MOVING BEYOND INFLUENZA

Practice Guidance for Expanding Pharmacy-Based Immunization Services Within the Appointment-Based Model

APhA

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Background

Immunizations play a critically important role in preventing infectious disease, and the underuse of immunizations for vaccine-preventable diseases is a significant public health concern in the United States.[1] Childhood vaccination programs have successfully reduced morbidity and mortality, yet the same success has not been seen in adults. Vaccine preventable diseases continue to cause a significant burden on patients and the U.S. healthcare system, with approximately 42,000 adults dying each year from vaccine-preventable diseases:[2]

- Invasive pneumococcal disease (IPD): 30,400 reported cases and 3,690 total deaths due in 2016, overwhelmingly occurring among adults[3]
- Influenza: 80,000 deaths in the 2017–18 season, exceeding a 30-year high by more than 20,000 cases[4]
- Pertussis: 17,972 reported cases of pertussis in 2016, with 22.5% of cases among adults 20 years of age and older[5]
- Hepatitis B: 2,791 reported acute cases and 18,100 estimated new infections in 2014[6]
- Herpes Zoster: approximately 1 million new cases annually[7]
- Human papillomavirus (HPV): 42.5% adults aged 18 to 59 years had genital infections due to any HPV type during 2013 to 2014[8]

One of the goals of Healthy People 2020 is to increase immunization rates and reduce preventable infectious diseases. Within these goals, there are very specific objectives for improving adult vaccination rates, many of which can be directly affected by pharmacists.[2]
The National Vaccine Advisory Committee (NVAC) Standards for Adult Immunization Practice represent a call to action for all health care professionals to:[9]

- Assess the immunization status of all patients in every clinical encounter.
- Strongly recommend vaccines that patients need.
- Administer needed vaccines or refer to a provider who can vaccinate.
- Document vaccines received by patients, including entering immunizations into immunization registries.

Adult vaccination rates are extremely low, and most adults are often not aware that they need vaccines. Research has shown that a recommendation from a health care professional is the strongest predictor of whether patients get vaccinated. Unfortunately, there are many missed opportunities for vaccination because many health care professionals are not routinely assessing vaccination status.[9] More than 320,000 pharmacists have been trained to administer vaccinations across the lifespan in all 50 states and in U.S. territories.[10] Pharmacists are uniquely qualified and positioned to meet NVAC Standards for Adult Immunization Practice and provide expanded vaccination information and services to adults and adolescents.

The appointment-based model (ABM) is a practice approach designed to improve patients' adherence to medications and build efficiencies in pharmacy operations.[11] Leveraging this model can support the expansion of pharmacy-based immunization services, allowing opportunities for pharmacists to evaluate a patient's immunization status, make a vaccine recommendation, provide a specific identified immunization, and improve vaccination rates.

Purpose

This guidance document outlines opportunities for pharmacists to leverage the ABM to expand the depth and breadth of immunization services provided to adults and adolescents.

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Expanding Immunization Services for Vaccines Recommended by the Centers for Disease Control and Prevention

Due to challenges in improving vaccination rates among adults, public health leaders—including the CDC, the National Vaccine Advisory Committee (NVAC), the American Cancer Society, and the President's Cancer Panel—have made recommendations to include pharmacists as alternative vaccine providers. The American Pharmacists Association's (APhA) Guidelines for Pharmacy-Based Immunization Advocacy encourage all pharmacists to adopt a level of involvement in vaccinations as educators who motivates people to be immunized, facilitators who host other health care providers to immunize, or as immunizers who administer vaccines to protect vulnerable people, consistent with state law.[1] These guidelines apply to all vaccines, as recommended by the Centers for Disease Control and Prevention (CDC), provided through pharmacy-based immunizations.

Improving Vaccination Rates through Pharmacy-Based Immunization Services

Pharmacists have answered this call and have demonstrated the ability to increase adult immunization rates and keep patients current with recommended vaccination schedules.[2] This is evidenced by the percentage of adults receiving influenza vaccinations in a community setting increasing from 6% in the 2004–05 influenza season to more than 18% in 2013–14.[3] A recent meta-analysis determined that pharmacist immunization programs had a substantial positive effect on immunization rates compared with usual care.[4] The demonstrated impact of pharmacist immunization programs on immunization rates indicates that pharmacists are a critical component of strategies to increase immunization rates in the United States and could help the nation reach Healthy People 2020 immunization goals.

Pharmacists are achieving these improved vaccination rates by reinforcing public health messages, assessing patient immunization needs, delivering strong recommendations for vaccines, and providing immunizations when appropriate. Pharmacists are also able to target vaccine recommendations based on patient health conditions, such as diabetes, heart disease, asthma, tobacco use, and pregnancy, which has the potential to improve vaccination rates among those at highest risk of severe illness.

Additionally, patients are often receptive to being vaccinated when the pharmacist engages in conversation about the patient's immunization status and provides clear recommendations for the vaccines that are needed. In a recent pilot project conducted by the APhA Foundation, pharmacists conducted complete assessments of a patient's vaccination history when the patient presented for an influenza vaccine. During these assessments, the pharmacists identified 1,334 unmet vaccination needs in patients eligible for vaccination and resolved 33.5% of these needs during the study period, resulting in a 41.4% increase in the number of vaccines administered and significant patient education provided.[5]

Expanding Access through Pharmacy-based Immunization Services

Pharmacists have demonstrated the ability to increase access to vaccines for adults and adolescents.[6] The CDC consistently recognizes that pharmacists are uniquely positioned to promote and provide vaccines to people in a wide range of communities,[7,8] and estimates that 28% of influenza vaccinations occur in pharmacies/stores.[8] Through pharmacies' convenient locations, flexibility, and extended work hours, pharmacists are often able to offer expanded access to vaccines to populations that may have limited access to other vaccine providers due to financial, geographic, or system barriers. To support this enhanced access, pharmacist authority to administer vaccines besides influenza has expanded across the country to meet the needs of specific communities.

In a recent survey, three-quarters of pharmacists reported they could vaccinate a greater number of people at their respective pharmacy location, indicating a potential underuse of pharmacies as alternative vaccination sites.[6] In a retrospective study of pharmacies in a major pharmacy chain, 30.5% of adults receive their vaccinations during evening, weekend, and holiday hours when traditional vaccine providers are typically unavailable. In particular, younger, working-aged healthy adults accessed a variety of immunizations during off-clinic hours.[9]

Overcoming Challenges in Pharmacy-based Immunization Services

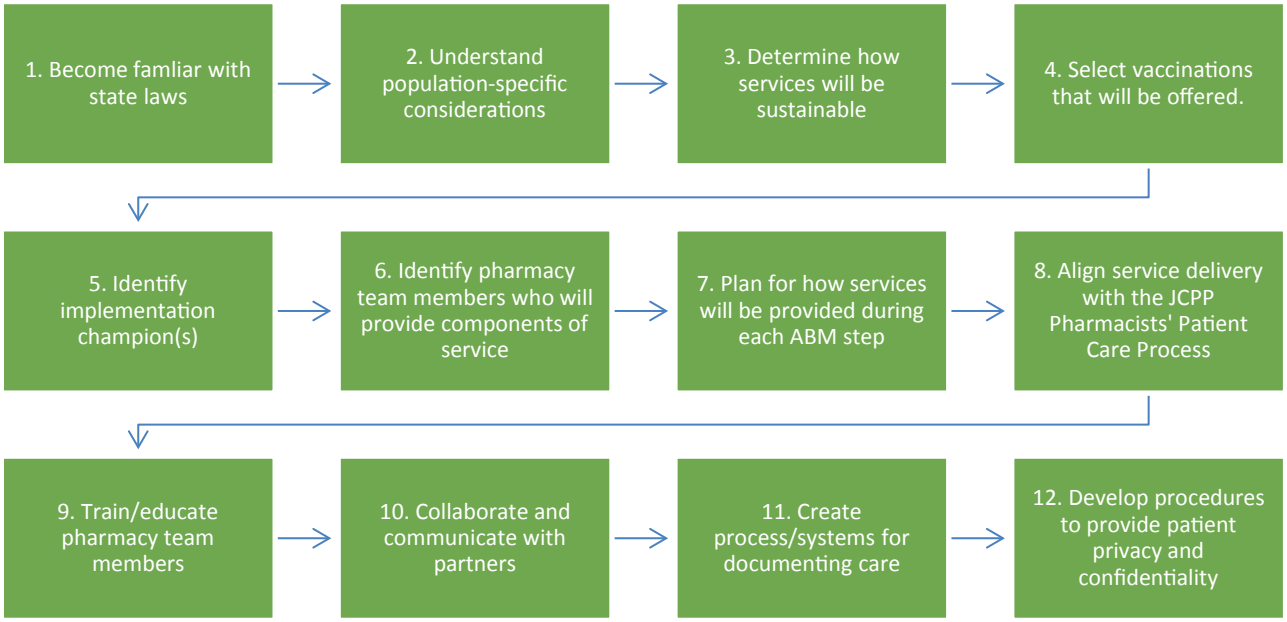
A recent study identified challenges to the provision of adolescent and adult vaccinations in pharmacy settings, with the most common challenges including reimbursement and insurance coverage, education of patients and parents, and pharmacist time constraints. Pharmacists also cited availability of the administration area, vaccine shortages, and cost of vaccine storage as challenges to provide immunizations to adults.[6]

Even in light of these challenges, pharmacists are well-positioned and prepared to provide immunization services beyond annual influenza vaccination, and pharmacy staff members, including

pharmacy technicians and student pharmacists, may provide support to the pharmacist and manage many of the operational or administrative aspects of immunization services. In particular, pharmacy technicians can play a vital role in identifying patients eligible for vaccination, checking the immunization information system (IIS; where authorized) for immunization history, managing paperwork, and coordinating billing. Pharmacy technicians may be a critical, and perhaps underutilized, resource for pharmacists who struggle to find time to complete additional clinical services during the dispensing workflow.[10] In states where there is a need for additional immunizers who can support pharmacists in providing patient care (e.g., Idaho), pharmacy technicians have been provided authority to administer immunizations.[11] Student pharmacists may administer vaccines in 49 states and in U.S. territories, provided that they have completed required training and are operating under the supervision of a trained pharmacist.

Figure 1 details a process for pharmacists and their teams to follow as they develop immunization services and provide them within the ABM pharmacy workflow. Information to help the pharmacy team complete the steps in this process is included within this document.

Figure 1: Process for Expanding Immunization Services within the ABM



Providing Immunization Services Within the Appointment-Based Model

Pharmacists have a significant role in administering vaccinations, and a recommendation from a pharmacist to a patient for vaccination can increase vaccination rates.[5] In a traditional community-based pharmacy practice, there are several opportunities for pharmacists to promote vaccinations on site, particularly during prescription drop-off or pick-up.[12]

Innovative and transformative practice models are repositioning the workflow and improving the efficiency and patient care experience in community-based pharmacy practice: the appointment-based model (ABM) is one such practice model. The ABM can be leveraged to obtain and assess vaccine histories, administer appropriate vaccines, and increase pharmacist engagement with patients. Pharmacists can use the workflow optimization from the ABM to engage with patients and complete a comprehensive vaccine assessment, encourage patients to receive needed vaccines, and administer vaccines as necessary. Recent research demonstrated that the ABM facilitated conversations about vaccinations and was a convenient approach to increase immunization acceptance.[12]

The Pharmacists' Patient Care Process can align with immunization services provided within the ABM. Pharmacists can use the chart in Figure 2 to plan and implement discussions with individual patients during an ABM appointment.

The ABM is centered on proactive, patient-centered care with core components that include medication synchronization, a pre-appointment call, and a scheduled appointment, when needed. The basic tenets of an ABM are the holistic care of the patient; regularly scheduled visits to the pharmacy by the patient; communication with the patient in advance of the scheduled visit to proactively assess needs related to medications and health conditions; and pharmacist–patient engagement on a regular basis to address these needs.[13] APhA's Leveraging the Appointment-Based Model to Expand Patient Care Services: Practice Guidance for Pharmacists provides detailed information about how the ABM can facilitate patient care delivery across many disease states and service types.[14]

Figure 2. Alignment of Immunization Activities in the Appointment-Based Model and the Pharmacists' Patient Care Process

PPCP Stage	Immunization Service Activity	Stages of the ABM When Activity May Take Place			
		Enrollment/Initial Medication Synchronization	Pre-appointment Call	Appointment Preparation	During Appointment
Collect	Gather immunization history from the IIS.	X	X	X	
	Obtain history of immunizations from primary care provider or EHR.	X	X	X	
	Obtain history of immunizations from patient/caregiver.	X	X		X
Assess	Assess the immunization needs of patient based on key factors such as age, disease/medication history, pregnancy status, tobacco use, environment, lifestyle, school entry, and upcoming travel.		X	X	X
	Screen for potential contraindications to vaccination.		X	X	X
Plan	Develop vaccine recommendation that will be made to patient/caregiver regarding needed vaccinations.		X	X	X
	Make recommendation to patient/caregiver regarding needed vaccinations. If you cannot provide vaccination, refer patient to a provider who can.		X		X
	If patient declines vaccination, document their refusal in your records.		X		X
	If patient agrees to recommendation, determine and communicate to patient/caregiver when vaccination will occur (now or appointment).		X		X
Implement	Review VIS and other immunization information with patient/caregiver.				X
	Administer vaccine to patient.				X
	Provide vaccine administration documentation to patient.				X
	Submit vaccine administration documentation to primary care provider.				X
	Submit vaccine administration documentation to IIS.				X
Follow-up	Monitor patient for syncope or adverse reactions for 15 minutes after administration of vaccine.				X
	Schedule follow-up for subsequent doses of multidose vaccine series.		X		X

ABM = appointment-based model; EHR = electronic health record; IIS = immunization information system; PPCP = Pharmacists' Patient Care Process; VIS = Vaccine Information Statement.

Identification and Enrollment of Patients

Pharmacists can identify patients for enrollment into an ABM program at any step of the dispensing workflow. Pharmacists often target patients for enrollment in the ABM who may also be eligible for enhanced immunization services, such as patients at high risk for medication problems and vaccine-preventable diseases, patients 60 years of age or older taking multiple medications, and patients with high-risk disease states, such as diabetes, asthma, and chronic obstructive pulmonary disease.[12] The information the pharmacy has on its population of patients enrolled in the ABM can help target future immunization-related interventions. Additionally, pharmacists should consider the types of patient health information that would be beneficial to have in the pharmacy system to fuel future service delivery and plan to collect that patient health information during enrollment, if possible.

Medication Synchronization

Medication synchronization facilitates the ABM workflow. The pharmacy staff should work with the patient and the patient's insurance to align all of the patient's medications to fill on one date—the sync date.[14] The routine medication synchronization date (e.g., every 30 or 90 days) serves as the articulation point for the pre-appointment call and the patient's appointment, which are pivotal for integrating immunization services into the ABM.

Pre-appointment Call

The pre-appointment call is an ideal time to collect vaccination history information from patients and alert patients if they are in need of immunization services. In some settings, pre-appointment calls are conducted via an automated system. In these instances, the pharmacy may choose to work with the technology vendor for the system to add a customized question about vaccine status to the roster of questions asked in a given month. Pharmacists can use a population health management approach by analyzing ABM enrollees' data to target the deployment of the pre-appointment call question about immunization status only to patients who meet certain risk factors for vaccine-preventable diseases. Sample questions that can be used in the pre-appointment call include:

- For all patients: Are you interested in having the pharmacist recommend immunizations that can help protect you from vaccine-preventable diseases?
- For all patients: Have you received your annual flu shot this year?
- For patients 65 years of age or older: As someone aged 65 years or older, you should receive a pneumococcal vaccine to protect you from pneumococcal disease and its complications such as pneumonia and meningitis. Have you received a pneumococcal vaccine since turning 65 years old?
- For patients 50 years of age or older: As someone aged 50 years or older, you may be at risk for getting the shingles. Our pharmacists are able to administer a vaccine that can help prevent shingles. Are you interested in receiving this immunization?

The answer to these questions can help identify patients who self-report not having received a needed vaccine or who are interested in having the pharmacist recommend appropriate immunizations. Once these patients are identified, the pharmacy team will have the opportunity for a more targeted conversation with each patient. Depending on workflow, this interaction may take place during the pre-appointment call or during the patient's appointment. If the interaction will occur during the pre-appointment call, pharmacists should complete the steps described below in the Appointment and Medication Preparation section to prepare themselves in advance of discussing immunization services with the patient.

Appointment and Medication Preparation

To prepare for patient interactions generated during the pre-appointment call, the pharmacist should research the patient's health history to develop a recommendation for which immunizations may be needed. This should include accessing the patient's vaccination history from the statewide/local IIS, if available. The patient's medical and pharmacy records may also have relevant information. A reconciled vaccination history should be completed, if required. Discussions with the patient provide an opportunity to gain additional information or reaffirm information that was previously collected. The pharmacist should assess whether there are unmet vaccination needs and, either during the pre-appointment call or at the appointment, offer to provide necessary vaccinations during the ABM appointment.

If the patient was offered and consented to the immunization service during the pre-appointment call, the pharmacist should prepare for the patient's appointment by reviewing individual patient records, assuring necessary supplies and vaccines are in stock, and preparing supplies for administering the needed vaccines.

Appointment and Vaccine Administration

During the appointment, the pharmacist may perform a variety of services, including the medication review, patient counseling, and further assessment of the patient's vaccination status.[12,14] The patient's appointment may be formally scheduled (e.g., a set date and time), or it may be more of an agreed upon pick-up day when the patient will likely visit the pharmacy. Regardless of the formality in scheduling, the appointment is an ideal time to provide immunization services.

Patients who have been offered the immunization during the pre-appointment call will be expecting the service when they arrive. The pharmacist should offer to provide and/or confirm the patient's interest in receiving the needed vaccinations during the appointment and administer these vaccines as indicated. However, if the pharmacy's immunization services were not previously discussed, the pharmacy team should use the appointment to gather any vaccine history information from those patients and other sources and then alert them of any needed vaccines. If a patient responds favorably, the vaccination can take place on the same day during the appointment or at the patient's next visit, depending on patient preference.

If a patient does not obtain the recommended vaccinations during the appointment, pharmacists should provide documentation in the dispensing system as a reminder to conduct appropriate follow-up with the patient during the next scheduled appointment.[12] Any vaccines provided should be reported to the IIS and notification provided to the patient's primary care provider, if known. Some states require physician notification of vaccinations.

Determining Immunization Service Offerings

Pharmacists should evaluate how the provision of expanded immunization services, delivered through the ABM, can create a clear service value for the patient and a discernable financial value for the practice. In addition to ensuring pharmacists have the legal authority to administer a specific type of vaccine in the state, the practice should evaluate the goals for establishing enhanced immunization services, such as filling gaps in patient and community health needs, increasing revenue, and differentiating service offerings from competitors. Assessing business opportunities within each vaccine area can highlight the immunization services that may be most beneficial.

Scope of Practice Considerations

Currently, laws and regulations in all states permit pharmacists to administer vaccines to varying extents. These laws and regulations vary across jurisdictions. This incremental expansion of pharmacist vaccination authority has allowed pharmacists to administer more vaccines to younger patients with less direct prescriber oversight.[15] The 2010 National Vaccine Plan has set a goal of 100% of states and territories that allow pharmacists to administer all routinely recommended vaccines for adults aged 19 years and older without a patient-specific prescription.[16] According to the APhA and National Alliance of State Pharmacy Associations (NASPA) annual survey of state immunization laws and regulations, as of January 2018, all but four states allowed pharmacists to administer all CDC-recommended vaccines.[17] However, there may be restrictions or detailed requirements for the provision of specific vaccine types. Some states may require protocols or prescriptions, and others may have specific age limitations for providing immunizations.

Depending on state laws, authority to provide immunizations may be provided by means of a collaborative practice agreement, a protocol, or a prescription. Pharmacists should confirm the applicable state laws, regulations, and requirements for establishing immunization services within their pharmacy practice. Protocols and collaborative practice agreements for immunization services should outline the scope of vaccinations offered, procedures to follow, documentation, and the medical management of adverse reactions, including a standing order for epinephrine and other interventions.

A larger, more diverse pharmacy team can assist to provide additional vaccinations. Pharmacy technicians and student pharmacists may play specific roles as part of the pharmacist-led team delivering immunizations. Pharmacists should check with their state board of pharmacy to confirm authority for these team members, required training, and conditions of supervision. The APhA Immunization Center provides an overview of pharmacist immunization authority across the country. To determine immunization rules and regulations for a specific state, contact the state board of pharmacy.

Specific recommendations and the supporting evidence for the broad use of collaborative practice agreements have been published in a white paper from the APhA Foundation, and this information may be useful to pharmacists expanding their patient care services.[18] Practical guidance for developing a collaborative practice agreement can be found in the CDC publication Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team[19] and through the NASPA website.

Immunization Type, Population, and Public Health Considerations

Pharmacists can most effectively select their immunization service offerings by aggregating information about immunization-specific factors and population and public health needs. Immunization-specific factors will help inform the pharmacist about which patients are eligible to receive the vaccination, the prevalence of the infectious disease, and vaccine-related information that may impact logistical or financial feasibility of the service. Population health factors can be determined by analyzing the pharmacy's and community's population demographics, chronic conditions, and eligibility for immunizations. Public health priorities are typically set by local, state, and national public health departments, and pharmacists should consider how they can provide services to address these hot topic immunization-related issues. Conversations with local and state public health officials as well as other providers in the community can help identify gaps and needs pharmacists can address. To access officials within local health departments, pharmacists can refer to the directory of local health departments from the National Association of County and City Health Officials.

Immunization Type

Considering the national landscape, vaccine-preventable diseases, and need for each type of immunization will provide a perspective on which immunization services could be well-suited to deliver in a specific pharmacy. APhA's Vaccine Considerations When Expanding Immunization Service Offerings details the current vaccination landscape for common immunization services beyond influenza that pharmacies choose to provide.

The vaccination rates, eligible patients, product factors, and previous pharmacist success with each vaccine area described in this resource can inform decisions about which immunization services to offer locally.

Population Health: Aging Adults

Certain vaccine-preventable diseases including influenza, pneumococcal, herpes zoster, tetanus, diphtheria, and pertussis specifically threaten the health of aging adults. Pharmacists can play a significant role in ensuring that older adult patients receive recommended vaccines at the recommended intervals. Disease prevalence in older adults is related to diminished immune function as well as the presence of comorbid conditions that further impair immunity. Pharmacists must have a thorough understanding of age-related changes in immune function, the types of available vaccines, and vaccination schedules for older adults.[20]

APhA, the American College of Physicians, and The Gerontological Society of America have collaborated to develop the guide Aging and Immunity: The Important Role of Vaccines to provide health care professionals with an understanding of the biological impact of aging on immunity, discuss the importance of and rationale for vaccinations, provide information to support the value of vaccination, and offer practical tips and strategies for supporting aging patients' health and overcoming barriers that may contribute to low rates of adult vaccinations.

Population Health: Adolescents

Pharmacists who wish to provide or expand adolescent vaccination programs, such as for HPV and meningococcal vaccines, must recognize that these services may require a higher level of counseling and management in comparison with typical adult patients. The process pharmacists must follow may vary depending on state laws and regulations; pharmacists should check the scope of authority in their state. Stocking and ensuring availability of vaccines for use in adolescent populations is important. Pharmacists should also examine consent laws for minors to determine the extent to which minors can legally and ethically consent to receive vaccines in their state or the consent requirements of parents and guardians.[21] Some pharmacists help increase awareness of the provision of adolescent immunizations by visiting local schools to promote vaccinations and educate parents about pharmacy resources available to provide vaccine administration. Informing local school districts that pharmacists may administer vaccines to adolescents, particularly those vaccinations that may be necessary for school entry, will also help expand adolescent vaccination programs.[6]

Emerging Public Health Opportunities in Immunization and Infectious Diseases

In the coming decade, the United States will continue to face new and emerging issues regarding immunization and infectious diseases, and the public health infrastructure must be capable of responding to emerging threats. State-of-the-art technology and highly skilled professionals, such as pharmacists, need to be in place to provide rapid response to the threat of epidemics. A coordinated strategy is necessary to understand, detect, control, and prevent infectious diseases, and pharmacists should be part of this effort. Examples of specific emerging issues include:[7]

- Providing culturally appropriate preventive health care is an immediate responsibility that will grow over the decade. As the demographics of the population continue to shift, public health and health care systems will need to expand their capacity to protect the growing needs of a diverse and aging population.
- New infectious agents and diseases continue to be detected. Infectious diseases must be looked at in a global context due to increasing:
  - International travel and trade
  - Migration
  - Importation of foods and agricultural practices
  - Threats of bioterrorism
- Inappropriate use of antibiotics and environmental changes multiply the potential for worldwide epidemics of all types of infectious diseases.

Pharmacists should stay informed on emerging issues and trends regarding immunizations and determine how these needs can be met through pharmacy-based immunization services. Pharmacists should consider signing up for notification alerts issued by local and state health departments.

Sustainability of Immunization Services

Determining the business model for immunization services is crucial to long-term sustainability, and these revenue streams can vary based on local and state payer partners. APhA's Billing Primer: A Pharmacist's Guide to Outpatient Fee-for-Service Billing provides a general overview of factors to consider in fee-for-service billing for pharmacists' services. Pharmacists may consider patients paying cash for patient care services as well as conduct outreach to health plans that provide services to the majority of patients to determine coverage of immunizations. In addition, many vaccine manufacturers have reimbursement support centers

to help with coding and billing questions. Coding and billing resources from the National Adult and Influenza Immunization Summit are also available for pharmacist access.

Some vaccines may be covered under the prescription drug benefits in a patient's health plan, while others are covered under the medical benefit in a patient's health plan. Some health plans consider vaccines as preventive services that require no copayment or deductible. Other health plans do not, and patients may have to pay a portion of the vaccine fee out-of-pocket. Vaccines other than influenza, pneumococcal, and hepatitis B (for specific patients) are covered by Medicare Part D. If a pharmacy serves Medicare patients, it must go through the process of becoming a certified Medicare Part B provider to bill Medicare for other vaccines as a medical benefit.[22]

In June 2011, national experts responsible for immunization planning, delivery, and patient care developed guiding principles for pharmacist-provided immunization compensation and recognition to help support the provision of vaccine services across the lifespan. These guiding principles are:[23]

- **Principle 1:** Patients, regulators, payers, and other medical providers should recognize pharmacists as qualified providers of immunizations and support their role in the medical home model.
- **Principle 2:** Patients should have access to trained and qualified pharmacist immunizers without barriers such as cost, location, or benefit design.
- **Principle 3:** Adjudication of vaccine claims should follow a nationally recognized, standard process including recognition of both product and administration costs.
- **Principle 4:** Pharmacists should maintain the highest level of professional competence to provide immunizations.
- **Principle 5:** To facilitate documentation and communication of the provision of pharmacist-provided immunization services, the profession should advocate for:
  - A core data set with standardized data elements and formats to enhance communication among and between stakeholders and payers.
  - An integrated multidirectional system that communicates with vaccine registries, providers, payers and health systems, and patients.
  - A central patient identifier to ensure complete and accurate patient records.
  - Continual investment to maintain, enhance, and improve these systems and to ensure safety and security of data.

Aligning with the Pharmacists' Patient Care Process

APhA describes the importance of creating an "immunization neighborhood" where collaboration, coordination, and communication occur among immunization stakeholders; these stakeholders are dedicated to meeting the needs of the patient and protecting the community from vaccine-preventable diseases. The process is patient and community centric, with an entire community invested in assessing, administering, and/or referring patients to receive appropriate vaccinations.[24]

Pharmacists are integral members of the immunization neighborhood and have positioned their immunization services as an important patient care offering. Following a process of care helps to create consistency between pharmacists and pharmacies, which can improve patients' trust in pharmacists as immunizers and help pharmacies become patients' routine point of access for all immunization needs.

APhA's Applying the Pharmacists' Patient Care Process to Immunization Services: A Resource Guide for Pharmacists helps pharmacists design and incorporate immunization services into pharmacy practice settings in alignment with the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists' Patient Care Process. [25] The following information provides a top-level summary of how the JCPP Pharmacists' Patient Care Process should be used to consistently deliver high-quality immunization services within the pharmacy's ABM.

Collect

A pharmacist or member of the pharmacy team should collect information from a patient, IIS, primary care provider, and other sources to support decision making about specific vaccines that may be indicated for the patient based on current ACIP recommendations. A pharmacist should also collect information to determine whether a patient may safely receive the recommended vaccines at that point in time.[26] Within the ABM, information collection can occur at any time, including during any interaction with the patient and in preparation for a pre-appointment call or appointment.

Assess

A pharmacist assesses the information collected and analyzes the need for vaccines in accordance with ACIP recommendations. The NVAC Standards for Adult Immunization Practice require all immunizing providers to assess immunization status in every patient care and counseling encounter and strongly recommend needed vaccines.[27] Areas to consider in determining which vaccines are indicated for a patient include age, health conditions, lifestyle, occupation, and travel. Pharmacists should screen patients for their current health status, allergies, present and past medical history, medications, vaccination history, altered immune competence, and pregnancy status.[26] In the ABM, assessments occur prior to making immunization recommendations to patients during the pre-appointment call or at the appointment.

Plan

A pharmacist develops an individualized, patient-centered care plan that includes a clear and strong evidence-based recommendation for needed vaccines. The plan is developed in collaboration with a patient or caregiver as well as physician or other health care professional, as appropriate. The care plan should be based on a pharmacist's assessment and address all currently needed vaccines as well as other vaccines needed in the near future. A patient-centered care plan includes a discussion with the patient to determine the patient's individual needs before formulating recommendations.[26] Motivational interviewing may be a useful tool for pharmacists to leverage when discussing immunizations with patients to increase patient readiness to receive needed vaccines.[28]

The NVAC Standards for Adult Immunization Practice call on all providers of health care to recommend immunizations. A strong recommendation from a health care provider can influence the outcome, resulting in a patient being administered a needed vaccine.[27] The elements leading to a strong recommendation are outlined in the Provider Self-Assessment of Strength of Immunization Recommendations, which is intended as a guide for providers to determine their current activities and approaches as well as identify areas for additional focus that will lead to consistency and strengthening of immunization recommendations.[26]

The ABM provides many opportunities to interact with the patient, share the pharmacist's assessment, and formulate a plan related to immunization needs. The plan should include pertinent areas of education for the patient, including education about vaccine-preventable diseases, vaccines, and how vaccines can help the patient, ensuring that myths are dispelled, and the patient has enough information and understanding to make a well-informed decision. Gaining patient understanding and support for a pharmacist's recommended plan is important. Respect of the patient's ultimate decision should be given. A pharmacist should include a plan to refer a patient if administration of the vaccine is outside the pharmacist's scope of practice or authority or if the vaccine is unavailable. The plan should also include a schedule for follow-up appointments for patients to complete any remaining doses in a vaccination series or to receive needed vaccines based on anticipated changes in age, health conditions, occupation, or lifestyle.[26]

Implement

A pharmacist implements the care plan in collaboration with a patient or caregiver and a physician or other health care professional, as appropriate. During the process of implementing the care plan, pharmacists must consider their state laws pertaining to their authority to immunize. Pharmacists should provide patient information, make vaccine recommendations, and provide the immunization when appropriate.[26] Ensuring that the receipt of the vaccination is documented within the patient medical records and the immunization registry is part of the NVAC Standards for Adult Immunization Practices.[27] Implementation of immunization services can be integrated into the ABM during the patient's routine pick-up appointment.

Follow-up: Monitor and Evaluate

Pharmacists who provide immunizations should have systems in place and training for appropriate monitoring and management of possible adverse reactions, which may range from injection-site reactions and syncope to more severe reactions, such as anaphylaxis.

A follow-up plan should be created for patients who may initially decline a vaccine recommendation, who may have temporary contraindications or precautions to a vaccination, or who were referred to another immunization provider.[26] Integrating some of the follow-up steps into future ABM-driven patient interactions can be an effective way to maintain the relationship with the patient and ensure their needs are met.

Expanded Immunization Program Implementation

Once a pharmacy's additional immunization services have been determined and aligned with the JCPP Pharmacists' Patient Care Process, the implementation team should form a plan for launching and improving the service. This includes identifying an implementation champion, educating and training involved staff, determining key tactics for communication and collaboration with other stakeholders, documenting care offered and provided, evaluating and improving the quality of the service, and ensuring patient privacy and confidentiality. Specific factors that the implementation team may want to think about before offering a new service are detailed in APhA's Questions to Consider When Expanding Pharmacy-Based Patient Care Services.

Identifying a Champion

Possibly the most critical step in establishing a new program or service is to appoint a pharmacist champion within the practice. This champion should take responsibility for planning and implementing the immunization service; ensuring that the practice is meeting established standards, guidelines, and best practices; and making certain that pharmacy personnel are trained and prepared to deliver enhanced immunization services. The immediate focus for the practice's immunization champion should be to evaluate needed resources (e.g., staffing, supplies, space, workflow accommodations). A valuable resource developed by the Immunization Action Coalition, Vaccinating Adults: A Step-by-Step Guide, provides comprehensive and practical information to help implement or enhance adult immunization services. The guide also includes resources and references to link pharmacists with current information on implementing immunization services.

Education and Training

As with all patient care services, it is important that all pharmacy staff have clinical confidence and competence to deliver the proposed service. Schools and colleges of pharmacy, state and national pharmacy associations, public health organizations, and many other entities have programs aimed at helping pharmacists and pharmacy team members develop and maintain their immunization-related knowledge and skills. It is crucial that all pharmacy staff who interact with patients provide consistent and accurate information.

The American Association of Colleges of Pharmacy has identified core entrustable professional activities for pharmacy graduates, which include having gained experience ensuring that patients have been immunized against vaccine-preventable diseases. The activities include determining whether a patient is eligible for and has received all CDC-recommended immunizations, administering and documenting CDC-recommended immunizations provided to adult patients, and the ability to perform basic life support if an adverse event occurs.[29]

APhA's Pharmacy-Based Immunization Delivery certificate training program (CTP) prepares pharmacists with the comprehensive knowledge, skills, and resources necessary to provide immunization services to patients across their lifespan. The program is based on national education standards for immunization training from the CDC. This practice-based training program emphasizes a health care team approach and seeks to foster the implementation of vaccine interventions to promote disease prevention and public health. APhA's Pharmacy-Based Immunization Delivery CTP is frequently required by state boards of pharmacy as a prerequisite to providing immunization services. Immunizing pharmacists must ensure continued competency on vaccine administration techniques. Pharmacists should commit to regular review of resources on specific vaccine injectors and information on how to administer intramuscular and subcutaneous vaccine injections.

Pharmacists involved in providing immunization services must keep up to date with new recommendations. Following ACIP recommendations is one way to remain current. The recommendations stand as public health guidance for safe use of vaccines and related biological products. CDC posts and regularly updates ACIP vaccine recommendations and guidelines. ACIP and APhA provide educational webinars as updates are implemented. These programs are available on www.pharmacist.com. Pharmacists may also subscribe to APhA's Immunizing Pharmacist e-newsletter, which is published bi-weekly.

Quality Assurance

Pharmacists are responsible for assuring appropriate quality control for vaccines delivered as part of their immunization services. The CDC's Vaccine Storage and Handling Toolkit provides information and resources to support proper storage and handling of vaccine supplies. The toolkit provides useful information for pharmacists, including:

- Vaccine organization and storage
- Vaccine temperature and storage equipment monitoring
- Vaccine inventory management, transport, and preparation
- Emergency storage, handling, and transport
- Vaccine storage and handling plans
- Standard operating procedures development

Collaboration and Communication

The immunization neighborhood strongly supports the sharing and exchange of immunization data and information. Communication should include connecting with the patient's primary care provider, if known, to ensure that the patient's immunization records are accurate and complete. All states have an IIS. These systems can help health care providers assess, document, and track patient immunization data, and the value of the IIS is optimized when all immunization providers report vaccinations to these systems. The IIS is vital for addressing gaps in immunization records and can be used to identify gaps in a patient's immunization history. These systems are also valuable during public health crises and natural disasters as patients and their health information may be displaced. Many states require pharmacies to report all vaccines administered to the registry. However, in some cases, pharmacists may not be provided access to these records, depending on the state or territory where they practice.

Documentation of Care Provided

Following administration of any vaccination, pharmacists should make an electronic report to the state/local IIS and provide notification to the patient's primary care provider, if known. It is the responsibility of both patients and their health care professionals to ensure that immunization records are up to date. Some patients may prefer to maintain an updated immunization record/card that they can personally share with members of their health care team. A sample immunization record can be found in APhA's Immunization Handbook for Pharmacists.

Patient Privacy and Confidentiality

As with any patient care service, patients have a right to expect that their privacy and confidentiality are respected and preserved. Privacy and confidentiality are core tenets of the pharmacy profession, and pharmacists must always comply with laws associated with privacy and confidentiality. As outlined in the Code of Ethics for Pharmacists, a pharmacist focuses on serving the patient in a private and confidential manner.[30] Pharmacists should have the appropriate space and facilities to provide immunization services. Spaces within the pharmacy where immunizations are provided should be private and convey a professional atmosphere. The space should also allow for provision of cardiopulmonary resuscitation, if needed, and room to safely provide the vaccine administration.

Conclusion

The ABM supports expansion of the depth and breadth of immunization services provided by pharmacists to adults and adolescents. Pharmacists can leverage the workflow optimization from innovative new practice models and strategies, such as the ABM, to complete a comprehensive vaccine assessment, encourage patients to receive needed vaccines, and administer vaccines as necessary. Pharmacists are well-positioned and prepared to provide immunization services beyond annual influenza vaccination. Moreover, patients are receptive to being vaccinated when the pharmacist engages in conversation regarding the patient's immunization status and provides clear recommendations for the vaccines that are needed. Pharmacists can play a significant role in ensuring that patients receive recommended vaccines at the recommended intervals across the lifespan, making a noble contribution to protecting people in their communities and safeguarding the public health.

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