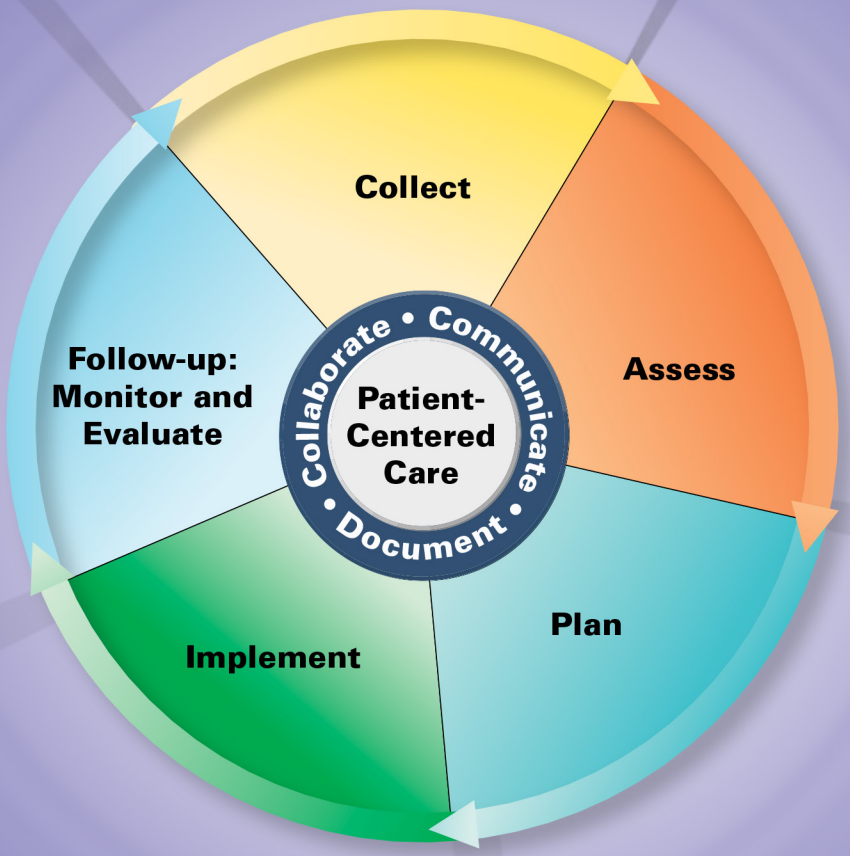
Applying the Pharmacists' Patient Care Process to

Immunization Services

A Resource Guide for California Pharmacists



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RESOURCES

Immunization Action Coalition (IAC) Screening Checklist for Contraindications to Vaccines for Adults - http://www.immunize.org/catg.d/p4065.pdf

Assess

- ☐ Assess immunization needs based on age, gender, health conditions, and immunization history.
- ☐ Assess IIS* records, patient records, and other sources of records.
- ☐ Assess precautions and contraindications to needed vaccine(s) (responses to Screening Questionnaire).

RESOURCES

CDC Adult Immunization Schedules - https://www.cdc.gov/vaccines/schedules/hcp/adult.html

California Dept. of Public Health (CDPH) Pneumococcal Vaccine Timing For Adults - http://eziz.org/assets/docs/IMM-1152.pdf

CDC Checklist for Determing Recommended Vaccines - http://www.cdc.gov/vaccines/hcp/adults/downloads/patient-intake-form.pdf

Plan

- ☐ Strongly recommend needed vaccine(s).
- ☐ Offer to administer vaccine or refer the patient to another health care provider who can and will administer the vaccine(s).

RESOURCES

Natl. Adult and Influenza Immunization Summit Quick Guide to Adult Vaccine Messaging - https://www.izsummitpartners.org/wp-content/uploads/2014/05/AdultVaccineMessaging2.pdf

Implement

- ☐ Provide patient education and Vaccine Information Statements (VIS).
- ☐ Administer needed vaccine(s) (or refer to an immunizing provider if you do not immunize or do not have authority to administer).
- ☐ Provide documentation to patient, patient's primary care provider (if known), and record in pharmacy records and state IIS*.

RESOURCES

CDC Vaccine Information Statements - https://www.cdc.gov/vaccines/hcp/vis/

IAC Administering Vaccines to Adults: Dose, Route, Site, and Needle Size - http://www.immunize.org/catg.d/p3084.pdf

CDPH Vaccine Administration Record - http://eziz.org/assets/docs/IMM-542P.pdf

CA Immunization Registry (CAIR) webpage for pharmacies - http://cairweb.org/home/pharmacies-and-cair/

CDPH Prenatal Flu/Tdap Flyer - http://eziz.org/assets/docs/IMM-1146.pdf

Follow-Up

- ☐ Monitor patient for 15 minutes after administration of vaccine(s) for syncope or adverse reactions.
- ☐ Schedule follow-up for subsequent doses of multidose vaccine series.
- ☐ Refer patient for other health, wellness, or follow-up services to their identified primary care provider or another provider (provide patient with documentation of referral).

RESOURCES

Medical Management of Vaccine Reactions in Adult Patients - http://www.immunize.org/catg.d/p3082.pdf

Vaccine Adverse Event Reporting System (VAERS) - https://vaers.hhs.gov/index

National Vaccine Errors Reporting Program (VERP) - http://verp.ismp.org/

*IIS=Immunization information system (aka registry)

Introduction

An estimated 40,000 to 50,000 adults die annually from vaccine-preventable disease in the United States.[1] Adult vaccination rates for routine recommended vaccines in the United States are low, and well below projected Healthy People 2020 targets.[2] The underuse of these widely available vaccines has created an opportunity for pharmacists to play a role in improving immunization rates and thus advancing public health.

Pharmacy-based vaccination services are provided by pharmacists trained in immunization delivery and provide a convenient and accessible option for receiving immunizations. A pharmacist's role in immunization practice has been described to include education, facilitation, and immunization. Examples of pharmacists serving in these immunization roles with successful outcomes are numerous. However, all pharmacists in the United States can now be active immunizers.

Pharmacists employ many different models and workflow practices in the delivery of pharmacy-based immunization services. To enhance immunization needs assessment, pharmacists may be able to use two electronic tools: the pharmacy dispensing system and their state or local immunization information system (IIS). An IIS, or immunization registry, as defined by the CDC "…are confidential, population-based, computerized databases that record all immunization doses administered by participating providers to persons residing within a given geopolitical area." Although this technology is deployed throughout the United States, participation is low among adult providers, but improving as Electronic Medical Record (EMR) and IIS systems and vaccine delivery to adults expands and improves. Thus, pharmacists must rely on multiple sources of information to construct a complete immunization history. As the IISs improve, they increasingly communicate directly with electronic health record systems in medical clinics and eventually will deal directly with the pharmacy dispensing system. Making these immunization records easily accessible to patients and all immunization providers is a goal of the Centers for Disease Control and Prevention (CDC) and other provider groups, such as the American Pharmacists Association (APhA). More information on IIS can be found at the American Immunization Registry Association (AIRA) website: www.immregistries.org/.

The term *Immunization Neighborhood* originated with the APhA and is gaining acceptance by immunization stakeholders. It is defined as "collaboration, coordination, and communication among immunization stakeholders dedicated to meeting the immunization needs of the patient and protecting the community from vaccine-preventable diseases."[3] This document will touch on all of these aspects as they are embedded within the Patient Care Process. Thus, it focuses on applying the Pharmacists' Patient Care Process (PPCP) of the Joint Commission of Pharmacy Practitioners (JCPP) to the provision of pharmacy-based immunization services.[4] The PPCP approach maximizes a pharmacist's role within health care delivery models that are collaborative and team based.

This guidance document has been written and formatted to align comprehensive components of a pharmacy-based immunization patient encounter

and recommendations from the National Vaccine Advisory Committee (NVAC) the Standards for Adult Immunization Practice with the original framework of the PPCP.[5] The colored columns to the right throughout this document are the PPCP steps as they have been published by JCPP, and the main document text describes how to integrate each PPCP step into immunization services.

Using principles of evidence-based practice for immunizations, a pharmacist proceeds as follows.

Collect

A pharmacist ensures the collection of necessary information about a patient to determine which vaccinations may be indicated, and screens for contraindications and precautions to administering those vaccines.

Necessary Information

A pharmacist should collect information from a patient that may support decision-making about specific vaccines that may be indicated for the patient based on current recommendations of the CDC's Advisory Committee on Immunization Practices (ACIP).[6] The following information will help in making decisions about vaccines indicated for special populations:

- Age
- Health conditions
- Occupation
- Travel
- Lifestyle

The CDC has produced a questionnaire checklist that targets these factors and can be used to collect this set of information (www.cdc.gov/vaccines/hcp/adults/downloads/patient-intake-form.pdf)[7].

A pharmacist should also collect information to determine if a patient may safely receive the recommended vaccines at that point in time. Necessary patient information to collect for screening for contraindications and precautions to vaccines is as follows:

- Current health status
- Present and past medical history
- Allergies
- Medications
- Vaccination history
- Pregnancy status (for women)

Collect[4]

"The pharmacist assures the collection of necessary subjective and objective information about the patient in order to understand the relevant medical/medication history and clinical status of the patient. Information may be gathered and verified from multiple sources, including existing patient records, the patient, and other health care professionals. This process includes collecting:

- A current medication list and medication use history for prescription and nonprescription medications, herbal products, and other dietary supplements
- Relevant health data that may include medical history, health and wellness information, biometric test results, and physical assessment findings
- Patient lifestyle habits, preferences, beliefs, health and functional goals, and socioeconomic factors that affect access to medications and other aspects of care"

A pharmacist is able to effectively collect this information from a patient using a screening checklist, such as the one available from the Immunization Action Coalition (www.immunize.org/catg.d/p4065.pdf)[8], before administering the vaccine.

Sources of Information

The information above may be gathered and verified from multiple sources including a patient's personal immunization record, state IIS, pharmacy dispensing system records, primary care providers (PCP), and patients' statements. Where possible, links that facilitate access to information electronically (e.g., patient electronic health record, immunization information systems, etc.) should be established. Use of multiple sources, if available, is important because each source has its own advantages and limitations.

Immunization Information Systems

An IIS gathers data on patients' immunization records from a variety of immunization providers with the goal of compiling a complete patient immunization record for continuity of care and public health interests. If all vaccine providers universally used their state IIS, it would be the most reliable source of a patient's immunization history, and each provider would have access to the information as needed. However, variability exists from state IIS to state IIS with regard to whether documentation is mandatory or voluntary, which providers are included, which age groups are required or even allowed to be documented, which vaccines are required, which vaccines are allowed to be entered, and how much historical immunization data the system contains. Immunization information systems that do not require all providers' names and all vaccines to be entered provide an incomplete record of a patient's immunization status, possibly leading to under- or over-vaccination. The efforts of federal, state, and local governments, together with the private sector, to provide meaningful, seamless, and multidirectional use will lead to greater value and application of the IIS data. Another limitation of IIS is the lack of connection of IIS information between states, and sometimes between counties within the same state, preventing providers' access to records outside their county or state.

Personal Immunization Record

A patient's personal immunization record (yellow card, immunization record card, patient record printout, etc.), if current, is a good source of immunization information. If a patient has this record, all immunization providers should be either directly updating that record or providing documentation, potentially making it the most comprehensive record. However, using a patient's personal immunization record has limitations: the patient may have multiple cards and the patient may fail to bring any records to the visit, or the cards may have been lost or misplaced. Educating patients regarding the importance of having ready access to their medication and vaccination records is important.

Pharmacy Dispensing System

The pharmacy dispensing system can be a valuable source of information, including a patient's allergies, age, demographics, and medications (used for determining an inferred diagnosis). An inferred diagnosis is an assumption made about a patient's disease state(s) based on their medications. For example, if a patient has insulin listed on their medication profile, he or she is likely to have diabetes. However, for drugs with multiple indications, a pharmacist will still need to verify the diagnosis with the patient or PCP. Another limitation of this system

is that immunization information is representative of only one pharmacy or some chain pharmacies may have access to information from multiple stores, but only within that organization. Immunization information may be missing from a patient's history if the pharmacy dispensing system purges patient data after a defined number of years. The pharmacy dispensing system could provide access to information that can be used to proactively communicate with patients in need of vaccination.

Other Health Care Providers

A pharmacist can also obtain information by contacting a patient's PCP, if one exists, or other immunization providers. However, a PCP may not always receive communications from other immunization providers if a patient has received immunizations elsewhere and therefore may have an incomplete record of the patient's immunization history. Also, contacting a PCP can be a time-consuming process, and the lag time in getting the information can be a barrier when a patient is at the pharmacy and ready to receive a vaccine. Ideally, the ability to exchange clinical information, such as vaccine status, electronically would assist pharmacists in assessing a patient's immunization status and reduce the administrative burden caused by telephonic and fax requests to physicians and their staff.

Patient-Provided History

Finally, a pharmacist may have to gather immunization information directly from a patient, caregiver, or family member, although with some possibility of error in the accuracy or completeness of the patient's recollections. Patients may readily be able to inform a pharmacist of current medical diagnoses, allergies, and medications, but the ability to recall immunization history and doses received is often challenging and inaccurate. Pharmacists should ask patients, family members, or a caregiver if they have an immunization record card or other documentation.

Assess

A pharmacist assesses the information collected and analyzes the need for vaccines in accordance with ACIP recommendations. The following are areas to consider in determining which vaccines are indicated for a patient.

Assess Patients' Vaccine Needs

Pharmacists should consider the following, as applicable, when determining which vaccines a patient needs.

- **Age**: ACIP-recommended immunization schedules list the age or age range when routine vaccinations should be received.[6] The CDC publishes two age-based routine vaccination tables for those from birth through age 18 years and for those 19 years and older. Within these CDC tables, age categories are further divided into recommendations based from birth to 6 years, 7 years through 18 years, 19 years and older, 60 years and older, and 65 years and older. For example, all people age 65 years and older should receive both the pneumococcal conjugate (PCV13) and pneumococcal polysaccharide (PPSV23) vaccines, and people 60 years of age and older should receive the zoster vaccine. Age is also important for vaccines with upper or lower age limits. In addition, a pharmacist's authority to administer a vaccine may be dependent on a patient's age.
- **Health conditions**: Whereas some medical conditions serve as a contraindication to certain vaccines (see the section titled "Screen for Contraindications and Precautions to Vaccines" in this document for an explanation), these

4 Assess

"The pharmacist assesses the information collected and analyzes the clinical effects of the patient's therapy in the context of the patient's overall health goals in order to identify and prioritize problems and achieve optimal care. This process includes assessing:

- Each medication for appropriateness, effectiveness, safety, and patient adherence
- Health and functional status, risk factors, health data, cultural factors, health literacy, and access to medications or other aspects of care
- Immunization status and the need for preventive care and other health care services, where appropriate"

same conditions may be an indication for the use of other vaccines. For example, pregnant women should receive a vaccine for tetanus, diphtheria, and pertussis (Tdap) during the third trimester of each pregnancy, and patients with an immunocompromising condition should receive pneumococcal vaccines. Other conditions or factors specifically identified by the CDC for vaccine recommendation include asplenia and persistent complement component deficiency; certain chronic diseases (diabetes, heart disease, lung disease, renal failure, liver disease), human immunodeficiency virus (HIV) and other immunocompromising conditions, cochlear implant candidate or recipient, and cerebral spinal fluid leaks.

- **Lifestyle**: Certain lifestyle factors and social history may indicate the need for a particular vaccination. For example, intravenous drug users and men who have sex with men should be vaccinated with hepatitis A and B vaccines, and patients with alcoholism and cigarette smokers should receive the PPSV23 vaccine. Other lifestyle factors that may indicate the need for vaccination are patients who were born outside the United States, are not in a long-term mutually monogamous relationship, or are in close contact with an international adoptee. College students living in dorms are at increased risk for meningococcal disease and should receive meningococcal (MCV4 before college and possibly MenB [serogroup B meningococcal]) vaccine.

- **Occupation:** Health care workers with exposure to blood and certain lab workers may be at increased risk for certain vaccine-preventable diseases. For example, health care workers should receive a complete series of the hepatitis B vaccine, and laboratory workers routinely exposed to isolates of *Neisseria meningitidis* are recommended to receive the meningococcal vaccine.

- **Travel**: International travel carries a risk of contracting not only vaccine-preventable diseases that occur domestically and abroad, but also some diseases found only in other countries. Some vaccine-preventable diseases, such as polio and diptheria, have been eliminated in the United States, but still occur in other countries. Endemic transmission of measles has been interrupted in the United States, but other developed countries, such as some in Europe, have diminished vaccination rates with a subsequent resurgence of disease. Other serious diseases such as typhoid, rabies, yellow fever, and Japanese encephalitis are indicated specifically for international travelers depending on their itinerary and activity. Proof of yellow fever vaccine may be required for entry into some countries and, when required, must be given at least 10 days before arrival. Travelers should make an additional appointment with a travel provider, or be referred to one, for a pre-travel consultation to ensure proper assessment, education, and management of potential health risks. The CDC Travelers' Health webpage (wwwnc.cdc.gov/travel/destinations/list)[10] and *CDC Health Information for International Travel* book (commonly called the Yellow Book)[11] provide vaccine and medication recommendations for specific destinations. Pharmacists across the country are serving as providers of travel health services.

It is important to proactively and regularly assess whether patients have had lifestyle, health, or occupational changes that may prompt the need for additional vaccines. A pharmacist should review

current ACIP vaccine recommendations before deciding to vaccinate patients who have been identified as eligible for vaccination.[12]

Screen for Contraindications and Precautions to Vaccines

Pharmacists should screen patients for the following before administering vaccinations:

- **Current health status**: Patients with moderate to severe acute illness should have all vaccines delayed until the illness has improved. Patients experiencing mild illnesses (e.g., diarrhea, upper respiratory infections, low-grade fever) or taking antibiotics are not contraindicated to receive vaccination. Discussions with or referral to a patient's PCP may be appropriate.
- **Allergies:** Allergies to medications, food, vaccine components, and latex should be assessed at each vaccination encounter. A patient's anaphylactic reaction to a previous dose of vaccine is a contraindication for subsequent doses. Vaccines with latex components or latex packaging (e.g., vial stoppers, syringe caps, syringe plungers) are contraindicated in patients with a history of anaphylactic reaction to latex. For an egg allergy in relation to the influenza vaccine, pharmacists should follow the CDC recommendations for influenza vaccination of people with a history of egg allergy[13], and the allergy is not necessarily a contraindication. A patient's history of anaphylactic reaction to gelatin is a contraindication to vaccination with gelatin-containing vaccines (e.g., standard trivalent inactivated influenza vaccine (IIV); live attenuated influenza vaccine (LAIV); measles, mumps, and rubella [MMR] vaccine).

  For a list of components in specific vaccine products (e.g., thimerosal, neomycin, polymyxin), refer to the CDC Pink Book, Appendix B (www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/appdx-full-b.pdf)[14], or the product's package insert.

- **Present and past medical history:** Some aspects of a patient's medical history may contraindicate or indicate the use of a particular vaccine. For example, a patient who is severely immunocompromised may be contraindicated for receiving an MMR (live) vaccine, but that very condition would be an indication for pneumococcal and influenza vaccines.

  History of neurological disease may be a precaution or contraindication to use of certain vaccines. The diphtheria, tetanus, and pertussis (DTaP) and Tdap vaccines are contraindicated for children who have a history of encephalopathy not attributed to an identifiable cause within seven days following administration of DTP (diphtheria, tetanus, and pertussis) and DTaP. An unstable progressive neurologic problem is a precaution to the use of DTaP and Tdap. A history of Guillain-Barré syndrome is a precaution for tetanus-containing and influenza vaccines. Patients with a personal or family history of febrile or afebrile seizures have a precaution for MMRV (measles, mumps, rubella, and varicella) vaccine. Simultaneous administration of single component MMR and single component varicella vaccine is an acceptable alternative for these patients.

- **Medications:** Patients being treated with immune globulin; chemotherapy; long-term, high-dose steroids and other immunosuppressive drugs (e.g., anti–tumor necrosis factor agents, adalimumab,

infliximab, etanercept); or radiation treatments in the past three months should postpone live-virus vaccines until immunosuppressive therapy has ended. MMR and varicella-containing vaccines should be postponed in patients who may have received a blood transfusion or certain blood products within the past 10 months.

Pharmacists should consult the most current ACIP recommendations for up-to-date information on intervals between live virus vaccines and immunosuppressive drugs, antiviral drugs, immune globulin, or blood product administration.

- **Vaccination history**: Determination of previous vaccines administered helps a pharmacist determine needed vaccines and appropriate spacing and timing of subsequent doses. For example, a pharmacist should assess if a patient has received any vaccines in the past four weeks, has had any serious reactions to vaccines, and has previously received the requested or recommended vaccine. Patients who have received either an injectable live-virus vaccine or LAIV in the past four weeks should wait 28 days before being administered another live-virus vaccine. Additionally, for a vaccine series or booster schedule, a pharmacist needs to determine the appropriate interval between doses based on a patient's vaccination record to determine when the next dose should be given or if a mistimed dose can be counted.

- **Altered immune competence:** Pharmacists should determine if patients have cancer, leukemia, HIV, AIDS (acquired immune deficiency syndrome), or other immune system conditions that may render them immunocompromised before administering live-virus vaccines (e.g., LAIV, MMR, varicella, zoster). With few exceptions (e.g., MMR in people with a CD4 count > 200 cells/μL), live-virus vaccines are contraindicated in immunocompromised patients.[15] Certain medications, as described earlier, may cause immunosuppression and thus leave a patient immunocompromised. Patients with asplenia, cochlear implants, and cerebral spinal fluid leaks are at risk for certain bacterial diseases, such as pneumococcus and meningococcus, but they are not considered immunocompromised and may receive live vaccines.

- **Pregnancy status**: For women of childbearing age, a pharmacist should verify with a patient whether she is pregnant or plans to become pregnant during the next month. Live-virus vaccines are contraindicated during pregnancy because of the theoretical risk of virus transmission to the fetus. Sexually active women who receive a live-virus vaccine should be instructed to practice contraception for one month following receipt of the vaccine.

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. Research indicates that a health care provider's recommendation is the strongest predictor of whether patients get vaccinated. Therefore, a pharmacist's plan to make a clear and strong recommendation to patients, whether they provide immunizations at their pharmacy or not, is important. Development of the recommendation occurs during the plan development phase and is reinforced within the plan implementation phase. The administration or referral occurs during the plan implementation phase of the process.

A patient-centered care plan includes a discussion with a patient to determine that patient's individual needs before formulating recommendations. 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 that 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.

Although many patients are motivated to action by a strong recommendation and the science underlying

Plan[4]

"The pharmacist develops an individualized patient-centered care plan, in collaboration with other health care professionals and the patient or caregiver that is evidence-based and cost-effective. This process includes establishing a care plan that:

- Addresses medication-related problems and optimizes medication therapy
- Sets goals of therapy for achieving clinical outcomes in the context of the patient's overall health care goals and access to care
- Engages the patient through education, empowerment, and self-management
- Supports care continuity, including follow-up and transitions of care as appropriate"

the need for vaccination, other aspects such as cultural beliefs and health literacy should be considered when communicating with patients. For example, in the Hispanic community, research indicates that the key values are family, religion, interpersonal relationships, respect, and hierarchy. The National Influenza Vaccination Disparities Partnership (www.cdc.gov/flu/partners/disparities.htm)[16] has several training resources for vaccine providers, and the Immunization Action Coalition has several resources for providers and patients with regard to risk communication topics, including talking about religious concerns (www.immunize.org/talking-about-vaccines/religious-concerns.asp)[17].

For pharmacy-based vaccination services, a limited number of health plans offer patients coverage for receiving vaccinations from a pharmacy, and, even when provided, they may not always cover all recommended vaccines. For example, vaccines may be covered only under a patient's medical benefit or pharmacy benefit, or sometimes covered under both benefits; and some vaccines are covered in the pharmacy under Medicare Part B or D. In the discussion of the plan, the pharmacist should address billing and cost-sharing with the patient because out-of-pocket costs may influence the patient's decision to receive the vaccine at this time, or to receive it from their PCP if their vaccine coverage is restricted to medical benefits[14].

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. A follow-up plan should also be created for patients who may initially decline a vaccine recommendation, who may have temporary contraindications or precautions to vaccination, or who were referred to another immunization provider.

According to the CDC, when in doubt about previous vaccination status, vaccinate!

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. Laws vary among states with regard to the need for a protocol, standing orders, or a prescription to administer a vaccine along with a potential minimum age limit and varying type of vaccines a pharmacist is authorized to administer. Information on current state laws pertaining to pharmacist authority to immunize is updated regularly on APhA's Immunization Center webpage (www.pharmacist.com/immunization-center)[18].

Provide Patient Information

In accordance with state and federal laws, a pharmacist should implement the plan by providing the patient with education and the appropriate and current Vaccine Information Statement (VIS) and administering all needed vaccines to the patient at the time of the encounter according to current guidelines. For patients whose primary language is not English, the Immunization Action Coalition has VIS documents in numerous languages (www.immunize.org/vis/)[19].

Make the Recommendation

Some patients may require more than just a statement that they need the vaccine before accepting the vaccination. Thus, providing a persuasive recommendation that includes information tailored

Implement[4]

"The pharmacist implements the care plan in collaboration with other health care professionals and the patient or caregiver. During the process of implementing the care plan, the pharmacist:

- Addresses medication- and health-related problems and engages in preventive care strategies, including vaccine administration
- Initiates, modifies, discontinues, or administers medication therapy as authorized
- Provides education and self-management training to the patient or caregiver
- Contributes to coordination of care, including the referral or transition of the patient to another health care professional
- Schedules follow-up care as needed to achieve goals of therapy"

specifically to a patient on why the vaccine is recommended and highlights consequences of the vaccine-preventable disease to the patient and the benefits offered by the vaccine may result in a better acceptance of a pharmacist's recommendation. For example, a strong recommendation, "I strongly recommend that you receive the pneumococcal vaccine today because it can protect you from diseases caused by pneumococcal bacteria, including pneumonia. These diseases could be very serious for you now that you are older," may be more persuasive than a passive recommendation, "You might want to consider getting the pneumococcal vaccine because you are over age 65." An assessment survey developed by APhA is provided as Appendix A on p. 23 of this document. This resource is intended to be used as a guide to determine current activities and approaches and also identify areas for additional focus.

For more hesitant patients, parents, and caregivers, the strong recommendation can be combined in a pneumonic known as CASE: **C**orroborate, **A**bout me, **S**cience, and **E**xplain/advise. Using the pneumococcal example from above, a pharmacist can make the CASE for immunization: "I understand you are concerned that this vaccine may not be safe given your health condition. Because I've heard this from other patients, I keep up to date on the research to provide the safest care possible. The CDC is recommending this vaccination because your condition puts you at higher risk for deadly pneumococcal disease. I strongly recommend this pneumococcal vaccine to help keep you healthy and reduce the risk of this serious disease."

If a pharmacist does not administer vaccines, cannot administer them according to state law, or does not have the needed vaccine available for administration, the pharmacist should refer a patient to other immunization providers for vaccination. Pharmacists making a referral should provide documentation or communication about the plan to the other provider, including a request for feedback on outcomes. They should also follow up with the patient at the next encounter to confirm that the patient received the needed vaccine(s).

The final part of implementation is vaccine administration. Pharmacists must be properly trained in all aspects of the vaccines and their administration, including the routes of administration and adverse event management. The APhA's Pharmacy-Based Immunization Delivery program (www.pharmacist.com/pharmacy-based-immunization-delivery) can provide that training. Whether vaccines are delivered on demand or scheduled, the APhA immunization training program provides a checklist of steps in the vaccine administration process[20]:

- Wash hands.
- Ensure the patient is seated.
- Identify and uncover the appropriate area and location on the patient for vaccination.
- Wipe the area with alcohol, and allow alcohol to dry.
- Tell patient to relax.
- Insert needle at 90° (or 45° for subcutaneous administration) to skin in a smooth, controlled motion while bracing against the arm.
- Depress the plunger.
- Withdraw the needle swiftly.
- Activate safety device immediately.
- Dispose of syringe in sharps container.
- Press cotton or gauze and tape to vaccination area on patient.
- Wash hands.

Correct administration of vaccines is essential for efficacy and safety of vaccines. The Immunization

Action Coalition provides a quick reference guide for administration of intramuscular and subcutaneous vaccines (www.immunize.org/catg.d/p2020A.pdf)[21] and the appropriate dose, route, site, and needle size for vaccines (www.immunize.org/catg.d/p3085.pdf)[22].

The California Department of Public Health provides a wealth of training videos (http://eziz.org/eziz-training/) and storage and handling job aids (http://eziz.org/resources/storage-handling-job-aids/) to support you in vaccine storage and handling and administration.

In addition to clear written protocols on the management of vaccine reactions[23], immunizing pharmacists should be trained in cardiopulmonary resuscitation (CPR) and have emergency supplies that consist of epinephrine, diphenhydramine, a blood pressure cuff, and a stethoscope.

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. Medical management of vaccine reactions can be found from the Immunization Action Coalition (www.immunize.org/catg.d/p3082.pdf)[23]. In compliance with the ACIP General Recommendations on Immunization Practice, pharmacists should instruct patients to remain seated in the pharmacy for at least 15 minutes following vaccination to monitor for any immediate syncopal or anaphylactic reactions.

Adverse events or side effects that occur any time after the administration of vaccines should be documented in a patient's records and reported to the Vaccine Adverse Event Reporting System (VAERS) online (https://vaers.hhs.gov/index)[24]. In addition, pharmacists should report vaccine errors to the National Vaccine Errors Reporting Program (VERP) of the Institute for Safe Medication Practices (http://verp.ismp.org/)[25] so it can explore the reasons for the error and develop recommended solutions. Documentation of these adverse events should also be communicated to the patient's PCP. The patient should be referred to other providers for management of any adverse events that are beyond the scope of the pharmacist or the practice setting.

A follow-up plan should also be created for patients who may initially decline a vaccine recommendation,

Follow-Up[4]

"The pharmacist monitors and evaluates the effectiveness of the care plan and modifies the plan in collaboration with other health care professionals and the patient or caregiver as needed. This process includes the continuous monitoring and evaluation of:

- Medication appropriateness, effectiveness, and safety and patient adherence through available health data, biometric test results, and patient feedback
- Clinical endpoints that contribute to the patient's overall health
- Outcomes of care, including progress toward or the achievement of goals of therapy"

who may have temporary contraindications or precautions to vaccination, or who were referred to another immunization provider.

During the subsequent patient encounter for this part of the PPCP, a pharmacist follows up with a patient to provide booster vaccines or completion of a vaccine series and to assess any changes in health status that may require additional vaccines. In addition, any changes in ACIP recommendations may necessitate the need for additional vaccines. In that situation, a pharmacist would go through the same steps in the patient care process, making modifications to the plan where necessary and administering additional vaccines when needed.

Collaborate, Communicate, Document

At the core of the Pharmacists' Patient Care Process and the Immunization Neighborhood is a pharmacist's continual engagement in *collaboration and coordination* with PCPs, other pharmacists, other vaccine providers, and community members; *communication* with patients, caregivers, and providers; and *documentation* of care provided.

Collaborate

As immunization providers, pharmacists can collaborate with other members of the Immunization Neighborhood by gathering information from, developing plans with, reporting receipt of immunization to, and referring patients to other health care providers, as needed.

In states where a pharmacist's authority to immunize requires a protocol or standing order, pharmacists should develop agreements with health care providers or health officials authorized to enter into these agreements that allow administration of vaccinations[18,26]. If a prescription is required for vaccination, a pharmacist should work with a patient's PCP to ensure a prescription is received and understand expectations for documentation and communication.

Public health and immunization coalitions are vital partners in the Immunization Neighborhood. Pharmacists should establish relationships with local and state public health departments to serve as conduits of messages from these departments, enter documentation of immunizations via the IIS, provide vaccines to the underserved in collaboration with public health departments, and participate in emergency planning for pandemics. Immunization coalitions provide a forum for all types of vaccine providers to share successes and challenges, to connect the private and public providers, and to bring together all immunization stakeholders focused on improving vaccination rates of communities.

Communicate

A pharmacist's communication with patients and providers should be done throughout the PPCP for immunization services. As discussed earlier, a pharmacist should clearly and strongly communicate to patients the need for vaccination(s) and provide up-to-date, appropriate education for patients to help them understand the benefits and risks of vaccinations. Patients should also be given written documentation of the immunization they received and written patient education in the form of the VIS.

Pharmacists should also communicate with a patient's PCP and prenatal provider, if known and appropriate, to provide documentation of receipt of vaccination. A pharmacist may be able to communicate the vaccine information to the PCP directly by documenting in the patient's health record (if access is provided), sending documentation by fax, or using another electronic mechanism. For patients who do not have a PCP, pharmacists should provide them with hardcopy documentation and should encourage them to carry and share that documentation with every member of their health care team. In addition, vaccinations should be reported to the state and local IIS.

Document

Ensuring documentation of vaccination is important for legal requirements, complete patient records, quality and continuity of care, and public health. A pharmacist should document receipt of the vaccination (1) in the pharmacy information management system (PIMS); (2) on a patient's personal immunization record card; (3) in the state and local IIS, in states that allow a pharmacist to enter vaccination information into the registry; and (4) to a patient's PCP and prenatal provider, if known and appropriate. Pharmacists practicing in a non-dispensing ambulatory care clinic will document vaccinations in a chart or electronic health record (EHR) instead of the PIMS, in addition to reporting to an IIS.

Under the National Childhood Vaccine Injury Act of 1986, vaccine providers are legally required to document the following with each dose of vaccination:

- Name of the vaccine (a complete list of commonly accepted abbreviations can be found at www.cdc.gov/vaccines/terms/vacc-abbrev.html)[27]
- Date of edition of the VIS and date the VIS was provided to the patient
- Vaccine manufacturer name and lot number for each vaccination
- Office address and name and title of the person who administered the vaccine
- Date the vaccine was administered
- Route of administration, location, and dose (commonly recorded)

This information can be recorded on the vaccine administration record or the PIMS, or both. Immunization records within a pharmacist's practice should not be purged. Documentation of serious health problems following vaccination should be entered into a permanent patient medical record and reported to the federal VAERS[20]. Respecting a patient's declination of recommended vaccines is important. In these cases, pharmacists are advised to document that recommendations were made and that the patient declined receipt of the vaccine at that time.

CONCLUSION

Immunization, like medication therapy management, is a process that involves careful planning and execution. The Pharmacist's Patient Care Process is a framework that can be utilized by numerous pharmacist patient care activities. The immunization process is especially amenable to this process, and a pharmacist should consider making the cycle of Collect, Assess, Plan, Implement, and Follow-up along with the NVAC Standards for Adult Immunization Practice, routine practice.[5] Finally, the process is only as good as the Immunization Neighborhood in which it exists, so pharmacists and other vaccine providers need to strive to constantly improve collaboration, communication, and documentation.

Appendix A

PROVIDER SELF-ASSESSMENT OF STRENGTH OF IMMUNIZATION RECOMMENDATIONS

*The NVAC Adult Immunization Standards call on all providers of healthcare to adult patients to assess, **recommend**, administer/refer and document immunizations. A **strong recommendation** from a healthcare provider can influence the outcome resulting in a patient being administered a needed vaccine. The elements leading to a strong recommendation are listed below. This self-assessment is intended as a guide for providers to determine their current activities and approaches and identify areas for additional focus that will lead to consistency and strengthening of immunization recommendations.*

Practice: _____	No or rarely	To some extent	Somewhat consistently	Consistently	Not applicable
Practice-site Focused					
Educational information / tools on immunizations provided to patients in waiting areas and other means of patient communications					
Provide immunization education tools / surveys at check-in for patients to review/complete while waiting					
Have immunization education messages in areas where the vaccine is administered (posters, brochures, video, etc.)					
Provide immunization messages thru electronic patient portals and/or appointment reminders					
Provide patient access to the immunization records					
Patient-Practitioner Interaction					
You and your staff clearly convey your strong vaccine recommendation ("I recommend you receive vaccine X because…," or "Vaccine X is recommended for you because…" vs saying "Vaccine X is an option if you want it.")					
SHARE the tailored reasons why the recommended vaccine is right for the patient given his or her age, health status, lifestyle, occupation, or other risk factors.					
HIGHTLIGHT positive experiences with vaccines (personal or in your practice), as appropriate, to reinforce the benefits and strengthen confidence in vaccination.					
SHARE your own immunization status with the patient (show how you walk the walk)					
ADDRESS patient questions and any concerns about the vaccine, including side effects, safety, and vaccine effectiveness in plain and understandable language					
REMIND patients that vaccines protect them and their loved ones from many common and serious diseases					
EXPLAIN the potential costs of getting the disease, including serious health effects, time lost (such as missing work or family obligations), and financial costs.					
Utilize open-ended questions to assess the patient's understanding of the information provided and/or identify beliefs / concerns					
Offer to administer the vaccine at the visit in which you make the recommendation.					
If you don't stock the vaccine, ensure the patient has clear directions about which vaccine to get and where to get it.					
Encourage patients to carry immunization record cards/ access to electronic immunization records					
Immunization information and recommendation delivered in language and way patient can understand (language, culture, other)					
If referring patient to another provider to receive the vaccination you provide a referral order / communication to the patient and/or the provider and request to receive information back when the patient gets vaccinated.					
Patient Action					
Patients take action based on your recommendation (vaccinated by you or someone else)					
Frequency (count number of checked boxes in each column – Goal is to have a higher number in consistently column)					

You may also complete the self-assessment at https://fs3.formsite.com/apha/IZRecommendation/index.html

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21. Immunization Action Coalition. How to Administer Intramuscular and Subcutaneous Injections to Adults. http://www.immunize.org/catg.d/p2020A.pdf.

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See the following websites for more immunization resources for California Pharmacists:

- Information for Pharmacies on the California Immunization Registry - http://cairweb.org/home/pharmacies-and-cair/
- California State Board of Pharmacy Regulation regarding Immunizations: Title 16, Section 1746.4- http://www.pharmacy.ca.gov/laws_regs/1746_4_oa.pdf
- California Department of Public Health immunization promotional materials for patients and staff - http://eziz.org/resources/immunization-promo-materials/


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