Pharmacists as immunizers to <u>Improve</u> coverage and provider/recipient satisfaction: <u>A</u> prospective, <u>Controlled Community</u> <u>Embedded Study with vaccineS</u> with low coverage rates (the Improve ACCESS Study): Study summary and anticipated significance

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Introduction

Although there are many safe and effective vaccines for adults, public perception is that vaccination is targeted primarily for infants and children.¹ The National Advisory Committee on Immunization (NACI) recommends a number of vaccines for adults and adolescents, including seasonal influenza vaccine (e.g., high-dose trivalent inactivated influenza vaccine [high-dose TIV] for those 65 and older), tetanus-diphtheriaacellular pertussis vaccine (Tdap), quadrivalent meningococcal conjugate vaccine (MenACWY) and meningococcal B vaccine (MenB).² As well, NACI recommends that people 50 years or older receive the herpes zoster (HZ) vaccine and that Canadians who travel to high-risk areas should consider vaccination to protect themselves against travel-related illnesses, such as hepatitis A, hepatitis B and typhoid fever.³⁻⁶ While NACI makes recommendations, it is provinces and territories that determine which vaccine programs will be funded and implemented. Unlike most childhood vaccines, which are publicly funded by provinces and territories, many adult vaccines are not publicly funded, which adds complexity to a patient's decision-making, as out-of-pocket costs not covered by health insurance may be contributing to low uptake of some vaccines.^{7,8}

Barriers to achieving optimal vaccination rates in adults are multifactorial. Some of the most common include lack of education about vaccines and vaccine-preventable diseases, lack of infrastructure to deliver vaccines, lack of access to vaccines, lack of public funding and attitudes of the public and providers toward vaccination.^{2,9-11} Adults are typically educated about preventative health care during face-to-face visits with physicians or nurses.¹² Providers note that the time required to provide vaccine education is considerable and patients' acute needs and current disease management generally take higher priority. New delivery models and a means of extending preventative health care delivery outside of traditional face-toface office visits are needed.¹³

Pharmacists are among the most accessible health care professionals 14 and have been identified by the public as a

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trustworthy source of health information.¹⁵ Moreover, people regularly visit community pharmacies for their health care needs, particularly in rural settings, due to extended hours and convenient locations.¹⁶ Pharmacists have regular contact with individuals at high risk for vaccine-preventable diseases and consequences, and proactively and systematically review patients' medical histories and medications and provide education and recommendations around immunizations. In addition, immunization recommendations by pharmacists can have a positive impact on a person's decision to be immunized.¹⁷ Given their extended operating hours, accessibility and established trust with patients, pharmacists are well positioned to provide preventive health care, including vaccination uptake and health system efficacy through vaccine administration.¹⁸

A 2016 systematic review on pharmacists as immunizers found an increase in vaccination rates and/or vaccine coverage when pharmacists were involved in the immunization process, regardless of their role (e.g., educator, administrator) or the vaccine administered. Of 14 studies that assessed pharmacist administration of vaccines, 12 were conducted in the United States, 1 in Canada and 1 in England. Most evaluated influenza vaccination; however, studies from the United States also evaluated other vaccinations: influenza and pneumococcal (n = 2), pneumococcal and HZ (n = 1), pneumococcal (n = 1), Tdap (n = 1) and HZ (n = 2).¹⁹ Studies in Canada examining pharmacists as immunizers have focused on influenza vaccination and demonstrated increased influenza vaccination uptake with pharmacist involvement.²⁰⁻²³

Currently, 9 provinces have legislation that allow pharmacists with appropriate formal vaccination training to provide immunizations to adults.²⁴ This legislation restricts the age of administration to older children, usually 5 years of age and older.²⁵⁻²⁷ The vaccines pharmacists are permitted to administer differ by province, with some limiting to influenza and others including travel vaccines and other routine and recommended vaccines.²⁸ The role of pharmacists in providing vaccinations beyond influenza has not been fully explored in Canada. It is an important area for further study, as many jurisdictions have added or are considering adding other vaccines to the list approved for pharmacist administration. For more information on pharmacists as immunizers, please see the special section in the November/December 2019 issue of CPJ. The Improve ACCESS Study aims to use an embedded community pharmacy-based implementation project to assess the effectiveness of a bundled pharmacist-delivery strategy consisting of communication and funding strategies on vaccine coverage.

Study description

Study design

The Improve ACCESS Study is a 2-year prospective, nonrandomized community-based comparison of an enhanced pharmacist-delivered immunization strategy to the standard pharmacist immunization approach in New Brunswick and Nova Scotia. The study is ongoing, with expected completion by the middle of 2020.

Setting

Four communities are participating in the study. One community in each province is an intervention site, where they will implement strategies specifically designed for each of the target vaccines. The second community in each province is the nonintervention site, where immunization practice continues without support of additional strategies. The study communities have been chosen based on population size (approximately 30,000 adults \geq 18 years of age, including those who are pregnant), having a stable population, serviced by a regional hospital and community pharmacies, interest of qualified community pharmacists who provide vaccinations and lack of substantial health care spillover to adjacent communities. Spillover is defined as a pattern of health care utilization where patients regularly receive care at different regional health centres. Based on these inclusion criteria, 4 communities have been selected: 2 urban/suburban communities in New Brunswick and 2 primarily rural communities in Nova Scotia. Within these 4 communities, a total of 48 pharmacies are participating in the study (23 intervention pharmacies and 25 nonintervention pharmacies). Pharmacies have been recruited to participate in this study through contact with pharmacy associations, meetings with pharmacy chain representatives (e.g., regional managers, directors) and by directly contacting pharmacy managers located in study communities.

Outcome measure

Vaccine coverage rate (the number vaccinated divided by the number eligible for vaccine) is the main outcome measure and will be compared between intervention and nonintervention communities. Due to the lack of complete immunization registries in the study provinces, the number vaccinated will be measured using multiple strategies for corroboration, including pharmacy databases to determine the number of doses administered to individuals eligible for receipt of vaccine relative to the total number of patients in the pharmacy databases in the eligible age range (e.g., adults ≥ 18 years of age), the number of vaccine doses distributed to pharmacies in all 4 communities (obtained from the manufacturer and Public Health) relative to the eligible population based on Statistics Canada census data, and a survey of the public before and after the intervention within the study communities to determine self-reported immunization status.

Community-embedded intervention <u>Study vaccines</u>

 Consultations with stakeholders were held to review NACI recommendations for adult vaccines and determine the vaccines that would be provided and evaluated in the study

	Publicly funded v	vaccine for adults	
Study vaccine	New Brunswick	Nova Scotia	Recommendations by NACI for routine adult immunization
Hepatitis A	No	No	 Travellers to hepatitis A–endemic areas Individuals at increased risk of infection, especially people with medical, occupational or lifestyle risks
Hepatitis B	No	No	 Travellers to hepatitis B–endemic areas Individuals at increased risk of infection, especially people with medical, occupational or lifestyle risks
High-dose TIV	No	No (except long- term care facility residents)	 Adults 65 years of age and older³¹
HZ	No	No	• Adults 50 years of age and older without contraindications ³
MenACWY	No	No	 Adults up to and including 24 years of age not immunized in adolescence High-risk individuals including those with occupational risk for exposure and underlying medical conditions Close contact with a case of IMD caused by MenACWY Travellers to areas where meningococcal vaccine is recommended or required
MenB	No	No	 Individuals at high risk of meningococcal disease caused by MenB, including those with occupational risk for exposure and underlying medical conditions Close contact with a case of IMD caused by MenB Risk during IMD outbreaks caused by MenB No contraindications to the vaccine and wish to be immunized³²
Tdap	Yes	Yes	 One dose in adulthood One dose in every pregnancy, ideally between 27 and 32 weeks of gestation
Typhoid fever	No	No	People travelling to endemic areasOccupational risk of exposure

TABLE 1 Summary recommendations and funding for study vaccines^{2,29,30}

HZ, herpes zoster; IMD, invasive meningococcal disease; MenACWY, quadrivalent conjugate meningococcal vaccine; MenB, meningococcal B vaccine; NACI, National Advisory Committee on Immunization; Tdap, tetanus-diphtheria-acellular pertussis vaccine; TIV, trivalent inactivated influenza vaccine.

- Stakeholders included the research team, pharmacists, pharmacy chains, funders, experts in the field, manufacturers and Public Health
- Vaccines chosen for this study are as follows (Table 1):
 Recommended and publicly funded vaccine: Tdap
 - The study is simulating public funding for Tdap, where the participating pharmacies agree to waive the injection fee as in-kind support for the study and the cost of the vaccine is covered through study partners
 - Recommended (for certain groups) but unfunded vaccines: high-dose TIV, MenB, MenACWY, HZ and travel vaccines to protect against hepatitis A, hepatitis B and typhoid fever
 - The study is using the current private market model where these vaccines are directly paid either by the individual or through private insurance

Enhanced outreach strategies

- Role of pharmacy teams in the intervention communities:
 - Focuses on integrating enhanced outreach strategies, using some or all of the strategies depending on what works best for their pharmacy and for their patients 18 years of age and older, but at least 1 strategy must be used
 - The enhanced outreach strategies include the following (Table 2):
 - Combining vaccinations with other services—timed marketing during influenza season, back to school, travel season and their usual practice
 - Targeted patient outreach—generate reports using pharmacy computer software for patients in specific age groups, on certain medications, and/or with certain medical conditions

					Targeted patient	
		Combining vaccina	Combining vaccinations with other services	S	outreach	Immunization weeks
Strategies	Influenza season	Back to school	Travel season	Usual practice	Generate reports using pharmacy software	Promote/screen for vaccine of the week
Vaccines	 High-dose TIV HZ MenACWY and MenB Tdap Travel 	 MenB and MenACWY Tdap 	 High-dose TIV MenACWY and MenB Tdap Travel 	 High-dose TIV HZ MenACWY and MenB Tdap Travel 	 High-dose TIV HZ MenACWY and MenB Tdap 	 High-dose TIV HZ MenACWY and MenB Tdap Travel
Activities	 Screen patients when they provide their health information for the influenza vaccine assessment 	 Discuss with families who are picking up supplies for children moving for postsecondary education 	 Discuss when requesting information about travel vaccines, as all routine vaccines should be up-to-date prior to travel 	 Discuss while: Completing medication reviews Filling or renewing prescriptions Providing over- the-counter counselling Answering prenatal questions 	 Use pharmacy computer computer software to run reports on: Age groups Certain medications Certain conditions 	 Host weekly events during quieter times and promote 1 vaccine during this week: Do medication reviews Vaccination assessments
Materials			• Prom • 0 0 0 0 0 0 0 0 0 0 0	Promote vaccines using: • Posters • Bag stuffers • Shelf talkers • Social media messaging		

Travel vaccines include hepatitis A, hepatitis B and typhoid fever.

HZ, herpes zoster; MenACWY, quadrivalent conjugate meningococcal vaccine; MenB, meningococcal B vaccine; Tdap, tetanus-diphtheria-acellular pertussis vaccine; TIV, trivalent inactivated influenza vaccine.

TABLE 2 Enhanced outreach strategies

- To serve as reminders to discuss immunization status, the pharmacists are putting alerts into their computer system to notify them the next time a patient comes into their pharmacy
- "Immunization weeks"—promote and screen for the "vaccine of the week"
 - This concept was developed in resourceconstrained areas where they do mass vaccinations on a preplanned day or week and adapted for our study³³
- Support materials: intervention pharmacies are being provided with study-specific vaccine-related materials that they can choose to use based on their practice setting and patients
 - These materials include information posters, patient assessment forms, information sheets, bag stuffers, shelf talkers and social media messaging
- Role of pharmacy teams in nonintervention communities:
- Continue immunization practice as before, with no study-specific education/training or support around enhanced outreach strategies

Education and support for intervention community pharmacists and pharmacy staff

- Training for pharmacy teams in intervention communities only—provide background information on the study, discuss the vaccines included in the study and explain the proposed enhanced outreach strategies for pharmacists to integrate into their practice
 - Provided to the intervention pharmacy teams in person or through a web-based video conference
- "Academic detailing"—provides up-to-date information on the study and study vaccines
 - Provided to pharmacists approximately every 3 months and individual follow-up is offered as required
 - Pharmacists in the intervention communities receive continuing professional development credits for completing the initial and ongoing training

Significance

The Improve ACCESS Study will demonstrate how research can be embedded into community-based pharmacy practice. Participating pharmacists will have the opportunity to be involved in community pharmacy-based practice research and, in the intervention communities, to have access to increased education. By expanding their role as immunizers, the pharmacists in the intervention communities will have an opportunity to learn different strategies for promoting vaccines to the public and implement these strategies into practice, which may assist them in providing vaccines more efficiently and effectively and gathering empirical evidence of the effectiveness of each strategy. Pharmacists in intervention communities will also be given the opportunity to expand the funded vaccination services they provide beyond influenza, by administering the Tdap vaccine in a simulated publicly funded model. This approach of simulating different payment models in community pharmacies could be applied in future studies of other vaccines, drugs or funding models.

This study brought a large group of stakeholders and partners together to develop a plan for studying community pharmacists as immunizers beyond influenza vaccine. This study has garnered interest from stakeholders across Canada and internationally, particularly from policymakers (such as public health), regulatory bodies, insurers and pharmacy organizations. It is anticipated that the study results will affect pharmacy practice around the scope of immunization practice regionally, nationally and even internationally. It may improve efforts to advocate for the community pharmacy as a primary health care destination or hub whose services are tailored to the community it serves.^{34,35}

In addition, this study will demonstrate the ability to complete a complex, multiple-site and multiple-vaccine intervention study in community pharmacies, which may increase the ability to scale up and apply in other provinces.

In summary, it is expected that this research will provide critical insights into the effectiveness of community pharmacists in improving vaccine coverage and may lead to pharmacists playing a larger role in immunization programs.

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