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Research Ethics and the Role of the Professional Bodies: A View From Canada

An increasing number of community physicians are involved in clinical research. Indeed, 60% of industry-funded research is now spent on “community-based trials.” This surge in community-based clinical trials has increased the number of clinical trials applications submitted to the drug regulatory agencies by pharmaceutical sponsors. Many have argued that the commercial interests connected to the conduct and outcome of these trials also increases the potential for conflicts of interest for participating physicians. The context in which these trials take place increases the potential for a host of practices that infringe on ethical, legal and clinical obligations of physicians. For example, financial recruitment incentives may lead to violations of the inclusion criteria and the consent process. It may result in inappropriate recruitment of patient participants and a blurring of the ethically significant distinctions between treatment and research. In some cases, it may be hard to distinguish research from the marketing of new products and attempts to influencing prescribing patterns.

The need for independent scientific and ethics review of all human subjects research is widely accepted including the evaluation of the potential impact of financial interests on research. Unfortunately, while conflicts of interests are often particularly problematic in the context of community-based research projects, physicians in Canada (and, for that matter, in other jurisdictions) have difficulty obtaining access to an independent REB. To fill this gap, we suggest that licensing agencies, that is, the provincial colleges of physicians and surgeons, exercise their regulatory authority and organize better oversight of industry-sponsored, community-based clinical trials.

A Recognized Need for Ethics Review

The need for research ethics review has been explicitly recognized by both the Canadian Medical Association (CMA) and many provincial Colleges. Both the CMA Code of Ethics and the related CMA Policy Statement require physicians to ensure that their research is “evaluated both scientifically and ethically” and is “approved by an appropriate ethics review body.”

Many Canadian Colleges’ research policies increasingly are aimed at the emerging concerns associated with industry-sponsored research and conflicts of interest. For example, a policy statement by the Manitoba College declares that a “physician should not participate in any industry-sponsored research activities without first confirming that the appropriate ethics committee has provided formal approval.” In New Brunswick, the College’s Code of Ethics adopts the CMA Code and further highlights that it “applies to community based physicians considering participation in drug marketing studies no less than primary investigators in basic clinical research projects.” Likewise, the Ontario College has adopted the CMA policy statement as a to guide physicians participating in industry-sponsored...
research. They require approval by an ethics review body of the physician may receive and that the study is scientifically and ethically sound.\textsuperscript{11}

Nevertheless, despite clear acceptance of the critical role of appropriate ethics review for practice-based research in Canada, only the College of Physicians and Surgeons of Alberta has taken active steps to ensure that this, in fact, occurs. In 1998, the Alberta College established the Research Ethics Review Committee (REC) to oversee the research activities of all its members.\textsuperscript{12} In Canada, the colleges have jurisdiction over all physicians, regardless of specialty. As such, before an Alberta physician can proceed with a research project, the physician must obtain approval from the REC or one of the recognized university Research Ethics Boards (REBs) in Alberta. In practice, this means that most community based research, which is almost entirely industry sponsored, is examined by Alberta’s REC.

This approach has a number of distinct advantages. First, research ethics review performed by the College is not associated with many of the institutional conflicts of interest that plague university and private REBs. As noted by many commentators, the strong financially based interests which institutions, such as universities and research centres, have in attracting and supporting research, creates conflicts that can compromise their internal review process.\textsuperscript{13} Likewise, there are financial conflicts inherently tied to private (for-profit) REBs, which are often the only alternative for community researchers lacking access to university review committees. While REB members of the College’s REB may have individual conflicts of interests that have to be scrutinized and avoided, the REB itself does not have a direct financial interest in the conduct and outcome of the research.

A second and closely related consideration, one that will be highlighted further below, is that protection of the public is recognized as one of the primary mandates of professional bodies.\textsuperscript{14} This statutory obligation, therefore, should focus the ethics review process on the interests and needs of the research subject/participant, thus further mitigating against even apparent conflicts of interest. Unlike other REBs, which may be housed in institutions with a variety of conflicting goals, a College REB’s mandate would derive from a duty that, at least in theory, is fairly focused on the interests of the public.

Third, the creation of provincial/College REBs has the potential to harmonize the review process in a given jurisdiction. Colleges have a clear governance role over their members for all physician researchers across their jurisdiction. In contrast, there can be significant variation in the approach and philosophy of institutionally based REBs, resulting in detrimental differences in the review process. As well, of course, institutional REBs do not have the same latitude as Colleges to sanction physician researcher for unethical research practices.

An Obligation to Develop College REBs?

Given the need for research ethics review in all clinical research, each Canadian provincial College should consider the creation of an REB. Indeed, for the reasons stated below, it can be forcefully argued that the Colleges have both the power and legal and ethical obligation to do so.

Statutory Duty to Protect the Public

Colleges are created with the explicit purpose of protecting the public interest. As stated in the British Columbia Medical Practitioners Act: “It is the duty of the College at all times (a) to serve and protect the public, and (b) to exercise its powers and discharge its responsibilities under all enactment in the public interest.”\textsuperscript{15} In Prince Edward Island, the Medical Act explicitly notes that the College must discharge its duties “in order that the interest of the public” is served.\textsuperscript{16} In Alberta, the Health Professions Act states that the College must “…protect and serve the public interest” and “…regulate the practice …of its members…” (Section 5(D)).\textsuperscript{17} Other enabling legislation and policy statements make similar reference to the central goal of protecting and serving the public.\textsuperscript{18}

Given this statutory duty, and given the growing and recognized issues associated with community based clinical research,\textsuperscript{19} developing an REB process seems a logical and essential role of Colleges. Indeed, participating in clinical research has become a significant component of community-based practice. Morin et al have suggested that, in the US, the number of physicians involved in “clinical research has increased 600% in 10 years.”\textsuperscript{20} There is little reason to believe that the percentage of increase is substantially less in Canada.

Surely it is appropriate to expect Colleges to take active steps to address an activity that involves a significant number of physicians and has implications for a large segment of the public. At least one College has noted that “the regulation of the profession requires both proactive and reactive measures.”\textsuperscript{21} In the current climate, creating a College-based REB system, as Alberta has done, can only be viewed as a sensible way for professional bodies to proactively address an issue that is directly related to their statutory obligation to protect the public interest.

It is also important to note that this general duty to protect the public gives Colleges across Canada the clear legal authority to establish research ethics boards.\textsuperscript{22} That is, because clinical research involves a close interaction between physicians and members of the public, Colleges are well within their jurisdiction to develop schemes, such as an ethics review process, to oversee clinical research. Indeed, in Alberta the Health Professions Act
Fiduciary Obligations?

In Canadian law, the physician-patient relationship has long been characterized as fiduciary in nature. In the Canadian Supreme Court case of Norberg v. Wynne, Justice McLachlin stated that "the most fundamental characteristic of the doctor-patient relationship is its fiduciary nature." 24 Fiduciary law places an obligation on health care providers to place the interests of patients above all else and to treat patients with the "utmost good faith and loyalty." 25 Clearly, this body of law has important implications for physicians involved in clinical research. For example, it heightens the obligation on clinical investigators to disclose and to avoid any possible conflicts of interest that could impact on the patient's interest and wellbeing. 26

While the fiduciary concept clearly applies to physicians, courts and commentators have expanded the concept to include various relationships such as lawyer/clients, corporate directors/shareholders, and government officials/public. 27 This has led some to suggest that institutions that have a mandate to consider the public good may also be considered fiduciaries. 28 It has been noted that this may and should apply to entities such as REBs. 29

Institutions generally do not have the same personal interaction and trust relation with individuals that characterizes many of the traditional fiduciary relations. However, the REB review system has been developed, in part, because of the perception that the dual role of physician-investigator creates a potential conflict, which warrants an independent assessment by a committee consisting of members who do not have a direct interest in the research. In a way, the REB is an institutional response to a potential threat to the fiduciary duties of physician-researchers. REB review can be seen as an extension the traditional physician-patient relation.

For similar reasons, it can be argued that the Colleges of Physicians and Surgeons may be subject to fiduciary law. As noted, Colleges have a statutory mandate to protect the public which, in itself, goes some distance to creating fiduciary obligations. As noted in the Supreme Court Case of Guelin v. The Queen: "where by statute, agreement, or perhaps unilateral undertaking, one party has an obligation to act for the benefit of another and that obligation carries with it a discretionary power, the party thus empowered becomes a fiduciary." 30 Moreover, Colleges have a long and visible history of serving the public. As such, it is fair to say that there is a reasonably formed expectation that Colleges are dedicated to the public good. Such reliance and expectation are further indications of a fiduciary relationship. 31

Given the above, it is certainly possible that a Canadian court could cast Colleges as a fiduciary in the context of overseeing the activity of community based clinical researchers. If so, fiduciary law creates another strong legal justification for the creation of community-based REBs to oversee community-based clinical research.

Professionalism and Public Trust

An issue closely related to the potential fiduciary obligations of physicians and Colleges is the role of professionalism. The relationship of trust between physician and patient is an essential element of the therapeutic nature of the practice of medicine. 32 Moreover, it is also necessary to both the public acceptance of research and the conduct of clinical trials. Without trust, patients may hesitate to participate in research protocols. 33 In fact, without a strong foundation of trust, "societal support for human participation in clinical trials will simply vanish." 34 Increasingly, a variety of commentators have cautioned that the emerging issues associated with clinically-based research, particularly industry-sponsored research, could compromise this relationship of trust. 35

Professions have an important commitment to building and maintaining public trust. 36 Society expects professionals to strive to meet high standards of conduct and "to enforce them upon colleagues within the guild." 37 As the entities charged with overseeing the conduct of the profession, Colleges have a vital role to play in this context. If emerging trends in the conduct of community based clinical trials raise issues that compromise the social perception of the medical profession, Colleges must take steps to ensure the integrity of the profession is maintained. The creation of an appropriate research ethics review process under the legislated authority of the Colleges would be consonant with such a responsibility.

Inadequacy of available REBs

Another strong justification for the development of a College REB process is the clear inadequacy of the existing system. In Canada, the formal research oversight process largely flows from the major public research funding entities and is focussed on research at academic institutions, primarily through the development and implementation of the national research ethics policy, the Tri-Council Policy Statement (TCPS). 38 Enforcement of the TCPS is essentially limited to research at academic centres. As a result, community based researchers must seek alternative means to implement the TCPS. In most Canadian jurisdictions the alternative has been the purchase of private (for profit) review — a review that lacks transparency, accountability and regulatory authority.

The protection of patients is clearly one of the most crucial obligations of the College. In light of the existing lacunae in the system and in light of the lack of reliable independent
REB review, the College have an obligation to look for alternative solutions. In the long run, a coherently organized uniform review system for all the forms of research, by the private or within academic institutions, and imposed through governmental regulation may provide a better solution. But in the meantime, the Colleges have an obligation to use their power to establish a better alternative.

Conclusion

Given the inaccessibility of academic REBs, and the enforced reliance on ethically compromised private (for profit) REBs for community-based research, it seems reasonable that Colleges should meet the need to protect both patients/participants and community researchers from possible misadventure. As well, given the success of Alberta's 'experiment', there now exists a straightforward template upon which other Colleges can build.

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References

15. Medical Practitioners Act, R.S.B.C. 1996, Ch 285, s. 3(1).
17. Health Professions Act, S.A. 2002, c. H-7. Though this law has been enacted, it will not apply to Alberta physicians until the relevant regulations have been developed and implemented.
34. Miller, supra note 32 at 439.