Effect of an Innovative Immunization Practice Model to Improve Population Health: Results of the Project IMPACT Immunizations Scaled Demonstration

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Abstract

Background: *U.S. adult vaccination rates remain low. Community pharmacists have skills and opportunity to improve this shortcoming. This study sought to evaluate an innovative practice model on identification of unmet vaccination needs and their resolution.*

Methods: *This prospective, multi-site, multi-state, observational study was conducted in 22 community pharmacy practices in Iowa and Washington. Adults receiving influenza vaccination, medication therapy review, prescriptions for diabetes or cardiovascular disease, or another clinical encounter with a participating pharmacist from December 2017 through November 2019 were included. Pharmacists reviewed vaccination forecasts generated by clinical decision support technology based on their state immunization information system (IIS) to identify unmet vaccination needs, educate patients, and improve vaccination rates. The primary outcomes were numbers of vaccination forecast reviews, patients educated, unmet vaccination needs identified and resolved, and vaccinations administered. Secondary outcomes included numbers of vaccination declinations; times a forecasted vaccine was not recommended because a contraindication was identified by the pharmacist; and times the patients declined a forecasted vaccine due to self-reported vaccination despite lack of documentation in the state IIS. Descriptive statistics were calculated.*

Results: *Pharmacists reviewed vaccination forecasts for 6,234 patients. The vaccination forecasts predicted there were 11,789 vaccinations needed (1.9 per person). 6,405 of the 11,789 unmet vaccination needs (54.3%) were fulfilled during the study period, including 60% on the same day. Of the forecasted needs, 1,085 (9.2%) were found to be previously administered and 59 (0.5%) contraindicated. The remaining patients received information about their personal vaccination needs and recommendations to be vaccinated.*

Conclusion: *Availability of vaccination histories during patient encounters allowed pharmacists to identify and resolve adult vaccination needs in independent and chain community practice settings.*

Keywords*:* Pharmacy, pharmacist, vaccine, vaccination, diabetes, cardiovascular disease

Introduction

It is well established that vaccines are a key component of public health that have helped to reduce the burden of infectious diseases. Yet, vaccination rates in the United States remain inadequate, as evidenced by continuing burdens of pneumococcal disease and zoster and outbreaks of measles and poliomyelitis.[1-5] Reasons for this deficiency are varied, but major contributors are vaccine confidence and access to care.[6-7] Access to healthcare, one element of which is vaccination, is particularly critical in primary care health professional shortage areas where the proportion of unmet primary care needs hover around 50%.[7]

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Fortunately, pharmacists have specific training and expertise in evaluation and administration of vaccines and 90% of Americans live within 5 miles of a community pharmacy.[8,9] Pharmacists' communication skills are also uniquely qualified to address patient concerns that can transform vaccine hesitancy into vaccine confidence.[10]

Project IMPACT (**IMP**roving **A**merica's **C**ommunities **T**ogether) Immunizations, [19] like other successful Project IMPACT initiatives before it,[11-18] was designed to implement and evaluate principle-centered processes of care that engage patients at the point-of-care and provide seamless opportunities for pharmacists to collaborate and communicate with other health care providers. In this pilot conducted in eight community practices, pharmacists identified and resolved a range of unmet immunization needs, identifying a mean of 1.45 additional vaccines due per person and increasing immunization rates by 41.4%. In more focused efforts during the COVID-19 pandemic, pharmacists proved to be a critical entry point for vaccination and resource to overcome vaccine hesitancy with over 50% of COVID-19 vaccines delivered in pharmacies nationwide.[20] With demonstrated scalability with

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COVID-19 vaccination and the success of the pilot phase of Project IMPACT Immunizations, a scaled-up demonstration project was designed and implemented.

Objective

The primary objective of Project IMPACT Immunizations Scaled was to assess scalability in identifying and addressing unmet vaccination needs and increasing vaccination rates. The authors hypothesized that:

1. A significant number and percentage of people presenting to the pharmacy for influenza vaccination or other clinical encounters would have additional unmet vaccination needs.
2. With clinical decision support tools available to the pharmacist at the point-of-care, the pharmacist would be able to identify unmet vaccination needs and educate people about their unmet needs.
3. When educated at the point-of-care, people with unmet vaccination needs would accept the opportunity for vaccinations.

Methods

Setting

Project IMPACT Immunizations Scaled was implemented in 22 community pharmacy practices, expanding both geographic locations and community pharmacy practice types to assess scalability across a generalizable spectrum of pharmacy practice environments (Supplementary Table 1). Nine practices participated in the 2017-18 cycle and 19 practices in the 2018-19 cycle, with six participating in both cycles.

Study Design

The scaled-up demonstration project applied a study design similar to the previously described Project IMPACT Immunizations pilot, adding additional entry points for vaccine assessment (Figure 1).[19] In brief, Project IMPACT Immunizations Scaled was a prospective, multi-site, multi- state observational study. Pharmacies were selected based on propensity for success using a proprietary tool. Participating pharmacies were provided a stipend to offset costs of participation.

Patients were selected by the pharmacist and were eligible for inclusion based on presentation at the pharmacy for one of four types of encounters:

a. presenting to the pharmacist requesting influenza or other vaccination,
b. medication therapy review,
c. a prescription or a consultation for diabetes or cardiovascular disease,
d. other clinical encounters where the pharmacist initiated a vaccine conversation.

For each included patient, the pharmacist completed a vaccination forecast review through the innovative practice model using the principle-centered approach as shown in Figure 1.

The primary endpoints for this study were:

- number of vaccination forecast reviews with patient education;
- number of unmet vaccination needs identified and resolved by vaccination during the study period; and
- number and types of vaccines administered by the pharmacist.

The secondary endpoints for this study were:

- number of vaccination declinations;
- number of times a forecasted vaccine was not recommended because a contraindication was identified by the pharmacist; and
- number of times the patients declined a forecasted vaccine because they said they already received it despite lack of documentation in the state Immunization Information System (IIS).

Vaccination Forecasts Utilized by the Pharmacists in the Study

When the pharmacist accessed the State IIS, the technology interface utilized a clinical decision support (CDS) model based on current ACIP recommendations[21] to generate a patient-specific forecast of vaccinations due that day. Vaccines routinely recommended by ACIP for adults [i.e., pneumococcal, tetanus-diphtheria with or without pertussis (Tdap/Td), zoster, human papillomavirus (HPV)] were forecasted based on date of birth and the absence of an electronic record of prior vaccination in the IIS. In addition, the CDS tool also forecasted vaccine needs if the patient had initiated but not completed a vaccination series for hepatitis A, hepatitis B, or measles-mumps-rubella (MMR).

Data Collection

After Institutional Review Board (IRB) approval and clinical trials registration (NCT03372967), initial data collection began on December 12, 2017, and continued through two 6-month patient care cycles (9 practices and 19 practices, respectively) concluding November 20, 2019. This gave participating pharmacies 6-month windows aligned with influenza vaccination seasons to implement the innovative practice model. Data were collected in the IIS and aggregate de-identified data were reported to the researchers. The data reported to the researchers included all administered vaccines to included patients that were documented by any healthcare professional in the IIS for the duration of the evaluation period. Data collection, use, and management procedures were compliant with the patient confidentiality provisions of the Health Insurance Portability and Accountability Act (HIPAA).

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Data Analysis

To be included in the evaluable population for data analysis, the following criteria must have been met:

- The patient was at least 18 years of age;
- The individuals were patients of participating pharmacies; and
- The pharmacist documented reviewing the patient's vaccination forecast.

To evaluate the change in vaccination rates from baseline to the end of the study, investigators determined the number of patients due for each vaccine based on ACIP recommendations at baseline. Investigators then determined how many patients were up-to-date with the vaccine at baseline and compared that to the number of patients up-to-date at the end of the study. To determine if there were any changes in the primary endpoints from the baseline measurement to the study end point, a series of McNemar tests comparing related proportions for paired pre- and post-implementation data ($\alpha = 0.05$) were performed to test for a difference for each vaccine. Clustering effects of sites were ruled out using preliminary comparisons on demographics before performing McNemar tests. For secondary outcomes and demographic data, descriptive statistics were reported.

Results

Study Population

During the study periods, the pharmacists documented review of vaccination forecasts with corresponding education for 6,234 patients. As shown in Table 1, 2,837 (45.5%) of these patients were identified based on routine prescription services (e.g., refill prescription, new prescription, diabetes or cardiovascular condition), 1,368 (21.9%) explicitly requested vaccination, and 1,243 (19.9%) presented for a medication therapy review. In 676 cases (10.8%), pharmacists developed vaccination forecasts for patients prompted by the pharmacist's clinical judgement. Of the 6,234 patients, 56.2% were female and 43.8% were male, with a mean age of 65.4 years. Other demographic characteristics appear in Table 2.

Vaccination Needs Assessed and Addressed

According to the vaccination forecasts, the 6,234 study patients needed 11,789 vaccinations at the time of assessment, including 1,914 influenza vaccinations and 9,875 other vaccinations (Table 3). For every patient who participated in this study, a mean 1.9 vaccines were forecasted as needed by the CDS tool.

Of the 11,789 unmet vaccination needs identified in patients who were eligible for vaccination, 6,405 (54.3%) were resolved during the study period (Table 3). Of these 6,405 resolved vaccinations, 3,838 (59.9%) were administered by the pharmacist on the same day, while 2,567 (40.1%) were resolved at a patient-initiated follow up visit at the pharmacy or another clinical venue. The most common forecasted vaccination need was zoster vaccine (80% of patients), followed by Tdap/Td (44%), influenza (31%), and pneumococcal (22%), among others.

Through assessment of history and consultation with the patient, pharmacists identified patients who declined vaccination (16.1%) and patients who were not vaccinated due to contraindications (0.5%) or because of self-report of receipt of the forecasted vaccine (15.4%). When a vaccine was not administered on the same day, the most frequent reason was planned follow-up. Table 4 enumerates other reasons for not vaccinating or for deferred vaccination.

Table 5 reports the number and proportion of patients who were up-to-date with the most routinely recommended adult vaccines at baseline and at the end of the study. Vaccination rates for pneumococcal, Tdap/Td, and zoster each increased by 9 to 17 percentage points, each statistically significant.

Discussion

The pilot phase of IMPACT Immunizations demonstrated the impact that community pharmacists can have on identifying and addressing unmet vaccination needs. The present study demonstrated the scalability of this model, assessing the vaccination status of 6,234 patients across multiple states and community practice types using real-time point-of-care access to IIS vaccination histories and CDS technology to support pharmacist efficiency.

This study adds to the literature of the effectiveness of community pharmacists in identifying vaccination needs, encouraging vaccination, and delivering vaccination in large and small communities, in large and small pharmacies (see Supplementary Table 1). During this study, pharmacists implemented the innovative practice model for several segments of their practice including patients requesting influenza vaccination, medication therapy review, or prescriptions for diabetes or cardiovascular medications from the pharmacist.

Real-time point-of-care access to IIS vaccination histories and clinical decision support technology made it feasible for pharmacists to efficiently assess the vaccination status of 6,234 patients during the study. These results support the hypothesis that many adults, even those seeking influenza vaccination, are unaware of their vaccination needs and emphasizes the importance of assessing each patient periodically to resolve vulnerabilities.

While the CDS tool streamlined the assessment process, it is important to recognize that a critical component of the process of care was the pharmacist assessment of the machine-generated forecasts. By engaging with the patient and using clinical judgment, pharmacists were able to identify contraindications or undocumented prior vaccinations. The pharmacist assessments minimized the potential for adverse events associated with contraindications and avoided potential duplications of therapy by identifying vaccinations received but

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not recorded by others. Combining the pharmacist's clinical judgment with a strong recommendation from a trusted pharmacist , a strong predictor of vaccine acceptance,[22-24] makes pharmacists influential agents of population health.

Notably, 32.6% (3,838 of 11,789) of the patients' unmet vaccination needs were resolved on the same day at the point-of-care. During Project IMPACT Immunizations Scaled, pharmacists fulfilled 54.3% of vaccination needs and provided education that can be expected to help resolve additional needs in the future. These results highlight the value of incorporating this process of care into routine pharmacy workflow, allowing pharmacists to maximize opportunities to vaccinate at the point-of-care. Other work has shown the effect of making vaccinations readily available on a daily basis on vaccine uptake.[25]

Even motivated, vaccine-confident patients seeking influenza vaccination were under- vaccinated against other preventable diseases. This study shows that there was an average of 1.9 vaccinations forecasted as being due for each patient that requested influenza or other vaccination, as has been seen in other studies.[26-27] Project IMPACT Immunizations Scaled demonstrated that when pharmacists had IIS data and clinical decision support tools, they were able to identify vaccination opportunities and reduce the number of unmet vaccination needs by 54%. While the process of care was implemented in pharmacies triggered largely by specific pharmacy service encounters, the principle-centered approach to this innovative practice model can be replicated, allowing pharmacists to identify unmet vaccination needs for other segments of the population who seek pharmacy services. By building upon this model and extrapolating it across America, pharmacists can continue to improve the nation's health by addressing unmet vaccination needs and improving vaccination rates. Since this study was conducted, the COVID-19 pandemic has made apparent the importance of the role of vaccine confidence in vaccine uptake. Future studies are underway to examine the ability of pharmacists to enhance vaccine confidence within the innovative practice model described in this research.

The feasibility of this practice model was supported through the use of three key elements: a systematic approach to identify patients (Figure 1), access to IIS data, and use of a CDS to identify unmet needs. The combination of these elements allowed pharmacists to efficiently implement this practice into existing workflow. While pharmacist clinical judgment is required in evaluating the vaccine forecast, the steps leading up to this can be completed by ancillary and support staff, further improving the efficiency and feasibility of this model.

Project IMPACT Immunizations Scaled was implemented in 22 community pharmacy practices in Iowa and Washington State to test an innovative practice model. Generalizability to practices across the United States may require further study. A larger, controlled evaluation could identify possible differences in population, process, provider, and practice types that could not be discerned herein. Further, the COVID-19 pandemic has resulted in more public focus on adult vaccinations that is not reflected in this study.

Conclusion

The results from Project IMPACT Immunizations Scaled validate that pharmacists can be part of the solution to a prolonged national public-health need. Tens of millions of American adults are susceptible to VPDs and most do not realize it. When pharmacists implemented the Project IMPACT Immunizations Scaled practice model, conducting comprehensive vaccination history reviews at the point-of-care, they identified a significant number of unmet vaccination needs (mean 1.9 needs per person), educated 6,234 patients, and delivered 6,405 doses of adult vaccines, resulting in less than 1 unmet vaccine need per person. Applying this model more broadly will improve vaccination rates across the United States to help **IMP**rove **A**merica's **C**ommunities **T**ogether.

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The opinions expressed in this paper are those of the author(s

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Table 1. Reason for Vaccination Need Assessment

Reason for Vaccination Need Assessment	Frequency (%)
Requested influenza or other vaccination	1,368 (21.9)
Refill prescription	1,266 (20.3)
Medication therapy management review	1,243 (19.9)
High risk condition (diabetes or cardiovascular disease)	980 (15.7)
New prescription	591 (9.5)
Other clinical encounter Unspecified	676 (10.8) 120 (1.9)
TOTAL	6,234 (100)

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Table 2. Patient Characteristics (N=6,234)

Age (years)	**Mean (SD)**
Range: 18 - 103	65.4 (14.2)
Gender	**n (%)**
Female	3,502 (56.2)
Male	2,732 (43.8)
Race (n=3,124)*	**n (%)**
White	2,739 (87.7)
Asian	29 (0.9)
Black	12 (0.4)
Other	344 (11.0)
Ethnicity (n=2,940)*	**n (%)**
Non-Hispanic	2,921 (99.4))
Hispanic	19 (0.6)
States	**n (%)**
Iowa	5,735 (92.0)
Washington	474 (7.6)
Others	25 (0.4)

* Total differs due to missing data.

Table 3. Unmet Vaccination Needs Identified and Met

Vaccine Type	# Unmet Needs n (% of 6,234 patients assessed)	Total # Vaccinations Administered n (% of unmet needs)	# Vaccinations at Point of Care on Same Day n (% of vaccinations administered)	# Vaccinations at Follow-up Visit n (% of vaccinations administered)
Zoster	4,997 (80.2)	3,960[A] (79.2)	2,259 (57.0)	1,701 (43.0)
Tdap/Td	2,751 (44.1)	620 (22.5)	419 (67.6)	201 (32.4)
Influenza	1,914 (30.7)	1,162 (60.7)	694 (59.7)	468 (40.3)
Pneumococcal	1,391 (22.3)	426 (30.6)	309 (72.5)	117 (27.5)
Hepatitis B	344 (5.5)	50 (14.5)	31 (62.0)	19 (38.0)
Hepatitis A	149 (2.4)	25 (16.8)	20 (80.0)	5 (20.0)
Hepatitis A and B[B]	--	90	46 (51.1)	44 (48.9)
Measles-mumps-rubella	107 (1.7)	52 (48.6)	47 (90.4)	5 (9.6)
Poliovirus	48 (0.8)	0	0	0
Human Papillomavirus	34 (0.5)	8 (23.5)	4 (50.0)	4 (50.0)
Meningococcal	30 (0.5)	12 (40.0)	9 (75.0)	3 (25.0)
Varicella	24 (0.4)	5 (20.8)	0	1 (100.0)
Total	11,789 (100)	6,405 (54.3)	3,838 (59.9)	2,567 (40.1)

A 969 patients received two doses of recombinant zoster vaccine.

B Combined Hepatitis A and B vaccine was given.

NOTE: Point of care vaccinations were administered at the pharmacy conducting the assessment of unmet needs. Follow-up vaccinations were administered at either the initial pharmacy or other care sites.

Tdap/Td – Tetanus and diphtheria toxoids with or without acellular pertussis vaccine

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Table 4. Reason Vaccination not Administered

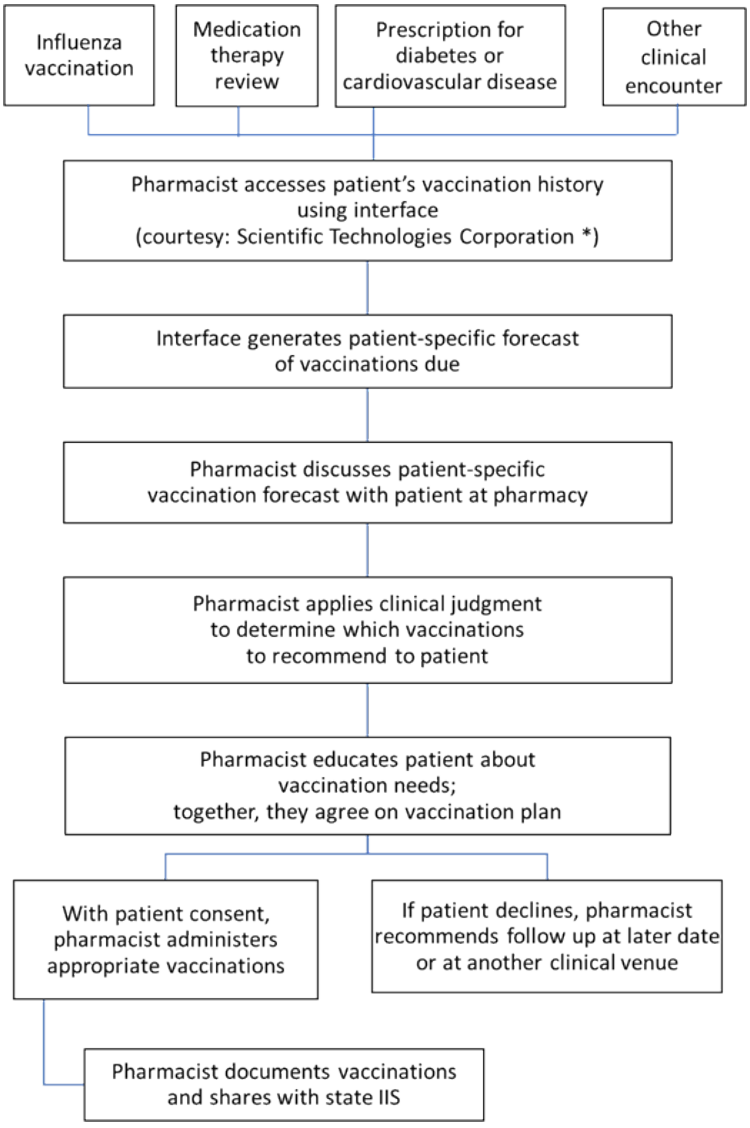
Reason Vaccination not Administered	Frequency (%)
Deferred to future date	3,735 (53.0)
Patient declined	1,134 (16.1)
History of prior vaccination	1,085 (15.4)
Vaccine not in stock	905 (12.9)
Vaccine cost	126 (1.8)
Vaccine contraindicated	59 (0.8)
TOTAL	7,044 (100)

Table 5. Up-to-Date Vaccination Rates at Baseline and End of Study

Vaccine	Baseline Up-to-date n (%)	End of Study Up-to-date n (%)	Statistical Significance
Pneumococcal	2,456 (67.7)	2,831 (78.1)	$p < 0.001$
Tdap/Td	3,940 (63.5)	4,491 (72.3)	$p < 0.001$
Zoster	589 (10.6)	1,558 (27.9)	$p < 0.001$

Tdap/Td = tetanus and diphtheria with or without pertussis; Pneumococcal includes PCV13 (pneumococcal conjugate vaccine) and PPSV23 (pneumococcal polysaccharide vaccine).

Figure 1. Flowchart of Practice Model to Identify and Resolve Vaccination Needs



IIS – Immunization Information System
* Scientific Technologies Corporation, Phoenix, AZ, https://immslink.stchome.com