Recommendations for Improving Adult Vaccination Rates and Reporting within Community Pharmacy Practice

The purpose of this white paper is to provide best practice recommendations for improving adult vaccination rates and reporting. The intended audience for this white paper includes pharmacists practicing in community settings.

This white paper was developed by the Pharmacy Quality Alliance (PQA) Adult Immunization Task Force and reviewed through a consensus-based process. The Task Force was sponsored by PFIZER®.

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LIST OF ABBREVIATIONS

APhA	American Pharmacists Association
ACIP	Advisory Committee on Immunization Practices
CAHPS	Consumer Assessment of Healthcare Providers and Systems
CDC	Centers for Disease Control and Prevention
EHR	Electronic Health Record
IAC	Immunization Action Coalition
IIS	Immunization Information Systems
ImmuSMART	Immunization Service Model for Adult Rate Improvement
IZTF	PQA Adult Immunization Task Force
MTM	Medication Therapy Management
NVAC	National Vaccine Advisory Committee
PCP	Primary Care Provider
PCV13	pneumococcal conjugate vaccine
PHIT	Pharmacy Health Information Technology Collaborative
PPSV23	pneumococcal polysaccharide vaccine
PQA	Pharmacy Quality Alliance
Td	tetanus/diphtheria vaccine
Tdap	tetanus/diphtheria/pertussis vaccine
VAERS	Vaccine Adverse Event Reporting System

INTRODUCTION

Pharmacists have long played a role in immunization practices. Prior to 1993, that role primarily comprised vaccine distribution during public health emergencies and mass immunization programs, such as the polio prevention programs of the 1950s-60s.[1] Faced with childhood immunization disparities during the early nineties, Donna E. Shalala, then Secretary of Health & Human Services, reached out to the American Pharmacists Association (APhA) to define an expanded role for pharmacists in delivering vaccinations.[1,2] In response to this charge, the 1996 APhA House of Delegates adopted policies to empower and support pharmacists in providing vaccinations.[3] Pharmacists were encouraged to advocate in such efforts by educating patients and promoting immunizations; collaborate with other healthcare providers; and administer vaccines.[3] Although childhood vaccination rates served as the initial catalyst in defining the modern role of pharmacist-administered vaccination, adult immunization has now become the primary focus.

The first pharmacist-based immunization training program was developed and delivered by the Washington State Pharmacy Association in 1994.[1] In 1996, the APhA "Pharmacy-based Immunization Certificate Training Program" was launched and stands as the gold standard in pharmacist immunization training.[1,4] Since its inception, the program has trained more than 280,000 pharmacists to administer vaccinations.[1,4] Today, immunization certification is a requirement within any accredited Doctorate of Pharmacy program in the US.[5]

Pharmacists' immunization roles received greater recognition and were greatly expanded in 2009 due to the H1N1 influenza pandemic. In response to this public health crisis, emergency declarations removed barriers and expanded pharmacist vaccination authority.[6] Today, pharmacists in all 50 states, the District of Columbia, and Puerto Rico have varying degrees of legislative authority to administer vaccines (e.g., administration of adult vaccinations only in certain states). Pharmacist-administered vaccination practices are guided by standards and recommendations developed by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP), the National Vaccine Advisory Committee (NVAC), and APhA.[7-10] In addition, several other nationally recognized organizations provide guidelines and support for pharmacy-based immunization programs (e.g., Immunization Action Coalition (IAC), Department of Health and Human Services' National Adult Immunization Plan).[11,12]

Continued expansion in pharmacists' scope of practice and increased non-traditional vaccination delivery by community pharmacy supports one of the goals described in Healthy People 2020; that is, "to improve vaccination rates and reduce vaccine-preventable diseases".[13] In 2012, APhA coined the term "immunization neighborhood" to describe "collaboration, coordination, and communication among immunization stakeholders

dedicated to meeting the immunization needs of the patient and protecting the community from vaccine-preventable diseases".[14] This approach and focus has been accepted as the guiding principle for serving the public health needs of our communities.[14]

Any expansion in scope of practice includes increased responsibilities. With respect to immunizations, such responsibilities include, but are not limited to, adequate documentation, reporting, and the establishment of initiatives to increase vaccination rates. With this increased scope, community pharmacists are perfectly poised to play a key role in the drive to develop more robust immunization information systems[15] and to improve performance on quality metrics related to immunization.

This white paper brings together multi-stakeholder, best practice recommendations for improving adult immunization rates within the community pharmacy. Through a consensus-based process, five key focus areas were identified; immunization screening; documentation and reporting; vaccine services prioritization; community pharmacy personnel vaccination; and cost and reimbursement barrier minimization. This white paper was developed by the Pharmacy Quality Alliance (PQA) Adult Immunization Task Force (IZTF; Appendix).

RECOMMENDATIONS

1. Immunization Screening Opportunities

   The National Vaccine Advisory Committee's Standards for Adult Immunization Practice advise that all healthcare providers should assess adult patients for their immunization status at every patient encounter.[8] Therefore, every healthcare provider, including pharmacists, carries the responsibility to screen patients in an effort to increase vaccination rates and to improve overall health. In order to minimize missed opportunities for vaccination in community practice, pharmacists have several resources available to them as detailed in the recommendations below.

   A. Query immunization information systems

      Rationale: Immunization information systems (IISs) are confidential, population-level electronic databases to which participating providers report vaccination administration. At a population level, IISs can be utilized to guide development of targeted programs aimed at improving vaccination rates. On the patient level, IISs provide consolidated immunization histories that can be used for clinical decision support, forecasting (next dose/vaccine recommendations), and determining appropriate patient vaccinations. Pharmacists should utilize IIS as a standard practice in their workflow before any vaccination is administered. This will help prevent duplicate doses and allow for comparison of previous

vaccinations to the current ACIP recommendations.[7,15] Links to the various state IISs can be accessed from the CDC website at http://www.cdc.gov/vaccines/programs/iis/contacts-locate-records.html.

To demonstrate how IISs can be used within pharmacy practice, PQA launched a research initiative titled, "Immunization Service Model for Adult Rate Improvement (ImmuSMART)". In this study, IISs are used to inform vaccination delivery at the pharmacy point of care through regularly occurring outbound automated calls (e.g., refill reminders) to patients conducted by a telephonic support vendor. Prior to the outbound call to the patient, an IIS technology vendor performs an automated immunization status assessment by submitting a query to the respective state IIS to compare the adult patient's existing immunization record to the recommended ACIP schedule. If gaps in vaccinations are identified and fall within pharmacy scope of practice for administration, the patient is asked whether he/she would like to receive identified vaccinations upon their next pharmacy visit. If the patient accepts, the vaccination will be administered at that next pharmacy visit. ImmuSMART is an example of how pharmacies can use a systems-level mechanism to streamline the immunization status assessment process and to seamlessly incorporate it into community pharmacy workflow.

B. Assess immunization status by utilizing the pharmacy dispensing system
Rationale: Pharmacists should routinely use the dispensing record to assess the need for patients to receive any missing vaccinations based on age and known comorbidities. Pharmacists also have a unique ability to identify high-risk patients based on review of their medication profile within the pharmacy dispensing system. Dispensed medications can indicate gaps in vaccination that need to be addressed. For example, pharmacists can identify and recommend hepatitis B and pneumococcal vaccination to patients receiving medications indicated for diabetes.[7] Pharmacists can also design immunization outreach programs, such as a program that targets persons for pneumococcal vaccination who are on medications for asthma. Moreover, pharmacists can explore opportunities for creating prompts, tips, or alerts within the review process for dispensed medications. Systems may include information on gaps based on patient history of medication profile. Pharmacists are encouraged to be familiar with and have an understanding of high-risk patient populations and disease states in the ACIP schedule in order to identify opportunities for vaccine recommendation and administration.

C. Leverage the Appointment-Based Model: Conduct immunization status screening during point-of-care activities (e.g., health screenings, yearly influenza vaccination administration, refill pick-up)
Rationale: The Appointment-Based Model (ABM) is a pharmacy operations model that allows pharmacy staff to perform a full review of medications each month to identify compliance issues and/or therapeutic gaps, including vaccinations. Outside of the ABM, pharmacists have other opportunities to conduct immunization status assessment. For example, influenza vaccination delivery occurs yearly on a large scale and is an excellent opportunity for pharmacists to conduct a full immunization status assessment. One example for conducting a status assessment includes the use of a brief patient questionnaire that can be completed while waiting for vaccine administration. Several organizations provide immunization screening questionnaires, including the CDC or the IAC.[11,16] In addition to the vaccine questionnaire, the IIS should be queried as previously described.

Counseling represents another opportunity for pharmacists to not only assess immunization status, but also to educate patients about vaccination and to document immunizations discussed or administered. This enables patients to play a primary role in maintaining their vaccination records and assist providers during future assessments. Providing clear, plain language to patients about which vaccines they received and when, will not only improve the patient's personal health record, but it will also serve to educate patients for the purposes of quality measurement that utilize survey data. For example, flu vaccinations among Medicaid, Medicare, and commercial health plans are measured through self-report within the Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys.[17]

D. Include immunization status screenings when performing medication therapy management services
Rationale: Medication therapy management (MTM) services encompass a broad range of activities including comprehensive medication reviews to identify medication-related problems and gaps in care. Immunization status assessment should be a core component of this process and of MTM services.[18,19]

Including immunization assessments in MTM services is a recognized gap by the PQA IZTF. As such, the IZTF has put forth quality measure concepts in an attempt to fill this gap. For example, the "Immunization Assessment within Medication Therapy Management" measure identifies the rate of routine immunization status assessments conducted during MTM session within the measurement period.

2. Documentation and Reporting

Immunization is a public health service that includes a responsibility for communication and documentation of services provided or referrals made as part of the accountable care for the patient. Appropriate and timely documentation and reporting of vaccine administration and/or adverse events helps to ensure proper administration of recommended doses, mitigation of excess or duplicative doses, and identification of vaccine safety concerns. As outlined below, pharmacists in the community play an integral role in adequate vaccination documentation and reporting.

A. Report vaccine administration to the appropriate state or jurisdictional Immunization Information System

Rationale: Immunization Information Systems are free to use, available in all 50 states, and offer providers a centralized database to access and consolidate patient immunization histories.[15, 20] Pharmacy reporting of vaccination administration to an IIS serves to provide comprehensive immunization records enhancing a provider's ability to deliver appropriate vaccinations. The value of a robust IIS has also been realized in numerous public health and natural disasters, such as Hurricane Katrina where the Louisiana Immunization Network for Kids saved much needed time and resources by removing the need to unnecessarily revaccinate children who had been displaced.[21]

However, IIS reporting and documentation laws vary by state or jurisdiction, and many even have mandatory IIS reporting requirements.[20] Even in states or jurisdictions where reporting is not required by law, it is recommended that every provider submit a record of vaccination delivery to the appropriate IIS.[20] Both recommended and optional reporting elements (e.g., patient name, vaccine type) can be found on the CDC's IIS website as well as links to state IIS registries.[16] However, currently, immunization reporting by pharmacies is sometimes hindered by incompatibility between IISs and pharmacy dispensing software. Allowing immunization information to be seamlessly available to all providers, as well as patients, could optimize completion of recommended vaccinations; however, this achievement will require additional progress in health information technology.[20, 22]

Quality metrics can also contribute to evaluation of immunization reporting. For instance, the PQA IZTF has set forth a measure concept, called the "Immunization Information System Reporting", which attempts to evaluate the rate at which adult immunization administration records are documented in an IIS.

B. Document pharmacist vaccination administration and/or referral to another provider within the Electronic Health Record (EHR)
Rationale: Although states now have IISs that can capture vaccinations over an individual's lifespan, immunization records for adults are still not well populated within these databases. Thus, until such time when adult vaccinations are reported as robustly as child and adolescent vaccinations within the IIS, it is essential to document the receipt of vaccinations in patients' EHRs. Even then IISs and EHRs should be seamlessly integrated so that information can be routinely reported and accessed through both platforms. The Pharmacy Health Information Technology (PHIT) Collaborative has focused on integrating pharmacist-delivered vaccinations into the EHR for many years. This goal is just one of 10 aimed to connect pharmacists to the patient EHR by: outlining how pharmacists can contribute to EHR Meaningful Use quality measures; and describing evidence of improved quality outcomes as a result of pharmacist-delivered patient care activities.[22]

In situations where the pharmacist is unable to administer the requisite vaccine, documentation of referral to another provider should be reported. Electronic documentation of health care information improves the care continuum for the patient. Additionally, pharmacist involvement in care becomes more evident when pharmacist interventions, including vaccine administration or referral documentation, are included in the patient's EHR.

When a pharmacist does not have EHR access, collaboration with the patient and the patient's care team can help bridge that gap. Interprofessional communication from pharmacist to the primary care provider (PCP) about vaccination administration and pharmacist review of and documentation in the IIS may prompt the PCP to also examine the IIS and update the EHR, thus, improving two practices. Interoperability of pharmacy dispensing systems and EHRs with IISs would serve to connect pharmacists with EHRs and thereby reporting to the IIS; pharmacists would effectively be sharing vaccination administration information with providers who are using EHRs that have bidirectional interfaces with jurisdictional IISs. Moreover, collaboration with the patient can further contribute to more accurate and complete record-keeping.

3. Vaccine Services Prioritization
Encouraging prioritization of vaccination services amongst pharmacy leadership and members of the pharmacy team can lead to improved integration into practice culture. Cultivating a culture of immunization priority within the pharmacy begins

simply in an area where the particular pharmacy has the capability to focus. Examples of program initiation and/or expansion efforts are detailed below.

A. Focus on seasonal influenza vaccination as a starting point to integrate immunization practices into community pharmacy
   Rationale: Influenza is a serious health risk especially for vulnerable populations, such as older adults, patients living with chronic health conditions, and pregnant women.[23] Historically, the influenza vaccine has the highest rate of administration, because it is an annual vaccine and has the largest eligible population. This is a great opportunity for a pharmacy new to providing immunization services. Development of an influenza vaccination program offers a focused area in which to setup and refine immunization workflow and procedure. Once workflow is established, pharmacists can further increase vaccination rates by developing their "immunization neighborhood" by offering off-site influenza vaccination clinics to employer groups and organizations.

B. Expand focus to include at least the most commonly needed vaccines for adults
   Rationale: Once an immunization workflow and policy have been developed and implemented, pharmacists can then expand their focus to include additional vaccines that are commonly recommended for adults such as tetanus/diphtheria vaccine (Td), tetanus/diphtheria/pertussis (Tdap) vaccine, pneumococcal conjugate vaccine (PCV13), pneumococcal polysaccharide vaccine (PPSV23), hepatitis B vaccine, and herpes zoster vaccine.[7,8] Outreach to members of the local "immunization neighborhood" will help prioritize and inform immunization services your practice provides to patients and the community.

C. Prioritize high-risk patients
   Rationale: Using screening methods recommended in Section 1 above, develop outreach programs to target high-risk patients as defined by the ACIP.[6] For example, pneumococcal vaccination is recommended for persons <65 years of age with chronic conditions such as diabetes, chronic heart disease, asthma and chronic obstructive pulmonary disease by the CDC. When patients pick up chronic medications, focused immunization status assessment and counseling can be conducted as suggested in Section 1B – 1C. In addition, as with any initiative, signage within your pharmacy can deliver targeted messages.

D. Implement a tracking mechanism (preferably automated) to alert patients receiving vaccines with multiple doses when their next vaccine is due
   Rationale: Missing repeated doses of serial vaccines limits the amount of protection conferred to the patient. For example, one dose of Twinrix confers

about 30% seroprotection for Hepatitis B, while the recommended three doses provide more than 95%.[24] Additionally, the dosing and timing of vaccines can be complicated as is the case with PPSV23 and PCV13. Thus, developing mechanisms to track doses and alert the patient via their preferred method (i.e., text, phone, email, or standard mail) will help ensure the completion of serial doses and reduce the number of unnecessary vaccinations. Many IISs provide these tracking mechanisms along with forecasting of vaccine doses and clinical decision support. Links to the various state IISs can be accessed from the CDC website at http://www.cdc.gov/vaccines/programs/iis/contacts-locate-records.html.[15] However, as a best practice, schedule a patient's next appointment for follow-up dose(s) in a series during the initial vaccine administration.

4. Vaccinate All Community Pharmacy Personnel

   Pharmacist and pharmacy staff immunization should be a fundamental aspect in the culture of the profession. Community pharmacy personnel (including pharmacy technicians and support staff) often serve as the first point-of-care for patients. As such, pharmacy staff are at risk for exposure to serious diseases. The CDC recommends that all healthcare workers, including pharmacists, be up-to-date with all recommended vaccines.[25] APhA adopted policies in 2007 and 2011 urging all pharmacy personnel to receive vaccinations specifically recommended for healthcare providers by the CDC guidelines.[9] As healthcare professionals, pharmacists should help raise awareness and assist with vaccination of other healthcare personnel.

5. Address Cost and Reimbursement Barriers

   As a vaccination provider and patient advocate, it is within the pharmacist's scope of practice to both understand insurance coverage for pharmacist-delivered vaccinations and assist patients in navigating their coverage needs. Furthermore, it is a pharmacist's responsibility to ensure patients receive adequate access to care. This includes not just serving as an advocate, but also acting as an ambassador to lower barriers to vaccination, including those attributed to cost and reimbursement.

   A. Remove or lower cost barriers to immunization by assisting with copay coverage and assistance programs for the uninsured patients

      Rationale: Pharmacists should familiarize themselves with methods to address common cost barriers for patients, such as unaffordable copays and/or lack of insurance. One way to become knowledgeable is to engage fully with other local providers.[14] This will facilitate a more comprehensive knowledge base in available local assistance programs offered for the uninsured. Additionally, engaging with local businesses and employers through off-site clinic offerings expands access, further develops the "immunization neighborhood", and if the clinic is sponsored

by the employer, will address cost barriers. Further, pharmacists can assist their patients by exploring patient assistance programs offered by some vaccine manufacturers.

B. Help patients to understand and navigate their insurance plan coverages by understanding coverage and reimbursement
Rationale: Pharmacists should learn to navigate specific types of barriers unique to various insurance providers and designs, including commercial, employer-based, Medicaid, or Medicare plans. In the Medicare space specifically, knowledge about which vaccinations are covered under Medicare Part B and Part D and how to bill for each will help pharmacists provide needed vaccines to patients.

Coverage inconsistencies complicate immunization reimbursement and compensation processes for pharmacies.[2,26] For example, Medicare Part B plans cover influenza, pneumonia, hepatitis B (for patients at increased risk), and other vaccines required as treatment for an injury or exposure, such as the Td vaccine. Medicare Part D plans cover all other vaccinations if they are deemed necessary and reasonable for disease prevention.[26] The fact that only certain vaccines are covered by two separate plans can often pose a challenges.[26] Furthermore, not all Medicare Part D plans can be billed directly and may require patients to pay upfront and submit for reimbursement.[26] Additionally, some Medicare Part D plans only cover part of a patient's co-pay, while others require high out of pocket costs.[26] Pharmacists are in a position to help patients find solutions for accessing vaccines. For example, pharmacists can recommend zoster vaccination for patients age 60-64 with commercial insurance in order to receive the vaccine before entering into Medicare Part D at age 65, which may result in the patient having to pay a higher co-pay. The pharmacy team can assist patients in understanding the patient's out of pocket costs by calling their Medicare Part D plan https://www.medicare.gov/find-a-plan/questions/search-by-plan-name-or-plan-id.aspx.

CONCLUSION

Pharmacist-delivered vaccinations represent a means for expanded patient access and expanded scope of pharmacist practice, including increased responsibilities for which the profession must be accountable. A commitment to improve adult vaccination rates is a public health service shared among the entire healthcare team and "immunization neighborhood". Shared responsibilities include immunization status assessment, recommendation, administration, referral, vaccination administration documentation, and the development of initiatives to increase vaccination rates. Other issues outside the scope

of this paper that were not addressed, but should be considered include: maintaining professional competencies; practice of appropriate storage, handling and administration of vaccines; reporting serious adverse events after vaccination to the Vaccine Adverse Event Reporting System (VAERS); and seeking education on the most up to date CDC vaccine recommendations. Additionally, with the shift from a volume-based to a value-based healthcare system, development of quality performance metrics to assess immunization efforts will continue to evolve. Pharmacists are perfectly poised to improve performance on evolving immunization metrics given their scope of practice and these best community pharmacy practices developed through a multi-stakeholder, consensus-based process.

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APPENDIX: PQA Adult Immunization Task Force Members

Established in 2006, the Pharmacy Quality Alliance (PQA) is a 501(c)3 designated non-profit alliance with over 190 member organizations. PQA is a multi-stakeholder, consensus-based membership organization. Through a collaborative process, PQA promotes appropriate medication use and develops strategies for measuring and reporting performance information related to medications.

The PQA Adult Immunization Task Force is composed of PQA members and external experts from various affiliations including community pharmacy, public health groups, healthcare, life sciences, technology organizations, health plans, medication therapy management entities, and pharmacy associations. The goals of the Task Force are to develop performance measure concepts aimed at improving rates and narrowing gaps in reporting of adult immunizations, and to identify community pharmacy immunization best practices.

The Pharmacy Quality Alliance would like to recognize and thank the members of the PQA Adult Immunization Task Force for their contributions to this white paper and continued collaboration in support of immunization initiatives.*

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* Some members of the IZ TF are not represented in this list, as they did not provide consent.