

Conflict of Interest Policies at Canadian Universities and Medical Schools: Some Lessons from the AMSA PharmFree Scorecard

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Résumé

Lancée en 2007, l'American Medical Students Association (AMSA) PharmFree Scorecard est un classement annuel des politiques de conflit d'intérêts (CI) de centres médicaux américains. Il se concentre sur les CI qui peuvent survenir lorsque la formation médicale est influencée par les particulier relations université-industrie. en ceux concernant l'industrie pharmaceutique et les dispositifs médicaux. Le PharmFree Scorecard s'est montré influent dans l'initiation de modification des politiques concernant la gestion des CI dans les institutions médicales américaines. Il fournit donc un point de départ utile pour une réflexion sur la manière et les raisons pour lesquelles les établissements d'enseignement médicaux dans d'autres pays - et pour nos fins, le Canada - devraient accorder plus d'attention à l'identification et à la gestion appropriée des CI. La méthodologie de la PharmFree Scorecard consiste à examiner la diversité des facteurs et des intérêts qui pourraient influencer l'enseignement médical, il s'agit donc d'une approche intéressante pour l'analyse des politiques de CI des écoles de médecine. Pour évaluer son utilité et son applicabilité à l'extérieur des États-Unis, nous avons décidé d'appliquer le PharmFree Scorecard aux politiques de CI des 16 universités canadiennes accueillent les écoles de médecine. Dans l'ensemble, les institutions canadiennes se classent très mal, particulièrement en ce qui concerne la disponibilité d'outils d'éducation et de formation concernant l'identification et la gestion de CI pour le personnel, les étudiants et les professeurs. Cependant, les différences entre les contextes d'enseignement médical aux États-Unis et au Canada (en ce qui concerne la gouvernance et le financement des universités par exemple) limitent, dans une certaine mesure, l'applicabilité directe du classement AMSA. Même si elles peuvent et doivent aller plus loin en élaborant leurs propres politiques de CI et procédures, les écoles de médecine canadiennes - et leurs universités d'accueil - ont néanmoins beaucoup à apprendre des indications fournies par le classement AMSA PharmFree Scorecard.

Mots clés

conflit d'intérêts, écoles de médecine, les politiques, Canada, American Medical Student Association (AMSA)

Abstract

Launched in 2007, the American Medical Students Association (AMSA) PharmFree Scorecard is an annual ranking of conflict of interest (COI) policies at American medical centres; it focuses on COIs that may occur when medical education seems likely to be influenced by university-industry relationships, especially those with the pharmaceutical and medical device industries. The PharmFree Scorecard has proven influential in stimulating changes in policy regarding the management of COI at American medical institutions, thus it provides a useful jumping off point for reflection on how and why medical education institutions in other countries - and for our purposes, Canada - should pay more attention to the appropriate identification and management of COI. The PharmFree Scorecard methodology examines a diversity of factors and interests that could influence medical education; as such, it is an interesting approach to analysing the COI policies of medical schools. To test its utility or applicability outside the US, we decided to apply the PharmFree Scorecard to the COI policies of the 16 Canadian universities hosting medical schools. Overall, Canadian institutions rank very poorly, especially in ensuring that education and training tools are provided to staff, students and faculty members to enable the identification and management of COI. However, differences between the US and Canadian medical education contexts, e.g., with regards to the governance and funding of universities, limit to some extent the direct applicability of the AMSA ranking. Canadian medical schools - and their host universities - nonetheless have much to learn from insights provided by the AMSA PharmFree Scorecard ranking, although they can and should go further in developing their own COI policies and procedures.

Keywords

conflict of interest, medical school, policies, Canada, American Medical Student Association (AMSA)



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Conflit d'intérêts

Williams-Jones et Smith sont des éditeurs de la revue, et travaillent en étroite collaboration avec Master (qui cosupervise le PhD de Smith) et Marsan (supervisé par Williams-Jones). Les quatre auteurs sont membres du Groupe de recherche sur les conflits d'intérêts, comme l'est Marsan.

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Conflicts of Interest

Williams-Jones and Smith are editors of the journal, and work closely with both Master (who co-supervises Smith's PhD) and Marsan (supervised by Williams-Jones). All four authors are members of the Conflict of Interest Research Group, as is Marsan.

Introduction

In the biomedical literature, much attention is given to the behaviour of health research and education institutions regarding the disclosure and management of conflicts of interest (COI) [1-3]. Of particular concern is the growing and problematic influence (i.e., creating bias) of the pharmaceutical and medical device industries in physician training, clinical practice and research [4,5]. As a result, medical schools and professional associations in North America and Europe have developed policies to address financial COI [6-9] and these have become the subject of much scholarly analysis [2,10-12]. In 2009, the Institute of Medicine (IOM) issued an exhaustive report examining the many issues raised by COI in medical research, education and clinical practice. The IOM propose a simple yet effective definition of COI: "A conflict of interest is a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest" [8, p. 46].

The American Medical Students Association (AMSA) PharmFree Scorecard is an important example of the attention being given to financial COI [13]. Essentially, the Scorecard evaluates the COI policies of US medical schools, mainly scrutinizing their interaction with the pharmaceutical industry. In recent years, the Scorecard has played a significant role in sensitizing US medical education institutions to the issue of financial COI, and to the need to adopt, enforce and make transparent and available their institutional COI policies [14]. Curious about the possibility of extending this approach to evaluations of non-US institutional COI policies, we decided to apply the AMSA ranking methodology to Canadian medical schools. It turns out, however, that for the most part Canadian medical schools do not have



their own COI policies because they are governed by the policies of their host universities, so we applied the AMSA method to these more general university COI policies. While one might argue that the AMSA method should only be applied to medical faculty COI – because of specific concerns related to pharmaceutical and medical device involvement in medical education – we decided that more general university policies would probably have the same essential content as those policies developed by and pertinent for medical schools. Medical schools share a common commitment towards both education and research, so while pharmaceutical and device industries may be involved in medical education, they are also major sponsors of medical research involving clinician-researchers and students in both the clinical and research settings.

Interestingly, the 16 Canadian university COI policies that we examined ranked very poorly according to the AMSA Scorecard. An analysis of these findings allowed us to identify important limitations with the AMSA method as it relates to evaluating the robustness of COI policies and procedures. Of particular concern is the Scorecard's focus on *financial* COI and the use of *disclosure* as the primary mechanism for the management of unavoidable COI. Specifically, the Scorecard grades disclosure as the *most* relevant management strategy for unavoidable COI in the eleven elements or "policy domains" evaluated, while it should, we argue, be the only the first part of a comprehensive management strategy. For example, when interacting with industry in the context of research collaborations or student training in industry settings, disclosure is an essential first step in managing the unavoidable COI that arise. Nevertheless, this first COI management step may and often should be followed by other mechanisms to reduce the risks or harms associated with COI (e.g., open discussion). The focus on disclosure shows, we argue, an important conceptual mismatch with standard recommendations in the ethics and policy literature [15,16], where disclosure is recognised to be a necessary but insufficient mechanism for managing COI. Finally, the AMSA Scorecard focuses on COI at the individual level rather than at the institutional level. That is, it does not consider how institutional arrangements (e.g., involvement with start-up companies, solicitation and acceptance of industry endowments for faculty positions, buildings or programs) may create important COI for the institution.

Despite these limitations, our critical approach to the AMSA Scorecard – and our application of it to Canadian university COI policies – provided important insights regarding areas in need of significant improvement, namely, the need to develop stronger COI policies, make them accessible and ensure *training* and support for faculty, staff and students in the identification and management of COI.

The AMSA Pharmfree Scorecard

Founded in 1950 under the auspices of the American Medical Association, AMSA is the largest independent US association of physicians-in-training. Because medical colleges have "social, moral and ethical obligations of the profession of medicine", AMSA lobbies for the "removal of COI in medicine" and for "evidence-based rather than marketing-based prescribing practices"; its primary concern are the involvement of the pharmaceutical and device industries in clinical education and research [17]. To launch its first evaluation in 2007, AMSA developed a comprehensive framework to assess the content of institutional policies. The PharmFree Scorecard grades US medical schools according to their policies regulating relationships between students, faculty members, and the pharmaceutical and device industries. In a context where industry involvement and influence in academia were raising concerns about financial COI, an issue that looked "inevitable" in US medical schools at the time, AMSA sought to bring attention to the problem of COI and to then pressure medical centres to implement strong policies limiting financial COI associated with university-industry relations [14].



Each year since 2007, the AMSA PharmFree Scorecard group invites "all U.S. schools of allopathic and osteopathic medicine" to voluntarily submit their COI policies for assessment[18].¹ Each policy received is anonymized, assessed and then graded by two independent assessors (names and affiliations listed on the AMSA website, www.amsa.org). The evaluation examines eleven aspects or "policy domains" where COI can arise and should be addressed: limits on gifts and individual financial relationships with industry, receipt of pharmaceutical samples and speakers' fees, purchasing authority, on-site/off-site industrial educational programs and scholarships, and faculty/medical student COI training. Each domain is scored on a three-point scale (0 to 3), for a maximum total score of 33 points for the best policy: 0 points for "Institutions that do not respond to requests for policies or decline to participate"; 1 point for "Policy is absent or unlikely to have a substantial effect on behavior"; 2 points for "Good progress toward model policy" and 3 points for a "Model policy" [18]. AMSA does not define what constitutes a "Model policy", but we can infer that it is one that provides guidance and recommended standards that could become a reference to ensure optimal governance. A letter grade is then assigned based on the final scores: $A \ge 85\%$, $B \ge 70\%$, $C \ge 60\%$, $D \ge 40\%$, F < 40%, and I = Inprocess. Institutions failing to report or declining to participate in the survey automatically receive an F grade. The methodology and complete results of the PharmFree Scorecard are available online [13].

Of 152 medical schools invited to participate in the 2011-2012 Scorecard, 149 participated; of the 152 schools, 28 schools received an A (18%), 74 (49%) a B, 15 (10%) a C, and 13 (9%) a D, while 9 schools (6%) received an F. Most of the remaining schools were granted "in progress" or "in process" designations due to ongoing policy development. An examination of the rankings over the five-year history of the survey reveals substantial change, particularly in the last two years. Only 14% of schools were ranked A or B in 2007-2008 compared to 67% in 2011-2012. These rankings through time show significant improvements between 2008 and 2012. This is a tremendous increase compared to the 79 (52%) schools that were assigned A and B in 2010-2011, 45 schools (30%) in 2009-2010, 29 (14%) in 2008-2009, and 21 (14%) in 2007-2008. COI has clearly become a central issue in medical administration and education and more US medical schools are recognizing the importance of implementing thorough COI policies [19].

While the 2011-2012 ranking reveals that some US medical schools still need to develop more appropriate policies and regulations regarding their relations with the pharmaceutical and device industries, the change in rankings over the previous five AMSA PharmFree Scorecards shows that there have been major improvements in the development of "model" COI policies.

Methods

From our perspective, the AMSA methodology is a fruitful starting point to evaluate institutional COI policies. Inspired by this methodology, we conducted our own evaluation and ranking of the COI policies of the 16 Canadian universities hosting medical schools. Contrary to the AMSA evaluation that focuses essentially on medical school COI policies, we examined the policies of Canadian academic institutions hosting medical schools, since few medical schools in Canada have independent COI policies. We did not contact institutions directly, but from the Association of Universities and Colleges of Canada (AUCC) website (www.aucc.ca) we were able to identify those institutions hosting medical schools and downloaded from their websites the most recent documents referring to COI policies or guidelines. Keywords (in English and French) used to retrieve these policies were: conflict of interest policy + name of institution, governance + name of institution; politique conflit d'intérêts + name of institution. Very often, COI policies were referred to in other policies (e.g., nepotism policy, solicitation for gifts, statement on consulting policy). These documents were collected between March and September 2010 (Table 1), thus some have probably changed in the intervening years; it should be noted, however, that 9 institutions had revised their policies

¹ Most of the medical schools sampled closely follow their host institution's policy (e.g., Dartmouth, Pittsburgh), although some medical schools also have specific policies for addressing COI arising from institutional holdings or investments (e.g., Stanford).



between 2006 and 2009. We can only speculate to the reasons for such revisions, but they may include increased attention to changing policies and practices at American institutions (including NIH requirements, which affect Canadian researchers with US financing), as well as moves to respond to recommendations from Canadian actors such as the Canadian Institutes of Health Research [20].

Institution	COI policies/guidelines	Effective Date			
Alberta	Conflict of Interest and Commitment and Institutional Conflict	June 26, 2009			
	Conflict of Interest and Conflict of Commitment Reporting Assessment	November 16, 2009			
	Procedure				
	Managing Conflict of Interest in employment procedure	June 26, 2009			
British Columbia	Conflict of Interest and Conflict of Commitment	March 2005			
Calgary	Conflict of Interest Policy	September 1, 1987			
Dalhousie	Conflict of Interest	June 24, 2002			
Laval	Politique sur l'intégrité en recherche et création et sur les conflits	May 20, 2009			
	<u>d'intérêts</u>				
Manitoba	Conflict of Interest	June 16, 2009			
	Gift and Gratuities offered to University employees	January 20, 2009			
	Nepotism	January 27, 2009			
McGill	Regulation on Conflict of Interest	June 15, 2009			
McMaster	Statement on Conflict of Interest in Research	March 11, 2009			
	Procedures for Inquiries and Hearings regarding Allegations of	March 27, 2002			
	Misconduct in Research for Faculty, Staff & Post-Doctoral Fellows at				
	McMaster University				
	Code of Conduct for Faculty	December 8, 1994			
	Academic Integrity Policy	September 1, 2008			
	Conflict of Interest Guidelines: Undergraduate and Graduate Studies	February 14, 2001			
	Conflict of Interest Policy for non-academic staff and academic	March 27, 2002			
	administrators				
	Statement on Consulting Policy and Procedures	January 14, 1976			
	Distribution of Income from the Sale of Instructional Materials	March 16, 1981			
	Staff Policy on Consulting and Freelancing	May 20, 1997			
Memorial	Conflict of Interest (policy)	March 31, 2009			
	Solicitation of Gifts Policy	April 1, 1987			
Montreal	Règlement sur les conflits d'intérêt	November 24, 2009			
Ottawa	Conflits d'intérêt – Membres du personnel	October 20, 2009			
Queen's	Conflict of Interest and Conflict of Commitment	September 28, 2001			
Saskatchewan	Conflict of Interest	December 12, 2008			
Sherbrooke	Politique, règles et procédures sur l'intégrité en recherche et sur les	May 20, 2006			
	conflits d'intérêts				
Toronto	Conflict of Interest – Academic Staff	June 22, 1994			
	Conflict of Interest – Librarians	March 9, 1995			
	Provost's Memorandum on Conflict of Interest and close personal	n/a*			
	relations				
Western	Conflicts of Interest	September 28, 2000			

Table 1: Canadian Institutional COI Policies and Guidel	ines
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*n/a = non-applicable

Due to the fact that our evaluation was based on those COI policies that were available online in 2010 - i.e., we did not explicitly solicit submissions as in the AMSA scoring - we had to adapt the AMSA scoring to replace their 0 evaluation for "Institutions that do not respond to requests for policies or decline to participate". We thus used the following 3 point scale, which focused on the content of policies:

- 0 points when a policy or guideline was absent or inaccessible, or lacked key policy elements (e.g., lack of COI training);
- 1 point when policy elements were partially treated or treated through another institutional policy (e.g., misconduct activities, no specific restrictions for non-academic activities, nothing specific to financial COI or conflict of commitment, no clear definition of COI, once-a-year disclosure);



- 2 points when policy elements were addressed, but still incomplete (e.g., no designated institutional COI committee, no clear path for disclosure management, no specific limits to gifts or donations, no public disclosure of COI); and
- 3 points when policy elements could be cited as models (e.g., determined % or \$ max. in equity holding in line with US federal requirements, disclosure prior to beginning of activity and COI management plan).

We did not conduct a blind review as in the AMSA exercise, but instead performed a thorough review of the different institutional policies and guidelines associated with COI issues to extract the most pertinent elements identified according to the AMSA framework; this was followed by a second review of those specific elements used for ranking institutions. A first coder evaluated all of the university COI policies, guidelines or procedures (when available), and a second coder verified the overall calculation of the first coder, but did not do any independent coding to calculate inter-coder reliability.

Results

Our application of the modified AMSA scoring to the 16 Canadian institutional COI policies produced some startling findings. At first glance, Canadian institutions appear to have very weak policies, as all received D or F grades, with the exception of the University of Sherbrooke, which obtained a C grade (Table 1).

Interest	Industry relationships							Education				Grade	
	Gifts	Consult.	Speaking	Public /	Samples	Purchasing	Sales	On-site	Off-site	Industrial	COI	%	Rank
		fees		internal		-	rep	training	training	scholarships	training		
University				disclosure									
Alberta	3	3	2	2	1	1	0	1	1	1	0	45%	D
British Columbia	3	3	3	2	1	1	0	1	1	1	0	48%	D
Calgary	1	1	1	2	1	1	0	1	1	1	0	30%	F
Dalhousie	3	3	2	2	1	1	0	1	1	1	0	45%	D
Laval	3	2	3	2	1	1	0	1	1	1	0	45%	D
Manitoba	3	3	2	2	1	1	0	1	1	1	0	45%	D
McGill	3	3	3	2	1	1	0	1	1	1	0	48%	D
McMaster	3	2	2	2	1	1	0	1	1	1	0	42%	D
Memorial	3	3	2	2	1	1	0	1	1	1	0	45%	D
Montreal	3	3	2	2	1	1	0	1	2	1	0	48%	D
Ottawa	2	3	2	2	1	1	0	1	1	1	0	42%	D
Queen's	2	2	2	2	1	1	0	1	1	1	0	39%	F
Saskatchewan	3	3	2	2	1	1	0	1	1	1	0	45%	D
Sherbrooke	3	3	3	2	1	1	0	1	1	1	2	55%	С
Toronto	3	3	2	2	1	1	0	1	1	1	0	45%	D
Western	2	2	2	2	1	1	0	1	1	1	0	39%	F

Table 2: Ranking Canadian Universities with the Modified AMSA PharmFree Scorecard

In this modified AMSA scoring, Canadian institutions may appear to perform particularly poorly with regards to interaction with industry when dealing with gifts, consulting, speaking, samples, purchasing matters, as those issues were almost non-existent or not available in any of the 16 COI policies. Similarly, policy mechanisms to address the involvement of industry in education or training were typically very weak or non-existent. So in terms of specific guidelines about industry involvement in university education, almost all Canadian policies obtained a grade of 1 out of 3. With regards to the implementation of mechanisms to provide at least minimal training for academic and administrative staff and students about how to deal with COI, all policies received a 0 grade, except for Sherbrooke which obtained 2 out of 3. These dramatic shortcomings in Canadian institutional COI policies may be explained by the fact that the policies did not include all of the policy elements adopted by AMSA (e.g., gifts, consultant services, purchasing authority), or because different COI issues are being addressed in a diversity of policies and procedures (e.g., McMaster). For example, we gave a poor score to policy elements such as gifts, or external consulting services, on-site or off-site training, public disclosure (e.g., on a web site), and industry scholarships because we could not find any references

to gifts and donations in the specific COI policy (e.g., University of Montreal). But that does not mean that such issues are not dealt with in another policy mechanism or through practical guidelines.

In some universities, there are so many policies addressing different aspects of COI (e.g., in policies on intellectual property, academic integrity, nepotism, purchasing guidelines, research ethics) that members of the institution (e.g., professors, researchers, students) may be either overwhelmed, not know which policy is most pertinent, or not even know that these policies exist. This situation is all the more problematic in the context of medical schools, where some members (e.g., professors, clinicianresearchers, students) are based in the university while others are fulltime in affiliated hospital research centres, which may have their own policies or guidelines. So while it may be important to have a cluster of overlapping and cross-referenced policies and guidelines addressing COI (e.g., the University of Manitoba COI policy is cross-referenced with policies or procedures dealing nepotism, research agreements, research ethics, gift and gratuities offered to University employees, responsibilities of academic staff with regard to students), we agree with the AMSA ranking that a central policy should deal with the major elements associated with financial (and non-financial) COI, if it is to be at all practical and relevant to members of the institution. A patchwork from different policies creates a higher risk of incoherence than does a central policy with a coherent framework.

Interactions between US medical schools and the pharmaceutical and medical device industries may date back further than in Canada, in part due to the stimulus provided by the 1980 US Bayh-Dole Act, and thus explain to some extent the significant attention given to managing the financial COI associated with industry involvement in medical education. Nonetheless, over the past 25 years there has been a tremendous increase in university-industry relationships in Canada, the recognition of which has lead Canadian institutions to consolidate various policies as well as develop explicit COI policies (see Table 1). When AMSA launched its first survey in 2007, many US medical schools may have been in the same position as Canadian institutions are today. And while the AMSA Scorecard is focused on those COI specifically associated with pharmaceutical and device industry involvement in medical schools, the AMSA exercise became an opportunity for US medical schools (and universities) to consolidate their own practices and policies and implement more robust COI governance mechanisms.

A thorough examination of the Canadian policies reveals that while still imperfect, many also show important strengths. The Canadian COI policies invariably cover a broader range of issues than those used in the AMSA ranking, likely due to the fact that these are university wide policies; that is, while these policies apply to medical schools, they are not focused on the concerns specific to medical schools (e.g., with regards to pharmaceutical or medical device industry involvement in education). For example, some financial COIs, such as receiving royalties for commercializing intellectual property and holding equity in spin-off companies appear not to be taken into account by the AMSA evaluation even though they are obviously a relevant concern for medical schools; the same concerns regarding undue influence of industry interests in medical education and research apply to relations with spin-off companies. Most Canadian and US university policies place restrictions on such financial interests [10]; and many non-financial COI are also accounted for in Canadian (and US) university policies (e.g., academic evaluation of faculty member's immediate family, use of the university's name for personal gain, supervision of graduate students when in relation with faculty members' spin-off companies).

There are some issues that certain Canadian COI policies do not address (e.g., thresholds for financial interests requiring disclosure, which are required by NIH regulations²); other issues may not

² Financial compensation from sponsors to investigators, or investigators' proprietary interests in a product under study (including stock options) have potential for causing bias and raise serious concerns about the integrity of research. Limiting financial interests or determining a financial threshold, either in the form of a specific monetary value or percentage of equity, may be seen as a safeguard to protect investigators and universities. Nonetheless, in practice it can be very difficult to determine and apply such financial thresholds.



be treated uniformly (e.g., disclosure processes); and finally, certain matters are often overlooked (e.g., COI issues related to intellectual property). Canadian university COI policies also ranked very poorly when it came to dealing explicitly with domains such as "purchasing authority", "industry sales representative" and "industrial scholarships". We did, however, find some of these issues addressed through other institutional policies (e.g., dealing with conflict of commitment or scholarships), although it is worth remembering our earlier criticism about having a fragmented approach to managing COI. And while some specific issues addressed in the AMSA ranking (e.g., consulting fees, gifts, industrial financial support to training activities) were absent from Canadian institutional policies, Canadian institutions also dealt with other issues not evaluated by AMSA, such as limits on patent royalties, equity in start-up companies or industry funding of research. The 16 Canadian university policies that all had relatively comprehensive COI policies and procedures, alongside other relevant institutional policies or guidelines on "research integrity", "conflict of commitment" or "ethical conduct of research" (e.g., University of Manitoba, McMaster University).

Discussion

Our findings correspond with those of a recent Australian study [21] that applied the AMSA methodology and found a lower overall mean score in Australian medical schools when compared to their US counterparts. But that does not mean that Australian or Canadian university COI policies are necessarily worse than those of US institutions or even that Canadian and US policies are comparable in terms of content. There are important limits – but also benefits – of applying the AMSA methodology outside the US context, that must be considered.

A major strength of the AMSA PharmFree Scorecard – and other COI policy comparisons [1,2,22-25] – is that it brings attention to the importance of having effective institutional policies to address COI associated with pharmaceutical and device industry involvement in medical education and professional training. However, while this attention to financial COI is essential and becoming quite widespread in higher education policy, there is a problematic tendency in American and Canadian university COI policies to not (or to inadequately) take into account non-financial COI. The reality is that not all COI are financial in nature – e.g., interests in academic promotion, personal or professor-student relationships [26], or even a particularly strong allegiance to a school of scientific thought [27,28]. Policies founded on this limited perspective may not recognize nor address adequately the other types of COI, which may also result in real or apparent loss of objectivity or create bias. Our concern, then, is that the focus of the AMSA Scorecard on financial COI – while legitimate in the context of their focus on university-industry relations – may contribute to the all-too-prevalent notion that *most if not all* problematic interests are financial, and that financial COI are invariably equivalent to fraud [29].

Overall, our study also corroborates findings by Lexchin and colleagues in their study of 74 Canadian academic health science centres, which demonstrates considerable variability in the scope, focus and quality of institutional COI policies [10]. It seems likely that most if not all US medical schools are conscious of these other types of COI (non-financial) and their possible impact on objectivity in health sciences research and medical education. AMSA is also sensitive to these issues, stating that: "While not addressed here, academic medical centers should also have robust policies to ensure the integrity of basic and clinical research, including policies to ensure that academic researchers working in collaboration with industry retain full control of study design, data, analysis and writing" [18]. Yet, in separating out non-financial COI, we feel the AMSA methodology misses an important opportunity to bring attention not only to the full diversity of COI, but also to the importance of implementing a variety of appropriate procedures to manage COI. More worrisome, though, is that this strategy may encourage the ever-present perception that it is only financial COI that matter or that could be potentially problematic.



Our study of Canadian institutional COI policies highlighted two important mechanisms for managing COI that are worth further examination: *disclosure* and *training*.

Disclosure

One of the main differences we observed in our study had to do with the manner in which disclosure is addressed in COI policies. The AMSA methodology gives a maximum score to public disclosure of COI (e.g., on a public website). This is likely based on the commonly held belief in the health sciences [12,22,30,31] – and reinforced by the NIH regulations implemented in 2012 for grants and cooperative agreements – that it is essential for all stakeholders involved to publicly disclose *all* real (actual) or potential (perceived) significant financial COI situations (e.g., financial interests over \$5,000) [32]. But from the AMSA study, we cannot tell how disclosures are managed (monitored) once they are filed because it does not score "COI management guidelines" for the cases where COI are unavoidable.

By contrast, our analysis of Canadian policies found that COI were often managed by internal mechanisms and not always through public disclosure. Many policies relied, for example, on Research Ethics Boards in their institution and affiliated hospitals to be informed of any COI related to clinical research, and empowered these committees to decide which management measures (e.g., requiring disclosure to participants or changes to the recruitments process) were most appropriate to manage the particular COI. Similarly, COI are among the issues covered in the 2010 2nd Edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS2), and are addressed in depth in Chapter 7 [33]. Because COI can jeopardize the integrity of research and the protection of research participants (and medical education, given the strong link between research and teaching), Canadian institutions are invited to develop appropriate policies, safeguards and procedures. Our review of Canadian COI policies found that some of the TCPS2 recommendations are still not common (e.g., a central mechanism for COI management). And while internal management processes may have some limits (e.g., some institutional COI may not be properly addressed), so too does internal and public disclosure if they are not dealt with appropriately (e.g., misinterpretation and unfounded public mistrust).

It has been shown that the disclosure of unavoidable COI can induce a sense of security on the part of the person disclosing – and for those witnessing the disclosure – that gives an unreasonable sense that the conflict has been resolved; in other words, disclosure may actually induce an unconscious cognitive bias in favour of the person disclosing because disclosure is viewed in a positive manner [34]. By contrast, the widespread negative perception of COI means that many people may not disclose even when it is obligatory for fear of the negative view of colleagues, i.e., that being in a COI means that they are unethical [29]. So for disclosure to be accepted as an appropriate response, students and researchers who recognise that they may be in an actual or perceived COI must also have a significant degree of confidence in institutional mechanisms, i.e., that in disclosing they will be dealt with fairly [35]. While disclosure (either internal or public) can, in many cases, be of utmost importance in managing financial and non-financial COI, it is arguably only one part of a robust and refined management process. Such a process should, we suggest, involve appropriate and specific institutional guidelines and training to assist faculty members, staff and students in the recognition and management of any COI in which they may actually, apparently or potentially be involved.

Training

The AMSA Scorecard's inclusion of COI training in its evaluation highlights the importance of COI education as a critical mechanism for building awareness and changing how individuals and institutions understand and deal with COI [36]. Even with the different academic contexts between the US and Canada, training is still viewed as important. However, all but one Canadian university scored 0 which shows a significant weakness in Canadian COI policies. There are many examples of training tools (e.g., online courses, conferences, workshops) developed by US academic institutions (e.g., Johns Hopkins University [37], the University of Texas Health Science Center at Houston [38],



Columbia University [39]) to help students, faculty members, and staff recognize the institutional nature of COI situations, and understand how private interests (either financial or non-financial) can affect judgment, objectivity and public trust.

Aside from the University of Sherbrooke, none of the Canadian universities hosting a medical school appear to have developed tools for helping students, faculty members or administrative staff in identifying and managing COI. This being the case, it will likely be very difficult for faculty, staff and students in these institutions to 1) accurately appreciate when they are in a COI, 2) recognize that such situations may cause potential harms (e.g., loss of objectivity, loss of trust), or 3) understand whose interests are at risk. Without appropriate education for specific COI situations (both financial and non-financial), it will be difficult to create a culture of ethics amongst the members of an institution and ensure compliance with institutional COI (and other ethics) policies. Training and education should be a key element in a COI policy that aims to build awareness and effective monitoring and management of COI [36].

Study Limitations

The application of AMSA Scorecard highlighted the importance of these two aspects, i.e., disclosure and training. However, the method used has important shortcomings that are important to note. First, as mentioned at the outset, the AMSA Scorecard was created to evaluate and rank (and ultimately influence) medical school COI policies as they related to pharmaceutical and medical device industry involvement. Our intention in applying the AMSA Scorecard was to see what items differed between the Canadian university and US medical school contexts, and to reflect on whether different approaches to dealing with COI were warranted. We are, nevertheless, sensitive to the fact that there are a few Canadian medical schools that have (or are in the process of) put in place their own COI policies and which may have more stringent provisions that are specific to and focused on those COIs typically found in medical schools.

With regards to our coding method, it was not blinded because we have been working on these policy documents for quite some time (since 2007) and could identify them simply by their content. Moreover, we did not have a particular interest in determining which Canadian university "won" or performed the best in our study because our objective was not the ranking itself. While the influence of excellent or poor AMSA rankings has been a powerful motivator for US medical schools (and thus a means of influencing change, at least providing a motivation to develop and provide COI policies), we were interested in reflecting on what this ranking system could tell us about the content of Canadian COI policies. Finally, while the second coder verified the conclusions of the first coder, we decided that independent coding to calculate inter-coder reliability was not necessary. This was decided because the coding method was done in a deductive matter (based on the AMSA Scorecard) and categories are quite precise, thus there is much less space for interpretation than in an inductive study where the coding scheme is established depending on the content analyzed.

Conclusion

A straightforward application of the AMSA PharmFree Scorecard to evaluating the quality of COI policies of medical education institutions outside the US is likely of limited direct utility. The considerations that are so important for the US context, namely the disclosure of financial interests in unavoidable COI and any involvement of the pharmaceutical and medical device industries in medical education, may be less of an issue (though still pertinent) in higher education systems such Canada's, where universities are funded primarily from public sources (e.g., federal and provincial governments). Further, in our study of Canadian universities, we found a variety of policies that were pertinent but not specifically focused on COI (e.g., conflict of commitment, nepotism, academic integrity, intellectual property, research ethics). A more in-depth and comprehensive examination of institutional approaches to managing COI would have found that most Canadian universities provided their



communities with a diversity of mechanisms to address COI [40]. However, while these diverse approaches might support attention to a broader range of COI (including non-financial), their very diversity and lack of coordination can also undermine appropriate COI disclosure and management.

As we have shown in our application of the AMSA Scorecard to 16 Canadian university COI policies, it is essential to 1) reflect on the *utility and limits of disclosure* as a COI management mechanism, and 2) develop and implement *training and educational tools* for students, faculty and administrators so that they are empowered to both identify COI and manage these situations when they cannot be avoided. The AMSA PharmFree Scorecard has clearly played an important role in motivating US medical education institutions to improve their financial COI policies, and more generally, has contributed to on-going international reflections on the need to develop and implement effective COI policies in medical schools and academic institutions more generally. With growing interest and sensitivity on the part of Canadian medical students to issues of COI, we might even see the rise of a "Canadian AMSA" movement, unless Canadian medical schools, universities or other governance bodies work proactively to develop "model policies" and procedures for the institutions.

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