POST-MARKET DRUG EVALUATION RESEARCH TRAINING CAPACITY IN CANADA: AN ENVIRONMENTAL SCAN OF CANADIAN EDUCATIONAL INSTITUTIONS

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ABSTRACT

Background
Ongoing efforts by Health Canada intended to modernize the legislation and regulation of pharmaceuticals will help improve the safety and effectiveness of drug products. It will be imperative to ensure that comprehensive and specialized training sites are available to train researchers to support the regulation of therapeutic products.

Objectives
The objective of this educational institution inventory was to conduct an environmental scan of educational institutions in Canada able to train students in areas of post-market drug evaluation research.

Methods
A systematic web-based environmental scan of Canadian institutions was conducted. The website of each university was examined for potential academic programs. Six core programmatic areas were determined *a priori* as necessary to train competent post-market drug evaluation researchers. These included biostatistics, epidemiology, pharmacoepidemiology, health economics or pharmacoeconomics, pharmacogenetics or pharmacogenomics and patient safety/pharmacovigilance.

Results
Twenty-three academic institutions were identified that had the potential to train students in post-market drug evaluation research. Overall, 23 institutions taught courses in epidemiology, 22 in biostatistics, 17 in health economics/pharmacoeconomics, 5 in pharmacoepidemiology, 5 in pharmacogenetics/pharmacogenomics, and 3 in patient safety/pharmacovigilance. Of the 23 institutions, only the University of Ottawa offered six core courses. Two institutions offered five, seven offered four and the remaining 14 offered three or fewer. It is clear that some institutions may offer programs not entirely reflected in the nomenclature used for this review.

Conclusions
As Heath Canada moves towards a more progressive licensing framework, augmented training to increase research capacity and expertise in drug safety and effectiveness is timely and necessary.

Key Words: *Post-market drug evaluation, curriculum, pharmacoepidemiology, education, drug safety, regulation*

It is hoped that recent efforts by Health Canada to modernize the legislation and regulation of pharmaceuticals and biologics will help to improve the ongoing monitoring of safety and effectiveness of drug products. Health Canada's proposed progressive licensing framework, discussed in detail elsewhere,[1] consists of the following four key elements: (a) adoption of a life cycle approach, (b) evidence-based decision-making, (c) good planning and (d) accountability. A key focus of the framework is to shift the focus from pre-market assessment to continuous assessment.

The government's intentions were first formally embodied in Bill C-51, "An Act to amend the Food and Drugs Act and to make consequential amendments to other Acts", given first reading in the House of Commons on April 8, 2008.[2] While the bill received substantial discussion, it did not become law before the 39th parliament ended on September 7, 2008 and the legislation has not been reintroduced. However, the government has not wavered from its earlier direction and in December 2013 a related focus was announced by Health Canada and some of the Bill C-51 measures were reintroduced within Bill C-17, the "Protecting Canadians from unsafe drugs Act".[3] The stated aim of Bill C-17 is to strengthen the oversight of therapeutic products throughout their life cycle.

As a result of continuing efforts to place a more intense focus on post-market drug evaluation; a critical issue has emerged that revolves around the training of adequate numbers of research scientists able to conduct this type of pharmaceutical research. Post-market drug evaluations can be defined as the medical discipline concerned with discovery of new knowledge of both the safety and effectiveness (clinical, economic etc.) of drugs following their release onto the market. Recently, there has been renewed interest by Canadian academic institutions to train graduate students for careers in public health, with several new Masters of Public Health (MPH) programs emerging. It would be expected that programs such as these, along with other graduate programs in population health and epidemiology, would provide the necessary graduates able to conduct the work required by Health Canada's progressive licensing framework. It is unknown, however, whether these programs actually provide graduate students with the necessary knowledge, skills and attitudes to lead post-marketing drug safety and effectiveness research studies.

If well implemented, the ongoing efforts to modernize the *Food and Drugs Act* and accompanying regulations will expand understanding of pharmacogenomics and will greatly strengthen post-market drug evaluation activities such as pharmacovigilance and risk management. In order to foster this development it will be imperative to ensure that comprehensive and specialized training sites are available throughout the country to train adequate numbers of researchers who are able to support the new approach to the regulation of therapeutic products.

The objective of this educational institution inventory was to conduct an environmental scan of the educational institutions in Canada that may be able to train students in areas of post-market drug evaluation research. The prevalence of core courses deemed essential in the training of post-market drug evaluation researchers was initially determined as reported elsewhere in the course of conducting a human resource survey requested by Health Canada's Office of Legislative Modernization and Renewal.[4]

METHODS

Data Sources

A systematic web-based environmental scan of all Canadian educational institutions was conducted in 2009 to determine which graduate programs have the capability to train students in the discipline of post-market drug evaluation research. This search was updated in February of 2014. A list of potentially eligible universities was initially abstracted from the 2013 MacLean's Guide to Canadian Universities.[5] All universities were considered potentially eligible. The website of each university was examined for potential academic programs able to train researchers in the area of post-market drug evaluation research. Eligibility criteria included the availability of a health-related graduate program that included courses in epidemiology and biostatistics, public

health, pharmacy, veterinary medicine or health informatics.

Data Extraction and Analysis

Information from all eligible graduate training programs was abstracted onto Microsoft Excel 2007 worksheets [Microsoft Corporation, Redmond WA]. Program details that were recorded included the numbers of graduates, the typical duration of graduate programs, contact information for program coordinators, program application dates and related other characteristics. Details were abstracted primarily from program websites; although, email contact was made with institutions to elicit any information not available online. Program courses were reviewed and categorized into 14 course categories considered potentially relevant to post-market drug evaluation research. Courses which did not fall into one of these categories were excluded. Of the 14 course categories identified, six were deemed to be core course categories essential to the training of researchers able to support the future requirements of the life cycle approach to post-market drug evaluation research. The core course categories were decided *a priori* by consensus among the members of the Child and Family Research Institute (a research institute working in partnership with BC Children's Hospital and Sunny Hill Health Centre for Children, BC Women's Hospital & Health Centre, agencies of the Provincial Health Services Authority; BC Children's Hospital Foundation; and the University of British Columbia), Working Group investigators and the Advisory Committee supporting the Health Canada survey.[4] The designated core courses were: a) biostatistics; b) epidemiology; c) pharmacoepidemiology; d) health economics and/or pharmacoeconomics; e) pharmacogenetics and/or pharmacogenomics; and f) patient safety and/or risk management and/or pharmacovigilance.

The prevalence of core and general courses by category was summarized by academic institution. Prevalence by institution, rather than by graduate program, was considered to be a better marker of course availability, as it was assumed that graduate students could take pertinent courses offered by other programs at their institution.

RESULTS

Twenty-three Canadian academic institutions were identified that had the potential to train students in post-market drug evaluation research.[4] Twenty institutions had programs training researchers in human health, two had separate programs for human health and for veterinary health, and one institution had a training program only for post-graduate veterinarians. Graduate programs within these institutions included Epidemiology (including veterinary), Community Health, Population and Public Health (including veterinary), Pharmacy, Health Informatics, Health Research Methodology, and Health Technology Assessment.

As shown in Table 1, the types of graduate degrees granted by the various institutions and programs were diverse. The most common programs awarded MSc and PhD degrees, with 31 for each offered throughout the country. There were 9 Masters of Public Health degree programs. In addition, there were 19 related degree-granting programs including post-BSc diploma programs and non-MSc Masters programs such as Masters of Health Informatics and Masters of Health Sciences. English is the language of instruction in 19 of the institutions, with courses taught in French at the Université de Montréal, Université Laval and the Université de Sherbrooke. The University of Ottawa is bilingual.

TABLE 1 Canadian institutions with potential to train graduate students in post-market drug evaluation research

Institution	Departments/Schools	Degrees Available	Total Grads/Year (Approx.)	PT Study Available	Thesis vs. Non-Thesis
University of British Columbia	Pharmaceutical Sciences, Population and Public Health, Bioinformatics	MSc, MHSc, MPH, PhD	100	Yes	Both
Simon Fraser University	Health Sciences	MPH, MSc	60	Yes	Both
University of Victoria	Health Information Science	MSc, PhD	10	No	Thesis
University of Northern BC	Community Health Science	MSc	6	No	Thesis
University of Alberta	Public Health, Epidemiology Pharmacy	MSc, MPH, PhD	58	Yes	Both
University of Calgary	Community Health Science	MSc, MCM, PhD	25	No	Both
University of Saskatchewan	Community Health and Epidemiology, Public Health, Pharmacy	MSc, MPH, PhD	32	Yes	Both
University of Manitoba	Community Health Science, Pharmacy	Diploma, MSc, MPH, PhD	30	Yes	Both
University of Toronto	Health Policy Management and Evaluation, Public Health, Health Informatics, Pharmacy	MSc, MHI, MHSc, MScCH	110	Yes	Both
McMaster University	Health Research Methodology	MSc, PhD	50	Yes	Thesis
University of Ottawa	Epidemiology and Community Medicine	MSc, PhD	20	No	Thesis
Queen's University	Community Health and Epidemiology	MPH, MSc, PhD	25	Yes	Both
University of Western Ontario	Epidemiology and Biostatistics	Certificate, MSc, PhD	40	Yes	Both
University of Waterloo	Applied Health Science	MSc, MPH, PhD	60 (Not known MSc, PhD)	Yes	Both
University of Guelph	Population Medicine	MSc, PhD, DVSc	30	Yes	Both
Lakehead University	Public Health	MPH	30	Yes	Both
McGill University	Epidemiology, Biostatistics and Occupational Health	MSc, PhD	45	Yes	Both
Université de Montreal	Community Health, Population Health, Veterinary Medicine, Pharmacy	Diploma, MSc, PhD	200 (incl. 60+ diploma)	Yes	Both
Université de Sherbrooke	Clinical Sciences	MSc, PhD	Not known	Not known	Not Known
Université Laval	Community Health, Pharmacy	MSc, PhD	15	Yes	Thesis
Dalhousie University	Community Health and Epidemiology, Health Informatics	MSc, MHI, PhD	15	Yes	Both
University of Prince Edward Island	Veterinary Medicine	MVSc, MSc, PhD	Not Known	Not known	Both
Memorial University	Epidemiology	Diploma, MSc, PhD	Varies	Yes	Both

An estimated 900 students graduate from these programs annually, with the number fluctuating yearly in relationship to issues such as funding. Approximately 500 of the students graduate with traditional thesis-based MSc and PhD degrees. The remaining programs were primarily non-thesis based masters (e.g., Masters of Public Health, Masters of Health Informatics) and graduate diploma programs. No specific information was discernible regarding the number of graduates from these programs with training in post-market drug evaluation research. However, it is clear from the breadth of courses available at these sites (many having little or no relevance to post-market drug evaluation)[4] that only a small minority of students actually receive training specialized to post-market drug evaluation research. While many MSc graduate students are currently being trained in the general area of drug evaluation, there appear to be additional places available in a number of doctoral programs across the country that are not currently being utilized.

The prevalence of the six courses designated as 'core' was determined for each institution (Table 2). Overall, 23 institutions taught courses in epidemiology, 22 in biostatistics, 17 in health economics/ pharmacoeconomics, 5 in pharmacoepidemiology, 5 pharmacogenetics/ pharmacogenomics, and 3 in patient safety/risk management/pharmacovigilance.[4]

Of the 23 institutions training researchers, one institution, University of Ottawa, offered all six core courses. McGill University and Université Laval each provided five core courses, and the University of British Columbia, University of Alberta, University of Calgary, McMaster University, Université de Montreal, and the University of Waterloo listed four of the core courses. The remaining 14 institutions taught three or fewer core courses (Figure 1). The prevalence of the other non-core courses is described in Table 3. It is clear that some institutions may offer programs that are not entirely reflected in the nomenclature used for this review.

TABLE 2 Prevalence of core courses*

Course	Prevalence
Epidemiology	23
Biostatistics	22
Health economics/pharmacoeconomics	17
Pharmacoepidemiology	5
Pharmacogenetics/pharmacogenomics	5
Patient safety/risk management/pharmacovigilance	3

* offered at 23 institutions described in Table 1

FIG. 1 Core courses by institution

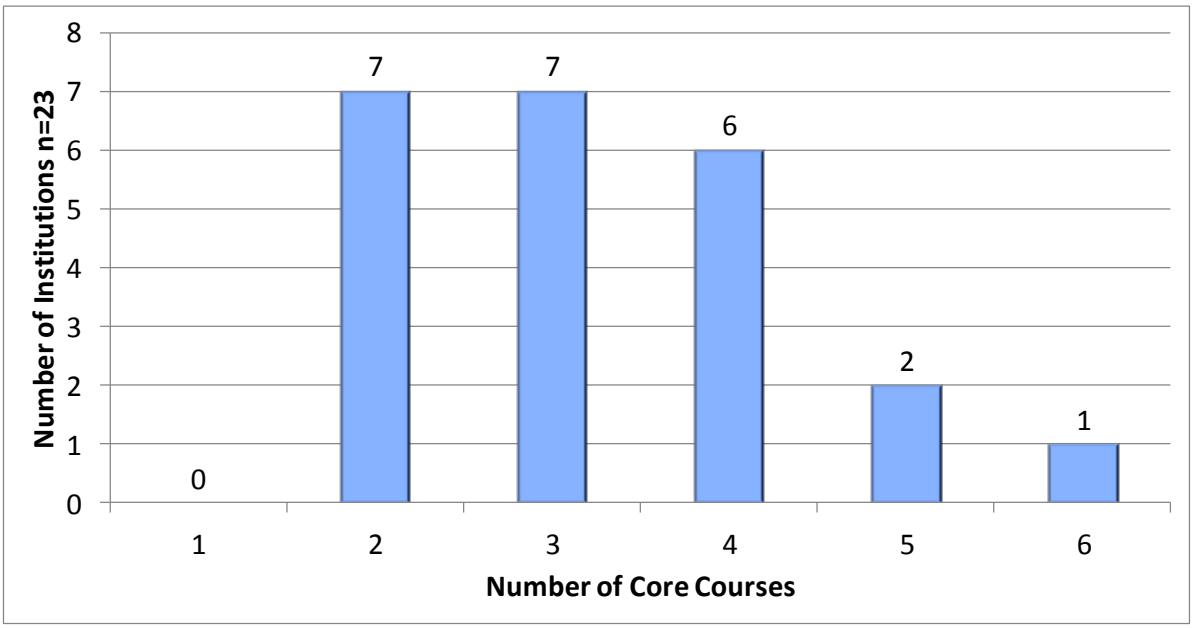

TABLE 3 Prevalence of non-core courses*

Course	Prevalence (n=23)
Health policy/law	20
Qualitative research design	15
Social determinants of health	11
Health Ethics	11
Health Informatics	10
Health technology assessment	7
Knowledge transfer/translation	5
Evidence based medicine	4

* offered at 23 institutions described in Table 1

DISCUSSION

To our knowledge, this is the first attempt to systematically review the preparedness of Canadian educational institutions to train post-market drug evaluation researchers. This educational inventory suggests that while a number of institutions theoretically have the potential to comprehensively and systematically train a new generation of such researchers, many programs may lack the essential core courses to ensure the necessary academic training. Although apparent deficiencies in the provision of the core courses varied by institution, few dedicated courses were being provided either in the area of patient safety/risk management/ pharmacovigilance or in pharmacogenetics/ pharmacogenomics.

The Canadian Institute for Health Information estimates that 33 billion dollars was spent on drugs in 2012,[6] amounting to almost 16% of total health care costs in Canada. Consequently, an increased emphasis on providing training specific to post-market drug evaluation is warranted. While it is not realistic that all graduate programs in public health and epidemiology become centers of excellence for training post-market drug evaluation researchers, a more concerted effort among programs to work collectively together to train such scientists is nevertheless important. The recent Health Council of Canada report on prescription drug safety recognizes the current limited research capacity for post-market drug evaluation in Canada and recommends that this deficit be addressed at the federal level. Specifically, it is stated that "the [Canadian Institutes of Health Research] should support graduate and postdoctoral fellowships in the area of pharmacoepidemiology, provide more support for early researchers, and increase funding for research infrastructure to ensure that researchers with the necessary level of expertise are available".[7] A recent example of such an effort is the innovative one year Drug Safety and Effectiveness Cross-Disciplinary Training (DSECT) program based at McMaster University.[8] This Canadian Institutes of Health Research-funded strategic training initiative brings together graduate students from a variety of interdisciplinary backgrounds and institutions and provides a multi-pronged practical training environment for future scientists.

A recent consensus report examining curriculum consideration for drug related comparative effectiveness research (CER) was published in response to the 1.1 billion dollars of funding allocated to CER in the United States.[9] The required knowledge, skills and abilities of those training in pharmaceutical CER are examined in detail with strong consensus on the areas of most importance for both researchers and decision makers. Quantitative skills in statistics, epidemiology, pharmacoepidemiology and pharmacoeconomics featured prominently in their results. Drug safety was also singled out as an important curricular focus. However, no mention was made of pharmacogenetics/genomics. Curricular considerations examined in the CER report but not examined in the present study included health policy, structure and function of the health system, pharmaceutical industry, pharmaceutical advertising, counterfeiting and pharmaceutical care (although the latter three were directed to the clinical decision maker rather than the researcher). Two recent studies examined pharmacoepidemiology and pharmacoeconomics curricula at US pharmacy schools.[10-11] Most schools covered pharmacoeconomics (77%) and pharmacoepidemiology (73%) as a part of the required curriculum. However, there was significant variation among schools with respect to the number of classroom hours during which these subjects were taught and whether elective courses were offered, either as a part of professional programs (PharmD) or graduate programs (MSc/PhD). While our study did not directly evaluate the performance of pharmacy schools in teaching these courses, we found that 7 out of 9 Canadian pharmacy schools had potential capacity to train researchers in post-market drug evaluation.

This environmental scan is subject to several limitations. The primary limitation was that it was sensitive rather than specific. Although all institutions with the potential to actively train individuals in post-market drug evaluation research were likely captured in this survey, it is unlikely that any of these institutions perceive their mandate to be focused on the training of individuals specifically seeking preparation for

post-market drug evaluation research. Furthermore, for purposes of this report data gathering was primarily web-based, and thus may have missed information potentially available through an onsite evaluation of an institution. As program details and course information could not always be confirmed with individuals representing those programs and institutions, relevant course information may have been omitted or misclassified. Another limitation is that potentially relevant programs such as residency programs in clinical pharmacology were not included. These clinical programs generally do not have specific courses advertised and offered consistently. Further, the few individuals in these programs often complete further formal degree programs already contained in this survey. Finally, as academic public health programs are rapidly evolving, it is probable that changes have occurred since completion of the original scan was completed with some programs being re-structured (and therefore renamed), and new initiatives emerging.

The 2010 Health Canada report published by our group made eight recommendations aimed at better support for the life cycle approach to the regulation of therapeutic products.[4] Of these eight, three are specifically pertinent to this educational inventory:

1) That Health Canada support a Task Force to develop a national syllabus that would guide universities interested in training highly qualified personnel able to support post-market drug evaluation studies, as few universities currently offer a comprehensive training program that focuses on all of the essential core courses.

2) That Health Canada act to increase awareness of career opportunities that support post-market drug evaluation. To encourage these targeted recruitments, consideration should be given to the development of a national scholarship program for highly qualified personnel in this specialized research field. A national web-based distance education program may facilitate graduate student training in post-market drug safety and effectiveness research methodology, by enabling the utilization of highly trained Faculty members currently based at a limited number of universities.

3) That Health Canada, in partnership with the Canadian Institutes of Health Research, develop strategies to improve capacity in post-market drug evaluation research targeted to marginalized populations and aboriginal peoples' health in order to promote the health of all Canadians.

If these three recommendations are implemented, Canadian institutions would be better able to train the post-market drug evaluation researchers desperately required to carry out the important task of ensuring safe and effective pharmaceutical care for our population.

CONCLUSION

In conclusion, while Health Canada's approach to progressive licensing is working incrementally toward enhanced regulatory scope, further increasing research capacity and expertise in safety and effectiveness is timely. As Canada's regulatory framework evolves, we recommend an increased collaboration between academic institutions and government with conjoint effort to improve the health of Canadians through better evaluation and regulation of pharmaceuticals.

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