

ASHP Guidelines on the Pharmacist's Role in Immunization

Purpose

Pharmacists can play an important role in disease prevention by advocating and administering immunizations. Such activities are consistent with the preventive aspects of pharmaceutical care and have been part of pharmacy practice for over a century.^{1,2} These guidelines address the pharmacist's role in promoting and conducting proper immunization of patients in all organized health care settings. The pharmacist's role in promoting disease prevention through participation in community efforts is also discussed.

Background

Each year, an average of 90,000 Americans die of vaccine-preventable infections such as influenza, pneumococcal disease, and hepatitis B.^{3,5} Most of these people visited health care providers in the year preceding their deaths but were not vaccinated.^{6–11} Influenza and pneumonia, considered together, are the fifth leading cause of death for Americans 65 years of age or older.¹² Although vaccination rates for U.S. children at the time they enter school exceed 95%, nearly 25% do not complete their primary series by the age of two years.¹³ Most American adults are inadequately vaccinated, particularly against pneumococcal disease, influenza, hepatitis B, tetanus, and diphtheria.⁶ Tens of millions of Americans remain susceptible to potentially deadly infections despite the availability of effective vaccines.

This long-standing failure to adequately immunize the U.S. population helped prompt the inclusion of immunization as a leading health indicator for Healthy People 2010.¹⁴ The renewed focus on immunization and the potential for increased vaccination needs in response to threats of bioterrorism should stimulate pharmacists, as well as other health care providers, to reassess what they and their institutions can do to improve immunization rates in their communities. Pharmacists can contribute to this effort by administering immunizations where scope of practice allows and by promoting immunization in other ways.

Immunization Administration

As health care providers, pharmacists can administer vaccines or host other health care professionals who can administer vaccines. Pharmacists must understand the legal and professional mechanisms by which authorization to administer vaccines is granted, as well as the additional responsibilities and considerations that accompany this expanded role. The feasibility of vaccine administration by pharmacists within a particular practice site or health care system can be determined by analyzing the issues of legal authority, training, and program structure.

Legal Authority. The pharmacist's authority to administer vaccines is determined by each state's laws and regulations governing pharmacy practice. At least 36 states permit vaccine administration by pharmacists as part of the scope of pharmacy practice.¹⁵ The American College of Physicians–American Society of Internal Medicine supports pharmacists as sources

of immunization information, hosts of immunization sites, and immunizers.¹⁶ Vaccine administration may occur pursuant to individual prescription orders or through standing orders or protocols. The Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices recommends the use of standing orders to improve adult immunization rates.¹⁷ Its recommendations encourage pharmacists, among other providers, to establish standing-order programs in long-term-care facilities, home health care agencies, hospitals, clinics, workplaces, and managed care organizations. The Centers for Medicare and Medicaid Services (CMS) no longer requires a physician order for influenza or pneumococcal immunizations administered in participating hospitals, long-term-care facilities, or home health care agencies.¹⁸ Development of state-specific protocols or standing-order programs can be facilitated through partnerships with state pharmacy associations, boards of pharmacy, and health departments.

Training. Although legal authority to administer vaccines may be granted through pharmacy practice acts, pharmacists must achieve competency in all aspects of vaccine administration. A comprehensive training program should address the following:

1. The epidemiology of and patient populations at risk for vaccine-preventable diseases,
2. Public health goals for immunization (e.g., local, regional, state, and federal goals),
3. Vaccine safety (e.g., risk–benefit analysis),
4. Screening for contraindications and precautions of vaccination in each patient,
5. Vaccine stability and transportation and storage requirements,
6. Immunologic drug interactions,
7. Vaccine dosing (including interpreting recommended immunization schedules and patient immunization records and determining proper dosing intervals and the feasibility of simultaneous administration of multiple vaccines),
8. Proper dose preparation and injection technique,
9. Signs and symptoms of adverse reactions to vaccines, adverse reaction reporting, and emergency procedures, such as basic and advanced cardiac life support (BCLS and ACLS),
10. Documentation,
11. Reporting to the primary care provider or local health department, and
12. Billing.

Live and videotaped programming is available through some state and national pharmacy associations and offered in many college of pharmacy curricula. Information regarding immunizations can change rapidly. To maintain competency, pharmacists must have access to current immunization references (e.g., CDC's National Immunization Program publications, including the "Pink Book"¹⁹) and continuing-education programs to stay abreast of evolving guidelines and recommendations.

Program Structure. A vaccine administration program requires a solid infrastructure of appropriately trained staff, physical space, and written policies and procedures to ensure appropriate vaccine storage and handling, patient screening and education, and documentation. The structure of a vaccine administration program must also provide for storage and disposal of injection supplies, disposal of and prevention of exposure to biological hazards as dictated by the Occupational Safety and Health Administration (OSHA), and emergency procedures (e.g., BCLS and ACLS). Pharmacists should be fully immunized to protect their health and the health of their patients.²⁰

Reimbursement. Immunization has repeatedly been shown to be cost-effective^{21–24}; it may be the most cost-effective practice in medicine. However, third-party reimbursement policies often do not provide coverage for recommended vaccines despite this evidence. A major exception is Medicare Part B, which not only covers immunization services for its participants but also recognizes and compensates pharmacists as mass immunization providers. Enrollment as a Medicare provider is required to bill for covered services. Provider status can be obtained through local Medicare offices, which also process CMS claims for reimbursement (CMS-1500 claims). The CMS Web site (www.cms.hhs.gov) is a useful source for billing information. Pharmacists should continue to closely monitor other immunization reimbursement policies and advocate third-party coverage for immunizations as a cost-effective preventive measure. For patients without insurance coverage, requesting out-of-pocket payments from the patient remains a viable option for pharmacists to obtain compensation for their immunization services.

Immunization Promotion

Pharmacists who do not administer vaccines can promote immunization through six types of activities: (1) history and screening, (2) patient counseling, (3) documentation, (4) formulary management, (5) administrative measures, and (6) public education.^{25,26} These promotional activities can also be integrated into or accompany a pharmacy-based immunization program.

History and Screening. Pharmacists can promote proper immunization by identifying patients in need of immunization. Tasks that support this objective include gathering immunization histories, encouraging use of vaccine profiles, issuing vaccination records to patients,^{27–34} preventing immunologic drug interactions,^{35,36} and screening patients for immunization needs.^{28–33,37–39}

Immunization screening should be a component of all clinical routines, regardless of the practice setting. All health care institutions should implement consistent, systematic monitoring systems and quality indicators to ensure that all patients are assessed for immunization adequacy before they leave the facility. The health care provider designated to identify patient immunization needs should have the authority, knowledge, and responsibility to provide or arrange for the immunization service.⁴⁰ Clinics that provide treatment for a large number of patients at high risk for contracting vaccine-preventable diseases (e.g., diabetic, asthmatic, heart disease, and geriatric clinics) have a particular obligation to employ immunization screening and ensure appropriate vaccine use.

Screening for immunization needs may be organized in several ways; prototype screening forms are available.^{39,41}

Pharmacists should seek out leadership roles in some or all of the following forms of immunization screening.

Occurrence screening. With this type of screening, vaccine needs are identified at the time of particular events, such as hospital or nursing home admission or discharge, ambulatory care or emergency room visits, mid-decade birthdays (e.g., years 25, 35, and 45),^{42,43} and any contact with a health care delivery system for patients under 8 years or over 50 years of age.

Diagnosis screening. This screening reviews the vaccine needs of patients with conditions that increase their risk of preventable infections. Diagnoses such as diabetes, asthma, heart disease, acute myocardial infarction, congestive heart failure, chronic obstructive pulmonary disease, hemophilia, thalassemia, most types of cancer, sickle cell anemia, chronic alcoholism, cirrhosis, human immunodeficiency virus infection, and certain other disorders should prompt specific attention to the patient's vaccine needs.^{12,33,42} The immunization rate for patients diagnosed with community-acquired pneumonia is considered a marker for quality by some accrediting bodies. Incorporating assessment of vaccination status into an institution's critical pathways has been shown to improve vaccination rates.⁴⁴

Procedure screening. Immunization needs are assessed on the basis of medical or surgical procedures using this type of screening. These procedures include splenectomy, heart or lung surgery, organ transplantation, antineoplastic therapy, radiation therapy, immunosuppression of other types, dialysis, and prescription of certain medications used to treat conditions that increase patients' risk of preventable infections.^{45,46} When designing and implementing automated prescription databases, pharmacy managers should consider specifications that allow retrieval of lists of patients receiving drugs that suggest the need for immunization.^{33,37}

Periodic mass screening. This type of screening is a comprehensive assessment of immunization adequacy in selected populations at a given time. Such screening may be conducted, for example, during autumn influenza programs or outbreaks of certain vaccine-preventable illnesses (e.g., measles and meningococcal disease).^{29,32,33} Schools and other institutions can perform mass screening when registering new students or residents. Mass screening may also be appropriate in areas where no comprehensive immunization program has been conducted recently. This type of screening helps improve vaccine coverage rates at a given time, but long-term benefits are much greater when such intermittent programs are combined with ongoing comprehensive screening efforts. Several states, including South Dakota, New Jersey, and Oklahoma, have enacted laws requiring that influenza and pneumococcal vaccines be offered annually to residents of nursing homes.

Occupational screening. This screening method focuses on the immunization needs of health care personnel whose responsibilities place them at risk of exposure to certain vaccine-preventable diseases or bring them into contact with high-risk patients (i.e., patients with those conditions listed in the *Diagnosis screening* section above). Health care providers who have contact with these patients should receive an annual influenza vaccination. Health care employers frequently provide immunization screening and vaccination of employees as part of employee health programs. OSHA requires that health care employers provide hepatitis B vaccination at no cost, on a voluntary basis, to all employees at risk for occupational exposure to blood borne pathogens.⁴⁷ Depending on their risk of exposure, it may be advisable for

members of the pharmacy staff to receive hepatitis B vaccination.

Screening for contraindications and precautions. After candidates for immunization have been identified, they should be screened for contraindications and precautions. A CDC-reviewed contraindication screening questionnaire is available.⁴⁸

Patient Counseling. Patients in need of immunization should be advised of their infection risk and encouraged to accept the immunizations they need. Patient concerns about vaccine safety and efficacy should be discussed and addressed.^{49,50} Health care providers can influence patients' attitudes regarding immunization.^{51,52} Physicians should be informed of their patients' need for vaccination if standing orders or collaborative practice agreements are not in place. Patients who need immunizations should be vaccinated during the current health care contact unless valid contraindications exist. Delaying vaccination until a future appointment increases the risk that the patient will not be vaccinated.

Advising patients of their need for immunization can take several forms. In the ambulatory care setting, individualized or form letters can be mailed to patients, patients can be called by telephone, or an insert can be included with prescriptions informing patients of their infection risk and the availability and efficacy of vaccines.^{30,33,53–55} Adhesive reminder labels can also be affixed to prescription containers for drugs used to treat conditions that may indicate the need for vaccination against influenza and pneumococcal disease (e.g., digoxin, warfarin, theophylline, and insulin³³); these labels would be analogous to labels currently in widespread use (e.g., "Shake well" and "Take with food or milk"). Such labels might read, "You may need flu or pneumonia vaccine: Ask your doctor or pharmacist." Chart notes, consultations, messages to patients, one-on-one conversations, and similar means can be used to communicate with inpatients and institutional patients.^{28,31,56}

Federal law requires that health care providers who administer diphtheria, tetanus, pertussis, measles, mumps, rubella, varicella, polio, *Haemophilus influenzae* type B, hepatitis B, and pneumococcal conjugate vaccines give the most recent version of the CDC-developed Vaccine Information Statement (VIS) to the adult or the parent or legal guardian of the child to be vaccinated.⁵⁷ VISs are available in many languages from state or local health departments or the CDC.⁵⁸ VISs are also available for other commonly used vaccines, such as influenza, pneumococcal polysaccharide, hepatitis A, meningococcal, and anthrax vaccines. Pharmacists should also ensure that informed consent is obtained in a manner that complies with state laws.²⁰

Documentation. The National Childhood Vaccine Injury Act of 1986 (NCVIA) requires all health care providers who administer vaccines to maintain permanent vaccination records and to report occurrences of certain adverse events specified in the act.^{57,59} The recipient's permanent medical record (or the equivalent) must state the date the vaccine was administered, the vaccine's manufacturer and lot number, and the name, address, and title of the person administering the vaccine. Pharmacists in organized health care settings may encourage compliance with this requirement by providing reminder notices each time doses of vaccines are dispensed.⁶⁰ Automated databases that allow for long-term storage of patient immunization information may provide an

efficient method for maintaining and retrieving immunization records.³⁹ Efforts to develop electronic vaccination registries, especially for children, are under way by states collaborating with CDC.⁶¹

NCVIA also mandates that selected adverse effects noted after any inoculation be reported to the Vaccine Adverse Event Reporting System (www.vaers.org).^{57,59,62} Because pharmacists have experience with adverse-drug-reaction reporting, they can take the lead in developing and implementing a program to meet this requirement, even if they are not responsible for administering the vaccine.

Patients should maintain personal immunization records that document all immunization experiences and function as a backup if the clinicians' immunization records are lost. Several personal immunization record forms are available. Public Health Service Form 731 (International Certificate of Vaccination), colloquially called the "yellow shot record," is used to document vaccines indicated for international travel but can also serve as a patient's personal record of vaccinations. The Immunization Action Coalition distributes a standard adult immunization record card developed in collaboration with CDC.⁶³ In addition, each state and the District of Columbia prints its own uniform immunization record form for pediatric immunizations, which may also be a suitable personal patient record. It has been recommended that adults carry personal immunization records in their wallets.⁴⁶

Formulary Management. Formulary systems in organized health care settings should include vaccines, toxoids, and immune globulins available for use in preventing diseases in patients and staff. Decisions by the pharmacy and therapeutics committee (or its equivalent) on immunologic drug choices require consideration of relevant immunologic pharmacetics, immunopharmacology, and disease epidemiology. Because of their expertise and training, pharmacists are well equipped to provide information and recommendations on which these decisions may be based.

It is the pharmacist's responsibility to develop and maintain product specifications to aid in the purchase of drugs under the formulary system.^{64,65} The pharmacist should establish and maintain standards to ensure the quality, proper storage, and proper use of all pharmaceuticals dispensed. Pharmacists must choose between single dose or multidose containers of vaccines on the basis of efficiency, safety, economic, and regulatory considerations. Pharmacists in institutions should develop guidelines on the routine stocking of immunologic drugs in certain high-use patient care areas.

Proper transportation and storage are an important consideration for immunologic drugs, including vaccines, because many require storage at refrigerated or frozen temperatures. Pharmacists have an important responsibility to maintain the "cold chain" in the handling of these drugs. Detailed references on this topic have been published.^{66–73} Storage considerations include the conditions in all areas in which immunologic drugs are kept, as well as a method for ensuring that immunologic drugs received by the pharmacy have been transported under suitable conditions.

It is important that methods be established for detecting and properly disposing of outdated and partially administered immunologic agents. Live viral (e.g., varicella, yellow fever, and smallpox) and live bacterial (e.g., bacille Calmette-Guérin) vaccines should be disposed of in the same manner as other infectious biohazardous waste.

Administrative Measures. Pharmacists on key committees (e.g., infection control and risk management) in organized health care settings can promote adequate immunization delivery among staff and patients by encouraging the development of sound organizational policies on immunization. Health care organizations should develop policies and protocols that address the following:

1. Hepatitis B preexposure prophylaxis for health care workers at risk for exposure to blood products and other contaminated items,^{45,74–76}
2. Hepatitis B postexposure (e.g., needle stick) prophylaxis for previously unvaccinated patients, health care personnel, and personnel who have been vaccinated but do not have a previously documented serologic response,^{45,74–76}
3. Rabies preexposure and postexposure prophylaxis,⁷⁷
4. Wound management guidelines designed to prevent tetanus and diphtheria,^{78,79}
5. Valid contraindications to vaccination to ensure patient safety and minimize inappropriate exclusions from vaccination,^{78,80,81}
6. Requirements for employee immunization against measles, rubella, influenza, and other diseases,^{42,82}
7. Tuberculosis screening of patients and staff,^{83,84}
8. Immunization of persons at high risk (e.g., patients with diabetes, asthma, heart disease, and pregnant or immunocompromised patients). Current authoritative guidelines on this subject should be consulted,^{42,46,58,85,86} and
9. Emergency measures in the event of vaccine-related adverse reactions. Such measures should address the availability of epinephrine and other emergency drugs, as well as BCLS and ACLS.

Public Education. Pharmacists have ample opportunities to advance the public health through immunization advocacy. Pharmacists can facilitate disease prevention strategies, because many potential victims of influenza and pneumococcal disease visit pharmacies and are seen by pharmacists daily. Pharmacists can lead local activities in observance of National Adult Immunization Week each October.³⁷ Working with local public health departments, state or national immunization coalitions, and other groups (e.g., state or local parent—teacher, diabetes, heart, lung, or retired persons' associations), pharmacists can promote vaccination among high-risk populations. Newsletters, posters, brochures, and seminars may be used to explain the risk of preventable infections to pharmacy staff, other health care personnel, and patients. Excellent resources are available from the Immunization Action Coalition and the National Coalition for Adult Immunization.

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These guidelines were reviewed in 2013 by the Council on Pharmacy Practice and by the Board of Directors and were found to still be appropriate.

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