Canadian pharmacists as immunizers: Addressing questions related to this new scope of practice

Sherilyn K.D. Houle, BSP, PhD

ABSTRACT

Currently, pharmacists in nine Canadian provinces can apply for authorization to administer drugs and vaccines by injection following the successful completion of a required training program and with evidence of certification in first aid and cardiopulmonary resuscitation. As more provinces and pharmacists embrace this new scope, questions are being raised about their readiness and ability to provide this public health service. This commentary addresses a number of questions commonly raised about pharmacists as immunizers, taking the position that pharmacists are able and willing to play a larger role in vaccination programs.

KEY WORDS: Immunization; vaccine; pharmacist

La traduction du résumé se trouve à la fin de l'article.

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The Canadian Immunization Conference, hosted by the Canadian Public Health Association in December 2016, featured a session on interprofessional approaches to immunization services, including the expanding role of Canadian pharmacists in this arena. In Canada, pharmacists in all jurisdictions except Quebec, Northwest Territories, Yukon, and Nunavut have some level of injection authority.¹ In all of these regions, pharmacists can administer the influenza vaccine, with other vaccines allowable under province-specific legislation. For example, in December 2016 Ontario expanded pharmacist vaccination authorization to include 13 vaccine-preventable diseases in addition to influenza, with a focus on vaccines indicated for travel.² It is important to note that this legislation excludes the administration of publicly funded vaccines; therefore, patients requiring these vaccines can either access the publicly funded supply through physician or public health clinics at no charge or can pay the cost of privately acquired product through the pharmacy. Across the country, pharmacists must complete a formal injection training program recognized by the province's regulatory body to be authorized to inject patients. The program includes a review of immunology, vaccine components, cold chain management, aseptic technique, injection administration by various routes, and the management and reporting of adverse reactions, including anaphylaxis. Current first aid and cardiopulmonary resuscitation certification is also required in order for pharmacists to be authorized to administer injections.

Since this activity has been added to the scope of practice for many Canadian pharmacists, a number of questions have been raised about pharmacists as immunizers, and these will be addressed here.

COLD CHAIN AND INVENTORY MANAGEMENT

The ability of pharmacists/pharmacies to achieve cold chain protection of temperature-sensitive products and fair allocation of

provincially funded vaccine, such as influenza vaccine, among all health professionals administering vaccines, has been discussed. Pharmacies are held to the same cold chain requirements as other health settings and have many years of experience safely storing refrigerated products, including insulin, biologicals, and compounded medications. Regular monitoring and recording of temperature, reporting/sequestering of product following cold chain breaches, protection from light, and safe transfer of product from the distributor to the pharmacy have been key components of pharmacy distribution practices for many years. Some may argue that greater cold chain assurance can be expected for pharmacy-administered vaccines than vaccines taken from pharmacies by patients for injection in other settings. Similarly, the efficient storing and tracking of inventory has been a requirement for pharmacies as dispensers of numerous costly, storage-sensitive, and tightly regulated medications. Pharmacy software programs track inventory levels in real time, and the quantities of medications ordered are determined by actual usage patterns to minimize the accumulation of excess inventory. The same inventory management approaches and record-keeping apply to vaccines.

PRODUCT RECALL AND SHORTAGE PROCESSES

Pharmacies already have the responsibility of addressing product recalls and shortages of medications, including prescription and non-prescription products, as part of safe dispensing and storage practices. Mechanisms are in place in pharmacies to efficiently and effectively identify and isolate affected products and notify affected

Author Affiliations

Assistant Professor, School of Pharmacy, University of Waterloo, Waterloo, ON
Correspondence: Sherilyn K.D. Houle, PhD, School of Pharmacy, University of Waterloo, 200 University Avenue West, Waterloo, ON N2L 3G1, Tel: 519-888-4567, ext. 21378, E-mail: sherilyn.houle@uwaterloo.ca
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patients. Similar policies and procedures are applied to injectable products, including vaccines, aided by the detailed inventory management capabilities of pharmacy-dispensing software programs.

MANAGEMENT OF ADVERSE REACTIONS

As health professionals, pharmacists are also regularly involved in the reporting of severe or unexpected adverse reactions from drugs. Reactions to publicly funded vaccines are reported to regional/provincial public health departments for monitoring of trends and additional follow-up, while reactions to other products are reported to the product manufacturer and the Canada Vigilance Program³ of Health Canada. Major reactions, such as anaphylaxis, are managed in pharmacies similarly to their management in community immunization clinics. Administration of epinephrine and diphenhydramine, monitoring of vital signs, and transfer to emergency medical services form the anaphylaxis protocols in community pharmacies. As epinephrine auto-injectors and oral diphenhydramine are regularly dispensed, these drugs are freely available in all community pharmacies and must be on hand as part of an anaphylaxis kit for any pharmacies administering injections. Pharmacists acknowledge the risks of vaccinating patients with a history of allergy to a vaccine or component, and are encouraged to refer these patients to health care facilities with additional resources if there is any cause for concern about a vaccine requested at a pharmacy. While pharmacists cannot make referrals directly to allergists for further investigation, a recommendation to consider a referral can be made to the patient's usual primary care provider. The collection of a patient's medical history, and information on allergies and intolerances (including foods that may indicate allergy to latex), as well as prior reactions to vaccines, are part of the pre-vaccination assessment for all patients receiving vaccines in community pharmacies, as they are in other health settings. Patients are also asked to remain in the professional services area of the pharmacy for a minimum of 15 minutes after vaccination to facilitate the detection and timely treatment of adverse reactions.

ACCESS TO VACCINES

Most community pharmacies stock an ongoing supply of regularly used vaccines, such as those against hepatitis A and B, and are able to efficiently order other less common vaccines from their usual distributors, often with same-day or next-day delivery. Pharmacies adopting a broader role in immunizing may also choose to adjust their on-hand inventory to anticipate needs and reduce delay in patients' access. Pharmacies wishing to administer the yellow fever vaccine must receive designation as a Yellow Fever Vaccination Centre from the Public Health Agency of Canada and provide the required International Health Regulations⁴ documentation to allow entry into countries where vaccination is mandatory. In provinces where pharmacists are not authorized to prescribe the vaccine, the pharmacist can administer the vaccine under this designation but cannot be the site's nominated health care practitioner for the purpose of designation as a Yellow Fever Vaccination Centre.⁵

VACCINATION OF YOUNG CHILDREN

All Canadian provinces authorizing pharmacist administration of injections limit this authority to exclude very young children; therefore, this practice is not intended to replace routine childhood immunization programs and examinations. British Columbia,⁶ Alberta,⁷ Saskatchewan,⁸ Ontario,² New Brunswick,⁹ Nova Scotia,¹⁰ and Newfoundland and Labrador¹¹ have legislation stating that pharmacists cannot vaccinate a child under age 5, although Alberta limits influenza immunization to children aged 9 and older. Pharmacists in Manitoba¹² cannot vaccinate children under age 7. Pharmacists in Prince Edward Island can administer the influenza vaccine to children aged 5 and older, but any other vaccines must be administered only to adults aged 18 and older.¹³

SEAMLESS CARE AND DOCUMENTATION

As dispensers of prescription drugs, pharmacies already extensively document all products and care provided to patients, and regularly liaise with other health professionals to provide seamless care. All provinces authorizing pharmacist administration of drugs or vaccines by injection specify that documentation of this activity be maintained and shared to reduce the risk of duplication among other professionals. Each province requires that notification of vaccinations provided by a pharmacist be communicated to the patient's primary care provider and/or that documentation be submitted to the provincial electronic health record, where available. Pharmacists are also expected to update the patient's personal immunization record, if such paper documentation is maintained by their province.

ADMINISTRATION OF UNNECESSARY VACCINATIONS

Finally, concerns have been raised about the potential for financial pressures from employers to encourage pharmacist administration of vaccines that are not required. The administration of a vaccine by injection must be evaluated for therapeutic appropriateness by the pharmacist, as with any other prescription drug dispensed or non-prescription drug recommended. A decision to provide a vaccination biased by any consideration beyond the patient's best interest may therefore be regarded as professional misconduct. Furthermore, legislation for the administration of vaccines does not automatically include prescribing authorization for Schedule I vaccines requiring a prescription. In Alberta and Nova Scotia, separate authorization can be obtained, which includes the ability to prescribe some Schedule I vaccines; however, additional credentialing and assessment are required for this authorization, and any prescriptions written by pharmacists with this authorization must be within their area(s) of competency. Pharmacists prescribing any therapies, including vaccines, take professional responsibility for the treatment decision and outcome, and must possess sufficient malpractice and liability insurance should adverse outcomes arise. Pharmacists not possessing authorization to prescribe Schedule I vaccines must still be in possession of a valid prescription for these products in order for them to be administered to patients. While the potential for conflict of interest cannot be ruled out when the same professional is involved in both the ordering and administration of vaccines, similar conflicts also exist in fee-for-service primary care clinics and

travel vaccine clinics. Pharmacists are held to the same ethical expectations as all health care providers who may benefit financially from the provision of care, and they confront such conflicts on a daily basis related to non-prescription product recommendations and the dispensing of prescriptions that may be of uncertain clinical benefit. The management of similar conflicts related to vaccines is not expected to be any different. It is also important to note that most staff community pharmacists (i.e., non-owners) are paid by hourly wage independent of the number of prescriptions filled, vaccines administered, or the provision of other services.

Finally, some provinces allow for pharmacist administration of some vaccines that are freely available to residents through the province's publicly funded supply but do not provide pharmacists access to the publicly paid product. In these situations, patients may choose to receive privately paid vaccination from the pharmacist if it is in the pharmacist's scope of practice to administer it. In these situations, the required informed consent process includes ensuring that the patient is made comprehensively and objectively aware of publicly funded product at no charge through public health clinics and other providers, and is voluntarily making the decision to pay for privately obtained vaccination.

Pharmacists have long been recognized as the most accessible health care professional nationwide, often available for extended operating hours and without an appointment. This accessibility and convenience has been cited as a key consideration among patients receiving vaccinations from pharmacists.¹⁴ At a time when vaccination rates are being affected by concerns over vaccine safety and effectiveness, difficulty accessing this service should not be an additional barrier faced by patients. As with prescription and non-prescription drug counselling, pharmacists are equipped to address questions related to product components and effectiveness, as this is part of the mandatory training modules, and provincial regulatory bodies further mandate minimum requirements for drug information resources in community pharmacies. Legislation, mandatory training, standards of practice, and professional accountability guarantee the safety of this activity. While regulations differ across provinces, pharmacists are expected to maintain knowledge and competence in immunization as part of their ongoing continuing professional development. Some provinces require that pharmacists who have not administered a minimum number of vaccines over a specified time period complete a refresher course to maintain certification. Repeated and consistent messaging to the public from all health professionals promoting vaccination, and pharmacists' ability to interact with members of the public who infrequently visit or do not have a regular primary care provider, may improve vaccine uptake by Canadians and should be encouraged. Pharmacists administering injections have been trained in vaccine storage, administration, and adverse event recognition and care, and provide a highly accessible option for individuals who would benefit from vaccination.

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RÉSUMÉ

À l'heure actuelle, les pharmaciens de neuf provinces canadiennes peuvent demander l'autorisation d'administrer des médicaments et des vaccins par injection après avoir réussi le programme de formation exigé et sur présentation d'un certificat de secourisme et de réanimation cardiorespiratoire. À mesure que d'autres provinces et d'autres pharmaciens profitent de cette nouvelle possibilité, des questions se posent sur leur préparation et leur capacité d'offrir ce service de santé publique. Notre commentaire aborde plusieurs questions couramment posées sur les pharmaciens en tant que vaccinateurs, en faisant valoir que les pharmaciens sont capables et désireux de jouer un plus grand rôle dans les programmes de vaccination.

MOTS CLÉS : Immunisation; vaccin; pharmacien