	3	3	2	2	0	0	1.67
COI Training	2	2	0	1	1	0	1.00
CME/CPD Guidelines	2	2	3	1	2	0	1.67
Disclosure of Relationship	3		3	2	0	0	1.83
Total Number of Criteria Presents (Out of 16)	14	15	14	13	10	9	Mean Policy Strength
Raw Score (Out of 48)	32	34	34	21	17	12	25
Policy Scores (%)	66.67%	70.83%	70.83%	43.75%	35.42%	25.00%	52.08%
Policy Grade (%)	C	B	B	D	E	F	D

Figure 2. Grading of Canadian medical schools' COI policies using a modified AMSA PharmFree Scorecard. *Indicates policies that were implemented at the time of review.

Given these differences in quality between implemented and non-implemented policies, it is difficult to make meaningful comparisons of Average Criterion Strength, especially because several criteria that were present in at least two out of the three implemented policies were absent in at least two out of the three non-implemented policies. Nevertheless, the Average Criterion Strength was still useful for identifying general strengths and weaknesses of policies. Strengths were considered criteria with an Average Criterion Strength of 2.00 or greater: Gifts and Meals (2.50), Support for Educational Programs (2.33), Support for Research (2.33), and Industry Access to Faculty, Trainees, and Students (2.17). Weaknesses were considered criteria with an Average Criterion Strength of 1.00 or lower: Guidelines for Compensation (1.00), Ghost-writing (1.00), Purchasing (1.00), COI Training (1.00), and Off-Campus Events (0.83).

Discussion

The new reality is that interactions between industry and physicians will continue to be pervasive throughout a physician's career. The current study provides new insight into how the medical profession recognized this potential for bias and produced accreditation policies and procedures to assure that medical education is not biased due to commercial support.

In addition, organizations like the AFMC have taken the initiative to bring key leaders in education to the table for discussion and standardization since 2010. The Brief Report of Highlights of the AFMC Hosted 2nd National COI Meeting alluded to the following challenges: disclosure requirements, buy-in from faculty, definition of what constitutes a COI, need for education, alignment with local health care facilities, and the reliance on industry support for Continuing Professional Development (CPD). The CFMS has taken a stand towards raising awareness and education in the early part of training. Canadian schools have recognized that the management of COI and bias is a serious issue needing new policy direction and innovative practices. Our finding that 35% of Canadian medical schools responded by creating formal policies indicates that schools are taking appropriate steps to address COI. It is also encouraging that half of existing policies have been implemented and the remaining policies will be implemented in the near future. However, there are still major steps to be taken moving forward as 11 schools (roughly 65%) still do not have formal COI policies.

Our results indicate that the strength of existing policies varied substantially, with Policies Scores ranging from 25.00% to 70.83% and a Mean Policy Score of 52.08%. However, our results also indicate differences between policies that have been implemented and those that have not, particularly in terms of overall policy strength. All implemented policies scored higher than non-implemented policies in our evaluation, and had Policy Scores ranging from 66.67% to 70.83%. These scores correspond to letter grades of C and B using AMSA's PharmFree Scorecard cutoffs. In contrast, Policy Scores of non-implemented policies ranged from 25.00% to 43.75%, or letter grades of F and D, respectively.

While implemented policies tended to address more criteria than non-implemented policies (14.3 vs. 10.7, respectively), this was not the only contributing factor to the difference in Policy Scores. Only one criterion from all three non-implemented policies received an ideal score of 3, compared to 21

criteria that received a score of 3 among implemented policies. Therefore, implemented policies not only covered a broader range of criteria, they also had stronger content.

Using the AMSA scoring system to evaluate similar criteria, the strength of university-wide COI policies ranged from 30% to 55% among Canadian universities with medical schools, with a mean score of 44% (Mathieu et al., 2012). However, it must be noted that the authors evaluated university-wide policies, whereas the present study evaluated policies specific to Canadian Faculties of Medicine. Therefore many of the weaknesses in university-wide COI policies reported by Mathieu *et al.* may be a result of evaluating general university-wide policies using a scoring system developed specifically for medical schools.

Our results also indicate a number of clear strengths and weaknesses among existing policies. While it is difficult to make definitive conclusions given distinct differences in criteria inclusion between implemented and non-implemented schools, some general observations can be made.

Four criteria had Mean Criterion Strengths greater than 2.00: Gifts and Meals (2.50); Support for Educational Programs (2.33); Support for Research (2.33); and Industry Access to Faculty, Trainees, and Students (2.17). Mathieu et al. also found that guidelines for research were strong among Canadian university COI policies and reasoned that this is because all of Canada's medical schools are part of research-intensive institutions. In contrast to our findings, Mathieu *et al.* identified Support for Education and Industry Access as weaknesses (Mathieu et al., 2012). As these issues are likely to be more common within medical education than in other disciplines, it is encouraging that Faculty of Medicine COI policies scored greater in these areas than university-wide policies. Five criteria had Mean Criterion Strengths of 1.00 or less: Guidelines for Compensation (1.00); Ghostwriting (1.00); Purchasing (1.00); COI Training (1.00); and Guidelines for Off-Campus Events (0.83). Many of these weaknesses were also identified by Mathieu et al. (Mathieu et al., 2012).

This study does have some inherent limitations. It must be acknowledged that the present study only evaluated COI policies from each school's Faculty of Medicine, although some criteria may be included in university-wide policies. However we felt it was important to focus within the context of medical education, as both the AMFC and CFMS have urged medical schools to adopt their own COI policies. While Faculties of Medicine still fall under the jurisdiction of broader university-wide policies, it is still critical to develop policies specifically for the physician community given the unique circumstances encountered by this population. Additionally, university-wide policies have been previously evaluated from a medical perspective (Mathieu et al., 2012).

While reviewing these policies does provide insight into their strength and quality, it does not allow us to assess how knowledgeable individual faculty members are about the policy or how closely the policies are being followed. Nevertheless, the development of strong policies is a necessary first step towards better management of COI among Canadian medical schools.

We believe this environmental scan will help raise awareness of the importance of this issue to those within the continuum of education and prepare them for the challenges in the shift from guideline to policy development and implementation. We hope that schools will take note of this study and improve the strength of their policies. We encourage Canadian Faculties of

Medicine to learn from the experiences of other schools in the development and implementation of their COI policies. Additionally, several excellent suggestions have been provided in the literature. Notably, Smith and Williams-Jones made exemplary recommendations for the development of COI policies in Canada (Smith & Williams-Jones, 2009).

Our goal is that a similar system to the AMSA PharmFree Scorecard will be put in place in Canada to grade medical school COI policies and track the progress in a continuous longitudinal initiative. AMSA has achieved great success with their initiative in the US, as the overall quality of medical school COI policies has improved every year since the introduction of their scoring system (AMSA, 2012). We believe similar success can be achieved in Canada. We propose that this could be done by some of the organizations in the National COI group such as CFMS, a Canadian organization similar to AMSA, in collaboration with academic CME/CPD offices in Canada.

In conclusion there are important lessons learnt from this early study, that is sharing of experiences in implementing these policies through education in Canadian medical schools would be beneficial through a national COI group. There is ongoing need to identify appropriate management of COI's and bias through educational strategies in all academic institutions. Academic health sciences centers should ensure that any and all partnerships between themselves and industry serve the best interest of patients. Using information gleaned from this study for longitudinal evaluation and continuous quality improvement in education is the vital next step.

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